The fundamental principles of Tympanoplasty were introduced by Zollner and Wullstein. These principles were directed towards restoration of middle ear function as well as ensured trouble free and stabilized ear.

Wullstein and Zollner classified Tympanoplasty according to the type of ossicular reconstruction needed. Five types of Tympanoplasty have been classified.

Type I Tympanoplasty: This is indicated in patients with presence of all the middle ear ossicles with normal mobility. Ossicular chain reconstruction is not needed in these patients. Efforts are made to close the perforated ear drum using temporalis fascia graft (Hong Kong flap). This procedure is also known as myringoplasty.

Advantages of using temporalis fascia as graft material:

1. It is an autograft with excellent chance of take
2. It is available close to the site of operation making its harvest easier
3. It has a low basal metabolic rate, brightening its success rate
4. Its thickness is more or less similar to that of tympanic membrane
There are two available techniques for performing myringoplasty / type I Tympanoplasty.
1. Overlay technique
2. Underlay technique

**Overlay technique:** This is a difficult technique to master. Here the graft material is inserted under the squamous (skin layer) of the ear drum. It is a difficult task peeling only the skin layer away from the tympanic membrane, placing the graft over the perforation and redraping the skin layer.

**Underlay technique:** This is a simpler and commonly used technique. Here the graft is placed under the tympano meatal flap which has been elevated hence the name underlay. The major advantage of this procedure is that it is easy to perform with a good success rate.

**Indications of Myringoplasty:**
1. Central perforation which has been dry at least for a period of 6 weeks.
2. As a follow up to mastoidectomy procedure to recreate the hearing mechanism

**Prerequisites for myringoplasty:**
1. Central perforation which has been dry for at least 6 weeks
2. Presence of normal middle ear mucosa
3. Intact ossicular chain
4. Good cochlear reserve

**Procedure:** Firstly a temporalis fascia of adequate site must be harvested and allowed to dry.

The surgery is performed under local anesthesia. Temporalis fascia graft is harvested under local anesthesia conventionally and allowed to dry. The external auditory canal is then anesthetized using 2 % xylocaine mixed with 1 in 10,000 adrenaline injection. About 1/2 cc is infiltrated at 3 - o clock, 6 - o clock, 9 - o clock, and 12 - o clock positions about 3mm from the annulus. The patient is premedicated with intramuscular injections of 1 ampoule fortwin and 1 ampoule phenergan.

**Step I:** Freshening the margins of perforation - In this step the margins of the perforation is freshened using a sickle knife of an angled pick. This step is very important because it breaks the adhesions formed between the squamous margin of the ear drum (outer layer) with that of the middle ear mucosa. These adhesions if left undisturbed will hinder the take up of the neo tympanic graft. This procedure will infact widen the already present perforation. There is nothing to be alarmed about it.

**Step II:** This step is otherwise known as elevation of tympano meatal flap. Using a drum knife a curvilinear incision is made about 3 mm lateral to the annulus. This incision
ideally extends between the 12-o clock, 3-o clock, and 6-o clock positions in the left ear, and 12-o clock, 9-o clock and 6-o clock positions in the right ear. The skin is slowly elevated away from the bone of the external canal. Pressure should be applied to the bone while elevation. This serves two purposes:
1. It prevents excessive bleeding
2. It prevents tearing of the flap.

This step ends when the skin flap is raised up to the level of the annulus.

**Step III:** Elevation of the annulus and incising the middle ear mucosa. In this step the annulus is gradually lifted from its rim. As soon as the annulus is elevated a sickle knife is used to incise the middle ear mucosal attachment with the tympano meatal flap. This is a very important step because the inner layer of the remnant ear drum is continuous with the middle ear mucosa. As soon as the middle ear mucosa is raised, the flap is pushed anteriorly till the handle of the malleus becomes visible.

**Step IV:** Freeing the tympano meatal flap from the handle of malleus. In this step the tympano meatal flap is freed from the handle of malleus by sharp dissection of the middle ear mucosa. Sometimes the handle of the malleus may be turned inwards hitching against the promontory. In this scenario, an attempt is made to lateralize the handle of the malleus. If it is not possible to lateralize the handle of the malleus, the small deviated tip portion of the handle can be clipped. The handle of the malleus is freshened and stripped of its mucosal covering.

**Step V:** Placement of graft (underlay technique). Now a properly dried temporalis fascia graft of appropriate size is introduced through the ear canal. The graft is gently pushed under the tympano meatal flap which has been elevated. The graft is insinuated under the handle of malleus. The tympano meatal flap is repositioned in such a way that it covers the free edge of the graft which has been introduced. Bits of gelfoam are placed around the edges of the raised flap. One gel foam bit is placed over the sealed perforation. This gelfoam has a specific role to play. Due to the suction effect created it pulls the graft against the edges of the perforation thus preventing medialisation of the graft material.

**Type II Tympanoplasty:** In this procedure the tympanic membrane is grafted to the intact incus and stapes. This procedure is very rarely used, since it is very rare for erosion of the handle of malleus to be present alone without the involvement of other ossicles. The neotympanum created is draped over the existing incus and stapes. There is a certain amount of obliteration of middle ear space.

Since the ossicular chain lever ratio is not normally maintained in these patients, they tend to have at least 30 dB hearing loss even after a successful surgery.
Type III Tympanoplasty: This technique is used only when a mobile suprastructure of stapes alone is present. In this surgical procedure the tympanic membrane graft is draped over the mobile suprastructure of stapes. This is also known as Columella effect. This type of middle ear is commonly seen in birds.

The middle ear space is really non existent. Even after successful surgery these patients still manifest with 30 – 40 dB hearing loss.

This surgical procedure is useful in patients without malleus and incus. Incus has the most precarious blood supply among the three ossicles.
Type IV Tympanoplasty: This surgical procedure is performed in patients only with mobile foot plate of stapes. The grafted ear drum is draped over the mobile foot plate. In these patients there is virtually no middle ear space at all. The grafted ear drum virtually drapes the promontory.

Even after successful surgery these patients still have about 40 – 50 dB hearing loss.
In this surgical procedure the round window is protected from the incoming sound waves. This helps in preserving the round window baffle effect.

Type V Tympanoplasty: In this surgical procedure a third window is created over the lateral semicircular canal. (Fenestra over lateral canal). This surgical procedure is outdated these days.

Belluci’s prognostic classification: Belluci used the status of middle ear cavity in determining the prognostic features of Tympanoplasty. He grouped those under 4 heads.

Group I: Patients with a dry ear for a period of at least 6 months fall in this category.

Group II: Patients with occasionally draining ear was included in this group.

Group III: Patients with persistent ear drainage associated with mastoiditis were included in this group.

Group IV: Patients with persistent ear discharge associated with palatal malformations (cleft palate) were included in this group.

Ossicular grafts have revolutionized Tympanoplasty procedure these days. These grafts help in the preservation of middle ear space, as well as produces excellent improvement in hearing.

Implants used for ossiculoplasty should satisfy four basic requirements:

1. They should be biocompatible and should not extrude / cause severe tissue reaction
2. They should improve / maintain hearing
3. They should be technically easy to use
4. They should maintain results over time

Austin in 1971 classified the anatomical defects found in the ossicular chain due to chronic suppurative otitis media. Isolated losses of handle of malleus and stapes suprastructure were not included in this classification due to their rarity.

Type I – Normal = M+I+S
Type II – M+S – Absent incus – Good prognosis

Type III – Malleus + Foot plate of stapes – poor prognosis

The forerunner of partial and total ossicular replacement prosthesis was Dr. Austin’s polyethylene malleus to foot plate strut. He designed the “sunflower Columella” designed out of Teflon. Teflon and polyethylene has the advantage of excellent air bone closure.

The following are the various categories of biomaterials used in ossiculoplasty:

1. Polyethylene tubing
2. Polytetrafluoroethylene (Teflon)
3. Gelatin foam (Gelfoam)
4. Silastic (Dimethyl silicone polymer)
5. Platinum – This material is very ductile, non magnetic and biocompatible.
6. Titanium alloy
7. Polycel and plastipore
8. Capcel – Hydroxyapatite
9. Otocel – Clear bioactive bioglass (ceramic material)
Comparison of prosthetic materials

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Cartilage</th>
<th>Autologous bone</th>
<th>Homologous bone</th>
<th>Plastic</th>
<th>Hydroxyapatite</th>
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<tr>
<td>Biocompatibility</td>
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<td>+++</td>
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<tr>
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<td>+</td>
<td>+</td>
<td>++</td>
<td>+++</td>
<td>++</td>
</tr>
<tr>
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<td>-</td>
<td>-</td>
<td>Possible</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>Required</td>
<td>-</td>
</tr>
</tbody>
</table>

Selection of prosthesis:

Factors to be considered while selecting an optimal prosthetic design are:

1. Status of ear drum
2. Status of residual ossicles
3. Severity of Eustachian tube dysfunction
4. Stability of prosthesis
5. Ease of placement
6. Sound conductivity
Stapes to malleus reconstruction:

When malleus is present, it can be used to help to stabilize the prosthesis and reduce the possibility of extrusion. The malleus is never directly aligned to the underlying stapes (M-S offset). A variety of implants have been designed to take advantage of the stabilizing effect of malleus.

Incus interposition: Guilford transposed the residual incus autograft on to its side so that it lies on the stapes capitulum and beneath the manubrium. Hearing results could be excellent if the middle ear anatomy is favorable. The incus remnants could be too short or long. Too long a incus prosthesis could lead to ankylosis. Revision surgery is difficult in such patients owing to the fixation of the prosthesis to the stapes and fallopian canal.

Zollner’s sculpted incus: Zollner popularized the sculpturing of Autologous incus. This helps in obtaining a better fit. It also reduces the incidence of subsequent ankylosis. Weher’s refined this technique to include homograft ossicles. This technique could be time consuming. Remnant Autologous incus could harbor cholesteatoma.

Grote Hydroxyapatite assembly: Grote developed the first commercial Hydroxyapatite prosthesis. Its configuration attempted to accommodate the M-S offset. This prosthesis should be placed lateral to the malleus necessitating dissection of the ear drum away from the malleus. There is also the associated risk of iatrogenic perforation of the ear drum.

Figure showing Grote prosthesis

Wehr’s Hydroxyapatite prosthesis: Wehr’s advocated sculpted homograft for incus interposition. He also developed Hydroxyapatite incus prosthesis in order to reduce the preparation time inside the operation theatre during ossiculoplasty procedures. This prosthesis had an anterior extension which was created to cradle the malleus. Biocompatibility of this material was really superior.
Figure showing the Wehr’s prosthesis. The anterior cradle supports the malleus.

Figure showing Weher’s prosthesis

There are two types of Weher’s prosthesis:

1. Incus replacement prosthesis

Figure showing incus replacement prosthesis
2. Incus – Stapes replacement prosthesis

*Figure showing incus – stapes replacement prosthesis*

Kartush Hydroxyapatite struts: These struts were designed to function as either a TORP or PORP. Hydroxyapatite was used. This prosthesis has a self locking mechanism. It has very low displacement and extrusion rates.

*Figure showing Kartush prosthesis*

Incus interposition ossiculoplasty: Incus due to its precarious blood supply commonly undergoes necrosis, especially its long process. Homograft incus was shaped and placed between the malleus and stapes head. A notch was created in the short process of the incus that fit under the malleus handle. This is done to stabilize the ossicle. If the stapes suprastructure was intact in the patient, the long process of incus was amputated. A small
cup was made in the amputated long process of incus. The head of the stapes fits into this cup. The notch prevented the prosthesis from being displaced anteriorly / posteriorly. The spring in the patient’s malleus would keep the prosthesis from being displaced inferiorly. Superiorly its position is maintained by the contraction of tensor tympani tendon.

When the stapes superstructure is absent, the long process of incus could be placed over the foot plate of stapes.

Pitfalls: With AID’s being common these days, incus homograft has given way to artificially designed prosthesis. Hydroxyapatite was commonly used to design these prosthetic incus replacements.

Factors that should be taken into consideration before designing the optimal prosthesis:

1. Proper tension is very important. A prosthesis that makes tension adjustment easy for the surgeon should be advantageous.
2. Prosthesis with masses less than 40mg is best for overall acoustic performance.
3. For improved high frequency performance, rigid low mass prosthesis (less than 10g) is the best choice.
4. Longer prosthesis produces excellent high frequency function at the expense of low frequencies.
5. Prosthesis that connects malleus to stapes appears to have no acoustic advantage over prosthesis that connects the ear drum to the stapes.
6. If the ear drum is conical, prosthesis with the head angulated at about 30° appears to be beneficial because the angulation increases the surface area in contact with the ear drum.

These prostheses may be used to reconstruct the ossicular chain during Tympanoplasty, in patients in whom erosion and discontinuity of ossicular chain has occurred. Long process of incus gets frequently eroded because of its precarious blood supply. In these cases the lenticular process of incus is still attached to the head of stapes. The incudo stapedial joint in these patients should be separated and the long process of incus removed. This is done because squamous debris could still be attached to the incus fragment. It is also preferable to remove the body of the incus, because it could also have squamous ingrowth. It can also have scar tissue blocking the antrum.

Surgical procedure:

The prosthesis is laid on its side on the promontory. The cup of the prosthesis is near the stapes and its notched portion close to the tip of the handle of malleus. With the help of a right-angle pick held in the surgeon’s left hand, the malleus is elevated, and with a
gently curved pick in the surgeon’s right hand, the prosthesis is brought up under the manubrium of the malleus. As it is brought to an upright position, the cup engages the head of stapes.

Figure showing the prosthesis laid on its side on the promontory

Figure showing the prosthesis being positioned
Ossicular reconstruction with prosthesis of Hydroxyapatite should not be attempted in cases of acute trauma / traumatic perforation of ear drum. It should be performed only after the drum has healed and stabilized.

Complications:

Owing to the biocompatibility of this prosthesis, the incidence of complications is rare.

1. Extrusion of the prosthesis.
2. Too short / Too long prosthesis could lead to increased extrusion rates
3. Failure to improve hearing

The success or failure of ossiculoplasty procedure could be assessed by calculating the Middle Ear Risk (MER) Index. In this index a value is assigned for each risk factor, and these values are added to determine the MER index.
<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Risk value</th>
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<tbody>
<tr>
<td>Otorrhea (Bellucci criteria)</td>
<td></td>
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<tr>
<td>I: Dry</td>
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</tr>
<tr>
<td>II. Occasionally wet</td>
<td>1</td>
</tr>
<tr>
<td>III: Persistently wet</td>
<td>2</td>
</tr>
<tr>
<td>IV: Wet ear with cleft palate</td>
<td>3</td>
</tr>
<tr>
<td>Perforation:</td>
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<td>Absent</td>
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<tr>
<td>Present</td>
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<td>Cholesteatoma</td>
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<td>Present</td>
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<tr>
<td>Ossicular status (Austin)</td>
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<td>0: M+I+S</td>
<td>0</td>
</tr>
<tr>
<td>A: M+S+</td>
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<tr>
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<tr>
<td>D: M-S-</td>
<td>4</td>
</tr>
<tr>
<td>E: Ossicle head fixation</td>
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</tr>
<tr>
<td>F: Stapes fixation</td>
<td>3</td>
</tr>
<tr>
<td>Middle ear: granulations / effusion</td>
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</tr>
<tr>
<td>-----------------------------------</td>
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<table>
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<tr>
<td>Staged</td>
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</tr>
<tr>
<td>Revision</td>
<td>2</td>
</tr>
</tbody>
</table>

According to MER:

- 0 – Best prognosis
- 2 – Mild risk
- 5 – Moderate risk
- 7 – Severe risk
- 12 – Worst prognosis
Ossiculoplasty using presculptured banked cartilage:

Homologous cartilage can be sculptured prior to surgery into TORP / PORP configuration. They can easily be stored by a tissue bank for use at a later date. It is configured in a self stabilizing manner with a disk shaped upper surface.

Donors should be screened serologically for Hepatitis and HIV antigens. Costal cartilage is ideal for this purpose. Graft material is harvested from the costochondral cartilages. These cartilages are fashioned into TORP type implants. The classic TORP configuration is about 8 mm long. It has a disk like head of about 4 mm diameter. The diameter of the shaft should be 2 mm in diameter.

Figure showing PORP configuration to be used when malleus is absent

Figure showing PORP configuration to be used when malleus is present
The disk-like top of the implant can be placed in contact with the posterior bony annulus for added stabilization. It is better to thin the cartilage in the area of contact with the annulus, thereby minimizing the potential for dense adhesions.

TORP configuration: Ossicular reconstruction in the absence of stapes suprastructure is technically more demanding. Cartilaginous homografts are effective if the patient has a wide oval window niche. Measurements are taken as described for PORP configuration. The length of the shaft should be trimmed and contoured as per requirements.

If there is a perforation in the tympanic membrane that corresponds with the location of the disk-shaped head of the reconstruction prosthesis, the head of the prosthesis itself can be used as a graft for the perforation. The surface of the TORP readily epithelializes.

Advantages of presculptured homograft cartilage as prosthesis:

1. The incidence of graft extrusion is rare
2. Contact of the implant with adjacent bony walls of middle ear can be consistent with excellent hearing results, because the cartilage remains flexible.
3. Hearing improvement is excellent
4. Operating technique is less demanding when presculptured cartilage homograft is used.

Ossiculoplasty with composite prosthesis: PORP’s and TORP’s designed out of composite materials was first popularized by Sheehy and Shea. Major advantage of using synthetic graft is there is no fear of transmission of diseases like HIV and Hepatitis. Composite prosthesis has two distinct portions: a Hydroxyapatite head and a plastipore or fluoroplastic shaft. The Hydroxyapatite head is a universal design, and no modification or intraoperative reshaping is required. The plastipore shaft is manufactured in such a way that it can be precisely trimmed to within a 0.5 mm variance on the basis of intraoperative measurements.

The type of Hydroxyapatite head that should be used in the prosthesis depends upon whether malleus is present or absent. In cases where malleus is present, the head of the prosthesis used should be in the form of a delicate hook. It is designed in such a way that the hook is positioned under the handle of the malleus. The Hydroxyapatite head to be used when the malleus is absent has a flat, egg-shaped design, with gently rounded edges. This design facilitates easy insertion under the ear drum without the need for cartilage interposition. This prosthesis is best used when the middle ear is healthy and free of disease.

The plastipore shaft is of two types:

1. Type I: The shaft has a hollow sleeve to accommodate the head of stapes
2. Type II: The shaft is more slender, wire reinforced. This design helps the shaft to rest directly on the foot plate of stapes/oval window.
There are 4 types of composite prosthesis designed to solve the four basic problems encountered during ossicular reconstruction. These situations include:

- Malleus present, stapes present
- Malleus present, stapes absent
- Malleus absent, stapes present
- Malleus absent, stapes absent

Figure showing the types of composite prosthesis

Contraindications for composite prosthesis:

1. Should not be used in patients with severe Eustachian tube function
2. Should not be used in patients with an obliterated middle ear space
3. Middle ear mucosa should be healthy and free of any disease
Cartilage harvested from rib is cut into 8 mm sections. They are then placed over sterile hard surface. Using a 4mm disposable dermal punch cylinders of cartilage are created each with 4 mm diameter and 8 mm long. From these cylindrical grafts, appropriately shaped TORP’s can be prepared. Cartilage material can be placed in sterile saline and put in glass specimen sterile bottles and sealed with a plastic seal.

PORP configuration: When stapes is present and mobile, a measurement is taken from the lateral most part of the capitulum of the stapes to the ear drum. 1 mm should be added to this value, and the TORP blank cartilage is trimmed to this measurement. A depression is made in the end of the shaft of the trimmed blank to accommodate the head of the stapes. The depth of this indentation could be about 0.5 – 1 mm. The 4 mm disk of the top of the implant should be in complete contact with the ear drum. If an intact malleus handle is present, the anterior most portion of the head of the implant can be trimmed to fit the handle. If the malleus handle is absent, a more flat configuration can be used.

Spandrel: This is a type of TORP. It has a wide head which can be slid under the ear drum and a narrow shaft. The length of the shaft can be reduced by cutting it. The shaft rests over the foot plate of stapes.
Parts of spandrel: It has a perforated shoe to allow protrusion of the wire core. It has a thin flange on the prosthesis head to avoid possible damage induced by a sharp edge of the Polycel disk.
Before assembling the prosthesis, air is removed from the Polycel casing by connecting the prosthesis and its shoe to a syringe containing Ringer’s solution and antibiotic.

This prosthesis ensures better closure of air bone gap.