Kaunas University of Technology

Faculty of Mechanical Engineering and Design

Investigation of the Capabilities of Artificial Eardrum

Master's Final Degree Project

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Kaunas, 2024

Kaunas University of Technology

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Industrial Engineering and Management (6211EX018)

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Investigation of the Capabilities of Artificial Eardrum

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Task of the Master's Final Degree Project

Given to the student – Shalini Murugesan

1. Title of the Project

Investigation of the Capabilities of Artificial Eardrum

(In English)

Dirbtinio ausies būgnelio galimybių tyrimas

(In Lithuanian)

2. Aim and Tasks of the Project

Aim: to investigate the vibrational behaviour of the artificial eardrum to repair tympanic perforations.

Tasks:

1. to analyse the usage of materials for the artificial eardrum;
2. to perform the conception and dynamic analysis of artificial eardrum;
3. to perform the harmonic analysis of the artificial eardrum under different boundary conditions;
4. to investigate the social/economical capabilities of artificial eardrum.

3. Main Requirements and Conditions

Parameter of artificial eardrum prototype; width - 8.5mm, thickness -1.75mm

4. Additional Requirements for the Project, Report and its Annexes

Not applicable

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Shalini Murugesan. Investigation of the Capabilities of Artificial Eardrum. Master's Final Degree Project, supervisor lect. Virginija Gylienė; Faculty of Mechanical Engineering and Design, Kaunas University of Technology.

Study field and area (study field group): Production and Manufacturing Engineering (E10), Engineering Sciences (E).

Keywords: eardrum; tympanic membrane; tissue engineering; tympanic perforations; artificial eardrum.

Kaunas, 2024. 67 p.

Summary

The eardrum is responsible for vibrating and sending the sound waves to the ossicle bones. Tympanoplasty is a surgery done to improvise hearing capability in patients with a perforated eardrum that does not cure on its own. The recent advancements in medical domain have allowed surgeons to use non autologous grafts and tissue engineered materials for the closure of tympanic perforations in tympanoplasty surgery. Even though autologous grafts are widely used by the surgeons in tympanoplasty surgery, it is not possible for every autologous graft to close tympanic perforations and restore hearing. The failure of tympanoplasty surgery may be due to the graft involved or surgical techniques and require revision surgery. Revision surgery leads to poor hearing results. Thus, the overall aim of the study is to investigate and evaluate the mechanical behaviour of artificial eardrum.Thus,to understand the capabilities of artificial eardrum, the artificial eardrum modelled with a tympanic ring is designed and the frequency and harmonic analysis of artificial eardrum is performed. The 3D CAD model of natural eardrum and artificial eardrum are modelled in SolidWorks with different materials and dynamic analysis is performed. Nonautologous materials have good mechanical properties and provide better hearing results compared to autologous materials. After designing, the constrains are applied to the natural and artificial eardrum and the mechanical vibrations of standard and artificial eardrum are evaluated using frequency analysis and harmonic analysis under different boundary conditions. The frequency analysis for artificial eardrum is evaluated using PRISM holography system and compared with the obtained numerical results of artificial eardrum. The socio-ecomic advantages of using artificial eardrum is analysed.

Murugesan Shalini. Dirbtinio ausies būgnelio galimybių tyrimas. Magistro baigiamasis projektas, vadovė lekt. Virginija Gylienė; Kauno technologijos universitetas, Mechanikos inžinerijos ir dizaino fakultetas.

Studijų kryptis ir sritis (studijų krypčių grupė): Gamybos inžinerija (E10), Inžinerijos mokslai (E).

Reikšminiai žodžiai: ausies būgnelis; būgninė membrana; audinių inžinerija; būgninės perforacijos; dirbtinis ausies būgnelis.

Kaunas, 2024. 67 p.

Santrauka

Ausies būgnelis yra atsakingas už vibraciją ir garso bangų siuntimą į kaulinius kaulus. Timpanoplastika – tai operacija, atliekama siekiant pagerinti pacientų klausą, kurių ausies būgnelis perforuotas ir neišgydomas savaime. Timpanoplastikos metu ausies būgnelio perforacijai užgydyti panaudojami paties paciento audiniai ar dirbtinės medžiagos. Nors autologinius transplantatus plačiai naudoja chirurgai atliekant timpanoplastikos chirurgiją, ne kiekvienas autologinis transplantatas gali uždaryti būgnelio perforaciją ir atkurti klausą. Pasitaiko atvejų, kai vidurinės ausies kokybė po operacijos yra įvertinama revizine opracija. Revizinė opracija gali sukelti blogus klausos rezultatus.
Tyrimo tikslas yra ištirti ir įvertinti mechaninį dirbtinio ausies būgnelio elgesį. Ko pasekoje atlikti eksperimentai, panaudojant dirbtinio ausies būgnelio prototipą, suprojektuotas dirbtinis būgnelis, sumodeliuotas su būgniniu žiedu, atliekama dirbtinio ausies būgnelio dažnio ir harmonikos analizė. Natūralaus ausies būgnelio ir dirbtinio ausies būgnelio 3D CAD modelis yra modeliuojamas SolidWorks programinio paketo su skirtingomis medžiagomis ir atliekama dinaminė analizė. Neautologinės medžiagos turi geras mechaninius savybes ir galėtų būti taikomos geresniems klausos rezultatams pasiekti. Atliekant projektavimą, suvaržymai taikyti natūraliems ir dirbtiniam ausies būgneliui. Mechaniniai virpesiai yra vertinami naudojant dažnio analizę ir harmoninę analizę, esant skirtingoms ribinėms sąlygoms. Gauti skaitiniai dirbtinio ausies būgnelio rezultatai, kurie palyginti su PRISM sistema gautais eksperimentiniais rezultatais. Galiausiai išanalizuotas socialinis ir ekonominis dirbtinio ausies būgnelio panaudojimo poveikis.

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Abbreviations:

TM–Tympanic Membrane
TMP – Tympanic Membrane Perforations
PLA–Polylactic Acid
CS–Chitosan
SA–Sodium Alganate
CAD-Computer Aided Design
PVDF-Polyvinylidene fluoride
PRISM- Precise Real-Time Instrument for Surface Measurement

Introduction

The human hearing system is a remarkable system for hearing sense. The auditory system is composed of various complex geometries and material mechanical properties. The human ear is composed of three main parts namely the pinna, the middle ear, and the internal ear. The middle ear comprises of an eardrum, ligaments and three ossicular bones. The eardrum is connected to the internal part of the ear by the ossicular bones. The anatomical structure that separates the pinna and the tympanic cavity is called the tympanic membrane. The purpose of the eardrum is to transfer the acoustic waves to the ossicular chain and transmit atmospheric pressure. The most common disease that affects the eardrum is the tympanic perforation. The tympanic perforation or diseases like chronic otitis media affect the entire tympanic membrane. The surgical procedures used to treat eardrum perforations are myringoplasty and tympanoplasty. Myringoplasty is used to repair small holes while Tympanoplasty is the most used surgical procedure for treating large tympanic perforations and eardrum repair to restore the functioning of the auditory system and protect the middle ear from infections. Various types of autologous and non autologous grafts are used for the repair of the tympanic perforations. Autologous grafts like temporalis fascia, cartilages, perichondrium are commonly used for tympanoplasty surgery. Even though the outcomes of tympanoplasty using autologous grafts like temporalis fascia ensured good hearing, the dimensional stability of grafts may lead to perforation residues when larger tympanic perforations are involved for repair. This leads to post revision surgery followed by poor hearing results The viability of graft and rate of success in tympanoplasty surgery depends on several factors such as age, perforation size, gender, tympanosclerosis presence, smoking habit and the failure of eardrum repair surgery may be due to the graft type used in surgery or surgical techniques. The closure rate of tympanic perforations using non autologous grafts is 90% irrespective of the material used. Non autologous graft materials have the capacity to resolve various problems in eardrum repair surgery like the elimination of graft harvest, promotion of the healing of wound and allows implantation of the graft within a clinical facility. To improve the stability and provide better hearing restoration and avoid revision surgery and evaluate dynamic behaviour, 3D models of artificial eardrum were modelled in Solidworks. Two artificial eardrums made of PVDF-steel and polystyrene-steel were modelled and frequency and harmonic analysis were conducted for analysing the dynamic behaviour of artificial eardrum under different boundary conditions. The outcomes of numerical analysis of artificial eardrums are compared. Then the frequency analysis of artificial eardrum is performed using holography PRISM system and the results of frequency analysis and numerical simulation of artificial eardrum was compared. The results showed an error between the obtained frequencies in numerical and experimemental study. The artificial eardrum improves the social quality of life and well being of humans by restoring hearing and avoiding revision surgery.

Aim: to investigate the capabilities of the usage and application of artificial eardrum
Tasks:
1. to analyse the usage of materials for the artificial eardrum
2. to perform the conception and dynamic analysis of artificial eardrum
3. to investigate the vibrational analysis, using the prototype of eardrum
4. to investigate the social/economical capabilities of artificial eardrum.

Hypothesis: Accurate thickness of fabricated artificial ear drum leads to better hearing results.

1. Literature Review of Tympanic Membrane

The most serious problem that hinders an individual capacity in their everyday life is hearing loss. The human ear is a mechanical system that helps in the transmission of acoustic sound from the pinna to the internal ear. The middle ear is composed of an eardrum, also known as the Tympanic Membrane (TM) and 3 ossicular bones. Whenever sound vibrations barely pass from the outer tympanic canal to the internal ear and the ossicles, conductive hearing loss occurs [1].

1.1. Anatomy of Tympanic Membrane (TM)

The TM is a flat, thin tissue that divides the middle and the outer ear at the bottom of the ear canal as presented in Fig. 1(A)[1]. The primary objective of TM is to convert environmental soundwaves into mechanical motion and results in the transmission of acoustic waves to the ossicular bones which is then transmitted to the inner ear's electromechanical sensory system. The eardrum primarily contains 2 regions namely pars tensa and pars flaccida [2]. The pars tensa fills most of the TM whereas pars flaccida is a comparatively loose triangular submembrane restricted to the superior area. Also, the eardrum is a tri-laminar structure with mucosal epithelium on the internal portion, lamina propria on the middle portion of ear and the epidermal layer on the exterior part as shown in Fig. 1B [3].

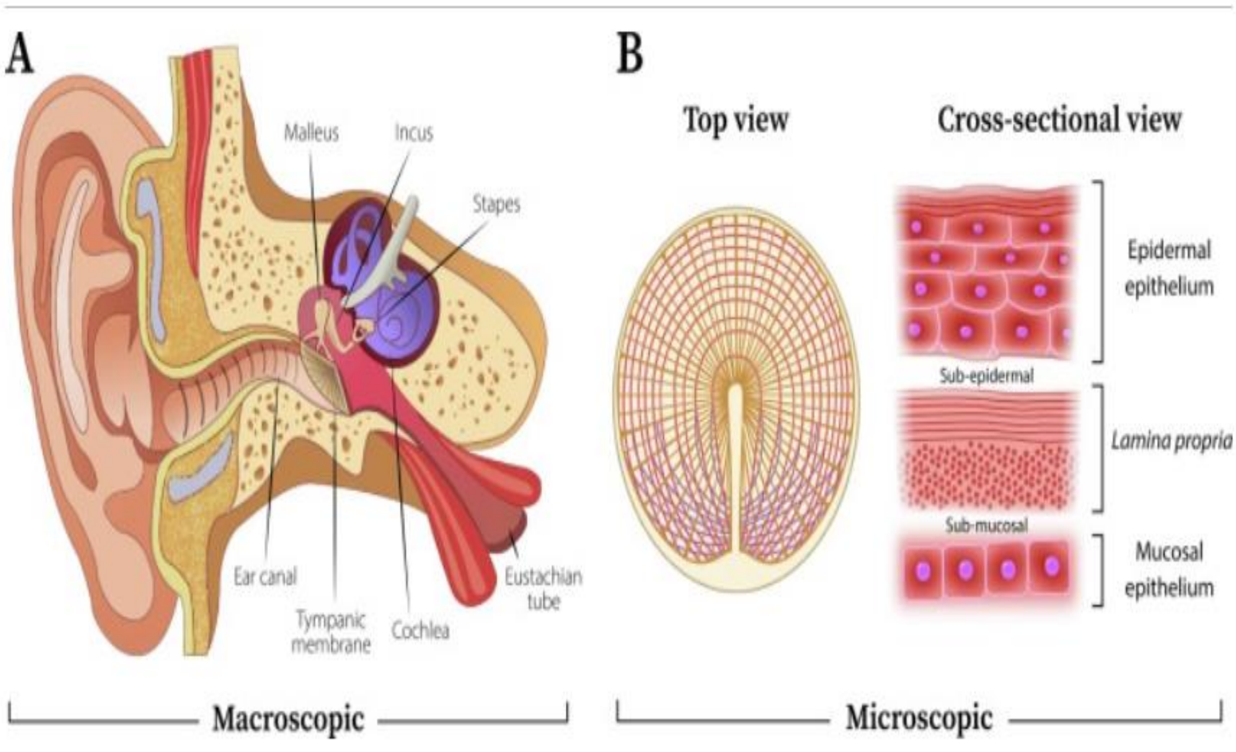


Fig. 1. A.Microscopic view [1] B.Microscopic view [3]

The ear drum is a thin,transparent membrane that is generally 0.074mm thick,ellipsoidal in shape and measures 8mm in width and 10mm in height. A 14 mg measurement would be appropriate mass for the eardrum[4]. Fig. 2 represents the human ear drum.

Fig. 2. Human ear drum [5]

1.2. Perforations of the Tympanic Membrane

The common prevalent injuries to the eardrum, tympanic membrane perforations, lead to total hearing loss because of poor sound transmission. Microbial infections, acoustical disturbances, and the ingestion of foreign bodies are common etiologies of TMP. Most prevalent pathogens disorder among them, particularly among young children is chronic otitis media [6]. A perforated TM originates from the infection's initial stage, middle ear inflammation, which is typically accompanied by a spontaneous outflow of infectious discharges into the nasopharynx through the eustachian tube. The most conventional surgical procedure to preserve middle ear ventilation in infants with persistent ear infections and chronic fluid buildup is by placing small, cylindrical tympanoplasty tubes. Nevertheless, a significant percentage of TMPs develop after tympanoplasty surgery, particularly when these tubes do not extrude on their own and a remnant gap exists upon removal [7].

The problems caused by TMP depend on the hole dimensions and the whereabouts of the hole in the eardrum. In most cases the perforations cure or heal within a month when a hole is formed. If the volume of the perforation does not reduce over a period of 2 months, then the otologist recommends fixing TMPs. The two main surgical procedures which are used to treat TMP's are tympanoplasty and myringoplasty. Tympanoplasty is commonly understood to be a surgical technique used to repair a damaged ear drum by the reconstruction of middle ear. Typically, it is divided into 5 categories based on how much rebuilding is needed. When the middle ear chain is undamaged and the link among the malleus bone and the TM is retained, myringoplasty is termed as type 1 tympanoplasty, which solely requires the repair of the perforated TM [8].

The signs of TMP's includes sudden pain, relief, otorrhea and tinnitus. Thus, both surgical procedures resulted in the successful closure of perforations, but subsequent perforations occur due to the pressure differences in the middle portion of ear which leads to revision surgeries. Due to the restricted supply of autologous transplant tissues, the surgeon usually does not have enough resources for the subsequent surgeries.

Perforated eardrums can lead patients to acquire chronic media otitis and if it worsens, an infection develops and destroys the ossicular bones and leads to hearing loss. In the final phase, the patient can suffer from complete hearing loss. In addition, a persistent infection on the tympanic membrane can migrate to the brain and result in meningitis or affects the middle ear and paralyze the facial nerves. Chronic otitis media added to a perforation can also result in mastoiditis. Furthermore, cholesteatomas may develop and destroy the middle ear bones namely malleus and stapes and cause pepetual hearing loss. Most of the patients undergo tympanic repair surgery to regain hearing [9].

The further restrictions are expensive capital expenditure, the need for accurate tissue carving using microsurgical skills, and potential for infection in homografts and xenografts. These simple grafts get easily detached after surgery and hence have a low success rate and little resistance to recurrent infections. In addition, large holes generally result in the failure of the outer membrane. This leads to the development of a poor tissue deprived of the strength of crucial components for the best conduction of sound. Due to the shortcomings of the prevailing surgical methods, there is a rising interest in the development of novel engineering methods for the creation of eardrum scaffolds along with appropriate medical properties and three-dimensional models [10].

1.3. Tissue Engineering for Tympanic Membrane

Despite the eardrum's capacity to renew itself, the holes in the eardrum need surgery with a variety of materials including paper patches and autologous tissues such as fascia, cartilage, fat, or perichondrium. Nevertheless, there are several restrictions on both the materials and surgical techniques used. Thus, the idea of tissue engineering is to make use of scaffolds and cells in the field's advancements. To adopt novel strategies that may be carried out in an outpatient, this field of tissue engineering ensures and permits the creation of new materials with high biocompatibility that replicate the mechanical characteristics of the natural TM. Moreover, they prove advantageous because of shortened recovery time and reduced expenses [11].

Currently, myringoplasty and tympanoplasty have high success rates in the closure of TM perforations and restoring the integrity and functionality of TM. But both the surgeries require the usage of anaesthesia and incisor in obtaining the graft material. Moreover, surgical complications occur resulting in multiple interventions in the closure of perforations. In the current scenario, nonsurgical, cost effective and safer alternatives are required which is satisfied by tissue engineering. The 3 principles of tissue engineering are aimed at the restoration and TM working. Unfortunately, the studies undertaken till now is unclear and has only demonstrated its benefits in models of animals or small group of people. Yet, the shortcomings and restrictions prevailing in the present surgical methods can be solved through tissue engineering which seems to be a promising field [12].

The suitable material for the repairing of TM is under study. Also, several varieties of grafts have been successfully used in myringoplasty surgery. Adipose grafts are utilized for eardrum lesions with a success rate achieved in temporal fascia, because these two options are the most usually used. Eventhough there are a variety of scaffolds and surgical procedures, several arguments prevail as to which is the best option for TM repair. The existing approaches have several pros and drawbacks as presented in Table 1.

Table 1. Pros and Cons of myringoplasty/tympanoplasty [13]

Pros of myringoplasty/tympanoplasty surgery	Cons of myringoplasty/tympanoplasty surgery
Rate of success is high.	Anaesthesia is needed for surgery.
Hearing results is good in case of smaller perforations.	Duration of surgery is longer.
Approach is least invasive.	Risk is high (open surgery)
Typical medical procedures.	Access to autologous grafts for revision surgery in eardrum repair is restricted.
	Incision is needed to obtain the graft.
	Inability for the closure of tympanic perforations because of poor regeneration of tissues around the damage. Reperforations occur frequently.
	Adverse effects such as retracted pockets, graft disapproval.

As a result, new strategies in the treatment of TM that gets beyond these limitations are needed. The use of tissue engineering, which attempts to make a membrane that replicates the shape, material mechanical characteristics, and functionality of the natural tympanic membrane, is an option with enormous promise for healing of the tympanic membrane. The pros and cons of tissue engineering are presented in Table. 2

Table 2. Pros and cons of tissue engineering [13]

Pros of tissue engineering	Cons of tissue engineering
Simplified eardrum repair surgery.	Primarily studies are based on animals with small perforation which heals in a short span.
Cost effective.	
Boosts the hearing results in tympanic perforation repair.	Absence of a common animal model to conduct study.
Opportunity to avail a readily accessible tympanic membrane for eardrum repair.	Detailed and complicated production of artificial synthetic parts.
Growth promoting elements boost the closure of perforations after surgery.	Inadequate human being individual research studies.
Certain scaffold design for material that mimics the mechanical characteristics of natural eardrum can be produced.	Possibility of negative effects of scaffold biomolecules.
	Concerns on laws and ethics regarding the use of xenografts

The researchers from Ear Science Institute of Australia produced an artificial ear drum using human skin cells. A specimen of artificial ear drum is represented in Fig. 3. The artificial ear drum is used for the replacement of damaged ear drum.

Fig. 3. Artificial ear drum [14]

1.4. Fabrication of Tympanic Membrane

Tympanic patches are developed as an alternative to surgical procedures or paper grafts to treat tympanic perforations. 3D printing technology was used to improve the artificial eardrum patch to overcome the traditional surgical techniques or the paper patch methods. The reasons for choosing polylactic acid, chitosan and sodium alginate for tissue engineering applications is due to their properties of biocompatibility and biodegradability [15]. Various concentrations of CS and SA were mixed with the pure PLA solutions and best concentration was identified for printability and finally PLA/CS and PLA/SA scaffolds were printed successfully using 3D printing method. While observing mechanical properties, it was observed that scaffolds had maximum level with pure PLA but there was a decline in the mechanical properties when CS/SA were added. Tensile properties of the 3D fabricated patches were like the tensile properties of the natural tympanic membrane [16]. The 3D printing technology has been excellent in replicating the exact thickness of natural tympanic membrane in the fabricated ear patches. The most distinguishing aspect of the fabrication of ear patches in tissue engineering is the ability to produce the ear patch of the desired pore size, thickness and surface morphology owing the entire credit to 3D printing technology.

Recent bio fabrication techniques include AM and electrospinning to manufacture scaffold morphologies. Electrospinning results in the production of nano to ultrathin fibres and the features resemble lamina propria of tympanic membrane [17]. The examples of AM techniques that enable the tympanic membrane is presented in Fig. 4.

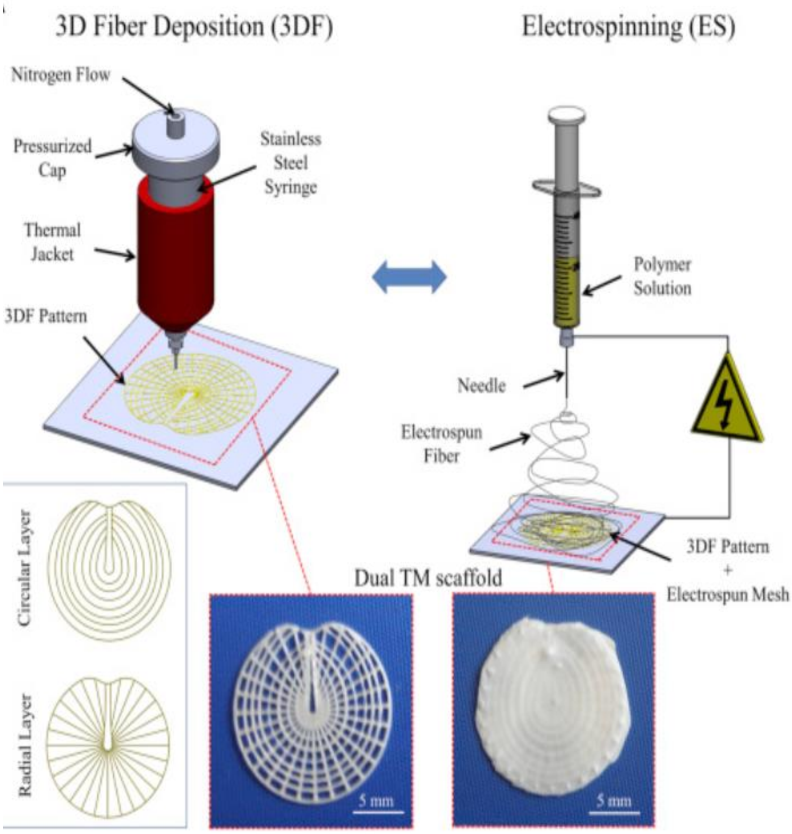


Fig. 4. Schematics of TM scaffold fabrication (radial and circular patterns) via AM nd electrospinning method [17]

Thus, tissue engineering saves lives and improves the quality of life. Patients feel uncomfortable during surgical procedures. The graft material is also not completely perfect because they create an opaque barrier in most cases and are not suitable for the restoration of acoustic function. Due to logistical challenges and lack of resources, high cost, patients from underdeveloped nations get affected. This is because of the lack of access to surgical grafting [18]. These flaws highlight the need for artificial ear drum in tissue engineering and to understand the capabilities of the artificial eardrums in treating tympanic perforations.

1.5. Chapter Summary

The most common problem in tympanic membrane is tympanic perforations and it is treated by myringoplasty or tympanoplasty deponding on the size of perforation. Autologous grafts are most widely used by surgeons in tympanoplasty surgery. Recent advancements in tissue engineering has resulted in grafts used for eardrum repair also provided 90% closure of perforations.

2. Materials

The common problem in otolaryngology which is often considered as chronic infection, loss of hearing, and middle ear trauma is tympanic membrane perforation or eardrum perforation. Tympanic membrane perforation (a thick wound) depends completely on lateral tissue for healing, yet it recovers quite well. 90% of perforations can naturally heal without treatment, however still 10% progress to chronic conditions. In the world, there are 330 million people who suffer from chronic otitis media. Perforation occurs at the rate of around 18% and patients complain of hearing loss, severe ear pain, tinnitus, and bleeding. 60% of patients have a serious hearing impairment. As a result, research into repairing a damaged tympanic membrane has endured [19]. Tympanic membrane repair is the primary surgical procedure used in clinics. The aim of the TM surgery is to repair the tympanic membrane perforations, to prevent reinfection and to restore hearing. The surgical treatment that is performed to repair tympanic membrane is called tympanoplasty [20]. Prior to the surgery, patients give their consent to tympanoplasty procedure. The risks associated with the surgery includes bleeding, postoperative surgery, bleeding, pain, further hearing loss, deafness and facial palsy caused due to facial nerve injury. The grafts used in eardrum repair can be divided into three categories namely autografts, synthetic grafts, and allografts or homografts.

2.1. Review of Natural Tympanic Membrane Graft Materials

The transplantation of a graft to the same individual is called autologous graft. Berthold achieved the authentic repair of TM for the first time in otology field by using a graft from forearm skin in 1878. The use of temporalis fascia in eardrum repair was initially proposed by Storrs in 1961 and was widely publicized. The common autologous grafts used in the tympanic membrane repair are temporalis fascia, perichondrium, cartilage, cartilage without perichondrium, veins, skin, fascia lata and fatty tissue [21].

Like skin repair, natural grafts are used in healing damaged or perforated eardrum. Specifically, autografts, biopolymers and decellularized tissues are the materials used. Generally, autografts consist of temporalis fascia, perichondrium or cartilages taken from the patient during tympanoplasty surgery. The connective tissues that are derived from tissue banks and xenografts are called decellularized tissues. These substitutions can boost host cell recruitment, proliferation and differentiation since the original molecules function is largely preserved [22].

<u>Temporalis Fascia</u>
The most primarily used graft in tympanoplasty surgery is temporalis fascia due to its easy accessibility to surgicial site. Also, the temporalis fascia is manipulated easily for implantation during tympanoplasty surgery. Thus, temporalis fascia becomes possibly incorporated with the natural TM after surgery. According to Danielle et al., the thickness and structure of the ear drum reconstructed using temporalis fascia differs from the natural tympanic membrane [23]. The temporalis fascia grafts used in successful tympanoplasty show significantly different thickness and structure than natural eardrum. Even after implantation, the thickness and structure of fascia grafts remains constant and do not vary much for several decades. The disadvantages of temporalis fascia graft are as follows:
Temporalis fascia graft has poor dimensional stability and hence leads to residual perforations in case of large TM perforations. The poor dimensional stability can contribute to the inadequate closure of TM in larger perforations. Rate of failure is high in ossiculoplasty, atelectatic ear, retraction pockets, eustachian tube dysfunctioning [24].

The tragal cartilage graft material has better survival rate than non autologous graft materials. In contrast to other autologous grafts, the rate of extrusion of tragal cartilage is very low.Fig. 5. shows broad tragal cartilage removed from perichondrium with full thickness.

Fig. 5.Cartilage cut into small palisades for eardrum repair[25]

The tragal cartilage is advantageous graft material because of the following reasons:

- Tragal cartilage is rigid and economical.
- Provides resistance to absorption.
- Survival rate is good.
- Graft can be taken out of the same surgical injury or damage [26].

The disadvantages of tragal cartilage graft material includes the following reasons:

- Lack of stiffness.
- Leads to tragal deformity and resorption of TM.

The temporalis fascia graft used in tympanoplasty surgery results in reperforations, or retraction occurs after eardrum reconstruction because the temporalis fascia grafts deform its shape. The shape of temporalis graft is changed because the graft shrinks and thickens unevenly after a few days of tympanoplasty surgery. Since the fascia graft is not as thick as cartilage, the vibrations of the cartilage are mechanically controlled in contrast to the temporal fascia. This causes the loss of hearing outcomes and sensonerinol hearing loss. The smaller pieces of palisade cartilage used for the tympanic membrane repair surgery provides improved mobility and acoustic impedance is lessened. The disadvantages of using palisade cartilage graft in tympanoplasty surgery is that the palisade cartilage grafts always interfere with the mechanism of sound conduction and hence result in poor restoration of hearing. The most popularly used grafts in tympanoplasty surgery in recent years is autologous fat. The success rate of using adipose tissue in TM perforation repair varies from 76% to 100%. Also, growth factors and angiogenesis released by fat grafts urge neovascularization and repair of tissues which increases blood flow around perforated ear drum [27]. An overall review of autologous graft materials is presented in Table 3 below.

Table 3. An overview of autologous graft materials[28]

Graft Material	**Methods**	**Observatory period**	**Results**
Temporal muscle fascia, vein	Comparison of the results of venous graft and temporal fascia graft in tympanoplasty surgery	2 weeks,1 month and three months after surgery	Temporal Fascia Absorption rate-80% Hearing improvement-66.7% Venous graft Absorption rate-83.3% Hearing improvement-70%
Fascia, cartilage	Compare outcomes between temporal fascia graft implanted in 31 patients & cartilage graft implanted in 82 patients in tympanoplasty surgery	One year	Average ABG gain Fascia-9.70dB Cartilage-9.78dB
Fat	Umbilical cord implants utilized in myringoplasty (twenty-eight people)	3-26 months	TM closure rate is completely successful in all patients.
Temporal muscle & perichondrium	Comparison of the outcomes between temporal muscle implant used in 71 patients and chondroperichondrium graft used in 61 patients in tympanoplasty surgery	2 years	Temporal fascia 60 patients-good tympana (new) 7 patients-reperforation Perichondrium 60 patients-Tympanum healed well. 1 patient-reperforation.
Fat	Fat graft eardrum repair	1 year	TM closure rate is 82.4%
Ear fat, abdominal fat	Different parts of fat used in tympanoplasty	Two months post surgery.	Both grafts proved to be effective in TM healing.

From Table 3, it can be interpreted that the absorption rate and hearing outcomes of venous graft is better than temporalis fascia graft. The tympanic membrane closure rate is better in fat grafts than other grafts. From Table 3, it is evident that the best choice for TM repair are temporal fascia and cartilage grafts. The acoustic transfer of sound, ABG closure and hearing gain is comparatively similar in both the groups. Also, the cartilage grafts are advantageous as operating time is less and rehabilitation is faster than fascia.

Although autologous materials like tragus cartilage, temporal fascia, skin grafts and others are often employed in clinical trials, obtaining them can harm the patient to varying degrees. Correction surgery is made when reperforation occurs because of infection or otorrhea after surgery. But there is difficulty in obtaining the surgical materials and, the materials used must be made on temporary basis. It results in scar marks post perforation repair and thus leads to an increase in operation time and pain. These grafts typically face difficulty integrating into the eardrum and are mechanically unstable. Another type of tympanoplasty involves an autologous transplant of cartilage taken from the outer ear. Although the cartilage grafting method has shown high mechanical stability after surgery. The autograft still needs to be hand-carved to the appropriate size and form, which may be quite problematic with oddly shaped TMPs. The claimed success rate for the 55,000 tympanoplasties carried out in the United States generally ranges from 43% to 100% and is heavily reliant on the knowledge and expertise of the surgeons [29].

Several pathologies that affect the tympanic membrane which includes otitis media, tympanosclerosis, perforation and cholesteatoma. In case of small perforations, paper patches have been used on the hole which induces self-repair through cell migration. But the drawback of self healing is that the eardrum might not have the functioning of middle fibrous layer. Contrarily, in tympanic membrane with large perforations, connective tissue grafts have been implanted through surgery as a replacement for tympanic membrane.

Allografts

The grafts that are derived from different individuals belonging to the same species but with a totally different genetic makeup are called allografts or homografts. The disadvantages of allografts are as follows:

- Risk for disease transmission
- Biocompatibility issues
- Probability of displacement is high.

The main restrictions of allografts include lack of human donors, biohazards and interdonor variability. The most used ones include urinary bladder matrix, swine small intestine submucosa (Surgisis) and acellular dermal matrix (Alloderm). Alloderm is of human origin and has been demonstrated in an animal model to be effective in healing acute and chronic perforations. These increase the infiltration process and lead to the quick development of Alloderm’s therapeutic uses and high success rates [30].

Disadvantages of natural TM materials

The life span of autologous grafts is very short and therefore leads to incomplete tympanic membrane regeneration. Also, they serve as an aid for the development of new cells. Hearing is not restored in 40% of cases after tympanoplasty. The reason for poor auditory recovery is due to the abnormal healing process of tympanic membrane and osscicular injuries. A second incision needs to be performed for TM repair using autologous materials and graft sampling side could get infected [31].

2.2. Review of Artificial Tympanic Membrane Materials

The techniques utilized for current TM reconstruction remain largely unchanged from those originally described by Sheehy for more than 50 years. The most used autologous grafts in transcanal or post auricular tympanoplasty to repair damaged TM includes vein, fascia, perichondrium, or cartilage.
Also, the hearing outcomes of eardrum repair surgery with autologous grafts reported failure rates upto 20% in several cases with large perforations. According, to 4 large reviews, 56% to 60% of postoperative patients had persistent conductive hearing loss more than 10dB [32].

For TM reconstruction, the autologous materials may not be the best option for various reasons.
1.Grafts may not be available for revision surgery and require a second incision harvest from the patient.
2.The mass and thicknesss of the autologous grafts' materials cannot be optimized for conduction of sound and halt TM retraction due to their structural properties.
3.Certain kinds of autologous graft materials possess structural flaws that could result in retraction, weakness and large reperforations.

An option which is readily available in the market may solve the present issues of autologous graft and become more significant in the modern age of transcanal endoscopic surgery. Researchers have sought to heal eardrum perforation using patch technology, gelatin sponge, and hyaluronic acid since 1960. But the application of these materials has its limitations. The instability in the success rate of tympanoplasty requires the need for new techniques to implant the graft onto the tympanic membrane without any overlap. Even though tissue transplantation and organ transplantation has been considered as a revolution in the field of medicine, there are some limitations like the unavailability of donor that hinder their usage on several million patients worldwide. There are various challenges like immunity response during the tympanoplasty/myringoplasty surgery which may lead to the refusal of transplanted autologous graft over a time. Hence, the onset of using tissue-based materials in TM regeneration [32].

There are several repair materials like hyaluronic acid, silk fibrion, collagen, chitosan, or biopolymers. They provide excellent mechanical support but lack cell proliferation and angiogenetic effects. Lee JM and Min J demonstrated that acellular dermis could successfully replace perichondrium in their comparison of perichondrium graft and human acellular dermis graft in TM repair [33]. Compared to the scaffolds, polymers have many advantages such as the ability to customise their shape, structure, size, and porosity. Thus, a review of outcomes of various non autologous graft materials has been present in Table 4.

Table 4.A overview of non autologous grafts used for eardrum repair [34]

Artificial Material	Methodology	Observatory area	Outcomes
Chitosan plus sodium based composite polylactic scaffolds	Different stents were prepared using 3D printing method for TM repair.	Physical and mechanical properties.	3D patches of PLA/CS, SA showed great results to repair TM [35].
Sterile acellular allogenic dermis	Transcanal Endoscopic Tympanoplasty (TET) was performed in 26 patients and Endaural Microscopic Tympanoplasty (EMT) was performed in 27 patients.	3 months post surgery.	Transplantation success rate TET group-92.3% EMT group-96.3% No significant difference [p=0.610]
Acellular human allogenic dermis	Air bone gap and hearing gas conduction were measured in 2 groups. Autologous perichondrium (33 patients) and acellular human dermal allograft (27 patients)	Success rate was achieved in 1- and 6-months post surgery	-Full closure of TM -Probability of difference is 0.5 -probability is small.
Gelatin sponge	Total 114 patients with TM holes were split by 2 categories. 1.Instant curing-57 patients 2.Gelatin sponge application-57 patients	3 months post operation	<u>Relieving rate</u> -Instant curing group-90.4% -Gelatin group- 94.5% -No significant difference obtained [36].
Bovine and equine pericardium	29 patients- Bovine pericardium 21 patients- equine pericardium	Recovery rate	Bovine pericardium-66% Equine pericardium-83% Equine pericardium-most effective.

Artificial Material	Methodology	Observatory area	Outcomes
Epidermal growth factor (EGF) and patch made of gelatin sponge	Total of 141 patients were split among three categories. EGF group-47 patients Gelatin patch group-47 patients Observation group-47 patients.	6 months	Closure pace EGF category- 97.8% Gelatin sponge category-86.7% Observation group-82.2% [38].
Fibroblast Growth Factor-2(FGF-2) added with gelatin sponge patch	Comparison of differences between Fibroblast Growth Factor-2 plus gelatin patches, gelatin sponge and observation category.	Closing rate	Perforation rate of closure 1.FGF-2 along with gelatin patch group-97.9% 2.Gelatin category-89.8% 3.Observation group-70.7%
Silk fibrion	Silk fibrion membranes were prepared and cultured with tympanic keratinocytes	Proliferation of cell	Tympanic keratinocytes growth is assistd by silk grafts [38].
Silk patch, paper patch	In 40 cats, silk patches were used for repair in left earlobes and paper in right ear lobes.	Curing time	Average curing time Silk patch-7.2±1.48 Paper patch-9.1±1.11 Difference in curing of each treatment was 1.9 days.
Gelatin Foam	Total 101 patients with TM holes were split among 3 categories. 1.Instant curing-30 patients 2.Gelatin foam repair application-31 patients. 3.edge approach +gelatin repair -30 patients.	3 months post operation	Relieving rate -Instant curing group- 85% -Healing rate of other two groups were 97%.

Artificial tympanic replacements can also be made using tissue engineering. In order to repair, preserve, and enhance the structure and functionality of injured tissues, a number of materials, techniques are employed.
Some of the materials utilized in artificial tympanic membrane are as follows.

- Polylactic acid
- Polylactic acid-glycolic acid
- Polyvinyl alcohol
- Polyethylene terephthalate

Tympanic membrane holes are fixed using polydimethylsiloxane patches immobilized with collagen. PDMS is the sought after biomaterial grafts because of its poor toxic nature, inertia, and excellent biomechanical properties. Tympanic membrane stents were made using chitosan (CS) and polylactic acid hybrid membranes, which were derived from various alkaline organic acids. The membrane has mechanical characteristics that are comparable to those of human tympanic membranes, according to SEM image analysis. It also has a consistent and steady nanofiber structure. CS/PVA membranes are hydrophilic, resistant to water, and have excellent biocompatibility through indirect cytotoxicity tests. The aforementioned properties of the membrane cause them to encourage tympanic membrane cell growth to aid in TM repair, and is anticipated that they will turn the membrane into scaffold substance for eardrum hole repair [39].

SEM was employed for in vitro degradation experiments, demonstrating their biodegradability, biocompatibility and excellent endurance. The metabolized products are taken by the body itself following the regeneration of the eardrum. The biological graft is a smooth substance which changes with the patient's anatomical structure, in accordance with the tensile test involved to assess the biomechanical characteristics of the polymer. The synthetic patch has a lower closing rate than the allogenic autograft because there is no need of general anaesthetics, the procedure takes less time, and there is less discomfort, it is still advantageous for transplantation. At the moment, the tympanic membrane patches made of nanomaterials like chitosan and collagen-modified polymers are of greater interest to academics. Strong plasticity, excellent biodegradability, and uniform mass production all contribute to the polymer stent's distinct benefits [40].

2.3. Review on Fundamental Properties of PVDF

PVDF is considered as one of favorite polymers of fluoropolymers family due to its mechanical strength,excellent stability at high temperatures, piezo electric properties and resistance to various chemicals like acidic solutions, solvents and fats. PVDF is a thermoplastic polymer and semicrystalline in nature [41]. Inspite of being semicrystalline, PVDF shows good thermal,chemical and mechanical properties among wide range of temperature. The unique feature of PVDF is piezoelectricity (a combination of mechanical properties and electrical properties), high chemical resistance and retention to purity standards. The five crystalline forms of PVDF includes alpha, beta, gamma, delta and epsilon. The beta form has a molecular chain with a zigzag structure having flourine on one side and hydrogen on the other side [41]. The beta phase is considered to be an interesting crystalline form because it has both ferroelectric and piezoelectric properties due to its polar structure [42]. The structural formula of PVDF is shown in Fig.4. below.

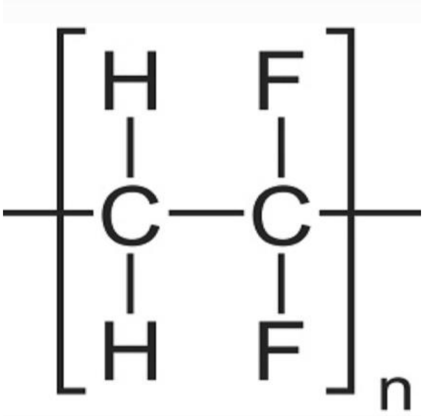


Fig. 6. Structural formula of PVDF [42]

2.3.1. Properties of PVDF

A characteristic feature that can be identified without chemical composition change is called physical property. For example,melting point,color,boiling point,texture,electrical conductivity etc.,. If the substance undergoes chemical change like transforming from one form to another, then it is called chemical property. PVDF falls under the list of fluorinated polymers. Hence,it has properties of high melting point and electrochemical stability. The chemical structure of PVDF is quite simple which makes PVDF exhibit good tensile strength and excellent resistance to creep and fatigue. The absorption of infrared rays is high in PVDF for the wavelength range 7-20µm [43]. The magnificient valuable properties of PVDF are as follows:

- Low melting point(177 º C).
- High mechanical stability.
- High thermal stability.
- High resitance to chemicals.
- High nuclear radiation resistance.
- High dieclectric constant.
- Low absorption of water.
- Higher mechanical strength than other fluoropolymers.

PVDF has the ability to take different forms of crystalline structure due to various sample preparation methods. The properties of PVDF thin film is presented in Table 5.

Table 5. Properties of PVDF thin film [43]

Properties	PVDF
Color	Colorless Opaque resin
Density(g/cm^3)	1.78
Young‘s Modulus at 23 ºC,MPa	1340-2000
Melting point, ºC, ASTM D-3148	177
Tensile stress at 23 ºC, Mpa	35-55
Elongation at 23 ºC, % ,Mpa	25-500
Dielectric strength,kV/mm,ASTM D-149	260-950

Materials like PVDF that possess piezoelectric properties tend to elongate when they are subjected to electric field by the generated mechanical strain. Hence, PVDF plays a major role in 3D printing of devices such as pressure sensors,fire sensors,actuators etc. The DU Pont corporation has the advantage to acquire high weight molecular PVDF which sounds technically important material. Electroactive polymers are given high importance because they have high capacity of converting mechanic action to electric charge. Hence, PVDF is employed as transducers for incoming signals. The electrical properties of PVDF prevent them from providing high insulation but they are used in pyroelectric converters due to ferroelectric and pyroelectric properties of PVDF [44]. The physical properties of PVDF allows them to be utilized in many applications. The distinguishing qualities of PVDF among various fluoropolymers which enables to acquire its top spot worldwide across several industries are as follows in Table 6.

Table 6. Qualities of PVDF and its explanation

Qualites of PVDF	Explanation
1.High heat resistance	Resistance to heat even at temperature fluctuations till -140ºC. Highly durable and flexible [44].
2.Ecofriendly material	Nontoxic and recyclable material. No toxic gases or hazardous chemicals are released into the environment when melted [45].
3.Composition of PVDF is pure	Components don‘t contain UV, lubricants, additives
4.Barrier to microorganisms.	Prevention of growth of algae,fungi . Valid for usage in food and medical industry.
5.Rarely combustible material	Low emission of smoke due to slow melting.
6.Easily processible material	Easy production of products in different shapes.
7.High product durability	High age resistivity (more than 50 years)

2.3.2. Applications of Using PVDF in Various Industries

1.Nuclear engineering-For handling waste in nuclear power plants, PVDF is utilized in making pipes, sheets due to its resistance characteristic feature.

2.Even in avaiation and aerospace industry, PVDF is used as seals, linings as the material provides flexibility and corrosion resistant.

3.In the field of electronics engineering, PVDF components are utilised as an insulator for electric wires due to lightweight and flexibility.

4.In the pharmaceutical industries, PVDF materials are utilised for packaging medical instruments as they provide exceptional sterility and cleanliness and enable autoclaving due to their excelent deformation feature and resistance to heat. PVDF surgical sutures also have high tensile strength and provides high chemical resistance.So, they would not cause any allergic reaction.

5.In biomedical industry, PVDF is considered as an highly stable and perfect material due to very low to minimum reaction to tissues and no capillarity and wicking which proves to be useful for surgery.PVDF is a synthetic surgical suture comprised of monofilament which is not capable of absorption. PVDF is ideally suited for use in cardiovascular surgery where it is necessary to withstand heart movement in situation where prosthetic valves and vascular anastomoses are involved. PVDF is also used in fixing prostheses, implants and even plastic surgeries [45].

A promising way to prevent the complications like inflamation, scar, wrinkling of prosthesis that occur during surgery is to use PVDF. It is also effectively used in reconstructive surgery. PVDF is also similar to polypropylene with respect to biocompatibility, bioresistance, resistance to infection but the former surpasses the latter in elasticity. Thus for evaluating the dynamic behaviour of prototype of artificial tympanic membrane, a prototype of TM is to be modelled and the material mechanical properties of PVDF is applied to the model to further analyse the frequency response and compare the results of frequency response of natural and artificial TM.

Stainless steel is utilized in ear prosthesis because of its biocompatible nature with the human tissues. It does not cause any allergy or obtain a potential immunity. This is an important feature as the material for implant should be accepted by the body without any side-effects. Stainless steel is corrosion resistant and hence does not cause any damage to the implants when eardrum is exposed to body fluids. Hence, the stainless steel eardums does not degrade over time as they as corrosion resistant and longevity, integrity of the stainless steel eardrum is ensured. The strength and durability of stainless steel is good to withstand the stress and strains of movement of ossicular chain. By using stainless steel, the eardrum rings can be shaped according to the patient‘s needs for surgery due to its malleability. Also, sterilization of implants made of stainless steel is easy to avoid harmful microorganisms and cost-effective compared to other materials[46].

High Impact polystyrene has good biocompatibity with the human body tissues and is light-weight in nature. The polystyrene is used to fabricate prostheses that needs good resistance and prolonged usage. The dimensional stability is good in polystyrene and hence this material is made use of in medical components [47]. Hence, PVDF, polystyrene and stainless steel are the materials chosen for the analysis of artificial eardrum.

2.4. Problem Definition

Tympanic membrane acts as a membrane with viscoelasticity and it is the entry portion of the sound wave transmission. The eardrum vibrates according to the frequency range of 20 Hz to 20000kHz. The eardrum changes its shape,mobility and transparency according to the middle ear pathologies [48]. Tympanic mebrane perforation is a rupture in the membrane which creates an opening between the middle ear and the pinna. The perforations are caused due to infections, penetration of objects, physical and blast traumasudden otalgia, otorrhea and vertigo. TM perforation is a hole which brings down the surface area which is responsible for sound conduction. In clinical words, Tympanic Membrane Perforations (TMP) can be termed as small, medium, total depending on perforation size. TMPs which are acute in nature show mild symptoms and if the perforation is around 80% they heal naturally within 3 months when proper precautionary measures like avoidance of water, cold air and imposed infection are taken. Rest of the cases lead to chronic perforations and does not heal naturally. The outcome of chronic perforation is chronic otitis media, choloesteatoma, recurrent infection and retraction packets. The size of the perforation and where is it sited and ear diseases add to conductive hearing loss. The eardrum perforations occuring as an effect of recurrent ottitis media leads to worklife imbalance in work-life, health, studies and social behaviour up to 360 million people globally [49].

There are various autologous graft materials like periosteum, cartilage, temporalis fascia, perichondrioum, fat in the tympanic membrane reconstruction. Though temporalis fascia provides good restoration of hearing, the dimensional stability could result in perforations in case of larger TM perforations are involved. The tympanic graft also results in poor restoration of hearing. Poor graft stability leads to failure of tympanoplasty surgery. The reason for failure is the addition of connective tissues. In such cases, cartilage grafts are used for revision surgery. But revision surgery may not lead to good hearing results. The autologous grafts required incision and in most cases grafts were not available for revision surgery and hearing is not restored in larger perforations.

Problem Solution

A key to the problems faced after tympanoplasty surgery is obtained by modelling a prototype of tympanic membrane with the artificial material and study the dynamic behaviour of both the natural TM and the artificial TM according to 2 different boundary conditions.

2.5. Chapter Summary

The most standard material for tympanoplasty surgery now is autologous temporalis fascia. But autologous materials require second incision and has high deformation and poor stability. This results in failure of tympanoplasty and requires revision surgery. Nevertheless, certain patients show recurrence and because of potential restrictions on the availability of autograft, the patients benefitted from biomaterial substitutes. The tympanoplasty surgery performed using autologous grafts pose a challenge based on cost, high performance, and safety. Artificial materials are easily available and particularly alloplastic materials provide high biocompatibility, mechanical stability, and ease of use. Also, new non autogenous biological scaffolds promote cell adhesion and have biocompatibility and mechanical stability than autologous materials. Thus, it is very important to choose the right suitable repair material to repair the tympanic membrane perforation which leads to improved hearing results and pus discharge.

3. Experimental Part

In the previous chapters, the ear perforations and materials used for the repair of eardrum is discussed. Tympanoplasty which is considered the simplest middle ear reconstruction procedure is widely used for TM perforation. After surgery, the tympanic membrane gets thicker and a layer is formed which is replica to that of the natural eardrum. Thus, tympanic membrane regains the same features and functionality after myringoplasty. The differences and changes that the tympanic membrane undergoes after myringoplasty seem to be quite unpredictable and unclear. The above- mentioned problem is presented in Fig.7. As the autologous grafts used in eardrum repair surgery did not provide better hearing results, the use of artificial eardrum in repair surgery is gaining attention as it is easily available and requires less incision. Hence, Finite Element is used to analyse and investigate such clinical scenarios involving acoustic mechanical behavior of the eardrum grafts and implants. In the subsections, the tympanic membrane is investigated in two ways. For this purpose, two CAD models of artificial eardrum are designed. The research aims to evaluate the dynamic behavior of the natural tympanic membrane and artificial tympanic membrane (prototype). The dynamic behaviour is analysed by performing frequency and harmonic analysis of the eardrums.

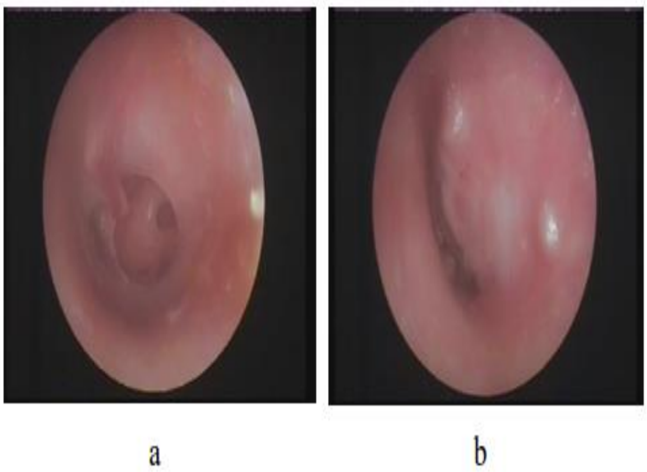


Fig. 7. a.TM with perforation before surgery. b.TM(thicker) after surgery [50]

3.1. Dynamic Analysis of Natural Tympanic Membrane

Numerous FE models of tympanic membrane are available in various literature sources. The models differ in geometry, material, boundary conditions and mechanical properties, dimensions. Several authors present various data of geometry based on anatomy or direct measurements from bones of middle ear. Regarding the FE modelling of TM, the investigation results on the geometry of tympanic membrane is presented in Table 7 below.

Table 7. Geometry of TM[50]

Parameter	Units	Real Dimensions
Diameter along the manubrium	mm	10
Diameter perpendicular to the manubrium	mm	8
Thickness	mm	0.3

The eardrum material characterisation is a matter of debate due to various invitro and invivo tests. Several research agreed upon density of tympanic membrane and poisson coefficients.Young's modulus value of 21 Mpa give excellent results in terms of hearing [50]. Thus,for the purpose of evaluating the dynamic behaviour of vibrations for natural tympanic membrane, a CAD model with recommended measurements as presented in Table 8 is modelled using Solidworks® Premium 2023 X 64 Edition software. CAD models are meshed using higher quality mesh. The material mechanical properties for linear elastic modelling prescribed in the model is shown in Table 8.

Table 8. Properties(Material) of TM[50]

Parameter	Units	Values
Density	kg/m^3	1200
Young's Modulus	MPa	21
Poisson Coefficient	-	0.35

The most efficient frequency for speech understanding are 500 Hz,100 Hz and 1500 Hz and this is the frequency range of humans. Moreover, the dynamic pressure is represented by the sound waves in human ear. Since there is no accurate data about the basic geometries of the human tympanic membrane, the dynamic analysis of natural eardrum with the cone of angle of inclination of 0^o is conducted. Fig. 8. represents CAD model of the natural tympanic membrane.

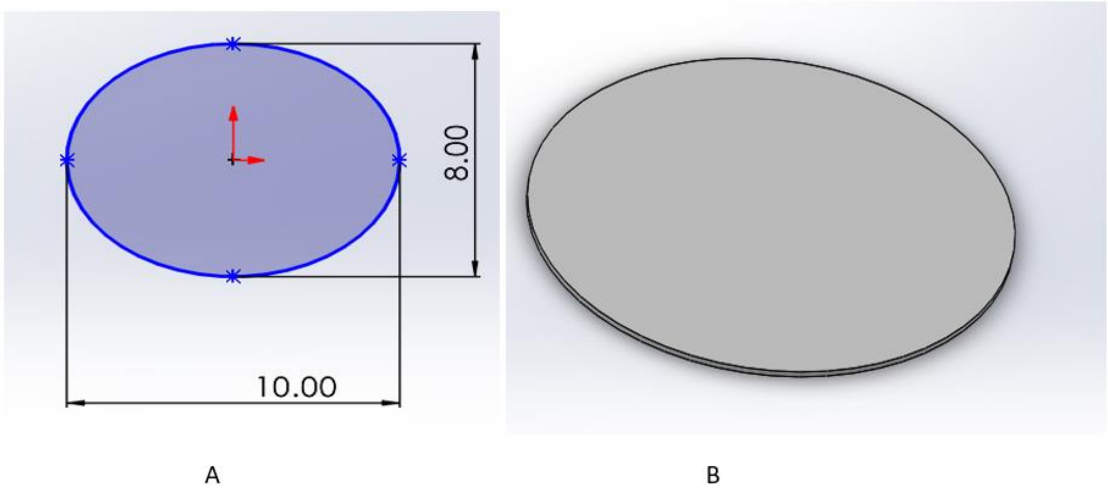
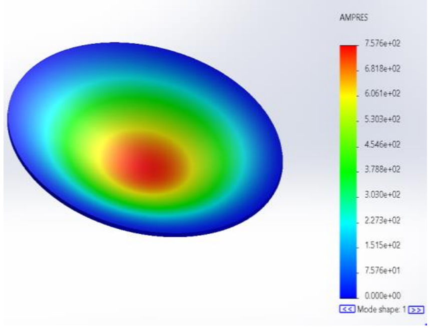
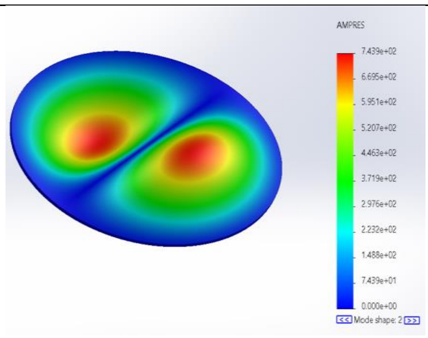
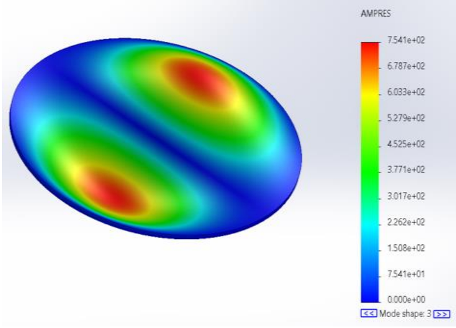
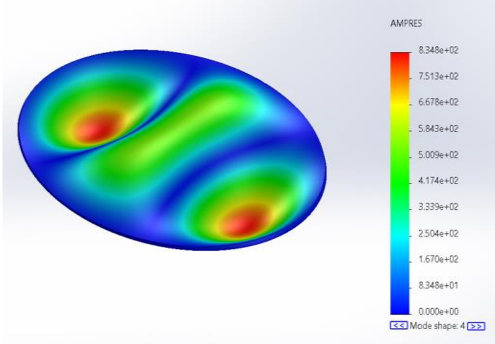


Fig. 8. A.Dimensions of natural TM B**.** CAD model of natural tympanic membrane

Pressure of 5psi is uniformly applied uniformly on the eardrum. A simplified version of TM was modelled to make calculations with reasonable cost and achieve accuracy at higher frequencies. Moreover, it provides the chance to compare results of dynamic analysis with previous results published around. The frequency analysis was performed with the TM model with the TM modes present without the ossicular part. In order to find out the frequency response of tympanic membrane, dynamic analysis was conducted. The dynamic analysis of intact TM is presented below in Table 9.

Boundary condition:Tympanic membrane is fully constrained.

Table 9. Frequency analysis of Intact TM (fully constrained)

Frequency Analysis of Natural Tympanic Membrane	
Modes and Frequency	Mode Shapes
Mode Shape 1- 249.92 Hz	
Mode Shape 2- 448.57 Hz	
Mode Shape 3- 531.93 Hz	
Mode Shape 4 – 818.8 Hz	

Modes 1,2,3 are simple patterns of vibrations as presented in Table 9. Since the ossicular chain is absent, the eardrum has a low effect at this frequency range. The 5th mode of vibration obtained at frequency of 904.28Hz contains four loops as presented in Fig. 9.

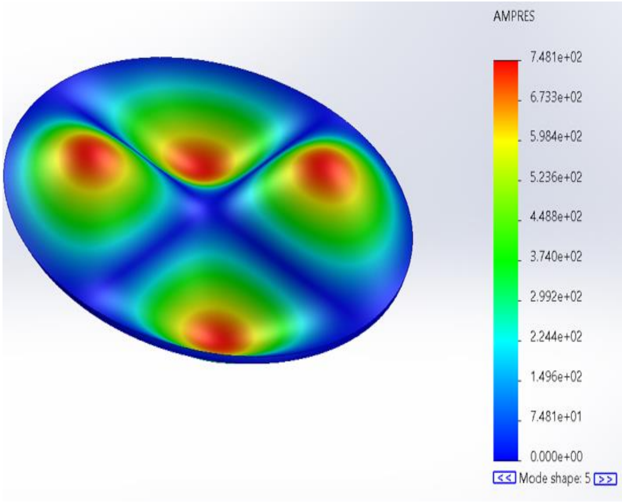


Fig. 9.Mode shape 5 at frequency of 904.28Hz of the natural TM

Table 9 shows the outcomes of the dynamic behaviour of the natural eardrum when eardrum is fully constrained. From Table 9 and Fig.10, the 1st five mode shape values of the tympanic membrane obtained is below 1000Hz. Thus, the resonant frequency value obtained here is below human speech frequency range. From mode shape 3 and 4, the minimum vibration is seen on the exterior part of eardrum. Fig.10. presents the first 5 modes and frequencies of natural tympanic membrane.

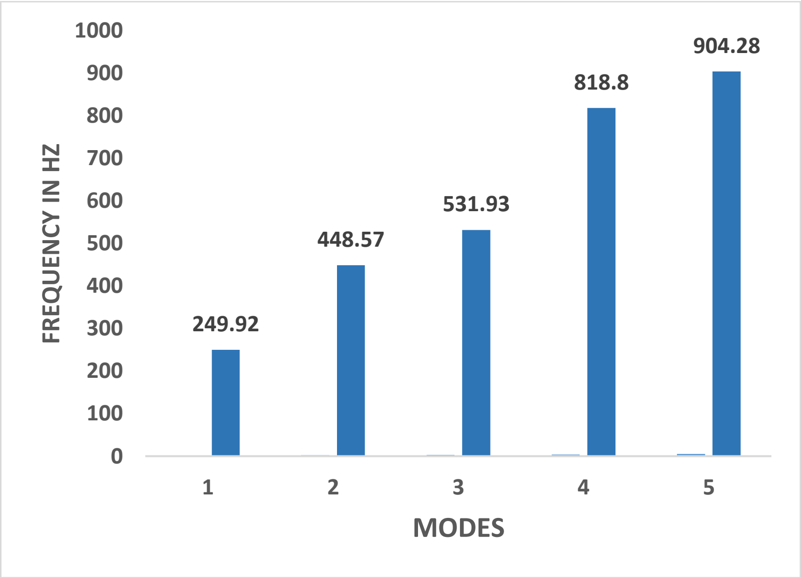


Fig. 10. Graphical representation of first 5 mode shapes and frequencies of natural TM

The key insight that can be drawn from the result is somewhat predictable. Also, it can be observed how the first few frequencies are correlated to the membrane stiffness by taking into considerations any exceptions that arises from boundary conditions or thickness of TM. Yet, it is very challenging to decide which model is best because each one yields unique outcomes. The other results, whichrange on the proposed elastic moduli, could be taken into consideration as acceptable, except for very low elastic modulus, which will be rejected as it seems to be unreal.

3.1.1. Harmonic Analysis of Natural Tympanic Membrane

To study and analyse the vibrations of the natural tympanic membrane, the harmonic analysis in Solidworks® Premium 2023 X 64 Edition software is conducted. The tympanic membrane is fully constrained and pressure of 5 psi is uniformly applied on the lateral side of tympanic membrane. For damping, Rayleigh damping value β is assumed to be 10^{-4} s and the same damping value is applied for harmonic analysis. The element is defined as solid type. In the element analysis, the total nodes is 28005 and total elements is 13643. Once the boundary conditions, fixtures and pressure is established, harmonic analysis is conducted and the outcomes of harmonic response at various frequencies is analysed.

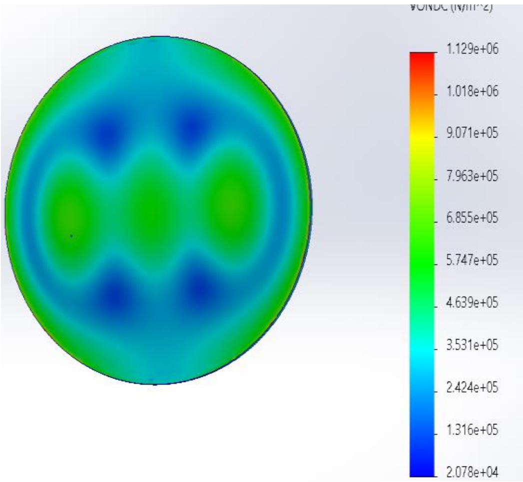


Fig. 11.Displacement of natural eardrum.

From the outcomes of harmonic analysis of tympanic membrane, maximum stress is exerted on face of TM and the highest maximum stress at a frequency of 2500 Hz is 1.120 x10^6 N/m^2 and the highest maximum displacement of 1.784mm at a frequency of 2500 Hz. Fig.12 shows the displacement of harmonic analysis of TM. From Fig.12, it can be observed that the highest maximum displacement in on the middle of eardrum.

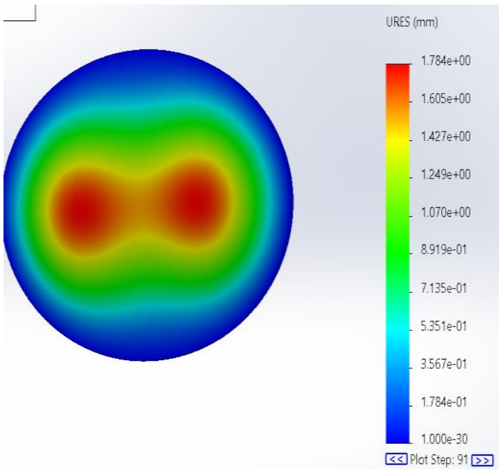


Fig. 12.Displacement of natural TM

3.2. Frequency Analysis of Artificial Eardrum 1

A prototype of artificial eardrum is modelled for repair in tympanoplasty surgery. The artificial eardrum is made of tympanic membrane and tympanic ring. The tympanic ring is included in the prototype because the tympanic ring helps to maintain integrity and shape of artificial eardrum and provides support to the structure of the artificial eardrum. During the tympanoplasty surgery,the tympanic ring helps to place the artificial eardrum in its correct position for proper functionin gothe ear. If the artificial eardrum is not fixed properly in its position, the sound waves do not get transmitted properly to the inner ear and more displacement takes places and results in the failure of tympanoplasty surgery.

The addition of tympanic ring in the artificial eardrum makes effective attachment and fixation of the artificial tympanic membrane within the human ear and secures the tympanic membrane for better hearing. The artificial eardrum mimics the structure of the natural eardrum as the tympanic ring relates to the tympanic annulus in the natural eardrum. The durability and resistance to wear and tear over time is increased by adding the tympanic ring in artificial eardrum. Such important factors need to be considered in designing prototypes for medical field because of the long term functionality of use in humans. Also, surgeons may find it easy for implanting and securing the artificial eardrum intact in its position as the tympanic ring facilitates better intergration of artificial eardrum within the ear.

Thus, to determine the dynamic behaviour for vibrations, a prototype of the artificial tympanic membrane is designed with the measurements i.e. diameter along the manubrium 88 mm and diameter perpendicular to the manubrium 93mm and thickness of 0.3 mm. The dimensions of the artificial eardrum is taken 10 times the dimensions of natural tympanic membrane due to limited research opportunities.The results of the frequency analysis is compared with the experimental results of the prototype using PRISM holography sytem. The dimensions of the tympanic ring are diameter along the manubrium is 87.31mm and diameter perpendicular to the manubrium is 82.88mm and thickness is 1.84mm. The Solidworks® v Premium 2023 x 64 Version Software was employed in creating CAD model of prototype of the artificial tympanic membrane with the dimensions mentioned above. The artificial eardrum is composed of tympanic ring and tympanic membrane as presented in Fig. 13. below.

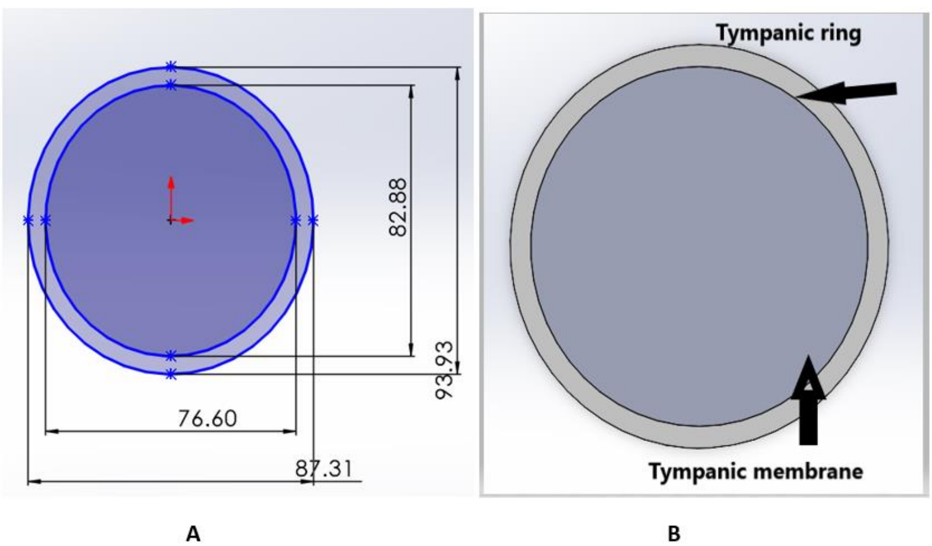


Fig. 13. A.Dimensions of the steel tympanic ring. B. 3D CAD model of prototype of TM

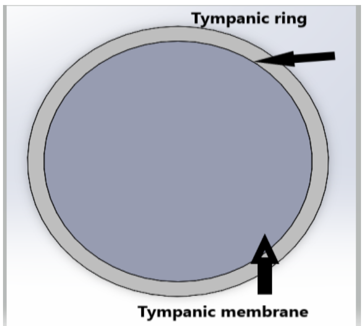
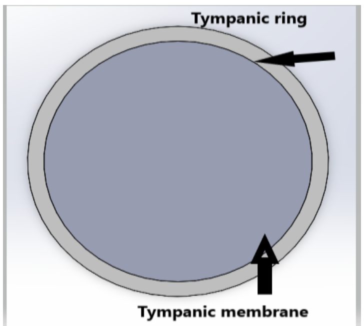
Inorder to conduct the frequency analysis of prototype of the tympanic membrane, boundary condition of fully constrained TM is considered and pressure of 5psi is applied on the tympanic membrane. In human beings, the tympanic membrane cannot withstand pressure above 5 psi and the ear drum may be ruptured when sound pressure exceeds 5 psi. PVDF and polystyrene materials are applied to the tympanic membrane and ASTM stainless steel is applied to tympanic ring. Two simulations of artificial eardrum are perfomed and the boundary condition is fully constrained. The same pressure is applied to the natural tympanic membrane also during the frequency and harmonic analysis. Then, the frequency analysis of both the simulations are compared. The material properties of PVDF and polystyrene are mentioned in the Table 10 below.

Table 10. Mechanical properties of PVDF and polystyrene [51]

Parameter	Units	PVDF	Polystyrene
Mass density	kg/m^3	1780	1050[32]
Elastic Modulus	GPa	3	3.4
Poisson Coefficient	-	0.4	0.325

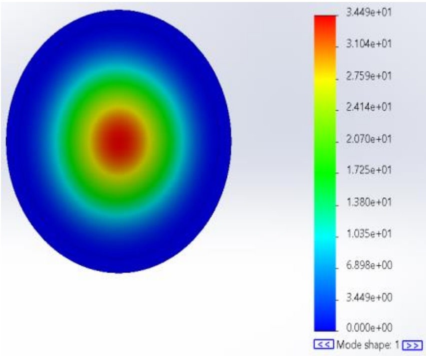
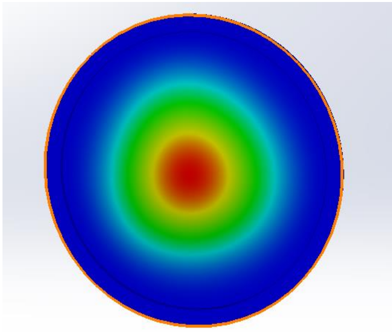
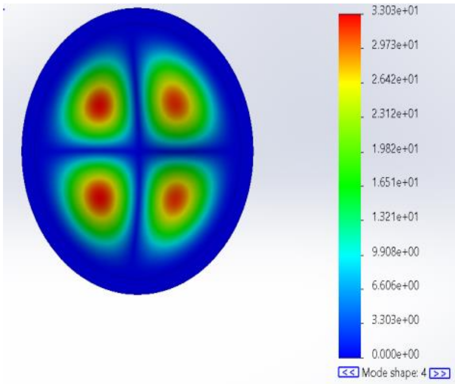
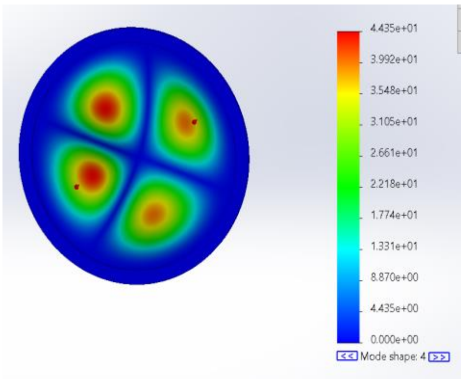
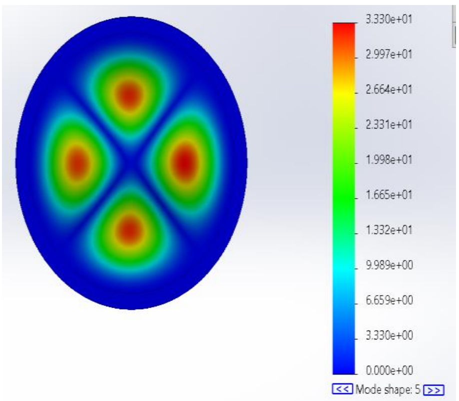
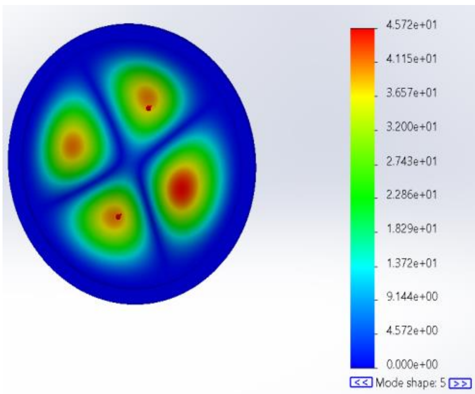
Boundary Condition-Artificial eardrum is fully constrained means the eardrum is prevented from being moved or deformed at all degrees of freedom. The function of the eardrum is to respond to the soundwaves and result in the transmission of the sound to the internal ear. This condition is usually used in simulations or analysis to understand the behaviour of eardrum. In real physiological conditions the human eardrum is not constrained fully. The 3D CAD model of artificial eardrum along with the boundary conditions and materials applied during simulation is presented in Table 11.

Table 11.3D CAD model of artificial eardrum with boundary conditions.

Description	Simulation 1	Simulation 2
Boundary Conditions	Artificial Ear drum is fully constrained. Artificial eardrum is intact in its position.	Artificial Ear drum is fully constrained. Artificial eardrum is intact in its position at the end of ear canal.
3D model of artificial eardrum		
Material Tympanic membrane	Polystyrene	PVDF
Material Tympanic ring	ASTM steel-436	ASTM steel-436

The calculated modes and frequencies of artificial eardrum 1 according to boundary conditions (fully constrained) and the material sapplied to tympanic membrane and tympanic ring is presented in Table 12. Table 12 presents the selected mode shapes and frequencies of artificial eardrum obtained using two different materials.

Table 12.Calculated modes and frequencies of artificial eardrum

Description	Simulation 1	Simulation 2
Boundary Conditions Materials TM Tympanic ring	Artificial Ear drum is fully constrained. PVDF ASTM stainless steel-436	Artificial Ear drum is fully constrained. Polystyrene ASTM stainless steel-436
Mode shape 1	Frequency-141.72Hz 	Frequency-273.205Hz 
Mode shape 4	Frequency-602.85 Hz 	Frequency-703.27Hz 
Mode shape 5	Frequency-604.24 Hz 	Frequency-716.61Hz 

From Table 12, in the PVDF-steel artificial eardrum, the first mode of vibration is a simple pattern in frequency f_1=141.72Hz and the fourth vibration mode has four fringes obtained at frequency f_4=602.85Hz and the fifth vibration mode has four fringes in frequency f_5=604.24Hz. The difference between the frequencies of fourth and fifth mode of vibration is 1.39Hz. Also, the deformation shape of fourth mode and fifth mode of vibration contains four loops and the shape looks similar.

From Table 12, in the Polystyrene -steel artificial eardrum, the first mode of vibration is a simple pattern in frequency f_1=273.205Hz and the fourth vibration mode has four fringes in frequency f_4=703.27Hz and the fifth vibration mode has four fringes in frequency f_5=716.61Hz. The difference between the frequencies of fourth and fifth mode of vibration is 13.34Hz. Also, the deformation shape of fourth mode and fifth mode of vibration contains four loops and the shape looks similar in this artificial eardrum.

From Table 12, the first resonant frequency occurs at mode 1 in 141.72 Hz for PVDF-steel eardrum and the minimum vibration is on the middle of the tympanic membrane. A similar pattern is obtained at mode shape 1 at frequency of 273.205Hz in polystyrene-steel artificial eardrum. It can be observed that all the mode frequency values are below the human speech frequency value. So, the protype will not cause any eardrum damage and transmits the pressure to the internal ear and results in good hearing. Fig.14 shows the graphical representation of calculated modes of vibrations and their corresponding frequency in Hz of PVDF-steel artificial eardrum.

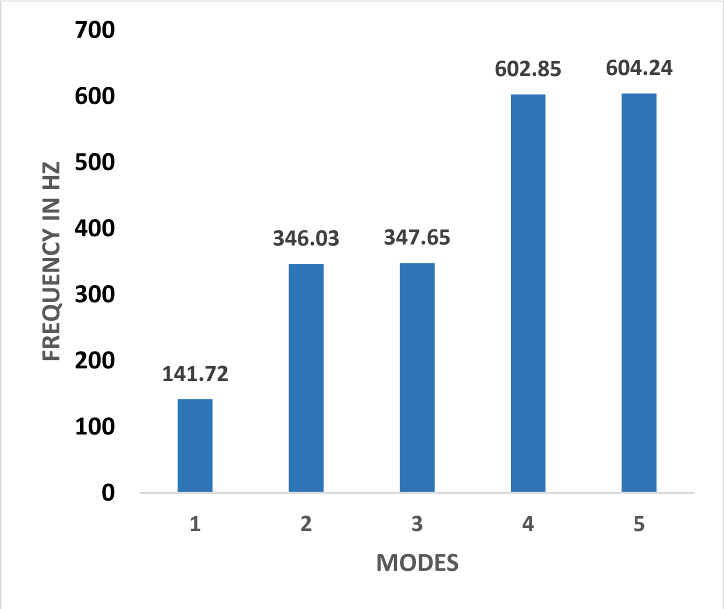


Fig 14. First 5 modes vs natural frequencies in PVDF-steel prototype

The frequency of 602.85Hz at mode shape 4 is much higher than the frequency at mode shape 3 with difference in frequency of 255.2Hz. The difference in frequencies shows the complexity in vibration pattern. The vibration pattern of mode shape 4 has 4 loops of PVDF-steel artificial eardrum as presented in Table 12. Even though the frequency difference between selected modes is high, all the 5 calculated modes of frequencies are within the human hearing frequency range and transmits sound waves to the inner ear. The graphical representation of calculated modes of vibrations and their corresponding frequency in Hz of Polystyrene-steel artificial eardrum is presented in Fig.15.

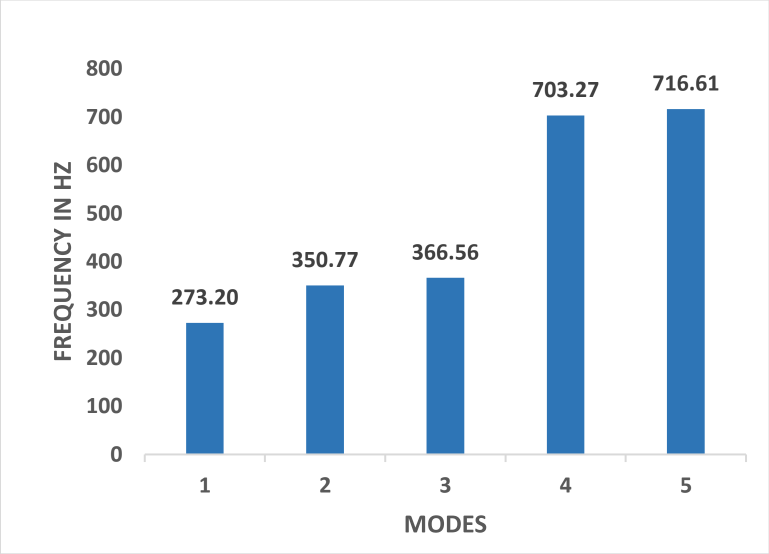


Fig. 15. First 5 modes vs natural frequencies in Polystyrene-steel prototype

The frequency of 703.27Hz at mode shape 4 is much higher than the frequency at mode shape 3(f_3=366.56Hz) with difference in frequency of 336.71Hz. The difference in frequencies shows the complexity in vibration pattern. The vibration pattern of mode shape 4 has 4 loops of polystyrene-steel artificial eardrum as presented in Table 12. Even though the frequency difference between selected modes is high, all the 5 calculated modes of frequencies are within the human hearing frequency range and transmits sound waves to the inner ear in polystyrene-steel artificial eardrum. The first resonant frequency is the frequency at which the artificial eardrum begins to vibrate. The first resonant frequency of PVDF-steel artificial eardrum is 141.72Hz and the the first resonant frequency of PVDF-steel artificial eardrum is 273.205Hz. If the first resonant frequency is higher, then the stability of the component is also higher. Also, at high frequencies the response time is fast, and the duration of vibrations is short. The PVDF-steel artificial eardrum has higher first resonance frequency than polystyrene -steel artificial eardrum. So, PVDF-steel artificial eardrum may provide more stability as they may be less prone to prolonged oscillations.

3.2.1. Frequency Analysis of Artificial Eardrum 2

The prototype of artificial eardrum 2 was modelled using the real dimensions of the natural eardrum and tympanic ring and the frequency and harmionic analysis of artificial eardrum is performed in Solidworks® Premium 2023 X 64 Edition software with 2 different boundary conditions.
Boundary Condition 1-Artificial eardrum is fully constrained.
Artificial eardrum is fully constrained means the eardrum is prevented from being moved or deformed at all degrees of freedom.
Boundary Condition 2-Artificial eardrum is not fully constrained.9/10 part of tympanic membrane is constrained and 1/10 part is left free. The described medical case where one part of the eardrum is left free and the other part is fixed or constrained is called flair ear. The flair ear is also called as flail segment. The flair ear occurs as a result of ear injury or trauma and part of the eardrum becomes detached or free while the rest of the eardrum remains fixed. Due tot he flair segment,the normal functioning of eardrum is affected leading to hearing loss. Therefore,the flair ear repair surgery in contingent on the condition of eardrum and severity and includes medications or surgery.

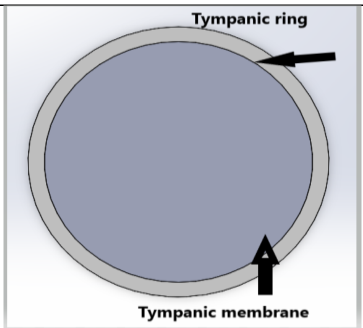
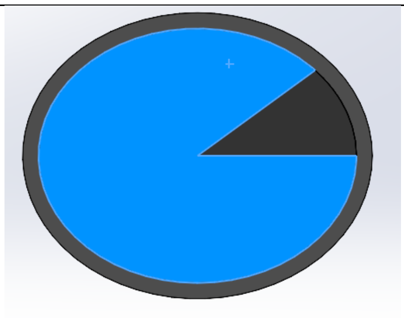
The material properties of tympanic membrane presented in Table 8 is applied to artificial eardrum 2 and the material properties of malleus is applied to the tympanic ring [52]. The frequency analysis of artificial eardrum 2 is performed under 2 different boundary conditions.The material properties of the tympanic ring is presented in Table 13.

Table 13.Material properties of Tympanic ring [52]

Parameter	Units	Values
Density	kg/m^3	$1.9 * 10^3$
Young‘s Modulus	N/m^2	$1.41 * 10^{10}$
Poisson Coefficient	-	0.3

The 3D CAD model of artificial eardrum 2 along with boundary conditions and materials applied is presented in Table 14.

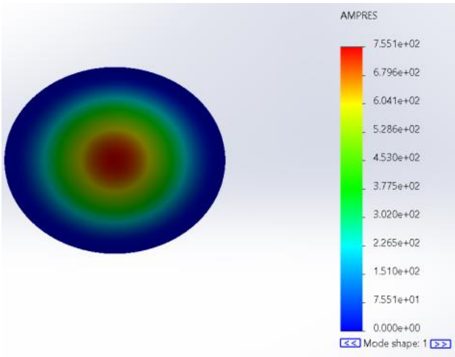
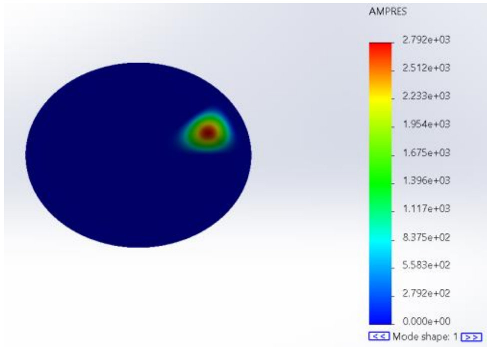
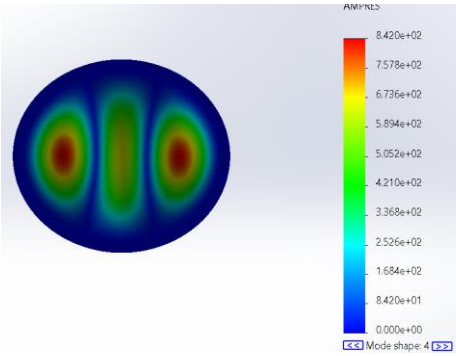
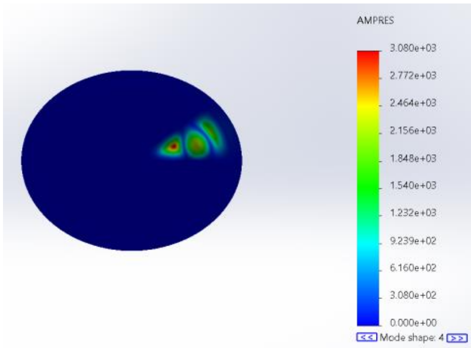
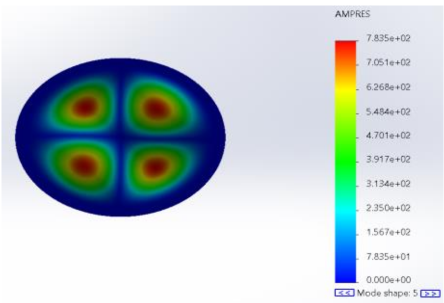
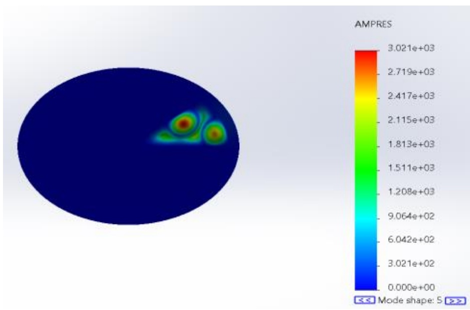
Table 14 .3D CAD model of artificial eardrum 2 with boundary conditions

Description	Simulation 1	Simulation 2
Boundary Conditions	Artificial Ear drum is fully constrained. Artificial eardrum is intact in its position.	Artificial eardrum is not fully constrained. Only One part of eardrum is free and all other part is constrained. Artificial eardrum is not intact in its position at the end of ear canal.
3D model of artificial eardrum		
Materials- Tympanic membrane	Natural TM	Natural TM
Material Tympanic ring	Natural Tympanic ring	Natural Tympanic ring

The selected modes and the obtained frequencies of artificial eardrum 2 under 2 different boundary conditions is presented in Table 15. When the artificial eardrum is fully constrained, the first mode of vibration is a simple cirular pattern in frequency f_1=1010.40Hz and the fourth vibration mode has three fringes in frequency f_4=1986.20Hz and the fifth vibration mode has four fringes in frequency f_5=2279.20Hz as presented in Table 15. The difference between the frequencies of fourth and fifth mode of vibration is 293Hz. Also, the deformation shape of fourth mode contains three loops while the fifth mode of vibration contains four loops. As the frequency increases, the deformation shape also becomes complex.

The selected mode shapes and the frequencies when the artificial eardrum is not fully constrained presented in Table 15 shows that the the first mode of vibration is a simple cirular pattern in frequency f_1=3741.40Hz and the fourth vibration mode has three fringes in frequency f_4=9050Hz and the fifth vibration mode has complex pattern in frequency f_5=11584Hz.

Table 15.Calculated modes and frequencies of the artificial eardrum 2

Description	Simulation 1	Simulation 2
Boundary Conditions	Artificial eardrum is fully constrained.	One part of the artificial eardrum is left free and other parts of the eardrum are fully constrained.
Materials Applied Tympanic Membrane tympanic ring	Natural Tympanic Membrane Natural tympanic ring	Natural Tympanic Membrane Natural tympanic ring
Mode shape 1	Frequency-1010.40 Hz 	Frequency-3741.40 Hz 
Mode shape 4	Frequency-1986.20 Hz 	Frequency-9050 Hz 
Mode shape 5	Frequency- 2279.20 Hz 	Frequency-11584 Hz 

From Table 15, it is observed that when the artificial eardrum is not fully constrained, the vibrations are observed only in the part where the eardrum is left free and vibrations are not obtained in the part of the eardrum which is constrained. The constrained part of the artificial eardrum is not vibrating as it should and hence this can affect the normal human hearing function. From Table 15, it is evident that in normal ear, the eardrum vibrates in accordance to the sound waves and has effective sound transmission to the inner ear where the sound vibrations are converted to electrical signals for brain to be interpreted as sound. But in the case of flail ear,the normal transmission of sound is disrupted. Since the vibration is observed only in the non constrained part of eardrum, the free part of eardrum can respond to soundwaves and vibrations are transmitted to the inner part of ear. Due to the lack of vibrations in the constrained part of artificial eardrum,the eardrum does not contribute effectively to the transmission of sound and hence hearing is affected and over a prolonged period of time leads to hearing loss. The first five modes and the frequencies of artificial eardrum 2(fully constrained) is presented in Fig.16. From Fig.16, the first five resonce frequencies of artificial eardrum(fully constrained) are in the range of 1010Hz to 2279Hz.

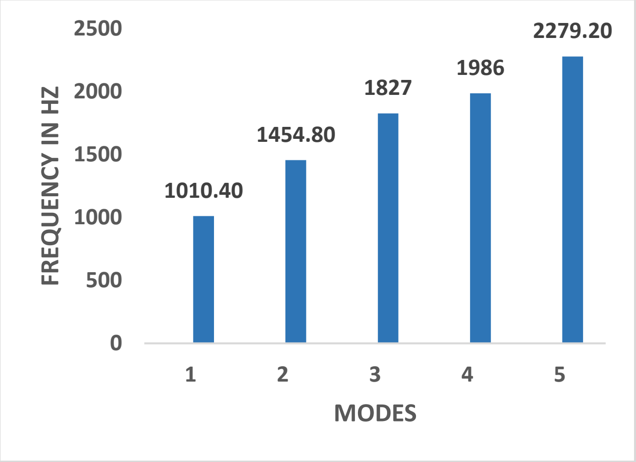


Fig. 16.Modes vs frequencies in artificial eardrum 2(Fully constrained)

The first five modes and the frequencies of artificial eardrum 2(not fully constrained) is presented in Fig.17. From Fig.17, the first five resonce frequencies of artificial eardrum(not fully constrained) are in the range of 3741Hz to 11584Hz.

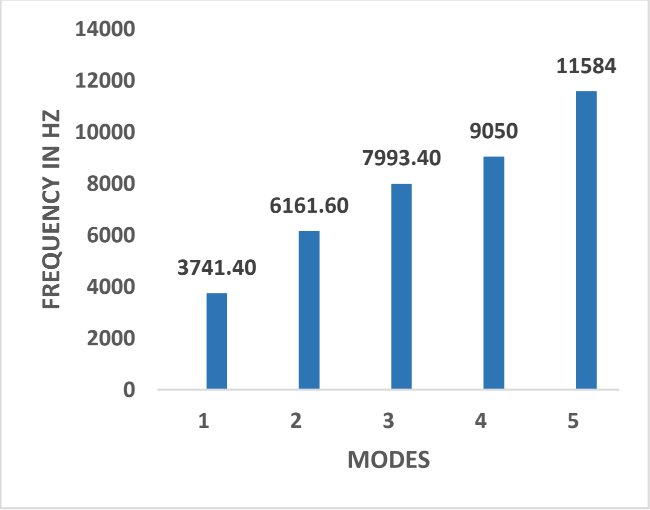
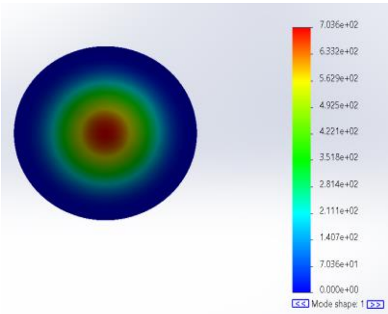
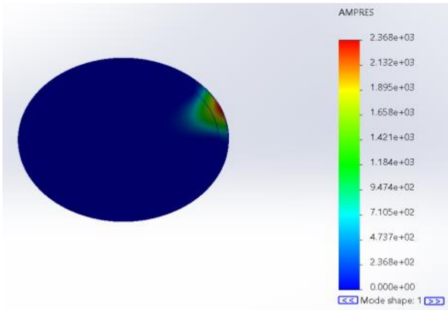
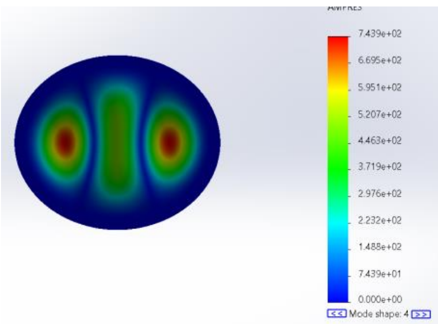
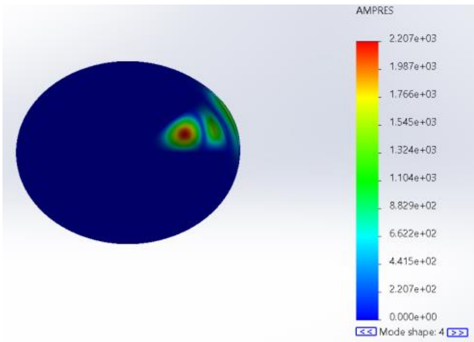
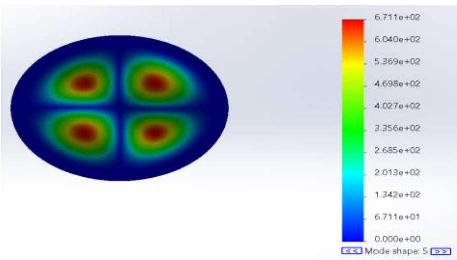
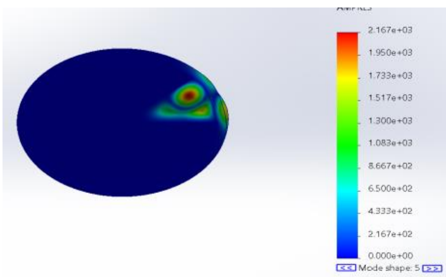


Fig. 17.Modes vs frequencies in artificial eardrum 2(9/10 part is constrained)

Even in the case of not fully constrained eardrum,the first five frequencies are within the human speech frequency values but the normal hearing is not achieved as the vibrations are not present in the constrained part of eardrum as seen in Fig. 17 and Table 15. The frequency analysis of artificial eardrum 2 where the tympanic membrane is of PVDF and the properties of malleus applied to the tympanic ring performed under 2 different boundary conditions (fully constrained and not fully constrained) is presented in Table 16.

Table 16.Calculated modes and frequencies of artificial eardrum 2 using PVDF

Description	Simulation 1	Simulation 2
Boundary Conditions	Artificial eardrum is fully constrained.	One part of artificial eardrum is left free and other parts are fully constrained.
Materials Applied Tympanic Membrane Tympanic ring	PVDF Natural tympanic ring	PVDF Natural tympanic ring
Mode shape 1	Frequency-3404.10Hz 	Frequency- 19828 Hz 
Mode shape 4	Frequency-10335Hz 	Frequency-54720 Hz 
Mode shape 5	Frequency-11578 Hz 	Frequency-75412 Hz 

When the artificial eardrum 2 (PVDF) is fully constrained, the first mode of vibration is a simple cirular pattern in frequency f_1=3404.10 Hz and the fourth vibration mode has three fringes in frequency f_4=10335 Hz and the fifth vibration mode has four fringes in frequency f_5=11378Hz as presented in Table 16. The selected mode shapes and the frequencies when the artificial eardrum (PVDF) is not fully constrained presented in Table 16 shows that the the first mode of vibration is a single loop in frequency f_1=19828 Hz and the fourth vibration mode has three fringes in frequency f_4=54720 Hz and the fifth vibration mode has complex pattern at frequency f_5=75412 Hz. In the artificial eardrum (PVDF), the vibrations are obtained on the edge of the membrane and ring in the free part of eardrum. There is a poor transmission of sound to the inner ear as there are no vibrations obtained in the constrained part of the artificial eardrum. The first modes of vibration and frequencies of artificial eardrum made of PVDF under fully constrained boundary condition is graphically presented in Fig.18.

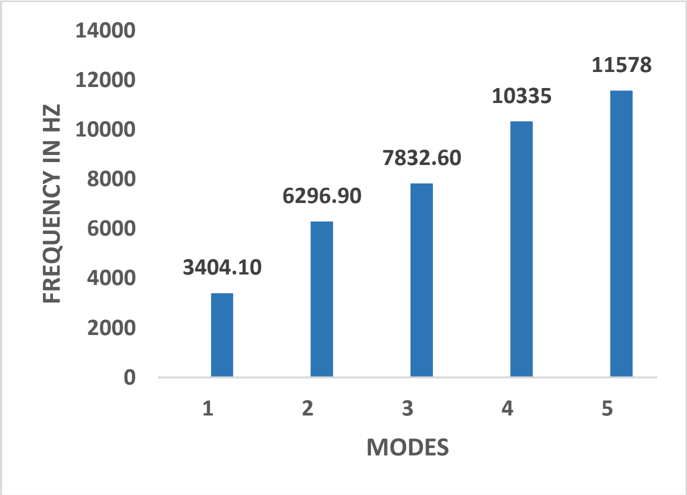


Fig. 18.Modes vs frequencies in artificial eardrum 2 (Fully constrained)

The first modes of vibration and frequencies of artificial eardrum 2 made of PVDF under not fully constrained boundary condition is graphically presented in Fig.19. From Fig.18 and Fig 19, the first mode shape frequency value of not fully constrained eardrum is comparitively much higher than the fully constrained eardrum.

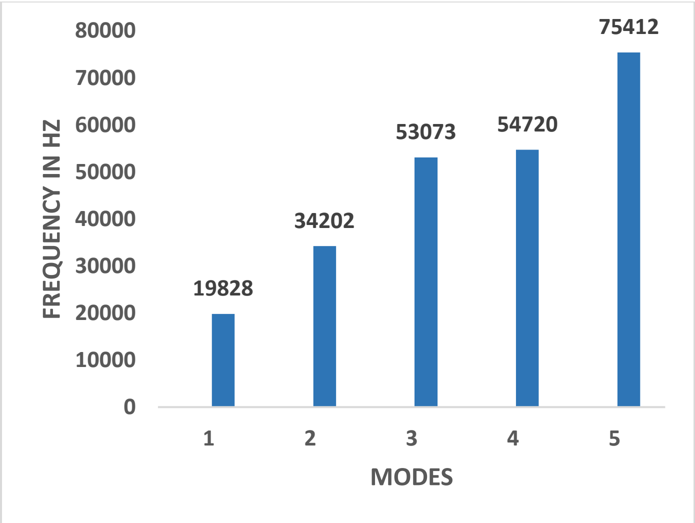


Fig. 19.Modes vs frequencies in artificial eardrum 2 (9/10 part is constrained)

3.3. Overall Results and Discussion of Frequency Analysis of Artificial Eardrum

The frequency analysis of artificial eardrum modelled using different materials and boundary conditions were performed and the vibrations and first 5 mode shapes obtained by the artificial eardrum were analysed. The comparison of first resonance frequency of artificial eardrum with different materials and constraints is presented in Fig.20. If the first natural frequency is high in artificial eardrum, the stability is more and then the artificial eardrum would not deform easily to external source of vibrations.

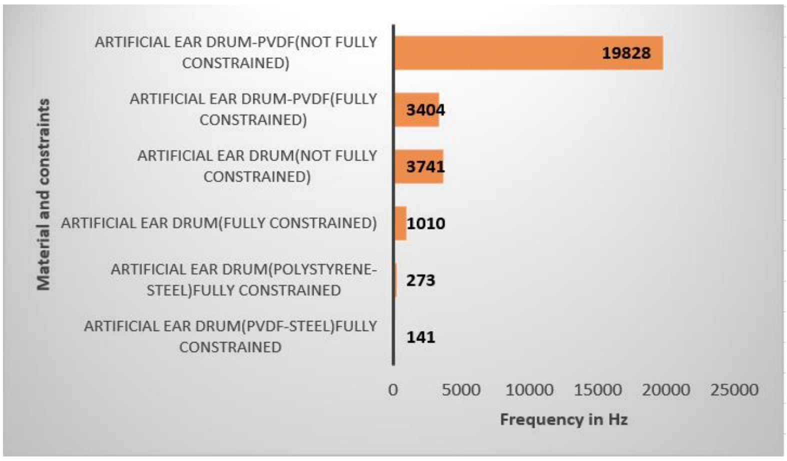


Fig. 20.Comparison of first resonance frequency

The first resonance frequency of the artificial eardrum of PVDF-steel (fully constrained) is 141Hz and for the artificial eardrum polystyrene-steel (fully constrained) is 273Hz. By comparing the prototypes of the artificial eardrum, the polystyrene-steel artificial eardrum has highest first resonance frequency and shows more stability than the PVDF-steel artificial eardrum.

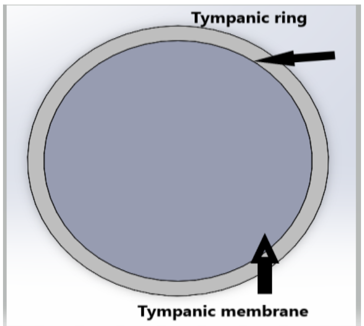
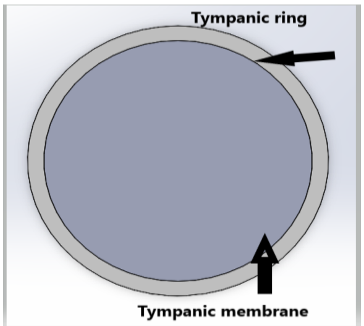
The first resonance frequency of the artificial eardrum (real dimensions, fully constrained) is 1010 Hz and for the PVDF artificial eardrum (real dimensions, fully constrained) is 3404 Hz. By comparing the artificial eardrum (real dimensions, fully constrained) with the PVDF artificial eardrum, PVDF eardrum can withstand external vibrations upto 3404Hz and deforms more at higher frequencies and hence shows more stability than the artificial eardrum with real material properties.

The first resonance frequency of the artificial eardrum (real dimensions, not fully constrained) is 3741 Hz and for the PVDF artificial eardrum (real dimensions, not fully constrained) is 19828 Hz. By comparing the fully constrained with not fully constrained artificial eardrum, the not fully constrained eardrum exhibits high frequency due to more freedom of movement.The first resonant frequency of PVDF eardrum (real dimensions, not fully constrained) is 19828Hz which is ultrasonic frequency and very much high compared to other resonant frequencies. This implies that such high first resonant frequencies are not perceived by the human hearing system and can cause potential physiological effects like hearing damage. When artificial eardrum is exposed to such high frequencies over a prolonged period of time at high intensity, it results in the damage of inner ear. The tympanoplasty surgery requires the artificial eardrum to produce less vibrations else the tympanoplasty surgery for perforations becomes more challenging. If more vibrations are produced by the artificial eardrum during tympanoplasty surgery, then the positioning and fixation of artificial eardrum becomes complicated and improper fixation leads to poor hearing results and revision surgery. Thus, the artificial eardrum made of PVDF(real dimensions) may provide good stability and hearing results in eardrum repair.

3.4. Harmonic Analysis of Artificial Eardrum

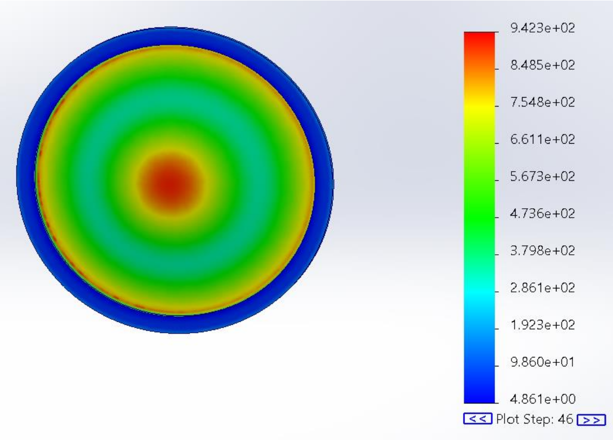
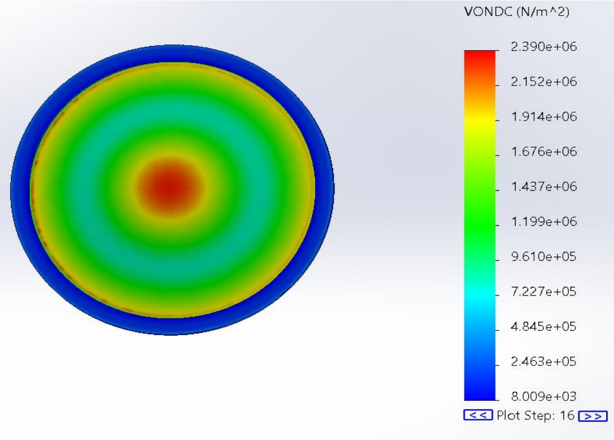
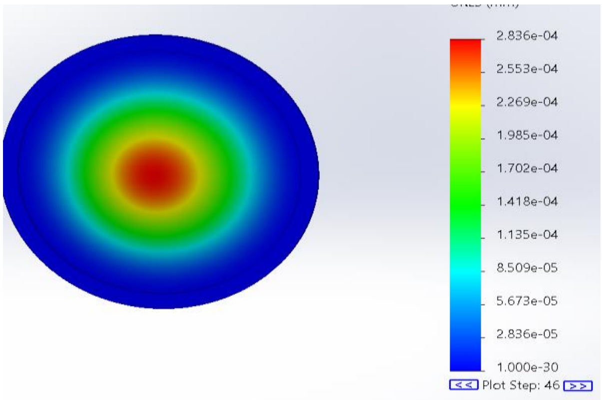
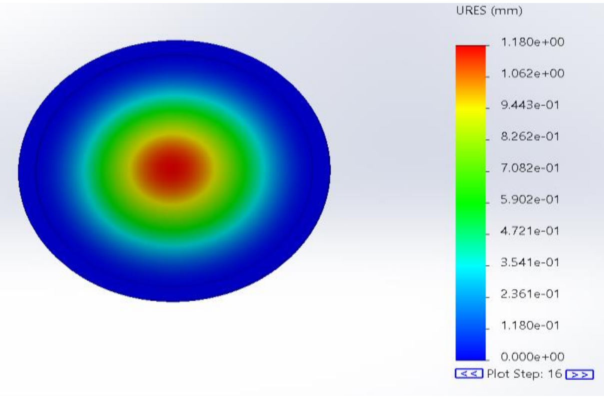
The investigation of the artificial eardrum models to understand how stress is distributed on the eardrum and maxium displacement occurs is performed using harmonic analysis method. The vibration properties of the artificial eardrum is demonstrated using harmonic analysis. During tympanoplasty or myringoplasty surgery,the artificial eardrum should be fixed intact in position. If the artificial eardrum is not fixed properly,then the sound waves are not transmitted properly to the inner ear and hence hearing is not restored and results in failure of tympanoplasty surgery. Thus the displacement and stress of the artificial eardrum is determined by different material combinations and boundary conditions. A pressure of 3psi is applied on the face of tympanic membrane and rayleigh damping of $\beta=10^{-4}$ s for harmonic analysis to obtain stress and displacement of the artificial eardrum. The CAD model used for frequency analysis of prototype of the artificial eardrum is used for harmonic analysis. Table 17 presents the boundary conditions and the materials applied for harmonic analysis of artificial eardrum.

Table 17.Boundary conditions of artificial eardrum for harmonic analysis

Description	Simulation 1	Simulation 2
Boundary Conditions	Artificial eardrum is fully constrained. Artificial eardrum is intact in its position.	Artificial eardrum is fully constrained. Artificial eardrum is intact in its position at the end of ear canal.
3D model of artificial eardrum prototype		
Materials- Tympanic membrane	Polystyrene	PVDF
Material Tympanic ring	ASTM stainless steel-436	ASTM stainless steel-436

The artificial eardrum is fully constrained, and the movement of freedom is restricted. The harmonic analysis was conducted with frequencies between 200 Hz and 2000 Hz, as the frequency for human sound detection is 20 Hz to 20 kHz, to observe the maximum stress and displacement obtained by the artificial eardrum. The outcomes of harmonic analysis of artificial eardrum prototype with material combinations is presented in Table 18.

Table 18.Outcomes of harmonic analysis with stress and displacement(fully constrained)

Boundary condition -Fully constrained	Fully constrained
PVDF-steel eardrum prototype	Polystyrene-steel eardrum prototype
Frequency-1000Hz Maximum stress values(VonMises Dc) N/m^2 Maximum stress-$9.423x10^2$ N/m^2  	Frequency-1200Hz Maximum stress values(VonMises Dc) N/m^2 Maximum stress-2.39 x 10^6 N/m^2 
Frequency-1000Hz Maximum displacement value- URES (mm) Maximum displacement-$2.836e^{-04}$ mm  	Frequency-1200Hz Maximum displacement value- URES (mm) Maximum displacement-$1.180e^0$ mm 

From Table 18, it is observed that, for a fully constrained PVDF-steel artificial eardrum, at a frequency of 1000 Hz, the highest maximum stress of 9.423x102 N/m^2 is obtained at the center of the tympanic membrane, while the least maximum stress is obtained on the surface of the tympanic ring. The highest maximum displacement of $2.836e^{-04}$ mm obtained at the middle of the tympanic membrane, while the least maximum displacement is obtained on both the tympanic ring and the tympanic membrane.

From Table 18, it is observed that, for a fully constrained polystyrene-steel artificial eardrum at a frequency of 1200 Hz, the highest maximum stress of is 2.39x106 N/m^2 obtained at the center of the tympanic membrane, while the least maximum stress is obtained on the surface of tympanic ring. The highest maximum displacement of 1.180 mm is obtained at the middle of the tympanic membrane, while the least maximum displacement is obtained on the surface of the tympanic ring and the tympanic membrane.

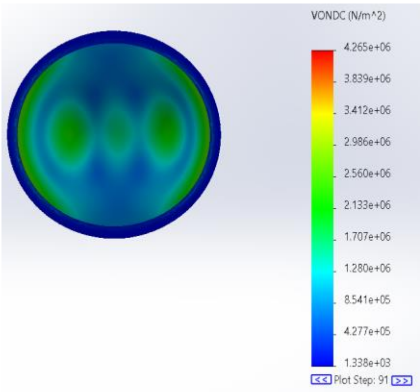
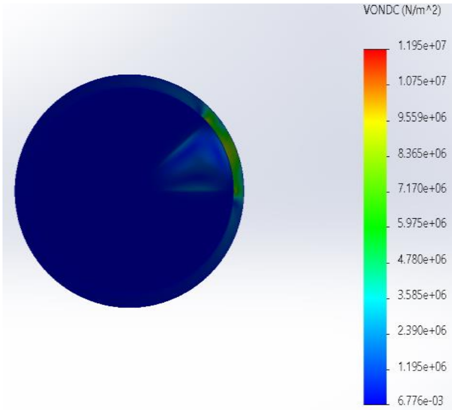
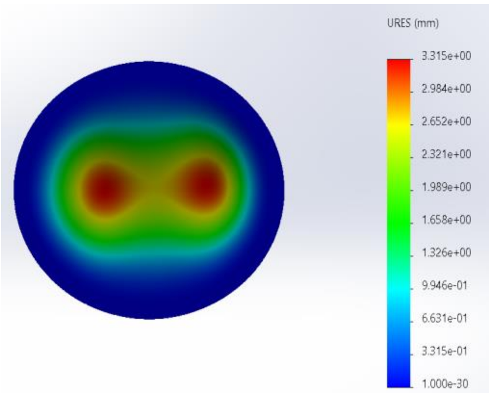
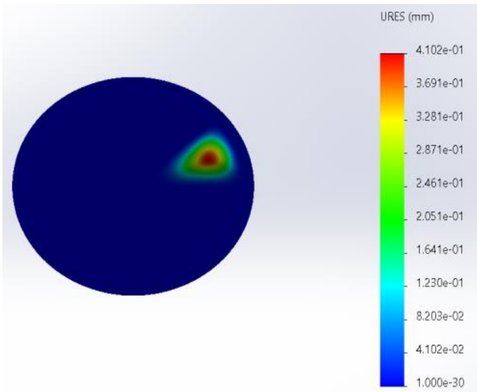
By comparing the maximum stress obtained by the PVDF-steel and polystyrene-steel artificial eardrums, under harmonic loading at a pressure of 3 psi, the least maximum stress ($9.423x10^2$ N/m^2)

is obtained by the PVDF-steel artificial eardrum. This demonstrates that the PVDF-steel eardrum structure is less prone to fail than the polystyrene-steel eardrum.

By comparing the maximum displacement obtained by the PVDF-steel and polystyrene-steel artificial eardrums under harmonic loading at a pressure of 3 psi, the least maximum displacement ($2.836e^{-04}$ mm) is obtained by the PVDF-steel eardrum. This demonstrates that the PVDF-steel eardrum structure exhibits more stiffness and does not deform much compared to the polystyrene-steel. If more displacement is obtained, then the sound pressure is not transmitted properly to the inner ear and then it affects hearing.

Table 19 shows the outcomes of artificial eardrum (modelled using natural eardrum dimensions) under two different boundary conditions. The boundary condition 1 is fully constrained and the boundary condition 2 is part of the eardrum is constrained and part of the eardrum is left free. This is called flair ear segment.

Table 19.Outcomes of harmonic analysis of the artificial eardrum(real dimensions)

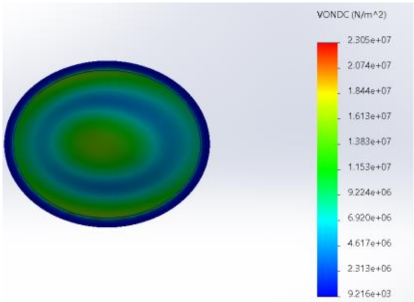
Boundary condition -Fully constrained	Not Fully constrained
Materials applied: TM-Natural TM Tympanic ring-natural tympanic ring	Materials applied: TM- Natural TM Tympanic ring-natural tympanic ring
Frequency-1500Hz Maximum stress values(VonMises Dc) N/m^2 Maximum stress- $4.266e^{06}$ N/m^2  	Frequency-1500Hz Maximum stress values(VonMises Dc) N/m^2 Maximum stress- $1.195e^{07}$ N/m^2 
Frequency-1500Hz Maximum displacement value- URES (mm) Maximum displacement-3.315 mm  	Frequency-1500Hz Maximum displacement value- URES (mm) Maximum displacement- 0.4102 mm 

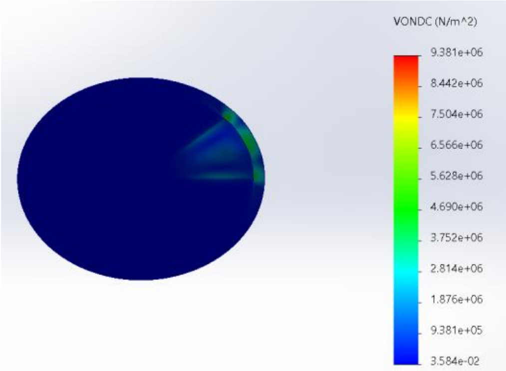
From Table 19, it is observed that, for a fully constrained artificial eardrum (natural eardrum dimensions), at a frequency of 1500 Hz, the highest maximum stress of $4.266e^{06}$ N/m^2 is obtained at the center of the tympanic membrane, while the least maximum stress is obtained on the tympanic ring surface. The maximum displacement of 3.315mm is obtained at the middle of the tympanic membrane, while the least maximum displacement is obtained on both the tympanic ring and the tympanic membrane.

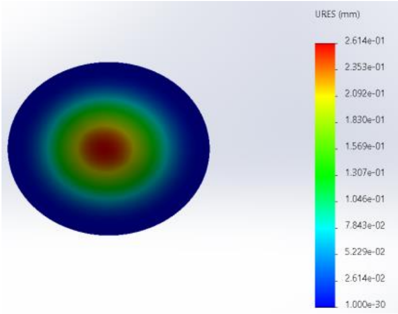
From Table 19, it is observed that, for a not fully constrained artificial eardrum (natural eardrum dimensions), at a frequency of 1500 Hz, the highest maximum stress of 1.195e^{07} N/m^2 is obtained at non constrained part of the artificial eardrum while the least maximum stress is obtained on the constrained part of the tympanic membrane. The highest maximum displacement of 0.4102mm is obtained at the non-constrained part of the tympanic membrane, while the least maximum displacement is obtained on the constrained surface of the tympanic ring and the tympanic membrane. By comparing the maximum stress obtained by the artificial eardrum under two different boundary conditions at a pressure of 3 psi, the least maximum stress (4.266e^{06} N/m^2) is obtained by the fully constrained artificial eardrum. This demonstrates that in the fully constrained artificial eardrum stress obtained is less and hence soundwaves can be transmitted to the inner ear efficiently and provide good hearing. By comparing the maximum displacement obtained by the artificial eardrums under two different boundary conditions at a pressure of 3 psi, the least maximum displacement (3.315 mm) is obtained by the not fully constrained artificial eardrum. If the displacement is more then the sound pressure is not transmitted properly to the inner ear and then it affects hearing. Table 20 shows the outcomes of artificial eardrum (modelled using natural eardrum dimensions) using PVDF material under two different boundary conditions.

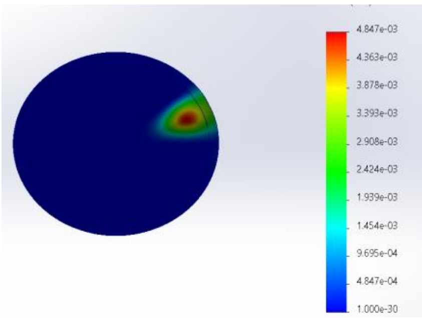
Table 20. Outcomes of harmonic analysis of artificial eadrum(PVDF) under 2 boundary conditions

Boundary condition -Fully constrained	Not Fully constrained(9/10 part is constrained)
Materials applied: TM-PVDF Tympanic ring-natural tympanic ring	Materials applied: TM-PVDF Tympanic ring-natural tympanic ring
Frequency-2000Hz Maximum stress values(VonMises Dc) N/m^2 Maximum stress-2.305x10^7 N/m^2	Frequency-2000Hz Maximum stress values(VonMises Dc) N/m^2 Maximum stress-9.381x10^6 N/m^2
Frequency-2000Hz Maximum displacement-2.614e^{-01}mm	Frequency-2000Hz Maximum displacement- 4.847e^{-03} mm





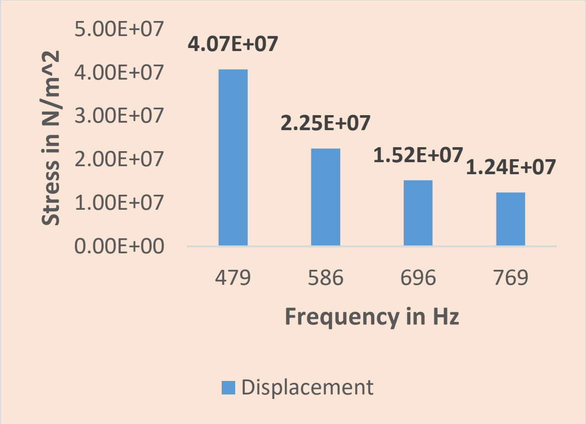




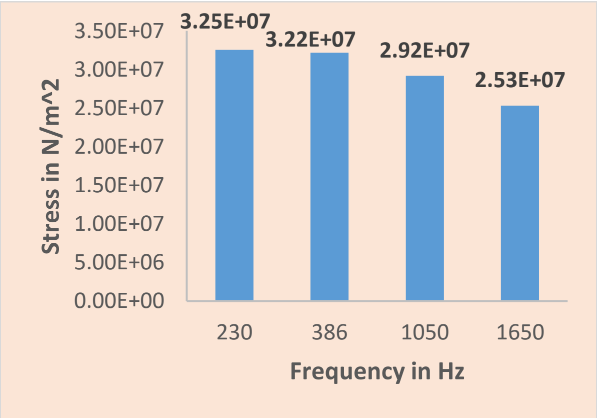
From Table 20, it is observed that the fully constrained artificial eardrum(PVDF), the highest maximum stress is on the middle of tympanic membrane and the maximum stress at a frequency of 2000Hz is 2.305×10^7 N/m^2. From Table 20, it is observed that the not fully constrained artificial eardrum, the maximum stress is on the non constrained part of the artificial eardrum and the highest maximum stress at a frequency of 2000Hz is 9.381×10^6 N/m^2 while the least maximum stress is obtained on the constrained part of tympanic membrane.
From Table 20, it is seen that the fully constrained artificial eardrum(PVDF), the maximum displacement is on the middle of the tympanic membrane and the highest maximum displacement at a frequency of 2000Hz is 0.261 mm. From Table 20, it is observed that the not fully constrained artificial eardrum(PVDF), the maximum displacement is on the non constrained part of the tympanic membrane and the highest maximum displacement at a frequency of 2000Hz is 4.847×10^{-3} mm.

3.4.1. Overall Results and Discussions of Harmonic Analysis of the Artificial Eardrum

The overall results of harmonic analysis of the artificial eardrum prototype of PVDF-steel and polystyrene-steel shows that the least maximum displacement of $2.836e^{-04}$mm and the least maximum stress of 9.423×10^2 N/m^2 is obtained by the PVDF-steel artificial eardrum as presented in Table 17. Thus, the PVDF-steel prototype exhibited least stress and displacement compared to the polystyrene-steel artificial eardrum. So, the PVDF-steel artificial eardrum can provide better stability and stiffness and results in good transmission of sound to the inner ear. Fig 21. presents the frequency in Hz and their corresponding stress of the artificial eardrum (natural eardrum dimensions) under fully constrained boundary conditions.



A

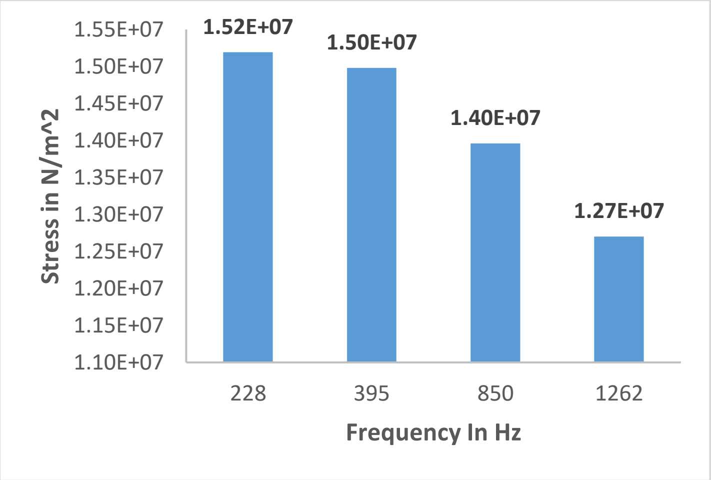


B

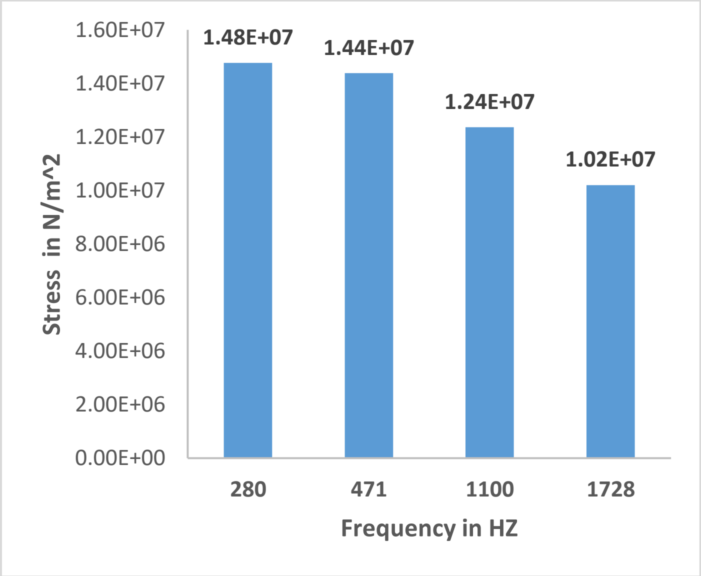
Fig. 21. Comparison of stress vs frequency in artificial eardrum(real dimensions,fully constrained) A.Artificial eardrum with natural eardrum properties applied B. PVDF eardrum.

From Fig.21 A it is observed that the highest maximum stress obtained by the artificial eardrum with natural eardrum properties applied is 4.07e^{07} N/m^2 at 479Hz and the least maximum stress obtained by the artificial eardrum is 1.24e^{07} N/m^2 at 769Hz when the eardrum is fully constrained. It is observed that the stress decreases as frequency increases as presented in Fig. 21 A.

From Fig.21 B, it is observed that the highest maximum stress obtained by the PVDF artificial eardrum is 3.25e^{07} N/m^2 at 230Hz and the least maximum stress obtained by the PVDF artificial eardrum is 2.53e^{07} N/m^2 at 1650Hz when the eardrum is fully constrained. As the frequency increases the values of stress do not follow a clear pattern and the highest stress is obtained at 230Hz which is the first resonant frequency obtained by the PVDF eardrum when fully constrained. Also, a sudden increase in frequency value from 386Hz to 1050Hz indicates that there is no much deformation of the artificial eardrum in those frequencies. Based on the obtained stress values, the value of least maximum stress is more in the PVDF eardrum than the artificial eardrum with natural eardrum properties applied. Fig 22. presents the frequency in Hz and their corresponding stress of the artificial eardrum(natural eardrum dimensions) under not fully constrained boundary conditions.



a



b

Fig. 22. Comparison of stress vs frequency in artificial eardrum(real dimensions,not fully constrained) a.Artificial eardrum with natural eardrum properties applied B. PVDF eardrum.

From Fig.22 A it is observed that the highest maximum stress obtained by the artificial eardrum with natural eardrum properties applied is $1.52e^{07}$ N/m^2 at 228Hz and the least maximum stress obtained by the artificial eardrum is $1.27e^{07}$ N/m^2 at 1262Hz when the eardrum is not fully constrained.It is observed that the stress decreases as frequency increases as presented in Fig. 22 A.
From Fig.22 B, it is observed that the highest maximum stress obtained by the PVDF artificial eardrum is $1.48e^{07}$ N/m^2 at 280Hz and the least maximum stress obtained by the PVDF artificial eardrum is $1.02e^{07}$ N/m^2 at 1728Hz when the eardrum is fully constrained. As the frequency increases, the values of stress do not follow a clear pattern and the highest stress is obtained at 230Hz which is the first resonant frequency obtained by PVDF eardrum when fully constrained.
When stress values of fully constrained and not fully constrained artificial eardrum are compared, the highest maximum stress is obtained in fully constrained artificial eardrum ($4.26x10^6$ N/m^2) as the entire eardrum is constrained. Among the fully constrained eardrum, the PVDF artificial eardrum has highest maximum stress of 2.305 x 10^7 N/m^2 at 230Hz. Even if the stress is minimum in non constrained eardrum, the condition of flair ear results in poor transmission of sound to the ossicular chain and prolonged flair ear condition leads to hearing loss completely if not treated immediately.

The displacement is maximum (1.180mm) in the polystyrene-steel artificial eardrum prototype compared to PVDF-steel eardrum when eardrum is fully constrained. The displacement is maximum in PVDF eardrum under fully constrained condition than the non constrained boundary condition. If the displacement is more then the sound pressure is not transmitted properly to the inner ear and then it affects hearing. After the tympanoplasty surgery, if hearing is not restored then revision surgery is required.The post operative results of revision surgery is not effective.The overall comparision of displacement of the artificial eardrums modelled with natural eardrum dimensions at different boundary conditions is presented in Fig.23.

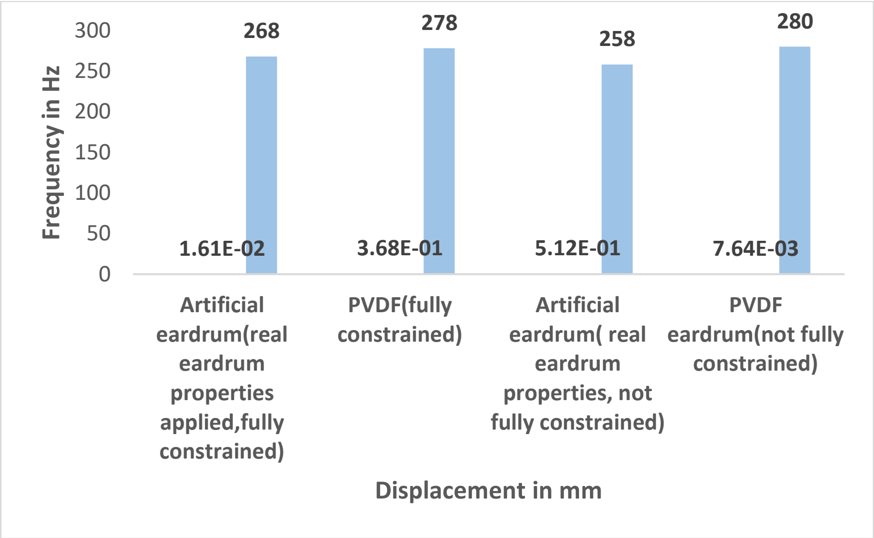


Fig. 23. Comparision of displacement vs frequency of artificial eardrum under 2 different boundary conditions.

The artificial eardrum with natural eardrum properties applied attained a high maximum displacement of $1.61e^{-02}$mm at frequency of 268Hz and the PVDF artificial eardrum obtained a high maximum displacement of $3.68e^{-01}$mm at 278Hz when the artificial eardrum is fully constrained.

The artificial eardrum with natural eardrum properties applied attained a highest maximum displacement of $5.12e^{-01}$mm at frequency of 258Hz and the PVDF artificial eardrum obtained a highest maximum displacement of $7.64e^{-03}$mm at 280Hz when the artificial eardrum is not fully constrained. When the artificial eardrum is fully constrained, the PVDF eardrum has the maximum displacement and when the artificial eardrum is not fully constrained, the PVDF eardrum exhibited least maximum displacement of $7.64e^{-03}$mm at 280Hz. The eardrum has to be fully constrained during eardrum repair surgery inorder to avoid movements of the eardrum during surgery and minimize displacement of the artificial eardrum.

3.5. Determination of Frequency of Artificial Eardrum by Using PRISM Holography System

An innovative and unique method for capturing and reconstructing the phase and amplitude of scattered light from a body that is illuminated is called holography. Holography depends on coherent light waves' diffraction and interference. A microscopic structure of interference structures which captures the interaction of 2 coherent beams is called hologram. A hologram is an interference pattern produced by two coherent laser beams registered through photography. One beam is emitted from the light source and the other beam is dispersed outward from the object. Thus, two laser beams are used for exposing holographic film which is then processed to create a three-dimension image when it is properly illuminated [53]. The ordinary light has weak temporal coherence. Ordinary light cannot be used in holography as has no interference capacity with itself. Hence, green lasers are used in holography to produce light beams.

3.5.1. Experiment with System PRISM

The determination of frequency analysis of artificial eardrum was conducted by a PRISM holography system. The dynamic process of eardrum can be visualized using holography system. The PRISM can measure dispacements which are less than 20nm and can finish and process measurements from experiments in a maximum of five minutes [54]. The schematic operation of system PRISM is presented in Fig.24. Table 21 lists the main characteristics of the PRISM holography system.

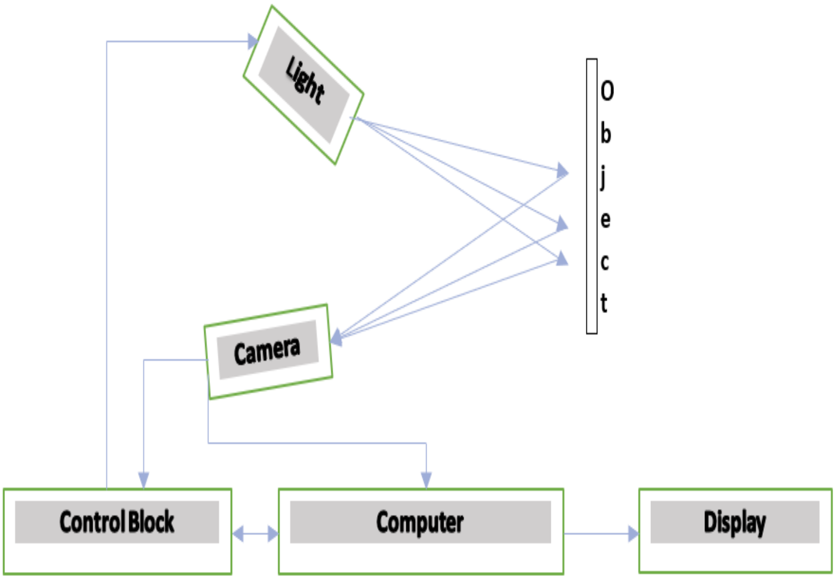
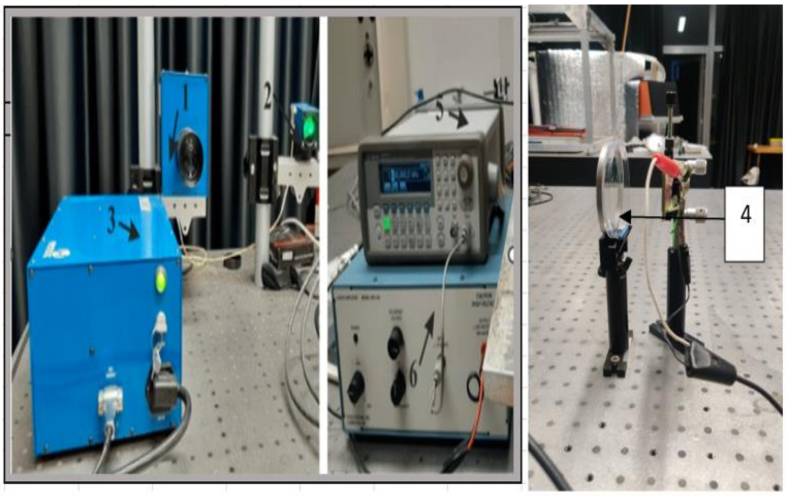


Fig. 24.Operation scheme of Prism holography system

Table 21.Main characteristics of the system PRISM

Sensititivity	<20nm
Boundary measurements	100µm
Measurement boundary	>100µm
Area of largest measurement	1m
Frequency at which data is registered	30 Hz
Distance to the object	>1/4m

The system PRISM consists of a control block which is considered as a major portion of the system. The control block split the green beam of laser of wavelength 532nm and power 20 mV into object beam and reference beam. The object beam is controlled by the camera lens and the camera registers the reflected light from the object and registers the interference pattern by combining both object and reference beam. Then, the transfer of interference pattern to the computer takes place and the interference pattern is processed with PRISMA-DAQ software. This enables real time monitoring of dynamic processes and deformations of the artificial eardrum.Fig.25 presents the PRISM holography experimental set up for the artificial eardrum.



1.Video head 2.Illuminating head 3.Control block 4.Artificial eardrum under study

5.Signal generator 6.Voltage amplifier

Fig 25.PRISM experiment setting.

3.5.2. Preparation of Prototype

The artificial ear drum prototype comprises of tympanic ring and membrane. The TM is fixed to the tympanic ring with help of glue. This prototype mimics the tympanic membrane. Thus, the analysis of frequency determination using PRISM system was conducted using 2 prototypes of the artificial ear drum. The tympanic ring was made of steel in both the prototypes. The tympanic membrane was made of a thin piezoelectric film (25 µm Bi-axially stretched PVDF) for artificial eardrum experiment

1 and polystyrene for artificial eardrum experiment 2. The material properties of PVDF and polystyrene are mentioned in Chapter 2 along with the dimensions of tympanic ring. Fig. 26 and Fig. 27 presents the PVDF-steel artificial eardrum and the polystyrene-steel artificial eardrum used for the frequency analysis in PRISM system.

Fig 26.Thin film of PVDF-steel artificial eardrum for PRISM experiment

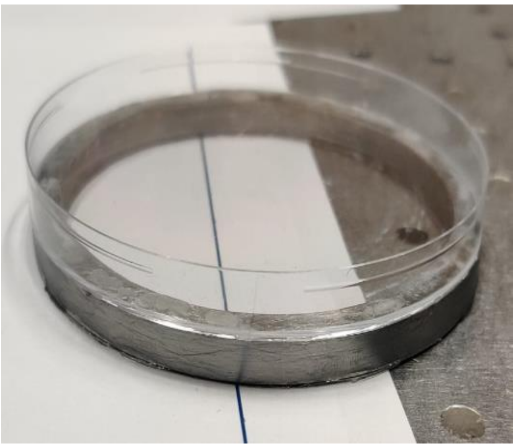


Fig 27.Polystyrene-steel artificial eardrum for PRISM experiment

A speaker was used to produce sound waves that pass through the tympanic membrane of the artificial eardrum and the dynamic response on the tympanic surface membrane at different frequencies was observed on the computer screen. The Frequency generator and voltage amplifier was used for the actuation of artificial eardrum. The PRISM system holography experiment was first conducted with the PVDF -steel artificial eardrum. The speaker was turned on and the amplitude was reduced more. There were some vibrations recorded on the computer, but they were non periodic vibration with fluctuations on the disc. Also, the tympanic membrane made of piezoelectric film is very thin and the sustaining capacity is high. The vibrations obtained on the inner side of tympanic membrane were complex and not flat. Thus, the PRISMA holography system did not produce positive results with the PVDF -steel artificial eardrum. The reason for failure may be the thin film of PVDF tympanic membrane. Next, the experiment was conducted using the polystyrene-steel in the PRISM holography system. The obtained vibration modes of the deformed surface of the polystyrene-steel artificial eardrum at different frequencies are present in Fig. 28.

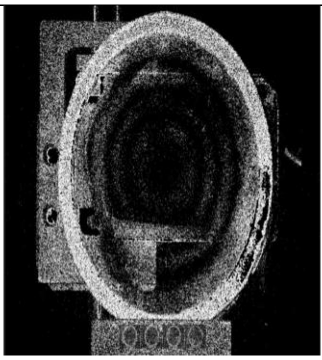
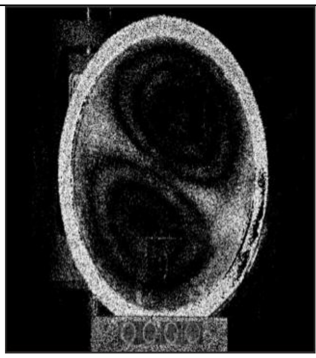
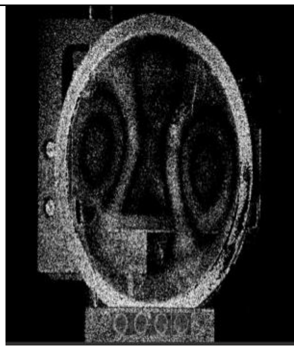
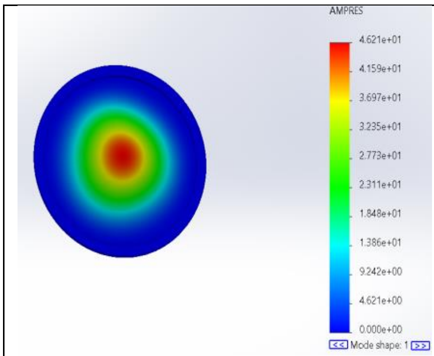
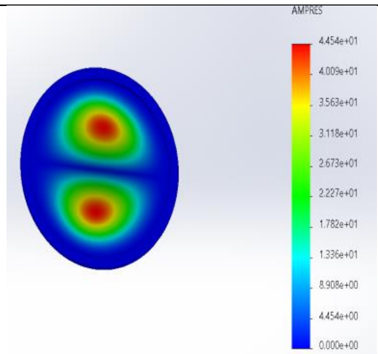
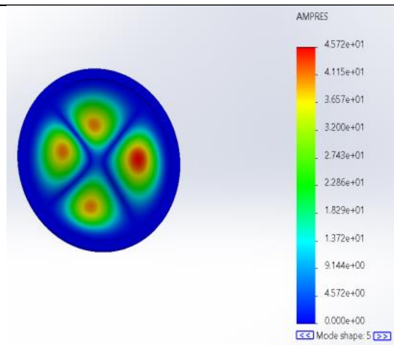
<table>
<tr><td>
Mode 1</td><td>
Mode 2</td><td>
Mode 3</td></tr>
<tr><td>320 Hz at 40mV</td><td>707Hz at 300mV</td><td>1077Hz at 500mV</td></tr>
</table>

Fig 28. Experimental (PRISM holography) system response of the polystyrene-steel artificial eardrum 2 at various frequencies

The first mode of vibration was obtained at 320Hz frequency with 40mV. The first vibration mode showed circular fringes pattern on the tympanic membrane. At a frequency of 337Hz at 100mV, similar deformation was obtained during the simulation of the polystyrene-steel artificial eardrum. The second mode of vibration was obtained at 707Hz frequency with 300mV with two fringes. The difference of frequencies obtained between first mode and second mode was high. The third mode of vibration was obtained at 1077Hz frequency with 500mV with 4 fringes. The numerical results of frequency study using the polystyrene-steel artificial eardrum is presented in Fig.29.

<table>
<tr><td>

Mode 1</td><td>

Mode 2</td><td>

Mode 5</td></tr>
<tr><td>Frequency -290Hz</td><td>Frequency-656Hz</td><td>Frequency-980Hz</td></tr>
</table>

Fig. 29. Numerical results of frequency response of polystyrene-steel artificial eardrum at various frequencies

3.5.3. Results and Discussion of PRISM Holography Experiment

At a frequency of 290 Hz a similar deformation of the polystyrene-steel artificial eardrum of mode 1was obtained. An error of 9.4 % was observed between the frequency analysis numerical simulation and experimental part. At a frequency of 656 Hz a similar deformation of the polystyrene-steel artificial eardrum of mode 2 was obtained. An error of 7.2 % was observed between the frequency analysis simulation and experimental part. At a frequency of 980 Hz a similar deformation of the polystyrene-steel artificial eardrum of mode 3 was obtained. An error of 8.9 % was observed between the frequency analysis simulation and experimental part. The error may be due to the material properties or glued part or thickness of the artificial eardrum.

3.6. Chapter Summary

The frequency analysis and harmonic analysis of the natural tympanic membrane and the artificial eardrum was performed and then the numerical results of analysis of the artificial eardrum was compared with the experimental results conducted with the PRISM holography system and the overall results are discussed.

4. Socio-Economic and Environmental Part of Artificial Eardrum

4.1. Improved Quality of Life

Deafness ranks as the third most significant cause of years lived with a disability, according to the worldwide burden of illness survey. Among adults, the effect of hearing impairment can be extremely severe, and it is correlated to a wide variety of results. In general, hearing loss or hearing impairment is linked to speech difficulties, less attentiveness among the group, tiredness, depression, diabetes, coronary heart disease, reduced physical wellness, loneliness, brain disease, loss of productivity, unemployment, premature retirement, and low standard of living and such patients generally find difficulty in adjusting with the society [55] [56].

Recently designed artificial eardrums using CAD technology in auricular rehabilitation has improved post surgical results especially patients' psychology and quality of life. Post-surgery patients quality of life has improved. Notable progress was seen in factors like comfort zone, positive attitude, appearance, and relationships with close fellowships. The advancements in tissue engineering and the use of artificial eardrum made of non autologous materials has resulted in closure of 90% perforations after tympanoplasty and improved the quality of life and hearing. Improved hearing leads to better communication with others and hence artificial eardrums makes the invididuals to communicate effectively even in noisy environments. The overall well-being of an individual is rised when artificial eardrum is used as the individuals do not isolate themselves. The physical and mental well-being of individuals is improved by the artificial eardrum post surgery [57].

4.1.1. Economic Impact

The cost of hearing aids used for restoring human hearing is presented in Fig. 30. The cost of class 1 hearing aid is 950 euros whereas the class 3 hearing aid is 2300 euros. In most of the cases the hearing aid did not restore normal human hearing. So, physicians advise patients to undergo surgery based on the diagnosis of patient problem inorder to restore human hearing.

Fig. 30. Hearing aid cost comparison

The middle ear surgery cost based on the level of surgery is presented in Fig. 31. It is observed that as the level of surgery increases the cost also increases accordingly. The middle ear surgery level 3 costs around 3000 euros.

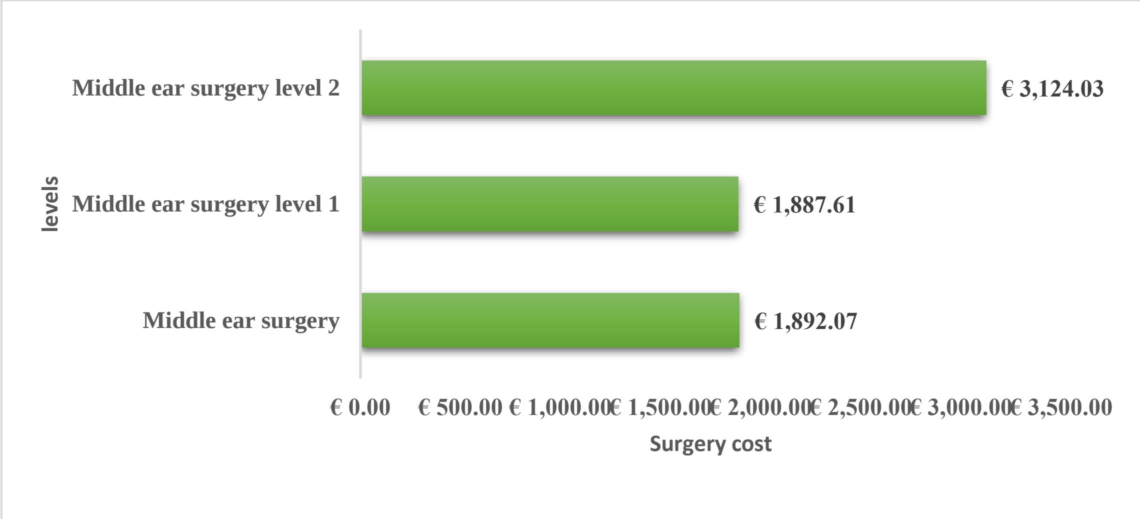


Fig. 31. Middle ear surgical cost

Middle ear surgery annual healthcare cost increased from 1130 euros to 1926 euros and the ossiculoplasty surgery annual health care increased from 956 euros to 1684 euros over the years as seen in Fig. 32 [58]. Thus, it is important to choose the effective implant in middle ear surgery to achieve good hearing results even though the cost of surgery has increased over the years. If the implant chosen is not compatible with the patient, then the revision surgery cost also adds up to the surgery cost. The artificial eardrum proves advantageous as it is cost-effective and does not require revision surgery and the use of artificial eardrum in tympanoplasty does not need incision and the need to look for grafts in revision surgery is avoided.

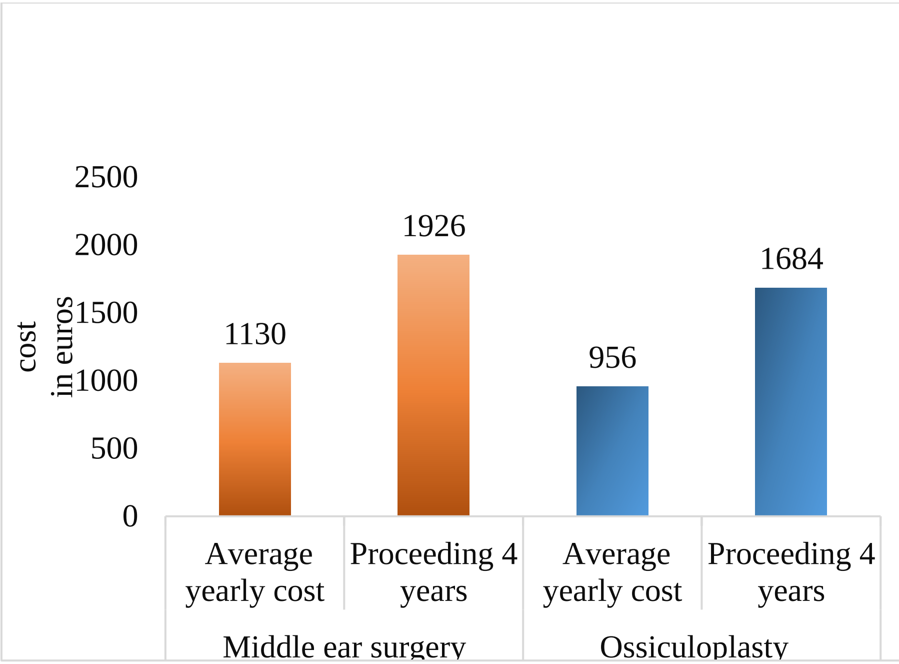


Fig 32.Comparison of surgery cost

4.1.2. Artificial Tympanic Membrane with Polystyrene

Polystyrene is a thermoplastic material with various uses. It has many good physical properties like high mechanical strength, better stability, and transparency. Polystyrene is capable of being mechanically recycled multiple times into new products without losing any of its physical properties.

It is simple to manufacture utilizing common polymer manufacturing techniques like extrusion, thermoforming, and injection moulding. It serves numerous medical purposes, such as the manufacturing of dental equipment, prostheses, and surgical tools. In the field of biomedical applications, polystyrene is ideal to use because of its modifiable nanocomposites with antibacterial properties. The characteristic that makes polystyrene widely employed in the manufacturing of scientific instruments and biomedical products is its biocompatibility. This characteristic also determines that the substance should not affect the human biological tissues and system. The cost of polystyrene petridishes used in the holography experiment is presented in Fig. 33. The cost of polystyrene petridish is economical.

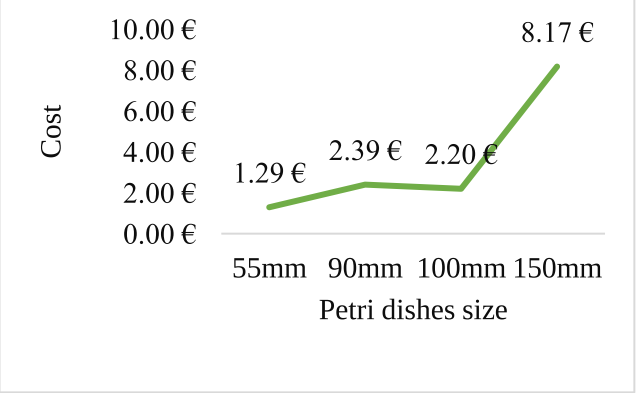


Fig. 33.Comparison of polystyrene petridish cost [59]

The additive manufacturing techniques used for the manufacturing of the artificial eardrums allows to create specific designs according to the patient needs and requirements as prescribed by the surgeon. The eardrum is a complex model and it has to be modelled with finest details and manufactured by the 3D printing technology. The traditional manufacturing methods involves more wastage of materials than the additive manufacturing techniques. The biocompatible materials with human tissues is chosen for the manufacture of artificial eardrum and hence an opportunity to choose combination of materials is obtained.The artificial eardrum obtained is durable for a prolonged time and flexible for eardrum repair. Also,3D bioprinting is cost-effective.The cost for purchasing additional tools in manufacturing is also not required. Thus, the manufacturing methods for the artificial eardrum has very low impact on the environment.

4.2. Chapter Summary

Thus, the artificial eardrum is considered a good choice for eardrum repair as no revision surgery is required. The non autologous material has the ability to provide around 90% closure of tympanic perforations and restore hearing better than autologous grafts and the quality of life is increased. The additive manufacturing techniques results in cost-effectiveness and saves time with less material wastage and the quality of life and social and well-being of patients is improved.

Conclusions

1. Recent advancements in medical industry have paved the waved the way for tissue engineered non autologous grafts and the use of non autologous grafts in tympanoplasty has provided hearing results better than the autologous grafts.

2. After the numerical modal analysis was performed, the polystyrene-steel artificial eardrum prototype (fully constrained) obtained a higher first resonance frequency of 273Hz compared to the PVDF artificial eardrum models. So, the polystyrene-steel prototype may offer increased stability and less prone to prolonged oscillations. On the other hand, the PVDF artificial eardrum obtained extremely high first resonance frequency of 19828Hz (very high frequency) for the not fully constrained model and 3404Hz for the fully constrained model. This implies that the eardrum must be properly constrained during eardrum repair surgery for effective transmission of sound to the inner ear and produce good hearing results.

3. After the numerical harmonic analysis was performed, it was found that the PVDF-steel artificial eardrum prototype (fully constrained) obtained the least maximum displacement of $2.836e^{-04}$ mm and stress of $2.39x10^{6}$ N/m^{2}. The PVDF artificial eardrum (fully constrained) modelled with natural dimensions obtained a least maximum stress $2.53e^{07}N/m^{2}$ at 1650Hz, while the not fully constrained model showed a least maximum stress of $1.02e^{07}N/m^{2}$ at 1728Hz and highest maximum displacement of $7.64e^{-03}$ mm at 280Hz. The PVDF artificial eardrum exhibited least maximum stress and displacement as frequencies increased. During the surgery, the stress and displacement of the artificial eardrum must be minimum for proper fixation of the eardrum. After performing the experimental study using PRISM system, the frequencies of the polystyrene-steel eardrum obtained by the PRISM holography system at mode 1, 2 and 3 are 320Hz, 707Hz and 1077Hz while the numerical results showed an error of 9.4%, 7.2% and 8.9%.

4. The modern biomaterials and additive manufacturing methods results in production of eco-friendly, biocompatible artificial eardrum with low wastage of materials. The further development of artificial eardrum could be good choice for the repair of perforated tympanic membrane aiming the avoid the revision operations and lower surgery cost.

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Appendix