Materials for ossicular chain reconstruction: History and evolution (Review)

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Abstract. The middle ear represents the anatomic space between the external auditory canal and the inner ear (Cochlea). It is comprised of the tympanic membrane, the ossicular chain [malleus (hammer), incus (anvil) and stapes (stirrup)] with the corresponding muscles and ligaments and the cavity of the middle ear. The main function of the middle ear is to convey vibratory energy (sound pressure) from the air to the cochlear fluids of the internal ear via the ossicular chain. Tympanoplasty represents a number of procedures used to re-establish the continuity of sound transmission from the tympanic membrane to the inner ear. Ever since the beginning of otologic surgery, various materials have been tested for ossicular chain reconstruction (OCR). The present review aimed to present, in a chronological sequence, the evolution of knowledge regarding this field of medicine, and to also discuss the advantages and disadvantages of different materials and designs of ossicular prostheses. The constant search for more efficient, easily tolerated and lighter materials has improved the acoustic rehabilitation process and has markedly reduced the rate of functional failure of these small prostheses.

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Contents

1. Introduction

Hearing loss of variable etiology represents one of the most challenging public health concerns affecting the worldwide population (1). The integrity of the auditory system is one of the prerequisites for the acquisition and proper development of oral language. An individual suffering from hypoacusis is more likely to have poorer professional results than his colleagues, will be less competitive in the labor market and will have less chances to complete a higher education (2,3). Etiologically, hearing loss is defined as having two main mechanisms: Conductive hearing loss (CHL) following the pathology of the external and middle ear with air-conduction impairment and sensorineural hearing loss following inner ear pathology with bone-conduction impairment. When both mechanisms are involved, mixed hearing loss is diagnosed. The middle ear represents the anatomic space between the external auditory canal (EAC) and the inner ear (cochlea). It is comprised of the tympanic membrane (TM), ossicular chain [malleus (hammer), incus (anvil) and stapes (stirrup)] with the corresponding muscles and ligaments and the cavity of the middle ear. The mastoid process and the Eustachian tube are accessories to the middle ear and play critical roles in aeration and pressure equalizing. The ossicular chain contains the smallest bones in the human body (4,5). Their highly specialized joints allow for soundwave transmission to the inner ear, but also for the augmentation of sound wave amplitude (matching the impedance the sound waves suffer, hence maintaining the intensity). The malleus resembles a club rather than a hammer and consists of three sections: The handle, neck

and head. The handle is firmly attached to the TM from the umbo to the upper margin (tympanic annulus). The head of the malleus and the body of the incus form a tight joint and are suspended by three ligaments, which leave the chain free to vibrate and transmit sound from the TM to the inner ear (6,7).

The Incus has the appearance of a premolar tooth with uneven roots than an anvil. The short process of the incus (the crus) is also fixed by a ligament to the posterior wall of the cavity, whilst the long process of the incus is bent near its end and bears a small bony knob that forms a loose ligament-enclosed joint with the head of the stapes. The stapes is the smallest bone in the body and barely weighs 3 mg. It consists of a base (footplate), resting on the oval window, as well as a head that articulates with the incus and is positioned at a 90˚ angle to the long process of the incus. The footplate has a diameter of 2.96±0.15 mm. and aligns well in the oval window. It is surrounded by an elastic annular ligament, which allows for the free vibration and transmission of sound to the cochlea. The incudomallear joint, is a gliding type of synovial joint, whilst the incudostapedial joint is a ball- and socket-type of synovial joint. Contrary to other synovial joints, the incudostapedial joint has a very limited range of motion and is usually only of springy character. The ossicles form a unit that moves together (8,9). CHL is the result of afflicting the transmission of sound waves from the external ear to the inner ear liquids which, in turn, displaces the basilar membrane of the organ of Corti (8). The causes for this are multiple and can reside with EAC obstruction, as well as, more frequently, with TM or middle ear disease.

The term tympanoplasty describes the procedures that re-establishes the continuity of the ossicular chain [usually concomitant ossicular chain reconstruction (OCR) and TM grafting]. This procedure involves the use of various types of ossicular prosthesis to replace damaged ossicles, in the attempt of providing the patient with more functional results and a higher level of social integration (3).

Since, for example, the stapes is the smallest bone in the human body, these prostheses are, in turn, very small in size (2-3 mm.) and can only be implanted and properly positioned via microscope guidance. Extensive research involving doctors, engineers, chemists and material resistance specialists has been performed in order to obtain the ideal material for use in OCR. The most important landmarks of this research are described in the present review. However, this goal has not yet been reached, although the theoretical conclusions are that such a material should maintain its shape, rigidity and acoustic properties, and should also be cost-effective and readily available. Biocompatibility, safety, the ease of insertion and shaping should also be amongst the properties of an OCR prosthesis (9). An ideal ossicular prosthesis should concomitantly fulfill all following conditions: An optimal similar shape to the replaced ossicle, small size, bio-integrated material, lightweight, cost-effectiveness and ease in modifying to the required shape. One cannot define an ideal prosthesis without considering its acoustic properties. A prosthesis is well-designed if it combines high stiffness and a low mass (10-13). Another parameter to consider in evaluating the functional results of OCR is the appearance of uncontrollable situations, since even optimally positioned prothesis can migrate post-operatively and dislocate from the adjacent structures (malleus handle, TM or stapes). Thus, the human factor becomes paramount, as the surgeon should achieve optimal functional results by placing the prosthesis properly, which is also dependent on experience, anatomy and a number of other uncontrollable factors (14,15). From a practical and experimental point of view, the most useful parameter to measure in order to obtain the quality control of a prosthesis is the middle ear transfer function which, ideally, is determined by directly measuring stapes velocity in response to a constant sound pressure at the TM using a trans-mastoid or trans-tegmen approach (14).

The two main types of design for ossicular prosthesis are the following: Partial ossicular reconstruction prosthesis (PORP) used to replace an interrupted ossicular chain with intact stapes superstructure and total ossicular reconstruction prosthesis (TORP), required when the stapes superstructure is absent, and the footplate is mobile.

2. Data collection

The present review aimed to present, in a chronological sequence, the evolution of knowledge regarding the field of otology (OCR), as well as the advantages and disadvantages of different materials and designs of ossicular prostheses. The constant search for more effective, easily tolerated and lighter materials has improved the acoustic rehabilitation process and has markedly reduced the rate of functional failure. An extensive review of the literature was accomplished by collecting data from various scientific databases, such as PubMed, Global Health Archive, BIOSIS Previews and MEDLINE.

3. History and evolution of ossicular chain reconstruction

From the very first documented medical records (Egyptian healers), ear discharge was associated with severe complications (16) and even Hippocrates observed that acute pain of the ear with continued high fever was a serious condition, due to the risk of the patient becoming delirious and even dying (17). The first attempts of ear surgery were documented in 1640 when Banzer attempted a TM reconstruction using a pig's bladder. Jasser was a pioneer of mastoid surgery in 1776; however, after an unfortunate incident in which the personal physician of the King of Denmark died of sepsis following this type of surgery, ear operations were discredited and went into oblivion for at least another hundred years (18,19). In 1853, Toynbee rediscovered mastoid surgery and several attempts at a tympanic reconstruction were made by physicians, such as Blake in 1877 and Berthold in 1878 (18,19). However, none of these pioneers considered the reconstruction of the ossicular chain, probably due to the lack of adequate optic equipment and anatomical knowledge of the area. The era of OCR began at the turn of the 20th century.

In 1901, the first documented attempt at repairing the ossicular chain was made by Matte, who named this procedure myringostapediopexy (20).

Between 1955-1956, the modern era of middle ear reconstruction began with Zollner and Wullstein. They emphasized the idea of creating a differential between sound pressure at the oval and round window by adapting each type of surgery to a specific ossicular problem. For example, in the case of

a missing incus, the graft was connected to the stapes head (type III or columellar tympanoplasty) (19,21).

The technique introduced in 1957 by Hall and Rytzner (22) for the treatment of otosclerosis was promising. It reconnected the stapes footplate to the TM by using autogenous grafts of incus or malleus (22). During this period, autogenous and alloplastic materials were at the height of their popularity. Wullstein introduced an artificial material (Palavit-vinyl-acryl plastic) in 1952, to connect the TM directly to the stapes footplate (19).

In 1958, Shea described the connection of the TM to the stapes head by using a polyethylene tube (19). Other researchers continued his work by using various types of polyethylene (PE) and other inert materials, such as Polytef (Teflon) and silicone elastomer (SILASTIC™) (23). The initial short-term hearing results were excellent; however, the harsh alloplastic materials had a large potential for extrusion, middle ear reactivity and/or penetration into the inner ear (23). As a result, numerous surgeons preferred more compatible, autogenous prostheses.

Several otologists began using autografts (transplantation of organs or tissues from one part of the body to another in the same person) for ossicular reconstruction. The body of the incus was most frequently harvested for ORC, although cartilage and cortical bone were also frequently used. These natural materials were well-tolerated and provided reliable functional results; however, they were also very brittle and required laborious and time-consuming sculpturing. There were also scars in chronically afflicted middle ears (23).

Homografts (transplantation of cells, tissues, or organs to a recipient from a genetically non-identical donor of the same species) (24) were first used for middle ear reconstruction in 1966 by House *et al* (25). This line of research later included novel solutions, such as irradiated tissues (ossicles, cartilage) and even harvesting 'en bloc' ossicles and TM (24,25). The hearing results and biocompatibility of the homografts proved to be similar to autografts; however, other concerns appeared, such as the risk of disease transmission (i.e., HIV or Creutzfeldt-Jakob disease) which led to a decline in their use.

Thus, the search for a safe, reliable, and easily available prosthesis continued. Plastipore, a high-density polyethylene sponge was first used by Shea (26) in 1976. Due to the porous nature of polyethylene and its lack of reactiveness, the in-growth of tissue is possible. The material is available commercially on a large scale and is very easy to trim with surgical instruments. Later on, a more refined yet similar thermal-fused porous polyethylene (Polycel) was developed. It allowed for the easy coupling of the prosthesis to other materials, such as stainless steel, which enabled various prosthetic designs (23). The main issue associated with the use of this material was the high rate of extrusion when in direct contact with the TM. A possible solution was proposed by Shea (26), and Brackmann and Sheehy (27) in 1979, which protected the TM with a disc of cartilage. As a result, Plastipore and Polycel TORPs and PORPs continue to be used with good long-term success today (23).

Ceramics made an appearance in ossicular reconstruction in 1979. These alloplastic materials were defined as either bioinert or bioactive (28). An extensive presentation of all biological and synthetic materials used for ossiculoplasty has been published in recent studies (28,29).

High-density aluminum oxide ceramic (bioinert implants) did not react with surrounding tissues and were popular in Germany and Japan. Glass ceramics (Ceravital) were used to create bioactive implants, which were bio-compatible and reacted with surrounding soft tissue and adjacent bone allowing for an excellent coupling between the implant and the ossicle (30). These bioactive implants were used, with various results obtained worldwide, even in the former communist bloc, including Romania (31). Bio-vitro-ceramic PAW-1 (Fig. 1) is a solid, bio reactive, synthetic biomaterial, comprised of fluorescent hydroxyapatite (HA) and wollastonite microcrystals encompassed into a vitreous mass (glass); the material is obtained by the controlled crystallization of a glass from the silicium-calcium-magnesium-phosphorus system with limited additions of boron trioxide and molecular fluoride. It represents a locally developed product (31).

Compared to other synthetic materials, ceramic implants allowed for direct contact with the TM without requiring a cartilage bridge; however, they were difficult to handle and shape because of their glass nature (23).

HA [$Ca_{10}(PO_4)_6(OH)_2$] is a bioactive material, easily integrated in the surrounding tissues and was first used by Grote (32) (calcium phosphate ceramic). A collagen-HA composite material, characterized by a strong interaction between the collagen fibers and the hydroxyapatite crystals, can be successfully used as a bone substitute. The shortcomings of HA are represented by its brittleness, which renders it technically difficult to sculpt (33). A possible solution came from chemically combining HA with other materials, such as Silastic or polyethylene. HA was also used in other types of biological prosthesis. Coralline porous HA became the most common material in ocular implants following primary enucleation. Made from a specific genus of reef-building coral, porous HA has a similar architecture to human cancellous bone, with interconnecting channels. Per se, HA represents the primary inorganic portion of human bones and the process by which implants of HA are made from sea coral, imply intense heat, which denatures proteins to reduce the immune response. When it is implanted in soft tissues, porous HA allows for the ingrowth of fibrovascular tissues in pores, and it has been demonstrated that unwrapped HA does not become encapsulated, as poly(methyl methacrylate) spheres or silicone (34).

In 1985, the incus and stapes prosthesis designed by Wehrs (24) was manufactured from HA and provided successful hearing results and a low extrusion rate 4 years after implantation. The advantage of good sound transfer function due to the high rigidity of the material was counterbalanced by the large mass of the prosthesis, which created high input impedance, and potentially obstructed the surgeon's view (24). A more recent development brought forward the combination of HA and polyethylene (HAPEX) to create an allograft material that approaches the mechanical strength of bone. but is soft enough to be cut with a knife (23).

Titanium prostheses made an appearance in 1993 in Germany (Fig. 2) and have remained the most popular choice for otologists ever since. They combine the rigidity and biocompatible of HA with lightweight (the specific density of titanium is <57% that of stainless steel). It is also non-magnetic, has

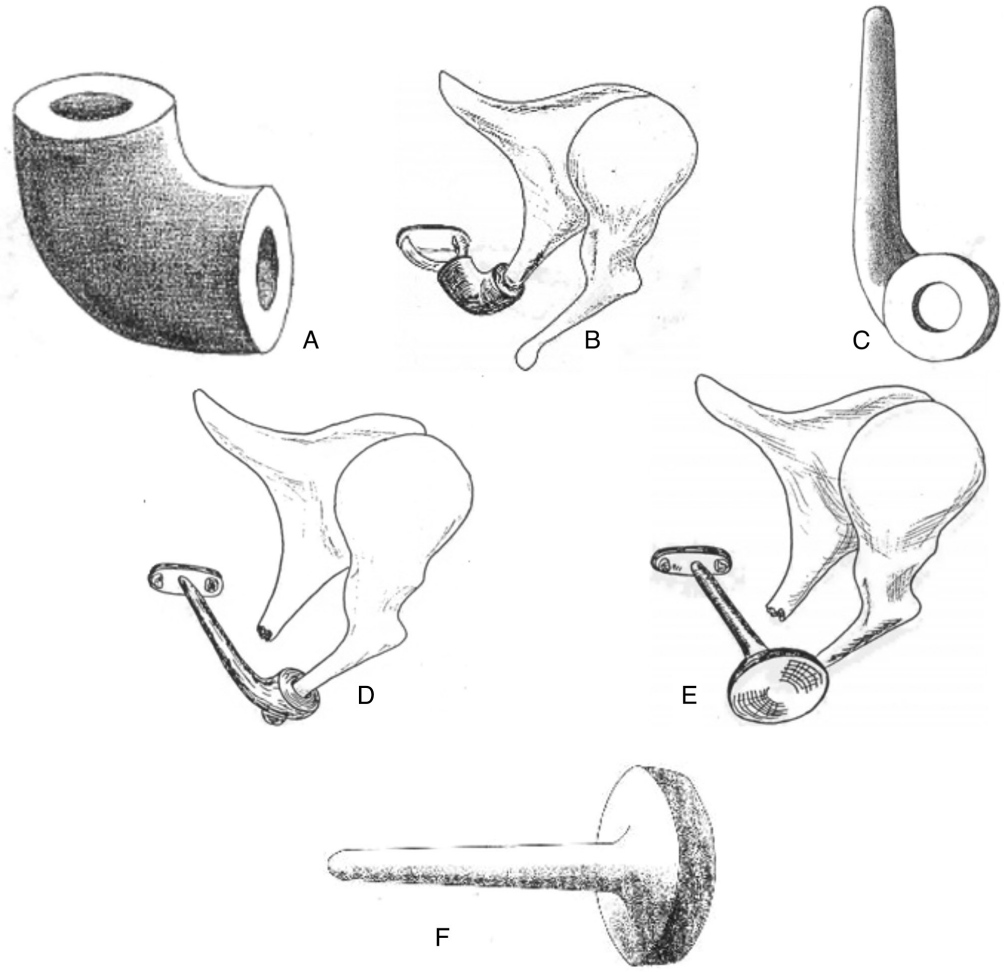

Figure 1. Various designs for bio-vitro-ceramic ossicular chain reconstruction prostheses from the authors' personal collection, part of an extensive study on bio-vitro-ceramic implant results (11,28). (A and B) Incudostapediopexy bio-vitroceramic prosthesis; (C and D maleovestibulopexy bio-vitroceramic prosthesis; (e and f) miringovestibulopexy bio-vitroceramic prosthesis.

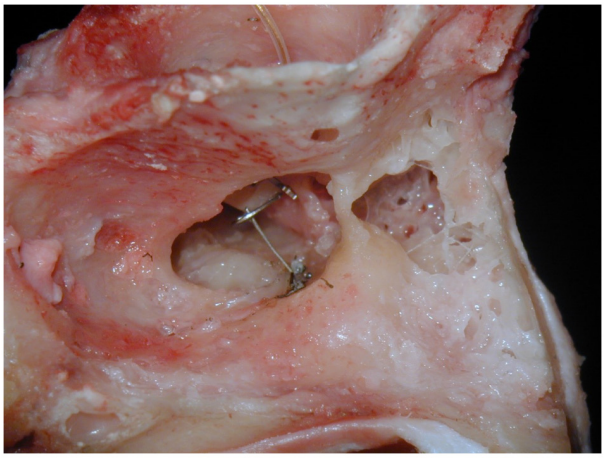

Figure 2. Inserted titanium total ossicular reconstruction prosthesis from the author's personal collection, part of a series of experiments on laser doppler vibrometry assessment of middle-ear titanium prosthesis results (10).

excellent biocompatibility, and can be manufactured in any required shape and size. The characteristics of this material allow for various designs and the majority of the titanium prostheses possess an open head which provides better visualization during placement (23). Cartilage protection for the TM is still necessary, and this brings about an interesting conclusion that we should consider all materials for ossicular reconstruction experiments. Several authors to date have published favorable hearing results with titanium prostheses and compared them with HA. Titanium may provide improved hearing responses at higher frequencies because of its low mass (35-38).

After a long and interesting history of material research, experimentation and evaluation, titanium prevailed among the alloplastic materials and is by far the most used for ossiculoplasty over the past years. This fact is due to its favorable properties of the material: Excellent acoustic transmission characteristics, very good biocompatibility and the possibility to develop particularly filigree design. This last property also allows integrating functional elements in the middle ear prostheses (29).

Although extensively used in the past for ossicular reconstruction, biomaterials (autografts), particularly the body of the incus and cartilage (tragal and/or conchal) have decreased in popularity as of late, due to the fact that they are not always available for harvest and they do not have the required mass, stiffness and thickness (28). Autologous materials have a high degree of tolerance within the middle ear and provide reliable hearing results, but are also difficult to sculpt and fixate to the soft tissues of the middle ear and prolong intraoperative time.

Modern tympanoplasty requires less biomaterials, usually conchal cartilage and temporal fascia, but their importance still remains high in repairing TM perforations and as interposed between soft tissues and synthetic (titanium) prosthesis in both overlay and underlay techniques.

4. Conclusions and future perspectives

Considering the present state of otologic surgery, it can be safely stated that the ideal middle ear implant does not exist. For all patients, follow-ups need to be performed regularly to detect the first signs of potential complications, regardless of the used implant. Future research and material development may provide an ideal prosthesis for OCR.

Present-day surgery uses autogenous and alloplastic prostheses with equally good outcomes. It is considered that the choice of prosthesis and material remains an issue for personal preference and experience, and it is recommended that each surgeon should try several variants and select the one that provides consistent, favorable results. It is also clear that other factors, such as material quality, surgical technique, the experience of a surgeon or the environment in which the prosthesis is placed, influences the functional results.

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Authors' contributions

HM, ITD and MR contributed equally to this work and should, therefore, be considered co-first authors. HM and MR conceptualization. MR, HM and ITD were involved in the data search and selection for inclusion in the review. HM, MAS and AIM were involved in the organization and integration of the data collected from various studies for the purposes of the present review, as well as in the graphical representations. MR and HM were involved in the writing and preparation of the original draft. MR and ITD were involved in the writing, reviewing and editing of the manuscript. MR, HM and ITD were involved in visualization. HM and MR supervised the study. HM, MR and ITD were involved in project administration. AIM and MAS made substantial contributions to the acquisition, analysis and interpretation of the data for inclusion in the review and provided a final review of the article. All authors have read and approved the final manuscript. Data authentication is not applicable.

Ethics approval and consent to participate

The patient whose implant is depicted in Fig. 2 provided informed consent for inclusion in the present study.

Patient consent for publication

The patient whose implant is depicted in Fig. 2 provided consent for the publication of data and any associated images.

Competing interests

The authors declare that they have no competing interests.

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