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Section 3: Diseases of the Ear

Part 3: Middle Ear and Mastoid

Chapter 33: Materials Used in Tympanoplasty

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Since the first tympanoplasty was performed by Toynbee in 1853, using a rubber disk and a silver wire, countless materials have been used to reconstruct the human tympanic membrane. It took one hundred years before techniques were advanced enough to make Wullstein and Zollner's split thickness skin graft the first practical tympanoplasty. The operating microscope, combined with better visualization and improved materials and techniques, has lead to widespread acceptance of tympanoplasty.

Definition of Procedures. A tympanoplasty must be differentiated from a myringoplasty. In 1960 the American Academy of Otolaryngology and Ophthalmology defined a *myringoplasty* as a procedure in which reconstruction is limited to the tympanic membrane. *Tympanoplasty* is defined as an operation to eradicate disease in the middle ear and to reconstruct the hearing mechanism with or without tympanic membrane grafting.

The purpose of this chapter is to discuss different aspects of materials used in tympanoplasty. To standardize evaluation, an ideal model is used. After discussing ideal characteristics, tympanoplasty implants and grafts are reviewed with respect to ideal criteria. The surgical techniques used to employ them are reviewed briefly. Clinical success (or lack thereof) is also examined. An example of each major category used to reconstruct the ossicular chain is reviewed. Finally, adjunctive materials, which are used as aids to improve the result of surgery, are discussed.

Ideal Materials

Before discussing specific materials, it is important to establish the standards by which they are judged. One must first ask what it is the graft or implant is attempting to achieve. These criteria establish an ideal model.

The first and most complex criterion concerns relative biocompatibility. In a general sense, biocompatibility refers to the ability of an implant to fool the host immune system into recognizing the graft as part of the host itself. With true biocompatibility, the body would not attempt to extrude a foreign body. Except for an autograft, nothing currently in use is tolerated in every situation. The process of fooling the immune system is accomplished by several different techniques. Each material has a slightly different solution to the problem of compatibility.

The second criterion is that the material must resist and tolerate infectious processes. The middle ear cavity is susceptible to infection because of its connection to the outside world by way of the eustachian tube. Some implanted materials are prone to infection due to characteristics of their surfaces that allow bacteria to collect and multiply. These characteristics are referred to as surface tension and smoothness of the finish. Another concern is the response of biologically active tissues to infections. Cartilage, for example, may be totally destroyed by an infectious process.

Any material implanted in young people must last for decades. The implants need to perform their function without becoming dislodged, fibrosed, or ankylosed. Once an implant is put into the middle ear, it must stay where it was placed and tolerate the biologic milieu. A number of ossicular replacements showed excellent early results, only to develop disappointing problems after 3 to 5 years. Ideally, no changes should occur that will result in weakening of the structure of a graft over time.

Finally, the results obtained must be generally reproducible. This really encompasses two slightly different issues: individual surgical experience and general ease of use. It is helpful for the surgeon to have prior experience with the techniques and the possible complications of a particular graft. If possible, surgeons should have laboratory experience with new grafts. Materials are most useful when they are easy to use and require a minimal amount of additional equipment and instruments.

Classification of Materials

The last half of the twentieth century has seen a burgeoning number of materials used in tympanoplasty. For the purpose of this chapter, these can be classified into three broad subgroups: autografts, homografts, and alloplasts.

Autografts

Autografts are obtained from the patient and returned to him. These are almost always the most favorable grafts to use for reconstruction. They are certainly immunologically compatible and usually are convenient to obtain. Sometimes disease or previous surgery has taken this option away from the surgeon. Materials used in this way include: fascia, areolar tissue, cartilage, perichondrium, periosteum, ossicles, and bone. In some cases it may be time-consuming to obtain these grafts, but it would be unusual for all of them to be missing. Sheehy summarized it best: "It is always preferable to use the patient's own tissues".

Homografts

Homografts are taken from cadavers and then processed. The obvious advantage is that they are available no matter what surgery or disease preceded the most current procedure. Homografts can be obtained from many "ear banks". The preservation method may vary from one ear bank to another. The technique to prepare these homografts involves taking a cadaveric

tympanic membrane and ossicles and preserving them in such a way that it reduces the antigenic load. There are at least three different ways of preserving the tympanic membrane, including the use of formaldehyde, cialit, and ethanol and freezing.

Perkins introduced the application of 4 per cent formaldehyde to the homograft tympanic membranes. This improved buffer gave good preservation but tended to make the material brittle and gave it a memory for shape that made it unwieldy. Marquet began using cialit (2-ethyl mercury mercaptobenzoxazol carbonic acid sodium) in 1963. It is generally used as a 1:5000 solution. Cialit is bacteriostatic and has an antimycotic effect. When this solution is used, homografts can be kept for no more than 12 months at 4 °C owing to tissue degeneration. The graft begins to desquamate, and this can be an indication that the graft will be rejected if it were to be implanted. Wehrs (1982) has reported the use of freezing with a 70 per cent solution of ethanol. He does not preserve the integrity of the ossicular chain in his technique. There are no known reliable time limits to judge how long the homograft can be preserved using this technique.

Disadvantages of homografts include the need to keep several sizes of grafts on the shelf in the operating room. Some grafts are of differing dimensions, and therefore the surgeon may need to select different sizes for different patients.

Alloplasts

Alloplastic materials are man-made and are the most convenient to obtain. They are available from a number of well-known manufacturers of these prostheses, in a number of sizes, shapes, and styles for implantation. Because the body responds to each new substance in a slightly different manner, alloplasts require extensive in vitro and in vivo tests.

Alloplasts must display some characteristics of biocompatibility. This may be achieved by being nearly bioinert and minimally interacting with the immune system. Buffer materials such as cartilage or perichondrium placed between the alloplast and the tympanic membrane limit the interaction and reduce the incidence of extrusion. An alternative approach is to encourage controlled ingrowth of fibrous tissue. In this way the implant can be incorporated into the middle ear and stabilized by the healing process. This concept remains generally accepted, even though questions appear in the literature. In addition to being biocompatible, an implant must be sterilizable. No toxins that could potentially damage the cochlea or the mucosa of the middle ear can leach from the implant.

Many materials have been tried, and they have largely failed over time to meet the structural and biocompatible criteria. Any surgically implanted device sold in the US must be approved by the FDA.

Tympanic Membrane Graft Materials

Historically, artificial materials (alloplasts) were first used to replace damaged tympanic membrane. Since that time the use of autografts and homografts have become more common. It is surprising that alloplastic materials were used before surgeons developed techniques to work with the patient's own tissue.

Autografts

The first use of autografts in the ear was done by Zollner and Wullstein in the mid-1950s. Both of these investigators used split-thickness skin grafts. These grafts were successful in that a dry ear was created, but there were problems. Obtaining a thin graft was not an easy task and required making a separate wound on the arm or other site. Later reports concentrated on inflammatory responses, eczema, reperforation, and lateralization. Vein grafts were developed by Austin, Shea, and Tabb in 1961. Again, it was necessary to make a small incision in the arm.

Fascia Grafts

Storrs first reported the use of fascia grafts in 1961. Fascia largely replaced the use of vein as a tympanic membrane graft. After this, other authors, reported success with connective tissue grafts of several types. These autografts offer numerous advantages. They cannot be rejected but they may fail to survive the surgical transfer. Using current techniques, they are usually available and reliable with only 5 per cent failing.

Areolar tissue overlying the temporalis fascia has been popular as a grafting material. It is thin, conveniently located, and has a very low metabolic rate. These characteristics make it very easy to use, and it duplicates the function of the tympanic membrane quite well. It is similar in chemical composition to that of the middle layer of the natural tympanic membrane. Fascia is composed largely of collagen fibers. It is usually prepared by drying the tissue under a heat lamp or a hot air dryer. This makes the material cellophane-thin and more resilient to manipulation.

Studies have shown that the external canal skin grows over the anterior margin onto the graft. Mucosa covers the medial surface. On examination after healing it is often difficult to clinically tell the grafted tympanic membrane from a natural one. While there are differing techniques used to place the graft, success rates approaching 95 per cent are cited in the literature by proponents of each technique.

Other tissues used in similar ways include perichondrium alone or periosteum. This has not been thoroughly studied. Perichondrium is convenient in that the tragal cartilage is just anterior to the external canal. Periosteum can be taken from the under-surface of the temporalis muscle and is used in a similar manner.

Grafting Techniques

There are several surgical techniques in which autografts are used for tympanic membrane grafting. These methods may be classified into two major, competing techniques. In one, the graft is applied over the existing tympanic membrane surfaces; in the other, the graft is applied under the tympanic membrane remnant.

Complications may arise with either of these methods. Lateralization and anterior blunting can occur when grafts are placed in an overlay fashion; Sheehy has suggested such grafts will have a lower "take" rate, being more prone to retract away from the anterior margin and leaving a gap. Proponents of the underlay technique have not reported this complication.

Homografts

In 1959 Betow introduced homograft tympanoplasty. In the USA, Chalet reported on its use in 1964. The use of these grafts requires some practice. A number of techniques are advocated by different authors, each purported to improve the results. Reports indicate that the graft "take" may be as high as 85 per cent. This figure includes only those cases in which the air-bone gap was 25 dB or less. The experience of Glasscock and House was far less satisfactory, obtaining only a 70 per cent success rate; for this reason they have abandoned the use of homografts.

Homografts are prone to some specific and unique problems. Early in the postoperative course, the oval window may become filled with granulation tissue. This occurred at a rate of 0.6 per cent in Betow's series of 800 patients. Multiple small perforations, which are the result of an immunologic rejection reaction, may occur as a late complication. This was reported to occur in 1.4 per cent of cases, with spontaneous resolution taking place about half of the time. Finally, the use of homografts is prone to the formation of adhesions, which occur in about 1.75 per cent of cases. An additional problem is a short shelf life once the homografts are obtained from the ear bank.

Ossicular Reconstruction

Ossicular reconstruction is a much more complex subject than tympanic membrane grafting. This is true for several reasons. First, there are many more materials from which to choose. In addition to autografts and homografts, an array of alloplastic materials are available. Second, there are a multiplicity of possible ossicular deficits. Dr. Paparella has classified these ossicular deficiencies, and they are covered in other chapters. Each of these ossicular problems leads to a condition in which certain techniques of disease control and ossicular grafting are more favorable than others. The combination of techniques for eradication of disease with methods for reconstruction leads to numerous variations. It is difficult to compare surgical results with this many variables.

In this section, grafts of human origin (i.e. cartilage and ossicles) are discussed individually with respect to how each meets the criteria for an ideal material.

Alloplasts are similarly reviewed, with one commercial version selected in each class to clarify important issues. Surgical techniques are briefly reviewed.

Autografts and Homografts

Cartilage

Cartilage is readily accessible and has been well studied. Usually it can be obtained from the tragus or the auricle itself. If these sites were previously harvested then banked cartilage is available. Cadaveric knee cartilage may be obtained from ear banks. Regardless of its origin, cartilage can remain viable and function as an ossicle, yielding reasonable hearing. Sterilization can be accomplished by a number of means, including gamma irradiation with 4 Mrads without apparent damage. Animal studies have shown that viable perichondrium reduces the resorption of the cartilage. Normal lactate dehydrogenase has been demonstrated in implanted animals. Postmortem histologic examination of these animal implants has shown live chondrocytes. Human cartilage implanted as a strut to replace ossicles has been recovered from humans after death from other causes. Histologic studies in these cases have shown that the chondrocytes have died and were replaced by calcification.

Surgical Use

Cartilage can be easily carved to fit as a rigid prosthesis. Shea and Glasscock (1967) reported a 65 per cent success in closure of the air-bone gap to 20 dB and 52 per cent to 30 dB. Altenau and Sheehy reported closure of the air-bone gap to less than 20 dB in 67 per cent of the cases. Although some studies have reported extrusion to be a problem, this is not thought to be intrinsic to the material. Other authors have shown minimal extrusion. One of the major problems with cartilage is its weak response to infection. Should the middle ear become infected, there is a great chance that the cartilage will resorb.

Cartilage is also used to cover alloplastic materials to improve their biocompatibility. This use is discussed later in the chapter.

Ossicles

Transposition of ossicles have been very successful. In this technique, the patient's own ossicle, which was dislocated or had to be removed to control disease, is replaced. It will tolerate carving or modification using the drill. "Banked" ossicles are also available. Many otologists bank ossicles obtained during neuro-otologic procedures or from their own sources and preserve them in the same manner that ear banks preserve homograft tympanic membranes.

Surgical Use

The most commonly used ossicular graft is the incus interposition graft. The incus is removed and sculpted to fit between the long arm of the malleus and the head of the stapes. Failures are usually a result of anatomic limitations, primarily the alignment of the stapes to the malleus. If the ossicle is tipped to one side, it will have a tendency to become unstable and fall off the head of the stapes. Aside from anatomic factors, the use of ossicles is limited by the disease process and by the extent of damage done to the other ossicles. Austin (1982) reported a 15 to 20 per cent rate of failure for incus interposition grafts. Similar techniques include the use of the head of the malleus over the head of the stapes.

Another source of ossicular replacement can be created for selected patients. Tjellstrom and Albrektson (1985) have shown that titanium forms can be implanted in the patient's tibial metaphysis; 5 months later they were able to reliably recover mature bone in the form. Only six patients were treated in this manner.

A major drawback to the use of ossicles has to do with fixation in the middle ear space to a nearby bony structure such as the promontory or the bony annulus.

Alloplastic Materials

Alloplastic implants are frequently used for the replacement of ossicles. Many early materials were not well tolerated for a variety of reasons. Newer developments have led to more dependable prostheses.

Ultra High Molecular Weight Polyethylene

Perhaps the most encouraging material currently in use is marketed under the name Plastipore. Plastipore, which is an ultra high molecular weight polyethylene, is 70 to 90 per cent porous; the pores are 25 to 50 microns in diameter. Tissue has been demonstrated to grow into these porous spaces. Plastipore is manufactured by differing techniques. Thermofusion of small particles is the preferred method, since it leads to a smoother and more regular surface. Although the material can be machined, this process may create rough surfaces and call allow a particulate dust to develop. Plastipore will tolerate ethylene oxide sterilization without degradation.

Implant tests done in animals have demonstrated little reaction to Plastipore. Prominent giant cell reactions suggestive of material degradation have not been observed. Shortly after implantation there is an inflammatory response; the significance of this response is questionable, since it is unclear whether this has any effect on long-term results. In the animal models, a capsule of fibrous tissue starts to form in 2 weeks. The inflammatory response shows macrophages and granulation tissue. This process abates in 1 to 3 months following implantation. Specifically, there is ingrowth of fibrous tissue into the pores, and this is thought to stabilize the graft. The course of human reactions is thought to follow that of animal models.

A problem noted with this material has been that the graft is occasionally dislodged from its intended position for no apparent reason. Plastipore prostheses that were recovered post mortem from human ears demonstrated no apparent degradation. They were, however, covered by an irregular envelope of fibrous tissue. There are no clinical reports of significant granulation tissue.

Clinical Use

Initial clinical data about Plastipore were very encouraging, with a number of authors reporting it to be well tolerated and to produce good functional results. Since it was first used by Shea in 1975, reports began to appear that in time the prosthesis would extrude through the tympanic membrane without an intercurrent infection. Some reports showed extrusion rates as high as 15 per cent. When used as a total ossicular replacement prosthesis (TORP), the air-bone gap could be closed to < 20 dB in only 43 per cent of cases, and within 30 dB in 85 per cent of cases. The problem of extrusion has generally been solved by the use of that Schuring (1982) refers to as a "semi-biologic prosthesis". Shea developed a technique that covered the tympanic membrane side of the prosthesis with cartilage. When the two techniques of Plastipore use are compared, the method that includes cartilage cover reduces the extrusion rate to approximately 3 per cent. Some investigators have stated that they soak the prosthesis in blood or serum to fill the pores before implantation. The efficacy of this technique is not clear at this time.

Polytetrafluoroethylene (Teflon)

Proplast, which is a carbon fiber in polytetrafluoroethylene (Teflon), was advanced as a grafting material several years ago and continues to be used for comparative purposes. Proplast is a bioinert, porous material similar to Plastipore; however, it has a lower modulus and lower tensile strength. This accounts for its tendency to bend and for its softer, more pliable consistency. Calcium has a tendency to grow into the material, but this does not stiffen the prosthesis sufficiently. More granulation tissue tends to form on Proplast than on Plastipore.

Bioactive Glass Ceramics

The newest alloplastic material is the class of bioactive glass ceramics. Ceravital is a popular member of this class. This material is 40 to 50 per cent SiO_2, 10 to 15 per cent P_2O_5, 30 to 35 per cent CaO, the balance being sodium, magnesium, and potassium oxides. Sterilization is tolerated without difficulty. Implant tests conducted to date show no degradation in 3-year follow-up studies. The surface is covered with hydroxyapatite. Over time, the hydroxyapatite becomes replaced to a depth of 30 microns with bone. Animal tests showed coverage with mucosa in 3 weeks or less; foreign body giant cells containing ceramic particles were also observed.

In clinical use, initial studies reported a 9 per cent extrusion rate. In these trials the prosthesis was in direct contact with the tympanic membrane.

Bioactive implants are a relatively new option. Further trials will be needed to establish their role in otologic surgery.

Adjunctive Materials

A group of spacers, fillers, supports, and adhesives used in tympanoplasty, referred to as adjunctive materials, are frequently used in otologic surgery.

Silicone Rubber

Silastic, which is a type of silicone rubber, is placed in the middle ear in some techniques of tympanoplasty and mastoidectomy to hold open an air space. It is also used when the promontory or other mucosal surfaces have been excoriated and the surgeon is concerned about scarring. If Silastic is heat-vulcanized into a stable pliable sheet, it is tolerated without difficulty in the middle ear. If a chemical plasticizer is used, it may leach from the sheets, acting as a toxin to the cochlea. Silastic tends to encourage the formation of a fibrous envelope. The material is difficult to stabilize in a secure position in the ear. If sharp edges contact the tympanic membrane or bone edge, a necrotic area can form. This can lead to extrusion and reperforation of the tympanic membrane or bony erosions in the middle ear. Silastic has also been noted to undergo some degenerative process in the middle ear over long periods of time such as 10 years; for this reason it is not recommended for long-term use.

Gelfoam

Of all the adjunctive materials, none is as ubiquitous as Gelfoam. Gelfoam is a denaturated, porous gelatin sponge first used after World War II. No matter what method of reconstruction is selected, virtually every otologic surgeon uses Gelfoam. It is a nearly perfect graft support because it is rigid enough to support a tympanic membrane or ossicular graft and will stay in the position in which it is placed. Gelfoam is nontoxic and nonallergenic. It is readily absorbed and is not easily extruded or pulled down the eustachian tube. Animal tests indicate that it is entirely resorbed in 45 to 54 days (Kitchens, 1976; Holzer, 1973). There is a round cell response, but no giant cells are seen. This sponge encourages the formation of fibrous tissue at a higher rate than naturally occurs in the ear.

When gelatin is made into film, this process of fibrous tissue formation is reduced in severity. Gelfilm is a film 0.075-mm thick designed to replace Silastic. When dry, this material looks like cellophane; when moistened it becomes rubbery. Gelfilm has been used as a tympanic membrane graft, but usually it is employed to prevent adhesions in the middle ear, in a manner similar to Silastic sheeting.

Tissue Adhesives

Cyano-Butyl Acrylate (Histoacryl)

Tissue adhesives may play an important part in tympanoplasty. Most American authors are hesitant to report results obtained with tissue glues because of the medicolegal atmosphere surrounding these materials. The FDA has not approved the use of cyano-butyl acrylate (Histoacryl). In repositioned ossicles, cartilage struts or partial ossicular replacement prosthesis (PORP) glue may be used to hold the graft in the intended position. Cyanoacrylates polymerizes in 2 to 3 seconds, and during this very brief time they are most toxic. The monomeric liquid glue has been shown to create an inflammatory reaction. It is clearly toxic to the cochlea in rabbits; therefore, any time that the oval window is open, the use of cyanoacrylates should be avoided.

There are also questions concerning the heat generated during polymerization, which may result in tissue necrosis and inflammation. Light microscope examination has shown mucous membrane destruction and giant cell invasion for a varying period of time in laboratory animals; the former subsequently resolves, with a good fibrous union.

Clinical use of cyanoacrylates on the dura has been most successful. Similar uses in the middle ear of animals, including the dog and monkey, also have been successful. While this glue has been commercially available for more than 10 years in Europe, it is still not approved by the FDA for clinical use in the USA.

Fibrin Glue

An alternative tissue adhesive is a more biologic material; namely, fibrin glue. This glue is made by combining two solutions. The first contains lyophilized human fibrinogen, factor XIII and plasmatic fibronectin, plasminogen, and aprotinin. The second solution contains calcium chloride and thrombin. When these two solutions are mixed the fibrinogen cross-links. The adhesive is slowly resorbed over a period of 14 to 18 days. Fibrin glue is commercially available in Europe but not in the USA. Alternatively, fibrin glue can be created from the patient's own blood if proper laboratory skills are available.

Conclusions

There are many choices for otologic surgeons to make when selecting materials for a tympanoplasty. It is recommended that surgeons select the most natural material for the task desired and that the surgeon obtain the most experience with this material and its surgical use prior to clinical application. Each case and situation requires judgment on the part of the surgeon to select the best method and material available for use on a particular patient.