Paparella: Volume II: Otology and Neuro-Otology

Section 3: Diseases of the Ear

Part 3: Middle Ear and Mastoid

Chapter 34: Temporal Bone Bank and Implants

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Succesful transplantation in otology has been restricted to implantation of allograft middle ear bones and more recently chemically preserved allograft tympanic membranes (TMs) for reconstruction of the diseased middle ear.

Since the early 1960s, allograft ossicles have been used by the majority of otologic surgeons to restore the middle ear sound conduction mechanism. However, chemically preserved allograft TMs have experienced a much more controversial evolution. Today, almost 20 years after the first successful reconstruction of a tympanic membrane with an allograft eardrum, over 3000 successful allograft tympanoplasties have been reported in the medical literature. At the time of this writing, allograft tympanoplasty is gaining in popularity.

History of Tympanoplasty

Modern tympanoplasty origins are generally traced back to Wullstein and Zollner, who repaired tympanic membranes with full-thickness and subsequently split-thickness skin grafts utilizing an overlay or lateral technique. Ensuing problems with thick, crusting tympanic membranes, graft breakdown, iatrogenic cholesteatomas, and poor hearing results encouraged surgeons in Euroe and the USA to develop improvements in grafting materials and surgical techniques. The introduction of autogenous (isograft) collagen as graft material greatly improved the anatomic success rate of tympanoplasty. Hermann first used temporalis fascia in Europe, and Storrs is generally credited with performing the first temporalis fascia graft in the USA. In the same year, Shea and Tabb each reported successful series of tympanic membrane repairs using isogenous vein grafts. Although connective-tissue grafts improved the "take" rate, there were still problems with anterior blunting, lateralization, and graft cholesteatoma.

The use of non-epithelial collagen tissue grafts (vein or fascia) allowed its placement on the undersurface of the tympanic membrane. In 1961, Austin and Shea reported a large series of underlay vein grafts. Through the 1960s, underlay or medial collagen grafting was popularized in this country by Glasscock, Hough, and many other otologic surgeons. By 1965, autogenous collagen (fascia or vein) used as an overlay or underlay graft had become the standard technique for repair of the TM in the USA. In Europe, allogenous collagen tissue was found to be just as effective as the autogenous (isograft) tissue being used in the USA. Collagen obtained from other humans and used for successful repair of TMs included perichondrium, pericardium, dura, and allograft fascia or dura.

The use of isograft vs allograft ossicles appears historically to have a less controversial clinical course. Beck and Franz first compared the use of preserved isograft and allograft

incudes and found little difference in hearing results. Since then, many surgeons have described techniques using a preserved allograft incus or malleus for reconstruction of the sound conduction mechanism. The use of ossicles provided good, long-term clinical hearing results, provided that stability could be obtained. This generally requires a stable host malleus to act as a foundation for stabilizing the shaped incus columella or incus interposition. Over time, minimal remodeling develops whether an isograft or allograft ossicle is used.

The problem of restoring the hearing in a patient with an absent malleus prompted Jansen to introduce the shaped, allogenous auricular or nasal cartilage to reconstruct the chronically infected ear without a malleus and stapes superstructure. Later, Brockman, Harris and Goodhill, and Pulec and Sheehy described good short-term results with allograft cartilage; however, long-term resolution of cartilage reduced the efficiency of hearing after several years, and the search continued.

The use of synthetic materials for reconstructing the ossicular chain, such as stainless steel, tantalum, Teflon, polyethylene, and Silastic all met with early but short-lived enthusiasm. Each of these synthetic materials eventually was extruded if placed against a vibrating biologic tympanic membrane. With the introduction of "biocompatible" synthetic material for ossicular reconstruction by Shea and Homsy in 1974, enthusiasm for synthetic ossicles was rekindled. Acceptable short-term hearing results for total ossicular replacement prostheses (TORPs) and partial ossicular replacement prostheses (PORPs) were reported by Sheehy, Smyth and colleagues, and others in the middle to late 1970s.

In 1982, in a 5-yer follow-up report on the results with PORPs and TORPs, Smyth found that only 27 per cent of the TORPs have satisfactory hearing. "These poor results coupled with digestion of porous polyethylene give little justification for the continued use of this material in tympanoplasty", Austin concurred.

Thus, to date, there has been no satisfactory solution for reconstructing the sound conduction mechanism of the severelyu damaged middle ear with completely absent tympanic membrane and ossicles. Historically, an isograft or allograft ossicle, if it can be stabilized against the host malleus, provides the best long-term results. If an allograft tympanic membrane with attached malleus can be transplanted into those patients with an absent malleus, the foundation for a stable ossicular chain reconstruction would be established.

Allograft Tympanoplasty

Table 1 summarizes the three different types of chemical fixation of allograft tympanic membranes and ossicles that have been used in those clinical series reporting 90 per cent or greater anatomic success rate. Each of these solutions impart unique chemical and physical properties to the allograft collagen, and thus the surgeon's indications and surgical techniques also vary considerably.

It is clear that isograft collagen (fascia, vein, perichondrium) provides satisfactory hearing and anatomic results in the majority of tympanoplasty cases. Therefore, the potential value of allograft eardrums lies in providing an alternative for those cases with extensive middle ear destruction. This author has restricted the use of formalin preserved allograft tympanic membranes to four specific indications (Table 2).

Table 1. Chemical Fixation Methods Used for Preservation of Allograft Tympanic Membranes and Ossicles

1. 70% alcohol

2. 4% buffered formaldehyde fixation and 0.5% buffered formaldehyde preservation

3. 4% buffered formaldehyde fixatin with 1:5000 aqueous Cialit preservation.

Data for hearing and anatomic results have been analyzed for nearly 500 patients who have received a buffered formaldehyde-preserved allograft tympanic membrane because of one of the above four indications. Anatomic results show that 96 per cent of these patients have an intact tympanic membrane and a dry, self-cleansing ear with no activity restrictions.

Long-term hearing results in patients reconstructed for severe chronic otitis media (indications 1 and 2 in Table 2) demonstrate that 85 per cent maintained a mean air-bone gap closure within 25 dB. Seventy-five per cent of the patients with congenital aural atresia have achieved similar hearing results. However, only 65 per cent of the patients with reconstructed radical mastoidectomy have maintained satisfactory hearing (one-third have developed persisten eustachian tube dysfunction postoperatively).

Table 2. Indications for Homograft Tympanoplasty

1. Previous failures with standard tympanoplasty technique.

2. High risk of failure with standard tympanoplasty technique (total perforation, absent malleus, slag burns).

3. Reconstruction of radical mastoidectomy.

4. Reconstruction of congenital aural atresia.

Otologic Tissue Banking

Choissone has illustrated the practical need for regional tissue banks to obtain, prepare, and distribute otologic tissue of the highest possible anatomic quality, sterility, and chemical stability. The American Association of Tissue Banks Standards Committee has outlined its requirements for tissue banks in general, but not specifically, for otologic tissue banking. In 1977, the faculty of the Second US Symposium on Homograft Tympanoplasty met to address the moral, ethical, and legal aspects of providing otologic allograft tissue to surgeons, while ensuring maximum protection for the donors and recipients.

The need for more otologic tissue banks should be dictated by the inability of existing banks to supply the regional demands for specimens. An ear bank represents a significant investment in time and money and should be self-supporting, maintained by its regional demand.

Medico-legal Aspects

There are significant medico-legal risks involved with obtaining, preparing, and distributing otologic tissue. Litigation has focused on two major areas of responsibility:

1. Obtaining and documenting permission.

2. Transmission of disease from donor to recipient (particularly viral diseases such as HIV-AIDS, hepatitis, leukemia, and Jakob-Creutzfeldt disease).

As organ and tissue transplantation of all types has increased, legal regulations for obtaining antemortem or postmortem donor permission are being more clearly defined. Each state has passed specific universal donor acts that clarify which relatives may give permission and how that permission must be documented. More recently, 28 of the 52 states have passed required request laws. These state laws legislate that hospitals or attending physicians are required by law to request permission for needed donor parts from the relatives of all patients who die in the hospital.

Besides donor permission, complete records of the source of biologic materials should include the donor's name and age, time and cause of death, how long after death the specimen isremoved, preparation details, and the destination of each specimen. The laboratory director should be able to trace all specimens from donor to recipient. Thus, should problems ever arise with the specimen, they can be satisfactorily analyzed and dealt with.

National and international laws regarding the shipment and distribution of biologic materials are complex, often unclear, and sometimes prohibitive. Increased legislative awareness and action in this area will be forthcoming as the demand for transplantation tissue of all types increases.

The American Association of Tissue Banks requires, as a condition for membership in its association, a non-profit laboratory status for all tissue banks. Several legal proceedings have been initiated against individuals who have allegedly profited from the sale of cadaver human parts. The moral, ethical, and legal implications of tissue banking require a sensitivity to these delicate issues.

Donor Requirements

Under normal environmental conditions, otologic tissue should be removed within 24 hours of death. Immediate refrigeration of the body minimizes enzymatic destruction of the tympanic membrane collagen and extends the time of post mortem harvest to 48 hours. The age of donor can be 6 to 80 years.

The transmission of infectious disease from donor to recipient is a major concern for most types of tissue (other than formaldehyde-fixed otologic tissue). Most other donor tissue (eg, skin, bone, corneas) is impanted unaltered and cannot be completely sterilized, particularly for viruses. This is not true of formaldehyde-fixation techniques, which effectively sterilize the otologic tissue against all known viral, bacterial, and fungal agents, provided the fixative techniques described below are follower. There is some risk to technicians removing

tissue from a donor with infectious disease; for this reason, patients with infectious hepatitis, AIDS, lymphoma, leukemia, Jakob-Creutzfeldt disease, and so forth are not considered satisfactory donors. Unfortunately these conditions often are not known until later, and therefore the technician must be schooled in removal techniques to eliminate the risk of inoculating themselves with the infecting agents through careless techniques such as inhalation; self-inflicted scratch or cut, rubbing eyes, nose, or mouth; and inadequate gloving or hand washing after tissue removal. Once the core speciment is placed in the 4 per cent formaldehyde solution for 24 hours, all known infecting agents are destroyed.

Donor Permission

Recorded donor permission, either written or tape-recorded, is obtained from the next of kin as defined by state law. Statutes vary, and a thorough familiarity with the regional legal requirements for obtaining permission in the specific state where the removal will be performed will minimize medico-legal risks. The request should be made in a concise and clear manner, and lay terms should be used. The laboratory personnel requesting permission should possess maturity and sensitivity capable of dealing with the relatives' grief. This often can be difficult, since permission must be obtained within a few hours of death, a period in which a person's sense of loss of a loved one is often most acute.

Removal of Core Specimens

Temporal bone specimens are removed intracranially after an open head autopsy, using a Stryker autopsy saw and a 1.5-inch core blade. Figure illustrates the relationship of the middle ear structures to the anatomic landmarks of the temporal bone on the left side, and the location of the saw cuts on the right. To minimize damage to the middle ear structures, the core saw should be positioned as far laterally as possible along the petrosal ridge, resting against the squamous portion of the temporal bone. The bone cutter should be slightly tilted toward the midline which will prevent any damage to the external facial surfaces.

The bone cores are secured using large bone-holding forceps. Care should be taken not to grip the superior portion of the bone core with the large bone-holding forceps, because this bony roof is very thin and an invasion of the cavity by the bone forceps will very likely destroy the desired middle ear structures. Using a scalpel, the muscular attachments on the inferior aspect of the bone core are carefully sectioned. The bone core can be positioned with the movement of the bone forceps. As the muscular attachments are sectioned, the bone core can be rocked more easily in the posterior direction, and further sectioning of the inferior attachments is accomplished until the core is free.

The procedure for removing the bone cores is non-sterile and can be performed before or after the embalming process. If removal is before embalming, the internal carotid arteries should be ligated after the bone core is removed. This will prevent the leakage of fluids during the embalming process and ensure better perfusion of the facial area. If removal is after embalming, there is no need to tie off the internal carotids.

Fixative

Temporal bone core specimens are placed immediately in 4 per cent buffered formaldehyde solution (pH 6.5) and stored for 72 hours. This sterilizes the tissue. Formaldehyde cross-links the unstable double bonds of the collagen in the tympanic membrane, increasing its chemical stability. The formalin-fixed collagen resists biologic degradation, allowing the host 3 to 4 months to vascularize the donor collagen.

After 72 hours of fixation, the donor tympanic membrane and ossicles are microscopically dissected. Through a transcanal approach, the thin squamous epithelial layer of the tympanic membrane and external canal are removed.

The major rejection antigens (T antigens) reside in the RNA and DNA of the donor cell nuclei. Collagen has relatively few nuclei. The squamous epithelium, however, has multiple donor cell nuclei, and removal of this thin squamous epithelial layer reduces the risk of host rejection. Allograft collagen incites little immunologic response and is widely used in many specialties (eg, cornea, heart valve, ligaments, and tendons).

Next, the bony roof of the epitympanum and antrum is removed. The tensor tympani tendon, the anterior malleolar ligament, and the incudo-ligament are sectioned. The tympanic membrane is then carefully removed from its bony annular groove. A small periosteal cuff remains superiorly for added stability on implantation.

Figure is a microphotograph of a formalin-fixed tympanic membrane with attached malleus and incus. The specimen is stored in a sealed container filled with 0.5 per cent buffered formaldehyde solution (pH 7). Provided the sterile seal is not broken, the specimen can be stored at room temperature up to 2 years.

The chemical stability of the 0.5 per cent formaldehyde preservative solution over this period of time should be checked by retaining samples of the solution under storage conditions and testing both pH and concentration.

Biologic Integrity

Only tympanic membranes that have perfect collagen should be used for transplantation; those that contain thin monomeric areas or areas of tympanosclerosis should be rejected. Approximately one out of every three tympanic membranes that are harvested are rejected because of biologic defects.

Sterility

Controls for bacterial, viral, and fungal sterility of the otologic implants must be rigidly enforced. The Midwest Ear Bank has used buffered formaldehyde as a fixative and preservative agent, in part because it guarantees complete sterility of the specimen. The Center for Disease Control in Atlanta uses formaldehyde to inactive ("kill") infectious viruses; a solution of 0.1 per cent formaldehyde will completely inactivate HIV (AIDS virus) within 20 minutes. Additionally, the Midwest Ear Bank periodically monitors the sterility of specimens to guarantee that this technique, does, indeed, completely perfuse and sterilize the

donor tissue. To date, after thousands of speciments have been shipped, no incidence of possible donor transmitted disease has been documented following the formaldehyde fixation and sterilization procedures described here.

Other types of tissue banks (eg, eye, bone, skin) do not prepare chemically sterilized tissue and therefore cannot effectively inactivate all viruses. Serologic testing of donors is required. Rigid laboratory controls to safeguard transmission of infectious disease from donor to recipient must be constantly monitored.

The responsibility of otologic tissue banks is as great. Fortunately, chemical fixation with formaldehyde permits an easier method for guaranteeing the sterility of otologic implants.

Clinical Effectiveness

It is advisable that careful monitoring of the clinical effectiveness of prepared otologic tissue be conducted by all ear banks distributing prepared middle ear tissue. An otologic surgeon should serve as director and/or consultant for the laboratory and make available the clinical studies of implantation of the bank's materials in his own patients. If this is not possible, then monitoring of several other otologic surgeons' cases should be carried out to guarantee the clinical effectiveness of the tissue being distributed.