

**TITLE: Ossicular Chain Reconstruction Techniques**  
**SOURCE: Grand Rounds Presentation, UTMB, Dept. of Otolaryngology**  
**DATE: June 29, 2009**  
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A disruption of the ossicular chain of the middle ear uniformly causes a symptomatic conductive hearing loss in patients. The otologic surgeon should be skilled in ossicular reconstruction to restore hearing. Disruption may occur in one of two forms: fixation or discontinuity. Fixation of the ossicular chain can be caused by malleus head ankylosis, ossicular tympanosclerosis, or scar bands seen in chronic otitis media. Discontinuity can occur with head trauma, most often dislocating the incudostapedial joint, or erosion by chronic otitis media/cholesteatoma. An eroded incudostapedial joint is seen in 80% of patients with ossicular erosion. The incus may be absent as well as the stapes superstructure.

### **Anatomy:**

The normal conducting apparatus of the middle ear consists of an intact tympanic membrane and three ossicles connected in series. Any disruption of these components can cause conductive hearing deficits. The orientation of the tympanic membrane is slightly oblique to the sagittal plane; it is roughly conical, pointing medially and anteriorly. The handle of the malleus is firmly attached to the medial aspect. The membrane is divided into two parts: the pars flaccida (the portion superior to the insertion of the manubrium) and the pars tensa. The point at which the inferior end of the manubrium inserts into the tympanic membrane is called the umbo. The malleus has two main parts: the manubrium, which adheres to the tympanic membrane, and the head, which articulates with the incus. The malleus head lies in the epitympanic recess.

The manubrium also has two processes: one anterior and one lateral. The region between the manubrium and the head is called the neck of the malleus. The chorda tympani crosses the medial surface of the malleus neck.

The incus is divided into 3 principal parts: a body and two processes (named short and long, respectively). The head of the incus articulates with the head of the malleus in the epitympanic recess. At the end of the long process of the incus is a small region called the lenticular process. The lenticular process articulates with the head of the stapes.

The short process of the incus is attached to the cavity wall by the posterior incudal ligament. As the name implies, the stapes looks like a stirrup. It has four components: a footplate, two crura (posterior and anterior), and a head. The head of the stapes articulates with the lenticular process of the incus. The footplate of the stapes covers the oval window.

### **Acoustic Impedance Matching:**

The acoustic resistance to the passage of sound through a medium is termed *impedance*. The transduction of vibratory energy from the air in the external auditory canal (low impedance) to the cochlear fluids (high impedance) is possible as a result of the impedance-matching function of the middle ear. Three levers accomplish the required pressure transformation for transduction. The first of the levers is described as the catenary lever, named after the theoretical shape a hanging chain or cable will assume when supported at its ends and acted on only by its own weight. The attachment of the tympanic membrane at the annulus amplifies the energy at the malleus because of the elastic properties of the stretched drumhead fibers. Because the annular bone surrounding the tympanic membrane is immobile, sound energy is directed away from the edges of the drum and toward the center of the drum. The malleus receives the redirected sound energy from the edge of the drum because of the central location of the manubrium.

The second lever is referred to as the ossicular lever. The malleus and incus acting as a unit, rotate around an axis running between the anterior malleolar ligament and the incudal ligament. The gain of the ossicular lever is the length of the manubrium of the malleus divided by the length of the long process of the incus (approximately 1.3:1). The ossicular lever taken alone produces a small mechanical advantage for sound transmission. The catenary lever is tightly coupled to the ossicular lever, because the tympanic membrane is extensively adherent to the malleus handle. Corrected calculations reveal a combined catenary-ossicular lever ratio of 1:2.3. The third lever, the hydraulic lever acts because of the size difference between the tympanic membrane and the stapes footplate. Sound pressure collected over the area of the tympanic membrane and transmitted to the area of the smaller footplate results in an increase in force proportional to the ratio of the areas. The average ratio has been calculated to be 20.8:1. Taking the three levers together, the middle ear offers a theoretical gain of approximately 34 dB.

The true gain of the middle ear is less than the theorized 34 dB. Ossicular coupling refers to the true sound pressure gain that occurs through the actions of the tympanic membrane and the ossicular chain. The pressure gain provided by the normal middle ear with ossicular coupling is frequency dependent. The actual mean middle ear gain is 20 dB at 250-500 hertz (Hz), reaching a maximum of 25 dB at 1 kilohertz (kHz), and then decreasing at about 6 dB per octave at frequencies above 1 kHz. The changes in gain above 1 kHz are caused by portions of the tympanic membrane moving differently than other portions, depending on the frequency of vibration. At low frequencies, the entire tympanic membrane moves in one phase. Above 1 kHz, the tympanic membrane divides into smaller vibrating portions that vibrate at different phases. Another factor is slippage of the ossicular chain, especially at frequencies above 1-2 kHz. Slippage is due to the translational movement in the rotational axis of the ossicles or flexion in the ossicular joints. In addition, some energy is lost because of the forces needed to overcome the stiffness and mass of the tympanic membrane and ossicular chain. Ossicular coupling is impaired when the middle ear space (including the mastoid cavity) is reduced. The difference in pressures

between the external auditory canal and the middle ear facilitates tympanic membrane motion. In the normal ear, the middle ear air pressure is slightly less than the pressure in the external canal. When the middle ear space is reduced (eg, by chronic ear disease or canal wall down surgery), the impedance and pressure of the middle ear increase relative to the external canal because the impedance of the middle ear space varies inversely with its volume. This reduction in pressure difference leads to a subsequent reduction in tympanic membrane and ossicular motion. The minimal amount of air required to maintain ossicular coupling within 10 dB of normal has been estimated to be 0.5 mL.

Austin identified five categories of anatomic defect and described each within the context of the associated prototypic hearing loss. The first category, tympanic membrane perforation with undisturbed ossicular continuity produced a hearing loss that was linearly proportional to the size of the perforation (loss of areal ratio + loss of catenary lever). The degree of hearing loss, flat across speech frequencies, was not altered by the location of the perforation on the drumhead. The second category, tympanic membrane perforation combined with ossicular disruption occurred in approximately 60% of Austin's patients and was the most common form of conductive hearing loss requiring surgical therapy. The incudostapedial joint was the most vulnerable ossicular articulation. The third category, total loss of the tympanic membrane and ossicles created a condition wherein sound pressure contacted the oval and round windows simultaneously, resulting in partial phase cancellation of the sound wave in the cochlear fluids. Conductive hearing loss was flat across speech frequencies and averaged 50 dB. More complete phase cancellation caused increased hearing loss compared with patients with partial perforations. The fourth category included those patients with ossicular disruption behind an intact tympanic membrane. This defect resulted in a maximal conductive hearing loss of 60 dB. The intact eardrum reflected sound energy back into the external auditory canal, causing an additional 17-dB conductive loss above what was expected from removal of the hydraulic and catenary-ossicular lever action. The decreased sound pressure also reached the round and oval windows nearly simultaneously, inducing phase cancellation in the labyrinthine fluids. The fifth category described a variety of congenital malformations with ossicular disruption and closure of the oval window. Also included were cases of obliterative otosclerosis with closure of the oval and round windows behind an intact drum. The expected flat loss from such a defect is 60 dB.

### **Repair Techniques:**

The goal of ossicular chain reconstruction is better hearing, most typically for conversational speech. Patient selection for ossicular reconstruction is largely based on the preoperative audiogram and on the potential to regain serviceable hearing. Bringing the operative ear to within 15 dB of the contralateral ear will enhance binaural input to auditory centers; A patient's perceived hearing improvement is best when the hearing level of the poorer-hearing ear is raised to a level close to that of the better-hearing ear. In patients with severe mixed hearing loss, ossicular reconstruction can be considered, because it may enhance the use of amplification.

Acute infection of the ear is the only true contraindication. Acute infection will most likely result in poor healing, prosthesis extrusion, or both. Relative contraindications include persistent middle ear mucosal disease, operating on the only hearing ear, tympanic membrane perforation, and repeated unsuccessful use of the same or similar prostheses.

## **Approach:**

Idiopathic malleus head fixation occurs in the epitympanum. 2 different surgical techniques are used in the treatment of malleus fixation syndrome. The attical fixation can be removed via a transmastoid approach without disruption of the ossicular chain. Alternatiely, an ossiculoplasty can be performed via a transcanal approach, removing the malleus head with the incus and reconstructing by incus interposition or by PORP. Martin (2009) reported a retrospective study including 24 patients (25 ears). The study concluded that there was no statistically significant difference between the 2 surgical techniques when post-op hearing was considered.

## **Using Patient's Tissues:**

Some form or degree of incus deficiency is the most common ossicular defect encountered. The goal of surgery is to reestablish the mechanical connection between an intact tympanic membrane and the oval window. This can be accomplished by a variety of techniques utilizing a variety of materials. The incudostapedial joint and the lenticular process of the incus are the most common sites of ossicular discontinuity. This defect can lead to an air-bone gap of up to 60 dB.

When erosion is limited to the most distal portion of the incus and when the incus and the malleus are mobile, a limited reconstruction can be performed. Applebaum designed a hydroxyapatite prosthesis for defects of the incus long process. The Applebaum prosthesis is a rectangular piece of hydroxyapatite with a groove through the proximal end extending the length of the rectangle. The groove stops short of penetrating the distal end of the rectangular prosthesis. At this distal end of the groove, a circular hole passes through the floor of the groove. The groove is designed to accommodate the remnant of the incus long process. The circular hole receives the stapes capitulum. The prosthesis is placed by gently lifting the long process of the incus and sliding it into the groove. Then the hole of the prosthesis is placed onto the stapes head. This procedure results in a stable connection requiring no further packing or tissue adhesion.

Advantages of the Applebaum prosthesis include the following: The prosthesis reliably bridges incus long process defects of up to 3 mm, It does not tend to loosen and lose continuity over time. The prosthesis avoids technical difficulty and time involved in constructing bone or cartilage bridges. It precludes removal of the incus for refashioning, and consequently it spares unnecessary destruction of the incudomalleal joint. The prosthesis can be immediately available in the operating room, saving the patient from unnecessary anesthesia time.

Another option for joint replacement is a Kurz angular prosthesis made of a gold shaft, gold cup, and titanium clips. The gold cup is placed initially on the head of the stapes. Next, the clips are crimped to the long process of the incus. One advantage of the device is that the shaft comes in various lengths to accommodate different size remnants of the long process of the incus.

More extensive erosion of the incus requires a more extensive reconstruction. Ossicular continuity can be restored between the stapes and manubrium of the malleus (if present). Alternatively, a “strut” or “columella” may be formed by an implant bridging from the capitulum or footplate to the tympanic membrane.

Interposition of incus body as a bridge between the stapes and the malleus was the original ossicular reconstruction surgery. If the incus is unavailable, the malleus head, or cortical bone, harvested from the mastoid cortex, may be used. This type of autograft is considered by some to be the procedure of choice. Incus interposition should only be considered when the angle between the long axis of the stapes capitulum and malleus handle is favorable (preferably  $<30^\circ$ ). Angles more than  $45^\circ$  prevent proper sound transfer between the stapes and malleus. Specifically, some sound energy is converted into an inefficient rocking motion at the footplate if the manubrium is too far anterior to the stapes. Disadvantages of autograft include prolonged operative time, possible displacement or resorption, the possibility of the autograft harboring microscopic cholesteatoma, and poor fit if the stapes superstructure is absent. Advantages include a low extrusion rate, low cost, and excellent biocompatibility.

### **Using Homografts:**

Irradiated homograft ossicles and cartilage were first introduced in the 1960s in an attempt to overcome some of the disadvantages of autograft implants. These have now fallen out of favor since the emergence of communicable diseases such as AIDS and Creutzfeldt-Jakob disease.

### **Using Allografts:**

A variety of synthetic materials have been used to manufacture a variety of prostheses. These allografts are the most commonly used materials for ossicular reconstruction today. Disadvantages include higher expense and possibly a higher extrusion rate. The latter is controversial. Advantages include the fact that the implants are readily available and presculpted, and the relative ease of use.

Numerous materials have been used to construct allograft ossicular prostheses. In the late 1970s, a high-density polyethylene sponge (HDPS) that had nonreactive properties was developed. HDPS has sufficient porosity to encourage tissue ingrowth. The original form was a machined-tooled prosthesis (Plasti-Pore); a more versatile manufactured thermal-fused HDPS (Polycel) arrived later. This latter form permitted coupling with other materials, such as stainless steel, thus lending itself to a wide variety of prosthetic designs. Clinical experience has shown the necessity of covering these HDPS alloplasts with cartilage to minimize the incidence of extrusion. Extrusion rates have averaged 3-5% in large series with 5-10 years of follow-up monitoring.

Hydroxylapatite is another bioactive material used for middle ear reconstruction. The nonporous and homogenous nature of dense hydroxylapatite resists penetration by granulation tissue. Hydroxylapatite is a polycrystalline calcium phosphate ceramic that has the same chemical composition as bone. It forms a direct bond with bone at the hydroxylapatite/tissue interface- If placed next to the scutum, osseointegration can occur, with subsequent conductive

hearing loss. With time, hydroxylapatite implants gradually become completely covered by an epithelial layer. The final epithelial layer contains all cell types characteristic for the middle ear, indicating good biocompatibility of the implant material.

Titanium is another common alloplastic material. Studies in rabbits have shown that within 28 days after implantation, a thin, noninflamed, even layer of epithelium forms over the inserted implant. Similar results in human studies have shown the same type of reactivity. Titanium forms a biostable titanium oxide layer when combined with oxygen. The properties of titanium make it possible to manufacture an extremely fine and light prosthesis with substantial rigidity in the shaft. Furthermore, differential processing of the material surfaces triggers various tissue reactions. For example, rough-milled surfaces are most appropriate in areas that contact cartilage or the stapes head or footplate. Conversely, the smoother the surface, the less connective tissue reaction occurs, and the epithelial covering is minimized. As far back as 1993, a group of surgeons designed the total (Arial) prosthesis and the partial (Bell) prosthesis. These are available commercially from Kurz. In 1996, Spiggle and Theis introduced new titanium prostheses that can be trimmed intraoperatively to the appropriate length.

### **Comparison of Techniques:**

Attempts have been made to standardize reporting success rates for various reconstruction methods and materials. According to the 1995 guidelines of the AAO-CHE, pre and postoperative air-conduction and bone-conduction thresholds are measured at 4 designated frequencies (0.5, 1, 2, and 3 kHz), then averaged. Success is defined as a mean postoperative air-bone gap of less than 20 dB and is the main outcome considered for this talk.

It is clear that optimal results depend not only on the qualities of the prosthesis, but also on the environment in which it is placed and the surgical techniques used. There have been a variety of prognostic systems proposed. Austin (1972) defined four groups in which the incus had been partially or completely eroded: A, malleus handle present, stapes superstructure present (60% occurrence), B, malleus handle present, stapes superstructure absent (23%), C, malleus handle absent, stapes superstructure present (8%), D, malleus handle absent, stapes superstructure absent (8%). Kartush (1994) proposed a scoring system called the middle ear risk index (MERI) to form an index score to determine the probability of success in hearing restoration surgery. MERI is used to describe the preoperative middle ear environment at the time of ossiculoplasty. It incorporates different classifications of middle ear disease and ossicular status, including Austin's. Dornhoffer (2001), unsatisfied with the clinical correlation of the MERI, further analyzed clinical data. 200 ears, reconstructed with HAPEX PORP or TORP, were analyzed. Ossicular chain status, mucosal status, otorrhea, +/- mastoidectomy, and revision surgery were all significant prognosticators. Of note, presence of the stapes superstructure was not influential. Dornhoffer proposed the Ossicular Outcomes Parameters Staging (OOPS). De Vos (2007) reported on 149 ears. Multivariate statistical analysis identified the predictive value of the presence or absence of the malleus handle and the mucosal status of the middle ear mucosa in the prognosis of ossiculoplasties. They did not show predictive value in CWU mastoidectomy, otorrhea, myringitis, or length of the prosthesis. Best results were obtained in the Austin A (S+M+) and B (S-M+) classifications, with no difference between the two. This contrasts with previous thoughts on the importance of the stapes superstructure. All

three studies of prognostic factors identify middle ear mucosal status and presence of malleus handle as important predictors of successful hearing restoration.

With such a variety of options and materials available for reconstructing the ossicular chain, the otologic surgeon must consider using the method that provides the best hearing result with the least chance of complications. The ideal study for comparison of techniques would be a single surgeon directly comparing techniques or materials on patients who had been risk stratified by a validated prognostic index, with reporting of complication rates and long-term follow up. This study does not exist. For this online chapter, studies published in the past decade are considered in order to assist the otologic surgeon in making an informed decision about which technique to use. A meta-analysis was not performed. Instead, the success rates of the various techniques were extracted, tabulated, and averaged.

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	Interposition	Titanium PORP	Non-titanium PORP	Titanium TORP	Non-titanium TORP
House (2001)			63%		58%
Iurato review (2001)	84%		82%		
Iurato study (2001)	85%				
Dalchow (2001)		76%		76%	
Ho (2003)		64%		45%	
Neff (2003)				89%	
Hillman (2003)		45%	60%		
Gardner (2004)		70%	48%	44%	21%
Martin (2004)		68%		40%	
O'Reilly (2005)	66%				
Schmerber (2006)		77%		52%	
Truy (2007)		72%	67%		
Vassbotn (2007)		77%		89%	
Siddiq (2007)		85%		46%	
DeVos (2007)		60%		60%	
Coffey (2008)		82%	50%	74%	50%
Emir (2008)	58%		56%		
Neudert (2009)	66%	66%			
Mean	72%	70%	61%	62%	43%

Several closing points should be emphasized. A standardized prognostic classification must be adopted in order to compare future results across multiple studies; Wide variations in the status of operated ears make it almost impossible to scientifically compare different reconstruction techniques. Multiple studies have shown that a cartilage cap should be used, when an allograft PORP or TORP is used, to minimize the extrusion rate of implants. Extrusion/ displacement rates of allograft prostheses are between 0.5-10% and are lower when a cartilage cap is used. Across the past 10 years of published reports, based on a non-statistical review of the data, titanium PORP yields approximately equivalent hearing results to incus interposition. TORP reconstruction most probably yields a poorer hearing result than PORP when all cases are considered. Considering the technical skill needed to successfully perform incus interposition, a general otolaryngologist should opt for titanium reconstruction prosthesis for ossicular chain reconstruction.

## **DISCUSSANT'S REMARKS**

### **Dr. Makishima**

Even if you have been a surgeon for over twenty years, the prognostic factors include (1) if the malleus is bearing mucosa, and (2) if the tympanic membrane is on top of it, do you have a middle ear space with that? Contraindications for OCR include if it is the only hearing ear. I know that a lot of you have not seen autografts, which are not much used now. And if there's nothing left, you can always use cortical bone from the mastoid. In Japan we would always have a chisel on the ear tray just for that.

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