CASE SERIES: REMODELLED AUTOSSICLE VERSUS TEFлон PORP

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ABSTRACT

BACKGROUND
A widely accepted technique used for eroded incudostapedial joint or partially eroded incus is tympanoplasty with remodelled incus or malleus. An alternate method used for grafting is using PORP with cymba conchal cartilage interface. This manuscript is a study which compares outcomes of remodelled autossicle with Teflon PORP with cartilage interface.

The aim of the study is to compare the restoration of hearing, postoperatively, in patients who underwent tympanoplasty for eardrum perforation with IS joint erosion with chronic otitis media (COM) using remodelled autossicle with Teflon PORP.

MATERIALS AND METHODS
In our study of 90 patients, patients presented with chronic otitis media and eardrum perforation and were followed for at least 6 month post operatively. In 45 patients, temporalis fascia grafts with remodelled incus and the rest (45 patients) had PORP (Teflon) with conchal cartilage interface.

Setting- Department of Otorhinolaryngology, SGT Medical College, Budhera, Gurugram, Haryana, India.

Study Design- A total number of 90 surgically fit cases of perforation of the tympanic membrane were selected with moderate conductive hearing loss, who needed surgery of tympanoplasty with reconstruction.


RESULTS
Our data indicates that remodelled incus provided satisfying hearing (post-operative AB gap <20 dB) improvement in 43/45(95.6%) patients whereas in the PORP with cartilage interface, we achieved satisfying hearing improvement in 41/45(91.1%) patients. All patients with remodelled incus had dry and complete uptake of graft. Extrusion of graft where PORP was used seen in 2/45(4.4%) patients.

CONCLUSION
The primary objective of middle ear and mastoid surgery for cases of COM with perforation is to achieve a dry ear and hearing improvement postoperatively. The main aim of this study is to compare the restoration of hearing, postoperatively, in patients who underwent tympanoplasty for COM using autoincus or Teflon PORP. Both remodelled incus & PORP provided satisfying hearing (post-operative AB gap <20 dB) improvement in >90% patients.

KEYWORDS
Partial Ossicular Reconstruction Prosthesis (PORP), Chronic Otitis Media (COM), Acute Suppurative Otitis Media (ASOM), Sensory Neural Hearing Loss (SNHL), Pure Tone Audiometry (PTA), Air Bone Gap (ABG).


BACKGROUND
The otologists often find necrosed ossicles in patients with moderate to severe conductive hearing loss. In the absence of an intact incus, Austin defined four types of ossicular chain defects: type A, malleus handle present, stapes superstructure present; type B, malleus handle present, stapes superstructure absent; type C, malleus handle absent, stapes superstructure present; and type D, malleus handle absent, stapes superstructure absent. The commonest ossicular chain defect is Austin type A, accounting for almost 60% of cases, with type B accounting for 23%, type C for 8% and type D for 8%.1,2

The most widely accepted method for repair of IS joint erosion is remodelled incus because advantages such as bio-compatibility, a very low extrusion rate, no risk of transmitting disease & cost-effectiveness.3

The introduction of PORP as augmentor material for ossiculoplasty has been shown to be well tolerated with minimal extrusion over time provided neotympanum is separated from prosthesis with cartilage. The displacement of prosthesis can be limited by making a groove for...
stapalisation of prosthesis. In all cases grafting was done with temporalis fascia. In all cases grafting was done with temporalis fascia.

Various materials of PORP have been used including Teflon, titanium, Gold. In our study we have used Teflon PORP for ossiculoplasty. A curved piece of conchal cartilage anchored in hypotympanum anteriorly is used as a interface between PORP and neotympanum to prevent extrusion. The aim of this study was to evaluate the long-term functional results of remodelled incus interposition and compare these results to those obtained with PORP.

Ethical Approval
Ethical clearance was obtained from SGT Medical college and university ethical committee for research on human subjects. Written informed consent was obtained from all the subjects using the standard consent form approved by the ethical committee.

MATERIALS AND METHODS
This study on hearing improvement after tympanoplasty using incus interposition and Teflon PORP in cases of chronic otitis media (COM) with eardrum perforation was done in the Department of Otorhinolaryngology SGT Medical College and Hospital, Budhera. The study period was from February 2014 to February 2017. A total of 90 cases of tympanic membrane perforation with moderate hearing loss on audiometry were selected from the outpatient department. Selection criteria were patients of both sexes ranging in age from 10 to 50 years who had COM, small, medium, large central perforation. Patient’s ear was medically treated and taken up for surgery after 4 weeks of dry inactive disease.

Exclusion criteria were patients with all acute serous otitis media (ASOM), atticocanal CSOM, otosclerosis, congenital hearing disorder, chronic serous otitis media with mixed or sensorineural hearing loss (SNHL), hearing loss due to serous otitis media, active intracranial complication and patients who did not turn up regularly for followup.

The following parameters were evaluated: Graft survival and perforation closure, postoperative otorrhea, improvement in pure-tone average, improvement in the audiometric air-bone gap and post-operative complications (wound dehiscence, sensorineural hearing loss, perichondritis, facial palsy and any other complication).

Successful graft take up was defined as having no residual perforation, retraction or lateralization. All the patients were observed for any postoperative discharge from the operated ear. In each case, the pre and postoperative pure-tone audiogram was evaluated and pure-tone average improvement at 500, 1,000, and 2,000 Hz was noted. In each case, the improvement in pure-tone audiometry, air bone gap (PTA-ABG) was also calculated in three frequencies (500, 1000 and 2000 Hz) and noted. Improvement in all patients of both study groups by PTA and PTA- ABG was calculated to exclude the sensorineural hearing loss occurring during the surgery or postoperative period.

Outcome failures were graft failures, reperforation, PORP extrusion, PORP displacement sensorineural hearing loss, retraction pockets, and perichondritis.

Patient Evaluation and Case Selection
A detailed history and clinical ENT Head-Neck examination including microscopic examination was done for all patients. Preoperative nasal endoscopy and throat examination was done. Pure-tone audiometry (PTA) was done in all patients who were enrolled into the study. For all patients x-ray of mastoids was taken of both the ears (Schuler’s view) and noted for mastoid aeration. All routine investigations of the patients were done as per preanaesthesia requirement. Then, the patients undergone middle ear surgery under general or local anaesthesia with sedation managed by the anaesthesiologist. Tympanoplasties were performed in 90 patients (45 with remodelled incus and 45 with PORP). The selection of the patients for incus and PORP was done randomly with alternate surgeries applied for the two types of ossiculoplasties.

Surgical Procedures
Surgical Procedures were Underlay Tympanoplasty, Cortical Mastoidectomy, Oscillocoupsy with incus interposition or PORP. For all of the above operations, a standard postaural (William Wilde’s) incision was used. In all the selected patients, tympanoplasty and cortical mastoidectomy was done. In all cases grafting was done with temporalis fascia. In both the incus interposition and PORP group, the new assembly was surrounded with pieces of antibiotic- steroid soaked dry spongostan for stabilisation of prosthesis. In all patients graft was secured through an anteriorly placed tympanomeatal tunnel. A small groove was created at lower end of PORP as well as in remodelled incus to accommodate the stapedius tendon. This was also found helpful in stabilisation of prosthesis. A cartilage sleeve harvested from the cyma conchal cartilage was placed between the PORP and the neotympanum anchored from anterior hypotympanum (Figures 1-7).
Postoperative Management
A mastoid dressing was applied after the operation and kept up to three days. IV antibiotics were given and patients were discharged on the third postoperative day after removal of mastoid dressing. The aural pack was removed after 4 weeks, ear graft was examined, and topical ear drops were advised.

Follow-up
Each patient was evaluated in an outpatient setting after 7 days, 4 weeks, two months, three months and 6 months. Antibiotics and analgesics were continued for 10 days. Antibiotic- steroid ear drops were continued for 3 months. Microscopic cleaning of each and status of graft observed was done at end of 4 weeks. On every visit, patients were asked about subjective improvement in hearing and watched for the development of any complications. Audiometric evaluation was made three months after the operation in each patient and recorded (postoperative audiometry at 3 months).

RESULTS
The male female ratio in our study was 1:2 (Figure 8). Majority 80% of patients were in between 20 and 40 years. The duration of ear discharge and decreased hearing was
also noted. The duration of discharge was between 3 years to 10 years.

The most common perforation seen was moderate, in 75% of patients, followed by subtotal, in 20% and small perforations were present in 5% of patients (Figure 9). All the patients were taken up after adequate medical treatment i.e. 4 weeks of completely dry ear.

Preoperative pure-tone audiometry was done in all patients (pure-tone average of air conduction was calculated in 500, 1000 and 2000 Hz). Pure-tone average ranged between 25 to 60 dB in all the 90 patients. In 10 patients, pure-tone averages were observed between 25 to 30 dB, 30 patients presented between 31 to 40 dB pure-tone averages, 28 patients presented between 41 to 50 dB pure-tone average and 22 patients presented with 51 to 60 dB pure-tone averages (Figure 10). Audiometrically, the air-bone gap is greater in the high frequencies than in the low frequencies.

In 54 patients, surgery was performed under local anaesthesia (2% xylocaine with adrenaline with intravenous sedation) and 36 patients it was performed under general anaesthesia.

The procedure performed was a type 1 underlay tympanoplasty with cortical mastoidectomy with PORP or incus interposition.

The preoperative average hearing loss in A and B was 41 to 55 db. The AB gap closure after 3 months of surgery in group A was 10 db in 38, 15 db in 2, 20 db in 2 and 30 db in 2. The AB gap closure in group B was 10 db in 36, 15 db in 4, 20 db in 1 and 30 db in 1 (Figure 11). Remodelled incus (group A) provided satisfying hearing (post-operative AB gap <20 db) improvement in 43/45 (95.6%) patients whereas in the PORP with cartilage interface (group B) we achieved satisfying hearing improvement in 41/45 (91.1%) patients.

<table>
<thead>
<tr>
<th>Type I Underlay Tymanoplasty + Cortical Mastoidectomy</th>
<th>Preop Hearing (Average)</th>
<th>Success Rate (%) Graft Uptake</th>
<th>Postop Hearing after 3 Months (Average) AB Gap 10db, 15db, 20db, 30db</th>
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<tr>
<td>Group</td>
<td>Procedure</td>
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<tr>
<td>A</td>
<td>Autoincus (45)</td>
<td>41 to 55 db</td>
<td>45</td>
</tr>
<tr>
<td>B</td>
<td>PORP (45)</td>
<td>41 to 55 db</td>
<td>43</td>
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Table 1

All patients with remodelled incus (group A) had dry and complete uptake of graft. Extrusion of graft where PORP (group B) was used seen in 2/45(4.4%) patients (Figure 11). We found 3 cases with only fibrous union between incus and stapes which was excised and reconstructed. An interesting finding of patient reporting occasional twitching of facial muscles at 4 weeks postop which subsided spontaneously at 2 months without any intervention. This could be caused by irritation of facial nerve by the PORP implant.

**DISCUSSION**

The advantage of the use of autoincus over PORP cannot be overlooked as its availability, moldability, integration and nil cost. Displacement, complete absorption, small remnant size, and possibility of harbouring microscopic disease are potential disadvantages use of autoincus. The main disadvantage of PORP is incidence of PORP extrusion/displacement and foreign body reaction. The presence of normal or minimally hypertrophied middle ear mucosa, patent eustachian tube orifice and mobile stapes footplate are prerequisites for ossiculoplasty. J. Heermann has advised to use separate knives for taking the skin incision and harvesting the conchal cartilage to avoid possibility of infection of the cartilage.

Analysis of the studied patient’s data revealed that, sex and age had no impact on postoperative hearing results. According to the available literature, age has no significant role in the success of tympanoplasty and failure rates are higher in patients below 10 years and above 55 years of age.

Hence in our study, the youngest patient was a 10 year-old male and the oldest a 50-year-old female. Iurato et al. have reported that equally good results may be achieved with autograft, homograft or alloplastic partial prostheses. With alloplastic total prostheses, 74% of patients had a postoperative ABG of 0-20 dB.

Multiple factors like Prosthesis design, surgical technique, and the underlying disease process are the most obvious variables affecting outcome. Studies by Meister et al. and Kelly et al. have suggested that mass of prosthesis is the most important variable and have recommended, therefore, that a prosthesis be as light as possible to optimize transmission of frequencies above 1000 Hz. Recent mathematical modeling by Zenner et al. has determined that a mass of 5 mg or less provides the maximal transfer of energy. In the same studies, the influence of an attached piece of cartilage was investigated. An inertial load of 30 mg had little or no effect on the transfer function for titanium and ceramic prostheses. High stiffness of prosthesis is important to prevent signal loss and distortion. The coupling of prosthesis to the tympanic membrane (or manubrium) and to the stapes superstructure or footplate also influences overall stiffness. A loose coupling can introduce unwanted resonance that can distort the primary signal.

The ideal prosthesis design, therefore, is one that combines low mass with high stiffness and that facilitates the surgeon’s ability to achieve a tight, permanent coupling between the tympanic membrane and stapes. Coffey et al. demonstrated significant benefit of titanium across frequencies in the normal hearing range, likely due in part to the advantages conferred by low mass and high stiffness. The intraoperative complications can be fracture of the stapes superstructure, dislocation of the stapes, tear of the annular ligament with a perilymphatic fistula, severe or total SNHL. Other long term complications can range from vertigo, erosion or extrusion of prosthesis.

**CONCLUSION**

The primary objective of middle ear and mastoid surgery for cases of COM with perforation is to achieve a dry ear and hearing improvement postoperatively. The main aim of this study is to compare the restoration of hearing, postoperatively, in patients who underwent tympanoplasty for COM using autoincus or Teflon PORP. Both remodelled incus & PORP provided satisfying hearing (post-operative AB gap <20 dB) improvement in >90% patients. It has been established by this study that tympanoplasty with autoincus has marginally better degree of graft take than PORP. Hearing is improved even if a mastoidectomy is required for the patients. Though the choice of graft material is dependent on the surgeon’s skill and experience, condition of the ossicular chain, the size of the perforation, and the presence of cholesteatoma, cartilage tympanoplasty gives ENT surgeons a reliable armamentarium in tympanoplasties. Despite its rigid nature, cartilage tympanoplasty delivers an excellent audioligic outcome comparable to temporalis fascia graft.
REFERENCES