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Main Article

Use of autogenic and allogenic malleus in tympanic membrane to footplate assembly — long-term results

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Abstract The objective of this study was to assess the functional performance and long-term stability of autogenic and allogenic malleus used for ossiculoplasty as tympanic membrane to footplate assembly. A retrospective study of 119 patients who underwent such ossiculoplasty in closed cavity mastoidectomy from 1989–2004 was carried out. There was no extrusion in any of our cases. Serviceable hearing (<20 dB air bone gap closure) was achieved in 24 out of 37 (65%) over long-term follow up of more than 1 year (mean and median for follow up being 37.4 and 30 months respectively). Thus malleus ossicle graft give acceptable long-term hearing results in one of the most difficult ossiculoplasty situations (absence of stapes suprastructure and malleus) with virtually no extrusion problems.

Keywords Malleus allografts · Ossicle grafts · Ossiculoplasty

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Introduction

When Zollner [1] and Wullstein [2] in the early 1950s introduced tympanoplasty in a systematic form, little attempt was made to reconstruct the middle ear sound transform mechanism and procedures were adapted to ossicular problems encountered. However, now most otologists favor Austin's classification [3], which is based on remaining portion of the ossicular system to be reconstructed. It offers a more technical and functional method of describing the state of middle ear, the type of disease and the best choice of graft material.

Absence of stapes suprastructure and incus ($M^{+}I^{-}S^{-}$) with or without malleus is supposed to be the most difficult reconstructive problems to obtain long-term serviceable hearing. A number of solutions are proposed for its management. Basically there are three propositions. These include the malleus footplate assembly using original malleus or neomalleus (transposition techniques), tympanic membrane to footplate assembly (long columella techniques) and classic Wullstein's type IV tympanoplasty. The first two could be used in both closed and open cavity formats while the last is limited to open cavity mastoidectomy. Hearing results of the first two techniques have been superior to type IV tympanoplasty [4]. These have been achieved with innumerable autogenic, allogenic and alloplastic materials. However alloplastic materials (except hydroxyapatite) have been progressively losing popularity despite early encouraging results due to high rates of extrusion and the absence of long term results [5, 6]. Though a disk of cartilage between the head of prosthesis and tympanic membrane has reduced the risk of extrusion, cartilage disk did not eliminate it entirely [7]. Hydroxyapatite has been more successful as regards to functional hearing but extrusion rates remain high when used as TM-footplate assembly [8, 9].

Autogenic and allogenic materials have been the choice of otologists since they had been proved successful over long term as regards to hearing and biodegradation. The extrusion rates of these materials have been negligible.

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Suspicions have been raised and histopathologically confirmed regarding failure to control infection in CSOM due to occult osteitis in the ossicle retained in middle ear. Therefore if there is no macroscopic erosion with adherent squamous epithelium over the remodeled ossicle, it does not appear to affect reconstruction. The same ossicles (malleus handle, stapes suprastructure) when left intact for other forms of ossiculoplasty have never caused any problems. The risk of transmitting infectious diseases like HIV and Creutzfeldt-Jacob disease (CJD) after tympano-ossicular allografts is hypothetical and has never been reported with current preservation techniques [10, 11].

Allograft ossicles and cartilage have been used extensively for ossiculoplasty since 1966 when House [12] introduced the concept. There is no immune rejection response or resorption [13]. Since then innumerable transposition and columella techniques have been designed. Previous attempts at TM-footplate assembly have not been as successful as TM-malleus transposition [14–16]. However all these attempts were made with allograft incus and we did not find any report of allograft malleus till recently when Vercruysse et al. [10] discussed use of malleus by transposition technique. They reported good and stable functional results with malleus allografts as malleus footplate assembly. We hereby report our long-term results with malleus autografts and allografts when used for TM-footplate assembly studied by retrospective analysis of 37 cases and discuss its advantages over other methods.

Materials and methods

A retrospective evaluation was carried out for 119 patients having ossicular defect $M^{\pm}I^{-}S^{-}$ undergoing Intact Canal wall mastoidectomy with ossiculoplasty by remodeled malleus autografts or allografts as TM-Footplate assembly. In some cases, the malleus oval window relationship was unfavorable or the malleus was absent or diseased. For long-term hearing result evaluation, we included only those 37 patients with CSOM with cholesteatoma related ossicular lesions with follow-up of at least one year.

Out of 119 patients, 2 had ossiculoplasty as second stage procedure and rest of them had primary ossiculoplasty. Pure tone audiometry (PTA) with air conduction (AC) and bone conduction (BC) was performed pre-operatively, at 3 months, 1 year post-operatively and then every year. Average for 500, 1000, 2000 and 3000 Hz was measured for pre-operative and post-operative AC, BC and AB gap. More than one year follow up PTA was available for 37 (31%) patients. Clinical follow up included follow up at 3 months, 1 year and then yearly. All the patients were operated under local anesthesia with sedation except children below 16 years and uncooperative adults. A post auricular approach was utilized except in cases of second stage ossiculoplasty where it was done through transcanal approach. After meticulous clearance of disease by Modified Intact Canal Wall mastoidectomy, if middle ear mucosa was normal and stapes footplate was mobile, a piece of temporalis fascia (TF) graft was kept between remodeled malleus and footplate to center the ossicle and prevent it from slipping and also to prevent bony ankylosis with promontory or facial canal. Underlay TF grafting was done by elevating superior and inferior tympanomeatal (TM) flaps. Malleus if present was completely separated from TM flaps by sharp dissection. TF graft was stabilized by gelfoam in middle ear and under anterior fibrous annulus by anterior window. TF graft was gently elevated posteriorly till the oval window was seen. Remodeled malleus was placed between footplate and neo-tympanic membrane (temporalis fascia) with articular surface facing superiorly (figure 4) so that the slanting head surface is stabilized under the TF -graft.

Shaping of the allograft malleus (Fig. 1) The malleus head is converted to a slanting surface with wide surface contact area with slope upwards when the articular surface is facing superiorly. Then the malleus is held in Derlacki's ossicle holding forceps (Fig. 2) and the malleus handle

Fig. 1 Showing autogenic/allogenic malleus before remodeling

Fig. 2 Showing remodeling of malleus

below the level of the lateral process is removed by a short 0.6 mm diamond burr tip. The inferior surface is given the shape of a shoe/boot (Fig. 3) with its size slightly smaller then footplate. These features stabilize the prosthesis from displacement from oval window and neo-tympanic membrane. The ossicle was temporarily supported by gelfoam soaked in antibiotic eardrops (Fig. 4). The TF graft is repositioned. Care is taken so as to have the length of prosthesis such as to allow slight projection of contact surface with TF graft. The attic defect has to be properly reconstructed using conchal cartilage. Care is taken to prevent contact between cartilage and remodeled ossicle. The external auditory canal was filled with gelfoam with antibiotic solution and cotton ball covered with antibiotic ointment kept over it.

Planned 2nd stage ossiculoplasty was carried out if middle ear mucosa was completely removed (thick silastic sheet placed), Eustachian tube orifice was obstructed by polypoidal mucosa (a strip of thick silastic sheet inserted in orifice) or if residual cholesteatoma was intentionally left over oval window.

Fig. 3 Showing autogenic/allogenic malleus after remodeling

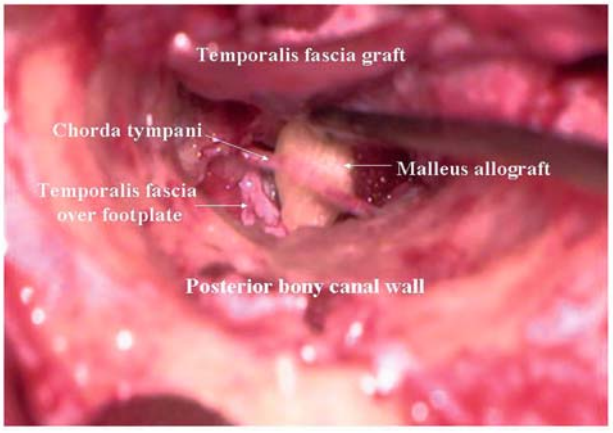

Fig. 4 Showing use of autogenic or allogenic malleus as a long columella ossiculoplasty graft in a closed cavity mastoidectomy

The data was analyzed in reference to age, primary/revision surgery, primary/second stage ossiculoplasty, presence/absence of stapes footplate, presence or absence of mobility of footplate and post-operative recurrence of disease. Hearing results were studied by pre-operative and post-operative hearing as revealed by PTA and analyzed as per the guidelines of AAO-HNS [17].

Results

The analysis revealed here includes only those 37 patients with more than one year of follow up. The follow up period ranges from 12 months to 118 months with a median of 30 months and average of 37.4 months. The age of the patients in our study ranged from 6 to 65 years with a median age of 30 years (average 29 years). All the patients had unsafe CSOM and underwent modified ICW mastoidectomy with primary ossiculoplasty except two where the procedure was staged. Intra-operative ossicular status was showing ossicular defect with necrosis of incus and stapes suprastructure. Though malleus was present in 20 of our cases it was removed, to clear cholesteatoma matrix from the attic. The same malleus (auto graft) is used after placing it in boiling water for a few minutes to clear the suspicious squamous debris. The stapes footplate was not fixed in any of these patients. In 12 of the patients autogenic malleus was used while in 25 of them 70% isopropyl alcohol preserved allogenic malleus was utilized. The cholesteatoma type included 7 attic, 21 posterosuperior (sinus) and 9 secondary acquired cholesteatoma. There was recurrence of cholesteatoma in one of these patients (unrelated to sculptured malleus ossicle used) and one of them required revision ossiculoplasty due to worsening of initially improved AB gap. There was no extrusion of either autogenic or allogenic malleus during the follow up period.

The comparison of hearing results that was obtained pre-operatively and on final follow-up is summarized in Table 1. There is a highly significant improvement in post-operative AB gap with a mean improvement of 11 dB sustained over the long term. Only four of the patients had post-operative AB gap worst than the pre-operative level. While one had revision ossiculoplasty, three were not willing for revision ossiculoplasty. The malleus allograft was found to be displaced from the footplate in the sole case we revised. There was a mean rise in post-operative BC of 2 dB but was not statistically significant. Serviceable hearing was considered to be present when the AB gap was less than 20 dB. Table 2 shows that only 5 patients (13.5%) had serviceable hearing before surgery, which increased to 24 (65%) after surgery over long term.

Discussion

M-I-S- configuration constitutes 36% of all the ossicular pathologies seen during surgery in senior author's practice.

Table 1 Hearing results obtained pre-operatively and on final follow-up

	Air conduction (0.5, 1, 2, and 3 kHz)			Bone conduction (0.5, 1, 2, and 3 kHz)			Air-Bone gap (0.5, 1, 2 and 3 kHz)		
	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range
Pre-operative (dB)	51	13	20–79	20.6	8.8	5-45	31	10	14–51
Early post-operative (dB)	42	14	29–71	21.9	8.9	10-52	20	9	6–38
Late post-operative (dB)	42	15.2	15–82	23	9.5	5-50	20	9	4–38
Change* (Early post-op)	12	13.1	–25–34	–1	4.9	–15-7	10	10.7	–11–29
Change# (Late post-op)	11	14.6	–27–43	–2	4.8	–15-10	1	9.3	–23–20
Change$ (early-Late Post-op)	21	10.6	10–52	–1	6	–15-10	0	9.3	–23–11

*p value < 0.001 (highly significant) for AC and AB gap and >0.05 (not significant) for BC

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$p value >0.05 (not significant) for AC, BC and AB gap

Table 2 Pre-operative and post-operative hearing results

	Post-op AC (In dB)				Post-op air-bone gap (In dB)			
	0 to 20	21 to 30	31 to 40	> 40	0 to 10	11 to 20	21 to 30	> 30
Pre-operative Number (%)	0(0)	3(8.10)	5(13.51)	29(78.37)	0 (0)	5 (13.5)	17 (46)	15 (40.5)
Early Post-operative Number (%)	0(0)	10(27)	10 (27)	17(46)	25(67.6)	6(16.2)	6(16.2)	0(0)
Late Post-operative Number (%)	1(2.7)	9(24.3)	10 (27)	17(46)	5 (13.5)	19 (51.5)	8 (21.5)	5 (13.5)

In some cases, malleus was deliberately removed for clearance of disease in the attic. Various techniques and materials have been reported for ossiculoplasty in M-I-S- situation. While alloplastic materials are not always tolerated below tympanic membrane even with cartilage interposition, autografts and allografts require fashioning intraoperatively, which is technically, bit challenging and increase operative time. Allograft cartilage has been considered the most successful with regards to functional hearing and extrusion rates [15, 16]. The cartilage homograft is helpful if the oval window niche is wide. But it is not recommended when oval window is narrow since narrow shaft losses prosthesis structural integrity and fixation of prosthesis can occur if the shaft contacts the walls of niche [4]. Allograft malleus has narrow shaft with boot shaped base that can fit into narrow niche without above-mentioned problems.

Merchant et al. [18] described five factors that can influence the performance of any ossicular prosthesis. These includes its stiffness, mass, position, tension imposed by the prosthesis on the tympanic membrane and the annular ligament (function of prosthesis length) and coupling of the prosthesis on the tympanic membrane and the stapes (how well a prosthesis adheres to footplate or tympanic membrane and its slippage). The experimental data showed that a prosthesis placed against the postero-superior quadrant of the tympanic membrane gave acceptable results as long as 3–4 mm of the prosthesis' diameter contacts the drum. The malleus ossicle graft described here meets all the above criteria with adequate stiffness, not more than 50 mg of prosthesis mass, proper positioning and adequate tension and coupling (which is enhanced by use of temporalis fascia between prosthesis and footplate) between tympanic membrane and footplate.

Bone allografts used previously for TM to foot plate interposition had all [14–16] used remodeled incus which usually falls short in length for closed cavity technique though it may work in open cavity techniques. Therefore previous studies did not produce consistently good results and had problems like displacement of prosthesis, lateral displacement of the footplate consequent to lateral retraction of the

neotympanic membrane during healing and fibrous or bony ankylosis between prosthesis and facial canal/promontory. In modified intact canal wall mastoidectomy, healing of the neo-tympanic membrane is more medial when compared to normal anatomical position. The malleus graft length is adequate to have contact with the undersurface of the tympanic membrane. Thus the malleus allograft as designed by us is slim, stiff and firm with adequate height and it prevents these problems. Also it undergoes fibrous attachment with footplate due to interpositioned fascia and with tympanic membrane. Ability to gain functional/serviceable hearing (AB gap ≤20dB) at one year in 65% cases is comparable/better then other long columella techniques. There has been no extrusion in our study. Occasional poor results may be due to poor eustachian tube function.

In fact, apart from closed cavity technique, we use allograft malleus long columella for open cavity techniques, in reconstruction of hearing in traumatic ossicular discontinuity, congenital auricular atresia, glomus tympanicum surgery (if incus is dislocated for tumor clearance) and in tympanosclerosis surgery with equally good functional hearing. It can be used even when stapes footplate is destroyed with intact endosteum of the vestibule (with TF interposition) and along with second stage stapedectomy when stapes is fixed. We also use it when malleus handle is present with absent incus and stapes suprastructure, as malleus handle has varied position. No single prosthesis can be used in all situations as the horizontal (anterior and posterior) and vertical (towards/away from promontory) position varies not only intra-operatively but also post-operatively due to recurrent retraction. Senior author (AM) has found frequent incidence of displacement of prosthesis and fibrosis between prosthesis and promontory/facial canal in such situations where the prosthesis was kept under handle of malleus.

Conclusion

The malleus allograft as designed by us is slim, stiff and firm with adequate height and narrow shaft with boot shaped base that can fit even into narrow niche. It suffices all the criteria for an ideal prosthesis. Overall we think malleus ossicle graft is an easy, less expensive and safer technique and gives acceptable long-term hearing results in one of the most difficult ossiculoplasty situations (absence of stapes suprastructure and malleus) with virtually no extrusion problems.

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