

Malleus–stapes assembly: experience with two prostheses

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Abstract

Tympanoplasty is often a necessary part of middle-ear surgery, the most common defect being that between an intact, mobile stapes and the malleus handle. The most readily available tissue is the patient's incus, reshaped to bridge the space between an intact stapes and the malleus. When the incus cannot be used, the hydroxyapatite Wehrs incus prosthesis[®] can be used as an alternative.

Twenty-six patients had an autograft incus ossiculoplasty and 20 patients underwent modified Wehrs incus prosthesis ossiculoplasty. The average post-operative air–bone gaps (ABGs) were 16.2 dB hearing loss (dBHL) and 17.2 dBHL, respectively. Air–bone gap closure to within 15 dBHL was achieved for 48 per cent of incus autografts and for 57 per cent of Wehrs prostheses, and to within 20 dBHL for 77 per cent and 62 per cent, respectively. Over four years follow up, the reconstruction was stable for each group, the ABGs being 17.7 dBHL and 17.1 dBHL, respectively.

Key words: Chronic Otitis Media; Ossicular Replacement; Tympanoplasty; Otologic Surgical Procedures

Introduction

Tympanoplasty is an integral part of modern otologic surgery, and various techniques have been described for reconstruction of the sound transformation mechanism. The most commonly encountered defect of the ossicular chain is a discontinuity in the presence of an intact malleus and an intact, mobile stapes. This defect may be the result of either a disease process or a consequence of disease eradication (e.g. dismantling an intact ossicular chain to fully remove a cholesteatoma). The reconstruction of this defect aims to restore communication between the tympanic membrane and the oval window. Assuming mobility of the stapes, the chosen reconstruction is dependent upon the anatomy remaining after disease removal; for example, following canal wall down mastoidectomy, the facial ridge may be so reduced in height that the tympanic membrane/graft sits on the stapes capitulum to form a myringostapediopexy. However, the hearing result, albeit good, is not as good as is achieved by restoring a connection between the stapes head and either the malleus or the tympanic membrane.¹

When reconstructing a defect between the stapes head and the malleus, the choice lies between using autologous tissue or some form of implant. Whenever possible, the senior author prefers to use autologous incus; the incus is reshaped, using diamond burrs, to bridge the space between stapes head and malleus, the shape used being tailored to the spatial relationship between the stapes and malleus.

If there is insufficient incus to create a stable repair then the Wehrs incus prosthesis[®] is used, modified to reduce its size in order to allow a more stable placement of both prosthesis and graft.²

This report aims to describe and compare the technical result of malleus to stapes head ossicular reconstruction using either autologous incus or a modified Wehrs incus prosthesis.

Material and method

The senior author's database of surgery for chronic otitis media was searched for patients who had undergone ossiculoplasty using either autologous incus or Wehrs incus prosthesis; the latter was remodelled, using an otologic drill, to better fit in the middle ear.²

Using the 0.5, 1, 2, and 4 kHz pure tone audiometry averages, the pre-operative and one year post-operative air and bone conduction thresholds, as well as the air–bone gap (ABG), were calculated. Additionally, for a smaller group with longer follow up, the one and four year ABGs were calculated. We recorded those who developed a post-operative sensorineural hearing loss.

The Mann–Whitney U test was used to compare the average post-operative ABG for the two prostheses. A chi-squared test was used to assess whether there was a significant difference in ABG closure to within 20 dB between the two prostheses. A *p* value of <0.05 was accepted as statistically significant.

Results

Fifty-two patients were identified as having undergone malleus–stapes assembly (MSA) ossiculoplasty using autologous incus or Wehrs incus prosthesis® (Gyrus ENT, Memphis, Tennessee) on 56 ears. Eight ears were excluded because one year post-operative audiometry was not available. The remaining 46 patients underwent surgery on 48 ears; 27 received autologous incus and 21 received a Wehrs incus prosthesis. In all cases that employed a Wehrs incus prosthesis, the primary reason for surgery was cholesteatoma or retraction pocket disease. For 17 patients, the ossiculoplasty was performed at the primary procedure; the other three had their ossiculoplasty as part of a second procedure (revision mastoidectomy (one) or second look tympanotomy (two)). In the autologous incus group, cholesteatoma or retraction pocket disease was found in 20 ears; the other seven ears showed adhesive middle ear (two) and perforated tympanic membrane (five). Twenty-two patients had their ossiculoplasty performed at the primary procedure; the other four underwent their ossiculoplasty during a second procedure (second look tympanotomy (three) or revision tympanoplasty (one)).

The demographic data are shown in Table I. Table II shows the average pre- and post-operative hearing thresholds for air and bone conduction as well as the ABG. The Mann–Whitney U test did not show a significant difference between the post-operative ABG for each prosthesis ($p = 0.8$). Table III shows the ABGs for those with longer follow up (average, 49 months; standard deviation, 18.8 months), and, again, the result is similar for both prostheses. Figure 1 illustrates the pre- and post-operative ABG. A chi-squared test showed no significant difference ($p = 0.27$) in ABG closure to within 20 dB between the two prostheses.

TABLE I

PATIENT DEMOGRAPHIC DATA

Prosthesis type	Age (years)	Sex (M:F)	Side (R:L)
Autologous incus	Range 7–52 Mean 29	12:14	12:15
Wehrs incus prosthesis	Range 11–68 Mean 35	7:13	9:12

M = male; F = female; R = right; L = left

TABLE II

PRE- AND POST-OPERATIVE HEARING RESULTS*

	Pre-op [dB (SD)]		1 year post-op [dB (SD)]		Average ABG [dB (SD)]	
	AC	BC	AC	BC	Pre-op	1 year post-op
Autologous incus ($n = 27$)	40.4 (18.2)	15.5 (10)	29.3 (10.2)	13.2 (7.9)	27.9 (11.1)	16.2 (6.3)
Wehrs incus prosthesis ($n = 21$)	37 (15)	15.5 (8.7)	32.7 (10.1)	15.5 (9.7)	21.4 (12.1)	17.2 (9.4)

*Average air conduction (AC) and bone conduction (BC) thresholds and average air–bone gap (ABG), pre-operative (pre-op) and 1 year post-operative (post-op).
 n = number of ears; SD = standard deviation

TABLE III
POST-OPERATIVE ABG AFTER 1 YEAR AND LONGER*

Follow up	ABG [dB (SD)]	
	Autologous incus [†]	Wehrs incus prosthesis [‡]
1 year	17.3 (5.4)	17 (6.7)
Longer	17.7 (8.5)	17.1 (9.3)

*Average longer follow up = 49 months. [†] $n = 11$; [‡] $n = 13$.
ABG = air–bone gap; SD = standard deviation

Not all patients had their ABG closed to less than 20 dB; five patients (three with autologous incus and two with modified Wehrs incus prosthesis) experienced prosthesis displacement (seen through the tympanic membrane in three patients, confirmed at revision surgery for the other two). Another seven patients had ABG closure to

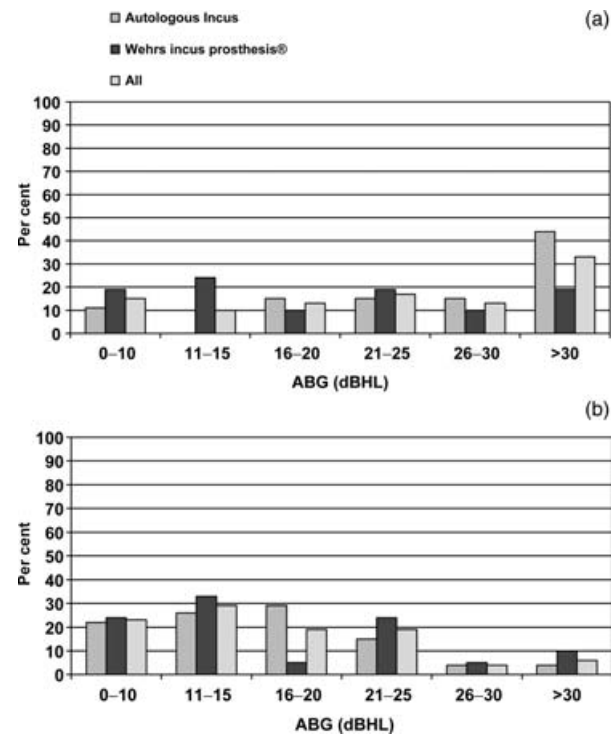


FIG. 1

(a) Pre-operative and (b) post-operative air–bone gap (ABG).

≤ 25 dB at one year but subsequent audiometry showed an ABG of ≤ 20 dB; these individuals could be considered to have obtained a borderline result.

Two patients had a post-operative sensorineural hearing loss; both were in the Wehrs incus prosthesis group. The hearing loss in each case was confined to 4 kHz and above. Both patients originally had an intact chain surrounded by cholesteatoma and had their ossicular chain disarticulated to allow removal of the disease. In one patient, who had disease dissected off the stapes, the 4 kHz threshold was increased from 0 dB to 50 dB. The other patient had an increase from 20 dB to 45 dB, with no other potential cause identified to account for the threshold elevation.

Discussion

Chronic otitis media is the commonest cause of ossicular discontinuity, with the long process of the incus most likely to be eroded; additionally, it may be necessary to disarticulate the incus during surgery to obtain access in order to remove disease. With an intact, mobile stapes and malleus, there are two primary methods available to reconstruct the incus defect: either by columella effect to tympanic membrane or by an MSA between stapes capitulum and malleus.

Although many prostheses have been used to bridge the gap between stapes capitulum and malleus, autologous incus, when feasible, is still a popular option; biocompatibility is assured and the tissue is well tolerated, maintaining its contour, size, shape and physical integrity for long periods.^{3,4} The bone can be shaped in different ways to adapt to the angular variations between stapes capitulum and malleus.⁵

Should the incus be severely eroded, reshaping may not be feasible. Also, there has been concern that the incus may harbour residual cholesteatoma. However, Rupa *et al.*⁶ studied the histopathological features of 113 ossicles (60 mallei and 53 incudes) removed from 73 patients during surgery for cholesteatoma, and they did not find intraossicular cholesteatoma in any ossicle studied. Interestingly, they also did not find a significant histopathological difference between eroded and non-eroded ossicles. This finding supports the use of autologous incus for ossiculoplasty during surgery for retraction pockets or cholesteatoma.

When the incus cannot be used, it is the senior author's preference to use the Wehrs incus prosthesis. The prosthesis notch is placed under the malleus handle and the hole in the base engaged on the stapedial capitulum.⁷ The Wehrs incus prosthesis is manufactured from dense hydroxyapatite, a synthetic material that resembles the mineral matrix of human bone. Hydroxyapatite has been shown, in *in vitro* studies, long-term animal studies and clinical studies,⁸ to give the best results, compared with the various other alloplastic implant materials used for middle-ear reconstruction. Additionally,

the composition is easy to remodel using the otologic drill, and this allows for better placement in the middle ear.²

Austin⁹ described MSA and reported the consequent hearing results. In his description, the incus body was reshaped according to the relationship between the stapes head and the malleus handle. Siddiq and East¹⁰ described their results using MSA with autologous incus in 24 patients (13 had cholesteatoma); 79 per cent achieved an ABG of ≤ 20 dB at an average of five months after surgery, and 71 per cent achieved the same at an average of nine years after surgery. Goldenberg¹¹ reported an ABG of ≤ 20 dB in 60 per cent of patients reconstructed with hydroxyapatite prostheses from stapes capitulum to malleus at one year post-operation and in 75 per cent of patients at an average of five years post-operation.¹² In comparison, 71 per cent of our patients had an ABG of ≤ 20 dB at one year post-operation and 63 per cent had the same at an average of four years post-operation.

Displacement or lateralization with possible extrusion and perforation are potential problems following ossiculoplasty, especially if the prosthesis sits in direct contact with the tympanic membrane. Interposition of cartilage between the tympanic membrane/graft and ossicular prosthesis will reduce extrusion but adds a further layer to the reconstruction. With autologous incus MSA, these complications are less frequent; positioning the Wehrs incus prosthesis so that it sits under the malleus handle will maintain a separation between the tympanic membrane and the prosthesis, so reducing the risk of extrusion.¹³ In our series, we did not routinely interpose cartilage between the Wehr's prosthesis and the tympanic membrane/graft, and there were no cases of extrusion. There were five patients who experienced displacement of their prosthesis and all of these had a poor hearing outcome.

Two patients had a post-operative sensorineural hearing loss. In both cases, the ossicular chain had needed to be disarticulated in order to remove cholesteatoma, and we think the disease exenteration is more likely to be the cause of the hearing loss than the ossiculoplasty.

There was a group of patients for whom the ABG closure was close to, but greater than, 20 dB after one year, but less than 20 dB at later assessments. These individuals may or may not have considered themselves to have had improved hearing; in some respects, these outcomes occupy the borderline between success and failure.

Conclusion

Malleus–stapes assembly using both autograft incus and modified Wehrs prosthesis ossiculoplasty is an effective technique for bridging a defect between stapes head and malleus and provides a good, stable long-term reconstruction.

- **This is a retrospective review of 52 patients undergoing malleus–stapes assembly ossiculoplasty using either autologous incus or Wehrs incus prosthesis**
- **The hearing results of the two groups were analysed. There was no statistically significant difference between the two groups for air–bone gap (ABG) closure to within 20 dB or in the average post-operative ABG**
- **Results suggest that both prostheses, when used to bridge a gap between an intact mobile stapes and the malleus handle, will have a stable, reliable outcome**

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