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Results After Revision Stapedectomy With Malleus Grip Prosthesis

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Abstract

Revision stapedectomy with a malleus grip prosthesis is a technically challenging otologic procedure. The prosthesis is usually longer and extends deeper into the vestibule than a conventional stapes prosthesis, creating the potential to affect the vestibular sense organs. The prosthesis also bypasses the ossicular joints, which are thought to play a role in protecting the inner ear from large changes in static pressure within the middle ear. The prosthesis is in close proximity to the tympanic membrane, thus increasing the risk for its extrusion. We reviewed our experience with revision stapedectomy with the Schuknecht Teflon-wire malleus grip prosthesis in 36 ears with a mean follow-up of 23 months. The air-bone gap was closed to within 10 dB in 16 ears (44%) and to within 20 dB in 26 ears (72%). The incidence of postoperative sensorineural hearing loss was 8% (3 ears). There were no dead ears. Extrusion of the prosthesis occurred in 1 case (3%). Nearly 50% of patients reported various degrees of vertigo or disequilibrium during the first 3 weeks after surgery. These vestibular symptoms resolved by 6 weeks in all but 1 case. We did not find evidence of damage to the inner ear due to the length of the prosthesis or due to the potential for direct transmission of changes in static pressures within the middle ear to the labyrinth. Our results are similar to those published in the literature for malleus attachment stapedectomy and conventional revision incus stapedectomy.

Keywords

conductive hearing loss; malleus; prosthesis; revision; stapedectomy

INTRODUCTION

Revision stapedectomy is a more challenging surgical procedure than primary stapedectomy and has less favorable hearing outcomes.¹ The revision procedure usually involves the replacement of an incus-to-oval window prosthesis. However, if the long process of the incus is eroded or there is epitympanic fixation of the malleus or the incus, then the technique of malleus attachment stapedectomy can be used to establish a pathway for sound transmission from the tympanic membrane to the vestibule.²

A malleus stapedectomy differs from a conventional incus stapedectomy in several respects: 1) the procedure is technically more challenging; 2) the prosthesis is usually longer and extends

deeper into the vestibule, creating the potential to affect the vestibular sense organs; 3) the prosthesis bypasses the ossicular joints, which are thought to play a role in protecting the inner ear from large changes in static pressure within the middle ear³; and 4) the prosthesis is in close proximity to the tympanic membrane, thus placing the prosthesis at some risk for its extrusion.

The Schuknecht Teflon-wire malleus grip prosthesis is commonly used at our institution and elsewhere for malleus stapedectomy, but only a few articles have described results after surgery using this particular prosthesis. In 1986, Schuknecht and Bartley² described the results in 40 cases, and in 2004, Hausler⁴ reported on 34 cases in which the Schuknecht malleus grip prosthesis was used. The aim of the present study was to review our contemporary experience with this particular prosthesis in patients undergoing revision stapedectomy, and to compare our results with those reported in the literature for malleus stapedectomy and revision stapedectomy.

MATERIALS AND METHODS

Patients

This retrospective study was approved by our Institutional Review Board. The medical charts of patients who had undergone revision stapedectomy for otosclerosis by 4 surgeons (authors M.J.M., S.D.R., J.B.N., S.N.M.) at the Massachusetts Eye and Ear Infirmary between 1994 and 2004 were reviewed, and patients who had undergone the malleus attachment procedure were identified. The data gathered included age, sex, number of previous operations, indication for revision, surgical details of the malleus attachment procedure, preoperative and postoperative audiometric thresholds, including speech discrimination (SD) scores, and type and duration of postoperative vestibular symptoms. Among 195 patients with revision stapedectomies, 33 patients with malleus attachment were identified, and there were 3 patients who underwent bilateral malleus grip stapedectomy, for a total of 36 ears.

Operative Technique

A transcanal approach under general anesthesia was the preferred method. The mobility of the ossicles was evaluated by palpation. If epitympanic ossicular fixation was encountered, the head of the malleus was amputated with a malleus nipper and the incus was removed. If the malleus was mobile and the incus was eroded, then only the incus was removed. The mucosal fold between the tympanic membrane and the manubrium (plica mallearis) was incised with a sickle knife to create a tunnel between the tympanic membrane and the manubrium (Fig 1 and Fig 2). Fibrous adhesions in the middle ear, if present, were lysed with a handheld argon laser (HGM Medical Systems, Salt Lake City, Utah). The previously placed stapes prosthesis was examined and removed. Fibrous tissue within the oval window was removed with either an argon laser or a stapes pick. Bony closure of the oval window was treated by reopening with an argon laser, a handheld drill (Skeeter Ultra-Lite, Medtronic-Xomed, North Jacksonville, Florida), or a footplate rasp. A Schuknecht malleus grip prosthesis (made of stainless steel wire and a Teflon piston) of suitable length and diameter was placed in position and crimped. The wire was then wrapped around the manubrium with a small hook (Fig 2A). A bend was introduced in the wire of the prosthesis so that the long axis of the piston became orthogonal to the plane of the stapes footplate (Fig 1B and Fig 2B). The length was chosen such that the lower end of the piston extended for a distance of 1.0 to 1.25 mm into the vestibule beyond the level of the footplate. The relatively long length of the prosthesis within the vestibule is meant to prevent its displacement out of the oval window when there is movement of the tympanic membrane in response to changes in middle ear static pressure (eg, vigorous nose blowing, sneezing). The mobility of the prosthesis was verified by palpation. The fenestra around the prosthesis was then sealed with Gelfoam or adipose tissue, and the tympanomeatal flap was replaced.

Audiological Evaluation

Postoperative audiological evaluations were performed at 6 weeks and at 1-year intervals. The most recent audiometric evaluation was used as the postoperative test for the present study. Each audiological evaluation included pure tone thresholds for air and bone conduction at 250, 500, 1,000, 2,000, and 4,000 Hz, the threshold for air conduction at 8,000 Hz, and SD scores. Pure tone averages (PTAs) for air and bone conduction thresholds were obtained by calculating the mean of the threshold values at 500, 1,000, 2,000, and 4,000 Hz. (In our institution, the pure tone threshold for 3,000 Hz is measured only when the difference between the thresholds at 2,000 and 4,000 Hz exceeds 20 dB. Because data for 3,000 Hz were not available for all patients, 4,000 Hz was used instead of 3,000 Hz to calculate the PTA). The postoperative air-bone gap (ABG) was calculated as the difference between the postoperative air and postoperative bone conduction PTAs. Changes in bone conduction thresholds were calculated as the difference between postoperative and preoperative PTA values for bone conduction.

Statistical Analyses

The statistical analyses were performed with Statistical Package for Social Sciences for Windows 11.0.0, 2001. An analysis of variance (ANOVA) test was used to compare the postoperative ABG levels and the change in bone conduction thresholds of cases stratified by the number of previous operations. The Mann-Whitney U test was used to compare the mean postoperative ABG levels of ears with recurrent versus persistent conductive hearing loss. The mean postoperative ABG level of patients with fibrous closure of the oval window was compared with that of those with bony closure by use of Student's *t*-test. A Pearson bivariate correlation analysis was performed to check for any correlations between the duration of hearing loss and the degree of postoperative ABG closure. A significance level of .05 was accepted for the various statistical analyses.

RESULTS

Patients

There were 9 men and 24 women. Their ages ranged between 23 and 86 years (mean, 52 years). There were 16 first revisions, 17 second revisions, and 3 third revisions. The indications for surgery were recurrent conductive hearing loss in 30 ears (83%) and persistent conductive hearing loss in 6 ears (17%). The duration of hearing loss ranged between 1 and 240 months (median, 9 months).

Operative Findings and Surgical Technique

There were 19 right ears and 17 left ears. General anesthesia was used in all cases except 1. The transcanal approach was used in 32 ears. An endaural or post-auricular incision was used in the remaining 4 ears, which had narrow external auditory canals. The intraoperative findings are shown in Table 1. Erosion of the long process of the incus was the most common finding and was seen in 30 ears (83%). For the 29 ears in which either bony or soft tissue closure of the oval window was encountered, refenestration was accomplished with an argon laser in 19 ears, a pick in 5 ears, a Skeeter drill in 3 ears, a KTP laser in 1 ear, and a footplate rasp in 1 ear. The dimensions of the prostheses used are shown in Table 2. A length of 5.5 mm and a diameter of 0.6 mm were used in the great majority of cases.

Postoperative Hearing Results

A stratification of the cases according to the number of previous operations is shown in Table 3. The mean preoperative and postoperative ABGs were 43.3 and 14.3 dB, respectively. Postoperative closure of the ABG was to within 10 dB in 16 ears (44%) and to within 20 dB

in 26 ears (72%). An ANOVA revealed that the outcome for those ears undergoing a first revision was significantly better than that for those that had 2 or more revisions ($p = .003$).

An analysis of cases according to the change in bone conduction PTA stratified by the number of previous operations is given in Table 4. An improvement in the bone conduction thresholds occurred in 13 ears (36%), whereas a loss of more than 20 dB was seen in 2 ears (6%). The mean preoperative and postoperative SD scores were 84% and 86%, respectively. One patient had a significant decrease in SD score, from 92% to 52%, although the ABG level was improved, from 38 to 18 dB. There were no dead ears. An ANOVA revealed that an increase in the number of previous operations did not increase the risk of postoperative sensorineural hearing loss ($p = .81$).

The mean postoperative ABG level of ears with recurrent conductive hearing loss was 14.0 dB, and it was not significantly different from the 16.0 dB value observed in ears with persistent conductive hearing loss ($p = .57$). Furthermore, the duration of the hearing loss was not correlated with the degree of ABG closure ($p = .23$). The mean postoperative ABG level of ears with fibrous closure of the oval window was 14.0 dB, whereas it was 18.1 dB in ears with bony closure. The difference was not statistically significant ($p = .43$).

Vestibular Symptoms

In 19 cases (53%), patients reported no vestibular symptoms after the surgery. In the remaining 17 cases (47%), patients reported various degrees of vertigo or disequilibrium that typically lasted for 1 to 3 weeks after surgery. The most common vestibular complaint was a brief bout of vertigo or a shift in the visual field with chewing, swallowing, or autoinflation. These various vestibular complaints resolved by 6 weeks in all but 1 case.

Follow-Up

The follow-up time ranged between 2 and 96 months (mean, 23 months). During follow-up, 3 patients had 1 revision operation, and 1 patient had 2 revision operations because of displacement of the malleus grip prosthesis. Extrusion of the prosthesis was observed in 1 ear. Because this patient had no vestibular complaints and the hearing was relatively good, no further surgery was performed.

DISCUSSION

It is well recognized that a malleus attachment stapedectomy is technically more challenging than a conventional incus stapedectomy procedure. A successful surgical outcome after malleus stapedectomy is dependent upon proper case selection and meticulous technique, and the following guidelines were recommended by Schuknecht and Bartley.²

1. Select for surgery only those cases with a normal (or near normal) tympanic membrane. Perforations, atrophy, retraction, and neomembranes are contraindications to this method....The membrane should be normally tense to ensure restriction of displacements associated with changes in middle ear pressures.
2. Select for surgery only those cases with a plica mallearis [our Fig 1], thus avoiding excessive contact of the prosthesis with the tympanic membrane, which can cause erosion and crusting, and may lead to osteitis of the manubrium and extrusion of the prosthesis.
3. Take special care to ensure that the length of the prosthesis is appropriate...

4. Crimp the prosthesis to the manubrium in a tight wraparound manner [our Fig 2A] because a loose prosthesis causes resorption osteitis at the site of contact with the bone and eventual extrusion.^{2(p534)}

Our emphasis regarding guideline No. 3 is that the prosthesis is not displaced out of the oval window when there is movement of the tympanic membrane in response to changes in middle ear static pressure (eg, swallowing, nose blowing, sneezing). To these four guidelines, we would also add that one should introduce a bend in the wire of the prosthesis so that the long axis of the piston becomes orthogonal to the plane of the stapes footplate (Fig 1B and Fig 2B). This configuration will ensure an optimum angle for good transmission of sound at the interface between the prosthesis and the vestibule.

The results of the present study of 36 ears with a mean follow-up of 23 months showed closure of the ABG to within 10 dB in 44% of ears and to within 20 dB in 72% of ears. The incidence of sensorineural hearing loss was 8%. Our results are similar to those of previous reports in the literature of malleus attachment stapedectomy,^{2,4-7} which are displayed in Table 5. A review of these articles reveals closure of the ABG to within 10 dB in 18% to 70% and to within 20 dB in 67% to 88% of ears, with a 0% to 8% incidence of sensorineural hearing loss.

There have been many published series of revision stapedectomy procedures; the majority of cases involved revision stapedectomy with attachment of the prosthesis to the incus. Reports published before 1997 were well summarized by Han et al.¹ A review of these reports, as well as reports published after 1997,⁸⁻¹⁵ indicates closure of the ABG to within 10 dB in 18% to 80% and to within 20 dB in 54% to 92% and a rate of sensorineural hearing loss of 0% to 20%. Thus, we conclude that the results of malleus attachment stapedectomy in our hands, as well as the results reported in the literature, are comparable to those after incus attachment in patients who undergo revision stapedectomy.

An important consideration is the effect of bypassing the ossicular joints that occurs after malleus attachment stapedectomy. In the normal middle ear, the ossicular joints serve to “uncouple” the stapes from the malleus in response to large excursions of the tympanic membrane–malleus complex due to changes in barometric pressure, vigorous nose blowing, sneezing, etc.³ It has been shown experimentally that displacements of the umbo of up to 1 mm are attenuated at the level of the stapes footplate, in which the excursions do not exceed 10 to 30 μ m. This phenomenon of reduced excursion of a stapes prosthesis in response to large displacements of the tympanic membrane–malleus complex is still preserved to some degree after an incus stapedectomy, but cannot occur after a malleus attachment stapedectomy procedure. Thus, the medial end of a malleus grip prosthesis is at risk of displacement out of the oval window. This possibility makes it important to use a relatively long prosthesis so that its medial end inserts more deeply into the vestibule (1 to 1.25 mm) than the 0.25-mm depth of insertion recommended for conventional incus stapedectomy. There are two concerns that arise as a consequence of placing such a long prosthesis. The first is the potential for the long prosthesis to result in vestibular stimulation or damage to the vestibular end organs. It has been our clinical experience that patients have more vestibular symptoms after malleus stapedectomy than after incus stapedectomy, but we have observed that these symptoms are temporary and subside within weeks. Our subjective clinical impressions were borne out by the present study, wherein we found that nearly 50% of patients had vestibular complaints for the first 3 weeks after surgery, but not over the long term. The most common complaints involved transient dizziness with changes in middle ear static pressure caused by nose-blowing, sneezing, belching, etc. These symptoms subsided with the passage of time, perhaps because of vestibular adaptation or because of maturation of fibrous tissue in the oval window, which may serve to stabilize the prosthesis and reduce the degree of its excursion in response to changes in static pressure. Another concern is the potential for deleterious consequences to the inner ear over the long term because of transmission of static pressures directly to the inner

ear, without the protective effect of the ossicular joints. We did not find evidence to indicate any negative consequences to the inner ear in our study. Similarly, others have also not reported long-term problems.^{2,4–7} It is possible that the inner ear is protected from deleterious consequences of changes in static pressure because of the safety mechanism provided by the helicotrema.

The design of malleus attachment stapedectomy prostheses continues to improve and evolve. For example, the Hausler⁴ modification of the Schuknecht prosthesis involves replacing the steel wire with a platinum wire that is flattened into a band at the level of the loop, so that it is easier to crimp the prosthesis. Another improvement is the Nadol modification of the Schuknecht design, involving the use of nitinol, in which the prosthesis is made “self-crimping” when heat is applied to the nitinol wire loop. Hausler¹⁶ also recently introduced a titanium prosthesis with a “ball and socket” joint that is meant to make the process of crimping and angulation easier. Fisch et al⁷ use an endaural approach with a superior canalplasty and a titanium prosthesis that can be used for both malleus and incus attachment. It is hoped that these and other modifications will result in improved surgical outcomes for this particularly challenging otologic procedure.

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Fig. 1.

Anatomic considerations for malleus attachment stapedectomy. **A)** Photomicrograph of temporal bone shows relationships among tympanic membrane (TM), manubrium, incus, and stapes footplate. Plica mallearis is mucosal fold that separates manubrium from TM. Plica mallearis permits placement of malleus grip prosthesis around manubrium while avoiding excessive contact of prosthesis with TM, thus preventing erosion through TM and extrusion of prosthesis. **B)** Schematic placement of malleus grip prosthesis. Manubrium is located anterior to level of footplate. Therefore, one must introduce bend into wire of malleus attachment prosthesis in order to make piston orthogonal to plane of footplate. Also, lower end of piston should extend 1.0 to 1.25 mm into vestibule to avoid its displacement out of oval

window when there is movement of TM in response to changes in middle ear static pressure due to sneezing, nose blowing, etc.

Fig. 2. Surgical technique for placement of malleus grip prosthesis. (Reprinted with permission. ²)
A) Wraparound loop attachment to manubrium. Shaft of prosthesis is held with small alligator forceps while end of wire is pulled with small hook. **B)** Surgical view of malleus grip prosthesis in place.

TABLE 1

Intraoperative findings

Finding	Ears	
	No.	%
Erosion of long process of incus	30	83
Subluxation of incus	3	8
Malleus fixation	3	8
Soft tissue closure of oval window	22	61
Bony closure of oval window	7	19
Obliterative otosclerosis	2	6

TABLE 2

Dimensions of prostheses

	Prostheses	
	No.	%
Length		
5.5 mm	29	80
5.75 mm	2	6
6.0 mm	5	14
Diameter		
0.4 mm	1	3
0.6 mm	34	94
0.8 mm	1	3

TABLE 3

Postoperative air-bone gap levels stratified according to number of previous operations

Air-Bone Gap (dB)	One Previous Operation	Two Previous Operations	Three Previous Operations	All Ears
≤10	12	3	1	16
11–20	4	7	1	12
21–30	0	5	0	5
>30	0	2	1	3

TABLE 4

Changes in bone conduction threshold stratified according to number of previous operations

Change in Bone Conduction Pure Tone Average	One Previous Operation	Two Previous Operations	Three Previous Operations	All Ears
>10-dB gain	1	0	0	1
1- to 10-dB gain	4	6	2	12
1- to 5-dB loss	6	7	0	13
6- to 10-dB loss	3	1	1	5
11- to 20-dB loss	1	2	0	3
20- to 30-dB loss	0	1	0	1
>30-dB loss	1	0	0	1

TABLE 5

Published reports of malleus attachment stapedectomy

Authors	Year	No. of Ears	Air-Bone Gap of ≤10 dB (%)	Air-Bone Gap of ≤20 dB (%)	Sensorineural Hearing Loss (%)
Sheehy ⁵	1982	146	51	81	4
Schuknecht and Bartley ²	1986	187	36	67	8
Tange ⁶	1996	41	70	88	0
Fisch et al ⁷	2001	56	18	77	3
Hausler ⁴	2004	39	40	85	8