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Ossiculoplasty with Intact Stapes and Absent Malleus: The Silastic Banding Technique

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Objective: To report an original method of ossicular reconstruction with intact stapes and absent malleus. Ossiculoplasty is performed with a total ossicular replacement prosthesis positioned from the stapes footplate to the under-surface of the tympanic membrane, using a Silastic banding technique to stabilize the prosthesis.
Study Design: A prospective study of ossicular reconstruction using the Silastic banding technique. A consecutive series of cases with intact stapes superstructure and missing malleus handle (Austin-Kartush Group C) is presented.
Setting: One tertiary referral center.
Patients: Ninety-nine patients who underwent total ossicular reconstruction with Silastic banding technique were enrolled in the study from January 2000 to December 2002.
Interventions: Ossiculoplasty with total ossicular replacement prostheses with Silastic Rubber Band for chronic otitis media and non-inflammatory disease.
Main Outcome Measures: Preoperative and postoperative audiometric evaluation using conventional audiometry. Air-bone gap, bone-conduction threshold, and air-conduction threshold were assessed. Postoperative audiometry was performed at the 6th, 9th, 12th, 18th, 24th, and 36th months.
Results: Overall, a postoperative air-bone gap closed to within 10 dB was achieved in 61.5% of cases. An air-bone gap smaller than 20 dB was obtained in 77% of cases. Postoperative improvement of air-conduction thresholds by at least 20 dB was found in 51% of cases. There was no case of postoperative sensorineural hearing loss. One case of extrusion of the prothesis was seen (1%).
Conclusion: Stabilizing the total ossicular replacement prosthesis with the Silastic banding technique when performing ossicular reconstruction is a safe, effective method when the stapes supra-structure is present and the malleus absent.
Key Words: Ossiculoplasty—Tympanoplasty—Middle ear prostheses—Silastic banding malleus—Hearing results.

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Reconstruction of the ossicular chain when the stapes is present and the malleus absent typically involves a prosthesis between stapes head and tympanic membrane or graft surface (1,2). However, these ossicular reconstructions are frequently unstable because the lack of fixation by the malleus at the proximal end of the prosthesis can allow displacement at either the proximal or distal ends.

The current report describes an original technique of Silastic (Silverstein Silicone Tympanoplasty Implant, Xomed-Medtronic, Jacksonville, FL, U.S.A.) banding (the Silastic banding technique) with the use of a total ossicular replacement prosthesis (TORP) from stapes footplate to tympanic membrane despite the presence of a stapedial arch. The TORP is attached to the intact stapes superstructure with a band that allows for better prosthesis stability. Hearing results are discussed.

MATERIALS AND METHODS

Patients

A prospective study was made of 99 patients who had ossiculoplasty with a TORP and Silastic banding technique during tympanoplasty. These patients were enrolled in the study between January 2000 and December 2002. A serial assessment of hearing status was conducted before and at regular intervals after surgery. All patients had at least 6 months of audiological follow-up after the operation. Fifty-six percent of the patients were women or girls, and 44% were men or boys. The mean age was 49 years (age range, 11–81 yr). There were five children (ages, <18 yr).

Surgery was performed on 100 ears in 99 patients. Cases were assigned to three groups according to the disease; there were 86 cases of chronic otitis media without cholesteatoma (86%), 10 cases of traumatic dislocation of the ossicular chain (10%), and 4 cases of congenital malformation of the ossicular chain (4%). Twenty-six ears (26%) required tympanic membrane

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grafting. The material inserted as an underlay graft to repair perforations was tragal perichondrium in all cases.

Fifty-nine of the 100 operated ears were revision cases (59%), and the cause of failure was identified as displaced prosthesis or autograft in 40 of 59 cases (68%), short prosthesis in 3 of 59 cases (5%), too-long prosthesis in 1 of 59 cases (1.5%), and erosion of the ossicular chain in 15 of 59 cases (25.5%). All cases had intact, healthy middle ear mucosa with no active cholesteatoma or inflammation.

The Austin classification (3) of ossicular defects as modified by Kartush (1) was used to define the ossicular status in our series. Cases studied were all classified into Austin-Kartush Group C (stapes present and malleus absent).

Surgical Technique for Silastic Banding Technique Stabilization

A video clip showing the surgical technique is available via the online version of the Journal at www.otology-neurotology.com. A transcanal procedure was used in all cases in the current series. The Silastic band is fashioned by creating a 1.2-mm disk with a specially designed punch (Xomed-Medtronic) from a thin sheet of Silastic. The disk is then fenestrated in its center with a smaller punch, which is available in three sizes (0.5, 0.8, and 1 mm) (Fig. 1). The size selected is based on the width of the stapes capitulum. The band should fit snugly around the stapes neck. The stapedius tendon is divided as closely as possible to the pyramid because an attempt will be made to place the band beneath the stapedius tendon to avoid lateral displacement (Fig. 2). In all cases, ossiculoplasty was performed using a Flex Hydroxylapatite (Flex-HA) TORP (Xomed-Medtronic). The prosthesis shaft is cut to the appropriate length, and the discarded distal tip is positioned between the stapes and the fallopian canal (Fig. 3). This acts as a buttress to avoid potential dislocation of the stapes during the procedure. It is removed later, after the completed ossiculoplasty.

The band is gently pulled superiorly toward the facial nerve with a curved needle. At the same time, the prosthesis shaft is introduced between the stapes and the band with the distal end lowered onto the center of the footplate (Fig. 4). The band is then released, and the prosthesis becomes firmly attached to the stapes (Fig. 5). This allows precise placement on the stapes footplate with sufficient rigidity. The "buttress" is then removed.

The foremost advantage of this technique is stability by means of keeping the distal end of the prosthesis in proper position, thus eliminating tipping or migration. This configuration prevents prosthesis displacement and avoids contact with the promontory or the posterior canal wall. The Silastic banding technique also prevents undesirable contact with a dehiscent or overlying facial nerve. In many ears with an intact stapes superstructure, there is enough room between the horizontal segment of the facial nerve and the stapes superstructure to place the shaft of a TORP. We prefer this location because it provides a reliable vertical alignment of the prosthesis with the overlying tympanic membrane. However, if a dehiscent facial nerve is too close to the stapes superstructure, the shaft of the prosthesis is positioned on the other side, between the stapes and the promontory.

In general, determining the exact length of a prosthesis can prove to be difficult when the malleus is absent. This new technique achieves an almost perpendicular position of the prosthesis to the footplate and the tympanic membrane, allowing the use of a standard stapes measuring rod. The distance from tympanic membrane to footplate is determined

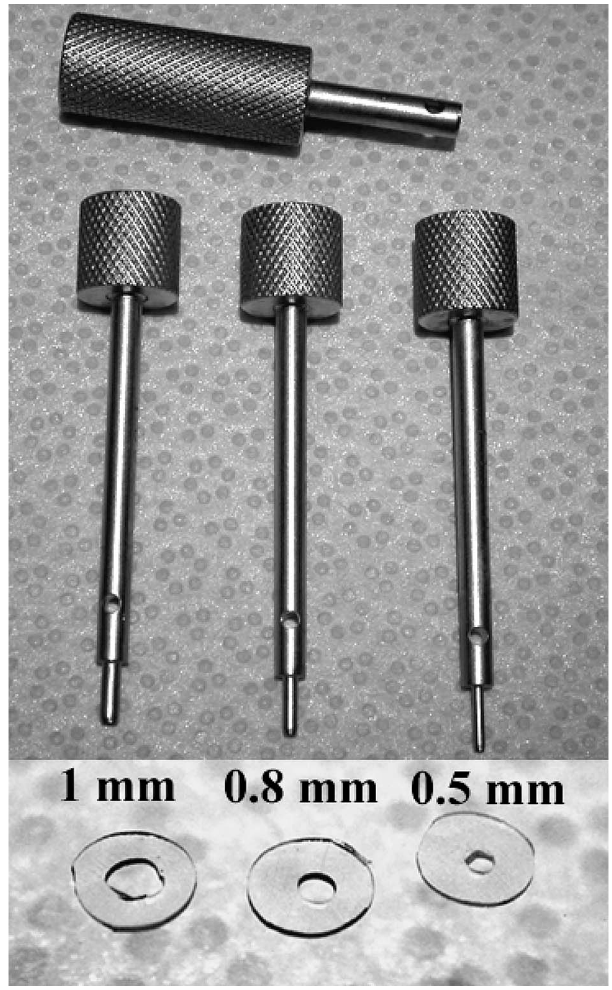

FIG. 1. Band is fashioned from a Silastic sheet with a punch, which is available in three sizes (0.5, 0.8, and 1 mm).

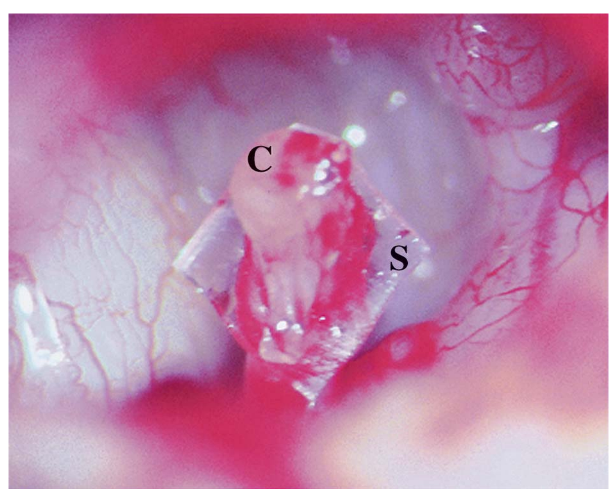

FIG. 2. Operative view of a left ear. The Silastic band (S) is positioned around the stapes capitulum (C), beneath the stapedius tendon, which has been previously divided.

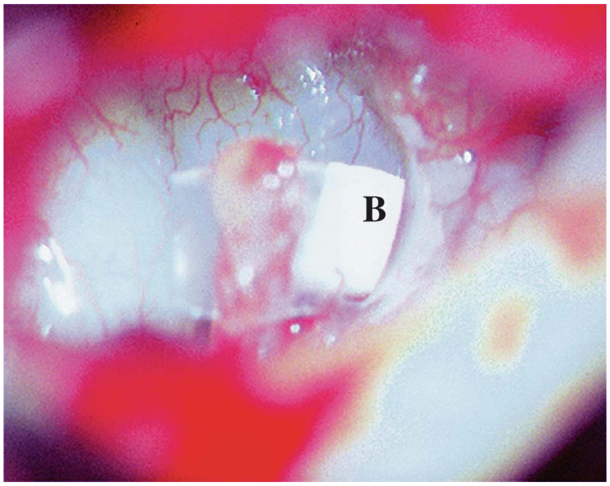

FIG. 3. A buttress (B) is made with the discarded distal tip of the prosthesis. It is positioned between the anterior crus of the stapes and the fallopian canal.

with elongated measuring rods (Xomed-Medtronic) for precise measurement within 0.5 mm, even in cases of lateralized tympanic membranes. The tympanomeatal flap is replaced in its anatomic position to verify the position of the head of the prosthesis beneath the under-surface of the tympanic membrane.

Audiometric Assessment

Audiometric evaluation included postoperative air-bone gap (ABG), postoperative air-conduction (AC) threshold, and postoperative bone-conduction (BC) threshold. Only AC and BC results that were obtained at the same time postoperatively were used for calculation of ABG and pure-tone average (PTA) values. We used four PTA values for BC and AC (0.5, 1, 2, and 4 kHz) that were obtained at the last follow-up visit. All patients had at least 6 months of audiologic follow-up. Audiometry was reported according to American Academy of Otolaryngology–Head and Neck Surgery guidelines (4), except for thresholds at 3 kHz, which were substituted in all cases with thresholds at 4 kHz.

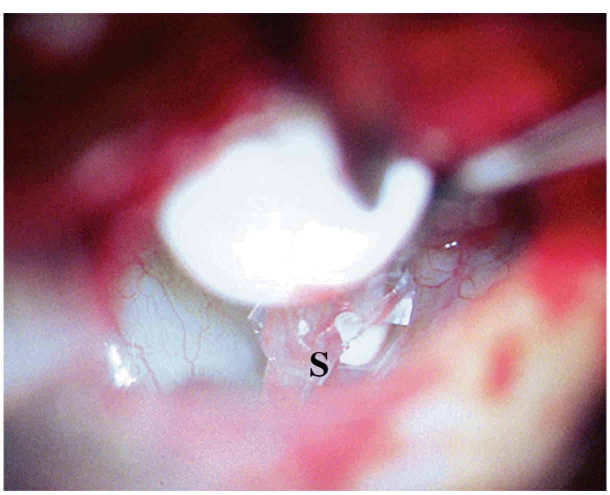

FIG. 4. Silastic band (*S*) is gently pulled laterally toward the facial nerve with a curved needle, and the prosthesis shaft is introduced between the stapes and the band.

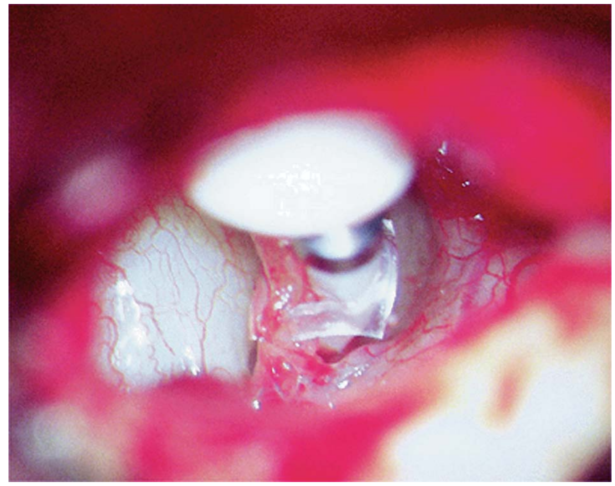

FIG. 5. Final view, showing the correct position of the prosthesis, which is firmly attached to the stapes.

RESULTS

Of the 100 cases in which total ossicular reconstruction with Silastic banding technique was performed, 96 had audiologic data available (96%). The average duration of follow-up was 15.2 months (range, 6–36 mo). Of the 96 cases that had more than 1 year of follow-up, complete hearing results were available in 62 cases (64.5%). A separate analysis was made for the entire series (96 cases) and for the 1-year follow-up series (62 cases) (4).

Audiometric Outcomes

Hearing results in 96 cases are presented in Table 1. There was no case of postoperative sensorineural hearing loss in the series. Prosthesis extrusion occurred in 1 of 96 cases (1%). The postoperative ABG (averaged over 0.5, 1, 2, and 4 kHz) was closed to 10 dB or less in 59 of 96 cases (61.5%) and to 20 dB or less in 74 of 96 cases (77%). The postoperative mean ABG was 11.75 dB compared with 33.6 dB preoperatively. Improvement of AC thresholds by at least 20 dB was obtained in 49 of 96 cases (51%). The average postoperative hearing threshold was 37.46 dB compared with 56.6 dB preoperatively. The mean postoperative BC level was unchanged in all cases. Because this technique may have the potential for mechanical trauma to the inner ear, specific assessment of the preoperative and postoperative BC threshold at 4 kHz was made, and no significant difference was found (34.5 dB postoperatively compared with 33.7 dB preoperatively).

Results according to disease in 96 cases are given in Table 2. The best results were obtained in surgery for posttraumatic dislocation of the ossicular chain (10 cases),

TABLE 1. *Hearing results in 96 cases (0.5, 1, 2 and 4 kHz)*

Mean ABG (dB)		Postop ABG (%)			Postop Mean AC (dB)		Postop gain in AC >20 dB (%)	Mean BC (dB)	
Preop	Postop	<10 dB	10–20 dB	>20 dB	Preop	Postop		Preop	Postop
33.6	11.75	61.5	15.5	23	56.6	37.46	51	23	25.71

ABG, air-bone gap; Postop, postoperative value; AC, air-conduction threshold; BC, bone-conduction threshold; Preop, preoperative value.

with an ABG closure to within 20 dB achieved in 8 of 10 cases (80%).

Hearing results in 62 cases with at least 1-year follow-up results are presented in Table 3. The postoperative ABG was closed to 10 dB or less in 41 of 62 cases (66%) and to 20 dB or less in 48 of 62 cases (77.5%). The postoperative mean ABG was 14.5 dB compared with 39.8 dB preoperatively. Improvement of AC thresholds by at least 20 dB was seen in 37 of 62 cases (59.5%). The average postoperative hearing threshold was 30.5 dB compared with 54.3 dB preoperatively.

Failures

In accordance with Moretz (5), failures were reported as ''known failure rate'' for the entire series (96 cases) and included severe sensorineural hearing loss (''dead ear''), prosthesis extrusion, and postoperative ABG greater than 20 dB. The overall rate of known failures was 24% (23 of 96 cases). There were 22 cases of postoperative ABG greater than 20 dB (23%), and there was 1 case of prosthesis extrusion (1%). This occurred within the first 6 months after surgery. In this ear, eustachian tube dysfunction with retraction of the tympanic graft was deemed to be the cause of the extrusion. There were no cases of perforation of the tympanic membrane or graft. No sensorineural hearing loss was observed in the series.

First Revisions

Ten of 23 failures underwent revision surgery (Table 4). The cause of failure was identified as short prosthesis in 6 of the 10 cases (60%). For these six cases, a longer prosthesis was introduced within the band, which had been positioned during the previous operation. The new average length was 6.5 mm compared with the 5.5-mm average length of the original failed prostheses. Prosthesis dislocation occurred in 3 of the 10 cases (30%). The cause of prosthesis dislocation was identified as a rupture of the Silastic band in all cases, and a new band was positioned. A long prosthesis was found in 1 of the 10 cases (10%).

Of the 10 patients undergoing revision surgery, audiometric data were available for 9. The average duration of follow-up was 7.5 months (range, 3–12 mo). Postoperative closure of ABG within 20 dB was achieved in five of nine cases (55.5%) and was not achieved in four cases (44.5%). After first revision surgery the mean ABG was 15.7 dB compared with 36.12 dB before revision. The average post-revision hearing threshold was 43 dB compared with 63.6dB before revision.

Second Revisions

Of the four revised cases with an ABG of greater than 20 dB, two underwent second revision (Table 4). After second revision the cause of failure was identified as a short prosthesis in both cases. The new prosthesis length was 8 mm in both cases compared with the 6- and 6.25-mm lengths of the previous failed prostheses. Preliminary results of the second series of revision cases were available for both cases. The duration of follow-up was 3 months for one case and 9 months for the other. An ABG closure to within 10 dB was achieved in both cases (100%). After second revision the mean ABG was 7.5 dB compared with 37.5 dB before second revision. The average hearing threshold after second revision was 32.5 dB compared with 62.5 dB before second revision.

Final Results

The overall success rate after the initial operation was 76%. This rate improved to 80% and 82% after first and second revisions, respectively.

DISCUSSION

The status of the ossicular chain as a determinant of hearing results has been somewhat controversial in the literature (6). Theoretically, the stapes superstructure

TABLE 2. *Results according to pathologic findings in 96 cases: Assessment of the postoperative air-bone gap*

Pathologic finding	N	Postop ABG (%) <10 dB	10–20 dB	20–30 dB	>30 dB
Chronic otitis	82	59.5	16.5	12.5	11.5
Ossicular chain dislocation	10	60	20		20
Congenital malformation	4	50	25	25	

Postop, postoperative; ABG, air-bone gap.

TABLE 3. *Hearing results in 62 cases for at least 1-year results (0.5, 1, 2, and 4 kHz)*

Mean ABG (dB)		Postop ABG (%)			Postop Mean AC (dB)		Postop gain in AC >20 dB (%)	Mean BC (dB)	
Preop	Postop	<10 dB	10–20 dB	>20 dB	Preop	Postop		Preop	Postop
39.8	14.5	66	11.5	22.5	54.3	30.5	59.5	14.5	16

ABG, air-bone gap; Postop, postoperative; AC, air-conduction threshold; BC, bone-conduction threshold.

should contribute little or nothing to the acoustic gain of the middle ear mechanism, whereas the malleus may be significant acoustically through its action as a cantilever and impedance matcher (7). Numerous authors (6,8,9–11) have emphasized the importance of the malleus in successful ossiculoplasty. However, other authors have found the presence of the malleus to be less relevant (12,13).

Moretz (5) reviewed a consecutive series of cases with intact stapes superstructure with an intact malleus handle (Austin-Kartush Group A) and without malleus handle (Austin-Kartush Group C). The ossiculoplasties were performed with either partial prosthesis positioned from the stapes to the drum or malleus or with total prosthesis positioned from the stapes footplate to the drum despite the presence of an intact stapes. In the series of Moretz (5), Group A cases had significantly smaller postoperative ABG than Group C cases. Mean ABG hearing results were better for Group A cases (17 dB) than for Group C cases (24 dB). There was no difference in mean ABG between partial and total reconstruction within either group. These results were similar to those of Goldenberg (14), with hydroxylapatite cap partial prostheses resulting in 18 dB mean ABG in his Group A series and 23 dB mean ABG in his Group C cases. In the series of Moretz (5), the failure rate was 23% for partial ossicular replacement prostheses but only 6% with total ossicular replacement prostheses; therefore, Moretz proposed that TORP would be the best choice for ossiculoplasty in Group C cases, as well as in Group A cases.

Few other authors have advocated reconstruction from the footplate of a normal stapes to the drum (5,12,15–18). In their series of 290 ossiculoplasties with hydroxylapatite prostheses, Coletti and Fiorino (17) used a TORP in all cases, even in the presence of the stapes superstructure. Lack of malleus in the presence of a normal stapes was found in 38 cases, and a TORP was interposed between the drum and the footplate with use of a strut of cartilage between the tympanic membrane and the head of the prosthesis. The postoperative ABG was closed to 20 dB in 64% of these cases of missing malleus at 1 year, and no extrusion was observed.

In our recent experience, there has been a clear tendency toward increasing the use of total ossicular replacement prostheses in Groups A and C cases. Today, partial ossicular replacement prostheses are used only in specific conditions, in cases in which there is an unusually narrow oval window niche that would not allow correct placement of a TORP shaft without contacting adjacent fallopian canal or promontory.

Vlaming and Feenstra (19) have demonstrated that a prosthesis should be placed along an imaginary line through the center of the footplate and the head of the stapes. Goode and Nishihara (20) have also shown that assemblies are often mechanically inefficient if angulated at an angle greater than 45 degrees from the axis of the superstructure. Our technique of Silastic banding allows prosthesis placement in a vertical plane and prevents contact with the promontory, which may impair sound transmission. The tilting motion of the footplate is negligible, regardless of the position of the distal tip of the shaft of the prosthesis on the footplate. In all cases in our series, the band allowed a proper prosthesis placement, particularly because the distal end of the prosthesis was always centered on the footplate. According to Vlaming and Feenstra (19), this configuration achieves an almost perpendicular direction of the forces to the footplate with optimal transfer function and minimal dissipation of energy (Fig. 6).

In case of missing malleus, Goldenberg (13) advocated the use of HA prostheses with a specific design. The hydroxylapatite head has in a flat, egg-shaped design, with gently rounded edges to be used directly under the tympanic membrane surface without the need for a cartilage interface. The intent of this design is to couple the stapes with a broad, flat surface beneath the overlying drum or graft. Goldenberg performed

TABLE 4. *Results of first (10 cases) and second (4 cases) revisions (0.5, 1, 2, and 4 kHz)*

Revisions	Cause of failure (n)			Available data (n)	Mean ABG (dB)		Postop ABG <20 dB (%)	Postop mean AC (dB)	
	Short prosthesis	Prosthesis dislocation	Long prosthesis		Preop	Postop		Preop	Postop
First revisions (10 cases)	6	3	1	9	36.12	15.7	55.5	63.6	43
Second revisions (2 cases)	2			2	37.5	7.5	100	62.5	32.5

ABG, air-bone gap; AC, air-conduction threshold; Preop, preoperative; Postop, postoperative.

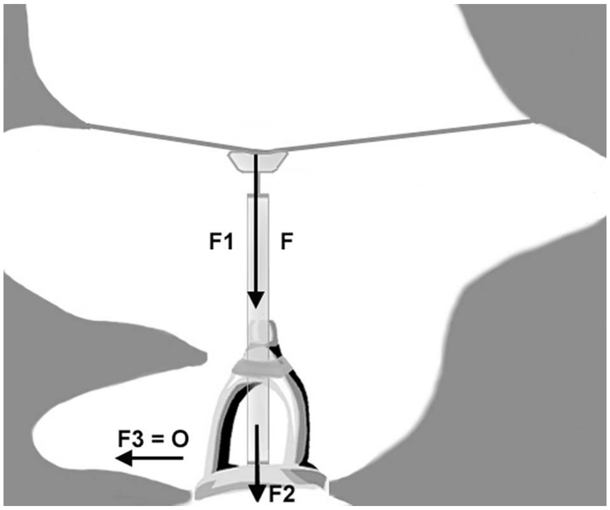

FIG. 6. Side view of a total prosthesis with the Silastic band between tympanic membrane and stapes footplate, showing forces acting on the contact points. Force F acting on the tympanic membrane can be resolved into three components F1, F2, and F3. Force F1 represents the force acting along the prosthesis. Force F2 represents the desired piston action, and Force F3 makes the footplate tilt and does not contribute to a net volume displacement into the cochlea. The configuration achieves an almost perpendicular direction of the forces to the footplate. Tilting is negligible.

70 implantations of HA partial and total ossicular replacement prostheses with this specific design in case of missing malleus. An ABG closure to within 20 dB was achieved in 43% of cases with PORP and in 30% with TORP (13).

In 1983, Brackmann et al. (12) reviewed 1042 operations in which Plasti-Pore partial and total ossicular replacement prostheses were placed in contact with the tympanic membrane. Overall, a postoperative ABG of less than 20 dB was achieved in 64% of cases. This consisted of 73% of the PORP cases and 55% of the TORP cases. Extrusion of the prosthesis occurred in 7% of the 1042 cases, and eustachian tube dysfunction with middle ear atelectasis was deemed to be the cause of extrusion in 30% of cases. However, this extrusion rate is also related to the biomaterial that was used in the series (21).

Re-creation of the malleus has been used (22,23). Without an intact malleus, Wehrs (24) suggested the use of a homologous drum and malleus, which usually requires staging for a stable reconstruction. More recently, Black (23) introduced a technique of neo-malleus ossiculoplasty by using an autograft neo-malleus strut and an assembly rather than a columella in cases in which the malleus was unavailable for assembly techniques. The strut was positioned overlying the ‘‘Spanner’’ implant and lateral to the stapes, and the drum or graft was then laid over the reconstruction. Within his Austin-Kartush Group A cases, although the malleus was present in 45 cases but malpositioned, it was repositioned and an ABG closure to within 20 dB was achieved in 67% of these 45 cases.

In his series of 228 cases, Moretz (5) categorized his failures as being disease or prosthesis related. Prosthesis failure included prosthesis extrusion, displacement, or fixation. Failures were reported as known failure rate in relation to the entire series of cases. The overall failure rate in his Group C cases was 20%, and 15% failed because of a prosthesis-related problem. Prosthesis displacement or fixation occurred in 23% of cases using the partial prostheses and in 6% of cases employing total reconstruction. In our series, the main cause of failure was identified as short prosthesis (Fig. 7), whereas the incidence of prosthesis displacement was low. The use of an elongated stapes measuring rod has been effective in enhancing the measurement of the distance between the tympanic membrane and the stapes. The average length of total ossicular replacement prostheses in our series was 5.75 mm (range, 4.50–8.50 mm). There was a tendency toward increasing the TORP length with time; the average prosthesis length was 5.25 mm within the first year of the current series, whereas it was 5.50 mm within the second year and 6.25 mm within the third year.

Few failures were due to ruptured Silastic in the current series (three cases in all). The cause of these ruptures remains unclear because all Silastic bands were fashioned from the same commercially available product. Different Silastic thickness or elasticity, or both, might be considered in the future, if long-term follow-up shows an increasing rate of ruptured Silastic band.

Our preliminary hearing results with this new technique of Silastic banding in cases of missing malleus are encouraging and compare favorably with the results reported by other authors in the same anatomic situation (5,14,25,26) (Table 5). Depending on the series, an ABG

FIG. 7. Postoperative computed tomography scan of a failed case (right ear, coronal view) showing a short prosthesis attached to the stapes with a Silastic band. There is no prosthesis dislocation. The short prosthesis is not in contact with the tympanic membrane, which is lateralized. However, the prosthesis stability remains good because of the presence of the Silastic band.

TABLE 5. *Austin-Kartush Group C hearing results in literature review*

Series (Ref. No.)	Material	n	Postop 0–10 dB	ABG 0–20 dB	(%) >20 dB	Mean ABG (dB)
Austin, 1976, (26)	Partial autograft or homograft	23	12	39	61	27
Black, 1991, (27)	HA PORP	13	15	54	46	
Goldenberg, 1994, (15)	HA PORP	7	14	46	57	23
Moretz, 1998, (6)	HA PORP	6	0	10	90	24
	HA TORP	4	0	25	75	24
Present study	HA TORP	96	66	77	23	12

Postop, postoperative; ABG, air-bone gap; HA PORP, hydroxylapatite partial ossicular replacement prosthesis; HATORP, hydroxylapatite total ossicular replacement prosthesis.

closure to within 20 dB was achieved for 10 to 54% of Austin-Kartush Group C cases compared with 77% in our series. Moreover, with this technique successful ossicular reconstruction from the stapes footplate to the drum is achievable at rates similar to or better than ossicular reconstruction using HA total and partial ossicular replacement prostheses positioned from malleus to stapes capitulum or footplate in Austin-Kartush Group A cases (27–29).

A theoretical risk of pressure necrosis exists for the superstructure, but we think this is unlikely. The prosthesis makes little contact with the superstructure and only does so at one location on the superstructure. However, considering the relatively short period of follow-up of the present series (15.2 mo), it will be important to observe outcomes after longer periods of follow-up.

CONCLUSION

The concept of the Silastic banding technique was developed to improve on results of cases that had been previously managed with columellae. With this technique the prosthesis is firmly attached to the stapes, thus decreasing the risk of displacement of the prosthesis despite the absence of the malleus. The current series of total ossicular reconstructions with Silastic banding in the absent-malleus, present-stapes situation has demonstrated successful ABG closure in 77% of cases. Successful ossiculoplasty can be achieved with similar rates of successful ABG closure in cases with malleus present.

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