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Stapes Release in Tympanosclerosis

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Tympanosclerosis in the middle ear space is common in Ethiopia and often involves the ossicles and particularly the stapes. Ear operations in Ethiopia are relatively expensive in this country of limited medical resources and a low average living wage. In this setting, 2-stage operations using prostheses become prohibitively expensive. Therefore, the recommended 2-stage approach for tympanic membrane perforation with tympanosclerosis and stapes fixation is impractical for Ethiopia.

We present a series of 67 patients who had a single stage tympanoplasty, removal of tympanosclerosis from the stapes suprastructure, and ossicular chain reconstruction using ossicular interposition. Crucial is the surgical technique employed for peeling the mound of tympanosclerotic plaque off of the stapes, which we term the stapes release. Controls were 67 patients with similar perforations and air-bone gap, but no tympanosclerosis. Most controls had ossciular discontinuity and were reconstructed with type III tympanoplasty.

Air-bone gap improved in both groups: 18 dB (11 dB standard deviation) in the stapes release group, and 23 dB (11 dB standard deviation) in the control group. Paired *t* test found these improvements in each group significant at $p < 0.001$. Among the preoperative subjects there were 40 with air-bone gap greater than 45 dB, and none less than 20 dB. Among the postoperative subjects, none had air-bone gap worse than 45 dB, while 25/67 (37%) stapes release and 44/67 (66%) controls had air-bone gap better than 20 dB. Three patients in each group failed to close their perforations completely (96% closure rate).

The only complications were two early cases of transient facial nerve weakness, which was avoided in subsequent cases by an alteration in technique. There was no deterioration of sensorineural hearing levels in either group's subjects postoperatively.

In conclusion, stapes release with ossicular interposition can be performed at the same time as tympanoplasty without exacerbation of sensorineural hearing loss. Tympanic membrane closure and hearing levels were similar between patients with and without stapes fixation from tympanosclerosis. **Key Words:** Developing country—Ear—Myringosclerosis—Stapes.

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Tympanosclerosis has been documented at an 11% rate in Tanzania (1) and at 28% in Ethiopia (2). Reports from the United States in the 1970s and 1980s also cited incidences as high as 30 to 40% (3,4) although clinically the numbers appear to be far lower in this century. Some authors state that tympanosclerosis is an ongoing process that will recur after operative removal (5–7) while others state it is the end product of inflammation and will not recur after surgery (3). Authors agree that the management of tympanosclerosis is very problematic when it involves the stapes and especially the stapes footplate (5,8–10). The removal of tympanosclerosis involving the stapes footplate can be associated with worsening of sensorineural levels (5,8–11) and much less commonly, facial weakness from manipulation of plaque over the horizontal facial nerve (3,6).

As Gormley stated in 1987: ''Stapedectomy for tympanosclerosis of the oval window niche is a contentious choice of treatment, performed by few and avoided by many (8).'' Some authors endorse a 1-stage operation with removal of plaque and placement of an ossicular interposition graft, or a prosthesis if possible (4,12). Others recommend a 2-stage approach initial myringoplasty, followed by prosthesis placement into a neo oval window (5,6,13–16). Still others recommend not even attempting stapes or oval window work in stapes tympanosclerosis (7,10,17).

We report here our case series of Ethiopian patients who had tympanic membrane perforations with tympanosclerosis of the stapes and footplate whom we treated with a 1-stage tympanoplasty and ossiculoplasty after stapes release from tympanosclerosis. Patients matched for age and perforation size without tympanosclerosis who underwent tympanoplasty with or without ossculoplasty serve as controls. The stapes release technique will be described.

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TABLE 1. *Distribution of the preoperative sizes of tympanic membrane perforations for stapes release and control subjects*

Perforation Size	Stapes Release Subjects	Control Subjects
>60%	27/67 (40%)	40/67 (60%)
30–60%	19/67 (28%)	23/67 (34%)
<30%	13/67 (19%)	3/67 (4%)
None	8/67 (12%)	1/67 (1%)

MATERIALS AND METHODS

This patient series investigation has received Institutional Review Board approval from the OtoRino-ENT Specialty Clinic Ethics and Patient Protection Committee.

Subjects were 134 patients who presented between June 2011 and May 2017 with tympanic membrane perforations, hearing loss, ossicular dysfunction, or ossicular fixation due to tympanosclerosis. Condition of the tympanic membrane and ossicles was documented intraoperatively and those patients with tympanosclerosis of the stapes and who underwent stapes release were selected as subjects, while the others with similar perforations and hearing loss served as controls. The control patients were operated during the same time frame as the stapes release subjects and tended to have ossicular discontinuity. Therefore, both stapes release and control subjects underwent type II tympanoplasty. Only subjects with dry, uninfected ears are reported here.

Audiometric testing consisted of air thresholds and masked bone thresholds for each ear both preoperatively and postoperatively. Controls without tympanosclerosis, who underwent tympanoplasty with or without ossiculoplasty, were selected if they matched the subjects in age, perforation size, and hearing levels. The preoperative and postoperative air-bone gap was expressed as the average of the air-bone gap at 0.5 kHz + 1 kHz + 2 kHz + 4 kHz. Postoperative audiograms were obtained 3 to 23 months after operation.

Statistical analysis of the change of hearing thresholds and the change of air-bone gap was performed using the statistical program SPSS 20 (IBM, Armonk, NY).

The stapes release technique is a 1-stage operation which involves two principal features. First the incus and the head of the malleus are removed as these are usually found to be fixated by tympanosclerosis in the epitympanum. Second, the stapes is always released from its tympanosclerotic fixation by removing the layers of tympanosclerosis under high magnification, using the crura as stabilizing features: a small, sharp sickle knife is interposed between the capitulum and the tympanosclerotic plaque and the layers of plaque are peeled lateral to medial along the surface of each crus. A curved rosen needle is often used in addition. The dome of the crura can resist pressure applied lateral to medial and all cleaning is stopped when the stapes becomes mobile. Care is taken to remain gentle in manipulation, and the plaque between the crura is left alone. After two cases of transient facial nerve weakness, care is also taken not to peel tympanosclerotic plaque off of the horizontal facial nerve canal. When the stapes or stapes remnant is free of tympanosclerosis, the interposition of cartilage or incus or malleus head are used as appropriate. Thereafter, the repair of the tympanic membrane is performed.

All tympanoplasties performed were transcanal. Graft materials were layered perichondrium, or perichondrium with attached cartilage island.

Types of ossiculoplasties were Tri-ossicle, or Type III with malleus head interposition, or Type III with incus body interposition. The Tri-ossicle approach reshapes the incus and reinserts it between the capitulum and the malleus. The Type III malleus head or incus body position these ossicles on the capitulum. After the malleus head or incus body is positioned on the capitulum or stapes remnant, then a cartilage cap is placed between the ossicular graft and the tympanic membrane. Most of the stapes continued to have an intact suprastructure after stapes release.

RESULTS

Subjects were 44 women (65%) and 23 men (35%) for a total of 67 total subjects in the stapes release group. In the control group were also 67 subjects—39 women (58%) and 28 men (42%). The average ages for the subjects were 26 years with a range of 12 to 56 years and standard deviation of 8 years.

Sizes of the tympanic membrane perforations (Table 1) were greater than 60% for 27 stapes release subjects (40%) and 40 controls (60%). Perforations between 30 and 60% were 19 in the stapes release subjects (28%) and 23 controls (34%). Perforations less than 30% were 13 for stapes release subjects (19%) and three for controls (4%). Eight stapes release subjects and one control had no perforation.

Preoperative air-bone gap (Table 2) for the stapes release subjects were 30 to 60 dB (mean, 43 dB; standard deviation [SD], 6 dB) and for the controls were 27 to 60 dB (mean, 43 dB; SD, 8 dB). The distribution of ranges of preoperative air-bone gap was as follows: no subject showed a preoperative air-bone gap less than 20 dB. The preoperative air-bone gap was 21 to 30 dB in six stapes release subjects (9%) and in three controls (4%). Preoperative gap between 31 and 45 dB was found in 37 stapes release subjects (55%) and 48 controls (72%). Gaps greater than 45 dB were found in 24 stapes release subjects (36%) and 16 controls (24%). Statistical analysis with *t* test found no statistical difference between these two groups' preoperative air-bone gap.

Duration of hearing loss and disease symptoms was more than 10 years in 66 of the stapes release subjects and

TABLE 2. *Preoperative air-bone gap for stapes release and control groups*

Pre-op Air-Bone Gap	Stapes Release Subjects	Control Subjects
<20 dB	0	0
21–30 dB	6/67 (9%)	3/67 (4%)
31–45 dB	37/67 (55%)	48/67 (72%)
>46 dB	24/67 (36%)	16/67 (24%)
Range, mean, SD	30–60 dB, 43 dB, 6 dB	27–60 dB, 43 dB, 8 dB

No subjects had preoperative air-bone gap below 20 dB, and 40 subjects had gaps above 46 dB. Statistical analysis found not significant differences in preoperative air-bone gap between the two groups.

SD indicates standard deviation.

TABLE 3. *Distribution of types of ossiculoplasty in stapes release subjects and controls*

Type of Ossiculoplasty	Stapes Release Subjects	Control SubjectS
Tri-ossicle	26/67 (39%)	21/67 (31%)
Type III with incus body interposition	11/67 (16%)	21/67 (31%)
Type III with malleus head interposition	28/67 (42%)	22/67 (33%)
No ossiculoplasty	2/67 (3%) stapes release only	3/67 (4%) tympanic membrane repair only

Numbers reconstructed by each technique are equivalent between stapes release and controls.

more than 5 years for the last one. Duration of hearing loss and disease symptoms was more than 10 years for all the control subjects.

Distributions of operations performed (Table 3) were 26 triossicle type (39%) in the stapes release subjects and 21 (31%) in the controls. Type III tympanoplasty with incus body interposition were 11 (16%) in the stapes release subjects, and 21 (31%) in the controls. Type III tympanoplasty with malleus head interposition were 28 (42%) in the stapes release subjects, and 22 (33%) in the controls. Two stapes release subjects had release of stapes only without ossiculoplasty, and three controls had tympanic membrane repairs only. All operations were operated by the same senior surgeon.

Reoperations ware required for 10 of the stapes release subjects and nine of the control group. Three subjects in each group needed reoperation to close a residual perforation. Five stapes release subjects needed a secondary lysis of adhesions, as did four of the controls. Three stapes release subjects needed ossicular repositioning as did one control.

Complications of surgery were fracture of the footplate with no sensorineural hearing loss drop in one stapes release subject, and two stapes release subjects with transient facial nerve weakness. The surgical technique was modified thereafter, avoiding removal of plaque from the horizontal facial nerve. There were no subjects with postoperative deterioration of their sensorineural levels.

Postoperative air-bone gap (Table 4) was improved for both groups, and the mean postoperative levels were 24 dB (SD 10 dB) in the stapes release group and 20 dB (SD 9 dB) in the control group. *t* test found that the control group's average postoperative air-bone gap was significantly better than that of the stapes release group ($p < 0.05$). The improvements of air-bone gap because of operations were: in the stapes release subjects 18 dB (SD 11 dB) and in the controls 23 dB (SD 11 dB). *t* test found that the improvements in air-bone gap after operation were highly significant in both groups, respectively ($p < 0.001$).

The distributions of ranges of postoperative air-bone gap were as follows (Table 4 continued): Among the stapes release subjects, 25 subjects (37%) achieved an air-bone gap less than 20 dB, while 44 controls (66%) achieved this level postoperatively. Postoperative air-bone gap of 21 to 30 dB was obtained in 28 of the stapes release subjects (42%) and 16 of the controls (24%). Finally, postoperative air-bone gap of 31 to 45 dB was obtained in 14 stapes release subjects (21%) and seven controls (10%). No subjects had postoperative air-bone gap more than 45 dB, although 40 subjects had had these gaps preoperatively (24 stapes release and 16 controls).

DISCUSSION

Treating the stapes which is fixated by tympanosclerosis has long been a difficult problem. Previous studies have reported conflicting hearing results after operations to treat the stapes fixated by tympanosclerosis. Some report hearing results in tympanosclerosis cases to be equivalent to non-tympanosclerosis cases (4,8). Some report that the hearing results are suboptimal (13,14,18), and inevitable drop in hearing in the months after surgery (7,10,19), while others state that air-bone gap did not increase with time (15). In the case-control series presented here, patients with tympanosclerosis fixating their stapes suprastructure or footplate fared as well as patients without tympanosclerotic fixation in the postoperative condition of their tympanic membrane and almost as well

TABLE 4. *Improvements in air-bone gap postoperatively*

Post-op Air Bone Gap	Stapes Release Subjects	Control Subjects
Improvement of air-bone gap (difference pre versus post)	18 dB (11 dB)	23 dB (11 dB)
Post-op levels—mean, SD	24 dB (10 dB)	20 dB (9 dB)
Number of subjects <20 dB	25/67 (37%)	44/67 (66%)
Number of subjects 21–30 dB	28/67 (42%)	16/67 (24%)
Number of subjects 31–45 dB	14/67 (21%)	7/67 (10%)
Number of subjects >45 dB	0	0

Stapes release subjects and controls showed highly significant improvements of postoperative air-bone gap ($p < 0.001$ for each). However, the final values for the postoperative air-bone gap were better for the controls than the stapes release subjects ($p < 0.05$). Notable is that there are no longer any subjects with a postoperative air-bone gap worse than 45 dB. And for the first time there are subjects with air-bone gap better than 20 dB.

in their hearing levels. Three subjects in each group needed a second operation to close a residual tympanic membrane perforation. Air-bone gap improved by 18 dB in the stapes release subjects and 23 dB in the controls. And this improvement was highly significant statistically for each group ($p < 0.001$).

Further, the distribution of postoperative air-bone gap shifted so that there were no longer any subjects in either group with gaps more than 45 dB and subjects with gaps less than 20 dB arose in both groups.

Complications from stapes manipulation or footplate removal in these cases have been repeated reported as increased sensorineural hearing loss (5,6,9,11,17) and facial nerve weakness if the tympanosclerosis over the horizontal facial canal is manipulated (3,6). In our series we found no changes in the sensorineural hearing levels after stapes release with ossiculoplasty. We had three cases of transient facial nerve weakness early on, but this complication was avoided by subsequent avoidance of removing plaque from the horizontal canal. Facial nerve monitoring might assist in avoiding this complication, but unfortunately it is prohibitively expensive in Ethiopia.

Classifications schemes for types of tympanosclerosis, distribution of tympanosclerosis, and types of ossiculoplasties in the presence of tympanosclerosis abound. Virtually all authors have introduced their own system. We, however, have focused here only on fixation of the stapes and how to release the stapes suprastructure and particularly the footplate. Our focus is solely on removing the incus with or without the malleus head, if these are fixating the stapes; and systematically removing the tympanosclerotic plaque from the stapes suprastructure, peeling from capitulum medially towards the footplate. We speculate that this strategy uses the structure of the crura to distribute the force of peeling off the plaque and thereby protect the footplate from trauma. The lack of trauma from cleaning (described by many of the other authors) is reflected by our stable postoperative sensorineural levels.

The distribution of tympanosclerosis in the middle ear in these Ethiopian patients is quite consistent: the tympanic membrane appears to be affected most commonly. Then, the tympanosclerotic plaque is added to each ossicle in turn—first malleus, then malleus-incus, then malleus-incus-stapes. Therefore, cases of stapes fixation by plaque are almost always accompanied by substantial malleus and incus fixation. In restoring ossicular vibration, usually the incus and malleus head have to be removed to free these from fixation in the epitympanum. In addition, the long and lenticular processes of the incus impede access to peeling the tympanosclerotic plaque from the anterior crus. With access to both of the stapes crura, this lateral to medial dissection removes the plaque, ultimately releasing the stapes, and avoids fracture of the footplate or annular ligament. We feel that our avoidance of stapedotomy—entry into the inner ear—helped protect these patients from postoperative sensorineural hearing loss.

A key economic feature of the stapes release technique is that it is a 1-stage procedure. Some authors state that stapes fixation by tympanosclerosis can be treated in 1-stage (20), some state that different scenarios need 1-stage or 2-stage (12–14,20), while others state that all procedures should be 2-stage (5,6,15,16,21). In addition, most previous authors have been able to place artificial prostheses for their patients (3,6,12,15,21,22). The financial situation in Ethiopia is somewhat more restrictive than in the countries of these authors—United States (3,4,12,21), Saudi Arabia (6,16,17), Turkey (7,13,15), Japan (14), Italy (11,20), Ireland (5), and Northern Ireland (8). In Ethiopia, medical resources are quite limited so that multiply-staged operations, prostheses, or postoperative hearing aids are simply not available. A single operation using the patient's own tissue for reconstruction is the only opportunity most Ethiopian patients will have for hearing improvement.

Finally, in previous reports, the ears in tympanosclerosis tended to be uninfected, or dry. In the United States, tympanosclerosis is not seen with cholesteatoma (3,4,22) while in Saudi Arabia cholesteatoma is often present (6). In our Ethiopian series, the ears were dry at the time of surgery, and tympanosclerosis was rarely accompanied by cholesteatoma.

In summary, we present a treatment strategy for tympanosclerotic plaques which are fixating the stapes, even in the presence of tympanic membrane perforation. A 1-stage procedure, using the stapes release technique, appears to safely improve hearing without sensorineural damage. Strengths of this study are the clear statistical outcomes. However, it is still limited by its retrospective nature of and the deliberate pairing of subjects with controls of equal hearing loss and with ossicular discontinuity.

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