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Sixteen years of experience with otosclerosis revision surgery: report of 105 cases

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Abstract. *Objectives:* Otosclerosis is a progressive disease of the bony labyrinth characterised by bone formation, which can cause conductive, mixed and, rarely, sensorineural hearing loss. Surgery on the stapes footplate can be successful for treating conductive hearing loss. However, complaints of new issues after surgery may prompt revision surgery. This report presents the results of revision stapes surgeries.
Methodology: Study population consisted of patients who had undergone revision stapes surgery. Indications, findings during surgery, and preoperative and post-operative audiological data were recorded. Success rates of the surgeries were evaluated statistically.
Results: Total of 105 cases was included in this study, and the major indication for surgery was hearing loss. Mean preoperative hearing threshold of the patients was 57.1 dB and the mean air-bone gap (ABG) was 27.4 dB; the respective postoperative values were 49.7 and 19.2 dB, respectively ($p<0.05$). Most common intraoperative pathologies were prosthesis-related problems and fibrotic bands/ adhesion in the middle ear.
Conclusions: Revision stapes surgery can yield successful results, especially with regard to persistent or late-onset conductive hearing loss. Likelihood of hearing gain may be decreased after repeated surgeries.

Introduction

Otosclerosis is a progressive disease of the bony labyrinth that may lead to conductive, mixed and rarely, sensorineural hearing loss. At present, there is no definitive treatment for otosclerosis, but surgical interventions may be effective in overcoming the conductive hearing loss in selected cases. Bone-conducting hearing aids or bone-anchored hearing implants are alternative options for these patients.[1] In addition, conventional hearing aids and active middle ear implants may be suitable for patients with mixed or sensorineural hearing loss.[1] However, cochlear otosclerosis may lead to profound or total hearing loss, for which cochlear implantation may be the only solution.[1]

Stapes mobilisation, lateral semi-circular canal fenestration, and total stapedectomy techniques have been performed to achieve better hearing levels in otosclerosis. Stapedotomy is the most commonly used technique at present.[1] Although the hearing outcomes of stapedotomy are generally satisfactory, deterioration of hearing may occur over time, thus necessitating revision surgery for otosclerosis.[2-8] In addition, vertigo and tinnitus may be additional indications for revision surgery.

Intraoperative findings in revision surgery may be related to the prosthesis, ossicles, and middle ear structures. The most common problems encountered during surgery are dislocation of the prosthesis and middle ear adhesions that adversely affect the mobility of the ossicles and prosthesis.

Here, we share our experience with revision otosclerosis surgery by discussing the indications for revision surgery and intraoperative findings. In addition, we evaluated the success rates of revision surgery for otosclerosis.

Materials and methods

Patients undergoing revision otosclerosis surgery at Izmir Bozyaka Education and Research Hospital, Department of Otorhinolaryngology between 1998 and 2014 were included in this retrospective study. The latest surgeries of patients who had undergone more than one revision surgery were evaluated. Indications were a persistent hearing loss, deterioration of hearing, total hearing loss, and vertigo. Preoperative audiological data and data on primary complaints were obtained in all cases. The transcanal approach was used to determine the pathology that had led to hearing loss or vertigo. The

required interventions were performed according to the pathology in the middle ear. Hearing thresholds were measured at 3 months postoperatively. The American Academy of Otolaryngology guideline values (0.5, 1, 2, 3, and 4 kHz) were used for pure tone audiometry. The distributions of the variables were evaluated with the Shapiro-Wilk test. Changes in dependent non-parametric variables were analysed with Wilcoxon's signed rank test using SPSS software (ver. 16.0; IBM Corp., Armonk, NY, USA).

Results

A total of 2,188 stapedotomy operations were carried out in our institution over the 16-year study period. Revision surgery was performed in a total of 108 cases. Three patients were not included in this study due to insufficient data, and we analysed the outcomes of the remaining 105 patients. In total, 46 of these patients (42.5%) were referred to our department; the remaining 59 (56.1%) were our own patients. The revision rate was 2.75%. There were 62 females (59%) and 43 males (41%).

The patients ranged in age between 17 and 70 years (mean, 45.2 years), and the follow-up period ranged from 3 to 65 months (mean, 30.8 months). The main complaints were a persistent hearing loss in 85 cases (80.9%), deterioration of hearing in 6 cases (5.7%), total loss of hearing in 4 cases (3.8%), and vertigo in 10 cases (9.5%) (Figure 1). Ninety-four patients had one revision surgery, while seven had two, three had three, and one had four revision surgeries. The mean preoperative pure tone air conduction (AC) threshold was 57.1 ± 17.5 dB and the mean air-bone gap (ABG) was 27.4 ± 9.3 dB. Four patients with total sensorineural hearing loss were not included in the statistical analysis regarding hearing evaluation.

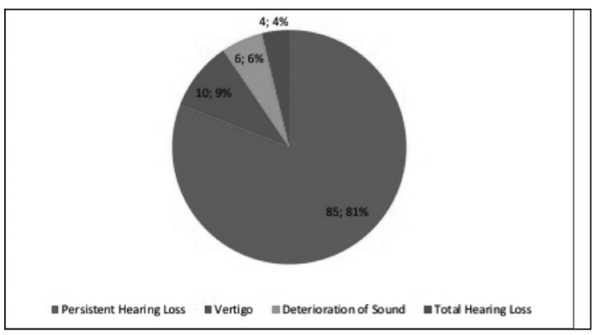

Figure 1
Symptoms of cases undergoing revision otosclerosis surgery.

Table 1
Intraoperative findings of the patients

Findings	Numbers
Prosthesis Problems	64
Fibrotic Bands/Adhesions	23
Necrosis of Incus Long Process	18
Intact Footplate	7
Perilymph Fistula	4
Repetitive Granuloma	4
Incudomalleolar Joint Fixation	3
Incus dislocation	1
Reobliteration	2
No findings	1

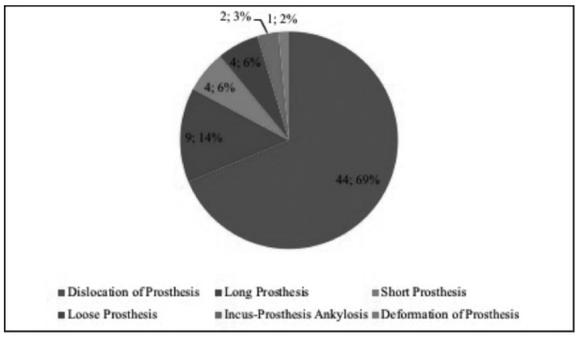

Figure 2
Intraoperative findings related to the prosthesis.

Surgical findings are presented in Table 1. As shown in Figure 2, problems were related to the prosthesis in 64 cases (60.9%). The main pathology was fibrotic bands and adhesions in 23 cases (21.9%), necrosis of the long process of the incus in 18 cases (17.1%), dislocation of the incudomalleolar joint in 1 case (0.9%), and fixation of the incudomalleolar joint in 3 cases (2.8%). The stapes footplate was intact in seven cases (6.6%) and obliterated in two cases (1.9%). Perilymph fistula was observed in four (3.7%) patients as the cause of vertigo and/or severe sensorineural hearing loss, and footplate granuloma was seen in four cases (3.7%).

Fibrotic bands and adhesions were lysed in 23 cases. The prosthesis was replaced in 65 cases (61.9%). Perilymph fistulas and repetitive granulomas were treated by sealing of the oval window with a tragal perichondrium graft in eight cases (7.6%). The necrosed long process of the incus was lengthened with hydroxyapatite bone cement (Otomimix, Gyrus Acmi ENT, Southborough, MA, USA) and a new Teflon prosthesis was

Table 2
Preoperative and postoperative hearing thresholds of the patients

	Preoperative	Postoperative	*P*-value
AC Average (dB)	57.1±17.5	48.7±18.5	0.001
BC Average (dB)	29.7±16.5	29.5±18.6	0.904
Air–boneGap (dB)	27.4±9.3	19.2±10.2	0.001
500 Hz AC (dB)	58.8±18.7	47.5±17.3	0.001
1000 Hz AC (dB)	53.9±18.4	46.1±19.9	0.001
2000 Hz AC (dB)	53.4±21.1	45.3±21.0	0.001
4000 Hz AC (dB)	62.3±20.6	55.7±24.3	0.001
SD Score	78.0±20.8	80.8±18.4	0.015

inserted in two cases (1.9%). A columellar effect was obtained with a total ossicular replacement prosthesis (TTP-Variac System; Kurz Medical, Dusslingen, Germany) in two patients. In nine cases, the symptoms were found to be related to an excessively long Teflon prosthesis, and the same piston was reinserted after shortening (8.5%). The incus was bypassed using a malleus piston (Smith and Nephew, Memphis, TN, USA) in five cases (4.7%) and a malleovestibular clip piston (Kurz Medical) in eight cases (7.6%). The problems in two of the cases with incudomalleolar fixation were resolved by lateral atticotomy and lysis (1.9%), but one required malleovestibular clip prosthesis.

The patients with preoperatively diagnosed total hearing loss were evaluated separately. In 101 cases, the mean AC threshold was 48.7 ± 18.5 dB and the mean ABG was 19.2 ± 10.2 dB. The patients showed significant improvement after revision surgery, with a mean hearing gain of 8.4 dB ($p<0.05$) (Table 2). ABG < 10 dB was observed in 52 patients (51.4%) and ABG < 20 dB was observed in 70 patients (69.3%). Use of the Shea malleus piston decreased ABG from 28.6 to 17.6 dB in five patients ($p<0.05$), while the ABG was decreased from 28.6 to 26.2 dB in eight patients in whom a malleovestibular clip piston was used; the difference was not significant ($p>0.05$).

The mean preoperative AC threshold was 47.5 dB and the mean ABG was 18.3 dB in 10 vertigo patients. The hearing showed further deterioration in these patients, and their mean postoperative AC threshold and ABG were 50.2 dB and 20.1 dB, respectively. The pathology was determined to be due to an excessively long prosthesis in four of these patients, and urgent revision surgery achieved a gap < 10 dB. In another patient, vertigo was controlled only after revision surgery, which was performed on day 7 after the initial surgery, and the AC level increased from 65 to 24 dB after reinsertion of the dislocated prosthesis. The pathology related to vertigo involved persistent granuloma in two patients and perilymph fistula in the others.

Among the patients referred to our department due to total sensorineural hearing loss, two showed repetitive granuloma and one showed perilymph fistula. There were no relevant intraoperative findings in one patient.

Discussion

Otosclerosis surgery can lead to satisfactory results for both the patient and the surgeon in selected cases. Stapedotomy is currently the most widely performed operation, and ABG ≤ 10 dB is accepted as the criterion for success.[9] Cases with less satisfactory hearing outcomes, or short- or long-term impairment of hearing quality, may require revision surgery.[3] Vertigo and severe tinnitus are additional indications of revision surgery for otosclerosis. Schmid et al.[4] reported that revision stapes surgery was required in 10% of patients who had undergone primary surgery. Our revision rate of 2.75% was therefore acceptable. This low rate of revision surgery may be related to surgeon ability or the types of materials used in surgery; in our centre, primary surgery for cases of otosclerosis is preferentially performed using a 0.6-mm thick fluoroplastic piston. This type of prosthesis is less harmful to the middle ear structures than metallic prostheses because its size and structure can be adjusted easily. In our opinion, consistent use of the same material reduces the probability of making mistakes during surgery.

The intraoperative findings in our cases indicated that the majority of problems were related to the prostheses. Dislocation of the prosthesis was observed in 41.9% of our patients, and this rate has been reported to range between 18.2% and 53.2% in different series.[2-7,10] A large stapedotomy hole, selection of a short prosthesis or fibrous bands, and adhesions were all suggested to be responsible for dislocation. Jovanovic[11] and Lescanne[12] reported that laser stapedotomy can reduce the rate of prosthesis dislocation. We preferred to use fat tissue harvested from the ear lobule to ensure a tight connection between the prosthesis and the hole in the footplate. In addition, the use of fatty tissue in stapedotomy can prevent perilymph fistula in the immediate

postoperative period. An improper stapes prosthesis length can also cause problems; a short prosthesis may lead to inadequate hearing gain, while a long prosthesis may cause vertigo.[13] Vincent et al.[3] reported a long piston in 4.6% of cases and a short prosthesis in 8.5% of patients. Schimanski et al.[13] detected a short prosthesis in nearly half of 343 cases of revision surgery. A loose prosthesis was suggested to cause pressure and aural fullness, as well as inadequate hearing gain, and was seen in 9% of patients.[4] A loose prosthesis was found in 3.8% of the patients in the present study. Fibrous bands and adhesions may also hamper mobility of the prosthesis and can lead to a conductive hearing loss in the long-term. Gros et al.[5] suggested that minor traumas could cause these adhesions and they advised utilisation of stapedotomy instead of stapedectomy.

Necrosis of the long process of the incus was another important finding in this study, in 17.1% of cases, and was also reported in 5%–49% of revision cases in various previous series.[2-7,10]. Different piston models have been suggested to prevent pressure necrosis.[14,15] Gerlinger et al.[15] studied 100 temporal bones and suggested that incus necrosis may not always be related to decreased blood flow, and can also occur due to mucosal damage and increased osteoclastic activity. Fluoroplastic prostheses have self-crimping features, and it is not necessary to squeeze the prosthesis to provide a tight connection with the incus. Therefore, blood flow is not impaired and the effect of pressure on the long process is reduced. In addition, we use the reverse stapedotomy technique in cases of otosclerosis to attach the prosthesis to the long process, and found that this technique was a more conservative intervention resulting in less incus damage and hypermobility. Lengthening of the long process with hydroxyapatite bone cement[16] or use of a specially designed prosthesis connecting the malleus to the vestibule[4] may be useful options for revision surgery. Meanwhile, some other groups have used a total ossicular replacement prosthesis (TORPs) with varying degrees of success.[17]

During revision surgery, a perilymph fistula was detected in 3.8% of our patients. Fluctuating hearing loss and/or vertigo may be the first signs of perilymph fistula. Such fistulas mostly occur within 5 years of surgery but have been reported as late as 13 years postoperatively.[18] Vincent et al.[3] reported that the majority of fistulas could be detected after the first 6 months following stapes surgery. We performed repeat operations in cases of a fistula between 1 and 17 months after the initial surgery. Postoperative computed tomography (CT) may be helpful in detecting perilymph fistula.[7] However, Bajin et al.[19] reported that pneumolabyrinth may be a sign of fistula only if detected more than 1 week after initial surgery.

Table 3

Audiological findings in different studies related to revision stapes surgery

Author	Number	ABG ≤ 10 dB (%)	ABG ≤ 20 dB (%)
Vincent et al.[3]	652	63.4	74.6
Lippy et al.[22]	483	71	86.3
De la Cruz et al.[21]	356	59.8	77.5
Hammerschlag et al.[20]	250	80	85
Somers et al.[18]	226	40	64
Schmid et al.[4]	172	55	84
Albers et al.[10]	106	55	96
Bakhos et al.[7]	89	52	80
Babighian et al.[6]	78	54	80
Gros et al.[5]	63	52.4	79.4
Our study	101	51.4	69.3

Audiological findings after surgery are valuable to determine the success of revision. An ABG < 10 dB was obtained in 51.4% of our cases. This rate varies between 40% and 80% in the literature, and ABG < 20 dB has been reported in 64%-96% of cases.[3-7,10,18,20-22] Therefore, our success rate of 69.6% can be considered acceptable (Table 3).

The rate of sensorineural hearing loss after stapedotomy varied from 1.3% to 7.7% in different series,[5,18,20-22] and the rate in the present study was 3.8%. Inner ear diseases mimicking conductive deafness, such as superior semi-circular canal dehiscence syndrome[23] or X-linked deafness,[24] should be taken into consideration. These cases are at risk of severe perilymph gushers and total hearing loss, and preoperative temporal bone CT should be performed in suspected cases.[24] Cochlear otosclerosis should be suspected in patients showing a gradual hearing loss. In such cases, preservation of residual hearing and use of a hearing aid may be advisable.[1] Of course, cochlear implantation remains another option if the hearing loss is beyond the limits of correction by hearing aids.[1]

This study had some limitations. First, it used a retrospective design. The prospective analysis would provide more information regarding the deterioration of hearing over time. It was not possible to determine the degree of hearing loss associated with individual findings, because there were multiple, major and simultaneous findings during the operations. In addition, it was not possible to compare hearing outcomes among those patients who did have a single finding, because of the disproportionate group sizes.

Conclusion

Primary stapes surgery is a very delicate intervention, and even the smallest surgical problems can lead to unsatisfactory results or deterioration of hearing over the long term. Persistent or late-onset conductive hearing loss can be corrected with revision surgery in the majority of cases. Severe vertigo and sensorineural hearing loss may be indicators of inner ear damage and necessitate urgent intervention. However, in most cases, the existing hearing loss cannot be recovered. The reverse stapedotomy technique using a fluoroplastic prosthesis can be employed to overcome conductive type hearing loss and avoid the various factors that may lead to revision surgery. Further prospective studies in larger numbers of cases are required to elucidate the reasons for the deterioration of hearing after stapes surgery and to determine the causes of an unsuccessful surgery.

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Ethics Committee Approval: this research was approved by the Izmir Bozyaka Education and Research Hospital Clinical Researches Ethics Committee under the number 02.12.2014-01.

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