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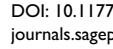

Revision Stapes Surgery in a Tertiary Referral Center: Surgical and Audiometric Outcomes

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Abstract

Objectives: To evaluate pure-tone audiometric results in otosclerosis patients undergoing revision stapes surgery following previous middle ear interventions.

Methods: A retrospective cohort study was performed in a tertiary referral center. Consecutive otosclerosis patients who underwent revision stapes surgeries, following previous middle ear interventions, for persistent conductive hearing loss, recurrent conductive hearing loss, or vertigo and had available postoperative pure-tone audiometry were included. Mean pre- and postoperative air conduction, bone conduction, and air-bone gap averaged over 0.5, 1, 2, and 3 kHz were obtained. Audiometric outcomes were obtained at 7 weeks postoperatively.

Results: In total, 63 consecutive otosclerosis patients who underwent 66 revision stapes surgeries were included. Air-bone gap improved significantly with a mean gain of 19 dB (95% CI, 15-22). Air conduction improved significantly with a mean gain of 18 dB (95% CI, 14-23). Bone conduction did not change significantly, with a mean deterioration of 0 dB (95% CI, –2 to 1). Air-bone gap closure to 10 dB or less was achieved in 38% of cases and to 20 dB or less in 80% of cases. Indication for surgery, previous type of procedure, primary cause of failure, and current surgical technique were not significantly associated with air-bone gap closure to 10 dB or less. Indication for surgery and primary cause of failure were associated with one another.

Conclusions: Compared to the available literature, a slightly larger gain in air conduction and air-bone gap was achieved in our study. Air-bone gap closure to 10 dB or less was achieved less often in our study.

Keywords

otology, otosclerosis, hearing loss, revision stapes surgery, audiometry, air-bone gap

Introduction

Otosclerosis is characterized by abnormal bone overgrowth that may cause fixation of the stapes footplate,[1] resulting in a conductive hearing loss. The (conductive) hearing loss can be treated using hearing aids or surgically in a procedure called stapedotomy. Primary stapedotomy is a highly successful procedure with reported success rates, defined as air-bone gap closure to 10 dB, between 72% and 94%.[2-4] Nonetheless, in some cases, primary stapes surgery is not successful, and a conductive hearing loss persists or recurs after surgery. Surgical success rates following revision stapes surgery are less favorable compared to primary stapes surgery, with reported success rates ranging between 40% and 80%.[5-10] It would be interesting to be able to predict postoperative success, particularly in revision stapes surgery, thereby enabling surgeons to better counsel their patients and more importantly, help them select patients for revision surgery.

In this retrospective study, we evaluated the indication for surgery, anatomical findings during revision surgery, type of surgical intervention performed, and postoperative pure-tone audiometric outcomes in otosclerosis patients undergoing revision stapes surgery in our tertiary academic center.

Materials and methods

Study population

A retrospective single-center cohort study was performed in a tertiary referral center in the Netherlands. Surgeries were

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performed by 2 otorhinolaryngologists (H.G.X.M.T and R.A.T) between January 2013 and January 2018. Patients undergoing revision stapes surgery for otosclerosis following previous middle ear interventions were included. Patients who had previously undergone middle ear inspection or an incomplete previous surgery were included as well as patients with a persistent or recurrent conductive hearing loss and patients with vertigo following primary stapes surgery. Cases with a complete air-bone gap closure or dead ear preoperatively as well as cases with chronic inflammatory sequelae, such as tympanosclerosis or fixation at the level of the posterior suprastructure, were excluded. Some patients underwent surgery on both ears or underwent multiple revision surgeries on the same ear. All of these surgeries were included, and therefore we refer to cases instead of patients throughout this article. Cases were excluded if the purpose of the surgical procedure was not improvement of the conductive hearing thresholds or postoperative audiometric results were not available. The preoperative, intraoperative, and postoperative characteristics of all cases were reviewed and tabulated in a computer database.

Surgical intervention

An endaural procedure with or without intercartilaginous incision was performed in all cases. The auditory ossicles and the chorda tympani nerve were identified after Rosen's incision and dissection of a tympanomeatal flap. Visual inspection by the surgeon intraoperatively was compatible with otosclerotic changes of the prefenestral or fenestral areas. Absence of chronic inflammatory sequelae such as tympanosclerosis and fixation at the level of the posterior suprastructure were ruled out. If possible, the chorda tympani nerve was preserved. Mobility of the auditory ossicles or a previously placed prosthesis was examined by gentle palpation. Adhesions were removed using microinstruments. If the stapes footplate had not already been (fully) fenestrated during previous middle ear surgery, a stapedotomy was performed. In these cases, the stapedial tendon was cut, the stapes superstructure was removed, and the stapes footplate was fenestrated with a KTP laser (Lumenis, Inc., Salt Lake City, Utah, USA), a Skeeter microdrill (Medtronic Xomed Inc, Jacksonville, Florida, USA), microinstruments, or a combination of these. If the previously placed prosthesis was dislocated, too long or too short, or no longer mobile, the prosthesis was replaced by a new prosthesis. A Causse Teflon prosthesis or a Kurz titanium prosthesis was used and placed between the incus and the fenestration when there were no incus or malleus abnormalities. In case of a short or erosive incus, a Kurz angular prosthesis was placed. In case of an absent incus, a Causse Teflon malleus prosthesis was connected to the malleus. The oval window was sealed with a blood clot and/or allogeneic tissue (Gelfoam, Pfizer, New York, New York, USA). In case of a small epitympanic space, the epitympanum was expanded with a Heermann chisel.

Pure-tone audiometry

The 1995 American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) Committee on Hearing and Equilibrium guidelines recommend the use of thresholds measured at 0.5, 1, 2, and 3 kHz when reporting hearing results.[11] Thresholds at 3 kHz are not routinely measured in the Netherlands, and therefore we interpolated 3 kHz thresholds by averaging the thresholds at 2 and 4 kHz.[12] The pre- and postoperative air-conduction and bone-conduction thresholds at 0.5, 1, 2, and 3 kHz and the corresponding air-bone gaps were averaged. In some cases, bone-conduction and air-conduction thresholds at 4 kHz exceeded the maximum volume that can be produced by our audiometer. In these cases, we do not know what the actual thresholds are at 4 kHz, and therefore we were not able to interpolate 3 kHz thresholds. We chose to average the thresholds at 0.5, 1, and 2 kHz in these cases (n = 7, 11%; at 7-week follow-up duration). Bone-conduction and air-conduction thresholds that were used for calculation of the air-bone gaps were obtained at the same time. Furthermore, air-bone gap closure to 10 dB or less and air-bone gap closure to 20 dB or less were calculated. The audiometric outcomes were obtained at 7 weeks postoperatively on average. Air-conduction thresholds were also evaluated with the Amsterdam Hearing Evaluation Plots.[13] For comparison of the results of our series with findings in the literature, articles published before 1995 were not included because prior to publication of the AAO-HNS guidelines, both the air conduction and bone conduction were not described in the majority of studies.

Statistical analyses

Means and standard deviations (SDs) and 95% confidence intervals (95% CIs) were calculated for continuous variables. Categorical variables were summarized by frequency and percentage. These variables were compared between different groups, such as before and after surgery and according to indication for revision surgery and surgical intervention. Continuous variables were tested for normality. A normal distribution of the data could not be assumed in any of the continuous variables. Therefore, the nonparametric Wilcoxon signed rank test was used to analyze the continuous variables. Categorical variables were tested using the Fisher's exact test. The statistical analyses were performed using IBM SPSS Statistics version 23.0 (SPSS Inc., Chicago, Illinois, USA).

Table 1. Baseline Characteristics of 66 Cases Undergoing Revision Stapes Surgery.

Variable	Cases Undergoing Revision Stapes Surgery
Number of cases	66
Age at surgery, mean (SD) in years	48 (12)
Sex, n (%) female	39 (59)
Bilateral otosclerosis, n (%)	35 (53)
Preoperative CT scan, n (%) yes	49 (74)
Previous surgical technique, n (%)	
Stapedotomy	34 (52)
Stapedectomy	5 (8)
Middle ear inspection	10 (15)
Incomplete previous surgery	7 (11)
Ossicular chain reconstruction	5 (8)
Other	3 (5)
Missing	2 (3)
Indication for revision surgery, n (%)	
Recurrent conductive hearing loss	26 (39)
Persistent conductive hearing loss	14 (21)
Incomplete previous surgery	24 (36)
Vertigo	2 (3)
Primary cause of failure, n (%)	
Incomplete previous surgery	24 (36)
Prosthesis dislocation	18 (27)
Prosthesis too short	10 (15)
Prosthesis too long	3 (5)
Incus erosion	3 (5)
Adhesions	4 (6)
Malleus fixation	2 (3)
Missing	2 (3)
Surgical technique, n (%)	
Stapedotomy without refenestration	21 (32)
Stapedotomy with (re)fenestration	36 (55)
Malleostapedotomy	5 (8)
Removal of adhesions	2 (3)
Mobilization of fixed malleus	2 (3)

Results

Study population

A total of 72 patients underwent 75 revision stapes surgeries. Eight cases were excluded because they underwent surgery for a perilymphatic fistula and the purpose of surgery was not improvement of conductive hearing. One case was excluded because postoperative pure-tone audiometry was not available. Therefore, we included a total of 63 patients who underwent 66 revision stapes surgeries. Table 1 presents an overview of the baseline characteristics of the included patients. Incomplete previous surgeries included removal of the stapes superstructure, followed by the encounter of a facial nerve dehiscence or floating footplate and the surgeon deciding not to complete the procedure and mobilizations or fenestrations of the stapes footplate without placing a prosthesis. Ossicular chain reconstructions included the placement of a partial ossicular replacement prosthesis in 3 cases and an incus interposition in 2 cases. Stapes fixation was overlooked in these cases. The main indication for revision stapes surgery was most frequently a recurrent or persistent conductive hearing loss. Of the cases with a persistent conductive hearing loss, 36% had previously undergone middle ear inspection or an incomplete previous surgery, and 21% had previously undergone stapes surgery with insufficient postoperative hearing improvement.

Intraoperative findings

An incomplete previous surgery was most often the primary cause of failure (36%, Table 1). This category includes cases in which a middle ear inspection was carried out previously, cases in which only the superstructure was removed after which the surgeon decided to abort surgery, and cases in which an ossicular chain reconstruction was carried out without fenestrating the fixed footplate. Floating footplates, obliterated oval windows, dehiscent facial nerves, narrow oval windows, and other anatomical abnormalities were reasons for not performing or completing stapes surgery. Consequently, most often a stapedotomy with (re)fenestration of the stapes footplate was carried out (55%).

Pure-tone audiometric results

The average follow-up duration was 7 weeks, with a range of 2 to 15 weeks. The postoperative mean air-bone gap was 15 dB (SD = 11) compared to 34 dB (SD = 12) preoperatively. The air-bone gap improved significantly with a mean gain of 19 dB (95% CI, 15-22). Air-bone gap closure to 10 dB or less was achieved in 38% of cases and to 20 dB or less in 80% of cases. The postoperative mean air-conduction threshold was 41 dB (SD = 17) compared to 59 dB (SD = 15) preoperatively. The air-conduction threshold improved significantly with a mean gain of 18 dB (95% CI, 14-23). The mean bone-conduction threshold did not change significantly, with a mean deterioration of 0 dB (95% CI, –2 to 1).

Figure 1 shows that (iatrogenic) cochlear damage of more than 10 dB occurred in 3 cases (5%). The postoperative bone-conduction threshold deteriorated 34 dB in 1 case. In the other 2 cases, postoperative bone-conduction threshold did not deteriorate more than 15 dB. There were no cases with a severe sensorineural hearing loss postoperatively, defined as a mean bone conduction threshold of more than 70 dB.

Pure-tone audiometric results stratified by indication for surgery are shown in Table 2. The biggest gain in air

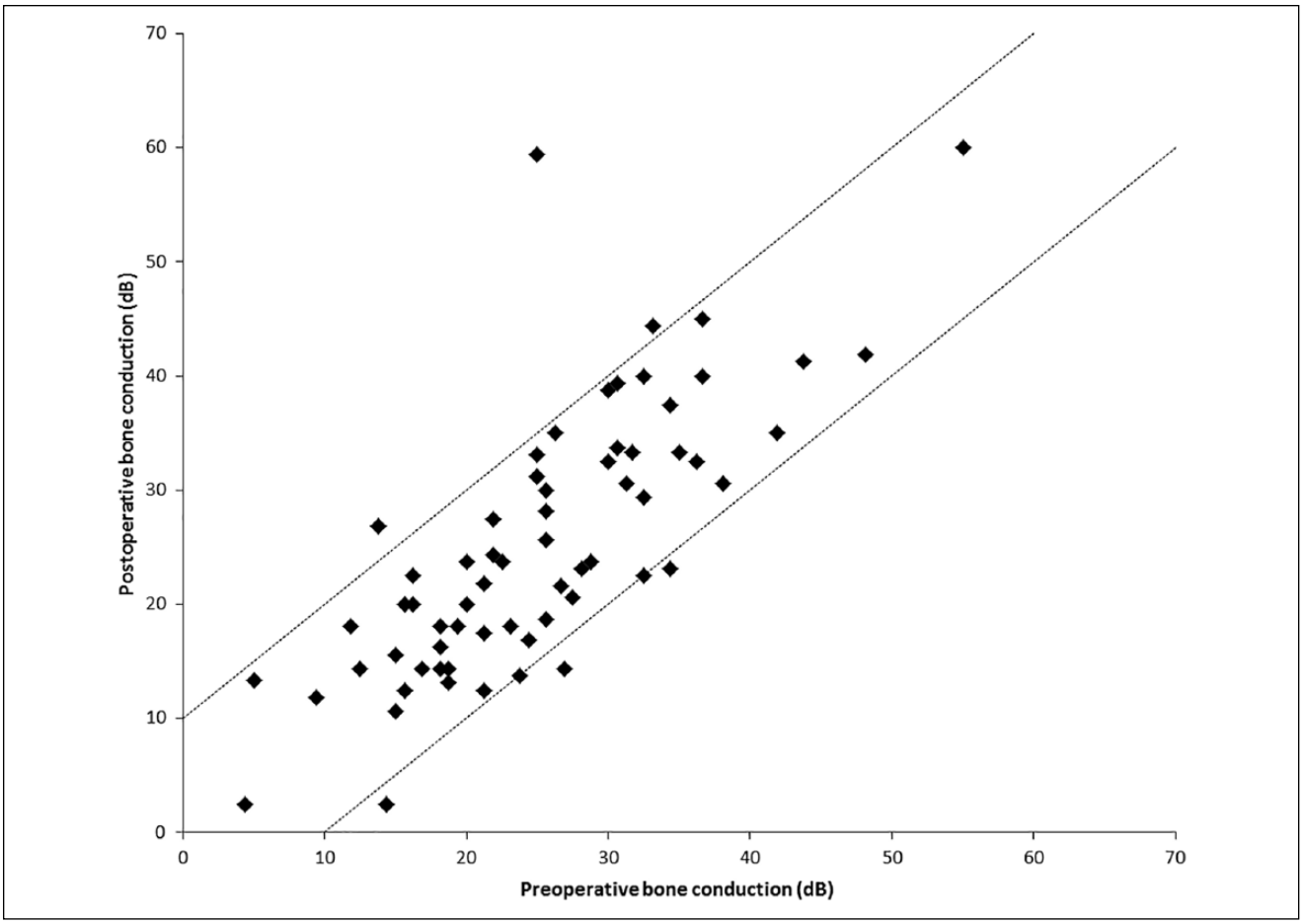

Figure 1. Amsterdam hearing evaluation plot (n = 66). The 2 diagonal lines enclose the cases in which bone conduction did not change more than 10 dB. If a case is located above both diagonal lines, it is defined as iatrogenic cochlear damage.

Table 2. Pure-Tone Audiometric Results Following Revision Stapes Surgery at 7 Weeks Follow-Up in 66 Cases, Stratified by Indication for Surgery.

	Mean Air Conduction			Mean Air-Bone Gap			Air-Bone Gap Closure	
Indication for Surgery	Preoperative dB (SD)	Postoperative dB (SD)	Gain dB (SD)[a]	Preoperative dB (SD)	Postoperative dB (SD)	Gain dB (SD)[a]	To 10 dB or Less (%)	To 20 dB or Less (%)
Recurrent conductive hearing loss (n = 26)	60 (16)	41 (15)	19* (18)	32 (13)	13 (9)	19* (16)	42	89
Persistent conductive hearing loss (n = 14)	57 (16)	46 (20)	12* (17)	33 (11)	21 (13)	12* (15)	21	57
Incomplete previous surgery (n = 24)	61 (11)	38 (16)	23* (15)	38 (10)	14 (10)	24* (13)	42	88
Vertigo (n = 2)	35 (16)	38 (21)	-3 (5)	16 (11)	17 (13)	0 (1)	50	50
Total (n = 66)	59 (15)	41 (17)	18* (17)	34 (12)	15 (11)	19* (15)	38	80

[a]Tested using the related-samples Wilcoxon signed rank test.
*$P < .05$.

conduction and air-bone gap was achieved in patients who had previously undergone middle ear inspection or an incomplete previous surgery (23 dB and 24 dB, respectively). Not surprisingly, the smallest gain in air conduction and air-bone gap was achieved in patients undergoing revision surgery for vertigo (–3 dB and 0 dB, respectively). Clearly

Table 3. Pure-Tone Audiometric Results Following Revision Stapes Surgery at 7 Weeks Follow-Up in 66 Cases, Stratified by Surgical Intervention.

	Mean Air Conduction			Mean Air-Bone Gap			Air-Bone Gap Closure	
Surgical Intervention	Preoperative dB (SD)	Postoperative dB (SD)	Gain dB (SD)[a]	Preoperative dB (SD)	Postoperative dB (SD)	Gain dB (SD)[a]	To 10 dB or Less (%)	To 20 dB or Less (%)
Stapedotomy without refenestration (n = 21)	51 (14)	43 (19)	8* (13)	29 (12)	18 (10)	10* (13)	19	67
Stapedotomy with (re) fenestration (n = 36)	62 (14)	36 (11)	27* (15)	37 (11)	12 (8)	25* (14)	50	92
Malleostapedotomy (n = 5)	71 (12)	61 (19)	10 (22)	43 (12)	24 (19)	18 (18)	20	60
Removal of adhesions (n = 2)	56 (22)	51 (39)	5 (17)	30 (7)	21 (24)	9 (17)	50	50
Mobilization of fixed malleus (n = 2)	63 (9)	50 (7)	13 (2)	26 (0)	10 (6)	16 (6)	50	100
Total (n = 66)	59 (15)	41 (17)	18* (17)	34 (12)	15 (11)	19* (15)	38	80

[a]Tested using the related-samples Wilcoxon signed rank test.
*$P < .05$.

inferior results were achieved in patients with a persistent conductive hearing loss, with a mean gain of 12 dB in air conduction and 12 dB in air-bone gap. Success rates and the rate of air-bone gap closure to 20 dB or less were also higher in patients who had previously undergone an incomplete surgery and patients with recurrent conductive hearing loss compared to patients with persistent conductive hearing loss.

Pure-tone audiometric results stratified by intervention are shown in Table 3 and Figure 2. The biggest gain in air conduction and air-bone gap was achieved with stapedotomy with (re)fenestration compared to all other surgical techniques (27 dB and 25 dB, respectively, compared to 5 dB to 13 dB and 9 dB to 18 dB, respectively). The smallest gain in air conduction and air-bone gap was achieved with the removal of adhesions (5 dB and 9 dB, respectively). Generally speaking, stapedotomy with (re) fenestration and mobilization of a fixed malleus were associated with higher success rates and higher rates of air-bone gap closure to 20 dB or less (50% and 92% to 100%, respectively). Stapedotomy without refenestration on the other hand was associated with the lowest success percentage (19%). Removal of adhesions was associated with the lowest rate of air-bone gap closure to 20 dB or less (50%).

Indication for surgery, previous type of procedure, primary cause of failure, and current surgical technique were not significantly associated with postoperative success. Indication for surgery and primary cause of failure were associated with one another ($P < .001$). In 50% of cases with a persistent conductive hearing loss, the prosthesis was too short, and in 29%, the prosthesis was dislocated. In 53% of cases with a recurrent hearing loss, the prosthesis was dislocated. All cases with incus erosion suffered from a recurrent hearing loss. In both cases with complaints of vertigo, the prosthesis was too long.

Discussion

Summary of main results

In this study, we evaluated hearing outcomes after revision stapes surgery in 66 otosclerosis cases treated in a tertiary referral center. Mean gain in air-conduction threshold was 18 dB, mean postoperative air-bone gap was 15 dB, and mean gain in air-bone gap was 19 dB. Air-bone gap closure to 10 dB or less was achieved in 38% of cases and air-bone gap closure to 20 dB or less in 80% of cases. None of the included cases suffered from a profound sensorineural hearing loss postoperatively.

Comparison with findings in the literature

Success rates of revision stapes surgery range between 24% and 80% in the available literature.[5-10,14-25] Our results lie well within this range. Table 4 compares our results to recently published studies on hearing results after revision stapes surgery. Success, defined as air-bone gap closure to 10 dB or less, was achieved in a lot fewer cases in our study compared to the other studies. However, the mean gain in air conduction and the mean gain in air-bone gap were higher in our study. The mean preoperative bone conduction was lower in our study compared with the other studies. Consequently, with similar mean preoperative air conduction, a larger reduction in mean air-bone gap had to be achieved in order to achieve a similar rate of air-bone gap closure to 10 dB or less. This raises questions about whether air-bone gap closure to 10 dB or less is

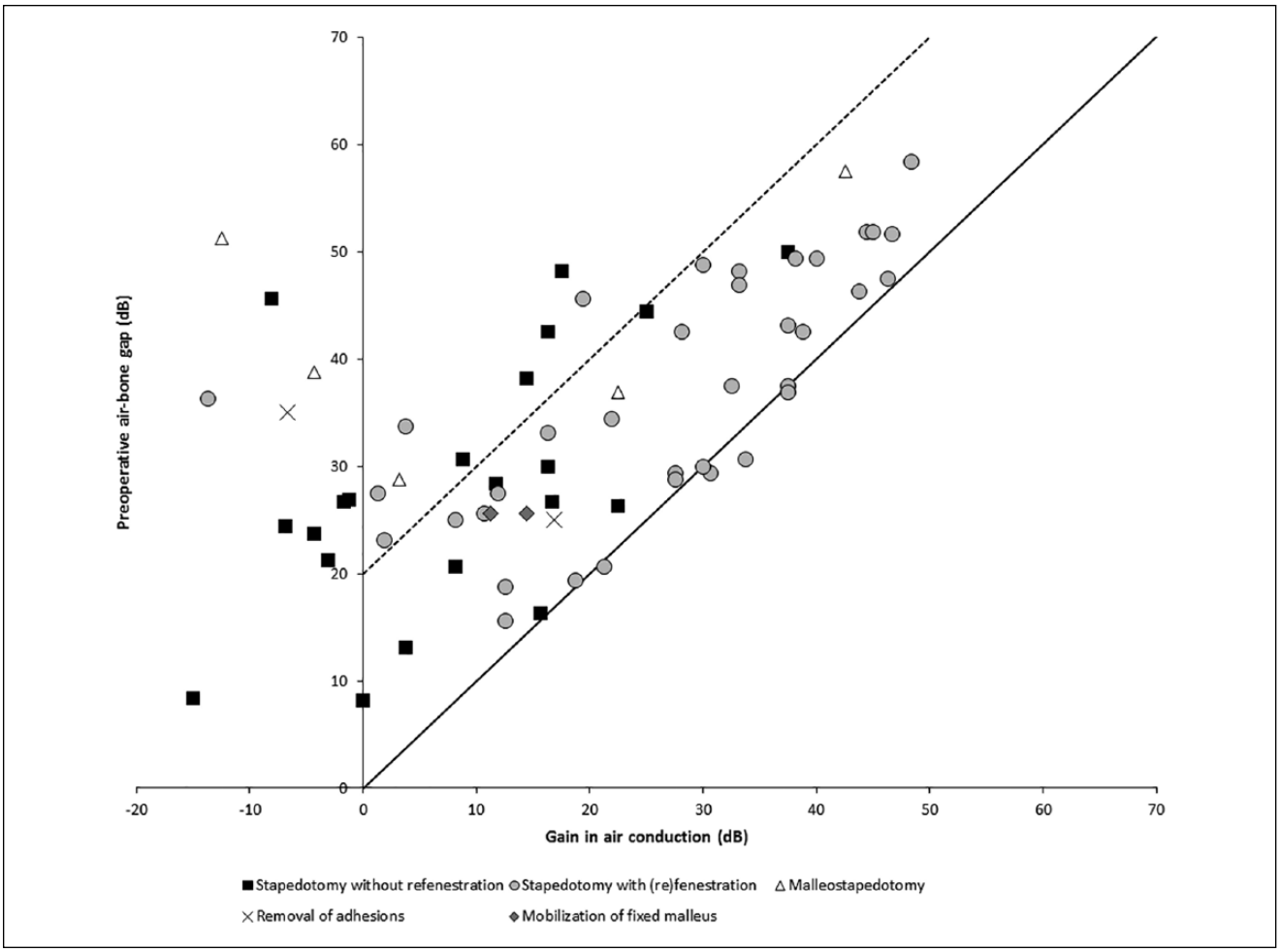

Figure 2. Amsterdam hearing evaluation plot (n = 66). The solid diagonal line indicates total air-bone gap closure. The area between the diagonal lines indicates successful surgery with an air-bone gap of 10 dB or less. Every point below the diagonal solid line indicates a gain in air conduction that is larger than one may expect from the preoperative air-bone gap (overclosure). An unsatisfactory surgical result in this graphic presentation is defined as a negative change in the air conduction threshold or a change in air conduction that was not enough to close the gap between the postoperative air conduction and the preoperative bone conduction to 20 dB or less. Every point above the dotted line indicates such a result.

representative in determining surgical success and whether other pure-tone audiometric results, such as mean gain in air conduction, are better suited to determine surgical success.

A recently published multivariable prediction model pointed out that type of the previously performed procedure, primary cause of failure, and type of the prosthesis placed during revision surgery are associated with postoperative success in otosclerosis patients undergoing revision stapes surgery.[26] In our study, previous type of procedure and primary cause of failure were not associated with success. The type of the prosthesis placed during revision surgery did not vary all that much in our study population; 61 cases received an incus-to-oval-window prosthesis, and only 5 cases received a malleus-to-oval-window prosthesis. In the majority of patients, a Causse Teflon prosthesis was placed between the incus and the footplate fenestration (80%). In our study, indication for surgery was associated with primary cause of failure. If a prediction model were to be used for patient selection for revision surgery and estimating hearing expectations preoperatively, it would be most useful to include variables that can be established preoperatively. Primary cause of failure cannot always be established preoperatively, but indication for surgery can be. In trying to determine the primary cause of failure preoperatively, it is important to read prior operative notes and obtain imaging.

Incomplete previous surgeries

An incomplete previous surgery was most often the primary cause of failure (36%, Table 1). In 22 out of 24 cases, an

Table 4. Comparison With Findings in the Literature.

Study	No. of Cases	Mean Air Conduction			Mean Bone Conduction			Air-Bone Gap Closure	
		Preoperative (dB)	Postoperative (dB)	Gain (dB)	Preoperative (dB)	Postoperative (dB)	Gain (dB)	To 10 dB or Less (%)	To 20 dB or Less (%)
Current study	66	59	41	18	25	25	0	38	80
Vincent[10] (2010)	538	59	46	13	31	34	−3	63	75
Bakhos[17] (2010)	89	56	42	14	30	29	1	52	80
Babighian[16] (2009)	78	60	43	17	28	29	−2	54	78
Gros[19] (2005)	63	62	49	13	35	36	−2	52	79
Lippy[8] (2003)	483	63	47	16	38	Missing	Missing	71	86

Table 5. Pure-Tone Audiometric Results Following Revision Stapes Surgery at 6- to 12-Month Follow-Up in 20 Cases.

Surgical Intervention	Mean Air Conduction			Mean Air-Bone Gap			Air-Bone Gap Closure	
	Preoperative dB (SD)	Postoperative dB (SD)	Gain dB (SD)[a]	Preoperative dB (SD)	Postoperative dB (SD)	Gain dB (SD)[a]	To 10 dB or Less (%)	To 20 dB or Less (%)
6- to 8-week follow-up	55 (13)	36 (14)	19* (17)	33 (11)	13 (7)	20* (14)	45	80
6- to 12-month follow-up	55 (13)	35 (13)	20* (18)	33 (11)	15 (8)	18* (14)	40	70

[a]Tested using the related-samples Wilcoxon signed rank test.
*$P < .05$.

outside otorhinolaryngologist carried out the primary surgery in a secondary center. In all of these cases, a regular stapedotomy could be performed without damaging the facial nerve or the inner ear. A well-exposed middle ear and oval window can be attained by performing a classic endaural Rosen's incision with or without intercartilaginous incision. The KTP laser or the Skeeter drill were used to fenestrate the stapes footplate in these cases. In some cases, stapes fixation was missed during primary stapes surgery. It is important to always test for mobility of the stapes footplate and test round window patency during middle ear surgery.

Long-term follow-up

At our center, follow-up duration is standardized at 6 to 8 weeks. A recent study shows that both air conduction and air-bone gap significantly improve between 6 weeks and 6 months postoperatively.[27] The improvement is maintained at 12 months follow-up. Pure-tone audiometry was performed at 6- to 12-month follow-up in only 20 cases in our study (30%, Table 5). In these 20 cases, hearing results were more favorable at 6- to 8-week follow-up compared to 6- to 12-month follow-up. These 20 cases received long-term follow-up as part of another clinical study[28] or because they were about to undergo another revision surgery. Therefore, these results are very likely to be biased.

Given that hearing outcomes improve up to 12 months postoperatively, it may be advisable to treat patients with a persistent postoperative conductive hearing loss conservatively and avoid revision surgery until 12 months after the initial surgery unless there is an urgent indication such as a perilymph fistula or an evident surgical cause for the failure such as a difficult interposition during the initial procedure and therefore a high suspicion of a misplaced prosthesis. In our study, the mean interval between the initial surgery and revision surgery was 77 months with a range of 2 to 399 months. Revision surgery was carried out within 12 months after the initial surgery in 24 cases (36%). In 14 of these, indication for surgery was an incomplete previous surgery.

Patient-related outcome measures

Audiometric results are useful in assessing surgical success and the (monaural) ability to detect sound and speech. However, audiograms do not provide us with information on effortless listening and the effect of high levels of listening efforts on quality of life. Health-related quality of life (HRQOL) is the relative burden of a disease on quality of life. Audiometric results and patient-reported quality of life do not necessarily correlate well in otosclerosis patients after stapes surgery.[29,30] In particular, patient-reported quality of life does not correlate well with postoperative

air-bone gap and change in the air-bone gap.[29] It is therefore our opinion that HRQOL should be implemented as an additional outcome measure after stapes surgery.

An essential requirement for implementation of measuring of HRQOL is the existence of a validated, disease-specific measurement instrument. Numerous studies have used self-designed questionnaires or generic HRQOL outcome measurements that have not been validated in a population of otosclerosis patients. The Stapesplasty Outcome Test 25 (SPOT-25) is the only validated questionnaire in otosclerosis patients undergoing stapes surgery.[31,32] The SPOT-25 must be validated for use in the Dutch language and culture before we can use the questionnaire in our otosclerosis patients. In a future study, we will validate the SPOT-25 for use in the Dutch otosclerosis population.

Conclusion

Pure-tone audiometric results of revision stapes surgery are inferior compared to primary stapes surgery. Nonetheless, our results show it is still a worthwhile intervention for otosclerosis patients with a recurrent or persistent conductive hearing loss or vertigo following previous stapes surgery. Air-bone gap improved significantly with a mean gain of 19 dB, and air conduction improved significantly with a mean gain of 18 dB. Air-bone gap closure to 10 dB or less was achieved in 38% of cases and to 20 dB or less in 80% of cases. Moreover, it is a safe procedure in experienced hands; no profound sensorineural hearing loss occurred, and in only 5% bone conduction deteriorated with more than 10 dB.

Declaration of Conflicting Interests

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