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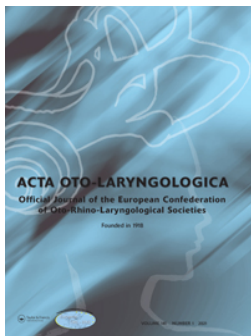
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Simultaneous bilateral stapes surgery after follow-up of 13 years

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ABSTRACT

Background: Eighteen patients underwent simultaneous bilateral stapes surgery in 2003–2006.

Objectives: We evaluated the long-term outcomes in this patient group, and assessed their hearing in noise and binaural hearing.

Material and Methods: Fifteen patients returned questionnaires concerning their hearing, taste function, and balance. Thirteen patients underwent pure-tone and speech audiogram, Finnish matrix sentence test, video head impulse test, and clinical examination on average 13 years after surgery.

Results: We found no significant difference in air- and bone conduction pure-tone average, speech audiometry, and the air-bone gap between the 1-year and the late postoperative visits. One patient had bilaterally a partial loss of the vestibulo-ocular reflex of unknown cause.

Conclusions and Significance: The hearing results 13 years after simultaneous bilateral stapes surgery remained good without any significant delayed complications. Simultaneous bilateral stapes surgery is a viable treatment option in selected patients with otosclerosis.

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Otosclerosis; stapedotomy; stapedectomy; bilateral stapes surgery; hearing loss; long-term results; speech-in-noise; Finnish matrix sentence test

Introduction

Otosclerosis is bilateral in almost 80% of the cases [1]. Nowadays stapedotomy is the most common surgical approach for otosclerosis, and long-term follow-up studies have shown no increased risk of sensorineural hearing loss (SNHL) in operated patients [2,3]. With successful bilateral stapes surgery, patients attain benefits of binaural hearing: improved sound localization, and hearing in noisy conditions [4]. Traditionally patients have undergone bilateral surgery sequentially.

Pure-tone audiograms alone are insufficient to depict hearing abilities in everyday noisy environments. This has given rise to various tests that assess speech recognition in background noise. While a conductive hearing loss attenuates the levels of both the speech signal and noise, a SNHL impairs speech understanding even though audibility is compensated by increasing the levels. Therefore, in SNHL, a higher signal-to-noise ratio (SNR) is required to retain speech understanding [5]. Furthermore, speech-in-noise tests can be utilized to assess binaural hearing abilities by measuring speech recognition thresholds (SRTs) in noise for co-located and spatially separated speech and noise configurations. The improvement in SRT by presenting the speech signal and noise from different directions with respect to the listener is denoted as spatial release from masking (SRM). SRM is largest when speech and noise emanate from different acoustic hemifields, and in excess of 6 dB when comparing SRTs in noise for co-located speech and noise in



the front with moving the noise source at 90 degrees on either side of the listener [6,7].

A cohort of 18 patients underwent a prospective study of simultaneous bilateral stapes surgery in Helsinki University Hospital in 2003–2006. Their hearing outcome and symptoms were studied at three months [8] and one year [9] postoperatively. The present aim was to evaluate the long-term outcomes of simultaneous bilateral stapes surgery in this patient group, and additionally, to assess their present-day hearing in noise for co-located speech and noise in the front as well as to evaluate their binaural hearing *via* SRM for a noise at 90 degrees on the side.

Material and methods

Eighteen patients (nine male, nine female; mean age 43, range 18–58 years) underwent simultaneous bilateral stapes surgery. Seventeen suffered from otosclerosis and one from osteogenesis imperfecta. Laser stapedotomy was performed for five ears and microdrill stapedotomy for 31 ears. In two cases, a partial stapedectomy was performed due to an unintended fracture of the footplate. A titanium prosthesis was used in 30 ears and a steel prosthesis in 6 ears. The diameter of the prostheses was 0.4–0.6 mm and the length was 4.0–4.5 mm. The details of the study set-up and surgical procedure have been described earlier [8,9].

We contacted all 18 patients and invited them to a follow-up visit. Fifteen out of the 18 patients returned two questionnaires. The first questionnaire was similar to the earlier studies, where the patients estimated their hearing,

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vestibular symptoms, taste sensation, and quality of life on a five-point scale. The second questionnaire was the Hearing Handicap Inventory for Adults (HHIA) [10] translated to Finnish, where the patients assess their hearing problems in 25 questions composed of a 13-item emotional subscale and a 12-item social/situational subscale with a total score ranging from 0 to 100 (larger score indicating more problems). Altogether 13 (72%) patients (six male, seven female; mean age 55, range 31–72 years) were met at the follow-up visit. The time from the surgery was 13 ± 0.2 years. One of us (TJ) interviewed the patient and made a clinical examination including tuning fork tests and otomicroscopy. All the patients gave informed consent for the study through a protocol approved by the Ethics Committee of the Helsinki University Hospital.

At the follow-up visit, we also conducted pure-tone and speech audiometry. We calculated the pure-tone average (PTA) for the mean thresholds at 0.5, 1, 2, and 4 kHz frequencies for air conduction (PTA-AC) and bone conduction (PTA-BC). We calculated the air-bone gap (ABG) by subtracting PTA-AC from PTA-BC. In speech audiometry we determined the maximum word recognition score (WRS) and the SRT in quiet.

Furthermore, we conducted the Finnish matrix sentence test (FMST), which is a validated speech-in-noise test in Finland [11,12]. The FMSTs were carried out in a sound field with randomized 20-sentence test lists with five-word sentences from the 5×10 words matrix. A non-fluctuating speech-spectrum shaped noise at a constant level of 65 dB SPL was used. To minimize the effect of repeated testing on SRT in noise [11,13], the patient first familiarized with the word matrix in writing. Subsequently, the patient was presented the first list of sentences with a fixed +10 dB SNR followed by another list with a varying SNR in an adaptive procedure converging to 50% speech recognition in noise. This familiarization phase was carried out with both the speech signal and the noise emanating from the front (S0N0). The three actual test lists were presented so that the noise came either from the front (S0N0), from the right (S0N+90), or from the left (S0N-90) at 90 degree incidence angle on the side of the patient in a counter-balanced order across patients. Since the patients were bilaterally operated, we combined the results of S0N+90, and S0N-90 settings. The results of the adaptive measurements are expressed as dB SNR: the smaller the dB SNR the better their hearing was in noise. To assess binaural hearing in noise we subtracted the mean of the S0N+90 and S0N-90 conditions from the S0N0 condition for each patient individually.

We also performed the video head impulse test (vHIT) with the ICS Impulse device running under Otosuite software (GN Otometrics, Taastrup, Denmark), and recorded the vestibulo-ocular reflex (VOR) gain of all six semicircular canals.

For statistical calculations, we used SPSS software, version 25 (SPSS Inc., Chicago, IL, USA). For group comparisons, we used one-way analysis of variance with Bonferroni correction, or Kruskal-Wallis test with Bonferroni correction in case of non-normal distribution of parameters and/or

non-continuous parameters. The data are presented as mean \pm standard error of mean (SEM).

Results

The results of the audiological findings at preoperative, 1-year postoperative, and late postoperative visit are presented in Table 1. We found no statistically significant difference between the PTA-BC values over the three time points ($p = .12$; one-way analysis of variance with Bonferroni correction). Moreover, we found no significant difference between the 1-year and the late postoperative values of PTA-AC ($p = .08$), ABG ($p = .97$), and SRT ($p = .38$). The mean air-conduction hearing thresholds over the three visits are presented in Figure 1. The high-frequency air-conduction hearing thresholds were 51 ± 4 dB HL at 6 kHz, and 65 ± 5 dB HL at 8 kHz. In WRS, we found no significant difference between the three time points ($p = .24$). The postoperative ABG categories are presented in Figure 2. Subjectively, six (40%) patients evaluated their hearing as good or excellent, eight (53%) as moderate, and one (7%) patient as impaired. There was no significant difference between the present data and the subjective hearing assessment at the 1-year postoperative visit ($p = .35$; Kruskal-Wallis test with Bonferroni correction). One out of 13 patients was using a hearing aid unilaterally because of slightly asymmetric hearing. Furthermore, bilateral hearing aids were fitted for one patient after the follow-up visit. Some of the other patients might also benefit from hearing aids but they were reluctant to hearing-aid fitting.

The mean SNR in the FMST was -8.3 ± 0.3 dB SNR in the S0N0 condition, and -12.4 ± 0.5 dB SNR in the S0N90 condition when averaged across the sides. The mean SRM was 4.1 ± 0.3 (range 2.8–6.2) dB SNR.

The mean HHIA score was 20 ± 6 , which indicates mild–moderate handicap. The mean scores of the social and emotional HHIA subscales were 8 ± 2 , and 12 ± 3 , respectively. The HHIA indicated no handicap in eight (53%), a mild–moderate handicap in five (33%), and a significant handicap in two (13%) patients. Despite some variation in SRM across patients, this did not correlate with the individual HHIA scores ($r = 0.13$, $p = .68$; Spearman's rank correlation).

The mean VOR gain measured by the vHIT was within the normative range in all semicircular canals. One patient had bilateral partial decrease of the horizontal VOR gain (0.67 on the right and 0.52 on the left) with overt refixation saccades. However, the postoperative period for this patient was uneventful, and she did not suffer from imbalance. The background for the partial, bilateral loss of the high-frequency VOR remains unclear, since the vHIT was not available preoperatively, and there was no history for dizziness. Eight (53%) patients had self-reportedly dizziness rarely or never, and seven (47%) patients occasionally. The severity of the dizziness was very mild in six (40%), mild in seven (47%), and moderate in two (13%) patients. The patients assessed that the dizziness had either no effect (73%) or mild effect (27%) on their daily activities.

Table 1. Audiological findings in patients that underwent simultaneous bilateral stapes surgery.

Parameter	Preoperative (n = 18)	1-year postoperative (n = 18)	Late postoperative (n = 13)
PTA-AC (dB HL; mean ± SEM)	42 ± 2	25 ± 1* (p < .0001)	30 ± 2* (p < .0001)
PTA-BC (dB HL; mean ± SEM)	21 ± 1	19 ± 1	22 ± 1
ABG (dB HL, mean ± SEM)	22 ± 1	6 ± 1* (p < .0001)	7 ± 1* (p < .0001)
WRS (%; median [range])	100 (92–100)	100 (84–100)	100 (92–100)
SRT (dB HL; median [range])	40 (25–60)	20 (10–40) ^a (p < .0001)	23 (15–40) ^a (p < .0001)

*Statistically significant difference between the preoperative value (one-way analysis of variance with Bonferroni correction).

^aStatistically significant difference between the preoperative value (Kruskal-Wallis test with Bonferroni correction).

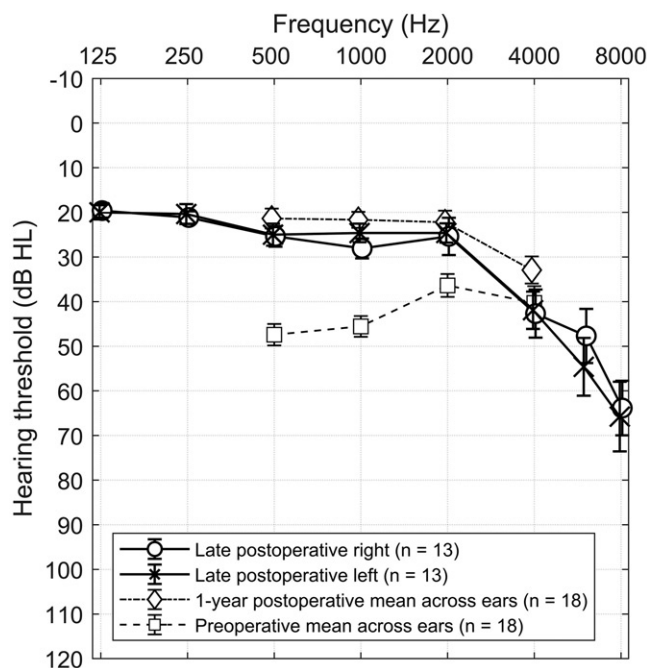


Figure 1. The average air-conduction hearing thresholds (mean ± SEM) at the preoperative, 1-year postoperative and late postoperative visits in patients that underwent simultaneous bilateral stapes surgery. The thresholds of 0.5–4 kHz are presented for the preoperative and 1-year postoperative visits and the thresholds of 0.125–8 kHz for the late postoperative visit.

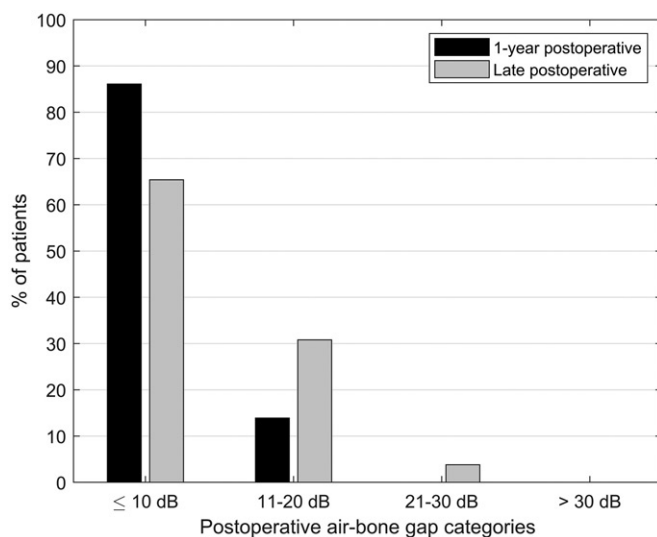


Figure 2. The air-bone gap categories at the two postoperative visits.

Nine (60%) patients self-assessed their taste function as good excellent, five (33%) as moderate, and one (7%) as weak. Eight (53%) patients assessed that ear surgery had no effect on their taste. Four (27%) patients assessed the effect as mild, two (13%) as moderate, and one (7%) as large.

After the initial bilateral stapes surgery, two patients underwent unilateral revision stapedotomy, both because the attachment of the prostheses to the incus had loosened. Revision surgery was thus needed in 2/36 (6%) ears. In both cases, the revision surgery took place 31 months after the initial surgery, and it was successful in closing ABG.

Discussion

In our follow-up study, we found no significant change in hearing performance between the 1-year and late postoperative testing implying that the results in simultaneous bilateral stapes surgery remain stable over a 13-year follow-up period. The sample size in our study is, however, too small to draw strong and generalizing conclusions on the long-term efficacy and safety of the procedure.

Our results in late ABG and PTA-BC are acceptable compared to a recent study with a 10-year follow-up after stapedotomy [14]. In our small group of patients neither PTA-AC nor PTA-BC changed significantly between the 1-year postoperative and the late postoperative visits indicating that not only was the ABG closure long-lasting but also the surgery posed no significant risk for sensorineural hearing loss at least in the frequencies 0.5–4 kHz. We found no changes in low-frequency pure-tone hearing thresholds, but a high-frequency (6–8 kHz) hearing loss was relatively common. In their study of 238 ears, Strömbäck et al. [15] found a significant hearing loss at 4–8 kHz in 6.5% of the ears one year after stapes surgery. In our small group of patients, it is difficult to distinguish the effects of aging, the progress of the otosclerosis, the surgery, and possible other factors affecting the high-frequency hearing.

In simultaneous bilateral stapes surgery patients, the S0N0 score of -8.3 ± 0.3 dB SNR in the FMST seemed somewhat worse than -10.6 ± 0.2 dB SNR in normal-hearing adults [13]. This seems acceptable since the patients in our study had in average a mild mixed hearing loss. The average SRM was also slightly less than what has been reported for normally-hearing listeners in the S0N90 condition (over 6 dB) [6,7]. In fact, our clinical results with the FMST suggest that SRM is approximately 10 dB in this condition, which is markedly more than the average SRM of 4.1 dB for the patients of the present study. Our sample size was most likely too small to reveal any correlations with the subjective data from the HHIA questionnaire.

The long-term vestibular performance in subjective assessment of the patients remained good after simultaneous surgery. Initial vestibular symptoms after the surgery were mild, and the present annoyance of dizziness was low on

average 13 years afterwards. Therefore, the risk for permanent imbalance after simultaneous, bilateral stapes surgery seems minute even over ten years postoperatively.

Taste disturbances are common after stapes surgery, but most recover within a year [16]. Based on our small group of patients, it is difficult to draw conclusions on how and to what extent the simultaneous bilateral stapes surgery affects taste in the long term. We did not address the issue systematically at the beginning of the study. Other factors as aging may contribute to taste, and we did not use any taste test to verify the possible changes objectively.

The amount of patients with otosclerosis and bilateral significant conductive component may vary depending on the disease and local circumstances including health care system characteristics. In western societies as in Finland, adequate surgical treatment is available fast and easily for all citizens, and most patients are not candidates for simultaneous surgery due to clinical factors, as the disease does not progress evenly between the sides. However, for some patients with simultaneous indication for surgery, simultaneous stapes surgery is a viable treatment option. We have continued offering simultaneous surgery for rarely available suitable patients of which some apt for simultaneous treatment. If the proportion of patients having a clear indication for simultaneous surgery is high enough, this approach may be beneficial for not only the individual patient, but the payer, too.

Conclusions

The long-term hearing results on average 13 years after simultaneous bilateral stapes surgery remain good without any significant delayed complications in our small patient group. Simultaneous bilateral stapes surgery is a viable treatment option in selected otosclerosis patients with significant bilateral conductive hearing loss.

Disclosure statement

The authors report no conflict of interest.

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