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Simultaneous bilateral stapes surgery

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Abstract

Conclusions. The patients recovered from the surgery as after unilateral surgery. The success rate for hearing improvement was good both subjectively and objectively, and this was also displayed in the quality of life. According to our study, simultaneous bilateral stapes surgery can be performed safely in selected patients with bilateral conductive hearing loss. *Objectives.* Otosclerosis is bilateral in the majority of patients. In this study we evaluated the outcome of simultaneous bilateral stapes surgery. *Subjects and methods.* Eighteen patients suffering from bilateral otosclerosis or osteogenesis imperfecta were prospectively included. After operation, hearing and vestibular function were followed by audiometry and visual feedback posturography (VFP). Patients estimated their hearing gain, the intensity of vestibular symptoms and quality of life score with a questionnaire during the follow-up period of 1 year. *Results.* The mean improvement in pure-tone average (PTA) air conduction (PTA-AC) was 18 dB (range 1–41 dB). The mean air–bone gap (AB-GAP) diminished from 22 dB (range 10–41 dB) to 7 dB on both sides (range 0–18 dB). The mean preoperative score of 2.3 for hearing improved significantly to 4.1 ($p < 0.001$). Vestibular symptoms were mild and temporary. The VFP was not permanently impaired in any of the patients. The quality of life score improved significantly from 3.4 to 1.3 postoperatively ($p < 0.001$).

Keywords: *Otosclerosis, stapedectomy, stapedotomy*

Introduction

A conventional treatment for otosclerosis with conductive hearing loss is surgery. Shea introduced total stapedectomy and reconstruction of the ossicular chain with an artificial prosthesis more than 40 years ago [1]. Surgical technique has since evolved to favor stapedotomy. Hearing results are good with both techniques [2,3].

In the case of bilateral disease, the feasibility of operating on the second ear is controversial. Some authors argue against bilateral surgery because of the risk of sensorineural hearing loss (SNHL), vestibular damage, or both [4–6]. If either complication were to occur bilaterally, it would create a major disability for the patient. The benefits of a second ear operation after successful unilateral surgery have also been questioned. It can be expected that the interaural difference will be well tolerated, if one ear has normal hearing, due to the dominance of the better hearing ear [7–9].

Nowadays, bilateral surgery is widely accepted due to the positive results of stapes surgery in long-term studies that show no increased risk of SNHL related to second ear operation [2,3,10–12]. However, there is no consensus concerning the optimal period between the two surgeries. The advantage of bilateral surgery is that the patient attains binaural hearing including the ability to localize sound [13–15]. If surgery was simultaneously performed on both ears, the total time spent in the hospital, overall medical leave, and the need for follow-up visits would be reduced.

Simultaneous bilateral operation has been successfully introduced in cataract surgery, where the complication profile resembles stapes surgery [16]. In both fields, bilateral complications would lead to major disabilities in perception. In ophthalmology

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the complications can be even more devastating, because opportunities for rehabilitation are limited when compared to rehabilitation in otology, where hearing aids and – in the worst case scenario – cochlear implants can be used.

In this study we evaluated the outcome and applicability of simultaneous bilateral stapes surgery.

Subjects and methods

The ethics committee of Helsinki University Central Hospital approved the study, and each patient gave written consent for the operation. Patients with bilateral conductive hearing loss were informed about the study by mail. Patients then had an appointment with the surgeon, and they were scheduled for either standard unilateral or experimental simultaneous bilateral stapes surgery according to the patient's preferences. All scheduled operations were primary operations. The patients were informed about the risk of $<1\%$ of unilateral, severe loss of sensorineural hearing and vestibular function. The risk percentage was derived from our institution's 20-years follow-up results for stapes surgery [3]. This would mean at minimum a bilateral risk percentage of $<0.01\%$ if the ears were considered independent from each other. We assessed that the actual risk of a bilateral complication would be between 0.01% and 1%. The surgeons who performed operations in this study were experienced senior surgeons. Their personal risk-rate was in agreement with these percentages.

Eighteen patients (nine men, nine women; mean age 43 years, age range 18–58 years) suffering from bilateral otosclerosis or osteogenesis imperfecta (one patient) were prospectively included. A single dose of cefuroxime 1.5 g (4 patients) or ceftriaxone 2 g (14 patients) was given as antibiotic prophylaxis. All dressings and instruments were changed after the operation on the first ear, and the second side was prepared for surgery separately. The same surgeon operated on both the ears under general anesthesia and the surgical approach was either transcanal (26 ears) or endaural (10 ears). Stapedotomy was done with a laser (5 ears) or micro-drill (31 ears). In two cases, a partial stapedectomy was done because of unintended fracture of the footplate. Prostheses were selected from different manufacturers or quality lots for each side to minimize the risk of infection or mechanical problem due to prosthesis. Titanium ($n=30$) or steel ($n=6$) piston prostheses, with a diameter of 0.4–0.6 mm and a length of 4.0–5.5 mm were used. All prostheses were crimped manually to the long process of the incus. After inserting the prosthesis, the opening on the footplate was sealed with small pieces of fascia or with blood.

Visual feedback posturograghy (VFP) was performed preoperatively and postoperatively to measure vestibular function. The VFP equipment is a custom-made force platform described more fully in our previous study [17]. Briefly, while standing on the platform, the patient's center of gravity (COG) was calculated and the movement of a COG marker was displayed on a computer screen. Patients were instructed to move their COG marker by leaning their body as rapidly and accurately as possible to given targets shown one at a time on the computer screen. A balance index (s/%) (BI) was calculated by dividing hit delay(s) to the targets with hold percentage (%) within the targets. According to our previous study, a BI ≤ 2.5 s/% can be considered normal [17].

The audiological examinations were carried out using a clinical audiometer, calibrated according to ISO standards. The mean thresholds at frequencies 0.5, 1, 2, and 4 kHz were used to calculate four-tone pure-tone average (PTA). Air conduction (PTA-AC) and bone conduction (PTA-BC) thresholds were recorded and the air–bone gap was calculated (AB-GAP; PTA-AC minus PTA-BC at the same time point). Closure of the AB-GAP and over-closure (mean average of preoperative BC at 1, 2, and 4 kHz minus postoperative BC values) were calculated. Speech discrimination audiograms were performed preoperatively and postoperatively. In addition, all patients estimated their hearing improvement, the intensity of vestibular symptoms, and quality of life score with a questionnaire containing a five-point qualitative scale.

Data derived during the follow-up period of 1 year were analyzed with a t test for paired comparisons for continuous parameters and with a Kendall's W test for non-continuous parameters. We used SPSS version 11.0 software (SPSS Inc., Chicago, IL, USA) and a p value of <0.05 was considered statistically significant.

Results

The mean preoperative PTA for AC was 43 dB (range 21–64 dB) and for BC 21 dB (range 8–34 dB), and the mean AB-GAP was consequently 22 dB (range 10–41 dB). Speech discrimination scores (SDS) varied between 96 and 100% (mean 99%) without any statistical difference between the first and second ears. Preoperatively, the mean PTA-AC was worse in the first ear (46, range 24–64 dB) than in the second (39, range 21–61 dB) ($p=0.014$).

One year after the surgery, the mean improvement in PTA-AC was 18 dB (range 1–41 dB) with mean PTA-AC 25 dB (range 13–46 dB). The mean AB-GAP diminished to 7 dB (range 0–18 dB). The

AB-GAP was within 10 dB in 81% of ears (29/36). The mean over-closure was 3 dB (range 10–18 dB). After surgery, no patient suffered a significant (>10 dB) sensorineural hearing impairment. Postoperative speech discrimination scores varied between 84 and 100%, with a mean of 98%. There was no statistically significant difference in SDS before and after the operation ($p=0.15$). Table I summarizes the preoperative and postoperative results on both sides. Subjectively, 13 patients (72%) appraised their hearing as good or excellent and the remaining 5 (28%) appraised it as moderate 1 year after the operation (Table II). The mean preoperative score for hearing was 2.3, and it improved significantly to 4.1 after the operation ($p<0.001$)

There were two cases of postoperative external ear canal infection. Both appeared on the second ear. They healed well with oral and topical antibiotics. Four patients had temporary taste disturbance after the operation, and in addition, two patients had minor disturbance prevailing a year after the operation. Neither of them considered it to be a significant problem.

Nine patients (50%) had vestibular symptoms within the first postoperative week. Using a five-point qualitative scale, six patients (33%) estimated that vestibular symptoms had mild to moderate influence on daily activities during the first postoperative week. All patients were discharged from the hospital as planned on the first postoperative day. The mean score for dizziness at 1 week of 1.9 did not alter significantly compared to that of 1.5 during the preoperative test (1 = no symptoms, 5 = severe symptoms). After 1 month two patients still had vestibular symptoms with mild influence on their activity. One year after the operation there were no residual vestibular symptoms. The mean score for dizziness was 1.1 at 1 month and 1.2 at 1 year postoperatively.

Table I. Audiological results in the first and second ears.

Parameter	First ear	Second ear
Preoperative PTA-AC (dB)	46 (24–64)	39 (21–61)*
Preoperative AB-GAP (dB)	26 (14–41)	19 (10–40)*
Postoperative AB-GAP (dB)	7 (0–15)	7 (0–18)
Number of patients (%) with postoperative AB-GAP 0–10 dB	14 (78)	15 (83)
Number of patients (%) with postoperative AB-GAP 11–20 dB	4 (22)	3 (17)
Over-closure (dB)	4 (−10 to 18)	3 (−8 to 17)
Postoperative PTA-AC (dB)	24 (13–36)	25 (13–46)
Number of patients (%) with postoperative PTA-AC 0–30 dB	12 (67)	15 (83)
Number of patients (%) with postoperative PTA-AC >30 dB	6 (33)	3 (17)
Postoperative SDS in % (range)	99 (92–100)	98 (84–100)
Number of patients with revision	0	1

PTA-AC, tone pure-tone average air conduction threshold; AB-GAP, air–bone gap; SDS, speech discrimination score.
*Significant difference between the ears ($p=0.01$).

Table II. Number of patients in different groups according to their subjective evaluation of hearing.

Hearing	Preoperative	1 month*	3 months*	1 year*
Severely impaired	2	0	0	0
Impaired	8	0	0	0
Moderate	7	0	0	5
Good	0	8	9	6
Excellent	0	8	8	7
Missing	1	2	1	0

*Significant difference from preoperative sensation ($p<0.001$).

The mean BI was 2.7 s/% (range 1.3–4.4) preoperatively. One week after the operation five patients (28%) had their BIs increased with 0.2–0.6 s/%, but the mean BI for the whole group of 2.2 s/% was slightly better than preoperatively. Three months after the operation, the mean BI was 2.0 s/% and only two of the patients had higher values than they had preoperatively. One year after the surgery the BI of all patients was equal to or better than their preoperative results, with a mean of 1.9 (range 1.0–3.4). Table III shows the subsequent changes in the BI.

The impact of the surgery on the quality of life score is depicted in Table IV. Patients estimated how their health status impacts on daily living, so that a diminished value demonstrates better performance and quality of life. The mean score improved significantly from 3.4 preoperatively to the final score of 1.3 at 1 year after the operation ($p<0.001$).

Discussion

Otosclerosis is bilateral in 60–70% of patients [18]. Therefore, for most patients, a decision about operating on the second ear ultimately has to be made. The present study was undertaken to evaluate the outcome of simultaneous bilateral stapes surgery. We applied a strict protocol to assess the risks and benefits of simultaneous bilateral stapes surgery in voluntary patients and the results show that this approach can be applied in appropriate and informed patients, without a significant delay in recovery and without compromising the long-term outcome.

Patients obtain binaural hearing after successful simultaneous bilateral surgery. De Bruijn et al. have

Table III. The mean (range) and the frequency of change in balance index preoperatively and postoperatively.

Parameter	Preoperative	1 week*	3 months**	1 year***
Balance index (s/%)	2.7 (1.3–4.4)	2.2 (1.4–3.3)	2.0 (1.2–2.7)	1.9 (1.0–3.4)
Improved (*n*)		13	16	18
Worsened (*n*)		5	2	0

Significant differences between preoperative and postoperative values: *$p = 0.02$, **$p = 0.001$, ***$p < 0.001$.

published a disability-oriented evaluation of bilateral stapedotomy. Both binaural hearing impairment (BHI) and percentage of impairment of the whole person (IWP) significantly decreased after the first surgery and again after surgery on the second ear, showing the importance of binaural hearing for the individual [14]. Our results that show a significant improvement in quality of life postoperatively is in concordance with the results obtained by De Bruinjns et al.

Stapes surgery carries a risk of severe SNHL. If this were to occur bilaterally, this would be devastating for the patient, although hearing can be rehabilitated with hearing aids or – in the most severe cases – with cochlear implantation. Because SNHL can occur years after operation, the risk of bilateral SNHL cannot be avoided with a waiting period of 1–2 years between the operations. Ludman and Grant reported 21 cases of severe or total SNHL in 1803 stapedectomies, and three of these arose more than 6 years after the operation [4]. Bilateral surgery does not seem to have an impact on the risk of SNHL. Faye-Lund et al. followed 122 patients with bilateral stapedectomy for an average of 12 years. SNHL was found in 21 ears, but no increased risk for SNHL after the second operation for either ear was found [11]. Mann et al. found 20 cases of severe SNHL after 1229 stapes operations, but none of these occurred bilaterally. Seven of these patients had received bilateral surgery [12].

The technique for stapes surgery has evolved from stapedectomy to small fenestra stapedotomy. Studies have shown that the operative method has no significant influence on the risk for SNHL [2,3]. Revision surgery contains a greater risk of SNHL [4]. Anatomical findings in the middle ear have been associated with an increased risk of SNHL and to the overall success rate of stapes surgery. Vincent et al. published long-term results of 3050 stapedotomies with 13 severe cases of SNHL. Four (31%) of these occurred in patients who had obliterative otosclerosis [19]. Daniels et al. reported anatomical findings and hearing results in 1800 bilateral stapedectomies. If total malleus head fixation or an obliterated footplate was found unilaterally or bilaterally, or if promontory overhang was encountered bilaterally, the success rate of having a bilateral AB-GAP <10 dB was significantly lowered [20]. Neither middle ear abnormality described by Daniels et al. was encountered in our study, nor was there any significant decline of over 10 dB in the PTA, or 15% in SDS postoperatively. The success rate of having an AB-GAP within 10 dB in at least in one ear was 100%, and in 81% of the patients it was achieved bilaterally. This success rate resembles those of larger studies [19,20]. The mean postoperative AB-GAP of 7 dB is comparable to that of 8 dB in our institution's previous study on unilateral stapes surgery [3]. Only one patient had an AB-GAP over 15 dB and thereafter underwent successful revision surgery. According to the protocol of this study, surgery would not have been preformed on the second ear if technical or anatomical problems appeared with the first ear. In one of the patients scheduled for simultaneous bilateral surgery, the operation on the second ear was postponed during the operation, because the footplate of the first ear was mobilized and a total stapedectomy had to be performed. Surgery on the second ear in this patient was performed at a latter date and the hearing results were successful in both ears.

Vestibular symptoms after bilateral surgery were found in half of the patients, which is slightly more than reported in the literature [21–23]. The information concerning vestibular symptoms was collected both orally and with a formal questionnaire. If any symptoms existed, they were certainly noticed. This may explain the higher prevalence of vestibular symptoms. Symptoms were usually mild and all patients were discharged from the hospital, as scheduled, on the first postoperative day. Only one patient had actual rotatory vertigo on the first postoperative day, but it subsided during the day.

Table IV. Subjective evaluation of general health's impact on quality of life on a 5-point qualitative scale.

Evaluation	Preoperative	1 month*	3 months*	1 year*
Very important	1	0	0	0
Important	8	0	0	0
Moderate	5	0	2	1
Mild	2	1	2	3
No effect	1	15	13	14
Missing	1	2	1	0

*Significant difference from preoperative value ($p < 0.001$).

Symptoms were rated on a five-point scale and nobody appraised their symptoms to be more than mild or moderate within the first postoperative week. Vestibular symptoms disappeared in all patients during the study period of 1 year. The BI in the VFP was followed and in five cases (28%) there was a minor regression in the results within 1 week, indicating some vestibular disturbance caused by the operation. In all patients the BI eventually recovered. A learning effect on repeated VFP tests explains the overall improvement in the BI. This effect was also seen in our study with healthy subjects [17]. In summary, our results on temporary, mild vestibular symptoms and signs are similar to those obtained with unilateral surgery [21–23].

Conclusion

According to our study, simultaneous bilateral stapes surgery can be performed safely in selected patients in the hands of experienced surgeons. In general, patients recovered from surgery as they would after unilateral surgery. The success rate of improving the air-bone gap within 10 dB was comparable to that of unilateral surgery. One significant advantage of bilateral surgery is that the patients could gain binaural hearing with one hospital stay and with less medical care. However, when considering the precautions and limitations of our present simultaneous approach, one should remain conservative, and advocate it only to voluntary patients with primary operations and normal anatomical conditions.

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