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Long-Term Hearing Outcomes Following Cochlear Implantation in Far Advanced Otosclerosis

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Abstract

Objective. This study aims to evaluate the long-term auditory performance at 5 years in patients with far advanced otosclerosis (FAO) after cochlear implantation compared to controls.

Study Design. A retrospective cohort study.

Setting. This study was conducted at a single tertiary medical center.

Methods. Patients with FAO were compared to a control group of postlingually deafened patients, selected from the same cochlear implant database. The following data were collected from medical records: age, sex, etiology, duration of hearing deprivation, prior stapes surgery, age at implantation, side of implantation, computed tomography scan findings, surgery details, postoperative complications, and hearing test results.

Results. A total of 41 patients with otosclerosis and 73 control cases were included in this study. The mean speech comprehension score at 5 years was 48.63% ± 24.66 in the otosclerosis group compared to 48.17% ± 23.08 in the control group ($P = .76$). Cochleostomy ($P = .01$), scala vestibuli insertion ($P < .001$), and postoperative dizziness ($P < .01$) were more common in the otosclerosis group. Facial nerve stimulation was observed in both groups: otosclerosis group 4 cases (9.8%) and control group 4 cases (5.48%) ($P = .39$). In the otosclerosis group, at 5 years, the average speech comprehension in patients with a previous stapedotomy was 39.3% ± 23.9 and 57.52% ± 22.45 in patients without a previous stapedotomy ($P = .02$).

Conclusion. Cochlear-implanted patients with otosclerosis achieve satisfactory long-term audiometric outcomes, although with higher surgical challenges and complication rates compared to other etiologies. Notably, we found that a history of stapedotomy can negatively impact long-term auditory outcomes after cochlear implantation.

Keywords

cochlear implantation, facial nerve stimulation, far advanced otosclerosis, hearing outcomes, long-term follow-up

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Otosclerosis is an osteodystrophy of the temporal bone, characterized by abnormal bone remodeling of the otic capsule in humans.[1-3] Histologically, bone resorption is observed, followed by vascular proliferation and the formation of sclerotic bone associated with a stroma of fibroblasts and histiocytes.[2] It affects 0.3% of the population, predominantly in white ethnic groups, especially in women (with a 2:1 ratio). It frequently affects both ears. Several etiological factors have been suggested to be involved in this pathology, including heredity, genetics, hormones, and viral infections.[1] The initial damage typically affects the footplate of the stapes, causing conductive hearing loss, which can be treated by stapedotomy or stapedectomy surgery or with a hearing aid. As the disease progresses, it can extend around the cochlea, leading to sensorineural hearing loss.[1] In about 10% of otosclerosis cases, this sensorineural hearing loss occurs concomitantly with the osteodystrophy progression toward the lateral wall of the cochlea's endosteum.[4-6]

Far advanced otosclerosis (FAO) was first described by House and Sheehy as a rare clinical condition, defined by an air-conduction threshold of at least 85 dB HL and an unmeasurable bone-conduction threshold.[7] In the era of cochlear implantation, speech discrimination scores are usually used, and the term "far advanced otosclerosis" is frequently applied to describe patients with otosclerosis who have severely reduced speech recognition abilities.

In patients with FAO, stapes surgery should be considered the first surgical option due to its good success

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rate and the possibility of providing functional hearing in a high percentage of cases, alongside the ongoing advancements in hearing aids.[8-10] Furthermore, stapes surgery does not preclude the possibility of future cochlear implantation in case of failure.

Most studies on cochlear implantation in otosclerosis patients have shown positive auditory outcomes, with improvements in vocal audiometry scores in silent environments, regardless of previous stapedotomy or stapedectomy.[3] Only 1 study showed a positive correlation between the extent of the disease on computed tomography (CT) and decreased auditory performance.[11] However, surgery can be complicated by ossification of the round window or the basal turn of the cochlea, causing implant insertion issues in 5% to 51% of cases, such as partial insertion or electrode translocation.[2] Finally, postoperative findings in otosclerosis patients revealed the need for higher stimulation levels and impedances, with increased rates of facial nerve stimulation (FNS) in its labyrinthine portion (10%). It's usually caused by the mid-electrodes, located at the upper basal turn of the cochlea near the labyrinthine section of the facial nerve and it can lead to decreased auditory performance.[2,3,12,13]

Many studies in the literature focused on hearing outcomes after cochlear implantation in patients with FAO, but few studies evaluated the long-term hearing outcomes in these patients (after 5 years).[14]

The primary objective of our study was to evaluate the long-term auditory performance at 5 years of patients with FAO after cochlear implantation by comparing their results to a control group. Secondary objectives included comparing peroperative and postoperative complication rates, particularly the risk of FNS and its impact on hearing outcomes compared to a control group.

Materials and Methods

This was a monocentric retrospective study conducted at a tertiary referral center between 2003 and 2019. Informed consent for data collection from medical records was obtained, and all procedures in the study were performed in compliance with the ethical standards of the institution and the 1964 Helsinki Declaration and its subsequent amendments (IRB approval: 2023-06178-01).

All patients included in this study received a cochlear implant for severe to profound sensorineural hearing loss with a speech discrimination score below 50% for words at 65 dB sound pressure level (SPL) in silence, using a monosyllabic phonetically balanced word list, with well-fitted hearing aids, according to national recommendations.[15]

Patients with FAO were compared to a non-FAO control group of postlingually deafened patients, selected from the same cochlear implant database. Each FAO patient was matched with at least 1 control. The 2 groups were comparable in terms of sex, age, age at implantation, period of implantation, implant type, preoperative pure tone average (mean of values at 500, 1000, 2000, and 4000 Hz), and duration of hearing deprivation. The control group was composed of patients implanted for other causes of hearing loss, such as progressive hearing loss, idiopathic deafness, familial hearing loss, sudden deafness, or Ménière's disease. Severe childhood hearing loss, meningitis, labyrinthitis, malformed cochlea, vestibular schwannoma, and neuroborreliosis were excluded from the controls to prevent false negative results in this group.

All FAO patients had at least 5 years of follow-up, while patients in the control group had less than 5 years of follow-up, but more than 2 years.

Fourteen cases were excluded with their matching control due to lacking follow-up, death, relocation, or explanted devices.

Otosclerosis was confirmed through a CT scan conducted before cochlear implantation, except for 1 patient but he had a previous stapedotomy surgery.

The following data were collected from medical records: age, sex, etiology, duration of hearing deprivation, prior stapes surgery, age at implantation, side of implantation, CT scan findings, surgery details, postoperative complications (such as tinnitus, dizziness, or FNS), and hearing test results.

CT scans of the temporal bones were analyzed by a senior neuroradiologist, noting fistula ante fenestram ossification, ossification around the cochlea, and the Rotteveel classification of otosclerosis as follows[11]:

- Grade 1: Otosclerotic focus anterior to the oval window or thickened footplate.
- Grade 2: Patchy retrofenestral involvement extending to the cochlea or surrounding the otic capsule.
- Grade 3: Diffuse involvement of the otic capsule.

Cochlear implantation was performed on an inpatient basis by senior otologists using standard surgical techniques, including mastoidectomy with posterior tympanotomy and access to the cochlea via the round window. The round window was prepared by removing the posterior superior bony overhang. If the round window was ossified, a cochleostomy was performed. The electrode array was inserted slowly and continuously into the tympanic ramp of the cochlea through a microincision in the anterior third of the round window membrane. No perilymphatic aspiration was performed.

Surgical observations, such as round window or cochlea ossification, incomplete insertion, and scala insertion, were documented. Implants from 2 different manufacturers were used, and the choice of implant brand and electrode type was recorded.

Audiometric assessments were conducted before and 5 years after cochlear implantation in a soundproof room, equipped with 3 loudspeakers positioned 1 m in front of the patient. Free-field speech audiometry in silence was conducted at 65 dB SPL. The pre-surgery measurements were taken from the ear that was to be implanted while

the patient was using a hearing aid, and the 5-year postsurgery measurements were conducted using the cochlear implant alone. Monosyllabic phonetically balanced word lists were used for this assessment.[15]

For control group patients with less than 5 years of follow-up, the most recent audiometry results available in the medical records were used, which were at least 2 years postimplantation for 9 patients, 3 years for 6, and 4 years for 2.

Statistical analyses were performed using JASP software (V0.19.1 Intel). The Shapiro–Wilk test was used to assess the normality of the distribution of quantitative demographic and audiometric data. If the data followed a normal distribution, the Student's t test was applied; otherwise, a nonparametric test such as the Mann–Whitney U test was used. For qualitative data, the Chi-squared test was performed, while Fisher's exact test was employed for data with fewer data points. For the final analysis, which involved comparing continuous and categorial data between 2 groups while accounting for repeated measurements, a linear mixed model with the Satterthwaite test method was used to compare the 2 groups.

To evaluate the correlation between CT scan grade and hearing performance, the nonparametric Kruskal–Wallis test was used.

Age, age at implantation, and hearing outcomes are expressed as means ± standard deviation (SD).

A P value of less than .05 was considered indicative of statistical significance.

Results

Demographic Data

A total of 114 patients were included in this study, conducted between 2003 and 2019. Among these, 41 were patients with otosclerosis and 73 were control cases. The cohort consisted of 44 women and 70 men, with a mean age of 75.9 ± 13.5 years. The average age at the time of implantation was 63.19 ± 12.16 years. In the otosclerosis group, 32 right ears and 9 left ears were implanted, while in the control group, 35 right ears and 38 left ears were implanted. The causes of hearing loss in the control group varied and included congenital hearing loss, Ménière's disease, progressive hearing loss, presbycusis, and undetermined or unknown causes of hearing loss.

When comparing each group independently, there was no significant difference between the otosclerosis and control groups in terms of age (otosclerosis group: 75.34 ± 12.79, control group: 76.2 ± 13.96, $P = .75$), age at implantation (otosclerosis group: 62.49 ± 10.62, control group: 63.59 ± 13, $P = .65$), sex ($P = .94$), or time of hearing deprivation ($P = .5$).

Main demographic data are shown in **Table 1**.

Surgery and Complications

Thirty-four patients received a MED-EL® (Innsbruck) cochlear implant (12 in the otosclerosis group and 22 in the control group), while 80 patients received a Cochlear® (Sydney) brand implant (29 in the otosclerosis group and 51 in the control group) ($P = .41$). A round window approach was used in 15 (36.6%) ears of the otosclerosis group, while cochleostomy was performed in 26 (63.4%) ears. In the control group, the round window approach was used in 45 (61.6%) cases and cochleostomy in 28 (38.4%) cases, with a significant difference between the 2 groups ($P = .01$).

Regarding the scala of insertion, the electrode array was inserted in the scala tympani in 33 (80.5%) patients and 8 (19.5%) in the scala vestibuli in the otosclerosis group. In contrast, all 73 (100%) patients in the control group received scala tympani insertions ($P < .001$). Cochlear ossification did not differ significantly between the 2 groups (otosclerosis group: 3 [7.3%] cases, control group: 8 [11%] cases, $P = .53$). Full insertion was achieved in 40 (97.6%) patients in the otosclerosis group and 70 (95.9%) patients in the control group ($P = .64$).

Postoperative tinnitus occurred in 10 (24.4%) patients in the otosclerosis group and 10 (13.7%) patients in the control group ($P = .15$), while vertigo was reported in 16 (39%) patients in the otosclerosis group and 10 (13.7%) patients in the control group ($P < .01$).

The occurrence of dizziness was not associated with the scala of insertion ($P = .88$) or the surgical approach ($P = .3$).

FNS was observed in both groups: otosclerosis group 4 cases (9.8%) and control group 4 cases (5.5%) ($P = .39$). Four patients had a perimodiolar electrode array, while 4 had a straight electrode array. Within the otosclerosis group, the distribution was identical, with 2 periomodiolar electrodes arrays and 2 straight electrodes arrays.

Main results of the surgery and its complications are presented in **Table 1**.

Hearing Outcomes

The mean speech comprehension score was 15.17% ± 19.9 before surgery and 48.63% ± 24.66 after surgery in the otosclerosis group, compared to 12.52% ± 17.26 before surgery and 48.17% ± 23.08 after surgery in the control group. The difference in hearing scores was not statistically significant before surgery ($P = .55$) or after surgery ($P = .76$) between the 2 groups.

Hearing outcomes did not differ according to electrode array insertion scala ($P = .28$).

The linear mixed model realized to evaluate the difference in hearing outcomes between the 2 groups over 5 years following cochlear implantation, using repeated audiometric measurements at 1, 2, 3, and 5 years, showed no significant difference ($F = 0.14$, $P = .71$) (**Figure 1**).

In the otosclerosis group, 20 patients had previously undergone stapedotomy. There were no significant differences between patients with or without previous stapedotomy, in the otosclerosis group, in terms of patient age, age at implantation ($P = .8$ and $P = .79$, respectively), sex ($P = .25$), or time of hearing deprivation ($P = .96$).

Table 1. Main Demographic Data of the Otosclerosis Group and the Control Group

		Cases (n = 41)	Controls (n = 73)
Age (mean)		75.34 years	76.20 years
Age at implantation (mean)		62.49 years	63.59 years
Sex	Female	16 (39%)	28 (38.4%)
Hearing deprivation (2 missing data)	0-5	15 (36.6%)	27 (37%)
	5-10	7 (17.1%)	17 (23.3%)
	10-15	8 (19.5%)	5 (6.85%)
	15-20	3 (7.3%)	5 (6.85%)
	20-25	3 (7.3%)	6 (8.2%)
	>25	5 (12.2%)	11 (15.1%)
Implant brand	Cochlear®	29 (70.7%)	51 (69.9%)
	MED-EL®	12 (29.3%)	22 (30.1%)
Side of implantation	Right	32 (78%)	35 (47.9%)
	Left	9 (22%	38 (52.1%)
Surgical approach	Round window	15 (36.6%)	45 (61.6%)
	Cochleostomy	26 (63.4%)	28 (38.4%)
Scala insertion	Scala tympani	33 (80.5%)	73 (100%)
	Scala vestibuli	8 (19.5%)	0 (0%)
Cochlear ossification	No	38 (92.7%)	65 (89%)
	Yes	3 (7.3%)	8 (11%)
Full insertion	No	1 (2.4%)	3 (4.1%)
	Yes	40 (97.6%)	70 (95.9%)
Tinnitus	No	31 (75.6%)	63 (86.3%)
	Yes	10 (24.4%)	10 (13.7%)
Dizziness	No	25 (61%)	63 (86.3%)
	Yes	16 (39%)	10 (13.7%)
Facial nerve stimulation	No	37 (90.2%)	69 (94.5%)
	Yes	4 (9.8%)	4 (5.5%)

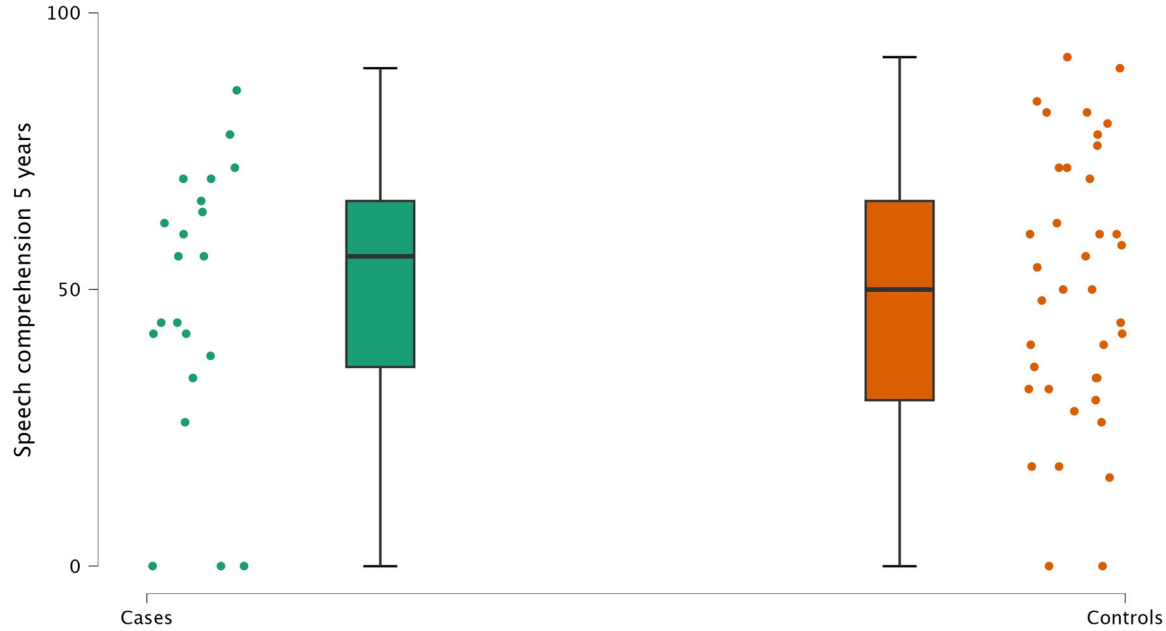

Figure 1. Hearing outcomes at the 5-year mark for the otosclerosis group (green) and the control group (orange). The difference between the groups was not statistically significant ($P = .76$).

The mean speech comprehension score before cochlear implantation was 9.60% ± 16.17 in the group with previous stapes surgery, compared to 20.48% ± 21.97 in patients without prior stapes surgery, although this difference was not statistically significant ($P = .12$). At the 5-year mark, the average speech comprehension was 39.3% ± 23.9 in the stapedotomy group and 57.52% ± 22.45 in the non-stapedotomy group ($P = .02$) (**Figure 2**).

Additionally, no differences were observed between the 2 groups regarding surgical findings (e.g., cochlear ossification [$P = .58$]) and postoperative complications (tinnitus, vertigo, or FNS [$P = .12$, $P = .9$, $P = .96$, respectively]).

Hearing outcomes in patients with FNS did not differ from the patients without FNS with mean speech comprehension at 5 years of 56.75% ± 16.99 and 47.69% ± 23.95, respectively ($P = .31$).

For patients with FNS, the mean speech comprehension at 5 years was 54% ± 21.35% in the otosclerosis group and 49% ± 33.57% in the control group ($P = .81$).

CT Finding

The CT results of 40 otosclerotic ears were obtained: 4 (10%) had fenestral disease (grade 1), 13 ears (32.5%) had a localised retrofenestral disease extending to the cochlea or surrounding the otic capsule (grade 2), and 23 ears (57.5%) had a diffuse disease of the otic capsule (grade 3). There were no significant differences in hearing outcomes between the 3 grades ($P = .81$) (**Table 2**). No significant correlation could neither be found between Rotteveel's CT scan classification and postoperative complications: FNS ($P = .19$), tinnitus ($P = .42$), or dizziness ($P = .33$).

Discussion

In this retrospective case-control study, we demonstrated that long-term hearing outcomes in patients with otosclerosis did not significantly differ from non-otosclerosis patients. Currently, this is the largest case-control study with long-term follow-up conducted on cochlear implant patients with otosclerosis.

Previous studies in the literature, which primarily focused on short- to mid-term hearing outcomes (less than 2 years) of FAO patients, reported similar results.[3-5,16,17]

We found that surgery was more complex in FAO patients, with an increased number of cochleostomies performed and scala vestibuli insertions, without any impact on audiometric outcomes as previously stated in the literature.[2,3]

Regarding postoperative complications, there was no difference in the incidence of tinnitus between the otosclerosis group and the control group; however, dizziness was more prevalent in the otosclerosis group. This observation had not been previously reported in the literature, and in our study, dizziness could not be attributed to the surgical approach or scala of insertion.

FNS was observed in 7.02% of patients. FNS is a rare complication of cochlear implantation, occurring in 0% to

Table 2. Mean Speech Comprehension and Standard Deviation at 5 Years, in the Otosclerosis Group, According to Rotteveel's CT Scan Classification

Rotteveel classification	Patients	Mean speech comprehension	Standard deviation
1	4 (10%)	50.50%	34.23
2	13 (32.5%)	44.00%	31.17
3	23 (57.5%)	50.96%	19.94

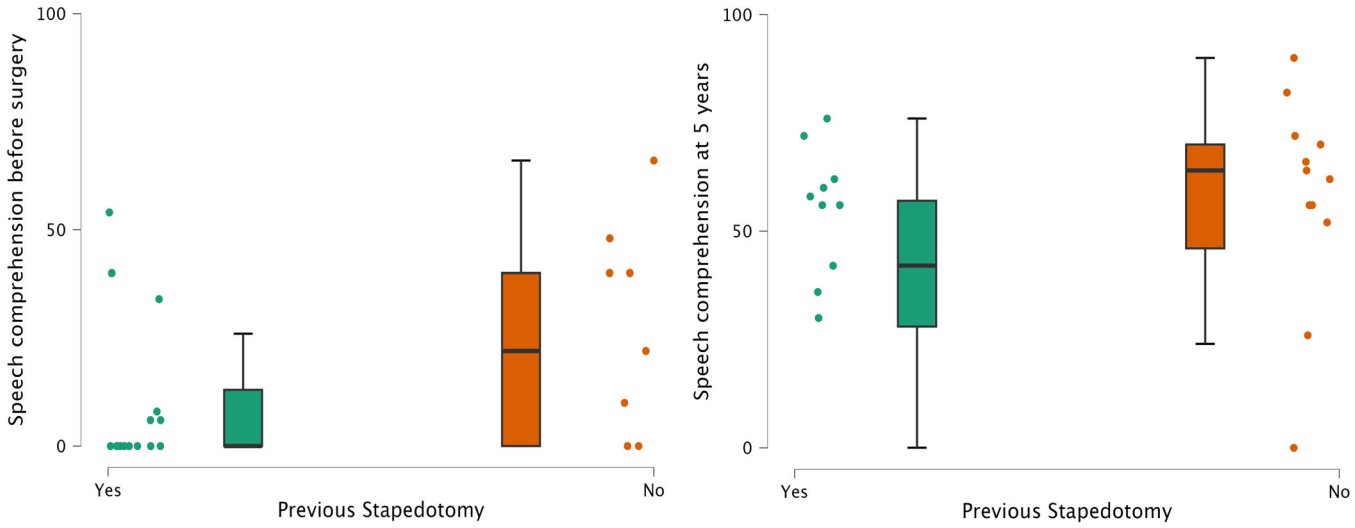

Figure 2. Speech comprehension before surgery and at the 5-year mark for the otosclerosis group, differentiated by whether or not a prior stapedotomy was performed (green = previous stapedotomy; orange = without previous stapedotomy). The difference was statistically significant at 5 years ($P = .02$).

38% of cases according to the literature.[2,3,11,18] It is well-established that FNS is more prevalent in otosclerosis patients. Various hypotheses have been proposed, including decreased impedance of the otic capsule due to osteodystrophy, increased bone conductivity, and changes in bone structure that form cavities, reducing the distance between the electrode and the facial nerve in its intralabyrinthine segment.[12,13,19] Most cases can be managed by modifying implant settings, such as deactivating electrodes, altering stimulation pulses, or reducing stimulation intensity. However, these adjustments can negatively impact hearing performance.[12,13]

In our study, the number of patients experiencing FNS was twice as many in the otosclerosis group, but the difference was not statistically significant. The presence of FNS did not affect hearing outcomes. Nevertheless, the sample size of patients with FNS in our study may have been too small to detect differences in hearing results.

FNS typically arises from mid-electrodes located near the upper basal turn of the cochlea, close to the labyrinthine portion of the facial nerve.[2,12,18]

It is more frequently observed with straight electrodes (6%-40%) compared to perimodiolar electrodes (0%); however, we were unable to confirm this in our study due to an equal number of patients with straight and perimodiolar electrodes.[2]

An interesting finding was that patients with a previous stapedotomy in the otosclerosis group appeared to have worse hearing outcomes at 5 years compared to those without prior stapedotomy. This result was not linked to age at implantation, longer periods of hearing deprivation, or surgical findings such as cochlear ossification. However, patients with a history of stapedotomy tended to present with poorer preoperative hearing levels, although the difference between the 2 groups was not statistically significant. While a similar result was reported in the literature with a smaller sample size, those patients were older at the time of implantation and presented with more severe conditions on CT scans, which was not the case in our study.[4]

Moreover, Marshall et al did not find any differences in outcomes for patients with prior stapes surgery, but their cohort was smaller, with a follow-up period of only 1 year.[18]

These findings challenge the notion that prior stapedotomy does not affect future cochlear implantation. Further studies should be conducted to confirm these observations.

Lastly, we used the Rotteveel classification, mainly used in the literature to compare hearing outcomes and extension of the disease on CT scans. Ninety percent of patients in our study showed retrofenestral disease extending to the cochlea or involving the otic capsule (grade 2 or 3). Similar findings were noted in the series by Rotteveel et al or Marshall et al, with 77% and 75% of patients having retrofenestral disease, respectively. The proportion of patients with purely fenestral disease (grade 1) was comparable with 7% in the study by Rotteveel et al and 17% in the study by Marshall et al.[11,18]

As in other studies, this finding did not influence hearing outcomes in our study.[11,18]

We acknowledge several limitations in our study, including its retrospective design and the limited number of patients included, but given that it concerns a rare condition, these limitations are understandable. Additionally, 17 patients in the control group had less than 5 years of auditory follow-up but more than 2 years. The matching criteria based on age, sex, age at implantation, period of implantation, implant type, duration of auditory deprivation, and preoperative tonal hearing loss limited the selection of control patients, which justifies this choice. We also assumed that, after 2 years, the auditory performance of the implant in the control patients would be stable.

Conclusion

In this case-control study, we confirmed the satisfactory long-term audiometric outcomes of cochlear-implanted patients with otosclerosis, showing similar auditory results to those with other etiologies. This study reaffirmed the predictable surgical challenges during implantation and noted a higher complication rate, with more frequent postoperative dizziness in this population. However, the rate of FNS showed no significant difference between the 2 groups in our study. Our results show a possible negative effect on hearing results of previous stapes surgery, not previously shown in the literature. Further studies are needed to confirm these results.

Author Contributions

Raphaële Quatre, data collection, analysis, interpretation, writing; **Martin Eklöf**, data collection, analysis, review; **Jeremy Wales**, review; **Åsa Bonnard**, design, interpretation, review.

Disclosures

Competing interests: None.

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Åsa Bonnard is the Principal Investigator.

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