Otosclerosis: Thirty-Year Follow-Up After Surgery
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Objectives: The aims of this study were to evaluate the hearing outcomes 28 to 30 years after stapedectomy in patients with surgically confirmed otosclerosis, and to evaluate inner ear involvement.

Methods: A retrospective clinical study was performed. Sixty-five consecutive patients who underwent stapedectomy at a tertiary referral center between 1977 and 1979 were included in the study. Medical records, including preoperative and postoperative audiograms, were reviewed, and a long-term follow-up clinical examination and pure tone audiometry were performed. The hearing outcome was compared with that of a reference population (ISO 7029) in terms of age and gender.

Results: Thirty years after stapedectomy, 66% of the patients’ ears studied showed a moderate to profound hearing loss. The deterioration was mainly caused by a sensory hearing loss. The hearing loss was significantly greater than that in the reference population for both air and bone conduction thresholds at the early and late stages of the disease. A large majority of the patients (88%) had bilateral otosclerosis.

Conclusions: Patients with otosclerosis have a sensorineural hearing loss that cannot be explained by age. Otosclerosis should be regarded as a middle and inner ear disease. Almost all patients with otosclerosis are in need of ongoing audiological rehabilitation and hearing aids.

Key Words: hearing threshold, long-term follow-up, otosclerosis, sensorineural hearing loss, stapedectomy.

INTRODUCTION
Otosclerosis is a mysterious disease that has confused and interested clinicians and researchers for centuries. In 1704, Antonio Maria Valsalva reported findings of a stapes fixation caused by ankylosis. The medical entity of hearing loss associated with stapes fixation was first described as a specific disease of the ear by Adam Politzer in 1893. Earlier, the ankylosic stapes was generally regarded as a complication of catarrhal inflammation of the middle ear and the hearing loss was considered a nervous deafness, because the tympanic membrane was intact.1 The etiologic and pathophysiologic mechanisms remain unknown despite intensive research. Different theories have been postulated; they include viral,2,3 endocrine, hormonal,4 and autoimmune factors.5 Genetic factors appear to play a vital role, and several genes have been localized, but no true candidate gene has as yet been identified.6-12 It is still not known whether the postulated autosomal dominant inheritance with reduced penetrance is the only mode of transmission, because approximately half of cases appear to be sporadic.13 Because the cause of otosclerosis is unknown, the disease remains incurable. The treatments that can be implemented are symptomatic: hearing aids or surgery to compensate for hearing loss, and medical treatment with sodium fluoride or bisphosphonates to reduce the progression of cochlear otosclerosis.14

Otosclerosis has a prevalence of approximately 0.3%15 in Western countries, with a peak onset in the third decade. Clinical otosclerosis is twice as common in women. It has traditionally been regarded as a middle ear disease, and during the past 50 years the development of surgical methods has been successful. In 1958, stapedectomy was introduced by Shea.16 Later, many modifications were made, and stapedotomy is now the most widely used technique.17 Many studies have shown good surgical results, including closure of the air-bone gap (ABG), on both a short- and long-term basis (up to 32 years).18,19 The inner ear component in otosclerosis has been extensively studied and debated. Histologic studies have questioned the relationship between histologic cochlear otosclerosis and sensorineural hearing loss.20-21 Audiological studies...
have reported various results. Several studies have reported a stable bone conduction (BC) threshold, whereas others have demonstrated a sensory hearing loss progression of various degrees. The sensorineural hearing loss has been interpreted as being age-related in the majority of cases.\(^2\) In contrast, a 2006 study by Topsakal et al.\(^2\) demonstrated a preoperative sensorineural hearing loss disproportionate to age. The term cochlear otosclerosis, which was previously only used to describe histologic otosclerosis with the replacement of the endosteal layer of the cochlea, has subsequently been used in conjunction with clinical otosclerosis to refer to sensorineural hearing loss that is presumably caused by otosclerosis, in contrast to age-related hearing loss.

In this study, the term cochlear otosclerosis refers to sensorineural hearing loss disproportionate to age in patients with otosclerosis. The question of the nature of the sensorineural hearing loss in otosclerosis remains unclear, and as there is a long lifetime expectancy with the disease, it is important to pursue long-term follow-up studies of audiological function. It is also of great importance to improve clinical expression and phenotype studies.

The aims of the study were 1) to analyze hearing in a group of consecutive patients who underwent stapedectomy for otosclerosis 28 to 30 years earlier, 2) to evaluate the degree of cochlear involvement in otosclerosis by comparing hearing loss in patients with otosclerosis with that in an age-matched reference population, and 3) to compare long-term hearing deterioration in operated ears with that in nonoperated otosclerotic ears. The study was reviewed and approved by the Regional Ethical Review Board, Gothenburg, Sweden.

**MATERIALS AND METHODS**

**Patient Selection.** The study included consecutive patients who underwent stapedectomy between 1977 and 1979 at the Department of Otolaryngology, Sahlgrenska University Hospital (Gothenburg, Sweden), a tertiary referral center. We included only patients born in 1930 or later who underwent stapedectomy between 1977 and 1979 for otosclerosis (i.e., progressive conductive hearing loss, impedance measurements indicating stapes fixation, and peroperative findings of stapes fixation). Ninety-three patients were invited to participate, and 65 subjects agreed to enter the study after giving their informed consent. The study population consisted of 42 women (65%) and 23 men (35%), all Caucasian. The mean age at surgery was 36 years (range, 20 to 48 years; SD, 6.6 years). The mean age at follow-up was 65 years (range, 48 to 77 years; SD, 6.6 years): for women 66 years (range, 48 to 77 years) and for men 64 years (range, 54 to 73 years). The ear that underwent surgery between 1977 and 1979 is referred to as the study ear, and the other is referred to as the control ear.

**Surgical Methods.** In 62 of the 65 patients, stapedectomy was the primary form of surgery for the study ear. Three patients had had stapes mobilization before stapedectomy. A wire prosthesis and fascia to cover the oval window niche were used in the majority of cases. A Teflon wire prosthesis and perichondrium were used in 7 of the 65 cases. Surgery was performed by 11 surgeons.

**Preoperative and Postoperative Audiometric Data (1977 to 1979).** The patients' medical records were reviewed. An audiogram was obtained less than 1 month before stapedectomy, except for 2 subjects (6 and 14 months before stapedectomy). Postoperative audiograms were obtained 1 to 34 months after stapedectomy (mean, 6.5 months; SD, 5.8 months). Preoperative and postoperative audiograms were available for 61 of the 65 patients: frequencies from 0.25 to 8 kHz were tested for air conduction (AC), and frequencies from 0.5 to 4 kHz for BC. The ABG was calculated, as well as the pure tone average (PTA) for AC and BC at 0.5, 1, 2, and 4 kHz. The guidelines from the Committee on Hearing and Equilibrium\(^2\) regarding the 4-tone PTA for 0.5, 1, 2, and 3 kHz could not be followed, because 3 kHz was not included in preoperative and postoperative testing.

**Follow-Up Data (2007 to 2008).** During the follow-up, an otomicroscopic examination and a structured interview (by Y.D.R.) were performed, as well as an audiological assessment. Audiological assessments were carried out with a clinical audiometer (AC 30, Interacoustics) calibrated according to the norms of the International Standards Organization. A pure tone audiogram including frequencies from 0.5 to 8 kHz was obtained. For AC and BC thresholds, the PTA values and ABG (0.5, 1, 2, 4 kHz) were calculated. Stapedial reflexes were tested in the nonoperated ears (at 0.5, 1, and 2 kHz), with a maximum stimulation of 110 dB. During the follow-up, a nonoperated control ear was considered to have otosclerosis if the audiogram showed a conductive or mixed hearing loss with a significant ABG (10 dB at 2 or more frequencies or 15 dB at 1 frequency) or with pathological stapedial reflexes.

The stapedial reflexes were considered pathological if no reflexes could be measured, provided that the hearing loss did not exceed 30 to 40 dB if conductive and 50 dB if sensorineural on the stimulus side, or if a biphasic reflex pattern was noted.\(^2\) The hearing was compared with that of a reference group from the ISO 7029 according to age and gender.\(^2\)
The BC value in the otosclerotic ears without surgery (23 of 65) was corrected according to the Carhart effect (5 dB at 0.5 kHz, 10 dB at 1 kHz, 15 dB at 2 kHz, and 5 dB at 4 kHz).22,29

Statistical Analysis. Patients with otosclerosis were compared with an otologically normal population.28 For each variable reflecting hearing deviation, a z-score was calculated. The z-scores were based on the 10th, 25th, 50th, 75th, and 90th percentiles presented for the normal material for each frequency and age at 10-year intervals. The 90th percentile was assigned the value of 1.28 (according to the normal distribution), the 75th percentile was assigned 0.67, the median was 0, the 25th percentile was −0.67, and the 10th percentile was −1.28. To obtain z-scores between and beyond the given percentiles, we used a linear regression model to interpolate and extrapolate the association between the z-score and the variable of hearing deviation. These linear regressions were piecewise linear, with breakpoints in the medians for each age and frequency. A z-score described how the values for the hearing deviation variable for patients with otosclerosis were related to those of the normal population of the same age and gender and at the same frequency.

Fisher’s test for paired comparisons was used to test whether the difference between z-scores after stapedectomy and at follow-up was not zero (ie, to test whether there was a difference between scores). Fisher’s test for paired comparisons was also used to test whether there was a statistical difference between the preoperative and follow-up PTA scores regarding AC and BC thresholds. Statistical analysis comparing study ears and otosclerotic control ears was performed in 23 patients with bilateral otosclerosis who only underwent surgery on the study ear by use of Fisher’s test for paired comparisons. Preoperative and postoperative audiograms of the patients who declined to participate in the study were reviewed and compared with those of the study group. No differences were found regarding age, gender, or preoperative and postoperative hearing outcomes.

RESULTS

The follow-up periods were 28 to 30 years. At follow-up, 57 of the 65 patients (88%) had bilateral otosclerosis and 8 (12%) had unilateral otosclerosis. Among patients with bilateral otosclerosis, 23 (35% of the total) had a nonoperated otosclerotic control ear. At the time of follow-up, 12 of the 65 study ears (18%) had had 1 revision, 4 (6%) had had 2 revisions, and 4 (6%) had had 3 revisions.

The mean preoperative AC PTA in the study ear was 53 dB, the mean preoperative BC PTA was 27 dB, and the mean ABG was 26 dB. The mean post-
operative AC PTA was 32 dB and the mean BC PTA was 22 dB, making the mean postoperative ABG 10 dB. The mean improvements were 21 dB in the AC PTA, 6 dB in the BC PTA, and 16 dB in the ABG. The mean improvement in AC threshold was most pronounced in the lower frequencies of 500 and 1,000 Hz (Fig 19).

The mean follow-up PTA was 51 dB for AC and 36 dB for BC, with a mean ABG of 15 dB. The mean AC PTA had deteriorated by 19 dB compared with the postoperative value. The mean BC PTA had decreased to 36 dB, compared with the postoperative value of 22 dB (Fig 1). The mean 30-year AC PTA showed no significant difference from the mean preoperative value (p > 0.30). The BC PTA demonstrated a significant deterioration in threshold compared with preoperative values (p < 0.0001; Fig 2 and Table 1). A summary of all of the data is presented in Table 2.

At the time of the follow-up, 66% of the study ears showed a moderate to profound hearing loss as calculated by the PTA. No major differences were seen regarding the BC PTA when the revision groups (ie, those with 0, 1, 2, and 3 revisions) were compared before and after stapedectomy and at follow-up. In terms of AC, no major differences were seen compared with the whole cohort, except for two findings. The first finding was that in 4 of the 8 patients in the groups with 2 and 3 revisions, no hearing gain was measured after stapedectomy. These patients had early revision. The second finding was an increase in AC threshold at follow-up in the group with 3 revisions. This increased PTA was due to the fact that 1 individual developed a severe hearing loss (AC PTA of 101 dB). The patient's hearing loss had deteriorated during the 1980s and 1990s in both ears, with a BC PTA that was equal between the ears. The control ear only underwent stapedectomy once.

The control ears with otosclerosis that were not treated by surgery had an AC PTA of 46 dB and a BC PTA of 34 dB at follow-up. After correction according to Carhart, the corresponding figure for BC was 25 dB (Fig 3 and Table 3). The mean PTA values for postoperative and follow-up AC and BC for each frequency were compared with those of a normal population with no history of ear disease, controlled for age and gender. The z-scores for both AC and BC thresholds, after stapedectomy and at the 30-year follow-up, were significantly worse than those of the reference group ISO 7029 (p < 0.001). The differences were significantly larger for AC than for BC and for postoperative values than for

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**Table 1. Audiometric Data for Study Ears**

<table>
<thead>
<tr>
<th></th>
<th>AC PTA</th>
<th>BC PTA</th>
<th>ABG</th>
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<tbody>
<tr>
<td>Preoperative</td>
<td>53 ± 11</td>
<td>27 ± 10</td>
<td>26 ± 9</td>
</tr>
<tr>
<td>Postoperative</td>
<td>32 ± 13</td>
<td>22 ± 9</td>
<td>10 ± 7</td>
</tr>
<tr>
<td>Follow-up</td>
<td>51 ± 19</td>
<td>36 ± 14</td>
<td>15 ± 9</td>
</tr>
</tbody>
</table>

Data are mean ± SD in decibels.

AC — air conduction; PTA — pure tone average for 0.5, 1, 2, and 4 kHz; BC — bone conduction; ABG — air-bone gap.

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**Table 2. Summary of Audiometric Mean Data for Study Ears by Frequency**

<table>
<thead>
<tr>
<th></th>
<th>0.5 kHz</th>
<th>1 kHz</th>
<th>2 kHz</th>
<th>4 kHz</th>
<th>6 kHz</th>
<th>8 kHz</th>
<th>PTA</th>
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<tbody>
<tr>
<td>Preoperative</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>AC (dB HL)</td>
<td>57</td>
<td>54</td>
<td>50</td>
<td>50</td>
<td>58</td>
<td>50</td>
<td>53</td>
</tr>
<tr>
<td>BC (dB HL)</td>
<td>25</td>
<td>24</td>
<td>33</td>
<td>27</td>
<td></td>
<td></td>
<td>27</td>
</tr>
<tr>
<td>ABG (dB)</td>
<td>32</td>
<td>30</td>
<td>17</td>
<td>23</td>
<td></td>
<td></td>
<td>26</td>
</tr>
<tr>
<td>Postoperative</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AC (dB HL)</td>
<td>28</td>
<td>26</td>
<td>31</td>
<td>42</td>
<td>54</td>
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<td>32</td>
</tr>
<tr>
<td>BC (dB HL)</td>
<td>20</td>
<td>18</td>
<td>25</td>
<td>26</td>
<td></td>
<td></td>
<td>22</td>
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<tr>
<td>ABG (dB)</td>
<td>8</td>
<td>8</td>
<td>6</td>
<td>16</td>
<td></td>
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<td>10</td>
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<tr>
<td>Follow-up</td>
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<tr>
<td>AC (dB HL)</td>
<td>41</td>
<td>44</td>
<td>52</td>
<td>67</td>
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<td>51</td>
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<td>ABG (dB)</td>
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<td>18</td>
<td>9</td>
<td>19</td>
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<td></td>
<td>15</td>
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<tr>
<td>Difference*</td>
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<tr>
<td>AC (dB HL)</td>
<td>13</td>
<td>18</td>
<td>21</td>
<td>25</td>
<td>23</td>
<td>35</td>
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<tr>
<td>BC (dB HL)</td>
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<td>10</td>
<td>3</td>
<td>3</td>
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<td>5</td>
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</table>

*Difference between postoperative and follow-up values.
At follow-up, there were no significant differences in PTA between the study ears and the 23 untreated otosclerotic control ears in terms of either AC or BC. After the correction according to Carhart, a significantly better BC threshold was noted for the otosclerotic ears without surgery (p < 0.001; Fig 3 and Table 3). The mean z-score for the untreated otosclerotic control ears was significantly lower than that for the normal population for both AC and BC with the Carhart correction. No gender differences were noted in PTA before or after stapedectomy or at follow-up, and as a result, all of the patients were analyzed as one group.

**DISCUSSION**

The aims of the present study were to assess hearing in patients with otosclerosis 28 to 30 years after stapedectomy and to evaluate sensorineural hearing loss in patients with otosclerosis by comparing their hearing thresholds with those of a normal population and by comparing operated versus nonoperated otosclerotic ears. Our study shows that hearing gained by surgery is lost at the follow-up and that the sensorineural hearing loss associated with otosclerosis cannot be explained simply by age. After the Carhart correction, the untreated otosclerotic ears had a significantly better BC threshold than did the operated otosclerotic ears, reflecting better-preserved sensorineural function.

The cohort of individuals included in this study was chosen in an attempt to have the longest possible follow-up period, with as few dropouts as possible. Of the 93 eligible subjects, 65 (70%) participated in the study. All patients underwent stapedectomy, the standard procedure of the 1970s, whereas the standard procedure of today is stapedotomy. In comparing the postoperative results of the two techniques, no significant difference is seen in the middle frequency range. Although a significant improvement in the higher frequencies has been reported in favor of the stapedotomy technique after operation and at shorter follow-up periods, a 20-year follow-up study by Aarnisalo et al reported no difference between the techniques (except at the single frequency of 2 kHz). As a result, in our opinion, the finding of long-term hearing deterioration after surgery in our study is probably valid even today in ears that undergo stapedotomy.

In the present study, 31% had one (12 of 65), two (4 of 65), or three (4 of 65) revision surgeries. Other studies have reported lower revision rates — approximately 11%— but they are not completely comparable, because their follow-up periods were considerably shorter and ranged from 1 to 26 years. The higher rate could also be due in part to the fact that the operations in our series were performed by 11 surgeons, both senior and in training. Another explanation could be that these surgeons were more likely to perform revision surgery than were surgeons in other studies. No major differences were seen in BC or AC thresholds at follow-up between the different revision groups (according to number of revisions), and as a result, the somewhat higher number of revisions in the present study did not affect the final hearing outcome.

Many studies have demonstrated that stapes surgery is a successful means of improving hearing, which we also found to be true. However, in a long-term perspective, we found that the hearing gained...
by surgery was lost. The indications for stapedectomy, as well as the preoperative and postoperative hearing levels for AC, BC, and ABG, were comparable to those in other studies. To our knowledge, one other study has followed a cohort with a uniform follow-up time of approximately 30 years. They followed 58 of 322 patients over a period of 33 years and found that the long-term ABG was largely maintained and that the patients' hearing had deteriorated during the time period. These results are similar to our results.

In our study, at the time of follow-up, 66% of the participants displayed a moderate to profound hearing loss. The deterioration was mainly due to a loss of cochlear function, whereas the ABG had only deteriorated by 5 dB during the 30-year period. To assess whether the sensorineural hearing losses in the operated ears were mainly due to age-related hearing loss, we made a comparison with the International Standardized Database, ISO 7029. At the present time, there are two International Standardized Databases for hearing threshold levels as a function of age: ISO 1999 database A (equal to ISO 7029), and ISO 1999 database B (otologically unselected population). Database A, which was chosen, describes the normal hearing distribution in an otologically normal population “free from all signs or symptoms of ear disease and from obstructing wax in the ear canals, and who has no history of undue exposure to noise.” Because the population was otologically normal, with no history of middle or external ear disease, the assumption was made that the AC threshold was equal to the BC threshold. The database describes hearing loss as a function of age and gender. A literature search revealed very few studies that used an accessible reference population for comparing results. We have found only the study by Topsakal et al. The statistical analysis comparing the study ears and the ISO control group with regard to both AC and BC on the basis of the described z-score revealed a highly significant difference both after operation and at the 30-year follow-up. This means that patients with otosclerosis have a significantly more pronounced hearing loss, compared with a normal-hearing population, measured by both AC and BC thresholds and both after operation and after 28 to 30 years.

Our results are in agreement with the study by Topsakal et al., who compared preoperative BC thresholds after the correction according to Carhart with ISO 7029. Our study indicates that the sensorineural hearing loss, both in the study ears and in the control ears with otosclerosis, is more pronounced in comparison to that of the normal population. When age-related hearing loss progresses with age, the differences decrease. However, it should be noted that the otosclerotic ears still have a significantly larger hearing loss than the reference population. The true nature of the sensorineural hearing loss progression seen in otosclerotic patients can be and has been the subject of a great deal of debate. In our opinion, the sensorineural hearing loss seen in elderly otosclerotic patients is a combination of otosclerosis and age-related hearing loss.

Different approaches have been used in attempts to investigate the cochlear component in otosclerosis. One approach was to compare otosclerotic ears that underwent surgery with the other, nonoperated control ears. In our study, 23 patients had an otosclerotic ear that had not undergone surgery at follow-up. The hearing result revealed no statistical differences in AC compared with the operated ears, and the same applied to BC until correction for the Carhart effect was made. With the Carhart correction, the BC threshold was significantly better in the otosclerotic ears that did not undergo surgery. This is in contrast to the theory that surgery enables sounds to reach the cochlea and thus protects it from premature degeneration due to inactivity. On the basis of our results, we suggest further studies to address audiological rehabilitation, hearing aid use, and quality of life in these patients.

CONCLUSIONS

Thirty years after stapedectomy, 66% of the subjects displayed a moderate to profound hearing loss in the study ear. Hearing deterioration was mainly caused by sensorineural loss. The sensorineural hearing loss was significantly greater than that in the ISO reference population, both early and late in the course of the disease. The difference in sensorineural function could not be explained by age. Otosclerosis should be regarded as a middle and inner ear disease. Surgery did not affect the audiological function in the long term, as there was no statistical difference between operated and nonoperated otosclerotic ears after 30 years. In our opinion, all patients with otosclerosis require ongoing audiological rehabilitation.

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