Stapedotomy vs Cochlear Implantation for Advanced Otosclerosis: Systematic Review and Meta-analysis

Yasin Abdurehim, MD1,2, Alexandre Lehmann, PhD1,3, and Anthony G. Zeitouni, MD1

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Abstract

Objectives. To compare the hearing outcomes of stapedotomy vs cochlear implantation in patients with advanced otosclerosis.

Data Sources. PubMed, EMBASE, and The Cochrane Library were searched for the terms otosclerosis, stapedotomy, and cochlear implantation and their synonyms with no language restrictions up to March 10, 2015.

Methods. Studies comparing the hearing outcomes of stapedotomy with cochlear implantation and studies comparing the hearing outcomes of primary cochlear implantation with salvage cochlear implantation after an unsuccessful stapedotomy in patients with advanced otosclerosis were included. Postoperative speech recognition scores were compared using the weighted mean difference and a 95% confidence interval.

Results. Only 4 studies met our inclusion criteria. Cochlear implantation leads to significantly better speech recognition scores than stapedotomy ($P < .0001$). However, this appears to be due to the variability in outcomes after stapedotomy. Cochlear implantation does not lead to superior speech recognition scores compared with the subgroup of successful cases of stapedotomy plus hearing aid ($P = .47$). There is also no significant difference with respect to speech recognition between primary cochlear implantation and those secondary to a failed stapedotomy ($P = .22$).

Conclusions. Cochlear implantation leads to a statistically greater and consistent improvement in speech recognition scores. Stapedotomy is not universally effective; however, it yields good results comparable to cochlear implantations in at least half of patients. For cases of unsuccessful stapedotomy, the option of cochlear implantation is still open, and the results obtained through salvage cochlear implantation are as good as those of primary cochlear implantation.

Keywords

otosclerosis, stapedotomy, cochlear implantation, speech recognition

Otosclerosis is an aberrant process of bone resorption of the labyrinthine capsule followed by reparative deposition of new, immature sclerotic bone. The most commonly affected location is around the oval window (fenestral otosclerosis), which results in conductive hearing loss due to stapes footplate fixation. As it undergoes a maturation process, the sclerotic bone increases in size and depth. In approximately 10% of patients, otosclerotic foci invade deeper into the labyrinth, resulting in retrofenestral otosclerosis; this process gradually leads to severe mixed hearing loss and then to profound sensorineural hearing loss (SNHL). Several studies have indicated that retrofenestral sclerotic foci may lead to hearing loss through disturbance of the ionic homeostasis of the cochlea by hindering ion recycling and reducing the endocochlear potential. This leads to dysfunction or loss of cochlear hair cells. SNHL may also be caused by lytic enzymes that are released from otosclerotic foci into the perilymph, altering its normal composition, or by narrowing of the cochlear lumen with resultant distortion of the basilar membrane.

Far advanced otosclerosis was first defined by House and Sheehy in the 1960s as an air conduction (AC) threshold of more than 85 dB and bone conduction (BC) threshold beyond the measurement limits of the standard clinical audiometers available at that time. In the current era of cochlear implantation (CI), speech discrimination scores are more likely to be used than pure-tone thresholds, and the term far advanced otosclerosis is no longer applicable.

1Department of Otolaryngology–Head & Neck Surgery, McGill University, Montreal, Quebec, Canada
2Department of Otolaryngology, First Teaching Hospital, Xinjiang Medical University, Urumqi, Xinjiang, China
3Centre for Research on Brain, Music and Language, Montreal, Quebec, Canada

Corresponding Author:
Anthony G. Zeitouni, MD, Department of Otolaryngology–Head and Neck Surgery, McGill University, 1001 Decarie Blvd, DO27020, ENT Clinic: DS1.3310, Montreal, Quebec H4A 3J1, Canada.
Email: anthony.zeitouni@mcgill.ca

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Therefore, in this systematic review, we use the term advanced otosclerosis instead of far advanced otosclerosis when referring to patients with SNHL and decreased speech recognition abilities or an AC threshold higher than 85 dB and even a poor/unmeasurable BC threshold.

In the literature, the proposed management policy for patients with advanced otosclerosis is controversial. Stapedotomy is a simple and cost-effective procedure that can achieve satisfactory results in patients with otosclerosis. Numerous authors have shown that stapedotomy followed by use of a hearing aid can restore acceptable hearing, even in advanced otosclerosis with profound SNHL.9-15 However, there is also evidence that this surgery is not as frequently successful in cases of advanced otosclerosis as in more traditional cases of otosclerosis. CI has a very high success rate and has thus been advocated for patients with advanced otosclerosis in many studies.16-20 To our knowledge, no systematic review summarizes the existing comparative studies. Therefore, a systematic review of stapedotomy vs CI for patients with advanced otosclerosis appears warranted.

Materials and Methods

Inclusion Criteria

Types of studies. Only comparative studies between stapedotomy and CI with respect to postoperative hearing outcomes were included. The exception was the inclusion of studies that compared the outcomes of primary CI with salvage CI after an unsuccessful stapedotomy. Conference abstracts, animal studies, comments, case reports, and review articles were excluded.

Types of participants. Patients with profound SNHL and decreased speech recognition abilities due to otosclerosis were included.

Types of interventions. Stapedotomy with postoperative hearing aids and CI.

Types of outcome measures. Speech recognition tests including word recognition scores (WRS) and sentence recognition scores.

Search Methods for Identification of Studies

Systematic searches for eligible studies were conducted in PubMed, EMBASE, and The Cochrane Library. There were no language or publication year restrictions. The following search strategy was used to identify eligible studies:

1. The search terms otosclerosis OR otoscleroses OR otospongiosis OR otospongioses were used in all 3 databases, and all studies with these terms were retrieved.
2. The same process was conducted using the terms stapedotomy OR stapedectomy OR stapedotomies OR stapedectomies OR stapes surgery.
3. The final set of search terms were cochlear implant OR cochlear implantation OR cochlear implants OR cochlear implantations OR cochlear prosthesis OR cochlear prostheses.

4. Any studies that contained at least one of the search terms from each of the 3 previous steps (1 AND 2 AND 3) were retained for screening.

Eligible publications were identified by 2 researchers independently. Titles and then abstracts were screened, and if they appeared to meet the inclusion criteria, full texts were retrieved and evaluated in detail. Screening and evaluation of studies were performed using EndNote X7 (Thomson Reuters, Philadelphia, Pennsylvania).

Data Extraction

Data were collected from each included study using a data extraction form that included the following fields: inclusion criteria, study design, study population, interventions, outcome measures, criteria for success, tool(s) for assessing audiological performance, and time of assessment.

Quality Assessment and Data Synthesis

The quality of included studies was assessed based on whether ethical approval was obtained, the design was prospective, eligibility criteria were specified, a power calculation was applied, appropriate controls were used, appropriate outcome measures were used, confounding factors were reported and controlled, appropriate analyses were made, and any missing data was accounted for. The level of evidence of each study was rated based on its design and quality according to the criteria of the Oxford Centre for Evidence-Based Medicine’s Levels of Evidence (2009). Data synthesis was performed by Review Manager 5.3 (Cochrane Collaboration, London, United Kingdom). Continuous outcome variables were compared using weighted mean differences and 95% confidence intervals (CIs). Because of the heterogeneity between outcome measures, a random-effect model was used for data pooling.

Results

Our search strategy identified 92 articles in total, of which only 4 studies met our predefined inclusion criteria.13,15,17,21 The flowchart of the study selection process is shown in Figure 1.

Study Characteristics and Methodological Quality

The design of all included studies was retrospective case control or case series. The characteristics and level of evidence of the included studies are shown in Table 1, and the methodological quality of the studies is displayed in a 100% stacked bar chart (Figure 2).

Criteria for patient selection. Patient selection criteria in all 3 studies we included to compare postoperative hearing outcomes between stapedotomy vs CI met the criteria of advanced otosclerosis.13,15,21 In Berrettini et al,21 the inclusion criteria were AC thresholds beyond 110 dB and 118 dB for stapedotomy and CI, respectively, and aided word recognition scores (WRS) less than 15% for stapedotomy and 4% for CI. In the study by Calmels et al,13 the inclusion criteria were blank diagram (unmeasurable air and bone conduction) and aided WRS below 30% at 65 dB for both treatment...
groups. Kabbara et al\textsuperscript{15} used the criteria of AC worse than 85 dB and aided WRS below 50\% at 60 dB for both treatment groups. In 1 study included to compare the outcomes of primary vs salvage CI, audiometric criteria for patient selection were not clearly specified, but it is obvious from the article that all patients had advanced otosclerosis based on positive findings on computed tomography (CT) scanning (n = 27) and/or previous surgery for otosclerosis (stapedotomy in 18 and fenestration in 2 patients).\textsuperscript{17} In all studies, radiologic criteria were also specified, with positive findings of otosclerotic foci on high-resolution temporal bone CT.

Criteria for success. Surgical success criteria also varied across studies. Two studies defined success as the ability to use aided telephone conversation,\textsuperscript{13,21} one defined success as aided WRS >50\% plus subsequent ineligibility for CI,\textsuperscript{15} and another study did not clearly specify any criteria.\textsuperscript{17}

Outcome Measures

The outcome measure was WRS in all 3 studies we included to compare postoperative hearing outcomes between stapedotomy vs CI (disyllabic WRS in 2 studies\textsuperscript{13,15} and open-set WRS in 1 study\textsuperscript{41}). In the study by Marshall and his colleagues,\textsuperscript{17} which we included to compare hearing outcomes of primary vs salvage CI, the outcome measure was sentence recognition scores (Central Institute for the Deaf sentence test). We used sentence score as it was the only speech score in this study to data synthesize for speech recognition.

**Stapedotomy vs CI.** The meta-analysis showed that the difference between stapedotomy and CI with respect to WRS was statistically significant and favoring CI (total mean difference, $-31.79$; 95\% CI, $-46$ to $-17.59$; $P < .0001$; \textbf{Figure 3A}).

**Successful stapedotomy plus hearing aid vs CI.** In 1 study,\textsuperscript{15} successful and unsuccessful cases of stapedotomy were analyzed separately to find possible predictors of good outcomes. In 2 other studies,\textsuperscript{13,21} it was possible to analyze the favorable and unfavorable outcomes of stapedotomy separately since original data were available. Therefore, we compared the outcome of successful cases of stapedotomy with CI (Table 2). The meta-analysis showed that the difference between successful stapedotomy plus hearing aid and CI with regard to postoperative speech recognition was not statistically significant (total mean difference, $-5.14$; 95\% CI, $-18.95$ to $8.67$; $P = .47$; \textbf{Figure 3B}).

**Primary CI vs salvage CI.** Postoperative speech recognition scores for primary CI and salvage CI secondary to an unsuccessful stapedotomy (stapes prosthesis present at the time of surgery) were also compared in 3 studies (Table 2).\textsuperscript{13,15,17} The meta-analysis comparing those 2 subgroups showed that the difference between primary and salvage CI was not statistically significant (total mean difference, 5.58; 95\% CI, $-3.35$ to $14.51$; $P = .22$; \textbf{Figure 3C}).

**Discussion**

The results of our meta-analyses showed that CI definitely leads to significantly better speech recognition scores than stapedotomy. The outcomes of CI were consistently good in all reported patients. This supports the opinion that the outcomes of CI are more predictable and consistent. Favorable outcomes for CI in most patients with advanced otosclerosis are not unexpected, since adults who have severe to profound hearing loss and who lost their hearing after speech and language development are the ideal candidates for CI.

When we compared the results of CI with the subgroup of successful cases of stapedotomy plus a well-fitted hearing aid, meta-analysis revealed that there was no significant difference with respect to postoperative speech recognition between CI and stapedotomy. This indicates that treatment with stapedotomy followed by a well-fitted hearing aid allows a considerable number of patients with advanced otosclerosis (4 of 6, 4 of 11, and 19 of 32 patients, respectively, in the 3 included studies) to achieve good speech recognition, comparable to those treated with CI.

To ascertain whether the presence of a previous stapedotomy has a negative impact on the outcome of subsequent CI, we compared postoperative speech recognition between primary CI and salvage CI secondary with an unsuccessful stapedotomy. Meta-analysis showed that the difference was...
not statistically significant, suggesting that the presence of a previous stapes prosthesis does not have any negative impact on salvage CI. In Figure 3C, it is evident that, although not significant, there is a clear trend favoring CI with a previous prosthesis. This is not because the previous prosthesis has a favorable effect on subsequent CI but because most patients who were previously treated with stapedotomy tend to have less severe hearing loss.

**Intervention for Advanced Otosclerosis**

Treatment for advanced otosclerosis has evolved over the past 20 years with the improvement in hearing aid devices and the availability of CI as an alternative surgical option.\textsuperscript{15,20,22} Yet, optimal surgical management may or may not include CI. Our systematic review indicates that correction of the conductive component of mixed hearing loss by stapedotomy followed by a hearing aid can be effective enough to achieve acceptable hearing for some patients. However, the results of stapedotomy for advanced otosclerosis in the included studies were quite variable—\textsuperscript{13,21} “very good in some cases but unsatisfactory in others.”\textsuperscript{15,21} The overall success rate of stapedotomy in this systematic review is 55%, and in the general literature, the reported success rates range between 36% and 89%.\textsuperscript{13,23}

Unlike the variable outcomes of stapedotomy, CI in patients with advanced otosclerosis consistently yields excellent results with regard to speech recognition.\textsuperscript{8,21} However, it is a much more expensive and complex procedure that involves surgical and postoperative programming challenges,\textsuperscript{2,21,24} and because of ossification and cochlear hyperdensity, problems such as extra drilling, incomplete insertion, or misplacement of electrode array also have to be taken into account.\textsuperscript{2,15,25}

In weighing the options between CI and stapedotomy, one also has to consider that stapedotomy has some advantages over CI. First, it is a less invasive procedure that can be performed endoscopically through a transcanal approach. The procedure can be performed under local anesthesia, which is an especially relevant benefit for the elderly and patients with comorbidities.\textsuperscript{13,20,27} Second, it is a less costly operation with minimal postoperative requirements (fitting of a hearing aid). As mentioned above, CI is much more expensive and much more demanding postoperatively, requiring intensive rehabilitation.

### Table 1. Study Characteristics and Level of Evidence.

<table>
<thead>
<tr>
<th>Study</th>
<th>Stapedotomy</th>
<th>Cochlear Implantation</th>
<th>Success Criteria</th>
<th>Outcome Measures</th>
<th>Time of Assessment, mo</th>
<th>Design</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berrettini et al, 2004\textsuperscript{21}</td>
<td>6</td>
<td>61 ± 28</td>
<td>5</td>
<td>98 ± 2.45</td>
<td>Aided telephone conversation</td>
<td>WRS, PTA</td>
<td>12</td>
</tr>
<tr>
<td>Marshall et al, 2005\textsuperscript{17}</td>
<td>—</td>
<td>—</td>
<td>30</td>
<td>75</td>
<td>Not clear</td>
<td>CID, HINT</td>
<td>12</td>
</tr>
<tr>
<td>Calmels et al, 2007\textsuperscript{13}</td>
<td>11</td>
<td>35 ± 36.3</td>
<td>7</td>
<td>80 ± 14</td>
<td>Aided telephone use and aided self-satisfaction</td>
<td>WRS</td>
<td>12</td>
</tr>
<tr>
<td>Kabbara et al, 2015\textsuperscript{15}</td>
<td>32</td>
<td>51 ± 34</td>
<td>34</td>
<td>73 ± 19</td>
<td>Aided WRS &gt;50%</td>
<td>WRS, PTA</td>
<td>12</td>
</tr>
</tbody>
</table>

CID, Central Institute for the Deaf sentence test; HINT, hearing in noise test; PTA, pure-tone audiometry; Retro, retrospective study; SR, speech recognition; WRS, word recognition score; —, no data available.
and programming. Third, because of acoustic stimulation, the quality of sound is more natural and music perception can be better preserved after stapedotomy.26 Last, in case of failure, the presence of a previous stapes prosthesis does not have any negative impact on subsequent salvage CI.

Given the uncertainty regarding the best surgical approach, Merkus et al8 introduced an algorithm based on speech recognition, CT classification, and the extent of the air-bone gap (ABG) to guide surgeons to either CI or stapedotomy for patients with advanced otosclerosis. In this algorithm, CI is proposed for patients with speech recognition scores \( \geq 30\% \). If scores are between 30% and 50%, treatment may be CI or stapedotomy. In cases of severe retrofenestral otosclerosis on CT, CI is proposed, whereas if the

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**Table 2. Subgroup Analysis: Stapedotomy (Success and Failure) and CI (with vs without Stapes Prosthesis).**

<table>
<thead>
<tr>
<th>Study</th>
<th>Stapedotomy Success</th>
<th>Stapedotomy Failure</th>
<th>Cochlear Implantation Salive (with Previous Stapes Prosthesis)</th>
<th>Cochlear Implantation Primary (without Previous Stapes Prosthesis)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n SR (%)</td>
<td>n SR (%)</td>
<td>n SR (%)</td>
<td>n SR (%)</td>
</tr>
<tr>
<td>Berrettini et al, 2004</td>
<td>4 80 ( \pm ) 10.6</td>
<td>2 22.5 ( \pm ) 2.5</td>
<td>12 72 ( \pm ) 15</td>
<td>12 72 ( \pm ) 15</td>
</tr>
<tr>
<td>Marshall et al, 2005</td>
<td>4</td>
<td>2</td>
<td>18 82 ( \pm ) 16</td>
<td>12 72 ( \pm ) 15</td>
</tr>
<tr>
<td>Calmels et al, 2007</td>
<td>4 80 ( \pm ) 10</td>
<td>7 8 ( \pm ) 10</td>
<td>4 85 ( \pm ) 11</td>
<td>3 74 ( \pm ) 15.5</td>
</tr>
<tr>
<td>Kabbbara et al, 2015</td>
<td>19 76 ( \pm ) 16</td>
<td>13 14 ( \pm ) 12</td>
<td>25 72 ( \pm ) 20</td>
<td>9 75 ( \pm ) 17</td>
</tr>
</tbody>
</table>

SR, speech recognition; ---, no data available.

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**Figure 3.** Postoperative speech recognition score: (A) stapedotomy vs cochlear implantation, (B) successful stapedotomy vs cochlear implantation, and (C) cochlear implantation with stapes prosthesis vs cochlear implantation without stapes prosthesis. CI, confidence interval; SD, standard deviation.
CT scan shows less retrofenestral involvement, the ABG would guide the surgeon to either stapedotomy or CI. If the ABG is 30 dB or more, stapedotomy is recommended as a cost-effective option with good chances for improvement of hearing. If the ABG is less than 30 dB, patients should be treated with CI rather than stapedotomy. On the surface, this algorithm appears to be a reasonable way to determine which surgical treatment should be performed. However, retrospective evidence suggests that CT findings (extent of retrofenestral sclerosis) and preoperative residual hearing (as measured by both pure-tone audiometry and speech recognition) are not sensitive or specific enough to predict the outcomes of stapedotomy.\textsuperscript{15,26} Moreover, there is evidence that, even in patients with unmeasurable air and bone conduction thresholds (a “blank” audiogram) and 0% speech recognition, stapedotomy followed by a hearing aid can still lead to a good result in up to 30% of patients.\textsuperscript{13,15}

Because of the advantages listed above, stapedotomy seems to be worth trying before considering CI in patients with advanced otosclerosis. However, the outcomes of stapedotomy are quite variable compared with CI and are difficult to anticipate because of the paucity of reliable predictive factors.\textsuperscript{8,26} Patients with less retrofenestral sclerosis, previous benefit from hearing aid use, and speech recognition scores above 50% have a higher success rate, whereas severe retrofenestral sclerosis with basal turn ossification and speech recognition scores less than 30% have been associated with a lower success rate.\textsuperscript{15} The variability in outcomes and the limitations of our study restrain us from making a solid recommendation. Treatment decisions rest on surgeons and informed patients, who should receive adequate counseling regarding the factors covered here.

**Limitations of This Systematic Review**

As secondary research and as in any other systematic review, our review was limited by the quantity and quality of available literature. Although patient inclusion criteria in all studies met the criteria of advanced otosclerosis, there were some differences. One limitation of this systematic review is that because there were only 3 studies available in each compared domain (stapedotomy vs CI, successful stapedotomy + hearing aid vs CI and primary vs salvage CI), it was not possible to perform a subgroup analysis according to speech recognition score in the inclusion criteria among these studies. In the studies included in the meta-analysis of primary vs salvage CI, the outcome measures were WRS in 2 studies and sentence score in 1 study. Although both WRS and sentence recognition score are both indicative of speech recognition, individual words are not equivalent to words presented in sentences, the former being more challenging than the latter due to the redundancy of information in sentences. All these heterogeneities may have produced biases. In addition, the retrospective nature of the included studies and their small sample sizes limit the level of evidence that can be provided by our systematic review.

**Conclusion**

CI leads to a statistically greater and consistent improvement in speech discrimination scores compared with stapedotomy. Stapedotomy is not universally effective; however, it yields results comparable to CI in at least half of patients. For cases of unsuccessful stapedotomy, the option of CI is still open, and the results obtained by a salvage CI are as good as those of CI when no prior stapedotomy was performed. Surgeons and their patients need to be aware of the results of our study and of its limitations when making an informed decision regarding treatment.

**Author Contributions**

Yasin Abdurehim, study design, literature searching, screening, data collection and synthesis, data analysis, drafting; Alexandre Lehmann, statistical analysis, critical revision; Anthony G. Zeitouni, study design, proofreading, final approval.

**Disclosures**

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**References**