

The Relationship between Stapes Prosthesis Length and Rate of Stapedectomy Success

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ABSTRACT

OBJECTIVES: To identify whether measurement of the prosthesis length is mandatory in patients requiring otosclerosis surgeries and to assess their postoperative audiometric outcomes. In addition, evaluation of prosthesis length used in revision compared to primary stapedectomy was carried out.

STUDY DESIGN: Case series with chart review.

METHODS: Chart review of 393 patients undergoing primary (321) versus revision stapedectomy (72) was performed in a tertiary referral center. The indication for surgery was the presence or persistence/recurrence of an air–bone gap (ABG) greater than 20 dB. Air and bone conduction thresholds (ACT and BCT, respectively), ABG as well as pure tone averages (PTAs) were determined for all patients, and the results were compared preoperatively and postoperatively.

RESULTS: Prosthesis length used ranged from 3.0 to 6.0 mm without differences between primary and revision groups. Of the revision surgeries, 62.5% were stapedectomies versus stapedotomies ($P < 0.001$). Patients showed significant decrease in speech discrimination score, with increased air and bone conduction thresholds as well as mean ABG and PTA before the revision surgeries as a first procedure failure. Prosthesis length changes occurred in 73.5% of the cases, with an average absolute change of 0.55 mm. Prosthesis length did not affect postoperative audiometric results between primary and revision groups, in all surgeries combined. When grouping stapes surgery into accurately versus inaccurately measured incus–footplate distance, significant differences were observed in prosthesis length employed ($P < 0.01$). Hearing outcomes were also better in the group in which an accurately measured prosthesis was chosen, as opposed to “standard-length” prosthesis.

CONCLUSIONS: This study corroborates postoperative success rates of revision surgeries, which show smaller improvements in hearing compared to a primary intervention. Accurate intra-operative measurement of prosthesis length was correlated with better audiometric results postoperatively.

KEYWORDS: stapedectomy, stapedotomy, prosthesis length, prosthesis measurement, otosclerosis

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Introduction

Primary stapes surgery for otosclerosis is one of the most commonly performed successful operations reaching air–bone gap (ABG) closure rates in up to 90% of cases.^{1–3} Failure of the primary stapedectomy or stapedotomy procedure, involving a recurrence of conductive hearing loss in most cases, does, however, occur and necessitates a revision of the initial procedure.

It is well recognized that overall hearing results following a revision stapes surgery are inferior to those obtained after a primary procedure.^{4–6} The rate of success of revision surgery has been described to range from 16% to 80% of cases,^{2,7} carrying an increased risk of sensorineural hearing loss (SNHL) postoperatively in up to 20% of cases.^{5,6,8,9} Additionally, the possibility of hearing improvement evaluated by hearing gain has been reported to decrease by 10% for each revision performed on the same patient.^{6,10} Various studies have therefore attempted to evaluate the causes for failure in stapedotomy

or stapedectomy procedures in order to potentially identify factors that can lead to prosthesis failure and avoid altogether the need for revision surgeries. The most common indications for revision stapes surgery, as identified in the current literature, include prosthesis malfunction, dislocation or displacement, inaccurate prosthesis length (either too long or short), eroded incus, fibrous adhesions, or re-fixation of the footplate.^{2,3,5,6}

There has been a gradual evolution in the surgical technique as well as in the types of prosthesis used in order to limit the amount of complications and increase the success rates postoperatively. Several studies in the literature have evaluated the effect of stapedectomy versus stapedotomy as well as prosthesis diameter in hearing outcomes following successful otosclerosis surgery.^{2,11,12} Studies describing the effect of prosthesis length, however, are limited.

Our objective was to identify whether intra-operative measurement of the prosthesis length in patients requiring

otosclerosis surgeries is mandatory and to assess the postoperative audiometric outcomes; an additional objective was to evaluate the prosthesis length used in revision compared to primary stapedectomy.

Methods

Study design. A case series with chart review of patients undergoing primary and revision stapedectomy or stapedotomy surgical procedures for conductive hearing loss, admitted to our tertiary care center or its affiliated hospital, was conducted. The medical records of 393 patients (166 men, 227 women) who had undergone surgery for otosclerosis between 2000 and 2011 were reviewed. Surgical interventions included in this study were stapedotomy and stapedectomy procedures. All procedures were carried out under local anesthesia. The cases included in this study were performed by multiple surgeons.

The study was approved by our Institutional Research Ethics Board and followed the standards of our Institutional Ethics Committee.

Indications for primary operations included conductive hearing loss due to otosclerosis. Indication for revision operations included persistence of conductive hearing loss after the primary procedure with an air–bone gap (ABG) of superior to 20 dB, vertigo, dislocated prosthesis, and incus lysis. The postoperative diagnosis of all cases was recorded along with preoperative and postoperative audiometric results. Patients who lacked complete preoperative and postoperative audiometric data were excluded from the analysis. Air and bone conduction thresholds (ACT and BCT, respectively), ABG calculated at each frequency, as well as pure tone averages (PTAs) at 500, 1000, 2000, and 4000 Hz, were determined for all patients, and the results were compared preoperatively and postoperatively. Hearing improvement was defined as a mean ABG <20 dB with no more than a mean of 10 dB bone conduction hearing loss.

Other information recorded included the age, sex, date of operation, number and type of surgical interventions (whether stapedectomy or stapedotomy), type of prosthesis used and its length and diameter, as well as the interval between primary and revision stapes surgeries. The prosthesis that was used for all primary and revision surgeries included in our groups of patients was the Schuknecht wire type. No interposition tissue was used. Only micro-pieces of Gelfoam were positioned around the prosthesis to prevent perilymphatic fistula.

Intra-operative prosthesis measurements. The accurate prosthesis measurement that we performed is defined as the measurement between the lateral part of the long process of the incus and the footplate, or the measurement between the middle thickness of the long process of the incus and the medial thickness of the footplate. In the latter case, measurement was performed after the stapedotomy (Fig. 1). The measurement was performed using a House strut caliper.

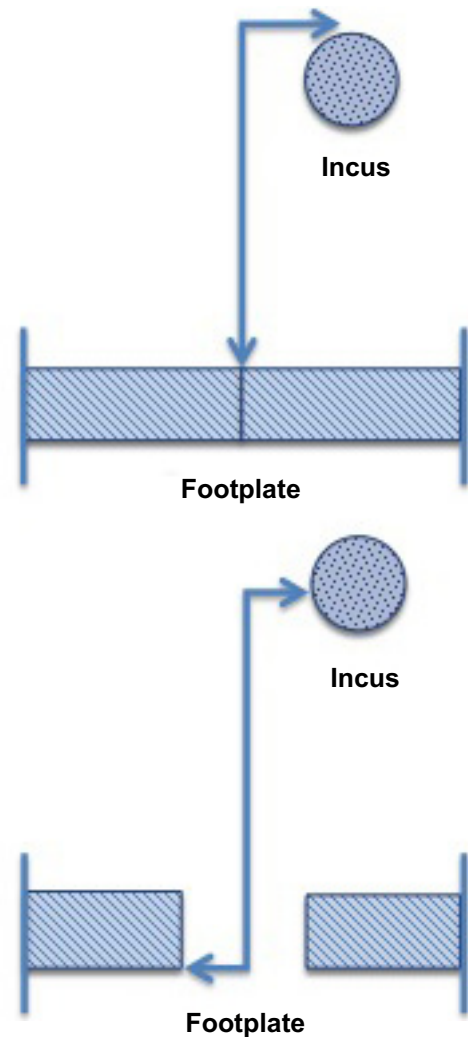


Figure 1. (Top) Accurate prosthesis length measurement between the lateral part of the incus long process and the footplate or (bottom) between the middle thickness of the incus long process and the footplate thickness performed post stapedotomy.

Inaccurate prosthesis measures were defined as the lack of intraoperative measurement or introducing a “standard-size” prosthesis with adjustments made according to the surgeons’ intra-operative observations.

Patient groups. Patients were divided into two separate groups according to whether they underwent a primary stapes surgery ($n = 321$), or whether they underwent revision surgeries ($n = 72$).

Data analysis. Statistical analysis was carried out to identify possible differences in primary versus revision groups. Student’s t -tests for equality of means as well as Chi-square tests were used to assess differences between a subgroup and the presence of recurrent surgical interventions. Fisher’s exact test was performed in cases where counts were less than 5. An ANOVA for repetitive measures was then performed to evaluate three factors: side of the surgery and hearing frequencies (considered intra-subject factors) and the type of



surgery (an inter-subject factor). All values are expressed as mean \pm standard deviation or percentages. A P -value < 0.05 was considered statistically significant.

All retrospective cases available over the period from January 2000 to December 2011 were used. Moreover, given the main objective of the study, ie, to detect a link between the length of the prosthesis and the development of the audiogram, with 85 patients (approximately the number of patients available for correlational studies in our group), one can detect a level of significance of 5%, with a power of 90%, and a correlation of 0.34.

Results

Population characteristics. A total of 491 operations for otosclerosis were reviewed from the charts of 393 patients. Table 1 summarizes the characteristic data of the patients admitted for otosclerosis with stapedectomy or stapedotomy procedures. Of these 393 patients, the average age at operation was 47.5 ± 12.1 years. This population included 166 (42.2%) men and 227 (57.8%) women. Seventy-four patients required bilateral operations. Twenty-four patients required more than one revision surgery.

A stapedotomy procedure was performed on 214 (54.5%) patients, whereas the other 179 (45.5%) patients had a total stapedectomy. Prosthesis length ranged from 3.0 to 6.0 mm,

with a mean of 4.32 ± 0.32 mm. The Schuknecht prostheses used were of diameter 0.6 or 0.8 mm.

Of the 72 patients who had undergone revision surgeries for persistent conductive hearing loss in the context of otosclerosis, 48 cases required one revision, 17 cases required two revisions, 5 cases required three revisions, and 2 cases required four revisions. The mean period between primary and revision operations was 10.7 ± 9.96 years with a range 0.25–42 years.

Table 1 shows the comparison between various characteristics of patients who had undergone a single intervention for otosclerosis versus those who had undergone revision surgeries. When comparing revision versus primary operations, the patients were of average age 51.2 and 46.8 years, respectively ($P = 0.005$). No significant sex-based difference was observed between primary and revision surgery groups.

Interestingly, there was a significant difference between patients having had a single surgery versus revision stapes surgery for otosclerosis with regard to the procedure used, ie, stapedotomy or stapedectomy. Results show that 58.3% ($n = 187$) of patients with a single primary otosclerosis surgery had undergone a stapedotomy compared to 35.7% ($n = 27$) of patients with revision operations ($P < 0.001$). Population characteristics between the two groups were also similar with regard to side of operation (right vs left ear), as well as the prosthesis length and diameter, for all procedures combined (Table 1).

Preoperative audiograms. Preoperative audiograms were available for 377 patients (309 patients undergoing primary surgery and 68 patients undergoing revision operations).

When using pairwise comparisons to compare the audiometric results at each frequency, the results demonstrated that patients who had undergone revision surgery had significantly higher ACTs when compared to those who had undergone a single operation (Fig. 2A) ($P < 0.001$ at 250 Hz, 1 kHz, 2 kHz, 4 kHz, and 8 kHz, and $P < 0.01$ at 500 Hz). Similar findings were observed when evaluating BCTs (Fig. 2B) ($P < 0.001$ at 250 Hz, 500 Hz, 2 kHz, 4 kHz, and 8 kHz, and $P < 0.01$ at 1 kHz).

Preoperative speech discrimination score (SDS) was significantly lower in revision surgery patients with a value of $90.8\% \pm 1.48\%$ versus $95.2\% \pm 0.654\%$ in those with a single operation ($P < 0.01$). The mean preoperative ABG was 35.6 ± 1.29 dB versus 30.6 ± 0.59 dB in patients requiring revisions compared to a single procedure, respectively ($P < 0.001$). Preoperative ABG at each frequency is shown in Figure 2C. PTA was also significantly higher in the revision surgery group ($P < 0.001$, data not shown) (65.7 ± 1.92 vs 53.05 ± 0.887).

Postoperative audiograms. Postoperative audiograms were obtained on average at 6 months for the first postoperative audiogram and 18.86 months for the second postoperative audiogram. When evaluating the two groups with regard to the first postoperative audiogram, patients who had undergone a

Table 1. Population characteristics for the primary and revision surgeries.

	PRIMARY ($n = 321$)	REVISION ($n = 72$)
Demographic variables		
Sex		
Male	135 (42.1)	31 (43.1)
Female	186 (57.9)	41 (56.9)
Age at intervention (years)	46.8 ± 12.3	$51.2 \pm 10.5^{**}$
Otologic Surgery		
Side (Right ear)		
	158 (49.2)	41 (56.9)
Procedure		
Stapedotomy	187 (58.3)	27 (37.5)**
Total stapedectomy	134 (41.7)	45 (62.5)**
Schuknecht prosthesis measures		
Length (mm)		
Mean	4.3 ± 0.29	4.35 ± 0.41
Min.	3.5	3.0
Max.	5.5	5.5
Diameter (mm)		
Mean	0.62	0.61
Min.	0.6	0.6
Max.	0.8	0.8

Notes: Results expressed as n (%) or mean \pm Standard Deviation. * $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$ primary vs. revision surgery groups.

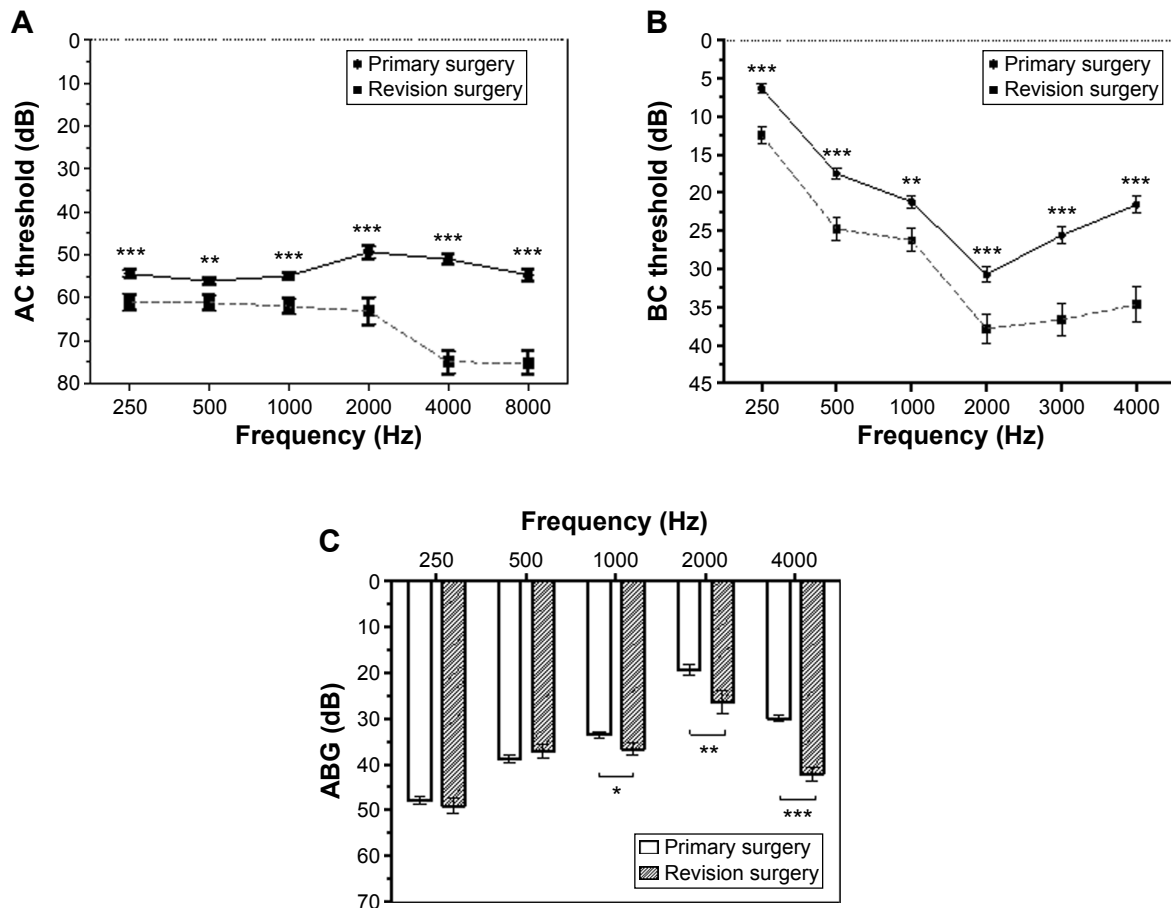


Figure 2. (A) Preoperative mean air conduction (AC) and (B) mean bone conduction (BC) thresholds for patients who had undergone a single primary surgery or revision surgery. (C) Preoperative mean air bone gap. Results are expressed as mean \pm SEM. *** $P < 0.001$, ** $P < 0.01$, * $P < 0.05$.

revision surgery had significantly higher ACT ($P < 0.001$) and BCT ($P < 0.01$) at all frequencies evaluated (Fig. 3A and B, respectively). The mean ABG was also significantly higher in the revision group at all frequencies ($P < 0.001$, Fig. 3C). Similar findings were observed for the second postoperative audiogram results (Fig. 4). The hearing improvement after stapedectomy, as determined by the difference between postoperative and preoperative audiogram results, was calculated. With regard to the hearing improvement between the first postoperative and preoperative audiograms, there was a significant difference in ACT between primary and revision surgeries at the lower frequencies (Fig. 5A). This difference in hearing improvement post-stapes surgery persisted following the second postoperative audiogram (Fig. 5B). The BCT also showed differences between the two groups, albeit to a lesser degree (Fig. 5C and D). ABG closure was significantly improved over time in the primary group versus the revision group at the lower frequencies as well ($P < 0.001$, Fig. 5E and F).

Although no differences were observed in the hearing improvement after stapedectomy up to the first postoperative audiogram in terms of SDS, PTA, and mean ABG, there was a significantly negative evolution of the SDS after the second

postoperative hearing evaluation in the surgical revision group ($P = 0.045$).

In order to answer the question of whether “standard-length” prosthesis would produce better postoperative audiometric results, we evaluated the effect of different lengths employed in our case series to the postoperative audiogram results between primary and revision surgeries. All procedures performed by multiple surgeons were included and divided solely based on whether a primary procedure or a revision surgery was done. No correlation was observed when evaluating the effect of prosthesis length on postoperative audiometric results between primary and revision surgeries.

Intra-operative prosthesis measurement—revision operations.

Prosthesis length. Data regarding the length of the previous prosthesis used in patients requiring revision surgeries was available only for 34 patients. This was due to the fact that some patients had their primary operation done at an outside center for which the operative notes were not available. Changes in prosthesis length between primary and revision surgeries occurred in 73.5% of these cases. Sixteen patients (47.1%) required a longer prosthesis and nine (26.5%) patients required a shorter prosthesis at revision, whereas similar

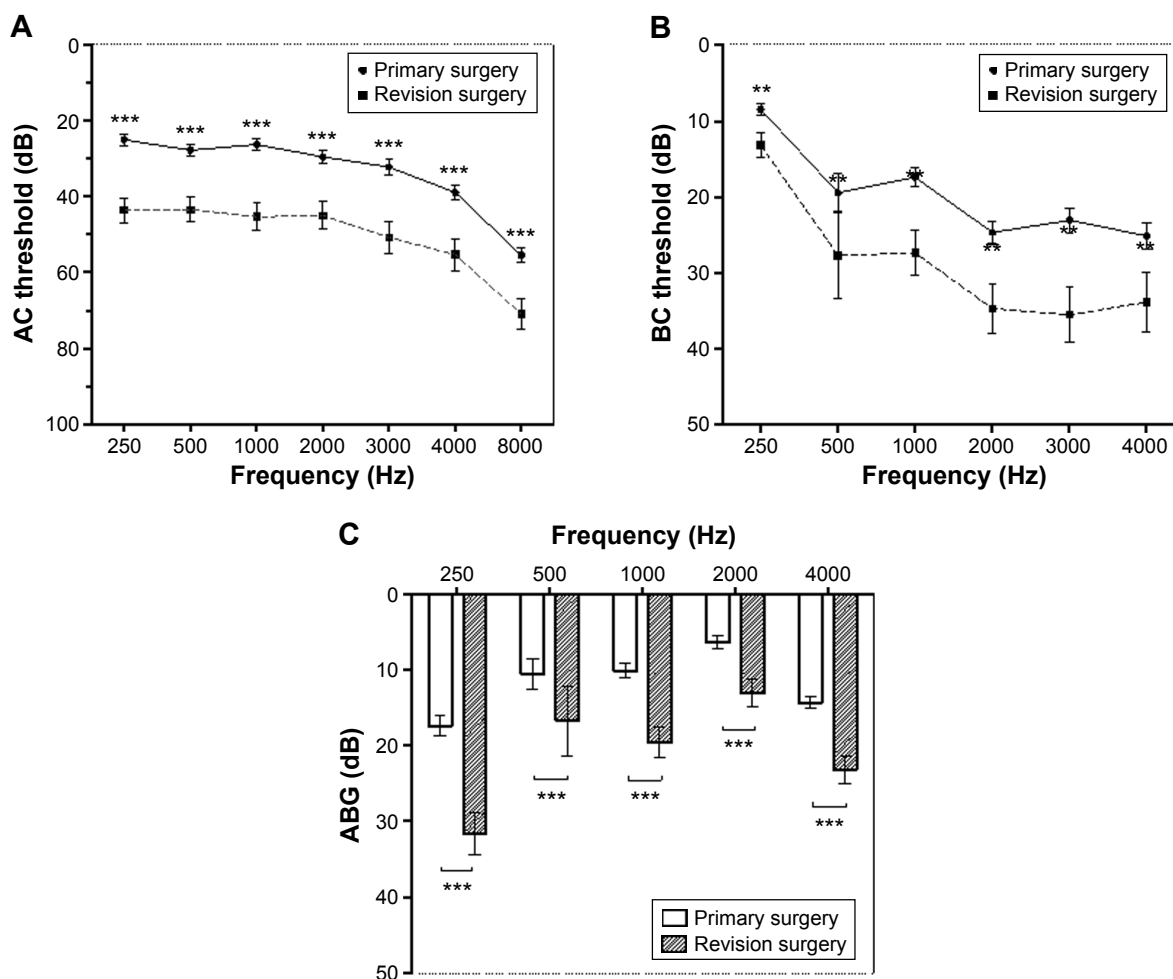


Figure 3. Results of the first postoperative audiogram. (A) Mean air conduction (AC) and (B) mean bone conduction (BC) thresholds for patients who had undergone a single primary surgery or revision surgeries. (C) Postoperative mean air–bone gap. Results are expressed as mean \pm SEM. *** $P < 0.001$, ** $P < 0.01$.

length prosthesis was utilized in nine (26.5%) patients. When prostheses of different lengths were employed, the average change in length was 0.55 mm at revision (range -2.25 to $+1.0$ mm). The -2.25 mm change in length was seen in one patient, who, after having 5-mm prosthesis inserted at the primary operation, presented with postoperative vertigo. At the revision surgery, the new prosthesis length was measured as 2.75 mm.

A subsequent analysis was completed to evaluate the prosthesis length in cases where accurate intra-operative prosthesis measurements were made and compared to the lack thereof. Initial results demonstrated a significant difference in the actual prosthesis length employed between these groups ($P < 0.01$). Interestingly, a significantly higher ACT was observed at all frequencies in the group where “inaccurate prosthesis measurements” were performed (Fig. 6A). Significant differences were observed with regard to BCT only at 4 kHz ($P < 0.001$, Fig. 6B). PTA was also seen to be significantly different between groups ($P < 0.001$). Evaluation of ABG showed a significantly increased gap in the “inaccurate

measurement” group at 250 Hz, 1 kHz, and 2 kHz (Fig. 6C). The mean ABG (at 250, 500, 1000, 2000, and 4000 Hz), however, was not significantly different ($P = 0.08$).

Discussion

Failure of a primary procedure for stapes surgery, often presenting with the reappearance of the ABG, sound distortion, or vertigo, may require patients to undergo revision procedures. This carries in itself a decreased success rate and an increased risk for negative outcomes such as SNHL.^{2,6–9} There are many factors that have been identified in the current literature as causes of primary procedure failure, with the most common cause being a dislocated or displaced prosthesis.⁵ The published literature has in fact suggested that one of the factors related to this displacement is the use of an incorrect prosthesis length.^{5,6} In fact, prosthesis measurement is described as an important step in stapes surgery; however, there is paucity in the current literature regarding whether the length influences the postoperative hearing results. Thus, this study’s objective was to identify the length of prosthesis used

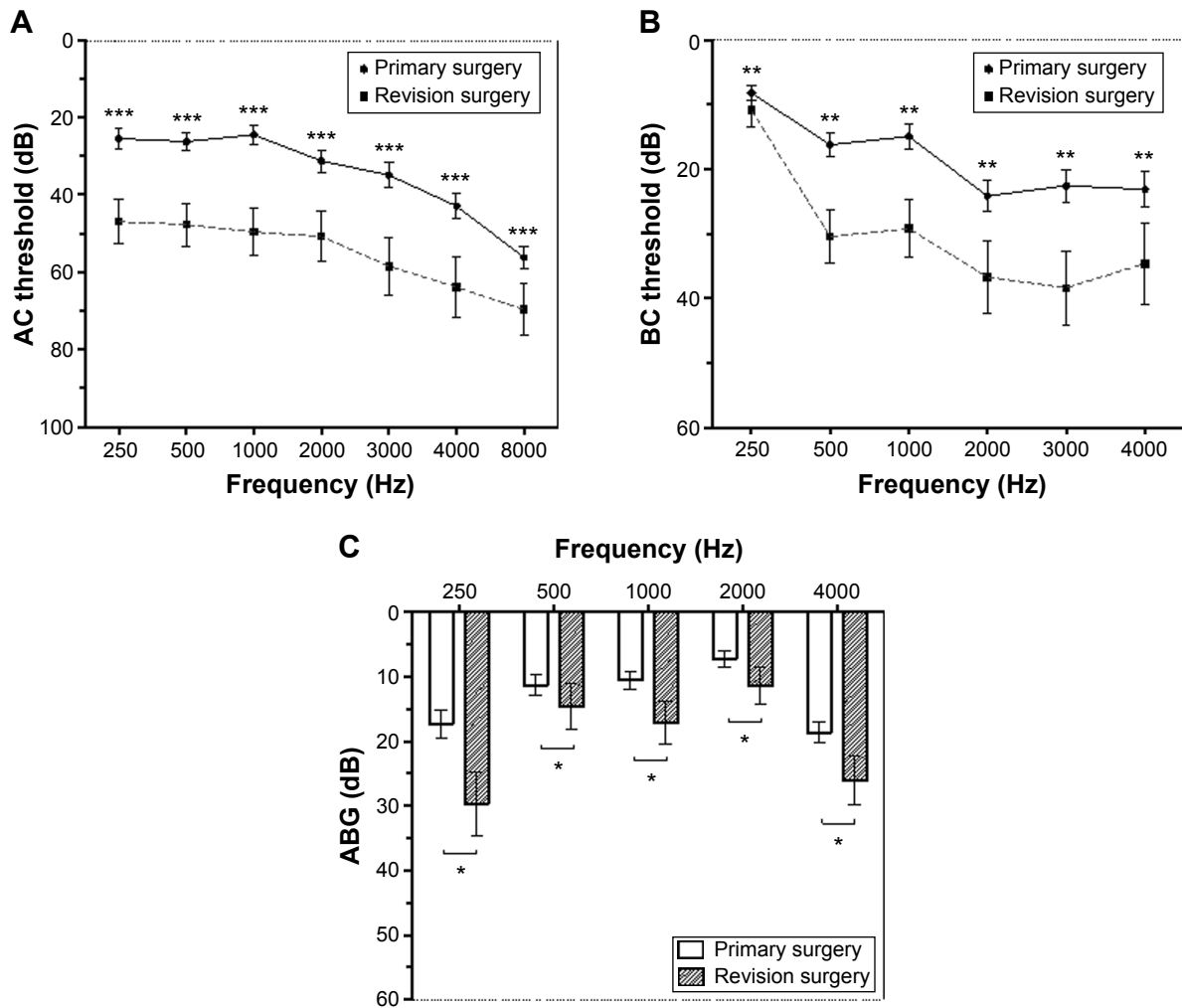


Figure 4. Results of audiogram at 18.3 months after operation. (A) Mean air conduction (AC) and (B) mean bone conduction (BC) thresholds for patients who had undergone a single primary surgery or revision surgeries. (C) Postoperative mean air–bone gap. Results are expressed as mean ± SEM. *** $P < 0.001$, ** $P < 0.01$, * $P < 0.05$.

in revision compared to primary stapedectomy, as well as to demonstrate the importance of accurate length measurement in postoperative audiometric outcomes.

In our series, the prosthesis length employed ranged from 3.0 to 6.0 mm when all surgeries were combined. Thus, this strengthens the notion that prosthesis measurement is an essential part of a successful stapedotomy or stapedectomy procedure, and that using a universal size, without proper measurements taken—such as the common 4.5-mm-length prosthesis described in 95% of cases¹³—should be discouraged. The prospective study by Portmann and colleagues¹⁴ has also reinforced this notion. Although their study looked at the use of the Portman clip or a Teflon prosthesis, which differs from the current study, they also showed different prosthesis lengths used, ranging from 3.5 to 5.0 mm, in both primary and revision surgeries. A prosthesis length of 4.75 mm was used in the majority of their patients. This indicates that various incus–footplate distances are possible in different individuals, and an accurate measurement of this distance will depend on

the area where the measurement is taken in addition to the type of prosthesis used.

Comparable to the findings described in the literature,^{2,12} stapedotomy was associated with better results, in that this technique was performed in most of the patients requiring only a single surgical intervention. The hearing results presented in this study are similar to those of previous studies^{3,6,9} demonstrating reduced hearing outcomes following revision surgery. Both preoperative and postoperative hearing results showed significantly inferior hearing levels in the revision group when compared to patients who had undergone a primary procedure. This has important implications, as the initial goal of the stapes procedure is to restore a certain percentage of hearing in the patients. Thus, in order to decrease the risk of revision procedures, those factors that can be controlled, such as prosthesis length, are important to determine, as it is more advantageous to succeed in the primary intervention itself.

Changes in prosthesis length between primary and revision surgeries occurred in 73.5% of the cases in the current

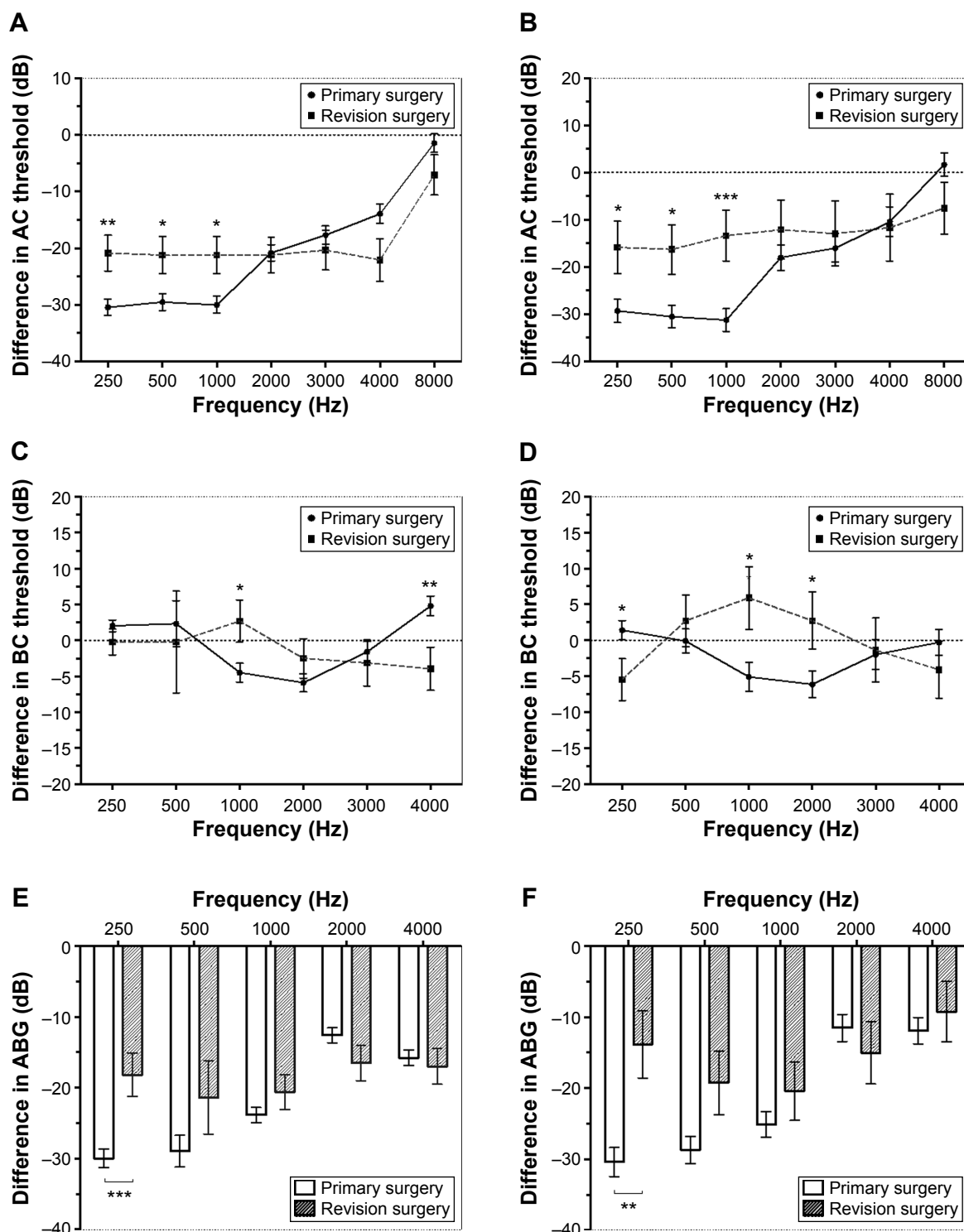


Figure 5. Hearing improvement after stapes surgery determined by the difference in postoperative and preoperative audiograms. (A, B) Evolution of mean air conduction (AC) thresholds. (C, D) Mean bone conduction (BC) thresholds. (E, F) Evolution of mean air–bone gap. Results are expressed as mean \pm SEM. *** $P < 0.001$, ** $P < 0.01$, * $P < 0.05$.

study. A longer length was required in 47.1% of the cases and a shorter length in 26.5% of patients having undergone a revision surgery. This corresponds to a significant proportion of patients, and falls within the reported range of 18%–82% for prosthesis displacement.⁶ Vincent and colleagues from their surgical series of revision stapes surgery identified short and

long prosthesis as causes for primary operation failure in 12.7% and 4.6% of cases, respectively.⁸ In a separate study, Gros et al described that the most common cause of primary stapes surgery failure included prosthesis malfunction and prosthesis displacement. They specify that the presence of incorrect prosthesis length occurred in 28.6% of the cases in

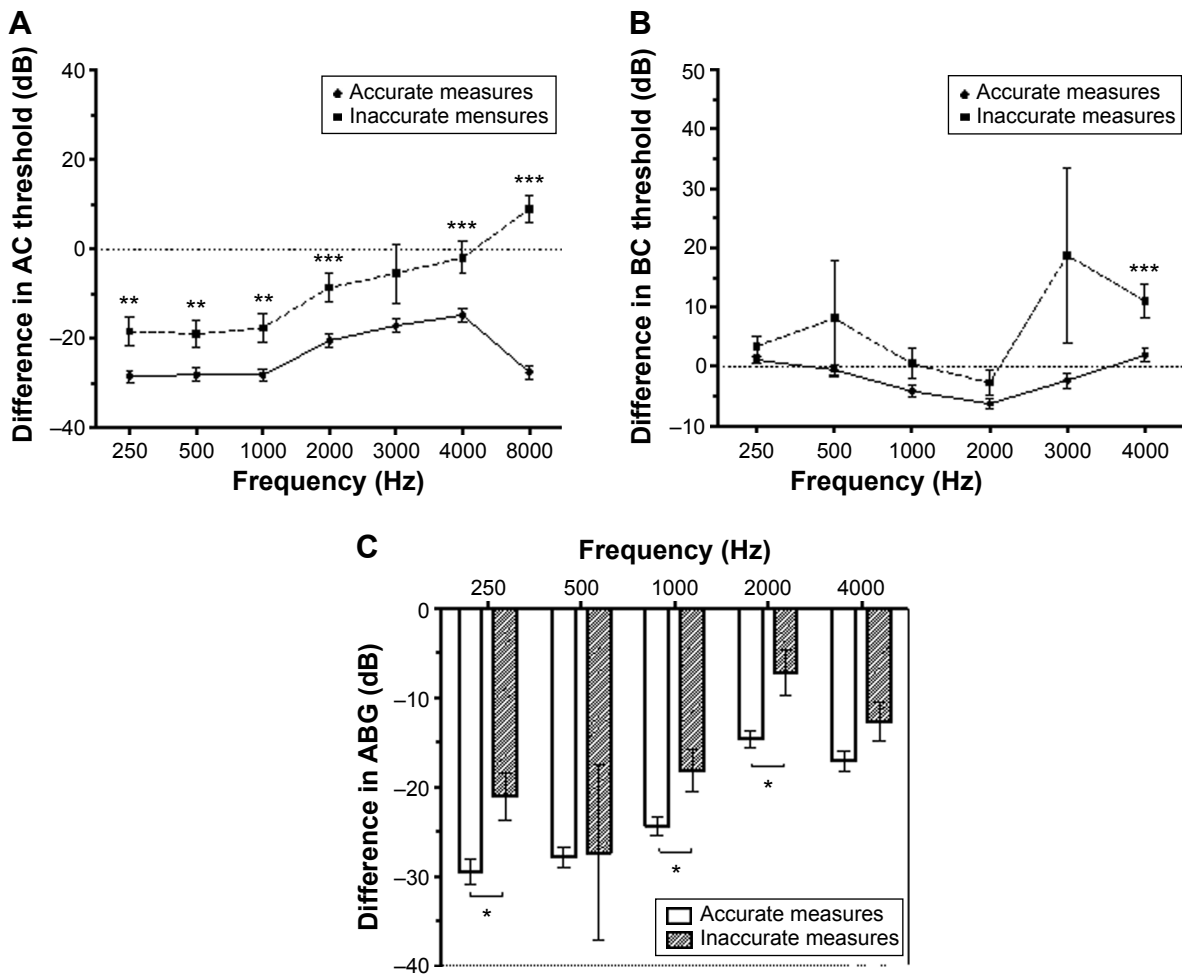


Figure 6. Evolution of the first postoperative audiogram comparing “accurate versus inaccurate” prosthesis measurements. Results are expressed as mean ± SEM. ****P* < 0.001, ***P* < 0.01, **P* < 0.05.

their study, and conclude that displacements of the prosthesis out of the oval window could have been circumvented had more accurate measurements been made in order to select the proper prosthesis length to be used.⁶ The biomechanics of the ear is well described in the literature, and it is known that the ear is exposed to changes in pressure, including changes in atmospheric pressure, during actions of daily life including swallowing, sneezing, diving, or flying. The changes in atmospheric pressure will produce displacements of the prosthesis, which has been shown to reach a maximum of 0.5 mm.¹⁵ Thus, this natural propensity to have an inward–outward movement of the prosthesis in the vestibule needs to be taken into account in order to avoid choosing a prosthesis that is too short or too long. In addition, it has also been implied that patients with an incorrectly shorter piston may not report sound distortions until the postoperative inflammation decreases, usually 2 months after the procedure.³ Thus, the intra-operative hearing experienced by the patient after prosthesis placement may not be entirely reliable. A prosthesis that is too long can produce symptoms such as vertigo, sensations of instability, or sensorineural hearing loss.^{3,13,16}

This has been described to occur either intra-operatively, or immediately following or a certain time after the surgical procedure. It can occur during swallowing or when pressure is introduced on the tragus.¹³ It may, therefore, be inferred that inaccurate measurements of the length between the incus and oval window are responsible for prosthesis displacement and thus the need for different lengths of the piston at the revision surgery. Our initial results demonstrated a significant difference in prosthesis length employed between patients where prosthesis length was accurately measured and the group of patients in whom inaccurate measurements were taken. In addition, the hearing improvement after stapedectomy was also significantly affected, with inferior results observed in the “inaccurate measures” group.

Various other causes of prosthesis failure do exist and have been described in the literature.^{2,3,5,6} Factors such as incus erosion or prosthesis malfunction itself, which can contribute to primary procedure failure, have been excluded from our study and thus are thought not to be contributing factors in the results demonstrated here. The retrospective nature of this study, however, does include certain limitations.



Information was obtained from postoperative notes and surgeon dictations, as well as any follow-up medical notes, and thus is subject to information bias, though this bias would be nondifferential.

Conclusion

This study further corroborates the postoperative success rates of revision surgeries, which have been shown to provide smaller improvements in hearing compared to a primary intervention. In addition, postoperative hearing outcomes following stapes surgery are superior when accurate measurement of incus-footplate distance is taken and an appropriate-sized prosthesis is chosen, as opposed to using “standard-length” prosthesis. Given the significant proportion of revision cases described in the literature, the effects of correct prosthesis length measurement are nonnegligible. Thus, to obtain successful postoperative audiometric results, and potentially avoid unnecessary otosclerosis revision surgery, accurate intra-operative prosthesis length measurement is recommended.

Author Contributions

Conceived and designed the experiments: CM, IS. Analyzed the data: CM, IS. Wrote the first draft of the manuscript: CM. Contributed to the writing of the manuscript: IS. Agree with manuscript results and conclusions: CM, IS. Jointly developed the structure and arguments for the paper: CM, IS. Made critical revisions and approved final version: IS. Both authors reviewed and approved of the final manuscript.

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