Stapedotomy Outcomes in the Treatment of Otosclerosis: Our Experience

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Objective: The main objective of our study is to identify whether there is measurable audiometric deterioration in patients undergoing stapedotomy with a follow-up of more than 8 years.
Material and method: We conducted a retrospective clinical study in which we reviewed a total of 150 case histories of patients with stapedotomy at our department between 1993 and 1997, with a successful initial audiological assessment using tone audiometry in the first 3 months after surgery and later audiometrical follow-up.
Results: We obtained a significant mean post-operative hearing impairment of 1.02 dB per year, with a pre-operative mean PTA of 51.45 dB, going on to early post-operative mean PTA of 26.71 dB, and later post-operative mean PTA of 35.42 dB, with all these changes turning out to be statistically significant.
Conclusions: The auditory level obtained after surgery worsens as the years go by, but always without exceeding the hearing loss prior to surgery.

Key words: Stapedotomies. Otosclerosis. Audiometric results

Resultados de la estapedotomía en el tratamiento de la otosclerosis: nuestra experiencia
Objetivo: Nos propusimos valorar el deterioro audiométrico de los pacientes intervenidos de estapedotomía, con un seguimiento mayor de 8 años.
Material y método: Realizamos un estudio clínico retrospectivo en el que revisamos un total de 150 historias de pacientes intervenidos de estapedotomía entre los años 1993 y 1997 en nuestro servicio, con buen resultado audiológico inicial valorado mediante audiometría tonal en los primeros 3 meses tras la cirugía y con seguimiento audiométrico posterior.
Resultados: Obtuvimos una media de deterioro auditivo postoperatorio significativa (1,02 dB por año), con una media auditiva preoperatoria de 51,45 dB, que pasa a una media de 26,71 dB en el postoperatorio temprano, y una media de 35,42 dB en el postoperatorio tardío; todos estos cambios son estadísticamente significativos.
Conclusiones: El nivel auditivo obtenido tras la cirugía empeora con el paso de los años; pero siempre sin sobrepasar la pérdida auditiva previa a la cirugía.

Palabras clave: Estapedotomía. Otosclerosis. Resultados audiométricos.

INTRODUCTION

Otosclerosis is a primary disease of the labyrinth bone capsule consisting of one or more localized foci in which bone resorption and deposition take place repeatedly. This focus may gradually invade the annular ligament and the stapes, causing bone ankylosis and deterioration of the air conduction of sound; among Caucasians in our country, this is the most common cause of transmission hearing loss.

The first description of ankylosis of the stapes in the autopsy of a deaf patient is attributed to the Italian anatomist and surgeon Antonio Valsalva in 1741. Other 18th-century anatomists and pathologists would also have described ankylosis of the stapes in autopsies of deaf people. In 1955, Rosen performed a transplatinar opening for re-establishment of incudo-labyrinthine transmission. For a long time, the operation would be called Rosen's second technique.[1]

Since then, the technique has been perfected and the merits of total stapedectomy, partial platinectomy, and platinotomy have been gradually discussed. In parallel, the interest of

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the interposition and the decision to carry it out have been analyzed, while different surgeons have tried to define the mode of transmission which is better suited and more reliable. Thus, the recent history of otosclerosis surgery is marked by the variety of procedures suggested. Some names, however, must be cited as pioneers; in the United States: Rosen, Shanbaugh, Schucknect, Shea, House, Armstrong; in France: Clero, Guillon, Portmann, Causse, and Martin.[2]

Treatment of otosclerosis can be medical or surgical, but undoubtedly the surgical treatment of otosclerosis is the preferred option for therapeutic esteem. Sodium fluoride (NaF) and biphosphonates are the 2 most commonly used substances for medical treatment of otosclerosis, but clinical studies are scant and their follow-up, very brief.

The surgical rationale is based on the social inconvenience causing concern to patients and on the hope of obtaining a substantial advantage with the operation. In practice, an intervention should only be considered in cases with deafness over 30 dB and a Rinne value in this order, although the possibility of recovery by bone conduction (Carhart effect) can and should be taken into account.[3]

The short-term results are undoubtedly very good in the literature consulted. The conflict or doubt arises when we question whether such good results can be sustainable in the long term and, especially, when the technique used is stapedotomy and not stapedectomy.

There are several published studies supporting the successful long-term results (over 5 years) of stapedectomy in its different variants (partial or total); nevertheless the same can not be said of stapedotomy, for which studies are few and the follow-up very short.

This is what motivated us to carry out the current paper, in which we analyze whether the good results achieved in the short term by stapedotomy in our service are maintained over time.

MATERIAL AND METHOD

We conducted a retrospective clinical study in patients operated on for stapedotomy in the period 1993-1997 at the otolaryngology service of our hospital.

A strict selection of patients who met the following inclusion criteria was made:

1. The surgical technique used in all patients should be stapedotomy.

2. All patients must have been operated on by the same surgeon.

3. Differential hearing threshold (DHT) ≤10 dB in the early post-operative period (first 3 months after surgery), at frequencies of 500, 1000, 2000, and 4000 Hz, as reflected in a tone threshold audiometry.

The basic technique was performed under local anaesthesia and sedation by common endaural approach and incudo-stapedial disarticulation, dissection of the stapes muscle, fracture of its branches and perforation of the plate with a hand borer or a punch. All types of prostheses used were of the piston type. In none of the cases was the oval window covered with any type of material before or after the placement of the prosthesis.

We reviewed a total of 150 histories which, after applying the inclusion criteria previously mentioned, were reduced to only 40 histories for a total of 46 ears operated.

Database

A database protocol was designed to collect data from the histories (Appendix 1). From the histories, we recorded:

– Epidemiological data: age, gender, location, bilateralism, presenting clinical signs

– Surgical data: date of operation, technique employed, surgical findings

– Audiometric profile: air route (AR), bone route (BR), and DHT with the mean of 500, 1000, 2000, and 4000 Hz frequencies in the pre-operative, early post-operative, and late post-operative periods

We collected the cases which presented complications such as vertigo and/or tinnitus.

Statistical Analysis

The results were recorded in an Excel spreadsheet which was then processed using the SPSS statistics package for Windows.

The descriptive analysis of quantitative variables was performed by determining the mean and standard deviation for continuous variables and absolute and relative frequencies for categorical variables.

The comparative analysis was performed using the non-parametric Friedman test (Friedman analysis of variance by ranks), taking into account the audiometric results in the 3 periods.

The accepted level of statistical significance in our work is P=.05.

RESULTS

Epidemiological Data

A total of 46 operated ears have been included in this study; 34 (74%) in women and 12 (26%) in men.

The age range is 36-81 years at the time of the intervention, with a mean of 52.04 (13.4) years. Eleven point one percent of patients were younger than 40, 40% were between 41 and 49, and 48.9% were over 50 years of age at the time of the intervention.

The most common clinical presentation among our patients was hearing loss (54.3%), followed by a combination of hearing loss and tinnitus (37%). Less commonly, we encountered the combined presentation of hearing loss and vertigo (6.5%) or the combination of hearing loss, vertigo, and tinnitus, which was only observed in 2.2% of patients.

We noted that there were more operations on the left ear (24 cases, 52.2%) than on the right (22 cases, 47.8%).

Early post-operative audiometry was conducted in an interval of 1 to 8 months after surgery, with a mean of 2.65 (1.64) months.

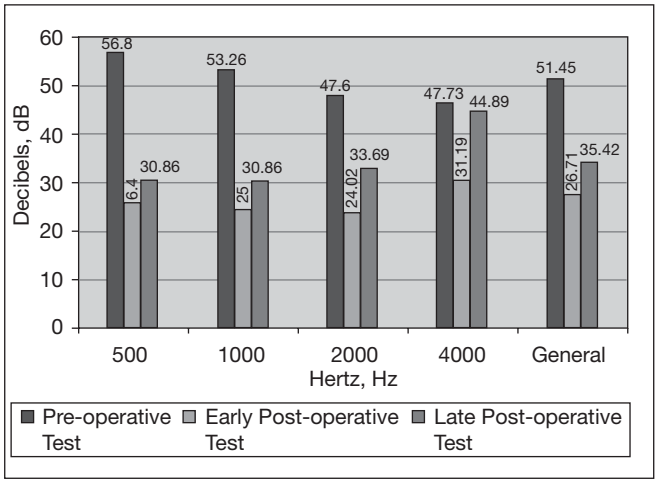

Figure 1. Analysis of the air route: the air route is more affected at low frequencies. Worsening of the late post-operative mean after an improvement in the early post-operative mean, without reaching the pre-operative mean air route hearing loss.

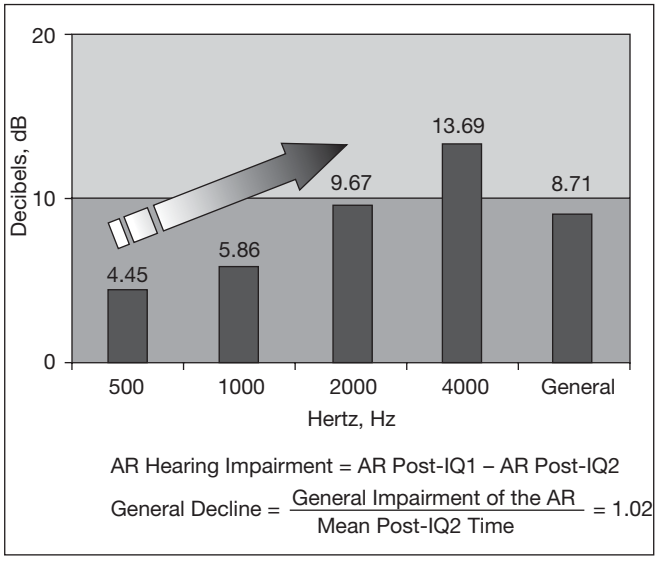

Figure 2. Analysis of the air route: the post-operative hearing loss increases as the frequency increases. The overall decline is estimated from the general deterioration in terms of post-operative study time.

The audiometric monitoring of our patients was conducted using tonal audiometry after a mean of 8.5 years (103 [21.69] months).

Audiometric Data

We report our findings as tone threshold audiometry in general and then in response to each separate frequency, comparing the pre-operative, early post-operative, and late post-operative audiometries. The descriptive analysis of each of the frequencies studied (500, 1000, 2000, and 4000 Hz), both for the bone and air routes and for the DHT, gave the overall mean for each frequency in the pre-operative, early post-operative, and late post-operative.

The comparative analysis showed that the changes in all frequencies were statistically significant for both the air route and for the DHT, when comparing the overall audiometric means of the pre-operative and early post-operative tests; we obtained the same result when comparing the early post-operative period with the late post-operative one.

Analysis of the Air Route

We have found that the airborne route is most affected at low frequencies, a typical sign of otosclerosis. Figure 1 shows, in the form of the audiometric mean, the improvement obtained after surgery (pre-operative mean 51.45 dB and early post-operative mean 26.71 dB), a statistically significant change ($P<.005$), and hearing worsens with time (late post-operative mean of 35.42 dB); although these audiometric levels are always better than those seen prior to surgery, the changes are not statistically significant.

We have tried to determine the deterioration of the air route over the long term, in order to determine a mean annual decline in patients operated on for otosclerosis. To achieve this, we subtracted the early post-operative (Post-IQ1) result from the late post-operative (Post-IQ2) one to obtain the overall deterioration of the air route at different frequencies (hearing deterioration AR = AR Post-IQ2 – AR Post-IQ1) and obtained a general deterioration of 8.71 dB. Analyzing the hearing impairment in the air route, we can observe a clear rise in the hearing impairment as the frequency increases (Figure 2).

By dividing the result by the mean follow-up time for our patients, we obtained the overall mean annual hearing impairment or general decrease, namely 1.2 dB per year in our study.

Analysis of the DHT

We recorded changes in the audiometric mean of the DHT for different frequencies (500, 1000, 2000, and 4000 Hz) in the 3 periods (pre-operative, early post-operative, and late post-operative), and obtained an overall mean of 28.3, 5.66, and 10.4 dB, respectively. Changes between the pre-operative and early post-operative were statistically significant ($P<.005$), while the changes between early and late post-operative tests were not statistically significant (Figure 3).

We divided our patients into 2 groups according to the late post-operative DHT observed (DHT>10 dB and DHT=10 dB). In this way we can establish 2 groups that enable us to make an objective assessment of the long-term evolution of DHT at each of the frequencies and in general (93.5% of cases presented DHT=10 dB compared to 6.5% who presented DHT>10 dB). The comparative analysis resulted in $P<.05$ (Figure 4).

Analysis of the Bone Route

An analysis of the audiometric mean of the bone route at different frequencies was carried out, and an audiometric gain was observed between the pre-operative period and the early post-operative at the frequencies of 1000 and 2000 Hz, these changes were not statistically significant. In the general mean it should be noted that the bone route loss goes from 23.4 dB in the pre-operative to 21.3 dB in the early

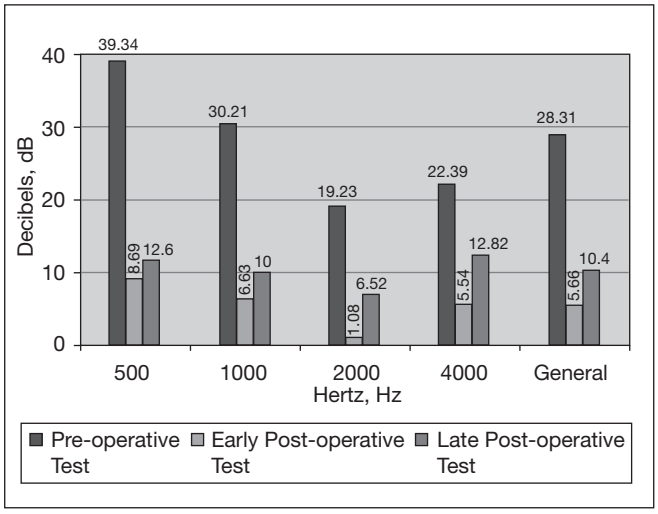

Figure 3. Analysis of differential hearing threshold (DHT): evolution of the DHT at the 3 different times (pre-operative, early post-operative, and late post-operative), in which a maximum impairment can be seen prior to surgery, falling to a minimum immediately after surgery and gradually increasing again over the years without reaching the initial values.

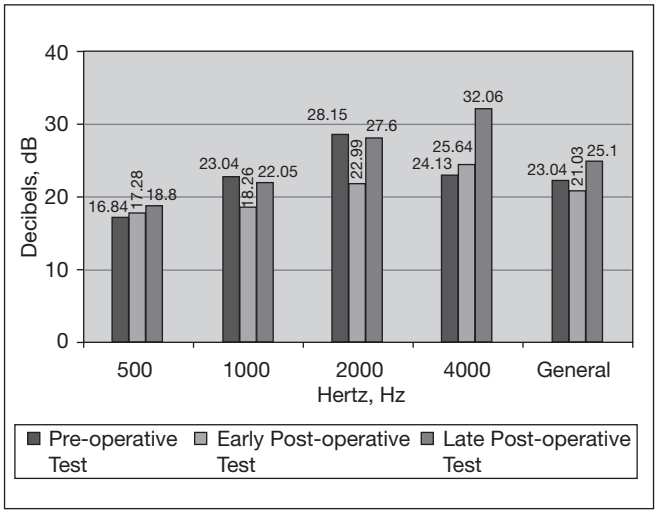

Figure 5. Analysis of the bone route: audiometric mean of the bone route at different frequencies. There is an audiometric gain between the pre-operative and the early post-operative period in the 1000 and 2000 Hz frequencies.

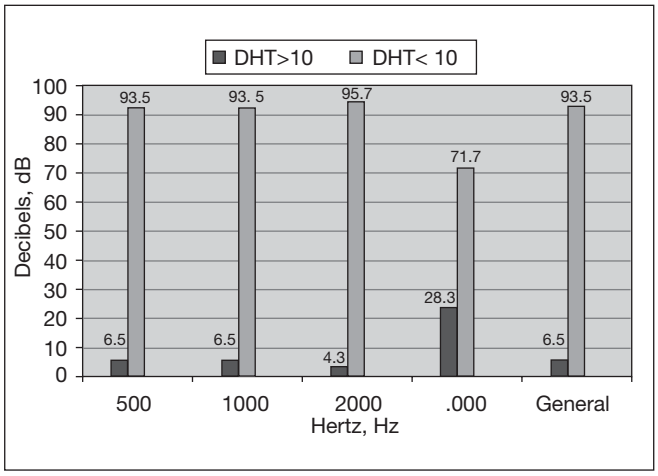

Figure 4. Analysis of differential hearing threshold (DHT): according to the late post-operative DHT seen in our patients, we divided them into 2 groups (DHT>10 dB and DHT=10 dB). Ninety-three point five per cent of cases presented DHT=10 dB compared to 6.5% who presented DHT>10 dB.

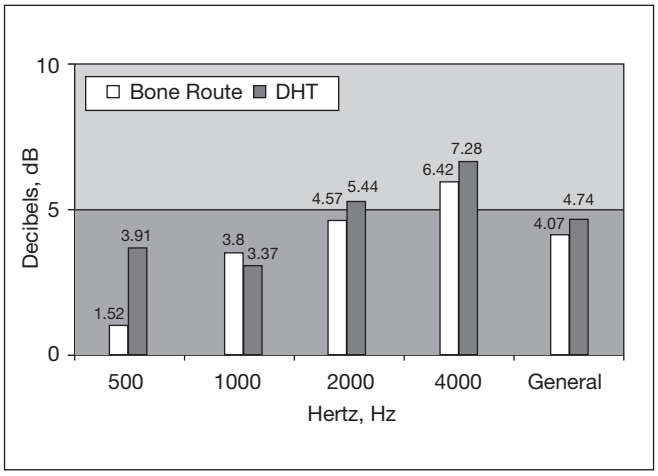

Figure 6. Analysis of bone route and differential hearing threshold (DHT): comparison of post-operative worsening of the DHT and bone route. The DHT impairment was greater than that of the bone route, but without statistical significance (*P*>.05).

post-operative test, and changes again late post-operatively to 25.1 dB (Figure 5).

Analysis of the DHT and Bone Route

We conducted a comparison of post-operative worsening of the DHT and the bone route separately, in order to carry out later a comparison between them. To achieve this, we subtracted the late post-operative audiometric mean from the early post-operative audiometric mean, and thus obtained the mean general impairment (for the DHT, this was 4.74 dB and 4.07 dB for the bone route) as well as the mean deterioration for each of the frequencies. The deterioration of the DHT was higher than that of the bone route, but without reaching statistical significance (*P*>.05) (Figure 6).

DISCUSSION

Many studies have shown that stapes surgery is a successful way to improve the hearing of patients affected by otosclerosis. Stapedectomy was introduced over 40 years ago, but today stapedotomy has become the most widely used.[4]

As for the airborne route, the short-term results are, without question, very good; Birch et al[5] show in their study a gain of between 25 and 35 dB on average for the air route,

while we obtained a mean gain of 24.74 dB. These results are very similar, given that the study by Birch et al is based on patients on whom stapedectomy was performed, while we carry out stapedotomy on all our patients.

Like other studies, we found a marked initial decrease in the hearing threshold for the air route at high frequencies, specifically at 4000 Hz, which went from 31.19 dB in the early post-operative test to 44.89 dB in the late post-operative one; these figures are very close to the pre-operative hearing levels, estimated at 46.73 dB.[6]

In the literature reviewed, we found that the overall decline in air route (500 to 4000 Hz) varies between 0.6 and 1.2 dB per year[7]; in our study, the deterioration or overall decline of the air route was 1.02 dB. In a study published by Aarnisalo et al,[4] which examines and compares stapedectomy with stapedotomy, there was an annual decline of 0.9 dB in the air route, the same for both techniques.

We believe it would be interesting to conduct a study to compare the drop occurring over the years in patients operated on for otosclerosis and compare that with the decline appearing in a normal population as a result of presbycusis. According to some authors such as Langman et al,[6] the hearing loss caused by age can be estimated at 1 dB per year. Although our study has not taken this into account, there are studies that have compared the post-operative deterioration in patients who have undergone surgery for otosclerosis with that in a normal population, and they indicate that the hearing deterioration is greater in patients operated on for otosclerosis.[8]

Undoubtedly, the DHT tends to increase after surgery as time goes by. In a study presented by Spandaw et al,[9] the DHT descended from 36 dB before surgery to 11 dB 1 year after surgery, only to rise again up to 17 dB 10 years after surgery. In our study, the overall mean DHT went from 28.31 dB before surgery to 5.66 dB 3 months after surgery, before increasing to 10.4 dB after 8 years.

One consideration to be taken into account is that the age and pre-operative bone thresholds do not affect the final hearing outcome, but there are significant differences between the DHT and age, with the higher DHT levels found in older patients. The best results were obtained in patients in their fourth decade of life.[10] In our study, we examined the DHT in the different age groups according to long-term post surgical results and no statistically significant differences were found, possibly because our study had a relatively small number of patients.

Other studies compare long-term outcomes for age groups,[5-11] and find a higher deterioration in those under 30 compared to those over 30 years of age. Age is thus considered to be a modifying factor in hearing evolution.

The hearing impairment for the bone route, in our study, was established at a frequency of 4000 Hz because this is the frequency most affected by surgical trauma and also by presbyacusis. Annual post-operative deterioration for the bone route in our study was 0.88 dB. This impairment in the bone route could be caused by presbyacusis.[12] Aarnisalo et al,[4] in their comparative study of 225 patients, found a deterioration of 0.8 dB for the bone route in stapedotomy and 0.9 dB for stapedectomy.

With regard to the assessment of deterioration in the bone route and the DHT, some studies[3] suggest that the long-term deterioration fundamentally affects DHT rather than the bone route. Our study confirmed that the DHT was the component most affected over the years, showing a deterioration of 4.74 dB versus the 4.07 dB of the bone route. It can thus be concluded that this involvement is produced more by the impairment of the on the ossicular transmission mechanism during the procedure than by cochlear otosclerosis or presbyacusis.

The symptom that most often affects patients with otosclerosis is hypoacusis, although the main reason for consultation is often tinnitus. In a study presented by del Bo et al,[13] 56% of patients had tinnitus before surgery. In our study, the figures are somewhat lower, only 44% of our patients subjected to surgery.

Vertigo is a common symptom in patients operated on for otosclerosis. In their study, Sedwick et al[14] found that 23.3% of post-surgical patients presented this symptom after stapedectomy or stapedotomy. Our study found occasional vertigo in 16% of patients, without any sign of permanent vertigo present in any case.

Although we did not carry out a comparative study between the different techniques of stapes surgery, we have conducted a literature search on the subject and we can say that no significant differences were found between the 2 techniques in the short or long term.[4]

Analyzing the data obtained in our study, we come to the following conclusions:

– The hearing level obtained after surgery worsened over the years, although it never surpassed the loss prior to surgery

– The most important changes in the different assessments carried out occur at a frequency of 4000 Hz

– Our study shows a decline after stapedotomy of 1.02 dB per year

– The largest part of hearing loss after stapedotomy throughout the years is attributed to the further deterioration of the DHT

– Complications caused by stapedotomy which persist throughout the years are very few

– As a result of our study, we can consider stapedotomy as an effective technique in the short and long term

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Appendix 1. M & M Stapedotomy Database

Name _____ Surname _____ Case no. | | | | | | |

DoB (day / month / year ____ / ____ / ____ Gender F ☐ M ☐ Occupation _____

Personal history: _____ Relationship _____ Illness _____

Disseased: Tinnitus ☐ Hypoacusia ☐ Vertigo ☐ Duration < 1 year ☐ > 1 year ☐

RE	500	1000	2000	4000
BR				
AR				
GAP				

Right acoustic reflex ☐

LE	500	1000	2000	4000
BR				
AR				
GAP				

Left acoustic reflex present ☐

Date of Surgery

RE __ / __ / __ day / month / year Surgical procedure: Stapedotomy ☐ Stapedectomy ☐ Local Anaesthesia ☐ General Anaesthesia ☐

LE __ / __ / __ day / month / year

Prostheses: Teflon Type ☐ Steel ☐ RE Size__ × __ LE SIZE__ × __ Surgeon: F ☐ R ☐ Others ☐

Incidents during surgery:

Narrow duct		Profuse bleeding	
Perforation of membrane		Plate alterations	
Postprocident wall		Luxation of the anvil	
Fibrosis of the oval window		Difficult placement	
Dissection of tympanic chord		Others	

Post-surgical hospital stay <24 h ☐ >24 h ☐ Post-operative impairment: Tinnitus ☐ Hypoacusia ☐ Vertigo ☐

Audiometry performed after _____ m/y

RE	500	1000	2000	4000
BR				
AR				
GAP				

Early post-operative audiometry

LE	500	1000	2000	4000
BR				
AR				
GAP				

Audiometry performed after _____ m/y

Revision Surgery: _____

Audiometry performed after _____ m/y

RE	500	1000	2000	4000
BR				
AR				
GAP				

Late post-operative audiometry

LE	500	1000	2000	4000
BR				
AR				
GAP				

Audiometry performed afters _____ m/y