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Performance assessment of ossicular chain reconstructions in a University hospital

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It remains to be demonstrated that normal, day-to-day routine surgery is as effective as it would appear from the literature, where the results of very experienced surgeons are presented. The object of this study was to measure our performance for ossicular chain reconstructions. One hundred and thirty-eight total and partial reconstructions performed by 13 different surgeons were evaluated. The population was divided into four different groups based on the presence or absence of the canal wall and stapes suprastructure. The results varied widely. A number of patients benefited greatly, whereas others experienced deterioration in their hearing. The best improvement (median 13 dB) was achieved in the group with an intact canal wall and absent stapes suprastructure. The postoperative air bone gap was better for autologous incus rather than prosthesis in the group where the canal wall and stapes were intact. There were three minor complications. This continuous feedback reports exceptional results (good and bad). The strengths and weaknesses of the department can be determined. This feedback indicates that this procedure is safe and beneficial for the patients in our Institution.

Keywords *ear surgery* *performance* *ossicular chain reconstruction* *ear diseases*

Patients are entitled to know what their chances are of recovering their hearing after an ear operation. It remains to be proven that normal, day-to-day routine surgery is as effective as it would appear from the literature, where the results of very experienced surgeons are presented. Ossicular chain reconstruction has been attempted since the end of the 1950s and early 1960s. Hall and Rytzner performed the first ossicular chain reconstruction using autologous ossicular bone in 1957.[1] Farrior was one of the surgeons to describe how to reshape the incus before interposition.[2] In 1966, House introduced the incus allograft.[3] The drawback of using bone is the risk of the presence of residual infection or transmission of diseases.[4,5] Wullstein was the first to use artificial, polyethylene implants in 1952, but abandoned these due to extrusion, infection and erosion of adjacent ossicles.[6] Shea designed a plastipore implant, but these still were prone to extrusion.[5] Brackman covered the prosthesis with cartilage to prevent extrusion.[7,8] Grote introduced hydroxyapatite as a material for ossicular chain reconstruction.[9] In our department, autologous incus is preferred. When this is not available, the Wehrs prosthesis and sometimes a Gausse prosthesis are used.[10]

To be able to make a performance analysis of the ENT Department of the university hospital as a whole, data for all ear operations is stored in a database. This OtoData system is a continuous follow-up which makes it possible to acquire data for performance analysis at any moment. The OtoData system allows selection of patient data by ossiculoplasty.

The aim of this study was to document the numbers and to measure our performance for ossicular chain reconstruction. The postoperative hearing levels and the complication rates provide an indication of performance for 138 consecutive ossicular chain reconstructions. Patients can make a well-informed choice about the suggested ear operation based on this evaluation.

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Patients and methods

PATIENTS

Of 1009 consecutive ear operations performed from July 1992 until June 1995, 138 involved an ossicular chain reconstruction. These were total and partial reconstructions with autologous incus, bone or prosthesis (PORP/TORP). The cases were selected from the OtoData continuous follow-up system. In 52 cases (38%), the reconstruction was only part of the operation (Table 1). At the ENT Department of the University Hospital Rotterdam, five members of staff perform ear operations on a regular basis. During this period, eight residents performed ear operations. Audiometry was added from the databases of the Audiometry Department. In 126 (91%) cases, both pre- and postoperative audiometry was made available, in order to enable a comparison.

METHODS

All ear surgeons dictated a form postoperatively, which contained key items about the identification of the patient and procedure, middle ear structures, mastoid contents and materials used. The secretary entered these data into a database in the hospital network when the dictated operation notes were typed out. This continuously ongoing data collection of all earsurgery (OtoData) was started on 1 July 1992.

Each record in the OtoData contains one surgical procedure. The follow-up ends on the date of the last outpatient clinic visit, or the date of reoperation on the same ear. The coupling with the database in which all audiometry is stored at the University Hospital Rotterdam (AZR) turned out to be impossible. The data had to be selected by hand and then added. Postoperative audiograms were not always performed. Also, not every operation was added to the database and some forms were incomplete or wrongly dictated. To compensate for these omissions it was decided to check and complete the records of the first 3 years.

The population that underwent an ossicular chain reconstruction was divided into four different groups: canal wall down/stapes suprastructure-missing (CWD/stap-); canal wall down/stapes intact (CWD/stap+); canal wall up/stapes suprastructure-missing (CWU/stap-); and canal wall up/stapes intact (CWU/stap+). The median Fletcher index (mean 500–1000–2000 Hz) air conduction thresholds and changes therein–rather than changes in air-bone gaps–are given for each group, showing the levels of the hearing losses that were treated. Air conduction was chosen because this is what the patient hears. ENT surgeons are used to audiograms; median pre- and postoperative audiograms are therefore also presented. Postoperative audiograms were planned 1 year after surgery. The 10th and 90th percentiles are plotted, in order to eliminate the influence of the range of the audiometer. When an ossicular chain reconstruction is performed in combination with a mastoidectomy, preservation of hearing was the aim. For comparison purposes, preoperative ABG rates are not presented. In the literature generally, the postoperative ABG is presented. In this paper, the postoperative ABG is presented in four categories: 0–10, 10–20, 20–30 and > 30 dB hearing loss.

Table 1. Combination surgery with ossicular chain reconstruction

Operation	*n*
CWU mastoidectomy	12
CWD mastoidectomy	11
Myringoplasty	9
Revised CWU mastoidectomy	8
Middle ear inspection	7
Revised CWD mastoidectomy	5
Total	52

CWU = canal wall up; CWD = canal wall down.

Results

In the series there were 74 male patients and 64 female. The average age was 35 years and the age distribution is shown in Fig. 1.

The median air-conduction thresholds, from the Fletcher index (mean 0.5–1–2 kHz) pre- and postoperatively, are given in Figs 2 and 3. The median improvement for each group is given in Fig. 4. Postoperative audiograms were performed, on average, 1.1 years (SD 0.93) after surgery. In the canal wall down/stapes suprastructure-missing group, the results were different for ossicular chain reconstructions performed in combination with other operations. If reconstruction was the main objective, the median improvement was 10 dB. If reconstruction was part of the operation, the median improvement was 0 dB. In the other groups, there were no dissimilarities between the results of reconstructions performed alone and those performed in combination with other operations. The results varied widely; a number of patients benefit greatly from the reconstruction, whereas others experienced deterioration in their hearing. The best results (median 13 dB) were achieved in the canal wall present/stapes suprastructure-missing group.

For autologous incus and prosthesis in the canal wall present/stapes intact group the postoperative ABG is shown in figure. Seventy-eight per cent of the own incus and 58% of the prosthesis have a postoperative ABG < 20 dB. In the canal wall present/stapes suprastructure-missing group the autologous incus results in a postoperative ABG < 30 dB in 85% and < 20 dB in 50%. The other groups are too small for reliable conclusions.

The median preoperative and postoperative audiograms are presented in Figs 6–9, with the 10th and 90th percentile.

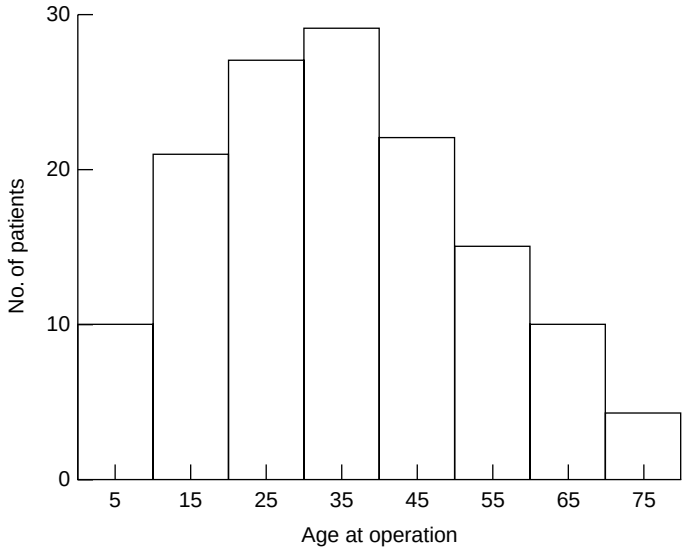

Figure 1. Number of patients per age group

These show that the main improvement in hearing occurs in the lower frequencies. The hearing loss was worse when the canal wall and/or stapes suprastructure was missing.

There were three minor complications (Table 2). There was one complication with prolonged morbidity (temporary loss of taste). There were no major complications with permanent damage.

Discussion

The OtoData continuous follow-up system allows us to monitor our audiological results in ossicular chain reconstructions. Results analysed with the OtoData are comparable to those in the literature. Moreover, the results of ossicular chain reconstruction in our hospital are not different from those reported elsewhere. Thirteen dB was the median hearing improvement in the group canal wall present/stapes suprastructure-missing group. Ten dB was the median hearing improvement in the canal wall down/stapes intact and canal wall present/stapes intact groups. In the canal wall down/stapes suprastructure-missing group, the median hearing improvement was 3 dB. In this group, the results are different for ossicular chain reconstructions performed in combination with other operations. If the recon-

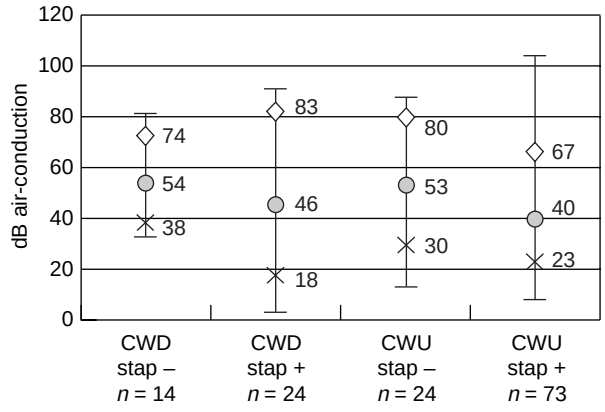

Figure 2. Preoperative median air conduction levels Fletcher index. Mean 500–1000–2000 Hz dB per group. X = 10th percentile; ◇ = 90th percentile; ○ = median.

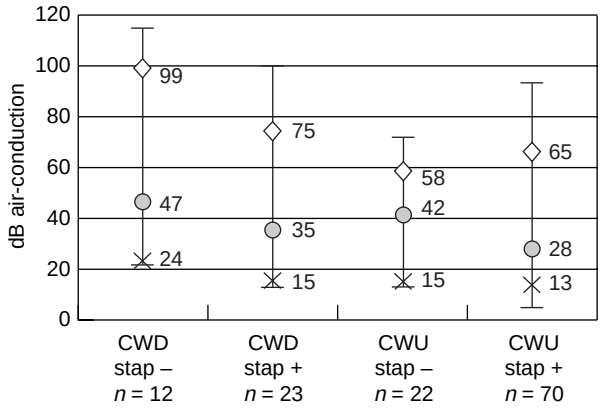

Figure 3. Postoperative median air conduction levels Fletcher index. Mean 500–1000–2000 Hz dB per group. X = 10th percentile; ◇ = 90th percentile; ○ = median.

Table 2. Complications in 138 ear operations with Ossicular chain reconstruction

Complication	Operation
Otological	
Loss of taste	CWU mastoidectomy
Perforation of the tympanic membrane	Ossicular chain reconstruction
General	
Urine retention	CWD mastoidectomy
Locked knee on dangling	Ossicular chain reconstruction

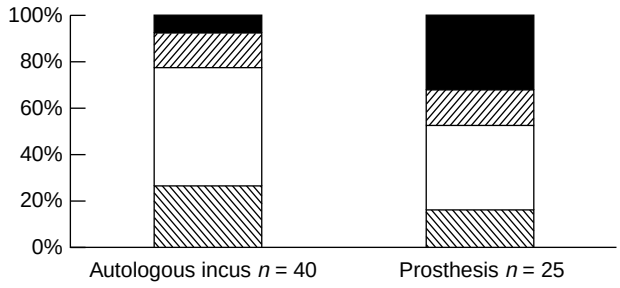

Figure 5. Postoperative air–bone gap Fletcher index (mean 500–1000–2000 Hz) for autologous incus and prosthesis, when canal wall and stapes are present. = > 30 dB (autologous incus, 3; prosthesis, 8); □ = 20–30 dB (autologous incus, 6; prosthesis, 4); = 10–20 dB (autologous incus, 20; prosthesis, 9); □ = 0–10 dB (autologous incus, 11; prosthesis, 4).

struction was performed as a single procedure, the median improvement was 10 dB. If the reconstruction was only part of the operation, the median improvement was 0 dB.

Mills reported an average hearing improvement of 11 dB when using cortical bone and 14 dB when using an ossicular graft.[11] Nikolaou[12] found a mean hearing improvement of 11 dB when using autologous incus: he reported 16–17 dB improvement when using a TORP (Polyethylene/Wehrs), 6 dB when using a Polyethylene PORP and 22 dB when using a Wehrs PORP. Vartiainen reported a hearing gain of 11 dB for all cases.[13]

The improvement in median air-conduction thresholds mainly occurs in the lower frequencies. Mills describes the same phenomena in his study of incus transposition and the use of cortical bone.[14]

A possible explanation for this modest median improvement might be the spread in improvement (Fig. 4). There are patients who benefit greatly from the ossicular chain reconstruction and there is a group that experiences deterioration of hearing. Rhageb reports a similar spread in air-conduction threshold changes.[15] Whether the amount of improvement can be predicted remains to be determined.

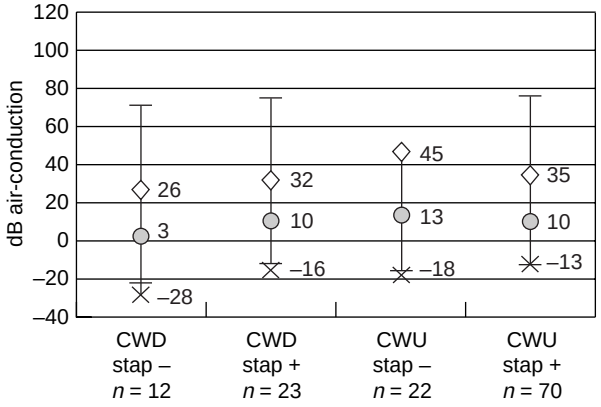

Figure 4. Change in median air conduction levels Fletcher index. Mean 500–1000–2000 Hz dB per group. X = 10th percentile; ◇ = 90th percentile; ○ = median.

When the stapes suprastructure is missing, the aim is to achieve a postoperative ABG < 30 dB. When the stapes is intact, an ABG of < 20 dB is acceptable.[16] When using these criteria, the incus interposition appears to be more successful than the use of a prosthesis when the stapes suprastructure and canal wall are present (Fig. 8). McElveen achieved a postoperative ABG of < 20 dB in 59% by using an IONOS PORP.[17] Wehrs reports a postoperative ABG of < 20 dB in 85%.[10] Slater describes a postoperative ABG of < 20 dB in 75% when using a PORP made of polyethylene ($n = 250$).[8] Brackman reports, when using a PORP, a postoperative ABG < 20 dB in 73% ($n = 1042$).[7] Our rates are slightly lower than those mentioned in the literature, possibly as a result of the larger number of surgeons and the fact that ossicular chain reconstructions were performed in combination with other operations.

Ragheb states that the stapes suprastructure does not add much to hearing preservation.[15] In this study, when the canal wall is intact, an absent stapes leads to better hearing results postoperatively (Fig. 4). However, the small numbers preclude a statistical analysis.

According to our study, postoperative hearing levels are worse when the canal wall is absent. In the case of his population (91% otitis media), Brackmann found that the presence of the canal wall had little influence on postoperative hearing.[7] Albu reports, however, that an intact posterosuperior bony wall is the most important predictive factor in the achievement of near-normal hearing.[18]

Complications mentioned in the literature are: damage to the chorda tympani, damage to the cochlea or labyrinth and facial nerve.[19,20,21] In this population, there were only three minor and one severe complication (postoperative loss of taste). The risk of complications is low.

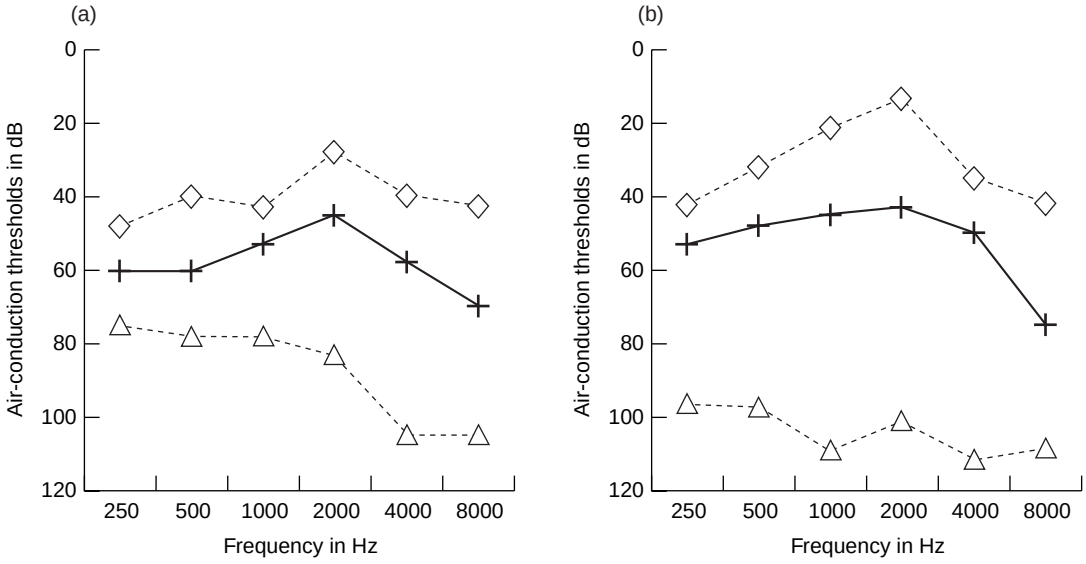

Figure 6. (a) Preoperative ($n = 14$) and (b) postoperative ($n = 12$) median air conduction audiograms with 10th and 90th percentile CWD/stap-. ◇ = 10th percentile; △ = 90th percentile; + = median.

Patients must be informed about the chances of recovering their hearing after an ear operation. In the Netherlands, a new law (WGBO) requires informed consent of the patient based on the results of the department where the treatment will be performed. The OtoData system makes this possible. On the basis of these results and a low complication rate, it may be said that generally speaking ossicular chain reconstruction is a beneficial and safe operation in our department. The benefits must, however, not be overestimated because there is a group that experiences deterioration in hearing.

Presenting a cumulative overview of 3 consecutive years of ossicular chain reconstructions by many ear surgeons in a training hospital in a very diverse patient population is

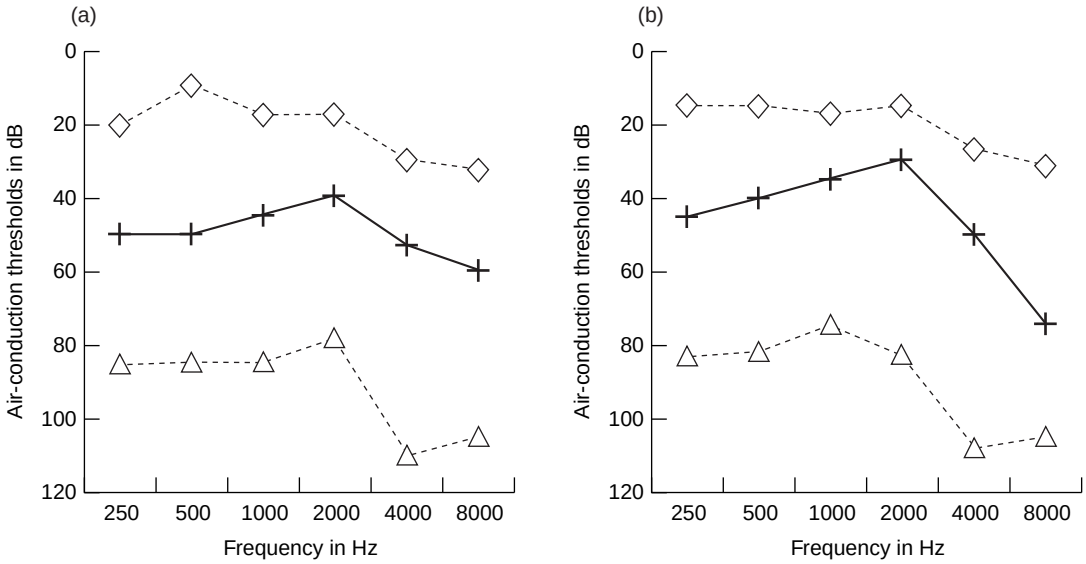

Figure 7. (a) Preoperative ($n = 24$) and (b) postoperative ($n = 23$) median air conduction audiograms with 10th and 90th percentile CWD/stap+. ◇ = 10th percentile; △ = 90th percentile; + = median.

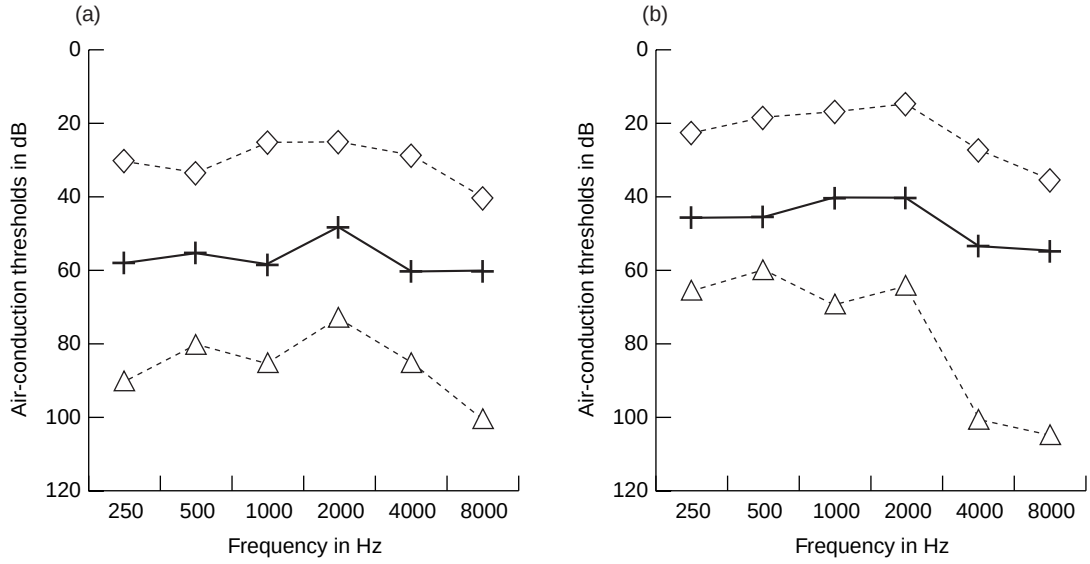

Figure 8. (a) Preoperative ($n = 24$) and (b) postoperative ($n = 22$) median air conduction audiograms with 10th and 90th percentile CWU/stap-. ◇ = 10th percentile; △ = 90th percentile; + = median.

not standard. It is therefore difficult to compare these results to the world literature. An evaluation of every separate kind of reconstruction or the statistical analysis of these small numbers would not seem appropriate. Long waiting lists mean that it is not known beforehand which surgeon is going to perform the ear operation. From a patient's point of view, then, the performance of the department as a whole on hearing improvement is important. To give adequate, clear information to this very diverse patient population, one needs to know the results for this whole group. Despite this unconventional approach, it seems that our day-to-day surgical efforts can stand up to the standard in the world literature.

The advantage of registering all ear operations in a continuous follow-up is that there is access to performance information. An overview of ear surgery can be generated

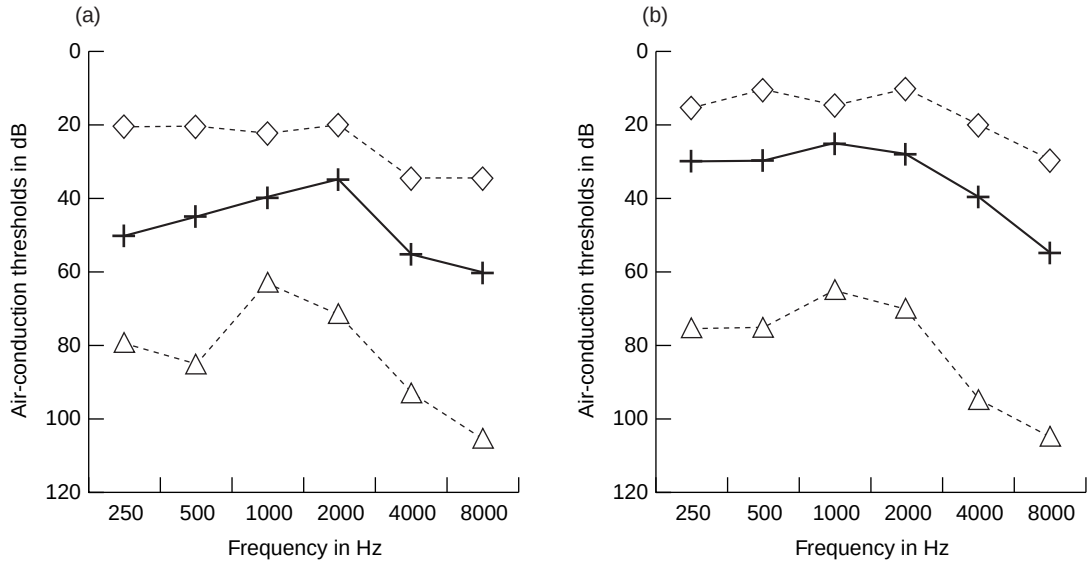

Figure 9. (a) Preoperative ($n = 73$) and (b) postoperative ($n = 12$) median air conduction audiograms with 10th and 90th percentile CWU/stap+. ◇ = 10th percentile; △ = 90th percentile; + = median.

at any moment. This follow-up system is also an easy search medium for finding appropriate patients for inclusion in retrospective studies. The drawback is that this data is very crude and only suitable for internal use. Our continuous follow-up reports exceptional results (good and bad). This allows us to determine the strengths and weaknesses of the department. Hereby the loop from registering additional data and giving feedback to the surgeons is closed. Mostly the crude overviews were a confirmation of our general feeling about the results of ear surgery. However when these data are presented to outsiders, a literature study and medical record research must be performed.

This paper is a trial for the presentation of performance data. It is hoped that more performance analysis will be presented in the future.

Conclusions

- This performance analysis shows that ossicular chain reconstructions are safe and beneficial for the patients at the University Hospital Rotterdam.
- When giving patient information, we can refer to our own performance analysis.
- Continuous follow-up gives access to performance data and makes inclusion of patients in a retrospective study easy.

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