Hearing Results After Tympanoplasty Are Stable Short-term: A Prospective Database Study

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Objective: To evaluate the short-term stability of post-operative hearing results after tympanoplasty.

Study Design: Prospective database study.

Setting: Tertiary referral center

Patients: 1,367 cases of tympanoplasty I–IV were registered in the OTOKIR database between February 2004 and November 2013.

Intervention: The authors included the 553 cases attending post-operative follow-ups at both 3 and 12 months.

Main Outcome Measure: Analysis of the changes in Pure-Tone Average (PTA) of Air Conduction (AC) and Air Bone Gap (ABG), and Speech Reception Threshold (SRT) between follow-ups were performed.

Results: The overall mean change between follow-ups was 0.7 dB, 0.5 dB and 0.3 dB for the AC, ABG and SRT, respectively. A majority of cases (87.7 %) had a change in AC of 10 dB or less, and only 7.6 % of the tympanoplasty type I cases had a decrease in AC of more the 10 dB. Of the 1,367 cases registered, 47.5 % of cases were lost to follow-up at 12 months.

Conclusions: Hearing results after tympanoplasty are stable during 3–12 months after surgery. In addition, a possible bias that compromises the validity of reported results is introduced at 12 months because half of the cases are lost to follow-up. Including results from 3-month post-operative follow-up when reporting on tympanoplasty could reduce bias in reporting and enable more centers to contribute valid results.

Introduction

Reports on the outcome of middle ear surgery are frequently based on comparisons between hearing and status of the drum and the middle ear before and after surgery. These parameters are often considered unstable immediately after surgery and a longer observation period is generally recommended to establish stability.[1,2] However, the number of patients lost to follow-up increases with a longer period of observation, subsequently introducing a selection bias to the results reported.[3]

The current American Academy of Otolaryngology—Head & Neck Surgery (AAO—HNS) guidelines on reporting the outcome after middle ear surgery specifies the hearing parameters that should be reported.[1] The guidelines also recommend reporting the clinical outcome of middle ear surgery with a minimum follow-up of one year.[1, 4, 5] The recommendations on the audiometric measures best suited for reporting were based on established evidence.[6, 7, 8] In contrast, the recommendation on the minimum follow-up period was based on expert opinion rather than studies on the change in hearing during the post-operative observation period. Most experts seem to favor a longer observation period with a wide variation in the number and timing of follow-ups, but there is a gap of knowledge on the actual stability of the results of middle ear surgery.[2, 6]

Post-operative follow-ups are routinely scheduled at 3 and 12 months in our center—as in many other centers. Our hypothesis is that the changes in hearing between these short-term follow-ups are without clinical significance for the majority of patients. A prospective middle ear surgery database is used to investigate the post-operative changes in hearing thresholds after tympanoplasty and discuss the effect of loss to follow-up on the outcome of middle ear surgery.

Materials and Methods

The OTOKIR database is a prospective middle ear surgery database based on MS Access (Microsoft, Redmond, WA, USA) and obtainable as a free download from the Internet.[3, 9]

We extracted data on 1,606 cases of tympanoplasty performed between February 2004 and November 2013 from the database at our institution. We excluded 21 surgeries staged for second look and 218 cases that had not yet reached the time for the 12-month follow-up due to recent surgery. This left 1,367 cases for analysis, of which the 553 cases that had attended both short-term follow-ups comprised the study cohort. Clinical examination and pure-tone and speech audiometry were completed at both the 3-month (2–6 months) and 12-month (≥12 months) post-operative follow-up.

The study cohort was divided according to the type of tympanoplasty (type I–IV)

performed, using the Classic Wullstein Classification.[10] The changes in pure-tone average (PTA) of air conduction (AC) and air-bone gap (ABG), and the speech reception threshold (SRT) between the 3-month and 12-month follow-ups were calculated. The PTAs of AC and ABG were calculated according to the AAO-HNS guidelines using the mean thresholds at 0.5, 1, 2 and 3 kHz.[1] The 95 % confidence intervals (95 % CI) of the mean changes were calculated. The changes in AC, ABG and SRT for each type of tympanoplasty were also used to calculate frequency distributions in 10 dB increments as recommended by the AAO—HNS guidelines.[1]

To attempt a characterization of cases lost to follow-up at the 3-month and/or the 12-month follow-up the lost to follow-up group was compared with the study cohort on the parameters age, gender, the perioperative finding of cholesteatoma and preoperative AC, ABG and SRT. The existing hearing data for the cases lost to follow-up, i.e. existing 3-month data for the cases lost to follow-up at 12 months, were also compared to the cohort.

Data were analyzed using Libreoffice Spreadsheet (The Document Foundation, Germany). The level of statistical significance was set at $p=0.05$. Independent samples t-test and χ^2-test of association was used as appropriate for comparisons between the study cohort and the cases lost to follow-up, and Student's t-test was used for comparisons between PTAs at 3-month and 12-month follow-up. Standard deviations (SD), the 95% confidence intervals (95% CI) were calculated for means and the Bonferroni correction was applied where multiple comparisons were made.

The regional ethics committee reviewed the protocol for this study and found that the study was exempt (H-6-2014-FSP-058).

Results

678 (49.6 %) of the total 1,367 cases found in the database were women and the mean age was 33 years. There were 906 cases of myringoplasty/tympanoplasty type I, 359 cases of tympanoplasty type II, 94 cases of tympanoplasty type III and 8 cases of tympanoplasty type IV.

Cases lost to follow up did either not attend any follow up (288 cases, 21.1 %), attended only the 3-month follow up (367 cases, 26.8 %) or only the 12-month follow up (32 cases, 2.3 %). Some cases (137 cases, 10.0 %) did not have complete audiometry at one or both follow-ups and were excluded. The study cohort consisted of the 553 cases (40.5 %) that had full attendance and complete audiometry. The differences in age, sex, cholesteatoma verified perioperatively, and preoperative hearing between the study cohort and the cases lost to follow-up are presented in Table 1. Only a minimal difference was found between the two

groups. For tympanoplasty type I, cases lost to follow-up were significantly older. For all types of tympanoplasty, significantly fewer cholesteatoma cases were lost to follow-up. The existing post-operative data from the cases attending only one follow-up are presented in Table 2.

For the study cohort, the mean changes of PTA of AC and ABG, and SRT were calculated (Table 3). The overall mean changes between follow-ups were in the range of 0.3–0.7 dB.

We calculated the frequency distribution of the changes between follow-ups in 10 dB increments for the different hearing measures (AC, ABG, and SRT) and tympanoplasty types (type I–IV) (Figure 1A–C). A majority of all cases (87.7 %) had a change in AC of 10 dB or less. 7.6 % of the tympanoplasty type I cases had a decrease in AC of more than 10 dB, 7.9 % had a decrease in ABG of more than 10 dB, and 4.6 % had decrease in SRT of more than 10 dB. A similar pattern was found for more advanced tympanoplasty (type II–IV) with a few more cases having a decrease of more than 10 dB with tympanoplasty types III and IV.

In Figure 2 we present our entire dataset in the form of scattergrams complying with the minimum reporting standards, we fully support this openness that facilitate metanalysis in future studies. [11]

Discussion

In this prospective database study comparing the change in hearing between 3-month and the 12-month follow-up, we found that the changes in hearing between these short-term follow-ups were minimal. Only a few cases (12.3 %) experienced a change in hearing thresholds of more than 10 dB between follow-ups. We set the level of clinical significance at 10 dB, reflecting the assumed precision of pure-tone audiometry and the sensitivity of the human ear. We do not believe that a statistically significant change in means of hearing parameters is of much value when the actual change in means are minimal and well below 10 dB. Loss to follow-up was found to be substantial but the more severe cases (cholesteatoma and tympanoplasty type II and III) were found to have a lower loss to follow-up. The difference in demographic parameters, preoperative hearing parameters and presence/absence of cholesteatoma between the group of cases lost to follow-up and the study cohort was found to be minimal and for most parameters insignificant (Table 1)

Most other studies have explored the preoperative to postoperative change following tympanoplasty using a retrospective study-design.[12, 13, 14, 15] Large-scale prospective database studies on hearing results after middle-ear surgery are primarily found in the research field of stapes surgery.[16, 17] A few studies, both retro- and prospective, include the short-term

postoperative results before 12 months.[12, 16]

In one retrospective study on the long-term stability of hearing after tympanoplasty type III and IV, the rate of success (defined as a PTA of ABG of 20 dB or less) was compared at 6 months and at 5 years postoperative.[18] Of the 422 cases included, 199 cases (47.2 %) attended the 5-year follow-up and an overall significant decrease in success (from 62.3 % to 54.3 %) was found. Cases were divided into subgroups for analysis of prognostic factors: patients with cholesteatoma/atelectasis, intact malleus, and adult patients in general, had a significant decrease in hearing success rate, whereas the tympanoplasty type III and IV subgroups did not show a significant decrease in hearing success rate, indicating that the pathology of the middle ear is more prognostic for the stability of success than the type of surgery performed. None of the subgroups had a mean decrease of 10 dB or more between follow-ups.

A retrospective study of 493 patients determined the necessary length of long-term follow-up after surgery for chronic otitis media.[2] During postoperative follow-up any subsequent middle ear pathology was recorded and based on this, the authors recommended following patients with cholesteatoma for 8 years, patients with granulating otitis media for 7 years and patients with sequelae of otitis media for 5 years. However, by design the study did not include any patients lost to follow-up before 12 months and all patients lost to follow-up later were excluded from analysis. A severe risk of selection bias therefore limits the risk estimation analysis and the interpretation of the results.

A prospective approach is essential to avoid this kind of bias. Using our prospective database, we have previously demonstrated that the graft failure-rate after tympanoplasty was underestimated by 6 % if patients defaulting from 12-month follow-up due to early graft failure at 3 months were not taken into account.[3] In this study, we also found that the graft take-rate after tympanoplasty declines about 6 % long-term regardless of tympanoplasty type and other prognostic factors.

Even though Austin in 1985 acknowledged that the role of loss to follow-up and the impact on reported results needed to be determined, it remains a subject largely unexplored.[6] Some of the cases were lost at the 12-month follow-up because of recurrence of cholesteatoma or re-perforation at 3 months and subsequent re-operation. These events are registered in our prospective database. Some patients were referred to us from Greenland and the Faeroe Islands and were scheduled for local follow-up whereas other patients might have moved, emigrated or died. Additionally, it is not unreasonable to suggest that some patients find the 12-month follow-up unnecessary because they experience an acceptable and stable hearing and our (limited) data could suggest this to be the case.

The high level of cases lost to follow-up in our study is consistent with that of other

middle ear prospective database studies, and it is a common occurrence in prospective data collection.[14, 16, 19, 20] Prospective data collection may be limited by loss to follow-up, but in retrospective data collection, that typically only include cases with complete follow-up, the bias of cases lost to follow-up is just as real but unaccounted for. If possible, we recommend including the number of cases lost to follow-up and analysis of this group in relation to the study cohort when reporting results, as to allow the reader to assess the validity of the reported results. We present a level of cases lost to follow-up that is comparable to that of other prospective middle ear studies, this leads us to conclude that this is a realistic level.

Most literature on the hearing outcome of middle ear surgery is retrospective, which often makes it more difficult to comply with the AAO—HNS guidelines for audiometric reporting and can lead to other concerns of methodological problems and bias such as a lack of distinction between short-term and long-term postoperative results, and sometimes pooling of short-term and long-term post-operative hearing results for analysis.[12, 16, 21, 22] This emphasizes the need for prospective registration of data and acknowledging loss to follow-up accurately. Prospective data collection allows for a more rigorous data control, making selection bias easier to detect and acknowledge.

We found only minimal and clinically insignificant changes in the hearing between the 3-month and 12-month follow-ups and short-term hearing results in tympanoplasty are generally stable. A shorter follow-up period could be suggested from these findings. However, there is a need to follow-up for re-perforation, cholesteatoma recurrence and implant extrusion and this could in some places possibly be done in specialist community practice rather than at referral centers. Prospective data collection is key for unbiased reports of the outcomes of middle ear surgery and with the correct methodology there is valuable information in the 3-month results.

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Table 1. Patient characteristics for study cohort compared to cases lost to follow-up.

	Study cohort	95 % CI	SD	Cases lost to follow-up	95 % CI	SD	Signifi-cance	Bonferroni correction
Type I/myringoplasty	n=328			n=578				
mean age	27.9	[25.8; 29.9]	19.1	32.6	[30.9; 34.4]	21.4	$p < 0.001$	significant
sex	48.2 % female 51.8 % male			47.6 % female 52.4 % male			n.s.	n.s.
cholesteatoma	15.2 %			12.1 %			n.s.	n.s.
AC preoperative	26.9 dB	[25.1; 28.7]	16.3	30.1 dB	[28.4; 31.7]	19.4	$p < 0.01$	n.s.
ABG preoperative	18.1 dB	[16.0; 20.3]	19.8	18.6 dB	[17.6; 19.7]	11.5	n.s.	n.s.
SRT preoperative	23.1 dB	[22.0; 24.3]	10.6	25.2 dB	[23.7; 26.8]	17.9	n.s.	n.s.
Type II	n=177			n=182				
mean age	39.4	[36.7; 42.1]		38.9	[36.1; 41.7]	19.3	n.s.	n.s.
sex	50.3 % female 49.7 % male			55.5 % female 44.5 % male			n.s.	n.s.
cholesteatoma	52.5 %			44.5 %			n.s.	n.s.
AC preoperative	38.2 dB	[35.6; 40.9]	17.9	40.3 dB	[37.6; 43.0]	18.5	n.s.	n.s.
ABG preoperative	23.2 dB	[21.5; 24.9]	11.6	23.4 dB	[21.6; 25.2]	12.2	n.s.	n.s.
SRT preoperative	33.7 dB	[31.3; 36.1]	16.2	35.0 dB	[32.4; 37.7]	17.9	n.s.	n.s.
Type III	n=46			n=48				
mean age	31.0	[25.6; 36.5]	18.3	33.7	[29.0; 38.5]	16.4	n.s.	n.s.
sex	58.7 % female 41.3 % male			45.8 % female 54.2 % male			n.s.	n.s.
cholesteatoma	45.7 %			52.1 %			n.s.	n.s.
AC preoperative	44.6 dB	[40.0; 49.2]	15.4	45.0 dB	[40.9; 49.1]	14.0	n.s.	n.s.
ABG preoperative	33.2 dB	[29.4; 36.9]	12.5	30.7 dB	[27.3; 34.0]	11.3	n.s.	n.s.
SRT preoperative	39.8 dB	[35.7; 43.9]	13.7	39.0 dB	[35.5; 42.6]	12.2	n.s.	n.s.
Type IV	n=2			n=6				
mean age	26.5	[-31.6; 84.6]	19.1	41.7	[13.6; 69.7]	28.0	n.s.	n.s.
sex	50.0 % female 50.0 % male			83.3 % female 16.7 % male			n.s.	n.s.
cholesteatoma	50.0 %			50.0 %			n.s.	n.s.
AC preoperative	45.0 dB	[40.7; 49.3]	1.4	56.6 dB	[27.8; 85.4]	26.3	n.s.	n.s.
ABG preoperative	41.0 dB	[36.7; 45.3]	1.4	33.2 dB	[15.1; 51.3]	16.6	n.s.	n.s.
SRT preoperative	37.5 dB	[26.8; 48.3]	3.5	50.0 dB	[17.2; 82.8]	26.8	n.s.	n.s.
All	n=553			n=814				
mean age	31.8	[30.2; 33.4]	19.4	34.2	[32.7; 35.6]	20.9	n.s.	n.s.
sex	49.7 % female 50.3 % male			49.5 % female 50.5 % male			n.s.	n.s.
cholesteatoma	29.8 %			22.0 %			$p < 0.01$	significant
AC preoperative	32.1 dB	[30.7; 33.5]	17.4	33.7 dB	[32.2; 35.1]	19.8	n.s.	n.s.
ABG preoperative	21.2 dB	[20.2; 22.1]	11.7	20.7 dB	[19.8; 21.6]	12.1	n.s.	n.s.
SRT preoperative	27.9 dB	[26.6; 29.3]	16.0	28.5 dB	[27.2; 29.8]	18.3	n.s.	n.s.

Table 2. Postoperative hearing parameters for study cohort at 3 and 12 months respectively compared with the existing 3- and 12-month hearing parameters for cases otherwise lost to follow-up.

	Study cohort	Cases lost to follow-up	Significance
Postoperative hearing at 3 months			
AC	22.2 dB	25.4 dB	$p < 0.01$
ABG	12.4 dB	14.2 dB	$p < 0.05$
SRT	18.0 dB	19.8 dB	n.s.
Postoperative hearing at 12 months			
AC	22.9 dB	22.3 dB	n.s.
ABG	12.9 dB	12.6 dB	n.s.
SRT	18.3 dB	18.5 dB	n.s.

Table 3. Change in hearing parameters.

	Follow-up results		Change between follow-ups			
	Mean 3 months	**Mean 12 months**	**Mean**	**95 % CI**	**SD**	**Signifi-cance**
Type I/myringoplasty (n=328)						
AC	18.5 dB	18.8 dB	0.3 dB	[-0.5; 1.1]	7.6	n.s.
SRT	14.8 dB	14.8 dB	0.08 dB	[-0.9; 0.8]	7.8	n.s.
ABG	10.4 dB	10.5 dB	0.07 dB	[-0.8; 0.9]	7.8	n.s.
Type II (n=177)						
AC	26.9 dB	27.7 dB	0.8 dB	[-0.2; 1.8]	6.7	n.s.
SRT	22.0 dB	22.0 dB	0.03 dB	[-1.2; 1.2]	8.1	n.s.
ABG	14.2 dB	15.2 dB	0.9 dB	[-0.1; 2.0]	7.3	n.s.
Type III (n=46)						
AC	29.4 dB	32.7 dB	3.3 dB	[0.6; 6.1]	9.6	p<0.05
SRT	24.6 dB	28.2 dB	3.6 dB	[0.1; 7.1]	12.0	p<0.05
ABG	19.0 dB	21.0 dB	1.9 dB	[-0.8; 4.7]	9.5	n.s.
Type IV (n=2)						
AC	41.5 dB	47.0 dB	5.5 dB	[0.6; 10.4]	3.5	n.s.
SRT	37.5 dB	42.5 dB	5.0 dB	[5.0; 5.0]	0	p<0.001
ABG	32.5 dB	35.5 dB	3.0 dB	[-4.8; 10.8]	5.7	n.s.
All (n=553)						
AC	22.2 dB	22.9 dB	0.7 dB	[0.1; 1.4]	7.6	p<0.05
SRT	18.0 dB	18.3 dB	0.3 dB	[-0.4; 1.0]	8.4	n.s.
ABG	12.4 dB	12.9 dB	0.5 dB	[-0.1; 1.2]	7.8	n.s.

Figures

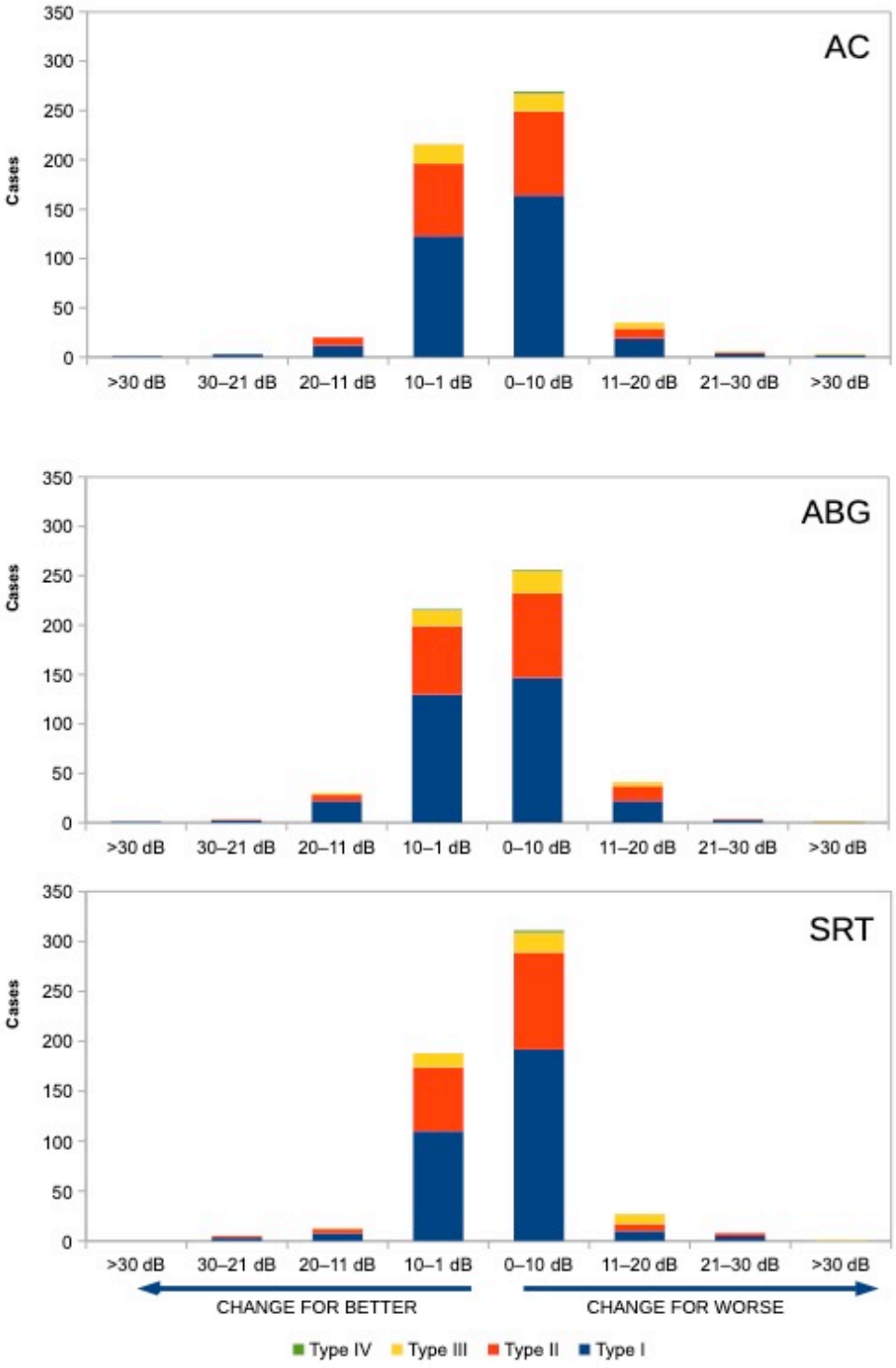

Figure 1A–C. Number of cases experiencing a change in hearing thresholds between the 3-month and 12-month follow-up for PTA of AC and ABG, and SRT for tympanoplasty type I–IV.

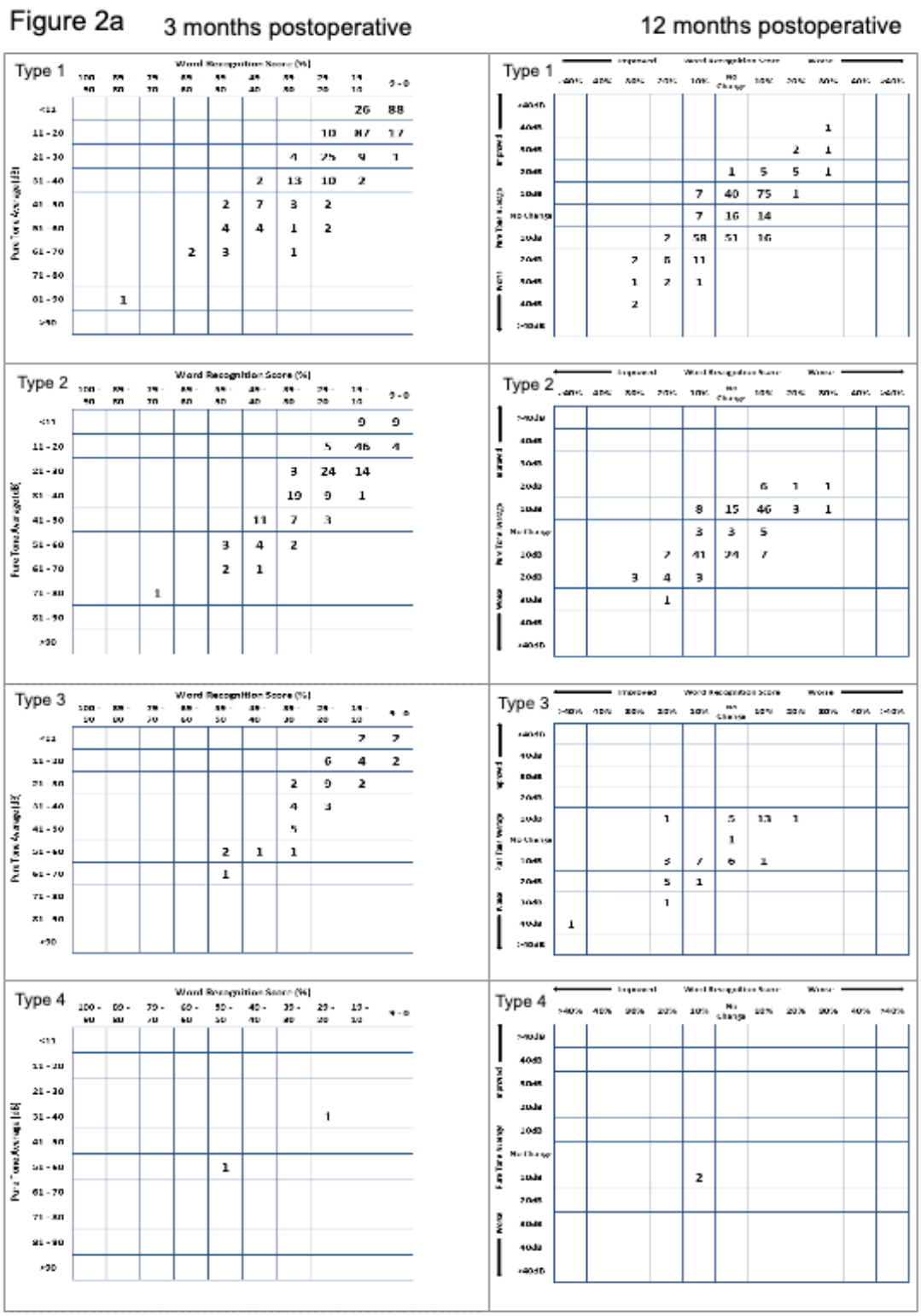

Figure 2A. Scattergrams of dataset for individual tympanoplasty types.

Figure 2b

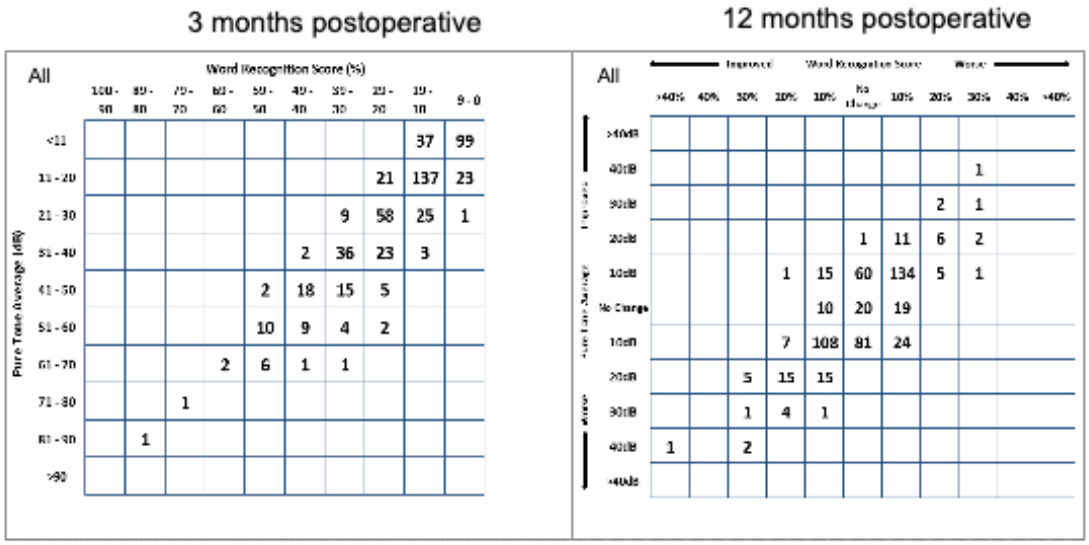

Figure 2B. Scattergram of dataset for entire study cohort.