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Cochlear implantation and residual hearing preservation long-term follow-up of the first consecutively operated patients using the round window approach in Uppsala, Sweden

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Objective: We conducted a long-term follow-up study to investigate the time course of residual hearing in our first 21 consecutively operated cochlear implant (CI) patients using the round window (RW) approach . The study may provide additional information about the influence of a flexible lateral wall electrode array on cochlear function.

Methods: Data were available for long-term follow-up (>5 years) in 15 patients. Pure tone audiometry (PTA) was assessed at 0.125–8 kHz preoperatively, and at one, three and >5 years postoperatively. Insertion angle, number of electrodes inside the cochlea, user-time of the processor and stimulation strategy were documented.

Results: Twelve out of 15 patients had residual hearing after a follow-up period of five years (mean 86 months, range: 61–103 months). Four out of 15 patients had >75% complete hearing preservation (HP), 8 out of 15 had 25–75% partial HP and 3 out of 15 patients had complete loss of hearing. There was a high correlation between insertion angle and HP.

Conclusion: Long-term HP was possible in 12 out of 15 cases. Even patients with complete hearing loss at long-term follow-up showed high performance in speech understanding and were full-time users.

Keywords: Hearing preservation, Cochlear implant, Follow-up

Introduction

As more patients with preservable hearing in the low-frequencies received cochlear implantation (CI), it became obvious that residual hearing may be preserved in several cases. Von Ilberg *et al*. first performed experimental and clinical investigations showing the rationale of combined electric and acoustic hearing (EAS) (von Ilberg *et al*., 1999). Thereby, a larger population of patients with sensory-neural hearing loss could be treated, and even those with severe mid- to high-frequency hearing loss and usable low-frequency hearing, or so-called partial hearing (Skarzynski *et al*., 2006). Conservation of cochlear function was associated with 'softer' surgery respecting scala tympani (ST) boundaries at insertion. Modified trajectory, electrode designs and additional oto-protective measures further improved the hearing preservation (HP) results. The technique offers new possibilities to treat children with language and speech deficiencies that are caused by mid- to high-frequency hearing loss during early development with remaining low tone hearing, that benefit little from hearing aid amplification (Carlson *et al*., 2017; Kuthubutheen *et al*., 2012; Meredith *et al*., 2017; Wilson *et al*., 2016). Despite initial success, it became apparent that long-term studies are necessary to validate conceivable progressive deterioration of residual hearing. As patients with more hearing are operated on, with or without acoustic amplification of the residual low-frequencies, it is essential to verify if the results are maintained over time. Moreover, there is a risk for structural damage that abolishes future options for regeneration therapy.

Despite growing experience and documentation, there is still no consensus about optimal electrode trajectory pathways and array designs for structure/hearing preservation. There is a strong recommendation that CI surgery in children should be performed with the principle of structure/hearing preservation, regardless of the degree of preoperative hearing (Rajan *et al*., 2018).

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In 2012, we presented our first results on HP CI surgery in 21 consecutively operated on patients using the round window (RW) approach (Erixon *et al.*, 2012). Patients were followed for one year after implantation to determine how frequently HP is possible using this approach and a flexible electrode (mostly 24 mm). Electrode insertion was rather shallow; surprisingly, all ears had measurable hearing afterwards, with an occasional low-frequency hearing loss of around 20 dB. Similar findings were demonstrated by other authors using either cochleostomy (CO) or RW approaches (Gstoettner *et al.*, 2004; Adunka *et al.*, 2004; Roland *et al.*, 2018; Skarzynski *et al.*, 2009; Skarzynski *et al.*, 2010).

Here, we reinvestigated all consecutive patients for measurable hearing. Results may add information about the vulnerability of the human cochlea over a longer time and determine if any ensuing decline of hearing is related to insertion depth or age at implantation.

Materials and methods

Patients

The study group consisted initially of 21 patients formerly described in a consecutive study of our first HP results (Erixon *et al.*, 2012). The evaluation was performed by an independent investigator not involved in the surgery. One patient died during the follow-up period and was therefore excluded from that first study. All patients had measurable hearing pre-operatively. Eleven patients had residual hearing in the low frequencies that was suitable for EAS (pure tone audiometry thresholds less than 65 dB at frequencies of 125–750 Hz). Nine patients were planned for electric stimulation only from the beginning but had wished to preserve their residual hearing. Mean age was 59 years (range: 19–87 years). Nine patients were female and eleven were male. All patients had a symmetric progressive hearing loss of unknown etiology, except for one patient with single-sided deafness since childhood and progressive hearing loss on the operated side. Four patients had hearing loss since childhood, seven since adolescence and nine with adult onset. Two patients already had a CI on the first side, and three patients were operated on later on the second ear. In fifteen patients, data for long-term follow-up (> 5 years) was available for evaluation. In five patients, it was not possible to obtain long-term follow-up data (two patients died and three moved to another area).

Surgery

Patients were operated on by the same surgeon from September 2008 to October 2010. In 20 cases, flex EAS electrodes were used (MedEl, Flex 24 mm long) with an insertion depth of 17.5–23.5 mm. In one patient, a soft flex electrode (MedEl, Flex 31 mm long) was used with an insertion depth of 28.5 mm. The surgical approach was via the RW after gentle drilling of the bony overhang. The electrode was inserted after a vertical incision of the membrane had been made. A corticosteroid solution (Triamcinolon 40 mg/ml) was injected into the middle ear while inserting the electrode slowly.

Radiology and measuring of insertion angle

The electrode position was confirmed by postoperative radiology (conventional X-ray, Stenver projection) in each case. The insertion angles of the electrode array were measured according to the method described by Verbist *et al.* (2010). The zero reference angle was chosen at the center of the RW and is the reason why numbers in this paper differ from those of our original study.

Follow-up audiometry

Hearing thresholds were assessed at 125–8 kHz preoperatively, at one and three years postoperatively, and a long-term follow-up > 5 years (mean 85 months, range: 63–103 months).

The percent of HP over the whole frequency range (125–8000 Hz) was calculated as stated by HEARRING group consensus (Skarzynski *et al.*, 2013) according to the following formula:

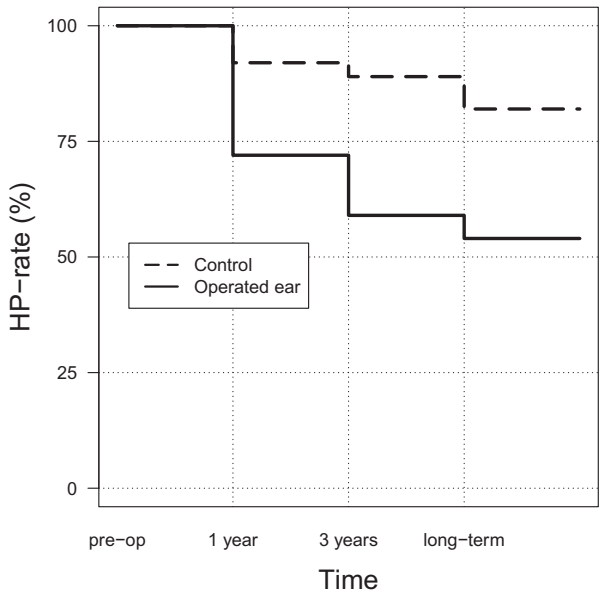
$$\mathrm{HP} = \left(1 - \frac{\mathrm{PTApost} - \mathrm{PTApre}}{\mathrm{PTAmax} - \mathrm{PTApre}}\right) * 100[\%]$$

In this equation, PTApre is pure tone average measured pre-operatively, PTApost is pure tone average measured postoperatively, and PTAmax is the maximal sound intensity generated by a standard audiometer, usually 120 dB hearing level (HL) like in our clinic.

The technique is independent of the recipients initial hearing and covers the entire range of PTAs from 0 to 120 db. Categorization of the degrees of relative HP is possible (complete HP, greater than or equal to 75%; partial HP, greater than or equal to 25–75%; and minimal HP, 0–25%; loss of all hearing as no measurable hearing). This method allows comparison of data from different investigators since data are independent of initial hearing. It presents the relative change as a percentage of hearing loss, and data can be converted to a categorical scale of HP (total, partial, minor, and complete loss).

A Kaplan Meier Analysis for both the operated side and non-operated side was calculated to show

Table 1. Kaplan Meier Survival Graph.



timing and degree of hearing decrease more easily (Table 1).

Swedish monosyllabic (MS) word recognition scores were recorded preoperatively and at the long-term follow-up.

Fitting of speech processor

One month after surgery, the patients were fitted with their speech processor. Different stimulation strategies were carefully evaluated by the patient and the engineers. We documented user-time and whether the patients were fitted with full-frequency stimulation (e-only), cut-off frequency stimulation strategy with acoustic stimulation in the lower frequencies (a + e), or natural hearing (n + e), both during the first year and at long-term follow-up. User-time of the processor was recorded (full-time user >8 h per day, part-time user <8 h per day, and non-user).

Results

Nineteen out of 20 patients had preserved residual hearing after one and three years postoperatively. In 15 cases, data for long-term follow-up >5 years postoperatively could be obtained. Twelve out of 15 patients had residual hearing after a follow-up period of over five years (mean 86 months, range: 61–103 months). Four out of 15 patients had >75% complete HP, 8 out of 15 had 25–75% partial HP, 3 out of 15 patients had complete loss of hearing (Figs 1–21, a is operated ear, b is non-operated ear). There was a high correlation between insertion depth and HP (Pearson test, $p < 0.002$). The patients with complete HP had a relatively smaller insertion depth compared to the patients with partial or complete loss of hearing. There was no correlation between HP and age at implantation (Pearson test, $p = 0.77$). Most (13 out of 15) patients who could be monitored by the long-term follow-up used their implants full-time. The patients gained great benefit from the devices. One patient was a non-user (probably due to dementia), and one patient was a part-time (3 h/day) user. A total of 12 out of 15 patients had the same stimulation strategies at long-term follow-up compared to the initial ones at activation. Three patients changed their stimulation strategy from a + e stimulation to e-only over the whole frequency range. Thirteen out of 15 patients had an increase in MS word recognition scores after implantation even after more than five years. The scores in those two patients who had a decrease are more difficult to interpret due to a change in our follow-up routines in the clinic (measurements at different dB levels) (Tables 2 and 3).

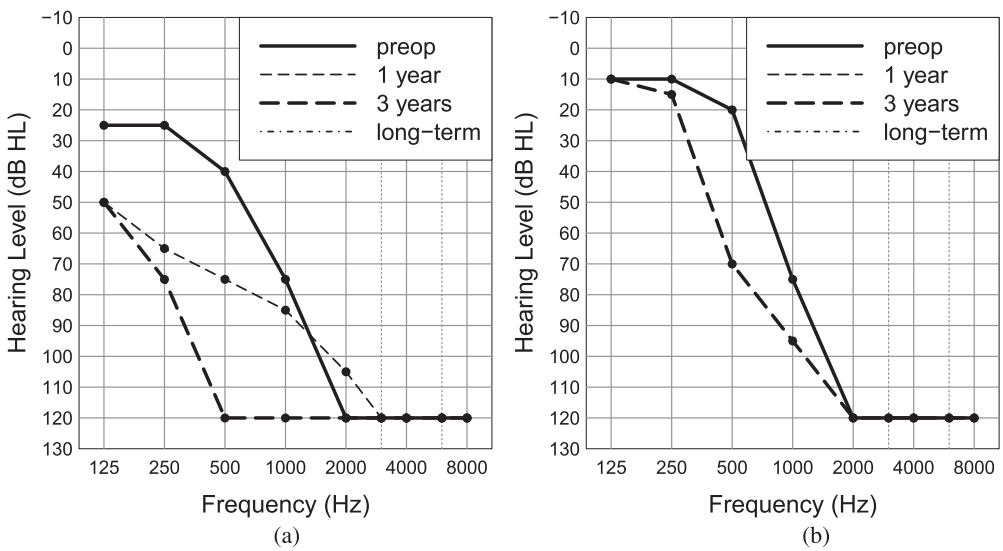


Figure 1. (a, b) Patient 1: (no long-term follow-up as patient moved to another area).

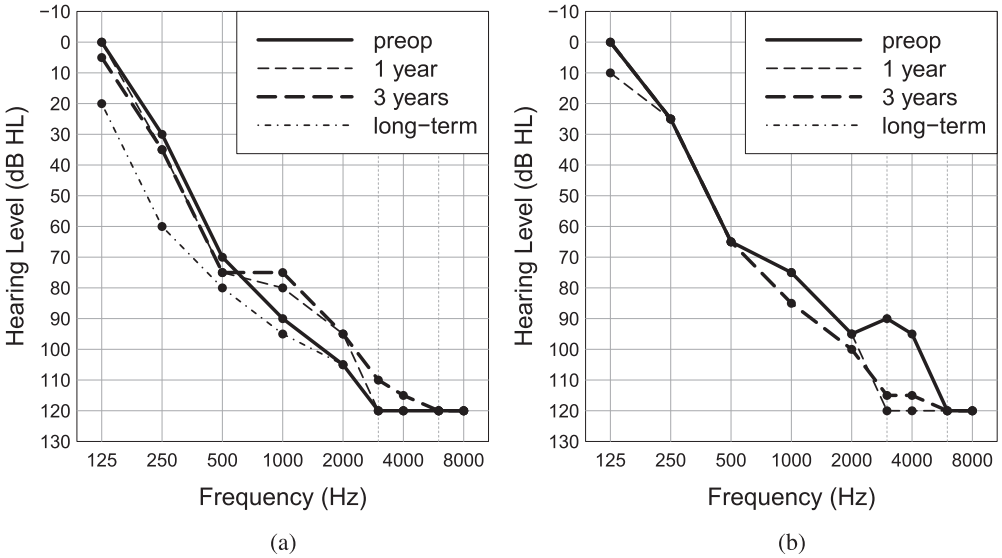


Figure 2. (a, b) Patient 2: 79% hearing preservation (HP).

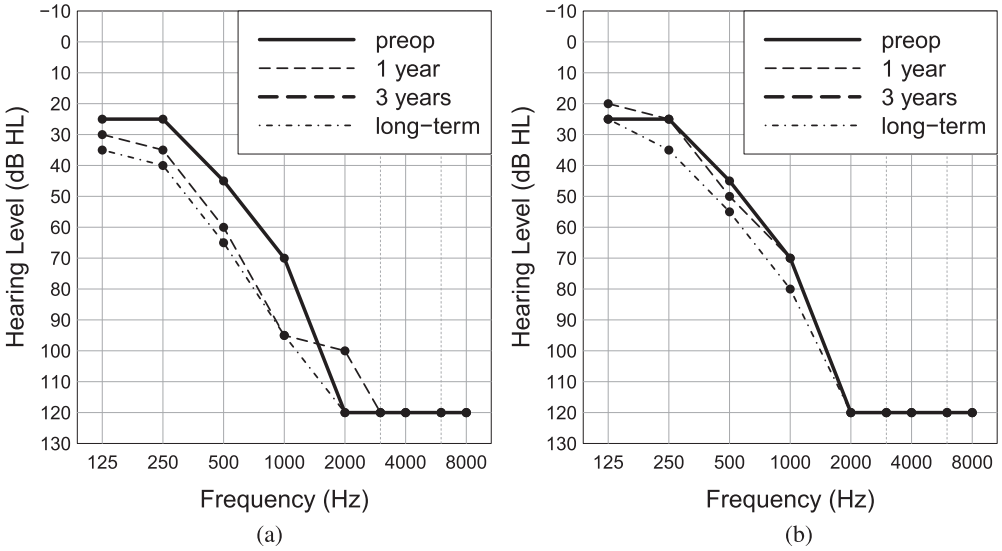


Figure 3. (a, b) Patient 3: 78% HP.

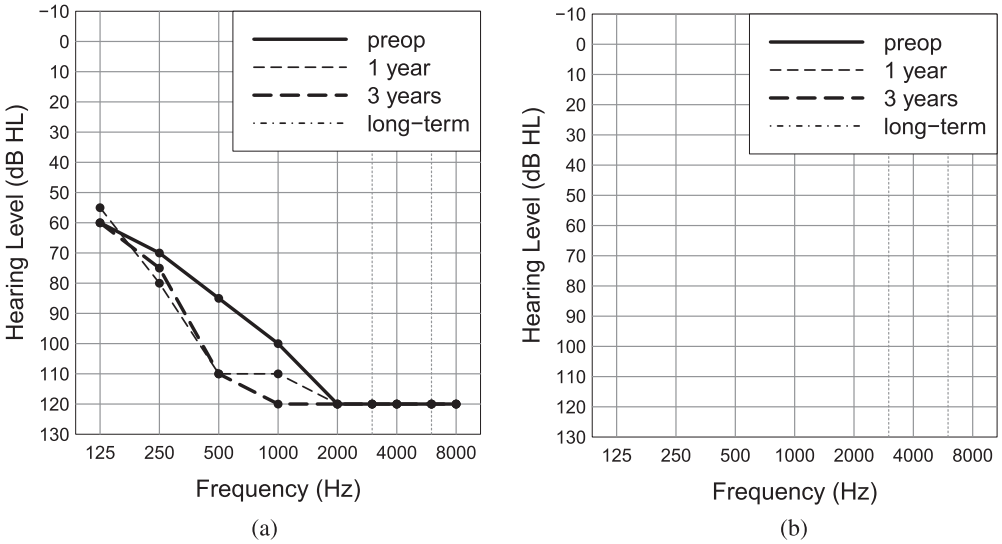


Figure 4. (a, b) Patient 4 (already had CI on the first ear, no long-term follow-up due to patients death).

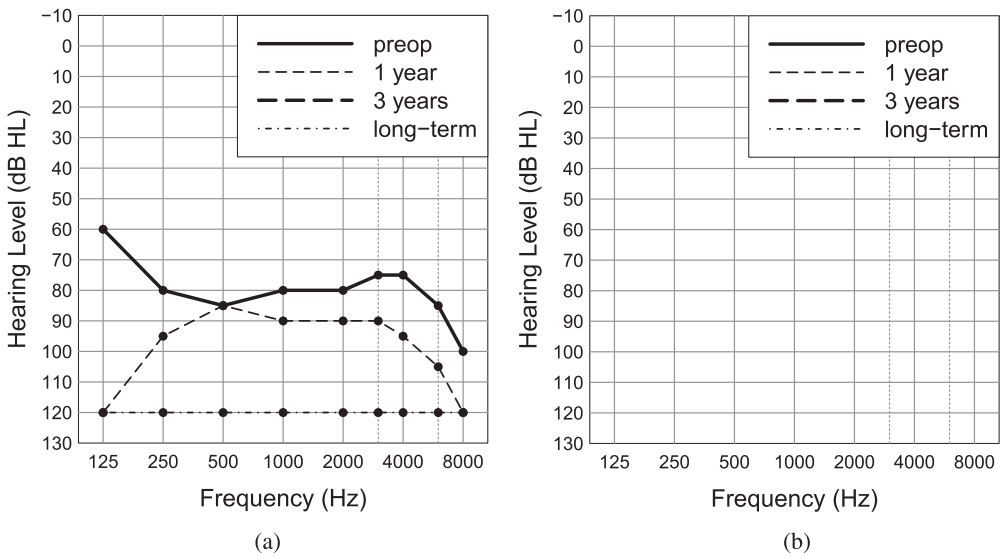


Figure 5. (a, b) Patient 5: 0% HP (already had CI on the first ear).

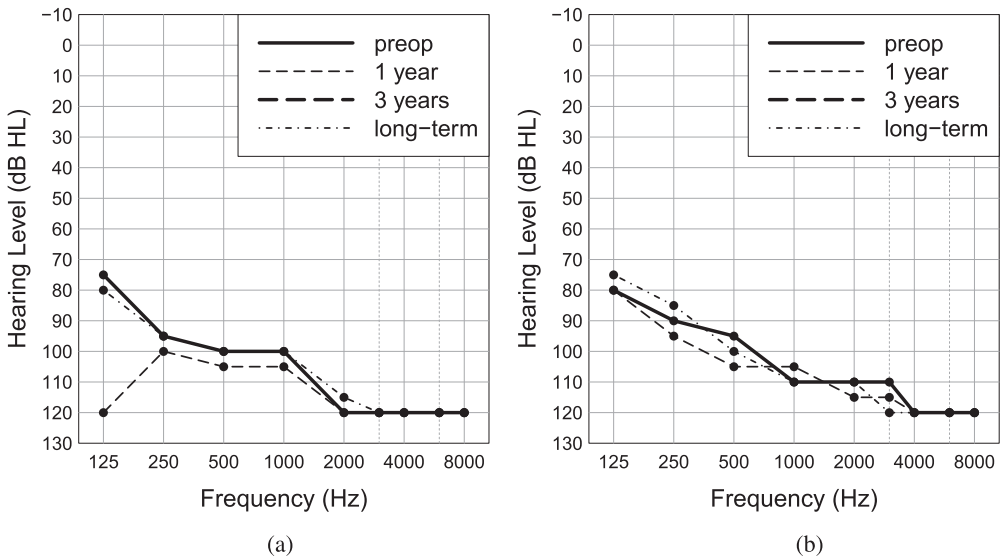


Figure 6. (a, b) Patient 6: 100% HP.

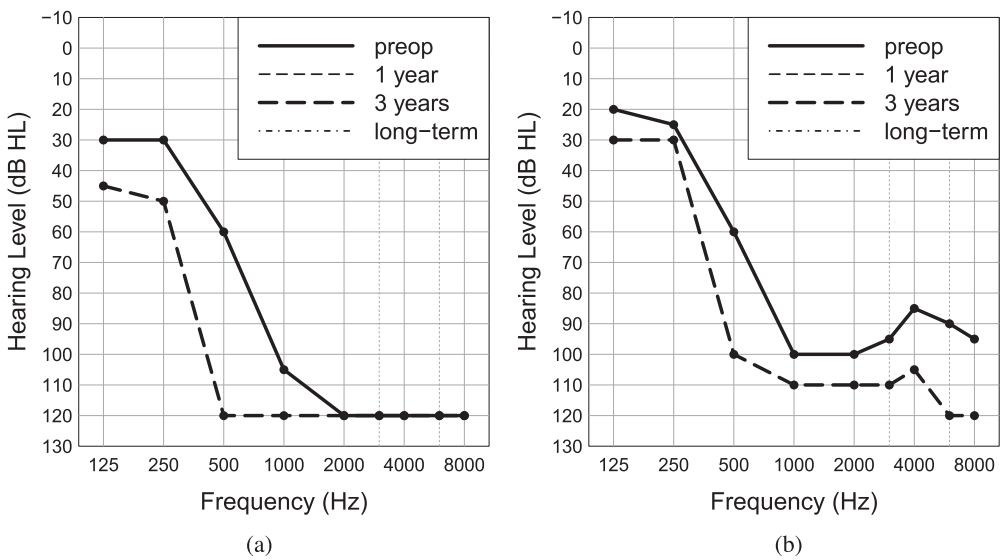


Figure 7. (a, b). Patient 7 (no long-term follow-up as patient moved to another area).

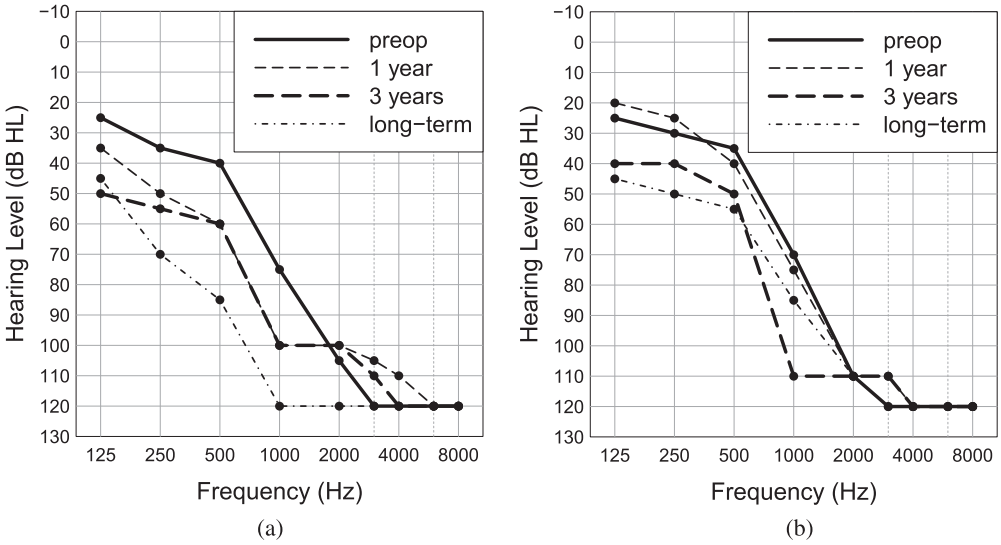


Figure 8 (a, b) Patient 8: 50% HP.

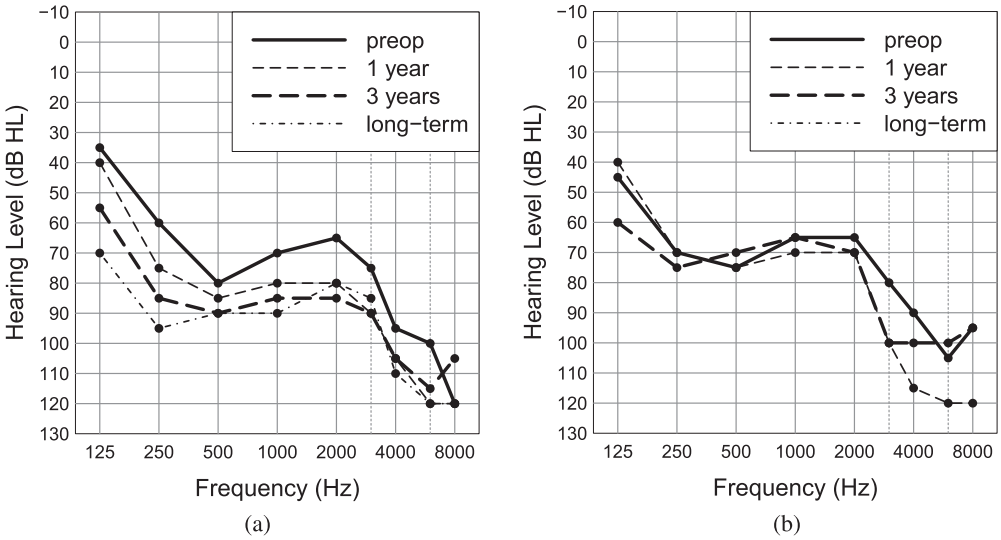


Figure 9 (a, b) Patient 9: 58% HP.

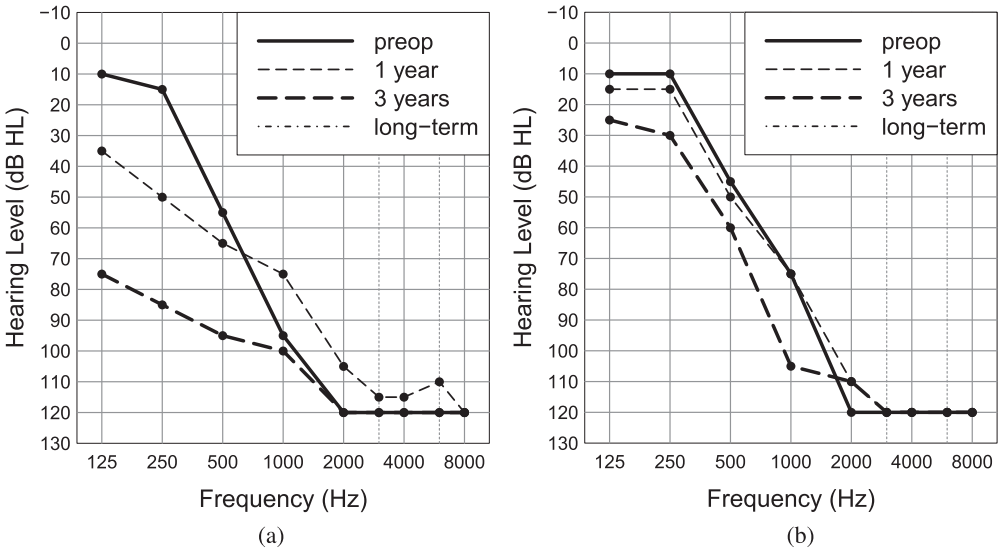


Figure 10 (a, b) Patient 10 (no long-term follow-up due to patients death).

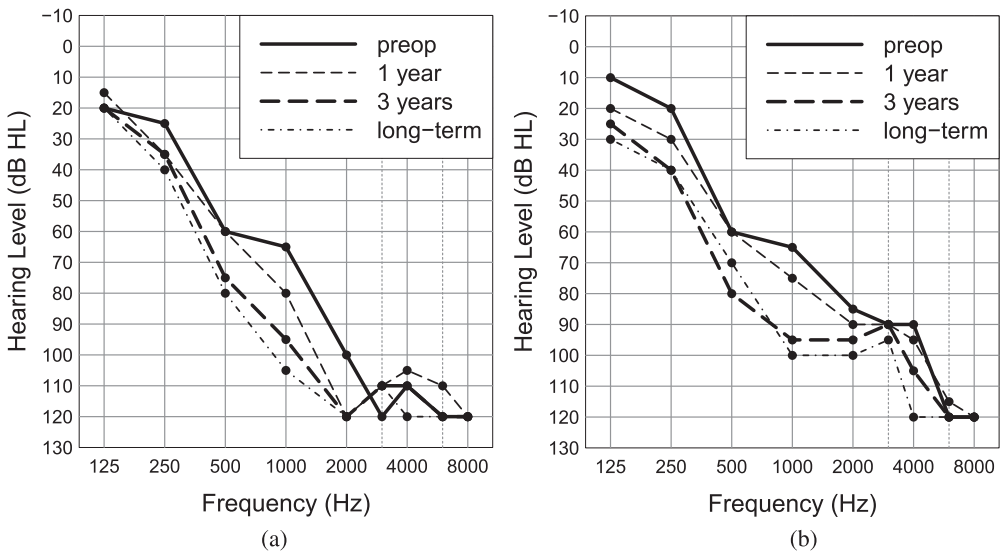


Figure 11 (a, b) Patient 11: 72% HP.

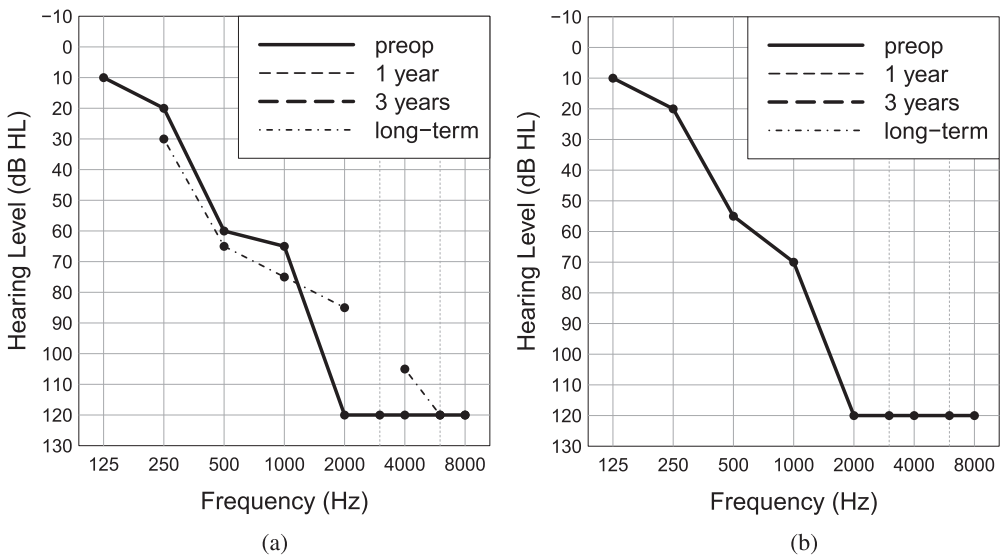


Figure 12 (a, b) Patient 12: 95% HP.

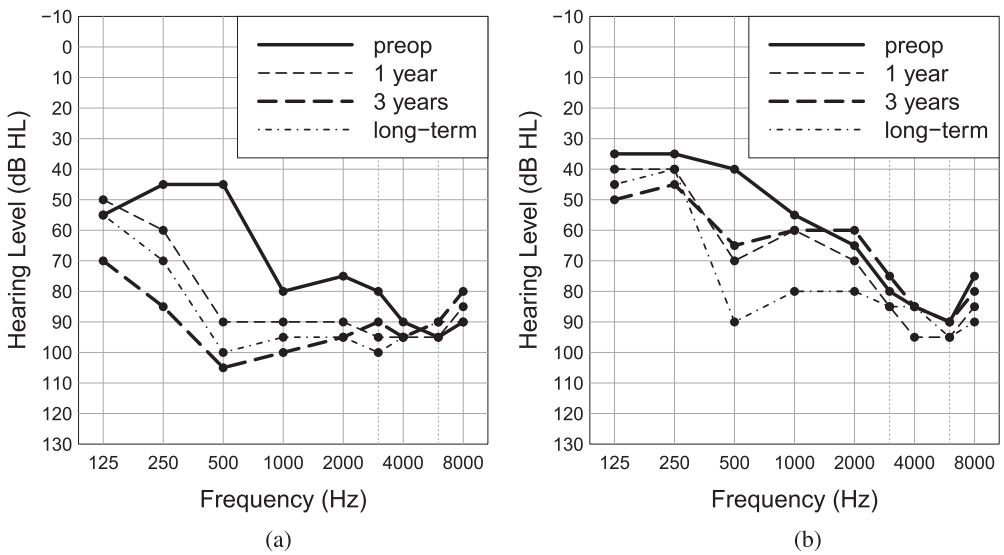


Figure 13 (a, b) Patient 13: 68% HP.

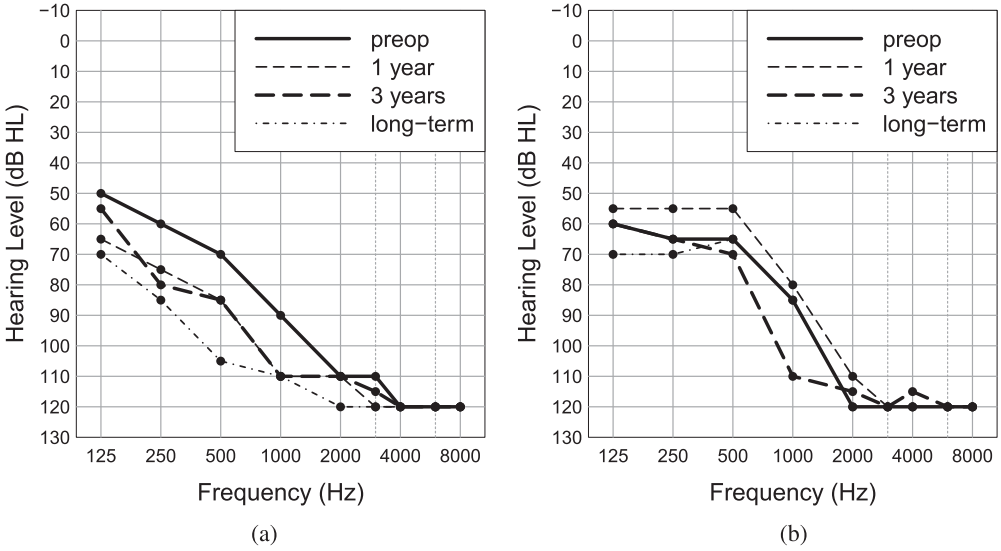


Figure 14 (a, b) Patient 14: 48% HP.

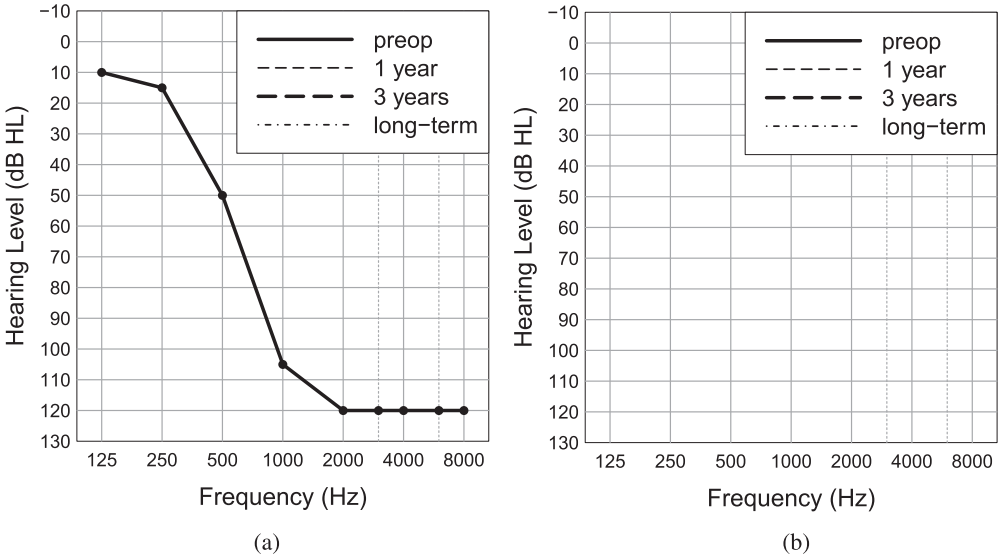


Figure 15 (a, b) Patient 15: excluded.

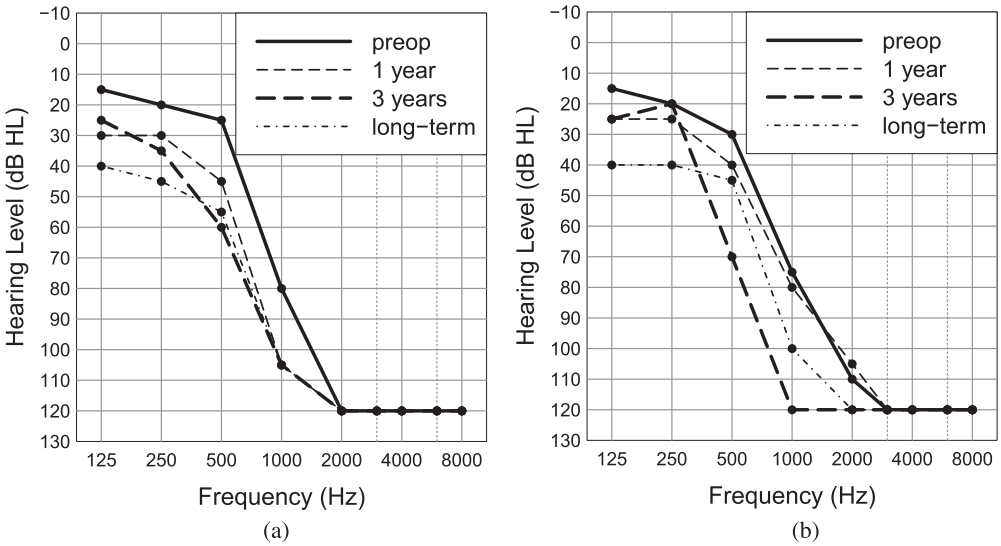


Figure 16 (a, b) Patient 16: 70% HP.

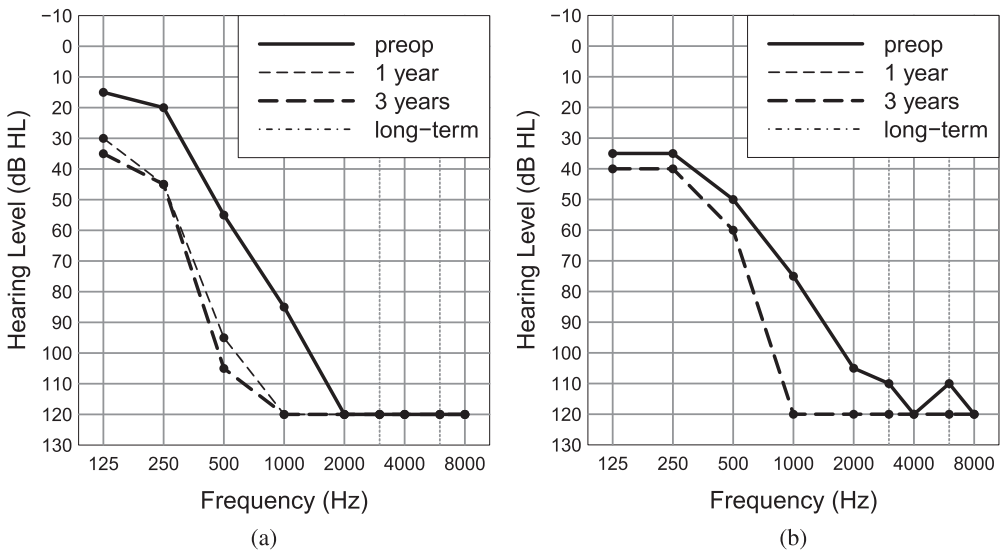


Figure 17 (a, b) Patient 17 (no long-term follow-up as patient moved to another area).

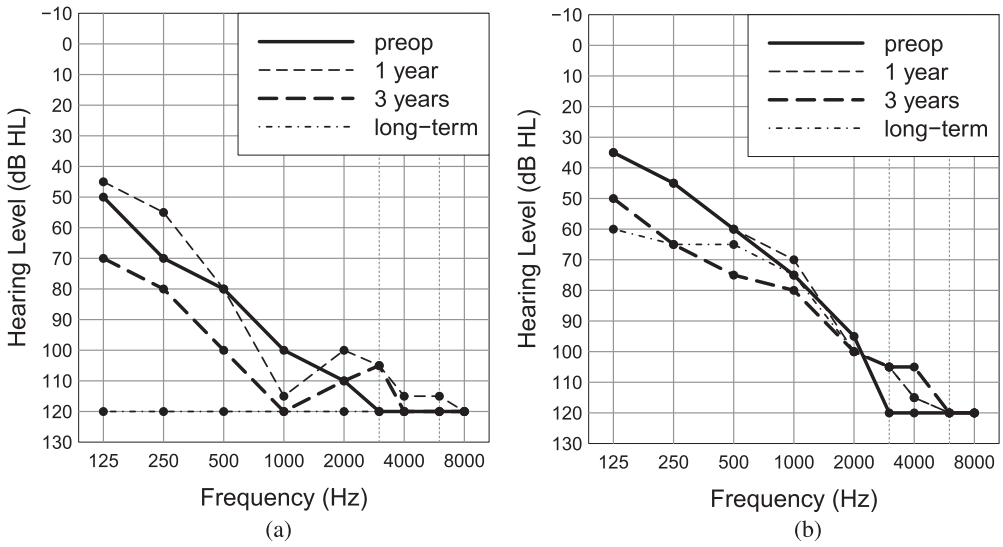


Figure 18 (a, b) Patient 18: 0% HP

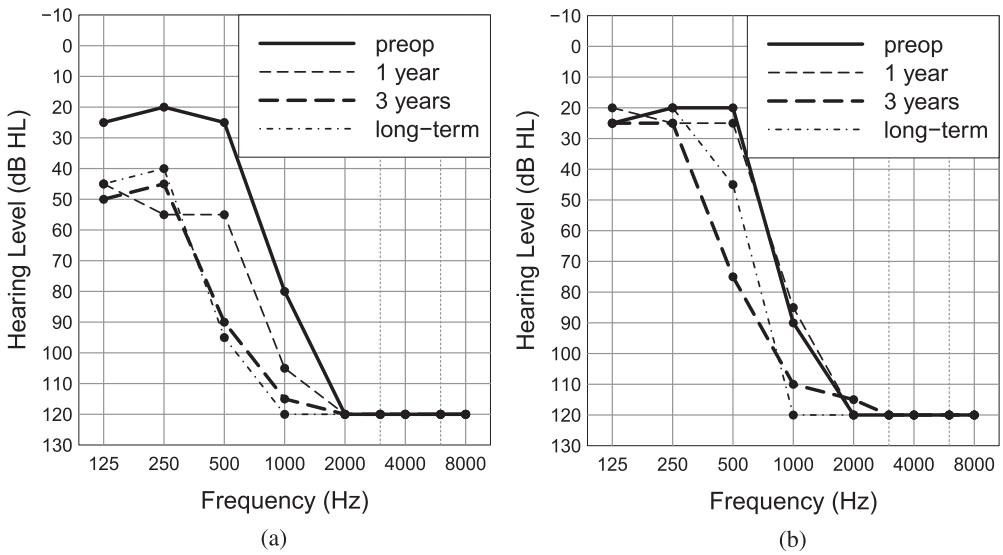


Figure 19 (a, b) Patient 19: 55% HP

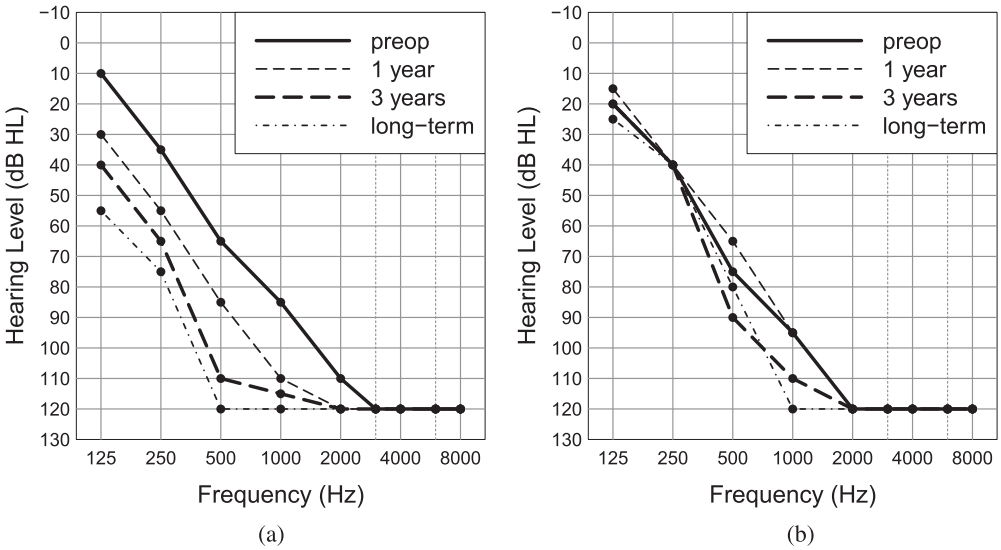


Figure 20 (a, b) Patient 20: 37% HP

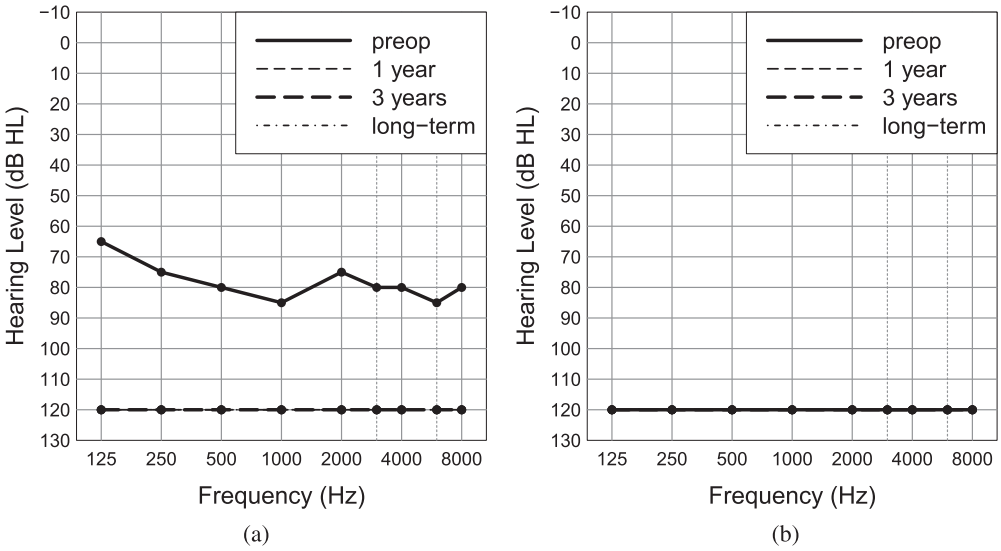


Figure 21 (a, b) Patient 21: 0% HP (single-sided deafness on the opposite side since childhood)

Table 2. Fifteen patients with long-term follow-up data.

Patient	Age at implantation	Electrode	Degrees	No of electrodes inside the cochlea	Hearing preservation
2	19	Sonata flex EAS	320	9	79%
3	87	Sonata flex EAS	275	9	78%
5	50	Sonata flex soft	540	12	0%
6	71	Sonata flex EAS	335	10	100%
8	70	Sonata flex EAS	290	10	50%
9	49	Sonata flex EAS	360	10	58%
11	69	Sonata flex EAS	320	10	72%
12	27	Sonata flex EAS	280	10	95%
13	48	Sonata flex EAS	380	11	68%
14	68	Sonata flex EAS	390	11	48%
16	70	Sonata flex EAS	360	12	70%
18	57	Sonata flex EAS	360	10	0%
19	72	Sonata flex EAS	315	10	55%
20	27	Sonata flex EAS	385	12	37%
21	75	Sonata flex EAS	450	11	0%

Degrees = electrode insertion angle verified by radiology; No of electrodes inside the cochlea verified by radiology.

Table 3. Stimulation strategies and hearing outcomes.

Patient	Long-term follow-up (month)	Stimulation	Stimulation (at long-term follow up)	MS preop (stimulation level)	MS postop	Hearing preservation
2	97	a + e	a + e	26% (75dB)	66% (65dB)	79%
3	63	a + e	non-user	4% (70dB)	non-user	78%
5	103	e only	e only	14% (70dB)	70% (65dB)	0%
6	103	e only	e only	8% BS (80dB)	46% BS (80dB)	100%
8	92	a + e	a + e	34% (65dB)	36% (65dB)	50%
9	86	e only	e only	28% (65dB)	70% (65dB)	58%
11	88	n + e	n + e	22% (75dB)	54% (65dB)	72%
12	72	a + e	no data	no data	no data	95%
13	85	a + e	e only	0% (80dB)	64% (65dB)	68%
14	84	a + e	e only	0% (70dB)	56% (65dB)	48%
16	84	a + e	a + e	42% (70dB)	62% (65dB)	70%
18	82	a + e	e only	34% (70dB)	70% (65dB)	0%
19	79	e only	e only	26% (70dB)	36% (65dB)	55%
20	80	a + e	no data	48% (75dB)	24% (65dB)	37%
21	73	e only	e only	44% (70dB)	30% (65dB)	0%

Stimulation a + e = acoustic and electrical stimulation, e only = electric stimulation only, n + e = natural hearing in low frequencies, and electric stimulation in the higher frequencies; MS = monosyllables; BS = bisyllables.

Discussion

Several prospective multicenter clinical trials have shown the efficacy and more or less the preservation of residual hearing over the short- and long-term at different ages using various electrode types (Carlson *et al.*, 2017; Gantz and Turner, 2004; Gstoettner *et al.*, 2006; Gstoettner *et al.*, 2008; Kiefer *et al.*, 2004; Roland *et al.*, 2018; Skarzynski *et al.*, 2012; Skarzynski *et al.*, 2010; Usami *et al.*, 2014; Wilson *et al.*, 2016). Meta-analysis of data is difficult to value because it is not possible to perform randomized, controlled double-blinded studies. Causon *et al.* made a retrospective analysis of the contribution of factors in CI HP outcomes (Causon *et al.*, 2015). Only 12 of 284 papers were approved for evaluation, including our original study. Seven factors had a significant positive effect on HP, namely, RW approach, stable hearing loss pre-peratively, shorter insertion angle, use of steroids intraoperatively or use of steroids via any timing, and flexible electrode array type. Those identified as having a congenital hearing loss had better hearing preservation outcomes than those identified as having acquired or idiopathic hearing loss. Caution is needed to interpret this finding as some of the etiological groups included had very small numbers of patients.

The present study did not focus specifically on EAS, but rather on the later effects of initially successful HP in consecutively operated on CI patients, using the RW approach. Since all but one patient had preserved hearing after one year, the long-term biological effects on hearing could be monitored. One limitation was that not all patients could be followed-up after five years due to their moves to other areas or death.

Similar initial preservation rates were obtained by Usami *et al.* using the RW approach and a flexible electrode (24, 31.5 mm) (Usami *et al.*, 2014).

After an initial increase of thresholds, hearing in some of our patients occasionally deteriorated or was lost over the longer term within a span of 3–5 years. Other patients maintained residual hearing with few or no signs of hearing loss progression compared to the un-operated on ear. Most patients had a rather shallow insertion, but there was a clear correlation between insertion angle and rate of HP (Pearson test, $p < 0.002$).

Moteki *et al.* examined low-frequency changes and EAS hearing in 17 ears up to 3–6 years, using a 24-mm electrode and RW approach (Moteki et al., 2017). Two groups of patients were noted: those with stable hearing and those with progressive loss in the lower frequencies. The authors suggested that an initial decrease of residual hearing after CI may be due to trauma or inflammatory responses in the cochlea. They believed that is unlikely that the same phenomenon occurs after 3–4 years. Instead, the reason may be a different etiology of disease. They concluded that, if a genetic background can be determined, one might predict hearing loss and EAS outcome. No genetic testing was performed in the present study.

In a meta-analysis by Santa Maria *et al.*, it was concluded that better HP was associated with cochleostomy (CO), slow electrode array insertion, soft tissue seal, and postoperative systemic steroids (Santa Maria *et al.*, 2014). Deep insertion, topical steroid use, and lubricant use for electrode array insertion did not provide an advantage. Bruce *et al.* implanted 14 adolescent ears with 31.5 mm MED-EL Flex-soft array (Bruce *et al.*, 2014). Average follow-up time was 2 years and 10 months, and some degree of preservation was achieved in all but one case. In an earlier study, successful HP was demonstrated in 12 out of 14 cases receiving a standard length electrode through CO for up to 23 months (Bruce *et al.*, 2011). Three out of 13

patients with initially successful HP had deteriorated by the time of subsequent follow-up. Longer electrode arrays and topical steroids were not associated with less low-frequency hearing preservation. Briggs *et al.* found that the CO must be made inferior, rather than anterior to the RW, to reduce intra-cochlear damage (Briggs *et al.*, 2005). That CO offers an advantage over RW application for HP was recently challenged by Eshraghi *et al.* (2017) and ÓConnell *et al.* (2016b). Moreover, histological analyses show less fibrosis and tissue reaction in the cochlea after RW application compared to CO (Adunka *et al.*, 2004; Linthicum *et al.*, 2017). Surprisingly, extended RW application was more damaging than alternative trajectories (Richard *et al.*, 2012). Our recent studies using micro-computed tomography with 3D rendering and synchrotron imaging demonstrated that anterior and antero-inferior CO regularly damage intra-cochlear soft tissues, such as the spiral ligament, while inferior CO occasionally left inner ear structures intact (Schart-Moren *et al.*, 2019). Mady *et al.* (2017) implanted 45 adults with either a peri-modiolar or straight lateral wall electrode array. Both electrode types were inserted through the RW and CO. They found that HP using lateral wall electrodes was better in the short term compared to peri-modiolar electrodes. In the long term, younger age was associated with better overall HP which for unknown reasons declined over time. Moran *et al.* (2017) used a thin straight electrode array through the RW in 139 CIs. According to the HEARRING criteria, 36.7% had complete preservation, 46.8% partial, 6.5% minimal, and 10.1% lost hearing. At 12 months, 74 patients showed HP rates of 20.3%, 47.3%, 14.9%, and 17.6% respectively. No patient or surgical factors were related to preservation rates. Hunter *et al.* (2016) used a mid-scalar electrode in 47 patients. A total of 66.7% underwent RW, 25.6% extended RW, and 7.7% CO approaches. At 6 months, 15% of the patients had complete HP, whereas 40% had partial HP. At 1 year, these percentages decreased to 0% and 38.5%, respectively. Age and type of approach were not correlated with HP outcomes at activation and 6 months postoperatively. O'Connell *et al.* (2016a) found that electrode design and surgical approach were predictors of scalar electrode location. RW and extended RW approaches were associated with higher rates of ST insertion compared to CO. Younger age and greater angular insertion depth were predictors of improved CNC scores. Helbig *et al.* (2016) presented results from 62 patients with a mean duration of 78 months for classic electrodes and 43 months for flexible electrodes. Postoperative preservation of hearing varied with no decisive difference among surgical approaches.

A deeper insertion would seem to increase the risk for intra-cochlear damage but provides extended cochlear coverage at the apex improving place pitch matching and faster adaptation to electric hearing (Buchman *et al.*, 2014; Dorman *et al.*, 1997; Hochmair *et al.*, 2015). Insertion depth impacts scalar position and number of electrodes in the ST and decreases the risk for inter-scalar translocation (Finley *et al.*, 2008; Radeloff *et al.*, 2008). Lower outcome scores are associated with greater number of contacts being located in scala vestibuli (Holden *et al.*, 2013).

All patients in our study had an increase in speech discrimination compared to preoperative scores. This was still measurable over the longer term, even if they had lost their residual hearing. When comparing speech discrimination scores in our data it is important to know that we modified measuring routines at our clinic. Currently, all monosyllables are presented at a fixed 65 dB level. Most patients in our studies were measured at higher dB-levels preoperatively.

A total of 12 out of 15 patients had the same stimulation strategies at long-term follow-up compared to the initial ones at activation. Three patients changed their stimulation strategy from a + e stimulation to e-only over the whole frequency range. One of these patients lost hearing while two had HP-rates of 48% and 58%. At a closer look at their audiograms (patient no 13 and 14) it becomes obvious that hearing in the critical frequencies of 250 and 500 Hz decreased over time which made a change to e-only stimulation necessary. This is also a relative limitation of the HEARRING methods of defining HP, though it considers the entire audiometric frequency range not only the PTA for the low frequencies.

In summary, our data add information about late effects on cochlear function following initial successful electrode placement. The findings further substantiate that occasional progressive loss of residual hearing occurs after initial CI preservation whose etiology needs further elucidation.

Conclusion

In our 21 first consecutive patients in our clinic that underwent hearing preservation CI-surgery, data of 15 patients were available for a long-term follow-up. Long-term HP was possible in most (12 out of 15) of the cases. There was a high correlation between insertion angle and HP outcome. Even patients with complete hearing loss experienced good performance in both speech discrimination results and user time of the processor.

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