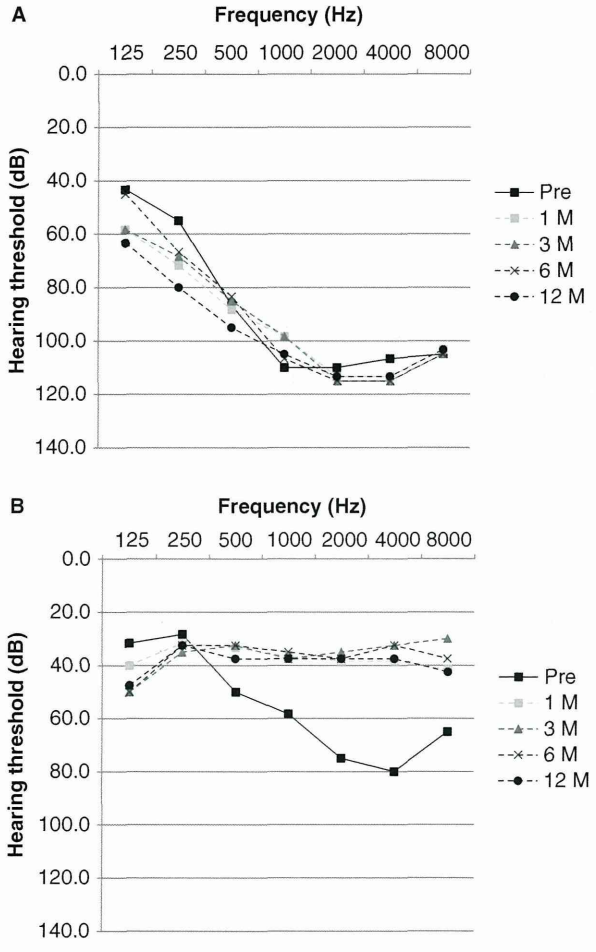

Figure 4. (A) Average audiogram of group 2. The lines indicate preoperative, and 1, 3, 6, and 12 months postoperative audiograms. Note that good hearing preservation could be achieved. (B) Hearing level of group 2 with electric acoustic stimulation (EAS).

perception tests, EAS showed the best results (Figure 5). EAS results were significantly better than the ES only results ($p = 0.002$ for word and $p = 0.01$ for sentence, paired t test).

Similar results were obtained for the patients in group 2, who had less residual hearing and received longer (31.5 mm length) electrodes. Good performance after EAS was observed. The average monosyllable discrimination score in quiet (67S 65 dBSPL) was improved from 28% preoperatively with hearing aid to 66.7% with EAS 12 months after the first fitting (Figure 6). The results for monosyllable, word, and sentence perception in noise were improved from 25%, 12%, and 25%, preoperatively with hearing aid to 66.7%, 82%, and 89% with EAS 12 months after the first fitting. In all of the conditions, EAS showed the best results (Figure 6).

Discussion

We first consider hearing preservation. We combined postoperative imaging with the referential tonotopic map and clearly showed that even with the use of a long electrode covering the residual hearing region it is possible to achieve hearing preservation with EAS.

Overall, hearing preservation as well as speech perception data obtained in this study correlate well with recent reports [5–11]. As to hearing preservation, residual hearing was well preserved even after deep insertion (full insertion of 24 mm or 31.5 mm length electrodes). As in other reports, hearing thresholds dropped at the initial cochlear implant activation 1 month postoperatively. In particular, hearing deterioration at 500 Hz was evident compared with 250 Hz or 1000 Hz. After initial deterioration, pure-tone thresholds were stable until 12 months. In particular, air-conduction hearing was elevated compared with bone-conduction hearing, suggesting that this initial deterioration may be most likely due to changes in cochlear micromechanics rather than acute acoustic trauma. This phenomenon could be explained by the slight lifting of the basilar membrane in the middle turn that was seen in a temporal bone study [16].

In contrast, a slight hearing improvement could also be observed in some cases (group 1, case no. 1, 1000 and 2000 Hz; group 1, case no. 10, 2000 Hz; group 1, case no. 21, 1000 Hz; group 1, case no. 24,

Table III. Average hearing thresholds of electric acoustic stimulation (EAS) patients in group 2.

	Air conductive hearing level (dB)							Bone conductive hearing level (dB)				
Timing	125 Hz	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz	8000 Hz	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
Preoperative	43.3	55.0	86.7	110.0	110.0	106.7	105.0	36.7	63.3	75.0	75.0	65.0
1 month	58.3	71.7	88.3	98.3	113.3	113.3	103.3	48.3	58.3	73.3	75.0	65.0
3 months	58.3	68.3	85.0	98.3	115.0	115.0	105.0	53.3	63.3	73.3	75.0	65.0
6 months	45.0	66.7	83.3	106.7	115.0	115.0	105.0	48.3	61.7	75.0	75.0	65.0
12 months	63.3	80.0	95.0	105.0	113.3	113.3	103.3	47.5	62.5	75.0	75.0	65.0

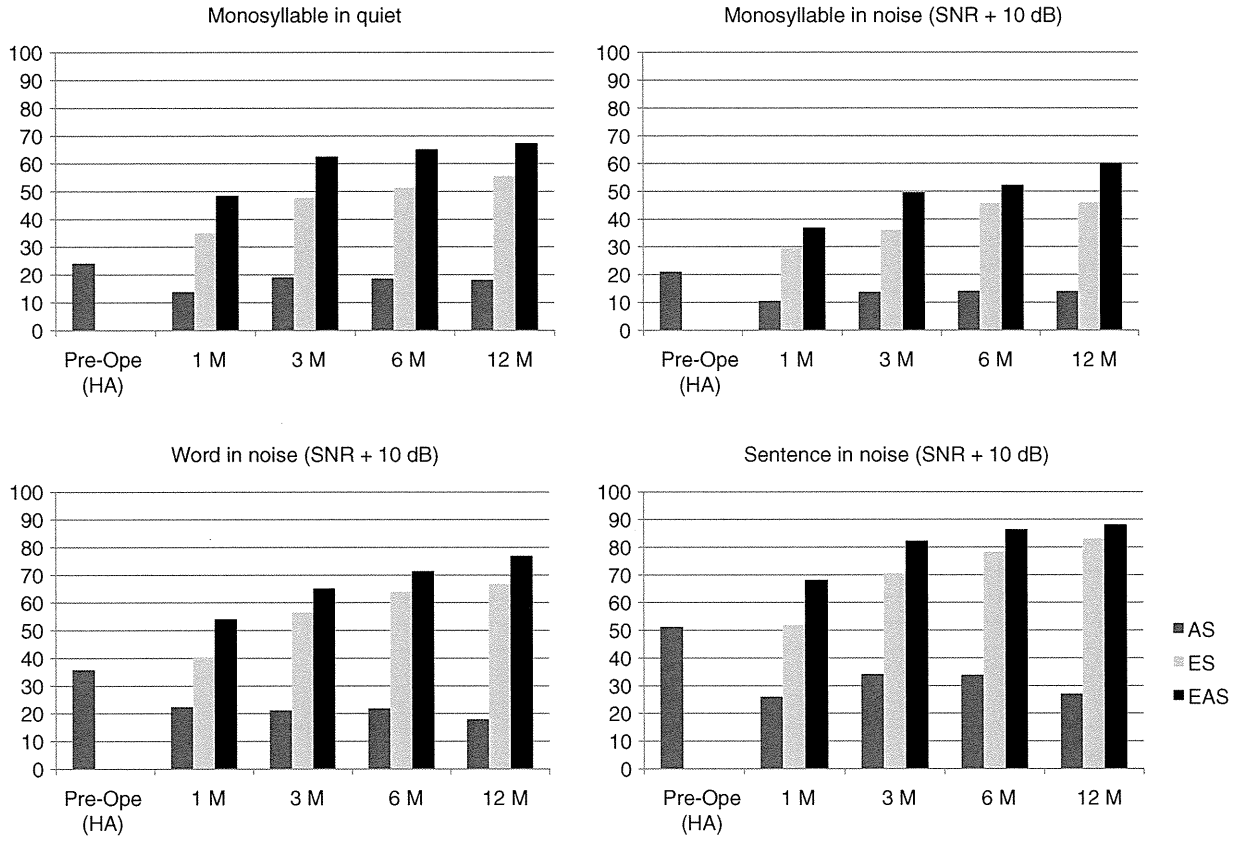

Figure 5. Speech discrimination and perception scores of group 1 (with FLEX24 electrode). Speech discrimination and perception scores were improved postoperatively with electric acoustic stimulation (EAS). SNR, signal-to-noise ratio.

2000 Hz; group 2, case no. 28, 1000 Hz; group 2, case no. 30, 500 and 1000 Hz), as seen in the preliminary data we have previously reported [12]. This phenomenon was constant until the 12-month evaluation, suggesting that this was not a measuring error but true improvement. This is probably due to alterations of the basilar membrane behavior occurring after electrode insertion.

We turn now to speech perception outcome. Hearing preservation could be achieved in a high number of patients, and combined EAS provided good speech perception in both quiet and noise. Speech discrimination and perception scores were improved postoperatively with EAS in both of our groups, indicating that (1) EAS is beneficial for Japanese-speaking patients within particular audiogram indications, and (2) EAS is also beneficial for patients with less residual hearing at lower frequencies. In the present study, patients with less residual hearing (case nos. 25–30) showed good results equal to those fulfilling the audiological criteria (case nos. 1–24), indicating that these patients are also good candidates for EAS. The current results indicated that the audiological criteria for EAS should not be limited to the conventional range of audiogram, but also expanded to the patients with less residual hearing.

Hearing loss in the majority of patients with residual hearing at lower frequencies is more or less progressive and therefore they may have fulfilled the audiological criteria for EAS at an earlier date. Actually an audiogram from the past showed that our case no. 27 in group 1 had previously fulfilled the audiological criteria (data not shown) and it is possible that this was also true for case nos. 25, 26, and 28–30. Throughout the selection process for EAS candidates, we have paid attention to the progressive nature of their hearing loss. We need to consider that patients who fulfill the criteria at a certain point possibly may not fit the criteria in the future. In contrast, most of the patients who did not totally meet the audiological criteria for EAS may have fulfilled the criteria several years before. Considering such progressive nature of hearing loss, audiological criteria should not be tightly limited to the conventional criteria for EAS. The present results support the proposition that the criteria could be expanded to include the cases with less residual hearing. Since shallow insertion of short electrodes cannot recruit neurons in the apical region,

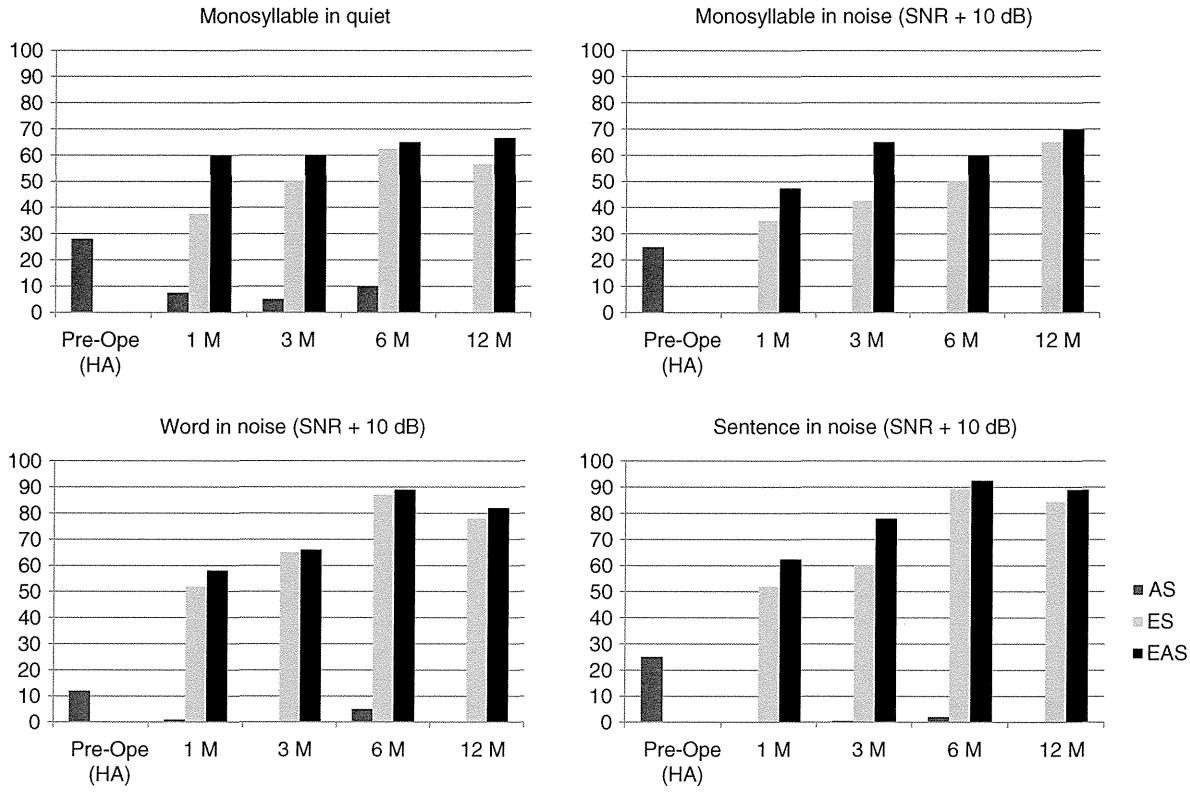

Figure 6. Speech discrimination and perception scores of group 2 (standard electrode or FLEXSOFT electrode with less residual hearing). Speech discrimination and perception scores were improved postoperatively with electric acoustic stimulation (EAS). SNR, signal-to-noise ratio.

deeper insertion would be the best solution to compensate for future hearing deterioration at the lower frequencies. However, full insertion with a long/medium electrode for the patients with residual hearing at the low frequencies is still a controversial field because of possible loss of their residual hearing due to mechanical trauma of the corresponding area.

In this study, 24 mm or 31.5 mm electrodes were chosen for all patients. FLEX24 was used for the patients with residual hearing that was more evident, while FLEXSOFT was used for the patients with less residual hearing.

The speed of progression, i.e. rapid or rather stable, may be dependent on the individual etiology. An unresolved issue is the prediction of progressiveness based on the etiology of individual hearing loss, but we have recently reported at least five genes that are responsible for the candidates for EAS, and therefore there is not a single etiology but rather a great genetic heterogeneity involved in this particular type of hearing loss [17–19].

In the present study, the responsible gene (*m.1555A>G, TMPRRS3, ACTG1*) was identified in 3 of 30 patients (Table I) [18,19], and will contribute to such decision-making in the near future.

The benefits of minimally invasive concepts in CI surgery are needed not only for the patients with residual hearing but also for the patients with profound hearing loss without any residual hearing, because structure preservation is critical for (1) future therapeutic interventions including gene therapy and/or regeneration therapy, and (2) vestibular function. If acoustic stimulation is not applicable due to less residual hearing, vestibular function could be a good marker for structure preservation. Our recent study on vestibular function of the patients with EAS clearly demonstrated that the patients have comparatively good vestibular function and it is important to preserve not only residual hearing function but also the vestibular function of the implanted ears, using minimally invasive surgical techniques [20]. The round window approach and soft electrode should be preferred to decrease the risk of damage to vestibular function [12].

Conclusions

EAS is beneficial for Japanese-speaking patients including those with less residual hearing at lower frequencies, indicating that current audiological

criteria for EAS can be expanded. Since hearing loss of EAS candidates is more or less progressive, full insertion of medium/long electrodes would be the best solution to compensate for future hearing deterioration at the lower frequencies. The benefits of minimally invasive concepts in CI surgery are crucial not only for the patients with residual hearing but also from the viewpoint of structure preservation in patients with profound hearing loss without any residual hearing.

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Declaration of interest: The Ministry of Health, Labour and Welfare approved our clinical research for Advanced Medical Technology using electric acoustic stimulation (EAS). Because the EAS devices had not yet been approved for clinical use in Japan, they were supplied by MEDEL. The Shinshu University Conflict of Interest Committee also approved the study. The authors alone are responsible for the content and writing of the paper.

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ORIGINAL ARTICLE

Effects of EAS cochlear implantation surgery on vestibular function

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Abstract

Conclusions: The patients who received electric acoustic stimulation (EAS) cochlear implantation had relatively good vestibular function compared with the patients who did not have residual hearing. The vestibular function was well preserved after atraumatic EAS surgery. The round window approach and soft electrode are preferred to decrease the risk of impairing vestibular function. *Objectives:* The aim of this study was to examine the characteristic features of vestibular functions before and after implantations in patients undergoing EAS. *Methods:* Vestibular functions in patients who underwent EAS implantation were examined by caloric testing and vestibular evoked myogenic potential (VEMP) in 11 patients before and in 13 patients after implantation. *Results:* Preoperative evaluation showed that of the 11 patients, most (73%) had good vestibular function. One of 11 patients (9%) had decreased response in postoperative VEMP but all of the patients had unchanged results in postoperative caloric testing.

Keywords: *Cochlear implant, VEMP, caloric test, preservation*

Introduction

Recently, a series of reports have shown the efficiency of electric acoustic stimulation (EAS) in patients with residual acoustic hearing in the lower frequencies [1]. The development of techniques such as soft surgery when performing cochleostomy [2], round window insertion [3], use of atraumatic electrodes [4,5], and postoperative steroid administration has enabled preservation of residual hearing after cochlear implantation (CI) surgery.

Current techniques of CI also facilitate remarkable improvement in hearing ability. However, consideration must still be given to the complications that can accompany a CI.

One possible such complication is impairment of vestibular function with resulting vertigo symptoms. The incidence of this complication as reported in the literature varies widely from 0.33% to 75% [6].

Although numerous studies have reported the effects of CI on the vestibular function in deaf patients, there have been no reports examining the vestibular function in patients who had residual hearing at lower frequencies, or of the postoperative effects on vestibular function of new atraumatic concepts of electrode and surgical techniques.

We recently published a preliminary report that the round window approach (RWA) is preferable from the viewpoint of vestibular function [7].

The aim of the present study was to further examine the changes in vestibular functions after implantation in patients who underwent EAS CI.

Material and methods

Patients

Thirteen patients (four males and nine females) who underwent EAS CI in our center were included in this

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study after obtaining informed written consent. The study was carried out with the approval of the Shinshu University Ethical Committee.

The age at implantation ranged from 30 to 60 years, and the mean age was 45.2 years. All patients fulfilled the following inclusion criteria: post-lingually acquired, bilateral sensorineural hearing loss (HL) with pure tone thresholds of <65 dB HL at the low frequencies (125, 250, and 500 Hz), of ≥80 dB HL at frequency 2 kHz, and of ≥85 dB HL at frequencies >4 kHz, and monosyllabic word recognition scores in quiet of ≤60% at 65 dB sound pressure level (SPL) in both ears in best-aided condition. Subjects were still included in this study if one of these frequencies was out of the mentioned decibel levels by only 10 dB or less.

Cochlear implantations

We performed CI with full insertion of the MED-EL FLEX$^{EAS®}$ electrode (MED-EL, Innsbruck, Austria) in all patients.

All surgeries were performed by a single surgeon and the RWA was applied for electrode insertion. Systemic antibiotics and dexamethasone were administered peri- and postoperatively. Residual hearing was successfully preserved in all patients (data not shown).

Vestibular testing

The patients were examined by caloric testing and vestibular evoked myogenic potential (VEMP) before or after implantation, or both, to obtain data on semicircular canal function and otolithic function, respectively.

In VEMP testing, electromyography (EMG) was carried out using a pair of surface electrodes mounted on the upper half and the sterna head of the sternocleidomastoid (SCM) muscle. The electrographic signal was recorded using a Neuropack evoked potential recorder (Nihon Kohden Co. Ltd, Tokyo, Japan). Clicks lasting for 0.1 ms at 105 dBnHL were presented through a headphone. The stimulation rate was 5 Hz, the bandpass filter intensity was 20–2000 Hz, and analysis time was 50 ms. The responses to 200 stimuli were averaged twice. Because the amplitude of the VEMP based on the unrectified EMG is correlated with the activity of the SCM muscle during the test [8], we measured the activity of the SCM muscle using the background integrated EMG response, the area under the averaged rectified EMG curve, from –20 ms to 0 ms before the sound stimulation. The correction of the amplitude was calculated as follows [9]:

Corrected amplitude (ms^{-1}) = amplitude of the averaged unrectified EMG (micro V)/background integrated EMG (micro V ms)

In caloric testing, maximum slow phase velocity (SPV) was measured by cold water irrigation (20°C, 5 ml, 20 s). We defined below 10°/s of SPV as areflexia and between 10 and 20°/s as hyporeflexia.

Statistical analysis

SPSS for Windows software (Chicago, IL, USA) was used for all analyses, and paired t test was applied when comparing differences in preoperative and postoperative vestibular functions. Statistical significance was set at $p < 0.05$.

Results

The results are summarized in Table I.

Semicircular canal function

Preoperative evaluation was performed bilaterally. Three of 11 patients (27%, nos 3, 4, and 5) showed areflexia or hyporeflexia in caloric testing. Patient no. 4 had bilateral areflexia, no. 5 had implanted ear areflexia and non-implanted ear hyporeflexia, and no. 3, had hypoflexia only in the non-implanted ear.

Postoperative caloric testing was obtained after 1 month or more. All 13 patients underwent postoperative caloric testing and 11 of them were also examined before the EAS implantations. Two (nos 4 and 5) of 13 patients (15%) had abnormal postoperative caloric test results in the implanted ear, although both of them also had abnormal results before implantations. Figure 1 shows the caloric response before and after EAS implantations for the implanted ear. Compared with before implantations, the results after implantations were unchanged in all of the 11 patients who underwent both preoperative and postoperative testing. One patient (no. 4) had areflexia both before and after implantation. The mean SPV was 28.06°/s preoperatively (SD = 17.61) and 28.68°/s postoperatively (SD = 15.53). There were no significant differences between results before and after implantations in caloric testing ($p = 0.67$).

Otolithic function

When preoperative evaluation was performed, no patients showed absent response in VEMP.

Postoperative VEMP was obtained after 1 month or more. All 13 patients underwent postoperative VEMP and 11 of them were also examined before EAS implantations. No patient had absent VEMP response

Table I. Summary of patients' details.

Patient no.	Age (years)/sex	Implanted side	Caloric test (°/s)				VEMP (ms^{-1})			
			Implanted ear		Non-implanted ear		Implanted ear		Non-implanted ear	
			Preop	Postop	Preop	Postop	Preop	Postop	Preop	Postop
1	41/M	R	NA	22.28	NA	20.74	NA	0.060	NA	0.068
2	47/F	L	NA	24.41	NA	9.09†	NA	0.029	NA	0.022
3	40/F	L	22.67	24.65	17.61*	17.76*	0.055	0.053	0.041	0.061
4	60/F	R	0†	0†	6.05†	0†	0.017	0.012	0.029	0.022
5	46/F	R	4.46†	8.31†	15.14*	19.94*	0.012	0.015	0.024	0.025
6	39/F	L	52.84	50	46.26	38.76	0.027	0.023	0.028	0.047
7	47/F	R	26.64	28.2	22.18	27.31	0.020	0.018	0.024	0.022
8	30/M	R	29.62	39.65	31.1	14.69	0.062	0.032	0.045	0.028
9	40/M	L	24.94	29.39	38.11	23.4	0.026	0.019	0.046	0.025
10	35/F	L	23.18	22.91	22.24	21.96	0.025	0.026	0.030	0.040
11	52/M	R	22.57	22.02	22.44	22.98	0.018	0.020	0.023	0.017
12	51/F	L	52.57	45.97	50.26	54.95	0.036	0.033	0.041	0.026
13	59/F	L	49.18	43.44	54.3	43.44	0.010	0.008	0.038	0.024

NA, not available.
*Hyporeflexia.
†Areflexia.

in the implanted ear. Figure 2 shows corrected VEMP amplitudes before and after EAS implantations for the implanted ear. Although one (no. 8) of the 11 patients (9%) had a decreased response in corrected VEMP amplitude, corrected VEMP amplitudes after implantations were unchanged in all but one of the patients, when compared with preoperative results. The mean corrected amplitude was 0.028 preoperatively (SD = 0.017) and 0.023 postoperatively (SD = 0.013). There were no significant differences between results before and after implantation in VEMP testing ($p = 0.095$).

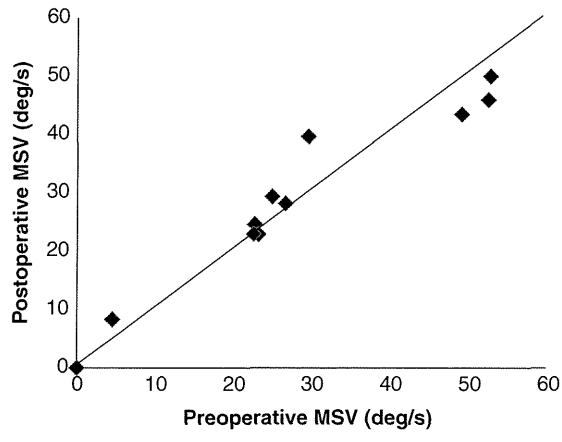

Figure 1. Results of caloric testing before and after EAS implantations in the implanted ear. There were no significant differences between preoperative and postoperative results ($p = 0.67$). MSV, maximum slow eye velocity.

Discussion

Previous reports showed that the frequencies of 'preoperative' vestibular disorders in profound hearing loss patients were about 30–73% in caloric testing [10–14] and about 11–65% in VEMP [10–15].

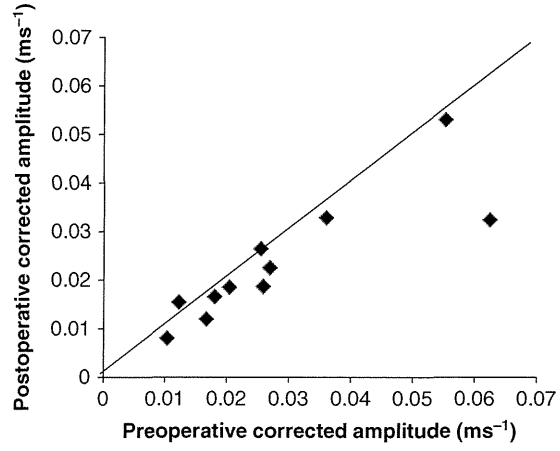

Figure 2. Results of VEMP before and after EAS implantations in the implanted ear. There were no significant differences between preoperative and postoperative results of VEMP testing in EAS implanted ears ($p = 0.095$). Corrected amplitude was used to compare the results.

In this study, we found that the 'preoperative' frequencies of vestibular disorders in hearing loss patients with residual hearing who received EAS were 27% and 0% in caloric testing and VEMP, respectively.

This finding suggested that vestibular function of the patients who underwent EAS was relatively good compared with the patients with profound hearing loss who underwent conventional CI.

In this study, to preserve such good vestibular function, atraumatic CI surgery (RWA with flexible thin electrode) was performed. Although one patient showed a decreased VEMP result, there was no hypofunction in postoperative caloric testing when compared with preoperative results in the implanted ear.

According to previous reports, various frequencies of postoperative deterioration in vestibular function were demonstrated. Postoperative hypofunction was found in 6–58% in the caloric testing [10–14,16–18], and 13–86% in VEMP [10–15]. One of the reasons for such variation is probably the surgical technique applied.

Todt et al. reported that hypofunction of postoperative VEMP was seen in 50% of patients who underwent cochleostomy and 13% of those with RWA Also, abnormal postoperative caloric testing results were seen in 42.9% of the patients who underwent cochleostomy and 9.4% of those who had the RWA [10].

Temporal bone studies have shown that an electrode insertion into the scala vestibuli involves damage of the osseous spiral lamina, basilar membrane, and vestibular receptors. The saccule was the most frequently damaged vestibular receptor, followed by the utricle and the semicircular canals [19].

However, when the electrode was inserted into the scala tympani, no vestibular damage was found [19]. Adunka et al. evaluated cochlear implant electrode insertions through the round window membrane histologically and reported that smooth implantations via round the window membrane resulted in deep, atraumatic insertions into the scala tympani [20]. Unintentional lesions to the basilar membrane can be avoided by using the round window as an exact anatomic landmark that is always in direct continuity with the scala tympani [20]. Previous histological and clinical studies clearly showed that the RWA is the technique that preserves the vestibular functions to the greatest extent and therefore is better than cochleostomy.

In the present study, the FLEX^{EAS} electrode was used for all of the patients. The cross-sectional diameter of the electrode is smaller than a conventional electrode, varying from 0.33 by 0.49 mm at the apex and to 0.8 mm at the basal, and a major feature of the device is its superior flexibility. Histology and dissection of human temporal bones performed by Adunka et al. confirmed the atraumatic character of this device [20]. Insertion forces with the conventional array and FLEX array were measured in an acrylic model of the scala tympani, demonstrating that insertion force could be reduced significantly by more than 40% with the FLEX^{EAS} electrode [4]. As in our previous study [7], such a smaller diameter and more flexible electrode might enable less damage to not only the cochlear tissue, but also the vestibular organs.

In conclusion, patients undergoing EAS implantation have good vestibular function compared with the vestibular function of the patients with profound hearing loss. It is important to preserve not only residual hearing but also the vestibular function of the implanted ears, using atraumatic surgical techniques. The RWA with soft electrode is preferable to decrease the risk of damage to vestibular function.

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Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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Standards of practice in the field of hearing implants

P Van de Heyning[1], O Adunka[2], S L Arauz[3], M Atlas[4], W-D Baumgartner[5], S Brill[6], I Bruce[7], C Buchman[2], M Caversaccio[8], M Dillon[2], R Eikelboom[4], G Eskilsson[9], J Gavilan[10], B Godey[11], K Green[7], W Gstoettner[5], R Hagen[6], D Han[12], S Iwasaki[13], M Kameswaran[14], E Karltorp[9], A Kleine Punte[1], M Kompis[8], J Kuthubutheen[15], V Kuzovkov[16], L Lassaletta[10], Y Li[12], A Lorens[17], M Manikoth[18], J Martin[19], R Mlynski[6], J Mueller[20], M O'Driscoll[7], L Parnes[21], H Pillsbury[2], S Prentiss[22], S Pulibalathingal[18], C H Raine[19], G Rajan[15], R Rajeswaran[14], H Riechelmann[23], A Rivas[24], J A Rivas[24], P Senn[8], P H Skarzynski[17], G Sprinzl[23], H Staecker[22], K Stephan[25], S Sugarova[16], S-I Usami[13], A Wolf-Magele[23], Y Yanov[16], M E Zernotti[26], K Zimmerman[21], P Zorowka[25], H Skarzynski[17]

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HEARRING quality standards: an Introduction

In 2005 the World Health Organization estimated that approximately 278 million people suffered from 'moderate to profound hearing impairment,' 80% of whom lived in low- and middle-income countries (WHO, 2010) where there is less access to competent medical professionals and modern medical procedures and technologies than in high-income countries. Furthermore, with the ageing populations in the developed world (United Nations, 2010) and their associated age-related hearing-loss (presbycusis), the need for assisted hearing solutions – even taking into account a hopefully broader application of preventive measures (e.g. rubella immunization, health education, quieter workplaces, etc.) and health-care infrastructure development – is clearly both significant and continued.

One of such possible hearing solutions is hearing implantation. Indeed, as of December 2010, approximately 219 000 people have been implanted, either uni- or bilaterally (National Institute on Deafness and Other Communication Disorders, 2011). As significant as the benefits of cochlear or middle ear implantation have been for recipients and their families, such implantation is still in its demographic infancy, serving a negligible fraction of those whom

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it could, and will, help integrate or reintegrate into the verbal bustle of everyday life and work.

'The best clinics – providing the best for the patient and comprehensive care' (HEARRING, 2012). With this motto, renowned specialists of four leading hearing implant centers formed the HEARRING group in 2008. Inspired by the collaborative nature of comprehensive cancer center networks, they sought a closer network to better pool their expertise and share information instead of relying solely on medical literature and – beneficial as they are – the individual personal contacts that medical congresses and conferences provide. In the following years, other centers from around the world have joined HEARRING: as of 2012, 23 clinics with numerous surgeons, audiologists, rehabilitationists, and other skilled professionals are collaborating under the HEARRING umbrella.

The 23 clinics in the HEARRING network are committed to creating and maintaining the highest standards of quality. We believe that consensus- and evidenced-based standards are essential to providing each potential implant user, regardless of age or where in the world he/she is treated, with the best possible hearing implant solution for the treatment of her/his individual hearing loss.

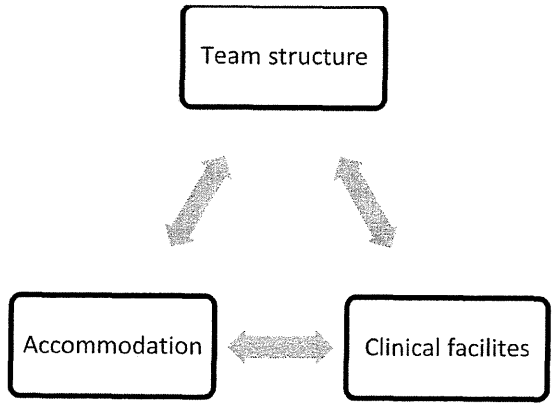
In order to try to ensure the best outcomes and the highest safety levels for every present or potential implant user in every clinic, the HEARRING group – under the direction of experts Prof. Christopher H. Raine, MD, Prof. Dr Rudolf Hagen, Prof. Dr Joachim Müller, Prof. Dr Benoit Godey, and Jane Martin – has created a series of standards that covers all aspects of the hearing implant solution process. These quality standards are based on the British Cochlear Implant Group's (BCIG) own quality standards and can be considered current best practice; indeed they have been approved and adopted by participating HEARRING clinics. These standards are not, however, a static picture; as technology and treatment options continually develop, these standards will be continually updated.

The BCIG was founded in 1989 – not long after implantation became common – to promote good practice and provide information and advice to professionals and the public on cochlear implant solutions. They, with the Royal National Institute for the Deaf, published 'Quality Standards for Adult Cochlear Implantation' (British Cochlear Implant Group and Royal National Institute for the Deaf, 2009), a series of 16 guidelines that are meant to be the *minimum* and *realistically achievable* baseline standards for clinics. HEARRING has used this original document as a blueprint for developing a series of six related sets of evidence-based standards, each tailored to fit a specific age category or procedure:

1. Quality standards for adult cochlear implantation
2. Quality standards for cochlear implantation in children and young adults
3. Quality standards for combined electric and acoustic stimulation (EAS)
4. Quality standards for middle ear implantation (MEI)
5. Quality standards for rehabilitation
6. Quality standards for minimal outcome measurements in adults and children.

With some slight variation (see Table 1), each set of standards has the same basic structure which can be divided into two subsections: (1) resources and (2) processes.

Resources: The Resources section is made up of three parts: team structure, accomodation, and clinical facilities.



Team structure outlines who every cochlear implant team should include and the minimum training and/or experience each member should have. It also describes the importance of establishing and maintaining a program of continued professional development: with national or international courses, conferences, and meetings each team member should be up to date with the latest cochlear implantation-related developments. Extending beyond the core team, this section also provides a list of 'additional support' professionals whose expertize need not be part of a core team but whom the core team should have ready access to if necessary.

Accommodation is about the provision and differentiation of the clinic's physical space: the size, suitability, comfort, and privacy of areas designated for staff, present or potential implant users, and waiting relatives. As different cultures have different spatial expectations and comforts, the HEARRING standards do not prescribe specific sizes but rather those that are 'suitable', 'sufficient', and 'large enough to comfortable accommodate'. Accomodation is also about access and communication. It covers providing the present or potential implant user with suitable

Table 1 The structural variations by Quality Standard

	Quality Standards for					
	Adult Cochlear Implantation	Cochlear Implantation in Children and Young Adults	Combined Electric and Acoustic Stimulation	Middle Ear Implantation	(Re)habilitation	Minimal Outcome Measurements
			Symbols: = equal	***≠ differs***	***+ in addition***	***– without (compared to basic document)***
Introduction	Individualized	=	Individualized	Individualized	Individualized	Individualized
Structure	Basic document	+ min of two surgeons, audiovestibular physician/ pediatrician, key worker, education, pediatrics	+ hearing aid acoustician – audiological medicine	– clinical scientists, physiologists, rehab therapists, speech and language therapists, clinical physiologists, engineers, tinnitus, balance, medical physics, genetic counseling, interpreter services, social services for the deaf, deaf advocacy	+ teacher of the deaf, key worker, parents, hearing aid acoustician, audiovestibular physician, cooperation with other services – otologist, audiologists, physiologists	NO
Accommodation	Basic document	+ suitable and family-friendly facilities	=	=	=	NO
Clinical Facilities	Basic document	+ spatial awareness	=	– OAE, electrically evoked potentials, balance function testing	NO	NO
Referral and Selection Criteria	CI selection *criteria*	CI in children/young adults *selection criteria*	EAS selection *criteria*	MEI selection criteria	NO	NO
Assessment Process	Basic document	+ ophthalmic assessment, family support and education, associated organizations, final outcome ≠ *receptive skills assessment*	+ APHAB test	12 weeks – referral for balance testing and genetic counseling, necessity for vaccination (meningitis), determination of UCL, *hearing aid testing, electrically evoked* response audiometry, promontory stimulation testing, OAE, details for communication, bilateral candidate assessment	≠ structure and content, children and adults are discussed separately – includes pre-op counseling	≠ describes basic sets of outcome measures to be used at routine visits for adults and children
Cooperation with Other Services	Basic document	+ newborn hearing screening	=	NO	NO (included in previous chapter)	NO
Pre-op Information and Counseling	Basic document	+ involvement of child, device	=	=	NO (included in previous chapter)	NO
Device	CI	NO (included in previous chapter)	EAS	MEI	NO	CI, but also applicable to other hearing implants
Surgery and In-patient Care	Basic document	+ monitoring of anesthetics and facial nerve – discussion of surgical procedure	=	– preservation of hearing, radiological examination	NO	NO
Fitting and Tuning	Basic document	+ electrophysiological measurements in the very young	=	+ rehabilitation	NO	NO

Continued

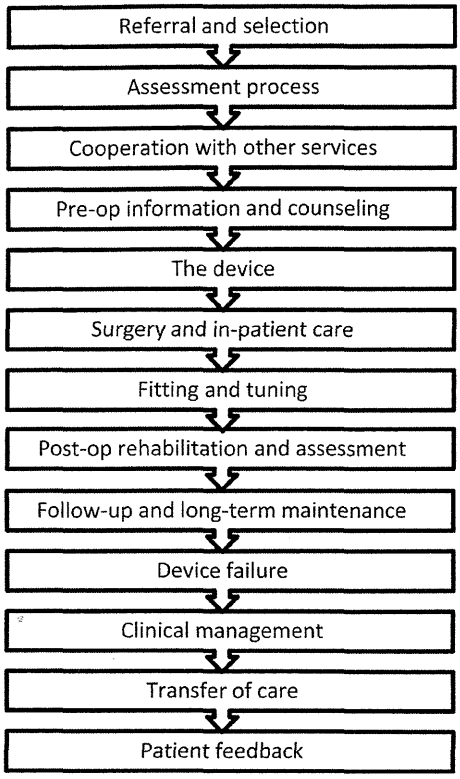
Table 1 ***Continued***

	Quality Standards for						
	Adult Cochlear Implantation	Cochlear Implantation in Children and Young Adults	Combined Electric and Acoustic Stimulation	Middle Ear Implantation		(Re)habilitation	Minimal Outcome Measurements
			Symbols: = equal	***≠ differs***	***+ in addition***	***– without (compared to basic document)***	
Post-op Rehabilitation and Assessment	Basic document	– lip reading, hearing tactics	=	– rehabilitation (included in previous chapter) ≠ post-op assessment		≠ structure and content, children and adults are discussed separately	NO
Follow-up and Long-term Maintenance	Basic document	+ assessment of FM systems	=	=		NO	NO
Device Failure	Basic document	=	+ detailed audiological reevaluation, consideration of a CI	=		=	NO
Clinical Management	Basic document	=	=	=		NO	NO
Transfer of Care	Basic document	=	NO	=		=	NO
Patient Feedback	Basic document	=	=	=		NO	NO

[1]The Quality Standards for Minimal Outcome Measurements in Adults and Children were based on the core elements of the other standards, and in itself describes procedural elements for routine assessment and reporting.

telecommuncations access to the clinic and, while in the clinic, with assistive listening devices and alerts.

As the name would suggest, the clinical facilities section outlines which technology should be available to be able to perform a variety of tests. Further, this section highlights the need to regularly calibrate instruments to nationally recognized standards.



Processes:

The clinics and professionals of the HEARRING network believe that providing users with individualized hearing solutions is a careful and detailed process that does not start and stop at surgical implantation. Each of the individual 13 steps is subdivided to provide more specific and in-depth guidelines. Taken together, the cumulative effect is a wealth of best-practice detail which covers every step of the implant experience from selection criteria to long-term maintenance.

The aforementioned six quality standards are published in full on the forthcoming pages followed by a table highlighting the key differences between the standards. It is the HEARRING group's hope that a wide adoption and implantation of these standards will lead to still a greater delivery of the highest quality comprehensive care and thus happier, better hearing implant users.

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ORIGINAL ARTICLE

Towards a consensus on a hearing preservation classification system

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Abstract

Conclusion: The comprehensive Hearing Preservation classification system presented in this paper is suitable for use for all cochlear implant users with measurable pre-operative residual hearing. If adopted as a universal reporting standard, as it was designed to be, it should prove highly beneficial by enabling future studies to quickly and easily compare the results of previous studies and meta-analyze their data. *Objectives:* To develop a comprehensive Hearing Preservation classification system suitable for use for all cochlear implant users with measurable pre-operative residual hearing. *Methods:* The HEARRING group discussed and reviewed a number of different propositions of a HP classification systems and reviewed critical appraisals to develop a qualitative system in accordance with the prerequisites. *Results:* The Hearing Preservation Classification System proposed herein fulfills the following necessary criteria: 1) classification is independent from users' initial hearing, 2) it is appropriate for all cochlear implant users with measurable pre-operative residual hearing, 3) it covers the whole range of pure tone average from 0 to 120 dB; 4) it is easy to use and easy to understand.

Keywords: *Cochlear implant, partial deafness, hearing preservation*

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Introduction

What hearing preservation is and why it is important in cochlear implantation

Maximum possible atraumaticity is a goal in most cochlear implant (CI) surgeries. The aim is to ensure that no other structures are compromised by the electrode and the electrode insertion in order to preserve the neural elements within the cochlea that are the target of electrical stimulation. This is a relatively new concern: soft surgery techniques pioneered in the 1990s [1] and refined with subsequent developments in surgical technique, electrode design, and intraoperative drug use [2–7] now allow (experienced) surgeons to preserve the residual hearing in a high percentage of people receiving CIs e.g. [3,8]. Hearing preservation was originally thought only necessary for electric-acoustic stimulation (EAS) candidates, as they, unlike CI candidates, could benefit from their residual hearing post-operatively. However, the benefits of hearing preservation (HP) surgery techniques are now also recognized for all CI users, even those whose residual hearing is too poor to be functional. More residual hearing and/or healthier neural interface promote(s) better speech discrimination due to the presence of additional acoustic cues and/or larger amounts of electrically induced information [9,10], and may also allow today's severely deaf users to benefit from treatment modalities not yet invented. With the trend toward increasingly atraumatic CI surgery and an industry focus on developing better surgical techniques and electrodes, future CI users are likely to enjoy better hearing preservation rates, much to their benefit. This could be particularly beneficial for very young children who will need several cochlear implantations during their life.

The need for hearing preservation classification system and the benefits it would bring

While the benefits of HP and the desire for it are widely known and agreed upon, there exists no widely used system with which to classify what exactly post-operative "hearing preservation" is. While experts, including many of the present authors, have commented on the pressing need for a single widely accepted HP classification system [11], thus far individual clinics/surgeons have reported their results in various HP classification systems of their own design (see Table I for an overview), all of which have some critical limitation. To illustrate these critical limitations we will give real-life examples drawn from the pre- and post-operative data of a set of 48 hearing preservation surgery cases (See Table II), all of whom were implanted after 2003 in either Warsaw or Antwerp and some of whom were subjects of previous studies [3,7,12].

Many systems are based on work with EAS users and are therefore reliant on a specific type of audiogram e.g. [2,3,8]. They may only consider the frequencies of a typical EAS audiogram e.g. [13,14]. The frequencies used in the HP classification systems usually vary as well. These typical-for-EAS systems do not consider hearing preservation in non-EAS cases, where a CI-recipient has less pre-operative residual hearing able to be preserved. For example, if a user has

Table I. Overview of the wide varying definitions of Hearing Preservation. CHP (complete hearing preservation), PHP (partial hearing preservation), HTL (hearing threshold level).

Publication	HP	%	Frequencies (kHz)	Definition
Kiefer et al. 2004 [13]	CHP	9/14	0.125, 0.250, 0.5, 1	Post-op HTL within 0–10 dB HL of pre-op HTL
	PHP	3/14		Post-op HTL 11–20 dB HL of pre-op HTL
Gstoettner et al. 2004 [10]	CHP	13/21	Not defined	Post-op HTL <10 dB HL of pre-op HTL
	PHP	5/21		Post-op HTL >10 dB HL of pre-op HTL
Balkany et al. 2006 [14]	CHP	9/28	0.250, 0.5, 1	Post-op HTL within 0–10 dB HL of pre-op HTL
	PHP	16/28		Post-op HTL >11 dB HL of pre-op HTL
Fraysse et al. 2006 [20]	HP	6/12	0.125, 0.250, 0.5 (separately)	Post-op HTL within 20 dB of pre-op HTL
Skarzynski et al. 2007 [3]	HP	9/10	0.125, 0.250, 0.5, 1, 2, 4	Post-op HTL within 0–10 dB HL of pre-op HTL
Gstoettner et al. 2009 [2]	CHP	4/9	0.125, 0.250, 0.5, 0.750	Post-op HTL within 0–10 dB HL of pre-op HTL
	PHP	5/9		Post-op HTL >10 dB HL of pre-op HTL
Gantz et al. 2009 [19]	HP	10/28	0.250, 0.5, 1, 2, 4	Post-op HTL <10 dB HL of pre-op HTL
Helbig et al. 2011 [4]	CHP	4/22	0.125, 0.250, 0.5	Post-op HTL within 0–10 dB HL of pre-op HTL
	PHP	13/22		Post-op HTL >10 dB HL of pre-op HTL

Table II. Subjects' pure tone averages by frequency (Hz) at pre-implant and 12 months post-implant. S#= subject number. PTA = pure tone average. RH = percent of residual hearing preserved. Post-op scores are shaded in gray. PTA is the mean score of 250, 500, 750, and 1000 Hz.

S#	125 (90)	250 (105)	500 (110)	750 (115)	1000 (120)	1500 (120)	2000 (120)	3000 (120)	4000 (115)	6000 (100)	8000 (95)	PTA	RH	Preservation
1	10	15	40	65	90	95	100	102.5	105	100	95	52.5	32.4%	81.5% = Complete
	10	15	45	75	105	107.5	110	112.5	115	100	95	60	26.5%	
2	20	25	50	67.5	85	102.5	120	117.5	115	100	95	56.9	25.8%	88.8% = Complete
	30	50	55	75	95	102.5	110	110	110	100	95	68.8	22.9%	
3	15	25	50	62.5	75	90	105	107.5	110	100	95	53.1	31.0%	84% = Complete
	20	50	70	80	90	90	90	100	110	100	95	72.5	26.0%	
4	15	15	30	67.5	105	112.5	120	117.5	115	100	95	54.4	26.2%	81.1 = Complete
	15	25	70	90	110	110	110	112.5	115	100	95	73.8	21.3%	
5	20	30	40	57.5	75	97.5	120	110	100	97.5	95	50.6	30.4%	72.1% = Partial
	45	55	70	75	80	95	110	110	110	100	95	70	21.9%	
6	15	0	5	50	95	97.5	100	100	100	95	90	37.5	38.2%	87.6% = Complete
	10	10	10	57.5	105	102.5	100	105	110	100	95	45.6	33.5%	
7	15	5	25	62.5	100	100	100	100	100	95	90	48.1	34.5%	32.3% = Partial
	30	55	95	107.5	120	120	120	117.5	115	100	95	94.4	11.2%	
8	15	20	25	52.5	80	77.5	75	82.5	90	92.5	95	44.4	41.7%	17.3% = Minimal
	75	90	105	107.5	110	110	110	110	110	100	95	103.1	7.2%	
9	5	5	10	10	10	52.5	95	97.5	100	97.5	95	8.8	52.3%	73.1% = Complete
	15	15	30	42.5	55	80	105	105	105	100	95	35.6	38.2%	
10	10	10	35	50	65	82.5	100	105	110	100	95	40	37.0%	0.6% = Minimal
	90	105	110	115	120	120	120	117.5	115	100	95	112.5	0.2%	
11	15	40	75	90	105	107.5	110	110	110	100	95	77.5	20.9%	103% = Complete
	30	45	70	82.5	95	102.5	110	110	110	100	95	73.1	21.5%	
12	5	15	30	50	70	80	90	100	110	100	95	41.3	38.4%	70.4% = Partial
	10	40	75	80	85	90	95	102.5	110	100	95	70	27.1%	
13	15	35	75	87.5	100	105	110	110	110	100	95	74.4	22.1%	55.1% = Partial
	45	60	100	100	100	110	120	117.5	115	100	95	90	12.2%	
14	20	50	80	87.5	95	100	105	105	105	100	95	78.1	22.1%	36.5% = Partial
	70	100	95	102.5	110	110	110	110	110	100	95	101.8	8.1%	
15	20	10	15	42.5	70	90	110	110	110	100	95	34.4	36.2%	7.4% = Minimal
	65	100	110	115	120	120	120	117.5	115	100	95	111.3	2.7%	

Table II. *(Continued).*

S#	125 (90)	250 (105)	500 (110)	750 (115)	1000 (120)	1500 (120)	2000 (120)	3000 (120)	4000 (115)	6000 (100)	8000 (95)	PTA	RH	Preservation
16	10	15	70	85	100	105	110	110	110	100	95	67.5	24.8%	97.5% = Complete
	0	25	75	87.5	100	105	110	110	110	100	95	71.8	24.2%	
17	10	5	10	22.5	35	65	95	102.5	110	100	95	18.1	46.3%	77.2% = Complete
	10	10	25	52.5	80	90	100	105	110	100	95	41.9	35.7%	
18	15	15	25	42.5	60	85	110	110	110	100	95	35.6	36.6%	69.5% = Partial
	15	25	55	80	105	105	105	107.5	110	100	95	66.3	25.4%	
19	10	15	35	52.5	70	87.5	105	102.5	100	97.5	95	43.1	36.4%	98.3% = Complete
	15	15	50	62.5	75	80	85	95	105	100	95	50.6	35.7%	
20	10	45	90	100	110	110	110	110	110	100	95	86.3	18.2%	31.8% = Partial
	80	95	110	110	110	110	110	110	110	100	95	106.3	5.8%	
21	15	25	35	55	75	92.5	110	110	110	100	95	47.5	32.0%	81.9% = Complete
	30	35	45	67.5	90	100	110	110	110	100	95	59.4	26.2%	
22	20	45	75	85	95	102.5	110	110	110	100	95	75	21.7%	57.1% = Partial
	40	85	90	100	110	110	110	110	110	100	95	96.3	12.4%	
23	40	35	25	37.5	50	75	100	105	110	100	95	36.9	36.2%	56.6% = Partial
	45	45	70	80	90	100	110	112.5	115	100	95	71.3	20.5%	
24	25	25	30	42.5	55	70	85	87.5	90	92.5	95	38.1	42.4%	18.5% = Minimal
	90	90	85	97.5	110	110	110	112.5	115	100	95	95.6	7.9%	
25	45	45	50	62.5	75	92.5	110	110	110	100	95	58.1	26.0%	36.5% = Partial
	65	80	100	105	110	110	110	110	110	100	95	98.8	9.5%	
26	15	10	45	67.5	90	97.5	105	105	105	100	95	53.1	31.0%	69.3% = Partial
	30	30	80	87.5	95	102.5	110	110	110	100	95	73.1	21.5%	
27	10	10	45	55	65	72.5	80	95	110	100	95	43.8	39.1%	75.1% = Complete
	10	10	55	75	95	102.5	110	105	100	97.5	95	58.8	29.3%	
28	10	10	20	47.5	75	87.5	100	107.5	115	100	95	38.1	36.6%	98.9% = Complete
	10	15	25	50	75	87.5	100	105	110	100	95	41.3	36.2%	
29	15	15	20	40	60	82.5	105	107.5	110	100	95	33.8	38.0%	86.4% = Complete
	15	10	45	62.5	80	90	100	105	110	100	95	49.4	32.9%	
30	40	35	50	70	90	100	110	110	110	100	95	61.3	24.8%	74.2% = Partial
	50	55	75	85	95	102.5	110	110	110	100	95	77.5	18.4%	
31	20	35	55	80	105	107.5	110	110	110	100	95	68.8	23.4%	17.7% = Minimal
	90	105	110	110	110	110	110	110	110	100	95	108.8	4.1%	

Table II. (*Continued*).

S#	125 (90)	250 (105)	500 (110)	750 (115)	1000 (120)	1500 (120)	2000 (120)	3000 (120)	4000 (115)	6000 (100)	8000 (95)	PTA	RH	Preservation
32	10	15	45	70	95	100	105	107.5	110	100	95	56.3	29.6%	103.5% = Complete
	10	25	55	72.5	90	95	100	100	100	97.5	95	60.6	30.6%	
33	40	55	55	57.5	60	67.5	75	87.5	100	97.5	95	56.9	34.7%	60.7% = Partial
	65	80	80	80	80	82.5	85	97.5	110	100	95	80	21.1%	
34	35	35	45	67.5	90	102.5	115	112.5	110	100	95	59.4	25.0%	36.4% = Partial
	50	65	105	110	115	115	115	115	115	100	95	98.8	9.1%	
35	75	75	70	82.5	95	105	115	115	115	100	95	80.6	13.8%	101.5% = Complete
	80	80	75	80	85	100	115	115	115	100	95	80	14.1%	
36	50	55	60	65	70	95	120	117.5	115	100	95	62.5	22.1%	43.9% = Partial
	85	90	80	87.5	95	107.5	120	117.5	115	100	95	88.1	9.7%	
37	65	65	60	67.5	75	82.5	90	92.5	95	95	95	66.9	27.1%	69.5% = Partial
	85	70	70	80	90	92.5	95	100	105	100	95	77.5	18.8%	
38	45	55	60	72.5	85	102.5	120	117.5	115	100	95	68.1	20.0%	23.7% = Minimal
	60	80	110	115	120	120	120	117.5	115	100	95	106.3	4.8%	
39	5	5	5	25	45	62.5	80	90	100	97.5	95	20	49.6%	81.7% = Complete
	15	10	15	40	65	80	95	100	105	100	95	32.5	40.5%	
40	20	20	40	65	90	102.5	115	115	115	100	95	53.8	27.5%	79.7% = Complete
	25	25	65	82.5	100	107.5	115	115	115	100	95	68.1	21.9%	
41	15	15	50	55	60	72.5	85	95	105	100	95	45	38.2%	43.8% = Partial
	65	70	80	85	90	100	110	107.5	105	100	95	81.3	16.7%	
42	10	15	10	37.5	65	65	65	75	85	80	75	31.9	51.9%	54.6% = Partial
	25	30	40	67.5	95	100	105	105	105	100	95	58	28.3%	
43	15	30	75	87.5	100	105	110	112.5	115	100	95	73.1	21.9%	77.4% =Complete
	45	60	80	90	100	105	110	110	110	100	95	82.5	16.9%	
44	60	55	85	95	105	112.5	120	117.5	115	100	95	85	12.4	105% = Complete
	45	55	90	97.5	105	112.5	120	117.5	115	100	95	86.9	13.0	
45	90	95	110	115	120	120	120	117.5	115	100	95	110	1.03	19.4% = Minimal
	90	105	110	115	120	120	120	117.5	115	100	95	112.5	0.2	
46	90	90	95	102.5	110	115	120	117.5	115	100	95	99.8	5	4% = Minimal
	90	105	110	115	120	120	120	117.5	115	100	95	112.5	.2	
47	60	85	95	97.5	100	95	90	87.5	85	82.5	80	94.4	20.9	34.4% = Partial
	90	105	110	110	110	105	100	100	100	97.5	95	108.8	7.2	
48	65	70	90	100	110	115	120	120	120	107.5	95	92.5	8.1	71.6% = Partial
	70	75	95	107.5	120	120	120	117.5	115	105	95	99.4	5.8	

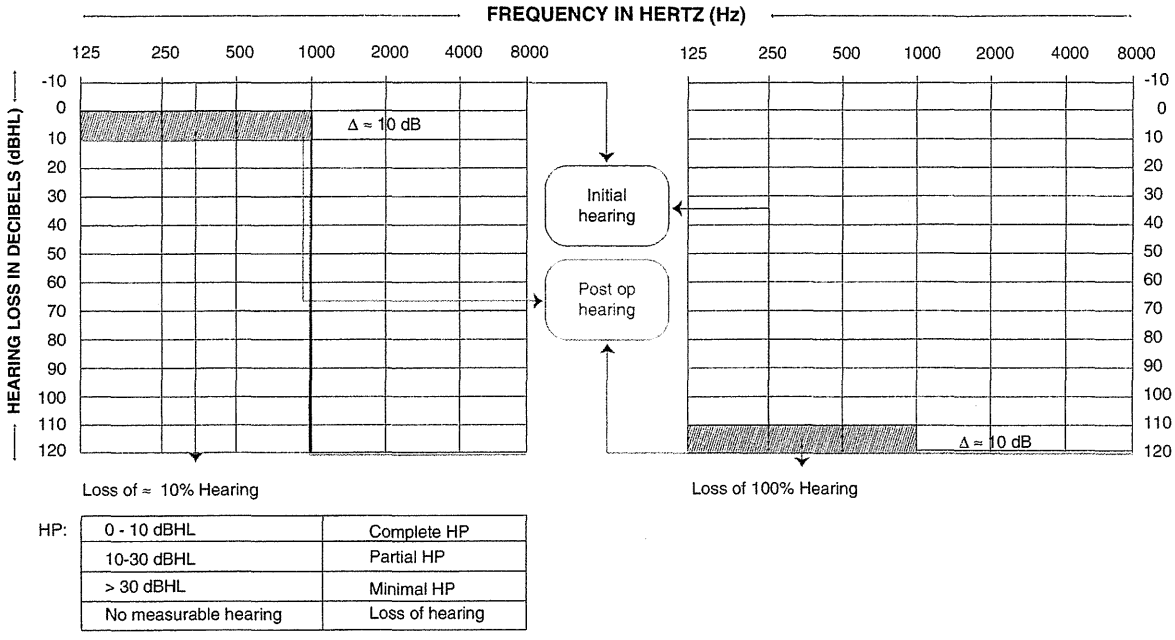

Figure 1. Categorical scale of hearing preservation.

a 110 dB pre-operative loss, and is measured post-operatively at 120 dB, is this 10 dB preservation? Not at all, we have reached limits of the audiometer. This can be seen with subject 4, 13, 15 at 2000 Hz.

A HP classification system also needs to address non-measureable points. Other methodological limitations include only having a 10 dB variation as "preserved hearing" e.g. [13].. Since tolerances in ANSI standards are from ± 3 to 5 dB of designated sound pressure levels, the standard error can potentially increase to ± 10 or 15 dB HL, depending on the listener's actual physiologic sensitivity [15], and classification may be influenced by this.

The most commonly used HP classification system is based on the equation HL = PTApost - PTApre (see Table I) and has 2 main disadvantages:

(1) It is dependent on the user's initial hearing. If a user lost around 10 dB on average across frequencies, and his/her pre-op audiogram is in the normal to mild hearing loss range in the low frequencies, he/she would still have 80–90% of remaining hearing and, according to the categorical scale (Figure 1), would be a case of "Complete HP". This can be seen with subject 6 (see Figure 2).

However, if the user's pre-operative hearing was in the range of 80 dB or worse, then post-operatively, with the same 10 dB loss, they would have no hearing at all, or at best 5% (see Figure 3); however, the hearing preservation would still be "Complete HP" according to this classification system. In such cases,

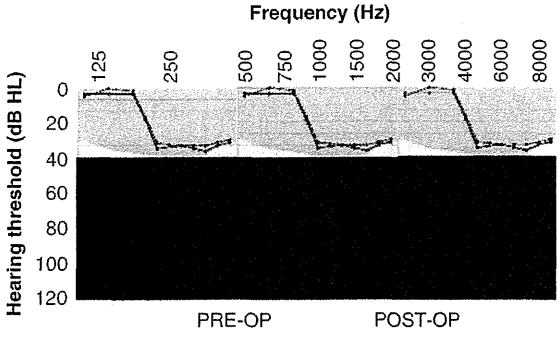

Figure 2. Subject 6 pre- and post-op scores.

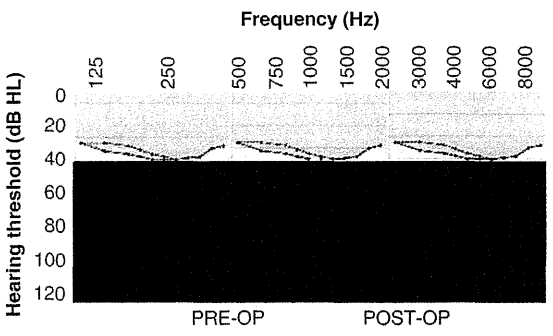

Figure 3. Subject 46 pre- and post-op scores.