Standards of practice in the field of hearing implants

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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.

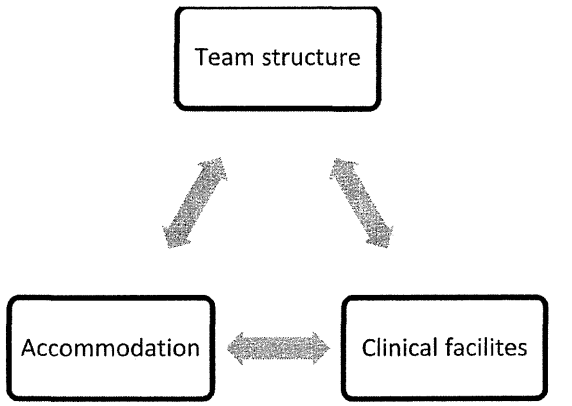
In order to try to ensure the best outcomes and the highest safety levels for every present or potential implant user in every clinic, the HEARRING group – under the direction of experts Prof. Christopher H. Raine, MD, Prof. Dr Rudolf Hagen, Prof. Dr Joachim Müller, Prof. Dr Benoit Godey, and Jane Martin – 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

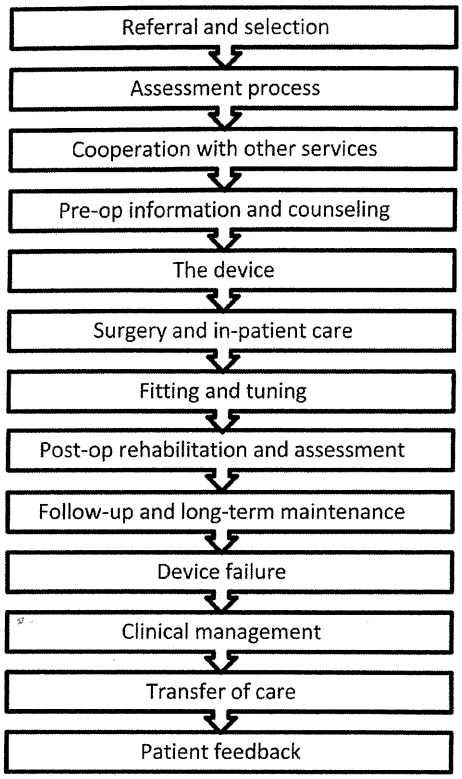
Table 1 ***Continued***

	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	

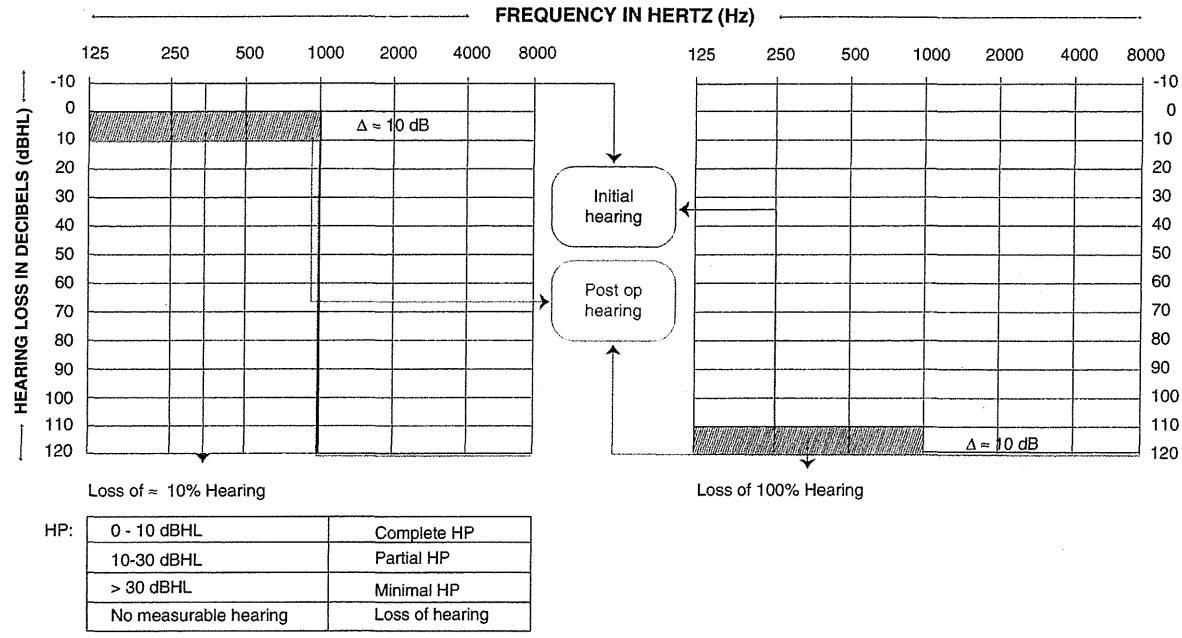

Figure 1. Categorical scale of hearing preservation.

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,

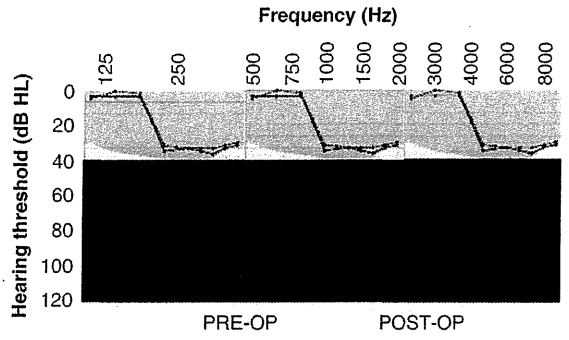

Figure 2. Subject 6 pre- and post-op scores.

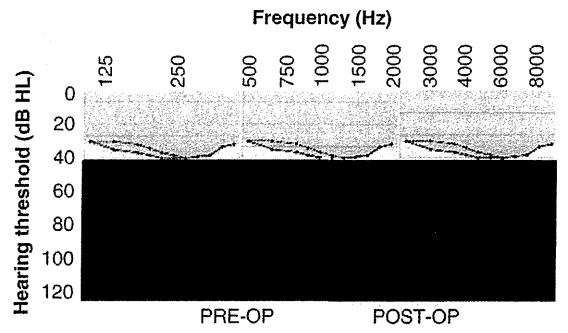

Figure 3. Subject 46 pre- and post-op scores.

as can be seen with subject 46, this formula is not a true reflection of a user's available post-operative hearing, and therefore, it is not a true measure of hearing preservation.

(1) This classification is not suitable for the range of standard cochlear implant users: the worse a user's pre-operative hearing is, the better his/her general results may seem. For example, for users with a pre-operative Pure Tone Average (PTA) worse than 90 dB there is no minimal hearing loss, and for users with a PTA worse than 110 dB there is no minimal and no partial hearing loss, both due to the floor-effect of the audiogram.

Lastly, the existing classification systems measure and discuss how much hearing is *lost*. A more patient-centric classification system which focuses on the extent of CI users' post-operative residual hearing, i.e. what they can hear, would be preferable.

The presence of these multiple systems has made it difficult to compare different studies' results. If, however, a standard system is used, there will be better reporting of surgical and device intervention. This, in turn, will allow to increase greatly the ease of study comparison and meta-analysis of data. Meta-analysis of data is particularly important in the hearing implant field, where conducting randomized, controlled double-blinded studies is impossible; sample sizes are often small (usually ranging from case studies to small groups of 10–20 subjects); and the use of different HP classification systems is a handicap for meta-analysis with their combined data. Meta-analysis of data using the same HP classification system would allow us to pool data for stronger evidence-based medicine e.g. [16]., and consequently, we would be better able to support health technology assessment for reimbursement.

Method

The HEARRING group proposes the following formula for qualitative HP classification:

$$\text{Relative change} = \frac{(\text{PTApost} - \text{PTApre})}{(\text{PTAmax} - \text{PTApre})}$$

where PTApost is pure tone average measured post-operatively, PTApre is pure tone average measured pre-operatively, and PTAmax is the limits of the audiometer.

Firstly, classification based on this equation is independent of initial hearing and can be used for all CI users with measurable pre-operative residual hearing (PTA: 0–120 dB). Because the classification is scaled to the pre-operative audiogram, we eliminate the effect of worse pre-operative hearing tending to produce misleadingly better post-operative HP results.

Table III. Scale for proposed HP classification system.

Percent of residual hearing preserved	Classification
>75%	Complete HP
>25–75%	Partial HP
0–25%	Minimal HP
No measurable hearing	Loss of hearing/No hearing

Secondly, the equation presents the relative change as a percentage of hearing loss, a user-friendly concept. The hearing loss is converted to preservation by calculating 100% - relative change in %:

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

where S is preservation numerical scale.

Thirdly, the numerical scale is converted to a categorical scale for ease of reporting. The categorization is defined in Table III.

The HP Classification System is based on a routine audiogram. The selection of frequency for pure tone average determination is based on ASHA guidelines as they, among the several audiometric procedure standards, are the most commonly used [17]. Hearing threshold levels should be obtained at octave intervals from 125 Hz to 8000 Hz. In addition, implementation of inter-octave frequencies is recommended and provides a more complete and accurate hearing profile. Missing inter-octaves are automatically interpolated in the formula sheet (see: www.hearring.com/HEARRING_HP_Calculation.xlsx).

The hearing threshold levels range from -10 dB HL to 120 dB HL, again based on the ASHA recommendation. However, one must consider the maximum output levels of the audiometer in the equation. The levels selected to fit the equation for all clinically available audiometers can be seen in Table IV.

So the maximum level was set to the most conservative minimal output of all available maximum

Table IV. Maximum detectable hearing (mdh) measurable for each frequency.

[Hz]	125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k
mdh	90	105	110	120	120	120	120	120	115	100	95

Table V. Subject 13.

Preservation numerical scale PS (%)	Kiefer et al. 2004	Balkany et al. 2006	Skarzynski et al. 2007	Gstoettner et al. 2009	Gantz et al. 2009	Rajan et al. 2012
55.1% = Partial HP	PTA_{PRE} = 42 dB HL	PTA_{PRE} = 70 dB HL	PTA_{PRE} = 74 dB HL	PTA_{PRE} = 53 dB HL	PTA_{PRE} = 86 dB HL	PTA_{PRE} = 42 dB HL
	PTA_{POST} = 68 dB HL	PTA_{POST} = 87 dB HL	PTA_{POST} = 90 dB HL	PTA_{POST} = 76 dB HL	PTA_{POST} = 99 dB HL	PTA_{POST} = 68 dB HL
	Not classified	Partial HP	Not classified	Partial HP	Not classified	Partial HP

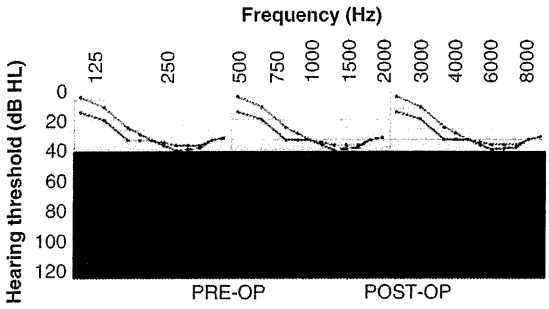

Figure 4. Subject 13 pre- and post-op scores.

output levels for each particular frequency, according to the literature and technical specifications of the most common audiometers.

The HEARRING group recommends using insert earphones when testing hearing for the preservation scale. Supra-aural headphones underestimate hearing loss as they may results in vibrotactile responses at higher intensity levels in the low frequency range [18]. Insert earphones have minimal contact between the earphone and skin leading to a reduction in vibration responses and a more accurate measurement of (low frequency) hearing thresholds.

Result

HEARRING's proposed HP classification system in use

From the 48 subjects in the Table II, we selected 3 as case studies to illustrate the results of our HP formula and to compare these results to how they would have been reported by previously published classification systems [2,3,6,13,14,19]. Key to the other systems is that they all calculate a pure tone average (PTA) using low frequency thresholds in four cases and two also include 4000 Hz [3,19]. There are also variations in which low frequencies are used in PTA calculations, e.g. [13,20] use 125 Hz whereas [14,19] do not. Our formula looks beyond the traditional EAS low frequency perspective by calculating up to 8000 Hz, thus taking high frequency hearing preservation into consideration (an important aspect in the future). It also calculates remaining low frequency hearing using all test frequencies.

Subject 13, a typical EAS case, was deemed by four classification systems to have partial post-operative residual hearing loss, however, three of the systems have no procedure for classifying hearing loss beyond either 10 [3,19] or 20 dB [13]. The system from [14] is also interesting in that all hearing loss beyond 11 dBHL is considered partial – which is a rather broad range (Table V, Figure 4).

Subject 35 shows that preservation is deemed to be complete across all schemes. However, by considering area, we can see the preservation is greater than 100%, this is because, instead of losing residual hearing area, this has actually increased and the formula shows this gain (Table VI, Figure 5).

Subject 45 is a perfect example of the increased descriptive accuracy of our formula. Other classification systems, e.g. [3,19] would consider a hearing loss of less than 10 dB to be hearing preservation, whilst the others call this complete preservation. We call this minimal hearing preservation. This is where the essence lies. The other systems only consider the pure tone average and thus one audiogram compared to the other. Our system looks at the remaining hearing and the value of that preservation to the user. In many cases, this value is of clinical importance, however, here, where there is limited hearing to start with, we are in some way able to also show structural preservation. Structural preservation is a key surgical goal, important for caring for the anatomy of the cochlear now, and for treatment modalities that. may be available in the future. So, although the hearing loss was minimal – the comparison is of one area of remaining hearing relative to a later area of remaining hearing. In this case, the area was minimal to begin with, and because most of this area was lost, the preservation is deemed minimal, showing some structural damage (Table VII, Figure 6).

Table VI. Subject 35.

Preservation numerical scale PS (%)	Kiefer et al. 2004	Balkany et al. 2006	Skarzynski et al. 2007	Gstoettner et al. 2009	Gantz et al. 2009	Rajan et al. 2012
101.1% = Complete HP	PTA_{PRE} = 79 dB HL	PTA_{PRE} = 80 dB HL	PTA_{PRE} = 91 dB HL	PTA_{PRE} = 76 dB HL	PTA_{PRE} = 94 dB HL	PTA_{PRE} = 73 dB HL
	PTA_{POST} = 80 dB HL	PTA_{POST} = 80 dB HL	PTA_{POST} = 92 dB HL	PTA_{POST} = 79 dB HL	PTA_{POST} = 94 dB HL	PTA_{POST} = 78 dB HL
	Complete HP	Complete HP	Complete HP	Complete HP	Complete HP	Complete HP

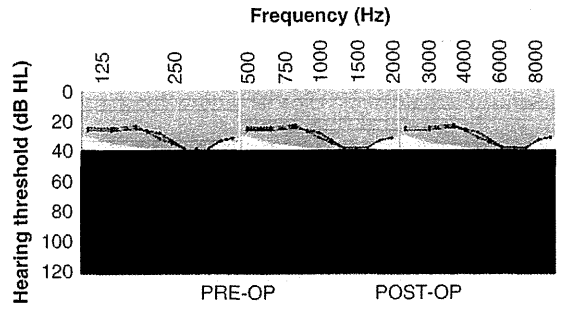

Figure 5. Subject 35 pre- and post-op scores.

The value of a percentage – some useful applications of the formula

The value of calculating a percentage and showing its uses can be demonstrated via a few examples, which are demonstrated here.

Example one

Individual clinics can obtain an overview about hearing preservation surgery outcomes. By calculating this formula, a clinic can see how many cases of complete preservation they have, how many losses etc. A clinic could then review how measured HP changes over time by looking at reduction in area.

Example two

Having a sufficient sample size to demonstrate statistical and clinical significance is key to proving outcomes of a methodology. One way to do this is to pool clinics' data to allow for a greater sample size, and to support multi-center studies. The formula data can be calculated to prove that preservation rates are the same, thus justifying pooling of the data. Using the cases from the Table II, we are able to compare outcomes from two centers and show that preservation is the same and thus data may be pooled.

We found no significant difference in percent of hearing preservation between Warsaw (n = 32) and Antwerp (n = 16) according to the results of the non-parametric Mann-Whitney U-test (p = 0.279).

Furthermore, no significant difference between the 2 centers in Hearing Preservation was reached for subjects with

- Complete HP (Warsaw: n = 15; Antwerp: n = 5; Mann-Whitney U-test: p = 0.896),
- Partial HP (Warsaw: n = 12; Antwerp: n = 8; Mann-Whitney U-test: p = 0.616), and
- Minimal HP (Warsaw: n = 5; Antwerp: n = 3; Mann-Whitney U-test: p = 0.655).

As no significant difference between the Warsaw and Antwerp data in Hearing Preservation was reached, their data can be pooled.

Example three

The data could be used for correlation analysis to see, for example, if the degree of hearing preservation is correlated to age at implantation. Using the subjects' percent of hearing preservation we found that:

(1) The correlation between the degree of hearing preservation and age at implantation was small and negative (r = -0.101) and not significant (p = 0.496)
(2) The correlation between age at implantation and Hearing Preservation when stratified for extent of Hearing Preservation did not show a significant correlation in cases of complete (r = 0.137; p = 0.565), partial (r = 0.042; p = 0.860), or minimal (r = 0.452; p = 0.260) hearing preservation.

Example four

The data could be used for comparison; for example, the outcomes of two different electrode array lengths. In this case, we can compare hearing preservation outcomes with two electrodes. In the earlier days of

Table VII. Subject 45.

Preservation numerical scale PS (%)	Kiefer et al. 2004	Balkany et al. 2006	Skarzynski et al. 2007	Gstoettner et al. 2009	Gantz et al. 2009	Rajan et al. 2012
20.0% = Minimal HP	PTA_{PRE} = 93 dB HL	PTA_{PRE} = 108 dB HL	PTA_{PRE} = 108 dB HL	PTA_{PRE} = 100 dB HL	PTA_{PRE} = 112 dB HL	PTA_{PRE} = 98 dB HL
	PTA_{POST} = 102 dB HL	PTA_{POST} = 112 dB HL	PTA_{POST} = 110 dB HL	PTA_{POST} = 103 dB HL	PTA_{POST} = 114 dB HL	PTA_{POST} = 102 dB HL
	Complete HP	Complete HP	HP	Complete HP	HP	Complete HP

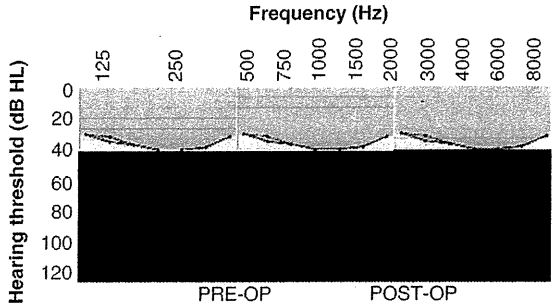

Figure 6. Subject 45 pre- and post-op scores.

EAS surgery, Warsaw used the MED-EL Standard electrode, which they only partially inserted, until the MED-EL Medium electrode was made available. We found that the electrode array length didn't have a significant difference on percent of hearing preserved for any class of hearing preservation: complete (Standard: n = 12; Medium: n = 3; Mann-Whitney U-test: p = 0.248), partial (Standard: n = 7; Medium: n = 7; Mann-Whitney U-test: p = 0.654) or minimal (Standard: n = 4; Medium: n = 1; Mann-Whitney U-test: p = 0.480) hearing preservation.

Discussion

To remedy the current lack of an accepted HP classification standard, the HEARRING group hereby proposes a comprehensive HP Classification System that 1) is suitable for reporting the hearing preservation results of all hearing preservation surgery cases, 2) is independent from the user's pre-operative hearing levels, and 3) considers the relative change of hearing thresholds. The system classifies HP when using an intervention system which comprises all elements of surgery (round window, cochleostomy, drugs used, blood contamination, etc.), the electrode itself (contacts, atraumaticity, length, coated or not), trauma due to the electrode and the surgery, as well as the fact that the electrode is a space filler.

The HEARRING group hopes clinicians put this system into practice not only because it clearly and accurately describes hearing preservation results, but because the system will enable a larger overview of hearing and structural preservation. By making the results of different HP studies more comparable, the application of our standard will allow better meta-analysis of data, thereby resulting in better evidence-based practice in the field of cochlear implantation.

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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7 診療科別先進医療

耳鼻科

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耳鼻咽喉科領域における先進医療

先進医療は，将来的な保険導入のための評価を行うことを目的として実施されている保険外併用療法であり，2012年9月末現在耳鼻咽喉科領域の先進医療としては，第2項先進医療，「三次元形状解析による体表の形態的診断」，「RET遺伝子診断」，「MEN1遺伝子診断」の3技術が，また第3項先進医療「残存聴力活用型人工内耳挿入術　両側性感音難聴（高音障害急墜型または高音障害漸傾型の聴力像を呈するものに限る。）」の1技術が承認されている。2012年4月まで第2項先進医療で実施されていた「先天性難聴の遺伝子診断」は先進医療での有効性が認められ，2012年度の診療報酬改定で保険収載された。現在実施されている技術のうち，第2項先進医療の3技術に関しては，形成外科，脳神経外科，内科，小児科，内分泌代謝科，外科で実施されているため，本稿では耳鼻咽喉科のみで実施されている「残存聴力活用型人工内耳挿入術両側性感音難聴（高音障害急墜型または高音障害漸傾型の聴力像を呈するものに限る。）」の1技術について詳しく解説を行う。

残存聴力活用型人工内耳挿入術の概要

難聴はコミュニケーションの大きな障害となるため，それに伴い日常生活や社会生活の質（クオリティ・オブ・ライフ：QOL）の低下を引き起こす。現在，保険診療として実施されている人工内耳の適応は，全周波数が90dB以上の重度難聴患者に限られており，高音急墜あるいは漸傾型の聴力を示す難聴患者は適応外となっている。しかし，高音急墜あるいは漸傾型の難聴患者に対して従来型の補聴器では十分な補聴をすることはできず，コミュニケーションに必要な聴力閾値までの補聴は困難な場合がほとんどであるため，現在の保険診療の範囲内に高音急墜あるいは漸傾型の聴力を示す難聴患者に対する有効な治療法は無いのが現状であった。

近年，高音急墜あるいは漸傾型の聴力を示す難聴患者に対する新しい治療法として，低音部は音響刺激，高音部は電気刺激を組み合わせることにより聴神経を刺激する「残存聴力活用型人工内耳」が登場し，欧米を中心に臨床研究が進められ欧州では臨床応用が認められている。（Kiefer et al., 2005；Gstoettner et al., 2008；Skarzynski et al., 2007）。

残存聴力活用型人工内耳は，体内に埋め込むインプラントと，体外に装着するスピーチプロセッサ（体外機）の2部分により構成されている。体外機のマイクロフォンより拾った音声情報を，周波数帯域に応じて音響刺激回路と電気刺激回路にそれぞれ分離し，低音部分はアンプにより増幅された音響刺激として外耳道経由で音声情報を内耳に伝える。一方，高音部分の音声情報はスピーチプロセッサで最適なパルスへと変換（コード化）された後に，体外機の送信コイルを経由して，体内に埋め込まれたインプラントの受診コイルに電磁誘導で信号を送信する。インプラントの先端は蝸牛に挿入されており，蝸牛内の電極アレイ間に電気パルスを送ることで，直接聴神経を電気的に刺激する（図1）。このように，音響刺激と電気刺激を組み合わせることで，従来の補聴器では聴取困難であった高音

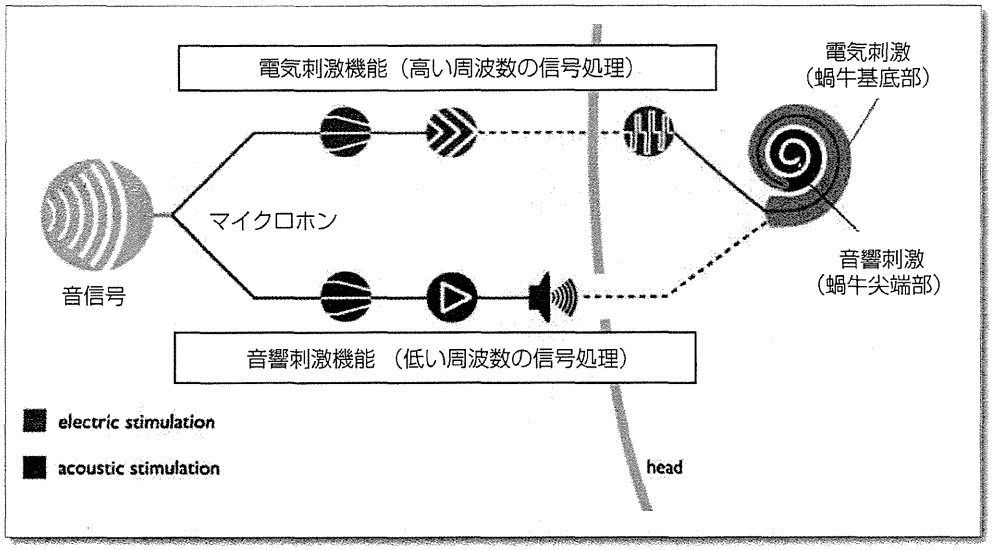

図１　残存聴力活用型人工内耳の動作原理

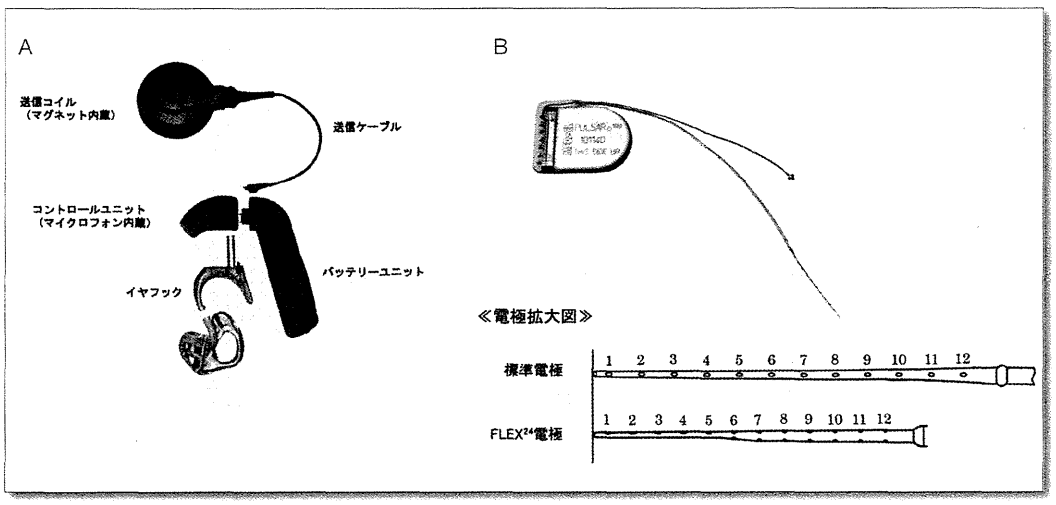

図２　残存聴力活用型人工内耳

A：スピーチプロセッサ（体外機）の形状を示す。コントロールユニットに内蔵されたマイクロフォンにより拾った音声情報を，周波数帯域に応じて音響刺激回路と電気刺激回路にそれぞれ分離し，低音部分はアンプにより増幅された音響刺激として，高音部分の音声情報は送信コイルを経由して，体内に埋め込まれたインプラントの受診コイルに電磁誘導で信号を送信する。

B：インプラントの形状を示す。従来の標準電極と比較して先端形状がより細く，柔軟性に富んだ形状に変更されており，低音部の残存聴力の保持（電極挿入に伴う蝸牛内の障害の軽減）に非常に優れている。

急墜あるいは漸傾型の聴力を示す難聴に対して効果的に補聴することが可能となっている。

従来，蝸牛に人工内耳電極を挿入することで，蝸牛の内部構造が障害され聴力はすべて失われると考えられていたが，インプラントの改良および手術手技の改良により低音部の残存聴力を温存したまま人工内耳電極を挿入することが可能となった点が本先進医療のポイントである。

残存聴力活用型人工内耳挿入術に用いるインプラント（PULSAR FLEX^{24}）は，人工内耳電極を蝸牛内に挿入する際に，低音部の残存聴力の障害を軽減することを目的に，電極の先端形状がより細く，柔軟性に富んだ形状に変更されており，従来の人工内耳を挿入する場合と比較して，低音部の残存聴力の保持（電極挿入に伴う蝸牛内の障害の軽減）に非常に優れている（図2：Adunka et al., 2004）。

また，手術手技に関しては，低音部の残存聴力を維持するため，round window アプローチという新しい

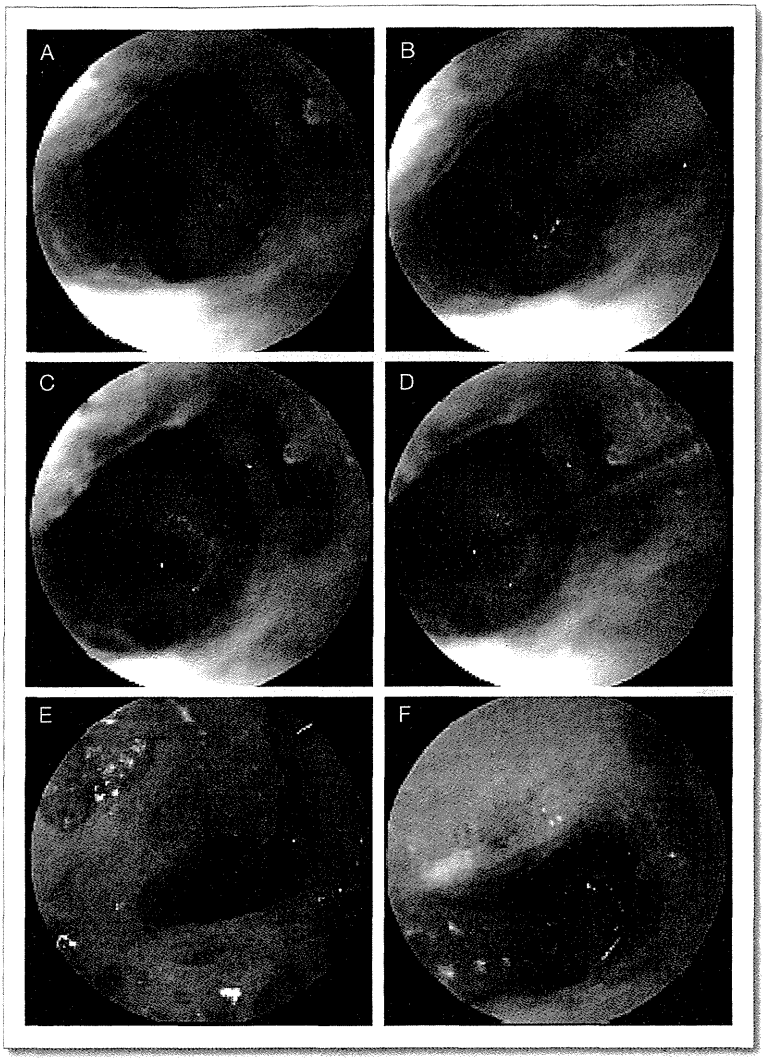

図３　Round Window アプローチ
A：通常の人工内耳挿入術と同様の手法で後鼓室解放を行う。B：正円窓の上部にある骨性のオーバーハングをドリルで切削する。C：切削後には正円窓が直視できる。D：正円窓膜をピックを用いて切開する。E・F：切開部より人工内耳電極を挿入する。（文献６より引用）

手術手技を用いる（図3：Adunka et al.,2004；Skarzynski et al.,2007；Usami et al., 2011）。round window アプローチは，蝸牛の回転軸に沿った方向から電極を挿入することで，挿入電極による蝸牛の内部構造の破壊を軽減する手術法であり，従来の人工内耳挿入術と比較して，低音部の残存聴力の維持に優れている。また，手術の安全性に関しては，電極挿入以外の部分は現在保険で承認されている通常の人工内耳手術とほぼ同様の手法を用いるため有害事象が起こる確率はきわめて低いと考えられる。

このように，本高度医療　残存聴力活用型人工内耳埋込は，低音部に残存聴力を有するため通常の人工内耳の適応（全周波数にわたり高度難聴）には該当しないが，補聴器での聞き取りは困難であり，従来治療法のなかった高音急墜あるいは漸傾型の聴力像を示す難聴患者に対して，聴取能の改善をもたらすことが可能であり，QOL の大幅な向上に寄与することが可能である先進性の高い医療である。

残存聴力活用型人工内耳挿入術の実際

残存聴力活用型人工内耳挿入術は，国立大学法人信州大学医学部附属病院，国家公務員共済組合虎の門病院，地方独立行政法人神戸市民病院機構神戸市立医療センター中央市民病院，国立大学法人長崎大学医学部

附属病院，国立大学法人宮崎大学医学部附属病院の5施設での実施が承認されている。

第3項先進医療「残存聴力活用型人工内耳挿入術」の適応は，気導聴力閾値が，125Hz，250Hz，500Hzが65dB以下，2000Hzが80dB以上，4000Hz，8000Hzが85dB以上（※ただし，上記に示す周波数のうち1箇所が10dB以内の幅で外れる場合には対象とする。）を満たし，かつ，補聴器装用下において静寂下での語音弁別能が65dBで60%未満である者となっている。

先進医療では，術前の検査として純音聴力検査を実施し適応聴力を満たしていることを確認するとともに，静寂下での語音弁別検査を実施して日本語単音節の聴取においても適応基準を満たすことを確認する。その後，麻酔等の手術適応のための各種検査を行った後に手術を実施する。手術後1ヵ月より体外機の装用を開始し，機械の調整を繰り返すとともに，12ヵ月後まで継続的に聴取成績の検討を実施している。

2010年7月に承認を受けて以降，現在までに24例の予定症例のうち23例の手術が完了しており，また，術後6ヵ月の有効性評価が終了した症例が14症例，12ヵ月のフォロー期間が完了した症例が9症例という状況である。術後6ヵ月時の有効性評価が終了した14例を対象に有効性に関する検討を行った結果，全例で装用下聴力閾値の大幅な改善を認めた。また，日本語単音節の聴取に関しても13例で改善を認めており，残存聴力活用型人工内耳の日本語話者に対する有効性が確認できつつある。このように残存聴力活用型人工内耳挿入術は，現在の保険診療の範囲内に治療法のない高音急墜型あるいは漸傾型難聴に対する治療法として非常に有効な治療法であり，早期に保険導入されることが適当であると考えられる。

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