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Audiology & Neurotology

Basic Science and Clinical Research in the Auditory and Vestibular Systems and Diseases of the Ear

Cochlear Implantation

1st International Electro-Acoustic Workshop
Toulouse, December 8–10, 2005

Guest Editor
Bernard Fraysse, Toulouse, France

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Attendees of the 1st International Electro-Acoustic Workshop, Toulouse, December 8–10, 2005

Cover illustration
Temporal bone section showing the Nucleus Hybrid-L research electrode designed for hearing preservation.
For details see articles by Briggs et al., pp. 42–48, and Lenarz et al., pp. 34–41.

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Editorial

The study of combining residual hearing with cochlear implants is increasingly important as cochlear implants become more successful in providing functional hearing for the severely and profoundly hearing impaired. Initially, 'bimodal' hearing was studied for a cochlear implant combined with residual hearing in the contralateral ear. More recently, due to the pioneering works of Christoph von Ilberg in Frankfurt and Bruce Gantz at the University of Iowa, it has been shown that very significant levels of hearing may be conserved after cochlear implantation and that this may be usefully combined with electrical stimulation in the same ear; this latter combination is termed 'electroacoustic' or 'hybrid' hearing.

In this special issue, we document presentations made at the 1st International Electroacoustic Workshop held in Toulouse, France in December 2005. This workshop provided an exciting forum for over 80 attendees as it brought together teams involved in both basic and applied aspects of combined electric and acoustic hearing.

Over 20 contributions were invited from all parts of Western Europe, the United States and Australia. Topics as diverse as cochlear anatomy and physiology, and speech, pitch and music perception were covered. Surgical technique and cochlear implant electrode technology were also explored with presentations from surgeons, engineers and radiologists. The benefits and issues in combined stimulation, surgical technique, electrode design and which approach may be most appropriate for which type of hearing loss were discussed in roundtables.

The current issue documents work from presenting authors and the round table discussions which has not been published elsewhere. I hope you will agree that the current volume constitutes a significant body of work which acts as a firm basis for future research and development, and will aid us in the clinical management of patients with residual hearing who may benefit from a cochlear implant.

We are very grateful to Professor Harris, the Editor-in-Chief, and the *Audiology and Neurotology* editorial team, the anonymous reviewers for their important input, and to the Cochlear company for their support in producing this supplement issue.

Bernard Fraysse, Guest Editor
Chris James, Scientific Program Coordinator

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Physiology of Hearing Loss

Psychophysical and physiological research using both humans and animals has provided some possible answers to the underlying causes of these deficits. The outer hair cells are known to be responsible for the sensitivity of the ear to low-amplitude sounds and also to provide sharp frequency tuning as result of their influence on basilar membrane vibration. In basilar membrane regions with only outer hair cell damage, gross spectral information from acoustic stimulation can still be transmitted to the brain as long as the sounds are amplified above the patient's thresholds. Poorer spectral resolution for speech sounds has been demonstrated in physiological recordings from animals with moderate hearing loss [e.g. Miller et al., 1997]. This will result in a patient who requires amplification for the softer sounds of speech, but with amplification, speech recognition (in quiet) can be quite accurate in most cases. However, the poorer frequency resolution often results in the patient having difficulty in noisy backgrounds, as compared to normal-hearing listeners.

If inner hair cells are damaged or missing in a region of the basilar membrane, the vital connections to the brain are no longer present (95% of the afferent 8th-nerve fibers are from inner hair cells), and the place-frequency information for those spectral regions is either missing or inaccurate. In these cases, acoustic presentation of speech, even when amplified, may not improve intelligibility. Results from animal studies have suggested that when the degree of hearing loss is 60–80 dB or greater, inner hair cells begin to be nonfunctional [e.g. Liberman and Dodds, 1984; Santi et al., 1982]. Of course, if all inner hair cells are missing, total deafness is the result and amplification provides no benefit. However, the much more common case is that inner hair cells are missing only in certain areas of the cochlea (usually the basal end). What is the effect of these regions of inner hair cell loss on speech recognition? The answer to this question also depends upon the acoustic cues for speech recognition.

Speech Acoustics

The acoustic features of speech can be roughly divided into three major categories. Each has different requirements in terms of the information that the cochlea needs to transmit to the brain. The most resistant to hearing loss is the speech feature of voicing, which is the presence or absence of vocal-fold vibration in a speech sound (i.e. /s/ vs. /z/). It is signaled by an increase in periodic energy across the entire spectrum of speech (particularly in the low frequencies). Thus, even a few functioning inner hair cells in the apex of the cochlea could presumably transmit voicing information. The speech feature most easily affected by hearing loss is place of articulation, which is the spectral information in a speech sound that signals where it is produced in the vocal tract (i.e. lips for /p/ vs. alveolar ridge for /t/). This spectral information is located primarily in the higher frequency regions of speech [Miller and Nicely, 1955], and it requires at least fairly specific spectral information, which is presumably transmitted by frequency-place coding in the basal half of the cochlea. Thus, regions of missing inner hair cells in the basal half of the cochlea could disrupt the transmission of place information. Manner, the remaining feature of speech, is the distinction between types of consonants (i.e. fricatives vs. stop consonants); it lies somewhere between voicing and place in terms of its acoustic and cochlear requirements.

Amplified Speech Presented in Quiet

Fitting hearing aids on patients with 'corner' audiograms has been a common strategy for many years. These patients can receive the gross amplitude cues of speech (i.e. voicing) and do get some benefit from amplification [Erber, 1972; Turner et al., 1995]. Today's hearing aids are capable, however, of providing gain across the entire speech frequency range. Skinner [1980] measured speech recognition for amplified speech in hearing-impaired subjects and found that for many listeners, making speech audible in the high frequencies could improve recognition, but in some cases, the higher-frequency amplification had limitations. At the time, she speculated that these limitations resulted from exceeding comfortable loudness levels. Hogan and Turner [1998], Ching et al. [1998], and Turner and Brus [2001] expanded upon the previous research by measuring the effectiveness of amplified (audible) speech in discrete frequency regions and then relating this to the degree of hearing loss. A striking finding emerged. For the lower frequency regions of speech (below approximately 2500 Hz), making speech audible improved recognition for nearly all hearing-impaired listeners. The improvements came primarily from increases in the perception of voicing, and to a lesser extent manner, consistent with their acoustic characteristics. However, for the higher frequency regions of speech, only when the degree of hearing loss was less than 60–

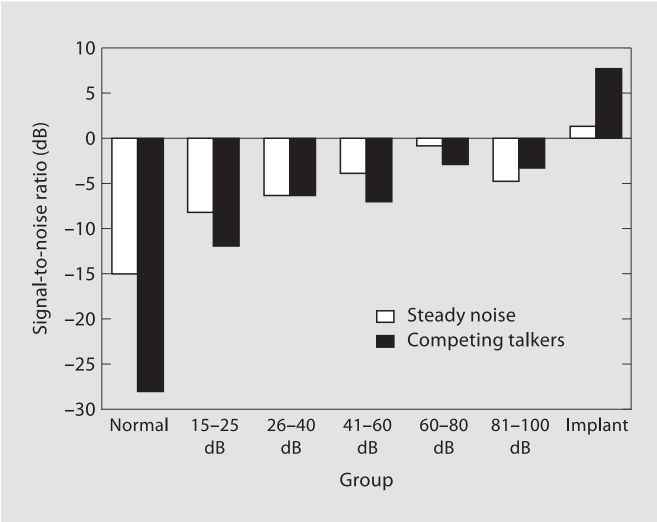

Fig. 1. The signal-to-noise ratio required for 50%-correct understanding of spondee words for various listener groups. The groups are divided according to average hearing levels at 0.5, 1.0 and 2.0 kHz. There were 20 subjects in the implant group and 7–10 subjects for each of the hearing loss groups. Speech was amplified to audible levels for all subjects.

80 dB, did amplifying speech consistently result in improvements. For greater amounts of hearing loss, adding amplified speech in these high-frequency regions often resulted in no improvements or in some cases, even a decrease in speech recognition. The speech feature of place of articulation was particularly affected by severe hearing losses, again consistent with its acoustic characteristics, and also with the hypothesis that regions of nonfunctional inner hair cells will disrupt the transmission of the required spectral information. Vickers et al. [2001] reported similar findings, and related the speech recognition results to psychophysical measures that suggested the existence of what they termed 'dead regions' on the basilar membrane. Can we accurately predict for individual patients which frequency regions will not benefit from amplified speech on the basis of the degree of hearing loss or on the results of a psychophysical test? Indeed, the effectiveness of amplified speech as a function of the degree of hearing loss does have variability across patients. An analysis by Summers [2004] suggested that noting when a high-frequency hearing loss is more than 90 dB is just as effective in predicting amplification benefit as using a psychophysical test. Like most predictive tests, there are going to be errors, both in terms of false positives and misses. Since the goal is to determine if amplified speech in certain frequency regions is beneficial, why not just test this directly, using filtered speech whenever the clinician has doubts of the effectiveness of amplification? Perhaps this should be a part of the evaluation for patients with severe high-frequency hearing losses. These topics deserve further research.

Speech in Background Noise

Understanding speech in background noise requires finer frequency resolution than in quiet [Fu et al., 1998], and when the background is other speech, the frequency resolution requirements are even more demanding [Qin and Oxenham, 2003]. Therefore most patients with even mild to moderate sensorineural hearing loss, whom we suspect of having missing outer hair cells, will have some difficulties in noisy backgrounds. The relation between frequency resolution and speech recognition in noise can be examined as a function of degree of hearing loss and the type of device the patient is using. Patients with normal hearing will have the most sharply tuned basilar membrane, whereas patients with a loss of outer hair cells will have a more broadly tuned vibration pattern. For patients using a traditional cochlear implant, the basilar membrane is not even used in providing frequency resolution; instead the even poorer frequency resolution of multi-channel electric stimulation determines the frequency resolution of the auditory system [Henry et al., 2005].

In figure 1, the signal-to-noise ratio for understanding speech in steady noise and in a background of competing talkers is displayed for listeners for a wide range of hearing losses, ranging from normal hearing to profoundly deafened individuals listening through traditional cochlear implants. Some of these data have been compiled from previous publications [Turner et al, 2004; Gantz et al., 2005]; additional data from patients with severe to profound hearing loss have been added. The target words were easy-to-recognize spondees; only the two poorest implant users were unable to score 100% accuracy in quiet, and their scores were 80%. Thus, this test measures the listener's resistance to noise, rather than the ability to understand difficult speech items. The signal-to-noise ratio reported in figure 1 is the level at which 50% of the targets could be recognized; the methods are described more fully in Turner et al. [2004]. These data are in agreement with the predictions made above regarding the frequency resolution of the auditory system. The normal auditory system is most resistant to noise, followed by listeners with sensorineural hearing loss, and the traditional cochlear implant user, with the poorest frequency resolution, is most affected by noise.

Conclusions

The ability to recognize amplified speech in quiet is affected by severe to profound hearing loss in the higher frequency regions. These deficits appear to be related to an inability to perceive the spectral cues of speech, and data on the physiology of hearing loss suggest that basal regions of the cochlea with missing inner hair cells can disrupt the perception of these spectral cues. In such cases, electric stimulation can permit these spectral cues to be transmitted to the brain. Poor frequency resolution of the auditory system leads to problems understanding speech in background noise. Electric stimulation results in even poorer frequency resolution than most sensorineural hearing losses, thus cochlear implant users have particular problems in noise backgrounds. Preservation of residual acoustic hearing, when possible, may be an attractive strategy for addressing this problem.

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Table 1. Mean hearing threshold levels, standard deviation (SD) and range of hearing threshold levels for children and adults

		Frequency, Hz				
		250	500	1000	2000	4000
Children (n = 29)	mean	85.3	96.2	105.7	112.8	113.1
	SD	15.7	12.7	8.2	10.6	12.4
	range	55.0–120.0	70.0–115.0	85.0–120.0	85.0–125.0	75.0–125.0
Adults (n = 21)	mean	83.3	89.3	98.1	109.8	113.6
	SD	18.9	16.8	14.9	17.3	15.3
	range	40.0–120.0	55.0–120.0	65.0–125.0	75.0–125.0	85.0–125.0

noise has a better signal-to-noise ratio (SNR) than the other ear. The brain can selectively attend to the ear with a better SNR. This 'head shadow' effect can give an advantage of about 3 dB on average. Even when the SNR at both ears are similar, binaural listeners can make use of interaural time/phase differences to partially reduce the impact of noise in speech perception. This 'binaural squelch' effect can give a 1–2 dB advantage. The interaural time and level differences for sounds coming to the two ears from different locations can also be used by the binaural auditory system to specify the source of sounds.

There is now accumulating evidence demonstrating that binaural benefits for speech perception and sound localization are possible for people who use binaural/bimodal hearing devices [for a summary, see Ching et al., 2004a]. Previous reports showed that binaural localization was better than monaural localization, and binaural speech perception was better than monaural performance for speech perception in quiet and in noise, both for adults and children. The improvements were due to effects of redundancy and head shadow. Access to binaural squelch, however, is limited by the deficient representation of timing information in existing CIs. Neither children nor adults were able to use interaural time difference cues for binaural speech perception [Ching et al., 2005a].

In addition to binaural advantages, there is some evidence showing that a hearing aid and a CI provide complementary information. Acoustic amplification with a hearing aid provides adequate low-frequency information whereas electrical stimulation with a CI does not [Vandali et al., 2005; Kong et al., 2005]. Low-frequency information relating to voice pitch has been found to enhance the segregation of competing voices thereby contributing to sentence perception in noise [Kong et al., 2005]. Furthermore, studies that examined speech information transmission in consonant perception revealed that significantly more voicing and manner information were received when listeners used bimodal hearing devices compared to using CIs alone [Incert, 2003; Ching et al., 2001]. Because existing sound-processing schemes for CIs convey inaccurate and inconsistent pitch cues [McDermott, 2004], the use of a hearing aid combined with a CI has been shown to lead to improved ability in musical tune recognition [Kong et al., 2005; McDermott, 2005].

Most of the previous studies reported findings based on small numbers of participants. This paper was aimed at presenting an overview of binaural advantages in speech perception and localization from a sizeable sample by drawing together four studies on children and adults. Information about how to fit a hearing aid to complement the use of a CI in the contralateral ear would be provided together with conclusions on who should have binaural/bimodal fitting.

Patients and Methods

Between 2000 and 2005, 29 children and 21 adults who received a CI in one ear were evaluated. The methods and results have been described in detail in four publications [Ching et al., 2001, 2004b, 2005a, b]. Briefly, the subjects received a Nucleus CI22 or CI24 device in one ear, and were fitted with a hearing aid in the other ear based on the NAL-RP prescription [Byrne and Dillon, 1986; Byrne et al., 1991]. The hearing thresholds of the nonimplanted ear of the subjects are given in table 1. A systematic procedure for optimizing a hearing aid to complement a CI was implemented for each individual [Ching et al., 2001, 2004c]. The subjects' experience of using bimodal hearing devices varied from 8 weeks to 8.8 years (mean = 2.5 years, SD = 2.1).

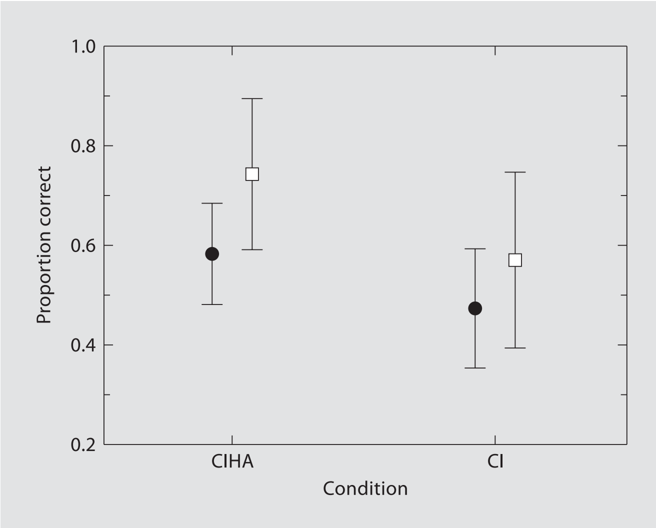

Fig. 1. Mean proportion correct for children (●) and adults (□) when they listened to sentences in babble noise presented at 10 dB SNR from the same loudspeaker. The two listening conditions were CI alone and CIHA. Vertical bars denote 0.95 confidence intervals.

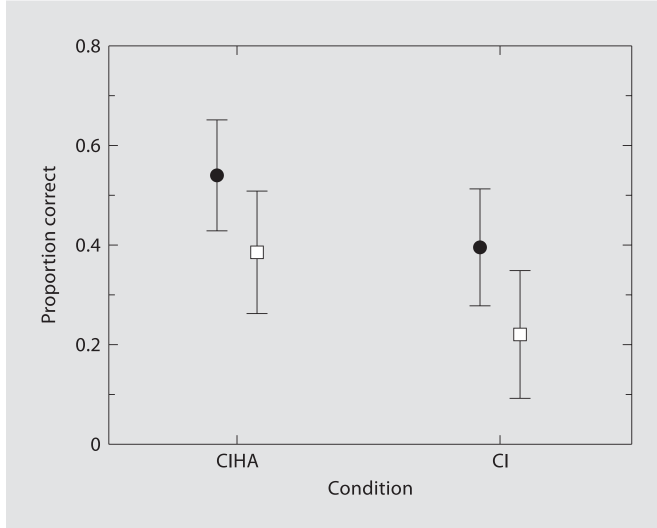

Fig. 2. Mean proportion correct for children (●) and adults (□) when they listened to sentences presented in babble noise at 10 dB SNR from spatially separated loudspeakers. Vertical bars denote 0.95 confidence intervals.

Evaluation of speech perception was carried out by presenting BKB sentences in 8-talker babble noise. The subjects were required to repeat verbatim the sentences heard. For assessing binaural redundancy effects, speech and noise were presented from the same loudspeaker positioned at 0° azimuth at a distance of 1 m at 10 dB SNR. For assessing the combined effects of binaural redundancy and head shadow, speech and noise were presented separately from two loudspeakers placed at ±60° azimuth at 10 dB SNR. Speech was presented from the side closer to the hearing aid and noise from the side closer to the CI. This test configuration was chosen because it maximized the potential contribution of a hearing aid by providing a better SNR at the ear with a hearing aid than that with a CI. If the binaural auditory system was able to attend to the ear with a better SNR, the binaural/bimodal performance would be expected to be better than the performance with a CI alone. If no advantage were obtained even in this favorable condition, then the use of bimodal hearing devices could be considered ineffective.

Sound localization on the horizontal plane was assessed by using an array of 11 loudspeakers spanning an 180° arc located in an anechoic chamber. All loudspeakers were closely matched using software-controlled digital filters. The subject was seated directly facing the centre of the array, at a distance of about 1 m. Pink noise pulses were presented from one of the loudspeakers in random order. The nominal presentation level was 70 dB SPL, with actual levels varying randomly around the nominal level by ±3 dB. Subjects had to identify the loudspeaker from which the sound originated. Performance was scored as number of loudspeakers between the stimulus and the response, expressed in degrees.

All evaluations of speech perception and localization were carried out when the subjects used a CI alone, and also when they used a CI with a hearing aid (CIHA). The hearing aid in the non-implanted ear was switched off when the subjects were evaluated in the CI condition.

Results

Speech Perception

Figure 1 shows the advantage arising from binaural redundancy for 25 children and 11 adults when they listened to sentences in babble noise at 10 dB SNR. Performance was scored as proportion of keywords correctly repeated. On average, the adults improved from 0.57 (CI) to 0.74 (CIHA), and the children improved from 0.47 (CI) to 0.59 (CIHA).

Analysis of variance using CIHA and CI scores as dependent variables, and device (CIHA vs. CI) and age (child vs. adult) as categorical variables revealed a significant main effect of device ($p < 0.0001$). The effect of age was not significant ($p > 0.05$). The results indicate that both children and adults perceived speech better when they used bimodal hearing devices than when they listened with a CI alone.

Figure 2 shows the binaural advantages arising from head shadow and binaural redundancy for 18 children and 15 adults when they listened to sentences in babble

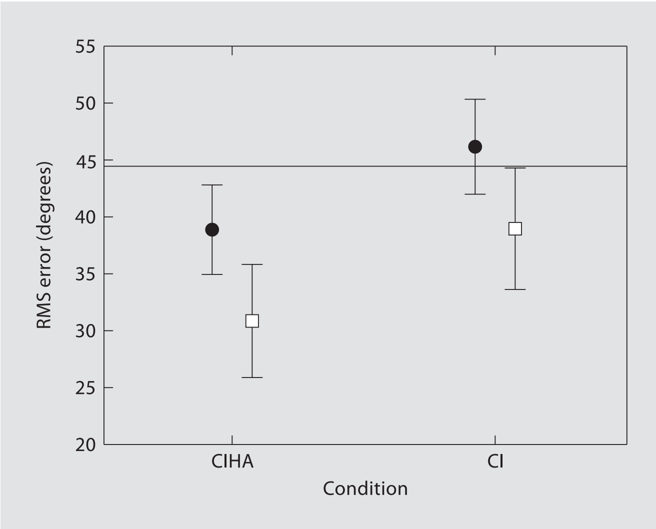

Fig. 3. Mean localization error for CI and CIHA. The horizontal line depicts chance performance. ● = Children; □ = adults. Vertical bars denote 0.95 confidence intervals.

noise at 10 dB SNR. The subjects included 14 children and 11 adults who participated in the previous experiment and additionally 4 children and 4 adults. Performance was scored as proportion of keywords correctly repeated. On average, the adults improved from 0.22 (CI) to 0.38 (CIHA), and the children improved from 0.39 (CI) to 0.54 (CIHA).

Analysis of variance using CIHA and CI scores as dependent variables, and device (CIHA vs. CI) and age (child vs. adult) as categorical variables revealed a significant main effect of device ($p < 0.0001$). The main effect of age was not significant ($p > 0.05$). For both children and adults, speech perception with binaural/bimodal hearing devices was significantly better than that with a CI alone.

To examine whether speech benefits were related to the amount of residual hearing of the subjects, we performed a correlation analysis between three-frequency average hearing thresholds (0.5, 1, 2 kHz) in the nonimplanted ear of the subjects and speech benefits (CIHA – CI scores) for both the condition when speech and noise were presented from the same loudspeaker and from spatially separated loudspeakers. Although the amount of speech benefits decreased with increase in hearing loss, the negative correlations were not significant for both conditions of presentation ($r = -0.33$, $p > 0.05$, and $r = -0.05$, $p > 0.05$, respectively). This insignificant relation is probably due to the restricted range of three-frequency average hearing thresholds of the subjects (range 73–118 dB HL; mean = 102 dB HL; SD = 11.2 dB).

We also investigated whether auditory experience affected the degree of benefit obtained by performing a correlation analysis between bimodal hearing experience and amount of speech benefits. No significant relation was found for both conditions of presentation ($r = 0.09$, $p > 0.05$, and $r = -0.32$, $p > 0.05$, respectively).

Horizontal Localization

Figure 3 shows the mean results in terms of RMS errors in localization for 29 children and 18 adults.

Analysis of variance using the error score for the CIHA and the CI conditions as dependent variables, and device (CIHA vs. CI) and age (child vs. adult) as categorical variables indicated that the main effect of age and condition was significant ($p < 0.02$, $p < 0.00001$, respectively). The interaction was not significant ($p > 0.05$). On average, the localization ability of both the child and adult groups with CI alone were not significantly different ($p > 0.05$), with both groups performing at chance level. Post-hoc analysis using the Tukey's honest significant difference test indicated that both groups located sounds better with CIHA than with CI alone ($p < 0.002$, $p < 0.005$, respectively).

We examined whether people who obtained greater binaural benefits in localization also demonstrated better speech perception in noise by performing a regression analysis between the difference scores for localization (CIHA – CI errors) and the difference scores for speech perception (CIHA – CI scores). On average, localization was not associated with use of binaural redundancy in speech perception ($p > 0.05$). However, improved localization was significantly correlated with enhanced perception of speech in spatially separated noise ($\beta = -0.38$, $p < 0.02$).

Discussion

The evidence summarized above clearly shows significant benefits in speech perception in noise and horizontal localization that arise from access to head shadow and binaural redundancy cues when a hearing aid is worn with a CI in opposite ears. Both children and adults derived binaural advantages from using bimodal hearing devices. Further, the improved speech perception in noise with bimodal hearing may be related also to the complementary speech information provided by a hearing aid and a CI. This is consistent with consonant perception results of some of the child and adult participants [Incert, 2003; Ching et al., 2001]. The evidence calls for making bimodal fittings routine in standard clinical management for children and adults who receive a CI in one ear, and who have residual hearing in the opposite ear.

The present finding that the amount of residual hearing is not significantly correlated with binaural speech benefits is consistent with a previous analysis of 14 studies that revealed no significant correlation between the three-frequency averaged (0.5, 1, 2 kHz) hearing thresholds and the difference between CIHA and CI speech scores [Ching, 2005]. The current evidence indicates that a hearing aid should be used even when the degree of hearing loss in the nonimplanted ear is severe or profound. Furthermore, the lack of significant correlation between auditory experience with bimodal hearing and amount of speech benefits implies that even people who have not used a hearing aid for a few years after implantation should be considered as candidates for binaural/bimodal fitting. For these people, binaural benefits would be possible within 3 months after bimodal fitting.

It is important to note that all children and adults who participated in the experiments reported in this paper had their hearing aids adjusted to complement their CIs. There are two basic principles for hearing aid adjustment. First, the hearing aid frequency response must be optimized for speech understanding, and the hearing aid must amplify sounds to comfortable loudness for low, medium, and high input levels. Second, when the hearing aid is used with a CI, loudness should be balanced between ears and sounds must be maintained at a comfortable listening level for low, medium, and high input levels. To meet the first requirement, the hearing aid should have wide-dynamic range compression capability, and should be fitted using an established prescription such as the NAL procedure [Dillon, 1999]. This procedure aimed to maximize speech intelligibility while maintaining normal overall loudness across a range of input levels. Real-ear measurements should be used to fit and verify that prescriptive targets are achieved. To optimize the fitting for an individual, a paired comparisons procedure can be used. This method allows the individual to choose a frequency response, between two alternatives, that is better for understanding speech [Ching et al., 2004c]. To meet the second requirement, a loudness balancing procedure can be used to adjust the gain of the hearing aid for different input levels so that loudness of speech is similar between ears. The detailed procedure for optimizing the frequency response and balancing loudness is published [Ching et al., 2004c] and a demonstration with detailed instructions is available via Cochlear College (www.cochlearcollege.com). This procedure has been validated by research showing that the binaural performance of children was significantly better after hearing aids were adjusted to complement CIs [Ching et al., 2001]. Our data on the results of fine tuning for adults and children indicate that minimal adjustments were required when the initial fitting was based on the NAL prescription [Ching et al., 2004c], with the individual fine tuning procedure resulting more often in modifications in gain rather than frequency response (greater adjustments in frequency response and gain would be required if the initial fitting were based on other prescriptions).

Conclusion

We conclude that all recipients of a unilateral CI who have measurable residual hearing in the nonimplanted ear should be fitted with a hearing aid in that ear. The hearing aid should be adjusted to complement the CI for each individual. Further, binaural performance with bimodal hearing devices, rather than monaural performance with a single CI, should be the baseline against which to judge if bilateral implants offer any advantage.

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the next, group data indicate that conventional long-electrode (LE) implants are much less effective at transmitting several structural features considered essential to accurate perception and enjoyment of music. Prior studies indicate that CI recipients on average resemble normal-hearing (NH) listeners in perception of rhythm [Gfeller et al., 1998; Kong et al., 2004; McDermott, 2004], but LE CI recipients are significantly less accurate than NH persons on tasks such as pitch discrimination (e.g. pure tone frequency difference limens; discrimination of direction of pitch change as a function of base frequency and interval size) and simple melody recognition [Gantz et al., 2005; Gfeller et al., 2002a, b]. Poor performance on each of these measures can be related to the lack of detailed frequency information transmitted through conventional LE CIs [Kong et al., 2005]. Prior studies of bimodal stimulation (LE CI + hearing aid in the nonimplanted ear) in which CI recipients were tested for pitch perception and/or melody recognition indicate the value of residual hearing for music perception tasks that require good pitch resolution [Büchler et al., 2004; Dillier, 2004; Kong et al., 2005]. The recent development of the Hybrid CI, which transmits the sound signal with both acoustic and electric (A+E) stimulation, has important implications for music perception, in that the preserved low-frequency acoustic hearing can usually provide finer spectral resolution than electrical stimulation [Gantz et al., 2005; Henry et al., 2005; Kong et al., 2005].

The aim of this study was to examine the effectiveness of the Hybrid CI in perception of real-world musical sounds such as familiar recordings and recognition of musical instruments.

Methods

The groups tested included: (a) recipients of conventional LE CIs (LE group), (b) recipients of the Cochlear Nucleus Hybrid CIs, acoustic + electrical stimulation [Gantz et al., 2005] (Hybrid group), and (c) adults with NH (NH group) as determined through a hearing screen. The groups were tested on recognition of two types of real-world musical stimuli: (a) excerpts from pop and country music recordings well known among Americans, and (b) recordings of solo musical instruments.

Real-World Song Recognition

Participants in this test included the LE group (n = 39), the Hybrid group (n = 4), and the NH group (n = 17). Members of the LE group used the following types of devices: Advanced Bionics Corporation Devices: HiResolution 90K, Clarion 1.0 and 1.2, and CII High Focus; Cochlear Corporation Devices: Nucleus 24, Nucleus 22, and Nucleus 24 Contour. The strategies used included SPEAK, ACE, CIS, and HiRes. The average length of CI use was 67.8 months (SD = 15.6), and the average age at time of testing was 61.9 years (SD = 15.6).

The Hybrid group all used a 10-mm internal electrode and CIS processing strategy. All 4 Hybrid recipients had usable residual acoustic hearing up to 750 Hz. During testing, 1 recipient used the 10-mm internal electrode only (this recipient chooses not to use hearing aids due to perceived lack of benefit), 2 used the 10-mm internal electrode plus a hearing aid on the ipsilateral side, and 1 used the 10-mm internal electrode plus a hearing aid on the contralateral side (this CI recipient does not normally use a hearing aid on the ipsilateral side). Their average length of CI use was 23.8 months (SD = 17.2) and average age at time of testing was 54.8 years (SD = 8.8).

The excerpts from the pop and country music recordings were 12–17 s in length and were presented in two conditions: (a) sung lyrics with instrumental accompaniment, and (b) the same song excerpt performed on musical instruments without sung lyrics. The stimuli consisted of complex blends of melodies, harmonies, timbral blends, rhythms, and sung lyrics. The items were presented in random order at 70 dBA in free field. Response was open set; no feedback was given on accuracy. Prior familiarity with the song title of each item was established following testing through a song title checklist.

Instrument Recognition

Participants in this test included the LE group (n = 174), the Hybrid group (n = 14), and the NH group (n = 21). Members of the LE group used the following types of devices: Advanced Bionics Corporation Devices: HiResolution 90K, Clarion 1.0 and 1.2, and CII High Focus; Cochlear Corporation Devices: Nucleus 24, Nucleus 22, and Nucleus 24 Contour; Ineraid internal array (Med-El CIS-Link external speech processor). The strategies used included Analog, MPEAK, SPEAK, ACE, CIS, SAS, and HiRes. The average length of CI use was 43.8 months (SD = 47.0), and the average age at time of testing was 59.9 years (SD = 14.6).

The Hybrid group all used a 10-mm internal electrode and CIS processing strategy. All participants in the instrument recognition test had usable residual hearing (thresholds better than 90 dB HL) up to at least 500 Hz. Approximately half of these had usable hearing extending to 750 Hz, and several had usable hearing out to 1000 Hz. One recipient used only the 10-mm electrode, 6 used the 10-mm electrode plus a hearing aid on the ipsilateral side, 2 used the 10-mm electrode plus a hearing aid on the contralateral side, and 5 used the 10-mm electrode plus hearing aids on both sides. Their average length of CI use was 13.9 months (SD = 9.3) and average age at time of testing was 53.8 years (SD = 10.3).

The test stimuli consisted of recordings of 8 well-known musical instruments playing in a solo rendition a 7-note phrase in either the low, medium, or high frequency range chosen to represent the most prototypical (as opposed to being in the extreme high or low) range of that instrument; only the piano (pitched percussion) was presented in more than one octave. The instruments were broken out by 3 frequency ranges for the fundamental frequency of the instrument (low = 131–262 Hz; medium = 262–524 Hz; high = 524–1048 Hz) and 4 instrumental families (strings, woodwinds, brass, pitched percussion). Each instrument was presented 3 times in random order; the response task was an unmatched closed set. Prior familiarity with each of the instruments was determined prior to testing. Participation required familiarity with at least 75% of the instruments in the test, and data anal-

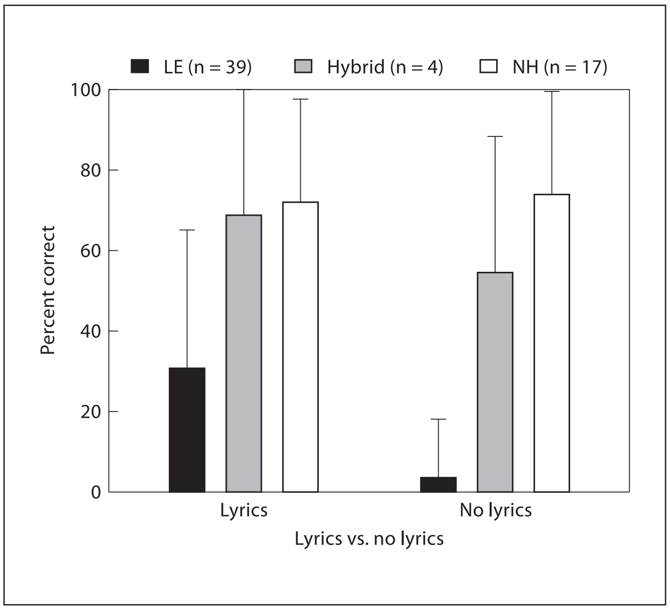

Fig. 1. Real-world melody recognition. Error bars indicate one standard deviation.

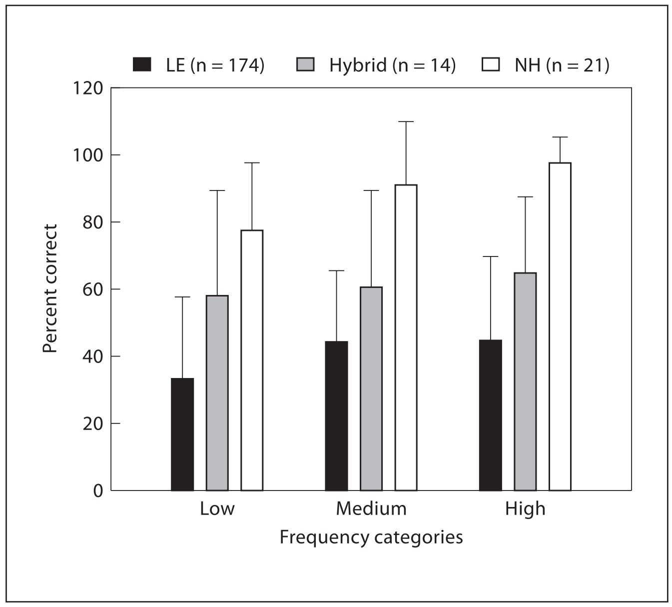

Fig. 2. Instrument recognition. Error bars indicate one standard deviation.

yses were based only upon those instruments identified by each participant as familiar prior to testing. No feedback was given on accuracy during testing.

Results

Real-World Song Recognition

No significant differences were found as a function of device or strategy for the LE group; therefore, all the LE devices and strategies were collapsed into one LE group for analyses. Due to small sample sizes, nonnormality of the data, and unequal group variances, nonparametric statistics were used. The Kruskal-Wallis test indicated significant differences among the three groups ($p < 0.0001$) on recognition of songs in the lyrics condition (fig. 1). We performed multiple comparison tests among the three groups using the Wilcoxon rank sum test with a Bonferroni adjusted α-level. The NH group was significantly more accurate for real world song recognition with lyrics than the LE group ($p < 0.0001$). In the no lyrics condition, there were also significant differences among the three groups ($p < 0.0001$). Both the NH and the Hybrid groups were significantly more accurate for real-world song recognition than the LE group ($p < 0.0001$).

Instrument Recognition

No significant differences were found as a function of device or strategy for the LE group; therefore, all the devices and strategies were collapsed into one LE group for analyses. As figure 2 indicates, there was a consistent pattern, with the LE group as least accurate, and the NH group as most accurate. The Kruskal-Wallis test indicated significant differences among the three groups ($p < 0.0001$) on instrument recognition including all three frequency ranges.[1] Multiple comparison tests indicated that the LE group was significantly less accurate ($p < 0.0001$) than the NH group at all 3 frequency ranges; the LE group was significantly less accurate than the Hybrid group in the low and high frequency ranges ($p < 0.0005$). The Hybrid group was significantly less accurate than the NH group at medium and high frequencies ($p < 0.001$).

[1] Interpretation of the overlapping error bars in figure 2 should take into account the use of a nonparametric test based on ranks and the small sample sizes. As is well known, when there are small sample sizes, individual values can have dramatic effects on the mean and the standard deviation. In this case, an extreme value caused the standard deviation to become inflated. The overlapping of the error bars is a direct result of these extreme values. Therefore, the diagram does not give an exact description of what is being tested, but the general idea can clearly be seen in that the bars themselves are different.

Discussion

These results contrast the performance of CI recipients with that of NH adults in two recognition tasks that use real-world stimuli (sound clips of recorded songs and of solo musical instruments). Because the song recognition task was open set and the instrument recognition task was an unmatched closed set task, some error can be attributed to cognitive aspects of the recognition task, e.g. tip of the tongue phenomenon when attempting to recall a song title [Gfeller et al., 2005], as well as to perceptual accuracy. Nevertheless, the performance of the LE group is clearly below that of the NH or Hybrid groups. Consistent with prior studies examining pitch discrimination and simple melody recognition [Gantz et al. 2005], Nucleus Hybrid CI recipients as a group performed more accurately than did recipients of conventional LE devices on more 'real-world' music listening tasks, particularly on song items without lyrics. It is interesting to note that the lowest score in the song recognition task was that of a 10-mm CI recipient who chose not to use hearing aids because of little perceived benefit from amplification. It is also of interest that the Hybrid group compared most favorably (19% less accurate) with the NH group on recognition of instruments in the low frequency range (trombone, cello, saxophone), as opposed to recognition in the middle (30.4% less accurate) and high frequency ranges (32.8% less accurate), suggesting that preserved low-frequency hearing made an important contribution in this task.

In conclusion, the greater accuracy of the Hybrid group should be attributed to preserved residual hearing (which may be in either the implanted or nonimplanted ear), which is responding to acoustic stimulation. These results indicate that preservation of low-frequency acoustic hearing is important for perception of real-world musical stimuli. However, the extent to which perceptual accuracy can be attributed specifically to residual hearing, which merits future study, will require formal testing in the condition of no electrical stimulation as well as confirmation of these results with larger samples.

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frequency based on cochlear place and expressed as proportion of the total length of OC. However, OC length cannot be determined in most temporal bone and imaging studies, and estimates of frequency based upon the average OC length may be inaccurate due to individual variability. Moreover, some contemporary 'perimodiolar' CI electrodes (e.g. the Contour™ electrode from Cochlear Limited, Sydney, Australia; the HiFocus™ with positioner and the new Helix™ electrodes from Advanced Bionics Corporation, Sylmar, Calif., USA) are designed with stimulating sites facing the modiolus, and the spiral ganglion (SG) cell somata within Rosenthal's canal are the presumed target of excitation for such electrodes. The SG turns on a smaller radius and terminates sooner than the OC at both the basal and apical ends of the spiral. Therefore, represented frequency in the SG must differ from that of the OC, at least over part of its course. The goal of this study was to derive an accurate frequency-position function for the human SG, based upon extrapolation from OC cochlear-place frequency and to explore the implications of the differences between SG and OC frequency maps with respect to the design and surgical insertion of CI.

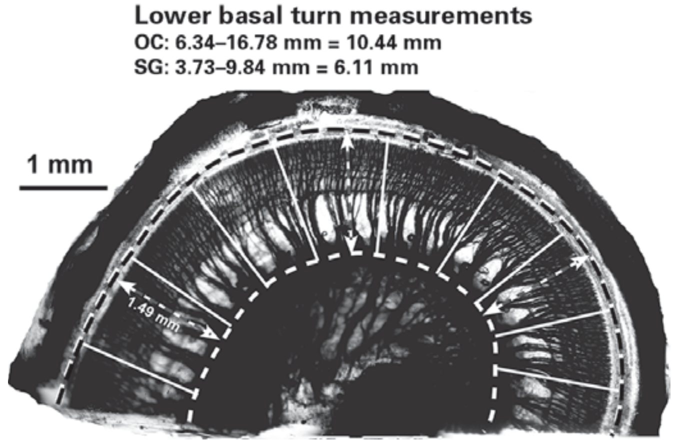

Fig. 1. Digital image of the lower basal turn of a human cochlea after epoxy embedding and surface preparation. The dashed white and black line indicates the OC, which was 10.44 mm long in this sector of the cochlea. The white dashed arrows indicate how measurements from radial sections were used in digital images to define the center of the SG. The inner white dashed line marks the approximate center of the SG (length, 6.11 mm in this segment). The solid white lines denote the trajectories of radial nerve fibers, as drawn to define a series of frequency-matched points on the OC and SG.

Materials and Methods

Human temporal bones (n = 7) were harvested from fresh cadaver specimens within 24 h postmortem and fixed by immersion in 10% phosphate-buffered formalin. Only one cochlea (left or right) was studied from each cadaver, to better assess individual variability. The round window was opened as soon as possible to facilitate diffusion of the fixative into the cochlea. The labyrinth was isolated and the otic capsule bone was drilled away to 'blue line' the cochlea. Specimens were then stained with osmium tetroxide (1% in 0.1 M phosphate buffer, pH 7.4) to visualize the radial nerve fibers. The cochlea was microdissected to expose the cochlear duct, and a marker (small notch in the stria vascularis) was created in the upper basal coil at the point nearest to the vestibule (V). The specimens were decalcified for 24–36 h to further improve visibility of the radial nerve fibers within the osseous spiral lamina and then embedded in epoxy. Each cochlea was bisected through the modiolus, and the individual half-coils were removed from the block and remounted on a glass slide in a surface preparation that contained both the OC and adjacent SG. All cuts through the specimens were made using razor blades so that tissue loss was negligible. Digital images of each piece of the surface preparation were captured and calibrated by capturing an image of a stage micrometer at the same magnification and superimposing this image on the specimen images. The OC was measured directly in the digital images by tracing along its approximate center (along the tops of the pillar cells, if visible) beginning at the basal extreme of the basilar membrane and measuring each segment of the surface preparation (fig. 1). Semi-thin radial sections were cut at regular intervals along the cochlear spiral and used to define the distance from the OC to the center of the SG, to examine the morphology and locate the points at base and apex where SG terminates. Next, the SG was measured along the series of points defining its center in the digital images, and the trajectories of the radial nerve fibers were traced to define a series of frequency-matched coordinates along the OC and SG.

Results

As shown in table 1, the OC lengths measured in the calibrated digital images demonstrated considerable intersubject variability, and ranged from 30.5 to 36.87 mm. The mean length of the OC was 33.31 ± 2.38 (SD) mm for the group of 7 cochlear specimens studied to date. In contrast, the average length of the SG was only 13.9 ± 0.79 mm (n = 6), with a range of 12.54–14.62 mm. Thus, on average, the SG was only 41% as long as the OC, and this ratio was fairly similar in cochleae of different sizes. Direct morphometric analysis demonstrated that Rosenthal's canal terminated and no SG cell somata were found directly radial to the most basal 2% and the most apical 11% of the OC, on average.

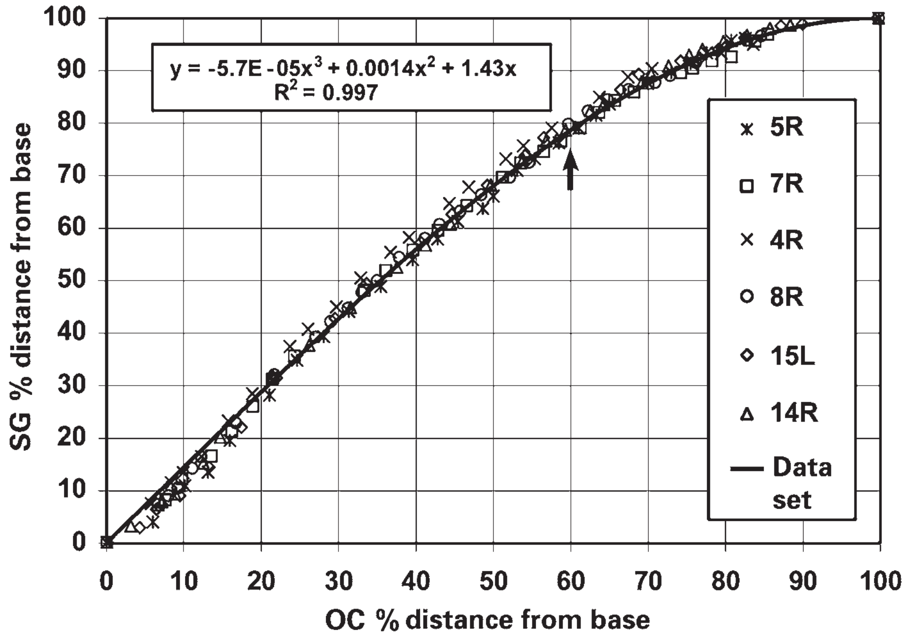

Fig. 2. Frequency-matched points along the OC and SG were determined by tracing the trajectories of radial nerve fibers. These data are plotted here for the 6 cochleae in our data set. A good correlation between percentage length along the OC and percentage length along the SG was demonstrated ($r^2 > 0.99$). The data were well fit by the cubic function shown in the graph. Mean location for V is indicated by arrow (see text).

Table 1. Summary of measurements in 7 cochleae

	Specimen							
	7R	4R	5R	8R	15L	14R	6R	mean
OC length, mm	30.5	32.31	33.44	36.16	32.45	36.87	31.41	33.31
SG length, mm	12.54	14	14.2	14.58	13.44	14.62	NA	13.90
SG length/OC length	0.41	0.43	0.42	0.4	0.41	0.4	NA	0.41
Percent OC basal without SG	1.31	1.98	3.47	1.38	2.13	1.84	NA	2.02
Percent OC apical without SG	11.64	9.22	11.33	10.26	11.37	12.99	NA	11.14
Percent OC length at V	59.08	59.36	64.74	55.56	61.14	NA	60.01	59.98
Frequency at V, Hz	1051	1035	764	1273	937	NA	998	1000

Data collected in 7 cochleae indicate relatively large intersubject variability in OC and SG lengths, but a fairly consistent ratio between the lengths of the two structures. Dissection error resulted in damage to the basal SG in specimen 6R and precluded measuring SG length. The marker in the stria vascularis for V was lost during processing of the cochlea and could not be identified in specimen 14R.

Frequency-matched coordinates on the OC and SG were determined by directly tracing the trajectories of radial nerve fibers at numerous points along the cochlear spiral in the digital images. These data are presented in figure 2. Percentage length along the SG was found to relate consistently and predictably to percentage length along the OC, with minimal intrasubject and intersubject variability. The data were fit by a cubic function that was constrained to begin at the point x = 0, y = 0, to end at x = 100, y = 100 and to be monotonic: $y = -5.7E\text{-}05x^3 + 0.0014x^2 + 1.43x$, where y = percentage distance from base of the SG and x = percentage distance from base of the OC. Since Greenwood's function defines frequency for the OC, SG frequency can then be calculated.

As anticipated, the frequency-position function for the SG is quite different from that of the basilar membrane for a large proportion of the cochlea, and particularly for the apical third of the cochlea. During cochlear dissections, an anatomical reference point was created by marking the site on the stria vascularis of the upper basal coil nearest to the center of the vestibule. This marker, which was termed V, was maintained throughout subsequent processing and embedding of each cochlea. The mean location of V in our study group was about 60% from the basal end of the OC (table 1), but on average this point was located 78% from the base of the SG, as indicated by the arrow in figure 2. It is interesting to note that the mean location for V is very close to the site where the radial nerve fibers begin to lose their radial orientation and begin to take a progressively more tangential course into the SG (mean, 60.8% ± 3.85 SD).

The represented frequency at our anatomical reference point V, as calculated using the Greenwood function, had a mean value of 1000 Hz, but it varied across quite a wide range from 1275 to 760 Hz for the specimens in our study. This landmark (point on basal coil nearest to the center of the vestibule) can be imaged in living subjects, so these data give us a preliminary estimate of the individual variability in the cochlear place frequency for a CI electrode positioned at V.

The relationship shown in figure 2 between distance along the OC and distance along the SG allows us to use Greenwood's equation to provide the first estimates of critical band distance in the human SG. Unlike critical band distance for the OC, which remains constant from base to apex, the critical band distance estimated along the SG varies as a function of position, and becomes progressively narrower from base to apex. Specifically, a critical band distance for the OC is suggested by Greenwood to equal 1/35 the basilar membrane length and is constant throughout the cochlea [Greenwood, 1990]. For our average cochlea, the OC was 33.31 mm long and the critical band distance would be 0.95 mm (1/35th of 33.31). SG critical band distances were estimated throughout the cochlea by using the function derived in figure 2 to estimate the length of ganglion associated with each millimeter of OC, as calculated for our mean SG length of 13.9 mm. Specifically, near the cochlear base one critical band distance on the OC (0.95 mm) corresponds to a distance of about 0.6 mm in the SG, whereas in the lower middle turn (24 mm from the base, ≈500 Hz) a critical band distance on the OC is still the same (0.95 mm) but the critical band distance in the SG is reduced to approximately 0.32 mm. This compression of critical band distance within the SG is particularly pronounced in the apical 40% of the cochlea (frequencies of 1 kHz and lower), where the radial nerve fibers begin to take an increasingly tangential course from the OC into the SG.

Discussion and Conclusions

Great intersubject variability was observed in both basilar membrane and SG lengths, especially in consideration of the limited number of cochlear specimens included in this series. OC length ranged from 30.5 to 36.87 mm (mean, 33.31 mm). This finding is consistent with numerous prior reports indicating great variability in human cochlear length [Kawano et al., 1996; Ketten et al., 1998; Skinner et al., 2002; Bredberg, 1968; Ulehlova et al., 1987; Hardy, 1988]. The SG was 40–43% as long and ranged in length from 12.54 to 14.62 mm (mean, 13.9 mm).

The represented frequency at our selected anatomical landmark V (the point on the basal turn closest to the center of the vestibule), as calculated using the Greenwood function, had a mean value of 1000 Hz, although it varied across quite a wide range from 1275 to 760 Hz for the specimens in our study. Our data suggest that in order to reach this 1000-Hz position in the average cochlea, a CI electrode carrier which is positioned under the OC would have to place a stimulating contact at a point 20 mm from the extreme base of the OC (i.e. 60% of 33.31 mm). This is probably a maximum estimate of the required insertion length to reach this point, because most surgeons insert the CI electrodes through a cochleostomy anterior to the round window and therefore several mm from the basal end of the OC.

On the other hand, some current CIs are designed to position stimulation sites facing the modiolus and as close as possible to the SG. The implicit assumption is that the SG is the target for electrical stimulation. In this case, if a CI electrode carrier achieved an ideal perimodiolar position directly adjacent to the SG, the approximate insertion depth required to reach V would be 78% of 13.9 mm or only 10.84 mm in the average cochlea, or 11.4 mm for the longest SG in our data set. Moreover, the maximum length of the SG in our series was less than 15 mm. These data suggest that an ideally positioned perimodiolar CI electrode targeting the SG probably would have to be inserted to a maximum depth of only about 15 mm in order to position stimulating contacts adjacent to the entire length of Rosenthal's canal. However, it should be noted that our measurements of SG length were made at the center of Rosenthal's canal. The exact distance along the modiolar wall to the apical terminus of the SG and the extent of intersubject variability must be determined empirically in future studies. This is an important issue, since shorter insertion depths are less likely to cause trauma to the cochlea [Wardrop et al., 2005a, b], thus optimizing clinical outcome. Particularly in the case of electroacoustic stimulation, shorter insertion depths may improve the chances for preservation of residual hearing.

Normalized length along the SG (% distance from the base) was highly correlated to normalized length along the OC, and was best fit by a cubic function. Since the Greenwood function allows calculation of frequency for the OC, this new equation provides a frequency-position function for the human SG. However, because of the individual variability in cochlear size, accurate estimates of frequency for CI electrodes positioned at different points along the OC or SG in living subjects will require a method of estimating OC or SG length in the imaging studies. We hypothesize that measurements of the basal turn diameter [e.g., see Escudé et al., this issue, pp. 27–33] may provide a reliable indication of overall cochlear size and may correlate to OC or SG length. Additional temporal bone studies are required to test this hypothesis.

The SG frequency-position function allowed us to calculate critical band distances for the SG. Unlike critical bandwidths for the OC, which remain constant throughout the cochlea, estimated critical band distances in the SG diminish systematically from base to apex. One intriguing implication of these calculations is that when individual electrodes are spaced at uniform intervals along the implant carrier, which is the case in most contemporary CI designs, the frequency shift between adjacent electrodes is greatest at the base and much more compressed for apical electrodes. An exception to the usual uniform spacing of electrodes is seen in the Contour Advance electrode which has reduced spacing at the apical end, but additional research is required to determine how this spacing would 'fit' the SG critical band distance compression with different insertion depths and in different individuals. Finally, it should be noted that electrode spacing is an extremely complicated issue with many other factors such as spread of excitation and channel interaction having an impact on optimum electrode spacing and stimulation patterns.

The longitudinal positions of CI electrodes in the cochlea have been correlated with pitch perception as well as with threshold, growth of loudness and speech intelligibility [Skinner et al., 2002]]. As subjects with greater residual hearing and better SG survival receive implants and advances in CI design permit more spatially precise stimulation, an accurate frequency map for the SG may provide a basis for better matching subjects' speech processor maps to the appropriate frequencies of CI stimulation sites, potentially increasing clinical benefits. In electroacoustic stimulation, more accurate estimates of the frequency-place function in individual subjects may allow investigators to determine preoperatively the precise length of an implant required to provide electrical hearing over the range of frequencies optimum for that individual, based upon the frequency range of their residual hearing.

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example, a typical fitting of a Nucleus speech processor could use analysis filter bands covering the frequency range 150–10823 Hz. The electrode position is harder to determine, although it can be revealed through CT [Ketten et al., 1998]. The topography of the stimulated neural elements is not at present completely understood. The standard approach for estimating the effective CF at each electrode contact has been based on the frequency-to-place mapping of the organ of Corti established by Greenwood [1990]. As recently shown by Sridhar et al. [this issue, pp. 16–20], the Greenwood map is not a realistic model for the CFs of CI electrodes placed near to the modiolus, for which a spiral ganglion map seems appropriate. A spiral ganglion frequency-to-place map assigns substantially lower CFs to a given electrode contact position than does Greenwood's organ of Corti map, especially for more apical electrode locations. It may therefore be important to consider proximity to the modiolar wall when estimating the effective CF of an electrode contact. An additional source of uncertainty is that the degree of neural degeneration in an individual implant recipient cannot be known in vivo, so that an estimation of the location of the neural elements that are stimulated by a contact in a pathological cochlea is always subject to some degree of error.

Notwithstanding our incomplete knowledge of the effective CFs along an electrode array, shifts of frequency-to-place mapping have demonstrable and sizable effects, so it remains the case that it is important to understand the significance of this aspect of mapping in making the best use of a CI, whether monaurally or bilaterally, and also when considering the combined use of a CI with residual hearing, whether ipsi- or contralateral.

In vivo CT data from human CI recipients suggest that typical array insertion depths may be around 20 mm from the cochlear base, with some deeper insertions up to 25 mm [Ketten et al., 1998; Skinner et al., 2002]. On the assumption that Greenwood's organ of Corti map is appropriate for estimating electrode CF, a 20-mm insertion corresponds to a CF for the most apical contact of around 1000 Hz, while the most basal contact will have a CF of above 10 kHz. Given this range of CFs over the electrode array, setting a speech processor to avoid a misalignment of speech processor filters to electrode CFs would entail delivering speech information extracted from the acoustic frequency range encompassed by the electrode CFs. Both the classic articulation index data [French and Steinberg, 1947], which assign relative importance values to frequency bands of speech, and recent data from simulations of CIs [Faulkner et al., 2003; Shannon et al., 2002] indicate that such a fitting would lead to reduced speech intelligibility as a result of the loss of significant low-frequency speech cues that lie below 1000 Hz. Clearly the preservation of frequencies that convey significant speech information is an important factor in choosing a frequency-to-place map for a CI and this may mitigate the disadvantage of a frequency-to-place map that does not match that of normal hearing.

A second reason to suppose that a natural frequency-to-place map may not be essential comes from studies showing perceptual adaptation to shifted frequency maps. Several studies have used acoustic simulations to study the ability of normal listeners to adapt to frequency-to-place maps entailing a substantial basalward shift of cochlear stimulation of around 6 mm [e.g. Rosen et al., 1999; Fu and Galvin, 2003]. In each case, the basalward shift had a large immediate impact on the intelligibility of speech, but after several hours of training, the effects of the shift were very much reduced. Direct evidence of adaptation to a change of frequency-to-place mapping in CI users has been reported by Fu et al. [2002]. In this study speech processor filters were shifted downwards in frequency by 0.68 or 1 octave. The 3 subjects all showed a marked initial drop in consonant and vowel recognition followed by a partial recovery of performance after 2 weeks of use of the lowered filters, while there was little further change in performance after 3 months of use.

Hence, both normal hearing listeners and CI users demonstrate the ability to at least partially adapt to changes of frequency-to-place mapping. When such changes are accompanied by an increase in the information provided by the shifted map, it may well be the case that, after a period of adaptation, a misaligned map which provides the most appropriate information is more beneficial than an aligned map that, as a result of a less than ideal electrode array position, must entail the omission of important frequency information [Faulkner et al., 2006].

Most studies of frequency-to-place mapping have focused on basalward shifts of approximately constant distance along the BM, which are close to shifts on a logarithmic frequency scale. Such shifts relate well to variations of insertion depth and are useful analogies to the frequency-to-place mapping in conventional monaural implantation. There is now increasing interest in the combined use of acoustic hearing aids with CIs [e.g. Offeciers et al., 2005]. In considering both monaural electroacoustic stimulation (EAS) and the use of contralateral hearing aids together with a CI, other forms of distortion of frequency-to-place mapping are likely to arise.

One such distortion will arise when the upper frequency limit of residual hearing lies well below the effective CF of the most apical electrode contact. There will in consequence be a medial range of cochlear places that cannot be stimulated either acoustically or electrically. Mid-frequency information is often of crucial importance in speech recognition, yet the preservation of frequency-place alignment would require that this information be discarded. The preservation of mid-frequency information in this case requires a warping of the frequency-to-place map to distribute this information around the places that cannot be stimulated. The first study reviewed here is a simulation in normal listeners that investigates their ability to adapt to maps that employ such frequency warping.

A second issue arises with binaural fittings. Consider a CI electrode array inserted such that the most apical contact has an effective CF of 1000 Hz or more, used in combination with contralateral amplification to acoustic hearing. Acoustic hearing will necessarily give rise to a frequency-to-place mapping that is determined by the basilar membrane, and hence, that accords to the Greenwood organ of Corti map, while this CI would typically be fitted with a basally shifted frequency-to-place mapping. In this instance, there is a mismatch of frequency-to-place mapping between the two ears. The second study reviewed here asks what the effect of such a mismatch might be and whether listeners can adapt to such mismatches after training. These questions are also important in the case of binaural CIs, where the two electrode arrays may be inserted to significantly different depths, so that here again there may be a mismatch of the frequency mapping between the two ears unless the different insertion depths are taken into account in the fitting of the speech processors.

Frequency-to-Place Mapping in EAS and Binaural Implants

Mapping around Medial Non-Responsive Regions of the Cochlea

In monaural EAS there may very well be a medial non-responsive cochlear region that is beyond the reach of the electrode array yet is lacking functional inner hair cells and hence cannot be stimulated acoustically. This may arise, for example, from the use of a short CI electrode [Gantz and Turner, 2004]. The preservation of important mid-frequency speech information can in such cases be achieved by warping the frequency-to-place map around the medial region. Acute studies of such frequency maps suggest that warping the frequency-to-place map in this way does not lead to improved speech recognition compared to maps that discard mid-frequency information [Shannon et al., 2002]. However, these were acute studies and listeners had no opportunity for extended experience of the frequency-warped maps. Given that listeners can learn to use distorted frequency-to-place maps that involve a simple basalward shift [Rosen et al., 1999], it may be premature to dismiss frequency-warped maps on the basis of acute experiments. For this reason, a recent study by Smith and Faulkner [2006] investigated whether normal listeners could learn frequency maps in which mid-frequency information was warped around a simulated non-responsive 10-mm medial region of the cochlea.

Method

One processor, called 'dropped', used a matched mapping that omitted frequency bands matching the 'missing' medial region (fig. 1). An 'adjacent-warp' condition shifted mid-frequency information to places just adjacent to the medial region, while the two lowest and two highest bands preserved a matched mapping (fig. 1). A 'spread-warp' condition encoded 6 bands covering the speech range, all being spectrally warped onto 3 apical and 3 basal bands (fig. 1). A final unwarped control condition mapped the 6 input bands of the spread-warp processor onto 6 carriers matching the frequencies of the input bands. All of the processors employed 6th order Butterworth analysis filters, while envelope extraction in each band used half-wave rectification and a 3rd order Butterworth 400-Hz low-pass filter.

Each of the 8 normal-hearing young adult participants was trained for a total of 3 h in each of the two warped conditions. Training employed live-voice connected discourse tracking, requiring the listener to repeat processed speech phrase-by-phrase. The subjects were split into two subgroups so that the order of the training conditions was counterbalanced over subjects.

Results

As figure 1 shows, the recognition of words in IEEE sentences increased significantly with training in both warped conditions. Subjects learned the 'spread-warp' mapping more readily, and here performance after training was statistically indistinguishable from that in the control condition in which the same 6 input bands were presented without frequency warping. Similar conditions were explored by Shannon et al. [2002] but without any opportunity for training. They found that performance was equivalent in 2 conditions similar to our adjacent-warp and dropped conditions, and concluded that listeners could not use warped spectral information. However, it is clear that this conclusion does not hold for listeners with just a few hours of listening experience.

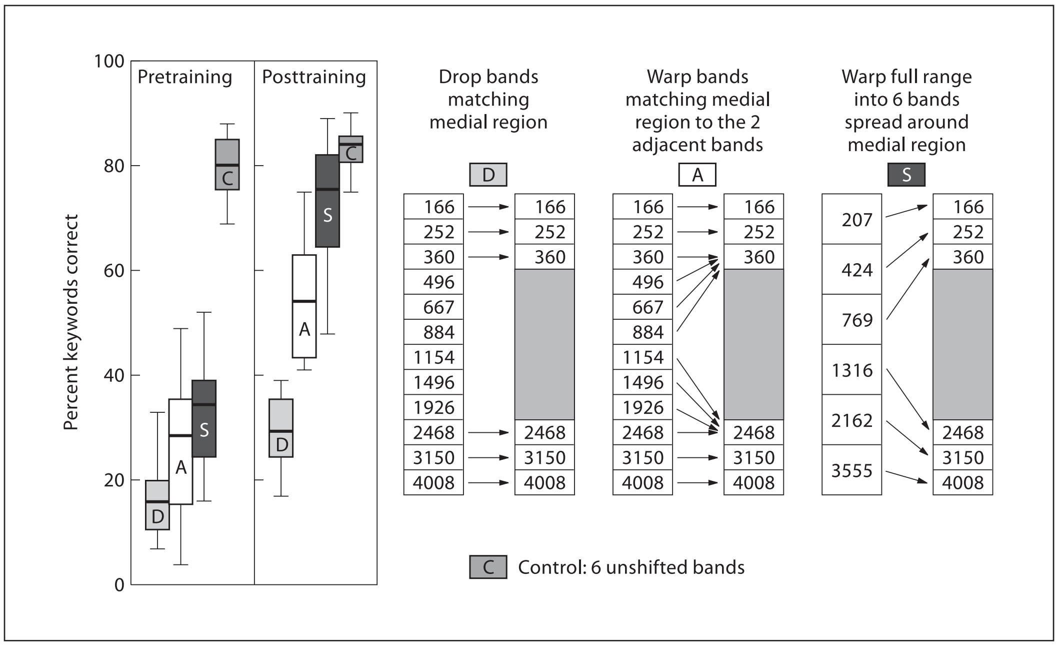

Fig. 1. Performance with IEEE sentences before and after training [Smith and Faulkner, 2006]. The main vocoder conditions are represented to the right. The characters overlaid on the graph indicate the condition. D: Mid-frequency information is dropped; A: mid-frequency information is warped into the adjacent bands; S: the 'spread-warp' condition in which 6 analysis bands covering the speech frequency range are warped to both apical and basal regions; C: control condition in which 6 bands are presented without warping. The box and whisker plots show the median score (bar) the interquartile range (box) and the complete range of scores (whiskers).

Binaural Mismatches of Frequency-to-Place Mapping

The frequency-to-place map distortions considered so far have all been monaural. When an implant is used in conjunction with a contralateral hearing aid, or with bilateral implants, it is readily conceivable that the two ears would be operating with different frequency-to-place maps. We have examined such a situation in a further simulation study [Faulkner et al., 2005]. Here we simulate two ears in which one is subjected to a basalward place shift. The issue of interest is whether normal listeners can learn to combine cues from this binaurally mismatched mapping.

Method

In order for the successful integration of cues to be readily observed, each ear received limited spectral information. A total of 6 analysis bands covering a frequency range of 200–5000 Hz were interleaved between the two ears so that each ear had access only to 3 spectral bands, with the carriers to one ear shifted upwards to represent a 6-mm basalward basilar membrane displacement. Envelopes were extracted from each analysis band using half-wave rectification and a 32-Hz 3rd order low-pass filter and imposed on sinusoidal carriers. Carrier frequencies were set at the logarithmic center of each unshifted band, and at frequencies shifted upwards to represent a 6-mm basalward basilar membrane shift from the center of each shifted band. Six normal listeners received 5 h of training with live-voice connected discourse tracking with speech presented through this binaurally mismatched processor.

Results

Intelligibility scores for words in simple BKB sentences are shown in figure 2. Although subjects did show statistically significant improvements in their performance with the binaurally mismatched processor over 5 h of training, and also showed signs of improvement when hearing only the 3 shifted bands, performance with the binaurally mismatched processor never rose above the performance seen with only the 3 unshifted bands. At the final post-training session, BKB sentence scores with these two processors were statistically indistinguishable. Additional tests with more difficult IEEE sentences showed the same outcome, and since with these materials maximum performance never exceeded 70% correct, this finding cannot simply be attributed to a ceiling effect. The main result suggests that what is learned in this instance is that the shifted information should be ignored. The training period in this study is plainly very short compared to the duration of exposure received by an implant user, but we find no indication that our subjects had learned to combine spectral cues to speech between the two mismatched ears. This finding suggests that if a substantial mismatch of frequency-to-place map arises between the two ears in the combined fitting of a CI and a hearing aid, or with a binaural CI fitting, this mismatch may prevent the most effective use of the spectral information conveyed by the two devices.

Discussion

Smith and Faulkner's [2006] finding of perceptual adaptation to a map warped around a medial dead region reinforces a gathering body of evidence that the human perceptual system is remarkably flexible in its adaptability to distortions of frequency-to-place maps, at least within the realm of speech perception. It also underlines the need for considerable caution in the interpretation of any effects of acute manipulations of frequency-to-place mapping. Additionally, this study makes clear that listeners can adapt to frequency-to-place distortions that go beyond the constant shifts of place along the basilar membrane that have been considered in previous work.

With specific reference to EAS, these data suggest that CI users with a medial non-responsive region need not be fit by speech processors that match filters to electrode positions, but rather that the CI speech processor should provide information over the full range of frequencies important for speech and that is not accessible to residual hearing. Gantz and Turner [2004] found poorer speech performance in 3 monaural EAS subjects implanted with a short 6-mm electrode compared to those with a more deeply inserted 10-mm electrode. They suggest that the poor performance of their 6-mm electrode subjects can be attributed to a shifted frequency-to-place mapping. Our results might seem to be in conflict with that interpretation. This conflict could be resolved by the assumption that there is a limit to plasticity for information received in extremely basal neural elements. The short hybrid electrode matches CFs ranging from around 8 kHz upwards on an organ of Corti map, and there are no published data suggesting plasticity to frequency-place misalignment at such high frequencies. There may also be interactions between the responses to acoustic and electrical stimulation involved in monaural EAS that are not represented in our simulations which could impact upon the ability of the system to adapt to the extreme frequency-to-place map distortion presented by the short electrode.

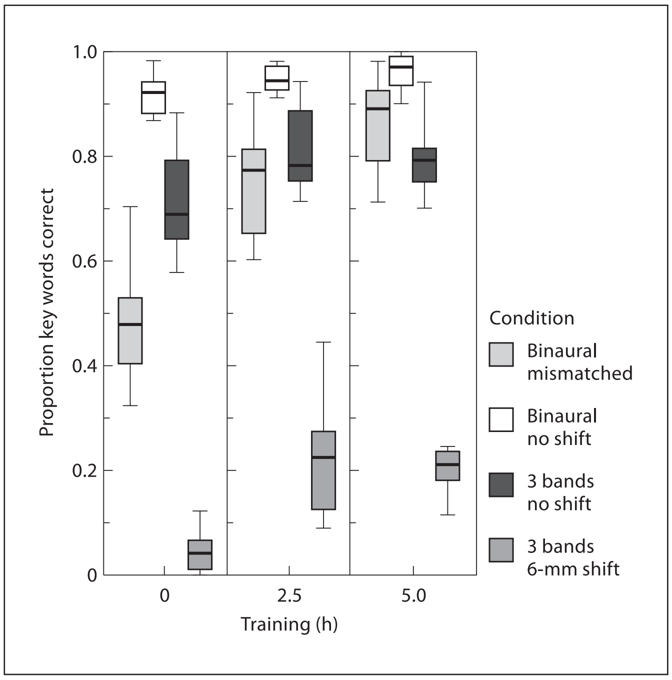

Fig. 2. Box and whisker plot showing performance in the recognition of words in BKB sentences over the course of training. Apart from the binaurally mismatched condition described in the main text, data are shown for 3 other conditions. 'Binaural – no shift' presents 6 interleaved bands to the two ears with no frequency shift. The two 3-band conditions represent performance with the individual ear components of the binaurally shifted processor.

Our simulations of binaurally mismatched maps seem relevant to frequency-to-place maps that overlap and are in conflict by representing similar frequencies in quite different cochlear places and/or very different frequencies in similar places. One important question that arises in this context is whether perceptual adaptation to frequency-shifted speech is a central cortical process, or whether it might have a lateralised component specific to each ear. It seems very unlikely that there is a lateralised adaptation during a few hours of experience, but this appears considerably more plausible with the many months of exposure experienced by implant users.

More research is clearly needed to test more strongly the finding that binaural mismatches of place map cannot be learned. If this is indeed the case, then there is a clear implication that such mismatches would be best avoided in the clinical fitting of both binaural CIs and of a CI with a contralateral hearing aid. This in turn leads to a need for clinically applicable methods to assess and correct any mismatch. If, on the other hand, such mismatches can be learned, but the learning process is a relatively difficult one compared to the learning of a novel monaural frequency-to-place map, there is a need to develop training techniques that facilitate the learning required to make full use of fittings with binaurally mismatched frequency-to-place maps.

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Muren, 1990; Xu et al., 2000]; approximately 25% of patients with congenital hearing loss have bony inner ear malformations indicated on computed tomography (CT) of the temporal bone. However, even for cochleae of normal appearance it is known that the organ of Corti varies in length substantially between individuals [Hardy, 1938; Kawano et al., 1996; Ketten et al., 1998; Xu et al., 2000] and that the number of turns of the cochlear spiral is variable. Moreover, there is substantial variation in the size of the otic capsule [Hardy, 1938; Dimopoulos and Muren, 1990].

High-resolution CT (HRCT) is performed routinely prior to cochlea implant surgery to identify the presence of malformations or ossification which may limit access to the scala tympani and prevent proper introduction of the electrode array. HRCT not only provides qualitative data in the form of cross-sectional or 3-D views [Kawano et al., 1996; Ketten et al., 1998] but also allows routine quantitative measurements in vivo to a resolution of 0.25–0.45 mm, depending upon the equipment in use.

The relatively large variations in the dimensions of cochlear structures (30–40%) coupled with a nominal cochlear scale of 1 cm suggested that HRCT would allow routine quantitative determination on interindividual differences in cochlear morphology.

In the current study we present data collected to answer two specific questions: Firstly, what are the variations in cochlear size that may be detected from routine HRCT? Secondly, how do variations in cochlear size influence the final maximum insertion depth angle achieved with cochlear implant electrode arrays? Insertion depth angle as defined by Xu et al. [2000] is thought to be a better reference for the position of cochlear implant electrodes than linear insertion depth since it removes the variation produced by the proximity of the array to the modiolus. It is important to have a good reference of the position of cochlear implant electrodes in order to predict, for example, the characteristic frequencies of neurons closest to individual electrodes [Xu et al., 2000; Ketten et al., 1998; Greenwood, 1990]. In addition, the desired position of the electrode may be defined in terms of angle; for example one full turn in order to better preserve low-frequency residual hearing [James et al., 2005; Fraysse et al., 2006; Skarzynski et al., 2003; Gstoettner et al., 2004]. In the case of the Nucleus 24 Contour Advance perimodiolar electrode array, insertion depth angles greater than about 400° appeared to result in poorer preservation of residual hearing [James et al., 2005; Fraysse et al., 2006].

Previous work by Adunka et al. [2005] describes one possible method to predict the final position of cochlear implant electrodes using HRCT. However, the method appeared time-consuming and required the drawing by hand of the path of an electrode array positioned against the lateral wall. In the current study we established a view of the basal turn of the cochlea and defined two measurements which could be routinely used to characterize the size of the cochlea and predict the final position of any electrode array, either for a 'straight' array which tends to follow the lateral wall or a perimodiolar array. In the latter case we aimed to empirically test the hypothesis that there is systematic variation in insertion depth angle versus cochlear size with the Nucleus 24 Contour Advance electrode array.

Methods

HRCT temporal bone data for 42 patients (23 female, 17 male; mean age 33.1 years, SD 22.1, range 0–74) who had been screened for cochlear anomaly were randomly selected from patients reporting with otologic disease. Data were collected for both ears.

HRCT data were collected with a Philips MX8000 system equipped with a 1024 × 1024 matrix detector. Helical slices were 0.65 mm deep, reconstructed every 0.3 mm with collimation at 2 × 0.6, and FOV 250; 140 kV 300 mAs exposure was used for adults, and 120 kV 250 mAs for children. This configuration gave approximately isotropic voxels of 0.25 × 0.25 × 0.3 mm resolution.

A view of the basal turn of the cochlea was developed as shown in figure 1. The aim was to view the lateral wall from the round window to one full turn (360°). The entire basal turn cannot be viewed using a single two-dimensional plane and thus a reconstruction was performed using a 1.0-mm layer, minimum intensity projection. This layer captures the extremity of the cochlear canal, either the scala tympani or scala vestibuli. The viewing angle was adjusted with the aid of the perpendicular sections (right side, fig. 1) to obtain a view which gave the largest area of dark pixels. In one view one can visualize the round window, oval window, basal turn of the cochlea, vestibule and the anterior branches of the lateral and superior semicircular canals.

The view developed allowed the largest distance from the round window, through the modiolar axis, to the lateral wall *A* and the perpendicular distance *B* to be measured as in figure 1. The complete procedure was repeated several times for four ears. The distances *A* and *B* obtained were always within 0.1–0.2 mm for the same ears; that is, within the voxel resolution of the images.

Similar preoperative HRCT data were available for 15 ears implanted with the Nucleus 24 Contour Advance electrode array as described by James et al. [2005]. Linear insertion depth was either 17 mm (n = 9), that is inserted up to the first silastic rib [James et al., 2005], or a 'complete' insertion of 19 mm (n = 6) up to the third rib. Postoperative 'cochlear view' X-rays for these patients were analyzed according to the method of Xu et al. [2000] to obtain the

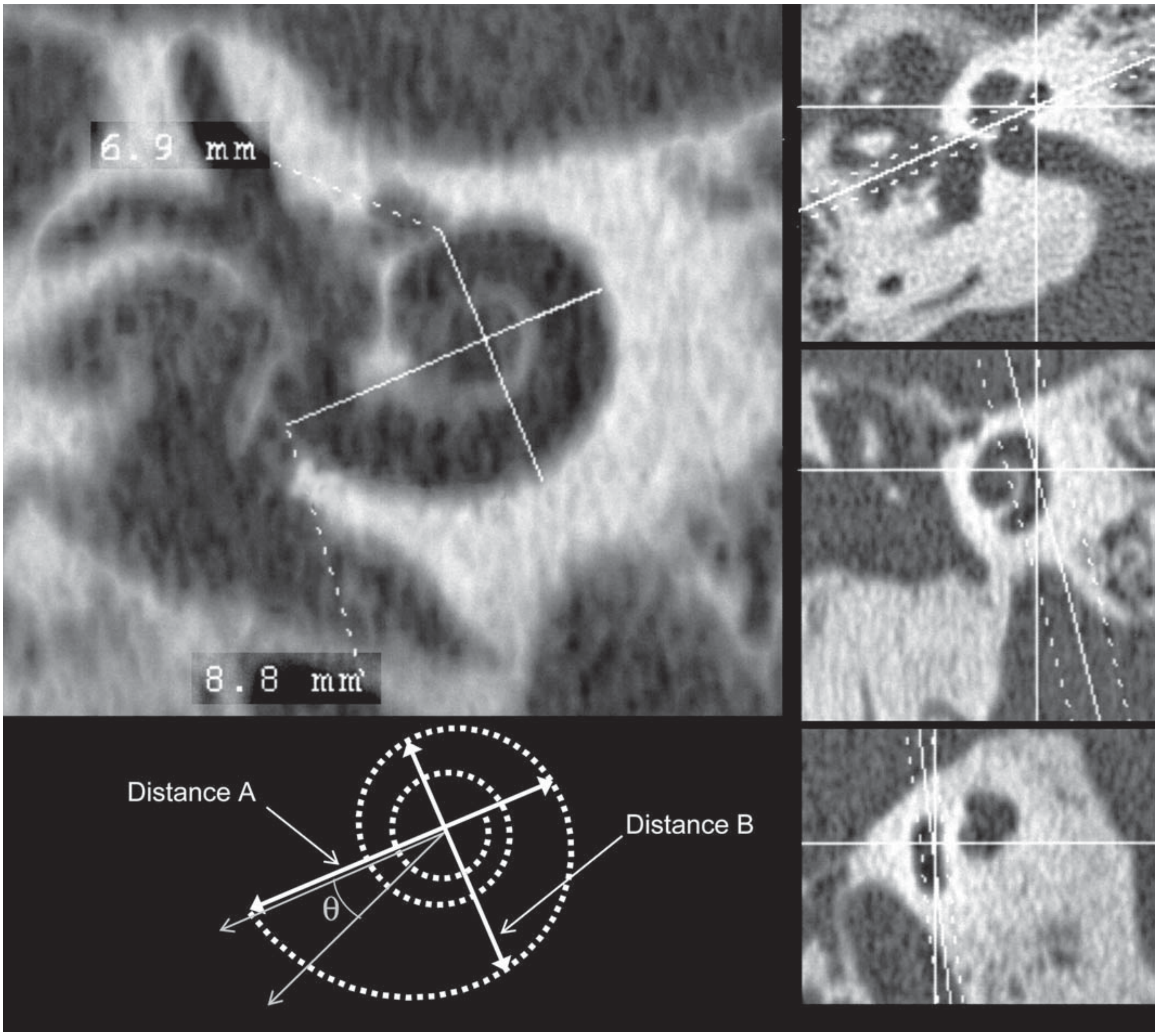

Fig. 1. Two-dimensional reconstruction from HRCT data of the basal turn of the cochlea using a 1.0-mm layer, minimum intensity projection. Distance *A*, here 8.8 mm, and perpendicular distance *B*, 6.9 mm, are measured using the scanner system. A schematic definition of distances *A* and *B*, spiral function equation 1 and insertion depth angle θ are also shown (lower inset).

insertion depth angles for individual electrodes. X-ray images were captured on a standard head X-ray system (Siemens) equipped with a digital capture plate, as suggested by Xu et al. [2000]. Care was taken to correctly visualize the superior semicircular canal, vestibule, electrode array and otic capsule [Dimopoulos and Murren, 1990].

Results

The mean difference between the two ears of individual subjects for the largest distance from round window to the lateral wall *(A)* was 0.23 mm (sig. > 0, $p < 0.001$). However, this difference was similar to the resolution of

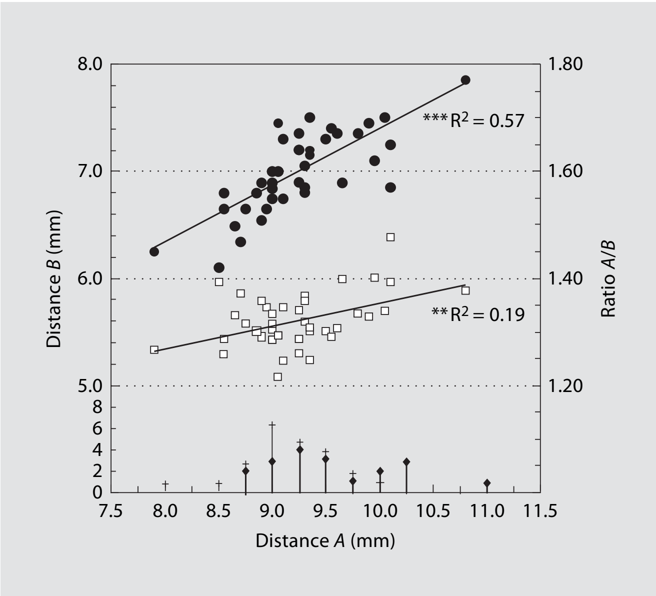

Fig. 2. Summary data for distances *A* and *B* measured for 42 individuals. Distance *B* is plotted against distance *A* (top, filled circles). Ratio *A/B* is plotted against distance *A* (middle, open squares). Significant linear correlations are shown (solid diagonal lines). Separate histograms of distance *A* are plotted for male and female ears (bottom, diamonds and crosses, respectively).

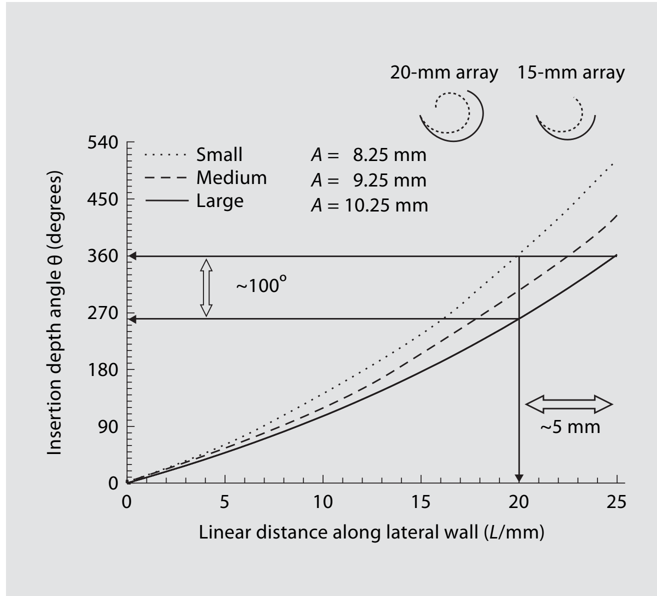

Fig. 3. Insertion depth angle versus distance along the lateral wall for small, medium and large cochleae. Inset (top right): scaled representations of the arc of the lateral wall as may be followed by 'straight' electrode arrays up to 20 and 15 mm, respectively, in small (dotted line) or large (solid line) cochleae.

the HRCT images (0.25–0.3 mm), and thus no inference could be made about real differences in cochlear size between the two ears. For the data analysis which followed, distances *A* and the perpendicular distance *B* (mean difference 0.22 mm) were averaged between ears for each individual.

A statistically significant mean difference was found between male and female ears for both distance *A* (9.43 vs. 9.05 mm, respectively, two-sample t, unequal variances $p < 0.05$) and distance *B* (7.15 vs. 6.86 mm, $p = 0.01$). No significant mean difference was found for the ratio *A/B* (mean 1.32), indicating no particular difference in morphology. A summary of the data for distances *A* and *B* is given in figure 2. The mean distance *A* was 9.23 mm (SD 0.53), and *B* 6.99 mm (SD 0.37).

There was a statistically significant correlation between distance *A* and distance *B* ($r^2 = 0.57$, $p < 0.001$), and between distance *A* and the ratio *A/B* ($r^2 = 0.19$, $p < 0.01$), where the ratio *A/B* tended to increase as *A* increased.

A spiral function (equation 1) was used to model the line tracing the outer wall or lateral wall of the cochlea. This single function provides a good fit to the path of the entire outer wall from base to apex without requiring multiple sections of simple or logarithmic spirals [Xu et al., 2000; Yoo et al., 2000].

$$r = A \times c/(\theta + \theta_c), \tag{1}$$

where r is the radial distance from the nominal centre of the modiolus to the outer wall, A is distance A and θ is the angle in radians from the round window as in figure 1. θ_c is a constant derived from the ratio A/B. For the purpose of good approximation, the mean ratio A/B = 1.32 gives a value $\theta_c \approx 4.1$ rad. c is a function of θ_c given by:

$$c = \theta_c(\theta_c + \pi)/(2\theta_c + \pi). \tag{2}$$

Substituting constants and applying calculus, the length L of the spiral arc for a particular angle θ expressed in degrees is approximated by:

$$L = 2.62\ A \times \log_e (1.0 + \theta/235) \tag{3}$$

Thus, the path length L of the lateral wall of the cochlea may be modeled using equation 3 for a given distance A and insertion depth angle θ (fig. 3). Figure 3 may be used to predict the insertion depth angle obtained for a 'straight' electrode which follows the outer wall of the scala tympani. In figure 3, the arc shapes for small (A = 8.25) and large (A = 10.25) cochleae are compared for lengths of arc 20 and 15 mm.

To test the hypothesis that insertion depth angle may be related to cochlear size, even for perimodiolar electrodes, data for 15 ears (14 patients) implanted with the Nucleus 24 Contour Advance perimodiolar electrode array were analyzed. Linear insertion depth was 19 mm for 6 cases, and 17 mm for 9 cases, where hearing preservation techniques were used in surgery as described in James et al. [2005] and Fraysse et al. [2006]. Distance A ranged from 8.35 to 9.95 mm. Analysis of postoperative 'cochlear view' X-rays showed a range of insertion depth angles between 330 and 495°. There was a statistically significant difference in mean insertion depth angles between the 17 and 19 mm groups (390 vs. 469°, two-sample t, unequal variances, $p < 0.01$). The insertion depth angle for the five most apical electrodes was measured from X-ray in 5 ears. This revealed an approximate relationship of 40–50°/mm for apical electrodes (when combined with the manufacturer's specifications of electrode spacing). This relationship and the mean difference in insertion depth angle found between the 17 and 19 mm groups were in agreement (i.e. ~80°).

A statistically significant negative correlation (r^2 = 0.51, $p < 0.05$) was found between insertion depth angle and distance A for the 17 mm group. This supports the hypothesis that for a perimodiolar array, such as the Nucleus 24 Contour Advance, cochlear size may influence insertion depth angle.

Discussion

The current investigation was designed to evaluate a method for the prediction of final insertion depth angle from standard preoperative high resolution CT data. The method described for defining the size of the basal turn was shown to be reliable at least to within the resolution of the HRCT scan. There was a strong correlation between the largest distance A from the round window to the lateral wall, and the perpendicular distance B. This coupled with the relatively modest variation in the ratio A/B suggests that to the first approximation distance A is sufficient for defining cochlear size.

The measurement of distances A and B appeared to be repeatable to within the voxel resolution of the HRCT. The authors would emphasize that an expert radiologist with great experience in the identification of both normal and abnormal cranial structures supervised the HRCT data collection, manipulated the image projection and made the measurements.

The variations in distances A and B obtained here from HRCT are similar to those obtained by Dimopoulos and Muren [1990] from 95 plastic castes for the 'transverse diameter' (SD 0.45 mm) and 'vertical height' (SD 0.35 mm). The slightly larger distances A (mean 9.23 vs. 8.68 mm) may reflect differences in locating the round window and the material. Although statistically significant, the mean difference in cochlear size found between male and female ears (~0.4 mm) remains much smaller than the overall variation in cochlear size of about 2.0 mm (95% CI).

The angle-to-length function equation 3 agrees well with anatomical measurements of the organ of Corti. For example, this equation gives 59% of the length of the organ of Corti as taken up by the basal turn, 30% for the second turn and 11% for the remainder, assuming 2.5–2.75 total turns. This is in good agreement with the histological data of Hardy [1938] with 58, 29 and 13%, respectively. Furthermore, from equation 3, variations in the predicted length would be directly proportional to variations in distance A. The range in distance A seen here was 2.9 mm, with a mean of 9.23 mm. This gives a 31% variation in total length which agrees well with the organ of Corti data of Hardy [1938] (range 10.0 mm, mean 31.5 mm). The authors also noted that the shape of the spiral function equation 1, with the θ_c = 4.1 (as derived here from the typical ratio A/B of 1.32), matched well with images of the scalae obtained in our laboratory either from fluid volume reconstruction based on MRI data (0.23-mm voxels) or from MicroCT images of temporal bones (0.1-mm voxels). This was not true for simple or logarithmic spirals.

The length of the lateral wall L, for a given insertion depth angle θ, may be calculated using equation 3 for a given distance A. The length L would be the longest path a 'straight' (e.g. not preformed) electrode may take. The actual insertion depth angle could be greater than this for a given 'linear' insertion depth since the array may take a straight path up until one half turn before first encountering the lateral wall on the far side of the basal turn. Contrariwise, any friction encountered at the distal end of the array will tend to push the array against the lateral wall at the basal turn and in the most extreme case, the array may start to 'kink' resulting in smaller than predicted insertion depth angles.

Figure 3 allows determination of the differences in linear insertion depth for a small, medium and large cochleae, defined by $A = 8.25$, 9.25 and 10.25 mm, respectively. It is important to note that the relative differences in linear insertion depth versus insertion depth angle will hold; for example, typically one would expect a range of 100° in insertion depth angles for a 20-mm electrode. Alternatively, a 15-mm electrode would be sufficient to obtain an insertion depth angle of 270° in a small cochlea, whereas a 20-mm electrode would be required in a large cochlea.

The data presented here for the perimodiolar Contour Advance electrode indicate that cochlear size may still influence final insertion depth angle despite a preformed shape. The insertion depth angles achieved for perimodiolar electrodes will be greater for the same linear insertion depth since the electrode array will tend to follow a tighter spiral, closer to the modiolus. For example, 17 mm was sufficient to reach about 390° for the perimodiolar electrode in average-sized cochleae ($A \approx 9.25$ mm) compared to about 25 mm for a 'straight' electrode following the lateral wall (fig. 3). At the apical end of the array, an increase of 1 mm in linear insertion depth gave about 45° increase in the insertion depth angle for the perimodiolar Contour Advance compared to about 25° increase for a 'straight' array modeled with equation 3 (fig. 3).

Two observations were noteworthy with respect to the insertion dynamics of the Contour Advance. The temporal bone trials reported in James et al. [2005] showed that linear insertion depths of more than 17 mm tended to result in the proximal part of the array being pushed away from the modiolus due to some friction at the apical end. Indeed, insertion depth angles for the 19 mm group studied here tended to saturate at about 500° for cochleae smaller than 9.5 mm. However, there was a significant linear relationship between insertion depth angle and cochlear size for the 17 mm group. Thus it appeared that in small cochleae attempts to increase insertion depth angle by increasing linear insertion depth to more than 17 mm were less effective than for larger cochleae.

One of the suggestions to improve conservation of residual hearing by the group led by Fraysse [James et al., 2005; Fraysse et al., 2006] is to limit insertion depth angles to about 400° for the Contour Advance. From the current data this was achieved with linear insertion depths of 17 mm only if distance A was greater than ~9.0 mm. The implication is that for smaller cochleae 16 mm should be sufficient to achieve insertion depth angles between 360 and 400°. It is important to note that these relationships will not hold for other types of perimodiolar electrode array in use; they will depend upon the precise dimensions and characteristics of the array as well as the method of introduction.

Conclusions

A view of the basal turn of the cochlea was developed which is easy to obtain from routine HRCT data. Measurement of the greatest distance between the round window and the lateral wall, distance A, is simple and repeatable and appears sufficient to define cochlear size. The normally formed cochlea varies by ~2.0 mm in distance A. By calculation this leads to >5.0 mm variation in the length of the lateral wall from 0 to 360°. This accounts for the large variation seen in insertion depth angles as observed from postoperative radiograms. The cochlear size measure described may be used to predict variations in final insertion depth angles for 'straight' electrode arrays using a simple mathematical function. Cochlear size can influence insertion depth angles for perimodiolar electrodes in that a significant negative correlation was found between insertion depth angle and distance A when using the Nucleus 24 Contour Advance perimodiolar electrode with a linear insertion depth of 17 mm. With this electrode it appears that linear insertion depth should be limited to 16 mm for cochlear sizes less than 9.0 mm to avoid exceeding an insertion depth angle of 400°.

Acknowledgement

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As CI technology improves, candidacy for implantation has become less restrictive such that individuals with severe hearing losses can be seen to benefit more from a CI than from conventional hearing aids (HAs). For severely hearing-impaired patients, an individual decision has to be made which ear to implant and whether a conventional HA may be used in combination with a CI [Dowell et al., 2004; Morera et al., 2005].

In 2005, the preliminary results of a prospective multicenter study investigating the preservation of residual hearing after implantation with a standard-length Nucleus Contour Advance perimodiolar electrode array have been reported [James et al., 2005]. The results indicate that insertion angles of >400° appeared to have greater risk of additional hearing loss at low frequencies (250–500 Hz). With a shorter insertion depth, some low frequency residual hearing could be preserved.

The benefits of a shorter electrode array with 10-mm length and 6 active contacts have been investigated with the Nucleus Hybrid CI [Gantz and Turner, 2003, 2004]. In a first group of 9 patients, the residual hearing at the low frequencies was preserved to within 10–15 dB. The potential shortcoming of the Hybrid device is that the array is limited to 6 active channels created in the straight part of the basal turn. This may be problematic once the hearing loss progresses and the CI would have to be replaced with a longer array.

In order to further investigate the optimal combination of electrode length, number of channels and hearing preservation, a new electrode array has been developed by the senior author (T.L.) together with Cochlear Ltd.

The aim of this first study was to evaluate the insertion safety in a temporal bone trial and the preservation of residual hearing after implantation with the new EAS electrode in a clinical trial.

Material and Methods

Device Description

The Nucleus Hybrid-L Cochlear Implant System is based on the Nucleus Freedom CI. The newly designed straight Hybrid-L electrode (fig. 1) was designed to reduce trauma to intracochlear structures and improve the rate of hearing preservation. It is shorter and smaller in diameter (0.35 × 0.25 mm at the tip) compared to a standard Contour electrode, but also has 22 half band ring electrode contacts spread over a length of 15 mm. The electrode lead wires are smaller in diameter (20 μm compared to 25 μm) to reduce the stiffness and increase flexibility. A stop point at 16 mm avoids overinsertion. A silicon wing was added to improve handling and to avoid rotation of the electrode after insertion so that electrode contacts face towards the modiolus. The electrode tip is profiled to guide the insertion. The use of half band ring electrodes allows a smooth outer (lateral) surface of the electrode to reduce friction.

Surgical Procedure

The basic surgical procedure is the same as for the standard Nucleus CI [Lenarz et al., 2004]. However, in contrast to other Nucleus straight and Contour electrodes, this device is inserted through the round window approach. The round window membrane is exposed by removal of the bony overhang. A straight incision is then made with a 22-gauge hypodermic needle (fig. 2a) that has a diameter which exactly fits to that of the electrode. The

Fig. 1. Design of the Hybrid-L electrode. A straight electrode with 22 half band ring contacts distributed over 15 mm. A positive stop at 16 mm intended to reduce the risk of overinsertion trauma. A silicone wing is attached for easy and safe handling, and to identify electrode orientation. The tip is profiled to guide insertion and reduce friction.

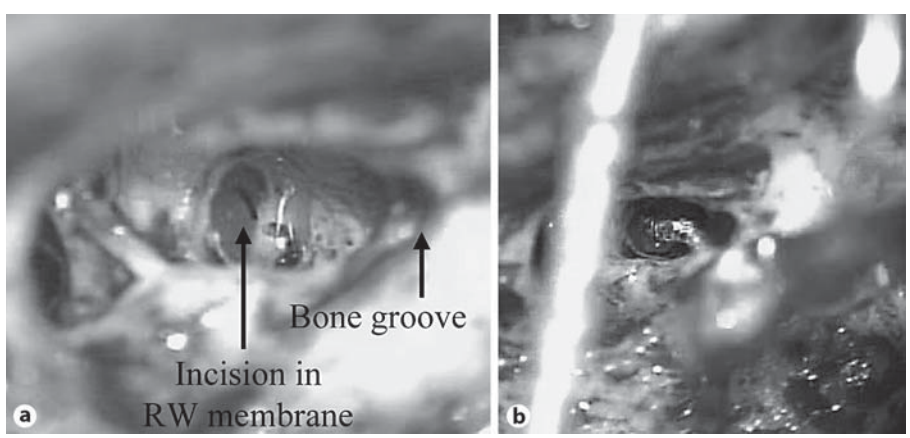

Fig. 2. a Intraoperative view on the round window showing the opening made with the hypodermic needle and the groove at the lower rim of the posterior tympanotomy for fixation of the electrode. **b** Insertion of the electrode array.

Table 1. Inclusion criteria

	Ear to be implanted		Contralateral ear	
	lower limit	upper limit	lower limit	upper limit
Pure tone thresholds				
≤ 500 Hz	No	60 dB	No	No
750–1500 Hz	No	No	No	No
≥ 2000 Hz	80 dB	No	No	No
Monosyllabic word scores (aided)	≥ 10%	≤ 60%	No	≤ 80%

electrode is grasped at the wing with a special forceps designed by the senior author (Storz company) and inserted under direct vision up to the stop point. Steroids (cortisone 500 mg i.v.) are administered intraoperatively. The expected benefit of this approach is a reduction of risks associated with the normal cochleostomy (drilling, removal of bone dust, mechanical trauma and suction of perilymph). It also guarantees a proper positioning of the array in the scala tympani. The silastic wing is fixed into a bone groove at the lower rim of the posterior tympanotomy (fig. 2).

Temporal Bone Insertion Study

The electrode was inserted in 22 temporal bones to evaluate the insertion characteristics and the risk of trauma to intracochlear structures. This was the basis to decide for the start of a human clinical study. Four of the 22 electrodes were prototypes without the positive stop but with the same characteristics as described above. These four electrodes have been inserted up to the last electrode contact.

Two surgeons performed 10 temporal bone insertions (4 without stopper) at the Medizinische Hochschule Hannover (MHH) and 12 at the University of Melbourne (UM) [see Briggs et al., this issue, pp. 42–48].

Fresh frozen human temporal bones were prepared and the surgical procedure was performed as described above. Afterwards, the bones were embedded in resin and sectioned parallel to the modiolus axis with the electrode in place. Serial cuts were made perpendicular to the electrode spiral. Each cross-section was photographed to document the position of the electrode relative to the walls of the cochlea [Stöver et al., 2005].

Clinical Evaluation

After the temporal bone insertion study, the clinical trial started first at the MHH and later at the UM. The objectives of the clinical trial are:

- To evaluate the preservation of residual hearing over time in severely hearing-impaired subjects implanted with the Nucleus Hybrid-L System.
- To determine whether speech understanding can be enhanced by combined electrical and acoustical stimulation while maintaining preoperative levels of acoustic hearing.

A total of 20 patients are planned who fulfill the selection criteria summarized in table 1. There are no audiometric restrictions for the contralateral ear.

All recipients are implanted with a Nucleus Freedom Hybrid-L implant. The patients are then fitted with an ITE HA only for frequencies with useful residual hearing (threshold <80 dB). The CI should cover the remaining frequency range. The frequency to electrode allocation is adapted to the residual hearing. The first (lowest) frequency channel not covered by the HA is mapped to the most apical electrode of the Hybrid-L implant. Channels below this cut-off channel are not transmitted by the CI.

A single subject repeated measures design is being used. Measured are unaided pure tone thresholds and speech performance using different modes of electroacoustic stimulation. Speech recognition is tested using the Freiburg Monosyllabic Word test in quiet at 65 dB, the HSM sentence test in noise with a fixed signal-to-noise ratio of +10 dB and the Oldenburg sentence test (OLSA) in noise (adaptive with noise fixed at 65 dB).

This study is conducted in accordance with ISO 14155 (International Standard for Clinical Investigation of Medical Devices) and follows the GCP guidelines. Medical Ethics Committee written approval and competent authority approval according to national laws have been granted before the start of the study.

Results

Temporal Bone Insertion Study

Minimal or no resistance was observed during insertion of the electrodes. A full insertion depth could be achieved with a single stroke insertion without buckling in the proximal region, which might occur with other straight electrodes (fig. 3c).

Temporal bone analysis showed no or less damage to cochlea structures compared to insertion of other Nucleus electrodes (fig. 3a, b). The electrode carrier was adequately positioned in the scala tympani under the basilar membrane with modiolus facing electrode contacts. No sign of damage to intracochlear structures was observed in 21 (95.5%) of the temporal bones. There were no cases of basilar membrane perforation [Briggs et al., this issue, pp. 42–48]. Specific findings were found in 2 cases; with a tip fold-over without damage to the cochlear structures in the 1st case and with slight damage to the lateral wall of the scala tympani in the 2nd case.

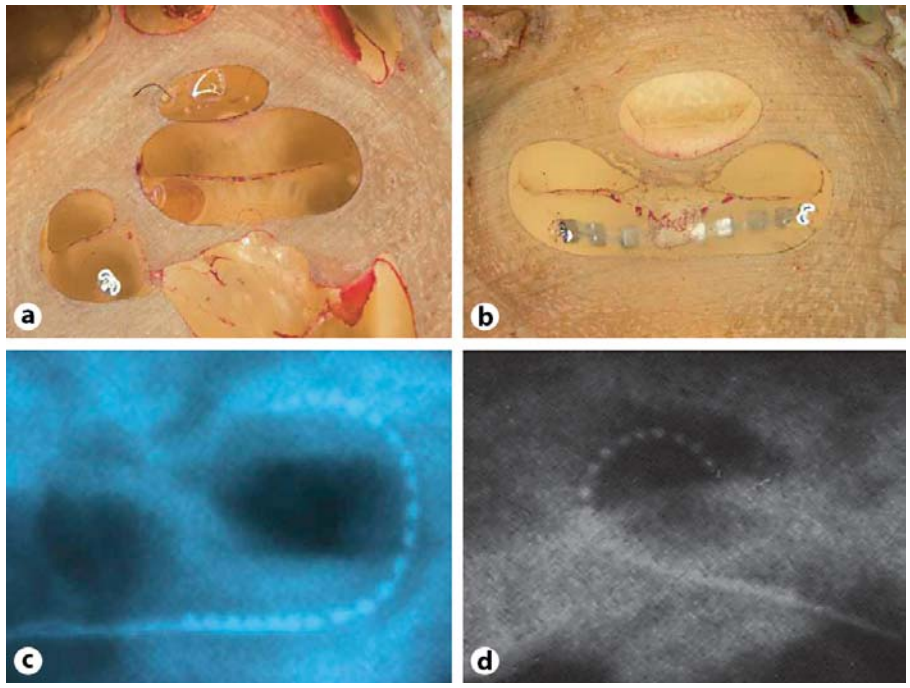

Fig. 3. Evaluation of the final electrode position. **a**, **b** Histological evaluation of a typical temporal bone insertion. X-ray of the electrode inserted into a temporal bone (**c**) and from the first human implantation in patient P1 (**d**).

Surgical Technique

Four patients have been implanted with the new device so far. The surgery was uneventful in all 4 cases. The round window membrane could be completely exposed by removing the bone overhang. The wing of the electrode could be easily squeezed into the bone groove, drilled at the inferior part of the posterior tympanotomy (0.6 mm) and helped to fix the electrode and avoid rotation of the array. The round window membrane could be easily incised with a 22-gauge needle. Its diameter was nearly equivalent to the size of the electrode. This allowed a proper closure of the opening by the inserted electrode (diameter 0.6 mm). The use of a specially designed angled forceps allowed a precise positioning, rotational and direction control and a single stroke one-handed insertion of the electrode. An additional connective tissue collar attached to the stop sign of the electrode helped to close the round window membrane. Postoperative X-ray revealed a proper intracochlear position with an estimated overall length of 240° (fig. 3d).

The electrode impedances were within the expected range and comparable to the impedances of standard CI electrodes. Electrical evoked stapedius reflex and NRT thresholds did slightly increase towards the basal electrodes reflecting the larger distance from the modiolus.

Clinical Evaluation

An initial air-bone gap of up to 40 dB was observed in 2 patients immediately after surgery but closed over the followings weeks. Bone conduction thresholds remained unchanged or showed only minor additional loss. A maximum loss of 35 dB was found at 1500 Hz for one recipient. However, in this recipient the air-bone gap has not recovered completely, but the patent is only 5 weeks after operation. The pre- and postoperative air conduction thresholds have been analyzed according to the procedures used by James et al. [2005]. A summary of the results is shown in figure 4. The average loss was 10.75 dB in the frequency range 250–1000 Hz and the median was 10 dB. Figure 4e shows the median loss for single frequencies and according results for the Contour electrode [James et al., 2005]. Only 1 of the recipients had measurable postoperative thresholds for frequencies above 1000 Hz. The values for not measurable thresholds have been set to 115 dB [see James et al., 2005]. Three patients already had no threshold or threshold at the audiometer limits preoperatively. Therefore, the median loss for frequencies above 1000 Hz may be underestimated. Postoperative fitting revealed normal pitch scaling with a regular electrode order. Using only the CI the patient complained about a high-pitched sound. After the switch on of the HA, he adapted quick-

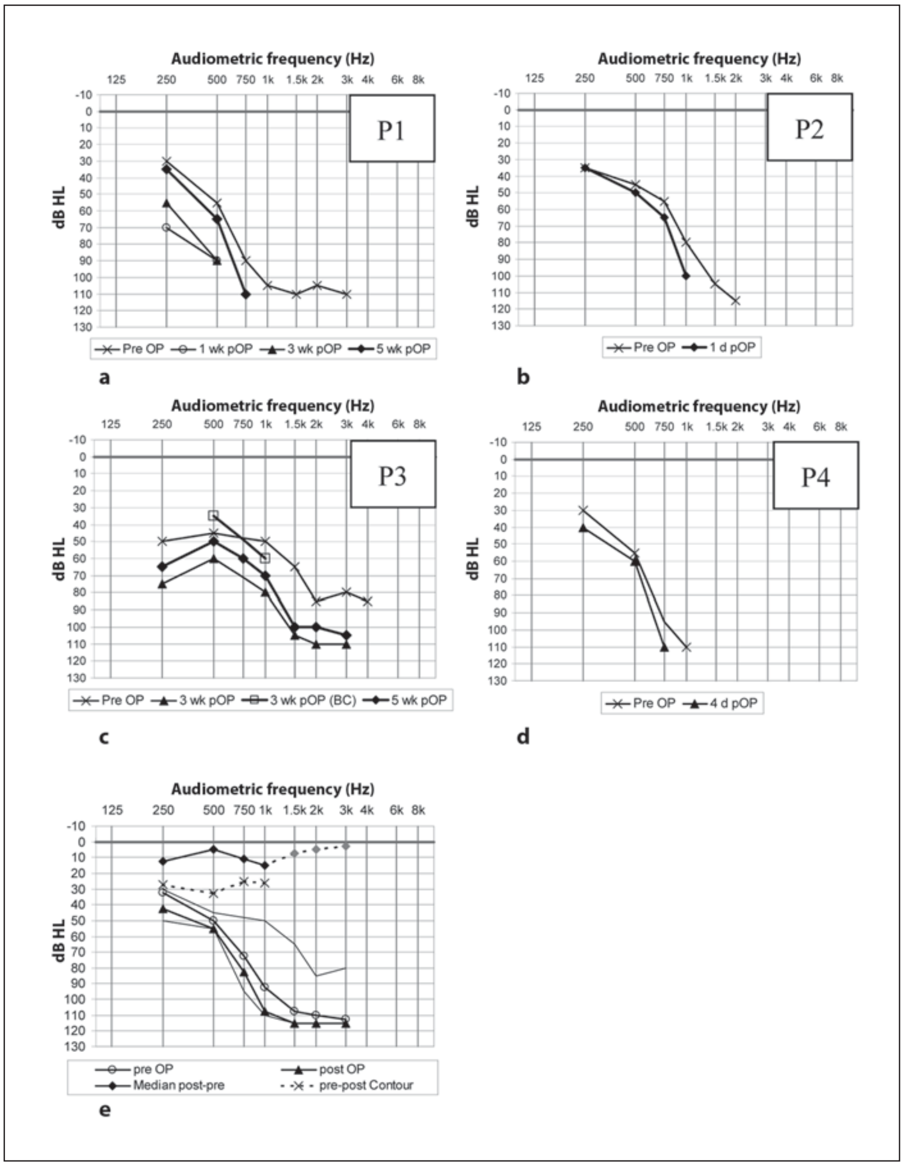

Fig. 4. Pure tone thresholds in the implanted ear. **a–d** Individual results at different stages during the trial due to sequential enrolment. The graphs demonstrate the preservation of the residual hearing for the first recipients implanted at the MHH (P1, P3, P4) and at the UM (P2). The air-bone gap in P3 has not yet fully recovered. **e** Preliminary group results for the median of pre- and postoperative thresholds are plotted together with the minimum and maximum thresholds (lines without markers). The median loss per frequency is shown in comparison to the results with the Contour electrode [James et al., 2005]. Values for frequencies above 1000 Hz are greyed out since they do not represent the complete group (see text).

ly to the full range of frequencies and pitches. An example of aided thresholds for wobble tones measured in the free sound field for the CI alone, the ipsilateral HA alone and the combination of both is shown in figure 5.

Speech recognition tests of the first patient 1 month after initial fitting showed a clear benefit of the combined condition (CI + both HA) compared to the preoperative situation. Postoperatively, the patient showed speech understanding with the CI alone of 40% monosyllables, 62.3% for the HSM sentence test in noise and 0.7 dB for the OLSA in noise. In the electroacoustic Hybrid condition (CI + ipsilateral HA), a further improvement of 27.5% for Freiburg Monosyllables and 0.65 dB for the OLSA was achieved.

Bilateral hearing (combined mode) using the HA on the nonimplanted ear showed an additional improvement over the Hybrid condition of 13.3% for the HSM and 3 dB for the OLSA (fig. 6). The overall improvement in speech recognition for the best aided condition postoperatively compared to preoperatively was 34.9% for the HSM sentence test and 4.3 dB for the OLSA. The speech scores also demonstrate a preservation of functional hearing.

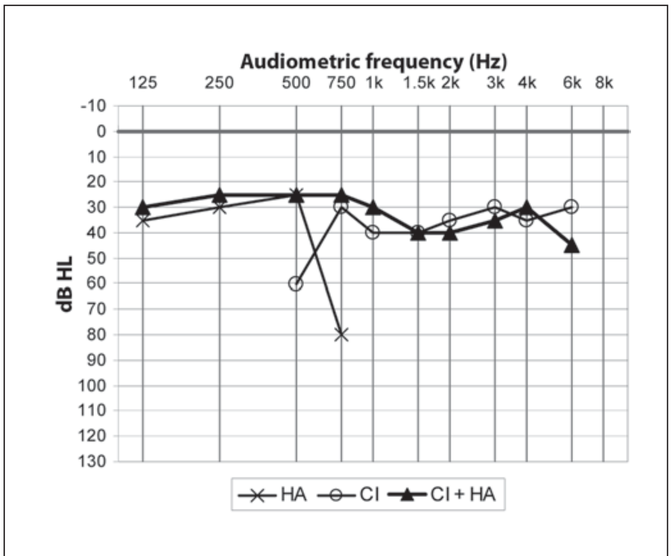

Fig. 5. Example of the aided threshold for warble tones, measured in the free sound field for the HA alone, the CI alone and the combination of both devices in the implanted ear. The threshold profiles demonstrate the turnover between HA and CI.

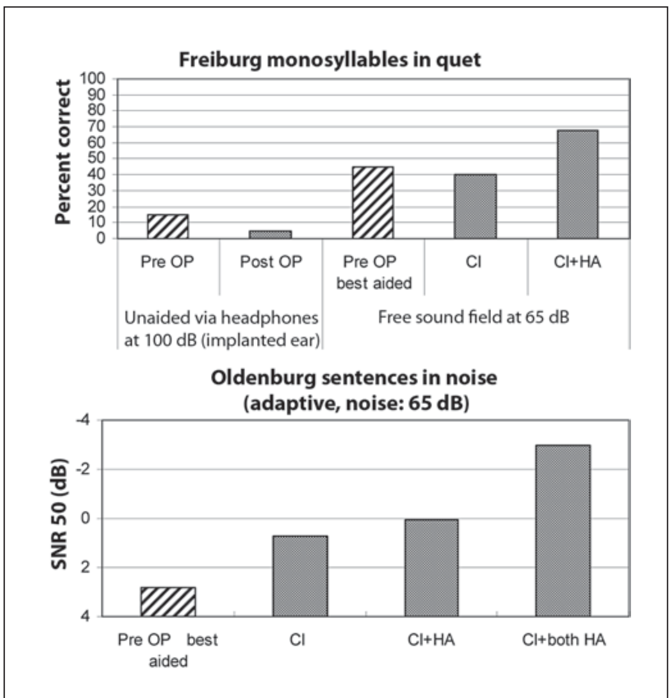

Fig. 6. Speech test results for recipient P1 at 1 month after initial fitting. The graphs show a clear improvement for speech recognition in quiet and in noise for the electroacoustic condition (CI + HA) and the combined mode (CI + both HA) over the preoperative situation with HA.

Discussion

Preservation of residual hearing in cochlear implantation has been prepared already by Lehnhardt [1993], proclaiming the soft surgery technique. Results were reported by Ruh et al. [1997]. It has become a clinically relevant issue recently when criteria for CI candidacy have been widened to patients with serviceable residual low-frequency hearing. These patients can show additional benefit from electroacoustic stimulation [von Ilberg et al., 1999; Gstöttner et al., 2004; Gantz et al., 2005]. However, this concept can be only recommended if hearing preservation is achievable with a high probability, which should be in same range as for stapedotomy (>95%). This concept requires a minimized insertion trauma and tissue reaction [Choi and Oghalai, 2005]. Several electrode concepts have been developed to achieve this goal. While Gstöttner et al. [2004] and Adunka et al. [2004] propose a thin and shorter version of a routine CI electrode with an insertion length of 20 mm, Gantz et al. [2005] have proposed a short electrode of 10 mm and carrying only 6 active electrode contacts. Pau et al. [2005] published the concept of an endosteal electrode placed between the outer wall of the cochlear and the endosteum to avoid any opening of the perilymph space. So far no clinical data are available from this concept.

While a short electrode can provide a high probability of hearing preservation, the benefit is clearly limited in patients with mid-frequency hearing loss due to the reduced insertion depth and the small number of electrode contacts. In addition, the benefit can be further reduced with progression of hearing loss.

Therefore, an optimized electrode was designed to combine the audiological advantages of a medium-length electrode array and the proven safety of a short array. It also should provide the full range of stimulation properties as with a regular CI system. The concept is based on the clinical observation that patients with straight electrodes had no significant performance reduction with different insertion depth provided that the number of active inserted electrodes was more than 15 [Hartrampf et al., 1995; Khan et al., 2005]. Several temporal bone studies have shown that the risk of damage to intracochlear structures is increased markedly with an insertion depth of more than 240° (equivalent to more than half of the basal turn) or with an insertion into the scala vestibuli [Adunka et al., 2005]. The current Hybrid-L electrode was designed to respect all these issues. Its overall insertion length of 16 mm with 22 active electrode contacts avoids overinsertion and reduces the insertion trauma significantly. Its tapered shape and the small diameter allow for a round window insertion and a proper placement in the scala tympani without buckling, as described in our studies and those by Briggs et al. [this issue, pp. 42–48]. No single case of basilar membrane perforation was found. The tip fold-over in 1 case could be related to over-insertion.

The advantages of this design were confirmed in the clinical study. The insertion was successful in all 4 cases with a proper placement in the scala tympani. Thinner electrode wires, half band ring contacts and a thinner diameter resulted in an increased flexibility and modiolus-orientated location compared to the straight electrode. The silicon wing helped to stabilize the position of the electrode and prevented a postinsertion rotation so that the electrode contacts were oriented towards the modiolus. The surgical results showed that the round window insertion is a reliable approach that allows the surgeon to control the whole process of insertion. Compared to the cochleostomy approach no bone drilling over the endosteum and removal of bone dust was necessary. Both might be dangerous due to impaired vision and accidentally opened perilymph space [Briggs et al., 2005].

Postoperative hearing preservation supports the validity of this electrode design.

The preliminary results for hearing preservation achieved in the present study (median postoperative hearing loss of 12.5 dB at 250 Hz and 5 dB at 500 Hz) appear to be more favorable than those achieved with longer electrodes. For example, Kiefer et al. [2004] reported 15 dB at 250 Hz and 17.5 dB at 500 Hz and James et al. [2005] found 27 and 33 dB, respectively. The results with the Hybrid-L are comparable to the hearing preservation of within 10–15 dB for the 6- and 10-mm short electrodes [Gantz and Turner, 2003]. However, the full range of 22 electrodes offers improved flexibility and lower risk of performance decrease due to long-term progression of the hearing loss.

Although an initial air-bone gap was found, this resolved over the following weeks. The conductive component can be explained by either fluid accumulation in the middle ear or changed properties of the round window and new tissue formation in the scala tympani. All three would lead to mechanical damping.

The auditory performance was significantly improved on the implanted ear using the combined electroacoustic stimulation. This was more efficient than either electrical or acoustic stimulation alone. These results support the concept of electroacoustic stimulation and hearing preservation even in patients with a serviceable residual low-frequency hearing. A larger number of patients is needed to draw definite conclusions.

The ongoing study will also help to define the selection criteria for this approach of hearing preservation. Due to the insertion depth and considering the Greenwood equation [Greenwood, 1961], the electrode shall cover the frequency range above 2 kHz. Therefore, patients with serviceable residual hearing in the lower frequencies should be suitable.

Conclusion

The Hybrid-L electrode is a newly designed medium-length, thin and autraumatic electrode for hearing preservation. It can be used for round window insertion, which allows full control on the insertion process. The results of temporal bone studies confirm the advantages and minimum damage to inner ear structures. First clinical results revealed the potential for hearing preservation and improved auditory performance using the electroacoustic stimulation mode provided an adequate surgical technique is used.

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Introduction

The improved performance of cochlear implant recipients in terms of hearing outcomes has resulted in an expansion of the selection criteria for cochlear implant candidates. Hence there are increasing numbers of candidates, with significant residual hearing particularly in the lower frequencies up to 1.5 and 2 kHz. A number of recent studies have demonstrated that cochlear implantation is possible using standard long electrode arrays with partial or complete preservation of the residual hearing being achieved [von Ilberg et al., 1999; Gstoettner et al., 2004, 2005; James et al., 2005; Neumann et al., 2005; Kiefer et al., 2004; Skarzynski et al., 2002]. This clearly indicates absence of intracochlear trauma despite electrode insertion via a scala tympani cochleostomy. Studies have also demonstrated that the combined use of acoustic stimulation of the low-frequency hearing via a hearing aid together with electric stimulation of the higher frequencies can provide better sound perception in some patients than electric stimulation alone [Gstoettner et al., 2005; James et al., 2005; Gantz et al., 2005].

Although Gantz et al. [2005] have demonstrated successful hearing preservation and combined electric and acoustic stimulation using a short (10-mm) electrode array, this short electrode array has the potential disadvantage of a mismatch between place of stimulation and perceived pitch of auditory percept. Although the electrodes on the array would be assigned to frequencies complementing the subject's acoustic deficiencies, the short length of the electrode and the resulting stimulation only in the lower basal turn may result in a higher pitch than would normally be perceived acoustically for the input frequencies assigned to those electrodes [Blamey et al., 1996; James et al., 2001]. Whilst a degree of central compensation for place/pitch mismatch may occur, previous studies have shown a strong interaction between the optimal frequency-place mapping, electrode insertion depth and speech recognition [Baskent and Shannon, 2005]. Following cochlear implantation there is always the potential for loss of residual hearing either due to the surgical procedure or due to progression of the underlying pathology. Therefore there is a potential benefit in having a longer electrode array with multiple electrodes within the cochlea that would allow for programming flexibility and pitch matching similar to that used with current electrode arrays.

Previous studies of the Nucleus straight banded electrode demonstrated that it was not suitable for hearing preservation procedures. Initial clinical experience with the straight banded array showed increased resistance with the round window membrane (RWM) route of insertion and associated reduced insertion depth [Webb et al., 1988]. To overcome this, the technique of scala tympani cochleostomy and removal of the crista fenestra was developed to facilitate greater insertion depth. However, depth of insertion is still limited and intracochlear trauma can occur when the electrode bands of the straight array contact the lateral wall of the scala tympani, spiral ligament and under-surface of the basilar membrane. The Contour Advance electrode array, which has half-band electrodes and a smooth lateral electrode surface, can be placed without significant intracochlear trauma [Tykocinski et al., 2001], and successful hearing preservation has been achieved when an 'advance-off-stylet' insertion technique is used [James et al., 2005]. Due to the large diameter of the electrode array (0.8 mm) a large cochleostomy is required. There is also increased potential for introduction of bone dust and blood into the basal turn of scala tympani and risk of perilymph leakage around the electrode array at the cochleostomy. Previous temporal bone studies have demonstrated that drilling a cochleostomy has the potential to damage adjacent basal turn structures [Dahm et al., 2000; Briggs et al., 2001]. This problem can be avoided by careful placement of the cochleostomy inferior rather than anterior to the RWM [Briggs et al., 2005].

A prototype electrode has been developed for potential hearing preservation cochlear implantation (fig. 1). While the electrode array is thin and flexible, it preserves torsional stability well and is designed to allow approximately 250° insertion of multiple electrodes. The array has 22 electrodes uniquely spaced over a 16-mm length (A), with a smooth outer surface and modiolar facing electrodes on the inner surface. The thin cross-section (proximal diameter of 0.55 × 0.40 mm tapering to a distal diameter of 0.35 × 0.25 mm) provides flexibility, whilst an oval cross-section provides torsional stability. A platinum stiffener (B) embedded in the proximal region reduces buckling effects. A silicone wing (C) aids handling and also identifies electrode orientation, with a silicone collar (D) providing a positive stop ensuring the electrode cannot be overinserted. The electrode is suitable for insertion either via a small cochleostomy (0.6–1.0 mm) or through the RWM, with a platinum band (E) adjacent to the collar aiming to promote tissue growth to assist in sealing.

The aim of this study was to assess the surgical handling characteristics of the electrode, both as RWM and cochleostomy insertion, to study the trajectory of inser-

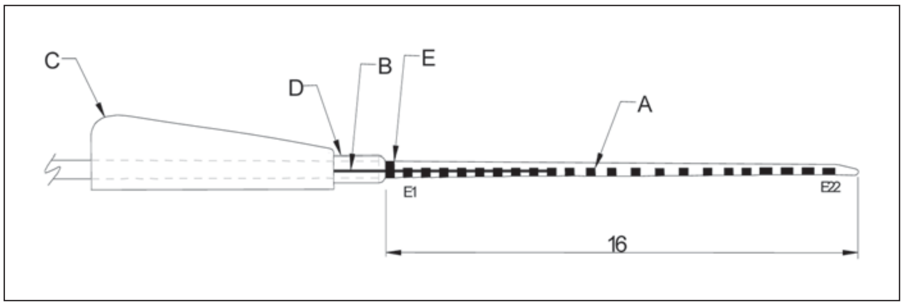


Fig. 1. Schematic diagram of prototype electrode. For more details see text.

tion within the cochlea and then to examine for the presence of intracochlear trauma using previously established histologic sectioning techniques.

Materials and Methods

Temporal bone safety studies were performed concurrently at the University of Melbourne and Medizinische Hochschule Hannover. Eighteen fresh frozen human temporal bones were thawed and prepared for cochlear implantation using a standard transmastoid facial recess surgical technique. In each specimen the RWM was exposed. This was achieved by a complete facial recess dissection with skeletonization of the chorda tympani and facial nerve. Initially, the round window niche was identified; the lateral bony overhang of sinus tympani was removed anterior to the facial nerve and inferior to the pyramid to allow clear visualization of the round window niche. The bony lip of the niche was drilled with a 1-mm diamond burr to fully expose the RWM. In the majority of specimens a mucosal fold or false membrane was present and was removed from the niche to expose the true membrane.

In 6 specimens a scala tympani cochleostomy measuring approximately 1 mm was created immediately inferior to the RWM. Care was taken to avoid bone dust entering the basal turn.

To examine the trajectory of insertion, electrode insertions in Melbourne were performed under fluoroscopic control with video recording of both the microsurgical procedure and the fluoroscopic image. For the RWM insertions an initial vertical incision was made in the inferior aspect of the membrane using a 21 gauge hypodermic needle. For all electrode insertions the electrode was held by the proximal flange wing using standard jeweller's forceps.

Following electrode insertion the temporal bone specimen was rotated in the X-ray beam to allow fluoroscopic examination parallel to the basal turn to confirm scala tympani position of the array. An additional high-resolution X-ray was taken perpendicular to the cochlea to measure insertion depth in degrees around the modiolus. The electrode array was then secured by application of histoacryl glue to the proximal electrode cable at the facial recess level.

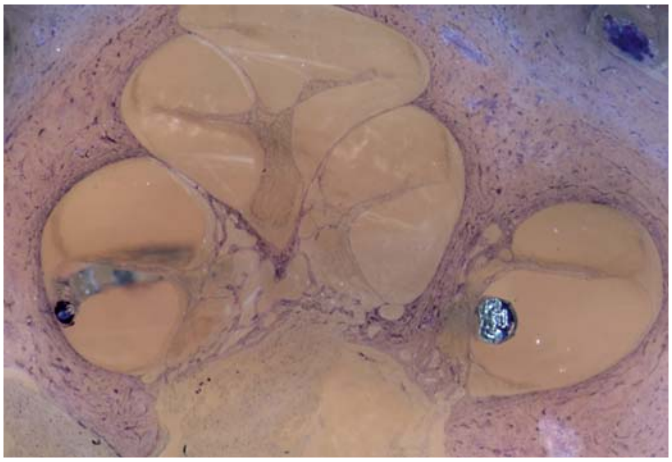
In each bone the stapes foot plate was removed to allow perfusion of the fixative, dehydrating solutions and the acrylic resin throughout the cochlea. The specimens were then fixed in 10% formalin, dehydrated in ethanol using serial concentrations progressing from 70 to 100% and immersed in degassed epoxy resin to achieve acrylic fixation. Vacuum is applied so that the epoxy mixture infiltrates the cochlea completely.

After embedding the specimens were X-rayed to assess the correct plane for sectioning. Excess portions of the temporal bone specimens within the epoxy blocks were trimmed to leave only the cochleae. After appropriate orientation the resized blocks were re-embedded such that the cochlear central axis was oriented parallel to the plane of sectioning, which is perpendicular to the electrode array.

The cochlear specimens were then serially sectioned using a grinding technique with a section thickness of 200 μm. For each section examined the specimen was polished and stained with toluidine blue and light microscopy and photography performed. In some specimens serial sectioning was performed through the entire cochlea, in which case the ascending basal turn was examined in the same plane as the initial reference plane. In other specimens, after the modiolar section was passed, the remaining specimen was rotated 90° and the specimen further sectioned perpendicular to the ascending basal turn.

Results

In all but one specimen a full electrode insertion was achieved with the surgeons noting minimal or no significant resistance. In one cochleostomy specimen, after initial full insertion, the electrode sprang back a few millimeters but subsequently remained in position when the array was pushed back to its previous insertion level. In one RWM insertion there appeared to be initial resistance at the RWM, possibly because the membrane incision was too small. Fluoroscopic analysis demonstrated that with the RWM insertions, the electrode does contact the modiolus in the proximal basal turn before the tip of the electrode contacts the lateral scala wall, after which the distal electrode maintains a lateral wall position around the ascending basal turn. These findings were confirmed on histologic analysis (fig. 2). In the cochleostomy specimens the electrode passes in a mid- or lateral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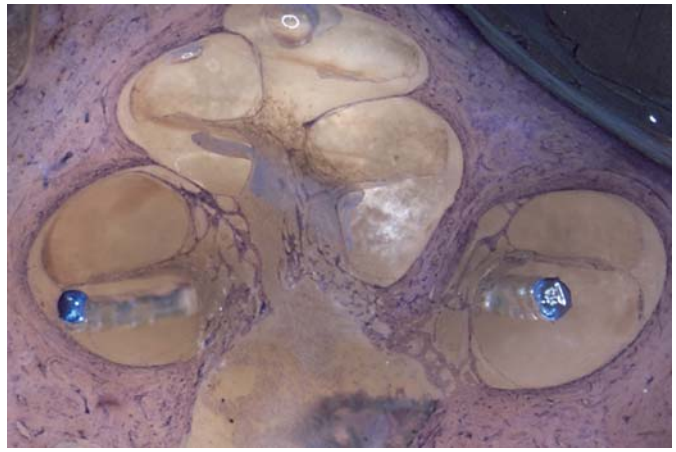
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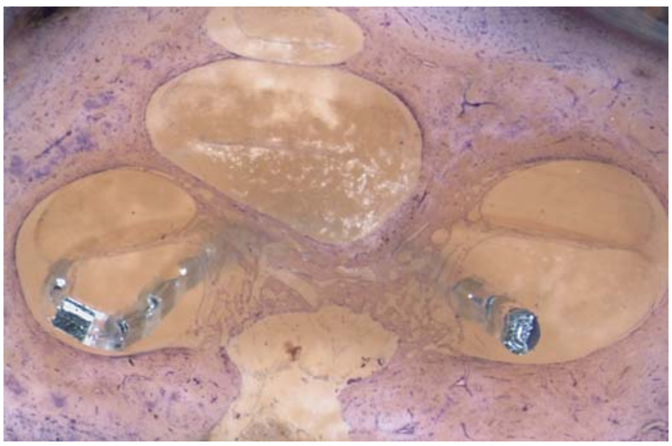
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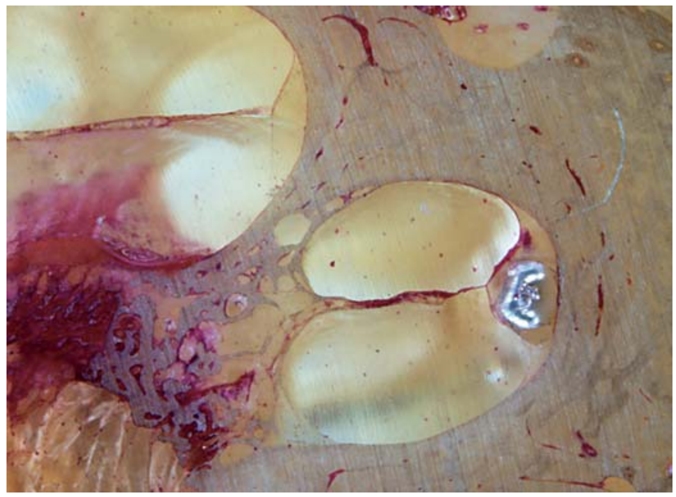
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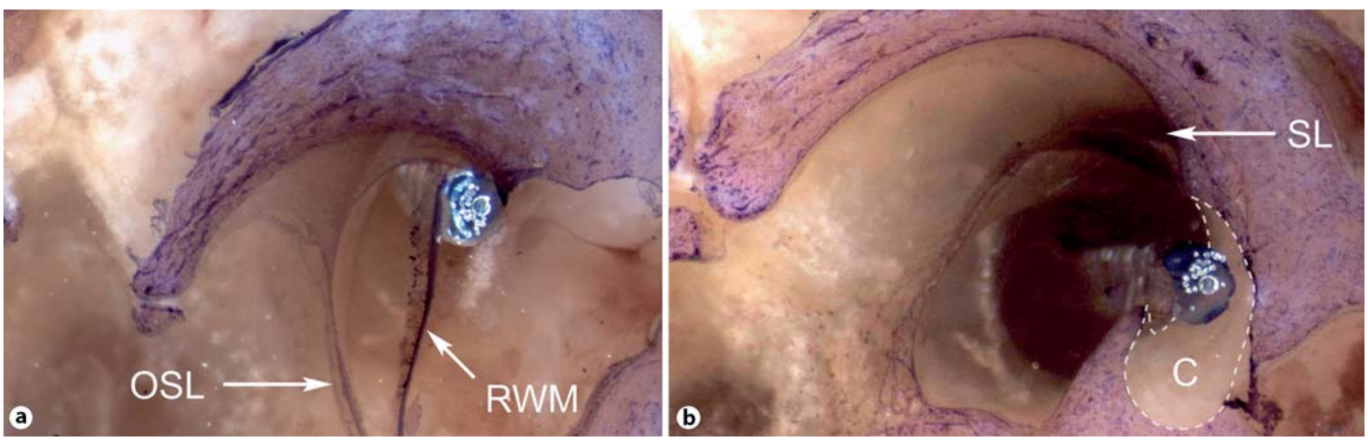

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Fig. 2. Round window insertion electrode position. Note the perimodiolar electrode location in the proximal basal turn.
Fig. 3. Cochleostomy insertion electrode postion. Note the midscala tympani location in the proximal basal turn.
Fig. 4. Electrode tip fold-over. Note intact basilar membrane.

Fig. 5. Section showing electrode lying in subendosteal position lateral to spiral ligament.
Fig. 6. a Electrode at RWM. Note the vertical alignment of the delicate osseous spiral lamina (OSL) and its proximity to the RWM. **b** Electrode at cochleostomy. Note the proximity of the cochleostomy (dashed line – C) to the spiral ligament (SL, arrow).

scala tympani position until contact with the lateral wall occurs in the ascending basal turn (fig. 3).

Fold-over of the distal electrode tip occurred in two RWM specimens. In one of these specimens, fluoroscopy demonstrated that the electrode tip was slightly curved laterally. Therefore, the electrode deflected more significantly from the modiolus, resulting in the electrode tip contacting the lateral scala wall at a greater angle causing the tip to fold over. Full insertion of both electrode arrays was still achieved without the surgeons feeling significant resistance. The electrodes remained within the scala tympani, and despite the tip fold-over there was no evidence of intracochlear damage particularly to the basilar membrane or spiral ligament on histologic examination (fig. 4).

In one specimen the electrode was found to penetrate the spiral ligament at the point of contact with the lateral scala wall and then to lie in a subendosteal position beneath the spiral ligament lateral to the basilar membrane and scala media (fig. 5). Possibly this occurrence was predisposed because the freezing and thawing of the specimens tends to result in delamination of the spiral ligament attachment. Certainly, further delamination can occur with the fixation and acrylic embedding process.

The final intracochlear electrode position was different between the RWM and cochleostomy groups. In the RWM group the proximal electrode is held closer to the modiolus along the basal turn by the crista fenestra at the inferior aspect of the round window. In the ascending basal turn the apical half of the electrodes were all in a lateral wall position regardless of the site of insertion. Because the cochleostomies were made immediately inferior to the crista fenestra, electrodes inserted via a cochleostomy all had a more lateral position within the proximal basal turn when compared to the RWM electrodes. For this reason the depth of the insertion was greater in the cochleostomy group with insertion angle ranging from 230 to 290°, with a mean of 255°, whilst the RWM group ranged from 220 to 270°, with a mean of 240°.

Histological examination of the cochleae did not demonstrate any trauma to the intracochlear structures, apart from the spiral ligament tear and endosteal position in one specimen in the ascending basal turn. In all cases of RWM insertion, the electrode passed through the membrane without damage to the adjacent vertical portion of the osseous spiral lamina and without any evidence of damage to the delicate modiolar wall in the proximal basal turn, where contact may have occurred (fig. 6a). In all cochleostomy specimens the cochleostomy site was confirmed as inferior to the RWM without injury to the spiral ligament, basilar membrane or osseous spiral lamina (fig. 6b). In the remainder of the basal turn the basilar membrane, osseous spiral lamina and spiral ligament were intact in all specimens. In particular there was no elevation of the basilar membrane or tearing of the spiral ligament in any specimens apart from the one with subendosteal position.

Apart from the tip fold-over cases, in all but one specimen the electrode array maintained the designed orientation with the electrode contacts facing the modiolus and the smooth outer surface contacting the lateral wall. In one cochleostomy specimen the proximal basal electrode contacts were facing the modiolus, but apically the electrode was rotated with the contacts facing the lateral wall. Although the electrode array contacted the under surface of the basilar membrane at the point of twisting there was no evidence of intracochlear trauma. Analysis of the insertion fluoroscopy in this specimen showed that the electrode was twisted prior to contact with lateral scala wall, indicating that the electrode was manufactured with a pre-existing twist rather than it occurring as a function of the insertion.

Discussion

The results of this study demonstrate that this prototype electrode can be successfully inserted using either a RWM or cochleostomy approach, achieving an average insertion depth of over 240° without causing significant intracochlear damage. It is particularly encouraging that despite the small electrode array diameter and flexible nature it has sufficient torsional stability for the smooth lateral surface of the electrode array to maintain contact with the lateral scala tympani wall and facilitate reasonably deep electrode insertion without resistance, thus avoiding elevation or tearing of the spiral ligament and the basilar membrane. This is an improvement on the previous Nucleus straight banded array; however, the lateral wall position may still limit depth of insertion if trauma is to be avoided and hearing preserved in clinical trials. With the straight banded array significant resistance to insertion occurs once the electrode contacts the lateral scala tympani wall. Previous studies have clearly demonstrated the potential for intracochlear damage when insertion beyond the point of first resistance is performed [Kennedy, 1987; Gstoettner et al., 1997] This problem of outer wall resistance and trauma has been overcome by development of the Contour and Contour Advance electrodes. In particular the Contour Advance electrode, which can be inserted using the advance-off-stylet technique, does not contact the lateral scala tympani wall or under-surface of the basilar membrane. The Contour Advance electrode would be suitable for hearing preservation implantation; however, due to its large diameter (0.8 mm at the proximal end) it requires a generous cochleostomy for insertion.

Recent studies and discussion in the literature have identified the potential for damage to the spiral ligament, basilar membrane and osseous spiral lamina occurring due to the creation of the cochleostomy [Briggs et al., 2001, 2005; Adunka et al., 2004]. If the cochleostomy is sited anterior, rather than inferior, to the RWM, there is the distinct possibility of significant trauma to the adjacent basal turn structures making successful hearing preservation less likely. The current study has demonstrated that if carefully sited inferior to the RWM, a cochleostomy measuring approximately 1 mm in diameter can allow entry to the scala tympani, without injury to the spiral ligament or basilar membrane and hence allow preservation of the adjacent scala media and organ of Corti.

Creating an inferiorly placed cochleostomy does require increased access to the region of the round window niche and inferior cochlear promontory. This necessitates a more complete facial recess dissection with complete skeletonization of the facial nerve and wide dissection of the chorda tympani – facial nerve angle and removal of the lateral bony lip of the sinus tympani. Whilst this can easily be done, many cochlear implant surgeons are not confident doing such a complete facial recess dissection. Whilst no studies have been performed to demonstrate a difference, it would appear likely that the chance of preserving residual hearing will be greater when the method of entry to the cochlea is a RWM incision compared to a cochleostomy drilled through the crista fenestra into scala tympani. When a cochleostomy is sited so as to enter scala tympani below the spiral ligament attachment, the endosteum that is encountered prior to opening the cochlear lumen is extremely thin and it is technically challenging to create even a small cochleostomy without loss of perilymph or without bone dust or blood entering the basal turn. Compared with the cochleostomy, exposure of the RWM is relatively straightforward and an incision of the membrane quite simple.

As previously demonstrated in the study by Adunka et al. [2004], the histological results of temporal bone sections obtained in this study did not demonstrate any intracochlear trauma that would suggest a disadvantage of a RWM insertion as compared to a cochleostomy approach. Although the depth of electrode insertion was slightly less with the RWM approach, the depth of 240° should be suitable for candidates who have significant residual low-frequency hearing, but equally should allow effective hearing restoration for any patients reliant on electric stimulation alone should there be complete hearing loss. It is of interest that the RWM insertion electrodes have a more favorable perimodiolar position along the proximal basal turn compared with the cochleostomy insertion. This might have a functional benefit in terms of electric stimulation thresholds and spread of excitation or may be a disadvantage if modiolar proximity varies along the array. The differences in terms of success of hearing preservation and function with respect to RWM or cochleostomy site of insertion will only be determined by clinical rather than temporal bone studies.

Further design modification may be necessary with this new electrode to reduce the tendency for the tip to fold over on contact with the lateral scala tympani wall. This would increase its suitability as a potential hearing preservation cochlear implant electrode.

Conclusions

Temporal bone insertions of a prototype hearing preservation electrode were achieved using both RWM and scala tympani cochleostomy approaches without evidence of significant intracochlear trauma on histological examination. We conclude from this study that the electrode is suitable for clinical trial in potential cochlear implant candidates who have preservation of low-frequency hearing. Whilst electrode insertion was achieved without trauma with either a RWM or cochleostomy approach, the potential disadvantages of the cochleostomy technique suggest that an initial round window insertion trial is appropriate.

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implant performance. In 1999, von Ilberg first described the electric acoustic stimulation (EAS) of the auditory system – a method, which combines residual 'natural' low frequency cochlear function with electrostimulation of a cochlear implant on the same ear – at the University of Frankfurt [von Ilberg et al., 1999]. Preliminary speech discrimination results were promising in that EAS led to markedly improved speech perception in noise compared to the cochlear implant alone mode. Although a lot of progress has been made ever since the introduction of EAS and further reports confirmed initial speech perception data [Kiefer et al., 2005; Gstoettner et al., 2004], most issues in hearing preservation and subsequent combined, ipsilateral EAS have remained unsolved.

It is generally believed that intracochlear trauma caused by insertion of the stimulation electrode contributes significantly to the success or failure of intra- and postoperative hearing preservation [Kiefer et al., 2004]. Therefore, cochlear implant companies provided more atraumatic arrays [Adunka et al., 2004b] and adequate modifications of the soft surgical technique have been developed [Kiefer et al., 2004; Skarzynski et al., 2003]. Despite all these efforts, clinical trials showed that hearing preservation was possible in most – but not all cases [Kiefer et al., 2005; Gstoettner et al., 2004; Skarzynski et al., 2003; Gantz and Turner, 2003; James et al., 2005].

The aim of this report was to evaluate long-term residual hearing in a series of 23 patients who underwent cochlear implantation with the goal of ipsilateral EAS.

Material and Methods

Subjects

Inclusion criteria for patients were bilateral sensoneurinal hearing loss with pure-tone thresholds of <60 dB HL in at least 2 of the frequencies 125, 250 and 500 Hz and of >60 dB at frequencies >1 kHz. Monosyllabic word recognition had to be ≤40% in the best-aided condition. The hearing loss should have been stable over at least 2 years prior to surgery (as assessed via pure-tone audiometry). Most patients had symmetric bilateral hearing loss, otherwise the poorer ear was implanted.

All patients of this prospective observational study have been implanted in Frankfurt. The study protocol was reviewed and approved by the local institutional review board. To determine hearing preservation beyond the acute setting after surgery, a follow-up period of at least 6 months after surgery was chosen. Thus, 23 subjects could be included in this evaluation. All patients were implanted with a MED-EL COMBI 40+ cochlear implant with either a standard 31.5-mm-long electrode or with a shorter electrode array to contribute to the limited insertion depths of EAS (medium electrode). The Combi 40+ M electrode has a reduced contact spacing of 1.9 mm (compared to 2.4 mm in the standard array). Thus, the overall contact distribution length is 22 mm in the Combi 40+ M electrode and 27 mm in the standard electrode.

After surgery, measurements of residual hearing were performed at defined intervals. Typically, all patients underwent fitting of the cochlear implant 3–4 weeks after implantation. To provide good performance with the cochlear implant alone, the ipsilateral hearing aid was provided 3 months after the initial fitting of the cochlear implant speech processor. Residual hearing was assessed at every visit. Also, all patients were advised to report to our clinic in case of any subjective change in their hearing.

Hearing preservation was considered complete when average low frequency (125–750 Hz) hearing loss was less or equal than 10 dB HL compared to preoperative pure-tone thresholds. Respectively, partial preservation was considered in cases of low-frequency hearing loss of more than 15 dB according to preoperative pure-tone thresholds. Long-term preservation was considered for completely and partially preserved hearing of more than 6 months. No detectable low-frequency thresholds were consistent with loss of residual hearing.

Surgical Procedure

In contrast to standard cochlear implantations, the surgical procedure for EAS is performed on a partly functioning inner ear. Thus, this kind of surgery has to be performed as atraumatically as possible – with preservation of vulnerable intracochlear structures like the osseous spiral lamina, the basilar membrane, the spiral ligament, and of course the organ of Corti.

In a large series of human cadaver temporal bone experiments, we were able to demonstrate atraumatic electrode insertions with the MED-EL device [Adunka et al., 2004a]. In those cases, the array was found to be sliding along the inferior part of the lateral wall of the scala tympani. Thus, achieving a similar intracochlear electrode position was the main goal of each in vivo surgery reported herein.

A mastoidectomy and facial recess approach to the middle ear without ossicular chain manipulations was used in all cases of EAS implantations at our institution. Careful opening of the scala tympani was performed via a cochleostomy anterior and strictly inferior to the round window. All drilling procedures at the promontory bone were carried out with slow rotating diamond drills and skeeters (from Stapes surgery) after mucosal bleeding has been stopped entirely. Special care was taken to expose the endostium over an area of approximately 1 mm^2 without opening it. By touching the stapes, inner ear fluid waves were transmitted along the cochlea and hence movements of the intact endostium were visible ('EAS fenestra assay').

Instillation of crystalline steroid solution (Triamcinolon, Volon A®) to the exposed endostium and to the round window for approximately 10 min was performed [Kiefer et al., 2004]. Additionally, the exposed endosteum was covered with a drop of hyaluronic acid (Healon®) before it was opened with a fine needle. Any suction of perilymphatic fluid was avoided. The electrode was then inserted in an inferior-anterior direction to achieve its desired sliding along the inferior and lateral wall of the basal turn's scala tympani. Electrode insertion was carried out slowly to allow compensational outflow of perilymphatic fluid according to the repressed volume of the electrode. Hence, damaging intrascalar hydrodynamic pressure waves were minimized. With the electrode carrier in place, the cochleostomy was sealed with a circular fascial flap.

Electrode insertion depth of 18–24 mm (360°) in the present study was chosen mainly for two reasons: (1) according to 'Greenwood' maps of cochlear frequency locations [Greenwood, 1990, 1996], this insertion length corresponds well to high-frequency regions, which are the aim of electrical stimulation, and (2) insertion depths of one full turn should provide good cochlear implant performance (for combined EAS as well as in case of loss of residual hearing). However, pitch perception from electrical stimulation may be lower than expected from Greenwood map.

Due to variations in cochlear size and diameter, preoperative radiological measurements were performed in order to predict the required insertion depth in mm to achieve a 360° insertion [Adunka et al., 2005]. This was done by using a high-resolution computed tomography-based 3-dimensional placement of reference points. Evaluation of this method showed fairly good accuracies if measurements included the basal and first part of the middle cochlear turn only [Adunka et al., 2005].

Results

A total number of 23 patients with significant residual hearing according to our protocol (15 females, 8 males; mean age at implantation 49.9 years; range 25.9–77.3 years) were implanted between 1999 and 2005 at the University of Frankfurt and could be included in this evaluation. Sixteen patients were implanted in the right ear and 7 patients received an implant in the left ear. The minimum follow-up time was 6 months after implantation.

Despite swelling of the cochlear endosteum in one case, no specific intraoperative findings or postoperative surgical complications were observed. Electrodes were inserted 18–24 mm, which did not always result in 360° insertions – obviously due to significant differences in cochlear size and shape among patients [Zrunek et al., 1980]. As mentioned before, a high-resolution computed tomography protocol was introduced in the late course of the study to predict the length of insertion in order to achieve more exact 360° insertions [Adunka et al., 2005].

At the final follow-up interval, patients were grouped according to their individual long-term hearing preservation outcome. Of the 23 patients, 9 (39.1%) showed complete hearing preservation under the terms of our protocol (average pure-tone threshold shift at 250–750 Hz compared to preoperative hearing less than 10 dB) over 7–70 months (mean 29 months; fig. 1).

In 7 patients, (30.4%) residual low-frequency hearing at the final evaluation was found to be partially preserved (average low-frequency hearing loss >15 dB but clear ipsilateral low-frequency acoustic hearing detectable) and was found to be stable over 6–70 months (mean 25.0 months, fig. 2). In 5 patients (21.7%) hearing could be preserved partially, but low-frequency hearing loss eventually progressed to complete deafness (no measurable acoustic hearing) after 7–18 months (mean 12.6 months) after surgery (fig. 3a–e). In 2 patients (8.6%) no hearing could be preserved and complete hearing loss was found immediately after surgery (fig. 3f–g). Both of the latter patients were implanted in 2000 and thus early in the process of this study.

Freiburger Monosyllabic word understanding scores in the group of patients with complete hearing preservation increased from 13.1% preoperatively to 75% in the EAS condition (fig. 4).

Discussion

This paper documents complete preservation of residual hearing in 9 of 23 patients implanted for EAS. Although 3 of the 9 patients have less than 2 years experience (fig. 1g–i), these patients are considered as having stable long-term preservation of residual hearing. The patients with partial hearing preservation (fig. 2) all had some initial hearing loss immediately after implantation which then proceeded in some cases. Thus, completely preserved immediate postoperative hearing may be used as a predictor for its long-term stability.

Acute postoperative deafness was encountered in less than 10% of our cases. In about 20% of our patients, progression of sensorineural hearing impairment lead to delayed deafness in the implanted ear after 7–18 months. The reason for preserving hearing in some cases and losing it in others is not clear yet. All surgeries were performed by 2 surgeons (W.K.G. and J.K.) who shared their experience.

To provide efficient combination of electric and acoustic stimulation, stable long-term hearing preservation seems to be of great importance. Patients need more time to adapt to EAS than to conventional cochlea implants. Previously, EAS results including short-term hearing preservation outcomes from two centers have been published [Kiefer et al., 2005; Gstoettner et al., 2004]. The current paper, on the other hand, reports on patients who had been implanted in Frankfurt only. Therefore, variations in patient selection, surgical procedure, and medical management have been minimized.

Another approach to EAS is shorter electrode insertions of 6–10 mm. In a multi-center trial involving this concept [Gantz et al., 2005], out of 21 patients, one showed

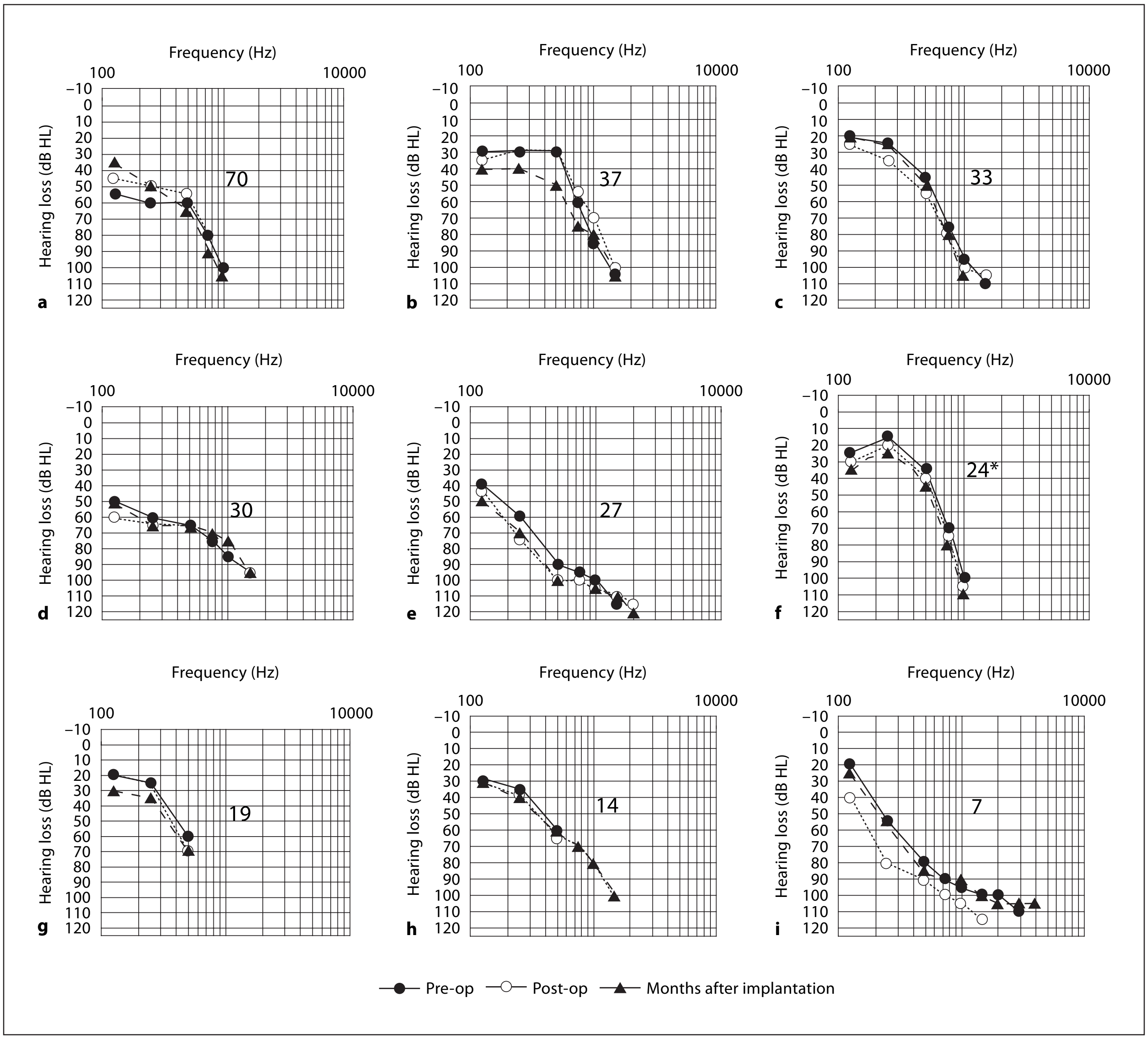

Fig. 1. Audiograms pre- and postoperatively and after 7–70 months of patients with complete hearing preservation. The patient indicated by an asterisk had a complete preservation of the inner ear function as demonstrated by bone conduction measurement. An additional air-bone gap of 15 dB is not illustrated on the audiogram. ● = Before operation; ○ = after operation; ▲ = months after implantation.

a delayed 30-dB drop in average pure-tone thresholds and another lost hearing completely after 2.5 months. Thus, their rate of hearing preservation is superior when compared to deeper insertions as used in this study. However, very limited insertions bear controversies as how to proceed in cases of complete hearing loss, since the cochlear implant alone may not provide sufficient speech perception abilities.

Very recently, first results of a multicenter trial investigating preservation of residual hearing after implantation with a standard length perimodiolar electrode (Nucleus Contour Advance electrode) have been reported

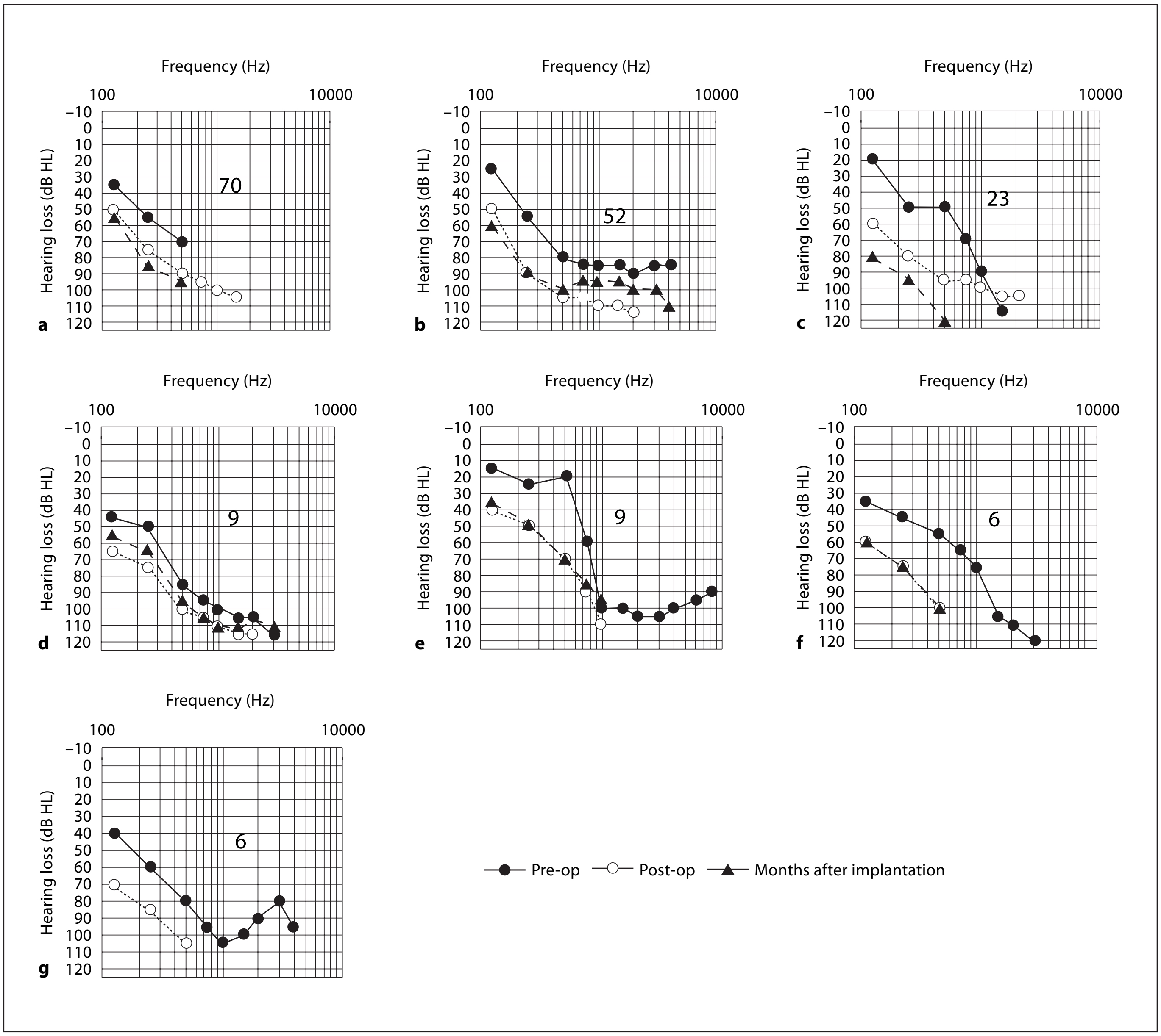

Fig. 2. Audiograms pre- and postoperatively and after 6–70 months of patients with partial hearing preservation. ● = Before operation; ○ = after operation; ▲ = months after implantation.

[James et al., 2005]. Insertion depths in this study were 17–19 mm (300–430°). Although perimodiolar electrodes seem to increase cochlear trauma [Gstoettner et al., 2001; Richter et al., 2001; Aschendorff et al., 2003], in this study only 2 of 12 patients had total hearing loss due to unexpected difficulties during surgery and half of the patients retained sufficient hearing for effective ipsilateral bimodal stimulation. A more recent cadaver study was able to confirm the result of relatively atraumatic insertions with modified perimodiolar electrodes [Adunka et al., in press]. Yet, long-term hearing preservation outcomes are expected with interest.

One of the most important steps of EAS surgery seems to be atraumatic opening of the scala tympani [Briggs et al., 2005]. Alternatively, opening of the round window membrane [Skarzynski et al., 2003] could be a safe access

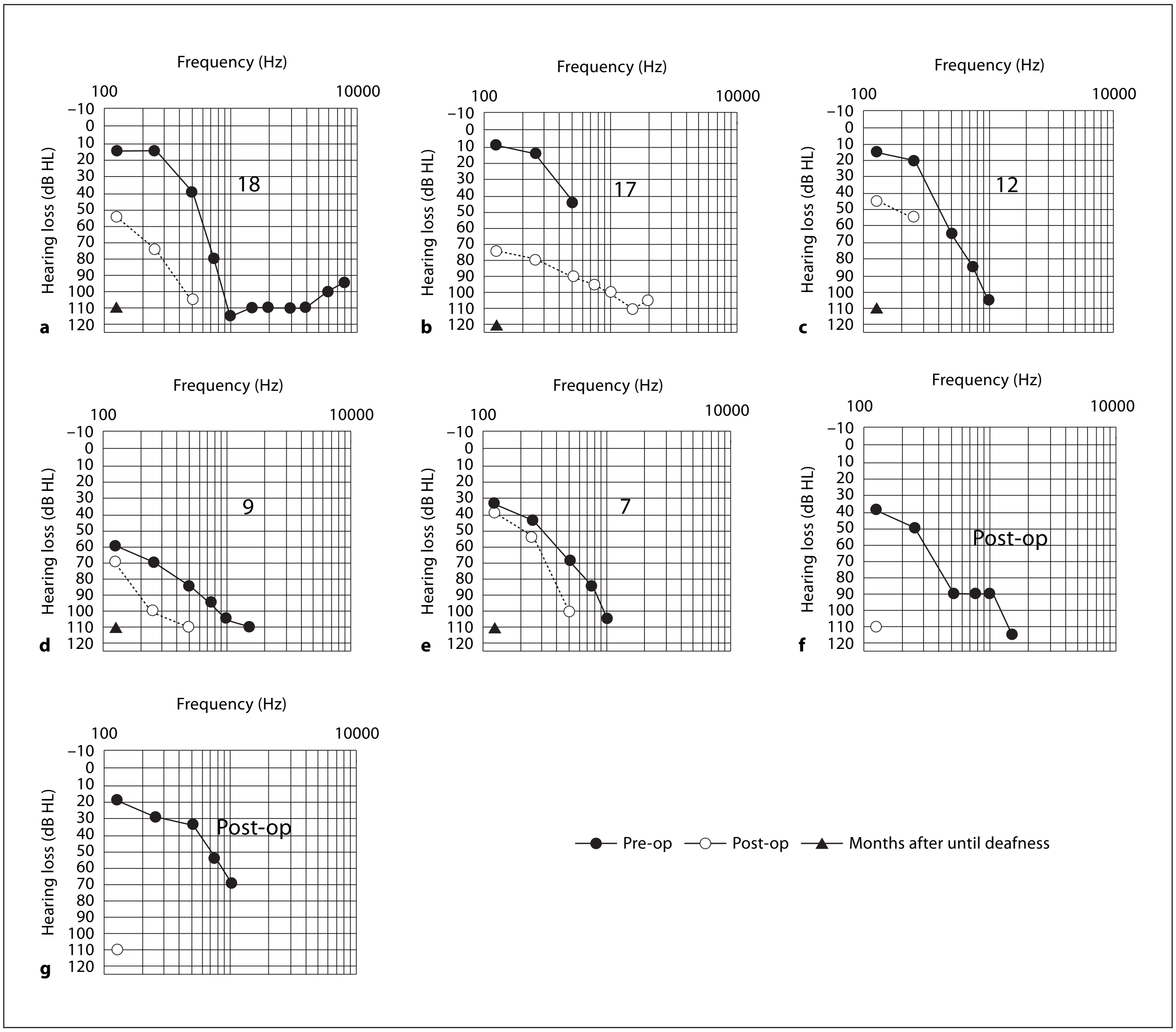

Fig. 3. Audiograms pre- and postoperatively. Two patients with early onset of deafness directly after implantation and 5 patients with late onset of deafness after 7–18 months after implantation. ● = Before operation; ○ = after operation; ▲ = months until deafness.

to scala tympani, avoiding trauma to osseous spiral lamina and to the basilar membrane [Adunka et al., 2004c]. However, basal cochlear anatomy including the round window area shows great variations [Zrunek et al., 1980]. Its exposure through the facial recess seems limited in some cases and thus an approach through the ear canal including raising a tympanomeatal flap might enhance visibility.

At present, basic science and research are trying to depict the exact mechanisms and importance of factors leading to hearing loss after electrode insertion. Interruption of particular pathways that result in hearing loss is the ultimate goal [Scarpidis et al., 2003]. Recent animal experiments [Eshraghi et al., 2005] suggest that hearing loss after cochlear implantation occurs in two stages: an early stage during or immediately after surgery and a de-

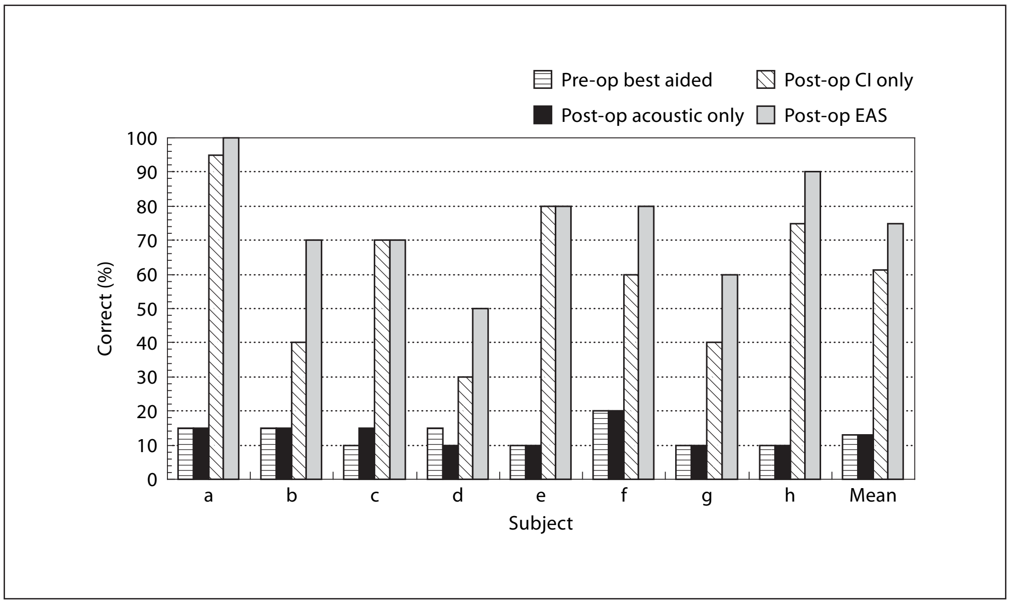

Fig. 4. Pre- and postoperative results of Freiburger monosyllables discrimination for patients with complete preservation of residual hearing. Subjects with at least 1 year of EAS experience are included. a–h correspond to figure 1.

layed stage occurring within the first few weeks after implantation. It is believed that protection from hair cell apoptosis might alter the delayed pathway positively [Scarpidis et al., 2003]. Hence, pharmacological treatment of hearing loss is currently one of the main topics in patient-oriented inner ear research. As part of it, pathways to delivery future pharmaceuticals to their site of action, e.g. the cochlear duct, are currently under investigation [Paasche et al., 2006]. Although sophisticated viral vectors might be the foundation of inner ear treatment in the future [Staecker et al., 2004], much simpler routes like topical drug application onto the cochleostomy opening during surgery – as described in this report – are currently used. Better residual hearing of future EAS candidates, however, demands a simpler, yet more direct route of drug application. Hence, extensive research has focused on the feasibility of intracochlear drug application, which might soon become clinically available.

Conclusions

This paper documents the feasibility of ipsilateral hearing preservation and its long-term stability in about 70% of patients when adequate surgical and medical measures are employed. Complete hearing loss in the acute postoperative setting and progression of initially preserved hearing to complete deafness over time was observed in a small subgroups of patients.

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quiet and in noise and for sound quality. Such benefits appear to be accessible for bimodal stimulation using both contralateral residual hearing [Armstrong et al., 1997; Dunn et al., 2005; Ching et al. 2004; Kong et al. 2005] or for 'electroacoustic' stimulation, or bimodal hearing with ipsilateral residual hearing [von Ilberg et al., 1999; Gantz and Turner, 2003; Kiefer et al., 2004; Gstoettner et al., 2004; James et al., 2005; Fraysse et al., 2006; Skarzynski et al., 2003].

A prerequisite for combined ipsilateral electroacoustic stimulation (EAS) is sufficient residual hearing after cochlear implantation. However, at this stage it is not clear what minimum level of residual hearing is required for speech recognition benefits to outweigh the practical disadvantages of additional use of one or more HAs with a CI. It appears that the question cuts two ways; a good level of residual hearing would tend to provide 'unaided' benefits, or, a very poor level of residual hearing could result in physical or loudness discomfort.

Due to studied improvements in the performance of patients with CIs, candidacy criteria have changed over the years from total deafness to a low level of open-set recognition of words or sentences. For example, the limit for candidacy in Germany is 30% monosyllabic word score, in France and Spain 50% disyllabic word score, and in the UK 50% sentence score [Fraysse et al., 2006]. With these criteria CIs are still shown to provide significant improvements in health utility [UK Cochlear Implant Study Group, 2004a] and are cost effective [UK Cochlear Implant Study Group, 2004b]. In these 'conventional' cases where preoperative scores are not negligible, the remaining 'acoustic' function of the implanted ear would otherwise be destroyed by the introduction of the electrode array unless specific precautions are followed.

In the present report, we analyze and present a subset of data collected in a larger study of conservation of residual hearing after cochlear implantation with a perimodiolar electrode, which is most often used with 'conventional' candidates for cochlear implantation. The progress of the multicenter study has been reported by James et al. [2005] and updated more recently by Fraysse et al. [2006]. The latter report identified that specific 'soft' surgical procedures should be adhered to in order to better preserve residual hearing after implantation. The inclusion criteria for this study included a minimum level of preoperative speech perception to be present in the ear to be implanted. There was no limitation placed on pure tone hearing threshold levels. However, in order to effectively aid residual hearing with a high-power in-the-ear (ITE) HA in combination with CI, maximum postoperative thresholds were limited to 80 dB HL for 125 and 250 Hz and 90 dB HL at 500 Hz. These limits corresponded to the maximum output characteristics of the Phonak Aero (or Valeo) 33 ITE and to vibrotactile sensations. Where 'soft' surgery was observed, median threshold increases at 1 month after operation were 15, 18 and 25 dB for 125, 250 and 500 Hz. In addition, there was some further degradation of thresholds in some cases over time and this appeared to happen more often where thresholds were poorer to start with. It was obvious that patients who started with thresholds at the limit of HA performance (e.g. above) would not be candidates for EAS; in addition, in about half of the cases threshold shifts would be greater than 20 dB.

For the current report, cases were selected from the larger study population where preoperative HTLs were $\leq$60 dB HL at 250 and 500 Hz. These levels might afford the subject some benefit either with a naked ear or from amplification with ITEs. Also, after discussion of the data with the study group and other experts in the field it appeared a nominal practical criterion where residual hearing may still be considered important in the light of cochlear implantation.

In the present data set, the additional selection criterion was strong adherence to the surgical protocol described by Fraysse et al. [2006] and shown to improve hearing conservation. One surgical criterion was relaxed; that is that the cochleostomy hole size could be up to 1.5 mm in diameter. Otherwise any other deviation removed the patient from the current subject group. Subjects were implanted at the centers included in the author list.

Methods

Subjects were 10 adults implanted with the Nucleus 24 Contour Advance perimodiolar electrode array. According to the following criteria, these 10 subjects were selected from the larger study population of 37 patients implanted at the time of writing. Preoperative hearing threshold levels were $\leq$60 dB HL at 250 and 500 Hz. Specific 'soft' surgical procedures were strictly observed as specified by James et al. [2005] and Fraysse et al. [2006]: A $\leq$1.5-mm cochleostomy hole was made anterior and inferior to the round window, a Healon bubble was placed over the opening to prevent entry of foreign bodies. Suction was avoided at this stage to prevent loss of perilymphatic fluid. The electrode array was inserted 17 mm to the first marker rib using the recommended 'advance-off-stylet' technique.

Preoperative hearing threshold levels were roughly symmetrical (≈10 dB) for all subjects. Thresholds were more or less stable over 1–2 months preoperatively. Etiology of deafness was unknown except for P19 who had some family history of hearing loss. All subjects, except P18 due to preference, were implanted in the worse ear according to thresholds ≥500 Hz. All subjects were refitted with state-of-the-art digital Phonak Aero/Valeo 33 ITE HAs at least 1 month prior to implantation. Subjects who generally wore only one HA (in the better ear) were given at least 2-month experience with the new bilateral aids. Equivalent performance with old versus new HAs was observed within this period.

Pure tone hearing threshold levels were recorded preoperatively, and postoperatively at 1–2 months and at 6 months or 12 months. Speech recognition was tested with 7 subjects with postoperative residual hearing as according to the criteria ≤80 dB HL at 125 and 250 Hz.

Postoperatively, subjects were given two types of speech processor program to evaluate; 'overlapping' and 'nonoverlapping-shifted'. The former maps the entire frequency range 120–8000 Hz across the array 18–22 active electrodes as with conventional CI. The latter used the same filter bands, but one to three low-frequency bands were deactivated so that there was no overlap for frequencies where thresholds were ≤80 dB HL. In addition, the filter band-to-electrode allocation was shifted apically by the number of deactivated channels. Subjects were given either 'overlapping' or 'nonoverlapping-shifted' MAPs to take home for the 1st and 2nd months postactivation in a balanced design. For the 3rd month, they could use either program at will. At the end of the 3rd month, they chose their preferred program which was then re-evaluated at 6 months. There were insufficient data at the time of writing to properly analyze the effect of speech processor program on performance. For the CI alone condition, the better score for either program was used.

For these 7 subjects, speech recognition was tested in quiet with words presented in sound-field at 65 dB SPL and for sentences presented at 70 dB SPL in multitalker babble with 5 dB SNR. In most cases, postoperative testing was performed at 6 months after implantation. Listening conditions were CI alone, with both ears plugged or CI+ipsiHA (e.g. non-implant ear plugged, ipsiHA active).

Results

Preoperative, and 1- to 2-month and 6- to 12-month postoperative audiograms are presented in figure 1 for all 10 subjects. There were 3 cases (P5, P19, P32) where immediately after operation low-frequency HTLs were considered to be at vibrotactile sensation levels (>85–110 dB HL, 250–500 Hz). In the remaining 7 subjects, there were some changes in postoperative hearing levels over time. HTLs measured between 6 and 12 months showed some recovery of pure tone thresholds for the lowest frequencies 125 and 250 Hz (notably P6), and some degradation at, for example, 500 Hz (P9, P18). These variations were reflected in median changes for the group; 26, 34 and 35 dB before operation to 1–2 months after operation, and 15, 26 and 47 dB before operation to 6–12 months after operation, for 125, 250 and 500 Hz, respectively.

Insertion depth angles obtained from 'Cochlear View' X-ray images [Xu et al., 2000] are indicated for each case in figure 1. A tip fold-over was observed for P6 resulting in a very low insertion angle of 285°. Otherwise, a large range of angles was observed 323–435° as previously reported in Fraysse et al. [2006]. There did not appear to be any strong systematic effect of insertion angle on changes in audiograms; however, the largest insertion depth angle of 435° seen in 2 cases (P5, P19) corresponded to the largest losses of residual hearing.

Percent correct scores for words in quiet are presented in figure 2. For the 7 subjects retaining significant residual hearing the mean preoperative score was 22% indicating limited open-set speech recognition ability. This was in agreement with audiograms where there would be only very limited or, indeed, no access to high-frequency speech information even with well-fitted HAs.

Postoperative word recognition scores with HA alone for the implanted ear were available for 5/7 subjects (fig. 2). It was not an aim of this study to monitor preservation of residual speech recognition; however, these cases showed that both hearing threshold levels and speech recognition can be preserved even with relatively large insertion depth angles of about 400° (P9, P37).

At 6 months after operation (fig. 2), mean word scores were 56% for CI alone, and 68% for CI plus ipsilateral HA ($p < 0.05$, two-tailed paired t test). Thus, on average there was considerable benefit from cochlear implantation in terms of speech communication ability, and in addition, added benefit from combined use of the ipsilateral HA.

Most subjects had negligible or nil preoperative scores for sentences presented in multitalker babble noise at 5 dB SNR (fig. 3). Postoperatively, mean scores were 61% for CI alone, and 75% for CI+IpsiHA ($p < 0.01$, two-tailed paired t test). This indicated the potential for a substantial level of speech communication in a high level of noise and extra benefit from combined ipsilateral stimulation.

Six subjects preferred the 'nonoverlapping-shifted' program; only S37 preferred the overlapping program. The latter was attributed to the use of CI alone away from work in order to 'rest' both ears. It is of note that this subject would need amplification in order to have access to low frequencies via residual hearing; this is not true, for example, for P6, P8 and P9.

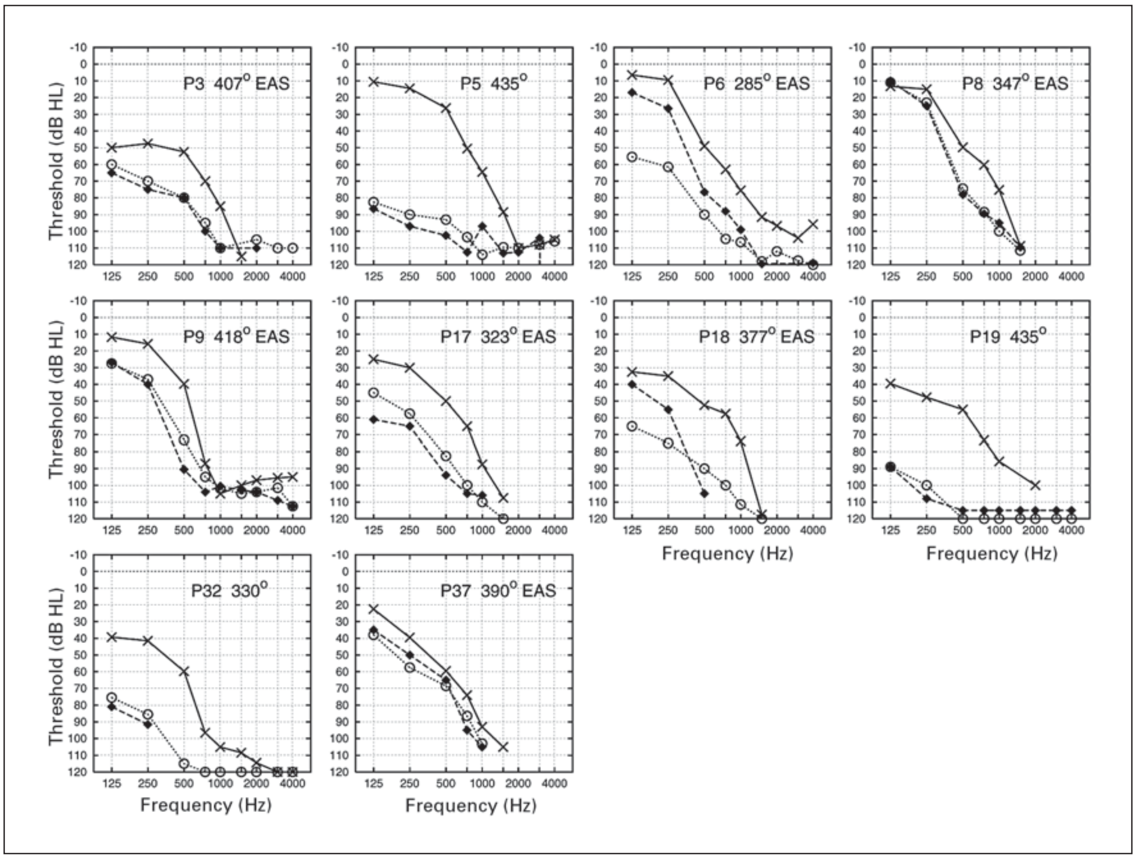

Fig. 1. Pure tone audiograms for 10 subjects implanted with the Nucleus 24 Contour Advance electrode array according to strict 'soft' surgery procedures. Audiograms were measured preoperatively (solid lines, crosses), then at 1 or 2 months after operation (dotted lines, circles) and at 6 to 12 months after operation (dashed lines, filled diamonds). Insertion depth angles measured from X-rays are inset [Xu et al., 2000].

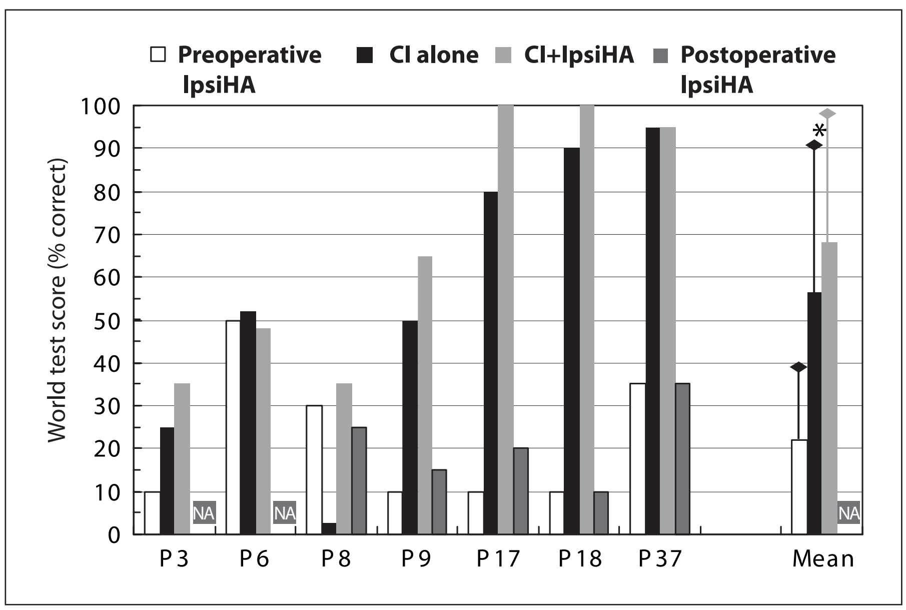

Fig. 2. Individual and mean percent correct recognition scores for lists of words presented in quiet at 65 dB SPL. Scores are shown for the implant ear only with the contralateral ear plugged. The ipsilateral HA was removed and the ipsilateral ear plugged for the CI alone condition. * $p < 0.05$, significant mean difference, two-tailed paired t test. Error bars = 1 standard deviation. NA = Not available.

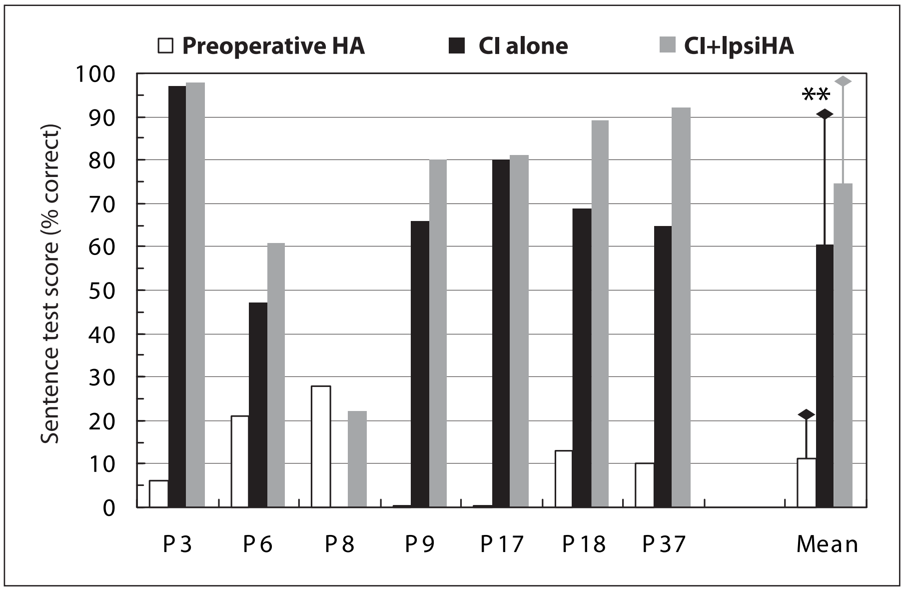

Fig. 3. Individual and mean percent correct word recognition scores for lists of sentences at 70 dB SPL presented in multitalker babble at 5 dB SNR. Scores are shown for the implant ear only with the contralateral ear plugged. The ipsilateral HA was removed and the ipsilateral ear plugged for the CI alone condition. ** $p < 0.01$, very significant mean difference, two-tailed paired t test. Error bars = 1 standard deviation.

Discussion

Ten subjects from a large study group of 37 implanted with the Nucleus 24 Contour Advance were selected based on their preoperative HTLs being equal to or better than 60 dB HL at 250 and 500 Hz. Useful postoperative residual hearing appeared to be retained in 7/10 or 70% of cases for at least 6 months. The initial reasons for loss of residual hearing in 3 cases (P5, P19 and P32) remain unclear. Relatively large insertion depth angles of 435° were seen for P5 and P19, respectively. Insertion depth angles exceeding about 400° appear to impact residual hearing more negatively when using the Nucleus 24 Contour Advance perimodiolar electrode [Fraysse et al., 2006]. It may be appropriate to further limit insertion depth for small cochleae as suggested by Escudé et al. [this issue, pp. 27–33].

The insertion depth angle for P32 was relatively low (330°); however, the surgeon reported some 'sticking' when moving the electrode off the stylet which may have resulted in increased trauma to the cochlea. It is of note that a tip fold-over did not produce large permanent deterioration in thresholds.

Fraysse et al. [2006] reported some changes in residual hearing over time for a larger data set of 27 cases. Only in 1 case (P12) did they see a substantial deterioration in HTLs over time where initially postoperative levels were sufficient for combined stimulation. This patient had preoperative hearing levels outside the range reported here.

On average, the current group of subjects benefited substantially from cochlear implantation alone in terms of word recognition in quiet. Exceptions were P6 and P8 who had long durations of high-frequency deafness which is known to heavily influence outcomes [Blamey et al., 1996; Yukawa et al., 2004]. However, the combined use of CI with residual hearing allowed P6 a significant level of sentence recognition even in a relatively high level of noise at 5 dB SNR (fig. 3).

Since the conception of the study, a confounding factor has been identified which appears to influence sentence recognition scores when tested in noise. Where earplugs are used to obtain the CI alone condition, there is the possibility of substantial 'acoustic leak'. This is particularly important where only mild or moderate levels of hearing loss are present in the lowest frequencies in either ear (e.g. P6, P8, P9). Initial results from testing with direct input to the speech processor to obtain a true CI alone condition indicate that the EAS advantage may be much greater than reported here.

Two subjects reported that they did not notice benefit from use of either the ipsilateral (P6) or contralateral (P9) HA and decided to discontinue use of these after 1 year. This was attributed to negligible gain being prescribed for the lowest frequencies, with only a very narrow band of effective amplification in the slope region of the audiogram.

The preservation of preoperative speech recognition using HA alone indicates that the function of low-frequency hearing may be also be retained after implantation.

For the 7 cases who were tested with EAS here, mean 6- to 12-month postoperative HTLs were 36, 48 and 84 dB HL for 125, 250 and 500 Hz and greater than 95 dB HL for higher frequencies. Thus, the presence of even rather limited low-frequency acoustic hearing for use with CI seems to provide some access to pitch information which appears to be missing from the electrically coded signal [Kong et al., 2005; Yukawa et al., 2004]. This appears to provide improved speech perception in background noise and improved sound quality either when combined contralaterally [Armstrong et al., 1997; Kong et al., 2005] or here ipsilaterally.

Conclusions

Hearing was conserved during surgery and over time in 70% of conventional candidates for cochlear implantation with low-frequency hearing threshold levels better or equal to 60 dB HL. These conventional candidates for CI also benefited substantially from improved speech recognition in noise when using combined ipsilateral electrical and acoustic stimulation.

Acknowledgement

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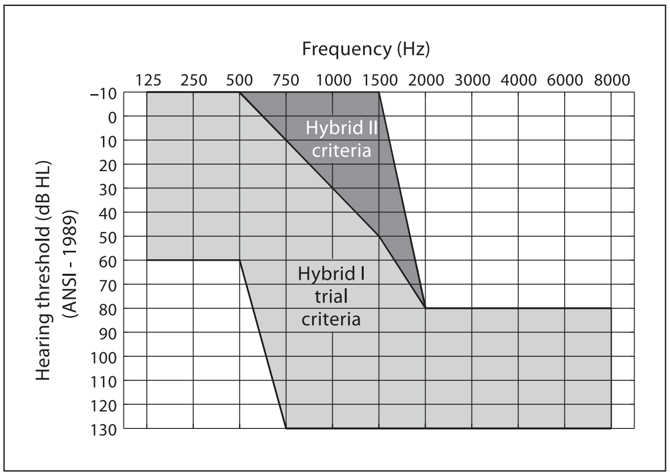

Fig. 1. Expanded audiometric selection criteria for Hybrid II implant FDA clinical trial (dark gray) and original audiometric selection criteria for Hybrid I FDA clinical trial (light gray). Subjects must have between 10 and 60% CNC word recognition in the implant ear and not more than 80% CNC word recognition in the contralateral ear.

Recent findings by the University of Iowa Cochlear Implant Team have highlighted the importance of residual low-frequency hearing for understanding in noise as well as appreciation of music [Gantz and Turner, 2003, 2004; Gantz et al., 2005; Turner et al., 2004; Turner and Gantz, 2004, 2005]. Residual acoustic low-frequency hearing contains important fine spectral information that enables the listener to distinguish a single talker from surrounding noise [Turner et al., 2004], and to identify fine pitch changes that are essential to recognition of melody [Gfeller et al., this issue, pp. 12–15]. The 10-mm Iowa/Nucleus Hybrid electrode was designed to be minimally invasive and only enter the descending basal turn of the scala tympani. Low-frequency hearing preservation has been accomplished using this electrode. Results with this electrode demonstrate that pure tone thresholds can be preserved as well as residual acoustic word discrimination [Gantz and Turner, 2004]. This approach differs from those using a longer electrode [Gstoettner et al., 2004]. Individuals implanted with the 10-mm electrode are able to combine acoustic plus electric speech processing, resulting in enhanced hearing in quiet, in noise, and enjoyment of music.

The Iowa/Nucleus Hybrid 10-mm implant has now been implanted in 48 severely hearing-impaired individuals in the United States under an FDA-controlled protocol (as of November 1, 2006). This short communication will describe the selection criteria for the present FDA clinical trial important aspects of the surgery, and the most recent preliminary results of those that have at least 9 months experience with the device. A subset of this trial includes long-term (12 months or more) results from subjects implanted at the University of Iowa.

Methods

Selection Criteria

A multicenter FDA clinical trial using the Iowa/Nucleus Hybrid implant is now ongoing in the United States. The trial has been conducted in two phases. The selection criteria have been expanded in phase 2 and the cochlear implant was modified to incorporate the new Freedom speech processing chip. In the phase 2 implant the auxiliary reserve electrode was eliminated. The audiologic selection criteria for both FDA clinical trials are shown in figure 1. The phase 1 selection criteria included CNC monosyllabic word scores between 5–50% in the implant ear and up to 60% in the contralateral ear. In phase 2 the CNC word scores were expanded to 10–60% in the implant ear and up to 80% in the contralateral ear. Twenty-five subjects were recruited into phase 1 and 22 have been implanted in phase 2 as of December 1, 2005. The CNC words are presented by audition only, in a soundfield at 70 dB SPL. Individuals who fall within this study group must speak English. Similar audiometric testing is obtained 1 month after operation at the initial setting of the device, at 3, 9, 12, 18 months, and then yearly following implantation. At each test interval the conditions include hearing aids only, implant only, hearing aid + implant in the ipsilateral ear, hearing aid contralateral + implant (bimodal), and bilateral hearing aids + implant (combined mode).

Surgical Implantation

Placement of the 10-mm short electrode implant is performed in a similar manner to the standard device with several important exceptions as previously described [Gantz et al., 2005]. The position and technique of creating the cochleostomy is critical to preserving residual hearing. Surgical techniques used should be similar to a 'drill-out' stapedectomy. The cochleostomy drilling is done at a slow speed, no suction of perilymph near the cochleostomy is allowed, and advancement of the electrode should be done slowly with the direction of the electrode placement parallel to the plane of the posterior external canal wall. The cochleostomy is created 2 mm anterior to the round window in the inferior portion of the scala tympani. It is important to visualize the entire round window prior to creating the cochleostomy. The anterior floor of the round window membrane assists in outlining the floor of the scala tympani. It is also important to recognize that the basal turn of the cochlea traverses medially from the round window as it advances toward the ascending basal turn. The position of the basal turn is approximately parallel to a line drawn down the posterior external canal wall. The cochleostomy is created in the inferior medial portion of the scala tympani. The opening into the scala tympani is only 0.5 mm. When a bluish color of the scala tympani is identified, a 0.5-mm burr is used to create a cochleostomy, preserving the endosteum. The final layer of endosteum is opened with a fine 0.2-mm Fisch right angle stapes pick. The 0.2 × 0.4-mm diameter electrode is gently introduced up to the guard that prevents further penetration of the electrode into the cochlea. A small fascia washer seals the cochleostomy.

Results and Discussion

The present clinical trial has been ongoing for over 3 years. Nine subjects have been using the device for more than 1 year. Hearing preservation immediately after operation has been maintained in 47/48 (98%) subjects implanted with the Hybrid electrode. One subject lost hearing with implantation. The implanting surgeon did not report any unusual anatomic problems or surgical issues. An additional subject lost all acoustic hearing 2.5 months after operation during a viral infection. Three other subjects have experienced hearing loss of more than 30 dB in pure tone thresholds 2–3 months after operation. They have required increased gains in their hearing aids, but are continuing to get benefit from combined acoustic plus electric hearing. Two additional subjects have demonstrated progressive hearing loss in *both* ears over a 2- to 3-year period. The etiology in one was autoimmune inner ear disease, while the other experienced a progressive sensorineural loss of unknown origin. The subject with autoimmune inner ear disease was implanted with a standard electrode in the contralateral ear 3 years after receiving the Hybrid. Hearing within 10 dB of preoperative thresholds have been maintained in 25 (52%), maintained within 11–20 dB in 15 (31%), preserved within 21–30 dB in 7 (14%) and >35 dB in 1 (2%). All others have maintained stable acoustic hearing, some for more than 3 years.

The preoperative acoustic speech discrimination has also been preserved in all 16 subjects implanted at the University. The preoperative CNC word scores are compared with the score obtained with binaural hearing aids prior to setting the implant 1 month after operation (fig. 2). In the entire clinical trial group postoperative acoustic only CNC word scores have been preserved in 44/46 of those that have preserved pure tone thresholds.

Nineteen subjects implanted during the FDA Hybrid I trial have reached at least 9 months or more years experience with their device (fig. 3). All but 4 of this group demonstrate significant [Thornton and Raffin, 1978] benefit from the acoustic plus electric hearing. Confidence intervals in figure 3 were drawn based on binomial comparisons for a 100-item word test. It will be in-

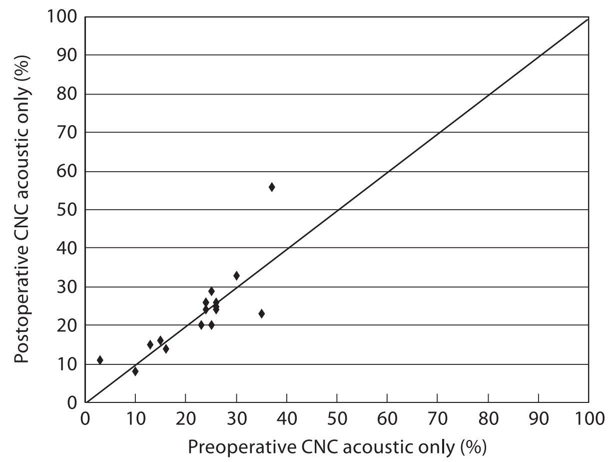

Fig. 2. Scatter plot of preoperative CNC word score using insert earphone in the implant ear compared with the 1-month postoperative CNC word score with an insert earphone. Subset of all subjects implanted at the University of Iowa (n = 16).

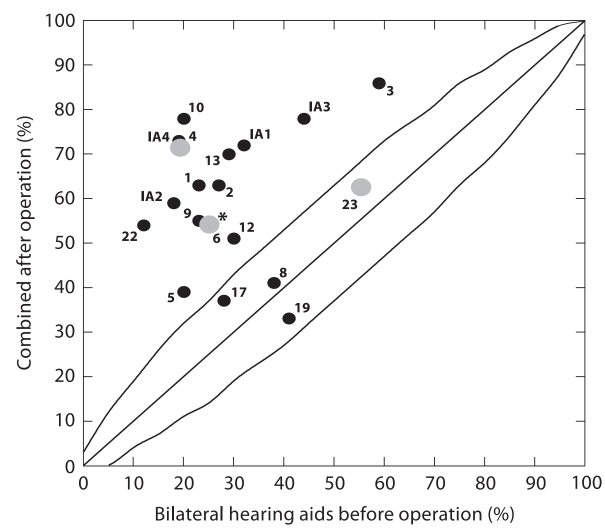

Fig. 3. Comparison of CNC words before operation with two hearing aids vs. combined acoustic plus electric hearing with two hearing aids and the Hybrid implant. Three of 19 subjects (gray dots, >30 dB change in LF thresholds) have experienced more than >30 dB change in pure tone thresholds 2–3 months after operation. Two of the three have demonstrated significant improvement. Curved lines indicate the 95% confidence levels [Thornton & Raffin, 1978]. Asterisk signifies bimodal.

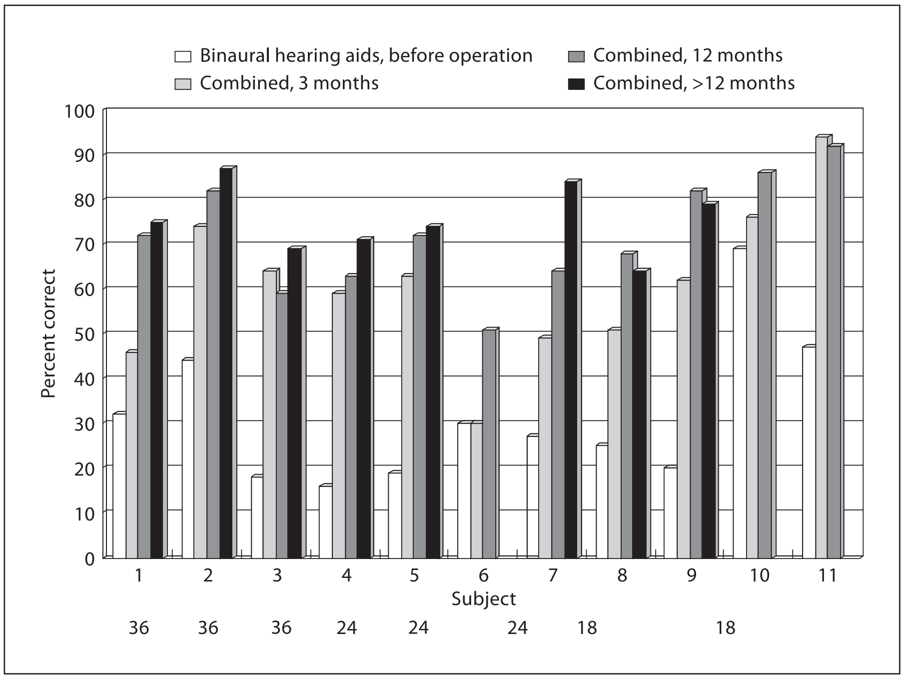

Fig. 4. Performance over time on the CNC word test demonstrating preoperative results with two hearing aids compared with scores using two hearing aids plus the Hybrid implant. Numbers below subject numbers reflect number of months at last test. CNC score before operation with binaural hearing aids = 32% correct, CNC word score of subjects with 12-month experience = 72%, and of those with >12-month experience = 75% correct in the combined mode (binaural hearing aids + Hybrid implant).

teresting to see if there is eventual improvement with more experience. Two of the individuals that have not gained benefit have a history of high-frequency hearing loss of more than 40 years' duration and 1 lost hearing prior to 16 years of age. The high frequency loss in this individual might be congenital.

The performance over time of 11 subjects (with 12 months or more experience) implanted at the University of Iowa is shown in figure 4. The average preoperative CNC word score of this group is 32% correct using two hearing aids. Those who have reached 12 months of use of the device have an average of 72% on CNC using two hearing aids plus the implant (combined condition). Subjects who have more than 1 year of experience are achieving an average of 75% correct words on CNC monosyllabic word test in the combined condition. All hearing was lost during a viral infection in subject 8. This individual more than doubled his preoperative score with two hearing aids using the implant in one ear and a hearing aid in the other (bimodal condition). Almost all subjects display improvement over time and in some there is substantial improvement during the 2nd year of use.

The benefit of preserving residual acoustic hearing is particularly evident when one looks at the recognition of speech in noise. The preserved residual hearing provides more accurate frequency resolution than electric stimulation [Henry et al., 2005], which is hypothesized to improve the ability to separate the target voice from background noise. The experimental measure was to determine the signal-to-noise ratio (SNR) required for 50% understanding of easy spondee words, presented in either steady background noise or competing voices. This task is described more completely in Turner et al. [2004]. Thus, a lower SNR is a better score. In figure 5, the SNRs for various groups of listeners sorted by device type and degree of hearing loss are presented. The long electrode users in this comparison (n = 20) are an unselected group of standard cochlear implant users and the patients with a moderate or greater hearing loss used a hearing aid. Also included are the 14 long-term Hybrid users tested at Iowa (11 long-term implanted at Iowa plus 3 who traveled to Iowa from other centers for testing). One striking finding was that the mean value for the Hybrid users is within 2 dB of the mean value for a group of mild-moderate sensorineural hearing loss patients, and that this is a considerable advantage over the large group of long electrode users.

An even more convincing demonstration is to compare all the long-term Hybrid users tested at Iowa who have preserved residual hearing (n = 14) with a group of the highest performing long-electrode users (n = 10) who

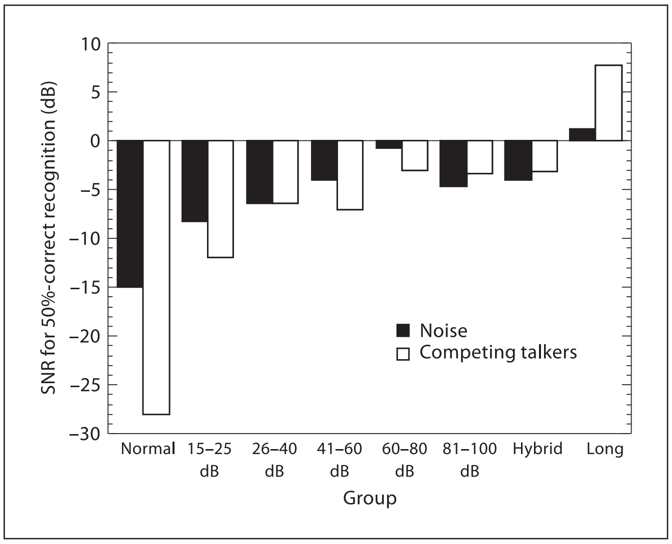

Fig. 5. Speech reception in multitalker babble and steady noise for various groups of listeners. The SNR required for 50%-correct recognition of spondees is plotted as a function of listener group. The hearing loss listeners are sorted by their pure tone threshold averages (500, 1000 and 2000 Hz). The implant listeners used either the Hybrid or traditional (long) electrode.

were matched in terms of their word understanding in quiet. This comparison shows the advantages of preserving residual hearing for understanding speech in noise, without the confounding factor of overall speech recognition abilities. The mean advantage for the Hybrid group in multitalker babble is 6.1 dB. For steady noise, the group mean advantage is 7.5 dB. Clearly, preservation of residual low-frequency acoustic hearing can provide significant benefits for the recognition of speech in background noise, even when compared to the 'star' long electrode users.

In our study hearing preservation has been accomplished in 96% (n = 45/47) of subjects implanted with the 10-mm Hybrid electrode. One subject experienced profound deafness immediately following surgery and 1 developed profound hearing loss 2.5 months after operation during a viral infection. The subject that lost hearing at 2.5 months after operation has been able to obtain significant benefit using the Hybrid in one ear and a hearing aid in the other. The limited length of the electrode appears to prevent penetration of the basilar membrane as can occur with longer electrodes as they advance into the ascending basilar turn. The 10-mm length does not advance into the ascending basilar turn. It is also suspected that creating a small 0.5-mm cochleostomy in the correct position is critical to hearing preservation. Hearing preservation in the Hybrid group includes pure tone threshold as well as residual acoustic speech perception. The 10-mm electrode appears to be better at preserving residual hearing and acoustic speech perception than that reported with 20-mm electrodes [Adunka et al., 2005]. In addition to improving speech perception in quiet, the electrical processing provided by the 10-mm electrode significantly improves the SNR for most subjects. Preservation of acoustic low-frequency hearing and acoustic speech perception is thought to preserve the fine spectral information necessary to hear speech in noise and discriminate fine differences in pitch for better music enjoyment. Melody recognition requires accurate perception of direction and magnitude of interval change for a sequence of pitches. The Hybrid implant group also exhibit near-normal pitch discrimination difference limens and can accurately determine the direction of pitch change for one semitone interval, which is similar to the performance of normal-hearing subjects in the low-frequency region. The pitch discrimination ability of the Hybrid subjects is a result of the preserved residual low-frequency acoustic hearing. The Hybrid group is also better at recognizing complex melodies and report near-normal timbre measures for frequencies below 1000 Hz compared with a group of standard electrode users as described by Gfeller et al. [this issue, pp. 12–15].

Many of the subjects that have been implanted with the Hybrid system to date have had preoperative hearing at the lower end of the candidacy selection criterion. Recently, those with more residual acoustic speech perception have been implanted with the Hybrid device in phase 2. It is expected that those with 25–60% residual speech discrimination may be the most appropriate candidates for this technology. The enhancement of recognizing speech in noise, as compared to the alternative of electric-only hearing of traditional cochlear implantation, appears to be a major advantage for this group of individuals.

As selection criteria for cochlear implants continue to expand, the importance of residual low-frequency hearing must be recognized. Placement of standard-length electrodes in this group has the potential to compromise residual hearing and reduce the ability of the subject to gain substantial improvement in SNR as well as appreciation of music.

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Discussion

Round Table 1: Benefits and Issues in Combined Electroacoustic Stimulation

Chair: E. Offeciers
Panel: T. Ching, N. Dillier, D. Fabry, M. Manrique, O. Sterkers, C. Turner

The panel discussed the expected benefits from combining acoustic and electrical stimulation in cochlear implant patients with some residual hearing.

Why combine a hearing aid and cochlear implant, and should the hearing aid be fitted to the ipsilateral or contralateral ear to the implant?

The consensus of the panel was that hearing aids should be fitted to both ears if possible to maximize the binaural hearing benefits from acoustic stimulation. Results from teams in Iowa, Toulouse, Paris and Melbourne have shown benefit from using bilateral hearing aids combined with a unilateral implant for speech perception in noise. Benefits were not as large when testing in quiet, suggesting that the acoustic signal was particularly helpful in extracting speech from background noise. The patients also found the sound quality of music and voices better using bilateral hearing aids with their cochlear implant.

At the University of Iowa, USA, the benefits of ipsilateral versus contralateral hearing aids in patients using the 10-mm Nucleus Hybrid cochlear implant have been studied. An adaptive speech-in-noise test was used. Unfortunately, the hearing losses were not symmetrical for the majority of patients. As the poorer ear was implanted, this introduced a bias of better performance in the contralateral fitted ear. Four patients had a symmetrical hearing loss in both ears with thresholds within 5 dB. For these patients, a 3–4 dB advantage in signal-to-noise ratio was found when using the Hybrid implant with the ipsilateral hearing aid compared to the contralateral aid.

However, while much is now known about fitting a hearing aid contralateral to a cochlear implant, the procedures for ipsilateral fitting are not so well defined. As is the case for a contralateral hearing aid fitting, the ipsilateral fitting will probably need to be optimized for use with the implant.

One of the difficulties facing cochlear implant clinics is that clinicians generally do not have a good working knowledge of hearing aids and the recent advances in digital aids. Therefore, if a candidate has worn the same hearing aid for more than about 5 years, then the hearing aid should be updated prior to making a decision about implanting that ear because the candidate may not be properly fitted. There is a need for a better convergence between hearing aid and cochlear implant technologies by cochlear implant clinicians. This will ensure that the candidate receives an accurate assessment of hearing aid benefit prior to implantation, and that the benefits from residual hearing plus a cochlear implant are obtained after implantation.

Should a cochlear implant be fitted to the better or poorer ear in the congenitally deaf child, given that the better ear can be fitted with a hearing aid?

In the past, it was often considered appropriate to implant the ear with more residual hearing because that (better) ear had received some stimulation. As both ears typically had a profound hearing loss, the loss of residual hearing was not considered as important as prior auditory experience.

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However, children now present as cochlear implant candidates with more residual hearing. It is much more important to consider how much residual hearing is available, whether a hearing aid can be satisfactorily fitted and the likelihood of successful aid use. The consensus of the panel was for the poorer ear to be implanted and a hearing aid fitted to the better ear.

Should bilateral cochlear implants be used in children with residual hearing?

The panel agreed that preservation of residual hearing is worthwhile because benefit has been shown when electric and acoustic stimulation are combined. If there is no preservation of residual hearing with simultaneous bilateral implantation, the advantages from acoustic stimulation will not be available. Therefore, it may be better to consider sequential bilateral implantation in children with residual hearing as this gives the option of measuring benefit from the contralateral hearing aid. If residual hearing can be preserved using a standard electrode array or the shorter Hybrid electrode, then it should be possible to provide low-frequency information using hearing aids. This would be a worthwhile objective.

Currently, there are not many procedures available to measure the benefit of hearing aids in young children and they are probably limited to pure tone audiometry and phoneme discrimination. Of these, phoneme discrimination would be the more critical test as it indicates functional benefit. Recent research at the National Acoustic Laboratories, Sydney, Australia, is examining the use of cortical evoked potentials to estimate this benefit. Compared are the unaided and aided cortical potentials to three speech-like stimuli with low-, mid-, or high-frequency information. If an optimally fitted hearing aid does not evoke the cortical potential, then the aided residual hearing is unlikely to provide benefit. This research is at an early stage but the preliminary outcomes look promising.

The panel felt that it is important to ensure that the central auditory system is stimulated in children. As pediatric candidates now have more residual hearing, defining the boundary on the use of bilateral cochlear implants or hearing aids is difficult. The amount and quality of residual hearing needed to ensure adequate auditory pathway stimulation is not known at this stage.

The effects of fitting only one ear on central auditory pathway development, in particular those components related to binaural hearing, can be very marked. For instance, there is evidence in the literature which shows that in children, if only one ear is aided then binaural hearing capabilities, such as sound localization, do not develop and not all benefits from using two hearing aids will be found with a later fitting of the second aid.

The panel also felt it important to consider the long-term future for these children. If standard bilateral implants are used, this may preclude future devices. Using arrays which are noninvasive and preserve hearing is preferable because they do not preclude future technologies.

Finally, the panel felt it would be useful to have a prospective study in children to compare bilateral cochlear implants with a cochlear implant and contralateral hearing aid.

What are the best ways to encourage hearing aid use in cochlear implant patients?

The panel agreed that it is important to demonstrate benefit from using a hearing aid. One method would be to have the patient document hearing aid use and benefit in a number of specific listening situations. Another approach would be to show benefit to the patient via testing, such as speech-in-noise where acoustic amplification is likely to be of benefit. It is important to consider the individual needs as to when hearing aids are likely to be of benefit. Hearing aid benefits may differ across individuals because of differences in daily activities. There may also be instances where patients will prefer to use both or just one device.

One factor to consider would be the amount of residual hearing. For fitting an ipsilateral hearing aid to a cochlear implant patient with preserved residual hearing, experience has shown that hearing aids are of minimal benefit with thresholds at 70–80 dB in the low frequencies. If there is a ski-slope loss with low-frequency thresholds around 30 dB, then a hearing aid is likely to be very beneficial.

Round Table 2: Surgical Techniques for Conservation of Residual Hearing

Chair: B. Fraysse
Panel: R. Briggs, B. Gantz, W. Gstoettner, T. Klenzner, T. Lenarz, A. Ramos, O. Sterkers

The panel discussed the rationale for hearing preservation, surgical techniques for preservation during implantation, and choice of electrode array.

What is the rationale for conservation of residual hearing in cochlear implant surgery?

The panel agreed that the main advantage of hearing preservation is to provide combined electroacoustic stimulation in the implanted ear. Long-term results from the Goethe University, Frankfurt, Germany, have shown that if hearing preservation is successful, the benefits of electroacoustic stimulation include better hearing in background noise, music appreciation, and better sound quality. In addition, finer fundamental frequency (F0) resolution is available from acoustic stimulation, which may aid speech recognition in the presence of background noise. Currently, cochlear implant speech coding schemes do not provide this level of pitch resolution.

There is also the need to be as atraumatic as possible so that there is minimal damage to cochlear structures, and residual hearing status can be used as an indicator of surgical trauma. With trauma and damage to cochlear structures, there is the potential loss of auditory function which may lead to poorer patient outcomes. Recent findings from Medizinische Hochschule Hannover, Germany, have shown that performance is poorer in those patients where the electrode array has been inserted into the scala vestibula or scala media, rather than in the scala tympani.

Finally, the panel agreed that it was important to preserve the best surgical environment for future cochlear implant technologies that may be available within the lifetime of the patient.

What are the most important surgical steps for hearing conservation with a cochlear implant?

The panel agreed that the most important factors for hearing preservation for insertion of the Contour Advance were:

- the site and size of the cochleostomy and correct access to the scala tympani,
- orientation of the electrode,
- a gentle insertion technique,
- avoiding aspiration of any fluid, and
- treating implantation as carefully as a stapes procedure where preservation of hearing is paramount.

Other factors included:

- Ensure that the electrode slides along the inferior lateral wall during insertion as this gives the least resistance for the free-fitting Contour Advance electrode.
- Minimize hand tremor during insertion. In the future, a micromanipulator may be helpful.
- Avoid any rapid pressure changes to cochlear fluids during insertion.
- Use a slow rotation drill and making sure bone dust and fluids are removed. This approach has been successfully used for insertion of the 10-mm Hybrid electrode.

The choice of electrode is the most significant factor influencing the overall surgical approach to insertion and hearing preservation. A cochleostomy is required for the Contour Advance electrode, while a round window approach can be used with the 16-mm Hybrid-L research electrode. A cochleostomy is used for the 10-mm Hybrid-S electrode.

The use of a cochleostomy or round window approach for insertion of the more flexible and thinner 10- and 16-mm Hybrid electrodes was not resolved by the panel. Important considerations included access and exposure of the insertion site and avoiding bone dust and other contaminants when a cochleostomy is used. The round window has the properties to heal itself, which may be an advantage for long-term hearing preservation. The studies in Iowa with the 10-mm Hybrid electrode have shown that residual hearing can be preserved when using a small cochleostomy, with small changes in patients' hearing thresholds and speech perception outcomes. Long-term residual hearing preservation with the 16-mm Hybrid electrode inserted via the round window will be investigated in the current studies with this array. There is clearly a need for long-term data on hearing preservation using cochleostomy and round window approaches for the 10- and 16-mm Hybrid electrode arrays. Currently, these data are not available.

Will surgical techniques necessary to preserve residual hearing be feasible for all cochlear implant surgeons?

The panel agreed that there are different levels of expertise for cochlear implant surgery. Implantation to preserve residual hearing requires specialist training, just as specialist training is required for stapes surgery. It is also important to recognize that hearing preservation will not be achievable in all patients. Specialist knowledge is also important to ensure correct access to the cochlea. For instance, properly skeletonizing the facial nerve and identifying the round window niche is essential to achieve the correct orientation for a hearing preservation insertion.

However, there was agreement amongst panel members that there is no reason why surgeons cannot be trained. Successful preservation of residual hearing is being achieved in the current multicenter studies in Europe and the USA, indicating that surgical techniques can be improved with training. These hearing preservation studies are using the Contour Advance and the 10-mm Hybrid electrodes.

There are now available electrode arrays of different lengths; which ones should be used with which patient and does this depend on the frequency range of residual hearing?

The panel agreed that not only is it important to consider preservation of pure tone thresholds, it is as equally as important to consider preservation of acoustic speech perception. For instance, if a patient has a 10% speech score preoperatively, then the long electrode would be the appropriate option. However, if a patient has a 50% speech score preoperatively, then shorter electrodes would be the better option. Experience at the University of Iowa in a small number of patients has suggested that pure tone thresholds can be preserved with the full insertion of the Contour Advance, but speech perception may not. However, experience in Toulouse, Paris and Melbourne with Contour Advance patients with preserved hearing has also shown preservation of acoustic speech perception. Further studies comparing threshold preservation and speech perception outcomes are needed.

For patients with good residual hearing, the panel agreed that the short array should be considered. For patients with some low-frequency residual hearing, then, an atraumatic insertion of a long array should be the option. The depth of insertion should be about 270–360° as there is an increased likelihood of damage with deeper insertion depths. It was noted that the diameter of the array may be more important than length with respect to insertion trauma. If the electrode is thinner in future designs, then length may become even less important.

Another factor that could influence the choice of electrode is the possibility of progressive hearing loss. A short 10-mm Hybrid electrode may not provide enough speech information after the loss of residual hearing. A longer electrode which preserves residual hearing may be more appropriate, and could be the electrode of choice for all patients where residual hearing preservation is required. On the other hand, it was noted that studies at the University of Iowa, USA, have shown that the average consonant confusion score from 9 patients with 10-mm Hybrid electrode at 12 months postoperatively was not significantly different than the average consonant score from a group of patients with a fully inserted standard electrode. Therefore, a 10-mm Hybrid electrode has the capability to deliver similar speech perception outcomes as the standard array.

What is the definition of successful preservation of residual hearing?

The panel agreed that the challenge for cochlear implant surgeons is to achieve postoperative hearing thresholds within 10 dB of the preoperative thresholds in 95% of patients. They also agreed that it is important to maintain similar levels of speech perception after implantation so that functional performance is not diminished. For instance, it may be possible to successfully amplify a 20-dB decrease in hearing thresholds so that the postoperative score is similar to the preoperative score with appropriate amplification.

Round Table 3: Electrode Design for Hearing Conservation

Chair: A. Ramos
Panel: R. Briggs, B. Gantz, P. Gibson, T. Klenzner, T. Lenarz, J. Patrick

The panel discussed the importance of insertion depth and electrode position in the cochlea on electrode design, and the long-term effects of foreign tissue on hearing preservation after cochlear implantation.

What can be considered a safe insertion depth?

Most of the data on trauma due to electrode insertion comes from temporal bone studies, where it is possible to evaluate damage to cochlear structures. However, outcomes are defined with respect to results in implant patients, where it is seldom possible to examine damage to the cochlear structures. Currently, there are temporal bone studies and long-term patient results for two electrode designs: the shorter 10-mm Hybrid array and the longer straight and Contour arrays. The panel agreed that in general, if the array is too long and too thick then the probability for hearing preservation is low. If the array is too short, then the likelihood of patient benefit is low, as was found with the initial 3 patients at the University of Iowa, USA, who were implanted with a 6-mm array of 6 electrodes. The shallow insertion depth of the 6-mm array produced pitch percepts that were too high for the patients to effectively use the device.

The panel agreed that the current ‘gold standard’ for preservation of residual hearing is the 10-mm Hybrid electrode. However, it is not applicable for the many implant candidates with moderate-to-severe levels of low-frequency residual hearing. The Contour Advance is a good electrode design for deep insertion and perimodiolar placement, without trauma to the basilar membrane and the lateral wall, and hearing preservation can be achieved. However, it is an electrode which is not suitable for implant candidates with considerable residual hearing.

The panel suggested that an ideal design would be a thin free-fitting electrode that can be inserted to follow the lumen of the cochlea, rather than the outer wall. The electrode contact area needs to be large enough to deliver the required electric current safely. Flexibility needs to be controlled along the array, with some sections requiring more flexibility than others.

Is perimodiolar electrode placement preferable in cases with residual hearing?

There are some advantages of a perimodiolar placement. It is known that perimodiolar placement results in lower power requirements because the electrode contacts are closer to the residual auditory nerve fibers. Also, perimodiolar placement ensures a more consistent and larger insertion depth angle. However, no significant differences in speech perception outcomes between modiolar and lateral wall electrode placements have been found.

Perimodiolar placement potentially increases the likelihood of damage to the basilar membrane. This is because the tip can face toward the basilar membrane and therefore penetrate the membrane during insertion. If the future design is for a perimodiolar thin electrode, there is more space in the scala closer to the modiolus compared to the outer wall, so a greater depth of insertion should be achievable. There will be design challenges to ensure the electrode tip does not move up toward the basilar membrane during insertion.

Will there be a need for different electrodes for different patients, and what would be the characteristics of the candidates that relate to the different electrodes?

The panel agreed that if there is no residual hearing, the Contour Advance is the preferred current option. It is an electrode designed for atraumatic insertion and consistent insertion depth.

The 10-mm Hybrid array would be the preferred option for candidates with preoperative monosyllabic word scores above 30–40%. Those with lower scores but with considerable low-frequency residual hearing, the new experimental 16-mm Hybrid-L array may be preferable. However, there are no long-term results for the 16-mm array as it has only been recently implanted in 2 patients. In particular, there are no data about the long-term effects of contact with the spiral ligament and the underneath of the basilar membrane in the ascending basal turn. Whether this will affect long-term acoustic hearing and fibrous tissue growth is not known at this stage.

It was also felt that for patients with preserved residual hearing, it would be more appropriate to examine long-term results for combined electrical and acoustic hearing. Stable bimodal outcomes is the desired objective as this is the everyday listening condition for these patients.

Finally, panel members suggested that an electrode array where the depth of insertion can be varied is needed to meet the large variations in cochlear dimensions between patients. It should be possible to measure these dimensions preoperatively and plan for the depth of insertion. This will also assist in hearing preservation as depth of insertion can be better controlled. It may be the case that arrays of different lengths are required.

What are the long-term issues of foreign-body reaction to the electrode array in the human cochlea for hearing preservation?

In studies at the University of Iowa, USA, using the 10-mm Hybrid electrode, data from 3 patients at 4 years postoperatively is available. Acoustic hearing thresholds and speech perception performance have remained stable. However, there have been 4 patients who lost their hearing between 2 and 3 months postoperatively. The cause of this loss is not known.

The panel felt that severe ossification or fibrosis should not develop as long as there is no severe trauma during insertion. Deterioration of hearing has been found in some patients several years after implantation, which is likely to be related to bacterial or viral infection. The connective tissue sleeve which develops around the electrode array creates a protective shield which assists in reducing foreign body reaction. Long-term outcomes over 15–20 years in many patients implanted with the Nucleus implant have shown stable impedances, stimulation levels and speech perception outcomes, indicating a stable intracochlear environment. Finally, it was agreed that the length of the standard (e.g. 25-mm straight, or 19-mm perimodiolar) array was not likely to be a contributory factor, so long as the insertion was as atraumatic as possible.

Round Table 4: Which Approach for Which Patient?

Chair: N. Dillier
Panel: B. Fraysse, B. Gantz, W. Gstoettner, C. James, A. Lorens, C. Turner

The panel discussed current selection criteria for implantation and electroacoustic stimulation.

What are the current limits for cochlear implantation? In particular, the hearing loss in the ear to be implanted and the contralateral ear, the type of hearing loss measure, and the nature of hearing aid evaluation.

It might be possible to provide pure tone threshold criteria for selecting the type of array to be used with candidates presenting for cochlear implantation. It is important to consider the shape of the audiogram, rather than just the pure tone average. However, for speech perception criteria there are differences across languages in test material and test difficulty to consider. The different speech tests can also be sensitive to the effects of high or low frequency hearing losses, and to the effects of background noise. It is also important to ensure the hearing aid is appropriately fitted, including replacing the current fitting with a more modern digital aid, and that there is an adequate hearing aid trial.

At Hôpital Purpan, Toulouse, France, the current criterion for a standard cochlear implant is disyllabic word scores of less than 50% correct. The candidate is fitted with a hearing aid and test material is presented at 65 dB SPL. For inclusion in the European electroacoustic study using the Contour Advance, the candidate must obtain a disyllabic word score between 10 and 50% and have a hearing loss of at least 70 dB at 1 kHz.

At the University of Iowa, USA, the current criterion for a standard cochlear implant is monosyllabic word scores below about 40%. For Hybrid candidates, the monosyllabic word score range is between 10 and 60% in the ear to be implanted, and up to 80% in the contralateral ear. Pure tone thresholds, although not as important as speech perception findings, incorporate near-normal low-frequency hearing with a high frequency loss, greater than 65–70 dB at 2 kHz and the higher frequencies. One consequence of severe hearing losses above about 70 dB is that hearing aids may provide minimal benefit. Well-fitted hearing aids and a hearing aid trial are important to demonstrate that aids provide minimal benefit and a 10-mm Hybrid cochlear implant is appropriate.

At the International Center of Hearing and Speech, Warsaw, Poland, the speech perception criterion for a standard cochlear implant is less than 30% word score in the ear to be implanted and 40% in the contralateral ear or bilaterally. This is the most important criterion, and the audiogram is not considered as a significant factor because it does not reflect functional performance. For electroacoustic stimulation using a 20 mm inserted electrode array, candidates can have near-normal hearing in the low frequencies, up to 40 dB loss for frequencies below 1 kHz, with a steeply sloping high frequency loss of greater than 60 dB per octave. Speech perception criteria for this group are 40% in the ear to be implanted and up to 50% for the contralateral ear or bilaterally. These criteria are expanding with more experience using electroacoustic stimulation.

The panel agreed that there is a need to develop further test materials for assessing candidates for electroacoustic stimulation. One possibility is to assess speech perception using different low-pass frequency cut-offs to determine the contributions of the higher frequencies. This would be particularly relevant for the Hybrid electrode arrays where high-frequency speech information is targeted. Studies at the University of Iowa, USA, and the National Acoustic Laboratories, Sydney, Australia, have shown that low-frequency hearing can provide significant benefit to cochlear implant patients, irrespective of the degree of hearing loss. This differs from the findings for high-frequency hearing loss where there is minimal benefit for losses above about 70 dB.

What are the upper and lower limits of audiological characteristics for electroacoustic stimulation?

The panel agreed that as selection criteria have changed and implant devices have improved over time, the performance of patients implanted within the last 5 years using a standard cochlear implant should be used to define these limits. The upper limit can be defined by bimodal performance, that is, combined electric and contralateral acoustic stimulation, as many candidates now have residual hearing. The lower limit can be defined by minimal low-frequency hearing.

For hearing thresholds greater than about 80 dB, especially in the mid to high frequencies, hearing aids often produce a highly distorted percept which provides minimal or no benefit when using hearing aids alone. Similarly, hearing aids are unlikely to be of benefit with a small dynamic range of hearing. However, patient benefit can be obtained from combining a small amount of residual hearing with a cochlear implant, in particular low-frequency hearing.

The panel recommended that when measuring performance of patients with residual hearing in the implant alone condition, it is important to remove any contribution from residual hearing using an ear plug in the free-field environment or by direct connection to the speech processor.

Is it important to achieve equivalent cochlear implant alone levels of performance in electroacoustic patients, such as those implanted with hybrid electrode arrays, when compared with standard cochlear implant patients?

The panel agreed that an important objective is to ensure that electroacoustic patients obtain the same degree of benefit as standard cochlear implant patients if all residual hearing is lost. It should also be an objective for residual hearing to be preserved so that the patient can benefit from electrical and acoustic bimodal stimulation.

A factor to consider is how much residual hearing the candidate has preoperatively, and how much can be preserved. Note that current outcomes suggest that about 25% of standard cochlear implant patients do not get a high degree of benefit using the implant alone. Therefore, replacing a shorter Hybrid array with a standard Contour Advance array in those cases where residual hearing is lost after surgery will not guarantee successful outcomes. Research has shown that the number of electrodes needed for successful outcomes is about 4–6 electrodes for speech understanding in quiet, and about 6–8 electrodes when listening in noise. However, a contributing factor could be where these electrodes are placed in the cochlea; in the basal portion for the 10-mm Hybrid array, the basal and mid positions for the longer 16-mm Hybrid array, or evenly distributed across the whole array for the Contour Advance. There is also some evidence from studies at the University of Michigan, USA, indicating that performance is poorer when stimulating only the basal portion of the array, compared with stimulation over the complete array or only the apical portion. In these studies, 10 electrodes were selected for stimulation in the different configurations.

How do you weigh the success rate of hearing conservation versus potential benefit?

The panel felt that current knowledge is not able to answer this question. There is a trade-off between the risk of losing residual hearing and the benefits from electroacoustic stimulation. Managing patient expectation of risk and potential benefit is a relevant issue for those candidates with residual hearing. It is important to manage the needs of the individual patient as the benefits from the hearing technology, hearing aids and cochlear implant, may not be enough to satisfy the needs of the individual.

One suggestion from the panel was implantation of the poorer ear as the best option because the patient can then combine electrical and acoustic stimulation from opposite ears. If hearing is preserved, then there is the added advantage of acoustic stimulation in the same ear as the cochlear implant.

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