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Preservation of residual hearing with cochlear implantation: How and why

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Abstract

Conclusions. Hearing may be conserved in adults after implantation with the Nucleus Contour Advance perimodiolar electrode array. The degree of hearing preservation and the maximum insertion depth of the electrode array can vary considerably despite a defined surgical protocol. Residual hearing combined with electrical stimulation in the same ear can provide additional benefits even for conventional candidates for cochlear implantation. *Objectives*. We present preliminary results from a prospective multicentre study investigating the conservation of residual hearing after implantation with a standard-length Nucleus Contour Advance perimodiolar electrode array and the benefits of combined electrical and acoustic stimulation. *Material and methods*. The subjects were 12 adult candidates for cochlear implantation recruited according to national selection criteria. A "soft" surgery protocol was defined, as follows: 1–1.2-mm cochleostomy hole anterior and inferior to the round window; Nucleus Contour Advance electrode array inserted using the "Advance-off-stylet" technique; and insertion depth controlled by means of three square marker ribs left outside the cochleostomy hole. These procedures had been shown to reduce insertion forces in temporal bone preparations. Variations in surgical techniques were monitored using a questionnaire. Pure-tone thresholds were measured pre- and postoperatively. Patients who still retained thresholds <90 dB HL for frequencies up to 500 Hz were re-fitted with an in-the-ear (ITE) hearing aid. Word recognition was tested in quiet and sentence perception in noise for the cochlear implant alone and in combination with an ipsilateral hearing aid. *Results*. Hearing threshold level data were available for 12 patients recruited from 6 of the centres. Median increases in hearing threshold levels were 23, 27 and 33 dB for the frequencies 125, 250 and 500 Hz, respectively. These median increases include the data for two patients who had total loss of residual hearing due to difficulties encountered during surgery. "Cochlear view" X-ray images indicated that the depth of insertion varied between 300 and 430°, despite modest variations in the length of the electrode inserted (17–19 mm). The insertion angle had some influence on the preservation of residual hearing at frequencies of 250–500 Hz. Six of the 12 patients retained sufficient hearing for effective use of an ipsilateral ITE hearing aid ($\leq$80 dB HL at 125 and 250 Hz; $\leq$90 dB HL at 500 Hz). Word recognition scores in quiet were improved from 10% to 30% with the cochlear implant plus ipsilateral hearing aid in 3 patients who had at least 3 months postoperative experience. Signal:noise ratio thresholds for sentence recognition were improved by up to 3 dB. Patients reported that they experienced greatly improved sound quality and preferred to use the two devices together.

Keywords: *Cochlear implants, combined electrical and acoustic stimulation, soft surgery*

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Introduction

Cochlear implants (CIs) have been shown to give considerable benefit in terms of speech understanding to severely and profoundly hearing-impaired adults and children [1,2]. A number of these patients have also received additional benefit from contralateral acoustic stimulation ("bimodal") via a conventional hearing aid (HA) [2,3]. This has the potential to improve speech recognition in both quiet and noise [2].

More recently, interest has focused on the possibility and benefit of combined electrical and acoustic stimulation, so-called "electro-acoustic" (El-Ac) stimulation, in the same ear [4,5]. This is only possible if sufficient residual hearing is preserved in the implanted ear. This has been realized by recent developments in technology and "soft" surgery techniques [6], combined with a better understanding of the structure and function of the inner ear.

The well-known benefits of cochlear implantation have been established for what are termed conventional or "long" multi-channel electrode arrays, such as the Nucleus CI22M, CI24M and Nucleus 24 Contour [1,7–9], the Med-EL Combi 40+[10,11] and the Advance Bionics HiFocus II [9]. All these electrode arrays are designed to be inserted to a depth exceeding 1 complete turn of the cochlea from base to apex, or 360°. Reports in the literature [12,13] have shown the potential to preserve residual hearing even when placing an electrode array this deep into the scala tympani. Recent work by groups in Iowa [5] and Frankfurt [7,8] was aimed at hearing-impaired patients who are not traditionally considered as CI candidates and who were characterized by severe and profound thresholds only at frequencies $\geq$1000 Hz, with near-normal or mild hearing losses in the low frequencies. These patients commonly present with monosyllabic word recognition scores >50%. In these cases the aim is to completely preserve relatively good preoperative performance with HAs while adding additional high-frequency information via the CI. Such patients were implanted either with a shorter 6–10-mm electrode array [5] or with a conventional array but with incomplete insertion not exceeding 360° or 18–24 mm [10,11]. The assumption here is that the smaller insertion depth is less likely to result in the loss of residual hearing, while the risk is that other surgical factors may reduce performance with HAs postoperatively. In both of these "short" insertion approaches, soft surgery techniques have been altered or refined with the goal of improving the level of preservation of residual hearing after implantation [5,10].

Herein we report hearing preservation and the potential for combined El-Ac stimulation in patients who are considered borderline candidates for conventional cochlear implantation. This study involves 13 CI centres from 8 countries across Europe and the aim is to eventually recruit up to 100 patients; this may allow us to consider variations in individual surgical technique as factors in the successful preservation of residual hearing after cochlear implantation, and may provide a broader picture of the potential of such techniques compared to results obtained to date at a few selected sites [5,8,10]. In this paper we present preliminary results obtained with 12 patients who were followed for at least 1 month after implantation.

A perimodiolar electrode array such as the Nucleus 24 Contour is suitable for conventional CI candidates and has been shown to perform as well as or better than so-called "straight" or non-preformed arrays [1] designed for a similar insertion angle but which generally follow the outer wall of the scala tympani when inserted [8]. The electrode array utilized here is the Nucleus 24 Contour Advance, which has the same nominal length of 19 mm as the Nucleus 24 Contour and is also a perimodiolar array designed for an angular insertion depth of 450–540°. The diameter of the array is 0.5 mm at the tip and a maximum of 0.8 mm at the proximal end. Thus the approach described here utilizes a "long" array, allowing conventional candidates for cochlear implantation to benefit from combined El-Ac stimulation in the same ear. The surgical techniques specified for the present study followed the general principles of soft surgery in cochlear implantation [6] and benefited from the experience of otological surgeons from the centres involved, with the aim of minimizing trauma which may result in the loss of residual hearing sensitivity. One aim of this study was to evaluate the success of these techniques, with small deviations, in preserving residual hearing. An additional aim was to study the benefits of combined El-Ac stimulation in the same ear where sufficient residual hearing remained after implantation. The performance of these patients was also compared to that of users of the CI only, i.e. those patients who received the same CI using the same surgical protocol but who did not retain sufficient residual hearing for effective use of an ipsilateral HA after implantation.

Material and methods

Surgical technique

A regular posterior tympanotomy was performed. Care was taken to leave the ossicular chain intact and

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untouched. The bed for the receiver/stimulator was prepared before entry into the middle ear. A 1.0–1.2-mm cochleostomy hole was specified in a low promontorial position, i.e. inferior and anterior to the round window niche (Figure 1). This position appears to allow a "straight" path into the basal turn of the scala tympani and avoids the osseous spiral lamina when entering the scala tympani [10], as shown in Figure 1. This appears to correspond to the "caudal" position specified by Kiefer et al. [10].

The size of the cochleostomy hole was designed to reduce the overall degree of trauma while allowing smooth, complete introduction of the electrode array (largest proximal diameter 0.8 mm). The cochleostomy hole was drilled so that the "blue" lining of the endosteum was visible. Then, a small amount of Healon (hyaluronic acid) was applied to prevent fluid leakage and the entry of foreign bodies such as bone dust before the cochlea was carefully opened with a separate tool. Suction was prohibited at this stage to avoid loss of perilymphatic fluid.

A novel technique called "Advance-off-stylet" (AOS) was designed by the manufacturer (Cochlear Ltd, Lane Cove, N.S.W., Australia) for the introduction of the electrode array to avoid significant contact with the lateral wall of the cochlea. The array is preformed to the shape of an "average" cochlea. Before insertion, the array is held straight by a stylet and inserted $\approx$8.5 mm into the cochleostomy hole, as indicated by a white marker dot placed on the electrode. At this point the stylet is held still and the silicon electrode carrier is pushed off the stylet so that it follows the curvature of the cochlea, thus minimizing the forces against the outer lateral wall

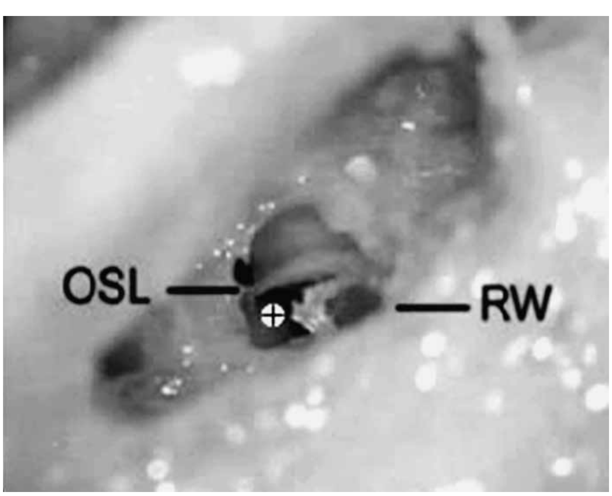

Figure 1. View of prepared temporal bone showing the position of the cochleostomy (*cross*) opening into the scala tympani relative to the round window (RW) niche, with the osseous spiral lamina (OSL) passing above. Photograph courtesy of R. Briggs, Co-operative Research Centre for Cochlear Implant and Hearing Aid Innovation, Melbourne, Australia.

(Roland JT, personal communication). For this study it was recommended that the electrode was inserted up to $\approx$17 mm (Figure 2A) so that the 3 square ribs remained outside the cochleostomy hole. This electrode array can be inserted up to 19 mm, so that all 3 ribs are pushed into the cochleostomy hole. However, observations in temporal bones made by some of the authors revealed that introduction of more than one square rib tended to result in the array being pushed away from the modiolus and towards the lateral wall at the point of the start of the turn (Figure 2B).

The specified "length" of insertion corresponds to all three "marker" ribs being left outside the cochleostomy hole. In temporal bones, insertion up to this point still resulted in maximum insertion angles which exceeded 1 turn, or 360°. After introducing the array, the cochleostomy hole was sealed with fascial tissue to aid in stabilizing the array.

Surgical questionnaire

Compliance with the surgical protocol defined above was monitored by means of a questionnaire. Additional information about the surgery, for example the use of drugs, was also collected in this format. In additional to indicating in a yes/no format whether the surgical procedures defined above had been adhered to, the following questions were posed. What was the size of the cochleostomy hole (e.g. other than 1.2 mm)? Which instrument was used to pierce the soft-tissue membrane? Was the basilar membrane visualized? Did bone dust enter the scala tympani? Which instrument/s were used to perform insertion of the electrode array? Was the insertion successful? Did you retract the electrode array? How easy was the AOS technique? What was the position of the marker ribs? Was the electrode stable after sealing the cochleostomy hole? What was the overall duration of surgery? For how long was the cochlea open? Was lubrication used (e.g. other than Healon)? Which drugs were used (either locally or systematically)?

Postoperative radiological evaluation

The final position of the implanted electrode array was assessed through analysis of X-ray images obtained with a modified Stenver's or "cochlear" view [8]. The form and position of the array relative to anatomical landmarks was evaluated according to the scheme of Xu et al. [8] using computer-assisted analysis to obtain the angle of insertion of the most apical electrode relative to the line between the centre of the cochlea spiral and the round window.

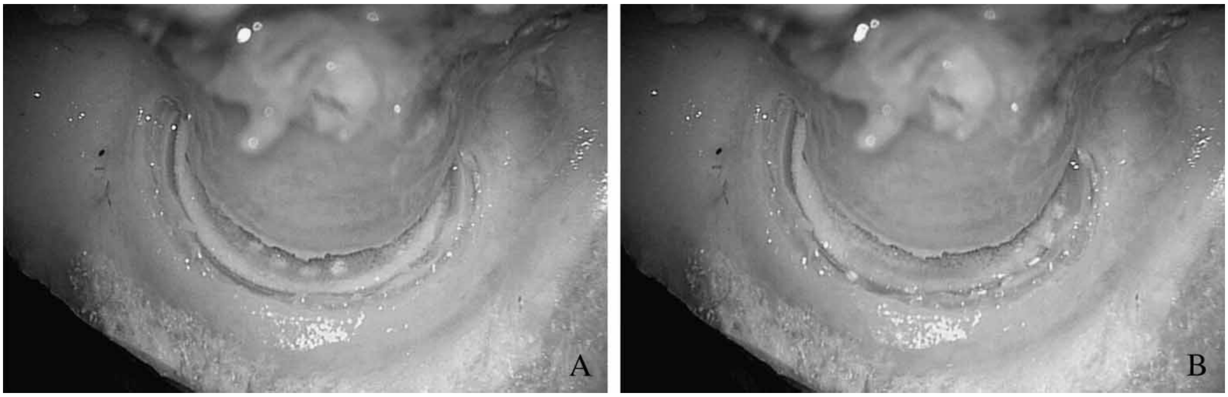

Figure 2. (A) The position of the electrodes in the basal turn when up to one square rib is introduced into the cochleostomy hole. The electrodes lie close to the medial wall. (B) When all three square ribs are introduced into the cochleostomy hole the electrode array tends to get pushed away from the modiolus towards the outer wall.

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Patients

The subjects were 12 candidates for cochlear implantation with a Nucleus 24 Contour Advance electrode array according to national criteria. The patients presented a range of aetiologies, HA experience and durations of deafness (Table I).

Subjects were selected for the study based on the following criteria: post-linguistically deafened adults (e.g. age >18 years at time of recruitment) with a minimum of 10% open-set word recognition with the ear to be implanted under the best aided conditions. This indicated that the patients had a minimum level of residual hearing preoperatively which might be effectively combined with a CI postoperatively. The study protocol received ethical approval from the CCPPRB Toulouse II (approval No. 2-03-23), the Manchester LREC (approval No. 03/CM/536), the Albert-Ludwig-University ethics committee (approval No. 123/03) and Freiburg Ethics Committee International (approval No. 03/1028) as well as individual hospital ethics committees and was in accordance with the revised Declaration of Helsinki (2002).

HA fitting

All patients were re-fitted bilaterally with state-of-the-art Phonak HAs preoperatively. In-the-ear (ITE) Aero 33 or Aero 22 HAs were fitted for those patients whose hearing thresholds were well within the fitting range of the instrument up to a frequency of at least 500 Hz (<60 dB HL) and who tended to have a "dead region"-type hearing curve or steeply sloping audiogram [14].

Using the DSL – Desired Sensation Level input/output (i/o) [15] frequency–gain rule as a basis, ITE HAs were fitted according to a "dead region"-type rule [14,16], where the gain for frequencies at which hearing thresholds exceeded 80 dB HL was reduced to improve loudness comfort and prevent feedback. The aims were to provide a fitting of comfortable loudness where dynamic ranges were small and where possible to use a small vent in the ear mould to avoid occlusion discomfort. These aims agreed with the consensus amongst HA professionals which indicated that, in these cases, provision of gain in the high frequencies at the prescription level often resulted in disuse of hearing instruments [16]. The DSL (i/o) gain prescription [15] was used as a starting point in the remaining patients who were fitted with Phonak Supero 412 behind-the-ear (BTE) HAs. "Super Compression" (linear amplification with output limiting) with optional noise reduction was used in both ITE and BTE HAs.

In most cases, patients had 1 month of experience with their new HAs before the first evaluation. Where patients had limited experience of HA use, this period was extended to at least 3 months to allow some time to acclimatize.

Evaluations and schedule

Patients were tested twice at an interval of 2–4 weeks prior to implantation. They were subsequently tested at intervals of 1 (CI activation), 2, 3 and 6 months after implantation.

Pure-tone air-conduction thresholds were used to monitor residual hearing in both ears. Where possible, a 1-dB step procedure was used to improve the test–retest reliability and precision of measurements, with 6 ascending runs of 1-dB steps for each frequency tested. The patients indicated when they first heard a tone for each run and this level was recorded. The mean of the six levels was taken as the hearing threshold level (HTL). In the remaining cases a conventional 5-dB step Hughson–Westlake procedure was used, with one data point per frequency per session. Where possible, preoperative HTLs at each frequency were represented by the

Table I. Summary of biographical, surgical and care information, and pre- to postoperative increases in HTL at 250–500 Hz for the 12 patients implanted.

Patient No.	Sex	Age (years)	Duration of deafness (years)	Aetiology	Ear	Piercing of soft tissue membrane?	Insertion performed with?	Drugs	Duration (h:min) Total	Duration (h:min) Cochlea open	Maximum insertion angle (°)	Increase in HTL at 250–500 Hz (dB)
1	M	60	10	Prog.	L	NA	Forceps	Cortico-steroid i.v.	2:00	0:30	393	>50.0
2	F	69	NA	NA	L	NA	NA	NA	NA	NA	NA	37.5
3	M	51	5	Prog.	L	Burr	Special claw	Cortico-steroid i.v.	2:15	0:10	407	24.0
4	M	30	30/6[a]	Cong./Prog.	R	Needle	Special claw	Cortico-steroid i.v.	2:10	0:10	420	30.0
5	F	50	50/2[a]	Cong./Prog.	L	Cochlear tool	Forceps	Cortico-steroid i.v.	1:30	0:10	430	69.5
6	M	60	NA	NA	R	NA	NA	NA	NA	NA	270	48.0
7	F	32	20	Prog.	R	Pick	Forceps	Cortico-steroid i.v. for 3 days + oral for 10 days	1:30	0:03	373	11.5
8	M	51	51/5[a]	Cong./Prog.	L	Pick	Surgical claw	Cortico-steroid + antibiotics i.v.	1:20	NA	347	17.5
9	F	34	15	Prog.	R	Pick	Surgical claw	Cortico-steroid + antibiotics i.v.	1:35	0:05	418	25.5
10	M	81	1	Prog.	L	Diamond drill	Surgical claw	Cortico-steroid + antibiotics i.v.	NA	NA	393	>40.0
11	F	27	2	Prog.	L	NA	NA	NA	NA	NA	385	16.0
12	F	56	11	Prog.	L	Pick	Surgical claw	Cortico-steroid + antibiotics i.v.	2:00	0:10	300	17.0

[a]Supposed congenital high-frequency deafness, followed by more recent progression.
Cong. = congenital; Prog. = progressive; NA = not available or not answered.

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average of the HTLs obtained from two preoperative sessions.

Performance with HAs and CIs was evaluated using isolated word recognition in quiet and sentence recognition in noise. Pre- and postoperatively, the implant ear was tested alone with the contralateral HA switched off or the contralateral ear plugged. Implant-alone performance was tested with the ipsilateral HA either switched off (HTLs > 50 dB HL) or plugged.

A list of at least 20 words (monosyllabic for Germany, disyllabic for France and Spain) was presented at a conversational level of 65 dB SPL for each test condition. Where possible, an adaptive sentence recognition in noise test was used to obtain the signal:noise ratio (SNR) for 50% correct recognition of words in sentences (SNR50). Elsewhere, lists of sentences were presented at 70 dB SPL with SNRs of 10 and 5 dB (France and Spain) to obtain a percent correct word score. Word scores for both SNRs were used to derive an equivalent SNR50 based on a performance–intensity function obtained with typical CI users to allow comparison across centres and languages.

Speech processor programming

Postoperatively, patients were divided into 2 groups according to residual HTLs in the implanted ear: "El-Ac" users, where HTLs were ≤80, 80 and 90 dB HL at 125, 250 and 500 Hz, respectively; "CI-only" users otherwise.

For both groups, initial activation of the Nucleus 24 Contour Advance CI to find the psychophysical threshold and comfortable levels for each active electrode was performed according to local clinical practice. CI-only users were treated as "normal" CI recipients. Patients used ESPrit 3G ear-level speech processors using, in most cases, a program or map with the advanced combination encoders speech processing strategy, 8 maxima and 900 pulses/s/channel.

El-Ac users were deemed able to benefit from amplification with the Phonak Aero 33 or 22 in the implanted ear up to HTLs of 80 dB HL. In this first postoperative session, El-Ac users were given one of two types of program: map A (normal or default); or map C, where low-frequency information is provided only by the HA and high-frequency information by the CI. In map C, the frequency:electrode allocation is shifted so that apical electrodes are in use.

The principle followed was to provide individual El-Ac users with the opportunity to experience both kinds of combined stimulation in order to obtain optimum benefit (maps A and C). After 1 month of experience the map was changed over and at 2 months these patients were able to switch between maps A and C in their speech processor. The rationale for and results of this manipulation are outside the preliminary scope of this paper; only the results obtained with the best and/or preferred program will be presented here.

Analysis of hearing preservation data

A review of the literature in which results of hearing preservation after implantation are reported revealed a range of approaches to providing group statistics. A major error is to leave out data points where no measurable threshold could be obtained after implantation. Thus the number of patients may be reduced to less than that of the study population, and may vary according to the test frequency. This also tends to bias the results favourably because the largest increases in HTLs are left out of the calculation. An alternative approach is to use an artificial value to represent total loss of hearing, perhaps at the limit of the audiometer output; however, this can also lead to underestimated group statistics.

In reporting pre- to postoperative differences we chose to use a statistic that incorporated all the data from the 12 patients. Thresholds that postoperatively exceeded the limit of the audiometer output are recorded as "not measurable" (NM). NM values were recorded here when thresholds exceeded maximum audiometer output limits of 83 dB HL at 125 Hz, 96 dB HL at 250 Hz and 120 dB HL for the remaining frequencies 500–4000 Hz. The central tendency of the data was represented by median values obtained for each test frequency. The NM values were all treated as "very large" levels so that they are always found at the high end of the distribution of data points for each frequency, either for the postoperative level or for the corresponding pre- to postoperative difference (Table II). Use of the median (or median change) rather than the mean avoids the problem of the non-numeric value of NM data points while still making it possible to give a valid measure of central tendency using all patients. The example calculation in Table II illustrates the underestimation of group mean or median differences when either an artificial value of 115 dB is used or the mean or median is calculated using only those data points where a postoperative HTL could be measured, compared to the method used in this paper.

Table II. Example calculations of measures of central tendency (mean or median) using the scheme used in this paper ("Median ($n=7$)", "true value" in italic) and other methods which tend to underestimate the change in HTLs.

	HTLs (dB)		Pre- to postoperative difference (dB)	
Summary statistic	Preoperative	Postoperative	True value	Artificial NM (=115 dB)
	110	115	5	5
	100	115	15	15
	90	110	20	20
	60	85	25	25
	110	NM	NM	5
	100	NM	NM	15
	80	NM	NM	35
Median ($n=7$)	100	115	*25*	15
Median ($n=4$)	95	112.5	17.5	
Mean ($n=7$)	92.9			17.1
Mean ($n=4$)	90	106.3	16.3	

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Results

Pre- and postoperative HTLs are presented for the 10 patients who retained measurable postoperative HTLs. Thresholds as low as 20–30 dB HL were retained for frequencies of 125 and 250 Hz, and as low as 80 dB HL at a frequency of 500 Hz. Six of the 12 patients retained thresholds within the range for using an ipsilateral HA (El-Ac users).

Two patients (P1, P10; Table I) suffered complete loss of residual hearing due to problems encountered during surgery. In the first case (P1), there were difficulties in handling the AOS insertion technique and the electrode had to be withdrawn and re-inserted. In the second case (P10), a great amount of drilling was required to pass into the cochlea capsule, which most likely resulted in damage to the osseous spiral lamina and ligament. The basal end of the cochlea appeared to be ossified. This was not detected in preoperative CT scans. In both cases the surgeons considered that soft surgery had not been accomplished.

HTLs at >1 month after implantation were available for six subjects, as shown in Figure 3. In general, levels were stable over a 2–7-month period for frequencies of 125–500 Hz. However, in one case (P11), hearing levels increased to above audiometer limits after the initial test 1 month after implantation. In another (P9), there appeared to be some degradation in the HTL at 500 Hz between 1 and 2 months. This then remained stable up to the longest postoperative interval of 7 months.

HTLs for frequencies of 125–1000 Hz for the complete group of 12 implanted patients are summarized in Figure 4. All patients had measurable thresholds preoperatively up to 1000 Hz. Median values for frequencies >1000 Hz are not presented here because there were often cases where thresholds were not measurable preoperatively.

The ranges of preoperative HTLs for the 12 patients studied are shown in Figure 4. The median HTLs preoperatively and at 1 month after implantation are presented for the 12 patients studied. In addition, the median increases in HTLs are presented. The median change can be interpreted as "half the patients had an increase in threshold of ≤X dB". Median increases in HTLs were 23–33 dB for the frequency range 125–1000 Hz. To enable further discussion of the data, the distributions of increases in HTLs at each frequency are presented in Table III.

Taking the data presented in Figure 4 and Table III together, increases in thresholds were typically between 10 and 30 dB. Median increases were much greater for the CI-only users compared to the El-Ac users (Table III), indicating that the success of surgery rather than preoperative HTLs played a larger part in determining whether patients could go on to use El-Ac stimulation.

The maximum angle of insertion of the electrode array obtained from analyses of postoperative X-ray images is shown for each patient in Figure 5, plotted versus the mean increase in HTLs for frequencies of 250 and 500 Hz; the largest increases were seen for these frequencies. The maximum insertion angle ranged from ≈300° to 430°, or about three-quarters to one and a quarter turns. A smaller angle of 270° was seen for a case shown on the left-hand side of Figure 5: from the X-ray image it appeared that the tip became folded over and this may have hindered

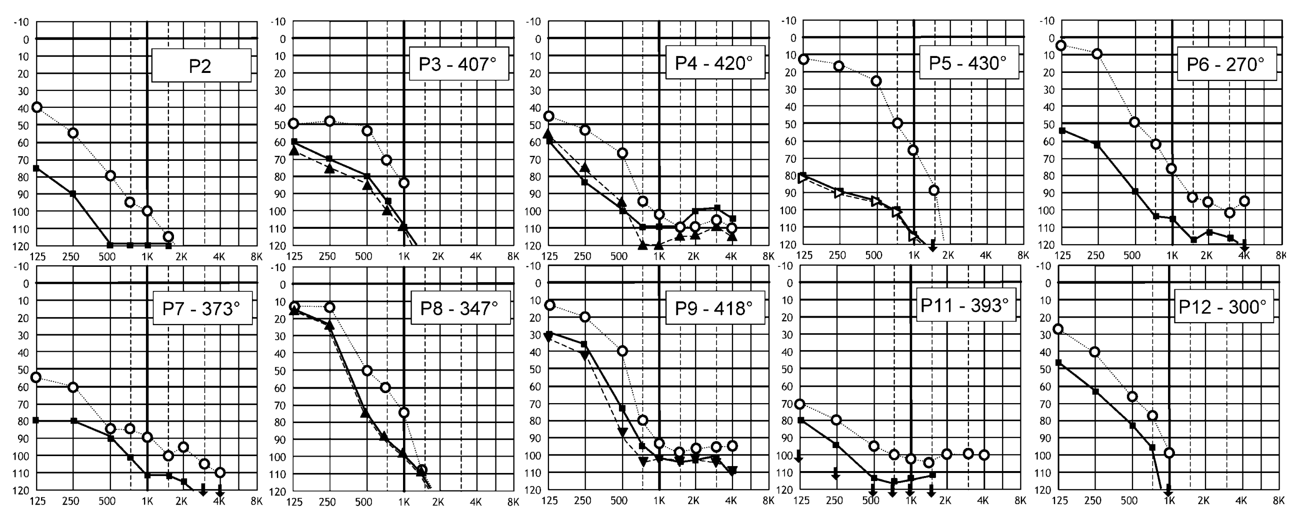

Figure 3. Short- and long-term HTL data for the 10 patients who retained measurable postoperative thresholds. Dotted lines with circles show preoperative HTLs and solid lines with squares shown 1-month postoperative HTLs. Dashed lines with filled upward-pointing triangles, solid downward-pointing triangles (one case) and open triangles (one case) represent HTLs at 4, 7 and 2 months, respectively. In one case (P11), HTLs were measurable at 1 month but exceeded audiometer limits at 2 months (*arrows*). Maximum insertion angles are also shown.

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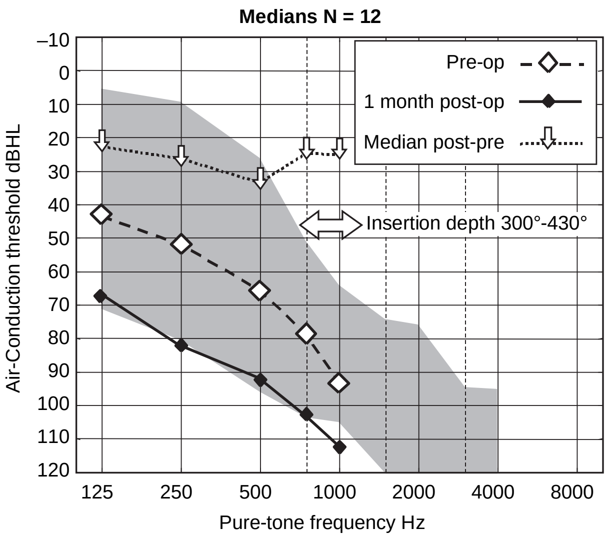

Figure 4. Median pre- and postoperative HTLs for 12 patients. The median increase in HTLs is also given. The shaded area represents the range of preoperative HTLs for the 12 patients implanted. The double-headed arrow represents the range of insertion angles in terms of characteristic frequencies [8]. See text for further explanation.

smooth progress of the array along the scala tympani.

Taking the three points at the lower right of the graph, two are the complete losses of residual hearing mentioned above and the other involved a larger cochleostomy hole and the greatest maximum insertion angle, despite leaving all three square ribs outside the cochleostomy hole. Much better preservation of residual hearing was seen with a similar angle of insertion (418°) for another patient where all 3 ribs were left outside the cochleostomy hole, but where a smaller cochleostomy hole (1.0–1.1 mm) was made. In summary, insertion depths $> \approx 400°$ appeared to start to have an influence on hearing preservation in the frequency region 250–500 Hz, whereas at smaller angles there were consistent increases in thresholds of 10–20 dB in cases where additional departures from the protocol or other problems were not reported.

Additional surgery information is presented in Table I for each patient. In most cases the cochlea was open for up to 10 min from penetration of the soft-tissue membrane to stabilization with fascia. The notable exception was 20 min for 1 patient (P1), as mentioned above, where the electrode array was withdrawn and re-inserted. Corticosteroids were administered intravenously during surgery in all cases, and in 1 case for up to 10 days after surgery. Antibiotics were administered intravenously in four cases. There were no other departures from the surgical protocol.

Preliminary speech recognition results were available for six patients who had at least 3 months experience using the CI. Three used an ipsilateral HA in combination with the CI (El-Ac users P3, P8 and P9), and 3 used a CI only (CI-only users P4, P10 and P11). Pre- and postoperative scores for isolated word recognition in quiet are given in Figure 6, and for sentence recognition in noise in Figure 7.

Two CI-only users (P10, P11) had notably good postoperative performance on isolated word recognition, and 2 El-Ac users experienced more modest benefit (P3, P9), although it still exceeded 40% in 1 case (P9). However, both these El-Ac patients enjoyed a benefit in terms of word recognition when using an ipsilateral HA in combination with a CI, giving a pre- to postoperative benefit of 25–55%. The benefit in terms of word recognition for the remaining CI-only and El-Ac users was relatively poor (up to 6 months) and this may have been due to the congenital component (Table I) of the hearing losses of these two patients, so that they required greater time to learn to use the additional high-frequency information provided by the CI.

The combined use of a CI and an ipsilateral HA appeared to give superior performance for listening in noise (Figure 7). The best performance for

Table III. Distributions and median increases in pure-tone HTLs measured preoperatively and 1 month after implantation for the 12 patients.

	Pure-tone frequency (Hz)				
Increase in HTL (dB)	125	250	500	750	1000
0–10	2	1	1	0	3
11–20	3	3	2	5	1
21–30	2	2	2	3	3
31–40	1	2	3	0	1
>40	4	4	4	4	4
Median ($n = 12$) (dB)	23	27	33	25	26
Median El-Ac users (dB)	19	21	26	22	25
Median CI-only users (dB)	52	55	53	39	35

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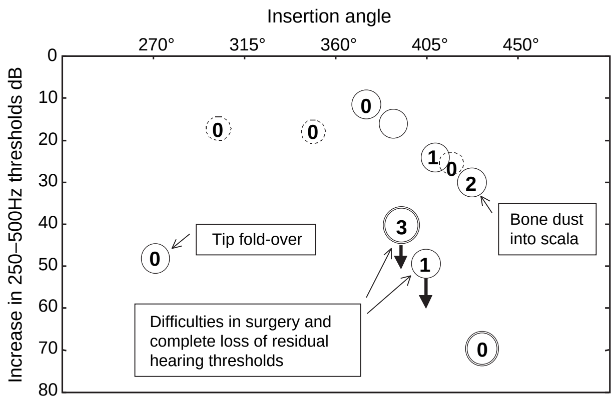

Figure 5. Pre- to postoperative increase in HTLs at 250–500 Hz versus angle of insertion obtained from cochlear view X-ray [8]. The number in each circle indicates the number of ribs reported to have been placed into the cochleostomy hole. Broken and double circles indicate that the diameter of the cochleostomy hole was <1.2 and 1.5 mm, respectively.

sentence recognition in noise was achieved by the two El-Ac users P9 and P3 despite relatively modest word recognition scores compared to the best CI-alone users. Subjectively, El-Ac users preferred the sound quality provided by combined use of a CI and an ipsilateral HA, despite also wearing a contralateral HA.

Discussion

The results presented here support the findings of three other centres working on combined ipsilateral El-Ac stimulation [5,10,11] in that they show that hearing may be preserved after cochlear implantation provided that an appropriate surgical protocol is followed. In our multicentre study we have shown that it is possible to partially preserve residual hearing after the introduction of a perimodiolar

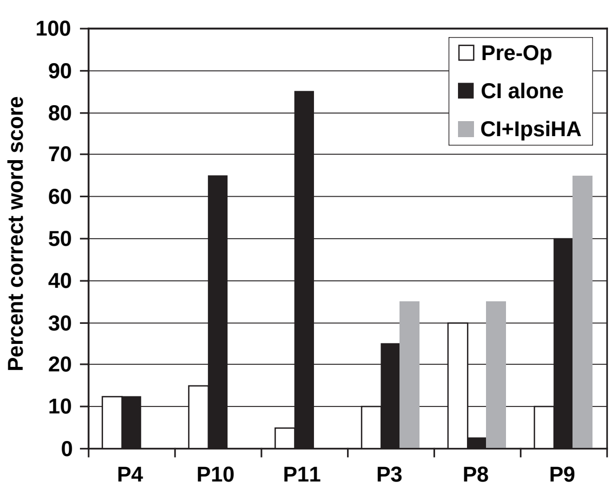

Figure 6. Recognition scores for isolated words presented in quiet at 65 dB SPL for three CI-only users (P4, P10, P11) and three El-Ac users (P9, P8, P3).

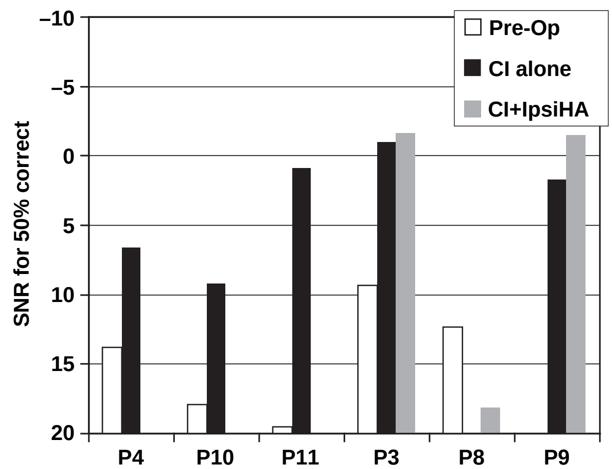

Figure 7. Speech reception thresholds in noise (SNR50) for three CI-alone users and three El-Ac users (a lower SNR indicates better performance).

electrode array. It is clear from the two cases in which the surgeons reported difficulties during surgery that if soft surgery is not achieved this will likely result in complete loss of measurable residual hearing. The group data for hearing preservation for the group presented here (Figure 4, Table III) include those two patients where there was total loss of residual hearing without the introduction of artificial values into the data analysis and thus provide a genuine indication of the likely change in HTLs due to cochlear implantation.

There was some indication of the possible influence of insertion depth on residual HTLs at 250 and 500 Hz (Figure 5). It appears that it is still possible to partially preserve residual hearing down to these frequencies even with an insertion depth as great as 420°, or nearly 1 and a quarter turns. The use of modified Stenver's or "cochlear" view X-ray images allowed confirmation of the angular position of the most apical electrode. This is not possible with measures only of linear insertion depth (i.e. in millimetres), as the position of the electrode relative to the lateral or medial wall and the size of the cochlea can have a great influence on the final angle of insertion and therefore on the proximity of the electrodes to residually functioning populations of inner and outer hair cells [8] and their associated characteristic frequencies.

Kiefer et al. [10] and Gstoettner et al. [11] presented data from studies where the aim was to place the electrode at about 1 full turn, or 360°. However, the insertion angles were not confirmed by X-ray analysis and the example shown by Kiefer et al. for a 24-mm insertion amounted to an insertion angle of 340°; this was the upper limit of their 18–24-mm linear insertion depth range. Kiefer et al. also implemented additional measures with the aim of

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preserving residual hearing, such as the application of corticosteroid (triamcinolone) into the cochleostomy hole and the use of a sheath to further prevent entry of blood or bone dust. The hearing preservation achieved in those dual-centre studies appears to be more favourable than that achieved in the present multicentre study. For example, Kiefer et al. [10] reported median increases in thresholds of 10, 15 and 17.5 dB for frequencies of 125, 250 and 500 Hz, respectively, compared to 23, 27 and 33 dB in the current study. Some of the difference may be attributable to the physical factors mentioned above or to the method of calculation or treatment of unmeasurable postoperative hearing levels or the exclusion of patients who experienced complete hearing loss due to soft surgery not being accomplished. The method used here included all 12 patients for the frequency range 125–1000 Hz, whether or not there was a loss of measurable threshold.

The results of Gantz and Turner [5] with short 6- or 10-mm arrays also appear to show moderately better group statistics. The greater overall insertion depths achieved in the current study may explain the difference in the best cases of hearing preservation: 0–10 dB in the studies of Gstoettner et al. [11] and Gantz and Turner [5], compared to 10–20 dB in the present study.

In the current study we also addressed the long-term stability of hearing thresholds after implantation. It is important to establish the long-term stability of residual hearing after implantation in order to plan the rehabilitative outlook. HTLs appeared to be stable in patients for up to 7 months after implantation, except in 1 case (P11) where they disappeared after 2 months. It is not clear what the cause was in this case: it was perhaps due to slow degradation of nerve survival or perhaps loss of the ability to integrate acoustic stimulation into a detectable sensation. The aetiology of deafness was unusual in this case, namely a neuro-degenerative disease (Merff syndrome). However, the benefit of cochlear implantation was striking in that there were high levels of word and sentence recognition in noise for this patient, perhaps due to the relatively short duration of profound deafness and the youth of this patient (P11; Figures 6 and 7).

This can be contrasted with the relatively poor CI-alone outcome for two other patients who might be classed as "peri-linguistically" deafened (P4, P8). The problem here is the definition of "post-linguistic onset of severe-to-profound deafness". In three patients it was suspected that they had suffered from severe-to-profound high-frequency deafness during childhood. In two cases these patients had not used HAs for long continuous periods and reported that hearing had only become "a problem" in more recent years. This indicates a reliance on low-frequency information plus lip-reading in order to communicate effectively. There would appear to have been some point where the progression of loss of hearing sensitivity necessitated further intervention. One common reason for non-use of HAs in this population is the problem of providing comfortable and effective amplification when HTLs increase dramatically from near-normal to profound levels over one octave [14,16]. The HA-fitting approach used in this study allowed patients to wear HAs for 3 or 4 months in everyday, often noisy, environments before implantation. Indeed, preoperative evaluations showed improvements in disyllabic word recognition performance over time from nearly 0% to nearly 50% in 1 case (P8). These kinds of improvements may postpone candidacy for cochlear implantation. Rapid postoperative improvement in speech recognition was only observed for two of the four cases with steep audiograms (P3, P9 vs P4, P8). More positively, all these patients now wear contralateral HAs which continue to give them benefit when used with a CI alone or with an El-Ac combination on the opposite ear.

The question to be posed in the near future is what are the relative benefits of insertion of a long electrode, perhaps with total loss of residual hearing, and insertion of a shorter electrode, or use of a shallower insertion depth, such that some or all of the residual hearing is conserved? The preliminary results presented here indicate that there is the possibility of preserving residual hearing up to 500 Hz with an insertion angle of 400° (our mean insertion angle was only a little less than that of 15 recipients who received a standard Nucleus Contour CI over the course of 1 year in Toulouse, with very satisfactory outcomes). Indeed, Kiefer et al. [10] and Gstoettner et al. [11] have reported informally that their patients who receive El-Ac-style short insertions perform as well or better than "standard" patients with insertions as deep as 720°. Thus, there appears to be no obvious disadvantage of a 360° insertion in terms of CI-alone performance where residual hearing is not preserved for other reasons. It may be that the reduced overall trauma to cochlear structures in those cases and in the present study contributes to the success of these patients. The patients studied by Gantz and Turner [5] had greater levels of preoperative hearing in general, greatly exceeding the maximum performance of candidates in the present study (monosyllable scores of 50–60% and 30%, respectively). The level of functional hearing was much greater for the patients of Gantz and Turner and thus it is perhaps better to look at those patients in the light of adding a CI to residual hearing rather than vice versa. The gains in speech perception may be outweighed by the loss of residual hearing. In this respect the short-electrode approach seems entirely appropriate, providing that the actual potential for damage is significantly reduced. It appears that the correct approach to opening the cochlea, whether via the round window [17] or as presented here via an anterior–inferior cochleostomy, is vital to avoid basal trauma, whether a long or short electrode is used. This should be coupled with systemic and perhaps local application of corticosteroid.

In addition to benefits in terms of speech perception, either in quiet or noise, we aim to have patients benefit from improved sound quality and enjoyment of music. There are ongoing studies into the additional benefits of combined El-Ac stimulation which will allow us to go much further in allowing patients both to have effective speech communication and to enjoy other aesthetic benefits of their sound environment. The continuation of the current study will allow a better understanding of the surgical factors involved in the preservation of residual hearing and the benefits of combined El-Ac stimulation across a number of centres in Europe.

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Conclusions

Hearing may be conserved in adults after implantation with the Nucleus Contour Advance perimodiolar electrode array. The median increases of 23, 27 and 33 dB presented here for frequencies of 125, 250 and 500 Hz, respectively represent the data from all 12 patients, including 2 where there was a complete loss of residual hearing due to problems encountered during surgery. The degree of hearing preservation and the final maximum insertion angle of the electrode array can vary considerably (from 300° to 430°), despite a defined surgical protocol. Insertion angles >400° appeared to impact hearing preservation at frequencies of 250–500 Hz. Half of the patients retained sufficient residual hearing after implantation to potentially benefit from combined use of a CI and an ipsilateral HA. Residual hearing combined with electrical stimulation in the same ear can provide additional benefits in terms of speech recognition in quiet and noise and sound quality for conventional candidates for cochlear implantation. Cochlear implantation with a perimodiolar electrode array can be of considerable benefit in these patients, whether residual hearing is conserved or not.

Acknowledgements

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