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Residual Hearing Conservation and Electroacoustic Stimulation with the Nucleus 24 Contour Advance Cochlear Implant

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Objective: To assess the conservation of residual hearing in recipients of the Nucleus 24 Contour Advance cochlear implant (CI) and the benefits of combined electrical and acoustic stimulation.
Study Design: Prospective multicenter study.
Setting: CI clinics in Western Europe.
Patients: Adult candidates for conventional cochlear implantation with a minimum preoperative word recognition score of 10% in the ear to be implanted.
Intervention: "Soft-surgery" protocol, including a 1- to 1.2-mm anterior and inferior cochleostomy hole with the electrode array, inserted 17 mm using the "advance-off-stylet" technique. Patients with postoperative pure-tone hearing threshold levels (HTLs) of 80 dB hearing loss or less at 125 and 250 Hz and 90 dB hearing loss or less at 500 Hz were refitted with an in-the-ear hearing aid for combined ipsilateral electrical and acoustic (El-Ac) stimulation.
Main Outcome Measures: A questionnaire to collect information regarding surgery. Pure-tone HTLs measured at intervals. Word recognition tested in quiet and sentence recognition tested in noise at 10 and 5 dB signal-to-noise ratio (SNR).
Hearing Conservation Results: HTL data were available for 27 patients. HTLs were conserved within 20 dB of preoperative levels for 33, 26, and 19% of patients for 125, 250, and 500 Hz, respectively. However, the recommended soft-surgery protocol was strictly followed in only 12 of 27 patients. For these 12 patients, hearing thresholds were conserved within 20 dB for 50, 50, and 33% of patients. Median threshold increases were 40 dB (250–500 Hz) for the whole group and 23 dB for the strict surgery group. Ten patients retained sufficient HTLs to enter the El-Ac user group.
Speech Recognition Results: Group mean recognition scores for nine El-Ac users for words presented at 65 dB sound pressure level were 45% for CI alone and 55% for CI + ipsilateral hearing aid ($p < 0.05$, paired t). For sentences presented in noise at 5 dB SNR, mean word scores were 46% CI alone and 56% CI + ipsilateral hearing aid ($p < 0.01$, paired t).
Conclusion: Hearing was conserved for conventional candidates for cochlear implantation where the recommended soft-surgery protocol was strictly followed. Combined ipsilateral electrical and acoustic stimulation provided considerable benefits for speech recognition in noise, equivalent to between 3 and 5 dB SNR, compared with CI alone. **Key Words:** Cochlear implants—Hearing aids—Soft surgery—Electroacoustic stimulation.
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Severely and profoundly hearing impaired adults can substantially benefit from a cochlear implant (CI) for speech understanding (1–3) and quality of life (3). Where residual hearing levels are significant in the contralateral nonimplanted ear, patients can also received additional benefit ("bimodal") via the added use of a conventional hearing aid (4). This has the potential to improve speech recognition, particularly in noise (5,6).

Ipsilateral combination of electrical and acoustic (El-Ac) hearing also seems to be able to provide similar benefits for speech recognition in noise and subjective improvements in sound quality (7,8). The prerequisite for this form of combined stimulation is a sufficient degree of residual hearing in the implanted ear. This has been realized via recent developments in technology and "soft-surgery" techniques (9) combined with a better understanding of the structure and function of the inner ear.

Recent work by groups in Iowa (8) and Frankfurt (10,11) was aimed at hearing-impaired patients who are not traditionally considered as CI candidates and who are characterized by having severe and profound thresholds

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only at frequencies at or greater than 1,000 Hz, with near-normal or mild hearing losses in the low frequencies. In the present study, we aimed to analyze the possibility of combining residual hearing with electrical stimulation in patients who are currently considered conventional candidates for CIs and who have nonzero preoperative speech recognition scores in the ear to be implanted.

A multicenter study undertaken in the U.K. (3) showed that sentence recognition and quality of life were significantly improved through cochlear implantation in patients with preoperative open-set sentence scores up to 50%, provided that the duration of severe to profound deafness was not greater than 30 years. Other studies have also shown benefits for these groups (12), and these have led to an expansion of the indication for CIs of the maximum preoperative speech recognition score. For example, in Germany and in Belgium (Flemish), there is at most a 30% recognition of monosyllabic words; in France and in Spain, at most 50% for disyllabic words; and in the U.K. and the U.S.A., there is at most a 50% recognition of sentences. There are subpopulations of candidates fulfilling these newer criteria who have a very significant amount of low-frequency residual hearing in both ears. These are extreme cases of the "ski-slope" audiogram where pure-tone hearing threshold levels (HTLs) up to 500 Hz may be near normal or moderately impaired, but with severe or profound levels of hearing loss at 750 Hz and above. The poor performance of these patients on speech recognition tasks is because of very limited speech information being conveyed in the low frequencies up to 500 Hz (13–16). An additional problem for these patients is difficulty obtaining a comfortable and effective hearing aid fitting; to provide amplification to the limited sensitivity in the midfrequency range, the lower frequencies may be overamplified. Finally, there is considerable evidence that amplification is ineffective, even under ideal conditions, for frequencies where HTLs exceed 90 dB of hearing loss (16) or correspond to regions of the cochlea with nonfunctioning inner hair cells (14,15). The result, as can be witnessed by many of these patients, is that conventional hearing aids are not comfortable to wear and provide very little or no perceptible benefit, and they often become nonusers. Thus, these patients are reduced to relying upon a combination of lip reading and limited voice and vowel detection to achieve some level of effective speech communication. These patients can be more impaired than some of their counterparts with relatively gently sloping audiogram curves who are more often and rapidly identified as candidates for cochlear implantation. In addition, because of nonuse of hearing aids, these patients may be deprived of even limited access to high-frequency speech information for many of their formative years.

The present article continues the reporting of a multicenter study that includes patients with both steeply and gently sloping audiograms who are candidates for cochlear implantation according to their speech recognition performance being within the criterion for conventional cochlear implantation. The first aim of the study is to test the efficacy of soft surgical procedures in conserving residual hearing in these patients when implanted with a Nucleus 24 Contour Advance perimodiolar CI electrode array (Cochlear Ltd., Lane Cove, Australia); this CI is expected to provide the same benefits whether or not residual hearing is conserved. The second aim of the study is to evaluate the benefits of combined ipsilateral El-Ac stimulation in these patients. For El-Ac stimulation, we defined a "sufficient" level of postoperative residual hearing as HTLs 80 dB hearing loss or less at 125 and 250 Hz and 90 dB hearing loss or less at 500 Hz. These HTLs correspond approximately to the upper limit of the specified fitting range of the most powerful in-the-ear (ITE) hearing aids on the market, the lower limit of vibrotactile-only sensations, and the limit of "effective" amplification as discussed above.

Some preliminary findings for the first 12 patients recruited to this study were published in James et al. (17). It was found that half of the patients implanted retained sufficient residual hearing for use of an ipsilateral hearing aid (ipsiHA). Two cases of a complete loss of measurable residual hearing were attributed to problems encountered during surgery. Surgical technique seemed to influence the degree of hearing conservation along with the final position of the electrode array. Insertion depth angles measured from postoperative "cochlear-view" (18) radiographic images varied considerably (300–430 degrees), despite only a small variation (17–19 mm) in the length of electrode inserted. In the present article, we present hearing conservation results for 27 implanted patients, allowing a better analysis of surgical factors, which influenced outcomes. In the previous preliminary report, early speech tests showed that there were additional benefits of speech perception recognition in three patients when using a combination of electrical and acoustic stimulation in the same ear (El-Ac users). In the present article, we report results for nine El-Ac users and seven patients using CI only. It should be noted that many of the patients continue to use a contralateral hearing aid in addition to either El-Ac or CI-only stimulation in the implanted ear. However, for the purposes of brevity, all testing reported here is for monaural listening, which is with the contralateral ear plugged where necessary. Also, we note that in total, 34 patients were reported to have been recruited for the study and implanted, but that insufficient follow-up or return of case report forms (particularly surgical questionnaires) led to the reduced numbers.

METHODS

Population

Patients were adult candidates for cochlear implantation with a Nucleus 24 Contour Advance CI according to national criteria. The patients presented with a range of pathogeneses, hearing aid experience, and durations of deafness (Table 1).

TABLE 1. *Biographical and surgery information given for each patient individually*

	Patient No.																										
	1	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	23	24	25	26	27	28	32	33	34
Age at implantation (yr)	70	65	30	50	60	32	51	34	81	27	56	35	77	25	51	40	65	NA	71	68	26	51	37	64	NA	NA	27
Duration of deafness (yr)	40	5	6	2	5	20	5	15	3	8	2	10	3	8	9	NA	7	7	2	6	0.3	0.5	NA	2	10	1.5	15
Etiology	Un.	Un.	Un.	Un.	Un.	Un.	Un.	Un.	Un.	Mit.	Un.	Tx.	Un.	Un.	Fm.	NA	Un.	Fm.	Un.	Mn.	NA	Mn.	Ot.	Un.	Un.	Un.	Un.
Deviations from surgical protocol																											
Ossicular chain touched															×												
Cochleostomy not anterior/inferior									×																		
Hole size >1.2 mm				×					×				×			×	×										
Healon not used									×				×														×
Suction of perilymph													×						×	×	×	×	×	×			×
AOS not performed																											×
Ribs into cochleostomy hole >1	×		×												×												
Total deviations	1		1	1					3				3		2	1	1		1	1	1	1	1	1			3
Other information																											
Membrane drilled		×							×				×						×	×	×	×	×	×			×
Bone dust into scala			×										×														
Corticosteroid not used										×		×	×		×	×	×									×	
Radiograph																											
Tip fold-over					×																						
Insertion depth angle (degrees)		407	420	430[a]	300[a]	373	347	418		385	315[a]	393	330[a]	420	403	323	377	435[a]					375	390[a]	330[a]		360
Preoperative/postoperative threshold difference																											
Mean, 250 and 500 Hz (dB)	48[b]	25	31	61	47	11	16	27	25[b]	17	20	10	43[b]	21	56	30	39	51[b]	23[b]	20[b]	26[b]	10[b]	118	27[b]	51[b]	9[b]	31

Gaps in patient numbering indicate where case report forms were not obtained for implanted patients. "×," deviations from the surgical protocol; AOS, advance off-stylet; Fm., familial; Mit., mitochondrial; Mn., Meniere disease; Ot., otosclerosis; Tx., ototoxic drug; Un., unknown. [a]Angles estimated according to the method of Calmels et al. (19). [b]Postoperative threshold "not measurable," difference = audiometer limit − preoperative level.

Preoperatively, patients had 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. In addition, patients were screened for etiologies, which may contraindicate implantation with a perimodiolar electrode array, such as ossification or cochlear malformation detected on preoperative computed tomographic scan.

Array Description

The electrode array of the Nucleus 24 Contour Advance has a nominal length of 19 mm and is designed to achieve a perimodiolar position via a preformed design with a desired angular insertion depth of about 450 degrees. This electrode array is similar to that of the Nucleus 24 Contour (1) CI and is suitable for conventional CI candidates. The diameter of the array is 0.5 mm at the tip and a maximum of 0.8 mm at the proximal end.

Surgical Procedures

Surgical procedures were defined as follows. In general, they followed the principles of soft surgery (9), with specific aims to reduce surgical trauma when placing the Nucleus 24 Contour Advance device: a posterior tympanotomy was performed. Care was taken to leave the ossicular chain intact and untouched at all stages. The bed for the receiver stimulator was prepared before entry into the middle ear. A small 1.0- to 1.2-mm-diameter cochleostomy hole was made in a low promontorial position (i.e., inferior and anterior to the round window niche) (17). This position affords a "straight" path into the basal turn of the scala tympani and avoids the osseous spiral lamina when entering the scala tympani (10). The cochleostomy hole was drilled until the "blue" lining of the endosteum became visible. A small amount of Healon (sodium hyaluronate) (Advanced Medical, Optics, Uppsala, Sweden) was applied to prevent fluid leak and the entry of foreign bodies such as bone dust. 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," or AOS, was designed by the manufacturer for the introduction of the electrode array to avoid significant contact with the lateral wall of the cochlea. Before insertion, the array was held straight by a stylet and inserted about 8.5 mm into the cochleostomy indicated by a white marker dot placed on the electrode. At this point, the stylet was held still, and the silicon electrode carrier was pushed off the stylet so that it follows the curvature of the cochlea, thus minimizing the forces against the outer lateral wall (17). For this study, it was recommended that the electrode was inserted up to approximately 17 mm so that the three square ribs remain outside the cochleostomy hole. This prevents the array from being pushed away from the modiolus and toward the lateral wall at the point of the start of the turn. Because it was hard to define first rib "at" the cochleostomy, zero or one rib into the cochleostomy were both deemed to be in keeping with the surgical protocol—with an uncertainty in linear insertion depth of 1 mm. After introduction, the array was stabilized at the cochleostomy by sealing with fascial tissue.

Surgical Questionnaire

Compliance with the surgical protocol defined above was monitored through a questionnaire (nonstandardized). Additional information regarding the surgery, for example, the use of drugs, was also collected in this form. In addition to indicating in a yes/no format that the surgical procedures defined above had been adhered to, the following questions among others were posed (17): which instrument used to pierce the soft tissue membrane? Bone dust into scala tympani? How easy was the AOS technique? Which drugs were used (either locally or systemically)?

Postoperative Radiologic Evaluation

The final position of the implanted electrode array was assessed through analysis of radiograph images obtained with a modified Stenver's or "cochlear" view (18). The form and position of the array relative to anatomic landmarks were evaluated according to the scheme of Xu et al. (18) using computer-assisted analysis to obtain the insertion depth angle of the most apical electrode relative to the line between the center of the cochlear spiral and the round window. Where insufficient landmarks were visible, the method of Calmels et al. (19) was used, where the straight portion of the electrode array in the basal turn of the cochlea was taken as a line of reference with no correction. This method had been shown to have a root-mean-square error of 22 degrees for the 15 cases compared with insertion depth angles measured according to the method of Xu et al. (18).

Hearing Aid Fitting

Preoperatively, all patients were fitted bilaterally with state-of-the-art Phonak digital hearing aids. ITE Aero 33 or Aero 22 hearing aids 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 hearing loss) and who tended to have a "dead region"–type hearing curve or ski-slope audiogram (14–16).

Using the desired sensation level (input/output) (20) frequency gain rule as a basis, ITE hearing aids were fitted according to a dead region–type rule (14–16), with the gain for frequencies where hearing thresholds exceeded 80 dB hearing loss reduced to improve loudness comfort and prevent feedback. Where possible, a small vent was used in the ear mold to remove occlusion discomfort. The desired sensation level (input/output) gain prescription (20) was used as a starting point in the remaining patients who were fitted with Phonak Supero 412 (Phonak AG, Stafa, Switzerland) behind-the-ear hearing aids. "Super Compression" (linear amplification with output limiting) with optional noise reduction was used in both ITE and behind-the-ear hearing aids.

Patients with limited experience in hearing aids were given 3 months of experience before starting preoperative testing to allow time to acclimatize to amplification and to obtain optimum preoperative results.

Evaluations and Schedule

Patients were tested twice with an interval of 2 to 4 weeks before implantation, then at 1 (CI activation) and 2, 3, 4, 7, and 13 months after implantation.

Pure-tone air conduction HTLs 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 six 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 median of the six levels was taken as the HTL. In the remaining cases, a conventional 5-dB step Hughson-Westlake procedure was used, with one data point per frequency per session. Preoperative HTLs at each frequency were represented by the average of HTLs obtained from two preoperative sessions.

Performance with hearing aids and CI was evaluated for isolated word recognition in quiet and sentence recognition in noise. Preoperatively and postoperatively, the implant ear was tested alone with the contralateral hearing aid switched off or the contralateral ear plugged. Implant-alone performance was tested with the ipsiHA either switched off (HTLs >50 dB hearing loss) or plugged. The order of the presentation conditions was randomized. Data for 3 months' postactivation were available for German-, French-, and Spanish-speaking patients.

At least 20 words were presented at a conversational level of 65 dB sound pressure level (SPL) in quiet for each test condition. Lists of monosyllabic words were used for German-speaking patients (Freiburger). Lists of disyllabic words were used for French-speaking patients (Fournier, two lists per condition) and Spanish-speaking patients (University of Navarra, lists for adults). These speech materials are habitually used in the evaluation of functional hearing loss and for candidacy for cochlear implantation.

Speech recognition was evaluated for sentences presented in multitalker babble. For most patients, lists of sentences were presented at 70 dB SPL with a signal-to-noise ratio (SNR) of 10 and 5 dB (France and Spain), with the number of correct words repeated to obtain a percent correct word score. French-speaking patients listened to lists of marginal benefit from acoustic amplification version 2 sentences (15 sentences per list, 100 words, Centre Hospitalier Universitaire, Toulouse), and Spanish speakers listened to "everyday sentences" (University of Navarra). Both of these tests were modeled on the City University of New York sentence lists (21).

For German-speaking Patients 3 and 4, the adaptive Oldenburger sentence-recognition-in-noise test was used to obtain the SNR for 50% correct recognition of words in sentences (SNR50). For these two patients, scores for SNRs of 10 and 5 dB were derived from the standard performance-intensity function obtained with typical CI users with these materials. This allowed comparison across centers and languages.

A within-subject design was used for analyzing speech test results. Paired *t* tests were used to make comparisons between conditions; for example, the difference in score between CI-alone and for CI + ipsiHA was tested against 0. Thus, the effect of differences in overall difficulty and performance-intensity functions, which exist between speech materials, was compensated for on a subject-by-subject basis. All test lists were randomly selected, without repetition, which served to remove any residual differences in list difficulty from the group analyses.

Speech Processor Programming

Postoperatively, patients were divided into two groups according to residual HTLs in the implanted ear: El-Ac users, where HTLs were less than or equal to 80, 80, and 90 dB hearing loss at 125, 250, and 500 Hz, respectively, or CI-only users otherwise.

Both groups were activated according to standard local clinical practices for the Nucleus 24 Contour Advance. CI-only users were treated as "normal" CI recipients. In all cases, patients used ESPrit 3G ear-level speech processors running the Advanced Combination Encoder speech processing strategy in most cases with eight maxima and 900 pulses per second per channel.

El-Ac users were deemed able to additionally benefit from conventional amplification where HTLs were less than or equal to 80 dB hearing loss. In this first postoperative session, El-Ac users were administered one of two types of program: MAP A (normal or default) or MAP C, where low-frequency information is provided only via the hearing aid, and only high-frequency information by the CI by switching off the low-frequency channels. In MAP C, the frequency-to-electrode allocation is also shifted so that apical electrodes are in use. Thus, individual El-Ac users were provided with the opportunity to experience both kinds of combined stimulation to find a preferred MAP. Half of the El-Ac users started with MAP A, and the other half started with MAP C. After 1 month of experience, the MAP was changed over, and after 2 months, these patients were able to switch between MAP A and MAP C in their speech processor. The speech perception results presented herein are for the best and/or preferred program with or without ipsiHA.

Data Analysis

A review of the literature reporting results for hearing preservation after implantation reveals a range of approaches to providing group statistics. The method defined in James et al. (17) was followed so that where HTLs exceeded the output limit of the audiometer, these points were still included in the analyses of preoperative to postoperative differences without the use of artificial values. This analysis is based upon median values so that the choice of representation of unmeasurable levels does not affect the measure of central tendency. Pure-tone audiometer limits were 80 dB hearing loss at 125 Hz, 95 dB hearing loss at 250 Hz, 110 dB hearing loss at 500 Hz, and 120 dB hearing loss for all other frequencies. Any thresholds above these levels were identified as "not measurable," and an artificially high value of "999" was entered into the calculation of median thresholds. Where preoperative HTLs were greater than 110 dB hearing loss, these individual points were excluded from the analyses from the onset.

The study protocol received ethical approval from the Comité Consultatif pour la Protection des Patients dans la Recherche Biomédicale Toulouse II (re. 2-03-23), the Manchester local research ethics committee (re. 03/CM/536), the Albert-Ludwig-University ethics committee (re. 123/03) and Freiburg Ethics Committee International (re. 03/1028), and individual hospital ethics committees, and was in accordance with the revised Declaration of Helsinki (2002).

RESULTS

Surgical Questionnaire

Case report forms were available for up to 1 month postimplantation for 27 patients (mean age, 50.0 yr; range, 25−81 yr; 15 left ears; 12 right ears). Biographical and medical histories for these individuals are summarized in Table 1. These patients reported with a mixture of pathogeneses and duration of severe-to-profound deafness (mean, 9.49 yr; range, 4 mo to 51 yr). Five patients reported high-frequency deafness with congenital or early childhood origins (Patients 4, 5, 8, 15, and 16).

Table 1 also provides results for each patient individually from completed surgical questionnaires. An "×" denotes where there was a deviation from the surgical protocol, and this was likely to impact negatively the conservation of residual hearing. The largest number of deviations (8/27) was shown for "suction of perilymph." Next, 5 of 27 patients were reported with cochleostomy hole diameter greater than 1.2 mm. One or more deviations were shown for 15 of 27 patients.

Other information was also available from analysis of the surgical questionnaire. These were aspects of the surgery or care of the patients, which were either not defined

TABLE 2. *Summary of preoperative hearing threshold levels (HTLs) for all 27 patients*

	Pure-tone test frequency (Hz)								
HTLs dB HL	125	250	500	750	1,000	1,500	2,000	3,000	4,000
Mean	47.9	53.9	67.8	80.0	89.7	100.4	100.4	101.7	103.2
Standard deviation	24.1	23.9	18.8	14.0	12.8	14.5	14.9	10.6	11.4
Median	48.5	52.5	67.8	82.5	90.0	106.0	100.5	104.6	105.0
Minimum	6.5	9.5	26.3	50.5	57.5	67.3	67.5	77.5	80.0
Maximum	90.0	90.0	96.5	103.3	110.0	117.5	120.0	120.0	120.0
n	27	27	27	27	27	26	23	20	19

Preoperative HTLs that were greater than 110 dB were removed from the data set to allow sufficient headroom for postoperative increases; thus, n is reduced for frequencies that are higher than 1,000 Hz.

in the protocol or not under the control of the surgeon. A diamond burr/drill was used to pierce the soft tissue membrane in 10 of 27 patients rather than a sharp and/or pointed implement as recommended by Lehnhardt and Laszig (9). The use of a drill to open the endosteal layer may result in the introduction of tissue or bone dust into the cochleostomy hole. Only in two patients was entry of bone dust into the scala explicitly noted. The use of corticosteroids was not specified in the protocol; however, in 20 of 27 patients, corticosteroid was administered systemically at or before the time of preparation of the patient for surgery. Significant problems were encountered during surgery in two patients (Patients 1 and 10) as previously reported by James et al. (17).

Postoperative Radiologic Evaluation

Results from postoperative "cochlear-view" radiograph allowed the final position and shape of the implanted electrode array to be visualized. Radiographs were available for 20 of 27 patients at the time of writing (Table 1). Mean insertion depth angle for this group was 376 ± 41 degrees (range, 300–435 degrees) according to the schema of Xu et al. (18). In one patient (Patient 6), a tip "fold-over" was detected, which seemed to result in a rather low insertion depth angle of 300 degrees.

Hearing Threshold Levels

Preoperative HTLs are summarized for all 27 patients in Table 2. Patients presented with a wide range (70–80 dB) of thresholds in the low-frequencies range (125–500 Hz), with a narrower range in the middle and high frequencies (750–4,000 Hz; 40–50 dB). This reflected a mixture of audiogram profiles from very steep, dropping abruptly between 500 and 750 Hz, to relatively flat. Median HTLs for the group were moderate to severe in the low frequencies. For 1,000 to 4,000 Hz, median levels were at 90 dB hearing loss or greater, indicating that as a group, these patients had very poor access to speech frequencies important for speech understanding and were unlikely to benefit from conventional amplification in these frequency ranges (16).

Differences between preoperative and postoperative HTLs are summarized in Table 3 for all 27 patients according to the scheme devised by James et al. (17). Increases in HTLs are broken down for each test frequency for 10-dB ranges from 0 to 10 dB to 40+ dB and "not measurable." For not measurable, an artificially high value, 999, was used for the purposes of calculating the median preoperative to postoperative differences across the group (Table 3).

As a group, more than 50% of patients retained measurable postoperative HTLs. However, only 19 to 33% of patients retained HTLs within 20 dB of preoperative levels for frequencies 125 to 1,000 Hz. Ten (37%) of 27 patients were in the El-Ac user group with HTLs at most 80 dB hearing loss at 125 and 250 Hz, and at most 90 dB hearing loss at 500 Hz.

To further understand the influence of surgical factors on HTL differences, the study population was divided into two groups: 12 of 27 patients, where no deviations from the

TABLE 3. *Summary of preoperative to postoperative differences in HTLs for all 27 patients*

	Pure-tone test frequency (Hz)				
Increase in HTL (dB)	125	250	500	750	1,000
0–10 (%)	11	7	4	7	19
11–20 (%)	22	19	15	15	4
21–30 (%)	7	19	11	11	15
31–40 (%)	4	7	19	11	11
>40 (%)	11	11	11	11	4
Not measurable (%)	44	37	41	44	48
Median (dB)	58.8	40	41	42.5	57.5

The percentage of patients with threshold differences falling into each decibel range is indicated for each frequency. "Not measureable" values occurred where postoperative HTLs exceeded the audiometer limits.

TABLE 4. *Summary of preoperative to postoperative differences in HTLs for the group "no deviations" (n = 12)*

	Pure-tone test frequency (Hz)				
Increase in HTL (dB)	125	250	500	750	1,000
0–10 (%)	25	17	8	8	25
11–20 (%)	25	33	25	25	8
21–30 (%)	17	17	25	25	25
31–40 (%)	0	0	8	8	8
>40 (%)	8	8	8	8	0
Not measurable (%)	25	25	25	25	33
Median (dB)	17.5	20.5	26	26.5	25

The percentage of patients with threshold differences falling into each decibel range is indicated for each frequency. "Not measureable" values occurred where postoperative HTLs exceeded the audiometer output limits.

surgical protocol were reported, and 15 of 27 for the remaining. In terms of preoperative HTLs, these two groups were roughly homogeneous, and thus, comparisons made between these two groups are largely unbiased. The analyses of HTL differences were recalculated for 12 of 27 patients where the surgical protocol was strictly followed. The results are provided in Table 4.

In the "no deviations" group, 9 (75%) of 12 patients had measurable HTLs, and 33 to 50% of patients retained HTLs within 20 dB of preoperative levels. In Figure 1, the mean increase in HTLs for 250 to 500 Hz versus insertion depth angle is plotted for each patient in each group individually, where a radiograph was available. To compare HTL increases between the two groups, the mean increase for 250 and 500 Hz was computed for each patient (Table 1). The median increase was statistically different for the two groups (no deviations = 23.1 dB; deviations = 60.6 dB; Mann-Whitney $U = 122.5$; $p < 0.05$).

It was hypothesized that insertion depth angle would influence the degree of hearing conserved preoperatively to postoperatively (e.g., Fig. 1). No statistically significant relationship was found between HTL increase and insertion depth angle regardless of surgical technique.

The systemic application of corticosteroids did not seem to consistently influence pre- to postoperative differences in HTLs.

Changes in Conserved Hearing Over Time

HTL data were available for nine patients at 2, 4, 7, and 13 months postimplantation. HTLs remained stable for five patients. HTLs were no longer measurable for Patient 11 in the implanted ear after 2 months, as reported in James et al. (17). Patient 7 had a large increase in HTLs in both ears at 2 to 4 months after implantation. Patient 13 seemed to have fluctuating hearing levels, decreasing HTLs at 2 to 4 months and increasing again at 4 to 6 months. HTLs for Patient 12 increased for the preserved low frequencies at 4 to 6 months. The cause of

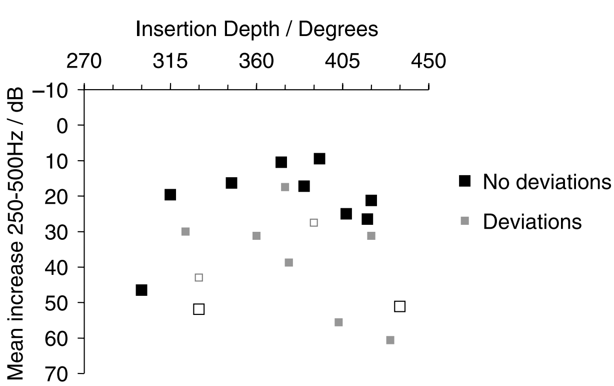

FIG. 1. Preoperative to postoperative increases in HTL (mean, 250 and 500 Hz) versus insertion depth angle for the groups "no deviations" (*large black squares*) and "deviations" (*small gray squares*) from surgical protocol. *Open squares* indicate where postoperative HTLs exceeded audiometer limits, and the difference was calculated using the audiometer output limit minus preoperative level.

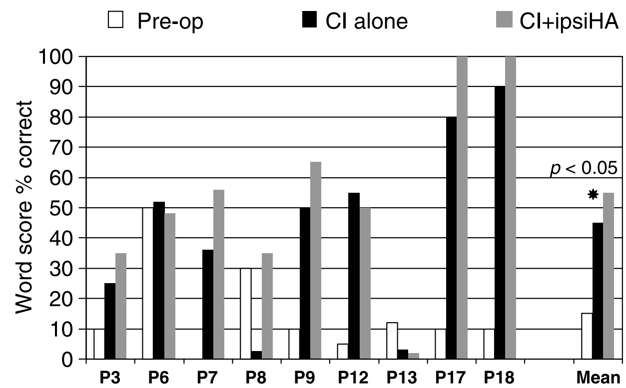

FIG. 2. Individual and mean percent correct scores for words presented at 65 dB SPL in quiet. Data are for nine El-Ac users with at least 3 months experience with the CI. *Significant difference in mean scores between CI alone and CI + ipsiHA (paired t, $p < 0.05$).

these changes in HTLs for these four patients has not yet been identified. HTLs for Patients 3, 4, 5, 8, and 9 remained stable up to the longest follow-up interval of 13 months after implantation. HTLs for Patient 6 recovered to within 20 dB of preoperative levels 2 to 3 months postoperatively and remained stable after this time.

Speech Recognition

Patients were divided into user groups postoperatively; those with HTLs of at most 80 dB hearing loss at 125 and 250 Hz and at most 90 dB hearing loss at 500 Hz were designated as El-Ac users, whereas the rest were designated as CI-only users. There were 10 El-Ac users (Patients 3, 6, 7, 8, 9, 12, 13, 17, 18, and 27) and 17 CI-only users. At this time, speech recognition results at 3 months or more postactivation were available for nine El-Ac users and seven CI-only users.

Mean preoperative word scores were 20 and 15% for the CI-alone and El-Ac user groups. Postoperative speech perception scores for CI alone varied considerably for both groups. Mean postoperative scores for isolated words presented at 65 dB SPL were roughly equivalent: 60% for CI-alone users (n = 7) and 55% for El-Ac users (n = 9). Individual and mean preoperative and postoperative word scores for the El-Ac users are provided in Figure 2. In 5 of 9 El-Ac users, there was a benefit of 10% or more with the use of an ipsiHA (CI + ipsiHA). There was a significant difference in the mean score of 10 percentage points between CI + ipsiHA and CI alone (paired t; $p < 0.05$). These differences were observed consistently between 1 and 3 months, with some patients reaching ceiling levels of performance on word tests at 3 to 6 months.

For speech recognition in noise, there was also considerable variability in performance within both groups. All patients except Patients 5 and 13 improved considerably on preoperative performance. Mean preoperative sentence recognition scores for the CI-only users and El-Ac users were 15 and 20% for 10 dB SNR, respectively, increasing postoperatively to 52 and 71%, respectively.

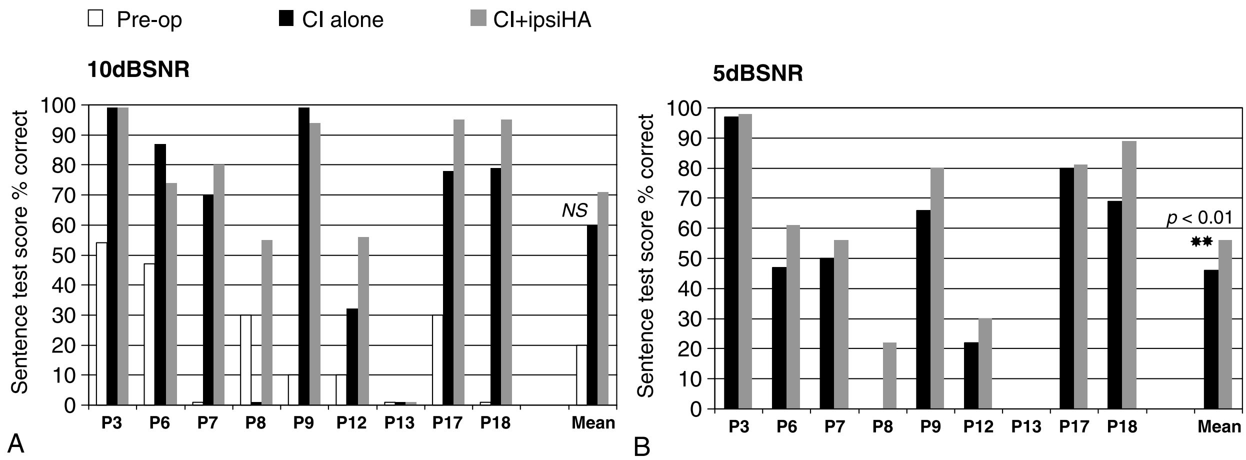

FIG. 3. Individual and mean percent correct scores for sentences presented in multitalker babble at 10 dB SNR (*A*) and 5 dB SNR (*B*). Data are for nine El-Ac users with at least 3 months experience with the CI. **Significant difference in mean scores of CI-alone versus CI + ipsiHA (paired *t*, $p < 0.01$). NS, not statistically significant.

Mean postoperative scores for the 5-dB SNR condition were 22% for CI-only users and 56% for El-Ac users.

Individual and mean scores for sentences presented in competing noise are presented for El-Ac users in Figure 3. There was no significant difference between mean scores for CI-alone and CI + ipsiHA at 10 dB SNR, possibly because of some patients performing at or near ceiling levels for CI alone. Sentence recognition at 5 dB SNR was substantially improved in many cases for the El-Ac users in the CI + ipsiHA condition, with the mean difference of 10 percentage points being statistically significant (paired *t*, $p < 0.01$).

El-Ac users sentence recognition scores were better on average than those for CI-only users, particularly at 5 dB SNR; 45% versus 22% for CI alone in each case. However, this difference did not prove to be statistically significant. Combining the two user groups, mean differences preoperative to postimplantation with CI alone were highly significant for word recognition in quiet and extremely significant for sentence recognition in noise (paired *t*, n = 16).

Speech Processing Preference

For the El-Ac users, 7 of 9 much preferred the modified speech processing MAP C to the standard MAP A. S12 and S13 preferred to use MAP A; these two patients had increasing/fluctuating HTLs at 4 to 6 months postimplantation. Speech recognition scores obtained between 1 and 3 months postactivation were approximately equivalent for the two programs; there was a trend that scores for sentence recognition in noise were best using MAP C with the CI + ipsiHA condition. At the time of writing, there was insufficient data to perform a statistical analysis.

DISCUSSION

It has been shown previously that a CI can be of considerable benefit for severely to profoundly hearing-impaired patients with significant preoperative open set speech perception (3,12). For the present study, population mean scores for CI alone were 30 to 40 percentage points better than mean preoperative scores for words presented at a conversational-voice level of 65 dB SPL in quiet and for sentences presented at a raised-voice level of 70 dB SPL in noise. There was a large range of variation in postoperative scores, with some patients going from zero score preoperatively to greater than 80% postoperatively, indicating a substantial ability to communicate, particularly in noise.

Three patients (Patients 5, 8, and 13) seemed to show little or no benefit with CI alone. Patients 5 and 8 were reported to have a strong childhood component to their hearing impairment and were not consistent hearing aid users before being identified as candidates for cochlear implantation. This supports the finding that speech recognition scores with CI are negatively correlated with duration of deafness (22,23). These two patients are likely to have been deprived of access to high-frequency speech sounds for most of their lives, requiring them to learn to use from scratch the new information provided by the CI. All three patients may improve their speech recognition given more than 6 months' experience and more rehabilitation, focusing on the use of high-frequency speech sounds.

Conservatively, without taking into account deviations from the soft-surgery protocol, up to 33% of patients may retain sufficient thresholds for combined ipsilateral electroacoustic stimulation. This is a long way off the rate for stapes surgery, where 92% of patients retain postoperative HTLs within 20 dB of preoperative levels, and 79% within 10 dB (24). However, there was strong evidence that adhering to the principles of soft surgery will improve hearing conservation; when deviation from the soft-surgical protocol was taken into account, 75% of patients were still able to use an ipsiHA according to our criteria of thresholds, at most 80 dB hearing loss at 125 and 250 Hz and at most 90 dB hearing loss at 500 Hz. Whether or not the conserved level of hearing was sufficient to be used effectively with an ipsiHA, it must be emphasized that cochlear implantation for this study population was a successful intervention.

On the request of one of the reviewers, additional speech testing was performed with three El-Ac users. Two of these were Patients 8 and 9, and one other patient was recruited after the time of writing. This latter patient had a mean preoperative to postoperative increase in HTLs of 12 dB. Postoperative recognition scores for words presented in quiet for the implanted ear using hearing aid alone were 25, 15, and 35%, respectively, compared with 30, 10, and 30% preoperatively. Thus, despite the introduction of a 17-mm electrode array, and modest but significant increases in pure-tone thresholds (11–27 dB), it seems that speech recognition performance can be preserved. This aspect deserves further study for this and other devices and surgical techniques.

Although a significant difference in hearing conservation was found between the group of 12 where the soft-surgery protocol was observed and the group of 15 where it was not, it is not clear that these differences can be attributed to differences in stated procedures. In the cases that are in the extreme, there may have been a poor positioning of the cochleostomy hole relative to the promontory and round window. A better definition of the best position for the anterior/inferior approach would certainly be useful in improving hearing conservation with the present electrode array. Perusal of a number of images taken intraoperatively indicates that the cochleostomy site was occasionally more superior than aimed for during surgery.

Another factor is the electrode array itself and the AOS technique devised for insertion to avoid contact against the lateral wall. The surgeons involved in the present study rated the AOS technique as anything between "very easy" and "very difficult." The degree of difficulty encountered did not seem to impact consistently across the group; however, the poor hearing conservation results observed in Patient 1 and initially for Patient 6 were certainly because of problems encountered in withdrawing the stylet.

Cochleostomy hole sizes of at most 1.2 mm were used in most patients. Although considerable increases in HTLs were not observed in all patients, the best hearing conservation results for 1.5 mm (e.g., Patients 17 and 18) were still 15 to 20 dB worse than those for the smaller cochleostomy holes. Because of the scale of the anatomy at the basal end of the cochlea, one can envisage that even a small increase in the size of trauma can impact significantly on the result. It was not apparent from the responses to the questionnaire that problems with the AOS technique and a higher rating of difficulty were related systematically to smaller hole sizes (≤1.2 mm), which potentially can "catch" the array (diameter 0.8 mm) at its proximal end.

Another approach to opening the cochlea in these patients may be via the round window, thus reducing the need for drilling the cochleostomy hole with associated trauma. The round window approach may have its own potential sources of trauma such as the lack of a straight path into the basal turn (25). This approach would likely require thinner and softer "straight" electrodes (26). Perimodiolar designs are unlikely to be suited to this approach.

The mean scores for speech recognition in multitalker babble (Fig. 3) were about equal for the CI-alone condition at 10 dB SNR and for the CI + ipsiHA condition at 5 dB SNR. This indicates that combined ipsilateral electrical and acoustic stimulation may provide up to 5 dB SNR benefit compared with CI alone. Although it is difficult to make direct comparisons, the scores in noise for the El-Ac users were in general somewhat higher than for the CI-only users even for the CI-alone condition, despite mean scores for words in quiet being approximately equal. Other approaches reported in the literature include the use of smaller insertion depth angles (≤340 degrees) achieved with the partial insertion (18–24 mm) of a straight electrode array (10,11) or the use of a shorter and thinner 10-mm electrode array such as the Nucleus Hybrid CI (8). The results from these previous studies seem to support shallower insertion depths as a means to achieve better hearing conservation. However, in the present study, no statistically significant relationship was found between increases in HTLs and insertion depth angles between 300 and 435 degrees, regardless of surgical technique (Fig. 1). Limiting the linear insertion depth to 17 mm did not provide consistent final insertion depth angles. For low angles, it is likely that there was some resistance to insertion or problem in controlling the insertion of the electrode array, which resulted in a smaller insertion depth angle (i.e., less close to the modiolus). For example, in Patient 6, the tip of the array was found to be folded over. Hearing conservation seemed to be poorer for patients with larger angles of 420 to 435 degrees; it seems plausible that further minor limitation of the length of insertion for the Nucleus 24 Contour Advance may enhance hearing preservation in patients who are identified preoperatively, via high-resolution computed tomographic scan, as having relatively small cochleae.

With smaller insertion depth angles, it has been found that there is the potential for lower overall performance with CI alone (22,23). Additionally, as evinced here for Patient 7, there is the possibility of continuing loss of residual hearing due to natural progression of the cause/pathogenesis or possible degradation over time due to the introduction of the electrode itself. However, other reports in the literature (10,11) suggest that even with shallower insertion depth angles (≤340 degrees), very good open-set speech understanding may be achieved for CI-alone, equivalent to that observed for patients with insertion depth angles as deep as 720 degrees or two full turns. Benefits of speech recognition in noise have also been observed in El-Ac users implanted with 10 mm or 20- to 24-mm straight electrodes (8,11) and in patients using a contralateral hearing aid (2,4–6). Recent work by Kong et al. (6) has shown that there is better perception of pitch by patients using even fairly limited contralateral residual hearing with a CI. Better perception of the voice pitch is likely to allow better separation of the target speaker from the noise background and thus enhance speech recognition. This finding has been confirmed when working with patients recruited in the present study either using the contralateral ear or both ears in combination with the CI. They seem to react much more quickly and are able to better analyze when the target voice is present in extreme noisy listening conditions compared with when using the CI alone. Patients also report other subjective benefits such as voices sounding more natural, reduced listening effort, and greater enjoyment of music and of film without the use of subtitles.

CONCLUSION

Hearing was conserved in 75% of 12 adult recipients of the Nucleus 24 Contour Advance perimodiolar electrode array, provided that soft-surgery techniques were strictly observed and cochleostomy hole size was limited to 1.2 mm. In the remaining 15 patients, the introduction of more than one rib into the cochleostomy hole (e.g., linear insertion length >17 mm), nonuse of the recommended AOS for introducing the electrode array, nonuse of Healon, and suction of perilymph may have seriously impacted success in hearing conservation. Systemic application of corticosteroids did not seem to consistently influence outcome. There was no statistically significant effect of insertion depth angle (300–435 degrees) on hearing conservation at 250 to 500 Hz.

Mean speech recognition scores (n = 16) for CI alone, both for words presented in quiet at 65 dB SPL and sentences presented in noise, were significantly greater than preoperative scores with optimally fitted hearing aids (mean difference, 30–50 percentage points). Ten of 27 patients retained sufficient residual hearing after implantation to potentially benefit from the combined use of the CI and an ipsiHA. Residual hearing combined with electrical stimulation in the same ear provided significantly greater mean recognition scores for words presented in quiet and for sentences presented in noise at 5 dB SNR (mean differences, 10% points). The latter difference was equivalent to between 3 and 5 dB SNR benefit for these patients.

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