

Expanded Indications for Cochlear Implantation: Perceptual Results in Seven Adults with Residual Hearing

Élargissement des recommandations d'implantation cochléaire: résultats perceptifs chez sept adultes avec audition résiduelle

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Abstract

Multichannel cochlear implants are recognized as effective sensory aids for profoundly deaf children and adults who are unable to benefit from conventional amplification. This paper discusses the application of the Nucleus 22 Channel Cochlear Implant System in seven severely-to-profoundly hearing impaired adults who demonstrated marginal benefit from conventional amplification, preoperatively. The seven subjects were implanted at the Denver Ear Institute as part of a multi-site clinical trial and completed a common program of aural rehabilitation and audiological assessment. The implanted subjects demonstrated significant improvements in sound detection, phoneme identification, and in open set speech recognition both when using the implant alone and in combination with a contralateral acoustic hearing aid. These preliminary results suggest that it may be appropriate to expand the indications for cochlear implantation to include individuals who have some residual hearing.

Résumé

On reconnaît que les implants cochléaires à canaux multiples sont des aides sensorielles efficaces pour les enfants et les adultes profondément sourds qui ne peuvent profiter de l'amplification conventionnelle. Le présent document traite de la mise en place du système Nucleus d'implant cochléaire à 22 canaux chez sept adultes atteints d'une déficience auditive sévère à profonde qui n'ont pas pu profiter de l'amplification conventionnelle avant l'opération. On a mis l'implant en place chez les sept patients au Denver Ear Institute dans le cadre d'un essai dans plusieurs cliniques; les patients ont ensuite suivi un programme commun de réadaptation auditive et subi une évaluation en audiologie. Les patients ont connu une amélioration importante dans la détection des sons, l'identification des phonèmes et l'identification de mots en utilisant uniquement l'implant ou l'implant et une prothèse auditive controlatérale. Ces premiers résultats indiquent que l'on pourrait étendre les recommandations d'implantation cochléaire aux particuliers ayant une faible audition résiduelle.

The Nucleus 22 Channel Cochlear Implant System has been available to postlinguistically deafened adults since 1985 in both the United States and Canada, and to deaf children and adolescents since 1990. The United States Food and Drug Administration released the device for use in these two populations on the basis of extensive clinical trials that were conducted throughout Europe, the United States, Canada, and Australia. In both the adult and pediatric trials, profoundly deaf individuals were selected for implantation only if they were unable to benefit from very powerful acoustic hearing aids. Currently, over 2000 such adults and 981 children have received the Nucleus Multichannel Implant in the United States and Canada and, as a group, they have demonstrated significant improvements in sound detection, enhanced lipreading abilities, and improved perception of both closed set and open set speech stimuli (Dowell, Mecklenberg, & Clark, 1986; Staller, Dowell, Beiter, & Brimacombe, 1991; Osberger, Miyamoto, Zimmerman-Phillips, Kemink, Stroer, Firszt, & Novak, 1991).

As the professional community has gained experience with cochlear implants, clinicians and researchers have identified an additional group of hearing impaired individuals who also may benefit from multichannel cochlear implantation (House & Berliner, 1986). Cochlear implant teams routinely evaluate severely-to-profoundly hearing impaired adults who benefit only marginally from conventional amplification and have hypothesized that these individuals also might be cochlear implant candidates.

Cochlear Corporation, in response to this hypothesis, filed an Investigational Device Exemption (IDE) application with the U.S. Food and Drug Administration in 1988. The IDE proposed a multi-center, clinical trial to study the safety and efficacy of the Nucleus Multichannel Implant in severely-to-profoundly hearing impaired adults with minimal speech recognition abilities. The IDE was approved in February of 1989, and since that time 51 investigational subjects have

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Table 1. Biographical Characteristics of the Seven Investigational Subjects.

Variable	Mean	Range	Percent
Age at Surgery (yr):	58.4	39-77	
Age at Onset of Severe/ Profound Hearing Loss (yr):	45.3	3-67	
Duration of Severe/Profound Hearing Loss (yr):	13.3	5-43	
Gender: Males:			71
Females:			29
Ear Implanted:			
Left:			57
Right:			43
Etiology: Otosclerosis:			14
Unknown:			86
Electrode Insertion Length (mm):	21.6	17-24	

been implanted at 18 investigational sites. The following sections present the subject selection criteria, review the audiological protocol, and discuss postoperative results for seven of the investigational subjects who were implanted at our own facility, the Denver Ear Institute.

Methods and Procedures

Subjects

Severely-to-profoundly hearing impaired adults were eligible for the clinical trial only if they demonstrated marginal functional benefit from an optimal amplification system. In this investigation, binaurally-aided, open set sentence recognition scores were used as indicators of marginal hearing aid benefit. Prospective subjects were required to score significantly above chance (2%), but not greater than 30% correct, on two different recorded sentence recognition tests (CID Sentences of Everyday Speech and Iowa Sentences Without Context) presented at 70 dB SPL in a calibrated sound field. Severely-to-profoundly hearing impaired individuals who met the sentence recognition criterion then were included in the investigation if they were at least 18 years of age and English speaking, and if their hearing loss was postlinguistic in onset. Patients who presented with radiologic, medical, or psychological contraindications were excluded from the clinical trial (Cochlear Corporation, 1989).

Table 2. Selected Tests from the Audiological Protocol.

Auditory Perceptual Skill/Test Method/Material
<i>Sound Detection</i> Unaided pure-tone and speech thresholds Aided warble-tone and speech thresholds
<i>Closed-set Phoneme Identification</i> Iowa Vowel Test Iowa Medial Consonant Test
<i>Open-set Speech Recognition</i> Iowa Sentences without Context Test CID Sentences of Everyday Speech Test NU#6 Monosyllabic Word Test: Word Score NU#6 Monosyllabic Word Test: Phoneme Score

Biographic information for the seven Denver Ear Institute subjects who participated in the investigation is presented in Table 1. As a group, these individuals became severely-to-profoundly hearing impaired at age 45 (*S.D.*: 23.9 years), used hearing aids for approximately 13 years (*S.D.*: 14.7 years), and were implanted at the age of 58 (*S.D.*: 14.0 years). For six of the seven subjects (71%) the etiology of the hearing loss was unknown and, at surgery, each of the participants received a fully-inserted, 22 channel electrode array (Mean Insertion Length: 21.6 mm, *S.D.*: 2.1 mm).

Audiological Protocol

A common audiological protocol was used with all investigational subjects at each of the 18 investigational sites (Cochlear Corporation, 1989). The protocol was administered preoperatively and then again at three postoperative intervals during the first year following implantation. The protocol was designed to evaluate a wide range of auditory perceptual skills and to do so in three different aided conditions: listening with the cochlear implant alone, with a conventional hearing aid fit to the nonimplanted ear, and binaurally, with the cochlear implant and contralateral hearing aid together. The perceptual skill hierarchy and the test measures that have been selected for discussion in this report are summarized in Table 2 (Owens, Kessler, & Telleen, 1981; Tyler, Preece, & Lowder, 1983).

Test Stimuli

The two phoneme identification measures (Iowa Vowels and Medial Consonants) and three open set speech recognition tests (Iowa Sentences Without Context, CID Sentences of Everyday Speech, and NU#6 Words) were recorded by one of

Table 3. Mean Unaided Hearing Thresholds (dB HL) for the Seven Investigational Subjects.

Hz	NON-IMPLANTED EAR		IMPLANTED EAR					
	Preoperative Mean	S.D.	Preoperative Mean	S.D.	6 Months Mean	S.D.	12 Months Mean	S.D.
125	88	37	102	40	115	26	111	27
250	87	21	105	27	107	17	114	22
500	95	18	111	19	124	10	121	12
750	100	19	113	16	123	9	122	11
1000	101	20	119	13	126	6	127	7
<i>Mean</i>	94		110		119		119	
2000	115	16	123	9	126	5	126	6
3000	116	18	123	10	129	2	128	5
4000	116	20	130	0	129	2	129	2
6000	128	5	128	5	130	0	128	5
8000	126	10	130	0	130	0	130	0
<i>Mean</i>	120		127		129		128	

the authors (JKS, an adult male speaker) and were played back through a cassette deck (Sony TC FX160) to a standard clinical audiometer (Madsen OB822). The pre-recorded speech stimuli were amplified (Crown 075 Amplifier) using a sound field speaker system (Allison Labs 2043) and were presented to the subjects at a sound pressure level of 70 dB. The presentation level was monitored continuously, throughout each of the evaluations, using a calibrated sound level meter and remote microphone system (Larsen-Davis 800B). The remote microphone of the sound level meter was placed at the head position of the listener, who was seated at an azimuth of zero degrees in an audiometric test suite (IAC Series 1200). Subjects provided oral responses to the test items, while the examiners (JKS and KAT) verified the responses and transcribed them onto prepared forms.

Postoperative Procedures

Following initial stimulation with the device and programming of the speech processor, each subject was required to complete an intensive program of aural rehabilitation conducted by two of the authors (KAT and JKS). The rehabilitation program was conducted during the first six-to-ten weeks of device use and consisted of both training procedures that were common to all of the investigational subjects and procedures that were designed to meet the communicative needs of the individual participants. Common procedures included equipment familiarization, optimization of the speech processor program, vowel and consonant identification tasks, and speech tracking exercises. Because it was assumed that these subjects would continue to use a contralateral hearing aid postoperatively, the objective of the rehabilitation program was to maximize each subject's performance when using the

acoustic hearing aid and the cochlear implant together. Accordingly, a variety of training materials were presented in seven different conditions: (1) lipreading alone, (2) lipreading with sound from the cochlear implant, (3) lipreading with sound from the contralateral hearing aid, (4) cochlear implant without lipreading, (5) hearing aid without lipreading, (6) cochlear implant and hearing aid without lipreading, and (7) lipreading with sound from both the cochlear implant and contralateral hearing aid. Each subject's performance was evaluated at the end of the rehabilitation program and again after six and 12 months of cochlear implant experience. The results that are reported in the following section reflect the performance of the seven Denver Ear Institute subjects at the latter two postoperative intervals.

Results

The primary selection criterion for inclusion in the clinical study was that subjects were required to score significantly above chance (2%) but no greater than 30%, binaurally, on the Iowa and CID sentence recognition tests. Typically, such persons have a better ear but, in a few cases, patients demonstrate a symmetrical hearing loss, with relatively equal speech recognition abilities. The seven subjects implanted at the Denver Ear Institute all had better hearing in the nonimplanted, hearing-aided ear.

Sound Detection

Table 3 shows mean preoperative unaided hearing thresholds for the better ear and mean pre- and postoperative hearing thresholds for the ear that received the cochlear implant. For

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Table 4. Mean Aided Hearing Thresholds (dB SPL) for the Seven Investigational Subjects.

Hz	NON-IMPLANTED EAR		Preoperative		IMPLANTED EAR		12 Months	
	Preoperative Mean	S.D.	Mean	S.D.	6 Months Mean	S.D.	Mean	S.D.
250	57	5	71	8	56	2	51	4
500	49	6	72	9	45	2	38	5
750	52	7	76	10	56	3	31	11
1000	53	7	77	9	54	4	47	8
2000	70	8	88	9	44	4	49	10
3000	85	10	98	6	35	4	38	12
4000	95	8	99	6	35	3	46	14
PTA	58		79		48		45	
SDT	52	6	70	10	50	2	42	8
SRT	CNT		CNT		67	7	55	13

CNT = Could not test

Table 5. Mean Scores (%) on a Battery of Speech Perception Tests for the Seven Investigational Subjects.

	CHANCE/ SAC	PREOPERATIVE			POSTOPERATIVE: 6 MONTHS			POSTOPERATIVE: 12 MONTHS		
		NI	I	B	NI	I	B	NI	I	B
<i>Closed-set Tests</i>										
Iowa Vowel Test:	11 / 22	48 (12)	16 (7)	52 (14)	55 (14)	63 (10)	77 (14)	54 (18)	70 (13)	80 (20)
Iowa Medial Consonant Test:	7 / 14	22 (8)	7 (5)	27 (11)	33 (10)	38 (20)	44 (18)	31 (10)	46 (18)	51 (19)
<i>Open-set Tests</i>										
Iowa Sentences:	0 / 2	13 (5)	1 (2)	20 (9)	29 (17)	37 (29)	57 (27)	29 (15)	58 (30)	63 (27)
CID Sentences:	0 / 2	21 (8)	2 (1)	26 (8)	34 (25)	44 (12)	57 (32)	42 (16)	55 (10)	65 (28)
NU#6—Word Score:	0 / 4	3 (2)	1 (1)	5 (3)	7 (2)	13 (6)	19 (14)	10 (3)	24 (8)	21 (13)
NU#6—Phoneme Score:	0 / 5	18 (9)	4 (4)	22 (9)	25 (9)	30 (20)	40 (18)	27 (9)	45 (19)	46 (14)

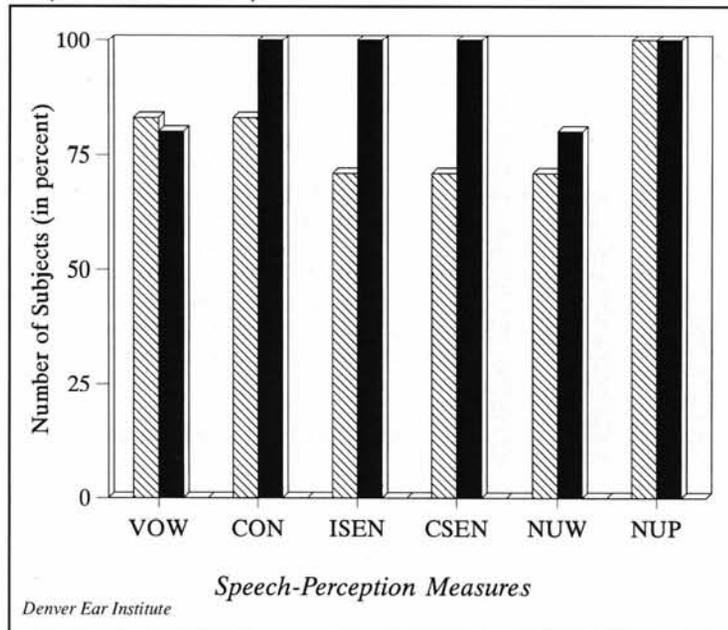
* = Significantly above chance score
 NI = Nonimplanted ear
 I = Implanted ear
 B = Binaural
 () = Standard deviation

these seven subjects, it is evident that the nonimplanted, hearing-aided ear was better, preoperatively, by an average of 16 dB in the low frequencies and 7 dB in the high frequencies. After surgery, the postoperative unaided hearing thresholds for the implanted ear decreased by an average of 9 dB in the low frequencies and 2 dB in the high frequencies. As others have reported, changes in unaided hearing sensitivity are to be expected, postoperatively, even though trauma to the structures of the cochlea typically is minimal following insertion of the Nucleus electrode array (Bogges, Baker, & Balkany,

1989; Linthicum, Fayad, Otto, Galey & House, 1991; Shepherd, Clark, Pyman, & Webb, 1985; Rizer, Arkis, Lippy, & Schuring, 1988).

The aided results for warble tones (5%) for these subjects are shown in Table 4. Note that, preoperatively, the better ear is the nonimplanted ear. Preoperatively, the aided pure tone average (500, 1000, and 2000 Hz) was 57 dB SPL for the nonimplanted, hearing-aided ear, and 79 dB SPL for the implanted ear. Postoperatively, the aided pure tone aver-

Figure 1. Comparison of pre- and postoperative performances of the 7 subjects observed in the implanted ear. The number of subjects (in percent) who displayed significant improvements, relative to their preoperative performances, at 6 months (the dashed columns) and 12 months (the dark columns) postoperatively is shown for six measures of speech perception: VOW = Iowa Vowel Test; CON = Iowa Medial Consonant Test; ISEN = Iowa Sentences Without Context; CSEN = CID Sentences of Everyday Speech Test; NUW = NU#6 words; NUP = NU#6 Phonemes.



age improved by 31 and 34 dB for the implanted ear at six and 12 months, respectively.

Sound field thresholds improved by an average of 20 dB in the low-to-mid frequencies (250 - 1000 Hz) and by 40 - 60 dB in the high frequencies (2000 - 4000 Hz). Postoperatively, there also was an improvement in speech detection of 20 and 28 dB at six and 12 months, respectively. Speech reception thresholds in the implanted ear were essentially unmeasurable preoperatively, due to the elevated pure tone detection thresholds and the lack of speech recognition. At the six-month postoperative visit, the implanted ear had an average speech reception threshold of 67 dB SPL, which improved to 55 dB SPL at the 12 month visit.

Speech Perception

Mean pre- and postoperative results for the open and closed set speech measures are presented in Table 5 for the non-implanted ear, the implanted ear, and the binaural condition.

Preoperative scores are better for the non-implanted ear and for the binaural test condition than for the ear selected for implantation. The mean scores for the binaural condition improved at six and again at 12 months postoperatively for all of the test measures. The binaural condition was consistently the best condition for all test measures except for NU#6 Words at 12 months postoperative. This finding was encouraging because a primary objective for these patients is to have them continue to use their contralateral hearing aid in conjunction with the cochlear implant.

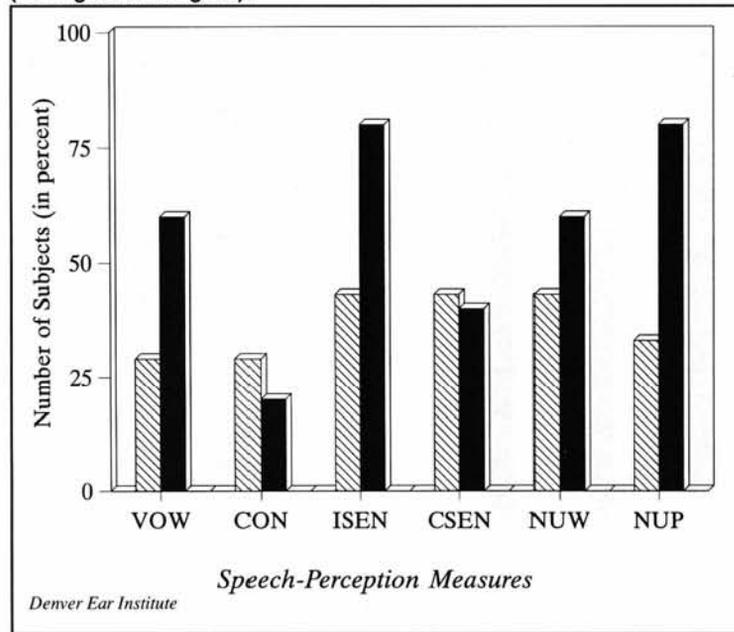
The mean scores also improved for all measures in the implanted ear at six and 12 months postoperatively. It is important to recall that these subjects had no open set speech recognition preoperatively in the implanted ear. Subjectively these seven patients all indicated that their hearing was improved and that the cochlear implant provided more help than the hearing aid in the nonimplanted ear.

Unexpectedly, this group of subjects demonstrated small postoperative improvements in both mean feature identification and open set, speech recognition scores in the nonimplanted ear. The mean Medial Consonant test score, for example, improved from 22%, preoperatively, to 33% after six months of device use, and the mean Iowa Sentence score improved from 13%, preoperatively, to 29% at the six-month test period. As reported by Durity (1982), these small improvements may be the result of the intensive aural rehabilitation program, but also may reflect learning effects and/or familiarization with the evaluative setting and test procedures over time. Additionally, it is possible that the implant somehow facilitates the subjects' ability to use the minimal cues that are provided by the contralaterally-worn, acoustic hearing aid. There may also be additive effects from the intense rehabilitation, the cochlear implant, and time. Whatever the reason(s), it is evident that this select group of patients has demonstrated some post-implant improvements in speech recognition.

Statistical Analyses

Statistical analyses were conducted to determine the significance of the observed findings using the individual data presented in the Appendix. Three binomial comparisons, as described by

Figure 2. Performances obtained with the cochlear implant are compared to those obtained with the hearing aid (in the contralateral ear) at two postoperative intervals. The data indicate the number of subjects (in percent) who displayed significantly better scores with the cochlear implant. The results obtained at 6 months (the dashed columns) and 12 months (the dark columns) postoperatively are shown for six measures of speech perception (see Figure 1 for legend).



Thorton and Raffin (1978) and Conover (1980), were conducted for each subject on each of the six test measures.

In Figure 1, postoperative performance is compared to preoperative performance in the ear selected for implantation. In Figure 2, performance with the cochlear implant is compared to performance with a contralateral hearing aid at two postoperative intervals, and in Figure 3, six and 12 month postoperative performance in the binaural condition is contrasted to performance with the contralateral hearing aid alone. With this analysis, a speech recognition score was considered to show significant improvement when the parameters of the Binomial Distribution for the implanted ear (alone or in combination with a contralateral hearing aid) was statistically greater ($p < 0.05$) than the score for the baseline condition on the same test.

In Figure 1, the implanted ear performance is compared preoperatively with performance at six and 12 months postoperatively. It is apparent that most of the subjects (70 - 100%) demonstrated significant improvement in the implanted ear. This finding is comparable to results obtained with other adult multichannel cochlear implant patients with a profound

hearing loss (Dowell, Mecklenberg, & Clark, 1986). Cochlear implant performance is compared to performance with a contralateral hearing aid at the two postoperative intervals in Figure 2. Twelve months post-implantation, 80% of the subjects scored significantly higher when using the cochlear implant as opposed to the contralateral hearing aid on the Iowa Sentences Without Context Test and on the NU#6 Word Test scored for phonemes. Similarly, 60% of the subjects showed improved phoneme recognition and vowel identification by the 12th postoperative month when using the cochlear implant. Binaural performance, as shown in Figure 3, was significantly better than postoperative performance with the contralateral hearing aid alone. This is especially evident 12 months postoperatively for vowel identification, sentence recognition, and phonemically scored monosyllabic words.

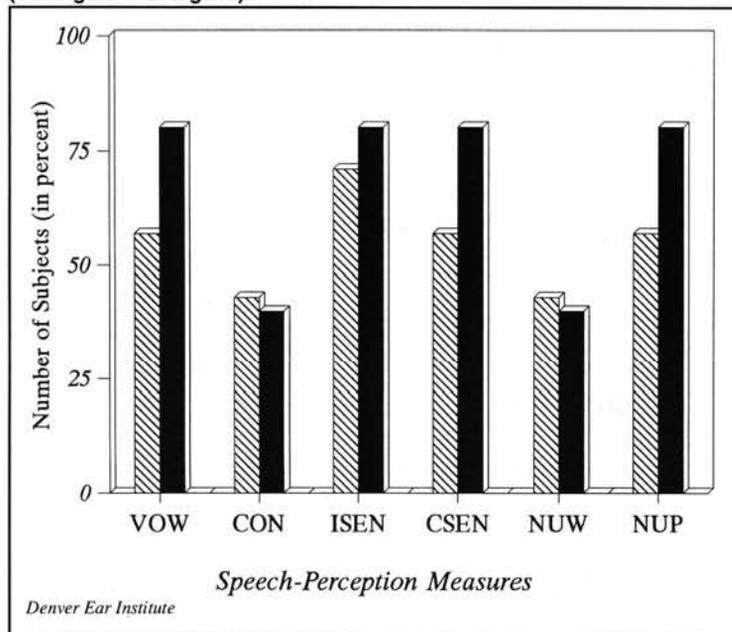
Discussion and Summary

Multichannel cochlear implants are known to be an effective sensory aid for post-linguistically deafened adults with a profound bilateral sensorineural hearing loss. Speech recognition scores provide an important basis for judging "profound" versus "severe" hearing loss for hearing aid and cochlear implant subjects. Profound hearing loss may include some audiometric responses, but open set speech recognition should be very minimal (<10%) using recorded word and sentence materials. For the subjects described in this paper, severe hearing loss includes minimal benefit from amplification, defined as binaurally-aided scores significantly above chance, but not greater than 30% correct, on two different sentence recognition tests.

We have reported our experience with a small group of subjects ($N = 7$) who have a severe-to-profound sensorineural hearing loss in their better ear (nonimplanted, hearing aid ear) and a profound loss in the ear selected for cochlear implantation. These subjects were part of a larger group participating in a multi-center clinical trial sponsored by Cochlear Corporation. Our seven subjects from the Denver Ear Institute, as a group and individually, showed significant performance improvements in speech identification and recognition following implantation with a multichannel cochlear implant.

The statistical results of this report confirm our own clinical impressions for these seven subjects. All of the sub-

Figure 3. Performances obtained with the hearing aid alone (in the contralateral ear) are compared with those obtained for the binaural condition (i.e., cochlear implant and the contralateral hearing aid) at two postoperative intervals. The data indicate the number of subjects (in percent) who displayed significantly better scores for the binaural condition. The results obtained at 6 months (the dashed columns) and 12 months (the dark columns) postoperatively are shown for six measures of speech perception (see Figure 1 for legend).



jects describe improved speech recognition and sound detection with their cochlear implant in comparison to their preoperative use of hearing aids. Five of the seven subjects continue to use their hearing aid in conjunction with their cochlear implant, and we encourage them to maintain the use of both devices. Two of the subjects feel that they do not get sufficient benefit from the addition of the hearing aid in the opposite ear even though our testing indicates that they have better performance in the binaural condition (hearing aid with cochlear implant). Eighty percent of the subjects demonstrated significant improvement on four of the six test measures for the binaural condition in comparison to their hearing aid alone by the one year post-implant test session. The trend for this significance also is apparent at the six month post-implant testing session for more than half of the subjects for vowel, sentence, and phoneme scores. The results illustrated in Figures 2 and 3 suggest a significant binaural effect and demonstrate the advantage of continued hearing aid use in this sample of multichannel cochlear implant patients. The statistically significant performance changes that were observed for the nonimplanted ear following postoperative aural rehabilitation were relatively small in magnitude

(see Table 5) compared to the much larger improvements that were observed for the implanted ear and binaurally.

At the present time the application of cochlear implants has been approved by the U.S. Food and Drug Administration for use in adults and children with a bilateral profound hearing loss and no significant open set speech recognition. We conclude that a multichannel cochlear implant also can be an effective sensory aid for subjects with severe-to-profound sensorineural hearing loss and minimal, aided speech recognition abilities.

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APPENDIX

Individual test scores (%) by evaluation interval and experimental condition (I = Implanted ear; NI = Nonimplanted ear; B = Binaural).

Subject	Preoperative			Postoperative 6 Months			Postoperative 12 Months		
	I	NI	B	I	NI	B	I	NI	B
#1	18	64	73	73	78	80	62	93	89
#2	7	36	33	56	49	60	44	20	51
#3				56	67	84			
#4	27	42	51	56	89	96	56	89	96
#5	9	38	44	27	71	76	31	67	67
#6	18	62	64	64	73	87	78	80	98
#7	18	47	47	56	11	56			

Subject	Preoperative			Postoperative 6 Months			Postoperative 12 Months		
	I	NI	B	I	NI	B	I	NI	B
#1	9	34	37	34	63	60	44	60	59
#2	6	11	13	21	21	19	20	19	23
#3				26	40	46			
#4	14	21	39	37	64	71	37	64	71
#5	6	26	29	29	34	27	26	41	40
#6	0	21	29	51	36	49	29	44	60
#7	9	16	14	31	10	39			

Subject	Preoperative			Postoperative 6 Months			Postoperative 12 Months		
	I	NI	B	I	NI	B	I	NI	B
#1	0	20	28	40	52	67	43	77	66
#2	0	9	2	5	0	9	17	9	20
#3	0	10	15	47	67	81			
#4	5	16	20	39	73	91	44	73	91
#5	0	8	23	7	33	47	13	50	57
#6	0	9	23	30	33	66	30	82	79
#7	1	16	27	34	0	42			

Subject	Preoperative			Postoperative 6 Months			Postoperative 12 Months		
	I	NI	B	I	NI	B	I	NI	B
#1	0	30	30	55	64	64	52	77	81
#2	0	18	14	3	2	2	26	27	23
#3	0	23	35	50	82	92			
#4	9	9	35	64	76	97	64	76	97
#5	0	14	18	5	30	42	39	48	64
#6	0	30	21	18	48	57	30	48	62
#7	6	22	30	41	4	47	30	48	62

Subject	Preoperative			Postoperative 6 Months			Postoperative 12 Months		
	I	NI	B	I	NI	B	I	NI	B
#1	0	4	8	14	10	28	14	40	28
#2	0	0	0	0	0	0	2	0	4
#3	0	0	6	4	16	34			
#4	2	10	8	16	46	36	16	46	36
#5	0	0	4	0	10	18	4	18	26
#6	0	0	6	10	10	14	12	16	12
#7	4	10	4	6	0	4			

Subject	Preoperative			Postoperative 6 Months			Postoperative 12 Months		
	I	NI	B	I	NI	B	I	NI	B
#1	3	23	31	39	28	50	38	60	51
#2	0	3	5	17	9	13	17	13	22
#3	0	20	25	29	42	56			
#4	8	23	32	29	59	59	29	59	59
#5	2	13	17	11	11	39	17	46	50
#6	8	13	25	27	33	43	33	46	50
#7	9	29	17	22		20			