Gochlear implants from model to patients
Briaire, J.J.

Chapter 6

Initial evaluation of the Clarion CII cochlear implant: Speech perception and neural response imaging

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Abstract

Objective: The Clarion CII is a promising cochlear implant with which our first ten patients have obtained excellent speech perception results. The NRI system yields high quality signals with a limited number of sweeps at a high sampling rate.

Design: The speech perception scores on CVC words without lip reading were monitored prospectively for the ten postlingually deaf patients implanted with the Clarion CII device in the period July 2000 until May 2001 in the Leiden University Medical Center. Peroperative and postoperative NRI recordings were made, applying various combinations of monopolar stimulating and recording electrodes with the alternating polarity paradigm available in the test bench software.

Results: Nine patients preferred the CIS, one the PPS strategy, none the SAS strategy. With their favorite strategy they acquired significant open set speech understanding within a few weeks, resulting in an average CVC phoneme score of 84% (word score 66%) at the end of the study (follow-up 3 to 11 mo). In speech-shaped noise, the average phoneme recognition threshold (PRT) was reached at a signal to noise just below 0 dB. The NRI recordings had clear N_1 and P_1 peaks if there was at least one contact between the stimulating and recording electrodes, necessitating just 15 sweeps for a reliable recording. We observed considerable inter-patient and inter-electrode variability, but for a given situation NRI input/output curves were stable over time. More apical contacts generally elicited larger eCAPs. Response amplitudes tended to peak at recording sites around apical and basal stimulating electrodes, suggesting a limited spread of excitation. Preliminary recordings with the forward masking paradigm were consistent with the ones with the alternating polarity scheme.

Conclusions: The Clarion CII is a promising cochlear implant with which our first ten patients have obtained excellent speech perception results. The NRI system yields high quality signals with a limited number of sweeps at a high sampling rate.

6.1 Introduction

Since the introduction of the first single-channel device in the mid-seventies cochlear implants have undergone a wide range of technical improvements, and speech perception performance has been increasing steadily. Now multi-channel cochlear implants are firmly established as effective options in the habilitation and rehabilitation of adults and children with bilateral profound hearing impairment (NIH Consensus Statement, 1995). They aim to stimulate the primary auditory nerve fibers in the cochlea by injecting electric currents into the inner ear.

Animal experiments (Shepherd et al., 1993) and computational models (Frijns et al., 1995; Frijns et al., 1996a) initially suggested a considerable influence on implant function of the exact position of the electrode in the scala tympani. The latest devices are designed to be in a peri-modiolar (also called modiolus hugging) position rather than lying along the outer wall of the scala tympani (Gstoettner et al., 1999; Tykocinski et al., 2001; Kuzma and Balkany, 1999). The possible advantages of being in a peri-modiolar position, i.e. closer to the nerve fibers to be stimulated, include a reduction of the stimulus thresholds and stimulating currents, a higher selectivity of stimulation and an increased dynamic range. Preliminary clinical experience with the Clarion HiFocus and the Nucleus® Contour® electrodes suggests that at least some of the advantages sought with peri-modiolar electrodes (esp. reduced thresholds) can be reached (Tykocinski et al., 2001; Kuzma and Balkany, 1999). In a recent article (Frijns et al., 2001) we compared the Clarion HiFocus electrode in the lateral and modiolus hugging position in our computational model of the electrically stimulated cochlea. We concluded that modiolus hugging in the basal turn favorably influences spatial selectivity and dynamic range. This is a consequence of the specific anatomy of the human cochlea. As contrasted to other species, in humans the distance from the medial wall of the scala tympani to the nerve bundle in the modiolus is much larger in the basal turn than in the middle and apical turns. In more apical sites a position near the outer wall is therefore more desirable to avoid so-called cross-turn stimulation of fibers in the modiolus.

Improved implant electronics and speech processing strategies are other technical aspects contributing to the clinical success of multi-channel implants. A major breakthrough was achieved by the introduction of the CIS (Continous Interleaved Sampling) strategy (Wilson et al., 1991). This strategy avoids electrode interactions by nonsimultaneous stimulation of the different electrode contacts in the array. There is laboratory evidence that increasing the rate of stimulation in CIS may further increase speech performance (Rubinstein et al., 1999b).

With the increasing numbers of prelingually deaf children that are implanted, there has been growing interest in objective measures of the electrode to neural interface such as stapedius reflex thresholds (Almqvist et al., 2000), the electrical auditory brainstem response (EABR)(Shallop et al., 1991) and the electrically evoked compound action potential (eCAP) of the auditory nerve. Initially, eCAP recordings could only be made intraoperatively (Gantz et al., 1994) or from cochlear implants that used a percutaneous plug to connect the speech processor with the internal electrode array (Brown et al., 1990). Since 1998 such recordings are possible from most patients and most electrodes with the Nucleus CI24M implant, through a system called Neural Response Telemetry (NRT®)(Abbas et al., 1999). Although the shapes of NRT threshold curves are roughly the same as subjectively determined threshold and most comfortable level curves, some additional behavioral information is still needed to program the processor reliably.

In the present article we present the initial clinical experience in the Leiden University Medical Center with the Clarion CII implant (Advanced Bionics Corp., Sylmar, CA), which combines the HiFocus electrode with positioner with newly designed electronics, which is capable of high-rate and/or simultaneous stimulation through 16 independent current sources. Its hardware also features new telemetry options, including recording of eCAPs via the intracochlear electrode array (called Neural Response Imaging, NRI). Here we will present speech perception data in quiet and in noise obtained with the new device, programmed in a mode that emulates the previous Clarion (CI) device. In addition we will demonstrate and discuss some of the possibilities for objective assessment of the electrode-to-neural interface, emerging from the NRI technique.

6.2 Patients, Materials and Methods

6.2.1 The Clarion CII Cochlear Implant

All patients in this study have been implanted by a single surgeon at the Leiden University Medical Center with the Clarion CII cochlear implant in the period immediately following the CE (Conformité Européenne) approval (July 2000) for its clinical use in deaf adults and children in the European Community. This

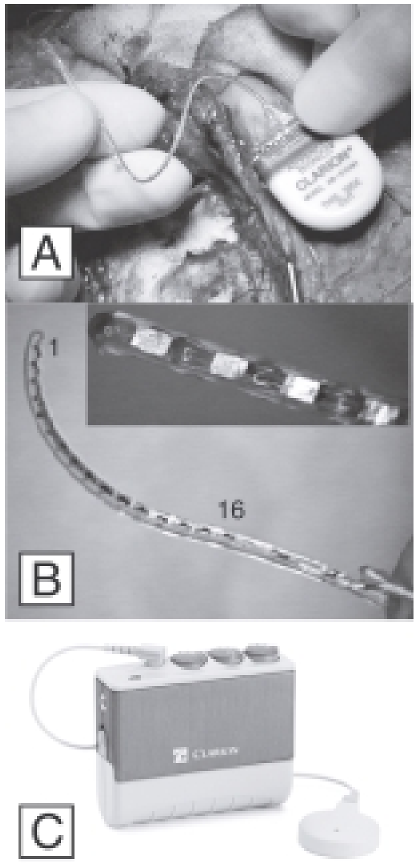

Figure 6.1: A The new implantable electronics of the Clarion CII implant (Advanced Bionics Corp., Sylmar, CA) is encased in the same ceramic housing as the previous Clarion Multi-Strategy implant.
B The modiolus hugging HiFocus electrode has 16 electrode contacts (0.4x0.5 mm), equidistantly spaced at 1.1 mm. The most apical contact is numbered 1, the most basal one 16.
C All patients in this study used the new Platinum speech processor.

implant, which obtained FDA approval in March 2001, is shown in Fig. 6.1. It incorporates the HiFocus electrode, which is brought into a modiolus hugging position by secondary insertion of a so-called positioner. The electrode contacts are numbered from 1 at the tip of the electrode to 16 at the basal end (Fig. 6.1^B).

The implanted electronics uses less power than its predecessor (referred to as the CI) and is driven by the Platinum® speech processor (PSP) shown in Fig. 6.1^C. The implanted circuitry contains 16 independent current sources (versus eight in the CI), which can be driven simultaneously. These linear current sources have an 11-bit (including sign bit) DAC, yielding a best resolution of 0.25 μA in the lowest of their 4 output ranges. The current sources in the CI had a log-based amplitude scale (9 bits including sign bit) with a 0.3 dB current step. With a 10 kΩ load the new current sources reach 63% of their final value in less than 1 μsec, which compares favorably with the 5 μsec needed in the CI. This improvement in the current source allows better timing of the pulses in a CIS type strategy. The basic design of the implant differs from all previous devices in the way the stimulus information is transmitted from the speech processor to the current sources. Traditionally, cochlear implants work by continuously updating the complete stimulus information from external components. This implant system first transfers a so-called pulse table containing the processing scheme (stimulus waveforms, pulse durations and/or update rates) into a memory bank in the internal electronics. During normal use, the speech processor transmits only amplitude information through the RF link to the internal electronics. This enables the total system to operate at rates up to 373,000 pulses per second, because it is less constrained by the limited bandwidth of the RF link. Currently, however, software limitations require the implant to operate in a mode that emulates the output of the conventional Clarion (CI) implant, allowing for a maximum of 8 active contacts and a maximum non-simultaneous update rate of 6500 biphasic pulses per second (75 μsec/phase) (Kessler, 1999).

6.2.2 Patient Demographics and Follow-Up

Here we report the 3 to 11 mo follow-up data of the first ten Clarion CII recipients (labelled consecutively A to J) implanted between July 2000 and May 2001 in the ENT department of the Leiden University Medical Center. They enrolled in the program of the Cochlear Implant Rehabilitation Center Leiden-Effatha (CIRCLE), run in collaboration with the Institute for the Deaf Effatha in Zoetermeer. As shown in Table 6.1 all patients were postlingually deafened

Table 6.1: Patient demographics of the 10 postlingually deafened implantees involved in the clinical study, listed in order of surgical implantation.

Patient	Gender	Age at implantation (yr)	Duration of deafness (yr)	Hearing loss Implanted Ear (dB HL)	Contralateral Hearing Loss (dB HL)	Etiology
A	F	62	2	115	>120	Progressive
B	M	43	>30	>120	115	Hereditary
C	F	38	>30	115	115	Hereditary
D	F	39	35	>120	115	Aminoglycosides
E	M	59	1	105	100	Ménière's disease
F	F	49	15	>120	>120	Progressive
G	F	52	23	>120	>115	Unknown
H	F	28	3	>120	>120	Hereditary
I	F	51	33	>120	110	Syndromal
J	M	14	2 months	>120	>120	Meningitis

Duration of deafness denotes the duration of the period of severe-to-profound hearing loss. The hearing loss is the average pure tone hearing loss in both ears for 1, 2 and 4 kHz rather than the conventional Fletcher Index (based upon the PTA thresholds for 0.5, 1 and 2 kHz), since these frequencies are more relevant for the speech reception in quiet and in noise.

(9 adults, 1 child) with a wide variety of etiologies. The preoperative objective assessment of the hearing loss with DPOAE's, ABR and ECoG responses (Schoonhoven et al., 1999) confirmed the pure tone hearing thresholds listed in Table 6.1. Preoperative CAT and MRI scans did not show any anatomical abnormalities, in 8 patients. In patient E a very anterior bulging of the sigmoid sinus and a slit-like narrowing of the scala tympani in the vicinity of the round window was observed. In patient J, deafened due to meningococcal meningitis, there were signs of intracochlear ossification in both cochleae.

Preoperative speech perception scores were measured in a free-field condition with adequately fitted hearing aids using the standard CVC word lists (prerecorded female speaker) of the Dutch Society of Audiology at 65 dB SPL (Smoorenburg, 1992). As contrasted with normal clinical use, the results of four lists (each 11 words, i.e., 33 phonemes) were averaged to obtain a single data point to increase the accuracy. If the candidates did not have adequately fitted hearing aids, their speech perception was tested with newly fitted ones after a trial period of at least 6 wk. The same test was used to evaluate the postoperative performance with the implant. If applicable, noise with a long-term frequency spectrum equal to speech (as available on the same CD used to present the words) was added to test the performance with the implant in background noise. As shown in Fig. 6.3 the average preoperative phoneme score was 8% (range: 0 to 23%), and the word scores were between 0 and

2%.

Preoperatively, using both hearing aids, seven patients could not complete a speech-tracking task without the help of lipreading at a speed higher than 10 words correct per minute (the point below which we discontinued the measurement). This test, which aims at measuring performance in real-life conditions (De Filippo and Scott, 1978), is more difficult to standardize than, e.g., CVC word tests. To minimize biases the test was conducted according to the protocol formulated by Matthies and Carney (1988), including their prompting and stopping rules. We used a live presentation of selected everyday texts (of 100-110 words, 7-10 words per phrase) by a single female speaker other than the speech therapist they trained with. After completion of the full text the total number of words was divided by the time it took to complete the test, yielding a score in words per minute (wpm). In the present paper we will present results for the sound-only condition. In this condition the scores of normally hearing listeners range between 90 and 100 wpm.

We also used sentence materials to test the postoperative performance of the patients in noise. For this purpose we presented the sentence test developed by Plomp and Mimpen (1979) from the standard CD (female speaker) in a free field condition. The standard 2 dB up (wrong result), 2 dB down (correct result) paradigm on sets of 13 sentences was used to adjust the level of the speech in standardized steady-state speech noise (65 dB SPL) in search of the speech reception threshold (SRT). In this relatively difficult test an answer is only scored as correct if the whole sentence is repeated flawlessly. Scores are considered to be reliable if the intra-test standard deviation is less than 3.0 dB. For normally hearing subjects the SRT is reached at a signal to noise ratio of approximately -5 dB.

In the CIRCLE program the rehabilitation starts immediately after the fitting, four to six wk after surgery. This newly developed training program (Frijns-van Putten et al., 2005) has a structure with ten levels of increasing difficulty, starting with simple discrimination tasks, and (if possible) building up to open set speech perception in noisy circumstances. The training does include listening to VCVs and CVCs, but the therapist never uses any words from the test materials to avoid biasing the test results. The training is given by a speech therapist and has an intensive start with 20 sessions of 30 minutes in the first two wk and 10 such sessions in the next two wk. In the next two mo up to 15 additional sessions take place, gradually diminishing in frequency. In the same 3-mo period each patient undergoes approximately 12 fitting sessions. Five of these are scheduled in the first week, and all patients are offered CIS, SAS as well as PPS processing strategies in this early phase. When making decisions on the parameters we always paid attention to maximizing the amount of high frequency information, like commonly done when adjusting conventional hearing aids to optimize speech perception in noise. For this purpose we tried to maximize the upper limit of the dynamic range (the M-level) for the basal-most electrodes or electrode pairs, even though patients often initially did not like the overall sound. At the same time we also tried to avoid cross-turn stimulation, which is expected to occur at more elevated stimulus levels, especially at apical electrode contacts (Frijns et al., 2001). This phenomenon results from excitation of modiolar parts of nerve fibers, originating from more apical cochlear turns than the one the stimulating contact is in. Due to the tonotopic organization of the cochlea such cross-turn stimulation is expected to produce lower-pitched sensations. Whenever patients reported such percepts for a particular electrode we reduced the M-level for that electrode (Frijns and Briaire, 2001). A detailed description of the fitting strategy is beyond the scope of the present article and will be published elsewhere.

6.2.3 Neural Response Imaging

One of the new features of the Clarion CII implant is the built-in capability to measure the electrically evoked compound action potential (eCAP) of the auditory nerve through the intracochlear electrodes, denoted by Neural Response Imaging (NRI). In itself such a measure of the electrode to neural interface is not new, as it was already available (as Neural Response Telemetry, NRT) in the Nucleus CI24M implant (Cochlear Corp, Sydney, Australia) (Abbas et al., 1999). The Clarion CII has an on-chip differential amplifier with multiplexed inputs, which returns from an overload condition due to a stimulus artefact within 20 μsec, thereby eliminating the need to switch off the inputs during stimulus delivery. The responses are captured with a 9-bit (8 bits plus sign) analog-to-digital converter, operating at sampling rates up to 60 kHz. This high rate is achieved by first storing the sampled data in the same piece of memory that is used to store the pulse tables for stimulation (see above) before transferring them on a sweep-by-sweep basis (approximately 1 per second) to the external computer for averaging. The present study mainly used the alternating polarity paradigm (Finley et al., 1997), an artefact rejection scheme, which is commonly used in acoustical CAP measurements (Versnel et al., 1992). According to this paradigm the responses to anodic-first and cathodic-first pulses are averaged, which eliminates the artefact, while the biological signals—which have the same polarity for both stimulus conditions—are retained. Alternatively, we performed some preliminary measurements with a forward masking paradigm (Brown and J., 1990), which makes use of the refractory properties of the auditory nerve.

For all NRI recordings we used biphasic pulses with 37.5 μsec phase duration and we averaged 15 sweeps ($\pm$ 1 sweep per second) of each stimulus presentation. In this study we used monopolar stimulation and recording modes. We short-circuited the stimulus and recording electrodes during approximately 190 μsec immediately preceding the stimulus onset to discharge them before each NRI sweep. It turned out that the device produced an internal interference signal, which was synchronous with the sweeps but independent of the stimulus strength, allowing us to subtract a so-called system signature from each sweep before further processing. In fact, this "system signature" was an NRI recording with the stimulus amplitude set to zero. Next, the recording was digitally blanked until 200 μsec after stimulus onset to prevent any residual artefact from disturbing the further post-processing, which consisted of zero-phase shift filtering based on a fourth order Butterworth low-pass filter with a cut-off frequency of 6 kHz. The effect of the different processing steps, which were performed in MatLab® version 5.3 (The MathWorks, Inc., Natick, MA), is illustrated in Fig. 6.2.

6.3 Results

During surgery no additional anatomical abnormalities were encountered. In subject E an "egg shell" like decompression of the sigmoid sinus was performed and the sinus was temporarily impressed during the formation of the posterior tympanotomy, the cochleostomy and the electrode insertion. The basal most end of his scala tympani had to be widened over a length of approximately 5 mm. In nine patients a complete and uneventful insertion of the HiFocus electrode was achieved, but in patient J, just 13 contacts could be inserted after a drill-out of the basal scala tympani. A postoperative CAT scan showed an insertion of approximately 270 degrees in the latter patient.

In line with our findings in the computational model (Frijns et al., 2001) we aimed to get the electrode in a modiolus hugging position only in the basal turn, while at the same time avoiding unnecessary damage to the intracochlear

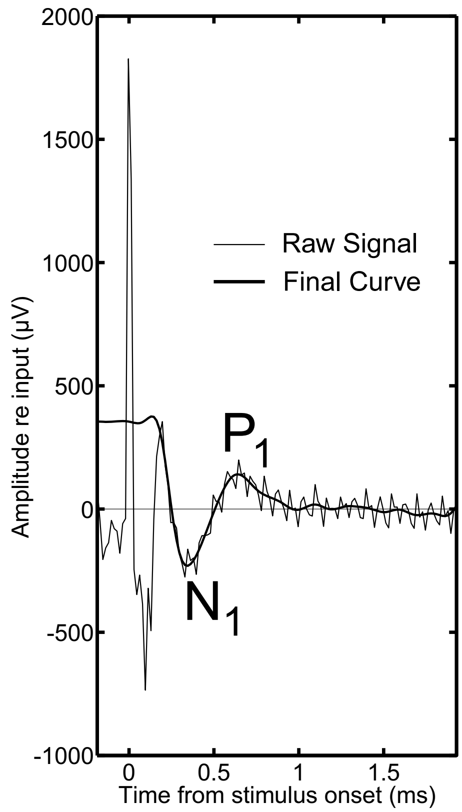

Figure 6.2: After subtraction of a "system signature" the recorded NRI data are first digitally blanked until 200 μs after stimulus onset (t=0). Then the signal is low-pass filtered using a zero-phase shift filter to eliminate high-frequency noise. Before the stimulus delivery the stimulating and recording electrodes are short-circuited to remove residual charge that might interfere with the NRI recording.

structures. Therefore, the insertion of the positioner was stopped if any increased resistance was felt, resulting in a 3 to 6 mm (8mm in patient J) protrusion of the positioner from the cochleostomy. A postoperative plain radiograph or CT confirmed the correct position of the electrode. We did not observe any postoperative complications.

6.3.1 Speech Perception in Quiet and in Background Noise

At the time of removal of the pressure bandage, seven days after surgery, a preliminary fitting with the CIS strategy was performed. At that time 5 of the 10 patients had considerable open set sentence recognition without lip reading within 10 minutes after hook-up. The final fitting took place 5 wk later. Then, the patients were fitted with an 8-channel monopolar CIS, and an 8-channel bipolar SAS strategy. After 1 week the strategy that resulted in the lower speech perception (which always happened to be the strategy the patients liked less) was replaced by an 8-channel monopolar PPS strategy. Surprisingly, nine patients after three mo had a definitive preference for the CIS strategy, and one (G) for the PPS strategy. Figure 6.3 shows the results for the CVC word test as obtained for all patients with their preferred strategy. The minimum follow-up was 3 mo, the longest 11 mo. The bars show the average scores at predetermined intervals (1 and 2 wk, 1, 2, 3 and 6 mo). For most patients an additional data point is available, measured with their implant still in emulation mode, immediately before they entered another study (not reported here), employing more electrodes, higher pulse rates, and shorter pulses. Figure 6.3^{A} shows the phoneme scores, as is the standard with this test in the Dutch setting, while Figure 6.3^{B} displays the same data as word scores, which is a more common way to look at these data in Anglo-Saxon countries. Both figures show a rapid increase in performance, which reaches an average of 80% for the phoneme scores and of 62% for the word scores at three mo, the longest follow-up completed by all patients. The average of the last phoneme scores obtained for all patients is 84% (Table 6.2), the corresponding word score 66%. It is noteworthy that patient J, who had a partial insertion of 270 degrees (13 contacts) fits in with the group so well.

The speech-tracking results (only measured at the predetermined follow-up intervals listed above) are shown in Figure 6.4. The steadily increasing scores (up to 66 wpm on the average at three mo) in this figure reflect the increased ease of listening subjectively reported by the patients. The tendency of the speech tracking performance to drop slightly for most patients from 3 to 6 mo may reflect the fact that none of the patients received formal training in this

Table 6.2: The phoneme scores on the NVA CVC word test (65dBSPL, free field, sound only, 44words per data point) at the end of the follow-up period (second column) in quiet and in speech noise with Signal-to-Noise ratios (SNR) of +10, +5 and 0 dB. The SNR for which 50% of the phonemes are correctly understood (column "SRT (CVC)") was calculated by linear interpolation. Similarly, the Phoneme Recognition Threshold (PRT) was calculated by linear interpolation of the phoneme scores, normalized by the data in quiet. The column SRT (Plomp) gives the Speech Reception Threshold (i.e., the average SNR for two consecutive measurements with 13 different sentences) for the Plomp & Mimpen (1979) sentences presented at 65 dB SPL. The bottom row shows the mean data for each column.

Patient	Duration of follow-up (wk)	SNR(dB)	∞ (%)	+10 dB (%)	+5 dB (%)	0 dB (%)	-5 dB (%)	SRT (CVC) (dB)	PRT (dB)	SRT (Plomp) (dB)
A	48		93	70	58	52	21	-0.3	-0.9	+5.5[a]
B	43		91	79	54	49	28	+1.0	-0.8	+4.6[a]
C	43		71	51	52	40	21	+4.2	-1.2	na
D	39		89	75	50	49	30	+5.0	-1.2	+7.0[b]
E	35		89	81	69	66	39	-3.0	-4.0	+3.6[b]
F	26		93	81	74	53	22	-0.5	-1.0	+2.2[b]
G	22		90	79	71	52	40	-0.8	-2.9	+9.6[b]
H	22		81	70	50	27	nt	+5.0	+2.9	+4.2[c]
I	13		63	46	35	22	nt	+11.2	+3.7	na
J	13		79	58	43	23	nt	+7.3	+4.1	na
		Mean	**84**	**69**	**56**	**43**	**29**[d]	**+2.9**	**-0.1**	**5.2**[d]

[a] 26 weeks of follow-up
[b] 13 weeks of follow-up
[c] 8 weeks of follow-up
[d] over tested patients
na = not available (even without noise not reliable)
nt = not tested

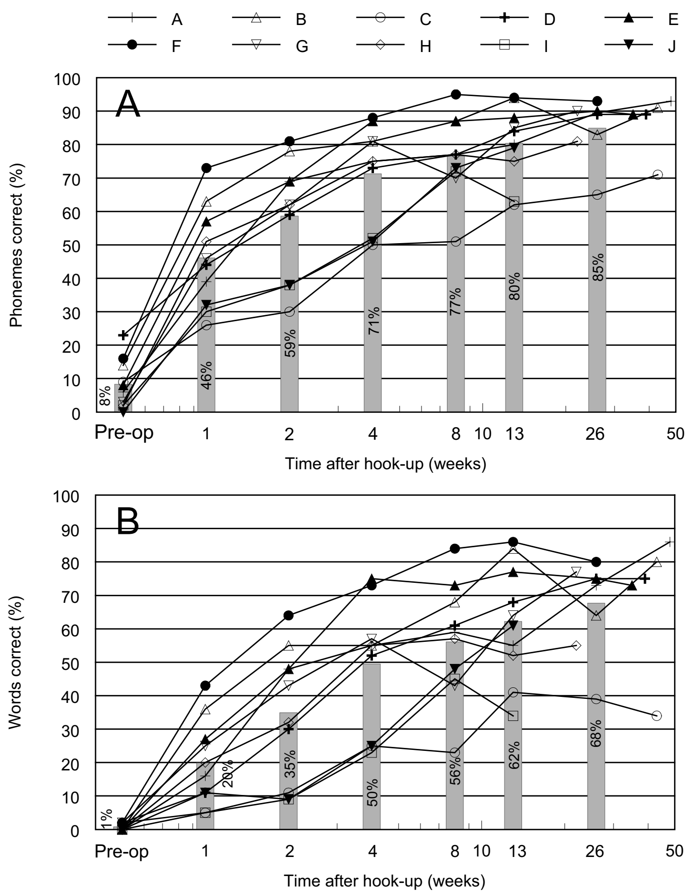

Figure 6.3: A Phoneme scores on a CVC word test in quiet (free field, sound only, 65 dB SPL) as measured pre operatively, at 1 and 2 wk, and after 1, 2 and 3 mo for the ten patients in this study. The individual scores are shown as lines, the average scores as bars. B Word scores on the same CVC word test in quiet as A.

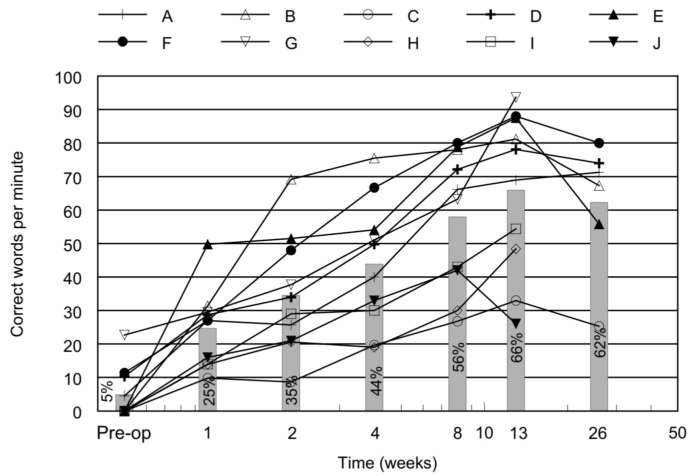

Figure 6.4: Results for the ten patients in Figure 3 of a speech-tracking test (sound only condition) as a function of time after hook-up. The individual scores are shown as lines, the average scores as bars.

period. However, the effect is small and it may be just coincidental, given the known limitations of the speech-tracking procedure. despite these limitations, it measures other capabilities than just hearing (such as the ability to use contextual information) and the performance ranking of the individual patients is somewhat different from that with the CVC word test.

Table 6.2 summarizes the performance in noise for the ten patients included in the study. Relative to the performance on the CVC test in quiet, all subjects show a significant decrease in performance at a +10 dB signal to noise ratio. The performance gradually decreases if the noise is increased in steps of 5 dB. At a +5 dB signal to noise ratio 8 of the 10 patients have phoneme scores above 50%, while four of them are still performing above this level at 0 dB signal to noise ratio. Generally speaking, the poorest performers in noise are the ones with the shorter follow-up (subjects H, I and J). Their scores were below 30% at the 0 dB level, and they were not tested at a -5 dB signal to noise ratio. As shown in Table 6.2, the 50% phoneme score, also known as the Speech Reception Threshold (SRT) is reached at a +2.9 dB signal to noise ratio (range: -3.0 to 11.2 dB) on average.

Table 6.2 also shows an estimate of the average phoneme recognition threshold (PRT) for each patient. The PRT is defined as the signal to noise ratio that produces 50% of the performance level in quiet (Fu and Shannon, 1999). In our group, the values range between -4.0 and + 4.1 dB (average -0.1 dB). The SRT as measured with the Plomp and Mimpen (1979) sentence test varied between +2.2 and +9.6 dB (average +5.2 dB). The three patients (C, I and J), who could not complete the latter task reliably, not even without noise, are the poorest performers. They have a phoneme score in quiet below 80%. With these patients the results depended strongly on the starting level of the speech for the first sentence.

6.3.2 Neural Responses

Figure 6.5 demonstrates the ability to record NRI input/output curves, both peroperatively and in awake patients. In these recordings the monopolar stimulating (#7) and recording (#5) electrodes were located in the middle of the array. To avoid subjective interpretation errors we developed software to determine the N_1 to P_1 peak-to-peak amplitude of the eCAP automatically. This amplitude shows a monotonic increase (up to a certain saturation level) with stimulus amplitude (Fig. 6.5$^{A\&B}$), while the latency of both peaks is hardly influenced by both stimulation intensity and time (Fig. 6.5^{C}). As illustrated in Figure 6.5^{B} the NRI threshold and the slope of the I/O curve are robust over time. This is remarkable, since the electrode impedances change rapidly after implantation, partly due to deposition of body substances, scar tissue formation and the formation of iridiumoxide on the contact surface after electrode activation (Peeters et al., 1998). Furthermore, these impedance changes explain the differences at high stimulus levels between the curves in Figure 6.5^{B}. While the current source did not reach its upper voltage compliance limit ($\pm$ 8V) at the time of implantation, it did at the first fitting, since the impedance of the stimulating electrode had risen from 3.1 kΩ to 10.9 kΩ. In line with this observation the patient did not perceive any increase in loudness for stimulus currents above 1 mA. However, after 2 weeks of usage the impedance had fallen to 8.7 kΩ, and the patient could no longer stand the high loudness associated with stimulus levels of 1 mA and above.

We also recorded I/O-curves in the other patients using various electrode combinations. Some typical results are shown in Figure 6.6. These recordings were in line with the observations in Figure 6.5^{B}, although there are large inter-patient variations in the eCAP amplitude, which also varies considerably with the position of the stimulating and recording electrode. In most cases

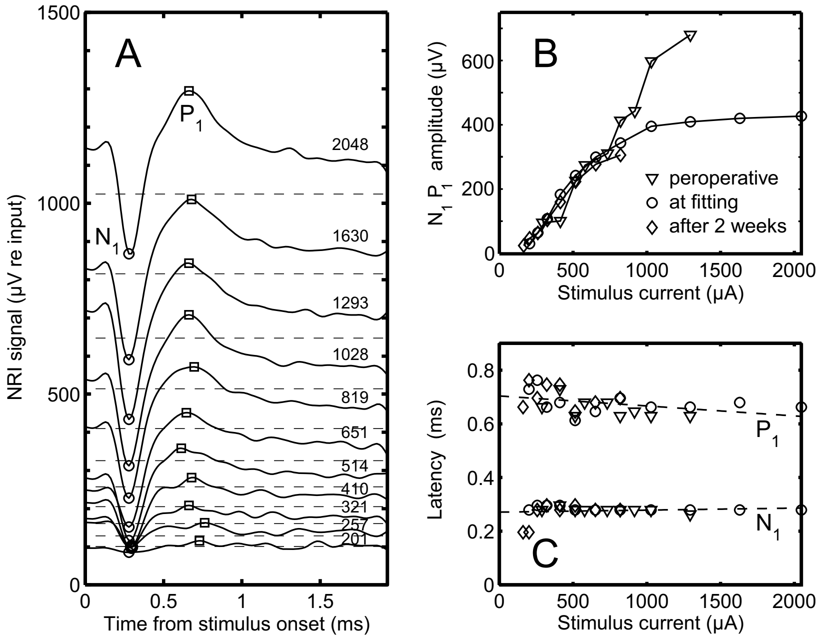

Figure 6.5: NRI recordings of patient F from the middle of the electrode array (alternating polarity paradigm, stimulating electrode 7, recording electrode 5).
A Traces for varying stimulus intensity recorded at the time of fitting. The N_1 (circles) and P_1 (squares) peaks have been determined automatically. To enhance the visibility the individual traces have been level shifted proportionally to the stimulus strength as indicated by the dashed lines. The numbers to the right indicate the stimulus current in μA.
B The N_1P_1 amplitude of the eCAP as a function of stimulus level, measured at three moments in time.
C The latency of the N_1 and the P_1 peak of the eCAP as a function of stimulus level for the same recordings as used in B. The symbols designate the moment the recording was made, as indicated by the legend in B. The dashed lines are the linear regression lines based upon all data.

however, more apical stimulating and recording contacts result in larger NRI response amplitudes, possibly due to the smaller cochlear dimensions in the apex and consequently the closer proximity of apical electrodes to the auditory nerve in the modiolus. Patient D, in whom we were not able to record a reliable NRI with electrode 7 as the stimulating electrode, forms an interesting exception. Since this patient produced normally shaped eCAPs for the other electrodes tested, including the neighboring electrode combination 10-8 this lack of response may be an indication of localized ganglion cell loss or other cochlear damage. The subjective T- (threshold) and M-levels for electrode 7, however, are not essentially different from its neighbors, while its pitch ranking is between them as expected.

Most NRI responses and subjective loudness saturate for stimulus levels above $\pm$ 700 μA. This is in line with the above-mentioned concept of reaching the compliance limit of the current sources, as electrode impedances around 10 kΩ are found after some time of usage in most patients. The latency of the N_1 and P_1 peaks (not shown in Figure 6.6), is much less variable than their amplitude and conforms with the range of values shown in Fig. 6.5^C.

In an attempt to document the spread of excitation we recorded NRI responses with all available electrodes for stimulating electrodes at apical, intermediate and basal positions in the cochlea (electrodes 3, 7 and 15 respectively). A typical result is shown in Fig. 6.7, where the eCAP amplitudes peak around the stimulating electrode for stimulating electrodes 3 and 15. This is in line with the expectations. However, for electrode 7 the response amplitudes increase gradually from basal to apical recording locations and there is certainly no peak around the stimulating electrode. This same result, that eCAP amplitudes do not peak around stimulating contacts in the middle of the array, occurred for all patients in which we could measure the NRI for this electrode. In many cases it was not possible to make reliable recordings with electrode contacts neighboring the stimulating contact, since the amplifier was driven into overload by the stimulus artefact. Therefore we routinely performed the measurements with one contact between the stimulating and the recording contacts.

Figure 6.8 shows the eCAP waveforms we recorded in three patients with a forward masking protocol as used with the Nucleus system (Abbas et al., 1999) with inter pulse intervals (IPIs) between the (equal intensity) masker and probe pulses of 350 and 500 μsec. This figure also shows the recordings with the alternating stimulus protocol, obtained in the same session with the same stimulation and recording contacts. The I/O-curves based upon the

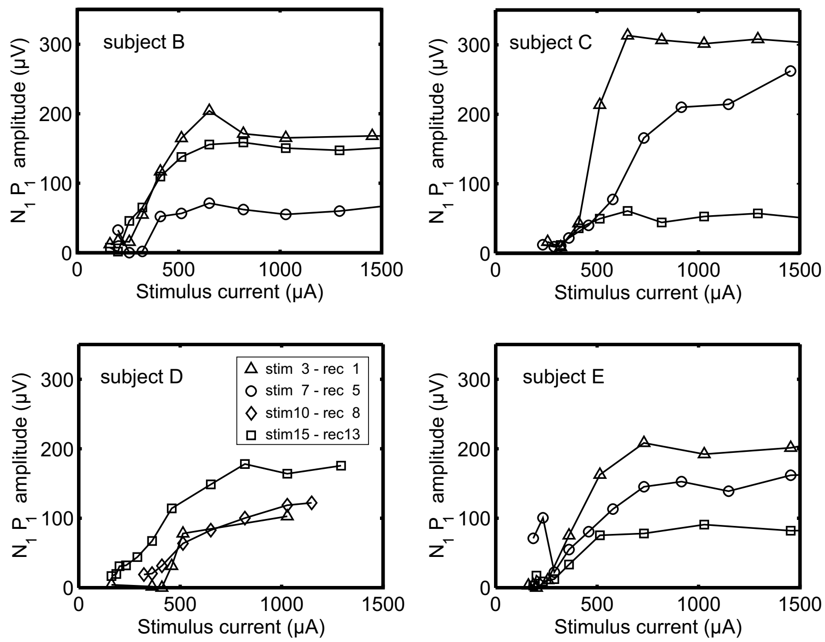

Figure 6.6: The N_1P_1 amplitude of the eCAP as a function of stimulus level as measured with the alternating polarity paradigm in four awake patients with stimulus and recording electrodes in three positions (△ = apical, ○ & ◇ = middle, □ = basal) along the electrode array. Saturation of the curves is due to the current source reaching its voltage compliance limit rather than due to saturation at a neural level.

N_1P_1 amplitudes of these recordings are shown in Figure 6.9. Patients B and C yielded clear responses, but the (intra-operative) recordings in patient G contained more noise and did not show any saturation in the I/O-curves for any paradigm. In all patients the alternating polarity paradigm yielded smaller N_1P_1 amplitudes than the forward masking protocol, especially at higher stimulus levels. In addition, the amplitude of the responses for the two forward masking paradigms tended to saturate at much higher stimulus levels than with the alternating stimulus paradigm (patients B and C). At such high stimulus levels we observed a steeply rising slope between the N_1 and P_1 peaks, often without a clearly visible N_1 peak, a phenomenon that never occurred with the alternating polarity paradigm. At lower stimulus levels the eCAP

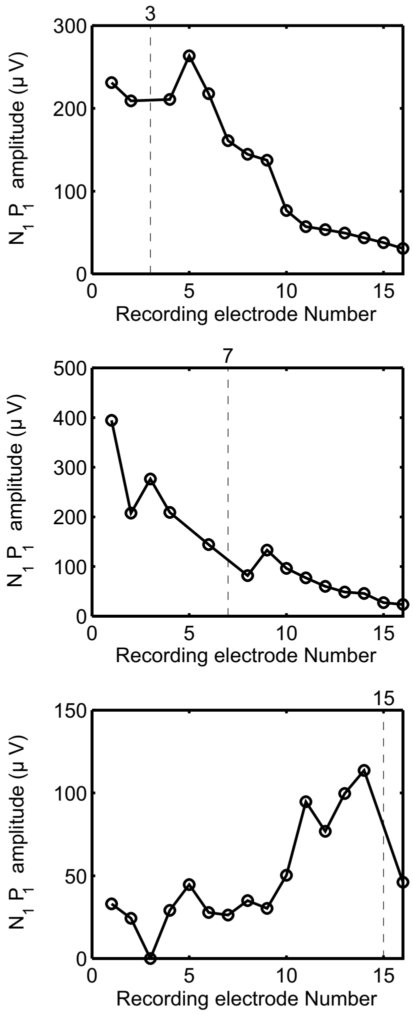

Figure 6.7: The eCAP amplitude (alternating polarity paradigm, stimulus level 731 μA) in patient E with stimulating electrode 3, 7 and 15, respectively, recorded from all other electrodes in the array.

waveforms were surprisingly comparable for the alternating polarity and both forward masking paradigms, while the slope of the I/O-curves was slightly lower with the alternating polarity paradigm. NRI-thresholds, determined by downward extrapolation of these curves, were almost identical for all three paradigms.

6.4 Discussion and Conclusions

In this article we presented the first clinical results obtained in the Leiden University Medical Center with the Clarion CII cochlear implant, which combines a modiolus hugging electrode with newly designed implant electronics and a new, externally worn, ("platinum") sound processor. Although the CII implant contains 16 independently driven current sources and is technically capable of high update rates, its clinical use is currently limited to a so-called emulation mode of the previous Clarion HiFocus implant. Surprisingly, in light of the favorable results reported for the SAS strategy with the original Clarion CI implant (Battmer et al., 1999), 9 subjects in our small but diverse group of 10 postlingually deafened adults had a definitive final preference for the CIS strategy over the SAS and PPS strategies, while 1 patient's final preference was the PPS strategy. With their preferred strategy we found quickly improving and ultimately excellent speech scores, both in quiet and in noise. In a recent survey Shannon (Shannon, 2001) found an ever-increasing performance for each generation of implants, up to a level of 45% words correct for a CVC word test in quiet with the newest Nucleus Countour and the original Clarion HiFocus implants. A highly comparable outcome was reported by Hamzavi et al. (2001) for postlingually deaf adults implanted with the MedEl® Combi 40/40+® cochlear implant after a follow-up of one y. Within 3 mo 8 of the 10 patients in our series scored 52% to 86%, which is 7 to 41 percentage points above the level of performance for CVCs reported by Shannon. Two subjects scored (4 and 11 percentage points) below this average level. The average phoneme and word scores on this test were somewhat higher (84% and 66%, respectively) when measured at the end of the follow-up period (i.e., after 3-11 mo, Table 6.2). Therefore, it is likely that the scores of most patients will improve further with additional listening experience, although we are certainly observing ceiling effects on the tests in silence.

Unlike other studies, in most patients the speed of improvement for phoneme scores seems to slow down already after 1 mo (Fig.6.3^{A}). For word scores such a plateau is not discernible (Fig.6.3^{B}). With speech tracking the upper

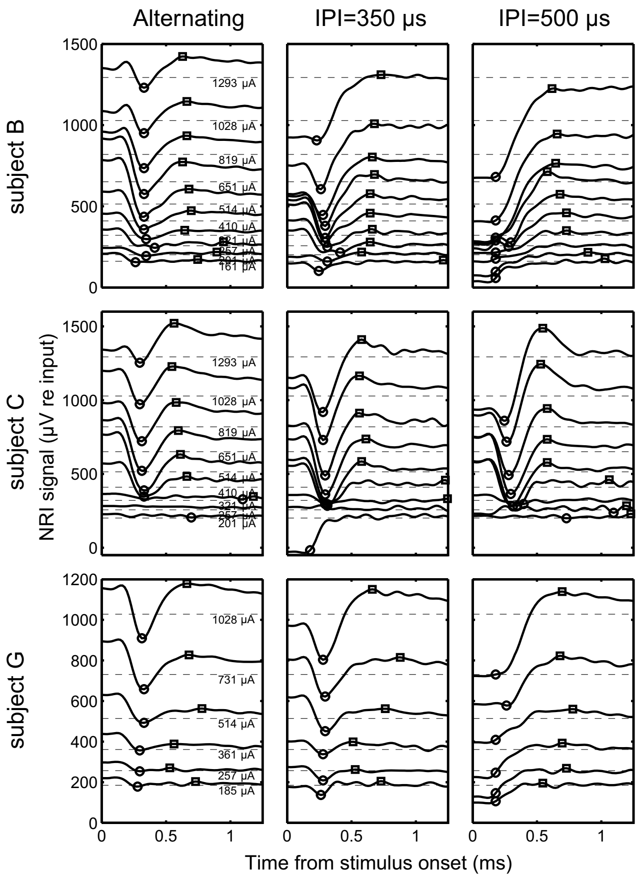

Figure 6.8: NRI recordings for patient B, C and G at various stimulus levels for stimulation electrode 3 and recording electrode 1. To enhance the visibility the individual traces have been level shifted proportionally to the stimulus strength as indicated by the dashed lines. The numbers to the right indicate the stimulus current in μA. For each patient the left most panel shows the results obtained with the alternating polarity paradigm, while the middle and right most panels show data obtained with the forward masking paradigm with a masker-probe interval of 350 μs and 500 μs, respectively.

limit of performance seems to be approached after approximately 2 mo (Fig. 6.4). An interesting observation in this small group of patients with little or no residual hearing is the fact that the time course of speech perception improvement, especially when measured as phoneme scores with CVC words (Fig. 6.3^{A}), shows a limited inter-patient variability despite their different preoperative conditions. Also, duration of deafness is not correlated with final performance for our subjects. The five next patients implanted in our clinic (with a follow-up of 2 wk to 2 mo), although fitted with a higher rate CIS strategy (1430 pps per contact, 8-16 contacts), confirmed this trend of limited patient variability, but of course larger series are needed to validate this observation.

The CVC word tests used in the present study are the common way to measure speech perception in the Netherlands and Flanders, both in routine clinical practice and with cochlear implant users. The standardized way is to report phoneme scores rather than word scores. Unfortunately, there are few published studies using this test material that allow a direct comparison with the data presented here. Mens (2001) used the same test material, presented at 70 dB SPL, and found phoneme scores between 0 and 80% (average 47%, equivalent word score $\pm$24%) in all 20 postlingually deafened patients implanted in the Nijmegen clinic who use the CIS strategy with a follow-up of 1 y or more. There may be some bias in his patient group, since he does not report any speech perception data on the 15 SAS users in his clinic (implanted with a Clarion CI with positioner). Wouters and van den Berghe (2001) report average phoneme scores around 61% (equivalent word score $\pm$34%) on the Flemish version of the NVA test for four good performers with the LAURA implant, which is in line with the results reported by Smoorenburg et al. (2001), who used the same speech material as we did and reported an average phoneme score of 65% in 10 Dutch users of the Nucleus CI24M implant. All in all, these results support the conclusion that the good results reported here are not caused by language or test differences.

We also tested the performance in background noise with CVC words (Table 6.2) and found a phoneme recognition threshold (PRT) of approximately 0 dB, and an SRT of approximately +3 dB. This is a good result in light of those reported by Fu and Shannon (1999), who found PRT values around +5 dB for Nucleus22 patients using a 4 channel CIS strategy. Wouters and van den Berghe (2001) report an SRT of nearly +10 dB for conditions similar to the ones used in the present study (speech and sound from the same direction) with four good performers with the CIS strategy on the LAURA prosthesis using the Flemish version of the NVA CVC word list.

One should keep in mind that all these results are far below the performance of normally hearing listeners, who have an average SRT (and PRT, since they score 100% in quiet) on the NVA CVC word test of -11 dB (-9 dB on the Flemish version; Wouters et al. (1994)). On the other hand, many patients wearing a conventional hearing aid for perceptive losses of 60 dB or above do not perform better than our Clarion CII users (Bosman and Smoorenburg, 1999).

Hamzavi et al. (2001) reported a 50% degradation of performance on German sentence material at signal to noise ratios between +10 and +15 dB. Although the test conditions are different, the performance of our group, with an average SRT around +5 dB on the Plomp and Mimpen (1979) sentence test, is probably more resistant to noisy listening conditions. Unfortunately, there is no literature on the use of this Dutch test on cochlear implantees, but it has been used in other centers in the Netherlands, where SRT's around +10 dB were found (Smoorenburg, personal communication).

There are a number of possible factors that may have contributed to the good clinical outcome for this group. First, there may be demographic factors. This is a small initial group, and the patients are relatively young (mean age at implantation 44 yr). However, none of the patients had any useful residual hearing, and the average duration of deafness (with a variety of causes) is approximately 17 yr. Second, there may be technical factors related to the implant or the fitting strategy. Although the implant was operated in a mode intended to mimic the original Clarion HiFocus implant, its electronics has been fully redesigned. As described above, the current sources have higher impedances and produce pulses with rise times around 1 μsec instead of 5 to 10 μsec as their predecessors did. This means that the non-simultaneous stimulation of the CIS-strategy is more precisely achieved with the CII implant.

Part of the relative insensitivity of speech perception to noise may be related to the fact that we deliberately maximized the dynamic range for the more basal electrodes, encoding for frequencies of 2 kHz and above (Frijns and Briaire, 2001), despite of the fact that the patients initially did not like those highly pitched sounds. Such a policy, which is common practice when fitting conventional hearing aids, is not generally used with cochlear implants. In general, hearing-impaired subjects tend to prefer speech signals with a high-frequency emphasis. The improvement of their speech-intelligibility performance with hearing aids can be accounted for by the amount of low-frequency cutoff, as published by Versfeld et al. (1999). In this respect the surgeon's policy not to insert the positioner too deep to avoid lower-pitched percepts due to cross-turn stimulation may have added value. As described in the section Patients, Materials and Methods, awareness of and elimination of cross-turn stimulation is another mainstay of the new fitting method used in our clinic. It will be described in detail in a future publication.

Finally, other center-specific factors such as the intensive start of the rehabilitation program with 2 half-hour training sessions per day during the first two wk and 1 such session per day during the next two wk, may account for the relatively rapid rise in performance with time. The initially frequent fitting sessions (5 in the first week) may also contribute to the rapid rise in performance. This cannot, however, explain the large amount of open set speech recognition found in five of the patients immediately following hook-up.

In this study we also performed an initial test with an important new feature of the Clarion CII implant, viz. its ability to record electrically evoked compound action potentials of the auditory nerve. Using the test bench (revision 3.45) of the system in combination with our own post-processing software we could record NRI responses with the alternating polarity paradigm at a sampling rate of 60 kHz. Unlike the Nucleus NRT system (Abbas et al., 1999), which has an internal sampling rate of 10 kHz, the internal amplifier in the Clarion CII does not require blanking during stimulus delivery. With its amplification set to 300, averaging 15 sweeps per stimulus presentation eliminated the noise sufficiently. Compared with the NRT system the recordings in the CII are much more detailed due to the higher sampling rate and the 9-bit ADC (Figure 6.5). However, despite of the fact that the required number of sweeps is much lower than the 50 to 200 commonly used with the NRT system, the test bench NRI system is effectively slower as the communication between the implant and the personal computer does not allow for more than one sweep per second rather than the 35 to 80 sweeps in the NRT system. Future versions of the interface are expected to allow higher sweep rates.

An interesting observation is that the overall shape of the signals obtained with the alternating stimulus paradigm does not depend on the stimulus intensity. They always show clear N_1 and somewhat broader P_1 peaks, and the latency of the peaks is virtually independent of stimulus levels. With the forward masking paradigm highly comparable responses are obtained for stimulus levels below 700 μA, but at higher levels the response has a steep slope between the (often hardly discernible) N_1 and P_1 peak. This dependence of the response morphology on stimulus intensity resembles the effects shown by Abbas et al. (1999)(; their Fig. 6.4). The fact that this phenomenon turns

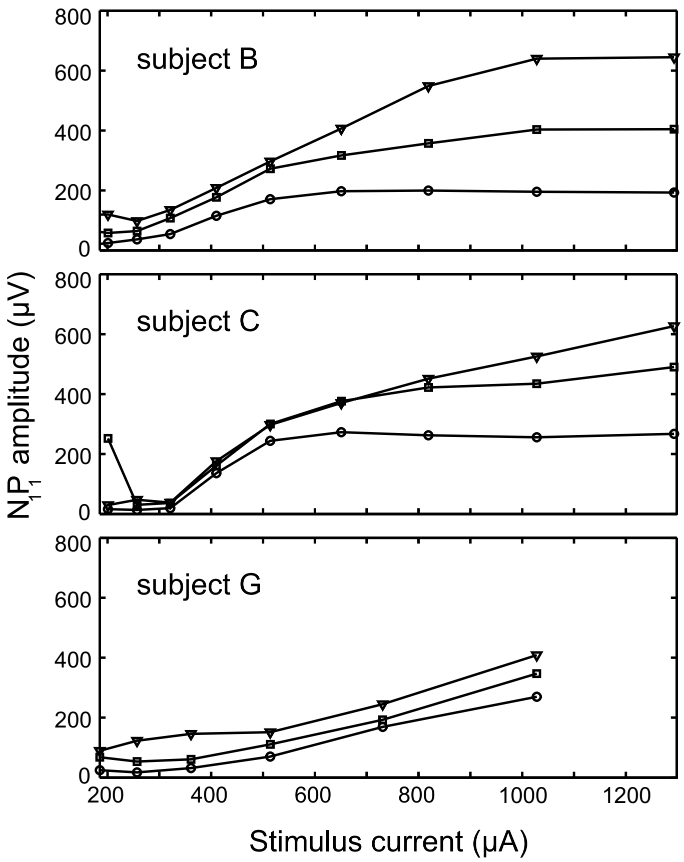

Figure 6.9: The N_1P_1 amplitude of the eCAPs shown in Figure 8 as a function of stimulus level. For all three patients (B,C and G) the data points for the alternating polarity paradigm are marked with open circles (○), while those for the forward masking paradigm are marked with a square (□, IPI= 350μs) and a triangle (∇, IPI=500μs), respectively.

out to occur in two implant systems with completely different designs, could mean that true electrophysiological processes inherent to the forward masking paradigm rather than technical limitations of the implant systems underly it. On the other hand, the fact that the distorted waveforms become apparent at current levels at or above what seems to be the voltage compliance limit of the current sources, may indicate that indeed a non-linearity of the recording system is responsible, as suggested by Abbas et al. (1999). A further analysis of the differences between the two recording paradigms is beyond the scope of the present article, but it is one of the topics currently under study in our laboratory, both in humans as well as in animal and computational models (Klop et al., 2004).

The ultimate goal of all objective measures in cochlear implantation is to derive parameters from them allowing for a reliable initial fitting of children. Currently such a paradigm is not yet available and the NRT system is mainly applicable to determine the shape and possibly the slope of the curves describing the threshold and maximum output level (Smoorenburg et al., 2001).

An important finding for the predictive use of NRI-recordings, especially peroperative ones, is the fact that our results are stable over time despite varying impedances of both the recording and stimulating electrodes (Fig. 6.5). This observation and the fact that NRI amplitudes vary unpredictably between patients and electrodes are consistent with the findings of Abbas et al. (1999). We find, however, a tendency for the largest responses to be recorded from the more apical recording sites, not only with apical stimulation (Fig.6.6) but also for stimulating electrodes in the middle of the array (7 in Figure 6.7). This may be due to the smaller dimensions in the apical turn relative to the basal turn, and to the slight embedding of the apical turn in the basal turn of the human cochlea (cf. Frijns et al. (2001)). As a result, apical recording electrodes are closer to the fibers excited in the modiolus, leading to a larger amplitude of the recorded eCAP. Of course the amplitude and shape of the eCAP also depend on the trajectory of the nerve fibers carrying the action potentials relative to the recording electrode. Future studies with computer models of the electrically implanted cochlea may lead to more definitive conclusions on the underlying volume conduction aspects of neural recording.

Similarly, such computer simulations will be of great value for the interpretation of NRI recordings with all nonstimulated electrodes, like the ones shown in Figure 6.7. Such recordings are intended to serve as an objective tool to measure the spread of neural excitation. However, while the patients report clear perceptual differences between all electrodes, the preliminary results in

Figure 6.7 suggest large overlap of the regions excited by neighboring electrodes. Therefore, we infer that the peaks that are found with this method are considerably broader than the actual neural response patterns. Another intriguing effect is the absence of any evidence for tuning around stimulating electrodes in the middle of the array, which subjectively do have clear tuning. Future research will have to explain this finding, which has also been reported by Battmer et al. (2001).

Based on the results presented in this article of the first patients implanted with the Clarion CII implant, we conclude that the Clarion CII is capable of delivering high amounts of speech information, even when operated in an emulation mode that mimics its predecessor, the Clarion HiFocus (CI) implant. We found very high open-set speech understanding, in a number of cases even without training. It is expected that the results can be further improved if the full technical potential of the implant is unleashed, e.g., with higher update rates or simultaneous use of all current sources. Although the clinical value of eCAP recordings still needs to be proven, we have shown that the NRI system yields a good signal quality and that its design has a great deal of flexibility. However, the current version of the NRI test bench imposes considerable limits on the speed of eCAP recordings.

6.5 Acknowledgement

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