Speech perception with cochlear implants: improving the interface

Feddo Bauke van der Beek

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Cover: engraving of Lucas van Leyden, “De chirurgijn”, 1524, Rijksmuseum Amsterdam
Layout: www.MidasMentink.nl

Speech perception with cochlear implants: improving the interface / F.B. van der Beek Thesis, University of Leiden, The Netherlands

ISBN: 978-90-9029323-3

Printed by Gildeprint (www.gildeprint.nl)

Speech perception with cochlear implants: improving the interface

Proefschrift

ter verkrijging van
de graad van Doctor aan de universiteit Leiden,
op gezag van de Rector Magnificus prof.mr. C.J.J.M. Stolker
volgens besluit van het College voor Promoties
te verdedigen op woensdag 11 november 2015
klokke 13.45 uur

door

Feddo Bauke van der Beek

geboren te Rotterdam

in 1976

Promotor: prof.dr.ir. J.H.M. Frijns

Co-promotor: dr.ir. J.J. Briaire

Promotiecommissie: prof.dr. P.C.W. Hogendoorn

prof.dr. G.J. Fleuren

prof.dr.ir. A.F.M. Snik (Radboud Universitair Medisch Centrum, Nijmegen)

prof.dr. W. Grolman (Universitair Medisch Centrum Utrecht, Utrecht)

dr. B.M. Verbist

Voor mijn ouders en Annemarie

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Introduction

INTRODUCTION

With cochlear implants, electrical pulses can restore sound to deaf ears and provide speech perception abilities to many deaf patients. The success of this technique is underscored by the large number of implanted patients; more than 300,000 patients have received implants over the last three decades [Clark et al., 2013].

Cochlear implant components

Contemporary multichannel cochlear implants consist of external and internal parts (Figure 1). The external part contains a microphone that receives the sound signal. The sound signal is then processed by a speech processor. Briefly, the speech processor codes the auditory signal into separate frequency bands. The coded signal is then sent through the skin to the internal receiver via a transmitter coil. The received signal is then transmitted to the electrode array, which is located in the scala tympani of the cochlea. The currents exiting the various electrode contacts stimulate the auditory nerve fibers in that portion of the cochlea.

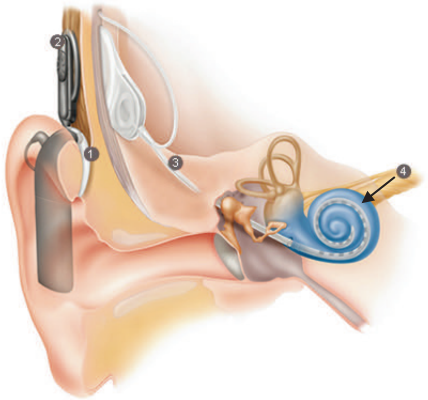

Figure 1: The basic components of a cochlear implant. 1: The speech processor 2: the microphone 3: the internal receiver 4: the electrode array in the cochlea

History

The invention of an electrical capacitor called the Leyden jar in 1745 allowed electrical currents to be stored. This innovation provided considerable inspiration for experiments with electrical currents. The first description of the use of an electrical current to elicit hearing in deaf individuals dates back to 1748. In a report from that period, Benjamin Wilson describes eliciting hearing in a deaf woman [Wilson B., 1752]. In 1800, Volta describes the sound evoked by the electrical stimulation of his own ear [Volta A., 1800]. The unpleasantness of the sound prevented him from repeating the experiment.

Djourno and Eyries, who began their experimental work in the 1950s, are considered the pioneers in the field of cochlear implants given their direct electrical stimulation of cranial nerve VIII [Eisen, 2003;Djourno and Eyries, 1957]. Based on their ideas, William House developed the first single channel cochlear implant [House, 1976]. This device merely functioned as a lip-reading aid. In the 1970s, multichannel implants, including devices designed by Ingeborg and Erwin Hochmair [Hochmair et al., 1979] and the first commercialized multielectrode device, developed by Graeme Clark [Clark, 1978;Mudry and Mills, 2013], were implanted for the first time. These multichannel implants also provided basic speech perception. In 1984, the FDA approved cochlear implants for adults, and approval for children followed in 1990. A next step in improving speech understanding with cochlear implants involved improving signal processing. A major step in that process was the development of continuous interleaved sampling (CIS), which yielded significant improvements in speech reception performance by preventing electrical interactions in the cochlea [Wilson et al., 1991]. Increasing numbers of both deaf adults and children have received implants since then.

Optimization

Although cochlear implantation can restore speech perception for many and numerous patients have been implanted, its results vary considerably among patients [Holden et al., 2013;Blamey et al., 2013]. Some patients merely experience closed-set speech recognition, and even well-performing patients experience hearing difficulties in real-life settings. Background noise remains a problem for cochlear implant patients [Spahr and Dorman, 2005;Fetterman and Domico, 2002]. Furthermore, tone recognition is only moderate in speakers of tonal languages, such as Chinese [Wei et al., 2004], and music appreciation remains poor for most cochlear implant users [McDermott, 2004]. Therefore, the optimization of cochlear implants is an ongoing process.

The microphone is the first part of the cochlear implant that influences the quality of the captured sound. Directional microphones attenuate noise and increase the signal-to-noise ratio. Because hearing in noisy situations remains a problem for most cochlear implant patients, directional microphones are used to improve speech perception in noisy conditions [van der Beek et al., 2007;Wolfe et al., 2012]. In recent years, directional microphones have become routinely integrated into the external parts of cochlear implants.

Further improvements have been obtained for speech processing. The greatest improvement in speech processing occurred with the introduction of CIS [Wilson et al., 1991], which decreases current interactions and thus increases channel independence. Further improvements have been attempted with the development of strategies that use higher stimulation rates to improve temporal resolution (HiRes, Advanced Bionics Corp., Sylmar, CA, USA; Fine Hearing, MedEl Corp., Innsbruck, Austria; MP3000, Cochlear Corp., Lane Cove, Australia) [Filipo et al., 2008a;Buechner et al., 2011] and virtual channels to improve spectral resolution (HiRes120, Advanced Bionics Corp., Sylmar, CA, USA). Additionally, the use of hearing aid technology to preprocess the speech signal in cochlear implants can facilitate hearing in specific circumstances.

The progression from single-channel to multichannel electrode arrays enabled the use of the tonotopic organization of the neural fibers in the cochlea. This technique proved to be a crucial improvement that made speech perception with cochlear implants possible [Mudry and Mills, 2013]. Although all current cochlear implant systems provide a higher number of channels, speech perception does not improve with the use of more than seven channels [Friesen et al., 2001]. Not all electrode contacts provide independent spectral information. The spread of currents through the highly conductive fluid in the cochlea prevents neuronal excitation in a restricted area. Various electrode arrays have been used to improve spectral resolution. Electrode contacts medially positioned in the cochlea near the neural elements facilitate excitation [Shepherd et al., 1993]. Hence, different cochlear implant manufacturers have developed medially positioned electrode arrays. These so-called perimodiolar electrodes offer improved speech perception [van der Beek et al., 2005a;Holden et al., 2013].

Furthermore, with the increased emphasis on preserving residual hearing, cochlear implants' electrode arrays are designed to induce as little trauma as possible [Lenarz et al., 2013;Tavora-Vieira and Rodrigues, 2013]. The result is short, thin and flexible electrodes that are less likely to damage vulnerable cochlear microstructures. Moreover, when residual hearing is preserved, the combination of electric and acoustic stimulation is feasible.

Finally, even an optimized electrode-neural interface should be adapted to the individual patient and to specific circumstances at different locations in the individual cochlea. This individualized tuning is performed during the fitting process, and numerous parameters can be set; however, the core parameters involve defining the threshold and maximum levels along the array. Research data concerning the stimulation levels that are useful in clinical practice primarily focus on speeding up the fitting process [Plant et al., 2005;Smoorenburg, 2007;Pfingst and Xu, 2004], and only a few studies report fitting improvements that would provide better speech perception [Gani et al., 2007;Zhou and Pfingst, 2014;Noble et al., 2014].

Outline of the present thesis

In this thesis, the parameters that influence the performance of cochlear implant users are analyzed. Specifically, we analyze the signal-to-noise ratio at the input of the processor, the intracochlear position of the electrode design, the spread of excitation (SOE) and settings of the clinically used levels. In **Chapter 2,** the effect of background noise on speech perception is assessed in a trial studying the improvement of speech perception in noise using directional microphones versus an omnidirectional microphone. To mimic real-life situations, speech-in-noise was presented in a specially designed set-up with a diffuse noise field. In **Chapter 3,** the effect of electrode design and intracochlear position is analyzed by comparing the speech perception scores of 25 patients with cochlear implants that were forced into a perimodiolar position with a silastic positioner and the speech perception scores of 20 patients in whom no positioner was used. The 20 no-positioner patients were further subdivided into superficially and deeply implanted subgroups, both of which included 10 patients. The intrascalar position of the individual electrode contacts was analyzed using HDCT scans, and stimulation thresholds, maximum comfort levels, and dynamic ranges were obtained.

Finally, these data were associated with the intracochlear conductivity paths calculated according to the potential distribution data acquired with electrical field imaging. **Chapter 4** focuses on the use of cochlear implants to measure the effectiveness of the electrode-neural interface using the electrically evoked action potentials of neurons in the cochlea. The effects of parameter setting on SOE measurements are described. **Chapter 5** presents an analysis of the predictability of fitting levels based on a review of the clinical levels of 151 cochlear implants recipients. The T- and M-level percentiles, their mutual relationship and their course during the first year after implantation are presented, and applicable predictive models for T- and M-levels are obtained from the dataset. **Chapter 6** describes the differences along the array of T- and M-levels and their relationship with intrascalar position. The insertion depth and distance to the modiolus are both taken into consideration. The focus of this study is the differences in levels along the array, especially towards the basal end of the array.

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2

Evaluation of the Benefit for Cochlear Implantees of Two Assistive Directional Microphone Systems in an Artificial Diffuse Noise Situation

F. B. van der Beek, W. Soede, and J. H. M. Frijns

Objective

People with cochlear implants have severe problems with speech understanding in noisy surroundings. This study evaluates and quantifies the effect of two assistive directional microphone systems compared to the standard headpiece microphone on speech perception in quiet surroundings and in background noise, in a laboratory setting developed to reflect a situation whereby the listener is disturbed by a noise with a mainly diffuse character due to many sources in a reverberant room.

Design

Thirteen postlingually deafened patients, implanted in the Leiden University Medical Centre with the Clarion CII device, participated in the study. An experimental set-up with 8 uncorrelated steady-state noise sources was used to test speech perception on monosyllabic words. Each subject was tested with a standard headpiece microphone, and the two assistive directional microphones, TX3 Handymic by Phonak and the Linkit array microphone by Etymotic Research. Testing was done in quiet at a level of 65 dB SPL and with decreasing signal-to-noise ratios (SNR) down to –15 dB.

Results

Using the assistive directional microphones, speech recognition in background noise improved substantially and was not affected in quiet. At an SNR of 0 dB, the average CVC scores improved from 45% for the headpiece microphone to 67% and 62% for the TX3 Handymic and the Linkit respectively. Compared to the headpiece, the Speech Reception Threshold (SRT) improved by 8.2 dB SNR and 5.9 dB SNR for the TX3 Handymic and the Linkit respectively. The gain in SRT for TX3 Handymic and Linkit was neither correlated to the SRT score with headpiece nor the duration of CI-use.

Conclusion

The speech recognition test in background noise showed a clear benefit from the assistive directional microphones for cochlear implantees compared to the standard microphone. In a noisy environment, the significant benefit from these assistive device microphones may allow understanding of speech with greater ease.

Speech recognition capabilities of cochlear implantees have increased rapidly over the past years.

Different studies have shown positive outcomes in identification tests for speech presented in quiet surroundings (Firszt et al., 2004; Ramsden, 2004; Rauschecker & Shannon, 2002; Parkinson et al., 2002; Anderson, Weichbold, & D'Haese, 2002; Frijns, Briaire, de Laat, & Grote, 2002). However, speech perception deteriorates rapidly when background noise is added (Spahr & Dorman, 2004; Fetterman & Domico, 2002). This deterioration can also be seen in real-life situations where patients report significant problems with speech recognition in noisy acoustical environments, such as social gatherings. In such environments, with multiple speakers present, the noise becomes diffuse and the level can easily exceed the speech reception level of listeners with impaired hearing, who use hearing aids or cochlear implants. Based on the abovementioned studies, the intelligibility scores for CVC phonemes or words for CI-users are less than 50%, resulting in poor intelligibility, while persons with normal hearing still reach good intelligibility with scores above 80% at an SNR of 0 dB (Plomp, 1977).

Many experiments are carried out to improve speech intelligibility in background noise for cochlear implant users. These approaches include increasing the number of electrodes and rates of stimulation, the use of a conditioning pulse and bilateral implants. These approaches focus mainly on processing the signal delivered to the electrode array in the cochlea. Besides these approaches, it is also possible to develop noise reduction algorithms or to use directional microphones. Knowledge of these algorithms and directional microphones is nowadays widely used for development of commercial hearing aids or assistive listening devices.

Results of experiments with persons with normal hearing and CI-users showed that a full analysis of the speech signal, spectral and temporal, is not required to understand spoken language in quiet surroundings (Shannon, Zeng, Kamath, Wygonski & Ekelid, 1995; Fu & Galvin, III, 2001). Although speech can be understood using only 4 spectral channels, extra spectral information is needed for understanding speech in background noise, and listening to music requires even more channels (Fu, Shannon, & Wang, 1998; Smith, Delgutte, & Oxenham, 2002). Experiments have shown improvement in speech recognition in background noise in CIusers with an increase in the number of active channels (Friesen, Shannon, Baskent, & Wang, 2001). The data of Friesen do show that an improvement is found of only 0.2–1.7 dB in SNR for consonants and vowels per doubling of electrodes. However, the maximum CNC word score at 0 dB is not higher than 5%. Additionally, experiments do show that the optimal number of channels for individual patients is lower than the number of electrodes available in most commercial implants as a rule (Frijns, Klop, Bonnet, & Briaire, 2003). Furthermore, speech in background noise and listening to music demands more temporal information than merely extracting the envelope of the speech signal (Smith et al., 2002). High rate stimulation showed increased speech perception in background noise (Frijns et al., 2003), and introducing stochastic resonance using a conditioning pulse was shown to be promising (Rubinstein & Hong, 2003) and is now tested in a clinical trial. The optimization of the dynamic range also shows improvements, albeit small, in speech in noise perception (James et al., 2002; Dawson, Decker, & Psarros, 2004).

Improvements in both spectrotemporal and dynamic information were achieved using electrical stimulation together with the residual hearing or bilateral implantation (Turner, Gantz, Vidal, Behrens, & Henry, 2004; Van Hoesel, Ramsden, & Odriscoll, 2002; Müller, Schön, & Helms, 2002; Laszig et al., 2004). Moreover, a two-microphone adaptive noise reduction system was used to obtain a better input-signal in noisy circumstances (Wouters & Vanden Berghe, 2001). These applications all showed improvements in understanding speech in background noise, although this was tested in typical laboratory settings, not matching real life situations.

Besides the developments in digital techniques (Wood & Lutman, 2004), directional microphones improve the signal for hearing aid users, who also suffer from a strong deterioration of speech recognition in conditions with interfering noise or sounds, by the attenuation of sounds from the rear and sides (Soede, 1993a, 1993b; Luts, Maj, Soede, & Wouters, 2004). Considerable improvement of speech perception in background noise could be achieved with those directional microphones. Luts et al. (2004) discovered improvements of 6 dB and higher in hearing aid users. However, everyday listening circumstances are different from clinical test set-ups, and these results must be seen in that perspective, which reduces the predictability of the benefit of directional microphones from straightforward clinical tests (Cord, Surr, Walden, & Dyrlund, 2004).

The purpose of the study presented in this paper was to quantify the effect of two assistive directional microphone-systems, primarily developed for use with hearing aids, on speech recognition in background noise for cochlear implantees compared to a standard omni-directional microphone of a cochlear implant system in a typical realistic situation with multiple noise sources in a reverberant situation. For this purpose, we evaluated the performance of the cochlear implantees in a set-up with 8 interfering noise sources, not just one or two noise sources.

MATERIALS AND METHODS

Experimental Diffuse Field Set-Up

Experiments were carried out in a sound-treated audiology room. Speech and noise were presented to the subject from identical self-powered loudspeakers (AV110, Conrad, Germany). Figure 1 shows a drawing of the experimental set-up. Eight loudspeakers were placed on the edges of an imaginary box (Soede, 1993b). Uncorrelated noise was played through a PC with an 8-channel sound card (Gina24, Echo Digital Audio Corp., CA) and directed to the eight loudspeakers. The ninth loudspeaker, from which the speech material was presented, was placed at 1 meter distance from the center and at 1.2 meters from the floor. This location was well within the reverberation distance of the room, which was measured to be 2 m or more for frequencies from and above 500 Hz.

For calibration and determination of the actual sound field, measurements were performed on a sphere in the center of the set-up. These measurements were felt necessary to correct for the position of each loudspeaker inside the room which could result in different sound pressure levels due to differences in distances, residual reflections of the walls, floor and ceiling (ceiling position or floor, at the edge or in the corner). The whole system was calibrated and equalized using pink noise. Equalization was done for each octave band between 250 and 8000 Hz with an equalizer program. After the calibration and equalization procedure, the measured spectrum of the front speaker and all 8 noise sources together was flat within 1 dB. Figure 2 shows the results of sound level measurements on three crosssections of a sphere with a diameter of 30 cm at the position of the listener's head (equator, meridian 45 degrees up and down) with noise coming from all 8 loudspeakers (1/3 octave band). In the 500 Hz 1/3 octave band, deviations were found with a maximum of ±3 dB. At 5000 Hz, the deviations were less than ±1 dB. Results between 1000 Hz and 4000 Hz were equal to the measurements at 5000 Hz. After calibration, and based on the measurements on the sphere, we may conclude that this set-up generates a good approximation of a diffuse noise field within the frequency range of interest.

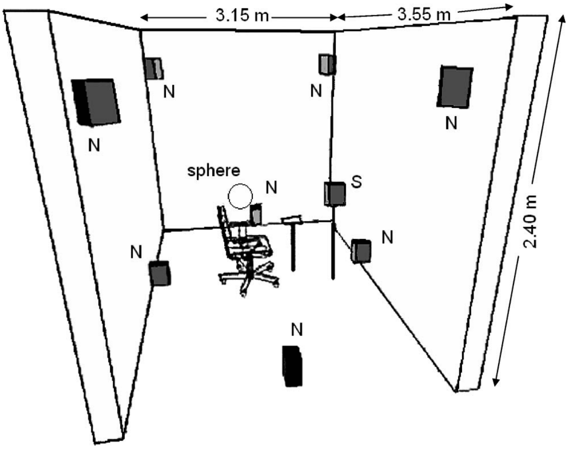

Fig. 1. Diffuse noise set-up with eight loudspeakers emitting background noise (N) and one loudspeaker for speech (S). The distance between the chair and the speech loudspeaker is 1.0 m. The stand for the hand-held microphone is located 0.75 m from the loudspeaker for speech. The sphere illustrates the position of the listener's head.

Speech and Noise Material

Speech and noise (stationary speech shaped) were used from the standard CVC word list on CD (prerecorded female speaker) of the Dutch Society of Audiology (Bosman & Smoorenburg, 1995). All words were balanced on a rms level, sub-lists were homogenous with regard to speech reception scores, and normative values were available (Bosman & Smoorenburg, 1995). Each list consisted of equivalent sub-lists of 11 Dutch three-phoneme monosyllables. In contrast to normal clinical use, where one list is used per condition, the results of four lists of 11 words (132 phonemes) per condition were averaged to obtain a single-data point to increase the accuracy by a factor of two. The speech-sound was played through a

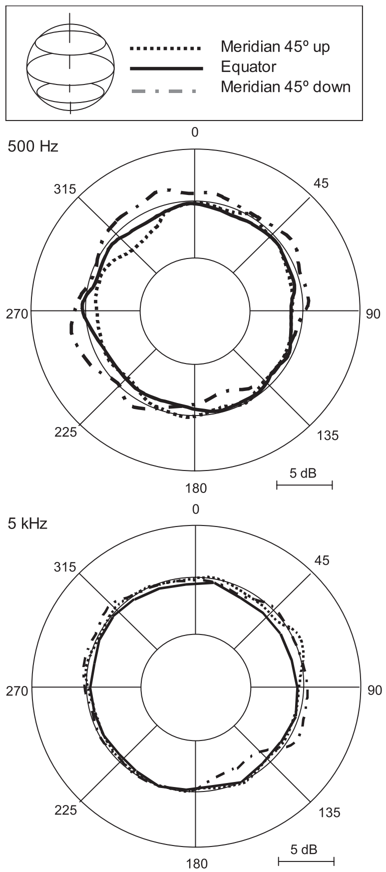

Fig. 2. Results of sound level measurements on a sphere with a diameter of 30 centimeters. Measurements are done at 3 cross-sections of the sphere for 500 and 5000 Hz.

compact disc player (CD720, Philips, The Netherlands) and presented by the speech loudspeaker at a fixed level of 65 dB SPL, measured at the position of the listener's head. The soundtrack with noise from the CD was extracted to the computer. The track was split into parts and divided over the different sound channels in order to prevent any correlation between the channels.

Microphones

The cochlear implant users involved in the experiment were all implanted with Clarion CII (Advanced Bionics Corp., Sylmar, CA) cochlear implants. The microphone of this implant is omnidirectional and incorporated in the headpiece. The headpiece was located on the skull, approximately 4 cm behind the ear.

Two directional microphones systems were tested: the handheld FM-system TX3 Handymic (Phonak, Bubikon, Switzerland) and the Linkit array microphone system (Etymotic Research Inc., Elk Grove Village, IL), which is worn on the head. The Handymic has been designed as a wireless FM-system and can be used in various ways, such as handheld, attached to the jacket of a speaker or it can be placed on a table (Figure 3A). The system may be of use in steady-state situations such as meetings, dining and at home in family situations. Especially when the microphone is placed near the speaker, a significant improvement of the signal to noise ratio can be obtained. The listener with impaired hearing must change the direction of the microphone manually if the source of interest moves around. The microphone can be used in an omni-directional, zoom and super-zoom mode. Based on the technical specifications, an articulation index weighted directivity index of the system, was calculated of approximately 8 dB for the microphone in super-zoom mode. Figure 3B shows the articulation index weighted polar diagram with an opening angle of approximately 130° (-6 dB point) and average noise reduction from the behind of 13 dB. During the experiment, the Handymic was placed on a one meter high stand, in front of the speech loudspeaker at 75 cm distance and in super-zoom mode. This simulated a listener holding the Handymic in his hand just in front of the body. We measured the sound level at 75 cm, with speech noise coming from the loudspeaker. Compared to a distance of 100 cm (center of the sphere), an increase was measured of the front signal of +1.5 dB. This will result in a difference in the speech-tonoise ratio of +1.5 dB compared to the center position. The Handymic's signal was sent to the speech processor by the wireless Microlink FM-system with the FM receiver by Bruckhoff Apparatebau (Hannover, Germany, type MicroLink CI+).

The Linkit array microphone system was developed as an assistive listening device for people with hearing impairment, with hearing aids either behind the ear or in the ear (Figure 3C). Its use is mainly intended for situations with background noise such as at parties and restaurants. While wearing the Linkit on the head, the user can move freely and pick out the signal in front. A hearing aid user can use the Linkit over the ear. The microphone's signal can be transmitted to the hearing aid wirelessly via induction. The array processing is based on the fixed sum beam forming, with three microphones inside the bar (Soede, Berkhout, & Bilsen, 1993a, Luts et al. 2004). The articulation index weighted directivity index equals 7 dB (measured on the head of KEMAR, Knowles, Itasca, IL). Figure 3D) gives the articulation index weighted polar diagram. Compared to the Handymic, the opening angle of 100° is slightly narrower while the average noise reduction from behind is 10 dB. The Linkit has an external audio output for use with the standardized Direct Audio Input (DAI) connector behind the hearing aids. This output signal of the Linkit was not yet fully adapted for use with the Clarion CII. A wire measuring 90 cm in length was used to connect the Linkit to the audio input of the speech processor for use with cochlear implants. To match the input-output sensitivity of the Linkit and the input of the processor of the cochlear implant, a 20 dB buffer-amplifier was used. During the tests, the Linkit was placed on the ear, contralaterally to the headpiece.

The output spectra of the Handymic and the Linkit were compared with each other. They were equal to each other within a margin of ±3 dB, within the frequency range of 500 and 4000 Hz.

Subjects and Test Sequence

25 Cochlear implantees who had been implanted at Leiden University Medical Centre and had more than 3 mo of experience with the implants, were invited to come to the hospital for an evaluation of the

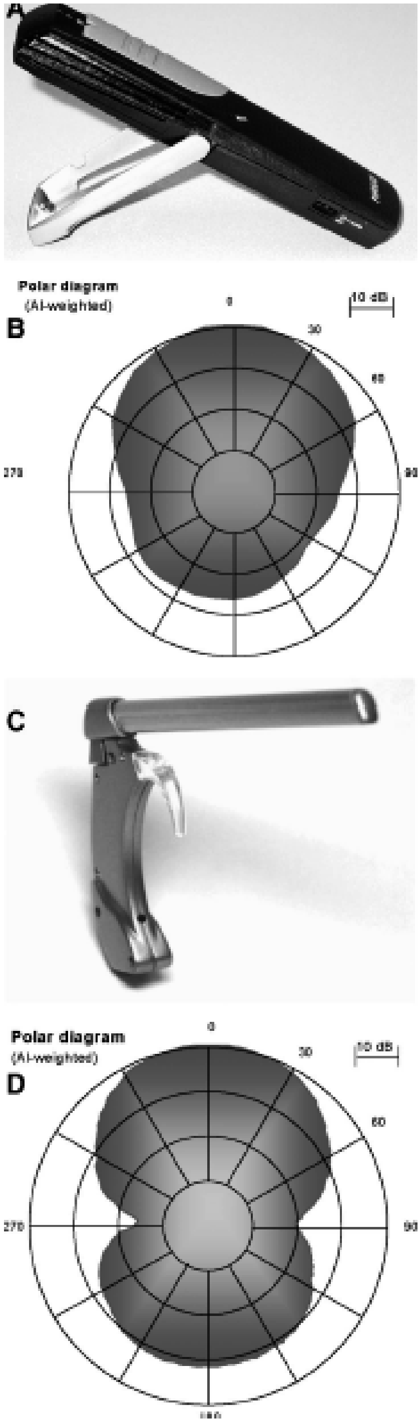

Fig. 3. (A) TX3 Handymic from Phonak (Bubikon, Switzerland) and (B) the AI-weighted free-field polar diagram. (C) Linkit array microphone system from Etymotic Research (Elk Grove Village, IL) and (D) the AI-weighted free-field polar diagram.

microphones in the test set-up. They would also have the chance to learn whether they could expect any benefits from the use of these microphones in their personal situations, at work or home. Thirteen people responded and were included in the test. All subjects were postlingually deafened adult users of the Clarion CII cochlear implant, having an average follow-up of 12.3 mo after implantation, ranging from 3–21 mo. The average age was 45.3 yr. All participants used a CIS (Continuous Interleaved Sampling) strategy on CII Platinum Speech Processor (PSP) worn on their bodies. Table 1 shows the patient demographics. The average phoneme score in quiet surroundings equalled 88%, with a range of 67–98%. Table 2 shows the average group results of the listening tests for quiet surroundings and SNR +10, +5, 0 and –5 dB in the standard situation with speech and noise coming from one loudspeaker which had been placed in front of the listener. These listening tests had been taken on a routine base as part of the standard clinical evaluations with speech and noise material from the standard CD. These clinical data can be used as a reference for comparison between a standard clinical test with speech and noise coming from one direction and our new set-up. Five subjects with normal hearing, aged between 22 and 25 were tested in the diffuse noise field set-up for a comparison of the performance of subjects with unimpaired hearing with our CI-patients. Each subject was seated in the imaginary center of the set-up, with the head at the same height as the loudspeaker in front of him or her. The cochlear implant users were allowed to adjust the level of the PSP to the most convenient loudness level based on running speech from the loudspeaker in front at the level used for testing (65 dB SPL) for each microphone array. There was no internal mixing of the signals of the directional microphones with the headpiece microphone. No change to the implant settings or to the position of the head was allowed during the test sequences. To minimize learning effects, the three microphones were tested in random order, based on a Latin square (ABC ACB BCA BAC CAB CBA with A = Headpiece, B = Handymic and C = Linkit). Sufficient lists of words were available, so that we did not have to repeat any list within a single session. Tests were performed in one session of 1.5 hr, with a short break. On average 53 lists were used for one subject to cover all situations.

Determination of Speech Reception Threshold

Every subject was tested at fixed noise levels: in quiet surroundings, at SNR +10 dB and SNR 0 dB with the headpiece microphone and the two directional microphones. Based on the individual results at +10 dB and 0 dB, extra tests were done for one or two extra fixed SNR ratios (e.g. +5, -5 or -10 dB) in order to obtain data points above and under a 50% phoneme-score. The estimation of the SRT for each individual can be calculated from this data by simple linear interpolation of the percentages found for the levels just above and below 50%. This elaborative procedure was chosen because it was not possible to determine the SRT with an adaptive procedure. The Dutch equivalent of the English HINT-test comprises intelligibility of sentences and thus expects 100% intelligibility.

Besides the determination of the SRT of the group, it is of interest to determine the absolute values of the phoneme scores at other SNRs. However, using the approach of score-dependent testing, we would obtain fewer data-points at SNR values of the e.g. +15, +5, -5 and -10 dB. Therefore, the data-points of each

TABLE 1. Demographics of cochlear implant users involved in this study

Subject	Age at implantation	Duration of severe deafness (yr)	CI-use (mo at moment of study)	Etiology	Results of standard clinical tests: Phoneme score in quiet (65 dB SPL)	Duration of CI-use for clinical test data in quiet surroundings
A	23	0.5	4	Meningitis	93	3 mo
B	62	4	21	Progressive	84	1 yr
C	38	37	20	Hereditary progressive	67	1 yr
D	39	36	19	Aminoglycosides	98	1 yr
E	49	2	9	Left unknown, Right glomustumor	71	6 mo
F	14	0.2	12	Meningitis	87	1 yr
G	43	39	13	Hereditary	89	1 yr
H	59	1	10	Sudden deafness	96	1 yr
I	52	23	14	Unknown	83	1 yr
J	59	1	18	Menière’s disease	88	1 yr
K	50	20	3	Unknown	82	3 mo
L	67	20	5	Noise induced	96	3 mo
M	49	15	12	Progressive	98	1 yr

The table gives the age at implantation, durations of severe deafness, CI-use and etiology. The last two columns give the average phoneme score in quiet surroundings obtained prior to the study, and the experience with the CI device at the time of the clinical test. All subjects were implanted with one cochlear implant. No hearing aid device was used in the contralateral ear.

subject were fitted with a psychometric curve. The group scores at SNR with fewer data points could be calculated using these psychometric curves. For the fitting, a x^2 function with three degrees of freedom was used as described by Schön et al. (2002). This function is equal to:

$$u(x) = u_q \text{ x } x^2 \,[\,2.37 + k \times (x - x_{0.5})]$$

where u is the speech reception score (in %) and u_q the fitted score in quiet surroundings. The constant k is proportional to the gradient of the curve at 0.5 X u_q, x is the signal-to-noise ratio, and $x_{0.5}$ is the signal-to-noise ratio at 0.5 X u_q. The parameters u_q, k and $x_{0.5}$ were used to fit the curve to the data.

RESULTS

Figure 4 shows the individual results (phoneme scores) for the CVC tests as obtained for all subjects with normal hearing and the cochlear implant users with the three different microphones. All cochlear

TABLE 2. Clinical results of 13 cochlear implant users, using their standard program

	Phoneme scores at SNR (%) in a standard set-up with speech and noise from one loudspeaker							Word scores (%)
Headpiece	Quiet	+10 dB	+5 dB	0 dB	−5 dB	−10 dB	−15 dB	0 dB
Average	88	74	64	47	36[8]	—	—	26
SD	9	17	14	18	8	—	—	14

The mean phoneme scores on the CVC word test in a standard set-up with speech and noise from the same loudspeaker (speech at a fixed level of 65 dB SPL, free field, 11 words per data point) in quiet surroundings and in background noise with SNRs of 10, 5, 0, 5, 10 and 15 dB. The mean values are given per SNR for the results of the standard listening tests done prior to this experiment. The numbers between the brackets denote the number of cochlear implant users tested at 5 dB. The last column gives the word-score at SNR <?> 0dBasa comparison.

implant users were tested in quiet surroundings and with a signal-to-noise ratio (SNR) of +10 dB and 0 dB. Depending on the CVC scores (below or above 50% at SNR 0 or 10 dB) for each individual cochlear implant user, additional tests were carried out at an SNR of +15, +5, -5, -10 or -15 dB. Besides this, each diagram shows the average CVC score per SNR (filled dots) and the psychometric curve (open dots) fitted according to the x^2 function method. The averaged numbers for each SNR are also summarized in Table 3. Note that for the intermediate SNR levels (+15, +5, -5, -10 and -15 dB), the average data-points were based on the results of a subgroup of the subjects. The last 4 rows of the table show the standard deviation of the individual results. The test-retest variability over all 4 lists and conditions was satisfactory (correlation equals 0.75 for data obtained at SNR 0 dB, within subject variability at 0 dB is 9% over the 4 lists). Table 3 also shows the average results in terms of the word-score at 0 dB for comparison of this study (and set-up) with other studies.

Calculation of SRT Values and Benefit

On the basis of the individual scores, we calculated the individual SRT values by a simple linear interpolation between two levels around the SRT and we calculated each by applying the curve-fitting method. Table 4 gives the average of all individual SRT values for the group based on the linear interpolation and the values of the curve-fitting. Next to these SRT values, Table 4 also shows the gradient of the interpolation line or curve at the SRT level expressed in %/dB. Figure 5 shows the individual results expressed as benefit compared to the headpiece in dB. These values are calculated by subtracting the SRT from the linear interpolated data for the Handymic or Linkit from the SRT found for the headpiece.

Phoneme and Word Scores Dependent on SNR

Table 3 and 4 show that the normal hearing reference group had 100% phonemes correct in quiet surroundings and +10 dB SNR, and 93% phonemes correct at 0 dB SNR. The SRT equals –13.4 dB. The average gradient equals 5%/dB at the SRT. In quiet surroundings, the average phoneme score on CVC words with the headpiece microphone for the group of cochlear implant users was 87%, being equal to the average obtained in other CVC tests prior to this study (see Table 2). With the Handymic and Linkit, a score of 85% and 86% respectively was obtained. In other words, the perception in quiet surroundings, with the speech loudspeaker placed in front, was not significantly influenced by the use of the directional microphone systems (p = 0.54 and p = 0.67 respectively). Figure 4B shows a rapid decrease in CVC scores with decreasing SNR for the headpiece microphone. At SNR 10 dB the phoneme score decreased to 71%, while at 0 dB the score went down to a CVC score of 42% and a word score of 21%. The resulting SRTs equalled +2.5 dB, based on linear interpolation and +2.6 dB based on the curve-fitting. A comparison of these results for the headpiece with the results of the listening tests prior to this study (Table 2) suggests that at +10 dB and 0 dB, the phoneme scores were lower than in the previous data. However, the difference is not statistically significant (p = 0.64).

For the two directional microphones, Figure 4C and 4D) a small not yet significant improvement in

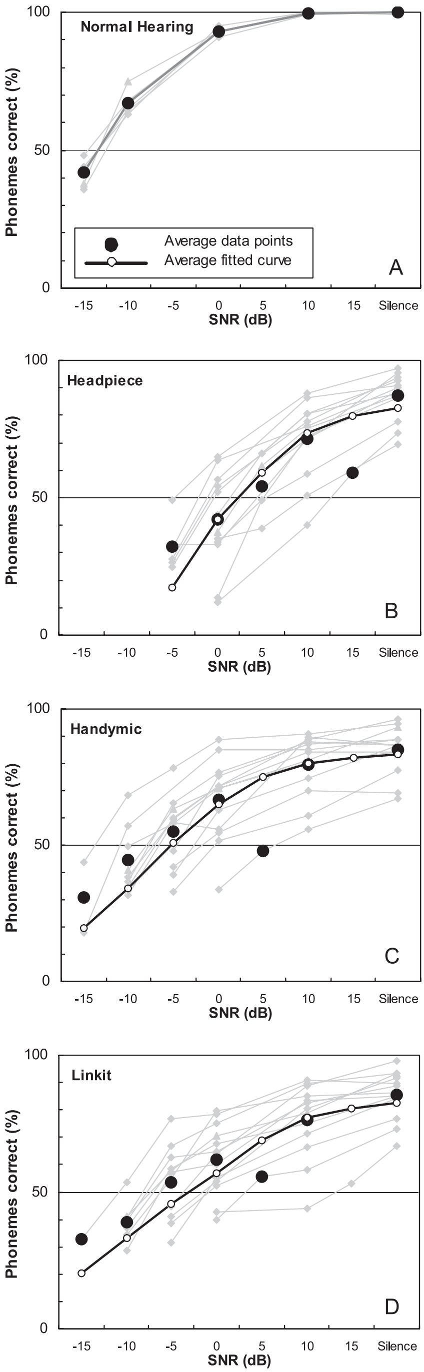

Fig. 4. The individual scores of each subject (gray markers and lines) and the average scores for both the group with normal hearing (A) and the group of cochlear implant users with the headpiece (B), Handymic (C) and Linkit (D) microphones.

phoneme scores over the headpiece microphone was already noticeable at 10 dB SNR: from 71% to 80% and 77% with the Handymic (p = 0.11) and the Linkit respectively (p = 0.36). At an SNR of 0 dB, the phoneme scores for the Handymic and the Linkit were 67% and 62% respectively for all subjects, the word scores were 44% and 38% respectively. At –5 and –10 dB, fewer subjects were involved. For the Handymic, the phoneme scores were 55% and 45% at –5 and –10, while the Linkit results equalled 54% and 39%.

Comparison of SRT and Benefit

The mean SRT values for the Handymic and the Linkit were significantly better than the SRT value obtained with the headpiece (p < 0.001, Students t-test). The lower average SRT value of the Handymic over the Linkit was not significant (p = 0.3). The results in Figure 5 show that the average benefit of the Handymic and Linkit over the headpiece equals 8.2 dB (SD = 2.6) and 5.9 dB (SD = 3.9) respectively. Of the subjects, 12 out of 13 received a positive benefit from listening with the Handymic or the Linkit. However, the results of subjects C and K are considerably different in comparison to the results of the other subjects and also beyond expectations based on the technical properties of the directional microphones. Subject C had a phoneme score in quiet surroundings of 67% prior to the testing. Her test results in quiet surroundings in this study were equal for all three microphones (67– 69%). For this subject, the intelligibility was immediately affected by the noise at SNR +10 dB. The scores went down to 51, 56 and 44% for the headpiece, the Handymic and the Linkit respectively. However, at SNR +5 and 0 dB, the scores were not yet reduced to the chance-level of the CVC material (being equal to 10%). At 0 dB, scores were maintained at 35, 34 and 43% respectively. Most likely, results for subject C were influenced by the shallow

TABLE 3. Test results of normal hearing (NH) and cochlear implant users in diffuse noise set-up

	Phoneme scores at SNR (%) in set-up								Word-scores (%)
Ear/Microphone	Quiet	+15 dB	+10 dB	+5 dB	0 dB	−5 dB	−10 dB	−15 dB	0 dB
NH/none [N = 5]	100	—	100	—	93	—	67	42	81
CI/Headpiece	87	59[1]	71	54[5]	42	32[6]	—	—	21
CI/Handymic	85	—	80	48[1]	67	55[11]	45[7]	31[2]	44
CI/Linkit	86	53[1]	77	56[1]	62	54[11]	39[8]	33[1]	38
	Standard deviations (%)								
NH/none	0.4		0.5		1.4				3.4
CI/Headpiece	8		14		17				12
CI/Handymic	9		11		15				18
CI/Linkit	9		14		13				15

Implant users used their own processor with the Linkit or Handymic connected to the audio input. The mean phoneme scores on the CVC word test (65 dB SPL, free field, 44 words per data-point) in quiet surroundings and in background noise with SNRs of 15, 10, 5, 0, 5, 10 and 15 dB. The mean values are given per SNR for 13 subjects. The numbers between the brackets denote the number of cochlear implant users that was tested at 15, 5, 5, 10 and 15 dB. The last column gives the word score at SNR <?> 0 dB as a comparison.

TABLE 4. SRT values based on linear interpolation between near points and curve fitting for whole group of data

	Linear interpolation		Curve fitting	
Ear/Microphone	SRT (SD) in dB	Gradient %/dB	SRT (SD) in dB	Gradient %/dB
NH/none	−13.4 (0.6)	5.0	—	—
CI/Headpiece	+2.5 (4.8)	4.6	+2.6 (4.8)	5.7
CI/Handymic	−5.7 (5.2)	4.7	−5.4 (5.3)	5.0
CI/Linkit	−3.4 (6.3)	3.9	−3.2 (6.6)	3.9

SRT values and gradients are averaged based on each individual SRT and gradient.

psychometric curve and the test-retest variability (SD 9% at 0 dB SNR). Subject K had been using the cochlear implant at the time of the research for 3 mo. It is most probable that the results were influenced by the lack of experience with speech in noise and the order of the tests. For this particular case, the tests started with the headpiece microphone, and followed by the Linkit and the Handymic. The score of 40% at SNR +10 dB resulted in an SRT of 12.4 dB with the headpiece which was poorest result of all our subjects. Standard clinical testing at 6 mo showed a score of 81% at +10 dB. Therefore, it is most probable that the results were influenced by the short usage of the cochlear implant and order of the tests.

Other Correlations

No correlation of the SRTs (linear interpolation or curve fitting) was found with duration of deafness, CI use or phoneme scores in quiet surroundings (all p-values > 0.2). We also analyzed the correlation between the individual SRTs with the headpiece and the SRTs found with the Handymic and the Linkit. Figure 6 shows the individual data for all 13 subjects, and the calculated results with linear regression. The regression lines show a fairly strong correlation with a gradient of 0.9 for the Handymic with R = 0.87 ($p < .001$) and 1.0 for the Linkit with R = 0.78 ($p < 0.01$). The difference in the gradient of the Handymic and the Linkit is not significant ($p > 0.9$).

DISCUSSION

This experiment shows the differences in speech understanding for the different microphones in an artificially built set-up with multiple noise sources. For the headpiece, results obtained in the artificially built set-up could be compared with those obtained in a clinical, single loudspeaker set-up. We expected poorer results for the headpiece in the new set-up compared to the standard tests with speech and noise coming from a single loudspeaker positioned at the front. This was based on the expectation that the location of the headpiece microphone at the back of the head would be worse than the position of the microphone of a hearing aid positioned behind the ear (BTE). For a hearing aid microphone positioned at BTE position, Soede et al. (1993b) measured a negative directivity of -1 dB with KEMAR in a cocktail party set-up. In this set-up, with speech coming from in front, the speech signal is attenuated with a small amount due to shading of the head, although the noise of the loudspeakers at the contralateral side is also partly attenuated. When data are compared at SNR +10 dB and 0 dB from Table 2, the data in the diffuse noise set-up is 3 percentage points (71% versus 74%) and 5 percentage points (42% versus 47%) lower than for a single-source set-up. Based on a gradient of 4.6%/dB around the SRT (see Table 4), this difference equals – 0.7 dB to -1.0 dB (Table 4). This difference of –1.0 dB is in line with Soede's (1993b) measurements in a comparable set-up with a microphone positioned behind the ear. However, results are not statistically significant ($p = .5$) due to the limited amount of tests done. Additional tests need to be done to determine the differences.

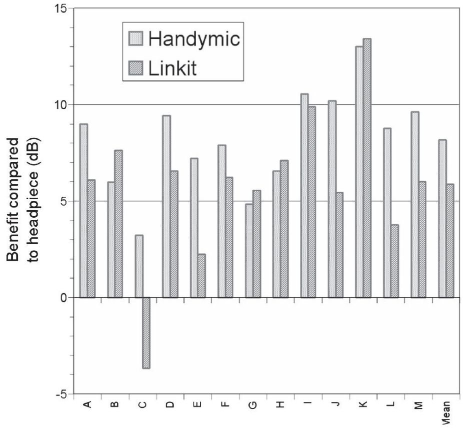

Fig. 5. Benefit of Handymic and Linkit compared to headpiece expressed in dB. Results for all subjects and the mean of the group (N = 13). The average for the Handymic and Linkit equals 8.2 dB (SD = 2.6) and 5.9 dB (SD = 3.9) respectively.

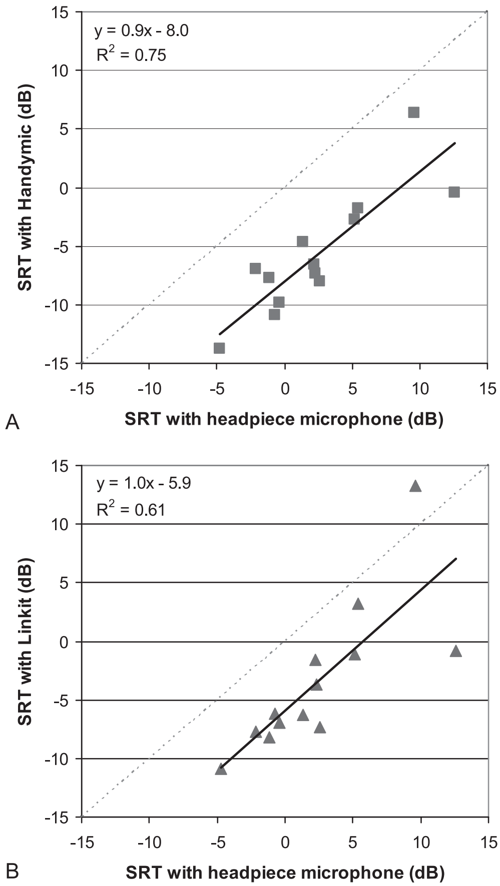

Fig. 6. Individual SRTs obtained with Handymic (A) and Linkit (B) as a function of the SRTs obtained with the headpiece microphone. The regression lines show a relatively consistent shift downwards independent of the CI– users performance level in background noise.

On average, for both the Handymic and the Linkit, an improvement of the SRT was found of 8.2 and 1.9 dB compared to the headpiece microphone (Figure 6). Luts et al. (2004) tested a prototype of the Linkit with listeners who were hearing impaired in a reverberant room and also found an average improvement of 6 dB. From this, we may conclude that cochlear implant users may receive the same benefit as hearing aid users.The improvements are large but were approximately 1 dB lower for both microphones than the values predicted on the basis of the technical specifications. For the Handymic, the articulation index weighted directivity index equals 8 dB and with an advantage in SNR due to the distance of 1.5 dB, a total improvement may be expected of 9.5 dB. For the Linkit, an articulation index weighted directivity index was equal to 7 dB based on measurements with KEMAR. The difference of 1 dB as found in this experiment appears to be comparable with results that are found by Soede et al. (1993b) and Luts et al. (2004). Soede found a difference of 1 dB between physical measurements and SRTs found with hearing impaired listeners and suggested the influence of extra noise by a small amount of reverberated speech in the room. This could also be the case for our set-up, although measurements did show that the listener was positioned within the reverberation distance of the loudspeaker. However, an additional unknown factor is the validity of weighing of the directivity index over all frequencies by the articulation index results in the case of cochlear implant users. The weights of the articulation index are based on listening tests for normal listeners and not for hearing impaired persons or electrical hearing. Future research is needed to determine the contribution of each frequency band to speech intelligibility in background noise for cochlear implant users. This is not only important for determining the effects of directional microphones but also for understanding effects of speech algorithms, the effects of pathology and spectral settings on speech intelligibility in noise.

The tests with the two subjects C and K resulted in unexpected benefits. The scores resulted in a very low benefit for the microphones for subject C and a very high benefit for subject K compared to the benefit of the whole group (Figure 5). No explanation can be found in type of cochlear implant or fitting method because they had the same implant and were fitted by the same audiologist. A possible explanation can be found in the fact that they started with a lower phoneme score of approximately 70% in quiet surroundings. Adding background noise resulted immediately in a drop of the intelligibility scores around the threshold level of 50%. Subject C was able to perform around threshold level for +10 dB SNR as well as 0 dB. This resulted in flat psychometric curves for the Headpiece and the Linkit and therefore, results can be influenced by the within subject test-retest variability which was found to be around 8% for the CVC scores. Subject K performed relatively poorly at a +10 dB SNR with the headpiece microphone. From these results, it can be concluded that the method of testing using CVC words at fixed signal-to-noise ratios, although 4 lists of 11 words were used, still may result in individual results beyond expectations based on the technical properties of the directional microphones. Future research is needed to refine the tests and test sequences. For the daily routine of clinical practice, it is now important to note that evaluation of the extra benefits of directional microphones, FM-systems or special noise programs requires repeated tests at various SNR levels before conclusions may be drawn.

The benefit of a directional microphone as experienced by our subjects depends on the SNR in daily practical situations. The use of a microphone array does not cause any decrement in speech perception scores in quiet or at high SNRs relative to scores with the headpiece microphone. The listening tests show an improvement of 8.2 dB and 5.9 dB based on the SRT for the Handymic and the Linkit respectively. This average improvement is higher than improvements of 1–2 dB found in other studies with more electrodes, higher rates or bilateral implantation (Friesen et al., 2001; Frijns et al. 2003; Turner 2004). The absolute word score at 0 dB reaches now 44% for the Handymic and 38% for the Linkit. These values are higher than the average value of 5% found by Friesen et al. (2001).

The improvement may be experienced by all CIusers and does, based on the regression analysis of the data (Figure 5), not depend on the personal SRT. From the results in Table 4, it may be concluded that for the cochlear implant users, the average gradient of the psychometric function, based on the curvefitting, equals 4.9%/dB. This means that a typical cochlear implant user, in a listening situation with SNRs just around the SRT, may expect a large average improvement of the phoneme score. For example, in a typical cocktail party or restaurant, SNR values of 0 dB and worse may be expected. The results of the listening tests in the diffuse noise set-up show that in situations with such an SNR, the intelligibility increases from poor (group average 42% in this test) to fair with a level above 62% (CVC score 67% for the Handymic and 62% for the Linkit). This change from below to above 50% might be of significant help to understand what is said and to ease conversation. However, we must not forget that this is still lower than the 5 listeners with normal hearing who can understand more than 90% of what is said, at this same SNR.

The trend of an extra benefit of 2.3 dB of the Handymic over the Linkit as found in this study can partly be explained by the closer positioning of the Handymic to the speech loudspeaker. This resulted in a better SNR in the position of the Handymic of +1.5 dB. This difference will also exist in real life and can be significantly more when the Handymic is held nearer to the mouth of the speaker. However, it must be kept in mind that the Handymic and the Linkit are designed for different applications and use. The choice of which device to use should be made on required improvement, the daily situation and personal appreciation. This was also found in our group. This study was initiated by the question as to whether our patients could benefit from directional microphone systems in practical situations in daily life. Only two subjects showed interest in evaluating the systems in daily practice. Both of them experienced severe problems in their daily work and welcomed any improvement in being able to focus on their tasks instead of having to be constantly engaged with communication only. Other subjects showed less interest, although they could expect a significant benefit. It is most likely that they manage to communicate in noisy social settings by the combined use of their cochlear implants and many years of experience of lip-reading.

CONCLUSION

With the current technical status, speech recognition using cochlear implants is good in quiet surroundings and there is even room left for speech recognition in background noise. With the use of directional microphone systems, this speech recognition in background noise can be substantially improved. Compared to an average speech reception threshold of +2.5 dB found with the standard headpiece microphone of the CII cochlear implant, the Handymic resulted in a benefit of 8.2 dB and the Linkit array microphone system in a benefit of 5.9 dB. When both directional microphone systems were tested, the CI subjects were able to recognize more than 62% of the phonemes presented at 0 dB SNR. This might be of great importance in situations such as restaurant or cocktail party settings. The improvement could make a difference in the way communication can be carried out. Instead of guessing the line of conversation by listening and lip-reading, this benefit could result in a fair intelligibility and so be of significant help in understanding what is said and in easing conversation.

ACKNOWLEDGMENTS

This research was financially supported by grants from Etymotic Research Inc., Elk Grove Village, IL.

Address for correspondence: W. Soede, PhD, ENT Department, Room J2-75, Leiden University Medical Centre, P.O. Box 9600, 2300 RC Leiden, The Netherlands. E-mail: W.Soede@lumc.nl

Received January 4, 2005; accepted September 1, 2006.

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Clinical Evaluation of the Clarion CII HiFocus 1 with and Without Positioner

F. B. van der Beek, P. P. B. M. Boermans, B. M. Verbist, J. J. Briaire, and J. H. M. Frijns

Objective

To study the clinical outcomes concerning speech perception of the Clarion CII HiFocus 1 with and without a positioner and link those outcomes with the functional implications of perimodiolar electrode designs, focusing on intrascalar position, insertion depth, stimulation levels, and intracochlear conductivity pathways.

Design

The speech perception scores of 25 consecutive patients with the Clarion CII HiFocus 1 implanted with a positioner and 20 patients without a positioner were prospectively determined. Improved multislice CT imaging was used to study the position of the individual electrode contacts relative to the modiolus and their insertion depth. Furthermore, stimulation thresholds, maximum comfort levels, and dynamic ranges were obtained. Finally, these data were associated with intracochlear conductivity paths as calculated from the potential distribution acquired with electrical field imaging.

Results

Implantation with a Clarion Hifocus 1 with positioner showed significantly higher speech perception levels at 3 mos, 6 mos, and 1 yr ($p < 0.05$) after implantation. Basally, the positioner brought the electrode contacts significantly closer to the modiolus, whereas apically no difference in distance toward the modiolus was present. Moreover, the patients with the electrode array in a perimodiolar position showed deeper insertions. The Tlevels and dynamic range were not significantly different between the positioner and nonpositioner patients. Furthermore, the intracochlear conductivity paths showed no significant differences. However, a basal current drain is present for the shallowly inserted nonpositioner patients.

Conclusions

A basally perimodiolar electrode design benefits speech perception. The combination of decreased distance to the modiolus, improved insertion depth, and insulating properties of the electrode array have functional implications for the clinical outcomes of the perimodiolar electrode design. Further research is needed to elucidate their individual contributions to those outcomes.

Speech perception is increasing rapidly in recent years for patients with cochlear implants (Ramsden, 2004). This is due to ongoing improvements in both cochlear implant electrode array design and new speech processing strategies. Some of these recent modifications are perimodiolar electrode designs that theoretically reduce current consumption, increase dynamic range, and give a higher selectivity of stimulation by placing the electrode contacts in closer proximity to the excitable neural elements. Initially, the beneficial influences of a medial position in the scala tympani were suggested by animal experiments (Shepherd, Hatsushika, & Clark, 1993) and by detailed computational models (Frijns, de Snoo, & Schoonhoven, 1995; Frijns, de Snoo, & ten Kate, 1996). A comparison of the Clarion HiFocus 1 electrode in lateral and modiolus hugging position was made in a computational model of the electrically stimulated cochlea (Frijns, Briaire, & Grote, 2001). The findings of this comparison were that at a perimodiolar position spatial selectivity and dynamic range were favorably influenced at the basal turn, whereas at more apical sites a position near the outer wall was desirable to avoid the possibility of so-called cross-turn stimulation, which we believe produces additional low-pitched percepts that are caused by excitation of nerve fibers originating from the cochlear turn above the location of the stimulating electrode contact.

After different perimodiolar designs were introduced, temporal bone studies proved the perimodiolar position of these electrodes (Cords et al., 2000; Fayad, Luxford, & Linthicum, 2000; Richter et al., 2002; Roland, Fishman, Alexiades, & Cohen, 2000; Tykocinski et al., 2000). A clear difference between the Clarion HiFocus 1 design with the partially space-filling Electrode Positioning System (EPS) and the Nucleus Contour was the fact that the HiFocus obtained the perimodiolar position mainly at the basal turn, whereas the stylet removal positioned the Contour electrode at the apical side toward the modiolus (Balkany, Eshraghi, & Yang, 2002). The effects of the latter electrode design have also been studied with cochlear view radiographs, and a more perimodiolar position at the apical side was shown (Cohen, Richardson, Saunders, & Cowan, 2003; Cohen, Saunders, & Clark, 2001; Saunders et al., 2002).

The predicted reduction in the electrical current required to activate the auditory system with perimodiolar electrodes was shown in animals and patients using electrical auditory brain response (EABR) measurements. Thresholds decreased and amplitudes of the wave V increased after bringing electrodes in a perimodiolar position (Firszt, Wackym, Gaggl, Burg, & Reeder, 2003; Pasanisi, Vincenti, Bacciu, Guida, & Bacciu, 2002). This effect was more robust basally with the Clarion HiFocus, whereas the Nucleus Contour showed lower thresholds at the apex (Wackym et al., 2004). Moreover, decreases of stapedius reflexes and electrical compound action potentials (eCAP) thresholds were found for the HiFocus using the EPS, being more pronounced basally (Eisen & Franck, 2004; Mens, Boyle, & Mulder, 2003). Furthermore, some studies showed that the Nucleus Contour had lower perception thresholds and lower maximum comfort levels compared with the Nucleus banded electrode, which takes a lateral position within the scala tympany (Parkinson et al., 2002; Saunders et al., 2002). Due to reduced thresholds and maximum comfort levels with the Contour electrode, the dynamic range did not show improvements (Saunders et al., 2002). Additionally, in pediatric recipients a predecessor of the Clarion HiFocus 1 showed lower perception thresholds and maximum comforted levels when implanted with a positioner (Young & Grohne, 2001).

In contrast with previous reports, another study did not show significant differences in T-levels between patients with the Nucleus Contour and the straight array (Hughes, 2003).

Better frequency selectivity is, in addition to lowered threshold stimulation levels, thought to be associated with improved speech perception. Different methods have been used to obtain estimates of the spatial selectivity, as the longitudinal spread of excitation along the tonotopic cochlea is of utmost importance for the spectral percepts of the patients. Psychophysical studies indicated that patients are able to exploit the tonotopic organization of the cochlea and a correlation was found between electrode discrimination and speech perception (Busby, Tong, & Clark, 1993). However, psychophysical measures of spatial selectivity failed to correlate with the distance of the electrode array to the modiolus (Cohen et al., 2001). Different approaches are needed to measure spatial selectivity without the drawbacks of subjective tests. An important role in measuring spatial selectivity may arise for the telemetry systems of the contemporary cochlear implants (neural response imaging/telemetry, NRI/ NRT, of Clarion and Nucleus cochlear implants respectively). These systems can measure both the intracochlear potential during current injection as well as the small biological potentials generated by the auditory nerve. Although spatial selectivity measurements using eCAP are still under development, recent data point out that a closer proximity of the electrode contacts to the modiolus is associated with a narrower excitation pattern (Cohen et al., 2003; Hughes, 2003). Recently, an impedance model has been developed, which can be used to study the spatial distribution of the injected current (Vanpoucke, Zarowski, Casselman, Frijns, & Peeters, 2004). This impedance model is based on objective measurements obtained with Electrical Field Imaging (EFI) of the Clarion cochlear implant.

Initial clinical evaluations of the Clarion HiFocus 1 (Frijns, Briaire, de Laat, & Grote, 2002) and Nucleus Contour (Tykocinski et al., 2001) showed excellent speech understanding. After implantation with the Nucleus Contour, a large variation in the degree of coiling across subjects could be observed. This variation in coiling is presumably surgeon and patient dependent and showed no significant effect on thresholds or speech perception (Marrinan et al., 2004). A recent study showed that the perimodiolar designed Nucleus Contour electrode contributed to improved speech understanding compared to its straight predecessor (Bacciu et al., 2005).

In 2002, the manufacturer of the Clarion HiFocus with a separate positioner system (Advanced Bionics Corp., Sylmar, CA) withdrew its system from the market. The decision to withdraw the positioner was made after the Food and Drug Administration reported meningitis cases associated with cochlear implantation (http://www.fda.gov/cdrh/safety/ cochlear.html). More research to reveal the causes of the meningitis of cochlear implant patients followed and recommendations concerning the prophylaxis and treatment were published (Cohen, Roland, Jr.,

& Marrinan, 2004; Lefrancois & Moran, 2003; Nadol, Jr. & Eddington, 2004; Reefhuis et al., 2003). Afterward, the array was inserted without positioner, as a one-component electrode, after a hypothesis was postulated suggesting that space between the positioner and the electrode could act as a possible pathway for bacteria to enter the cochlea. Although histologic evidence did not support this pathway as part of the pathogenesis of meningitis, a precise explanation for the increased incidence of meningitis is still lacking. The withdrawal of the positioner from the market provided the clinical opportunity to study the influence of the positioner on speech perception. After the withdrawal, the implantation procedure in our clinic continued in the same manner, with the exception that the implantation was performed without insertion of a positioner. The electrode array implanted was the same for all patients and furthermore they encountered the same patient selection, implanting surgeon, fitting procedures, and rehabilitation.

The positioner group (P-group) was implanted between July 2000 and July 2002. The 25 patients of this group were described earlier (Reference Note). The nonpositioner group (NP-group) was implanted between July 2002 and March 2003. This NP-group consisted of 20 patients. For both groups now, at least 1 yr of follow-up of speech perception scores is available. In this study, differences in speech perception found between the group with the perimodiolar electrode implanted as designed and the latter group are presented. Additionally, speech perception scores and the radial distances to the modiolus and the insertion depths, determined with MSCT (multislice computer tomography) for each electrode contact, will be correlated with perception thresholds and dynamic range. Finally, to obtain more insight into the effects of the positioner on intracochlear current pathways, electrical field imaging and modeling measurements (Vanpoucke et al., 2004) are discussed.

TABLE 1. Patient demographics

	P-group	NP-group		
N	All 25	All 20	NPs (n=9)	NPd (n=11)
Age at implantation (yr)	44.9 (13.4; 14.0–67.0)	59.9 (10.8; 40.0–76.0)**	60.1 (7.6; 50.0–71.0)**	59.6 (13.3; 40.0–76.0)**
Duration of deafness (yr)	18.5 (15.0; 0.2–43.0)	16.8 (14.5; 0.3–46.0)	16.7 (16.5; 0.3–46.0)	18.8 (14.4; 2.0–46.0)
Preoperative phoneme scores (%)				
Ipsilateral	6.3 (9.8; 0.0–33.0)	7.2 (11.0; 0.0–42.0)	2.0 (6.0; 0.0–18.0)	11.5 (12.5; 0.0–42.0)
Contralateral	4.0 (9.8; 0.0–45.0)	2.3 (5.9; 0.0–24.0)	0.3 (1.0; 0.0–3.0)	3.8 (7.7; 0.0–24.0)
Preoperative tone audiogram (%)				
Ipsilateral	111.6 (12.4; 85.0–130.0)	117.7 (12.0; 83.3–130.0)	119.6 (14.5; 83.3–130.0	104.2 (14.6; 85.0–130.0)
Contralateral	116.1 (7.8; 103.3–130.0)	109.6 (15.4; 85.0–130.0)	116.1 (14.5; 90.0–130.0)	116.1 (10.0; 101.7–130.0)

Data are averages with standard deviations of the population and minimal and maximal values between brackets. Significant differences, marked (p 0.01), are between the P-group and the marked NP-group.**

MATERIALS AND METHODS

All 45 patients in this study have been implanted in the Leiden University Medical Center with a Clarion CII HiFocus 1 cochlear implant. After having implanted the first 25 patients with a partially inserted positioner (P-group), the implantation of the next 20 patients was performed in our center in the same manner only without insertion of this positioner (NP-group). In the group with the positioner (P-group), this positioner was placed between the electrode array and the outer wall. The positioner was designed to have a slightly shallower insertion than the HiFocus electrode array. Furthermore, it was partially inserted with the insertion tool, resulting in a protrusion of the positioner from the cochleostomy of approximately 5 mm. All patients had a full insertion of the electrode array, except for one P-patient, deafened by meningitis. During implantation in this patient, a resistance was encountered and the four most basal contacts were not positioned inside the cochlea. The NPgroup was limited to 20 patients because, after this group, the patients in our clinic were implanted with the new HiRes90K implant with HiFocus 1J electrode.

After the operation of the ninth patient without a positioner, a trend of stagnation of growth in speech perception was detected through analysis of the initial results of the first six hooked-up NP-patients, with a maximum follow-up of only 2 mos. Additionally, the most basal electrode contacts in those six patients showed higher T-levels than the other contacts. Two factors were considered to be possible causes of these changes: decreased modiolar approximation and shallower insertion. Only the latter could be controlled in absence of the positioner, and it was decided to aim for a deeper insertion in the patients implanted afterward. The jog of the electrode was now placed inside the cochleostomy instead of just in front of it. No extra resistance was encountered during insertion of the electrode array. The results of the NP-group will be presented separately for the group of the first nine patients, having a shallow insertion (NPshallow, NPs-group) and the second group of 11, intended to have a deeper insertion (NPdeep, NPd-group).

All patients included in this study were postlingually deafened. More demographics of the patient groups are given in Table 1, causative factors in Table 2. The data show, besides significant differences in age, a good similarity in between groups with respect to duration of deafness and preoperative scores. Median preoperative phoneme scores, determined with headphones using standard speech audiometry at the ipsilateral ear, were 0% for all groups. In general, the worse hearing ear was chosen for surgery, except for two cases in which unilateral vestibular function and unilateral cochlear patency urged implantation of the better ear.

TABLE 2. Causes of deafness in the various patient groups

	P-group	NP-group		
	All 25	All 20	NPs (n = 9)	NPd (n = 11)
Hereditary	10	10	4	6
Trauma	1	1	1	0
Antibiotics	1	0	0	0
M. Meniere	1	1	1	0
Meningitis	3	1	0	1
Otosclerosis	0	1	1	0
Unknown				
Progressive	7	5	1	4
Sudden deafness	2	1	1	0

Speech Material

Speech discrimination scores were assessed during normal clinical follow-up at predetermined intervals, starting 1 wk after initial fitting. The standard Dutch speech test of the Dutch Society of Audiology, consisting of phonetically balanced monosyllabic (CVC) word lists, was used (Bosman & Smoorenburg, 1995). Although this test is typically scored with phonemes in the Netherlands and Flanders, the data are also shown as word scores, which is a more common reporting method in AngloSaxon countries. For tests in noise the standard speech–shaped noise from the same CD was used. To improve test accuracy, four lists (44 words) were administered for each quiet and noise condition. All testing was done in a soundproof room, using a calibrated loudspeaker in frontal position at 1-meter distance. Subjects were tested in quiet at speech levels of 65 and 75 dB SPL. When the average phoneme score in quiet was higher than 50%, subjects were also tested in noise at a speech level of 65 dB. Speech scores in noise were assessed at maximally four signal-to-noise ratios (SNR), starting with an SNR of +10 dB and continuing at +5, 0 and –5 dB SNR until the phoneme score was lower than half the score in quiet. However, some patients had to stop before this criterion was reached because they could not tolerate the higher noise levels. For further analysis, the speech recognition threshold (SRT) and phoneme recognition threshold (PRT) were calculated from the acquired data (Hochberg, Boothroyd, Weiss, & Hellman, 1992). The SRT is the SNR at which the patient scored 50% of the phonemes correct. The PRT was defined as the SNR at which the phoneme score was half the individual patient's score in quiet.

Radial Distances and Insertion Depths

With a dedicated MSCT data acquisition protocol, developed at the department of neuroradiology of the Leiden University Medical Center, imaging of the implanted electrode array was obtained (Verbist, Frijns, Geleijns, & van Buchem, 2005). In contrast to previous CT imaging of implanted electrode arrays, all individual electrode contacts were discernible and their relation to fine anatomic cochlear structures was visible. Initially, the improved MSCT technique was not available, and postoperative scans of only 15 of the 25 P-patients have been acquired. MSCT scans of all 20 NP-patients were available for analysis.

Figure 1A shows an electrode array inserted with positioner. Between the basal lateral wall of the cochlea and the electrode, a hypodense area is visible. This corresponds with the location where the positioner is situated. As the positioner takes the space at the outer wall, the electrode is displaced toward the modiolus. Because the positioner is only partially inserted, it does not force the electrode into a perimodiolar position at the apical end of the cochlea. Moreover, the material properties will tend to straighten the electrode. The radius of the cochlea is smaller than the radius of the electrode array in its natural position and without force toward the modiolus at this apical part of the cochlea the electrode will follow the outer curve. The MSCT scan shows that more apically the electrode is indeed located close to the lateral wall and that a hypodense space exists between the electrode and the modiolus. Figure 1A only shows the position of the electrode in the basal turn, whereas the apical tip of the electrode is not visible and was projected on another slice.

The electrode inserted without positioner (Fig. 1B, NPs-patient) tends to be positioned laterally throughout

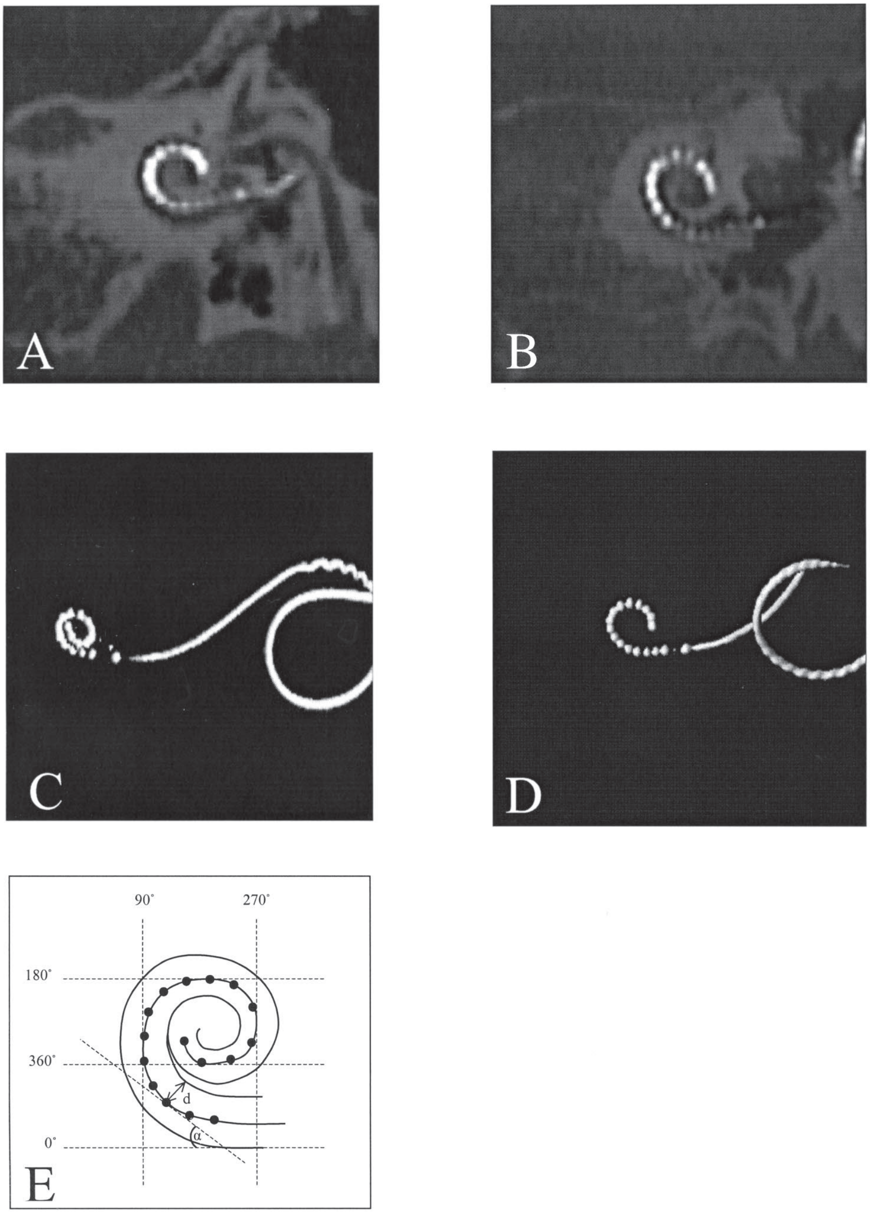

Fig. 1. Typical oblique multiplanar reconstructions of MSCT scans of implanted cochleas with (A) and without (B) the use of a positioner show, respectively, a medial and a lateral position of the basal electrode array. Three-dimensional-reconstructions (C & D), using the MSCT scans, show insertion depths of the apical tips (not seen on A) of the same electrode arrays displayed in A and B. The diagram (E) shows the coordinate system used to determine the insertion angle. The angle ð illustrates the insertion angle of an electrode contact expressed in degrees, and d shows the radial distance from this contact to the modiolus.

its entire length, leaving more space between the electrode contacts and the modiolus compared with the P-patients. The path following the outer turn is longer than the path the electrode follows with the positioner inserted. This causes a less deep insertion of the electrode when no positioner is inserted. Figure 1 (C and D) shows three-dimensional reconstructions of typical implants of the P-group and the NPs-group, respectively. The latter shows a less deep insertion compared with the P-group. After hand-marking the centers of the electrode contacts as well as the modiolar contour the radial distance of each electrode to the modiolus was automatically determined. Interconnecting lines were automatically drawn between successive electrode contacts. The angles between these lines and a reference line along the basal part of the cochlea were calculated. The position of the electrode contact was expressed as the cumulative angle between those lines. The coordinate system, based on Chen et al. (1999), is illustrated in Figure 1E.

T-Levels, M-Levels, and Dynamic Range

All patients in this study used a CIS strategy. Except for 5 patients in the P-group, who were hooked up with a HiRes strategy, the first 3 mos the SCLIN emulation mode with 8 active contacts and 833 pps/contact (75 jLsec/phase) was used. At 6 mos, 26 patients of the 45 patients used a HiRes strategy programmed with the BEPS software package, whereas 37 patients were using the HiRes strategy at 1 yr of follow-up (1400 pps/contact, 21 jLsec/ phase, ranging from 8 to maximally 16 active contacts). In the Discussion section, we argue that HiRes experience is probably not a contributing factor to any differences in speech perception scores between the Pand NP-groups. For all electrode contacts, the thresholds (T-levels) and the most comfortable loudness levels (M-levels) were determined during fitting by following the Leiden fitting strategy (Frijns et al., 2002; Reference Note). The T-levels were obtained in burst mode with an updown-up method and an up sloping M-level profile was used. The M-levels of the basal electrode contacts were increased with the intention to improve consonant understanding, especially in background noise. Further adjustments were done with running speech. If patients experienced a dominant low-pitched sound, the apical M-levels were reduced.

Both the Tand M-levels included in this study were obtained after approximately 3 mos of implant use in SCLIN emulation mode. Tand M-levels acquired from the five P-patients who always used HiRes were not comparable to those of the SCLINpatients, as the result of different stimulation rate and pulse duration. Therefore, levels of all the NP-patients but only of 20 of the P-patients are analyzed in this study. The dynamic range was defined as the M-level minus the T-level.

Electrode Impedances and Conductivity Paths

Immediately before hook-up, the standard clinical method for recording impedances using the telemetry facility was used. The impedance of every electrode contact was measured to get some information about the tissue and fluid surrounding the electrode. To obtain a clearer picture of the current pathways in the cochlea, electrical field imaging modeling (EFIM) measurements were performed (Vanpoucke et al., 2004). With these measurements, each electrode contact is consecutively stimulated in monopolar mode and

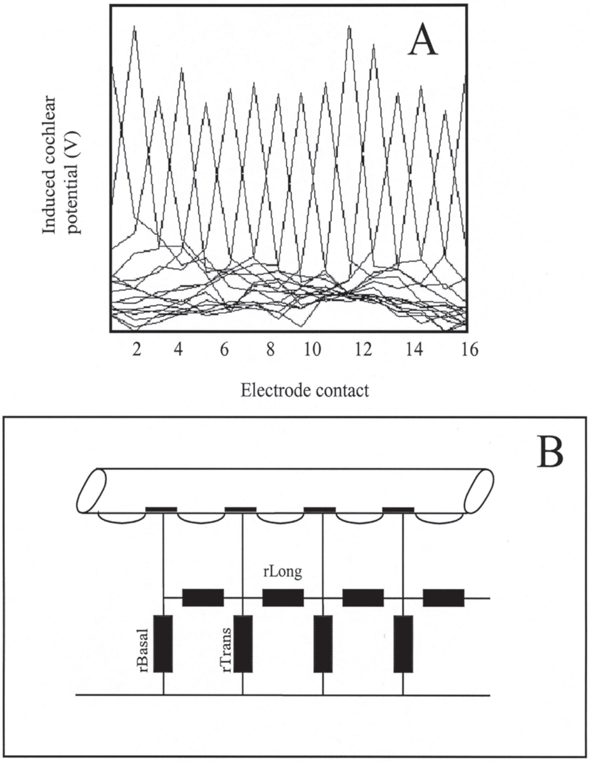

Fig. 2. With potentials, captured with electrical field imaging (EFI) (A), resistors are modeled, which reflect the local electrical conductivity of the cochlear tissues. The model consists of 15 longitudinal and 15 transversal resistors, representing the resistance between adjacent electrodes. A basal resistor, representing the resistance between the basal electrode in the cochlea and the reference electrode on the implant casing, terminates the model (B).

the induced intracochlear potential is captured at all electrode contacts (Fig. 2A). From the intracochlear impedance map, a leaky resistive transmission line model is derived b using multidimensional optimization algorithms. The electrical tissue model is a ladder network with 15 sections (Fig. 2B). Each section consists of a longitudinal and a transversal resistor and corresponds physically to the cochlear segment between consecutive contacts. The longitudinal resistors represent the current flow along the scala tympani and the transversal resistors model the current straying out of the cochlea. The model is terminated by a basal resistor. This basal resistor models the current drain from the basal end of the cochlea to the reference electrode located at the implant case. From the model, a tissue impedance can be derived at the stimulation contact, resembling the tissue input impedance seen at a particular stimulation contact. EFIM measurements were performed in 20 of the P-patients and 16 of the NP-patients after 1 yr of cochlear implant use. In 11 of the 20 P-patients, both a CT scan and EFIM measurements were performed. Of the NP-patients, EFIM measurements obtained after 1 or 2 mos were also available.

RESULTS

Speech Perception in Quiet

The bars in Figure 3 show the average scores for the monosyllabic CVC-word tests in quiet for both the P-group and the NP-group. The data are displayed as phoneme scores (Fig. 3A), which is standard for this monosyllabic word test, and are also displayed as word scores (Fig. 3B) for a better international comparison. One year of follow-up was complete for both the P-group and the NP-group. During the follow-up period, both groups show an increase in performance on the speech tests, which is the most rapid in the first weeks after initial fitting. However, after 1 mo, the performance of the NP-group tends to lag behind the P-group, and at 3 mos and 6 mos, the differences in speech perception scores reach significant levels ($p < 0.05$). Also at 1 yr of follow-up, the NP-patients score significantly lower than the P-patients (73% versus 83%, $p < 0.05$). Further analysis of the speech perception scores of the NPs-group and the NPd-group only revealed limited differences between both groups (Fig. 3C). Although initially the speech perception scores tend to increase more rapidly after implantation for the NPs-patients, the differences did not reach significant levels at 1 yr ($p > 0.1$).

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Demographic factors showed little differences between the Pand NP-groups, except for the age. As shown in Table 1, the average age of the P-group and the NP-group differed by 15 yrs. However, in neither group is the age of the patient at implantation correlated significantly with speech perception. This is illustrated in Figure 4A, where speech perception scores at 1 yr were plotted against age of the Pand NP-group and no significant correlations were found ($R^2 < 0.001$, $p > 0.9$ and $R^2 = 0.002$, $p > 0.9$). Boththe P-group and the NP-group contain patients with a wide range of duration of deafness, ranging from a couple of months up to more than 40 yrs (Table 1). Interestingly, in both groups, no significant correlation exists between speech perception and the duration of deafness before implantation as shown in Figure 4B ($R^2 = 0.10$, $p > 0.1$ and $R^2 = 0.007$, $p > 0.7$).

Speech Perception in Noise

Speech scores in noise obtained 1 yr after initial fitting were analyzed. Data were available for all P-patients and 17 NP-patients. Three patients of the NP-group (2 NPs, 1 NPd) did not participate in the speech in noise tests because their phoneme scores in quiet were lower than 50%. First, the phoneme scores measured at +10, +5, 0, and -5 dB SNR were compared between the two groups. The average scores at +10 and +5 dB SNR of the NPpatients were consistently lower than the average scores of the P-group ($p < 0.05$). However, for the 0 dB and -5 dB SNR conditions, there were no significant differences between the average group scores. The lack of significance could be due to the fact that a substantial number of poorer performing patients was not tested at 0 and -5 dB SNR because the stop criterion for this test was already met at +5 dB SNR. In addition, for each of the 25 P-patients and the 17 NP-patients the SRT and the PRT (phoneme recognition threshold) were derived to characterize the ability to discriminate speech in noise. The average PRT as well as the average SRT for the P-group (-0.9 dB SNR and +1.2 dB SNR, respectively) were

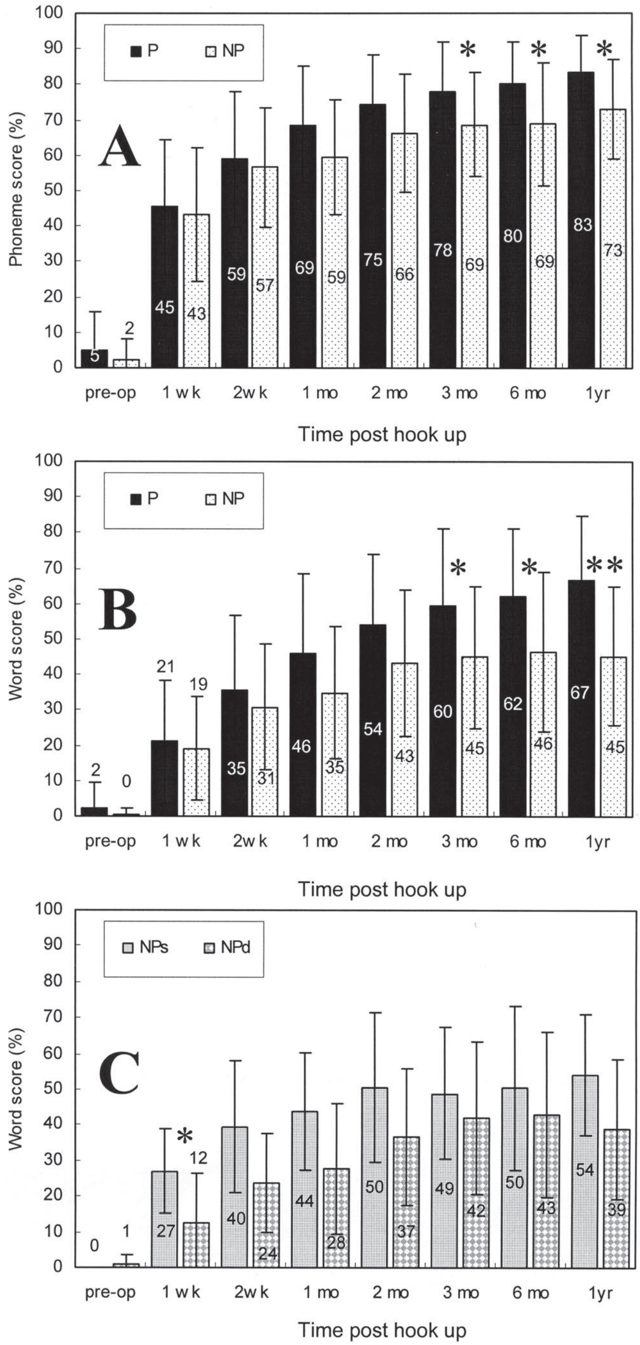

Fig. 3. Speech perception on monosyllabic (CVC) words in quiet of the positioner-group (P) and the nonpositioner-group (NP) plotted as phoneme scores (A) and as word scores (B) as a function of time after hook-up. Word scores of the NP- group are shown for the NPs-group and the NPd-group separately in C. Significant differences between speech per- ception scores of both groups are marked (*p < 0.05; **p < 0.01). The number of patients in the subgroups is shown in Table 3.

TABLE 3. Number of subjects represented in each part of Figures 3, 4, 5, 6, and 7

Figure 3, A and B			Preop	1 wk	2 wk	1 mo	2 mo	3 mo	6 mo	1 yr		
	P:	n=	25	25	25	25	25	25	25	25		
	NP:	n=	20	20	20	20	19	19	19	19		
	NPs:	n=	9	9	9	9	9	8	9	8		
	NPd:	n=	11	11	11	11	10	11	10	11		
Figure 3C			Preop	1 wk	2 wk	1 mo	2 mo	3 mo	6 mo	1 yr		
	NPs:	n=	9	9	9	9	9	8	9	8		
	NPd:	n=	11	11	11	11	10	11	10	11		
Figure 4, A and B												
	P:	n=	25									
	NP:	n=	19									
	NPs:	n=	8									
	NPd:	n=	11									
Figure 5A												
	P:	n=	15									
	NP:	n=	20									
	NPs:	n=	9									
	NPd:	n=	11									
Figure 5B			0-60	60–120	120–180	180–240	240–300	300–360	360–420	420–480	480–540	540–600
	P:	n=	15	15	14	14	14	14	12	8	6	1
	NP:	n=	13	19	20	20	20	17	10	8	4	1
	NPs:	n=	9	9	9	9	9	6	2	1	0	0
	NPd:	n=	4	10	11	11	11	11	8	7	4	1
Figure 5C												
	P:	n=	15									
	NP:	n=	19									
	NPs:	n=	8									
	NPd:	n=	11									
Figure 6, A and C												
	P:	n=	12									
	NP:	n=	20									
	NPs:	n=	9									
	NPd:	n=	11									
Figure 6, B and D			0–60	60–120	120–180	180–240	240–300	300–360	360–420	420–480	480–540	540–600
	P:	n=	12	11	11	11	11	11	6	4	5	0
	NP:	n=	13	19	20	20	20	16	6	8	3	2
	NPs:	n=	9	9	9	9	9	5	1	1	0	0
	NPd:	n=	4	10	11	11	11	11	5	7	3	2
Figure 7, A, B, and D			0–60	60–120	120–180	180–240	240–300	300–360	360–420	420–480	480–540	540–600
	P:	n=	11	11	10	10	9	10	9	6	4	0
	NP:	n=	11	15	16	16	16	13	7	6	4	2
	NPs:	n=	8	8	8	8	8	5	1	1	0	0
	NPd:	n=	3	7	8	8	8	8	6	5	4	2
Figure 7C												
	P:	n=	20									
	NP:	n=	16									
	NPs:	n=	8									
	NPd:	n=	8									

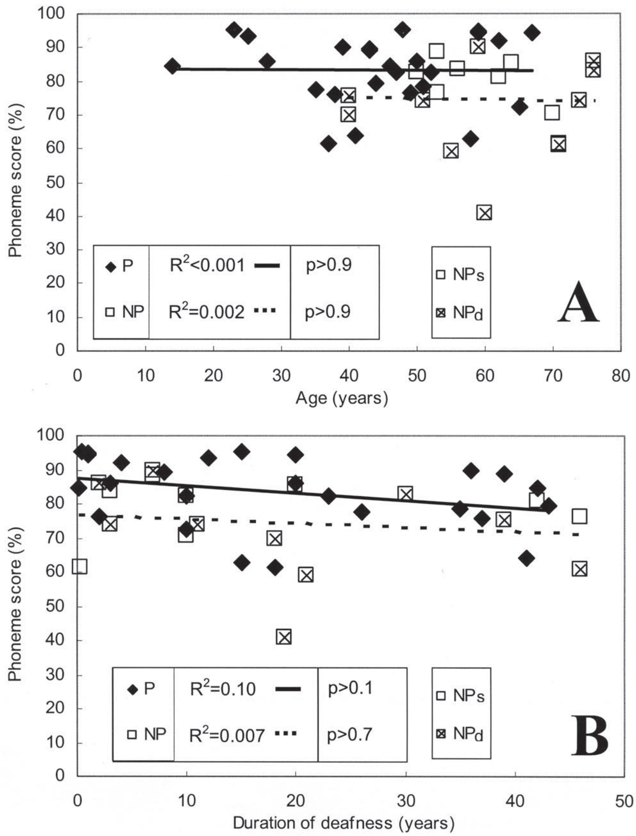

Fig. 4. A, Phoneme scores on monosyllabic (CVC) words in quiet after 1 yr of follow-up of the positioner-group (P) and the nonpositioner-group (NP) plotted against the age at implantation. The lack of correlation is shown by trend lines, R^2 and p values. B, Phoneme scores after 1 yr of follow-up of the positioner-group (P) and the nonpositioner group (NP) plotted against the duration of deafness. The lack of correla- tion is shown by trend lines, R^2 and p values. The number of patients in the subgroups is shown in Table 3.

both significantly lower ($p < 0.05$) than the scores for the NP-group (+1.2 dB SNR and +4.9 dB SNR, respectively). Neither the average speech in noise scores nor the PRT and SRT values showed a significant difference between the NPs-group and the NPd-group.

Distance to Modiolus and Insertion Depth

As described in the Materials and Methods section, the measurements determined the radial distance from the center of each electrode contact as seen on the MSCT to the modiolus. To obtain the actual distance of the electrode surface to the modiolus the distance from the center to the surface (approximately 0.25 mm) should be subtracted from the measured distance. Moreover, a silicone bleb, located between the contacts at the medial side of the array accounts for approximately 0.15 mm of the measured distance, as the electrode

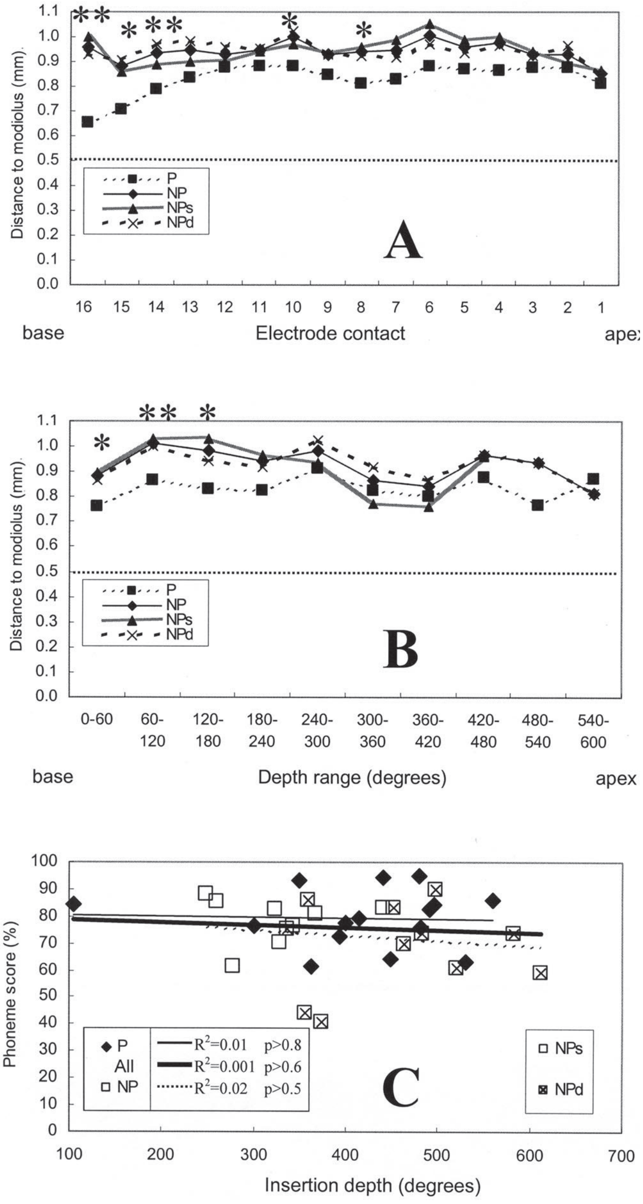

Fig. 5. Radial distances of center of electrode contacts to the modiolus, shown per electrode contact (A) and per depth range (B). Significant differences between the P- and NP- groups are marked (*$p < 0.05$; **$p < 0.01$). Dashed lines reflect the combined contribution to the measured distances of the space between the center and the surface of the contacts, the silicon blebs, located medially on the array between adjacent electrodes, and the average standard error. C, Phoneme scores after 1 yr of follow-up of the positioner group (P) and the nonpositioner-group (NP) plotted against the insertion depth of the most apical electrode contact. The lack of correlation is shown by trend lines, R^2 and p values. The number of patients in the subgroups is shown for electrode contacts and for the depth ranges in Table 3.

3

cannot come closer to the modiolus due to mechanical constraints. Furthermore, preliminary results from phantom studies performed in our clinic showed additionally an average error in distance from the modiolus of approximately 0.1 mm. These extra distances are plotted in Figure 5 (A and B) as a horizontal dotted line at 0.5 mm from the modiolus. As shown earlier, the positioner is intended to push the basal electrode contacts toward the modiolus (Fig. 1). This effect was confirmed by the analysis of the MSCT scans, which showed that the basal electrode contacts of the P-group are located closer to the modiolus than those of the NP-group (Fig. 5A). This difference is more prominent basally than apically, and the most basal electrode contacts as well contacts as 10 and 8 in the middle region show significant differences in distances to the modiolus. Interestingly, the space between the basal contacts and the modiolus in the P-patients shows that the contacts are pushed toward and not firmly pressed onto the modiolus, probably because the partially inserted positioner is not completely space filling.

The first 9 NP-patients have a shallow insertion compared with the P-group. The most basal electrode contacts of the NPs-group show a trend to be close to the cochleostomy, with the 16th contact at an insertion angle near 0 degrees (Table 4). Consequently, the electrode contact 16 of those NP-patients is located in the part of the cochlea that is by far the widest part. Therefore, the radial distances of those electrode contacts to the modiolus are larger than those of the same contacts in electrode arrays, which were inserted somewhat further in the cochlea. Moreover, the average location of the apical electrode contacts of the NPs-group is significantly less deep than that of the P-group (327 versus 468 degrees: $p < 0.01$). Although the apical contacts of the NPsand P-groups are in a clearly different location, the decision to insert deeper made the position of the NPd-group's apical electrode again at a location more comparable to that of the P-group. However, the most basal contact of the NPd-group was located significantly deeper than that of the P-group ($p < 0.01$). All observed differences in insertion depth did not reveal significant correlations with speech perception scores (Fig. 5C) ($p > 0.5$).

To compare the radial distances between groups at the same cochlear location, the electrode contacts were converted to angle of insertion. The radial distances of the electrode contacts to the modiolus for 10 depth ranges are shown in Figure 5B. In line with the findings per electrode contact, the radial distances of the electrodes at the three basal most depth ranges differ significantly between the Pgroup and the NP-group (0 to 60 degrees: $p < 0.05$; 60 to 120: $p < 0.01$; 120 to 180: $p < 0.05$), whereas the distances at the apical ranges do not differ significantly ($p > 0.4$). For the different depth ranges in the cochlea, the radial position of the electrode contacts of the NPsand NPd-groups were similar.

T-Levels, M-Levels, and Dynamic Range

Contrary to the expectations based on the fact that the contacts in the P-group are closer to the nerve fibers in the modiolus, the overall T-levels of the P-group tend to be higher than those of the NP-group, although this is not statistically significant ($p > 0.3$) (Fig. 6A). Wide ranges exist for the T-levels, especially for the P-patients, which can prevent small differences between groups to reach significant levels. Although the interindividual Tlevels vary greatly, the intra-individual T-levels along the array show great consistency

TABLE 4. Insertion depths of electrode contacts, in degrees as measured on multislice CT scans

	P-group	NP-group		
Insertion depths of electrode contacts (degrees)	15 of 25	All 20	NPs (n = 9)	NPd (n = 11)
Most apical	439 (73; 105–559)	401 (105; 278–612)	327 (60; 278–441)*	468 (92; 336–612)
Most basal	6 (13; −10–35)	35 (41; −7–130)*	2 (11; −7–25)	65 (35; 10–130)*

Data are averages with standard deviations of the population and minimal and maximal values between brackets. Significant differences, marked (*p 0.01), are between the P-group and the marked NP-group. Position of the cochleostomy can lead to negative values.

within each group. The T-levels of the P-patients do not show big differences along the array, with slightly higher thresholds basally. The differences along the array are much more profound in the NPs-group, with a sharp increase of the T-levels at the basal side of the array (as seen in Fig. 6A). This basal increase in T-level (T-level at contacts 16 and 15 minus T-level at contacts 14 and 13) of the NPs-patients is significantly larger than that of the P-group ($p < 0.01$). The differences in basal T-levels rise between NPs and P are also significant, when the T-levels are plotted per depth range, although with a lower significance level ($p < 0.05$) (Fig. 6B). In the NPsgroup, this basal ward increase of T-levels (as a percentage of the average overall level) is significantly correlated with the insertion depth ($p < 0.05$). Together with the reduced growth of speech perception scores, this was an argument to change the operation technique and insert deeper. As was expected, the T-level profile of the NPd-group showed the more even shape of the P-group again (Fig. 6A). However, the overall T-levels of the NPsand NPdgroups are at equal levels ($p > 0.9$).

Within each group there is a small but significant negative correlation between the T-levels, averaged per individual, and the speech perception as measured with monosyllabic words (R = -0.64, $p < 0.01$, R = -0.55, $p < 0.05$, for the P and NP groups, respectively). This means that within groups, patients with lower T-levels tend to have better outcomes. However, this does not hold between groups, as the P-group has better outcomes in spite of slightly higher T-levels.

The M-levels do not show any significant difference between the groups in absolute levels, nor in shape of the profiles. The shape of the M-level profile was set according to our clinical fitting method (Reference Note). Because of the definition of the dynamic range as a subtraction of the M-levels and T-levels, the dynamic range is basally smaller in the NPs-group as a result of the basal increase of the T-levels (Fig. 6, C and D).

Electrode Impedances and Conductivity Paths

The standard impedance measurements as obtained before initial hook-up show a tendency to be higher at the basal end of the scala tympani for the P-group. More detailed information was obtained with EFI measurements.

Figure 7A shows longitudinal resistances (r_{Long}) along the electrode array as calculated with the EFI model (Vanpoucke et al., 2004). This r_{Long} shows no significant differences between the patient groups. Differences seen in the depth ranges >360 degrees are mainly due to a limited number of subjects in the

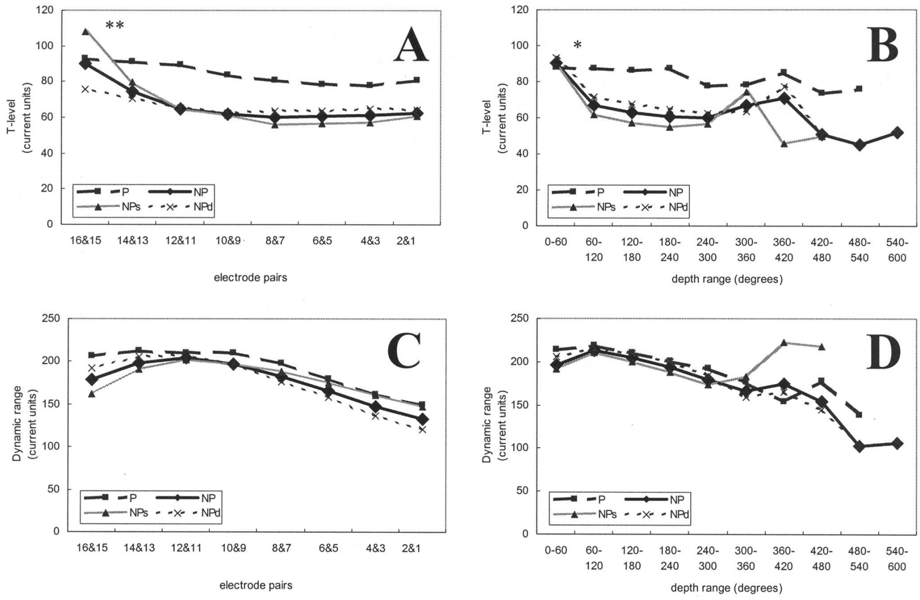

Fig. 6. T-levels of the positioner-group (P) and the nonpositioner-group (NP), shown per electrode contact (A) and per depth range (B). The NP-group is split into the group of the first 9 shallowly inserted patients (NPs) and the last 11 deeper implanted patients (NPd). Significant differences in basal increases in T-levels between the P-group and the NPs-group are marked (*$p < 0.05$; **$p < 0.01$). C and D show the dynamic range of each group per electrode contact (C) and per insertion range (D). The number of patients in the subgroups is shown for electrode pairs and for the depth ranges in Table 3.

subgroups and do not reach significant levels. The resistances in transversal direction (r_{Trans}) are more than a factor 100 higher than the corresponding r_{Long} values (Fig. 7B). Therefore, a longitudinal conductivity path along the array will dominate in all groups. As found for longitudinal resistances, the transversal resistances along the array do not show significant differences between the groups. An important factor, as indicated by the EFIM measurements, is the basal resistance (r_{Basal}) (Fig. 7C), which is at least 5 times the r_{Long} value in all groups. This is the resistance from the basal contact of the cochlea to the reference electrode contact. This r_{Basal} reveals differences between the subgroups. The basal resistance of the NPs-subgroup is significantly lower than the r_{Basal} of both the P-group and the NPd-group. In contrast to the basal resistances, the tissue resistance, the global impedance between a given electrode and ground, does not show significant differences between the Pand NP-groups (Fig. 7D). Moreover, the NPs and NPd show comparable values (not plotted in Fig. 7D). However, the r_{Tissue} of the NP-patients measured 1 or 2 mos after implantation were lower at the basal side of the cochlea, differing significantly with the data obtained after 1 yr (Fig. 7D). Also, the r_{Long} and r_{Trans} of the NP-group showed this basal increase.

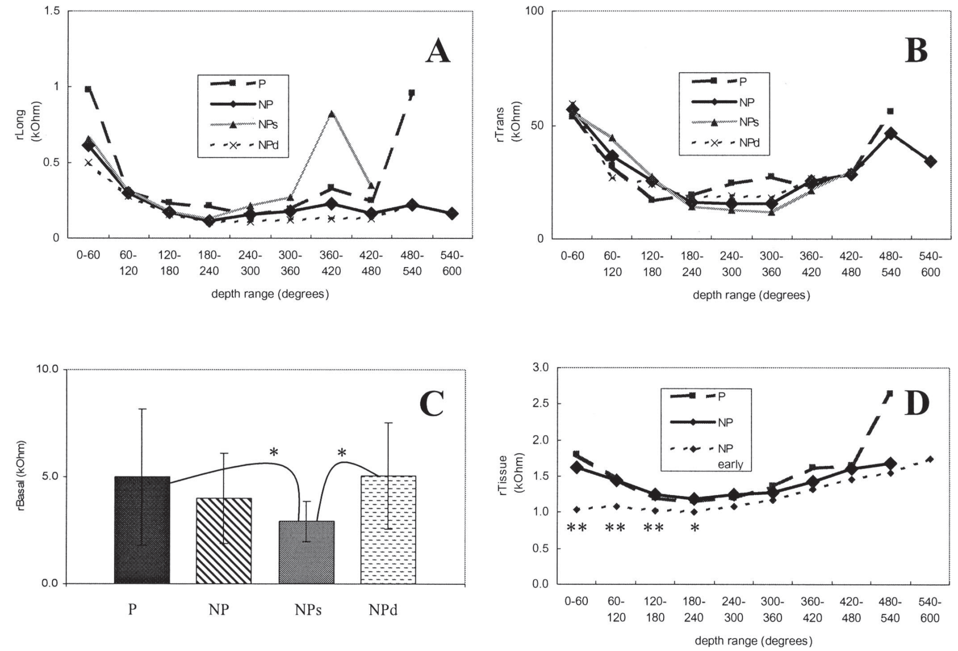

Fig. 7. The longitudinal r_{Long} (A) and transversal r_{Trans} (B) resistances per depth range as acquired with the EFI (Electrical Field Imaging) model. C, Basal resistance r_{Basal} represents resistance from the basal electrode contact to the reference contact for all patient groups. Significant differences, marked (*$p < 0.05$; **$p < 0.01$), are between the P- and the NP-groups, except when indicated differently. D, Average total tissue resistance r_{Tissue} at each electrode contact, one for the P-group and for the NP-group at several months and 1 yr after implantation. Significant differences, marked (*$p < 0.05$; **$p < 0.01$), are between the NP-early versus the P- and the NP-groups. The number of patients in the subgroups is shown for the depth ranges in Table 3.

DISCUSSION

In this study, the clinical effects of bringing the HiFocus I electrode array in a perimodiolar position were examined. This study became possible after the withdrawal of the positioner from the market in 2002. Intrascalar position, insertion depth, stimulation levels, and intracochlear conductivity pathways were studied to find an explanation for the decrease in speech perception after implantation without perimodiolar positioning of the array.

The study shows better speech perception with a perimodiolar electrode design. The learning curve was much steeper in the patients with the perimodiolar electrode (P-group), and their speech recognition reached significantly higher levels from 3 mos up to at least 1 yr. Additionally, significant differences in speech perception in noise were demonstrated. International comparison of the results with other studies showing a perimodiolar position of the Contour electrode contributes to the outcomes is complicated by language differences (Bacciu et al., 2005). Comparison of our speech perception results with sparse published data from Dutch cochlear implant users shows that even the NP-patients from this study show speech perception scores that are in line with or above those using other state-of-the-art cochlear implants (Smoorenburg, Willeboer, & Vandijk, 2002). On top of this performance, extra improvement is shown in the patients with the positioner.

It is of utmost importance to try and understand the causes of the differences found between the groups in this study, especially because the less favorable outcomes were obtained in patients implanted later in time, which at least is not in line with the general trend of continuously improving speech perception with cochlear implants (Ramsden, 2004). Future electrode designs, taking into account these findings, should aim at regaining this improved speech perception.

The first factor analyzed in an attempt to explain the improved speech perception was if the array was really positioned closer to the modiolus in the P-group as intended. This was confirmed with the MSCT scan technique developed in our center (Verbist et al., 2005). In line with the findings of Balkany et al. (2002), the data from this study show that the approximation with the positioner takes place primarily at the basal side of the cochlea, whereas the apical contacts follow the lateral wall. Although this basal decrease to the modiolus is small, it accounts for a considerable part of the free space between the electrode array and the modiolus as seen in the NPpatients. Improved speech perception confirmed the benefits of this position as expected on the basis of computational models of the cochlea (Frijns et al., 2001).

Additionally, with the positioner pushing the electrode towards the inner curvature of the scala tympani, a deep insertion could be reached, with the most basal electrodes still in the most basal region of the cochlea. This position in the cochlea could contribute to the higher speech perception scores in the P-group compared with the NP-group. The potentially beneficial effects of stimulation along the entire cochlea have been suggested earlier (Hochmair et al., 2003), because it could allow for a more natural frequency to place mapping. This might facilitate speech perception, which is in line with the findings reported by Baskent & Shannon (2003). Furthermore, if a certain area in the cochlea has suffered neural cell death, stimulation of other parts of the cochlea is still possible with this large insertion length. After the shallow insertion of the first 9 patients without a positioner, it was aimed to regain the higher speech perception scores as obtained by the P-group through a deeper insertion. Although the threshold for the basal electrode contact decreased with a deeper insertion for the NP-patients, the NPd-patients did not show significant speech perception scores after 1 wk compared with the NPs-patients. Regarding the value of apical stimulation, researchers report contrasting results. Some studies described a significant contribution of the most apical regions to speech perception (Hochmair et al., 2003; Yukawa et al., 2004), but other ones showed improved speech perception with the most apical contacts turned off (Boex, Kos, & Pelizzone, 2003).

In the present study, there are few (if any) confounding variables that can explain the improved performance in the P-group, rather than the use of the positioner itself. Of course the groups with and without positioner were separated in time, the separation being marked by the withdrawal of the positioner in

July 2002. Although this made randomization of the patients over the groups impossible, the patient groups were demographically highly comparable (Table 1). Moreover, the selection criteria, the surgeon, and the rehabilitation scheme were the same for both groups. The follow-up of both groups took place in a prospective way with the same tests at predetermined intervals. The higher average age at implantation in the NP-group was the only significant demographic difference between the groups. However, this age difference is not likely to explain the differences in speech perception, for no correlation was observed between age at implantation and speech perception within each of the groups. This finding is in line with a recent multicenter study, which also showed no systematic association of speech perception with age at implanta-tion (UK Cochlear Implant Study Group, 2004). Additionally, the different amount of usage of HiRes programs between the Pand NP-groups is not a very likely explanation for the differences in speech perception in silence. In line with previous research performed in our clinic (Frijns, Klop, Bonnet, & Briaire, 2003) and elsewhere (Friesen, Shannon & Cruz, 2005), the present study did not reveal any significant effect of high rate stimulation or number of electrodes used on speech perception in quiet for both groups ($p > 0.2$ and $p > 0.3$ for the Pand NP-groups, respectively). Moreover, the average time of experience with those HiRes strategies was the same at 1 yr (P versus NP: 8 mos).

As reported elsewhere (Reference Note 1), the duration of deafness is not a predictor of postoperative performance in the P-group. The data in the present study lead to the same observation for the NP-group, excluding the positioner as a cause for the lack of correlation between duration of deafness and performance. This is a surprising outcome, which is in contrast with the majority of previous studies (Gomaa, Rubinstein, Lowder, Tyler, & Gantz, 2003; UK Cochlear Implant Study Group, 2004; van Dijk et al., 1999) and in line with a few others (Hamzavi, Baumgartner, Pok, Franz, & Gstoettner, 2003). Interestingly, the lack of correlation persists in the total group with both Pand NP-patients, even if the three meningitis cases in both groups are excluded from the analysis.

In an attempt to understand the implications of the changed intrascalar position on speech perception, physiological features expected to underlie these implications, such as stimulation levels, were examined in this study. Literature describes lower thresholds and higher amplitudes, as seen with acute EABR, eCAP, and stapedius reflex measurements (Cords et al., 2000; Eisen & Franck, 2004; Firszt et al., 2003; Mens et al., 2003; Pasanisi et al., 2002; Wackym et al., 2004) after modiolar approximation of the electrode. Moreover, findings for the Clarion Preformed electrode and the Nucleus Contour electrode reported lower perception thresholds (Cohen et al., 2003; Parkinson et al., 2002; Saunders et al., 2002; Tykocinski et al., 2001; Young & Grohne, 2001). Although the positioner pushed the electrode array toward the modiolus, as confirmed by the postoperative MSCT scans, the threshold and maximum comfort levels were not lower in the P-group (Fig. 6). A firm explanation for the lack of reduction of the stimulation levels was not found. However, a possible explanation for the stable stimulation levels can be the improved spatial selectivity associated with the basally perimodiolar position. With such a position the stimulation threshold of the nerve fibers closest to the electrode contact may be reduced (as predicted by Frijns et al., 2001), but in the meantime the increased spatial selectivity may cause fewer nerve fibers along the cochlea to contribute to the percept, which, consequently, may still be unperceivably soft. Hughes (2003) also showed stable T-levels with the Nucleus Contour electrode compared with its straight predecessor. As a plausible additional effect, she suggested that temporal integration mechanisms might be responsible for determination of T-levels instead of electrode position in the cochlea.

Since the beneficial effects of the positioner are not due to changes in stimulation levels, other factors must be involved. The improvement in speech perception from a perimodiolar design may then be primarily due to improved spatial selectivity. Better performance in electrode discrimination correlates with improvements in speech perception (Busby et al., 1993), and modiolar approximation produces improvements in the outcomes of psychophysical forward masking measurements (Cohen et al., 2001). Although promising, eCAP measurements have not been able to link changed spatial selectivity profiles with speech perception (Cohen et al., 2003; Hughes, 2003). Such objective information about the spatial selectivity, obtained with NRI recordings, was not collected routinely in the patients reported here. Therefore, such data are only available for some individual patients, and no conclusions for the groups could be drawn.

The EFIM measurements, reflecting the local electrical conductivity of the cochlear tissues, do not give a clear explanation for the improved speech perception in the P-group. The insulating silastic positioner seems to have a limited effect on the current flow in the cochlea. However, the lack of such an insulating positioner seems to cause lower basal resistance values in the NPs-patients, which might cause injected current to flow easily out of the basal cochlea. This could explain why basal electrodes were less potent in stimulating nerve fibers in the NPs-group, which, in turn, can explain why these patients have higher thresholds at basal contacts. Deeper insertion of the electrode arrays causes the basal current leak to decrease to the level of the P-patients. Besides the depth of insertion, the time passed since the implantation seems to increase the impedances, whereas repeated measures in the NP-patients showed significant increase in the resistors basally. The higher resistances occur especially in the wider basal part of the cochlea and might be due to postimplantational accumulation of scar tissue. However, densitometry measurements made in our clinic after 6 mos showed no differences with the CT scans obtained immediately after surgery. EFIM measurements of resistances obtained after the 1-yr measurements showed stable situations. Because we did not perform the early EFIM measures in the P-patients, we could not confirm if the insulating positioner caused initially higher impedances compared with impedances of the NP-patients, as shown by the trend in the standard impedance measures, or that this occurred due to fibrosis during the first year as likely in the NP-patients.

In the future, more research has to be carried out to find the factors that have functional implications on speech perception with cochlear implants and in which way those factors can be favorably manipulated in future cochlear implant designs. The patients who are currently being implanted with the long HiFocus 1J electrode connected to the same implanted electronics can help to elucidate the effect of deeper insertion. Furthermore, spatial selectivity measurements with NRI/NRT and studies with an improved computational model can presumably give more insight in the role of spatial selectivity in speech perception and how this spatial selectivity can be influenced by future electrode designs.

The data in the present study influenced the design of future electrodes. We believe that it will be beneficial to have an electrode array, which has insulating silastic along the back of the array at the basal side giving it only basally a perimodiolar position, apically a lateral position and a full insertion depth. The HiFocus4L electrode is a single component implant (Frijns, Briaire, Zarowski, Verbist, & Kuzma, 2004), designed to meet these criteria and to regain the speech perception as was achieved with the perimodiolar array with a partially inserted positioner. The clinical results of the patients implanted with these new devices will help to complete more parts of the puzzle.

CONCLUSIONS

Speech perception is favorably influenced by a basally perimodiolar electrode position. The change in radial distance, insertion depth, and insulating properties probably all contribute to the improved speech perception found with the HiFocus I electrode with separate positioner. These improved speech perception levels should be regained using the insights obtained from the patients implanted with various perimodiolar implants. Further research has to elucidate the individual contributions of the properties of specific perimodiolar designs.

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Effects of parameter manipulations on spread of excitation measured with electrically-evoked compound action potentials

Feddo B. van der Beek, Jeroen J. Briaire & Johan H. M. Frijns

ABSTRACT

Objective

This study investigated the spread of excitation (SOE) profiles derived by eCAP measures and analysed the effects of various parameter settings.

Design

SOE was measured using the forward masking technique (selectivity), as well as with a "fixed stimulus, variable recording" (scanning) technique. SOE profiles were produced at three current levels and at three sites along the array. Additionally, effects of the position of the recording electrodes and artefact rejection methods were studied in five subjects. Furthermore, correlation between SOE data and speech perception data was tested. All data were analysed using linear mixed models.

Study sample

Measurements were performed intraoperatively in 31 users of the Advanced Bionics HiRes 90K cochlear implant.

Results

The selectivity method produced narrower excitation profiles than the scanning method, showing an asymmetry along the array with wider SOE apically. Moreover, the position of the recording electrode shifted the SOE curves towards the recording contact, enhancing asymmetry. Neither significant effects of current level or artefact rejection methods were observed, nor a significant correlation with speech perception.

Conclusions

SOE profiles obtained with the scanning method are wider than with the selectivity method. Both are insensitive to various parameter settings, although selectivity curves are shifted towards the recording contact.

Most currently available cochlear implant (CI) systems use silicone electrode carriers that are positioned in the scala tympani of the cochlea and support typically between 12 and 22 electrodes spread over some 20–30 mm of the cochlea, i.e. about 60%–90% of its total length from the round window. The longitudinal arrangement of stimulating electrodes is designed to retain the tonotopic organization of the cochlea, whereby high frequency components of the incoming acoustic signal are delivered to electrodes near the base and lower frequency components towards the apex. Use of multichannel implants in this way therefore attempts to provide "place-pitch" spectral information, whereas characteristics of the stimulation patterns delivered to individual electrodes provide information on loudness changes over time, i.e. temporal information.

The resolution of the spectral information provided by the CI depends on several factors. One factor is the number of electrodes used or, more specifically, the spacing between them. However, the assumption that the use of more closely spaced electrode contacts might provide greater frequency resolution has not been supported by experimental evidence (Friesen et al, 2001; Frijns et al, 2003). Better electrode discrimination has been shown to be correlated with better speech understanding (Zwolan et al, 1997), but it is clear from experimental studies that use of a larger number of electrodes does not always result in better speech understanding. Indeed, when other parameters are kept constant several studies have found no improvement in speech discrimination in quiet for electrode numbers greater than about seven (Friesen et al, 2001; Garnham et al, 2002; Frijns et al, 2003).

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One likely explanation for this is that every electrode does not necessarily produce a pitch percept that is distinct from the others. As shown by psychometric tuning curves, the regions of neuronal excitation produced by adjacent electrodes overlap significantly, particularly when monopolar stimulation (referenced to a remote electrode outside the cochlea) is used (Boex et al, 2003). Several studies have shown improvements in speech discrimination when such electrodes with considerable overlap are de-activated (Boex et al, 2003; Frijns et al, 2003; Arnoldner et al, 2007). Apart from this limited spatial selectivity, electrical channel interaction also has an influence. Therefore, many strategies, such as continuous interleaved sampling (CIS) attempt to minimize channel interaction by interleaving of the stimulus pulses between channels (Wilson et al, 1991).

A better understanding of the spread of excitation (SOE) in the implanted cochlea would be beneficial in many ways, including the identification of which electrodes to de-activate and to improve electrode design in future cochlear implants. Measuring the SOE can be performed through psychophysical testing (Chatterjee

& Shannon, 1998; Boex et al, 2003; Cohen et al, 2003; Dingemanse et al, 2006; Hughes & Stille, 2008; Nelson et al, 2008), from recordings of the electrically-evoked compound action potential (eCAP) of the auditory nerve (Cohen et al, 2003, 2004; Abbas et al, 2004; Hughes & Abbas, 2006a, 2006b; Klop et al, 2009; Hughes & Stille, 2010), or simulated using computer models (Frijns et al, 2001; Cohen, 2009).

Theoretically, electrodes that produce more localized excitation would be more likely to provide better pitch acuity and less channel interaction. However, previous research showed no correlation between pitch ranking and eCAP SOE (Hughes & Abbas, 2006a).

The attraction of eCAP measurements, in particular, is that these can usually be performed in young children, either intraor postoperatively, whereas psychophysical testing would often be impossible. Even in adults, psychophysical testing can be time-consuming and clinical eCAP procedures can be semi-automated and thereby made straightforward to perform clinically. Thus, it may be possible to identify the electrode contacts with narrower SOE, as part of the goal to identify an ideal subset of electrode contacts in an individual.

eCAP recordings can be used in several ways to evaluate the SOE and are usually made using the back telemetry capabilities of the CI. A relatively basic method (termed "scanning" in this paper) is to stimulate one electrode contact and then measure the evoked response on all the other contacts along the array (Frijns et al, 2002; Cohen et al, 2004) (Figure 1, A). The amplitude profile of the responses thus obtained is not a direct measure of the SOE (as even a very narrow region of excitation can be detected some distance away) but wider regions of excitation would be expected to result in wider scanning profiles. For artefact reduction alternating polarity is incorporated in some clinical fitting software (used with Advanced Bionics cochlear implants), because it is a faster method than the subtraction method with masker and probe (Klop et al, 2004). A theoretically more precise method (termed "selectivity" in this paper) is analogous to the production of psychophysical forward-masking tuning curves, whereby a masker is applied to each electrode contact in turn, while a fixed "probe" contact is stimulated subsequently. The response amplitude indicates the amount of overlap between masker and probe (Figure 1, B). A limitation of this method is that the SOE of an electrode is derived from the neural excitation of two different electrodes (the masker and probe electrode). Residual charge from the masker pulse on the neural membranes of non-excited fibers could potentially change the region responding to the probe pulse, leading to a systematic deviation from the actual region of overlap. Additionally, the SOE of the masker contacts can vary along the array, which will affect the derived SOE of the electrode contact of interest. However, eCAP selectivity curves so produced have been shown to match behaviorally-obtained psychophysical tuning curves (Cohen et al, 2003), which theoretically suffer from the same limitation.

Besides eCAP thresholds, eCAP-derived SOE measures are not a totally accurate reflection of the neural excitation. There are several characteristics of eCAP measures that might account for this. First, the position of the recording contact can affect certain characteristics of SOE measures. One limitation of intracochlear measurements is that the recording electrode needs to be located some distance away from the stimulating electrode contact. As the electrical pulse generated at the stimulating electrode is much larger than the neural response, the stimulus introduces a large artefact when the recording electrode is nearby. Another parameter, which may affect comparisons between different studies, is that not all researchers have used the same position of the recording contact. Indeed, there is even some discrepancy between publications from the same group: Cohen et al (2004) use varying the position of the recording contact as the main principle of what here is called the scanning method to measure SOE, while Cohen et al (2003) show negligible effect of the position of the recording contact. Hughes and Stille (2010) showed generally higher eCAP amplitudes with recording electrodes towards the apical end of the array, in agreement with the scanning data presented by Frijns et al (2002). However, this effect of recording position showed only a limited shift in selectivity measures (Hughes & Stille, 2010).

eCAP-based SOE profiles become wider with increasing current levels. Most SOE measures, however, have been obtained using small numbers of awake CI users (Cohen et al, 2003, 2004; Abbas et al, 2004; Eisen & Franck, 2005; Hughes & Abbas, 2006a, 2006b; Hughes & Stille, 2008). Performing measurements in awake subjects limits the current range that can be used, due to loudness tolerance issues. In line with Abbas et al (2004), the recent study by Hughes and Stille (2010) has shown a significant influence of current levels on SOE, but this was only seen in one third of the measurements. Furthermore, asymmetry in SOE along the array has been reported, but not quantified in detail (Cohen et al, 2003; Hughes & Abbas, 2006b; Cohen, 2009; Hughes & Stille, 2010).

Apart from effects of level, location along the array and recording electrode, comprehensively analysed in a recent study by Hughes & Stille (2010), there are other likely factors potentially influencing the SOE. Some of these factors have to our knowledge not been considered by previous studies, and will additionally be investigated in this study. For selectivity measures the position of the probe is usually fixed and that of the masker varied. It is not known whether the same SOE is obtained if the masker is fixed and the probe varied. Theoretically, one would expect that it would be, since the measurement in both cases is the neural response from the region of overlap between the regions of excitation produced by the masker and the probe. Another parameter which could influence data obtained with scanning measurements is the artefact rejection method used (alternating polarity, or the forward masking method). Two different artefact rejection methods were therefore compared in this study.

To date, no clear correlation between SOE measures and speech understanding has been reported (Hughes & Stille, 2008), but this may have been due to inappropriate statistical methodology. Hughes and Stille (2008) averaged the normalized amplitudes across SOE functions and subsequently performed linear regression to look for correlation between SOE width and individual speech perception scores. However, several parameters, such as the use of different electrode contacts along the array, could have affected the analysed outcome. In order to investigate parameters separately and to quantify the effects of the individual parameters, linear mixed models were used in our study (Fitzmaurice et al, 2004).

The principal aim of the present study was to compare the two eCAP-based methods (scanning and selectivity) to measure SOE using the " neural response imaging (NRI) " system of the Advanced Bionics HiRes 90K implant in a relatively large patient group. More specifi cally, we aimed to identify and quantify parameters that limit the ability of these methods to determine the true excitation area within the cochlea. For this purpose, the scanning and selectivity methods were compared and the effects of several recording param-eters were analysed, including (1) position of the probe electrode (apical, middle, and basal electrodes) and (2) level of the stimulus. Additionally, in smaller subgroups the effects of (3) the position of the recording electrode, (4) masker position fi xed and probe position variable versus probe position fi xed and masker position variable, and (5) artefact rejection method (forward masking or alternating polarity) were analysed. Furthermore, we tested for correlation between selectivity measures and the subjects ' speech perception abilities. All data were taken into account separately, using linear mixed models.

METHODOLOGY

Subject characteristics

Thirty-one subjects were included in the study. All subjects were unilaterally implanted with an Advanced Bionics' HiRes 90K cochlear implant with the HiFocus 1J electrode array, which has 16 contacts spaced 1.1 mm apart. Patient demographics are shown in Table 1, A.

Test procedure

Neural response imaging (NRI) was used to obtain eCAP measurements intraoperatively, during the implantation surgery. Using the bionic ear data collection system (BEDCS) research software, test parameter (electrode contact) sequences were pre-set for the recording of scanning and selectivity series (see below). Parameters used were as follows: monopolar biphasic pulses, cathodic first; pulse duration: 32 μs/phase; masker-probe interval: 500 μs, sampling rate: 56 kHz; gain: 300; 32 averages. If eCAPs could be observed then no adjustments in settings were made during the measurement series. Five patients, in who no eCAPs were seen in BEDCS intraoperatively, were not included in the study. It is important to notice that their demographic characteristics, however, were not essentially different from the study group.

Scanning and selectivity measures

Scanning measures (Figure 1, A) were obtained by stimulating one electrode contact (masker and probe at a single contact) and recording the eCAP response sequentially at all other locations along the array (Cohen et al, 2004). Forward masking was used for artefact rejection, but for a subset of five subjects the alternating polarity method was also used for artefact rejection at the stimulating electrode (raw waveforms with forward masking and alternating polarity are shown in Figure 1, C). The numbers of subjects tested with the different parameter settings for scanning and selectivity measurements are summarized in Table 1, B.

Selectivity measures (Figure 1, B) were obtained by using a traditional forward masking technique as described previously (Cohen et al, 2003). All subjects were tested with the masker contact fixed and eCAP amplitudes measured for different probe electrode positions, which were stimulated after a 500 μs interval.

Table 1. A: Patient demographics. B: The numbers of subjects per scanning measure are shown using the forward masking artefact rejection scheme and with the alternating polarity artefact rejection method. For selectivity measures the numbers of subjects are shown where the position of the masker or probe electrode was fixed, and which recording electrode was used relative to the probe electrode.

A

Patient demographics	
Age (years)	35 (average range 1–86)
Duration of deafness (years)	9.8 (average range 0.1–47)
Sex	16 male / 15 female
Child/Adult	12 C / 19 A
Implant type	HiRes 90K HiFocus 1J
Aetiology	progressive/congenital (17), meningitis (8), rubella (2), trauma (2), sudden idiopathic (1) and osteogenesis imperfecta (1)

B

Measure	*Modification*	*Subjects (n)*
Scanning	Forward masking	29
	Alternating polarity	5
Selectivity	Masker position fixed, recording 2 contacts apical	28
	Masker position fixed, recording 2 contacts basal	5
	Probe position fixed, recording 2 contacts apical	5
	Probe position fixed, recording 2 contacts basal	5

Raw wave forms are shown in Figure 1, D. The recording electrode contact was set two contacts apical to the fixed masker contact (as Abbas et al, 1999) and in five patients the recording contact was additionally set two contacts basal to the masker. In this subset of five subjects the measurements were repeated with the probe position fixed and the masker position varied. Subjects for all subsets were chosen on the basis of chronological order and included both children and adults.

Both selectivity and scanning measures were performed at three points along the array. Measurements were obtained at an apical electrode (EA, electrode 3 or 4), a middle position (EM, electrode 7, 8, or 9), and a basal position (EB, electrode 13, 14, or 15). Additionally, for all methods and electrode contact positions, measurements were performed at three different current levels. The effect of masker and probe levels were compared between the current ranges: low (0.6–0.8 mA), medium (0.9–1.0 mA), and high (1.2 mA). Note that these measurements could only be performed in patients under general anesthesia, as even the "low" level used is in the upper range of the electrical dynamic range found in normal clinical practice M-levels. This is due to an inherent noise limitation of current eCAP recording systems, which do not allow SOE measures to be made at stimulus levels around subjective thresholds.

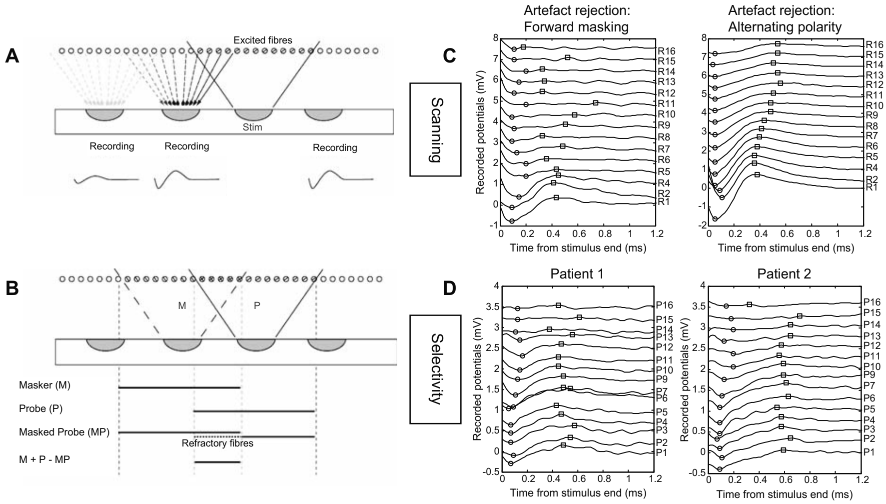

Figure 1. A: For scanning measures a single probe electrode contact is stimulated (Stim) and the response is recorded at all electrodes individually. Recordings at electrodes further away from the stimulating electrode results in lower eCAP amplitudes (shown below electrode array). B: Selectivity measures are made by stimulating a masker electrode contact (M) immediately before the probe contact (P). The neural population stimulated by the masker will then be in a refractory state when the probe is activated, so that the response to the probe will be reduced in proportion to the amount of overlap. When the measurements of masker alone and probe alone are summed and the measurement of masker and probe combined is subtracted (M + P - MP) the eCAP measurement will show the overlap between the cochlear region excited by M and P. C & D: Raw waveforms of individual patients are shown with detected peaks marked (N1, circles; P1, squares). C: waveforms of an individual patients' scanning data using the forward masking and the alternating polarity artefact rejection method. Each waveform labeled with corresponding recording electrode (R1, R2, R3…). D: waveforms of selectivity data from two individual patients (as always in selectivity measurements a forward masking technique was used). Each waveform labeled with the corresponding position of the probe (P1, P2, P3…).

Speech perception

Speech discrimination scores were obtained for all 19 adult cochlear implants users in the study group during normal clinical follow-up at predetermined intervals, starting one week after initial fitting. The data used for analysis in this study were the scores obtained at two years of follow-up. Four patients had to be excluded from the analysis, one patient since he was deceased (of a natural cause) 1.5 years after implantation, one prelingually deaf patient, and two patients for whom only scanning data and no selectivity measures were available. All subjects used the HiRes processing strategy. The standard Dutch speech test of the Dutch Society of Audiology, consisting of phonetically balanced monosyllabic (CVC) word lists, was used (Bosman & Smoorenburg, 1995). To improve test reliability, four lists (44 words) per condition were administered. Although this test is typically scored with phonemes in the Netherlands and Flanders, the data are shown as word scores, which is a more common reporting method in Anglo-Saxon countries. All testing was performed in a soundproof room, using a calibrated loudspeaker in frontal position at one metre distance. Subjects were tested in quiet at speech levels of 65 dB SPL in a CI-only condition.

Analysis

Signal processing was performed off-line using Matlab. eCAP amplitudes were automatically detected using Matlab software (as per Frijns et al, 2002) and plotted against the electrode positions along the array. Curves that did not show eCAP amplitudes above 0.1 mV were not included in the analysis. This criterion was not reached in 16% of the responses, mainly in the low current range. The average of the peak amplitude, for both selectivity and scanning, was 0.6 mV. The curves were normalized by taking the value at the electrode contact of interest and dividing all values along the array by this value. Next, both flanks of the selectivity and scanning curves were fitted by a 4th order polynomial.

The width was defined as the number of electrode contacts (spaced 1.1 mm apart) from the stimulated contact to the point at which the normalized amplitude reduces to 0.6. For the middle contact both the width in the apical (EM-A) as well as the basal direction (EM-B) were calculated. In cases where the minimum value did not drop to 0.6 the width was set as the limit of the array in the apical or basal direction (as per Abbas et al, 2004). In previous studies both 50% and 75% of the peak amplitude have been used as a measure of the width of the region of excitation (Cohen et al, 2003; Hughes & Abbas, 2006a). For this study, 60% of the peak amplitude, determined on the basis of the fitted, normalized curves, was selected as a trade-off between obtaining as many curves as possible and being able to measure differences between distinctive profiles along the array.

Figure 2 shows typical selectivity curves recorded in one subject. The figure shows the normalized eCAP amplitudes obtained at the three current levels. A horizontal line indicates 60% of the amplitude. The horizontal solid arrows then indicate the width of the curve (in basal or apical direction) as defined above for the highest current level.

Statistics

The design of this study is basically a within-patient analysis with three factors, which means that at the patient level the measurements are correlated. So-called linear mixed models take this correlation into account, by considering the responses from a subject to be the sum of so-called fixed effects, affecting the population mean, and random effects, associated with a sampling procedure (e.g. subject effects). The random effects often introduce correlations between cases and should be taken into account to elucidate the fixed, population affecting, effects. The SE (standard error of the mean) generated by the model is used in significance analysis. Using linear mixed models enables investigation of the effects of each parameter separately as well as the interaction between different parameters. Furthermore, linear mixed models can effectively use all data, even when one or more data points are missing (Fitzmaurice et al, 2004). In the present study SPSS 16.0 was used to construct mixed linear models to address the influence of the measuring technique, the electrode position, and the current level separately. For significance levels in this study t-tests are used, both in the context of descriptive statistics as well as with linear mixed models.

To create a comprehensive overview data are plotted in boxplots. However, it should be noted that boxplots

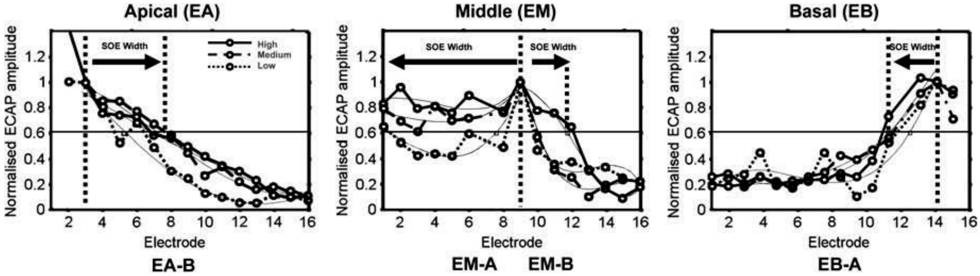

Figure 2. Selectivity curves obtained in one subject, in response to stimulation at the apical electrode contact (EA, left), middle contact (EM, middle) and basal contact (EB, right). The figures show the normalized response amplitudes recorded from locations along the array, using low (dotted line), medium (dashed line), and high (solid line) current levels, together with the 0.6 criterion line. The width of the curve is then defined by the number of electrodes above the 0.6 line (indicated by arrows) for apical electrode in basal direction (EA-B), middle electrode in apical and basal direction (EM-A, EM-B), and basal electrode in apical direction (EB-A). The location of electrode of interest (dotted line over full figure height) and position where curve meets the 0.6 criterion (dotted line over half figure height) are indicated.

are not completely matching the analysis with mixed linear models, which take missing data points into account.

For analysis of subsets of data, three additional linear mixed models were constructed with only data of the fi ve subjects tested in the subset. Besides the comparison of scanning versus selec-tivity measures, these subsets included the analysis of selectivity measures alone as well as the measurements with the recording contact at apical or basal position, and with the masker or probe fi xed. Additionally, a subset with data on artefact rejection method in scanning was analysed. Furthermore, a mixed linear model was constructed in which the patients ' speech perception was compared with their selectivity widths measured with the apical recording position. Using a mixed linear model made it possible to take the current level and location along the array into account in the analysis with speech data.

RESULTS

Comparison of scanning vs. selectivity

Figure 3 shows boxplots for scanning (upper panels) and selectivity (lower panels) measures at the apical (EA-B), middle in apical and basal directions (EM-A and EM-B respectively), and basal (EB-A) electrodes, measured at three different current levels (low, medium, and high).

The majority of curves (95% for selectivity and 75% for scanning) met the 0.6 criterion. However, for the curves of the middle electrode contact in the apical direction this criterion was often not met (42% for scanning and 14% for selectivity). The curves that did not meet the 0.6 criterion were set as the limit of the array in the apical or basal direction (as per Abbas et al, 2004).

Descriptive statistics, showing the means and differences of scanning and selectivity along the array, are summarized in Table 2. The calculated linear mixed model, containing data of 31 different subjects (for 26 subjects, measures of both scanning and selectivity were obtained, for three subjects only scanning data, and for two subjects only selectivity measurements), confirmed differences in the width of curves obtained using the two methods. Scanning produced significantly wider curves than selectivity (mean 7.4 contact spacing (SE 0.26) vs. 4.7 spacing (SE 0.27), $p < 0.01$). An example of scanning and selectivity curves in a typical subject is shown in Figure 4, A. The influence of the method was largest for basal and apical contacts and less prominent for the middle contact in the apical direction (Table 2). No factor associated with the outliers as seen in Figure 3 could be identified.

Comparison along the array

A second linear mixed model was constructed that included only the selectivity measurements (i.e. excluding the scanning data) of 28 subjects in order to examine the effect of stimulating electrode contact position on this SOE measure. This model confirmed the differences in curve width along the array for the selectivity measure as shown in Table 2. The curves of EM-A were the widest, followed by the EA-B, EB-A, and EM-B. Taking EA-B as a reference, EM-A was 1.0 contact spacing wider (SE = 0.38, $p = 0.01$), EM-B was 2.0 contacts narrower (SE = 0.38, $p < 0.01$), and EB-A was 1.2 contacts narrower (SE = 0.41, $p < 0.01$). These effects are illustrated in Figure 2, which shows a typical example in an individual patient. Levels of significance for the differences found are shown in Table 3.

Table 2. Descriptive statistics including mean widths in terms of electrode contacts for scanning (top rows) and selectivity (lower rows) for the different electrode contact locations (with standard deviations). Significance levels are shown in the bottom row. Data shown are descriptive statistics and are incorporated in the linear mixed model for further analysis of separate parameters, which are described in the Results section.

	EA-B	*EM-A*	*EM-B*	*EB-A*
Scanning				
Mean	8.2	6.8	5.9	9.0
Std. Dev.	4.0	1.1	2.4	3.6
Selectivity				
Mean	5.3	6.3	3.3	4.2
Std. Dev.	3.5	2.5	1.8	2.8
Significance	$p < 0.01$	$p < 0.1$	$p < 0.01$	$p < 0.01$

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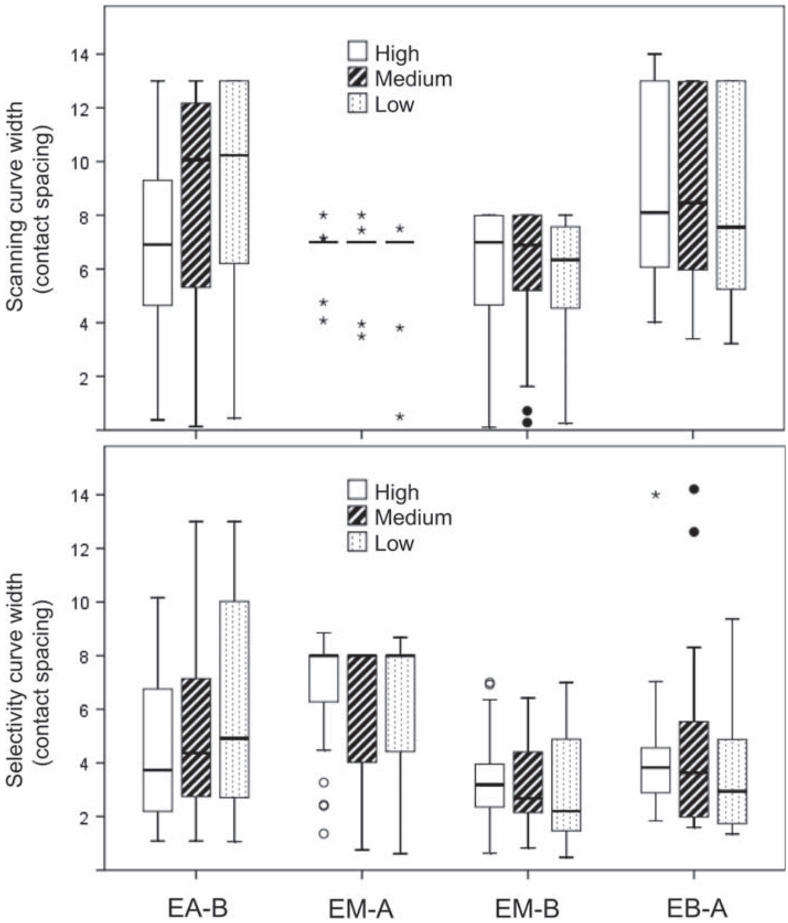

Figure 3. Boxplots of SOE measurements. The top row shows the scanning measurements at the different electrode positions EA-B (apical), EM-A (middle in apical direction), EM-B (middle in basal direction), and EB-A (basal) with the widths measured at three current levels, low, medium, and high. The lower figure shows the corresponding selectivity measures. The boxes represent the interquartile range (IQR, i.e. 25%–75%), with the median indicated by a horizontal line. The ends of the whiskers represent the lowest data point still within 1.5 IQR of the lower quartile, and the highest data point still within 1.5 IQR of the upper quartile. Outliers (indicated with a circle) are cases with values between 1.5 and 3 times the IQR, and extremes (indicated with an asterix) are cases deviating more than 3 times the IQR.

Current levels

Before normalization, the eCAP amplitude obtained at different current levels varied consistently by a factor of up to two between the low and the high current level in almost all patients. Informal inspection of the data in Figure 3 suggests that while there was a large spread in the widths obtained in different subjects, the majority of individual subjects produced curves of similar width with different stimulus levels. There were, however, some notable exceptions, some subjects showing large changes in curve width with changing stimulus level.

In some cases the highest current level indeed produced the widest curves. In Figure 4, B, an example of an individual patient is shown for the middle electrode. For this individual patient the SOE is wider for the highest current level compared to the lower current levels. However, across all subjects the second linear mixed model showed that the curve widths of the medium and high intensity were not significantly different from those found at the low intensity (p = 0.5, and p = 0.8 respectively).

Recording electrode

The third linear mixed model with data of fi ve subjects (summa-rized in Table 4) revealed signifi cant effects of the recording site on the width of the selectivity measures. Generally, the curves tended to shift in the direction of the recording electrode. For the apical electrode (EA-B) the width was 1.5 contact spacing smaller when measured apically compared to basally, and for the basal electrode (EB-A) the width was 1.7 contacts wider when measured apically. The results from the electrode in the middle of the array (EM) did not show signifi cant differences between the recording contacts.

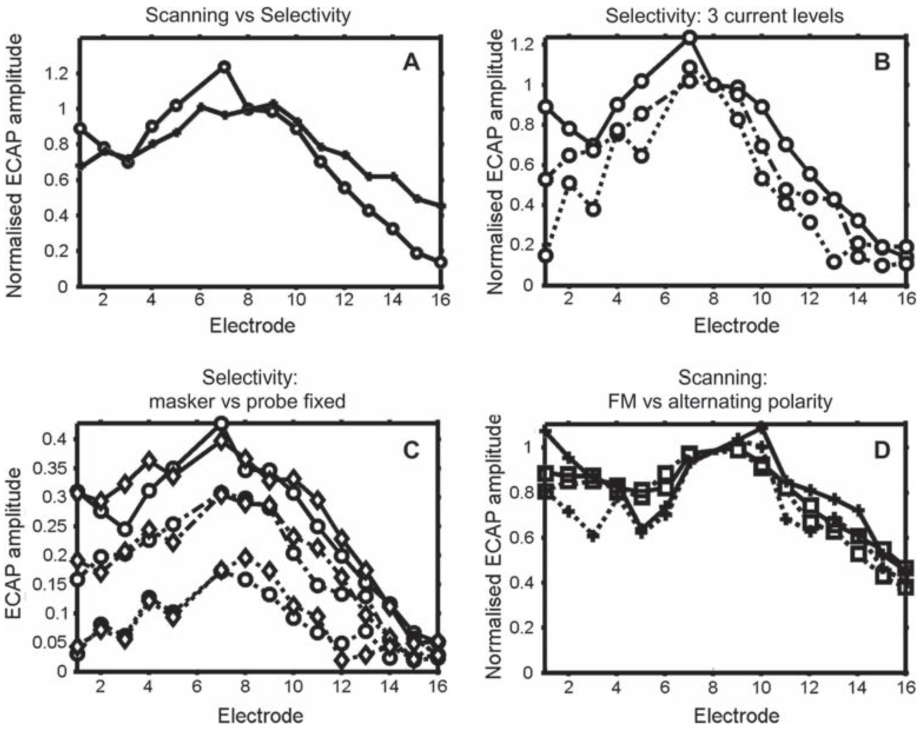

Figure 4. A: Curves showing normalized eCAP amplitudes obtained using scanning (solid symbols) and selectivity measures (open symbols) in one representative subject. B: Selectivity curves at the middle electrode position for three current levels (Low: dotted line; Medium: dashed line; High: solid line). C: Selectivity curves in one representative subject with masker electrode fixed (circles) and probe fixed (diamonds) at the three current intensities (Low: dotted line; Medium: dashed line; High: solid line). Note that the eCAP amplitude is not normalized in C in order to illustrate level effects on the eCAP amplitude. D: Scanning curves obtained using the forward masking (plus sign) and alternating polarity (square) artefact rejection scheme at High (solid lines) and Medium (dashed lines) intensities.

Table 3. Significance (p-value) of difference in width of selectivity measures along the array (t-statistic and degrees of freedom between brackets).

Selectivity	*EA-B*	*EM-A*	*EM-B*	*EB-A*
EA-B				
EM-A	$\mathbf{p = 0.01}$ ($t = 2.56$; $dF = 289.7$)			
EM-B	$\mathbf{p < 0.01}$ ($t = -5.43$; $dF = 289.7$)	$\mathbf{p < 0.01}$ ($t = -7.95$; $dF = 289.3$)		
EB-A	$\mathbf{p < 0.01}$ ($t = -2.86$; $dF = 292.2$)	$\mathbf{p < 0.01}$ ($t = -5.21$; $dF = 291.2$)	$\mathbf{p = 0.03}$ ($t = 2.17$; $dF = 291.2$)	

Masker or probe fixed

In five subjects two sets of selectivity measures were performed, one with the position of the masker fixed and one with the probe contact fixed. Apart from some outliers at EB-A, the widths along the array and for different current levels showed similar profiles. Figure 4, C, illustrates the small differences in masker-fixed versus probefixed curves across location and current level in a typical subject. The third linear mixed model using the data of all five subjects is summarized in Table 4. Results showed very similar curve widths for masker or probe position fixed for all electrode contacts (mean differences 0.3 to 0.2 spacing, not significant).

Artefact rejection method

A linear mixed model was generated using the data from the five subjects in which the scanning measurements were performed using the forward masking and the alternating polarity artefact rejection schemes. The curves of those subjects showed the same shape for both methods, as illustrated by an example in Figure 4, D, and differences did not reach significance levels.

Table 4. Mean differences between widths (contact spacing) obtained for selectivity measures with the masker fixed or the probe fixed, with significance (Sig.) levels (left columns). The right columns list the mean differences (with significance levels) of the widths obtained with the recording contact 2 apical or 2 basal relative to the contact of interest.

Measure	*Difference masker vs. probe fixed (contact spacing)*	*Sig.*	*Difference apical vs. basal recording (contact spacing)*	*Sig.*
EA-B	−0.3	0.62	−1.5	<0.01
EM-A	0.2	0.75	1.0	0.08
EM-B	−0.2	0.69	−0.01	0.99
EB-A	−0.3	0.60	1.7	<0.01

Selectivity vs. speech perception
The average monosyllabic word score at two year follow up in the 15 adult CI-recipients in this study was 62% words correct (range 20%–91%). A final linear mixed model, containing the data of the 15 persons with selectivity data and speech perception data showed that no significant prediction could be obtained for speech perception using the width of the selectivity curves, taking location along the array and current level into account (p = 0.3).

DISCUSSION

No study has been able to verify the hypothesis that eCAP derived SOE measures are correlated with speech understanding (Hughes & Abbas, 2006b; Hughes & Stille, 2008). In line with this, no correlation was found in the present study. Theoretically, SOE would be expected to correlate with spectral resolution, which is an important component of speech recognition. The principle aim of this study, therefore, was to analyse the variables influencing SOE measures, which might indicate possible reasons for this lack of correlation. Two fundamentally different methods of measuring SOE were compared and the effects of several variables presumed to influence SOE were investigated.

The finding that scanning produces wider curves than selectivity measures has been previously reported by Cohen et al (2003) and Hughes & Stille (2010), and is in line with theoretical expectations. This can be explained as follows: in the scanning method, where recordings are made at several points along the electrode array, the current from the stimulating contact (i.e. stimulus artefact) and the current generated by the nerve fi bers (neural response) both spread easily through the fl uid of the cochlea and result in a potential at the recording electrode some distance from the stimulating contact. The selectivity method, however, using a fi xed recording contact mainly shows the spread of excitation of the stimulating pulse. Wider curves for scanning were evident at all positions analysed with the excep-tion of the middle contact measured in the apical direction. This exception is likely a consequence of the method and due to the fact that many curves for both methods did not reach the 0.6 criterion. The rationale for the choice of this 0.6 criterion was covered in the methodology section. The limitation of the method resulted in the introduction of arbitrary, fi xed values at the ends of the array as proposed by Abbas et al (2004) and complicated comparison along the array and across subjects. shows the spread of excitation of the stimulating pulse. Wider curves for scanning were evident at all positions analysed with the exception of the middle contact measured in the apical direction. This exception is likely a consequence of the method and due to the fact that many curves for both methods did not reach the 0.6 criterion. The rationale for the choice of this 0.6 criterion was covered in the methodology section. The limitation of the method resulted in the introduction of arbitrary, fixed values at the ends of the array as proposed by Abbas et al (2004) and complicated comparison along the array and across subjects.

Recorded responses are larger when the recording contact is close to the responding neural fibers. The presence of a significant shift in the SOE illustrates that, for both scanning and selectivity measures, the outcome is to some extent influenced by current spread from the fibres towards the recording contact, leading to a skewing of the SOE curve towards the recording electrode. Consequently, it was evident that apical recordings (i.e. with the recording electrode apical to the fixed probe or masker) shift the recorded flank of the SOE curve apical-wards, and basal recordings basal-wards. As a consequence, the data presented here (which have mainly been recorded from an apical position) show a shift of the SOE in the apical direction, resulting in a smaller SOE width for EA-B (Figure 2) and an increase in SOE width for the EB-A condition (Table 4). In contrast, the middle electrode (EM) did not show such a clear shift. However, this may be because most of the EM-A curves did not reach the 60% criterion resulting in arbitrary, fixed values, reducing the possibility of showing the effect of the recording locations.

Our findings are in contrast to data presented by Cohen et al, who reported little overall difference between selectivity recordings made apically or basally (Cohen et al, 2003, 2004). And although Hughes and Stille (2010) describe that for recording positions equidistant from the probe, amplitudes were generally larger when recorded from the apical side, only in a small minority of cases different recording positions resulted in a significant shift in selectivity measures. There is also a lack of consistency in other previous studies. eCAP measurements have sometimes been obtained from apical recordings (Busby et al, 2008), sometimes from basal recordings (Lai et al, 2009), and sometimes not clearly specified (Cohen, 2009). This lack in consistency in the use of recording contacts makes interpretation of conclusions about SOE measurements difficult.

For the selectivity measures, asymmetry along the array was seen, with wider SOE functions at the apical contact than at the basal contact (Table 2). This is generally in agreement with other studies (Eisen & Franck, 2005). Moreover, in line with previous research, an asymmetry in the middle of the array was evident (Cohen et al, 2003; Cohen, 2009). However, asymmetry in the middle part does not imply an asymmetry in the neural excitation (Cohen, 2009). This can be explained as follows: the forward masking paradigm measures overlap of excitation produced by different contacts. This overlap consists of neurons excited by the contact of interest (the probe) and neurons excited by the masker. If the width of the pattern of excited nerve fibres is not constant along the array, but wider in the apex than in the base, then the overlap of a probe in the middle with an apical masking contact would be larger than with a basal masking contact. The resulting SOE curve would thus become asymmetric towards the apex, as is seen in the data of the present study. Psychophysical experiments of SOE determine thresholds of masking and are thus theoretically less influenced by the width of excitation of the masking contact. Accordingly, psychophysically obtained forward masking curves have shown no significant asymmetry (Cohen et al, 2004; Nelson et al, 2008). The differences between the SOE seen in the apical and basal parts of the cochlea may relate to the smaller distance to the modiolus or a smaller volume of the apical cochlea. Alternatively, a larger SOE apically could be due to crossturn stimulation, which is known to be more likely apically where the cochlea is more tightly coiled (Frijns et al, 2001). These factors caused by the tapered morphology of the cochlea may produce a truly asymmetric excitation of nerve fibers. Such real asymmetric spreading of excitation is, however, enhanced by limitations of the recording methodology.

The use of tonotopy is one of the key contributing factors to the speech perception potential of multichannel cochlear implants. Theoretically, a well controlled, limited SOE would allow for more independent information channels, which could ultimately lead to better speech understanding. Unfortunately, like other studies (Hughes & Abbas, 2006a; Hughes & Stille, 2008) we were not able to demonstrate any significant correlation between SOE and speech perception. In this perspective it is worthwhile to reconcile the fact that the data in the present study were obtained at high current levels, and that we observed no inter-level differences in excitation width for normalized data. Nevertheless, the eCAP amplitudes obtained at these current levels varied by up to a factor of two between the low and the high current levels, suggesting that the response was not in saturation. However, in some individual cases with low noise levels and relatively large eCAP amplitudes, a clear decrease in SOE width could be seen with decreasing current levels. Surprisingly, these findings do not confirm previous research that was able to demonstrate level effects on SOE in patients, tested at the upper portion of the behavioral dynamic range (Abbas et al, 2004; Hughes & Stille, 2010). For the subjects of our study measurements at current levels used in daily use may show narrower SOE curves, but with present hardware limitations (especially system noise levels) it was not possible to test this hypothesis by measuring at low current levels.

Additionally, the fact that intraoperatively derived eCAP SOE measures are compared with speech perception measured two years later could account for the lack of correlation. eCAP measures are known to change over time (Hughes et al, 2000, 2001; Gordon et al, 2004) and SOE measured at the same time as the speech perception test would have given additional information. Unfortunately, however, it turned out to be not feasible in our clinical setting to re-assess SOE in the same patient group two years postoperatively.

For the selectivity curves this study showed no significant differences between a roving masker (with fixed probe) position and roving probe (with fixed masker). This is in agreement with theoretical expectations as both probe or masker fixed should measure the same overlap between the areas excited by masker and probe and should therefore give the same response. The advantage of the first condition is that the distance between recording electrode and probe is constant, stabilizing possible artefacts in the recorded response. On the other hand, with a roving probe the distance of the probe to the recording contact is larger at locations remote from the contact of interest (i.e. the masker contact), resulting in a reduced artefact interference. The conformity in response with probe or masker fixed indicates that SOE curves are relatively robust in relation to artefacts and other secondary effects.

In contrast to selectivity, scanning allows both forward masking as well as alternating polarity as the artefact rejection method. The choice of method did not appear to affect the widths of the recorded scanning curves. The alternating polarity artefact rejection takes slightly less time and is used in clinical practice (with Advanced Bionics cochlear implants), but has the disadvantage of averaging different latencies produced by anodal and cathodal stimuli (Klop et al, 2004). This effect of averaging latencies has a noticeable effect on individual eCAP amplitudes and waveforms, but evidently has limited effect when relative amplitudes are compared in SOE measurements. This limited effect on SOE measures may make scanning data using different artefact rejecting methods comparable in future research. However, for a final answer with respect to the comparability of the artefact rejections methods further research is indicated.

The large range in age and duration of deafness suggests that at least some difference in surviving nerve fibers would be present among the patients, which, in turn, could affect the SOE results. As these parameters turned out not to correlate significantly with our data (age, $p = 0.8$; duration of deafness, $p = 0.5$), it is concluded that they do not play a major role in explaining differences in SOE found in this study.

CONCLUSIONS

The main conclusions from our analysis of 31 subjects are that broader excitation profiles are measured using the scanning method compared to the forward masking technique. Secondly, along the electrode array an asymmetric SOE is seen, with wider spread apically. Thirdly, at high stimulation levels no clear effect of level on SOE was observed. Additionally, in this study no correlation between the width of SOE curves and speech understanding could be seen. With respect to the recording parameters, even in a subgroup of five patients it was possible to demonstrate that the choice for position of the recording contact influences the measurement of the SOE, shifting the curves towards the recording contact and enhancing measured asymmetry. Furthermore, a relative robustness of measurements was indicated by the facts that (1) for the selectivity measures no significant effect of the choice of fixed or varying probe was observed, and (2) comparable data could be obtained with different artefact rejection routines for scanning. However, the latter conclusions were based on the analysis of subgroups of just five patients each. To make a definitive statement on these two issues, a further study in larger patients groups is warranted.

ACKNOWLEDGEMENTS

The authors like to thank Ron Wolterbeek for statistical advice, Paul Boyd for language editing, Peter-Paul Boermans for ongoing support, and Advanced Bionics Corp., Valencia, California, USA and the Heinsius Houbolt Fund, The Netherlands for financial support. The data were presented under the title 'Effects of parameter manipulations on spread of excitation measured with electricallyevoked compound action potentials' at Objective Measures in Auditory Implants: 6th International Symposium, September 23, 2010, St Louis, Missouri, USA.

Declaration of interest

The authors report no conflict of interest. The authors alone are responsible for the content and writing of this paper.

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5

Population-Based Prediction of Fitting Levels for Individual Cochlear Implant Recipients

Feddo B. van der Beek, Jeroen J. Briaire & Johan H. M. Frijns

ABSTRACT

Objectives

This study analyzed the predictability of fitting levels for cochlear implant recipients based on a review of the clinical levels of the recipients.

Design

Data containing threshold levels (T-levels) and maximum comfort levels (Mlevels) for 151 adult subjects using a CII/HiRes 90K cochlear implant with a HiFocus 1/1 J electrode were used. The 10th, 25th, 50th, 75th and 90th percentiles of the Tand M-levels are reported. Speech perception of the subjects, using a HiRes speech coding strategy, was measured during routine clinical follow-up.

Results

T-levels for most subjects were between 20 and 35% of their M-levels and were rarely (<1/50) below 10% of the M-levels. Furthermore, both Tand M-levels showed an increase over the first year of follow-up. Interestingly, levels expressed in linear charge units showed a clear increase in dynamic range (DR) over 1 year (29.8 CU; SD 73.0), whereas the DR expressed in decibels remained stable. T-level and DR were the only fitting parameters for which a significant correlation with speech perception ($r = 0.34$, $p < 0.01$, and $r = 0.33$, $p < 0.01$, respectively) could be demonstrated. Additionally, analysis showed that Tand M-level profiles expressed in decibels were independent of the subjects' across-site mean levels. Using mixed linear models, predictive models were obtained for the Tand M-levels of all separate electrode contacts.

Conclusions

On the basis of the data set from 151 subjects, clinically applicable predictive models for Tand M-levels have been obtained. Based on one psychophysical measurement and a populationbased Tor M-level profile, individual recipients' Tand Mlevels can be approximated with a closed-set formula. Additionally, the analyzed fitting level data can serve as a reference for future patients.

INTRODUCTION

Defining stimulation levels in cochlear implant recipients is an essential part of the fitting procedure. It becomes an increasingly time-consuming task for cochlear implant centers due to the increasing number of recipients. Moreover, particularly in children or complicated cases, this process is based on behavioral responses and therefore strongly depends on the audiologist's experience. It is well known that threshold and maximum levels vary considerably between recipients [Wesarg et al., 2010], and a lot of effort is put into obtaining these levels, mostly using multiple behavioral or objective measurements of the individual recipient. Although the number of cochlear implant recipients has risen dramatically over the years, average mean levels along the array were, to our knowledge, only published for Nucleus (Cochlear, Sydney, N.S.W., Australia) implant recipients [Wesarg et al., 2010], and a widely applicable reference of levels and level profiles is lacking. For the present study, a data set of levels for 151 adult subjects using a CII/HiRes 90K cochlear implant (Advanced Bionics, Sylmar, Calif., USA) has been obtained. Threshold levels (T-levels) and maximum comfort levels (M-levels) were analyzed, looking for ways to generate generally applicable level profiles. Moreover, it was investigated whether this data set could serve as a reference for determining levels during initial and follow-up fittings. This knowledge could especially be helpful in children or other difficult cases not providing proper feedback.

The fitting process increased in complexity over the years due to the increasing number of parameters which can be varied, but defining the threshold and maximum levels continues to be its core. Although levels are implemented differently for each cochlear implant manufacturer and different units and names are used, an upper limit for electrical stimulation per active electrode contact is always defined. For readability, all maximum and most comfortable levels will be referred to as M-levels throughout this manuscript.

In an attempt to produce a reasonably automated prediction of levels and facilitate the fitting process, many studies have investigated whether objective measures such as evoked stapedius reflex threshold (eSRT), auditory brain stem response (eABR) or compound action potential (eCAP) could predict the Tand M-levels or level profiles [Shallop et al., 1991; Mason et al., 1993; Brown et al., 1994, 1999; Hodges et al., 1999; Brown et al., 2000; Allum et al., 2002; Seyle and Brown, 2002; Smoorenburg et al., 2002; Brown, 2003; Gordon et al., 2004; Cafarelli et al., 2005; Caner et al., 2007; Miller et al., 2008; Alvarez et al., 2010; Botros and Psarros, 2010; Jeon et al., 2010]. The general conclusion of these studies is that objective measures can be indicative of levels, but unfortunately, significant correlations between eSRT, eABR and eCAP measurements and Tand M-levels were shown to be of moderate strength and not appropriate for predictions in individual users. Some studies found a substantial correlation of the level profile with the eCAP profile (r = 0.82) [Smoorenburg et al., 2002], but this could not be confirmed by others [Cafarelli et al., 2005; Abbas et al., 2006]. The eCAP thresholds are routinely above behavioral thresholds but not always below maximum comfort levels [Miller et al., 2008]. Thus, one should be careful not to overstimulate when fitting M-levels on the basis of eCAP measures. Although more difficult to measure than eCAPs, some groups advocate the use of eSRTs in order to avoid overstimulation when determining M-levels

[Allum et al., 2002; Gordon et al., 2004; Caner et al., 2007]. Currently, in most clinics, eCAPs replaced eABR measurements for practical reasons. Despite all efforts, however, automated fitting based on objective measures has not replaced the traditional behavioral method in daily practice.

Since automated prediction of levels cannot be obtained and objective measures can only provide guidance for fitting, behavioral information is used. To speed up the fitting procedure, the amount of behavioral information is routinely reduced. For instance, the commonly used monopolar stimulation mode shows less across-site variation than bipolar stimulation, providing relatively flat profiles along the array, making interpolation feasible [Pfingst et al., 2004]. For fitting, M-levels can be obtained on some electrodes, and the levels of the intermediate electrodes are based on interpolation [Plant et al., 2005] or on the aspect of the live-voice stimuli [Smoorenburg, 2007]. Although generally yielding a significantly lower speech perception, flat M-profiles appear to be useful, especially in children or other recipients who are not able to provide reliable behavioral feedback [Boyd, 2010].

Also for the T-levels, behavioral levels can be applied and interpolation used for time saving. Alternatively, the T-levels are sometimes set at 10% of M-levels (in fact, it is the default in the SoundWave fitting suite for the CII/ HiRes 90K implant) or even at 0 μA. This minimization of T-levels does not create a decrement in speech understanding [Spahr and Dorman, 2005; Boyd, 2006], although T-levels can be of importance in more challenging listening circumstances as in soft speech [Holden et al., 2011].

Govaerts et al. [2010] recently proposed an automated fitting procedure, based on clinical level data, further adjusting those levels using psychoacoustic test results. In this approach, fitting is not solely based on comfort, as is common in clinical practice, but rather is outcome driven. Although this would be interesting, the authors did not yet publish the statistical data concerning their population levels, nor the correlation between psychoacoustic test results (e.g., pure-tone and speech audiometry, loudness scaling) and fitting levels. The idea of an outcomedriven fitting is consistent with the fitting procedure used in our clinic, where, during fitting, emphasis is given to the higher frequencies by introducing a slightly upsloping M-level profile towards the basal electrodes [Briaire, 2008]. This approach was based on experience with hearing aids, where increases in high-frequency information led to improved speech understanding in noise [Versfeld et al., 1999].

Despite the enormous research effort applied to obtain simple fitting procedures and the large amount of time spent by audiologists in programming numerous cochlear implant recipients, no large data sets of recipient levels are published with the intent to offer normative data. However, Wesarg et al. [2010] and Smoorenburg [2007] analyzed large data sets of Tand M-levels of Nucleus implant recipients to investigate parameters that determine those levels. Tand M-levels are shown to vary considerably, but the dynamic range (DR) was, on average, 50 current levels (SD 20) in Nucleus 22 (bipolar stimulation) [Bento et al., 2005] and Nucleus 24 cochlear implant users (monopolar stimulation) [Wesarg et al., 2010]. This means that the thresholds were about 9 dB lower than the M-levels, i.e., the T-levels were on average at 35% of the

M-levels. Pfingst and Xu [2005] reported a strong correlation between DRs within subjects with bipolar or monopolar stimulation and showed a mean DR of 8.1 dB for those using monopolar stimulation. Although some level data concerning MED-EL recipients were published [Sainz et al., 2003; Boyd, 2010], no T-level distribution or DR could be derived from these studies. Bonnet et al. [2012] reported a T-/M-level ratio between 14 and 21% (8.5–6.8 dB DR) for CII/HiRes 90K implants, depending on the rate used.

During the initial period of cochlear implant use, regular fittings are common, but thereafter, fitting can also be necessary – and, indeed, changes over time in levels have been described. Smoorenburg [2007] reported increases in Tand M-levels for both adults and children. In contrast to Smoorenburg [2007], Walravens et al. [2006], Hughes et al. [2001] and Wesarg et al. [2010] showed stable T-levels in adults after initial fitting. In children, Hughes et al. [2001] showed that Tand M-levels continued to increase months after implantation and first fitting. The eCAP thresholds also increased over time, suggesting changes beyond simple learning effects [Hughes et al., 2001]. Zwolan et al. [2008] and Henkin et al. [2006] showed increases in M-levels for children, with the largest increase in the first months. No comparable quantification of change in levels over time can be distilled from the studies mentioned above.

All effort put into fitting is meant to maximize speech understanding for the individual recipient. However, Shannon [2002] showed that speech understanding is relatively unaffected by amplitude changes such as peak or center clipping or amplitude compression. Modest effects of average fitting levels on speech perception have been found [Pfingst et al., 2004; Pfingst and Xu, 2005], with significant predictive values of M-levels and DR. This confirmed other work, showing that a larger DR correlated with better speech perception [Blamey et al., 1992].

Although it was predicted by Pfingst et al. [2004] that M-levels would correlate better with speech understanding than would T-levels, across-site variance of T-levels correlated more with speech understanding than did across-site variance of M-levels [Pfingst and Xu, 2005]. The fact that across-site variation in T-levels is correlated with speech understanding gives strength to the hypothesis that excluding electrodes with aberrant patterns of neural stimulation could improve speech recognition. With tripolar pulses, Bierer et al. [2010] demonstrated considerable across-site variation and showed that electrodes with higher thresholds have broader tuning curves and smaller DRs. With monopolar stimulation, this across-site variation was much smaller. However, even with monopolar stimulation, numerous researchers report higher thresholds at the basal end of the electrode array [Thai-Van et al., 2001; Smoorenburg et al., 2002; Sainz et al., 2003; Miller et al., 2008; Lai et al., 2009; Botros and Psarros, 2010; Wesarg et al., 2010]. Nowadays, fitting at the basal part of the cochlea receives extra attention as electric acoustic stimulation is emerging [Adunka et al., 2010] and shorter electrodes are being used [Gantz et al., 2009; Lenarz et al., 2009].

The aim of this study is to predict fitting parameters on the basis of behavioral levels for a group of 151 cochlear implant recipients, all implanted with a Clarion HiFocus 1/1 J electrode. The Tand M-levels obtained during regular follow-up 1 year after implantation provided the basis for this prediction. To allow populationbased fitting, universal templates for Tand M-levels were constructed to limit the amount of behavioral information required. Additionally, to serve as guidance for fitting children or other difficult-to-fit cochlear implant recipients, normative data are reported. Furthermore, the T-/M-level ratio was explored as well as the course of the levels in the first year. Finally, the predictive value of Tand M-levels for speech understanding in our relatively large study group was examined.

SUBJECTS AND METHODS

Subjects

Clinical data for 151 postlingually deafened adult cochlear implant recipients were analyzed for this study. All used either a CII or an electrically identical HiRes 90K cochlear implant with a HiFocus 1/1 J electrode array, which was fully inserted into the cochlea (Advanced Bionics). These subjects were implanted between

2002 and 2008 in the Leiden University Medical Center. All implantations during this period were performed by only two surgeons. Subjects younger than 16 years were not included in this study. The subject demographics are shown in table 1. All subjects used the HiRes processing strategy. Fifteen postlingually deafened adult subjects additionally implanted during this period were not included in the study, for a variety of reasons (table 2).

Stimulation Levels

T-levels were measured for each active electrode contact separately while delivering a 300-ms pulse train of biphasic pulses in the following up-down-up procedure. Per electrode contact, stimulus levels were increased, starting at 0 clinical units (CU), until the subjects indicated that they heard a sound. Next, the current was increased above this approximate T-level to provide a clearly audible percept on which the subject could focus. Subsequently, the level was decreased again until the subject indicated that he/ she did not hear the sound anymore. Then, the level was decreased somewhat further to reach a definitely subthreshold level. Finally, the level was raised again to find the final T-level. For the M-levels, at initial fitting, a profile was introduced with an up to 25% (in linear clinical units) emphasis for the more basal electrode contacts [the electrode numbering in Advanced Bionics devices is from apical (1) to basal (16)]. Subsequently, the processor was set in live speech mode, and live speech at normal voice level was then administered to the subject while all of the M-levels were increased simultaneously until speech was reported to be comfortably loud. At this time, the subject was asked to assess the sound quality. First, an open question was asked, but, if needed, adjectives (low-pitched, muffled, high-pitched, sharp) were suggested to facilitate the description of the sound quality for the patient. If the percept had a very low or muffled quality, the M-levels of the apical electrodes were reduced while maintaining a smooth M-level profile. If the sound was described as too sharp, the slope of the M-level profile was lowered until the patient accepted the sound quality but never

Table 1. Patient demographics

Number of patients	151
Average age, years	57
Range	17 – 86
Average duration of deafness, years	22
Range	0.1 – 60
Female/male ratio	94/57
Etiology	
Progressive	117
Medication	4
Ménière	5
Meningitis	14
Otosclerosis	6
Trauma	3
Usher	2
Average monosyllabic word score at 1 year, %	57
Range	5 – 93[1]

Implant type: CII/HiRes 90K (HiFocus 1/1 J electrode).
[1] Subset of 132 subjects.

Table 2. Number of implanted patients excluded from the study

Mentally handicapped	5
Non-Dutch speaker	1
Deceased, natural cause	3
Facial nerve stimulation	1
Incomplete insertion	2
Device failure	3
Total	15

further than a straight horizontal line [Briaire, 2008].

For most subjects, 12 electrodes were active, but 31 of the subjects were fitted with less active electrodes. The rationale to fit in most cases with 12 active electrodes was based upon previous research [Frijns et al., 2003]. Missing data points due to different numbers of electrodes being active would prevent the possibility of effectively plotting percentiles or averages along the array in line graphs, as plotted data would be from varying numbers of subjects.

Therefore, the data from two neighboring electrode contacts were averaged. This allowed level data along the array to be shown at the 8 electrode contact duos, each representing data from all subjects. In line with the convention used by Advanced Bionics, the levels are expressed on a linear scale in clinical units [pulse width (μs) × amplitude (μA) × 0.0128447]. In the manufacturer's clinical fitting software (SoundWave), T-levels are set as a percentage (10%) of M-levels. Therefore, also in the present study, the interrelationship between Tand M-levels was expressed as a percentage (T-/ M-level ratio = T-level/M-level × 100). Although this does not provide the DR in linear clinical units, the DR in decibels can easily be derived: DR (dB) = 20 log[100/(T-/M-level ratio)].

To assess intrasubject variation and to facilitate the comparison with previously published data [Pfingst and Xu, 2004], the data were recalculated and expressed in decibels: I (dB) = 20 log[I (CU)/1,000 × 20.6 (CU)]. This, for instance, enables the data to be seen more in line with data presented in Cochlear's current levels, which are also on a logarithmic scale. In line with Pfingst et al. [2004], across-site mean (ASM) and across-site variance (ASV) were calculated in order to be able to analyze fitting levels both across as well as within subjects. Both Tand M-levels were determined during regular clinical fitting sessions, approximately 8 times during the first year. The Tand M-levels of the initial fitting (about 4 weeks after implantation) and the levels obtained at 1 year of cochlear implant use were used for this study.

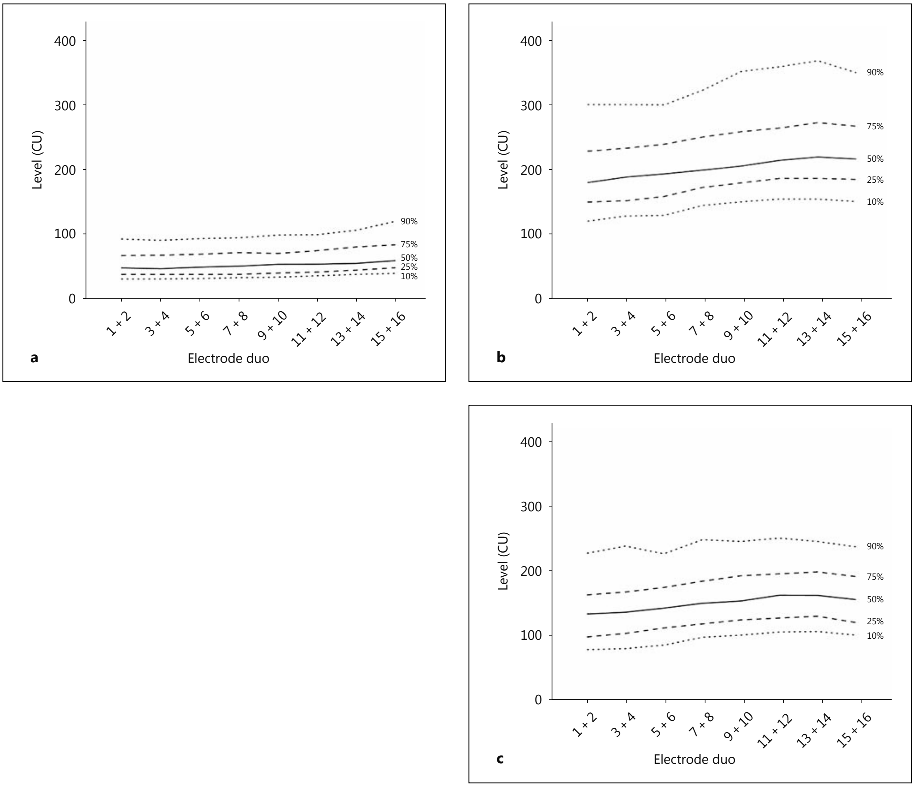


Fig. 1. Percentiles for T-levels (a), M-levels (b) and DRs (c) in clinical units. Data from two adjacent electrode contacts were combined and plotted as an electrode duo to include subjects with fewer than 16 active electrode contacts.

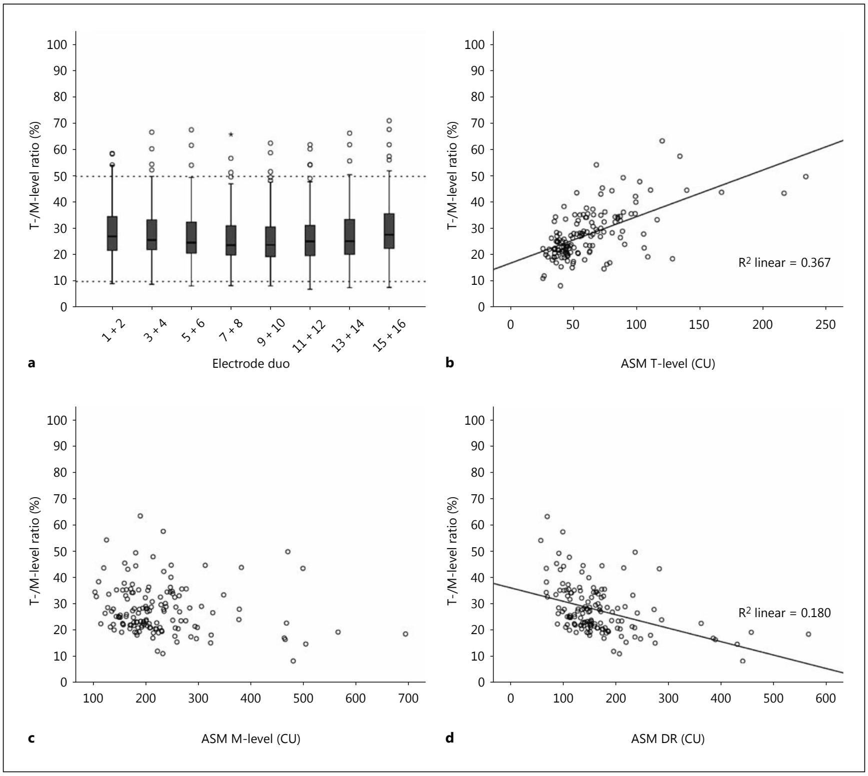


Fig. 2. a Box plot of T-/M-level ratio along the array (whiskers at 1.5 × IQR). °= Outlier; * = extreme. b Patients' overall T-level vs. patients' T-/M-level ratio with the linear fit line. c Patients' overall M-level vs. patients' T-/M- level ratio. d Patients' overall DR vs. patients' T-/M-level ratio with the linear fit line.

Speech Perception

Speech discrimination scores were obtained during normal clinical follow-up at predetermined intervals. The data used for analysis in this study were the scores obtained after 1 year of follow-up. For 19 of the 151 subjects included in the study, speech scores at the 1-year follow-up were not available for logistical reasons. The standard Dutch speech test of the Dutch Society of Audiology, consisting of phonetically balanced monosyllabic (CVC) word lists, was used [Bosman and Smoorenburg, 1995]. As described previously [van der Beek et al., 2005], the speech material was presented in free field in quiet at a level of 65 dB.

Statistical Analysis

All data analysis was performed using SPSS 19.0 (IBM, Armonk, N.Y., USA). Mixed linear models were used to analyze the data and to construct predictive models. These models aimed to predict Tand M-level profiles using only one measured level at one fixed individual electrode contact. In a mixed linear model, responses from a subject are thought to be the sum of fixed and random effects. The effects which affect the population mean are called fixed. If an effect is associated with a sampling procedure (e.g., subject effect), it is called random. These random effects often introduce correlations between cases and therefore should be taken into account to elucidate the fixed effects which impact the population. Using mixed linear models enables the investigation of the effects of each parameter separately as well as of the interaction between different parameters. Furthermore, mixed linear models can effectively use all data, even when one or more data points are missing [Fitzmaurice et al., 2004]. The predictive models for Tand M-levels were based on randomly selected subgroups of 70% of the subjects in order to be able to predict levels in the remaining 30% and correlate those predictive values with the measured values. To improve reliability, 10 different random selections per predictive model were performed.

RESULTS

Figure 1 shows the percentiles for T-levels (fig. 1a), Mlevels (fig. 1b) and DRs (fig. 1c) at the 1-year follow-up. Data are presented in clinical units to enable comparison of levels with different pulse widths. T-levels, M-levels as well as DRs showed an increase towards the basal end. The T-levels reflected real measurements of the individual levels at each individual electrode contact, whereas the M-levels were set for the subject using a profile fitting method with emphasis on the higher frequencies.

The ratio of T-/M-level is shown in a box plot in figure 2a. The median T-/M-level ratio for all the electrode duos was between 20 and 35%, corresponding to a DR of 9–14 dB. The whiskers are located at 1.5 × interquartile range (IQR). A 10% or smaller ratio only occurred in a very limited number of cases (>1.5 × IQR). Assuming a normally distributed data set, this means that about 1 out of 50 (theoretically 2.15%) has a ratio of 10% or below. Furthermore, from figure 2a, it can be seen that the ratio was fairly stable along the array. Figure 2b shows that about one third of the variance of the T-/M-level ratio could be predicted by the T-level ($r = 0.61$, $p < 0.01$). On the other hand, the T-/M-level ratio did not show any correlation with the M-level (fig. 2c), while it had a significant negative correlation with the DR ($r = -0.42$, $p < 0.01$; fig. 2d). The overall T-level turned out to be very weakly correlated with duration of deafness (approx. 4 CU per decade; $r = 0.22$, $p < 0.05$) and not correlated at all with age at implantation ($p = 0.63$). In contrast, the overall M-level was not significantly correlated with duration of deafness ($p = 0.57$), but a small but significant negative correlation was found with age at implantation (approx. 15 CU per decade; $r = 0.23$, $p < 0.01$).

The changes in T-level, M-level and DR during the first year are shown in figure 3. Figure 3a shows the levels along the electrode array during initial fitting and after 1 year of follow-up, expressed in clinical units. Figure 3b shows the same data, now plotted using a decibel scale. M-levels (fig. 3a) showed a larger increase (40.6 CU; SD 83.8) than T-levels (11.0 CU; SD 24.3), resulting in an increase in DR (29.8 CU; SD 73.0). T-and M-levels expressed in decibels (fig. 3b) showed an approximately equal increase (1.8–1.7 dB; SD 3.58–2.78), resulting in a stable DR in the first year (–0.2 dB; SD 3.2).

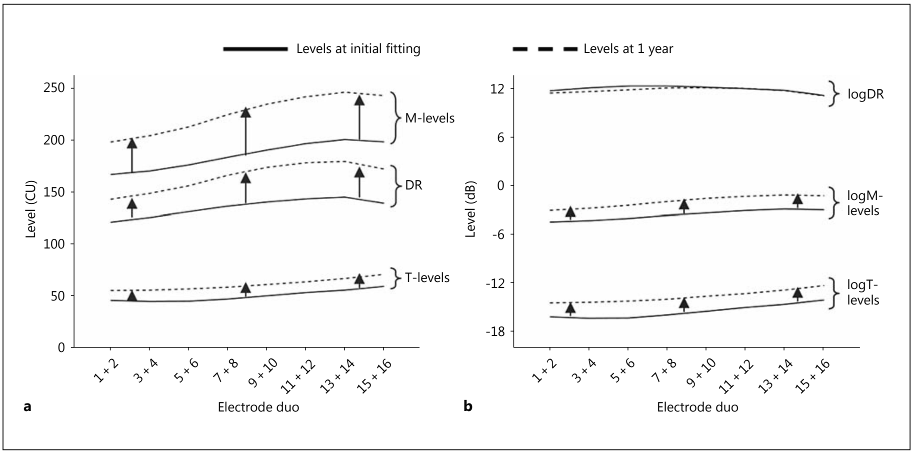


Fig. 3. T-levels, M-levels and DRs at initial fitting and after 1 year in clinical units (a) and in decibels (b). Arrows point from the initial fit line towards the 1-year data.

In figure 4, speech perception scores are plotted against the ASM and ASV of levels. Figure 4a, c shows a significant correlation between speech perception scores and T-level and DR ($r = 0.34$, $p < 0.01$, and $r = 0.33$, $p < 0.01$, respectively). No significant correlation of speech perception with the ASM of the M-level was found. Figure 4d–f illustrates the absence of a significant correlation between speech perception and ASV of the T-level, M-level or DR. These panels also show that the ASV was relatively small in most cases, with data clustering around a value of 1 or 2 dB, meaning a relatively flat level profile. The word scores showed a small negative correlation with duration of deafness (3% decrease in word score for a 10-year duration of deafness; $r = 0.23$, $p < 0.01$; data not shown).

The solid lines in figure 5a show the T-values (in decibels) along the array (measured 1 year postoperatively) for 4 quartile groups of the overall T-level. For all groups, an increase towards the basal end was found, which was independent of the actual overall T-level. A mixed linear model based on the measured T-levels of randomly chosen 70% of the subjects found that the best fit of this increase was given by the following quadratic function with only $electrode^2_{duo}$ and $electrode_{duo}$ as significant parameters:

$$T\text{-}level\ (electrode_{duo}) = 0.04 \times electrode^2_{duo} + 0.03 \times electrode_{duo}\ (in\ dB). \qquad (1)$$

The interaction of $electrode_{duo}$ with the ASM of T-levels did not reach significance ($p > 0.05$).

To predict the T-level for each 16 separate electrodes for an individual subject, instead of the 8 electrode duos, $electrode_{duo}$ from equation 1 should be substituted by (½ × electrode + ¼). Finally, the overall level can be determined by measuring the T-level measurement of one electrode. It turned out that the best

5

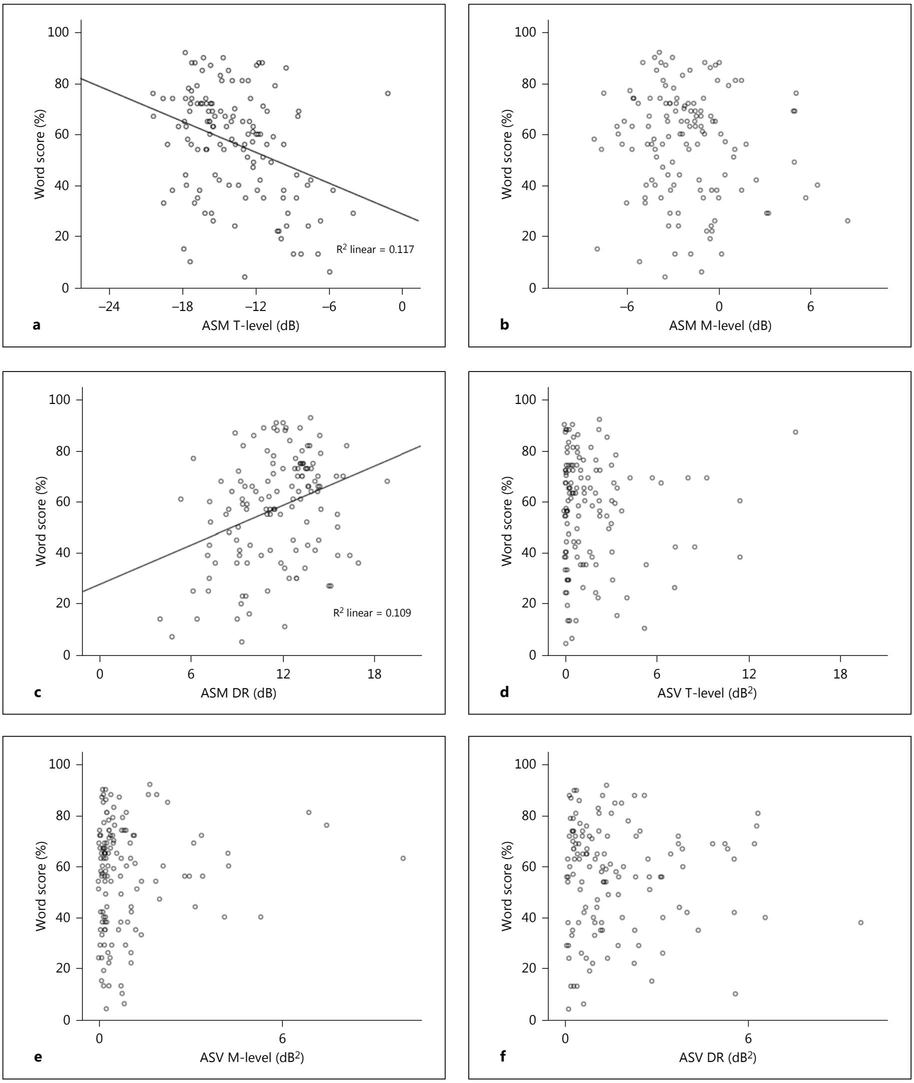


Fig. 4. Word scores vs. the ASM of the T-level (a), M-level (b) and DR (c) as well as vs. the ASV of the T-level (d), M-level (e) and DR (f).

prediction (with a mean correlation coefficient of r = 0.94 over the whole array) was given by the T-level of electrode 7, yielding the following prediction formula:

$$\textit{T-level}\,(\textit{electrode}) = 0.01\,(\textit{electrode}^2 - 7^2) + 0.025\,(\textit{electrode} - 7) + \textit{T-level}_{\textit{electrode}\ 7}\,(\textit{in dB}). \qquad (2)$$

As shown in figure 5b, the neighboring electrodes in the center of the array provided comparable results, while the mean r was reduced at both ends of the array (to r = 0.86). R-values for electrodes 2, 5, 9 and 14 are not shown in figure 5b, since these electrodes were active in only less than 33% of the subjects (table 3).

The goodness of fit of equation 2 for the individual T-levels was tested in the remaining 30% of the measured data (fig. 5c; table 3a). Figure 5c shows scatter plots of the predicted T-levels versus the measured T-levels for all 16 electrode contacts, while table 3a provides the associated numerical data. Again, it is clear that the predictions are slightly better for the center region of the array. This procedure was repeated with a number of other random selections of 30% of the population, with essentially the same result.

To obtain a T-level profile expressed in clinical units, equation 2 can be reformulated as follows:

$$
\begin{aligned}
&T\text{-}level\left(electrode\right)\\
&= T\text{-}level_{electrode\,7} \times 10^{\frac{1}{20}\left(0.01\left(electrode^2-7^2\right)+0.025\left(electrode-7\right)\right)}\\
&= T\text{-}level_{electrode\,7} \times 10^{\left(0.2\left(electrode^2-7^2\right)+0.5\left(electrode-7\right)\right)}\ (in\ CU). \qquad (3)
\end{aligned}
$$

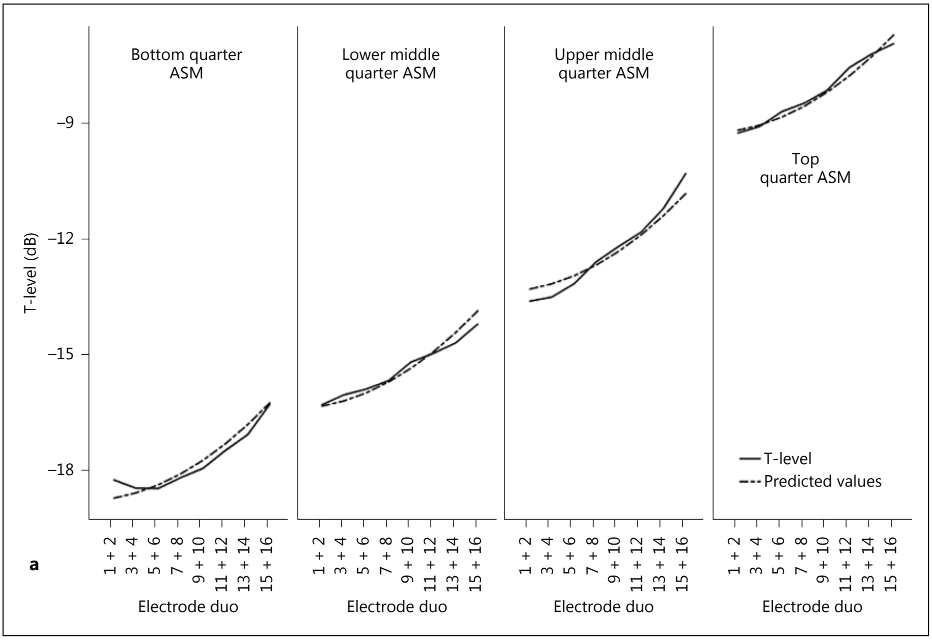
A fit comparable to figure 5c was made for the M-level profile (not shown), and, again, a high predictability could be obtained with a measurement on only one electrode contact (table 3b). On the basis of a similar mixed linear model, the M-levels along the array could be predicted with equations 4 and 5 (in decibels and clinical units, respectively):

$$
\begin{aligned}
&M\text{-}level\left(electrode\right) = 1.8\left(\cos\left(15\frac{\pi}{32}\right)-\cos\left(\left(2\,electrode+1\right)\frac{\pi}{32}\right)\right)\\
&-0.118\left(electrode-7\right)+M\text{-}level_{electrode\,7}\ (in\ dB)\ \text{and} \qquad (4)
\end{aligned}
$$

$$
\begin{aligned}
&M\text{-}level\left(electrode\right) \qquad (5)\\
&= M\text{-}level_{electrode\,7} \times 10^{\frac{1}{20}\left(1.8\left(\cos\left(15\frac{\pi}{32}\right)-\cos\left(\left(2\,electrode+1\right)\frac{\pi}{32}\right)\right)+0.118\left(electrode-7\right)\right)}\\
&= M\text{-}level_{electrode\,7} \times 10^{\left(36\left(\cos\left(15\frac{\pi}{32}\right)-\cos\left(\left(2\,electrode+1\right)\frac{\pi}{32}\right)\right)+2.36\left(electrode-7\right)\right)}\ (in\ CU).
\end{aligned}
$$

M-level profile (with emphasis on higher frequencies) was set during fitting in our clinic (see Subjects and Methods).

The bars in figure 6a, b show the mean differences between the predicted and measured T-levels, while the dashed lines indicate the lower and upper borders of the 95% prediction interval for the individual electrode con-tacts, expressed in decibels (fig. 6a) and clinical units (fig. 6b). Figure 6c, d shows the same data for the M-lev-els. It is clear that the size of the 95% prediction interval increases with the distance from electrode contact 7, at which Tand M-levels are measured, in spite of the fact that the model predicts the mean levels accurately alongthe whole array.



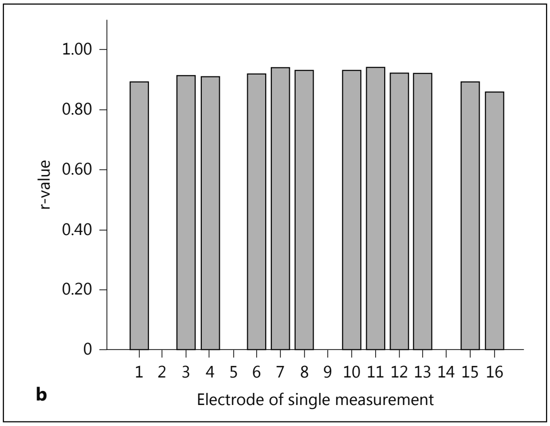


Fig. 5. a Measured and predicted T-levels fitted with a random 70% of the population. Data plotted in quartile groups of ASM. b Distribution of r-values fitting with single T-level measures at differ- ent electrodes (electrodes 2, 5, 9 and 14 not included; electrodes active in less than 33% of the subjects).

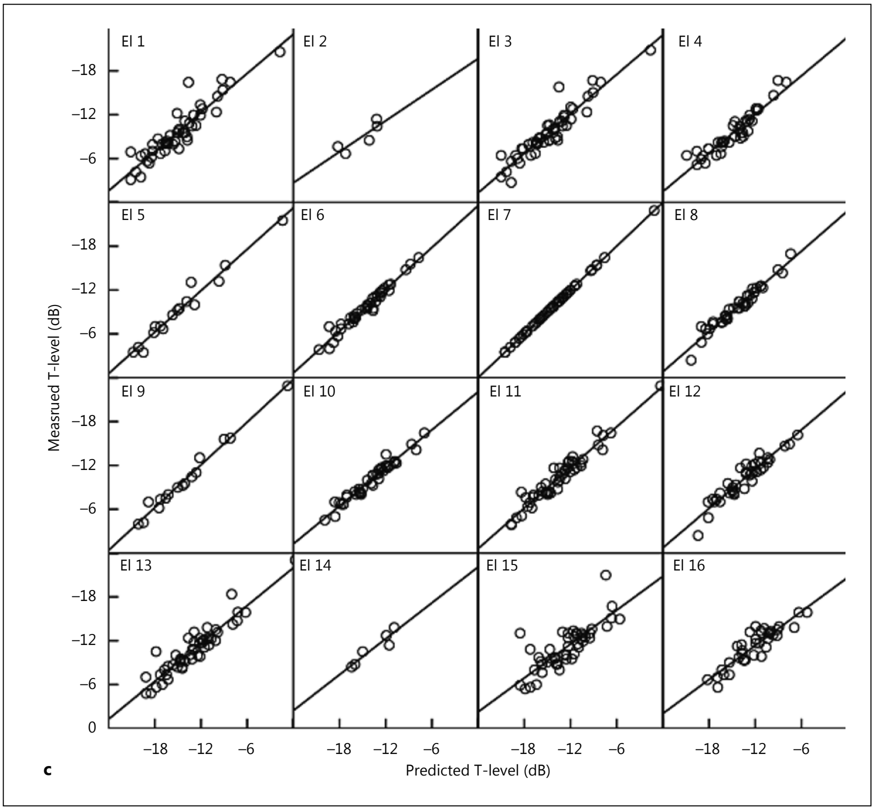


Fig. 5. c Scatter plot of the measured T-levels vs. predicted T-levels for the remaining 30% of the population for each electrode.

Table 3. Prediction errors and r-values per individual electrode contact (prediction based upon a randomly chosen subset of 30% of the subjects)

a T-levels

Electrode	Valid, n	Prediction errors (dB)			Mean ± 1.96 SD	Prediction errors (CU)			Mean ± 1.96 SD
		r	mean	var	95% prediction interval	r	mean	var	95% prediction interval
1	49	0.92	0.61	2.06	−2.2 to 3.4	0.92	3	139	−20 to 26
2	5	0.86	0.10	1.46	−2.3 to 2.5	0.87	0	35	−12 to 12
3	49	0.94	0.38	1.62	−2.1 to 2.9	0.94	2	107	−19 to 22
4	39	0.94	0.38	1.02	−1.6 to 2.4	0.96	2	32	−9 to 13
5	16	0.98	0.06	0.82	−1.7 to 1.8	0.99	−1	82	−19 to 17
6	39	0.98	0.21	0.33	−0.9 to 1.3	0.99	1	8	−4 to 7
7	50	1.00	0.00	0.00	0.0 to 0.0	1.00	0	0	0 to 0
8	39	0.98	0.00	0.44	−1.3 to 1.3	0.98	0	15	−8 to 7
9	16	0.99	0.13	0.42	−1.1 to 1.4	1.00	0	22	−9 to 9
10	39	0.98	−0.09	0.49	−1.5 to 1.3	0.97	−1	27	−11 to 9
11	50	0.97	−0.18	0.84	−2.0 to 1.6	0.98	−2	54	−16 to 13
12	39	0.95	−0.38	0.93	−2.3 to 1.5	0.95	−3	49	−17 to 11
13	50	0.94	−0.24	1.65	−2.8 to 2.3	0.96	−3	128	−25 to 19
14	6	0.94	0.57	0.74	−1.1 to 2.2	0.93	3	35	−8 to 15
15	50	0.85	−0.38	3.86	−4.2 to 3.5	0.88	−4	370	−42 to 34
16	37	0.90	−0.64	1.69	−3.2 to 1.9	0.89	−6	151	−30 to 18

b M-levels

Electrode	Valid, n	Prediction errors (dB)			Mean ± 1.96 SD	Prediction errors (CU)			Mean ± 1.96 SD
		r	mean	var	95% prediction interval	r	mean	var	95% prediction interval
1	49	0.96	−0.01	0.77	−1.7 to 1.7	0.95	−3	786	−58 to 52
2	5	0.92	−0.34	0.89	−2.2 to 1.5	0.91	−4	220	−33 to 25
3	49	0.97	0.00	0.58	−1.5 to 1.5	0.97	−1	542	−47 to 44
4	39	0.95	0.21	0.61	−1.3 to 1.7	0.97	3	281	−29 to 36
5	16	0.99	−0.08	0.37	−1.3 to 1.1	0.98	−2	507	−46 to 42
6	39	0.96	0.04	0.42	−1.2 to 1.3	0.98	0	214	−29 to 28
7	50	1.00	0.00	0.00	0.0 to 0.0	1.00	0	0	0 to 0
8	39	0.97	0.09	0.31	−1.0 to 1.2	0.99	2	134	−21 to 25
9	16	1.00	−0.09	0.16	−0.9 to 0.7	1.00	−4	135	−27 to 19
10	39	0.97	−0.11	0.35	−1.3 to 1.1	0.98	−2	235	−32 to 28
11	50	0.99	−0.25	0.19	−1.1 to 0.6	0.98	−6	444	−47 to 35
12	39	0.97	−0.14	0.38	−1.4 to 1.1	0.98	−2	493	−45 to 42
13	50	0.99	−0.31	0.28	−1.3 to 0.7	0.98	−8	557	−54 to 38
14	6	0.95	−0.67	0.53	−2.1 to 0.8	0.97	−13	122	−35 to 8
15	50	0.98	−0.34	0.47	−1.7 to 1.0	0.97	−8	663	−59 to 42
16	37	0.96	−0.18	0.67	−1.8 to 1.4	0.98	−2	611	−50 to 47

var = variance.

DISCUSSION

The present paper demonstrates how the group profile of Tand M-levels in a relatively large population can be described in closed-set formulas and how this can serve as a starting point for fitting individual cochlear implant recipients. With the help of equations 2–5, the measure-ment of the Tand M-level at just one electrode contact along the array suffices to obtain a prediction of Tand M-levels along the array (fig.6; table 3), which can be ap-plied in a simplified and time-efficient fitting procedure. In particular, it can be a

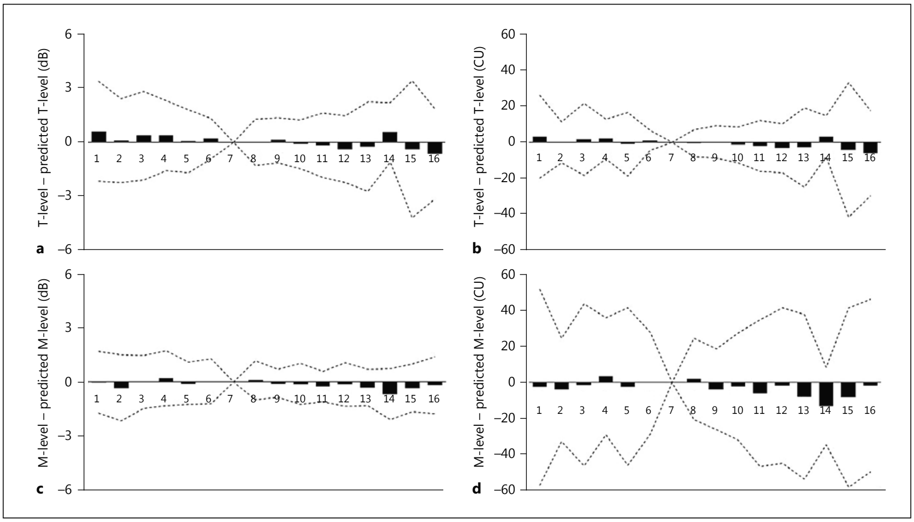


Fig. 6. Prediction error means (bars) and 95% prediction intervals (dashed lines) of T-levels in decibels (a) and clinical units (b) as well as of M-levels in decibels (c) and clinical units (d).

useful way to fit children and other recipients, which are not able to give sufficient feed-back during fitting procedures.

The use of these predictive equations matches well with the trend of using simplified fitting methods, which are mainly based on interpolation between electrodes and the fact that profiles are relatively flat for monopolar strategies [Plant et al., 2005; Boyd, 2010]. The main im-provement presented in this paper is the closed-set for-mulation in relation to the observation that the fitting lev-els (when expressed in decibels) show a level-indepen-dent increase towards the basal end of the electrode array (fig.5 a).

Although equations 2 and 3 were derived on the basis of measured T-levels of individual electrodes, it is not clear to what extent these equations can be generalized, since all patients were fitted in the same clinic, which might have enhanced intersubject similarities. Further-more, it must be taken into account that, unlike the T-levels, the M-levels in our population were fitted with a preset profile with emphasis on the basal electrodes, which is definitely reflected in equations 4 and 5.

Up to now, eCAP-based profiles still cannot provide proper settings and are only used as a starting point and continue to be used in combination with subjective pa-tient-derived information. Although eSRT or eABR pro-vides complementary information to eCAP measures, the latter are nowadays used more often for predicting levels, mainly for practical reasons.

Another interesting observation relates to figure 2 , which shows that most T-levels are 20–35% of the

M-levels. This corresponds to a DR of 9–14 dB. This is ob-viously less than the 20 dB DR obtained when T-levels are set at 10% of the M-levels, which is the default set-ting in SoundWave, the manufacturer's fitting software. The 9to 14-dB electrical DR is in line with the data reported by Wesarg et al. [2010] for Nucleus cochlear implant recipients. In previous studies, even lower DRs of around 8 dB were described [Pfingst and Xu, 2005]. Although research showed that speech perception is not negatively influenced by lower T-levels, at least not directly, some recipients may prefer strategies with higher T-levels [Spahr and Dorman, 2005]. Moreover, higher T-levels were shown to be beneficial for speech understanding at low sound levels and other challeng-ing listening situations [Holden et al., 2011]. However, even if programs with higher T-levels lead to better per-ception of soft speech, they carry an increased risk of inducing buzzing sounds in quiet, and a trade-off must be made.

Normative data about levels in our study population can help in evaluating the overall level for an individual recipient. When a profile in a pediatric subject is fitted on the basis of an estimated level at a single electrode contact, the Tand M-levels can be held against the per-centiles of our adult cochlear implant users (fig. 1). If the measurement for subjective levels performed in the sub-ject is clear, no adjustments have to be made. However, if the audiologist is in doubt about the subject's reaction and stimulation is at a high level, it may be prudent to set the levels in a normal or average range. However, it is important to realize that the data presented here are for adults, and that a similar study with pediatric subjects still has to be done. Zwolan [2005] and Wesarg et al. [2010] showed that a lot of differences exist between dif-ferent implant centers, highlighting the large influence of the local audiologists' practice. Further, Zwolan [2005] showed that children got used to higher M-levels easily, introducing the risk that M-levels are set higher and higher on consecutive fittings, thereby ultimately risking overstimulation. To deal with this risk, some groups pro-pose the use of eSRT measures [Allum et al., 2002; Gor-don et al., 2004; Caner et al., 2007]. However, in our cen-ter, the behaviorally determined M-levels of 43 children under 5 years of age were not significantly higher than the M-levels in the adults of the present study (mean 277 vs. 226 CU; $p = 0.069$). Additionally, figure 4 a shows that using the manufacturer's default to set T-levels to 10% of M-levels will result in understimulation in the majority of cases. Therefore, it is worthwhile to measure actual T-levels, as this will most likely improve the perception of soft speech.

Figure 2 c shows that the M-level is not a good predic-tor for the T-/M-level ratio, as these values are not cor-related. However, overall T-levels have been shown to hold at least some predictive value for overall M-levels (fig. 2 b), which is in line with Wesarg et al. [2010]. This might be due to the fact that (even in a monopolar mode) T-levels give information about the neural excitability of the region around the electrode contact. If this region is easily excited, it is likely that the neighboring area will also be easily excited with an increasing current, resulting in a relatively low M-level. The M-level, however, gives infor-mation about a very wide region of excitation along the cochlea. It might well be that it does not reflect the neural status of the region nearby the electrode, which is directly influencing the T-level for that electrode. When comparing the relationships between Tand M-levels reported here with the findings in other publications, one should keep in mind that the results can be influenced by the way of setting M-levels.

Especially when fitting recipients, which cannot give clear responses, it is valuable to know that Tand M-levels tend to increase over time, as shown in figure 3. This finding was partly confirmed by previous research [Hughes et al., 2001; Henkin et al., 2006; Walravens et al., 2006; Smoorenburg, 2007; Zwolan et al., 2008; Wesarg et al., 2010]. These rising levels over time could be explained by new intracochlear fibrous tissue formation [Somdas et al., 2007] or by increased behavioral loudness tolerance [Hughes et al., 2001].

Interestingly, no significant increase in electric DR was shown over time if it was expressed in decibels, whereas it evidently increased if it was expressed in clinical units. This relates directly to the ongoing debate whether electrical stimulation levels should be expressed in linear units or on a logarithmic scale. The loudness theory of electrical stimulation proposed by Zeng and Shannon [1994] would be better suited with a linear current scale. Kwon and van den Honert [2006], however, argue that a logarithmic scale would match better with subjective loudness growth when dealing with larger electric stimulation ranges. Moreover, the fact that, in clinical practice, levels are expressed in both logarithmic (Cochlear) and linear scales (MED-EL, Advanced Bionics), makes it difficult to compare published data between manufacturers. In our data, an average increase of 1.7–1.8 dB over 1 year was evident for both Tand Mlevels, whereas increases, if expressed in clinical units, differed considerably between T-levels (11.0 CU) and Mlevels (40.6 CU). Apparently, expressing fitting levels in decibels facilitates the translation of our findings to clinical practice.

The data plotted in figure 4 show the significant correlation between speech perception and T-levels ($r = 0.34$, $p < 0.01$) and DR ($r = 0.33$, $p < 0.01$), respectively. This underlines the value of setting appropriate T-levels in an individual patient. However, our findings support the use of a preset profile for the M-levels. Firstly, M-levels were not significantly correlated with speech perception. Secondly, the use of the preset M-level profile with emphasis on the higher frequencies led to speech perception scores (on average 57% words correct in a monosyllabic word test) which are in line with word scores in the recent literature (65% in Holden et al. [2011]; 50% in Finley et al. [2008]). This is contrary to the use of a flat M-level profile, as this was shown to negatively influence speech understanding [Boyd, 2010]. Nevertheless, other factors are expected to be larger contributors to speech perception. Although not confirmed by all research groups [Roditi et al., 2009], duration of deafness was repeatedly shown to be a predictor of speech perception, with up to 30% of the variance explained by this single factor [Gantz et al., 1993; Waltzman et al., 1995; Rubinstein et al., 1999; Friedland et al., 2003; Gomaa et al., 2003]. In the present cohort, this effect is much less prominent – although still significant – with, on average, a 3% reduction in monosyllabic word score per decade of deafness. A similar effect was found for age at implantation.

Figure 5 shows that some other factor (or factors), but not the overall level, causes an increase in levels towards the basal end of the electrode array, and this increase turned out to be level independent when levels were recalculated from clinical units to decibels. An increase in T-levels towards the basal end was reported by more researchers. Some authors blame an offset towards the base on the increased distance to the modiolus [Gordin et al., 2010], others ascribe it to new bone formation [Fayad et al., 2009] or a basal current drain [van der Beek et al., 2005]. In addition to the higher levels at the base, Boyd [2010] mentioned nonuse of the most basal electrodes in a substantial number of cases. This nonuse of basal electrodes was not present in our study population.

In spite of the fact that T-levels are higher for basal electrodes, figure 1c does not show a decrease in DR towards the base. This is a consequence of the emphasis on the higher frequencies in the preset M-level profile, which, in turn, might be beneficial for speech understanding, as discussed in relation to figure 4.

Propst et al. [2006] showed that the variation in eCAP amplitudes along the array was etiology dependent (GJB2 vs. non-GJB2) and argued that this was due to differences in neural survival. This explanation is in line with the general finding of steeper eABR growth functions in the apex than at the base and the fact that eCAP growth curves predict speech perception in individuals with significant residual hearing [Gordon et al., 2007; Kim et al., 2010].

In line with this, the large intersubject variability in fitting levels is commonly attributed to differences in neural survival. The present study, however, demonstrated that the increase in the levels towards the base was independent of the levels themselves (fig. 5). Therefore, it is less likely that this increase was caused by differences in neural survival along the cochlea.

CONCLUSIONS

A practical aid to the fitting procedure has been introduced, enabling fast fitting in cochlear implant recipients. Based on one measurement and a population-based Tor M-level profile, individual recipients' Tand M-levels can be predicted with a closed-set formula. Although fitting levels increased consistently over time, the electrical DR (in decibels) appeared to be constant, with T-levels between 20 and 35% of M-levels. In recipients lacking reliable behavioral feedback, the percentile plots of levels for our population can serve as a reference to avoid underand overstimulation.

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6

Intra-cochlear position of cochlear implants determined using CT scanning: impact on the clinical fitting levels

F.B. van der Beek, M.D., J.J. Briaire, Ph.D., K.S. van der Marel, M.D., B.M. Verbist, M.D. Ph.D., J.H.M. Frijns, M.D., Ph.D.

ABSTRACT

Objectives

In this study, the effects of the intra-cochlear position of cochlear implants on the clinical fitting levels were analyzed.

Design

A total of 130 adult subjects who used a CII/HiRes 90K cochlear implant with a HiFocus 1/1 J electrode were included in the study. The insertion angle and the distance to the modiolus of each electrode contact were determined using high-resolution CT scanning. The threshold levels (T-levels) and maximum comfort levels (M-levels) at one year of follow-up were determined. The subjects' degree of speech perception was evaluated during routine clinical follow-up.

Results

The depths of insertion of all the electrode contacts were determined. The distance to the modiolus was significantly smaller at the basal and apical cochlear parts compared with that at the middle of the cochlea ($p<0.05$). The T-levels increased toward the basal end of the cochlea (3.4 dB). Additionally, the M-levels, which were fitted in our clinic using a standard profile, also increased toward the basal end, although with a lower amplitude (1.3 dB). Accordingly, the dynamic range decreased toward the basal end (2.1 dB). No correlation was found between the distance to the modiolus and the T-level or the M-level. Furthermore, the correlation between the insertion depth and stimulation levels was not affected by the duration of deafness, age at implantation or the time since implantation. Additionally, the T-levels showed a significant correlation with the speech perception scores ($p<0.05$).

Conclusions

The stimulation levels of the cochlear implants were affected by the intra-cochlear position of the electrode contacts, which were determined using postoperative CT scanning. Interestingly, these levels depended on the insertion depth, whereas the distance to the modiolus did not affect the stimulation levels. The T-levels increased toward the basal end of the cochlea. The level profiles were independent of the overall stimulation levels and were not affected by the patients' biographical data, such as the duration of deafness, age at implantation or time since implantation. Further research is required to elucidate how fitting using level profiles with an increase toward the basal end of the cochlea benefits speech perception. Future investigations may elucidate an explanation for the effects of the intra-cochlear electrode position on the stimulation levels and might facilitate future improvements in electrode design.

INTRODUCTION

Cochlear implants provide useful speech perception for many recipients. The variation in performance, however, is large and in many cases unexplained. Different biographical and audiological factors concerning the patient (i.e., the duration of deafness and pre-operative speech perception scores) are known to affect post-operative performance [Holden et al., 2013;Blamey et al., 2013]. Additionally, factors concerning the electrical-neural interface play a role in the post-operative performance. Factors affecting this interface include the distance to the modiolus, the amount and density of excitable nerve fibers, the amount of fluid surrounding the electrode and the presence of scar tissue. Several studies have shown that the intra-cochlear electrode position is correlated with speech perception scores [Holden et al., 2013;van der Beek et al., 2005;Finley et al., 2008]. The relationship between the intra-cochlear electrode position and the outcomes of cochlear implantation appears to be a reflection of the efficacy of the transfer of the electrical stimulus to the nerve fibers. The efficacy of stimulation is determined not only by patient-dependent factors but also by the manner in which the electrical signal is presented [Wilson et al., 1991]. The manner in which the signal is presented along the array is established for each individual during the fitting procedure. In this study, the effects of the intra-cochlear position (the distance to the modiolus and the insertion depth) on the fitting levels of cochlear implant recipients were investigated, and the results provide insights for improving future device fittings and designs.

During implant fitting, many parameters can be set; however, the threshold (T-level) and maximum comfort levels along the array continue to be the core parameters that are defined. Although the levels are implemented differently, and different units and names are used by each cochlear implant manufacturer, an upper limit for electrical stimulation per active electrode contact is always defined. For readability, the maximum and most comfortable levels (called the M-level, C-level, and MCL by manufacturers) will be referred to as M-levels throughout this manuscript. Previous studies have demonstrated that there is a certain level of conformity in the M- and T-level profiles, both of which tend to increase toward the basal end of the cochlea [Smoorenburg, 2007]. This increase has been observed for cochlear implants produced by different manufacturers (Cochlear Corp., Lane Cove, Australia; Advanced Bionics Corp., Sylmar, CA, USA; and MedEl Corp., Innsbruck, Austria) [Thai-Van et al., 2001;Smoorenburg et al., 2002;Polak et al., 2005;Cafarelli et al., 2005;Miller et al., 2008;Lai et al., 2009;Botros and Psarros, 2010;Baudhuin et al., 2012;D'Elia et al., 2012;Vargas et al., 2012;van der Beek et al., 2015]. Furthermore, both perimodiolar and more lateral electrodes (Nucleus Straight vs Contour) show higher levels basally [Polak et al., 2004]. However, these studies did not determine whether there was a direct correlation between these levels and the exact location of the electrode array within the cochlea and thus the distance to the targeted nerve fibers.

Using computed tomography (CT), the intra-cochlear position of individual contacts can be visualized, and the electrode-modiolus distance and the insertion depth of each electrode can be measured [Verbist et al., 2010a;Ruivo et al., 2009;van Wermeskerken et al., 2009;van der Beek et al., 2005]. The effects of the cochlear position of the implant, as determined using post-operative CT scanning, on the clinical stimulation levels have been investigated in only a few studies, and the contribution of various factors could not be determined [van der Beek et al., 2005;Long et al., 2014]. Radiological imaging has not been investigated as a possible technique for retrieving additional data regarding processor fitting in individual patients.

However, there is evidence that the distance to the modiolus affects the electrical-neural interface. Sheperd et al. studied animal models and found that approximating the stimulating electrode to the modiolus resulted in lower stimulation levels [Shepherd et al., 1993]. Perimodiolar approximation is thought to improve the efficacy of stimulation. However, although Saunders et al. showed that perimodiolar-designed electrode arrays decreased the T- and M-levels, the dynamic range did not increase as predicted [Saunders et al., 2002]. Additionally, others could not confirm that perimodiolar approximation led to lower T-levels [Marrinan et al., 2004;Huang et al., 2006;van der Beek et al., 2005;Long et al., 2014]. Kawano et al., however, showed a correlation between the distance from the electrode to Rosenthal's canal using histological specimens and the level profile [Kawano et al., 1998]. The distance to the modiolus is affected by the design and placement of the electrode array. In addition to these electrode-dependent factors, the difference in the diameters of the scalae, which have a clearly smaller scalar diameter at the apical end compared with the basal end, potentially affects the distance from the electrode to the modiolus [Rebscher et al., 2008]. In addition to the scalar diameter, the cochlea exhibits other obvious anatomical differences (e.g., the thickness of the osseous spiral lamina) in subsequent turns. However, although the anatomy of the basal vs the more apical cochlear turns differs considerably, no study has investigated the relationship between the distance between the modiolus and the electrode contacts and the corresponding stimulation levels at different insertion angles.

The variation in the numbers of surviving neurons along the cochlea was proposed as another possible explanation for the position-related differences in the stimulation level profile. Nadol et al. demonstrated that spiral ganglion cell (SGC) degeneration was more severe at the basal end of the cochlea than in the apical turn [Nadol, Jr., 1997]. Additionally, Polak et al. found larger ECAP amplitudes and amplitude-growth curves apically in the cochlea and attributed these to the different SGC densities throughout the cochlea [Polak et al., 2004]. Propst et al. (2006) also argued that the stimulation differences observed along the array were caused by the unequal distribution of degenerated neurons because the etiology most likely to account for uniform neuronal damage along the cochlea (GJB-2) did not show ECAP amplitude differences along the array [Propst et al., 2006]. Furthermore, Long et al. showed that the degree to which the distance between the electrode and the modiolus could predict the T-levels correlated with the speech perception scores, and they argued that differences in the content of neural elements along the cochlea caused these variations [Long et al., 2014]. Researchers have also assumed that the excitation width of the commonly used monopole stimulation mode averages out small variations in the level profile [Bierer and Faulkner, 2010].

To explain the less-efficient basal stimulation, other researchers have noted the difference in impedance caused by the larger volume of fluid near the basal electrodes [van Wermeskerken et al., 2009] or by the basal current path through the round window [Micco and Richter, 2006;van der Beek et al., 2005]. Furthermore, cochlear damage at the time of implantation and the resulting formation of new tissue and bone might negatively affect the electrode-neural interface. Adunka et al. (2004) reported that the cochleostomy procedure caused destructive trauma to the cochlea [Adunka et al., 2004]. Additionally, Li et al. reported the formation of new fibrous tissue, mainly at the basal end of the cochlea [Li et al., 2007]. Other researchers confirmed that most of the new intra-cochlear fibrous tissue formation occurred at the basal end of the cochlea [Fayad et al., 2009]. Moreover, Kawano showed that intra-cochlear fibrous tissue and bone growth was correlated with T-levels [Kawano et al., 1998].

The value of basal stimulation in speech perception was shown by Finley et al., who reported that bypassing the basal part of the cochlea had a detrimental effect on speech perception [Finley et al., 2008]. This correlation may be related to the fact that the ECAP measures showed a smaller spread of excitation in basal cochlea compared with the apical portion [Eisen and Franck, 2005;van der Beek et al., 2012]; however, the psychophysical tuning curves did not confirm this difference in spatial selectivity along the array [Nelson et al., 2011].

The goal of this study was to show the effect of the intra-cochlear position of cochlear implants on the clinical fitting levels. The analyses were performed for all of the individual contacts, thus spanning the first and part of the second turn of the cochlea, using the angular location and the distance to the modiolus as the parameters. In our center, the M-levels were fitted using a pre-set profile with an increase at the basal end of the cochlea in an attempt to improve speech understanding under noisy conditions by enhancing the high-frequency information [Frijns et al., 2002]. Therefore, the M-levels established in our center were not suitable for investigating the effect of the intra-cochlear position on these levels. Furthermore, even without using a pre-set profile, M-levels are not objective measures that can be used to study correlations with intra-cochlear positions because the perception of maximum comfort is highly subjective. To ensure the patient's comfort and avoid sharp-pitched sounds, some audiologists lower the basal M-level during fitting. In centers in which the M-levels are set without an increase toward the basal end [Wesarg et al., 2010], the dynamic range (DR) will substantially decrease basally. The T-levels, in contrast to the M-levels, show a firm correlation with the degree of speech perception [van der Beek et al., 2015], and most of the correlations described in the present study were discovered using the T-levels.

Additionally, the correlations between the duration of deafness, the age at implantation, and time since implantation and the stimulation levels at different angles of insertion in the cochlea were determined to provide further insight into the factors that affect the efficacy of the electrode-neural interface. Implications for fitting are discussed, as are possibilities for future research and electrode development.

Table 1: Patient demographics.

Patient demographics	
Number	130
Age (years)	56 (avg; range: 17-84)
Duration of deafness (years)	22 (avg; range: 0.1 -60)
Sex	83 F/47 M
Implant type	CII/HiRes 90K HiFocus 1/1J
Etiology	Progressive: 100; Medication: 4; Meniere's disease: 5; Meningitis: 12; Otosclerosis: 4, Trauma: 3; Usher syndrome: 2
Monosyllabic word score at 1 year (%)	57 (avg; range: 5-93)

MATERIALS & METHODS

Subjects

The clinical data for 130 post-lingually deafened adult cochlear-implant recipients who used either a CII or an electrically identical HiRes 90K cochlear implant with a fully inserted HiFocus 1/1J electrode array (Advanced Bionics, Sylmar, CA, USA) were analyzed in this study. These subjects were consecutively implanted between 2002 and 2008 at the Leiden University Medical Center. Two surgeons performed all of the implantations during this period. An extended round-window insertion was performed in all cases. Subjects younger than 16 years old were not included in this study. The demographical information for the subjects is summarized in Table 1. All of the subjects used the HiRes processing strategy. For a variety of reasons, 36 post-lingually deafened adult subjects who were implanted during this period were excluded from the study (Table 2), mainly because of a lack of reconstructable CT data (see below).

Intra-scalar position

All of the implanted patients received a postoperative CT scan to confirm that the cochlear implant had been properly inserted. To analyze the intra-scalar position, serial multi-planar reconstructions were executed [Verbist et al., 2005]. The insertion angle and the position of each electrode contact were determined using a 3D coordinate system based on international consensus [Verbist et al., 2010a;Verbist et al., 2010b] and an in-house designed post-processing program (Matlab, Mathworks, Novi, MI, USA; Figure 1). The accuracy

Table 2: Number of implanted patients excluded from the study.

Patients excluded from study:	Number:
Mentally handicapped	5
Non-Dutch speaker	1
Deceased, natural cause	3
Facial-nerve stimulation	1
Incomplete insertion	2
Device failure	3
No follow-up level data available	4
Could not reconstruct CT data	17
Total	36

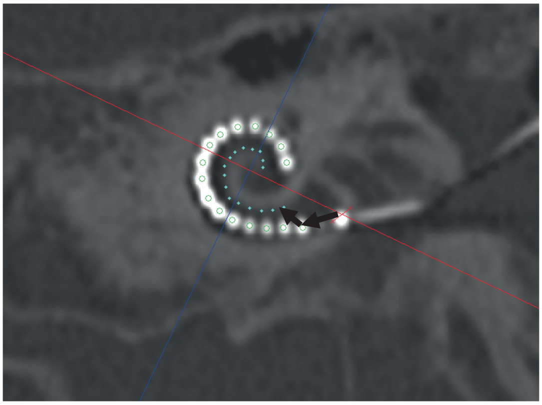

Figure 1: Multiplanar reconstruction of a post-implantation CT scan showing the intra-cochlear location of the individual contacts. The arrows indicate the distance to the modiolus and the insertion depth of the most basal electrode contact.

of this method of measuring the rotational angle and the distance to the modiolus was validated previously [Verbist et al., 2010a]. Because the scanning protocol was in development during the first inclusion period, 17 subjects had CT scans that were not of sufficient quality to allow multi-planar reconstructions. Those patients were not included in this study (Table 2).

Stimulation levels

All of the patients were fitted with the (monopolar) HiRes strategy. Both the T-level and the M-level were determined during regular clinical fitting sessions that took place approximately 8 times during the first year. The T- and M-levels obtained at one-year of follow-up were used in this study. Additionally, to evaluate the effects of time on the levels, the levels observed at the initial fitting were included in the data set. The T-levels were measured separately for each active electrode contact while delivering a 300 ms pulse train of biphasic pulses in an up-down-up procedure. For each electrode contact, the stimulus levels were increased, starting at 0 CU, until the subjects indicated that they heard a sound. Next, the current was increased above this approximate T-level to provide a clearly audible percept on which the subject could focus. The level was then decreased again until the subject indicated that he or she did not hear the sound. Then, the level was decreased somewhat further to reach a definite subthreshold level. Finally, the level was increased again to determine the final T-level. To determine the M-levels at the initial fitting, a profile was introduced with an emphasis up to 25% (in linear clinical units; CUs) for the more basal electrode contacts (the electrode numbering in Advanced Bionics devices is from apical (1) to basal (16)). Subsequently, the processor was set to live-speech mode, live speech at a normal voice level was administered to the subject, and all of the M-levels were increased simultaneously until speech was reported to be comfortably loud. At this time, the subject was asked to assess the sound quality. First, an open question was asked, but if needed, adjectives (e.g., low-pitched, muffled, high-pitched, or sharp) were suggested to help the patient in describe the sound quality. If the percept had a very low or muffled quality, the M-levels of the apical electrodes were reduced while a smooth M-level profile was maintained. If the sound was described as too sharp, the slope of the M-level profile was lowered until the patient accepted the sound quality; however, the slope but was never lower than a straight horizontal line [Briaire and Frijns, 2008].

For most of the subjects, 12 electrodes were active, but one-fifth of the subjects were fitted with fewer active electrodes. In most cases, the rationale for using 12 active electrodes was based on the results of previous research [Frijns et al., 2003]. Following the convention used by Advanced Bionics, the levels were expressed on a linear scale in clinical units (pulse width (μs) x amplitude (μA) x 0.0128447). Additionally, the data were recalculated and expressed in dB [Pfingst and Xu, 2004], as follows: I (dB) = 20 log (I (CU)/1000 x 20.6 (CU)).

Table 3: Mean insertion angles and distances to the modiolus of electrodes 1 (apical) to 16 (basal).

Electrode	Insertion (degrees)		Distance to modiolus (mm)	
	Mean	SD	Mean	SD
1	472.32	73.77	1.01	.22
2	433.47	69.03	1.04	.23
3	397.55	64.09	1.10	.24
4	363.49	58.85	1.16	.24
5	332.41	54.72	1.22	.25
6	303.25	51.57	1.26	.22
7	275.14	48.28	1.27	.21
8	248.46	46.11	1.29	.23
9	222.54	43.67	1.29	.25
10	198.07	41.61	1.27	.24
11	175.10	39.81	1.28	.25
12	153.00	38.00	1.30	.22
13	131.91	36.16	1.30	.22
14	111.69	34.92	1.26	.23
15	92.06	33.26	1.20	.25
16	72.45	31.12	1.22	.32

Speech perception

Speech discrimination scores were obtained during normal clinical follow-up sessions that occurred at predetermined intervals. The scores obtained at the one-year follow-up were analyzed in this study. The standard Dutch speech test of the Dutch Society of Audiology, consisting of phonetically balanced monosyllabic (CVC) lists of words, was used [Bosman and Smoorenburg, 1995]. The speech tests were performed in a free field using a speech signal of 65 dB HL, as previously described [van der Beek et al., 2005].

Statistics

SPSS 19 software (IBM Corp., Armonk, NY, USA) was used for the regression analysis and to test the differences among the mean values (t-test). Local regression (LOESS) fits were used to optimize the fitting for all of the loci along the electrode array. To obtain a regression function that could be easily represented using a mathematical formula, mixed linear models were used to obtain quadratic fits.

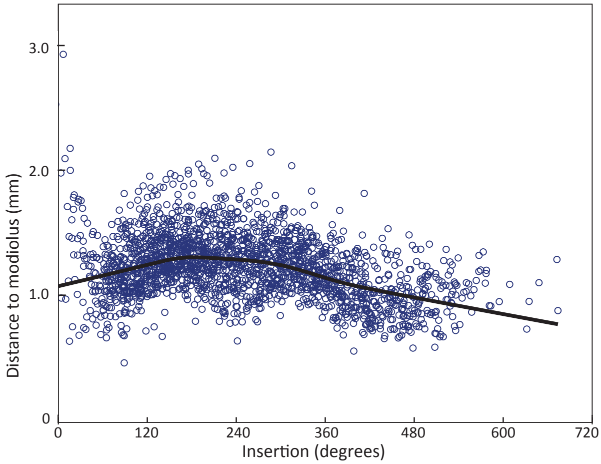

Figure 2: The distance to modiolus of each individual electrode contact plotted against the insertion depth. A LOESS fit is shown.

RESULTS

Table 3 shows the intra-scalar positions of the electrode contacts along the array. The mean insertion depth and the distance to the modiolus from each of the electrode contacts were measured. The mean insertion depth of the most apical electrode (1) was 472° (SD 73.8°). Figure 2 shows that the distance to the modiolus from the basal electrode contacts was smaller than that of the contacts that had been inserted at ¾ of a turn (270°). The contacts with an insertion angle beyond this point were also a shorter distance from the modiolus. Statistical analysis using Student's t-test showed that these variations in the modiolar distance along the array were significant (see Table 4).

The scatter plots in Figure 3 show the T-levels vs the insertion depths expressed in CU (A) and in dB (B). A large variation in the levels can be observed. The population was divided into 4 percentile groups based on their average T-levels. For each percentile group, a LOESS fit is shown in the same colors as the data points.

Table 4: Mean distance to the modiolus from different parts of the cochlea. Significant ($p<0.05$) differences in pairwise comparisons of the column mean values are indicated under the category with the larger mean value.

	Part of cochlea (in degrees)							
	0-120		120-240		240-360		>360	
	(A)		(B)		(C)		(D)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Distance to modiolus (mm)	1.19	.27	1.32	.23	1.26	.21	1.01	.20
Significant differences	D		A C D		A D			

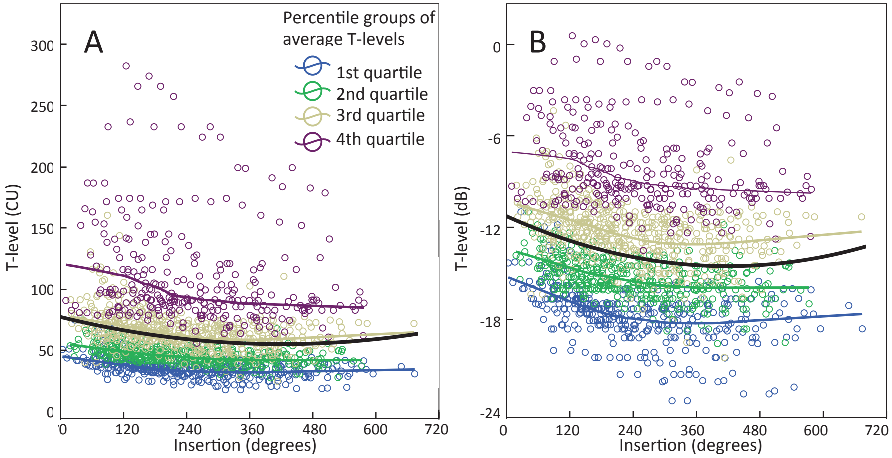

Figure 3: Scatterplot of the individual T-levels per electrode contact, expressed in CU (A) and in dB (B), vs the insertion depth. The population was divided into percentile groups according to the overall T-levels, and the fits for the sub-groups are shown (lowest quartile: blue; lower-middle quartile: green; upper-middle quartile: yellow; upper quartile: fuchsia). The black fitting line is the quadratic fit for the entire population.

Furthermore, the quadratic fit for the total group is shown in black. An increase in the T-levels toward the basal end is clearly visible in all of the (sub)groups. Toward the apical end, a flat profile or a minor increase was observed. Whereas Figure 3A shows different degrees of increase in the T-levels toward the basal end, converting the data to dB (Figure 3B) shows that this basal increase was comparable in all 4 of the percentile groups. The quadratic fit for the population as a whole showed an increase of 3.4 dB.

Table 5 shows the speech perception scores for the four percentile groups according to their overall T-levels. The percentile group with the lowest T-levels showed significantly better speech perception (68.9% word score) compared with the other percentile groups, whereas the percentile group with the highest T-levels showed the worst speech perception scores (44.2% word score).

Table 5: Speech-perception scores for the four percentile groups according to the overall T-levels. Significant ($p<0.05$) differences in the pairwise comparisons of the column mean values are indicated under the category with the larger mean value.

	Percentile group according to the T-levels							
	1 (0-25%)		2 (26-50%)		3 (51-75%)		4 (76-100%)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Word scores (%)	68.9	15.5	51.9	24.3	51.5	15.5	44.2	28.1
Significant differences	2 3 4		4		4			
T-levels (CU)	35.3	7.0	46.2	6.9	62.8	12.6	102.6	40.8
Significant differences			1		1 2		1 2 3	

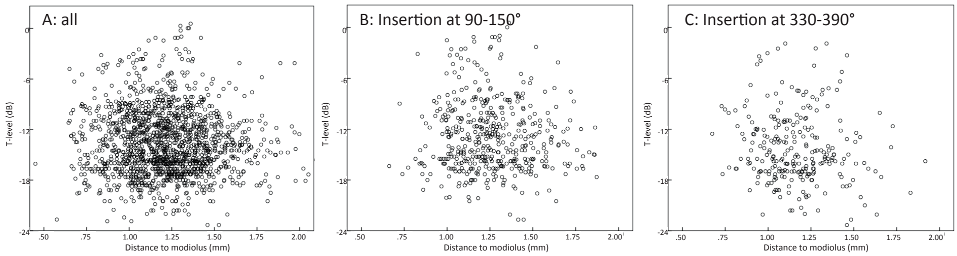

Figure 4: Scatter plot of the individual T-levels per electrode contact vs the distance to the modiolus. A: all electrodes; B: electrodes inserted between 90 and 150°; C: electrodes inserted between 330 and 390°.

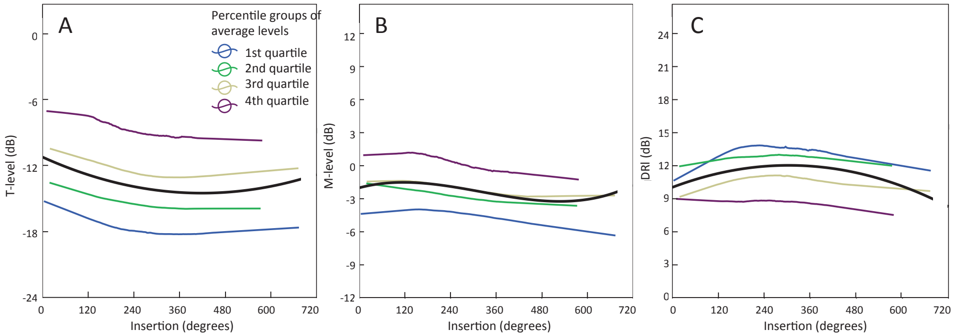

Figure 5: The LOESS-fitting lines of the quartile groups according to the overall T-levels (A), M-levels (B) and dynamic range (C). The black fitting line is the quadratic fit for the entire population.

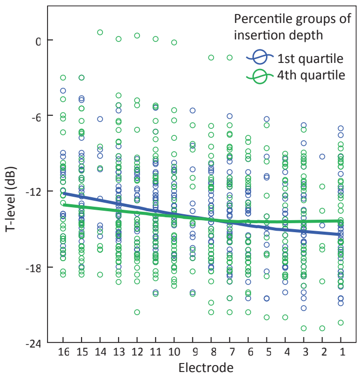

Figure 6: Scatterplot of the T-levels per electrode contact for the sub-groups with the 25% most shallowly and 25% most deeply inserted electrodes (Table 6).

Figure 4A shows the scatterplot of the distance to the modiolus vs the T-levels for all of the individual electrode contacts. Clearly, there was no significant correlation between the distances to the modiolus and the T-levels. Furthermore, the distance to the modiolus was not significantly correlated with the T-levels for different sections of the cochlea. Figures 4B and C show the data for two random subsections, 90-150° and 330-390°, and the lack of a significant correlation. The patients' word scores were not significantly correlated with the distance between the modiolus and the array (p=0.06) or the insertion depth of the array (p=0.8)

Figure 5 shows the fits of the T-levels (A; previously shown in Figure 3B), M-levels (B) and DRs (C) for the percentile groups and the entire population. As was found for the T-levels (Figure 5A), the M-levels (Figure 5B) of the entire population increased toward the basal end (T-levels: 3.4 dB; M-levels: 1.3 dB), consistent with the fact that the M-levels in our population were established using a preset profile with an emphasis on the basal electrodes. However, for the lowest 3 percentile groups, the increase in the M-levels toward the basal end was smaller than the increase in the T-levels, resulting in decreased average basal DRs (average 2.1 dB; Figure 5C). The percentile group with the highest T-levels did not show this decrease in the DR. Additionally, as Figure 5C shows, the subjects in the percentile group with the lowest T-levels had the highest DR (13.6 dB, SD 2.6), and the percentile group with the highest T-levels had the smallest DR (9.5 dB, SD 3.2). The basal increases in the T-levels of the four subgroups were not significantly different (p>0.12).

Figure 6 shows the data for the 25% of subjects with the most deeply inserted electrode arrays and the 25% with the most shallowly inserted arrays. The electrode contacts rather than the insertion angles are plotted on the x-axis to mimic the representation of the T-levels that was obtained using the clinical fitting

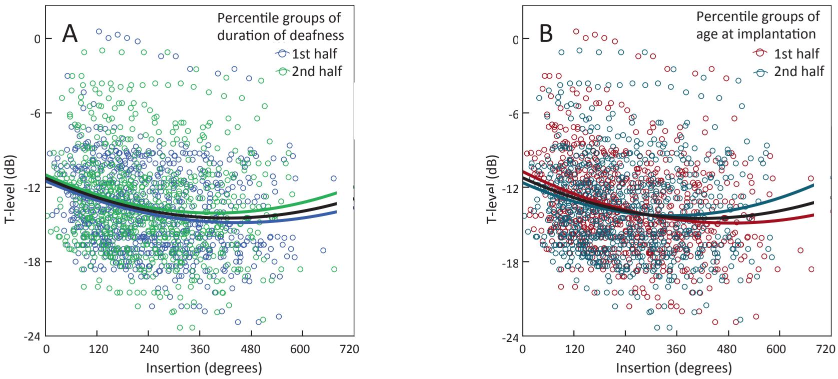

Figure 7: A: The T-levels vs the insertion depth for two sub-groups comprising the half of the patients with the longest (blue) and shortest (green) durations of deafness, showing the fits of the sub-groups and the overall fit. B: The T-levels vs the insertion depth for the two sub-groups of the half of the patients with higher (red) and lower (blue) ages at implantation, showing the fits of the sub-groups and the overall fit.

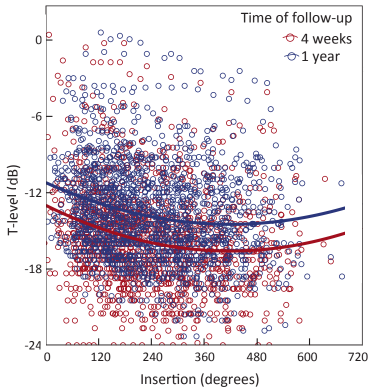

Figure 8: The T-levels vs the insertion depths at the initial fitting (red) and after one year of cochlear implant usage (blue). The fits are shown in matching colors.

software. The most deeply inserted arrays did not show a significant increase in the T-levels along the array, whereas the most shallowly inserted arrays showed significant differences in the levels along the array (2.9 dB, p<0.05).

Figure 7A shows the scatterplots of the T-levels vs the insertion depth for the subgroups of the 50% of patients with the shortest (blue, mean 7.0 y, SD 4.4) and the 50% with the longest durations of deafness (green, mean 37.0 y, SD 13.4). The mean T-levels of the two sub-groups were not significantly different (mean value-13.8 dB, SD 3.7; mean value-13.4 dB, SD 3.7, p=0.53). Furthermore, the quadratic fits showed that the increase toward the basal end was not significantly different for the two subgroups (3.2 dB vs 3.4 dB, p=0.17). Figure 7B shows the T-levels vs the insertion depth for the sub-groups comprising the 50% of patients with the lowest (red, mean value-44.2 years, SD 10.2) and the 50% of patients with the highest age at implantation (blue, mean value-67.9 years, SD 6.6). The mean T-levels did not significantly differ (mean value-13.5, SD 3.5; mean value-13.6 SD 3.8, p=0.29), and the basal increases were comparable (3.3 dB vs 3.4 dB) and not significantly different (p=0.18). Despite the similarities in the T-levels, as Figures 7A and B show, the speech perception scores of the two sub-groups based on the duration of deafness (mean value-59.8%, SD 21.5; mean value-53.3%, SD 21.4) or the age at implantation (mean value-59.9%, SD 21.2; mean 54.1% SD 21.2) were not significantly different (p<0.05).

Figure 8 clearly shows that the T-levels were higher overall at one year of cochlear implant use (blue) than at the first fitting (red; -13.6 dB, SD 3.7 vs -15.5 dB, SD 3.8, p<0.01), but the profile along the cochlea remained essentially unaltered. No significant differences in increase in T-levels along the array were observed between the data at one year and at the first fitting (p=0.09).

DISCUSSION

Clinical research has shown a correlation between the DR and speech perception that endorses the need for setting the proper fitting levels for cochlear implants [Blamey et al., 1992;Pfingst et al., 2004;Pfingst and Xu, 2005;van der Beek et al., 2015]. The aim of the present study was to determine whether radiological data provided additional information for setting the speech-processor map levels. Therefore, the intra-scalar positions of individual cochlear implant electrode contacts was determined according to the CT scans of 130 post-lingually deafened subjects, and their correlations with the clinical fitting levels along the array were studied. Interestingly, the fitting levels did not show any correlation with the distance between the electrode contacts and the modiolus. Speech perception was not significantly correlated with the insertion depth or the distance from the electrode array to the modiolus. Furthermore, the increase in levels at the basal end of the array was not significantly correlated with the subjects' mean stimulation level, duration of deafness, age at implantation or time since implantation.

Clearly, the angular location of an electrode contact affects its T-level (Figure 3), and whether the additional knowledge obtained from a radiological analysis would help with fitting the patient was considered. A previous study [van der Beek et al., 2015] showed that T-levels could be fitted by determining the T-level at one electrode contact and applying a closed-set formula for the T-level profile based on group data. Adding radiological data to such a model might further increase the applicability of this approach for clinical programming. Two sub-groups were created that included the 25% of subjects with the most shallowly inserted electrodes and the 25% with the most deeply inserted electrodes (Table 6). Figure 6 shows that the insertion depth of the array significantly affected the T-level profile. This effect was further analyzed by adding the insertion depth to the population-based predictive formula for the levels [van der Beek et al., 2015]. Although this process yielded a significant parameter, it did not increase the predictability of the levels (data not shown).

The lack of correlation between the T-level and the distance to the modiolus (Figure 4) precluded the use of this radiological parameter when setting the fitting levels. However, it is important to note that the electrode-to-modiolar distance measurements in this study were all determined for an electrode that was designed to be positioned at the lateral wall. Furthermore, the studies in which perimodiolar arrays were compared with straight (lateral) arrays did not demonstrate an unequivocal correlation between the modiolar-electrode distance and the levels. Some studies showed that perimodiolarly positioned electrodes were associated with lower levels [Saunders et al., 2002], whereas others did not find such an effect for the distance to the modiolus [Huang et al., 2006;Marrinan et al., 2004;van der Beek et al., 2005;Long et al., 2014]. Gordin et al. showed that lateral packing of the cochleostomy decreased the basal ECAP thresholds and increased the mid-array thresholds [Gordin et al., 2010]. The packing most likely decreased the basal distance to the modiolus and increased this distance for the mid-array. This hypothesis is consistent with the distances to the modiolus that were observed in our study population (Figure 2), in which an extended round-window approach with lateral packing was applied. Nevertheless, despite the smaller distance from the basal contacts to the modiolus (Figure 2, Table 4), the T-levels increased at the basal end of the cochlea, and an increased electrode-to-modiolar distance was ruled out as the cause of this increase toward the base.

A T-level profile with increased levels toward the basal end (Figure 3) has been frequently reported in the literature [Polak et al., 2005;Botros and Psarros, 2010;Smoorenburg et al., 2002;Lai et al., 2009;Thai-Van et al., 2001;Miller et al., 2008;Baudhuin et al., 2012;D'Elia et al., 2012;Vargas et al., 2012;Cafarelli et al., 2005;van der Beek et al., 2015]. However, there is no clear explanation for this phenomenon. Elucidating the causes of this phenomenon could provide insights for improving fitting and future electrode development. Although a clear increase in the T-levels toward the basal end was observed in various sub-groups (Figure 5A), not all of the subjects showed such an increase. The variation among the subjects could be caused by different factors. However, 20% of the intra-patient variation was related to the basal increase in the T-levels, suggesting that there is a common cause for this occurrence (Figure 3B, quadratic fit, r=0.2).

An increased threshold level suggests a suboptimal neural-electrode interface. If the basal increase is caused by central pathways, no possible improvements at this particular site can be expected in the near future; this would also be the case if neural degeneration is the cause of the increase. If other peripheral aspects cause the deterioration of the neural-electrode interface and cause differences along the array, determining their contribution might lead to improvements in future electrode designs.

Based mainly on data obtained using experimental animals, Shibata et al. concluded that deafness generally causes neural degeneration that leads to a progressively smaller number of SGCs [Shibata et al., 2011]. However, Rask-Andersen et al. showed that even with degeneration of the organ of Corti, the SGCs were preserved [Rask-Andersen et al., 2010]. In our population, neither a longer duration of deafness nor an increased age at implantation affected the absolute levels or their profile along the array (Figure 7). Because SGCs can survive even after a long duration of deafness [Rask-Andersen et al., 2010] and the duration of deafness had no clear effect on the stimulation levels (Figure 7), the progressive degeneration of the neural elements, starting in those involved with the high frequencies, appears not to be the cause of the wide variation in the levels or the basal increase in the levels. Other factors (e.g., etiology) are likely to affect neural excitability and therefore the stimulation levels. However, although the patients' T-levels varied greatly, the level profiles did not depend on the T-level (cf. also Van der Beek et al., 2015), and all of the sub-groups consistently showed a basal increase in the T-levels, as Figure 5 shows. The widely varying overall levels are generally thought to be correlated with an etiology-of-deafness-based factor or another patient-specific factor, making it less likely that the consistent, level-independent basal increase is associated with the same factor. In contrast, Propst et al. showed that patients who presumably had experienced neural degeneration that was equally distributed along the cochlea (GJB2 patients) had the same eCAP thresholds along the array, whereas the non-GJB2 patients had different thresholds along the array. Unfortunately, no direct connection between Propst et al.'s data and neural degeneration can be made because they did not conduct histological evaluations [Propst et al., 2006]

Another possible explanation for the basal increase could be the growth of fibrous tissue around the array. Indeed, tissue growth was mostly observed basally [Fayad et al., 2009;Li et al., 2007;Adunka et al., 2004]. Further, Kawano et al. found a correlation between new tissue formation and overall stimulation levels [Kawano et al., 1998]; this study, however, reported on only 5 subjects and did not show the varying effects of tissue formation on the levels along the array. Furthermore, Figure 8 shows that the increase in the basal levels was the same at the initial fitting as at the 1-year follow-up. Therefore, if tissue formation was the cause of the basal increase, the effects would have to have occurred within the first 4 weeks following implantation (i.e., prior to the first fitting) and would not change in the year afterward.

Because the basal increase in the stimulus levels was quite consistent among the different sub-groups with different overall stimulation levels and speech-perception scores, this phenomenon is likely to be the result of independent of factors that cause differences in the overall levels. For example, basal trauma caused by drilling an extended round window or a cochleostomy is an overall level-independent factor [Adunka et al., 2004].

Based on the collected data and the analysis described above, we are inclined to conclude that the basal increase in the T-level is an inherent property of electrical stimulation in the human scala tympani. Therefore, the basal increase in the T-level should be caused by anatomical factors that are present in most patients. The thicker modiolar wall at the basal cochlear end [Shepherd and Colreavy, 2004] or the size of the basal scala [Rebscher et al., 2008] could be potential causes. The size of the basal cochlea could cause electrodes to be positioned on the floor of the basal turn, resulting in electrodes that are relatively far from the osseous spiral lamina, which would increase the thresholds, particularly in the presence of the peripheral processes of the SGCs [Shepherd et al., 1993].

CT data demonstrating the intracochlear position of the electrodes can facilitate fitting patients whose depth of insertion is well outside the normal range. For the average patient, CT data will be of limited help, particularly because the distance between the contacts and the modiolus does not have a significant effect on the stimulation levels. Most likely, a combination of factors causes the differences in stimulation levels along the array. Further research should be performed to elucidate the individual contributions of those factors. This knowledge might help to improve electrode design. At present, patients can be fitted with sufficient emphasis of the basal part of the cochlea, using published data as references. Finally, based on this data, different fitting strategies should be examined to assess the effect of those strategies on the daily performance of the implant.

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General discussion

Hearing is improved, but further improvement is desired

Cochlear implantation has restored hearing for many patients, both adults and children. The quality of life of these patients has improved as a result of the new communication possibilities that arise from implantation. However, significant outcome variability persists; outcomes range from excellent results to minimal open set word recognition [Holden et al., 2013]. Even the best-performing patients experience difficulty hearing and understanding speech in noisy surroundings [Spahr and Dorman, 2005;Fetterman and Domico, 2002]. In addition, most patients experience limited music appreciation [McDermott, 2004]. Therefore, there is a continued strong desire for further improvements in cochlear implants.

Technical limits are improvable

Outcome limits are attributable to both patient factors and implant-related factors [Blamey et al., 2013;Holden et al., 2013]. Although biographical data can be used to help identify patients with proper indications for cochlear implantation and the candidacy criteria have been broadened, unfavorable biographical or audiological factors are not likely to be therapeutically altered in the near future. Improvements in cochlear implant outcomes are more likely to result from technical improvements in cochlear implants. The optimization of the different parts of the cochlear implants is an ongoing process. Although no significant leaps in progress have been made in recent years, any improvement represents a small step forward for (future) cochlear implant users.

Microphone improvements

The first step toward improving a patient's perception of a signal transmitted by a cochlear implant to the patient's auditory neurons involves improving the quality of the incoming signal. The most troublesome issue for cochlear implant patients is listening to speech signals in noisy surroundings [Spahr and Dorman, 2005;Fetterman and Domico, 2002]. Directional microphones can address this problem by transmitting the speech signal while attenuating background noise. Consistent with experiences with directional microphones in hearing aids, directional microphones in cochlear implants clearly result in improved speech understanding in noisy circumstances, including an improvement of up to 8 dB in speech reception thresholds (SRT) [Wouters and Vanden Berghe, 2001;Razza et al., 2013;van der Beek et al., 2007]**[Chapter 2]**. However, improvements in the quality of the incoming signal do not completely solve problems with hearing in noisy situations. After clinical tests with directional microphones were performed in our clinic, only a limited number of patients acquired a directional microphone despite the fact that all of the patients demonstrated clear improvements in the laboratory setting **[Chapter 2]**. Aesthetic issues may have played a role, as the external directional microphones used in the study by van der Beek et al. (2007) were rather large. However, the improvements obtained with directional microphones are relatively large compared with the 1-2 dB improvement in SRT obtained with more electrodes, higher rates [Friesen et al., 2001;Frijns et al., 2003] or bilateral cochlear implantation [Ricketts et al., 2006]. Although built- in directional microphones are used by cochlear implant patients in very limited circumstances, the microphones impart a clear added value in those circumstances [Mosnier et al., 2014]. Alternatively, noise reduction algorithms are used to improve the quality of the incoming signal. Although listening comfort in background noise improves with noise reduction algorithms [Buechner et al., 2010], not all studies could demonstrate a significant benefit in terms of speech intelligibility in noise [Dingemanse and Goedegebure, 2014].

Electrode-neural interface improvement and perimodiolar positioning

In addition to improvements of the incoming signal, improvements of the electrode-neural interface are beneficial to patient perception. Theoretically, electrodes located near excitable neural elements increase the dynamic range and provide increased selectivity of stimulation. Data from Shepherd et al. indicating that electrodes closer the modiolus facilitated neural excitation in cats [Shepherd et al., 1993] encouraged the design of electrodes with a perimodiolar position. Computer modeling confirmed the potentially beneficial effect of the perimodiolar position [Frijns et al., 2001], and different perimodiolar electrodes have been developed. The Advanced Bionics HiFocus (Advanced Bionics Corp., Sylmar, CA, USA) electrode was intraoperatively forced into a perimodiolar position with a silastic positioner, whereas the Nucleus Contour (Cochlear Corp., Lane Cove, Australia) electrode was designed to be placed in a perimodiolar position via the removal of a stylet. Multiple experiments with cochlear specimens revealed a perimodiolar location of the inserted electrodes [Cords et al., 2000;Fayad et al., 2000;Richter et al., 2002;Roland, Jr. et al., 2000;Tykocinski et al., 2000]. Compared with the Nucleus Contour (Cochlear Corp., Lane Cove, Australia), for which the removal of the stylet places the array in a primarily apical perimodiolar position, the perimodiolar position of the HiFocus electrode array is primarily located in the basal turn [Balkany et al., 2002]. However, the positioner was withdrawn from the market after a number of implanted patients developed meningitis. Although the relationship between meningitis and the positioner could not be clearly established, it was assumed that forcefully inserting the positioner might damage cochlear structures and create a pathway for bacteria [Seyyedi et al., 2013]. The withdrawal of the positioner and the subsequent implantation of the same HiFocus electrode without the use of the positioner enabled researchers to study the effect of the intracochlear location of the electrode array on speech perception [van der Beek et al., 2005a] **[Chapter 3]**. CT data confirmed in vivo that the electrode array was primarily placed in the basal perimodiolar position. This position provided enhanced speech perception; however, because medial placement also entailed a greater insertion depth range, the effects of these two factors could not be separately analyzed. Furthermore, the insulating properties of the silastic positioner precluded a basal current drain, which may have influenced the effectiveness of the basal electrodes. Additionally, patients who were fitted without a positioner exhibited increased threshold levels for the electrodes at the basal end of the cochlea, a phenomenon that was not observed in patients whose arrays were placed with a positioner.

Several cochlear implant manufacturers have developed perimodiolar electrodes. As previously described, a considerable amount of research has been performed using cadaveric temporal bones to determine whether the electrodes had a perimodiolar location after implantation [Fayad et al., 2000;Richter et al., 2002;Roland, Jr. et al., 2000;Tykocinski et al., 2000;Balkany et al., 2002].

Furthermore, different studies have analyzed the effects of the intracochlear position on electrically evoked auditory brainstem responses (eABRs), electrically evoked compound action potentials (eCAPs), and stapedius reflex measurements [Cords et al., 2000;Eisen and Franck, 2004;Firszt et al., 2003;Mens et al., 2003;Pasanisi et al., 2002;Wackym et al., 2004].

Moreover, these perimodiolar electrodes are implanted in many patients worldwide. However, surprisingly few studies have described the clinical effects of perimodiolar positioning [Basta et al., 2010;Saunders et al., 2002;van der Beek et al., 2005b;Holden et al., 2013;Esquia Medina et al., 2013;Hughes and Abbas, 2006;Fitzgerald et al., 2007;Filipo et al., 2008]**[Chapter 3]**.

Significant variations in speech perception scores among cochlear implant populations make comparative research difficult. Because of the considerable variation among patients, which is mainly caused by factors other than differences in electrode arrays [Blamey et al., 2013;Holden et al., 2013], studies must include large groups of patients if they wish to identify the significant effects of electrode design. Moreover, in those large patient populations, factors other than the one being investigated must remain fixed. However, given the considerable length of time required to include numerous patients from one center in a study, new factors - such as newly developed electrodes, new fitting strategies or even different indications for implantation - are likely to be developed before such studies can be conducted. Combining groups from different clinics to obtain larger study populations is also difficult given that fitting is performed differently at different centers [Zwolan, 2005;Wesarg et al., 2010]. In addition, many centers, especially European centers, use different speech reception tests. These differences among centers can be partially addressed by ranking the speech performances of groups [Holden et al., 2013;Blamey et al., 2013].

To continually improve electrode array designs, it is important to study the effects of the electrodes that are currently clinically available. The number of implanted patients makes it possible to conduct studies with large patient populations. However, studies that include more than 1000 cochlear implant patients are rare [Blamey et al., 2013], and even outcome studies that include more than 100 subjects are limited [van der Beek F.B. et al., 2014;Holden et al., 2013;Vargas et al., 2012] **[Chapter 5]**. Although numerous patients have been implanted with perimodiolar electrodes and the clinical effects of these electrodes could be studied in great detail, new designs are often introduced without a clear understanding of their clinical outcomes. In addition, their designs may be altered without regard for how the changes might impact their beneficial effects.

Measuring spectral resolution

It is important that adequate methods are used to analyze the potential improvement in the spectral resolution of the optimized location in the cochlea. The measurement of the electrically evoked action potentials (i.e., eCAPs) of the cochlear nerve fibers in patients with cochlear implants presents promising possibilities [Abbas et al., 1999;Frijns et al., 2002]. Various studies using spread of excitation (SOE) measures have demonstrated that the SOE was smaller in the basal portion of the cochlea [Eisen and Franck, 2005;van der Beek et al., 2012]**[Chapter 4]**. These findings indicate enhanced spectral resolution in the basal portion of the cochlea. However, psychophysical SOE measurements did not exhibit differences along the array [Cohen et al., 2004;Nelson et al., 2008]. The advantage of measuring SOE with eCAPs is that the measurements provide information about the electrode-neural interface and whether psychoacoustic measures are also influenced by central auditory pathways. However, no significant correlation between eCAP-measured SOE and speech perception has been demonstrated [Hughes and Stille, 2010;van der Beek et al., 2012][**Chapter 4**]. Furthermore, eCAP SOE measures are strongly influenced by various parameters [van der Beek et al., 2012;Hughes and Stille, 2010] [**Chapter 4**]. This result indicates that care should be taken when considering statements about eCAP measurements of the SOE in the cochlea. Additionally, this finding is consistent with the fact that eCAP thresholds are not sufficiently correlated with the clinical stimulation levels required for fully automated fitting [Botros and Psarros, 2010]. In short, eCAPs can provide information about the electrode-neural interface, although more research is needed to link the data with clinical outcomes. As Chapter 4 shows, the parameters that influence eCAP measurements must be determined before eCAPs can be used effectively to analyze or predict clinical outcomes.

Measuring outcomes using clinical stimulation levels

In addition to eCAPs and speech perception scores, stimulation levels provide information about the effectiveness of the electrode-neural interface, especially how effectively the cochlear implants promote sound perception. Moreover, it is likely that thresholds and maximum levels are less influenced by central effects than speech perception scores are. In addition, T-levels can measure the effects of the electrode array design in different areas of the cochlea. The threshold levels for electrical stimulation are theoretically a good measure of the stimulation's effectiveness. T-levels exhibit a positive correlation with speech perception [van der Beek et al., 2015b] [**Chapter 5**]; however, only a few studies that included large groups of patients present T-level data [Vargas et al., 2012;van der Beek F.B. et al., 2014;van der Beek et al., 2015a] [**Chapter 5,6**]. It is difficult to compare patient data given the considerable interpatient variability in levels, especially when stimulation levels are expressed as linear current units, which is the default setting in Advanced Bionics software (Advanced Bionics Corp., Sylmar, CA, USA). Moreover, level data comparisons among cochlear implants produced by different manufacturers are hindered by the use of different scales for stimulation levels. For example, manufacturer Cochlear Corp. (Lane Cove, Australia) uses current levels, which are measured with a logarithmic scale. Logarithmic scales can reveal intrapatient differences even in cases of significant overall level variation. Stimulus levels can be recalculated to demonstrate intrapatient effects by converting the linear scale to dB [Pfingst et al., 2004;van der Beek F.B. et al., 2014][**Chapter 5**] or by normalizing the data [Vargas et al., 2012]. Additionally, few studies contain large collections of T-level data because in many centers, T-levels are not measured clinically for each electrode contact. This lack exists because studies have reported that T-level settings do not have a significant effect on speech perception [Boyd, 2006]. Although these studies contained only a limited number of patients, and other studies have demonstrated the value of establishing T-levels [Spahr and Dorman, 2005;Holden et al., 2011], T-level measurement in many centers is limited to a few electrodes, and interpolation is used to expedite fitting. Alternatively, T- levels may not be measured and instead are set at 10% of the M-levels [Baudhuin et al., 2012]. In our clinic, T-levels are measured and established for each individual electrode contact, thus allowing us to analyze the course of the T-levels along the cochlea. When a positioner was used, the T-levels along the array exhibited a relatively flat profile. However, the patients without a positioner in our study population showed a patient-independent increase in the T-level profile towards the basal end of the cochlea **[Chapter 3,5,6]**. Indeed, with deeper insertions, these increases were no longer evident **[Chapter 3,6]**. When this basal increase in T-levels is not fitted, the basal dynamic range is reduced **[Chapter 6]**. To facilitate future fittings, a model was developed wherein the standard T- level profile was combined with a T-level measurement for an individual patient at just one electrode contact. Although the retrospective study by van der Beek et al. (2015) did not include an intervention and thus did not assess the effect on speech perception, Zhou et al. (2014) revealed that setting proper T-levels for electrode contacts with worse modulation detection thresholds could improve speech perception [Zhou and Pfingst, 2014].

Additionally, T-level increases did not exclusively occur in the most basal portion of the cochlea; ranges of up to 300 degrees insertion depth were associated with increases **[Chapter 6]**. Furthermore, this increase was not caused by a larger distance from the modiolus; the distance to the modiolus of the basalmost electrodes was smaller than the distance to the more apically located electrodes **[Chapter 6]**. Furthermore, the basal increase in T-levels was independent of the duration of deafness and was stable the first year of cochlear implant use **[Chapter 6]**, indicating that neural degeneration and increased scar tissue formation are less-likely underlying causes.

Differences in the shape and position of the array along the cochlea are needed

Differences in threshold levels [van der Beek F.B. et al., 2014;Vargas et al., 2012;van der Beek et al., 2015a] **[Chapter 3,5,6]** and SOE [van der Beek et al., 2012;Hughes and Stille, 2010] **[Chapter 4]** and clear differences in anatomy (Figure 1) indicate that different electrode designs along the array may be useful. However, with a few exceptions, electrodes are not designed to adapt to different anatomical situations along the array. Moreover, the effect of the anatomy of the cochlea on the electrode-neural interface has not been studied in detail. These effects are difficult to study because of a number of restraints (e.g., considerable variability in outcomes among patients and differences in human and animal anatomy). However, a large collection of outcome data can be acquired by studying patients implanted with different cochlear implant electrodes.

Future research

Future research should quantify the clinical effects of electrode design, especially differences along the array. Performance data from everyday clinical practice is available for all cochlear implant centers. The enormous number of patients with cochlear implants makes studies with large samples feasible. With clinical data from large study populations, even small effects of various parameters can be identified. The effects of those parameters can be further quantified in more fundamental, laboratory-based settings as a prelude to improved electrode design in the future.

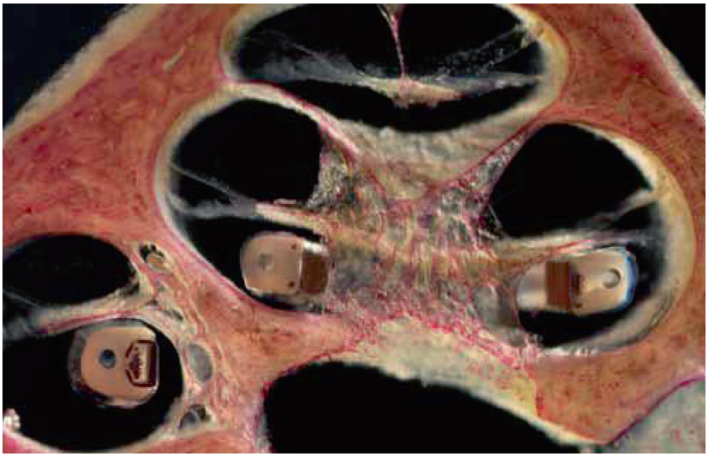

Figure 1: cadaveric temporal bone implanted with a cochlear implant. Clearly anatomic differences are seen in subsequent cochlear turns.

Variations caused by factors other than the electrode-neural interface impede comparative studies. However, assessments of large numbers of implanted patients using the described techniques (e.g., ranking speech perception outcomes and, in particular, studying normalized or dB-converted T- levels) can provide useful information about the effectiveness of different aspects of the electrode- neural interface. Additionally, combining these data with clinically acquired CT information could provide great insight into the clinical effects of intracochlear positioning. When analyzing the intratympanic position of the electrode, one should focus on the distance to the neural elements not just in the medial-lateral plane but also in the perpendicular direction, that is, in the plane from the bottom of the scala tympani towards the osseous spiral lamina and the basilar membrane. Moreover, various other parameters that might influence the electrode neural interface (e.g., residual hearing, the etiology of deafness, fibrosis) can be studied by correlating those parameters with the clinically available stimulation levels along the array.

Finally, outcome studies that analyze newly introduced electrode arrays will provide information about other aspects of electrode design. Combining those data with previously acquired data could elucidate the benefits and disadvantages of different aspects of electrode design. Thus, future electrode designs could retain their beneficial features and continue to improve their poor features.

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7

SUMMARY

Cochlear implants, which provide hearing for the deaf, have evolved in recent decades from single-channel implants to multichannel implants that are able to restore speech perception abilities for many. Cochlear implantation has eased communication with the hearing world and has greatly facilitated language development in children. However, considerable variation in performance exists among subjects, and speech perception in background noise continues to be troublesome for most, if not all cochlear implant recipients.

Cochlear implants consist of external and internal parts. The external part contains a microphone to pick up the sound signal. The sound signal is then processed in a speech processor. Basically, the speech processor codes the auditory signal based on separate frequency bands. Subsequently, the coded signal is sent through the skin to the receiver of the internal part by a transmitter coil. The received signal is then passed to the electrode array, which is located in the scala tympani of the cochlea. The signal leaving the different electrode contacts stimulates the auditory nerve fibers present in that portion of the cochlea. Cochlear implants form an interface between an audio signal and the nerve fibers of the deaf ear. This thesis focuses on optimizing the way in which the incoming speech signal is transferred to the excitable neural elements in the cochlea.

Chapter 1 provides a general introduction to the matters discussed in this thesis. It gives a historical overview of the developmental steps of cochlear implants, and it presents the outline of the present thesis.

Chapter 2 describes a study that analyzes the potential benefit of preprocessing the incoming signal to increase the signal to noise ratio for cochlear implant recipients. For thirteen cochlear implant patients, speech perception using directional microphones was compared with speech perception using an omnidirectional microphone. To mimic real-life situations, speech in noise was presented in a specially designed environment with a diffuse noise field. With assistive directional microphones, speech recognition in background noise improved substantially, and speech recognition in quiet was not affected. At an SNR of 0 dB, the average CVC scores improved from 45% for the headpiece microphone to 67% and 62% for the TX3 Handymic and the Linkit directional microphones, respectively. The speech reception threshold (SRT) improved by 8.2 dB with the TX3 Handymic and 5.9 dB with the Linkit, compared with the headpiece. It is concluded that these assistive microphones will allow users to understand speech in noisy environments with greater ease.

Chapter 3 studies several clinical aspects of the use of perimodiolar electrodes. It compares the data of 25 patients, who were implanted with a Clarion HiFocus 1 with a silastic positioner, with that of 20 patients in whom the same implant was used, but without positioner. After one year of implant use, the patients who were implanted with a positioner showed a significantly better speech perception (67 vs 45% words correct on CVC words in quiet, $p < 0.01$), while the pre-operative characteristics were comparable between the groups. CT scans showed that the positioner brought the electrode closer to the modiolus basally, whereas apically, no difference in distances from the modiolus was present. Additionally, the positioner

led to deeper insertion. Although the intracochlear conductivity paths of the two groups did not show significant differences, a basal current drain was seen for the shallowly inserted non-positioner patients. It was concluded that a basally perimodiolar electrode design benefits speech perception. The combination of decreased distance from the modiolus, increased insertion depth, and the insulating properties of the electrode array have functional implications for the clinical outcomes associated with the perimodiolar electrode design. Further research is needed to elucidate these factors' individual contributions to those outcomes.

Chapter 4 focuses on the application of the cochlear implant's ability to record the electrically evoked action potentials (eCAP) of the neurons in the cochlea to measure the effectiveness of the electrode-to-neural interface. The study investigated the spread of excitation (SOE) profiles using eCAP measures and analyzed the effects of various parameter settings. Measurements were performed intra-operatively in 31 users of the Advanced Bionics HiRes 90K cochlear implant. SOE was measured using the forward masking technique (selectivity) as well as with a "fixed stimulus, variable recording" (scanning) technique. SOE profiles were produced at three stimulus levels and at three sites along the array. Additionally, the effects of the position of the recording electrodes and artefact rejection methods were studied in five subjects. All data were analyzed using linear mixed models. The selectivity method produced narrower excitation profiles than the scanning method, showing asymmetry along the array with broader SOE apically. Moreover, the position of the recording electrode shifted the SOE curves towards the recording contact, enhancing asymmetry. Neither significant effects of the current level nor artefact rejection methods were observed, nor was any significant correlation with speech perception found.

Chapter 5 reports a study that analyzed the predictability of fitting levels for individual cochlear implant recipients based on a review of cohort data. The data included the threshold levels (T-levels) and maximum comfort levels (M-levels) of 151 adult subjects who used a CII/HiRes 90K cochlear implant with a HiFocus 1/1 J electrode. The 10th, 25th, 50th, 75th and 90th percentiles of the T- and M-levels are reported. The subjects' speech perception was measured using a HiRes speech coding strategy during routine clinical follow-up. The T-levels for most subjects were between 20 and 35% of their M-levels and were rarely (< 1/50) below 10% of the M-levels (which is the manufacturer's default). Furthermore, both the T- and M-levels increased over the first year of follow-up. Interestingly, the levels expressed in linear charge units showed a clear increase in dynamic range (DR) over 1 year (29.8 CU; SD 73.0), whereas the DR expressed in decibels remained stable. The T-level and DR were the only fitting parameters for which a significant correlation with speech perception ($r = 0.34$, $p < 0.01$, and $r = 0.33$, $p < 0.01$, respectively) could be demonstrated. Additionally, the T- and M-level profiles expressed in decibels turned out to be independent of the subjects' across-site mean levels, as demonstrated with mixed linear models. Based on the data set from 151 subjects, clinically applicable predictive models for the T- and M-levels of all separate electrode contacts were obtained. These closed-set formulae allow the close approximation of individual recipients' T- and M-levels based on just one psychophysical measurement. Additionally, the analyzed fitting level data can serve as a reference for future patients.

Chapter 6 presents an analysis of the effects of the intracochlear position of cochlear implants on the clinical fitting levels. A total of 130 adult subjects who used a CII/HiRes 90K cochlear implant with a HiFocus 1/1 J electrode were included in this study. The insertion angle and the distance to the modiolus of each electrode contact were determined using high-resolution CT scanning. The T-levels and M-levels at one year of follow-up were determined. The subjects' degree of speech perception was evaluated during routine clinical follow-up. The distance to the modiolus was significantly smaller at the basal and apical cochlea compared with the middle of the cochlea ($p < 0.05$). On average, the T-levels increased by 3.4 dB toward the basal end of the cochlea. The M-levels, which were fitted in our clinic using a standard profile, also increased toward the basal end, although to a lesser extent (1.3 dB). Accordingly, the dynamic range decreased toward the basal end (2.1 dB). No correlation was found between the distance to the modiolus and the T-level or the M-level, and the correlation between the insertion depth and stimulation levels was not affected by the duration of deafness, the age at implantation or the time since implantation. The stimulation levels of the cochlear implants were affected by the intracochlear position of the electrode contacts, which were determined using postoperative CT scanning. Interestingly, these levels depended on the insertion depth, whereas the distance to the modiolus did not affect the stimulation levels. The T-levels increased toward the basal end of the cochlea. The level profiles were independent of the overall stimulation levels and were not affected by the patients' biographical data, including the duration of deafness, the age at implantation or the time since implantation. The overall T-levels, however, showed a significant (negative) correlation with the speech perception scores ($p < 0.05$). Future investigations may lead to an explanation for the effects of the intracochlear electrode position on the stimulation levels, which might, in turn, facilitate future improvements in electrode design.

Chapter 7 contains a general discussion of the results and the main conclusions of the studies described in this thesis. Although clinical improvements in speech perception can be obtained by improving the interface with directional microphones and intrascalar positioning, more research is needed to improve the quality of the interface of cochlear implants. First, the quality of eCAP measurements (e.g., the signal to noise ratio) should be enhanced to obtain a more detailed picture of the electrode-to-neural interface. Furthermore, it is worthwhile to continuously collect and analyze data on clinical stimulation levels for all existing and future electrode designs. Such research might ultimately elucidate the effects of intracochlear position and various other interface parameters on clinical outcome. This research in turn may contribute to the ongoing improvement of cochlear implants' interfaces and resulting improvements in speech perception with cochlear implants.

SAMENVATTING

Cochleaire implantaten, die horen mogelijk maken voor doven, hebben zich in de laatste decennia geëvolueerd van single-channel implantaten tot multichannel implantaten die voor velen spraakverstaan mogelijk hebben gemaakt. Cochleaire implantatie heeft de communicatie met de horende wereld vergemakkelijkt en heeft taalverwerving sterk verbeterd voor dove kinderen. Er bestaat echter nog aanzienlijke variatie in performance tussen personen en spraakverstaan in achtergrond lawaai blijft problematisch voor velen, zo niet voor alle cochleair implantaat ontvangers.

Cochleaire implantaten bestaan uit externe en interne onderdelen. Het externe gedeelte bevat een microfoon om het geluidsignaal op te pikken. Het geluidsignaal wordt dan verwerkt in de geluidsprocessor. Kortweg gezegd codeert de spraakprocessor het auditieve signaal in verschillende frequentie banden. Vervolgens wordt het gecodeerde signaal door de huid naar de ontvanger van het interne gedeelte gestuurd door een zendspoel. Het ontvangen signaal wordt dan doorgegeven naar de elektrode array, die zich in de scala tympani van de cochlea bevindt. Het signaal, dat een van de verschillende elektrode contacten verlaat, stimuleert de auditieve zenuwvezels, die aanwezig zijn in dat gedeelte van de cochlea. Cochleaire implantaten vormen een interface tussen een audio signaal en de zenuwvezels van het dove oor. Dit proefschrift focust op het optimaliseren van de manier waarop het binnenkomende spraaksignaal wordt overgedragen op de exciteerbare neurale elementen in de cochlea.

Hoofdstuk 1 geeft een algemene inleiding op de materie die besproken wordt in dit proefschrift. Het geeft een historisch overzicht van de ontwikkelingsstappen van cochleaire implantaten en biedt een overzicht van het huidige proefschrift.

Hoofdstuk 2 beschrijft een studie die analyseert wat het potentiële voordeel is voor cochleaire implantaat ontvangers om door preprocessen van het binnenkomende signaal de signaal-ruisverhouding te verbeteren. Van 13 cochleaire implantaat patiënten is spraakverstaan met directionele microfoons vergeleken met spraakverstaan met een omnidirectionele mircofoon. Om levensechte situatie na te bootsen, werd spraak in ruis gepresenteerd in een speciaal ontworpen omgeving met een diffuus ruis veld. Met de hulp van directionele microfoons bleek spraak herkennen in achtergrond lawaai substantieel te verbeteren, en spraak herkenning in stilte werd niet negatief beïnvloed. Bij een signaal-ruisverhouding (signal-to-noise ratio, SNR) van 0 dB verbeterde de gemiddelde CVC scores van 45% voor de headpiece microfoon naar respectievelijk 67% en 62% voor de TX3 Handymic en de Linkit directionele microfoons. De spraakverstaan drempel (speech reception threshold, SRT) verbeterde met 8.2 dB SNR met de TX3 Handymic en met 5.9 dB voor de Linkit vergeleken met de headpiece. Geconcludeerd wordt dat deze ondersteunende microfoons in een rumoerige omgeving mogelijk maken dat gebruikers met meer gemak spraak kunnen verstaan.

Hoofdstuk 3 bestudeert verschillende klinische aspecten van het gebruikt van perimodiolaire elektrodes. Het vergelijkt de gegevens van 25 patiënten, die geïmplanteerd werden met een Clarion HiFocus 1 met een siliconen positioner, met die van 20 patiënten in wie het zelfde implantaat was gebruikt, echter zonder positioner. Na 1 jaar van implantaat gebruik lieten de patiënten die werden geïmplanteerd met een positioner een significant beter spraakverstaan zien (67% vs 45% woorden correct van CVC woorden in stilte, $p < 0.01$). CT scans lieten zien dat de positioner de elektrodes basaal dichter bij de modiolus brachten, terwijl apicaal er geen verschil in afstand tot de modiolus aanwezig was. Verder leidde de positioner tot een diepere insertie. Alhoewel de intracochleaire stroomgeleiding van de twee groepen geen significante verschillen lieten zien, werd wel een basale stroomlekkage gezien bij de niet-positioner patiënten met een ondiepe insertie. Geconcludeerd werd dat een perimodiolair elektrode ontwerp voordelen heeft voor spraakverstaan. De combinatie van een verminderde afstand tot de modiolus, een diepere insertie en de isolerende eigenschappen van de elektrode array hebben functionele implicaties voor de klinische uitkomsten met een perimodiolaire elektrode ontwerp. Verder onderzoek is nodig om van deze factoren de individuele bijdrage voor deze uitkomsten op te helderen.

Hoofdstuk 4 focust op het toepassen van het vermogen van het cochleair implantaat om met elektrisch opgewekte actie potentialen (electrically evoked action potentials, eCAP) van de neuronen in de cochlea de effectiviteit van de elektrode-neurale interface te meten. De studie onderzoekt de profielen van spreiding van excitatie (spread of excitation, SOE) door gebruik te maken van ECAP metingen en analyseert de effecten van verschillende parameter instellingen. De metingen werden per-operatief verricht in 31 gebruikers van het Advanced Bionics HiRes 90K cochleair implantaat. SOE werd gemeten met de "forward masking" techniek (selectivity) en een "vaste stimulus, variabele meting" techniek (scanning). SOE profielen werden geproduceerd op drie stroom niveaus en op drie posities op de elektrode array. Hiernaast werd het effect van de positie van de meetelektrode en artefact-onderdrukkingsmethode bestudeerd in vijf personen. Verder werd de correlatie tussen SOE data en spraakverstaan data getest. Alle data werden geanalyseerd met linear mixed models. De selectivity methode produceerde smallere excitatie profielen dan de scanning methode, waarbij een asymmetrie werd gezien langs de elektrode array, met bredere excitatie spreiding apicaal. Bovendien verplaatste de positie van het meetelektrodecontact de SOE curves richting het meetcontact, waardoor de asymmetrie toe nam. Geen significante effecten van het stroomniveau noch van de artefact-onderdrukkingsmethoden werden gezien, noch werd enige significante correlatie met spraakverstaan gevonden.

Hoofdstuk 5 beschrijft een studie die de voorspelbaarheid analyseert van fitting niveaus voor individuele cochleair implantaat gebruikers. De studie is gebaseerd op een analyse van cohortgegevens. De gegevens bestaan uit de drempel niveaus (threshold levels, T-levels) en de maximale luidheid niveaus (maximum comfort levels, M-levels) van 151 volwassen personen die een CII/HiRes90K cochleair implantaat met een HiFocus 1/1J elektrode gebruiken. De 10e, 25e, 50e, 75e en 90e percentiel van de T- en M-levels worden gerapporteerd. Het spraakverstaan van de personen, gebruik makend van een HiRes spraak-coderingsstrategie, werd gemeten tijdens routine klinische follow-up. De T-levels van de meeste personen bevonden zich tussen de 20 en 35% van hun M-levels en kwam zelden (<1/50) onder de 10% van de M-levels (hetgeen de standaard van de fabrikant is). Verder namen zowel de T- als de M-levels toe in het eerste jaar van follow-up. Interessant genoeg lieten de niveaus uitgedrukt in lineaire charge units een duidelijke toename in dynamisch bereik (dynamic range, DR) zien gedurende 1 jaar (29,8 CU; SD 73,0), terwijl de DR uitgedrukt in decibellen stabiel bleef. De T-levels en DR waren de enige fitting parameters die een significante correlatie met spraakverstaan lieten zien (respectievelijk: $r = 0,34$; $p < 0,01$; en $r = 0,33$; $p < 0,01$). Verder bleken de T- en M-level profielen uitgedrukt in decibellen onafhankelijk te zijn van de proefpersoon zijn gemiddelde level. Dit werd gedemonstreerd met behulp van mixed linear models. Gebaseerd op de set gegevens van 151 personen werden klinisch toepasbaar voorspellingsmodellen voor T- en M-levels voor alle losse elektrode contacten verkregen. Deze formules, gebaseerd op de beschreven set gegevens, maken het mogelijk voor een individu de T- en M-levels nauwgezet te benaderen op basis van slechts een psychofysische meting. Verder kunnen de geanalyseerde fitting niveau gegevens als een referentie dienen voor toekomstige patiënten.

Hoofdstuk 6 presenteert een analyse van de effecten van intracochleaire positie van cochleaire implantaten op de klinische fitting niveaus. In totaal 130 volwassen proefpersonen, die een CII/HiRes 90K cochleair implantaat met een HiFocus 1/1J elektrode werden geïncludeerd in de studie. De insertie hoek en de afstand tot de modiolus van elk elektrode contact werd bepaald met behulp van hoge resolutie CT-scans. De T-levels en de M-levels werden bepaald na 1 jaar van follow-up. Het spraakverstaan werd geëvalueerd tijdens routine klinische follow-up. De afstand tot de modiolus was significant kleiner in de basale en apicale gedeeltes van de cochlea, vergeleken met het midden van de cochlea ($p < 0,05$). Gemiddeld namen de T-levels toe met 3,4 dB richting het basale eind van de cochlea. De M-levels, die in onze kliniek met een standaard profiel gefit werden, namen ook tot richting het basale eind, echter in mindere mate (1,3 dB). Overeenkomstig nam het dynamisch bereik af richting het basale eind (1,2 dB). Er werd geen correlatie gevonden tussen de afstand tot de modiolus en de T-levels of de M-levels en de correlatie tussen de insertie diepte en de stimulatielevels werd niet beïnvloed door de duur van doofheid, de leeftijd bij implantatie of de tijd sinds de implantatie. De stimulatie niveaus van de cochleaire implantaten werden beïnvloed door de intracochleaire positie, zoals bepaald met behulp van CT-scan. Interessant genoeg, zijn deze niveaus afhankelijk van de insertiediepte, terwijl de afstand tot de modiolus geen effect heeft op de stimulatie niveaus. De T-levels namen toe richting het basale eind van de cochlea. De niveau profielen waren onafhankelijk van de overall stimulatie niveaus en werden niet beïnvloed door de patiënt zijn biografische gegevens, inclusief de duur van doofheid, de leeftijd ten tijde van implantatie of de tijd sinds de implantatie. De overall T-levels, echter, lieten een significant negatieve correlatie met spraakverstaan zien ($p < 0,005$). Toekomstig onderzoek zou verklaringen kunnen opleveren voor de effecten van de intracochleaire positie op de stimulatie niveaus, die mogelijk op hun beurt verbeteringen in toekomstige elektrode ontwerpen kunnen opleveren.

Hoofdstuk 7 bevat de algemene discussie van de resultaten en de belangrijkste conclusies van de studies in dit proefschrift. Alhoewel klinische verbeteringen in spraakverstaan bereikt kunnen worden door het verbeteren van de interface met richtmicrofoons en intrascalaire positionering, is meer onderzoek nodig om de kwaliteit van de interface van cochleaire implantaten te verbeteren. Allereerst zou de kwaliteit van eCAP metingen (bijv. de signaal-ruis verhouding) verbeterd dienen te worden om een meer gedetailleerd beeld van de elektrode-neurale interface te krijgen. Verder is het van belang om continue gegevens over klinische stimulatie niveaus van alle bestaande en toekomstige elektrode designs te blijven verzamelen en deze te analyseren. Dergelijk onderzoek zou uiteindelijk kunnen ophelderen wat de effecten zijn van intracochleaire positie en van verschillende andere aspecten van de interface op klinische uitkomsten. Dit onderzoek kan bijdragen aan het voortdurend verbeteren van de interface van de cochleaire implantaten en daarmee resulteren in het verbeteren van spraakverstaan met cochleaire implantaten.

CURRICULUM VITAE

Feddo Bauke van der Beek was born in Rotterdam on March 12, 1976. He attended secondary school at the Christelijk Lyceum Dr. W.A. Visser't Hooft in Leiden and graduated in 1994. In that same year, he began his medical study at the Leiden University. In the course of his academic internship, he performed research on the effects of fractionated irradiation on osteosarcoma cells at the Atomic Bomb Disease Institute in Nagasaki, Japan, in 1999, under the guidance of Prof. Y. Okumura and Dr. K. Okaichi.

In 2003, he began his research in the field of cochlear implants as a physician researcher at the Leiden University Medical Center (LUMC), which was the origin of the present thesis. From 2005 to 2010, he was trained as an otolaryngologist at the LUMC (supervisors Prof. Dr.Ir. J.H.M. Frijns and Dr. A.G.L. van der Mey), Westeinde Hospital, The Hague (supervisor Dr. H.P. Verschuur) and Rijnland Hospital, Leiderdorp (supervisors Dr. J.H. Hulshof and Dr. M.L. Sassen). From 2010 to 2013, he worked as an otolaryngologist in a combined appointment in the Diaconessenhuis Hospital and the LUMC in Leiden. In 2013, a two-month clinical observership was combined with research in the cochlear implant field at the Unfallkrankenhaus Berlin (Prof. Dr. A. Ernst, Dr. I. Todt and Dr. J. Wagner). From 2013 to May 2015, he worked as an ENT staff member at the LUMC with a focus on otology and cochlear implantations.

Since May 2015, he has worked as an ENT surgeon in the Medical Spectrum Twente in Enschede. He has been married to Annemarie van der Beek-Kreeft since 2009, and they have two sons, Jan (2010) and Gijs (2012).

CURRICULUM VITAE

Feddo Bauke van der Beek werd geboren in Rotterdam op 12 maart 1976. Zijn gymnasium eindexamen haalde hij in 1994 op het Christelijk lyceum dr W.A. Visser't Hooft te Leiden. In datzelfde jaar ving hij aan met de studie geneeskunde aan de Universiteit Leiden. In het kader van de wetenschappelijke stage werd in 1999 onderzoek verricht naar het effect van gefractioneerde bestraling op osteosarcoom cellen in het Atoombom Ziekte Instituut in Nagasaki, Japan, onder leiding van prof. Y. Okumura en dr K. Okaichi.

In 2003 ving hij aan met onderzoek naar cochlear implants als arts-onderzoeker in het LUMC, hetgeen de aanzet was tot het huidige proefschrift. Van 2005 tot 2010 werd hij opgeleid tot KNO-arts in het LUMC (opleider prof. dr J.H.M. Frijns, plv opleider dr A.G.L. van der Mey). De perifere stages werden gevolgd in het Westeinde ziekenhuis (B-opleider dr H.P. Verschuur) en Rijnland ziekenhuis (B-opleiders dr J.H. Hulshof en dr M.L. Sassen). Van 2010 tot 2013 werkte hij als KNO-arts in een gecombineerde aanstelling in het Diaconessenhuis en het LUMC te Leiden. In 2013 werd gedurende twee maanden wetenschappelijk onderzoek gecombineerd met een clinical observership in het Unfallkrankenhaus in Berlijn bij prof. dr A. Ernst, dr I. Todt en dr J. Wagner. Vanaf 2013 tot mei 2015 heeft hij gewerkt als staflid KNO in het LUMC met als aandachtsgebied otologie en cochleaire implantaties.

Sinds mei 2015 is hij werkzaam als KNO-arts in het Medische Spectrum Twente in Enschede. Hij is getrouwd met Annemarie van der Beek-Kreeft sinds 2009 en zij hebben de zonen Jan (2010) en Gijs (2012).