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

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Abstract

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 peri-modiolar electrode designs, focussing 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, 6 months and 1 year (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 peri-modiolar position showed deeper insertions. The T-levels 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.

Conclusion: 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 peri-modiolar electrode design. Further research is needed to elucidate their individual contributions to those outcomes.
Introduction

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 peri-modiolar 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 electrical stimulated cochlea (Frijns, Briaire, & Grote, 2001). The findings of this comparison were that at a peri-modiolar 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 fibres originating from the cochlear turn above the location of the stimulating electrode contact.

After different peri-modiolar designs were introduced, temporal bone studies proved the peri-modiolar position of these electrodes (Tykocinski 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 peri-modiolar 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 peri-modiolar 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 peri-modiolar 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 peri-modiolar 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 tympani (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 peri-modiolar 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 FDA 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 peri-modiolar 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 (multi slice 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 modelling measurements (Vanpoucke et al., 2004) are discussed.

**Material & Methods**

All 45 patients in this study have been implanted in the Leiden University Medical Centre 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 centre 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 NP-group 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 felt during insertion of the electrode array. The results of the NP-group will be presented separately for the group of the first 9 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.

Speech Material
Speech discrimination scores were assessed during normal clinical follow-up at predetermined intervals, starting one 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 Anglo-Saxon countries. For tests in noise the standard speech-shaped noise from the same CD was used. To improve test accuracy, 4 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 4 signal to noise ratios (SNR), starting with a 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 patients’ score in quiet.
Table 1. Patient demographics

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<th>NP-group</th>
<th>NPs-group</th>
<th>NPd-group</th>
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<td></td>
<td>All 25</td>
<td>All 20</td>
<td>NPd (n9)</td>
<td></td>
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<tr>
<td>Age at implantation (yr)</td>
<td>44.9 (13.4;14.0-67.0)**</td>
<td>59.9 (10.8;40.0-76.0)**</td>
<td>60.1 (7.6;50.0-71.0)**</td>
<td>59.6 (13.3;40.0-76.0)**</td>
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<td>Duration of deafness (yr)</td>
<td>18.5 (15.0;0.2-43.0)</td>
<td>16.8 (14.5;0.3-46.0)</td>
<td>16.7 (16.5;0.3-46.0)</td>
<td>18.8 (14.4;2.0-46.0)</td>
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<td>Preoperative phoneme scores (%)</td>
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<td>Ipsilateral</td>
<td>6.3 (9.8;0.0-33.0)</td>
<td>7.2 (11.0;0.0-42.0)</td>
<td>2.0 (6.0;0.0-18.0)</td>
<td>11.5 (12.5;0.0-42.0)</td>
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<td>Contralateral</td>
<td>4.0 (9.8;0.0-45.0)</td>
<td>2.3 (5.9;0.0-24.0)</td>
<td>0.3 (1.0;0.0-3.0)</td>
<td>3.8 (7.7;0.0-24.0)</td>
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<td>Preoperative tone audiogram (%)</td>
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<tr>
<td>Ipsilateral</td>
<td>111.6 (12.4;85.0-130.0)</td>
<td>117.7 (12.0;83.3-130.0)</td>
<td>119.6 (14.5;83.3-130.0)</td>
<td>104.2 (14.6;85.0-130.0)</td>
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<tr>
<td>Contralateral</td>
<td>116.1 (7.8;103.3-130.0)</td>
<td>109.6 (15.4;85.0-130.0)</td>
<td>116.1 (14.5;90.0-130.0)</td>
<td>116.1 (10.0;101.7-130.0)</td>
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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.

Table 2. Causes of deafness in the various patient groups

<table>
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<th>NPs-group</th>
<th>NPd-group</th>
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<td>0</td>
<td>0</td>
<td>0</td>
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<td>Progressive</td>
<td>7</td>
<td>5</td>
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<td>4</td>
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<td>Sudden deafness</td>
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<tr>
<td>Total</td>
<td>25</td>
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<td>9</td>
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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 peri-modiolar 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 (figure 1B, NPs-patient) tends to be positioned laterally throughout 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 centres 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.

Figure 1. Typical oblique multi-planar 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 illustrates the insertion angle of an electrode contact expressed in degrees, and d shows the radial distance from this contact to the modiolus.
T-levels, M-levels & Dynamic Range
All patients in this study used a CIS-strategy. Except for five 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 μsec/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 μsec/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 P and NP groups. For all electrode contacts the thresholds (T-levels) and the most comfortable loudness levels (M-levels) were determined during fitting following the Leiden fitting strategy (Frijns et al., 2002; Reference Note). The T-levels were obtained in burst mode with an up-down-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 T- and M-levels included in this study were obtained after approximately 3 mos of implant use in SCLIN emulation mode. T- and M-levels acquired from the five P-patients who always used HiRes were not comparable to those of the SCLIN-patients, 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 the induced intracochlear potential is captured at all electrode contacts (figure 2A). From the intracochlear impedance map, a leaky resistive transmission line model is derived by using multi-dimensional optimization algorithms. The electrical tissue model is a ladder network with 15 sections (figure 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- and the NP-group. The data are displayed as phoneme scores (figure 3A), which is standard for this monosyllabic word test, and are also displayed as word scores (figure 3B) for a better international comparison. One year of follow-up was complete for both the P- 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 reception scores of the NPs- and the NPd-group only revealed limited differences between both groups (figure 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).

Demographic factors showed little differences between the P- and 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 ys. 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 P- and NP-group and no significant correlations were found ($R^2<0.001$, $p>0.9$ and $R^2=0.002$, $p>0.9$). Both the 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 $R^2=0.007$, $p>0.7$).

**Figure 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).
Figure 3. Speech perception on monosyllabic (CVC) words in quiet of the positioner-group (P) and the non positioner-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 perception scores of both groups are marked (*p<0.05; **p<0.01). The number of patients in the subgroups is shown in Table 3.
Figure 4. A, Phoneme scores on monosyllabic (CVC) words in quiet after 1 yr of follow-up of the positioner-group (P) and the non positioner-group (NP) plotted against the age at implantation. The lack of correlation is shown by trendlines, $R^2$ and $p$ values. B, Phoneme scores after 1 yr of follow-up of the positioner-group (P) and the non positioner group (NP) plotted against the duration of deafness. The lack of correlation is shown by trendlines, $R^2$ and $p$ values. 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

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| Figure 7C | P: | n= 20 |
| NP: | n= 16 |
| NPs: | n= 8 |
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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 NP-patients 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 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 Method 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 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 (figure 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 (figure 5A). This
difference is more prominent basally than apically, and the most basal electrode contacts as well contacts 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.

**Figure 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 non positioner-group (NP) plotted against the insertion depth of the most apical electrode contact. The lack of correlation is shown by trend lines, R² and p values. The number of patients in the subgroups is shown for electrode contacts and for the depth ranges in Table 3.
The first 9 NP-patients have a shallow insertion compared to 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 NPs- and 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 (figure 5C) (p>0.5).

Table 4. Insertion depths of electrode contacts, in degrees as measured on multi slice CT scans

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<tr>
<td>Most apical</td>
<td>439 (73;105-559)</td>
<td>401 (105;278-612)</td>
</tr>
<tr>
<td>Most basal</td>
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*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.

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 3 basal most depth ranges differ significantly between the P-group 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 NPs- and NPd-groups were similar.

Figure 6. T-levels of the positioner-group (P) and the non positioner-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 patient in the subgroups is shown for electrode pairs and for the depth ranges in Table 3.

T-levels, M-levels & Dynamic Range
Contrary to the expectations based on the fact that the contacts in the P-group are closer to the nerve fibres 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) (figure. 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 inter-individual T-levels vary greatly, the intra-individual T-levels along the array
show great consistency 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 figure 6 A). 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) (figure 6B). In the NPs-group 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 (figure 6A). However, the overall T-levels of the NPs- and NPd-groups 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 (figure 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$_{\text{Long}}$) along the electrode array as calculated with the EFI-model (Vanpoucke et al., 2004). This r$_{\text{Long}}$ 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 subgroups and do not reach significant
levels. The resistances in transversal direction \( (r_{\text{Trans}}) \) are more than a factor 100 higher than the corresponding \( r_{\text{Long}} \) values (figure 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 \( (r_{\text{Basal}}) \) (figure 7C), which is at least five times the \( r_{\text{Long}} \) value in all groups. This is the resistance from the basal contact of the cochlea to the reference electrode contact. This \( r_{\text{Basal}} \) reveals differences between the subgroups. The basal resistance of the NPs-subgroup is significantly lower than the \( r_{\text{Basal}} \) of both the P- as 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 P- and NP-group (figure 7D). Moreover, the NPs and NPd show comparable values (not plotted in figure 7D). However, the \( r_{\text{Tissue}} \) 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 (figure 7D). Also the \( r_{\text{Long}} \) and \( r_{\text{Trans}} \) of the NP-group showed this basal increase.

**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 peri-modiolar 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 which 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.

**Figure 7.** The longitudinal \( r_{\text{Long}} \) (A) and transversal \( r_{\text{Trans}} \) (B) resistances per depth range as acquired with the EFI (Electrical Field Imaging) model. C, Basal resistance \( r_{\text{Basal}} \) 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 \( r_{\text{Tissue}} \) 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 range in Table 3.

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 favourable 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, ...
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 NP-patients. 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 to 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 to 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 (Boëx, Kos, & Pelizzzone, 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 randomisation 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 multi-centre study, which also showed no systematic association of speech perception with age at implantation (UK Cochlear Implant Study Group, 2004). Additionally, the different amount of usage of HiRes programs between the P- and 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 P- and NP-groups, respectively). Moreover, the average time of experience with those HiRes strategies was the same at 1 year (P versus NP: 8 mos).

As reported elsewhere (Reference Note), the duration of deafness is not a predictor of post-operative 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 P- and 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 post-operative MSCT scans, the threshold and maximum comfort levels were not lower in the P-group (figure 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 fibres 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 fibres 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 to 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 fibres 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 to 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.
Conclusion

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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References

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


**Reference note**
