Original Article

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*Rolf D. Battmer**
Norbert Dillier†
Wai K. Lai†
Benno P. Weber†
Carolyn Brown‡
Bruce J. Gantz‡
J. Thomas Roland‡
Noel. J. Cohen§
William Shapiro§
Joerg Pesch||
Matthijs J. Killian#
*Thomas Lenarz**

*Medizinische Hochschule Hannover, Hannover, Germany,
†University Hospital Zürich, Zürich, Switzerland,
‡University of Iowa Hospitals and Clinics, Iowa City, IA, USA,
§New York University School of Medicine, New York, NY, USA,
||Cochlear GmbH Hannover, Hannover, Germany,
#Cochlear Technology Center, Mechelen, Belgium

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Evaluation of the Neural Response Telemetry (NRT) capabilities of the Nucleus Research Platform 8: initial results from the NRT trial

Evaluación de la capacidad de la Telemetría de Respuesta Neuronal (NRT) de la Plataforma 8 de Investigación de Nucleus: resultados iniciales del estudio NRT

Abstract
The purpose of this study was to evaluate the performance of the new features of the Nucleus Research Platform 8 (RP8), a system developed specifically for research purposes. The RP8 consists of a research implant, a speech processor and a new NRT software (NRT v4), and includes comparisons of the different artefact-cancellation methods, NRT threshold, and recovery function measurements. The system has new artefact-suppression techniques and new diagnostic capabilities; their performance has been verified in animal experiments. In this study, NRT data were collected from 15 postlingually deafened adult cochlear implant patients intraoperatively and up to 6 months postoperatively after switch-on. The initial investigation in two clinics in Europe focused primarily on the enhanced NRT capabilities. Results from the trial in two European clinics indicate that NRT measurements can be obtained with lower noise levels. A comparison of the different artefact-cancellation techniques showed that the forward-masking paradigm implemented in the Nucleus 3 system is still the method of choice. The focus of this report is on recovery function characteristics, which may give insight into auditory nerve fiber properties with regard to higher stimulation rates.

Sumario
El propósito de este estudio fue evaluar el desempeño de las nuevas características de la Plataforma 8 de Investigación de Nucleus (RP8), un sistema desarrollado específicamente para propósitos de investigación. La RP8 consiste en un implante experimental, un procesador de lenguaje y un nuevo programa NRT (NRT v4), e incluye comparaciones con los diferentes métodos de cancelación de artefactos, con los umbrales NRT y las medidas de recuperación de función. El sistema tiene nuevas técnicas de supresión de artefactos y nuevas capacidades diagnósticas; su desempeño ha sido verificado en experimentos con animales. En este estudio, los datos de la NRT se colectaron de 15 pacientes, adultos ensordecidos y usuarios de un implante coclear, tanto trans-operatoriamente y hasta 6 meses después de la activación del implante. La investigación inicial en dos clínicas en Europa se concentró primariamente en el incremento de la capacidad de la NRT. Los resultados del estudio en dos clínicas europeas indican que las mediciones de la NRT puede obtenerse con niveles menores de ruido. Una comparación de las diferentes técnicas de cancelación de artefactos mostró que el paradigma de enmascaramiento anterógrado, implementado en el sistema Nucleus 3, continúa siendo el método de elección. La atención de este reporte se concentra en las características de la función de recuperación, que puede proporcionar conocimiento de las propiedades de las fibras nerviosas auditivas y su respuesta a tasas mayores de estimulación.

The first direct intracochlear recordings of the electrically evoked compound action potential (ECAP) were achieved with the Nucleus 24 cochlear implant in 1996, and the method of Neural Response Telemetry (NRT) was validated in a multicenter trial (Brown et al, 1998; Abbas et al, 1999; Dillier et al, 2002). These NRT recordings are now widely used to help in the cochlear implant (CI) fitting process and monitor device integrity (Brown et al, 2000; Hughes et al, 2000; Mason et al, 2001; Thai-Van et al, 2001; Seyle & Brown, 2002; Smoorenburg et al, 2002; Gordon et al, 2002; Kiss et al, 2003). One of the major clinical benefits of NRT is the reduction in the time needed for mapping very young children and those recipients who are unable to give appropriate feedback with the use of behavioral fitting methods. Although the time spent on NRT measurements has been successfully reduced with the current commercial NRT system, manual parameter optimization and NRT data analysis are still required (Lai, 1999). The use of an enhanced amplifier and new software to further automate NRT measurements and to improve the precision of the ECAP recordings is being investigated in several studies. The Nucleus Research Platform 8 (RP8) CI system has been specifically developed for such research purposes. The initial investigation focused on the enhanced NRT capabilities. The main objective of this investigation was to define clinical default parameters and evaluate the effectiveness of the artefact-reduction techniques implemented in the NRT software. In this article, we present some preliminary results of this investigation and focus on recovery function measurements.

Corresponding author: Dr Rolf-D. Battmer
Department of Otolaryngology,
Karl-Neuberg-Str. 1, 30625 Hannover, Germany
E-mail: bat@hno.mh-hannover.de

Methods

The RP8 system

The RP8 system comprises:

- the CI24RE research implant with the Contour electrode array with Softip
- the Laura L34SP body-worn research speech processor
- the Nucleus Programming Environment, including an administration module, a fitting module and an NRT module

The RP8 has an improved amplifier with a lower noise floor and better linearity. Four new artefact-cancellation methods are implemented in addition to the standard artefact-cancellation method implemented in the Nucleus 3 system.

The new methods are as follows:

- Alternating polarity (AP). In this method, the polarity of the biphasic pulse, and thereby the artefact, is alternated. The response to the alternating short biphasic stimulus is relatively stable in latency, and the ECAP is found by averaging the response to both polarities.
- Scaled template (ST). In this method, a subthreshold artefact template that is scaled to match the suprathreshold stimulus artefact is used. The scaled artefact template is subtracted from the suprathreshold recording to obtain artefact-free ECAPs.
- Masked response extraction (MRE). This is an implementation of the method described by Miller et al (2000). This method is used to record ECAP recovery functions by varying the interval between masker and probe.
- Artefact-reduction pulse (ARP). In this method, use is made of a third phase, also called ARP, in addition to the biphasic pulse. The current level of the ARP is adjustable, and an automated method has been implemented to minimize the artefact. ARP can be combined with any of the previous methods.

Subjects

Fifteen recipients were recruited for this study. All recipients met the inclusion/exclusion criteria listed below.

INCLUSION CRITERIA

1. Eighteen years of age or older.
2. Postlinguistic onset of bilateral severe-to-profound sensorineural hearing loss, with no known congenital component.
3. Duration of severe-to-profound sensorineural hearing loss in the ear selected for implantation of 15 years or less.
4. Native speakers in the language used to assess speech perception performance.
5. Willingness to participate in and to comply with all requirements of the protocol.

EXCLUSION CRITERIA

1. Ossification or any other cochlear anomaly that might prevent complete insertion of the electrode array, as confirmed by medical examination and tests including magnetic resonance imaging (MRI).
2. Signs of retrocochlear or central origin of hearing impairment as confirmed by medical examination and tests including MRI.
3. Medical or psychological conditions that would contraindicate surgery (e.g. active middle ear infections, tympanic membrane perforation).
4. Additional handicaps that would prevent participation in evaluations.
5. Unrealistic expectations on the part of the subject, regarding the possible benefits, risks and limitations that are inherent to the procedure and prosthetic device.

Measurements

In the RP8 study, we investigated and compared the effectiveness of the different artefact-cancellation methods by recording amplitude growth functions (AGFs) and recovery functions on different electrodes during regular study visits. Measurements were done both intra- and postoperatively.

AGF

AGFs of the ECAPs were recorded at least on electrodes 3, 5, 10, 15 and 20, with use being made of the following artefact-cancellation methods: forward masking (standard method), AP, ST, and ARP. AGFs were measured in steps of five current levels (CLs). Measurements close to threshold were done in steps of two CLs. From these AGFs, the ECAP thresholds (T-NRTs) were determined with use of the linear extrapolation method. T-NRTs are correlated with behavioral threshold (T) and comfort (C) levels. In this article, we present a recipient with double-peaked ECAPs in whom AGFs and behavioral T and C levels have been recorded on most electrodes.

RECOVERY FUNCTION

The recovery functions were measured with use of the MRE method. In order to obtain a complete recovery function, the masker probe interval (MPI) was varied between 100 and 10 000 μs, and the reference MPI was set at 300 μs. In each recipient, recovery functions were measured on different electrodes with use of a masker and probe CL close to the loudest acceptable presentation level (LAPL). In a few subjects, the recovery functions were studied at three different CLs.

At short MPIs, all auditory nerve fibers are assumed to be in their absolute refractory state, and no neural response can be recorded. With increasing MPI during the relative refractory period, an ECAP appears and increases in amplitude with increasing MPI until a saturation level is reached at which all fibers recover from refractoriness. Recovery functions are fitted with a mathematical model proposed by Müller-Deile et al (2003): $F(\mathrm{MPI}) = A(1 - \exp[-\alpha(\mathrm{MPI} - T_0)])$. A is the maximal amplitude of the neural response at saturation level, T_0 is a measure of the absolute refractory period, and α is the time constant of recovery during the relative refractory period. The recovery functions recorded on different electrodes and at different stimulation levels will be compared by means of their T_0 and α.

Results

AGFs and artefact-cancellation methods

The initial results with the RP8 system show the benefits of the new amplifier. ECAP recordings had about five times lower noise floors, and less stimulus artefact could be achieved with fewer averages than with the Nucleus 3 system. The initial results obtained with the different artefact-cancellation methods

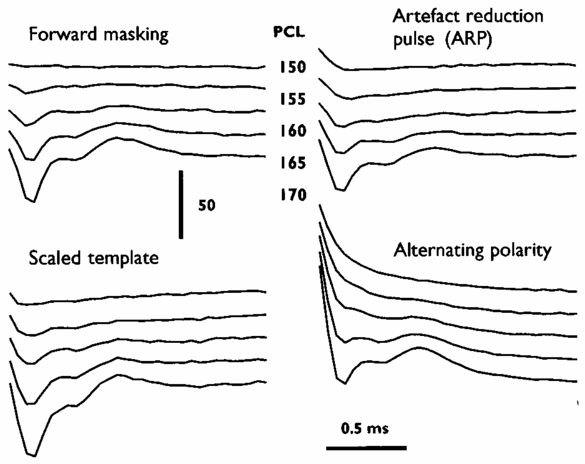

Figure 1. Comparison of different artefact-cancellation techniques. The forward-masking method implemented in the Nucleus 3 system gives the best results.

in one recipient are presented in Figure 1. In all currently included recipients, the forward-masking method, also implemented in NRT v3.0, has been successful. The ARP and ST methods seem to be the most promising of the new techniques. The results obtained with the MRE method are discussed below.

For all recipients, it was possible to obtain recordings on all electrodes measured with use of the forward-masking method. In one of the recipients, ECAPs with a clear double-peaked pattern were observed (Figure 2). This pattern has been described previously as a type II response by Lai & Dillier (2000).

T-NRT and behavioral T and C levels

In the recipient with a double-peaked response, we obtained AGFs and extrapolated ECAP thresholds (T-NRTs) on electrodes 3–22. Figure 3 shows that in this recipient the T-NRT profile correlates well with the behavioral T profile and C profile. On the electrodes in the middle of the array, T-NRTs are close to the behavioral T level, while T-NRTs tend to shift towards the behavioral C level at the basal end of the array. The typical double-peaked response was found primarily in the middle of the array (electrodes 8–18).

Recovery functions

The NRT software of the RP8 platform allows the recording of recovery functions with use of the MRE method. Figure 4 shows a set of ECAPs recorded at different MPIs, with use of a reference MPI of 300 μs. From these ECAPs, the N_1P_1 amplitude was calculated in order to obtain the recovery function (Figure 5), which was fitted with the exponential model. Figure 6 shows the decrease in N_1 latency with increasing MPI.

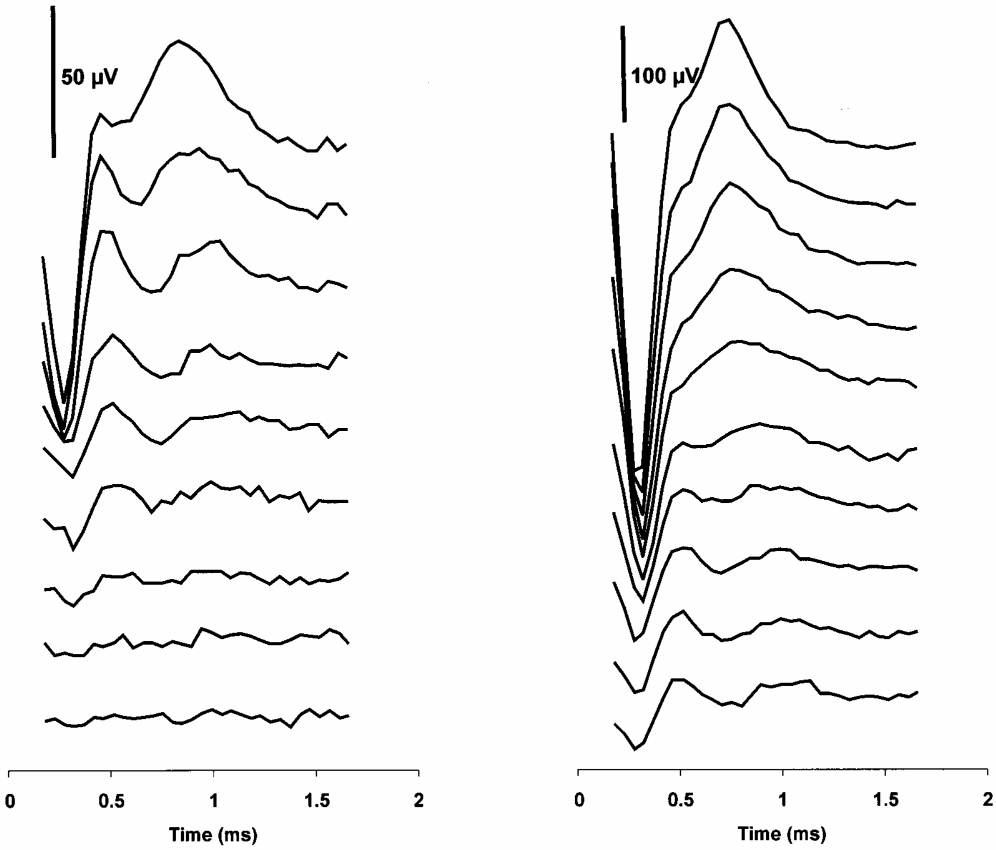

Figure 2. Responses of a recipient with clear double peaks, with use of the forward-masking method. Note that the second component wave following the P_1 peak disappears at higher current levels.

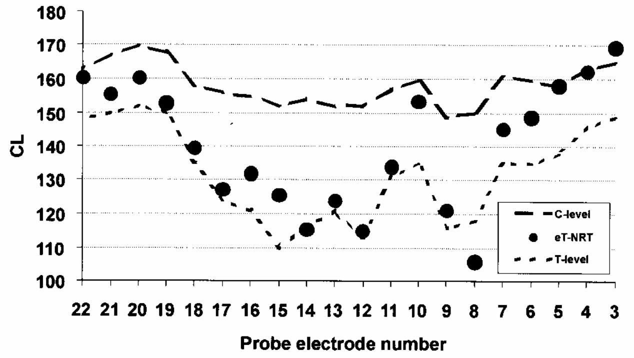

Figure 3. Extrapolated T-NRT (eT-NRT) profile compared to behavioral threshold (T) and comfort (C) levels. Correlation (eT-NRT, C level) = 0.87, and correlation (eT-NRT, T level) = 0.92.

A series of four recovery functions at different stimulation levels (CL: 165, 170, 180 and 195) is shown in Figure 7. The corresponding α and T_0 values are shown in Table 1. As expected, the saturation level increases with CL. Furthermore, α and T_0 decrease with increasing stimulation level.

A series of five recovery functions at different electrodes (electrodes 5, 8, 10, 15 and 20) is shown in Figure 8. In this series, the saturation level was kept between 70 and 140 μV in order to allow a fair comparison among electrodes. Table 2 shows the corresponding α and T_0 values. In this case, there seems to be no great variability in refractoriness on the different electrodes.

Discussion

The new amplifier in the RP8 system allows ECAP recordings with low noise levels, which holds promise for more detailed and faster ECAP recordings in future Nucleus systems. Double-peaked responses can be easily recognized with use of this system,

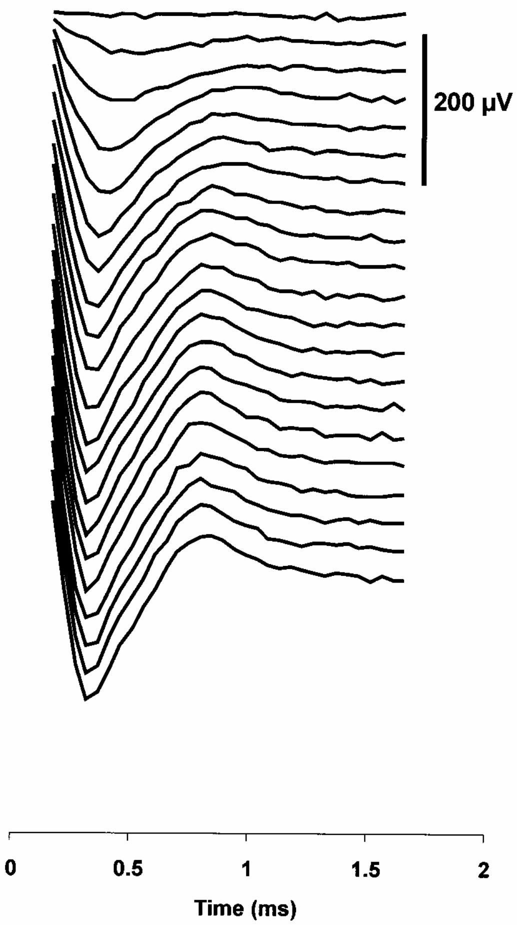

Figure 4. Recordings of a recovery function measurement. From top to bottom, the masker probe interval varied from 400 μs to 10 000 μs.

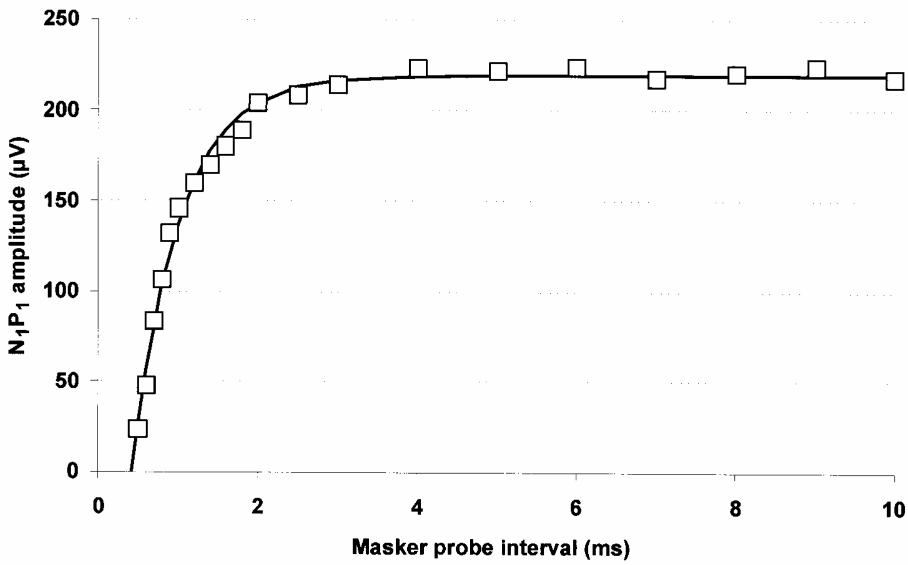

Figure 5. Fitted recovery function: $F(MPI) = A(1 - \exp[-\alpha(\mathrm{MPI} - T_0)])$. Parameters: $\alpha = 1.7 \times 10^{-3}\,\mu s^{-1}$, $T_0 = 425.7\,\mu s$, $A = 219.0\,\mu V$.

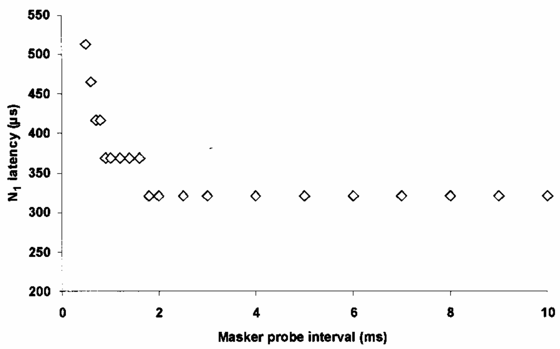

Figure 6. N_1 latency as a function of masker probe interval.

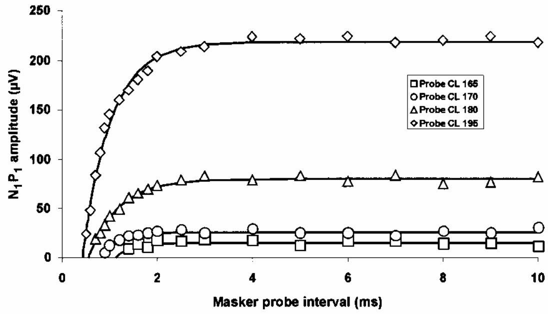

Figure 7. Recovery function fitting with different probe current levels (CLs) (electrode 5).

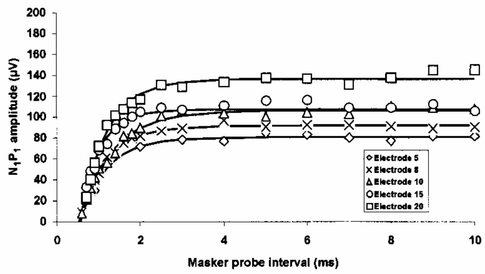

Figure 8. Recovery function fitting with different probe electrodes.

and the clinical implications of double-peaked responses need further investigation. The forward-masking artefact-cancellation method is well recognized as the gold standard. The ARP and ST are promising new artefact-cancellation methods that will allow faster recordings and make it possible to investigate new stimulation paradigms in Nucleus CI recipients. In the recipient presented in this article, the T-NRT profiles correlate well with behavioral T and C levels and are close to the behavioral T level.

There is a potential for recovery functions to be used in fitting. For example, Shpak et al (2003) showed a correlation between recovery and rate preference, and Müller-Deile et al (2003) demonstrated that there is a potential for recovery functions to be used in NRT-based fitting. Our preliminary results in one recipient suggest that the time constants of the recovery function may vary with CL and are relatively constant along the electrode array. In order to further identify the clinical use of the recovery function, more results are needed in a diverse clinical population.

The results of the RP8 study will open new opportunities to extend the clinical application of NRT and will help to optimize the recipient's individual stimulation parameters, improving speech recognition and sound quality.

Table 1. Recovery function parameters for fitting with different probe current levels (CLs)

Probe CL	*α (×10⁻³)*	*Saturation*	*Threshold*
165	3.5	14.7	1127.9
170	2.9	25.9	833.9
180	1.6	79.5	559.2
195	1.7	218.4	428.3

Table 2. Recovery function parameters for fitting with different probe electrodes

Electrode	*Probe CL*	*α (×10⁻³)*	*Saturation*	*Threshold*
15	160	2.1	107.2	541.7
20	180	1.6	136.5	566.3
10	170	1.3	106.3	522.1
5	175	1.5	80.8	542.7
8	170	1.6	91.5	529.1

CL, current level.

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