The effect of pulse rate on temporal resolution and speech intelligibility in cochlear implant users

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21134

Source
NTR

Health condition

Cochlear implant
Pulse rate
Temporal resolution
Speech intelligibility

Sponsors and support

Primary sponsor: Maastricht University Medical Center (MUMC+)
Source(s) of monetary or material Support: Maastricht University Medical Center (MUMC+)

Intervention

Outcome measures

Primary outcome

There are three main objectives in this research project:

1. Investigate the correlation between varying the CI pulse rate and temporal resolution by means of AMDT at two modulation frequencies

2. Investigate the correlation between varying the CI pulse rate and speech intelligibility by means of standard CVC speech test at normal speech level and LIST

3. Investigate the reproducibility of the measurements, as these are performed in a test-retest fashion.

For the listening task in objective 1, the main study parameter is the amplitude modulation detection threshold (AMDT) of postlingual CI users as a function of pulse rate at two modulation frequencies. The AMDT, a measure of temporal resolution, is the minimal modulation depth needed for the subject to distinguish amplitude modulated from amplitude unmodulated noise samples. For objective 2, the main study parameter is speech intelligibility (phoneme score for CVC and SRT for LIST) as a function of pulse rate. For objective 3, the intraclass correlation coefficient and 95% confidence intervals will be determined.

Secondary outcome

As secondary outcomes, correlation coefficients will be calculated between the obtained AMDTs at different modulation frequencies and between AMDTs at different modulation frequencies and speech intelligibility scores for each pulse rate.

Study description

Background summary

Rationale:

Spectral and temporal resolution are thought to be key contributors to understanding speech by cochlear implant (CI) users. In theory, increasing temporal resolution would enhance discrimination of fast intensity fluctuations in speech. However, clinical studies seem to indicate the opposite; they show a better speech understanding at reduced pulse rates, although the majority of these studies do not mimic real-life situations. In most cases, the pulse rates of only 1 or 2 electrodes are altered whereas other electrodes are deactivated. Therefore, additional information is required on the effects of pulse rate on speech intelligibility in a more real-life test environment.

Objectives:

To determine the (in)direct effect of CI pulse rate on speech intelligibility by means of (1) a standard test for temporal resolution: amplitude modulation detection (AMD) at two different modulation frequencies, (2) speech intelligibility tests (words in quiet and sentences in noise) and (3) investigate the reproducibility of the measurements.

Study design:

Interventional prospective cohort study to investigate correlations between pulse rate and speech intelligibility in post-lingually hearing impaired adult CI users.

Study population:

The study population consists of adult cochlear implant users from the CI-team South-East Netherlands patient population with an onset of deafness/severe hearing loss after the age of 4 years (post-lingual). No upper age limit is defined, since the participation depends on their willingness and ability to participate. Participants should have at least 1 year of experience with the uni- or bilateral cochlear implant(s) from the brand Cochlear.

Main study parameters/endpoints

The main study parameters are the temporal resolution capabilities – expressed as amplitude modulation detection threshold (AMDT) - and speech intelligibility – expressed as phoneme score (words in quiet) and speech recognition threshold (sentences in noise) - as a function of CI pulse rate in post-lingually hearing impaired CI users.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The intervention, i.e. replacement of the subjects' speech processor with our own speech processor with preprogrammed MAPs during the tests, is equal for all subjects. This will increase time efficiency and ensure proper functioning of the speech processor during experiments. Associated risks are therefore considered minor to negligible. Participation does require time and effort from the subjects. Although we expect no direct benefits noticeable by the subjects when altering the pulse rate, the obtained results may contribute to optimized speech processing strategies in the future.

Study objective

CI pulse rate is known to affect temporal resolution and speech intelligibility. Based on

literature it is hypothesized that low pulse rates decrease temporal resolution, but increase speech intelligibility.

Study design

N/A

Intervention

The patients that comply to the in- and exclusion criteria have specific types of speech processors, each of which is able to carry a maximum of 4 programs (MAPs, which drive the implant electrodes). To minimize risk for the patients CI, increase time efficiency and ensure proper functioning of the speech processor during experiments, we will not use the patient speech processor, but our own processors (same type as used by patient) that carry preprogrammed MAPs. The processors are programmed using the standard clinical fitting software Custom Sound™ from Cochlear, with 3 different pulse rates. These preprogrammed MAPs will be based on the MAP that the patient uses the most. A comparison will be made between the various MAPs in terms of amplitude modulation detection thresholds and objective speech understanding scores.

Contacts

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Eligibility criteria

Inclusion criteria

• Mother tongue Dutch

• Oral communication as primary mode of communication

• Age at inclusion: capacitated adult (≥ 18 years of age)

• Onset of severe hearing impairment after the age of 4 (post-lingual)

• Minimally 1 year experience with the CI, i.e. at the time of inclusion the first fit should be ≥ 1 years ago (first CI in case of bilateral user)

• CI (either unilateral or bilateral) should be from the brand Cochlear

Exclusion criteria

• Non- or impaired Dutch speaker

• Sign language or lip reading as primary mode of communication

• Incapacitated persons <18 years of age

• Onset of severe hearing impairment before the age of 4 (pre-lingual)

• Patients that had their first fit < 1 year ago

• Patients that use (a) CI(s) other than from the brand Cochlear (bilateral CIs are always of the same brand)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-08-2014
Enrollment:	19
Type:	Actual

Ethics review

Positive opinion

Date:	10-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4449
NTR-old	NTR4572
Other	ABR : 48906

Study results

Summary results
N/A