EEG-based and psychophysical test methods for characterizing the impact of electrode interactions on the auditory processing of Cochlear Implant users

Published: 05-08-2020
Last updated: 09-04-2024

The main objective of the study is to better explain disappointing speech recognition in individual cases, with as ultimate goal to find optimal individual settings for the sound processor (outside the scope of this project). We test two new methods...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49718

Source
ToetsingOnline

Brief title
New methods for characterizing the auditory processing of CI users

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
Deafness, hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen

Source(s) of monetary or material Support: Stichting Technische Wetenschappen;project nr. 14899,Advanced Bionics

Intervention

Keyword: auditory processing, Cochlear Implants, Electroencephalography, Psychoacoustics

Outcome measures

Primary outcome

The primary study parameters are the differences in response between pairs of CI electrodes. The response in case of the EEG measurement (passive task) is the neural power at frequencies of interest, determined by the two stimulation patterns of the two CI electrodes. For the reaction-time method (active task), the response is the manual response-reaction-time to a perceived change in the sound.

Secondary outcome

The secondary study parameter is the correlation between outcomes of the speech and spectro-temporal modulation tests as determined with the App and with the standard lab test methods.

Further study parameters are the electrode impedances and eCAPs.

Study description

Background summary

Cochlear implant (CI) users display a considerable and largely unexplained variability in speech recognition: some users reach more than 80% word recognition scores, for others, scores are disappointingly low (e.g., 50% or less). The variability is even increased in noisy environments. Possible sources of this variability are multifold. These can be device-related, for example, differences in the precise locations of CI electrodes in the cochlea, and interference between electrodes because of overlapping auditory nerve

populations, together with suboptimal individual settings of the sound processor. Alternatively, or in addition, the cause of variability may be subject-related, for example degeneration of the auditory nerve, deficiencies in the more central auditory processing, or cognitive factors. Spectro-temporal resolution seems to be an important factor in speech recognition. We investigate two new methods to measure the spectro-temporal resolution, including * in a controlled way - the impact of CI electrode interactions on the processing of temporal and spectral information. Two CI electrodes will be stimulated simultaneously employing basic pulse patterns. The response of the auditory system to this known input is then measured either with EEG, without any active involvement of the subject, or with a simple, but information-rich, reaction-time task, designed to largely eliminate cognitive factors.

Study objective

The main objective of the study is to better explain disappointing speech recognition in individual cases, with as ultimate goal to find optimal individual settings for the sound processor (outside the scope of this project). We test two new methods to measure spectro-temporal resolution on electrode-level, excluding influences of the sound processor and largely excluding cognitive influences. Results will be compared to results with a more conventional spectro-temporal test including the sound processor, and with speech recognition tests.
The secondary objective is to evaluate an App for obtaining data. Being able to perform a part of the measurements at home is now more relevant than ever. Further we aim to contribute to disentangling the impact of the above-mentioned sources of variability on speech recognition.

Study design

This is an explorative study with between-subject and within-subject comparisons. Outcomes will be compared with speech recognition results and with standard objective measures as electrode impedance and electrically evoked compound action potentials (eCAPs), an indication of the response of the auditory nerve.

Study burden and risks

Full participation involves three visits to Nijmegen, each with a duration of 3 hours. The third visit is only necessary for the participants in the EEG measurements (10 of the 16 subjects). In addition, all subjects will be asked to perform measurements at home using an App, this will in total take about 10 hours. Measurements are non-invasive and have negligible risks. EEG devices employed in this study are CE approved. The research interface used for the CI stimulation in a part of the measurements, although not CE approved, guarantees electrical current levels below physiological safety limits, and has low risk,

as described in the attached investigational medical device dossier. There will be no direct benefit for the participants.

Contacts

Public
Radboud Universiteit Nijmegen

Heyendaalseweg 135
Nijmegen 6525 AJ
NL
Scientific
Radboud Universiteit Nijmegen

Heyendaalseweg 135
Nijmegen 6525 AJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Healthy
* Aged 18 or older and mentally competent
* Unilateral CI wearers with a CII or HiRes family implant manufactured by Advanced Bionics.
* Native Dutch speaker
* Written informed consent

Exclusion criteria

* Disability which could interfere with the completion of the tests (e.g., psychiatric problems).
* For the EEG measurement: a subject with very thick hair or a skin condition on the skull which makes the skin extremely sensitive.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2020
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO

Date:	05-08-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL74369.091.20