Channel discrimination along all contacts of the cochlear implant electrode array.

Published: 15-05-2020
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Validate and improve the new experimental algorithm.

Ethical review	Approved WMO
Status	Completed
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49194

Source
ToetsingOnline

Brief title
PIDMS-II

Condition

- Hearing disorders

Synonym
deafness, perceptive hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Channel discrimination, Cochlear implant, electrode array, psychometric curves

Outcome measures

Primary outcome

Distinguishable inter-contact distances (ICD; e.g. channel discrimination) as determined by two separate tests. We are interested in the correlation between the found ICDs in both tests. Also, we want to improve the first version of the software, leading to more user-friendliness.

Secondary outcome

Relate the results from both methods to position in the cochlea and consonant-vowel-consonant (CVC) scores, and possibly to patient demographics (e.g. time since implantation, age). We also want to compare the results of this study to the group we included earlier, to see if the results are similar and the algorithm is performing as expected.

Study description

Background summary

Cochlear implants provide people with severe hearing loss or deafness the ability to acquire functional hearing by electrically stimulating the auditory nerve fibres in the cochlea. The most commonly used stimulation strategy (monopolar stimulation) introduces a lot of current spreading through the cochlea. Consequently, various electrode contacts excite the same neural fibres. Several studies have shown that patients are often not able to discriminate between two neighbouring electrodes (Bierer & Faulkner, 2010; Bonham & Litvak, 2008). Furthermore, no improvement in speech perception has been found as the number of active electrodes increase beyond eight (Friesen, Shannon, Baskent, & Wang, 2001; Shannon, Fu, & Galvin, 2004). These results indicate that the CI recipients are not able to take full advantage of the provided spectral information.

In a recent study (METC application registered under P02.106.AB), we tested 30 subjects and the results revealed that the channel discrimination of CI users is linked to their speech perception (Biesheuvel, Briaire, de Jong, Boehringer

& Frijns, 2019).

The results from the previous study have proven the clinical value of the discrimination test. Now we want to include the test in clinical routine as a tool for helping the audiologist with cochlear implant fitting, and possibly leading to improved speech perception. Before doing this, however, we can pursue improvements identified in the earlier study, and validate the software against a control test, such as comparison to psychometric curves (Wichmann & Hill, 2001) or the Just Noticeable Difference value of the contact, similar to what we have done before (Snel-Bongers, Briaire, Vanpoucke, & Frijns, 2011).

Study objective

Validate and improve the new experimental algorithm.

Study design

The total duration of the study is estimated to be 2 years (0.5 fte / year). Each subject will have to come to the ENT-department twice, for two to three hours, including breaks. The first time the researcher will guide them through both the tests step-by-step. The data from this test will be used for validation of the algoritm. We will also evaluate how well the subject would be able to go through the tests independently, by discussing with them what they found confusing (about the user interface for example) and how we can improve on this.

On the second test day, the subject has to go through the tests as independently as they can (supervised by the researcher). This data can also be used for validation, but mostly serves the goal of making an accessible test for in the clinic.

On the test days, the patient will be briefed on the two tests that will be done. The tests are the experimental algorithm (essentially the same test as in METC application P02.106.AB) and control algorithm, based on psychometric curves or the Just Noticable Difference tests (chapter 2). In all cases, the patient is subjected to electrical stimulation just as is done in normal use of the CI.

The tests are randomly allocated (every subject has an equal chance to start with test 1 or 2 respectively). The tests will be separated by a break.

We also use the subjects demographic and retrospective performance data from their medical records for further evaluation.

Study burden and risks

There are no known potential risks involved in this study. The subjects are presented with electrical stimuli just as in normal use of the CI. We are extensively testing the software before subjecting subjects to the stimuli. A potential benefit may be that a subject can be better fitted through more insight into their use of the spectral information provided by the CI.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Legally capable.
- Fluent in Dutch, preferably being their native language.
- Aged 18 or older.
- Implanted with an Advanced Bionics HiRes90K 1J, HiRes90K MS or CII+ positioner Cochlear Implant.

- At least 6 months of experience with their CI.
- Has read the protocol, willing to participate and have signed informed consent.
- Agree that their data is analysed and are presented pseudonimized, together with the data of other participants.

Exclusion criteria

- Too high impedance variations across electrode contacts.
- Disorders other than a hearing impairment that could affect the study results, such as psychiatric disorders or physical disorders that would limit their ability to undergo testing (e.g. depression).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	29-07-2020
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	15-05-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-11-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL71501.058.19

Study results

Date completed:	19-02-2021
Results posted:	09-08-2022

First publication
23-07-2022