Optimizing cochlear implants for better perception of speech on speech

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

Summary

ID

NL-OMON44061

Source
ToetsingOnline

Brief title
OCISS

Condition

- Hearing disorders

Synonym
deafness, hearing-loss

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Advanced Bionics Corporation

Intervention

Keyword: cochlear implants, cocktail-party, speech perception, vocal characteristics

Outcome measures

Primary outcome

The primary outcome will be the difference in VTL perception between two speech sounds on a given test. This will be measured by a variety of metrics, such as the JNDs, speech reception thresholds (SRTs), and percent-correct responses. Additionally, measures for percentage responses will be used. Verbal responses given by subjects will be audio recorded for offline analyses. This will only be obtained if they give their written consent.

Secondary outcome

Not applicable.

Study description

Background summary

Cochlear Implant (CI) devices are electronic prostheses that are implanted in deaf and hard-of-hearing patients to help restore their auditory sensation. These implants transduce incoming acoustic signals into pulse sequences that can be used to stimulate an electrode array implanted within the cochlea. In spite of the high success rate of CI devices in restoring hearing to profoundly deaf patients, there exist major limitations to the current clinical state-of-the-art devices. Despite having high performance on speech-in-quiet tasks, CI patients exhibit major difficulties in situations in which the target speech is masked by one or more competing talkers. To segregate competing talkers in such a situation, normal hearing (NH) listeners make use of voice differences that are principally supported by two vocal dimensions: the glottal pulse rate (GPR) and the vocal tract length (VTL). GPR defines the fundamental frequency (F0) or voice pitch, while VTL is related to the size of the speaker. It has been shown in a previous study, however, that CI users do not make use of these two dimensions to identify the gender of a speaker (Fuller et al., 2015). In contrast to NH listeners, CI patients can only utilize F0 cues and

not VTL to make judgments about the talker*s gender. Moreover, in the SpIdCI protocol (METc 2012.392), we identified that spectral distortions induced by the implant (for example as a result of frequency quantization and spread of excitation across electrodes) are more likely to affect VTL cues than voice pitch (Gaudrain and Ba*kent, 2015). In the present study we will investigate, for the first time, how multiple parameters of the CI influence the perception of these vocal dimensions. Better understanding of how these parameters affect VTL perception in CI users will allow a more optimal fitting of these devices for better speech intelligibility in cocktail-party settings.

Study objective

The main goal of the study is to optimize the perception of vocal characteristics through a cochlear implant. It will span a number of aspects: psychophysical characterisation, its relation to speaker discrimination, its relation to single voice intelligibility, its relation to competing voices segregation, and its relation to voice emotion recognition. The study focuses primarily on vocal-tract length (VTL), however F0 will also be manipulated.

Study design

The study is an observational study, with both within-subject and across-group comparisons. In all experiments of the study, a measurement variable is collected as a function of VTL (and F0), manipulated parametrically. The subjects are presented with auditory stimuli and given a behavioural task. They then have to make a judgement and either have to provide an answer on a computer screen, or they are requested to provide a verbal response. Thus, the measurement variables will be, in different experiments: percent-correct discrimination and percent-correct identification. For the tasks in which the subjects will be requested to respond verbally, their responses are to be recorded for offline processing. This will only be acquired after they have given a written informed consent. For CI subjects, they will be required to perform the tasks while using research speech processors, whose parameters have been modified according to the study objective of this project. Their own processors will not be changed in any way. The proposed project consists of 6 experiments spreading over 2 years. Different participants will be recruited for each experiment, which consists of maximum 2 sessions of 2 hours (NH) or 3 hours (CI). This duration may be extended upon the request of the participants, or in the case of recording verbal responses. For practical reasons, at the end of the experiment, they will be invited to participate in other experiments of the project. For experiment 6, CI participants will be asked to wear a research speech processor for an extended time period (a few weeks to a few months), after which they would come for a psychophysical test. For this experiment, 3 sessions will be held: in the first session, their baseline performance while using their own clinical processors will be evaluated. Additionally, the research processors will be fitted with the subjects* clinical maps. After the

acclimatization period of a few weeks, they will come for the second and third sessions that contain the actual psychophysical test.

Study burden and risks

There is no known risk, nor benefit associated with participation. Given the absence of risk for the participants* health, the METc of the UMCG has granted exemption of compulsory insurance for this study. The test session will last for a maximum of 3 hours per listener, including breaks. Session duration can easily be accommodated on the request of the participant as needed. The sound level will always be adjusted to a comfortable listening level for the participant. Only for Experiment 5 will the subjects be asked to come for 3 sessions, and will be asked to document the duration of use of the research processor over the course of several weeks.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in the NH group of this study, a subject must meet all of the following criteria:
- Be aged 18 years or more.
- Have no history of hearing or language disorder.
- Have no vision deficit (after correction) and be able to manipulate a mouse.
- Participants must generally in good health.
In order to be eligible to participate in the CI group of this study, a subject must meet all of the following criteria:
- Be aged 18 or more.
- Score more than 50% in the NVA speech in quiet intelligibility test (to allow good communication with the experimenter).
- Have no vision deficit (after correction) and be able to manipulate a mouse.
- All have comparable devices, or at least devices with comparable electrode-array length, whichever is the most common.
- Participants must generally be in good health, apart from hearing-impairment.

Exclusion criteria

- For the NH group, participants who have audiometric pure-tone average threshold higher than 25 dB-HL over mid-frequencies, in the better ear (Stephens, 1996). This will be measured during the first session.
- All subjects who appear not in good health.
- All subjects who show signs of claustrophobia.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2017
Enrollment:	231
Type:	Actual

Ethics review

Approved WMO Date:	02-02-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
Other	201501199
CCMO	NL54251.042.15