Psychophysics for the Detection of Temporal Fine Structure Performance in Normal Hearing and Cochlear Implant Users

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

Summary

ID

NL-OMON53623

Source
ToetsingOnline

Brief title
PSYFI

Condition

- Hearing disorders

Synonym
hearing loss, Sensorineural hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Stichting Life Sciences Health - TKI / Health~Holland,Advanced Bionics Corporation

Intervention

Keyword: Cochlear Implants, Hearing Loss, Temporal Fine Structure

Outcome measures

Primary outcome

Main study parameters are performance in psychophysical tests for expressed in the relevant units, such as speech reception threshold (SRT), ripples per octave (RPO), just noticeable difference (JND) and correct percentages.

Secondary outcome

Secondary study parameters are subject characteristics possibly influencing performance and discrimination abilities like using a cochlear implant, type of implant, electrode position in the cochlea, duration of implantation, duration of hearing loss/deafness, recent Consonant-Vowel-Consonant (CVC) scores and demographics.

Study description

Background summary

A cochlear implant (CI) is a device that provides people with severe hearing loss or deafness the ability to acquire functional hearing by electrically stimulating the auditory nerve. CI users have a good understanding of speech in quiet situations. One of the most pressing problems is the understanding of speech in real life conditions, where there often is competing noise. Other difficult conditions include pitch variation in tonal languages, emotion in speech (prosody), sound localization and music perception (Dincer D'Alessandro et al., 2018; Liu et al., 2017; Moore, 2008; Rubinstein, 2004).
Sound can basically be split into an envelope (variation of amplitude over time) and into temporal fine structure (TFS, representing variation in frequency and phase over time). CIs mainly encode the envelope and only a very

limited amount of TFS. The ability to detect temporally encoded frequency information helps to detect the fundamental frequency, to perceive subtle pitch variation and to perceive timbre differences in music. With the inclusion of TFS, the sound quality of CIs would greatly improve. The TEMPORAL project is targeting this very important problem by applying AI techniques to create or modify speech encoding strategies to optimize listening in difficult situations.

Study objective

The aim of this current proposal is to compare test methods for determining TFS performance, to establish detection thresholds for both CI users and normal hearing subjects and to produce normative data for the computer model and machine learning system. A wide range of psychophysical tests exists to directly and indirectly test TFS performance. Methods to test TFS directly were developed by Moore and colleagues, the TFS1 (Moore & Sek, 2009) and TFS-LF (Hopkins & Moore, 2010). Other tests focus on areas of improvement such as speech recognition in noise (Houben et al., 2014; Smits et al., 2013), pitch perception (Snel-Bongers et al., 2011; Vaerenberg et al., 2011) and music perception (Moon & Hong, 2014) and are indirect ways of detecting TFS. While these psychophysical tests have been used separately, no direct comparison has been made. Such a comparison provides insight in the relative performance of several aspects of hearing. It will also show which test is optimal for determining TFS performance. All subjects will undergo tests that are selected for their capability to inform TFS performance and provide input for computational models. In addition, tests are included that measure speech performance. Selected tests are all acoustical, meaning they are played through speakers or headphones. TFS tests compared with speech tests will provide valuable information on which tests are suitable for this purpose. Results from TFS tests provide baseline values for input in the computer models and further research. To limit contamination of the data by cognitive factors and ease of implementation into the machine learning system, we will focus on task-specific (discrimination tasks or n-alternative forced choice) psychophysical experiments.

Study design

This study is a prospective single-centred cross-sectional study. The total duration of the study is estimated to be 2.5 years. CI users and normal-hearing subjects are included as study group. Each subject will participate in a maximum of 3 non-consecutive test days. Each test day consists of a test session that lasts for approximately 3 hours, with breaks between each test and additional breaks if needed. The setting is the LUMC ENT department where there is long-standing experience with psychophysical testing.

Study burden and risks

This study is performed on CI users and normal hearing subjects. The study is considered to involve negligible risk and minimal burden. Benefits to the CI population at large may be a better and more efficient method of testing TFS performance. Given the small risk and high yield of this research it is an ethically justified study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for CI users:
Implanted with a cochlear implant at least on one side
16 years of age or older
At least 6 months experience with their CI

Speech scores in quiet of at least 60%

Inclusion criteria for normal-hearing subjects:
16 years of age or older
Average pure-tone threshold of 35 dB or less across a frequency range of 500 - 4000 Hz.

Exclusion criteria

Exclusion criteria for CI users:
Disorders other than a hearing impairment that could affect the study results
Not able to complete 2 hours of consecutive testing
Not native Dutch speaker

Exclusion criteria for normal-hearing subjects:
Disorders that could affect the study results
Not able to complete 2 hours of consecutive testing
Not native Dutch speaker

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-12-2022
Enrollment:	50
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	22-07-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	23-01-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	20-02-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	19-02-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL81378.058.22