Nonsimultaneous Rapid Pulse Trains (RaPiT) with Current Steering for Loudness Integration as a Basis for a new Loudness Encoding Strategy in Cochlear Implant Subjects

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1.To assess if multiple sequentially steered pulses can reach appropriate loudness while main-taining a single percept in cochlear implant subjects2.To compare loudness growth of sequentially steered pulse trains with those of conventional monopolar...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hearing disorders
Study type	Interventional

Summary

ID

NL-OMON52632

Source
ToetsingOnline

Brief title
RaPiT-study

Condition

- Hearing disorders

Synonym
Loudness perception in patients with a cochlear implant

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cochlear implant, Current steering, Loudness encoding

Outcome measures

Primary outcome

We will create and evaluate loudness curves for multiple sequentially steered modalities. In the first stage, we will look at pulse characteristics for loudness balancing like pulse ampli-tudes at threshold level (TL) and most comfortable level (MCL), pulse width, amount of sequential pulses, interpulse interval (IPI) and physical space between stimuli for the different modalities.
In the second stage, we will evaluate loudness growth by matching and ranking the experimental modalities in comparison to monopolar stimulation (MP).

Secondary outcome

Subject characteristics possibly influencing loudness growth or discrimination abilities like electrode position in the cochlea, recent CVC scores and demographics like duration of deafness.

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 fibers in the cochlea.
Current steering had created the possibility to stimulate nerve regions in

between electrodes. By stimulating two adjacent electrode contacts evenly, an intermediate pitch percept is heard. The pitch can be shifted by shifting the ratio of current being delivered to the two electrode contacts. Among others, Snel-Bongers et al. (2012) has proven that virtual electrodes behave similar to physical electrodes.
Sequential current steering provides an alternate means of inducing loudness and pitch perception. Frijns et al. (2009) found similar excitation patterns between simultaneous and compensated sequential stimulation in a computational model. The comparison of simultaneous and non-simultaneous current steering reveals that a patient cannot perceive differences between a single large pulse and multiple spatially or temporally separated smaller consecutive pulses when the spatial offset and/or temporal delay is small. Presenting pulse trains instead of single biphasic pulses can increase loudness perception without the need to increase the total amount of current per pulse (van Wieringen et al. 2006). With this principle, it is hypothesized that a pulse train of several small pulses spaced by means of current steering can be perceived as similarly loud as a single larger pulse. Loudness growth will be also greater when a pulse phase is not directly compensated by the opposite-polarity phase, as is the case with conventional biphasic pulses (Deeks et al. 2018). Therefore, we will also create pulse trains where the opposite-polarity phases of the concurrent pulses will follow after all cathodic phases have stimulated the auditory nerve fibers. Unpublished computational modelling work at our clinic has established these pulse trains as a viable option for inducing loudness. Optimal characteristics of these pulse trains in terms of number of sequential pulses, pulse phase duration, interpulse interval and interpulse distance are unknown. This study aims to find the optimal characteristics for sequentially steered pulse trains in order to induce controllable loudness growth and the perception of a single percept.

1. Snel-Bongers J, Briaire JJ, Vanpoucke FJ, Frijns JHM. Spread of excitation and channel interaction in single-and dual-electrode cochlear implant stimulation. Ear Hear. 2012;33(3):367-76.
2. Frijns JHM, Kalkman RK, Vanpoucke FJ, Bongers JS, Briaire JJ. Simultaneous and non-simultaneous dual electrode stimulation in cochlear implants: evidence for two neural response modalities. Acta Otolaryngol. 2009 Jan 8;129(4):433-9.
3. van Wieringen A, Carlyon RP, Macherey O, Wouters J. Effects of pulse rate on thresholds and loudness of biphasic and alternating monophasic pulse trains in electrical hearing. Hear Res. 2006 Oct 1;220(1-2):49-60.
4. Deeks JM, Carlyon RP, Epp B, Guérit F, Marozeau J. Effects of the relative timing of opposite-polarity pulses on loudness for cochlear implant listeners. J Acoust Soc Am. 2018 Nov 9;144(5):2751-63.

Study objective

1.To assess if multiple sequentially steered pulses can reach appropriate loudness while main-taining a single percept in cochlear implant subjects
2.To compare loudness growth of sequentially steered pulse trains with those of

conventional monopolar stimulation.
3.To assess if multiple sequentially steered pulses can reach appropriate speech understanding in cochlear implant subjects.

Study design

A prospective single-centred cohort study will be conducted with a maximum of three non-consecutive test days. A basal, a middle and an apical electrode pair will be fitted with several different pulse train modalities. For each modality the subjects will undergo conventional loudness balancing, loudness ranking and loudness balancing tasks. Also, subjects will subjectively evaluate the sound qualities of the most promising modalities.
If these tasks reveal a single loudness and pitch percept through pulse trains, all electrode pairs may be fitted with the most promising modality and undergo spectral tasks, temporal tasks and speech testing in a later phase.

Intervention

Stimuli will be created with the Bionic Ear Data Collection System (BEDCS) of Advanced Bionics (Valencia, CA) and administered through a Harmony CI Research Processor (CE 0123, Valencia, CA) connected to a personal computer. Stimuli will remain within the voltage compliance limits of the device.

Study burden and risks

The Harmony Research Processor has voltage compliance limits which will not be exceeded and assure safe use. We will create and test variations of conventional stimuli which have no higher risk or burden than the burden of a clinical fitting. People may temporarily experience a light headache or a temporarily return of suppressed tinnitus after listening to sound stimuli for three hours. No other risks are known.
Subjects will not have a direct benefit through participation in this study.

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

Competent adult CI-users (Advanced Bionics HiRes90K variant)
Subjects understand the Dutch language
Cochlear Implant received at least 9 months prior to date of first measurement
CVC-scores (consonant-vowel-consonant) at least 70%

Exclusion criteria

Subjects who are unable to complete 3 hours of psychophysical testing on a test day due to a medical condition or otherwise.
Severe tinnitus
Hyperacusis

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-11-2020
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	25-08-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-08-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-04-2022
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	NL72344.058.20