Directional Microphone Systems for Bimodal Listeners

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Evaluate the performance of directional microphone systems in binaural (bimodal or bilateral) cochlear implant users

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

Summary

ID

NL-OMON43822

Source
ToetsingOnline

Brief title
Bimodal Zoom

Condition

- Hearing disorders

Synonym
deafness, profound sensorineurinal hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Advanced Bionics Corporation,fabrikant CI: Advanced Bionics

Intervention

Keyword: bimodal fitting, cochlear implant, directional microphones, hearing aid

Outcome measures

Primary outcome

The primary outcome is the effect of microphone configuration on speech recognition performance in noise. Two main effects are distinguished:

- Symmetric directional benefit, defined as the difference between the standard omnidirectional configuration, and the directional multi-microphone system in both CI and HA.
- Asymmetric effect, defined as the difference between a symmetric (directional multi-microphone system in both CI and HA) and an asymmetric directional configuration (standard omnidirectional microphone in HA and directional multi-microphone system in CI).

With the amendment "Binaural Beam" the following primary study parameters were added:

- Symmetric binaural directional benefit, defined as the difference between the omnidirectional configuration and the binaural beamforming system when listening with both CI and HA.
- Asymmetric binaural directional benefit, defined as the difference between the omnidirectional configuration and the binaural beamforming system when listening with CI alone.

With the amendment "Bilateral Zoom" the following primary study parameters were

added:

- Bilateral monaural directional benefit, defined as the difference between the standard omnidirectional configuration and the monaural beamforming system when listening with two CI*s.
- Bilateral binaural directional benefit, defined as the difference between the standard omnidirectional configuration (test condition 1) and the binaural beamforming system (test condition 3) when listening with two CI*s.

Secondary outcome

Secondary outcomes in this study are:

- Asymmetric directional benefit, defined as the difference between the standard omnidirectional configuration in both CI and HA, and an asymmetric directional configuration (standard omnidirectional microphone in HA and directional multi-microphone system in CI).
- Effect of masker type, defined as the performance difference between a stationary speech-shaped background noise and a fluctuating competing talker.
- Listening effort, defined as the effort it takes to listen to speech in noise in the different directional and masking conditions.

With the amendment "Binaural Beam" the following secondary study parameters were added:

- Omnidirectional bimodal benefit, defined as the difference between hearing with both CI and HA in the omnidirectional mode compared to listening with only a CI in omnidirectional mode.
- Binaural directional bimodal benefit, defined as the difference between

hearing with both CI and HA when binaural beamforming is activated compared to listening with only a CI when binaural beamforming is activated.

With the amendment "Bilateral Zoom" the following secondary study parameter was added:

- Bilateral pinna effect, defined as the difference between the pure omnidirectional configuration and the pinna located standard omnidirectional configuration when listening with two CI*s.

Study description

Background summary

Cochlear implantation (CI) has become standard practice to restore hearing in severely hearing-impaired patients by providing multi-channel electrical stimulation to the auditory nerve. Although CI-patients can achieve high levels of speech recognition in quiet, speech recognition in noise still remains one of the most challenging tasks. One way to improve performance in noise is to benefit from binaural hearing (hearing with two ears). For individuals with residual contralateral hearing, a CI in one ear can be combined with an acoustic hearing aid (HA) in the other ear. This is known as bimodal hearing. For individuals without residual hearing a second CI can be an opportunity in the rare case. This is known as bilateral hearing. A second way to improve speech recognition in noise is to improve the quality of the signal before it is offered to the ear. To that end directional microphone systems are designed as they focus on the speech signal in front and reduce the noise from other directions. Nowadays, directional microphone algorithms are available for HA*s as well as for CI*s. Both approaches (binaural hearing and directional systems) are considered complementary, however they are not yet evaluated conjointly.

Study objective

Evaluate the performance of directional microphone systems in binaural (bimodal or bilateral) cochlear implant users

Study design

A cross-over repeated measures design is carried out to single-blind evaluate the performance of directional microphone systems. For each directional setting, speech recognition performance in noise and listening effort are assessed using two different masking materials (stationary noise versus fluctuating talker).

Intervention

During a test session subjects are provided with the latest speech processor for the CI and when applicable a state-of-the-art hearing aid allowing different microphone configurations: standard omnidirectional processing versus directional multi-microphone processing.

Study burden and risks

Study associated health risks are thought of as non-existent since this is a study with no invasive interventions. The topic under investigation is the effect of different directional microphone systems. This is a pre-processing feature of hearing devices that are currently available on the market (CE-marked) and are commonly used in current CI and HA patients. All products will be used within their indication in normal clinical hearing rehabilitation and not in combination with other products.

Only the software used for CI-fitting in bimodal session 2 does not have a CE-marking. The risk of using this software however are considered to be non-significant (see IMDD in section D of the research dossier).

Despite the low risks, participation however takes time and effort from subjects: two test sessions of approximately 3 hours for the bimodal group and a single test session of approximately 3 hours, for the bilateral group.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Bimodal group:
In order to be eligible to participate in the bimodal group of this study, a subject must meet all of the following criteria:
* capacitated adult (>18 years of age)
* patient of CI-team South-East Netherlands
* user of a unilateral cochlear implant (CI) of the brand Advanced Bionics (AB)
* first fit CI ><= 6 months ago
* wearing CI speech processor (almost) always (i.e. circa 10 hours a day)
* wearing a contralateral hearing aid >50% of the time (i.e. circa 5 hours a day)
* able to perform the speech-in-noise test (i.e. speech recognition in quiet >50%)
* willing and able to visit the azM and participate in testing
* agreed to participate in this study (by informed consent);Bilateral group:
In order to be eligible to participate in the bilateral group of this study, a subject must meet all of the following criteria:
* Capacitated adult (>18 years of age)
* Patient of CI-team azM, RadboudUMC or UMCU
* Former subject in the study *Bilateral Cochlear Implantation Benefits in Adult Users of the HiRes(R)
* 90K Bionic Ear System* (NL24660.018.08/NTR1722) who completed the full follow-up period of four years since the first implantation
* User of bilateral cochlear implants (CI*s) of the brand Advanced Bionics (AB)
* First fit of second CI *<= 6 months ago
* Wearing CI speech processor in both ears (almost) always (i.e. circa 10 hours a day)
* Able to perform speech-in-noise test (i.e. speech recognition in quiet with bilateral CI >50%)
* Willing and able to visit the azM and participate in testing
* Agreed to participate in this study (by informed consent);And additionally in the case of a

patient of CI-team UMCU or RadboudUMC:
* Agreed to let the research team of the current study inform the own CI-team respectively of his/her participation in the current study (by informed consent)
* Agreed to let the research team of the current study retrieve his/her basic audiological information from the CI-team UMCU or RadboudUMC (by informed consent)

Exclusion criteria

Bimodal group:
A potential subject who meets any of the following criteria will be excluded from participation in the bimodal group:
* non fluent in Dutch
* < 18 years of age or incapacitated
* bilateral cochlear implant user (CI+CI) ;Bilateral group:
A potential subject who meets any of the following criteria will be excluded from participation in the bilateral group:
* non fluent in Dutch
* < 18 years of age or incapacitated

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-03-2015
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	Hearing Aid / Speech processor Cochlear Implant + software (remarks below
Registration:	No

Ethics review

Approved WMO Date:	28-01-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-12-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-07-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL51559.068.14

Study results

Date completed:	04-11-2016
Actual enrolment:	24