DMP title

Project Name Decoding imagined speech from electrocorticography (FWO DMP) - DMP title

Project Identifier u0013308

Grant Title G0C1522N

Principal Investigator / Researcher Marc Van Hulle

Description Technology that translates brain activity into speech could be transformative for patients deprived of it. Studies have reported impressive results when decoding intracranial recordings, called electrocorticography (ECoG), in response to performed or perceived speech. However, to serve the needs of the speech impaired, one should aim for non-vocalized speech, also called imagined or inner speech. Despite intensive efforts, this remains an elusive challenge. Several observations can be made which we believe prevent progress. Current speech decoders are developed and tested offline, per subject and speech mode, as the acutely implanted ECoG electrodes serve a clinical need and time for experiments is limited. We propose a new multiway decoder that accounts for the nonlinear relation between ECoG and speech features, that is fast to respond, and that facilitates the transfer of model knowledge across speech modes and subjects. We will then use the decoder, prior developed based on model transfer, to provide real-time audible feedback to the subject when attempting imagined speech, which we hypothesize to be crucial for the subject to master imagined speech production. When successful, this project can contribute to future developments based on chronic brain implants aimed at improving the quality of life of speech-impaired patients.

Institution KU Leuven

1. General Information

Name applicant

Marc Van Hulle

FWO Project Number & Title

G0C1522N

Decoding imagined speech from electrocorticography

Affiliation

- KU Leuven

2. Data description

Will you generate/collect new data and/or make use of existing data?

- Generate new data
- Reuse existing data

Describe in detail the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a table (see example) or as a data flow and per WP or objective of the project. If you reuse existing data, specify the source of these data. Distinguish data types (the kind of content) from data formats (the technical format).

Type of data	Format	Volume	How created?
observational, experimental data,...	textual (.txt, .csv)	100kB	propriety computer task output, experimenter's notes, ...
Electrocorticography (ECoG)	numerical (Micromed data format)	100GB	Micromed device ouput
voice recordings using directional microphone	numerical (48 kHz .wav file @ 24-bit)	1GB	Audiotechnica AT875R voice recorder
MR images	images (DICOM)	1GB	pre/post implant MR images
functional mapping data	text & figure (jpg,.pdf)	100kB	post implanted patient responses to electrode currents
photographs during implantation	images (.jpg)	1 GB	photos taken by surgeon
basic clinical information	text (.txt)	10kB	collected by clinician during clinical workup

3. Legal and ethical issues

Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to your file in KU Leuven's Register of Data Processing for Research and Public Service Purposes (PRET application). Be aware that registering the fact that you process personal data is a legal obligation.

- Yes

Privacy Registry Reference: G-2022-4697

Short description of the kind of personal data that will be used:

age, gender, education level, voice, and basic clinical information (diagnosis, drug history)

See also the Service Agreement (UZGent reference KW/2092/NEL/004/057) between UZGent and KU Leuven and an ethical approval (BC-06016) granted by the Commission Medical Ethics of UZGent (BUN B670202042877).

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, add the reference to the formal approval by the relevant ethical review committee(s)

- Yes

Privacy Registry Reference: G-2022-4697

Yes there are ethical issues as:

- research involves human participants (patients)
- personal data collection and processing
- tracking or observation of participants
- further processing of previously collected personal data (‘secondary use’)
- physical interventions on the study participants (invasive techniques)

The collected data can be considered as “data containing personal information” and is covered by a Service Agreement (UZGent reference KW/2092/NEL/004/057) between UZGent and KU Leuven and an ethical approval (BC-06016) granted by the Commission Medical Ethics of UZGent (BUN B670202042877).

Does your work possibly result in research data with potential for tech transfer and

valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?

- Yes

A Service Agreement (UZGent reference KW/2092/NEL/004/057) between UZGent and KU Leuven has been signed on 20 May 2020 that stipulates both parties' responsibilities, data protection (GDPR), ownership of results and publications (copyright), and intellectual property rights (IPR).

Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions are in place?

- Yes

See the Service Agreement (UZGent reference KW/2092/NEL/004/057) between UZGent and KU Leuven tipulates the conditions of disseminatation and exploitation.

4. Documentation and metadata

What documentation will be provided to enable reuse of the data collected/generated in this project?

The clinical data KU Leuven receives from UZGent falls under a Service Agreement (UZGent reference KW/2092/NEL/004/057) between UZGent and KU Leuven, and an ethical approval (BC-06016, BUN B670202042877) granted by the Commission Medical Ethics of UZGent.

At KU Leuven the data will be processed (e.g. epileptic activity removed, electrode selection, data filtering, modeling, classification, regression) as described in the Methods section of FWO project G0C1522N (Decoding imagined speech from electrocorticography).

Documentation kept with the ECoG and patient's voice recordings:

- observational data i.e. notes made by the experimenter on how well the patient was motivated to engage in the experiment, reasons for early stopping, reason why part of the experiment could not be done (technical difficulties, attending to the patient,...), etc. all kept in a logbook

- photographs of brain implant during implantation taken by the surgeon

- functional mapping data recorded by surgeon which functionally labels the electrodes of the implant (e.g. which electrodes represent the mpouth muscle area and auditory cortex)

- basic clinical information collected by the neurologist during the clinical workup of the patient such as presence and frequency of epileptic seizures

Will a metadata standard be used? If so, describe in detail which standard will be used. If no, state in detail which metadata will be created to make the data easy/easier to find and reuse.

- Yes

The generated metadata will be <100 GB and according to the EDF or Micromed file standard but will not will be shared to 3rd parties without prior approval of the Commission Medical Ethics of UZGent (ethical approval B670202042877, 25/6/2020) and in compliance with the Service Agreement (UZGent reference KW/2092/NEL/004/057) between UZGent and KU Leuven.

5. Data storage and backup during the FWO project

Where will the data be stored?

The data received by KU Leuven is a copy of the original data stored at UZGent on a secure, password- protected computer, separate from the patient dossiers from which it is a partial excerpt.

How is backup of the data provided?

Disk mirroring with daily automatic incremental back-up of the data received by KU Leuven.

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely. If no or insufficient storage or backup capacities are available then explain how this will be taken care of.

- Yes

The data is stored on a secure, password-protected storage facility that is back-upped daily, not

accessible by external parties, and large enough to cater for all data planned to be received during the said project.

What are the expected costs for data storage and back up during the project? How will these costs be covered?

Storage resources at KU Leuven are covered by grants of the KU Leuven PI. Preservation at UZGent's servers is secured for 25 years, as it concerns patient data, in as far as legal and contractual agreements apply.

Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

The data received by KU Leuven will be stored on a secure, password protected computer at KU Leuven not accessible by external parties and on encrypted disks. Portable disks (e.g. USB sticks) will be encrypted as well. Persons that have access to the data are listed in the ethical approval (BUN B670202042877, granted on 25/6/2020 by the Commission Medical Ethics of UZGent). The received data is a copy of the original data stored at UZGent on a secure, password protected computer, separate from the patient dossiers from which it is a partial excerpt.

6. Data preservation after the FWO project

Which data will be retained for the expected 5 year period after the end of the project? In case only a selection of the data can/will be preserved, clearly state the reasons for this (legal or contractual restrictions, physical preservation issues, ...).

ECoG recordings, voice recordings, pre/post implant MR images, functional mapping data, photographs during implantation and basic clinical information.

Where will the data be archived (= stored for the longer term)?

After the end of the project, the data received by KU Leuven will be preserved for 10 years at KU Leuven, in as far as legal and contractual agreements apply. The original recordings are preserved for 25 years at UZGent's servers, as it concerns patient data, in as far as legal and contractual agreements apply.

What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?

Storage resources are charged to the KU Leuven PI's grants and/or to the department. The storage facility is already available (so no setup costs) and yearly estimated costs are less than 1000 Euro.

7. Data sharing and reuse

Are there any factors restricting or preventing the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

- Yes. Specify:

As it concerns patient data, in as far as legal and contractual agreements apply as stipulated in the Service Agreement (UZGent reference KW/2092/NEL/004/057), the data received by KU Leuven is stored on a secure, password protected computer not accessible by external parties and on encrypted disks. Portable disks (e.g. USB sticks) will be encrypted as well.

At KU Leuven only persons approved in the ethical approval of UZGent can access the data (BC-06016 (BUN B670202042877) granted on 25/6/2020 by the Commission Medical Ethics of UZGent and valid till 2025, which replaces previously granted ethical approvals EC/2014/0029; EC2016/0222 and EC/2016/0979).

Which data will be made available after the end of the project?

As it concerns patient data, sharing with 3rd parties is only admissible after prior approval by UZGent's Ethical Committee (ethical approval B670202042877, 25/6/2020) and in compliance with the Service Agreement (UZGent reference KW/2092/NEL/004/057) between UZGent and KU Leuven.

Where/how will the data be made available for reuse?

- Other (specify):

As it concerns patient data, sharing with 3rd parties is only admissible after prior approval by

UZGent's Ethical Committee (ethical approval B670202042877, 25/6/2020) and in compliance with the Service Agreement (UZGent reference KW/2092/NEL/004/057) between UZGent and KU Leuven.

When will the data be made available?

As it concerns patient data, sharing with 3rd parties is only admissible after prior approval by UZGent's Ethical Committee (ethical approval B670202042877, 25/6/2020) and in compliance with the Service Agreement (UZGent reference KW/2092/NEL/004/057) between UZGent and KU Leuven.

Who will be able to access the data and under what conditions?

As it concerns patient data, sharing with 3rd parties is only admissible after prior approval by UZGent's Ethical Committee (ethical approval B670202042877, 25/6/2020) and in compliance with the Service Agreement (UZGent reference KW/2092/NEL/004/057) between UZGent and KU Leuven.

What are the expected costs for data sharing? How will the costs be covered?

Possible costs are part of the prior approval by UZGent's Ethical Committee (ethical approval B670202042877, 25/6/2020) and in compliance with the Service Agreement (UZGent reference KW/2092/NEL/004/057) between UZGent and KU Leuven.

8. Responsibilities

Who will be responsible for data documentation & metadata?

Marc Van Hulle is responsible for the data received from UZGent, in compliance with the Service Agreement (UZGent reference KW/2092/NEL/004/057) between UZGent and KU Leuven.

Who will be responsible for data storage & back up during the project?

Marc Van Hulle is responsible for the secure, password-protected storage data at KU Leuven of the data received from UZGent, in compliance with the Service Agreement (UZGent reference KW/2092/NEL/004/057) between UZGent and KU Leuven.

Who will be responsible for ensuring data preservation and reuse ?

The PI Marc Van Hulle bears the end responsibility.

Who bears the end responsibility for updating & implementing this DMP?

The PI bears the end responsibility of updating & implementing this DMP.