DMP title

Project Name Bioinspired design of personalized controllers for active prostheses - DMP title

Project Identifier u0137811

Grant Title 1SF7322N

Principal Investigator / Researcher Wouter Muijres

Description Healthy individuals walk seemingly effortless but failure to restore locomotion after amputation reveals how challenging this task is. Amputated body parts do not contribute to gait propulsion or stability, leading to reduced walking performance. Active prostheses emerged to address the loss of propulsive capacity. Although active devices are capable of providing the mechanical work needed for locomotion, they fail at restoring walking performance. We hypothesize that current active prostheses fail at restoring gait performance because their control is incompatible with amputee movement strategies. Besides motor function, amputees lack feedback from the amputated limb segments which is crucial for balance control. Therefore, prosthesis controllers that are designed to reduce the metabolic cost of walking might not be effective for amputees who prioritize stability. In addition, there might be large inter-subject differences in how much individuals prioritize stability over effort. The goal of this project is to design and validate controllers for active prostheses that optimize the synergetic user-prosthesis behavior for transtibial amputees. We will use computational and experimental approaches. We will develop a simulation framework to design prosthesis controllers that optimize walking performance according to the userâ€™s stability preferences. Controller design will be inspired by insights in human balance control derived from experimental observations. In this project the novel active ankle prosthesis controller will be designed and validated based on computer simulations and experimental data. This means that the data set acquired in the different studies will encompass: 1) Data used for simulations of amputee locomotion (e.g. models and scripts for simulations pipeline), and 2) experimental data of amputee locomotion (e.g. motion capture, oxygen consumption, and EMG data)

Institution KU Leuven

1. General Information

Name applicant

Wouter Muijres

FWO Project Number & Title

1SF7322N - Improving gait performance of transtibial amputees through bioinspired design of personalized controllers for active prostheses

Affiliation

- KU Leuven
- Other

Université catholique de Louvain

2. Data description

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

- Generate new 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).

	Origin/source	Type	Format	Volumes	WP
Primary physical data	Informed consent form	Text	Printed paper (text)		WP1,2,3
Primary physical data	Clinical examination	Text	Printed paper (text), Excel (.xlsx)	750Mb	WP1,2,3
Primary digital data	Gait analysis (3D motion analysis, electromyography, force plates)	Numerical software specific data	.c3d	11.2Gb	WP1,2,3
Primary digital data	dynamic simulations of movement (inverse)	Numerical software specific data	.mot .sto	11.2Gb	WP1,2,3
Primary digital data	Predicitive simulations of movement	Numerical software specific data	.mat	11.2Gb	WP1,2
Primary digital data	Musculoskeletal models	Numerical software specific data	.osim	1.5Gb	WP1,2
Primary digital data	Oxygen consumption data	Numerical software specific data	.txt	1.5GB	WP1,2,3

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:

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

Two types of personal data will be gathered:
Personal information for contact purposes (e.g. name, address, phone number, e-mail), which will not be used in any further analysis. Participants will be asked whether this information can be stored in a database for future research, via a separate informed consent procedure in accordance with the General Data Protection Regulation.

Personal information for research purpose, consisting of socio-demographical data (e.g. gender, date of birth, handedness) and data concerning medical status (e.g. disease severity, time since amputation, amputation level, medication intake, functionality), via the study-related informed consent procedure in agreement with the General Data Protection Regulation.

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

We will conduct research experiments on humans. The study will be submitted to the Ethical Committee UZ / KU Leuven for approval before december 2022.

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

Data from this project may considered to claim intellectual property rights on the advise of Leuven R&D's valorisation team. LRD, in collobration with the legal department of the UCL, will be responsible for patent management and eventual licensing. Data may be used for industrial collaborations and will then be defined as KU Leuven and UCL background by LRD in good faith.

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

In the event of disclosing information about the prototype prostheses, used in this project, the third-party agreement with the industrial partner involved in the development of the prototype states that the third-party (i.e. the industrial partner) has the right to 1) ask for a 60-day delay, 2) ask information to be remained trade secret, or 3) propose modification to the presentation or publication.

4. Documentation and metadata

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

The following documentation will be provided: (1) a table of content (excel file and csv) with all project-related experiments including experiment number, date of implementation and name of the researcher who stored the experiment, (2) a brief description of the goal of the experiment and related work package (word and txt file), (3) a detailed protocol or link to an existing standard protocol (SOP) which will enable other researcher to repeat the experiment, (4) all data or link to another file with the (raw) data, (5) if appropriate, illustrations of the data with legends and
statistical analysis. In case that documentation is written or available in notebooks or stored on other files a link will be provided. With the help of these documentations every authorized researcher will be able (1) to look up all the information of the performed experiments and (2) to repeat the experiments in exactly the same way.

All data will be coded. This will consist of:
Approved Ethical Commission: description of study protocol (.pdf);
Informed Consents Form: original black copies (.pdf) and signed hardcopies (printed paper);
Experimental protocols: description how the data are collected and generated (software, materials, set-up, settings (.docx) and how data are processed (software, protocol, guidelines, …) (.docx, read.me text files);
Measurement forms: notes during data collection (printed paper);
Raw experimental data: storage of original physical data and folders with original digital data in software-specific files;
Processed data: folder with digital data in the software-specific files,spreadsheets with results (.CSV, .xls);
Patient identifier record: name of included subject, and subject study code (.xls) This patient record file is the only document that provide the link between the study code of the patient and patient’s identity;
Subject recruitment files: only subject study code, personal data (for example, age, weight, height, …,) short overview of assessments. The subject recruitment files described the measurements info for each patient, whereby the patient’s identity is coded;
The patient identifier record (PIR) will be stored separately on another location than the subject recruitment files, using the service from UZ Leuven (password protected network location) to keep private data safe and this is supervised by the PI.

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.

- No

Metadata will be provided as readme, word, excel or xml files, containing all settings and technical descriptions of the experiments and data processing workflows. Raw experimental data (from the 3D movement analysis and strength tests) will be managed on a software specific data management plaform. In addition, readme files and logbooks will be generated to describe the different decisions taken in the processing workflow (filtering, labeling etc.).

5. Data storage and backup during the FWO project

Where will the data be stored?

Metadata and documentation will be stored on the laptop of Wouter Muijres in a folders which is synchronized with the KU Leuven OneDrive. A backup of the data will be saved on a harddisk. The KU Leuven shared drives are an option for saving data for the longterm (10 years after project completion).

How is backup of the data provided?

Data will be stored on the shared drives of KU Leuven (automatically backupped), on a harddrive, and the KU Leuven OneDrive environment (Automatic backup).

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

Currently available

- 2 Tb storage capacity is available on the KU Leuven cloud service.
- 2 Tb harddrive is available

Option to extend current storage

- KU Leuven shared drive
- Additional harddrive

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

1 Terabyte storage is anticipated as a need wand will be covered by the grant (approx 520€/terabyte/year).

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

All data will be stored in a protected environment. Research data can only be accessed by a login following KU Leuven's policy for identifier and with pasword. The digital, pseudonymised, data (i.e. coded and containing no personal information) will be stored in a secure university environment. The PI of this project (Friedl De Groote) will be the only one who can grant access to this network drive. The separate and uniquely double password coded “Subject Identification Code List”, which
matches identifying codes with the subjects’ names, will be managed by the principle investigator (Friedl De Groote) and stored separately, using the Digital vault for private data service of the ICTS, KU Leuven. This system involves a secure and operating system in ICTS’s special, secure environment for private data.

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, ...).

Both raw physical and digital data , as well as the processed data will be stored for a 10 year period after the end of the project.

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

Digital data will be archived on the secured university’s network drive, described in part 5 of this DMP. Additionally, data will be stored offline on two external hard drives when the project is finished. Hard copies (eg. the Informed Consent forms, measurement forms and paper lab notebooks) are kept in locked cabinets in the PI's lab.

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

For this project data storage of 2 Tb is anticipated, resulting in a cost of 1040 euro per year, that can be covered by the grant and beyond.

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:

Data not involving the use of the prosthesis prototype can be shared following open science standards taking in consideration privacy and ethical regulations. However, data that reveil technical specification of the prosthesis prototype cannot freely be shared with the public, as a result of the confidenciallity agreement with the industrial partner. Nevertheless, data that reveil specification that have been disseminated through patenting and/or publication (in collaboration with the industrial partner), are free to be shared.

Additionally, IP protection and valorisation initiatives may restrict sharing of the data.

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

All data will be made available after appropriate IP protection if this is applicable The full anonymized dataset will be made available after publication of the data (upon simple request to the PI). Importantly, only data of participants who granted their approval for re-use, either within the research group (closed data) or outside the research group (open data), will be made available (also see ‘Who will be able to access the data and under what conditions?’). This will be added to the informed consent.

During the project as well as after the end of the project, the published data will be available via an open access repository and upon request by email to the PI. These published data contain the results of processed coded data presented in tables. Reference databases for gait analyses will be

established by the end or after the end of the project. As part of the valorisation plan, these databases maybe put available for external users through open source pathways. In that case, these data will be made available after appropriate IP protection. Patient-specifc data will only be shared ensuring the privacy of the patients (e.g. body weight, body length). Decoded personal data will never be shared.

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

- In an Open Access repository
- In a restricted access repository
- Upon request by mail

The main output of the project will be original scientific research papers. These will adhere to KU Leuven's and FWO's Open Accesss policy. In the context of Open and accessible science, original datasets will be made available with publication, either as supplementary files or using a datasharing platform such as figshare or Znodo using a CC-BY licence. Upon reasonable and specific request, any data subset and analysis can be made available.

For data transfer filesharing via KU Leuven OneDrive or Belnet transfer (secure) will be used.

When will the data be made available?

If there are no breaches of the confidenciality agreement, data will be made available immediately unless specific IP protections remain to be set.

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

All participants will be asked whether the data gathered in the context of this project can be reused for other research purposes, both within the research group (closed data) or with other

researcher inside or outside KU Leuven (open data), via an informed consent procedure. Data of participants who granted this permission will only be shared with research groups who submitted a written request to the PI of this project (Friedl De Groote). Data will only be shared if the research is approved by the ethical committee and participants will be informed regarding this secondary use. In principle any researcher upon reasonable request or through the data repositories.

During the post-project trajectory, data remains available for involved researches and will be made available to external users upon request, with contact via LRD, with a CC-BY licence.

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

No costs are expected. If any occur, they will be covered by the requesting parties.

8. Responsibilities

Who will be responsible for data documentation & metadata?

The PhD researcher (Wouter Muijres) and postdoctoral researcher associated with this project (Maarten Afschrift) will be responsible for data documentation & metadata, under supervision of the PI's (Friedl De Groote & Renaud Ronsse).

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

Data management, storage and back up will be performed by the PhD researcher (Wouter Muijres) and postdoctoral researcher (Maarten Afschrift) associated with this project, under supervision of the PI's (Friedl De Groote & Renaud Ronsse).

Who will be responsible for ensuring data preservation and reuse ?

The PI (Friedl De Groote) will be responsible for ensuring data preservation and reuse.

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

The PI (Friedl De Groote) bears the end responsibility of updating & implementing this DMP.