DMP title

Project Name DMP_FWO_1SF1822N - DMP title

Project Identifier 1SF1822N

Grant Title 1SF1822N

Principal Investigator / Researcher Friedl De Groote, Bram Van Den Bosch

Project Data Contact Bram VDB: +3216376669, bram.vandenbosch@kuleuven.be

Description A brain lesion occurring around birth causes cerebral palsy (CP) in about 1 out of every 500 newborns. CP causes a broad range of impairments in motor control and musculoskeletal function that impair walking ability (gait). Two thirds of the children with CP are ambulatory and most of them receive orthopedic surgery, i.e. single-event multilevel surgery (SEMLS), to correct bony deformities and muscle contractures in their early teens. Unfortunately, SEMLS does not improve gait in 1 out of 4 children. Predictive simulations of movement have great potential to improve clinical decision making by allowing orthopedic surgeons to compare the outcome of different treatment options before entering surgery. Yet the ability of predictive simulations to capture the effect of SEMLS on the gait in CP remains to be demonstrated. Furthermore, existing simulations do not capture foot deformities while 93% of the children with CP develop such deformities. Feet form the interface between the body and ground and therefore foot mechanics has an effect on whole body movement, further stressing the importance of improving foot models. We therefore aim at developing a personalized dynamic foot model and to integrate it into the predictive simulations of gait which is crucial to bring this promising tool into clinical practice.

Institution KU Leuven

1. General Information

Name applicant

Bram Van Den Bosch

FWO Project Number & Title

1SF1822N

Predictive simulations of walking, strengthened by novel personalized dynamic foot models, to improve treatment outcome of orthopedic surgery in children with cerebral palsy.

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).

In the table below, a complete dataset for one subject is described. We estimate to generate about 75 gigabytes of data for one subject. On a total of 25 subects, this means we will generate roughly 1.9 TB of data.

Type of data	Place of Origin	Format	Volume	how created
Data collection				
Synchronized 3D and analog data	UZ Leuven, campus Pellenberg	.c3d	150 MB	exported from Vicon system and anonymized
RGB video	UZ Leuven, campus Pellenberg	.mts .avi	25 GB	regular RGB cameras

Clinical exam	UZ Leuven, campus Pellenberg	.xlsx	15 KB	Anonymized excel export
Instrumented spasticity assessment (if with IMU)	UZ Leuven, campus Pellenberg	.xlsx .mat	150 MB	Export from in house software and anonymized
MRI image slices	UZ Leuven, campus Gasthuisberg	DICOM	450 MB	Export from MRI imaging software and anonymized using DicomCleaner
Data description	Office, Leuven	.pdf .xlsx	5 MB	Trialdescriptions, gathered on paper during the measurements is converted to a digital format
Pre-processing				
labeled 3D data	Office, Leuven	.c3d	150 MB	labeling in Vicon
Extracted marker data	Office, Leuven	.trc .m	100 MB	using MATLAB script
Extracted and filtered analog data	Office, Leuven	.mot .sto .m	1.2 GB	using MATLAB script
MRI images that are visible in in-house software	Office, Leuven	.xlsx .hdr .img .dat .w	600 MB	file conversion using MicroDicom, MRIcro, XMedCon and NotePad++
splitted and downsampled video-files	Office, Leuven	.avi	15 GB	video files are splitted in seperate files for each trial
Processing				
muscucloskeletal model based on MRI images	Office, Leuven	.mcs .stl .pvsm .vtk .txt .proj .osim .m	200 MB	Scheys et al. (2006)
Markerless/hybrid tracking	Office, Leuven	.avi .yaml .h5 .csv .mat .pickle .png .txt .index .meta .trc .m	30 GB	Using DeepLabCut and MATLAB

calculated inverse kinematics and dynamics	Office, Leuven	.osim .mot .xml .sto .m	100 MB	Inverse analysis workflow OpenSim, using MATLAB API
Musculoskeletal model on which virtual surgery was performed	Office, Leuven	.osim .mat .asc .vtp .m	100 MB	Pitto et al. (2019)
personalized dynamic foot model	Office, Leuven	.mat .osim .txt .m	20 MB	fitting of kinematic and kinetic data
Predictive simulations	Office, Leuven	.mat .txt .mot .m	1 GB	Falisse et al. (2019)
Post-processing				
Statistics	Office, Leuven	.m .fig .mat .r .pproj .csv .dat .txt	50 MB	Statistics using MATLAB and R
Figures and videos	Office, Leuven	.m .fig .png .svg .psd .avi	2 GB	Figures created by MATLAB, compiled in Adobe Photoshop and Illustrator. Videos created with OpenSim and edited in Adobe Premiere
Dissemination	Office, Leuven	.docx .pptx .pdf .html	200 MB	Microsoft Office, NotePad++

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

This study will be an amendement to approved project s64909 by EC UZ Leuven / KU leuven
Short description of the kind of personal data that will be used:

- Personal data for contact purposes

Recruitement is done by a researcher affiliated to UZ Leuven. They will use KWS to look up contact details and contact the possible patients. These data will not be used by the KU Leuven researcher for analyses.

- Personal data for research purpose

Important for our analyses and later dessimination we will gather following personal data: age at date of measurement, gender and data concerning medical information. The latter consists of clinical exam measurements, GMFCS score, previous surgeries/interventions and planned surgery.

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 reserarch on patients. The study protocol will be an amendment to an existing ethical approval by EC UZ Leuven / KU Leuven (s64909).

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?

- No

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?

- No

4. Documentation and metadata

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

Throughout the project the main researcher will take note of the performed steps. At the end of the project, this information will be compiled into a document with all relevant information for replication of the results. This document will contain links to standard operating procedures used and an online repository with all the code that was used.

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. 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?

Data, metadata and documentation will be stored on the laptop hard disk drive (HDD) of Bram Van Den Bosch (u0138016) in a folder which is synchronized with his KU Leuven OneDrive. OneDrive will be used since multiple researchers will work with the data. The KU Leuven shared drives are an option for saving data for the longterm (10 years after project completion).

For transferring data between locations (UZL - Gasthuisberg, UZL - Pellenberg, KUL officice) an encrypted USB thumb-drive will be used when encrypted online transferring (https://filesender.belnet.be) is not possible.

How is backup of the data provided?

Data will be stored on KU Leuven OneDrive for Business, which has regular automatic back-ups and on the HDD of the laptop of Bram Van Den Bosch (u0138016).

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 on KU Leuven OneDrive
- 2 TB on HDD laptop Bram Van Den Bosch (u0138016)

Option to extend current storage:

- Upon reasonable request, the capacity of the KU Leuven OneDrive can be extented to 5 TB.
- Additional external HDD.

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

We expect no additional cost for data storage. If we eventually need extra storage space, costs associated whit this will be covered by the FWO bench fee.

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. The digital, pseudonymised, data (i.e. coded and containing no personal information) will be stored in a secure environment.

The separate and password coded “Subject Identification Code List”, which matches identifying codes with the subjects’ names, will be managed by the ethical approval PI (Kaat Desloovere) and stored separately in the secured UZ Leuven environement.

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. The Informed Consent forms are stored in a locked cabinet at UZ Leuven campus Pellenberg. Measurement forms and paper lab notebooks are kept in locked cabinets in the PI's (Friedl De Groote) 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, we expect to generate about 2 TB of data. These will be stored on the lab's storage HDD. This has an expected cost of about €80 and can be covered by the FWO bench fee.

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)?

- No

All data that will be used is from participants that signed the informed consent form which states the sharing of data following open science standards.

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

The full anonymized dataset will be made available after publication of the data (upon simple request to the PI). 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 corresponding author. 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. Patient-specifc data will only be shared ensuring the privacy of the patients (e.g. body mass, 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 Zenodo 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?

- Upon publication of the research results

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

The full dataset will be uploaded in an open source research platform such as Zenodo as an open access dataset under a CC-BY license. Therefore, it will be available to anyone for any purpose, provided that they give appropriate credit to the creators.

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 (Bram Van Den Bosch) associated with this project will be responsible for data documentation & metadata, under supervision of the PI's (Friedl De Groote & Kaat Desloovere).

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

The PhD researcher (Bram Van Den Bosch) associated with this project will be responsible for data storage & back up, under supervision of the PI's (Friedl De Groote & Kaat Desloovere).

Who will be responsible for ensuring data preservation and reuse ?

The PI's (Friedl De Groote & Kaat Desloovere) 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.