DMP FWO - Ruixuan

Project Name HARMONY - DMP FWO - Ruixuan

Grant Title 1S36322N

Principal Investigator / Researcher Ruixuan Li

Description Pedicle screw placement (PSP) is an effective approach for spine fusion surgery. Robot-assisted PSP offers a disruptive approach that makes PSP safer and more precise. Current robotic systems still have several issues: they expose patients and surgeons to radiation, the reachable accuracy is limited as they do not update their path despite non-negligible patient motion and motion between intervertebral segments due to drilling. To address these issues, HARMONY introduces a robot-assisted ultrasound(US) motion tracking system that allows online updating of navigation paths improving PSP accuracy. A lightweight KUKA robot will be integrated with an innovative hybrid ultrasound tracking mode. The developed system features autonomous force-controlled US imaging to reconstruct and track the spine during the intervention. Through the co-manipulated operation, the surgeon can take over control over US imaging if necessary. The developed prototype system will be verified in preclinical experiments.

Institution KU Leuven

1. General Information

Name applicant

Ruixuan Li

FWO Project Number & Title

Title: HARMONY - Hybrid ultrasound for robotic motion tracking in spine surgery

File number: 89630

Affiliation

- KU Leuven

Robot-Assisted Surgery Group, Department of Mechanical Engineering

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).

Type of Data	Format	Volume	How created
2D B-mode ultrasound images	.jpeg/,png;	200 GB	Ultrasound images of the 3d printing models(i.e. spine model and US calibration model) for ultrasound reconstruction.
Force/Torque data	.csv; .dat	10 GB	Measurement of force and torque between US probe and phantom during scanning.
1D A-mode ultrasound measurement	.csv; .pdf	50 GB	Measurement of A-mode signal with spine phantom.
CAD model	.stl	10 GB	Spine models download from the open library for ultrasound scanning. Custom-designed models such as ultrasound probes and optical markers.
Analysis scripts and code	.py; .cpp; .hpp; .ipynb; .m	10 GB	Self-written code, script and statistics datasets
Computational models	.h5; .hdf5	20 GB	Models defined by the Code that already used for the ultrasound image segmentation
Processed data, results and data description	.txt; .pdf; .doc; .png; .xls	10 GB	The outcome of this project. Results can be tables, figures and text explaining those. Processed data of all raw data sources described above will be stored in .xlsx or .txt format, depending on the type of data. Data description and the subject document will be achieved as pdf.

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.

- No

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)

- No

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

 For future IP possibilities, we will contact LRD for help.

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?

New group/team members get training on how to perform the experiments and how to store and handle the collected data. The stored experimental design and protocol (.docx file) will be available for the group members.

Furthermore, standard guidelines and instructions are available as .readme, stored on Gitlab. In this way, the information given during the training can easily be reread and refreshed.

Physical hardware: Components and 3D printings will be stored in the lab after the end of the project.

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

The experiments are unique, but the data will be standardized according to data type to make it easier to interpret the structure.

the ultrasound images during the various scans will be stored as .png according to the phantom.

5. Data storage and backup during the FWO project
Where will the data be stored?

The data will be stored on KU Leuven administered drives (large volume storage) immediately after collection.

How is backup of the data provided?

The cloud-based(KU Leuven OneDrive and KU Leuven GitLab) and ICTS storage solutions are backed-up as part of the offered services.

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 thU Leue storage and backup capacity is sufficient during the project for the anticipated data volumes. The storage volume is around 1 TB, and the cloud-based volume is around 2 TB. Furthermore, network drive and cloud storage space can be readily expanded upon request to KU Leuven IT services.

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

Back-up cost per TB (KU Leuven ICTS): 295€/year. In case expenses are needed, part of the allocated FWO project budget can be used. The costs will be covered by the running costs on the grant.

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

In this project, no sensitive personal data will be used. The lab policy is that the researchers have only access to the data from the project they are involved in.

Furthermore, the storage is mainly hosted in the KU Leuven ICTS data center, with a mirror in the second ICTS centre. Access to data is conditioned by KU Leuven security groups

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, ...).

Digital data: ultrasound images and measurement data will be retained for the 5 year period expected by KU Leuven.

Physical data: components and 3D models will be available upon request after the end of the project.

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

The data will be stored on the university's central servers on a data archive drive (with automatic back-up procedures) for at least 10 years, conform the KU Leuven RDM policy.

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

The database (i.e. ultrasound images and force measurement) that will be compiled to realise objective 2, will be hosted on the servers of KU Leuven. Expected costs will be around 500 Euro/per year for storage beyond project duration will be limited and covered by the research group.

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

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

Data will only be made available in case of publications that require the publication/disclosure of the dataset.

Physical data will be made available after the end of the project. After the end of the project

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

- In a restricted access repository
- Upon request by mail
- Other (specify):

Different data types will be made available by different means according to the nature of the data and request.

For example, ultrasound images may be shared with group members for new analyses.

The developed scripts will be stored in a restricted repository.

Publications relating to the study will be provided in open access via Lirias 2.0.

When will the data be made available?

- Upon publication of the research results

Data will only be made available to other researchers after publication of the research results. The initial results of the first cross-sectional analyses will be made available in abstract form at the earliest opportunity, however the underlying data will not be made available for reuse until after publication.

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

As stated above, only requests via mail will be answered. Privacy and legal experts will be consulted when sharing data with researchers outside of the research group. Commercial reuse is not allowed.

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

The major cost of data-sharing will be long-term large volume storage after completion of the project. Possible costs, linked to open repositories and data uploading, will be covered by the project budget.

8. Responsibilities

Who will be responsible for data documentation & metadata?

The researcher, when her contract has ended the responsibility shifts towards Prof. Emmanuel Vander Poorten to ensure data preservation and reuse.

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

The researcher will be responsible for data storage & back up during the project. When the researcher's contract has ended, the applicant can rely on the support of the Division RAM's research manager.

Who will be responsible for ensuring data preservation and reuse ?

The researcher will be responsible for ensuring data preservation and reuse. Towards the end of the project, the responsibility for long-term data preservation and reuse will be assigned in agreement with the KU Leuven Division RAM.

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

The end responsibility for updating and implementing the DMP is with the supervisor Prof. Emmanuel Vander Poorten.