DMP title

Project Name FWO: STIFFNESS TAILORED NONDEGRADABLE AND DEGRADABLE FRACTURE FIXATION PLATES FOR MIDSHAFT CLAVICLE FRACTURES - DMP title

Project Identifier 1S87723N

Grant Title Grant number still unknown

Principal Investigator / Researcher Pieter Ansoms

Description Design of nondegradable and degradable fixation plates for midshaft clavicle fractures. Data is being collected to develop and validate models.

Institution KU Leuven

1. General Information

Name applicant

Pieter Ansoms

FWO Project Number & Title

1S87723N: Stiffness tailored nondegradable and degradable fracture fixation plates for midshaft clavicle fractures

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
CT scans	.dcm	50GB-100GB	preoperative (fractured clavicle) and postoperative (clavicle with fixation plate), also retrospective CT scans from UZ Leuven database
x-ray	.dcm	<1GB	during patient follow-up (after 1.5, 3, 6 and 12 months)
sonographs	.dcm	1GB-10GB	during patient follow-up (after 3 and 6 weeks)
clavicle, plate and screw models	.inp .stl	1GB-10GB	previous research (BioMeTiom project) and newly generated in this project
matlab code	.m	<1GB	previous research (BioMeTiom project), contains code for the generation of statistical shape models and the prediction of muscle attachment site location
fuzzy logic code	.fis	<1GB	fuzzy logic files are read by matlab and provide bone healing output data based on mechanical and tissue-related input data
word documents or pdf or ...	.docx .pdf	<1GB	surveys to assess patients' risk factors for fracture healing
biodegradation test data	.xlsx .jpeg	<1GB	numeric data, graphs and pictures
simulation results	.xlsx .png	1GB-10GB	numeric data, graphs and figures
python code	.py	<1GB	coding for the in-silico model happens mainly in python

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

Patient data (CT scans, x-rays, sonographs and surveys) are used. In order to maintain patient confidentiality, all data from the participating study patients will be coded. UZ Leuven will maintain the link between the patient’s identifier codes and the patient’s names.
The privacy approval is part of the GDPR (S66438).

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

The clinical trials and data collection have been approved by the ethical committee (S66438).

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

Yes, the patient data, along with model data and test data are confidential for valorisation at a later stage.

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?

- Python and Matlab code are explained with text in between the lines of the code to explain what the code does.

- Patient data (CT scans, x-rays, sonographs and surveys) will be labeled with an identifier number. The link between this number and the patient is maintained by UZ Leuven. A clear labeling system and foldering will be used to structure the various kinds of data belonging to a patient. For the medical images, the DICOM metadata standard will be used.

- Simulation results are accompanied by an excel file specifying relevant simulation parameters and input data 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

No metadata standard will be used. But the above-mentioned documentation for code, the use of folders and the recording of simulation parameters for simulations ensure the correct interpretation of the data and allow for easy reuse.

5. Data storage and backup during the FWO project

Where will the data be stored?

All software and data will be stored on the university's servers. These are automatically backed up. Also, OneDrive servers with automatic backups will be used. After completion of the project, prof. Joost Duflou (STIFF) and prof. Jos Vander Sloten (promotor) will take over this task.

How is backup of the data provided?

The data will be stored on the university's central servers with automatic daily back-up procedures.

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

There is currently sufficient storage and backup capacity during the project.

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

Costs for data storage and backup (I-drive, J-drive and OneDrive) are accounted for in the C2

project (STIFF) budget.

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

Only authorized persons have access to the data. Persons have access to individual storage on the university's servers. Servers that are available to everyone in the project, will be used to store/share data that everyone is allowed to have access to (OneDrive).

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, ...).

All clinical data (CT scans, x-rays, sonographs) and data that is used for papers (in case the community asks for details about the research) will be retained for at least 25 years after the end of the project.

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

Data stored on university's servers (K-drive) with automatic back-up for at least 10 years.

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

K-drive is used for long term achiving. The cost for this is €100/TB/year. Estimated volume of data is between 200GB and 400GB.

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

There are no restricting factors. The (anonymized) patient data should only be used by those who are granted access by the ethical committee.

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

Data that is used for papers will be made available upon publication.

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

- In an Open Access repository
- Other (specify):

Open access (SimTK for opensim data, GitHub for code) and paper data on request.

The research data repository (RDR) will also be used to store data, including all the necessary documentation that will help others understand the data and make it fully reusable.

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?

Professors involved in the research and future researchers in the department. Open acces data for everyone.

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

Data sharing on SimTK and GitHub is free.

8. Responsibilities

Who will be responsible for data documentation & metadata?

Pieter Ansoms will be responsible for documenting the generated matlab and python code for the in-silico model, as well as for the structure in and the documentation of the (anonymized) patient-data. Anonymization of this data and the documentation thereof will be handled by Dr. Michiel Herteleer and Prof. Harm Hoekstra

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

All researchers are responsible for storage and backup of the data they produce.

Who will be responsible for ensuring data preservation and reuse ?

During the project, all researchers are responsible for storage and backup of the data they produce. After completion of the project, Prof. Joost Duflou (STIFF) and prof. Jos Vander Sloten (promotor) take over this task.

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

Day-to-day data management is the responsibility of Pieter Ansoms. The overall data management, especially in the long term, is the responsibility of the supervisor, prof. Jos Vander Sloten.