Mechanics and mechanobiology of medical textiles for cardiovascular applications

A Data Management Plan created using DMPonline.be

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Template: FWO DMP (Flemish Standard DMP)

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Project abstract:

Loss of muscle mass and strength after cast immobilization is a well-known example of stressshielding. Far less understood are the mechano-adaptive phenomena related to external reinforcement in cardiovascular applications. In the Ross procedure, a pulmonary artery is placed in aortic position as a so-called autograft. Dilatation is a common adverse effect leading to failure, due to the inability of the autograft to rapidly adapt to a high pressure environment. Textile mesh wrapping can stabilize this dilatation, but causes stress-shielding on the longer term. To reach the equilibrium between dilatation prevention and promotion of benign biological adaptation, we propose to reinforce the autograft with a biodegradable external support. A biomechanical computational framework will be developed that can simulate the effect of an external mesh support in a dilating autograft. The finite element model will make acute and longterm predictions of autograft geometry and composition. This will allow to determine optimal mechanical and biodegradable properties of the textile mesh. The model will be informed through data of existing animal trials and advanced multi-axial mechanical testing. The optimized mesh will be produced using electrospinning technology and implanted in a sheep animal trial of the Ross procedure. This validation step will prove the potential of the computational framework, and emphasize the importance of numerical modeling in a clinical context.

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FWO DMP (Flemish Standard DMP)

1. Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

				Only for digital data	Only for digital data	Only for digital data	Only for physical data
Dataset Name	Description	New or reused	Digital or Physical	Digital Data Type	Digital Data format	Digital data volume (MB/GB/TB)	Physical volume
		Please choose from the following options: • Generate new data • Reuse existing data	*Please choose from the following options:* • Digital • Physical	*Please choose from the following options:* • Observational • Experimental • Compiled/aggregated data • Simulation data • Software • Other • NA	*Please choose from the following options:* • .por, .xml, .tab, .cvs,.pdf, .txt, .rtf, .dwg, .gml, … • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
Samples related to animal experiments	Collected tissue samples related to animal trials. Can be stored in different preservation modes depending on the application (formol for histology, PBS for mechanical testing,...).	Generate new	Physical	Experimental	NA		<100dm³
Samples related to electrospinning experiments	Collected polymeric samples related to electrospinning process (can be in a degraded state).	Generate new	Physical	Experimental	NA		<100dm³
Output data related to experiments	For animal experiments: • Clinical data: data regarding general health and biometric parameters of animals • Geometrical data: medical scans (CT, MRI, US), pictures of the tissue samples • Histological data: histological slices, accompanying images, accompanying quantitative data (e.g. sample thickness, constituent fraction) • Mechanical data: raw data of the mechanical tests For electrospinning experiments: • Polymer imaging: microscopic scans, SEM, microCT images etc... of produced samples • Scaffold degradation data: quantitative data of different degradation studies and characterization methods (GPC, FTIR, DSC,...) • Scaffold mechanical data: raw data of the polymeric mechanical tests	Generate new + Reuse existing data	Digital	Observational, experimental	Animal trials: .dicom (imaging), .jpg (histology), .tiff (DIC mechanical testing), .xlsx (raw mechanical testing) Electrospinning process: .bmp (microscopy), .csv (degradation study), .tiff (DIC mechanical testing), .xlsx (raw mechanical testing)	<5TB	
Processing code data	• Matlab code to process geometrical and histological data of animal trials + output results files • Matlab code to process polymer imaging and degradation data + output results files • Parameter fitting code: Matlab code to process raw data of the mechanical experiments + output results files (can be material parameters, stress-strain, pressure-diameter etc...)	Generate new + Reuse existing data	Digital	Software, Simulation data	.m (scripts) .mat (results)	<1TB	
Computational modelling data	• Abaqus FE files (models and user materials) + output results files • Matlab scripts + output results files • Python scripts + output results files	Generate new + Reuse existing data	Digital	Software, Simulation data	Abaqus: .cae (model), .inp (input), .odb (output) Matlab: .m (scripts), .mat (results) Python: .py (scripts), .csv (results)	<1TB	

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

Output data related to experiments:

- Mechano-biological adaptation of the pulmonary artery exposed to systemic conditions: https://doi.org/10.1038/s41598-020-59554-7
- Back to the root: a large animal model of the Ross procedure: http://dx.doi.org/10.21037/acs-2020-rp-21

Processing code data:

- Parameter fitting code: GitLab repository: BMe - Soft Tissue Biomechanics / parameter_fitting_code · GitLab (kuleuven.be)
-

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes, animal data

Animal trial is foreseen in a later stage of PhD project. Ethical approval documents will be provided in time: CTC documents, informed consent forms, communication with ethical committees, etc.

Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.

- No

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- Yes

If applicable, IP protection will be investigated for the developed medical textile, in collaboration with the KU Leuven LRD office.

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/Data transfer agreements/ research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

2. Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g., in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, Codebook.tsv etc. where this information is recorded).

Samples and output data related to animal experiments:

- metadata: data related to the identification of the tested tissue/animal. For biological samples, metadata is created upon registration at FIBEr – KU Leuven Core Facility for Biomechanical Experimentation , according to predefined fields, which is then safely stored in the FIBEr database.
- Test protocols: SOPs and specific protocols of the performed mechanical tests. For the testing protocols, the FIBEr template is used, provided and reviewed by FIBEr's lab manager.
- Manuals: manuals for operating the testing devices, performing the scans, histology, etc.

Samples and output data related to electrospinning experiments:

- metadata: data related to the identification of the tested polymers (composition, solvent) and electrospinning process (voltage, collector distance, environment, pumping rate,...)
- Test protocols: SOPs and specific protocols of the electrospinning process, degradation studies and mechanical testing.
- Manuals: manuals for operating the different characterization devices.

Processing code data:

- All Matlab codes are properly annotated and contain a readme-file describing its content.

Computational modelling data:

- All generated models, subroutines, processing and analysis code are accompanied with a readme-file and contain a header to describe their content, author(s) and last modification date.

Presentations:

- Progress reports
- Conference presentations
- PhD progress presentations

Publications:

- Latex files
- Figures
- Reviewer comments
- Revision letters
- Pdf

Project applications

Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.

- No

Information provided above.

3. Data storage & back-up during the research project

Where will the data be stored?

Output data related to experiments:

- NAS buffer storage for temporary storage during data processing, located within FIBEr and hosted by SET-IT
- The FIBEr database hosted at ICTS
- Large Volume Storage (K-drive)

Processing code data:

- OneDrive for Business cloud storage
- GitLab (kuleuven.be)

Computational modelling data:

- OneDrive for Business cloud storage
- GitLab (kuleuven.be)

Presentations, publications and project applications:

- OneDrive for Business cloud storage
- SharePoint online-site
- Large Volume Storage (K-drive)
- shared network drive (J-drive)

How will the data be backed up?

All data are stored on the university's central servers (I-drive, J-drive, Kdrive, FIBEr database and KU Leuven's gitlab space) with automatic daily back-up procedures. If not located in one of the above drives, all research-related documents are to be stored in (I) a folder on the researcher's pc that is synced with OneDrive for Business cloud storage or (II) the MECH - STB - Documents SharePoint online-site

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

Sufficient space is available on the university's central servers (J-drive, K-drive, FIBEr database and KU Leuven's Gitlab space).

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

All data is securely stored on KU Leuven servers and only accessible by members of the research unit through authentication.

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

KU Leuven charges a fixed price per TB on the different storage locations, whereby the average usage is charged on a yearly basis. For the current project, we expect to collect a total of 1 TB of **processed** data on the FIBEr database, and 500 GB on the J- and K-drive and Gitlab. The overall costs are expected to be less than €500/yr, financed by the current FWO project for the duration of the project.

4. Data preservation after the end of the research project

Which data will be retained for at least five years (or longer, in agreement with other retention policies that are applicable) after the end of the project? In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

All datasets will be retained for 10 years after the end of the project according to KU Leuven RDM policy (and for publications, until 10 years after the work has been published). Some of the biological and polymeric samples can physically be destroyed after mechanical testing and can possibly not be retained due to preservation issues. Moreover, it will not be possible to physically preserve polymeric structures which underwent degradation studies.

Where will these data be archived (stored and curated for the long-term)?

All data stored in the FIBEr database stays there for at least 10 years after the project/publication. All data in the J-drive, Gitlab, OneDrive and SharePoint will be moved to archival storage (KU Leuven's K-drive). All open access code data will remain on Gitlab.

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

The costs will not exceed €500 and will be covered by the budget of the supervisor.

5. Data sharing and reuse

Will the data (or part of the data) be made available for reuse after/during the project? In the comment section please explain per dataset or data type which data will be made available.

- Yes, in a restricted access repository (after approval, institutional access only, …)
- Yes, in an Open Access repository
- No (closed access)

Output data related to experiments, processing code data, computational modelling data will all be

- publically available via Gitlab, or
- made available within KU Leuven via the FIBEr database and the K-drive upon request, or
- shared via data repositories such as KU Leuven RDR.

Physical data will remain closed access for the research group.

If access is restricted, please specify who will be able to access the data and under what conditions.

Members of the research unit will be able to access the data under institutional access via the shared drives.

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)? Please explain in the comment section per dataset or data type where appropriate.

- No

Where will the data be made available? If already known, please provide a repository per dataset or data type.

Animal samples as well as electrospun scaffolds will all physically be stored in FIBEr.
Output data related to experiments:

- FIBEr database
- K-drive

Processing code data

- GitLab (kuleuven.be)
- K-drive

Computational modelling data

- GitLab (kuleuven.be)
- K-drive

When will the data be made available?

Data will be made available after publication in peer-reviewed journals.

Which data usage licenses are you going to provide? If none, please explain why.

CC BY, in which appropriate credit must be given to the author and indication of changes must be made, and CC BY-NC, which adds a non-commercial term to the CC BY license.

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.

- Yes

KU Leuven RDR uses a DIO.

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

Costs for open-access publications can be up to €3000 per publication. Sharing large datasets via data repositories can also be costly. Costs for open-access publications and possibly for data sharing via repositories (if not free in use) will be covered by the budget of the project.

6. Responsibilities

Who will manage data documentation and metadata during the research project?

The PhD researcher is responsible for data documentation and metadata.

Who will manage data storage and backup during the research project?

The PhD researcher is responsible for data storage and back up during the project.

Who will manage data preservation and sharing?

The PhD researcher is responsible for ensuring data preservation and sharing via the shared storage drive during the PhD project. After the PhD project, the supervisor will be in charge of this.

Who will update and implement this DMP?

The PhD researcher is responsible for updating & implementing this DMP during the project. After the PhD project, the supervisor will bear the end responsibility of updating & implementing this DMP.