How do cardiovascular diseases and their treatments affect the microstructural-mechanical relationship? An advanced 3D microstructural analysis & modeling approach - Data Management Plan

A Data Management Plan created using DMPonline.be

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Project abstract:

Cardiovascular diseases (CVDs) are still the leading cause of death worldwide. Treatment options such as balloon angioplasty often fail. One reason for this failure is that the treatment applies too high mechanical forces for the vascular tissue, inducing inflammation and re-obstruction of the blood vessel, named restenosis. However, the exact mechanism by which restenosis develops is still not fully understood. One hypothesis is that the treatment causes an alteration in the tissue microstructure. To investigate this hypothesis, this PhD thesis aims to combine advanced 3D imaging and computational modelling, leading to more biofidelic models. The first objective is to create a database of microstructural properties of healthy & diseased vascular tissues. For this, we will use 3D contrast-enhanced microfocus computed tomography (CECT). Using this database, a microstructureinspired model will be created via a multiscale approach starting from a representative volume element (RVE). The RVE will be parametrized, enabling adaptation of the microstructural parameters to understand how they influence the mechanical behavior. Finally, to calibrate and validate the model, macro- and microscale mechanical tests will be performed. For the latter, 4D-CECT will be used, which combines in-situ mechanical loading with CECT imaging. The combined imaging and modeling approach of this PhD project will improve the insights into the failure mechanisms of some of the treatments for CVDs.

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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
1. Data from imaging experiments (WP1)							
		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	
Dataset 1.1 - Tissue samples	Tissue samples: human and animal arteries (porcine, rat, mice, sheep). Animal arteries come from the slaughterhouse or from clinical experiment at GHB. Human arteries come from the biobank or from the clinics (with ethical approval)	Generate new data	Physical sample				Not stored
Dataset 1.2 - Clinical data	Data regarding general health and biometric parameters or animal/patient	Generate new data	Digital	Observational, experimental	.txt,.csv,.pdf,.xlsx, .docx	<100MB	

Dataset 1.3 - Imaging data	Grey-scale images from the Nanotom M uCT and from the synchrotron. RGB images from 2D classical histology and second-harmonic generation	Generate new data & reuse existing data	Digital	Experimental, Images	.bmp, .tiff, .jpg	<50TB	
Dataset 1.4 - Protocol (image analysis & sample preparation)	Protocols on how to prepare sample, post-process and analyze the images. Python, matlab codes to process the images.	Generate new data & reuse existing data	Digital	Observational, Simulation data	.txt,.csv,.pdf,.xlsx, .docx, .ipynb, .py	<1GB	
2. Microstructure-inspired model (WP2)							
Dataset 2.1 - parametric code	python code generating a microstructural representative volume element	generate new data	Digital	Simulation data	.py, .ipynb	<1GB	
Dataset 2.2 - simulation	Codes to mesh the RVE and perform virtual mechanical tests	generate new data	Digital	Software (Abaqus, Ansa, matlab)	.ansa, .inp, .for, .f, .m	<10GB	
Dataset 2.3 - materials parameters	Resulting materials parameters of simulation or use materials properties from literature	Generate new data & reuse existing data	Digital	Numerical data	.csv, .mat	<100MB	
3. Experimental mechanical characterization (WP3)							
Dataset 3.1 - Mechanical data	Raw data of the mechanical tests	generate new data	Digital	Experimental	.mat, .csv, .text	<1TB	
Dataset 3.2 - Parameter fitting code	Matlab code that has as input the raw data of the mechanical experiments and as output the material parameters of a certain constitutive model	generate new data by reusing existing code	Digital	Software (Matlab)	.mat,.dat	<1GB	

Dataset 3.3 – Geometrical data	Pictures and microscopic images of the tissue samples, thickness measurement pictures and accompanying quantitative data (Camera, laser scanning, microscope)	generate new data	Digital	Experimental, Observational	.jpeg,.tif,.csv	<10GB	
Dataset 3.4 - Tissue samples	Tissue samples from slaughterhouse or from the clinics	generate new data	Physical	Experimental	Not stored (mechanical test destructive)		

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:

- Dataset 3.2 - Parameter fitting code from PhD thesis Heleen Fehervary: Fehervary, H., Vander Sloten, J., & Famaey, N. (2018). *Planar Biaxial Testing of Soft Biological Tissues*.
- Dataset 2.3 - materials parameters:
  - Marino, M., Pontrelli, G., Vairo, G., & Wriggers, P. (2017). Coupling microscale transport and tissue mechanics: modeling strategies for arterial multiphysics. In *Modeling of microscale transport in biological processes* (pp. 77-112). Academic Press.
  - Hoeve, C. A. J., & Flory, P. J. (1974). The elastic properties of elastin. *Biopolymers: Original Research on Biomolecules*, *13*(4), 677-686. https://doi.org/10.1002/bip.1974.360130404
  - Lillie, M. A., & Gosline, J. M. (2007). Mechanical properties of elastin along the thoracic aorta in the pig. *Journal of biomechanics*, *40*(10), 2214-2221. (https://doi.org/10.1016/j.jbiomech.2006.10.025)
- Dataset 1.3 & 1.4 - imaging data and protocols:
  - Dataset from my ContrasTTeam research group not published yet
  - Maes, A., Pestiaux, C., Marino, A. *et al.* Cryogenic contrast-enhanced microCT enables nondestructive 3D quantitative histopathology of soft biological tissues. *Nat Commun* **13**, 6207 (2022). https://doi.org/10.1038/s41467-022-34048-4 (https://doi.org/10.1038/s41467-022-34048-4)
  - Lisa Leyssens et al., Non-destructive 3D characterization of the blood vessel wall microstructure in different species and blood vessel types using contrast-enhanced microCT and comparison with synthetic vascular grafts., Acta Biomateriala, soon to be published

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
- Yes, human subject data

We have collected human tissue samples from donors (atherosclerotic femoral arteries from amputed people) and we will collect animal tissue from our collaboration with surgeons in Gasthuisberg, UZLeuven or from the slaughterhouse. The corresponding EC Research and ECD numbers are S62776 and 103/2016, respectively.

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 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).

1. Data from imaging and mechanical experiments
The documentation of the experiments consists of:

- Ethical approval documents: CTC documents, communication with ethical committees, etc.
- Test protocols: SOPs and specific protocols of the performed mechanical test
- Manuals: manuals for operating the testing devices, performing the scans, etc
- Elabjournal containing all the imaging parameters selected and pictures of experiments

2. Data from material parameter optimization
The parameter fitting code is properly annotated and contains a readme-file to describe its content.
3. Data from simulations
All generated models and subroutines are accompanied with a readme-file and contain a header to describe their content, author(s) and last modification date.
4. General computing code
All generated processing and analysis code is accompanied with a readme-file and contains a header to describe its content, author(s) and last modification date.

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

1. Data from imaging and experimental experiments

Data related to identification of the tested tissue/animal/patient. For our biological samples, metadata is created upon registration at FIBEr, according to predefined fields, which is then safely stored in the FIBEr database.

For the imaging experiments, all information (acquisition & processing parameters) are stored in elabjournal as well as in the properties of the acquisition file and image dataset.

Specific protocol that was used to perform the mechanical test on a certain tissue. For our testing protocols, the FIBEr template is used, provided and reviewed by FIBEr's lab manager.

2. Data from material parameter optimization

Resulting parameters are always accompanied by a report of the parameter fitting run, indicating settings of the parameter fitting code.

Any in-house developed code is properly annotated and accompanied by a readme-file.

3. Data from simulations

Data related to identification of the animal/patient.

Abaqus and LS-Dyna automatically generate metadata for every simulation, according to their own standards.

Any in-house developed code is properly annotated and accompanied by a readme-file.

4. General computing code

Any in-house developed code is properly annotated and accompanied by a readme-file.

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

Where will the data be stored?

Apart from non-sensitive raw images, data will be stored on facilities of the research unit or university. This includes:

- FIBEr's database for experimental data, hosted at ICTS NAS buffer storage for temporary storage during data processing, located within FIBEr and hosted by SET-IT Google Cloud
- Storage for archiving of non-sensitive raw images.
- Git repository for code development.
- OneDrive for office files.
- KU Leuven shared drives and personal drive for office files.
- Large Volume Storage (LVS) for storing imaging datasets backed-up by UCLouvain.
- Elabjournal containing all the experimental protocols.

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, LVS by UCLouvain) 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, (III) a copy of the image datasets stored on physical hard drive.

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, KU Leuven's gitlab space, UCLouvain LVS). Moreover, for the UCLouvain LVS, it is possible to increase the storage and backup capacities by paying more.

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 and UCLouvain 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. UCLouvain also charges a fixed price per TB for the LVS storage (150€/TB per year). For the current project, we expect to collect a total of 1 TB of data on the FIBEr database, less than 30TB of images stored in LVS at the end of the project, and 500 GB on the J- and K-drive and gitlab. The overall costs are expected to be less than €2000/yr, financed in part by the current FWO project for the duration of the project and by other project grants from the promotors.

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 5 years after the end of the project (and for publications, until 5 years after the work has been published). Biological samples are destroyed after mechanical testing and can in any case not be retained due to preservation issues. Human samples used for imaging purposes only without testing and used in a publication will be retained for 5 years in the freezer of UCLouvain, at IREC Morf departement. However, the animal samples will be discarded once a paper is published on the topic.

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 5 years after the project/publication. All data in the J-drive and on gitlab will be moved to archival storage (KU Leuven's K-drive). All the imaging datasets used for publications will be archived for 5 years.

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

The costs will not exceed €5000 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, …)
- Other, please specify:

For each outcome of the PhD project (models, imaging datasets, new techniques, etc), IP rights will be ad hoc discussed with the partners involved in the project and the Tech Transfer Office of the KU Leuven. Trade off between patenting and open access will be considered. Once IP is protected, the outcome will be made available via Open Access repositories or upon request after publication. Especially for the imaging datasets, which are very large (>50GB/dataset), the data will be made available upon request and can be send via BelNet Filesender. For the biological samples, they will not be available for reuse or shared.
For the mechanical data and the models, they will be made available within KU Leuven via the FIBEr database and the K-drive upon request, via scientific papers and 'data papers' if supported by the journals, via
data repositories, such as for example Zenodo, or other repositories upon request, etc.

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

The restriction of the imaging datasets comes mainly due to the large size of the datasets, and the related cost for long term storage in open access repositories. Therefore, the datasets will be made available upon request, and can be send via BelNet FileSender. Once IP is secured and once the related results, datasets are published, everyone should be able to obtain access to the imaging datasets upon request. For the smaller datasets (i.e. models, protocols, mechanical data), once published, the datasets should be accessible via open access repository.

Members of the research unit will be able to access the data via the shared drives.
The scientific community will have access to the data under the following conditions of use: 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.

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.

- Yes, Other

My PhD is a joint-PhD between the university of KU Leuven and UCLouvain. Therefore, a joint-PhD agreement has been signed, which states that the property, publication, use and protection of the results of the research is common to the two host institutions and are required to be in conformity both with the specific procedures in each of the two communities as well as the relevant internal regulations of each institution. Any cases of potential conflict in the provisions will form the subject of arbitration between the KU Leuven and the UCLouvain. This can restrict or prevent the sharing of my data. Furthermore, the large size of the imaging datasets and the cost related to long term storage in open access repositories, can also be a restriction to sharing in open access such datasets. In this case, the imaging datasets will be made available upon request.

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

For the publications, it will made available on DIAL and LIRIAS, the universities repositories for papers and conference abstracts. For the datasets smaller than 50GB, it can be made available on zenodo (https://zenodo.org/) and can be linked to the ORCID number and the DOI.

When will the data be made available?

When IP is secured for both universities (UCLouvain, KU Leuven) and upon publications of the results, then the data will be made available.

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

Providing usage licences or not will be ad hoc discussed for each type of datasets with the partners involved in the project.

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.

- No

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

Our large datasets are stored on LVS where university members can have access to the data upon request. The cost is about 150€ per TB per year. This is for storage, but we can give access to the datasets upon request. Cost will be covered on other grants than the FWO mandate budget (bench fee), from the both promoters.

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.