Challenging and underpinning the evidence for the coiling-clipping paradigm in cerebral aneurysm treatment through multimodal stratification (1SH1424N)

A Data Management Plan created using DMPonline.be

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Project abstract:

Cerebral aneurysms (CA) are local aberrations in intracranial arteries, which occur in 1-3% of the population. The most dreaded consequence of a CA is a rupture, which causes a subarachnoid hemorrhage (SAH). This catastrophic occurrence is fatal in 26-50% of patients, where the surviving population is often left disabled.
Treatment of CA can be either through an endovascular approach or surgically clipping the aneurysm, where to this day there are still raging debates on the best treatment modality for both ruptured and even more so for unruptured CA. Given the severe morbidity and mortality associated with an aneurysmal SAH, further investigation is required for the preferred treatment choice for each individual aneurysm since, to our knowledge there is no clear consensus-study which delineates a decision-making tree or protocol for surgical clipping versus endovascular therapy for CA.
Key objectives of the doctoral thesis:
To review the different evidence-based factors which advocate a clipping- or coiling based strategy and perform a study which includes artificial intelligence to aid decision-making.
Developing a 3D model which can simulate the aneurysm clipping in each individual case, which can be used as a teaching tool for aneurysm clipping, and to identify and anticipate different pitfalls which might occur during surgery.

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FWO DMP (Flemish Standard DMP)

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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, .csv,.pdf, .txt, .rtf, .dwg, .gml, … • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
Literature review search data	obtained from queries from web-databases	Generate new data	Digital	NA	.enw .ciw	<100.000kB	
Papers	downloaded from web-database	Reuse existing data	Digital	NA	.pdf	<3GB	
Numerical data from papers	extracted from individual papers	Reuse existing data	Digital	NA	.xls	<2GB	
Numerical data from AI-study	extracted from survey	Generate new data	Digital	Observational	.xls	<2GB	
Individual patient data	extracted from patient files	Reuse existing data	Digital	Observational	.xls	<2GB	
Patient imaging	extracted from the patient files	Reuse existing data	Digital	Observational	.dcm	<35GB	
3D-rendering data	converted from DICOM images through dedicated 3Dprogram	Generate new data	Digital	Observational	.stl	<5GB	
3D-models	printed	Generate new data	Physical	Experimental			<1m³
Study documentation	Investigator Site Files	Generate new data	Physical	NA			Multiple binders for each study

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:

Existing literature used for text mining.
Existing patient data from the hospital's EMD system

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, human subject data

This research involves human participants, and thus ethical approval will be obtained.
Ethical approval is obtained at Ethische Commissie Onderzoek UZ/KU Leuven on 07 DEC 2023 for study with internal reference number s68324, entitled '3D-printed intracranial aneurysms: a validation study' for the collection of retrospective data for 3D-modelling.
Ethical approval will be applied for at Ethische Commissie Onderzoek UZ/KU Leuven for the study with clinical application of the 3D-model.
Ethical approval will be applied for at Ethische Commissie Onderzoek UZ/KU Leuven for the study which includes AI to aid decision making.

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.

- Yes

Regular personal data will be used for proper conduct of the studies (subject logs).
Special/sensitive categories of personal data that will be processed are health data and images and will be pseudonymized.

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

Once it becomes clear whether the results have potential for tech transfer and valorisation, this will be further discussed with the legal department of KU Leuven (LRD).

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

At this moment there are no 3rd party agreements for the restriction of exploitation or dissemination of the data. If in the future there is a question for this, individual deidentified participant data and related documents used for the study can be made available on reasonable request. Depending on the data requested, additional collaborators will be consulted and a decision will be made about the appropriateness of the use of data. If approved, a data-sharing agreement must be signed before a deidentified version of the data set is made available.

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).

All data and accompanying information will be stored exclusively on KU Leuven servers, Onedrive. All data will be accompanied with a

README file or tab that outlines the exact data collection procedure, especially important for the experimental data. All experimental work is prepared by extensive preparations, each step is logged. Standard operating
procedures are written out in the lab and safely stored together with the experimental data in the same folders, to allow easy recovery of the metadata. All team members have access to these metadata.

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.

- Yes

Yes, all metadata for experimental work are well maintained in the lab repository of procedures. They follow a standard format and vocabulary

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

Where will the data be stored?

All data are stored at the KU Leuven Onedrive, the KU Leuven Large Volume Storage L-drive, or the UZ Leuven servers (for clinical data). No data will be stored on local computers, etc.

How will the data be backed up?

Data will be backed up regularly on an external hard drive, which is password encrypted and kept by the investigator in a locked down compartiment.

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

Our estimation is that we will have <1 terrabyte of data to store. This is possible on the encrypted UZ Leuven servers. For backing up the data locally, this also won't provide a problem, as we are already in posession of such a hard-drive.
As for the physical models, these can be stored safely in the laboratory of experimental neurosurgery, where there is ample place (well over the required $1m^3$) for the 3D models.

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

The data are stored on the KU Leuven servers, only accessible with double authentication.

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

All costs are covered by the departmental group, or otherwise through existing grant funding.

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...).

Data collected and used within the scope a clinical studies within this project will be retained for 25 years after the end of the respectives studies as per CTC/EC/legal guidelines.

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

Data will be kept on the available servers as well as on an external hard drive, which is password encrypted and kept by the PI in a locked down compartiment.

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

Expected to be free of charge due to the small size of the data.

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, …)

If in the future there is a question for this, individual deidentified participant data and related documents used for the study, they can be made available on reasonable request. Depending on the data requested, additional collaborators will be consulted and a decision will be made about the appropriateness of the use of data. If approved, a data-sharing agreement must be signed before a deidentified version of the data set is made available.

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

See above.

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, Ethical aspects

As we are dealing with individual patient data, albeit deidentified, ethical concerns still exist. Due to this reason, we will not be making our data publicly available.

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

NA

When will the data be made available?

NA

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

NA

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?

NA

6. Responsibilities

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

The researchers who generate the data are responsible for all data. The supervisor will handle long-term preservation of the data.

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

The primary researcher, Georges Versyck, is in charge of this.

Who will manage data preservation and sharing?

The PI; Prof. Dr. Steven De Vleeschouwer

Who will update and implement this DMP?

The primary researcher as long as he/she is involved and afterwards the PI.