Development of innovative zirconia implants from novel materials, surface modification to biological responses

A Data Management Plan created using DMPonline.be

Creator: Stevan Cokic

Affiliation: KU Leuven (KUL)

Funder: Fonds voor Wetenschappelijk Onderzoek - Research Foundation Flanders (FWO)

Template: FWO DMP (Flemish Standard DMP)

Principal Investigator: n.n. n.n.

Data Manager: Stevan Cokic, n.n. n.n., n.n. n.n.

Project Administrator: Stevan Cokic, n.n. n.n.

Grant number / URL: G088123N

ID: 198000

Start date: 31-12-2022

End date: 30-12-2026

Project abstract:

Zirconia ceramics are rapidly becoming the material of choice for metal-free dental implants, because of their superior mechanical characteristics, excellent biocompatibility with low bacterial plaque affinity and natural aesthetics. The long-term clinical success of dental implants largely depends on their osseointegration potential, which is highly influenced by surface chemistry and topography. The osseointegration potential of zirconia, however, is suboptimal, especially since high failure rates and peri-implant crestal bone loss have recently been reported in a number of human trials. Surface modification by acid etching, sandblasting, injection molding, laser micro-patterning and plasma nano-coatings have been suggested to tailor the implant surface for improved cell attachment, proliferation and differentiation during bone healing. Yet, due to a lack of relevant 3D cell-culture models and long-term in-vivo studies, the nature of cell-zirconia surface interactions is insufficiently known. We aim to address the knowledge gaps that exist between material design and manufacturing of zirconia and its final clinical application as dental implant. Using an interdisciplinary research approach, encompassing thorough surface characterization along with novel 3D cell culturing and animal experimentation, the biological response to zirconia implant-surface modifications will be investigated, particularly focusing on the formation of the tissue-implant interface.

Last modified: 09-06-2023

Development of innovative zirconia implants from novel materials, surface modification to biological responses
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	
SEM images	Scanning microscopy images	Generate new data	Digital	Experimental	.TIF of .JPEG	<100GB	
XRD data	X-ray diffraction	Generate new data	Digital	Experimental	.njc, raw, csv	<1GB	
µRaman data	Micro-Raman spectroscopy	Generate new data	Digital	Experimental	.OPUS, jpg	<1GB	
TEM images	Transmissional electronic microscopy images	Generate new data	Digital	Experimental	.TIF of .JPEG	<100GB	
TEM grids	TEM grids for imaging	Generate new data	Physical	Experimental			8 grid boxes
Micro-CT data	Micro-computer tomography	Generate new data	Digital	Experimental	,TIF	<5TB	
Hardness and toughness data	Hardness and toughness testing	Generate new data	Digital	Experimental	.txt	<100MB	
P3B, 4-point bending data	Fracture strength	Generate new data	Digital	Experimental	.txt	<100MB	
3D optical and laser profilometry data	3D optical and laser profilometry measurements of materials surface	Generate new data	Digital	Experimental	.stl	<100GB	
Histology and immunohistochemistry data	Histology sections and immunohistochemistry slides	Generate new data	Physical	Experimental			15 small boxes for glass slides (can be stored on the shelf)
PCR data	Real time qPCR files	Generate new data	Digital	Experimental	?	<5TB	
Light microscopy data	Light microscopy images	Generate new data	Digital	Experimental	.TIF	<5TB	

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:

Only new data will be used.

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, dual use

Use of human cells as approved by the Ethics Committee Research UZ/KU Leuven under the file number S54254.
Ethical approval of the animal study will be requested in due time when all project details of the planned animal research are known.

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

Commercial valorization is not a a direct goal of this project. However, if such an opportunity presents itself, it will be discussed among the staff and collaborators involved in the project.

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.

- Yes

*A **PATENT application** (ref. ZI921151) was submitted on 28-11-2021 to KU Leuven LRD (IP officers: Ivo Roelants, Ivo De Baere) for an European**PATENT** for the invention of a zirconia ceramic-based material with very good mechanical (toughness – hardness - strength) properties: "Cation grain-boundary stabilized transformation induced plasticity in Ce-TZP ceramics" (F. Zhang, M. Li, B. Van Meerbeek, J. Vleugels) (EP22176376). The search report and written opinion of the European Patent Office (EPO) attorney confirmed the primary novelty of our invention, upon which the inventors will amend claims and create clarity before 31-05-2023.*
This new zirconia-ceramics formulation will be used in the current project (patent pending; one of the patent holders is co-promoter of the current FWO project).

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. Internal:
Raw data (temporary data, digital notebooks) will be stored on the UZ Leuven cumulus server with automatic back-up. All data will be stored in folders with the names clearly indicating the folder content.
Research-project Protocols will be saved in the form of MsWord or pdf files.
In addition, regular reports based on the data will be generated using Microsoft Word. PowerPoint files will be used for presentation at regular internal meetings.
In both the Word reports and Powerpoint presentations, the file names of the raw data files will be included.

2. External:
Publications of results in scientific international (and national) peer-reviewed papers. Data in publication format will be published.
The last manuscript version, based on which the paper was accepted for publication, will be uploaded in the KU Leuven Lirias bibliography system. In case of publication in an open-access journal, the journal pdf of the paper will be uploaded.

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

During each experiment, a detailed logbook will be used (different logbooks for the different experimental setups). Logbooks will contain the date, a brief description of the performed experiment, the parameters used for each measurement, as well as the names of all the saved files. The names of the files will be structured in a comprehensible way: system studied/date/main parameters used. In addition, data will be stored in a folder per experimental setup, the type of investigated system and the corresponding date. In this way, by tracking the corresponding logbook notes, each file can be easily found on the local computers controlling the setup and on the server of the laboratory. The analysis files will contain notes describing the analysis procedure and mention which original data files are included. A readme file describing the goal of the experiment and the analysis procedure will be stored in the folder where the data is saved.

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

Where will the data be stored?

The data will be stored via a password-protected cloud storage solution (UZ Leuven cumulus google drive) that allows sharing with the researchers involved in the project. Copies can be made and kept on personal devices.

How will the data be backed up?

Data in the home directory of the users is backed up periodically. Snapshots of the home directories are also taken. The important data will be stored on the KU/UZ Leuven 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

Unlimited.

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

Password protected user accounts ensure that only the persons of the account can access the working data. The data generated during the project will be systematically transferred to the cloud storage server. Only the researcher and (co)-promotors will have access to the shared folders where the data, reports and presentations will be stored.

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

The expected costs for data storage will not exceed a few hundred euro for external hard disks. This will be covered by the bench fee of the project.
There is no cost for the UZ Leuven cumulus drive.

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 the generated data will be stored on the cloud storage server for a period of 5 years
after the end of the project.

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

All the generated data will be stored on the cloud storage server (UZ Leuven cumulus google drive) for a period of 5 years after the end of the project.
Beyond 5 years after the end of the project, one of the following options will be picked
(1) continuation of storing the data on the cloud storage server or (2) transferring the
data to the KU Leuven central servers for archiving.

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

No additional costs are expected at this moment.

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, ...)

The written reports and Powerpoint presentations summarizing the results obtained can be made available. The (raw) data used in publications can be made available on a repository, if e.g. requested by the Editors or Publisher of a scientific journal, or individual researchers.

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

If access is restricted, promoter and co-promoters will be able to access the data. Upon request or within research group, access to the samples and data can be granted.

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.

Upon request by mail.

When will the data be made available?

Upon publication of the research results. Description of the full scientific method and results will be made available with journal publications (and upon request).

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

We will consult the License selector tool in order to choose the best license that fits our data.

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

We will use DIO that is commonly used in KU Leuven RDR repository.

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

No costs associated with data sharing.

6. Responsibilities

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

The promoter, co-promotors and FWO post-doctoral researcher will be jointly responsible for data documentation during the research project.

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

The promoter, co-promoters and the FWO post-doctoral researcher involved in this project.

Who will manage data preservation and sharing?

The promoter and the FWO PostDoctoral researcher involved in this project.

Who will update and implement this DMP?

The promoter and the FWO PostDoctoral researcher involved in this project.

Development of innovative zirconia implants from novel materials, surface modification to biological responses
Application DMP

Questionnaire

Describe the datatypes (surveys, sequences, manuscripts, objects …) the research will collect and/or generate and /or (re)use. (use up to 700 characters)

/

Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)

Designation of responsible person:
Promoter: Prof. Kirsten Van Landuyt (kirsten.vanlanduyt@kuleuven.be)
Co-promoter: Prof. Bart Van Meerbeek (bart.vanmeerbeek@kuleuven.be)
Post-doctoral researcher: Stevan Cokic (stevan.cokic@kuleuven.be)
Storage capacity/repository:
The data will be stored via a password-protected cloud storage solution (UZ Leuven cumulus google drive) that allows sharing with the researchers involved in the project. Copies can be made and kept on personal devices. Moreover, Data in the home directory of the users is backed up periodically. Snapshots of the home directories are also taken. The important data will be stored on the KU/UZ Leuven central servers with automatic daily back-up procedures. There is unlimited storage/back-up capacities.
Promoter and co-promoters will have an access to data.

What's the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)

We do not wish do deviate from the principle of preservation of data for the minimum of 5 years.

Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)

In this project we would be working with commercial and harvested human cell cultures and animals. Use of human cells as approved by the Ethics Committee Research UZ/KU Leuven under the file number S54254. Ethical approval of the animal study will be requested in due time when all project details of the planned animal research are known.

Which other issues related to the data management are relevant to mention? (use up to 700 characters)

There are no other issues related to the data management.

Development of innovative zirconia implants from novel materials, surface modification to biological responses
DPIA

DPIA

Have you performed a DPIA for the personal data processing activities for this project?

- Not applicable

Development of innovative zirconia implants from novel materials, surface modification to biological responses
GDPR

GDPR

Have you registered personal data processing activities for this project?

- Not applicable