Toward 4D-printed foot orthotics based on pressure-driven shape adaptability for the remote management of at-risk diabetic feet

A Data Management Plan created using DMPonline.be

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Project abstract:

Diabetes-related foot disease is one of the ten leading causes of disability, and the main reason for amputations. Its chronic complications and social impact claims for a prompt and effective prevention measure. The ORTEADA project will revolutionize the concept of foot orthotic by developing a novel pressure-assessment-driven, electrically activated, shape-adaptable material system with a patient-centred approach. First, we will develop a sensor layer capable of measuring the foot plantar pressure distribution. Second, we will develop an electro-active shape-adaptable material for the orthotic. Third, we will quantify the dose-response effect of the customized foot orthotics on the plantar pressure distribution. Fourth, we will create those new foot orthotics using additive manufacturing. Finally, we will design the control electronics and software to make the shape-adaptable foot orthotic protoype, and conduct a pilot study.

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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.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		Indicate: ***N****(ew data) or* ***E****(xisting data)*	Indicate: **D**(igital) or **P**(hysical)	Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
Sensor - S	Sensor synthesis protocol	N	D	T	pdf	<1GB	
Sensor - C	Sensor electrical and mechanical characteristics	N	D	N	excel	<1GB	
Sensor - M	Sensor modeling	N	D	M	pdf	<1GB	
Sensor - D	Data acquisition with sensor	N	D	N	excel	<1GB	
Sensor - SO	Sensor software: app to visualize pressure data from sensor	N	D	SO		<100GB	
Sensor - P	Sensor prototype	N	P	prototype	pictures technical drawing		thin layer
SAM - S	Shape-adaptable material synthesis protocol	N	D	T	pdf	<1GB	
SAM - C	Shape-adaptable material characterization	N	D	N	excel	<1GB	
SAM - I	Shape-adaptable material characterization with SEM	N	D	I	pdf	<100GB	
SAM - M	Shape-adaptable material auxetic structure modeling	N	D	M	pdf	<1GB	
SAM - V	Shape-adaptable material validation testing	N	D	N	excel	<1GB	
SAM - P	Shape-adaptable material prototype	N	P	prototype	pictures technical drawing		size of shoe insole
DRE - S	3D scans of feet	N	D	I	obj, stl, cad	<5TB	
DRE - P	Barefoot Plantar pressure distribution	N	D	N	csv, fpm	<1TB	
PRT - P	Protocol for 3D printing of the developed material with auxetic structure	N	D	T	pdf	<1GB	
PRT - S	Protocol for microprinting of pressure sensor	N	D	T	pdf	<1GB	
CTRL - P	Protocol to control electronics	N	D	T	pdf	<1GB	
CTRL - A	Algorithm development to control the shape adaptable layer	N	D	T	pdf	<1GB	
CTRL - SO	Implementation of algorithm and programming in microcontroller	N	D	SO	source (C files) code	<100GB	
CTRL - V	Validation of pressure redistribution	N	D	N	excel	<1GB	
CTRL - S	Pilot study of prototype	N	D	T	pdf	<1GB	
CRF	Case Report Form	N	D	T	txt	<1GB	
ICF	Informed Consent Form	N	P	T			
VICON	3D motion analysis	N	D	A	c3d	<100GB	

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:

No existing data will be reused in this project.

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, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- Yes, human subject data (Provide SMEC or EC approval number below)

This will not be the case in the first year of the project yet. We will update this DMP when we will work with personal data.

Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- Yes (Provide PRET G-number or EC S-number below)

This will not be the case in the first year of the project yet. We will update this DMP when we will work with personal data.

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

We will make new materials and structures for a new type of foot orthotic. The research is on a quite fundamental level, but it does have an economic and societal impact. The project aims at develop a smart shape-adaptable foot orthotic, offering an innovative solution for the at-risk feet of diabetic patients. The project has the ambition to demonstrate a fully functioning prototype within a laboratory setting (TRL4). Therefore, we think that follow-up projects, such as internal C3 project or VLAIO R&D projects, rather than the current C2 project, will develop the prototype further towards a product or technology at TRL6, which can then be licensed to companies. First, the sensor layer can be used to inform patients about the state of their foot during an activity. The sensor layer could be connected to a mobile application so the person can follow the condition of their foot. This is a very important aspect, as patients are in many cases unable to feel any protective sensation in their extremities. Second, the sensor layer will be designed to be sensitive to pressure changes during a pressure load. This concept could also be useful in other applications, such as tactile gloves with haptic feedback.

Shape-adaptable materials, such as irreversible shape-memory polymers, are available on the market (e.g. stents). Some electro-active polymers, such as the so-called artificial muscles, show a reversible shape change when a high voltage is applied. A material thinner than about 6 mm (required for the foot orthotic) that can withstand or enable a shape change based on an electric stimulus triggered by the processed sensor signal, under the pressure exerted by the weight of a human body does not exist on the market. Hence, the product we will develop in ORTEADA can be classed as groundbreaking. Furthermore, the concepts and materials developed for this foot orthotic will be transferrable and could lead to many other applications in the health, sports and mechatronics sectors (e.g., anti-decubitus solutions, sport shoes, soft robotics, etc.). Our technology will be a major breakthrough in the field, and there is potential for future spin-offs to reap the economic benefits.

Also regarding the manufacturing process in this project, our solution for a smart 3D-printed foot orthotic is a huge step forward, because it integrates a printed sensor layer and the 3D-printed electro-active shape-adaptable auxetic material. Our solution consists of (i) a sensor layer made with printed electronics; (ii) a mapping algorithm to pre-stretch the flat substrate according to the curved foot orthotic; (iii) a shape-adaptable layer based on auxetic material; (iv) an algorithm that triggers the shape-adaptable layer based on the sensor values measured on the sensor layer. There is no technology on the market that can compete with our solution, as there is currently no electro-active shape-adaptable product providing a real solution for diabetes patients, let alone a manufacturing process to make it.

The project is designed in a manner that the above aspects on technological valorization are independent of each other. The data sets each have their own valorization potential regardless of the success of other aspects.

The data sets associated with potential commercial valorization involve:

- Sensor: SENSOR - S, SENSOR - SO, SENSOR - P
- Shape-adaptable material: SAM - S, SAM - M, SAM - P
- 3D printing: PRT - P, PRT - S
- control electronics and integrated system: CTRL - P, CTRL - A, CTRL - SO

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or 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

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).

For each of the characterization analyses, the measurement procedures and conditions, instrument type, settings, etc will be recorded in text documents.
We will add the following metadata for the datasets:

- Sensor - S: details on investigation, investigator, topic and keyword, publication, dataset, datafile, parameters, authorisation
- Sensor - C: details on investigation, investigator, topic and keyword, publication, materials, dataset, datafile, parameters, authorisation
- Sensor - M: details on investigation, investigator, topic and keyword, publication, model, dataset, datafile, parameters, authorisation
- Sensor - D: details on investigation, investigator, topic and keyword, publication, materials, dataset, datafile, parameters, authorisation
- Sensor - SO: details on investigation, investigator, topic and keyword, publication, sample, dataset, datafile, parameters, authorisation
- Sensor - P: details on investigation, investigator, topic and keyword, publication, material, model, dataset, datafile, parameters, authorisation
- SAM - S: details on investigation, investigator, topic and keyword, publication, dataset, datafile, parameters, authorisation
- SAM - C: details on investigation, investigator, topic and keyword, publication, materials, dataset, datafile, parameters, authorisation
- SAM - I: details on investigation, investigator, topic and keyword, publication, materials, dataset, datafile, parameters, authorisation
- SAM - M: details on investigation, investigator, topic and keyword, publication, model, dataset, datafile, parameters, authorisation
- SAM - V: details on investigation, investigator, topic and keyword, publication, materials, dataset, datafile, parameters, authorisation
- SAM - P: details on investigation, investigator, topic and keyword, publication, material, model, dataset, datafile, parameters, authorisation
- DRE - S: details on investigation, investigator, topic and keyword, publication, sample, dataset, datafile, parameters, authorisation
- DRE - P: details on investigation, investigator, topic and keyword, publication, sample, dataset, datafile, parameters, authorisation
- PRT - P: details on investigation, investigator, topic and keyword, publication, dataset, datafile, parameters, authorisation
- PRT - S: details on investigation, investigator, topic and keyword, publication, dataset, datafile, parameters, authorisation
- CTRL - P: details on investigation, investigator, topic and keyword, publication, dataset, datafile, parameters, authorisation
- CTRL - A: details on investigation, investigator, topic and keyword, publication, model, dataset, datafile, parameters, authorisation
- CTRL - SO: details on investigation, investigator, topic and keyword, publication, model, dataset, datafile, parameters, authorisation
- CTRL - V: details on investigation, investigator, topic and keyword, publication, materials, dataset, datafile, parameters, authorisation
- CTRL - S: details on investigation, investigator, topic and keyword, publication, material, model, dataset, datafile, parameters, authorisation
- VICON: UID, date, session ID
- CRF: UID, REDCap, authorisation

Will a metadata standard be used to make it easier to find and reuse the data?
If so, please specify which metadata standard will be used.

If not, please specify which metadata will be created to make the data easier to find and reuse.

- Yes

We will use the RDR data repository of KU Leuven. A metadata standard is automatically applied upon depositing the data. The metadata model will include fields that are required, recommended and optional. Using this data repository, the data sets will be findable and reusable.
Data captured from human beings will be managed with RedCap software.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- OneDrive (KU Leuven)
- Other (specify below)
- Large Volume Storage

We will explore novel solutions for data storage, such as Active Data Management Platform (https://icts.kuleuven.be/sc/english/storage/admp)

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

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

KU Leuven has IT specifications for data storage and management. Based on the confidentiality of the data, storage space, possibility to share data with colleagues, type of data, metadata, etc, IT provides tailored solutions. The recommended storage is SharePoint on premise or online-site or Teams-site. Only the persons involved in the project will be able to access the data. If other (third party) persons or research groups are interested in the data, then we will discuss this among the PIs of the project.
Large volume data will be stored on the dedicated platform of the KULeuven (LVD storage @ drives.kuleuven.be)

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

No extra costs. The platform of Sharepoint, Teams or the Active Data Management Platform is offered free of charge by KU Leuven.

Data Preservation after the end of the Research Project

Which data will be retained for 10 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 data will be preserved for 10 years according to KU Leuven RDM policy
- All data will be preserved for 25 years according to CTC recommendations for clinical trials with medicinal products for human use and for clinical experiments on humans

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

- KU Leuven RDR
- Large Volume Storage (longterm for large volumes)

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

Free for KU Leuven staff

Data Sharing and Reuse

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

- Yes, as embargoed data (temporary restriction)

The data that are important in terms of potential further commercial valorization will need to be kept confidential, and thus no access until patent is issued and granted if applicable.

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

The data will be restricted / embargoed until the work is published or patented. Only the specific investigators involved in the research project will have access to the data during the restriction / embargo period.

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 per dataset or data type where appropriate.

- No

Some data may be used for patent application afterwards, and in this way, they would be restricted temporarily.

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- KU Leuven RDR (Research Data Repository)

When will the data be made available?

- Upon publication of research results

Or for some data, after patenting.

Which data usage licenses are you going to provide?

If none, please explain why.

- CC-BY 4.0 (data)

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- No

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

The mentioned storage types are free for staff at KU Leuven.

Responsibilities

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

The PhD researchers working on the research project and generating the data will make the dataset files along with the metadata. They will ensure uploading and storing the datasets during the course of their PhD and the project.

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

The PhD researchers working on the research project will take care of data storage and backup during the research project, and they will be supervised in this task by the promotors of the research project.

Who will manage data preservation and sharing?

The promotors of the research project will be responsible for the long-term data storage, preservation and sharing of data. Specifically, this will be Prof. Deschamps for datasets DRE - S, DRE - P, and CTRL - S. Prof. Vandeginste will be responsible for the long-term data storage, preservation and sharing of all other datasets.

Who will update and implement this DMP?

The promotors of the research project will update this DMP and make sure it is implemented. This is Prof. Deschamps for DRE - S, DRE - P, and CTRL - S, CRF- ICF-VICON, and thus all medical or patient related data, whereas Prof. Vandeginste will manage updates and implementation of the other datasets in this DMP.