Plan Overview

A Data Management Plan created using DMPonline

Title: Three-dimensional virtual surgical planning and patient-specific osteosynthesis with drilling guides for acetabular fracture surgery.

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Template: UMC Utrecht DMP

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Project abstract:

Rationale: In acetabular fracture surgery, achieving an optimal reconstruction of the articular surface improves the functional outcome and decreases the risk of progressive osteoarthritis and the subsequent need for total hip arthroplasty. With the current implants, it regularly occurs that a good anatomical reduction and optimal operative fixation of the fractured acetabulum won't be achieved. Unfortunately, conventional plates often don't fit to the shape of each pelvis and don't hold the surgically reduced fracture fragments perfectly in place despite multiple intra-operative bending and contouring manoeuvres. We developed an innovative method to design, produce and apply patient-specific plates with drilling guides for acetabular fracture surgery. The aim of this study is to assess whether this approach will improve the quality of the reduction, and operative fixation, functional outcome and surgeon's efficiency compared to the conventional osteosynthesis. Objective: To assess whether patient-specific implants for acetabular fracture surgery result in a more accurate reconstruction of the articular surface in comparison to conventional plate osteosynthesis. Study design: All patients who will be included in this multicentre prospective cohort study will be operated for an associated acetabular fracture with either a conventional implants (control group) or patient-specific implants (intervention group). The treatment allocation will depend on the centres in which the patient will be treated (1 Level 1 trauma centre using the conventional implants and 1 Level 1 trauma centre using the patient-specific implants). For manufacturing the patient-specific implants, CT data will be used to create a 3D computer model of the fractured pelvis. The personalised implants and drilling guides, tailored to both the shape of the pelvis and the type of fracture, will be designed and produced within a few days and finally applied during surgery. Study population: Patients (>18 yrs) presenting with an acute (2 weeks from the injury) displaced acetabular fracture for which a surgical intervention is indicated. Intervention: The intervention group will be surgically treated with patient-specific implants and the control group will be surgically treated with conventional implants. Main study parameters/endpoints: The primary endpoint is the residual fracture displacement (in mm), as measured on the postoperative CT-scan. The secondary endpoint includes patient reported outcome, which will be assessed with validated follow-up questionnaires at one-year follow-up. Additionally, surgery related factors e.g. the total time for intra-operative bending manoeuvres, plate positioning and fixation, the surgeon's satisfaction about implant fitting will be assessed. For the patient-specific implants, the accuracy of the screw positions will be assessed by matching the preoperative virtual planning with the post-operative CT images.

ID: 78695

Start date: 01-07-2021

End date: 30-06-2028

Last modified: 11-06-2021

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Three-dimensional virtual surgical planning and patient-specific osteosynthesis with drilling guides for acetabular fracture surgery.

1. General features

1.1. Please fill in the table below. When not applicable (yet), please fill in N/A.

DMP template version	29 (don't change)
ABR number *(only for human-related research)*	NL72975.042.20
METC number *(only for human-related research)*	METc 2020/086
DEC number *(only for animal-related research)*	
Acronym/short study title	DREAM-3D
Name Research Folder	xx-xxx_DREAM-3D
Name Division	Surgical Specialties
Name Department	Traumasurgery
Partner Organization	UMCG
Start date study	01-07-2021
Planned end date study	30-6-2028
Name of datamanager consulted*	D. Steins
Check date by datamanager	10-06-2021

1.2 Select the specifics that are applicable for your research.

- Clinical study
- Multicenter study
- WMO
- Use of Questionnaires
- Interventional study

2. Data Collection

2.1 Give a short description of the research data.

Objective: To assess whether patient-specific implants for acetabular fracture surgery result in a more accurate reconstruction of the articular surface in comparison to conventional plate osteosynthesis.

Population: Patients (>18 yrs) presenting with an acute (2 weeks from the injury) displaced acetabular fracture for which a surgical intervention is indicated. (N=30)

For this multicenter prospective study we will analyse the residual fracture displacement on the postoperative CT of patients who sustained an acetabular fracture. For this, we will collect data on demographic information, fracture and radiographic characteristics, operation specifications and complications. This data will be collected from patients' electronic health records. In addition, we will ask patients to fill in validated patient-reported outcome measurements (PROMs) questionnaires regarding physical functioning, quality of life, sports and work at 0 months, and 12 months after the injury.

We will obtain informed consent for the collection of the patients' data, which will also include informed consent for the possibility to obtain medical records from other hospitals or the GP where the patient has been treated. Furthermore, informed consent will be asked to store the personal data for the use of research in the future (FAIR data) and to use the patients' email address to send the patient-reported questionnaires online.

For the collection of the data described above, a study specific eCRF is designed in REDCap. In this eCRF the data will be entered and digital questionnaires about physical functioning and quality of life will be sent out to the study patients for completion. The infrastructure of REDCap has access management, audit trail and an automated back-up in place.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	75	EPD (HiX)	REDCap	Quantitative	.csv / .sas7bdat	0-10 GB
Human	75	eCRF	REDCap	Quantitative	.csv / .sas7bdat	0-10 GB
Human	75	CT scans	?	Images	?	?
Human		EQ-5D-5L?	REDCap	Quantitative		0-10 GB
Human		SMFA	REDCap	Quantitative		0-10 GB
Human		LEFS	REDCap	Quantitative		0-10 GB
Human		PROMIS	REDCap	Quantitative		0-10 GB

2.2 Do you reuse existing data?

- No, please specify

This is a prospective study, all data will be collected prospectively

2.3 Describe who will have access to which data during your study.

All participants will receive a research ID number in the dataset, using a subject identification code. The key table will be maintained by the investigator separately from the eCRF and the extracted datasets and will have secured access.

Type of data	Who has access
Direct identifying personal data	Research team, Datamanager
Key table linking study specific IDs to Patient IDs	PI, Datamanager
Pseudonymized data	Research team, Datamanager

2.4 Describe how you will take care of good data quality.

1. Experimental data from patients will be collected in an electronic Case Report Form (eCRF) in a certified Data Capture Tool: REDCap. In the eCRF, skips and validation checks are built in. Data quality will be checked by Jan Bottema (research coordinator UMCG). Data collection will be frozen before analysis.

#	Question	Yes	No	N/A
1.	Do you use a certified Data Capture Tool or Electronic Lab Notebook?	x		
2.	Have you built in skips and validation checks?	x		
3.	Do you perform repeated measurements?	x		
4.	Are your devices calibrated?		x	
5.	Are your data (partially) checked by others (4 eyes principle)?	x		
6.	Are your data fully up to date?	x		
7.	Do you lock your raw data (frozen dataset)	x		
8.	Do you keep a logging (audit trail) of all changes?	x		
9.	Do you have a policy for handling missing data?	x		
10.	Do you have a policy for handling outliers?	x		

2.5 Specify data management costs and how you plan to cover these costs.

#	Type of costs	Division ("overhead")	Funder	Other (specify)
1.	Time of datamanager	X		
2.	Design of eCRF			UMC Groningen
3.	Data Capture Tool licence fee			UMC Groningen
4.	Storage	X		
5.	Archiving	X		

2.6 State how ownership of the data and intellectual property rights (IPR) to the data will be managed, and which agreements will be or are made.

The data is owned by the department of Surgery of the UMCG. The data will be available for future reuse at the digression of the principal investigator. A clinical trial agreement between the UMCU and UMCG is drafted ans will soon be signed between the two parties.

3. Personal data (Data Protection Impact Assessment (DPIA) light)

Will you be using personal data (direct or indirect identifying) from the Electronic Patient Dossier (EPD), DNA, body material, images or any other form of personal data?

- Yes, go to next question

I will process personal data. I have consulted the division datamanager and I do not have to complete a full DPIA, but a miniDPIA.

3.1 Describe which personal data you are collecting and why you need them.

3.2 What legal right do you have to process personal data?

- Study-specific informed consent

3.3 Describe how you manage your data to comply to the rights of study participants.

Right of Access	Research data are coded, but can be linked back to personal data, so we can generate a personal record at the moment the person requires that. This needs to be done by an authorized person.
Right of Objection	We use informed consents.
Right to be Forgotten	In the informed consent we state that the study participant can stop taking part in the research. Removal of collected data from the research database cannot be granted because this would result in a research bias

3.4 Describe the tools and procedures that you use to ensure that only authorized persons have access to personal data.

1. We use the secured Research Folder Structure that ensures that only authorized personnel has access to personal data, including the key table that links personal data to the pseudoID.
2. We make use of a certified Electronic Data Capture (EDC) tool (RedCap). To send surveys, email address will be used in the EDC, but this is encrypted for the users in such a way that users can send emails to subjects without seeing the actual email address. No personal data other than email address will be used in the EDC.

3.5 Describe how you ensure secure transport of personal data and what contracts are in place for doing that.

1. In case we need to transport personal data with colleagues, we use Surffilesender with encryption.
2. We have a Research Agreement with UMC Groningen. The agreement is stored at location: L:\Onderzoek\Traumatologie\xx-xxx_DREAM-3D\B_Documentation\6_Contracts

4. Data Storage and Backup

4.1 Describe where you will store your data and documentation during the research.

The digital files will be stored in the secured Research Folder Structure of the UMC Utrecht. We will need +/- 50 GB storage space, so the capacity of the network drive will be sufficient.

4.2 Describe your backup strategy or the automated backup strategy of your storage locations.

1. All (research) data is stored on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT).
2. During data collection, automatic backups will be made in the Electronic Data Capture Tool REDCap

5. Metadata and Documentation

5.1 Describe the metadata that you will collect and which standards you use.

The eCRF specifically designed for this study in REDCap also provides a data dictionary or codebook containing descriptive information on all data variables and if applicable its units of measurement. This data dictionary or code book is extracted from REDCap in CSV file format

5.2 Describe your version control and file naming standards.

We will distinguish versions by indicating the version in the filename of the master copy by adding a code after each edit, for example V1.1 (first number for major versions, last for minor versions). The most recent copy at the master location is always used as the source, and before any editing, this file is saved with the new version code in the filename. The file with the highest code number is the most recent version.

6. Data Analysis

6 Describe how you will make the data analysis procedure insightful for peers.

For further analyses, extractions of the cleaned raw data will be made from this information system that will be explored using statistical and data science tools (SPSS, 23.0 for Windows (IBM Corporation, Armonk, NY)). All syntaxes describing data processing and analysis will contain or be accompanied by comments and descriptions explaining the code and the decisions made.

7. Data Preservation and Archiving

7.1 Describe which data and documents are needed to reproduce your findings.

The data package will contain: the raw data, the study protocol describing the methods and materials, the script to process the data, the scripts leading to tables and figures in the publication, a codebook with explanations on the variable names.

7.2 Describe for how long the data and documents needed for reproducibility will be available.

Data and documentation needed to reproduce findings from this non-WMO study will be stored for at least 15 years.

7.3 Describe which archive or repository (include the link!) you will use for long-term archiving of your data and whether the repository is certified.

After finishing the project, the data package will be stored at the UMC Utrecht Research Folder Structure and is under the responsibility of the Principal Investigator of the research group. When the UMC Utrecht repository is available, the data package will be published here.

The links to the folder is:

\\ds\DATA\HS\Onderzoek\Traumatologie\xx-xxx_DREAM-3D

7.4 Give the Persistent Identifier (PID) that you will use as a permanent link to your published dataset.

I cannot publish the dataset in an external repository. Therefore, I do not have a PID.

A description of the research project is registered in the UMCG Research Register: 202000092. This register is only accessible for UMCG researchers.

8. Data Sharing Statement

8.1 Describe what reuse of your research data you intend or foresee, and what audience will be interested in your data.

The raw data can be of interest for other researchers or for spin off projects

8.2 Are there any reasons to make part of the data NOT publicly available or to restrict access to the data once made publicly available?

1. Our data will be shared with third parties after approval of the Principle Investigator. The criteria and time period will be determined on a case-by-case basis.

8.3 Describe which metadata will be available with the data and what methods or software tools are needed to reuse the data.

All data and documents in the data package mentioned in 7.1 will be shared under restrictions.

8.4 Describe when and for how long the (meta)data will be available for reuse

- Other (please specify)

to be determined

8.5 Describe where you will make your data findable and available to others.

As the data is privacy-sensitive, we publish the descriptive metadata in the data repository with a description of how a data request can be made (by sending an email to the corresponding author). In the event that peers like to reuse our data this can only be granted if the research question is in line with the original informed consent signed by the study participants. Every application therefore will be screened upon this requirement. If granted, a data usage agreement is signed by the receiving party.