Dutch Research for the Evaluation of Acetabular fracture Management in 3D

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28665

Source
NTR

Brief title
DREAM-3D study

Health condition

Acetabular fracture

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: SNN grant

Intervention

Outcome measures

Primary outcome

The primary endpoint is the residual fracture displacement (in mm), as measured on the postoperative CT-scan.

Secondary outcome

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.

Study description

Background summary

Background of the study:
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 of the study:
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 (3 Level 1 trauma centers using the conventional implants and 3 Level 1
trauma centers 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 (if applicable):
The intervention group will be surgically treated with patient-specific implants and the control group will be surgically treated with conventional implants.

Primary study parameters/outcome of the study:
The primary endpoint is the residual fracture displacement (in mm), as measured on the postoperative CT-scan.

Secundary study parameters/outcome of the study (if applicable):
The secondary endpoint includes patient reported outcome, which will be assessed with validated follow-up questionnaires at oneyear
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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):
The extent of burden and risks for patients participating in the study is considered low, because the main parts of the operative procedure itself won’t change. Moreover, our pilot study with patient-specific implants for acetabular fracture surgery (N=10) demonstrated that this technique is feasible, safe and appears to be effective.

Study objective

Better fracture reduction using patient-specific implants compared to conventional implants

Study design

Follow-up at 6 weeks, 3 months, 6 months and one year.

Intervention

The intervention group will be surgically treated with patient-specific implants and the control group will be surgically treated with conventional implants.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients ≥ 18 years with an acute (2 weeks from the injury) displaced acetabular fracture will be included after a signed informed consent.
- Associated type acetabular fracture types (posterior column and wall, transverse and posterior wall, T-type, anterior column and posterior hemitransverse, both column fractures).

Exclusion criteria

- Elementary acetabular fracture types (isolated posterior wall, isolated posterior column, anterior wall, anterior column and transverse fractures)
- ‘Late’ acetabular fractures more than 2 weeks after the injury
- Pathological fractures
- Patient with previous hip surgery or surgery in the pre-peritoneal space (Stoppa approach) making an anterior or posterior pelvic approach hardly possible.
- Patient unfit for acetabular surgery (e.g. anterior and posterior approach in one tempi).
- Patients with body-mass index (BMI) >35.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-04-2021
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9399
Other	METC UMCG : METc 2020/086

Study results