Assessment of the performance and clinical importance of 3D printed patient specific guides in distal radius malunion surgery

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To assess the performance of a distal radius osteotomy supported by 3D guides in patients suffering from a radius malunion by comparing the pre-planned radius correction to the actual correction derived from a postoperative CT.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Observational invasive

Summary

ID

NL-OMON54451

Source
ToetsingOnline

Brief title
PSGs in radius malunion surgery

Condition

- Fractures

Synonym
Radius Malunion, Residual malalignment after Radius fracture

Research involving
Human

Sponsors and support

Primary sponsor: OCON Orthopedische kliniek

Source(s) of monetary or material Support: eigen middelen OCON

Intervention

Keyword: Computed Tomography, Patient Related Outcome Measures, Patient Specific Guide, Radius Malunion

Outcome measures

Primary outcome

To assess the performance of distal radius osteotomies, two 3D angles are generated. One 3D angle is generated between the preoperative and the planned orientation and one between the preoperative and postoperative orientation. These 3D angles will be used to find the coherence between the planning and the operative result which will be statistically tested using a non-inferiority margin. These results will be compared to patient related outcome measures to find the coherence between surgical result and patient satisfaction. This coherence will be tested using a Pearson correlation (normal distribution) or Spearman correlation (non-normal distribution).

Secondary outcome

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Study description

Background summary

Distal radius fractures resulting in a malunion after initial treatment have an incidence of 5-6.5 per 10,000 person-years. Historically, two perpendicular X-ray images have been used to assess the severity of these malunions. Based on these X-ray images, the decision to operate and the degree of correction were determined. Research then showed that X-ray was unable to assess the axial rotation component in radius malunions which was the cause for suboptimal surgical corrections. Since CT is capable of 3D assessment, it was introduced

for assessment of radius malunions and planning of radius osteotomies. Since the last decade, these CT scans have been used to create surgical guides which translate the planned correction to the operating room.
The operative result is currently still evaluated using two perpendicular X-ray images although research has shown this not to suffice in proper evaluation of radius malunions. This study aims to objectively evaluate the surgical result after surgery using surgical guides by obtaining a CT scan postoperatively for 3D evaluation.

Study objective

To assess the performance of a distal radius osteotomy supported by 3D guides in patients suffering from a radius malunion by comparing the pre-planned radius correction to the actual correction derived from a postoperative CT.

Study design

A cohort study consisting of 20 patients.

Study burden and risks

Additional to the regular care, a postoperative CT of both forearms is needed to perform this research. The CT scan, which takes approximately 10-15 minutes of the patient*s time, will be planned on the day the patient visits the clinic for regular follow-up. The CT has a dose of 0.029 mSv which corresponds to 2% of the annual Dutch background radiation. There is no expected risk associated with participation in this research. Participation in this research has no consequences for the regular care of the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

The patient will undergo/underwent distal radius correction osteotomy surgery with the use of PSGs designed in OCON Centre of Orthopaedic Surgery.

Exclusion criteria

The patient has a contraindication for CT scans.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-12-2020
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	04-11-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-07-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-02-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-06-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-09-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL74563.100.20