# Analysis of instability patterns in acute scaphoid fractures by 4-dimensional computed tomographic imaging

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Despite the severe clinical consequences of a scaphoid nonunion, the kinematical mechanisms that influence the healing process of a scaphoid fracture are still poorly understood. Until now, all in-vivo research is based on step-wise static imaging...

| Ethical review        | Approved WMO           |
|-----------------------|------------------------|
| Status                | Recruitment stopped    |
| Health condition type | Fractures              |
| Study type            | Observational invasive |

# Summary

## ID

NL-OMON45313

**Source** ToetsingOnline

**Brief title** Kinematical patterns in acute scaphoid fractures

## Condition

• Fractures

**Synonym** fracture of the scaphoid bone, fracture through the boat-shaped bone

#### **Research involving** Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

#### Intervention

Keyword: 4D-CT scan, Fracture, Kinematics, Scaphoid

#### **Outcome measures**

#### **Primary outcome**

The aim is to estimate the motion of the distal fragment relative to the proximal fragment expressed in two parameters (rotation and translation). For these experiments the apparent changes in position of the fragments with respect to each other are displayed as a rotation around a Helical Axis of Motion (HAM)28 and translations along the HAM. The HAM notation therefore reduces the standard motion parameters (3 translations and 3 rotations) to one rotation and one translation. We will define the mean ( $\mu$ ) and standard deviation (\*) of the displaced group and non-displaced group.

#### Secondary outcome

A: Because of the small sample size we will only be able to describe a trend: time to union in relation to the motion of the distal fragment relative to the proximal fragment expressed in two motion parameters; rotation and translation. The HAM notation reduces the motion parameters from 3 translations to 1 translation; and 3 rotations to 1 rotation around an axis.

B: For the second analysis, the carpal kinematics of each carpal bone will be described by 3 translation parameters and 3 rotation parameters expressed in terms of a general coordinate system of the radius, and recorded as a function of time. The HAM translation and rotation of each carpal bone and inter-fragmentary bone displacement will be compared between the injured wrist

and the non-injured wrist in each individual. We expect to find significant

changes in the dynamics of carpal bones during motion of the wrist in patients

with a scaphoid fracture.

# **Study description**

#### **Background summary**

Scaphoid fractures are the most common fractures of the carpals and account for 50% to 80% of all carpal fractures in young and active patients. The scaphoid acts as a lever between the proximal and distal carpal rows of the wrist and therefore plays an important role in carpal stability and wrist mechanics6. Although union rates vary, approximately 10% to 15% of all scaphoid fractures progress to nonunion. Because nonunion of the scaphoid leads to changes in the wrist mechanics, carpal instability and secondary degenerative changes, known as a scaphoid nonunion advanced collapse (SNAC), it is important to diagnose those acute fractures that are prone to nonunion.

Scaphoid fractures are considered unstable when they are more than 1 mm displaced. However, whether displaced fractures truly demonstrate an unstable motion pattern during wrist motion has never been objectively analyzed. It is well recorded that the nonunion rates are considerably higher when a fracture is more than 1mm displaced, with approximately a 55% chance of malunion or nonunion, in comparison to an 90% overall rate of union in scaphoid fractures. Other factors associated with the development of a scaphoid nonunion are the fracture location, vascular supply, concurrent carpal ligament injury (carpal instability) and time to treatment.

In an attempt to diagnose those fractures that are prone to nonunion, numerous different scaphoid fracture classification systems are available to improve treatment selection and prognosis. Current fracture classification is based on plain radiographs, two-dimensional CT- or three-dimensional CT scans. However, static imaging procedures do not evaluate any instability that might occur during normal wrist motion. These imaging techniques only evaluate osseous damage and have proven to be unreliable to detect ligament damage, whilst ligament damage is present in approximately 34-63% in acute scaphoid fractures. If ligament injuries are neglected at time of surgery, this could lead to symptomatic carpal instabilities and osteoarthrosis of the wrist.

Since prevailing classification systems are based upon static imaging and fracture instability is considered the most important factor associated with nonunion, there is still no consensus about the best fracture classification

method. Furthermore, considering the fact that the majority of nondisplaced fractures are treated conservatively, predicting instability might improve identification of the subset of scaphoid fractures unlikely to heal in a cast. Therefore, management of patients with scaphoid fractures could be further improved with more reliable diagnostic tools to detect interfragmentary motion and associated ligament damage, and subsequently identify those fractures that are prone to nonunion. This study protocol is the first to obtain 4-dimensional and quantitative data regarding the pathological kinematics of the wrist following scaphoid fracture, using in vivo motion analysis. We compare the wrist in the same individual, because anatomic variance of carpal ligaments and osseous geometry are known, possibly resulting in altered kinematics.

#### Study objective

Despite the severe clinical consequences of a scaphoid nonunion, the kinematical mechanisms that influence the healing process of a scaphoid fracture are still poorly understood. Until now, all in-vivo research is based on step-wise static imaging procedures. With static imaging one cannot detect any instability that occur during normal wrist motion. Therefore previous research about fracture instability is based on assumptions, with only time to union as their outcome parameter.

This will be the first study to investigate dynamic wrist motion patterns, by a novel 4-D-CT method. This imaging technique is readily available in the AMC, providing us the unique opportunity to visualize in vivo carpal kinematics. By describing fracture instability patterns and ligament damage, we can provide new insights in the etiology of a scaphoid nonunion and possibly alter (surgical) treatment strategies.

#### Research questions:

I . Are there differences of interfragmentary motion patterns between displaced and non-displaced scaphoid fractures?

II A. Is there a correlation between motion pattern in an acute scaphoid fracture and the development of a scaphoid nonunion?II B. Can we detect carpal ligament damage from the motion patterns of carpal bones in acute scaphoid fractures?

#### Study design

This study is an observational pilot study. Both wrists will be scanned and analyzed by our 4D-CT method during flexion/extension and radioulnar deviation. We will include participants from the Academic Medical Center, Amsterdam. Acquisition of the 4D data will be conducted at the Academic Medical Center, Amsterdam.

We include patients with a one-sided scaphoid fracture (diagnosis based on a

radiograph or CT-scan), and a contralateral healthy wrist without history of wrist injury. No control group is necessary, because of the information from the contralateral wrist of the patient and data available from a former study group. All patients will undergo a standard CT scan and the 4DCT protocol.

The patient will be categorized into:

- Nondisplaced or minimally displaced fractures

- Displaced fractures; defined as a >1-mm gap or step-off between the bone segments

Based on a standard CT scan the patients with displaced fractures will receive surgery with screw fixation (if agreed with the patient). The nondisplaced patient arm, will receive cast treatment without immobilization of the thumb29. Follow-up will be conducted with CT scans (Force CT scanner and SOMATOM AS+ CT scanner). The treatment and follow up are standard care in the AMC. The patients will be scanned as soon as possible at the emergency department with the Force CT scanner, following the in detail described scanning protocol below. When the patient is in pain, pain medication will be provided, as is standard of care, according to the Pijnprotocol \* Acute volwassenen \* SEH (versie 1) at the emergency department. If patients ar in too much pain, they will be excluded from the study. If the patient is presented to the emergency department late in the evening or at night and is willing to come to the AMC in the first week after presentation to participate in the study, travel costs will be compensated.

#### Study burden and risks

We expect that the burden and risk associated with participation is low. The aim is to include patients during their visit at the emergency department at the AMC. If the patient is presented to the emergency department late in the evening or at night and is willing to come to the AMC in the first week after presentation to participate in the study, travel costs will be compensated.

The radiation exposure of the 4D-CT scans is estimated to be 0,5 mSv for the patients. We do not need a healthy control group. The exposure is within the categary IIa (0,1-1 mSv) of the International Commission on Radiological Protection (ICRP), which qualifies as: minor risk.

# Contacts

**Public** Academisch Medisch Centrum

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# **Trial sites**

## **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

## **Inclusion criteria**

- Patients with a one-sided scaphoid fracture
- Patients are over the age of 16 years
- Patients who are willing and able to give informed consent

## **Exclusion criteria**

- Surgical history of the scaphoid fracture
- A history of trauma (treated with a cast or surgically) to the contralateral non-fractured wrist
- Not able to understand the written informed consent
- Pregnancy
- (Peri-)lunar dislocation
- Pain, to the degree that the patient is not able or willing to move the hand

# Study design

# Design

| Study type: Observational invasive |                         |
|------------------------------------|-------------------------|
| Masking:                           | Open (masking not used) |
| Control:                           | Uncontrolled            |
| Primary purpose:                   | Diagnostic              |

## Recruitment

КП

| INL                       |                     |
|---------------------------|---------------------|
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 28-06-2017          |
| Enrollment:               | 24                  |
| Туре:                     | Actual              |

# **Ethics review**

| Approved WMO       |                    |
|--------------------|--------------------|
| Date:              | 02-05-2017         |
| Application type:  | First submission   |
| Review commission: | METC Amsterdam UMC |

# **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 CCMO **ID** NL60680.018.17