

# Analysis of the kinematical pattern in scaphoid nonunion by 4-dimensional computed tomographic imaging

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This will be the first study to investigate dynamic wrist motions patterns, by a novel 4D-CT method, in patients with scaphoid nonunion and will give us dynamic information of the carpal bones before and after surgery. We will specifically test the...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Fractures
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON46098

### Source

ToetsingOnline

### Brief title

Kinematical patterns in scaphoid nonunion

### Condition

- Fractures

### Synonym

not consolidated fracture through the boat-shaped bone, not consolidated scaphoid fracture

### 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, Kinematics, Nonunion, Scaphoid

## Outcome measures

### Primary outcome

The aim is to gain basic dynamic information (motion patterns) of the carpal bones of the proximal and distal row in patients with scaphoid nonunion. We specifically test the hypothesis that the fracture location with respect to the scaphoid apex is related to the kinematic pattern. Because anatomic variance of the insertion of the dorsal intercarpal ligament is known, this study compares the fractured wrist with the contralateral \*unharmed\* side in the same individual.

We expect to detect abnormal motion patterns, which we will quantify in measurable values (3 translations and 3 rotations of carpal bones during motion of the hand). Delineation of specific motion patterns and discriminative values of dynamic information of the carpal bones will enable us to set up new definitions for diagnosing scaphoid nonunion wrist pathologies.

### Secondary outcome

1. The aim of rescanning patients with scaphoid nonunion after a reconstructive procedure is to investigate if these procedures have benefits for the wrist kinematics.
2. The aim by using the MHQ questionnaire before and after treatment is to evaluate if there is a correlation between the pathological kinematical pattern and the patient complaints.

# Study description

## Background summary

The main function of the scaphoid is complex; it acts as a lever between the proximal and distal carpal rows of the wrist and plays an important role in the carpal stability and wrist mechanics. Nonunion after fracture of the scaphoid leads to changes in wrist mechanics, bone loss, a humpback deformity, carpal instability and secondary degenerative changes, known as a scaphoid nonunion advanced collapse (SNAC) wrist. The changes following scaphoid nonunion are a significant clinical problem with a large impact on the functionality of the wrist and the quality of life of the individual patient. Scaphoid fractures are the most common fractures of the carpals and although union rates vary; approximately 10% to 15% of all scaphoid fractures progress to nonunion. There are several ways to diagnose scaphoid nonunion, such as: plain radiography, CT-scans, MRI scans and currently there are some studies with 3-dimensional imaging with CT- or MRI- scans. But these are all static imaging procedures and because of the complexity of the movement of the scaphoid, it is impossible to predict the exact kinematics. Static measurements do not evaluate any functional effects that might occur during wrist motion with scaphoid nonunion. Therefore it is important to obtain detailed 4-dimensional information about the pathological kinematics of the wrist that may lead to degenerative changes when scaphoid nonunion occurs. Until now, only static 3 dimensional evaluation of the kinematics have taken place, a 4D method would give us the ability to study the true kinematical pattern of a SNAC wrist.

## Study objective

This will be the first study to investigate dynamic wrist motions patterns, by a novel 4D-CT method, in patients with scaphoid nonunion and will give us dynamic information of the carpal bones before and after surgery. We will specifically test the hypothesis that the fracture location with respect to the scaphoid apex is related to the kinematical pattern. This is clinically important for better decision making in treatment planning of scaphoid nonunion for the individual patient. Because motion patterns of the carpal bones vary between individuals and anatomic variances are known, this study compares the fractured wrist with the contralateral \*unharmed\* side in the same individual. We expect to detect abnormal motion patterns, which we will quantify in measurable values: 3 translations and 3 rotations. Delineation of specific motion patterns of the carpal bones will enable us to set up new definitions for diagnosing scaphoid nonunion wrist pathologies. We will also investigate the relation between the kinematical pattern and the patient complaints; and by rescanning patients with scaphoid nonunion after a reconstructive procedure, we will investigate the benefit of such interventions.

## Study design

Observational study.

Study procedure:

Both wrists of the patients will be scanned by our 4D-CT method during flexion/extension motion (FEM) and radioulnar deviation (RUD). 3 months after a reconstructive procedure the operated wrist is scanned again with the same protocol. A MHQ questionnaire will be filled in before and three months after reconstruction of the scaphoid nonunion. Since not all patients are eligible for the postoperative 4D-CT scan, due to additional operative procedures, we need to include additional participant to be able to answer our secondary research objective. To answer the research question we will need to include 12 participants with a pre-operative DISI stance of the lunate and 12 participants with a normal stance of the lunate. The patients who are included pre-operatively and are eligible for post-operative scanning, will still be scanned post-operatively and included in the analysis of post-operative research question.

## Study burden and risks

The radiation exposure of 4D-CT scans is estimated to be 0.7 mSv for the patients. We do not need a healthy control group. The exposure is within the category IIa ( $0,1 * 1$  mSv) of the International Commission on Radiological Protection (ICRP), which qualifies as: minor risk. Findings from 4D-CT scans will be used for a better decision making for the patients involved.

The patients will be scanned twice, one time before surgery and one time 3 months after surgery, this visit will take a few hours. Travel costs are included.

The postoperative study population: the radiation exposure of 4D-CT scans is estimated to be 0.5 mSv for the patients. The exposure is within the category IIa ( $0,1 * 1$  mSv) of the International Commission on Radiological Protection (ICRP), which qualifies as: minor risk.

## Contacts

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Pre-& postoperative group:

- Patients with a one-sided scaphoid nonunion
- The contralateral wrist has no history of trauma
- Patients are over the age of 16 years

Postoperative group:

- History of a one-sided scaphoid nonunion
- Successful reconstructive procedure
- The contralateral wrist has no history of trauma
- 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 nonunion (pre-&postoperative group only )
- A history of trauma to the contralateral non-fractured wrist
- Not able to understand the written informed consent
- Pregnancy
- Familiar with skeletal and/or connective-tissue diseases

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 13-04-2016

Enrollment: 44

Type: Actual

## Ethics review

Approved WMO

Date: 26-02-2016

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 22-12-2016

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 06-04-2017

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 26-10-2017

Application type: Amendment

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	ID
CCMO	NL56112.018.15