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# Analysis of instability patterns in acute scaphoid fractures by 4-dimensional computed tomographic imaging – A prospective cohort pilot study protocol

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ABSTRACT

*Introduction:* A scaphoid fracture is the most common carpal fracture. When healing of the fracture fails (nonunion), a specific pattern of osteoarthrosis occurs, resulting in pain, restricted wrist motion and disability. Scaphoid fracture classification systems recognize fragment displacement as an important cause of nonunion. The fracture is considered unstable if the fragments are displaced. However, whether and how displaced bone fragments move with respect to one another has not yet been investigated in vivo. With a four-dimensional (4D) computed tomographic (CT) imaging technique we aim to analyze the interfragmentary motion patterns of displaced and non-displaced scaphoid fragments. Furthermore, the correlation between fragment motion and the development of a scaphoid nonunion is investigated. We hypothesize that fragment displacement is not correlated to fragment instability; and concurrent nonunion is related to fragment instability and not to interfragmentary displacement.

*Methods:* In a prospective single-center cohort pilot study, patients with a one-sided acute scaphoid fracture and no history of trauma to the contralateral wrist are illegible for inclusion. Twelve patients with a non-displaced scaphoid fracture and 12 patients with a displaced scaphoid fracture are evaluated. Both wrists are scanned with 4D-CT imaging during active flexion–extension and radio-ulnar deviation motion. The contralateral wrist serves as kinematic reference. Relative displacement of the distal scaphoid fragment with respect to the proximal scaphoid fragment, is described by translations and rotations (the kinematic parameters), as a function of the position of the capitate. Non-displaced scaphoid fractures are treated conservatively, displaced scaphoid fractures receive intraoperative screw fixation. Follow-up with CT scans is conducted until consolidation at 1½, 3 and 6 months. This trial is registered in the Dutch Toetsingonline trial registration system, number: NL60680.018.17.

*Ethics:* This study is approved by the Medical Ethics Committee of the Academic Medical Center, Amsterdam.



## 1. Introduction

The human wrist is a complex arrangement of eight carpal bones (Fig. 1). Within the collection of carpal bones, the scaphoid plays a key role in carpal stability and wrist mechanics [1]. Scaphoid fractures account for approximately 60–70% of all carpal fractures [2], which predominantly occur in young, active men of working age who fall onto an outstretched hand [3]. When healing of the fracture fails (nonunion), the period in which the hand is immobilized sometimes exceeds 4–6 months, resulting in productivity loss and associated costs for society [4].

*Abbreviations:* 3D, three-dimensional; 4D, four-dimensional; AMC, academic medical center; CT, computed tomographic; FE, flexion–extension; mm, millimeter; mSv, millisievert; RU, radioulnar.

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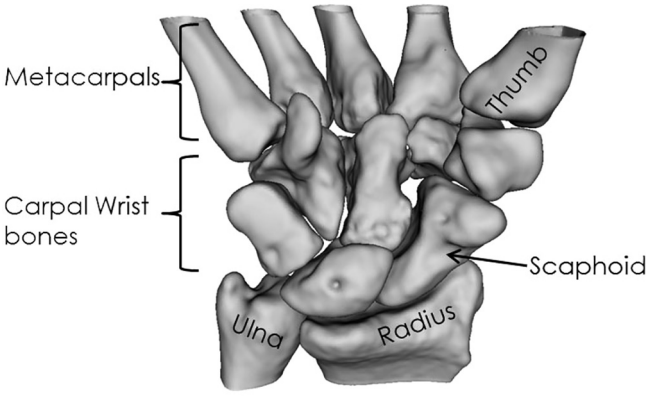


**Fig. 1.** The scaphoid articulates with 5 surrounding bones. It plays a key role in the stability of the wrist and wrist mechanics.

To identify fractures that are prone to nonunion, 13 different scaphoid fracture classification systems are available. The classification systems are based on (1) fracture location, (2) fracture plane orientation, and (3) fracture stability/dislocation [5]. Although scaphoid fractures have an overall union rate of 90%, scaphoid bone fragments with a 1-mm (mm) dislocation are associated with union rates up to only 55% [6]. Within the group of patients with a dislocation it is not clear why the union rate is low, since fundamental understanding of mechanisms and causes of poor healing are lacking. An important reason for this knowledge gap is that current diagnosis of fragment instability is based on plain radiographs or CT scans of a static wrist. Steady-state imaging cannot reveal inter-fragmentary scaphoid motion when moving the wrist [7], although it is likely that inter-fragmentary motion will play an important role in fracture healing [8]. We hypothesize that fragment displacement is not correlated to fragment instability; and concurrent nonunion is related to inter-fragmentary motion and not to interfragmentary dislocation.

## 2. Aim of the trial

*Primary objective:* What are the differences of interfragmentary motion patterns between displaced and non-displaced scaphoid fracture fragments?

*Secondary objective:* Is there a correlation between the motion patterns found between scaphoid fracture fragments and the development of a scaphoid nonunion?

## 3. Methods

### 3.1. Study population

All patients with an acute scaphoid fracture are informed about the research project during their visit to the emergency department. Information is provided through personal explanation and written brochures. Subjects are included after signing a written informed consent.

#### 3.1.1. Inclusion criteria

- Patients with a one-sided acute scaphoid fracture (on radiograph or CT scan)
- Patients are over the age of 16 years
- Patients who are willing and able to give informed consent

#### 3.1.2. Exclusion criteria

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

### 3.2. Trial site and sample size calculation

This protocol describes a prospective cohort pilot study and will be conducted at the Academic Medical Center (AMC), Amsterdam. It is the first time that this technique is used for the clinical evaluation of acute scaphoid fractures. A power analysis is performed with the nQuery advisor program. When the sample size is 12, a two-sided 95% Confidence Interval (95%-CI) for a single mean will extend $0.566\delta$ from the observed mean, assuming that the standard deviation is $\delta$ and the confidence interval is based on the large sample $z$ statistic [9]. In total we aim to include 24 participants: 12 participants with a displaced scaphoid fracture and 12 participants with a non-displaced scaphoid fracture.

### 3.3. Planned study conduct

After inclusion in the emergency department, patients will undergo a standard CT scan and a 4D-CT scan of both wrists with the Somatom Force CT scanner (Somatom Force, Siemens Healthineers, the Netherlands).

Based on the standard CT-scan, the patient will be categorized into:

- Nondisplaced or minimally displaced fractures
- Displaced fractures; defined as a >1-mm step-off between the bone segments. This is measured as a translation of a scaphoid fragment relative to the inertial axis of the scaphoid.

When the patient is in pain, pain medication will be provided, according to the pain medication protocol of the emergency department and on discretion of the treating physician. Patients presented to the emergency department in evenings, nights or weekends and willing to participate, will be scanned during the cast change in the first week after presentation (Fig. 2).

#### 3.3.1. Hand motion protocol

Both wrists of the patient are scanned during flexion–extension (FE) and radioulnar (RU) deviation. The patient is scanned in prone position, with the arm extended forward. The wrist is placed in a special positioning device to immobilize the elbow and to fixate the radius. The device has a grip bar and FE and RU motion axes. The RU axis is locked and a low dose 4D-CT is made in 10 s when the patient moves the wrist actively from extension to flexion. A second 4D-CT scan is made after the FE axis is locked and a 10 s active motion from radial to ulnar deviation follows. First the unharmed wrist is scanned. A regular dose static CT scan of the forearms in neutral position is obtained, to evaluate the alignment of the fracture fragments after wrist motion. The neutral position is accomplished by aligning the third metacarpal with the dorsal surface of the forearm.

#### 3.3.2. Image acquisition

The 10 s of 4D-CT data acquisition will result in 32 volume reconstructions. Each volume reconstruction belongs to a certain position of the hand during the dynamic motion. For reconstruc-