

Clinical evaluation of wrist*s scapholunate ligament injury by new developed 4-dimensional computed tomographic (CT) imaging

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By introducing a novel method for studying dynamic wrist motions we expect to set up a new non-invasive method which is expected to result in early diagnosis of abnormal carpal movements after ligament disruption. By comparing healthy individuals...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational invasive

Summary

ID

NL-OMON38896

Source

ToetsingOnline

Brief title

4D-CT

Condition

- Tendon, ligament and cartilage disorders

Synonym

wrist instability - Scapholunate ligament dissociation

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W, Fonds Nuts Ohra

Intervention

Keyword: Carpal biomechanics, scapholunate ligament, wrist motion, wrist's Kinematics

Outcome measures

Primary outcome

Intervention:

In all groups both wrists will be scanned by our 4D-CT method during flexion/extension and radioulnar deviation. Same scans are obtained once again while axial loading is extended during flexion/extension and radioulnar deviation. 3 months after a reconstructive procedure the operated wrist is scanned again to evaluate and study the effects of such operations. A novel method for 3D dynamic imaging of the wrist is introduced, which uses Computed tomographic (CT) imaging. The open geometry of the CT provides a compliant workspace for several postures.

Main study parameters/ endpoints:

We expect to find changed motion patterns in wrist after a scapholunate ligament injury and even after reconstruction of this ligament. From this study acquired information would enable us to lay down the principles of a non-invasive tool for detection of carpal instabilities that occur after ligament injury.

Secondary outcome

not applicable

Study description

Background summary

Due to complex architecture of the wrist, the wrist joint is associated with several problems of overuse, damage and instability. Scapholunate dissociation (SLD) caused by disruption of the scapholunate ligament is arguably the most common form of carpal instability. Due to delayed diagnosis sooner or later carpal instability results in irreversible degenerative changes of the wrist. SLD may not show definite abnormalities in static radiologic study, but may show abnormalities during wrist movement. There are several ways to diagnose SLD, such as: plain radiography, videofluoroscopy, ultrasound, arthroscopy and MRI scans. All of these have disadvantages like static imaging, being invasive, time consuming, over projection of carpal bones and poor resolution which will result in problems during diagnosing,. So a non-invasive method which could provide us dynamic 3D information would give us the opportunity to detect dynamic wrist pathologies after ligament injury. For this reason we recently introduced a new method for the acquisition of dynamic 3D images of a moving joint. 4D-CT gives us the ability to study individual wrist bone movements patterns which is expected result in earlier diagnosis of SLD.

Study objective

By introducing a novel method for studying dynamic wrist motions we expect to set up a new non-invasive method which is expected to result in early diagnosis of abnormal carpal movements after ligament disruption. By comparing healthy individuals with those with scapholunate ligament dissociation we will detect abnormal motion patterns which we will quantify by 3 translations and 3 rotations (6 degrees of freedom) of each individual wrist bone. Such delineation of specific motion patterns will enable us to set up new definitions for different wrist pathologies, such as ligamentous injuries, that are based on the dynamic properties of the wrist joint. By rescanning patients with scapholunate ligament ruptures after a reconstructive procedure we will investigate benefits of such interventions. Information from this pilot study will be used for an upcoming accuracy study where the diagnostic value of our method will be determined.

Study design

Diagnostic case-control pilot.

Study burden and risks

For healthy individuals this means a net radiation exposure of 0.3 mSv. For people with scapholunate

ligament dissociation this exposure will be 0.6 mSv.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

First part of the study will assess only healthy volunteers.

For the second part of the study: People with a proven scapholunate ligament lesion; For the third part of the experiment patients from the second group are scanned after a reconstructive surgery.

Exclusion criteria

For the first part of the study:

- Injury or disorders of the wrist in history
- Familiar with skeletal and/ or connective-tissue diseases
- Not able to understand the written informed consent.
- Pregnancy

For the second and third part of the study

- Not able to understand the written informed consent.
- Pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO	
Date:	04-10-2013
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	ID
CCMO	NL44780.018.13