Biomechanical consequences of a combined palmar and dorsal scapholunate ligament reconstruction: an evaluation using 4D CT.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational invasive

Summary

ID

NL-OMON52123

Source
ToetsingOnline

Brief title
4D CT evaluation SL-reconstruction

Condition

- Tendon, ligament and cartilage disorders

Synonym
rupture of the ligament between the boatshaped and the moonshaped carpal bone, Scapholunate ligament injury

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, ligamentreconstruction, rotation, scapholunate

Outcome measures

Primary outcome

The aim is to gain dynamic information (motion patterns) of the scaphoid relative to the lunate. 3- Dimensional movement is divided in six parameters. For comparison of the scaphoid relative to the lunate, twee mean parameters (rotation and translation) have to be calculated. 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) and translations along the HAM. Our aim is to determine a standard deviation of motion of the scaphoid and lunate using a 95% confidence interval.

Secondary outcome

For analysis of the wrist joint, every motion (HAM), 3 translations parameters and 3 rotation parameters of the carpal bones will be defined in relation to radial positioning. Comparison of the operated and contralateral wrist of every patient will be made. The expectation is that there is a significant change in dynamic of the carpal during motion of the wrist after combined scapholunate reconstruction. The hypothesis is that the volar reconstruction is not physiological.

Study description

Background summary

Carpal stability is needed for a normal, painless function of the wrist joint and subsequently of the hand. The scapholunate (SL) ligament has a crucial role in this providing this stability. This ligament consists of a dorsal, proximal and a palmar part. Literature tells us that the dorsal part anatomically is the strongest and resistent part, and biomechanically the important part in stabilisation. It facilitates rotation and keeps scaphoid en lunate together. Recent 4D-CT studies support this theory by showing that the scapholunate rotational axis runs through the dorsal proximal pole of the scaphoid.

Traumatic SL-ligament tears may lead to instability of the wrist. When left untreated this may give pain and diminished grip strength in the short term and degeneration of the wrist joint in the long term. When ligament repair is not possible anymore, hand surgeons nowadays perform a ligament reconstruction, using a tendon strip. Several techniques have been described, roughly categorized in dorsal reconstructions and combined palmar/dorsal reconstructions.

Study objective

Contemporary research haven*t performed dynamic examination related to the long and short term. consequences of this techniques. A better understanding of the biomechanical function of the scapholunate ligament is necessary to facilitate decision making for choosing surgical reconstruction procedures and improving consensus.

In this research we have chosen to evaluate biomechanics, with four-dimensional computerized tomographic (4D-CT) in patients with restoration of the scaphoid-lunate ligament with the combined dorsal and palmar technique. This means that we compared range of motion in multiple axis (biomechanics) in the scaphoid and the lunate carpal bones after this combined reconstruction. With use of advanced 4D-CT it is capable to examine the wrist in motion. Simultaneously abnormal motion can be compared with the contralateral wrist. This way we hope to determine a standard deviation of motion between the scaphoid and lunate and furthermore to specific improve innovation of operation techniques. This study protocol is the first to obtain 4-dimensional and quantitative data regarding the biomechanics of the wrist following combined scaphoid-lunate ligament reconstruction, using in vivo motion analysis.

Objectives
1. Is the location of the scapholunate rotation axis altered after combined palmar and dorsal scapholunate ligament reconstruction?

2. Is the range of motion of the wrist altered after combined palmar and dorsal scapholunate ligament reconstruction?

Hypothesis: The volar (palmar) reconstruction is not physiological

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. A comparison is made in normal kinematics between de wrists of individual patients, this to minimalize anatomical variation. We will include participants from the Hand Clinic Amsterdam and the Amsterdam University Medical Centre (AUMC) location Vumc. Acquisition of the 4D data will be conducted at the Academic Medical Centre, Amsterdam.

Participants are informed about the research trough an information brochure, followed with a telephone conversation. After extensive information and written informed consent, they participate in this study. No control group is needed because of the information from the contralateral non-injured wrist of the patient and data available from a former study group. All patients will undergo a standard CT scan and the 4DCT protocol. No categorization will be performed.

Study burden and risks

The radiation exposure of 4D-CT scans in addition to conventional CT scanning is estimated to be 0.4 mSv for the patients. We do not need a healthy control group, since the contralateral wrist of the patient is routinely scanned as clinical reference. 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 future patients with scapholunate ligament ruptures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients who underwent one-sided palmar and dorsal reconstruction of the SL ligament after traumatic rupture with a maximum follow up of 5 years
Patients who are over the age of 16 years
Patients who are willing and able to give informed consent

Exclusion criteria

Surgical history of the carpus.
A history of trauma (treated with a cast or surgically) tot the contralateral 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

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-03-2021
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	18-02-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-06-2022
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	NL75504.018.20