Biomechanical consequences of a combined palmar and dorsal scapholunate ligament reconstruction

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22859

Source
NTR

Brief title
SL reconstruction 4D-CT

Health condition

scapholunate dissociation

Sponsors and support

Primary sponsor: no additional sponsors were needed for this study. Funding was organized by the University Amsterdam Medical Centre
Source(s) of monetary or material Support: AUMC Department of Plastic surgery and hand surgery

Intervention

Outcome measures

Primary outcome

Primary study parameters/outcome of the study:

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

Secundary study parameters/outcome of the study (if applicable):
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. Objective of the study:
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

Study objective

Hypothesis: The volar (palmar) reconstruction is not physiological

Study design

1 october 2021 inclusion of patients eligible for 4D-scanning
31 january 2022 completion of estimation of N=10 patients.
31 december 2022 initial study endpoint.

Intervention

4D-CT scan, comparison injured with contralateral non-injured wrist.

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Eligibility criteria

Inclusion criteria

Inclusion criteria
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Patients with a one-sided palmar and dorsal scapho-lunate ligament reconstruction after traumatic rupture with a maximum
follow up of 5 years.
- Patients are over the age of 16 years
- Patients who are willing and able to give informed consent

Exclusion criteria

Exclusion criteria
A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Surgical history of the carpus
- 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:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2021
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-10-2021
Application type:	First submission

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
NTR-new	NL9819
Other	METC AMC : METC75504

Study results