Biomechanical consequences of a combined palmar and dorsal scapholunate ligament reconstruction

Gepubliceerd: 22-10-2021 Laatst bijgewerkt: 18-08-2022

Hypothesis: The volar (palmar) reconstruction is not physiological

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22859

Bron
NTR

Verkorte titel
SL reconstruction 4D-CT

Aandoening

scapholunate dissociation

Ondersteuning

Primaire sponsor: no additional sponsors were needed for this study. Funding was organized by the University Amsterdam Medical Centre
Overige ondersteuning: AUMC Department of Plastic surgery and hand surgery

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

Hypothesis: The volar (palmar) reconstruction is not physiological

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2021

Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9819
Ander register	METC AMC : METC75504

Resultaten