Dynamisch CT-onderzoek bij patiënten met een rotatiebeperking in de onderarm na een trauma

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First, to develop a 4D computer-assisted diagnostic method for estimating the cause of posttraumatic impairment of the forearm. This method is intended to allow differentiation of motion patterns reflecting mutual impingement of radius and ulna from...

Ethische beoordeling	Positief advies
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24617

Bron NTR

Verkorte titel 4D-IRECT Pilot Trial

Aandoening

Radius, Fracture, Kinematics, 4D-CT scan, Fractuur, Kinematica

Ondersteuning

Primaire sponsor: Dr. S.D. Strackee Department of Plastic, Reconstructive and Hand Surgery, AMC

Overige ondersteuning: Annafonds / Nederlands Orthopedisch Research en Educatie Fonds (NOREF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The aim is to quantify the free range of motion (rotation) of the radius relative to the ulna and the proximodistal translation in the distal radioulnar joint (DRUJ) during forearm rotation. Since the proximal radius rotates about the capitellum of the humerus, while the distal radius rotates around the tip of the ulna, radius motion can be expressed in terms of translation along and rotation about a Helical Axis of Motion (HAM). The HAM notation therefore reduces the standard motion parameters (3 translations and 3 rotations) to one rotation and one translation. We will compare the mean (μ) and standard deviation (δ) of the healthy versus the affected forearm rotation. The main endpoint is to study whether we can differentiate between osseous (impinged) versus non-osseous (non-impinged) motion patterns as origin of restricted forearm rotation.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Distal radius fractures are associated with posttraumatic sequelae such as symptomatic malunion in 5% (NL:3,400/year) leading to persistent symptoms of pain, loss of function and posttraumatic wrist arthritis. Typical posttraumatic impairment related to malunion involves restricted forearm rotation, which is a pathology of forearm "dynamics". In the absence of imaging techniques that can visualize the true dynamic behaviour of the forearm in 3D, conventional imaging techniques are used. These conventional techniques, such as radiography (2D), or MRI or CT (3D), take a snapshot in which the cause of the dynamic pathology is rarely seen. The physician therefore has to rely on indirect suggestive findings that coexist with the underlying dynamic restrictions, such as edema or abnormal bone configurations. Dynamic 3D imaging, or 4D imaging (in which time is added as the fourth dimension), has the potential to visualize and quantify forearm motion in 3D. It enables to diagnose if restricted forearm motion is related to bone deformity caused by the malunion, resulting in osseous impingement, or due to rupture or adhesions, resulting in deviating motion patterns without impingement. 4D imaging is therefore expected to make the difference in objectively diagnosing dynamic pathologies!

The proposed study aims at shifting the paradigm of using static 2D/3D musculoskeletal imaging to 4D imaging, and to bring dynamic assessment to the clinic. It enables more specific diagnosis and treatment decision for dynamic pathologies in the complex field of reconstructive surgery of the forearm.

Objectives: First, to develop a 4D computer-assisted diagnostic method for estimating the cause of posttraumatic impairment of the forearm. This method is intended to allow

differentiation of motion patterns reflecting mutual impingement of radius and ulna from those caused by soft tissue pathology. Secondly, to develop a classification based on the estimated motion patterns and assess its reliability. Finally, to assess physiological mechanics of the radioulnar joint and symmetry in motion patterns between two healthy forearms on 4D CT scans.

Study design: Observational pilot study Study population: Patient group: subjects with posttraumatic forearm impairment: 20 Skeletally mature patients above 16 years of age with a posttraumatic impairment of the forearm and a non-injured contralateral forearm. Group without radioulnar joint trauma: 20 skeletally mature patients above 16 years of age with no history of forearm trauma. Intervention: Subjects without and without posttraumatic forearm impairment: Both forearms will be scanned by our 4D-CT method during forearm rotation (supination-pronation).

Main study parameters/endpoints: As an uninjured radius normally rotates +/- 180 degrees around the ulna at the distal radioulnar joint (DRUJ), the aim is to estimate the pattern of restricted motion of the posttraumatic (malunited) radius relative to the ulna, expressed in rotation at the level of the DRUJ. The main endpoint is to study whether we can differentiate between osseous (impinged) versus non-osseous (non-impinged) motion patterns as origin of restricted forearm rotation.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The radiation exposure of 4D-CT scans is in addition to conventional CT scanning. The contralateral forearm 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. While radiation exposure does not allow unlimitedly forearm imaging, due to the absence of organs in limbs, radiation risks are extremely low. As motion is guided voluntary, there is no risk of harm either. Findings from 4D-CT scans will be used for a better decision making for future patients with posttraumatic impairment of the forearm.

patients are included in the Netherlands and France.

Doel van het onderzoek

First, to develop a 4D computer-assisted diagnostic method for estimating the cause of posttraumatic impairment of the forearm. This method is intended to allow differentiation of motion patterns reflecting mutual impingement of radius and ulna from those caused by soft tissue pathology. Secondly, to develop a classification based on the estimated motion patterns and assess its reliability. Finally, to assess physiological mechanics of the radioulnar joint and symmetry in motion patterns between two healthy forearms on 4D CT scans.

Onderzoeksopzet

n.a.

Onderzoeksproduct en/of interventie

Both forearms of the subjects with and without posttraumatic forearm impairment are scanned with a 4D-CT scanning technique. A low dose 4-dimensional CT scan is made of the forearm in 10 seconds according to the following protocol:

Both forearms of the subjects with and without posttraumatic forearm impairment are scanned during forearm rotation. The subject is scanned in prone position, with the arm extended forward (superman position). The forearm is placed in a special positioning device to immobilize the elbow and to fixate the hand. The device has a grip bar and a pronosupation motion axis.

First a regular dose static CT scan of the forearm in neutral position is obtained (hence with the thumb facing the ceiling).

Secondly the low dose 4D-CT is made while a voluntary pronation-supination motion axis is imposed using an apparatus for guided motion that is restricted to the one plane of forearm rotation (Figure 2). The shoulder of the subject is stabilized in 180 degrees of antegrade flexion and elbow in 30 degrees of flexion when instructed to hold the bar. Within 10 seconds the subject moves the forearm actively from pronation to supination. The motion pattern is first practiced. With Subjects with posttraumatic forearm impairment we start scanning on the unharmed forearm, and secondly the posttraumatic forearm.

The radiation exposure of 4D-CT scans of both groups is within the category IIa (0,1 - 1 mSv) of the International Commission on Radiological Protection (ICRP), which qualifies as: minor risk.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Subjects with posttraumatic forearm impairment:

- Patients with a one-sided posttraumatic impairment of forearm pro- and/or supination
- Patients are over the age of 16 years
- Patients who are willing to give informed consent

Subjects without posttraumatic forearm impairment:

- Subjects are over the age of 16 years and
- Subjects who are willing to give informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Subjects with posttraumatic forearm impairment:

- A history of trauma to both forearms and/or
- Not able to understand or give informed consent and/or
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- Pregnancy

Subjects without posttraumatic forearm impairment:

- A history of trauma to one or both forearm(s)
- Not able to understand or give informed consent
- Pregnancy

Onderzoeksopzet

Opzet

Туре:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	30-07-2018
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies Datum: Soort:

25-07-2018 Eerste indiening

Registraties

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Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

RegisterIDNTR-newNL7195NTR-oldNTR7386Ander registerMEC AMC : L64090.018.17

Resultaten