4D-CT examination to evaluate range of motion obstructions and underlying causes in scheker implants

Published: 21-06-2021
Last updated: 04-04-2024

Primary objective: To use 4D-CT to find possible relations between functional deficiencies of patients with an Aptis Scheker prosthesis and important prosthesis characteristics like implant placement and implant design.Secondary objective: To...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON51086

Source
ToetsingOnline

Brief title
Quantification of DRUJ implant kinematic performance, 4D-EXTEROUS

Condition

- Joint disorders

Synonym
DRUJ arthroplasty, DRUJ implant, Forearm prosthesis

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, DRUJ, implant, kinematics

Outcome measures

Primary outcome

The main study parameters will be the range of motion (ROM, pro-sup and flex-ext), grip strength, patient reported outcome measures (PROM), the position of the radius with respect to the ulna and the position of the axis of rotation. The latter two will act as independent variables in a linear regression to find out if and how they influence the first four parameters. The main study endpoint will be to optimize implant characteristics (size, placement, kinematic behavior) to improve wrist function.

Secondary outcome

nvt

Study description

Background summary

Evaluation of distal radioulnar prosthesis performance is not very common and does not seem necessary since studies report that prosthesis longevity and patient satisfaction are high (>90%)1,2 . However, the complication rate is approximately 25% This raises the question whether patient satisfaction and prosthesis longevity are valid indicators of prosthesis performance.

A better way to evaluate the performance on an implant is by a quantitative comparison to the healthy contralateral joint, which can be considered to be the gold standard. Range of motion, motion pattern and the position of the rotational axis of the forearm are some parameters that describe the function of the wrist quantitatively.

With the emergence of four dimensional computed tomography (4D-CT) technology quantitative evaluation of DRUJ motion has become feasible.

Combining regular- and 4D-CT in the follow up of patients who have undergone DRUJ arthroplasty would objectify prosthesis performance. Moreover, a quantitative kinematic assessment may reveal limitations in the use or design of current DRUJ prostheses and could improve future use of DRUJ prostheses.

Study objective

Primary objective: To use 4D-CT to find possible relations between functional deficiencies of patients with an Aptis Scheker prosthesis and important prosthesis characteristics like implant placement and implant design.

Secondary objective: To provide a 4D-CT based method for quantifying DRUJ implant performance. This method will be based on a comparison of kinematic parameters of the arthroplastic- and the healthy contralateral DRUJ.

Study design

This study is a cross sectional study. Both forearms will be subjected to one 3D-CT scan and three 4D-CT scans. The 4D-CT scans will be performed during forearm rotation (pronation to supination) and wrist movement (extension to flexion). Further performance characteristics will be analysed by performing a grip strength measurement, a goniometric measurement and by filling out a short questionnaire. We will include patients from the Academic Medical Center, Amsterdam. Processing of the 4D data will also be conducted at the Academic Medical Center, Amsterdam.

Study burden and risks

The radiation exposure the patient will receive falls within category IIa of the International Commission on Radiological Protection (ICRP), which qualifies as: minor.

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 regard to implant placement and sizing as well as improving the design of new DRUJ implants.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Patients have undergone unilateral arthroplasty of the DRUJ by use of an Aptis Scheker prosthesis, at least six months after the procedure.
- Patients have undergone the procedure at the Academic medical centre, Amsterdam
- Patients are over the age of 18 years
- Patients are willing to give informed consent

Exclusion criteria

- A history of trauma or injury to the contralateral forearm
- Not able to understand or give informed consent
- Pregnancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-01-2022
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	21-06-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-09-2021
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	NL76173.018.21