Study of thumb base joint motion with 4D CT

Published: 01-08-2020
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Primary Objective: To access the geometries and the motions of thumb base joint.Secondary Objective(s): To assess factors (such as gender, hand dominance, and hand size) that might affect the bone geometries and the joint motions.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49372

Source
ToetsingOnline

Brief title
Study of thumb base joint motion with 4D CT

Condition

- Joint disorders

Synonym
thum base joint implant, thumb base arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: tu delft en/of reinier de graaf

Intervention

Keyword: 4D CT, carpal bones, carpal joints, thumb base

Outcome measures

Primary outcome

Statistical models of shapes and motions will be developed based on the

collected data.

Secondary outcome

The effect of factors, such as gender, hand dominance, and hand size, on the

geometries and the motions will be assessed.

Study description

Background summary

Arthritis is a disease that leads to irreversible joint damage and disability, which greatly affects the living quality. Joint replacement is one of the treatments. More research is needed to optimize the implant design for the joints at wrists. We will investigate the shape and motion of thumb base joint by developing statistical models.

Study objective

Primary Objective:
To access the geometries and the motions of thumb base joint.

Secondary Objective(s):
To assess factors (such as gender, hand dominance, and hand size) that might affect the bone geometries and the joint motions.

Study design

Quantitative study: Statistical analysis and modeling of the bone geometries and the thumb base joint motion of the 4D CT data.

Study burden and risks

Participants will receive radiation doses during their participation. However, the dose is negligible and the effect will be controlled. There is no direct benefit to the participants. But, the study could help to develop a more comprehensive understanding of the thumb base joint. The results can provide guidance and improvement of thumb base implant designs. The results may also be useful for the diagnosis and treatments of wrist arthritis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) No history of trauma or disease in both wrists;
2) More than 18-year old
3) Voluntarily participate in and sign the informed consent

Exclusion criteria

1) Volunteers who refuse to sign the informed consent;
2) Volunteers who have a history of hand trauma or disease with either wrist;
3) Volunteers who are suggested not to take extra radiation dose for other purposes, such as pregnancy and breastfeeding.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-08-2021
Enrollment:	46
Type:	Actual

Ethics review

Approved WMO

Date:	01-08-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	07-01-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	16-09-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL70432.058.19