Building participant-specific biomechanical models of the knee through the integration of dynamic computed tomography images and biomechanics lab data.

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Our primary aim is to develop methods and assess the feasibility of creating a participant-specific biomechanical model of the knee that integrates biomechanics data with dynamic computed tomography (CT) imaging data to determine 3D tibiofemoral and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON54118

Source
ToetsingOnline

Brief title
Modeling of the knee, with imaging and biomechanics (MOK)

Condition

- Other condition

Synonym
asymptomatic, healthy

Health condition

no pathology evaluated in this study, healthy participants only

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: biomechanics, computed tomography, knee

Outcome measures

Primary outcome

Through a complete knee flexion/extension cycle, we will quantify: dynamic 3D

force vectors in tibiofemoral and patellofemoral joints.

Secondary outcome

Through a complete knee flexion/extension cycle, we will quantify: dynamic

cartilage stress distributions in tibiofemoral and patellofemoral joints; and

skin artefact.

Study description

Background summary

OA is expected to be the most prevalent disease in the Netherlands by 2040 . The knee is the most common joint affected by OA, and knee OA is responsible for more physical disability than any other disease among older adults. Knee OA is predominantly held to be caused by biomechanical factors that lead to increases in cartilage stress. Current methods used to evaluate knee biomechanics contain substantial error due to factors such as skin motion artefact, and often ignore biomechanics of the patellofemoral joint, preventing accurate estimates of cartilage stress. Novel methods are urgently needed to quantify both tibiofemoral and patellofemoral movements and forces in order to accurately and precisely measure knee cartilage stress.

Study objective

Our primary aim is to develop methods and assess the feasibility of creating a participant-specific biomechanical model of the knee that integrates biomechanics data with dynamic computed tomography (CT) imaging data to determine 3D tibiofemoral and patellofemoral joint force vectors. Our secondary aims are to quantify knee cartilage stress distributions as a function of boney alignment, movement and forces; and to quantify skin motion artefact during knee movements.

Study design

This technical development uses a cross-sectional observational design involving not more than five volunteers

Study burden and risks

Participants will visit two locations for complete data analysis, in total requiring approximately 2 hours of their time plus travel. Dynamic CT scans will be acquired at IJssellandziekenhuis, this session takes approximately 45 minutes. The CT scan protocol will give a very low total dose of radiation of approximately 0.5 mSv, the risk of this dosage is negligible. For comparison, a normal CT scan of the hip is 3 mSv and the thorax is 18 mSv (22). The yearly exposure to radiation from natural sources in the Netherlands is approximately 2 mSv. Biomechanics data collection will take place at TU Delft, this session takes approximately 75 minutes. Participants will be asked to perform 3 to 5 trials each of simple tasks: slowly bending and straightening their knee, squatting, and walking at a self-selected pace. These are tasks well within what would be considered a usual daily activity, and the risk is thus negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Age 18 - 65 years old
Asymptomatic knees
Provide written informed consent

Exclusion criteria

Neurological conditions
Rheumatic conditions
Currently undergoing treatment for cancer
Musculoskeletal injuries affecting the lower extremities
Pain in the foot, ankle, knee, hip or low back
Pregnancy
Any other contraindications to radiation exposure
Unable to speak, read and write in Dutch

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2023
Enrollment:	5
Type:	Anticipated

Ethics review

Approved WMO Date:	13-08-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-10-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL76580.078.21