Validating the Positioning Protocol for Whole Leg Radiography

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Primary Objective: Test-retest reliability of the measured HKA when patients are positioned following our specific positioning protocol.The main study parameter will be measured using the method as in the current practice. This is a manual method,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON48169

Source
ToetsingOnline

Brief title
Whole Leg Radiography Protocol

Condition

- Tendon, ligament and cartilage disorders

Synonym
Damaged cartilage, Osteoarthritis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Hip Knee Angle, Positioning Protocol, Reproducibility, Whole Leg Radiograph

Outcome measures

Primary outcome

To investigate the test-retest reliability of the patient positioning protocol

an Intraclass Correlation Test will be performed.

Secondary outcome

Different methods for the measurements of the HKA on a WLR will be tested for

correlation and differences using Bland-Altman plots and Intraclass Correlation

Tests.

Study description

Background summary

Important in the management of varus or valgus induced osteoarthritis (OA) are whole leg radiographs (WLR) [1]*[6]. WLR*s are being used to determine the amount of malformation in the leg. These malformations result in increased load bearing to a certain knee compartment, at the same time an unloading in the opposite compartment. The increased stress on the carti-lage can cause OA. To determine whether there is a malalignment in the leg, the hip knee angle (HKA) is measured on a WLR.

Literature describes many new insights regarding the varying positioning of patients during a WLR and the effects on the measured HKA. Known affecters are: knee flexion and exten-sion, foot rotation, hip rotation, weight-bearing and foot positioning [4], [6]*[20]. There is for instance a difference in patient positioning between a single or double legged WLR which af-fects the measured HKA. However, no standard or optimal limb positioning protocol for the WLR is widely known or is being used [6], [9], [11], [17], [21], [22]. Sheehy and Cooke pro-posed a more standard protocol, which is to the best of our knowledge not widely implement-ed or validated [6], [17].

Pre-operative planning uses such WLR*s, where the amount of correction is derived from the measured HKA. Therefore, pre-operative planning is prone to

errors if patients are not posi-tioned correctly for a WLR, resulting in under- or overcorrection when performing a correction osteotomy. Thereby, variances in positioning pre- and post-operative result in wrong interpre-tation of surgical results. For instant postoperative pain affects the weight-bearing and there-fore the HKA. [7], [12].

We strongly recommend a more standardized and uniform approach for the positioning of the patients, which would be suitable to implement in the current care. We believe that the Akagi line is a good representation of the antero-posterior alignment of the knee-joint, described by Akagi et al. as the line between the centre of insertion of the posterior cruciate ligament to the medial border of the tuberosity [23]*[26]. When using known literature describing the tibial rotation, the mean is about 25 degrees external rotation but with a high standard deviation, where there is no difference between OA patients and healthy population [27]*[31]. This angle is between the Akagi line and antero-posterior line of the malleoli [26]*[30], [32], [33]. The an-gle between the Akagi line and longitudinal axes of the feet in neutral stance is around 10 de-grees, and 0 degrees with the first metatarsus [29], [34]*[39].

We believe that a uniform and standard protocol should be implemented, with the focus on eliminating leg rotation and take the mean tibial rotation into account. Patients are positioned in full extension with their heels touching each other and the feet pointing outwards with 25 10 degrees of rotation. This is achieved by drawing a V on the ground with an angle of 50 de-grees between the two lines by placing two feet templates on the ground with an angle of 20 degrees in between, the feet are 10 cm apart from each other. The patients have to place their medial border of the feet against the lines with the heels against the crossing point of those lines. Practitioners thereby control the hip rotation, by placing the upper body in a straightforward position. No handlebars or support are allowed to ensure full weight-bearing. The practitioners additionally instruct the patient to distribute the weight equally to each leg. This protocol is currently being used at UMC Utrecht. However, its reproducibility is not tested yet.

The aim of this study is to determine the test-retest reproducibility of the developed positioning protocol for WLR*s of a patient over time. The measured HKA will be used as the main pa-rameter to calculate the reliability. At the same timeThe second objective of this study,: we want to compare three different measuring methods for the measurement of the HKA. This includes one manual method as being used in the current practice and two semi-automatic methods.

Study objective

Primary Objective: Test-retest reliability of the measured HKA when patients are positioned following our specific positioning protocol.
The main study parameter will be measured using the method as in the current

practice. This is a manual method, where the practitioner uses an angle tool pro-vided by Sectra and available in Pacs IDS 7 image viewer. The practitioner has to select 3 points on the WLR, the centre of the femoral head, the centre of the tibial spines and the centre of the talus. This is a standardized method with proven re-producibility [4].

Secondary Objective: Compare different measurement methods for calculating the HKA on a WLR. The first method is the manual technique, the other two methods are semi-automatic.

Study design

Prospective explorative study, with whole leg radiographs.

Study burden and risks

Patients will be treated following current regular practice and have no direct benefit of par-ticipating in this study. Results will help to elucidate the performance of the patient posi-tioning protocol and may provide tools for improvement of (novel) cartilage repair strate-gies.

The additional risks of one extra radiograph is an added radiation dosage for a patient of 0.0192 mSv, as determined by our Radiology Division. In 2016 the RIVM reported an av-erage radiation dose of 0.004 mSv during a West-European flight. The RIVM also re-ported a yearly background radiation dosage of 2.6 mSv per citizen per year.

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

Patients with knee joint degeneration (osteoarthritis) eligible in regular clinical practice for a WLR.
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Good knowledge of the Dutch language
- Signed informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participa-tion in this study:
- Pregnant women
- Patients aged under 18
- Patients who are limited in communication
- Patients who are incompetent

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):	07-02-2020
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	26-09-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL70660.041.19

Study results

Date completed:	03-06-2020

Actual enrolment:	30