Advanced Imaging of Tibia and Hindfoot in Orthopaedic Surgery

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

Summary

ID

NL-OMON45405

Source
ToetsingOnline

Brief title
AIOS

Condition

- Joint disorders

Synonym
Malalignment

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Advanced Imaging, Hindfoot, Q3DCT, Tibia

Outcome measures

Primary outcome

1.Investigating bilateral symmetry on 3DCT:

Bilateral symmetry of the tibia and fibula by grade of symmetry (in percentage).

2. Medial Distal Tibial angle 2D-Xray versus 3DCT

MDTA as measured on reconstructed AP X-ray in degrees: angle between the joint orientation line and the mechanical axis of the tibia. In 2D-Xray, the axes are determined by manual geometric measurements. The mechanical axis is the line between proximally the midpoint of the tibia plateau and distally the midpoint of a circle drawn to touch all three cortices of the tibial meta-epiphysis.
MDTA measured with Q3DCT: the mechanical axis of the tibia passes through the centre of the knee joint line to the centre of the ankle plafond. After segmentation of the bones out of the 3DCT image, the axes can be automatically determined by calculating the axes of inertia, which is based on principle component analysis yielding three orthogonal vectors (the direction of the axes) and three eigenvalues. The axis with the smallest eigenvalue identifies the long axis of the bone, the z-axis. The origin is chosen where the z-axis intersects the vitual bone surface. The x-axis is perpendicular to the z- axis and points in the direction of the distal tip of the medial malleolus. The y-axis is orthogonal to the x-, and z-axes.

3. Hindfoot Alignment views 2D-Xray versus 3DCT

The percentage of variation of translation of the MLA over the tibiotalar joint line as measured by the method of Haraguchi et al as induced per 5 degrees deviation of the projection angle.

4. Orientation and shape of the articular surface of the subtalar joint on 3DCT

To describe the 3D orientation of the normal of the articulating joint facets in a coordinate system based on the principle axes of the calcaneus, the talus and the mechanical leg axis (MLA). Means and SD will be given as a new standard reference for a healthy population.

Secondary outcome

1. Investigating bilateral symmetry on 3DCT

Differences between the left and right tibia and fibula are described by differences in length in coronal and sagittal axis, width (both in mm), angles (in degrees), rotations (in degrees) and joint orientation of the tibial plateau and the tibial plafond compared to each other and the mechanical axis (in degrees).

2. Medial Distal Tibial angle 2D-Xray versus 3DCT

Not applicable.

3. Hindfoot Alignment views 2D-Xray versus 3DCT

Assessment of inter and intraobserver reliability as measured using the intercorrelation coefficient.

4. Orientation and shape of the articular surface of the subtalar joint on 3DCT

To describe the 3D shape of the articulating joint facets expressed by the parameters of a saddle shape. Curves of the saddle are described as being part of a circle (percentage of the full circumference) with a given radius (in mm). Means and SD will be given as a new standard reference for a healthy population.

Study description

Background summary

Ankle joint problems after injury are a major social-economic burden. Treatment outcomes vary due to a lack of quantitative data. It is of great importance to gain better understanding of the anatomy to ensure optimal patient care. Both fracture treatment as well as correction of malalignment could benefit from a better understanding and graphic depiction of the anatomy. Fracture union with deformity (malunion) is a common complication after an ankle fracture. A corrective osteotomy should correct three-dimensional positioning parameters (translations and rotations). In preoperative planning the unaffected leg could serve as a template for the injured leg, but basic 3-dimensional anatomical studies are necessary to assess the level of bilateral congruency. Currently bilateral symmetry is assumed, despite the lack of quantitative research on this topic. Establishing the extent of bilateral symmetry would mean a break-through in the research, treatment and preoperative planning of various lower leg abnormalities, especially in procedures that require patient-specific instruments. In addition to comparison by computed tomography (CT) for bone symmetry, malalignment is also assessed using standing long-leg radiographs. In case of malalignment this is a cheaper method compared to a CT scan. However, the influence of projection angle deviation is unknown, something that may be assessed using 3DCT models.

Study objective

The aim of the four imaging studies in this combined protocol is to investigate the bilateral symmetry of the human ankle joint using quantitative 3D computed tomography (Q3DCT); the accuracy of the medial distal tibial angle as measured on two dimensional (2D) radiographs compared to Q3DCT as a reference standard; the optimal projection angle for a lower leg alignment view used to assess hindfoot alignment; and to investigate the anatomy of the subtalar joint. Q3DCT

is an ideal tool for these four studies as it provides the possibility to measure in 3D and is more accurate than Q2DCT.
Through performing the above-mentioned studies, we will acquire valuable information concerning lower leg symmetry, anatomy and alignment which can be used as fundamental basis in patient treatment. This Q3DCT database can also be used for future research purposes.

Study design

Descriptive imaging study

Study burden and risks

The radiation exposure of scans is estimated to be in the order of 0,5 mSv per participant. This exposure lies in the category IIa (0-1 mSv) of the ICRP qualified as a minor risk. This study carries no direct benefit for the participating volunteers, however, these techniques will be of benefit in preoperative planning for future patients with malalignment requiring reconstructive surgery.

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

- Healthy volunteers
- Over the age of 18 years
- Both legs are unaffected

Exclusion criteria

- Injury/ disorders or serious complaints of the leg/ankle/foot in history
- Familiar with skeletal and/or connective tissue diseases
- For females: pregnancy
- Not able to understand and/or give written informed consent
- Underwent a CT-scan 1<= year ago or has a CT-scan planned within the upcoming year

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	24-03-2017
Application type:	First submission
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	NL60684.018.17