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Proper plate configuration after open wedge high tibial osteotomy

Submission date
18/05/2016

Recruitment status
No longer recruiting

Registration date
02/06/2016

Overall study status
Completed

Last Edited
30/11/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is the most common type of arthritis and affects millions of people worldwide. It occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, causing stiffness, pain and a reduction in the range of movement. The knee is the most common joint to be affected by OA and in many sufferers, the pain prevents people from moving around leading to muscle weakness and disability. An open wedge high tibial osteotomy (OWHTO) is a type of procedure in which the proximal tibia (end of the shin bone) is cut and reshaped in order to relieve pressure on the knee joint. During this procedure, a wedge of bone is removed from the outside of the tibia, under the healthy side of the knee. When the surgeon closes the wedge it straightens the leg bringing the bones on the healthy side closer together, creating more space between the bones on the damaged side. This is then held in place with an artificial plate and screws. The aim of this study is to develop a new place that better fits the shape of the tibia after the procedure.

Who can participate?
Adult patients who have had an OWHTO to treat knee OA.

What does the study involve?
During this study, CT scans taken after the OWHTO procedure are used to create a 3D model of the proximal tibia and locking plate used. This is then reviewed in order to measure the different parts of the tibia in order to find out what the best shape for the locking plate would be.

What are the possible benefits and risks of participating?
There are no benefits or risks for participants in this study.

Where is the study run from?
Seoul National University Bundang Hospital (South Korea)

When is the study starting and how long is it expected to run for?
March 2014 to May 2015

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Youn Seuk Lee

Contact information

Type(s)
Scientific

Contact name
Dr Yong Seuk Lee

Contact details
Department of Orthopaedic Surgery
Seoul National University College of Medicine
Bundang Hospital, 166 Gumi-ro
Bundang-gu
Seongnam
Korea, South
463-707

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Morphologic analysis of the proximal tibia after open wedge high tibial osteotomy for proper plate configuration

Study objectives
The purpose of this study is to devise a new plate that best fit the post-contoured anatomy of the tibia by evaluating the surface geometry of the plate positioning site after an open wedge high tibial osteotomy (OWHTO).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Seoul National University Bundang Hospital IRB, 23/02/2015, ref: B-1502/286-104

Study design
Retrospective observational case series

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
This study involved the retrospective evaluation postoperative CT scans taken for patients who underwent OWHTO using a locking plate were used for the reconstruction of the 3D model with Mimics v.16.0 (Materialise, Leuven, Belgium) of the proximal tibia and locking plate.

Morphologic analysis of the proximal tibia was performed using the following parameters:
1. The radii in the axial plane were measured at the head and neck positions. The radii of the head were measured at 3 positions (Head_Top, Head_Mid, and Head_Bot) and those of the radii of the neck, at 2 positions (Neck_Top and Neck_Bot). The radii of the coronal plane were measured at 2 positions.
2. Two angles were measured at block insertion in the coronal plane: θ-1 was the angle between the contour line of the proximal fragment and the line connecting the end point of the proximal fragment and the end point of the distal fragment, and θ-2 was the angle between the contour line of the distal fragment and the line connecting the end point of the proximal fragment and the end point of the distal fragment.
3. Horizontal distance (Distance X) was measured between the end point of the proximal fragment and the end point of the distal fragment.
The parameters were measured at 3 borders because the contours were underwent changes in the proximal fragment (head), gap (neck), and distal fragment (shaft).

Intervention Type
Other

Primary outcome measure
Post-correction bone geometry is measured through a morphologic analysis of the proximal tibia.

Secondary outcome measures
No secondary outcome measures.

Overall study start date
01/03/2014

Completion date
23/05/2015

Eligibility

Key inclusion criteria
All patients who underwent an open wedge high tibial osteotomy (OWHTO) for the treatment of medial uni-compartmental osteoarthritis with a varus deformity.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
From March 2012 to June 2014, 31 uni-planar and 38 bi-planar osteotomies were evaluated

Total final enrolment
69

Key exclusion criteria
1. Two or three compartmental osteoarthritis
2. Rheumatoid arthritis

Date of first enrolment
01/08/2014

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Korea, South

Study participating centre
Seoul National University Bundang Hospital
82 Gumi-ro 173(baekchilsipsam)beo
Bundang-gu
Seongnam-si

Gyeonggi-do
Korea, South
463-707

Sponsor information

Organisation
Seoul National University Bundang Hospital

Sponsor details
Department of Orthopaedic Surgery
Seoul National University College of Medicine
Bundang Hospital, 166 Gumi-ro
Bundang-gu
Seongnam
Korea, South
463-707
+82 31 787 7199
smcos1@hanmail.net

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00cb3km46

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/05/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/10/2016	30/11/2020	Yes	No