Patient Matched Osteotomy to Correct Angular Deformities in Knee Arthrosis

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To assess the radiological, clinical, and functional outcome of osteotomies around the knee using 3D CT planned patient-matched cutting blocks at three, six and twelve months post-operatively.

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON40812

Source
ToetsingOnline

Brief title
Patient Matched Osteotomy

Condition

- Joint disorders

Synonym
bow-leg, x-leg/o-leg

Research involving
Human

Sponsors and support

Primary sponsor: Maartenskliniek Woerden
Source(s) of monetary or material Support: Stichting Orthoreasearch;Sint Maartenskliniek

Intervention

Keyword: Angular Deformities, Knee Arthrosis, Osteotomy, Patient Matched

Outcome measures

Primary outcome

Radiographic alignment in both coronal and sagittal planes measured at 3 months using x-ray and CT imaging .

Secondary outcome

1. Evaluate patient function and satisfaction at each follow-up using *The Oxford Knee Score* (OKS), *Knee Injury and Osteoarthritis Outcome Score* (KOOS) and *EQ-5D* pre-operatively and post-operatively at 3 months, 6 months and 12 months.

2. Record operative time and any complications.

3. Three dimensional assessment of the deformity correction at three months using a low-dose CT scan of the tibia.

Study description

Background summary

The use of osteotomies to correct angular deformities around the knee has been a surgical option for delaying, and potentially preventing, the progression of knee osteoarthritis, especially in younger and physically more active patients in whom total knee arthroplasty is undesirable. Pre-operative digital osteotomy planning has been shown to have a high inter-rater reliability, irrespective of the user*s experience. This operative plan is precise, however the majority of surgeons still rely upon relatively crude and ipso facto unreliable intra-operative measurements to guide the operation, which may explain the

relatively poor results. Surgical navigation may improve accuracy but the longer and more complex procedure may be associated with increased costs, and complications, as has been the case in arthroplasty, where clinical benefit has not been convincingly demonstrated. We propose to translate two technologies that are already commercially available in arthroplasty into the field of corrective osteotomy. Utilising standing radiographs and a pre-operative low dose CT scan, the surgeon will plan deformity correction in three dimensions. From this a 3D cutting block will be manufactured. If proved valid and reliable, patient-matched cutting blocks offer a low-cost, straightforward method of achieving a precise deformity correction. This will facilitate further studies into the optimal degree of correction required to reduce, and possibly prevent, progression of osteoarthritis in patients.

Study objective

To assess the radiological, clinical, and functional outcome of osteotomies around the knee using 3D CT planned patient-matched cutting blocks at three, six and twelve months post-operatively.

Study design

A prospective multicentre study.

Intervention

The surgeon will determine the desired angular correction with the aid of standard radiographs and pre-operative three-dimensional CT-scan. The surgeon will also specify the fixation device (plate and screws) used to stabilise the osteotomy. Osteotomy will be carried out according to the local investigating surgeon*s technique. The key difference in this study is that a patient-matched cutting block will be used to assist positioning and angle of the saw cut, and provide guidance on the degree of angular correction as per the pre-operative plan.

Study burden and risks

The patient matched cutting block will only act to fine tune the bony cuts and drill holes during surgery, rather than replacing the surgeon*s normal operative skill and technique, which should minimise any potential risks. The cutting block will be manufactured from nylon, which is known to be safe and nontoxic. Two additional CT scans will be performed as part of the study (pre-op and 3 months post-op), which will mean additional exposure to radiation. However, the radiation dose will be small given that this will be low dose and focussed on the proximal tibia. Subjects have to fill in questionnaires at visits, taking about 4 x 15 min in total.
There is no direct benefit for the subjects, other than the expected, but

hypothetical, more precise deformity correction.

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

- considered suitable candidate for an osteotomy around the knee
- consenting to an osteotomy around the knee
- considered medically fit for surgery
- between 18 to 70 years of age

Exclusion criteria

- not suitable for an osteotomy around the knee
- collateral ligament(s) insufficiency
- who declines surgery
- lacking capacity to consent
- does not understand Dutch (written and verbal)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-04-2014
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-04-2014
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

Approved WMO

Date:	25-11-2014
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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
Other	IRAS project ID: 123744
CCMO	NL48604.048.14