MCL-laxity in valgus knee deformity before and after closing wedge high tibial osteotomy

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1. To assess the effects of a CWHTO on the MCL and LCL laxity.2. To assess the effects of a CWHTO on the patient*s experience of collateral ligament instability.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON44060

Source
ToetsingOnline

Brief title
MCL-laxity after CW-HTO

Condition

- Joint disorders

Synonym
bow-leg, x-leg

Research involving
Human

Sponsors and support

Primary sponsor: Maartenskliniek Woerden
Source(s) of monetary or material Support: balans Sint Maartenskliniek

Intervention

Keyword: Collateral Ligament, High Tibial Osteotomy, Instability, Laxity

Outcome measures

Primary outcome

The main study parameter is the difference in radiologically measured joint opening (in degrees) on the medial and lateral side of the knee when testing the MCL and LCL tension laxity in extension and flexion before and after a CWHTO.

Secondary outcome

The secondary study parameter is the difference in patient*s subjectively experienced varus/valgus instability before and after a CWHTO.

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. A varus producing medial closing wedge high tibial osteotomy (CWHTO) can be used to treat valgus malalignment deformity of the knee. Coventry (1985, 1987) stated that, by removing a bony wedge on the medial side of the proximal tibia, a laxity of the superficial medial collateral ligament (MCL) is introduced. Till date no study has evaluated the MCL-laxity before and after a varus producing medial CWHTO for valgus malalignment of the knee. We hypothesize that MCL laxity does not change after a CWHTO, and that the lateral collateral ligament (LCL) laxity also does not change after a CWHTO. Furthermore, we hypothesize that varus/valgus instability is not subjectively experienced after a CWHTO.

Study objective

1. To assess the effects of a CWHTO on the MCL and LCL laxity.
2. To assess the effects of a CWHTO on the patient*s experience of collateral

ligament instability.

Study design

Investigator-initiated prospective observational pilot cohort study

The study will be performed at the Maartenskliniek Woerden.
Measurement points are: preoperative and six months postoperative.

Study burden and risks

The burden to the adult patient is two sets of short questionnaires (one preoperative and one postoperative at six months) and eight additional stress radiographs of the knee (four preoperative and four at six months postoperative). Study visits can be combined with the day of the surgery and the already planned visits to the outpatient clinic. The patient will receive refund of travel expenses in case it is not possible to combine the postoperative measurement with a visit of the outpatient clinic. There are no known risks of the ligamentous stress apparatus, which is routinely used in orthopaedic outpatient clinic care.

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

1. Symptomatic valgus malalignment located in the proximal (high) tibia
2. Indication of a CWHTO, based on the severity of the complaints and the observed deformity according to Paley (2002)
3. Age 18-65 yr
4. No knee ligament laesions

Exclusion criteria

1. previous MCL surgery
2. previous ipsilateral total hip replacement
3. BMI greater than 30
4. Valgus malalignment for which the orthopaedic surgeon does not see an indication for CWHTO

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-07-2015
Enrollment:	13
Type:	Actual

Ethics review

Approved WMO Date:	18-03-2015
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	29-06-2015
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	21-01-2016
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
CCMO	NL52106.048.15