Patient-specific cutting blocks to improve tibial tubercle transfer surgery for patients with patellar instability

Published: 02-08-2018
Last updated: 11-04-2024

The primary goal of the current research is to determine the accuracy of the procedure using patient-specific cutting guide. Secondary endpoints are surgical time needed and the guides* fit onto the patients* tibia.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Interventional

Summary

ID

NL-OMON46282

Source
ToetsingOnline

Brief title
Patient-specific cutting blocks in TT surgery.

Condition

- Musculoskeletal and connective tissue disorders congenital
- Bone disorders (excl congenital and fractures)
- Bone and joint therapeutic procedures

Synonym
Kneecap luxation, Patellofemoral Instability

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Orthopaedics, Patellofemoral Instability, Surgery, Surgical Planning

Outcome measures

Primary outcome

The primary objective of the current research is to determine the accuracy of

patient-specific cutting guides for tubercle transfer surgery.

Secondary outcome

The secondary objectives of the current research is to determine the time

needed to correctly place the cutting guide onto the patients* tibia and to

assess its fit.

Study description

Background summary

Patellofemoral instability is one of the most frequent types of knee problems in adolescents and young adults. During a patellar dislocation the patella dislocates from its normal position, which occurs mainly when the knee is flexed between 0 and 30 degrees1*3. The incidence of primary patella dislocations depends on age and varies from 31:100.000 (10-19 years), to 11:100.000 (20-29 years), and 2:100.000 (30-49 years)4*8.

Recurrent patellar instability has many causes. One of the most common causes is a malposition of the tibial tubercle -the insertion point of the patellar tendon on the tibia- compared to the trochlear groove. Surgical treatment aims to restore normal patellar tracking by repositioning of the tibial tubercle in distal and/or medial direction.The current surgical procedure is performed free hand, completely relying on the skill and experience of the orthopaedic surgeon.

During surgery, the tibial tubercle is detached from the tibia using a flat- or V-shaped osteotomy. The tubercle is then re-attached at the desired position with two countersink screws.

As a result of free hand surgery, it is hard to reproduce the pre-operatively planned displacement. This causes inaccurate repositioning of the tubercle and imperfect re-alignment. Imperfect realignment is associated with patient dissatisfaction, continued instability and dislocation in 10% of the cases as well as an increased risk of postoperative fractures 9,10.

We hypothesize that improving the accuracy of the tubercle transfer with the aid of surgical cutting guides has a positive effect on stabilization, postoperative fractures and pain.
The Orthopedics department of the Radboudumc has therefore developed patient-specific surgical cutting guides for tubercle transfer surgery.

Study objective

The primary goal of the current research is to determine the accuracy of the procedure using patient-specific cutting guide. Secondary endpoints are surgical time needed and the guides* fit onto the patients* tibia.

Study design

Single institution, prospective, interventional study in the Netherlands.
We will include 10 patients with recurrent patellofemoral instability, for whom conservative treatment has failed and tubercle transfers surgery is indicated. Outpatients will be recruited by Dr. Ing. S. van de Groes, orthopedic surgeon in Radboudumc.

In the current standard clinical practice, a static CT scan and X-ray are made to investigate the tibial tubercle-trochlear groove (TTTG), height of the patella and the shape of the trochlea. Based on the scans a surgical treatment plan is established. During the follow-up after the surgery an X-ray is made.

Based on the preoperative CT scan and the preoperative planning made by the orthopedic surgeon, patient-specific cutting guides will be developed. The cutting guides have already been thoroughly tested in cadaver studies.

In this study, the preoperative CT scan will be used to create patient-specific cutting blocks to transfer the tibial tubercle to a new location, which is determined by orthopedic surgeon Dr. Ing. S. van de Groes. A difference in comparison to the standard clinical practice is that patients will get a postoperative CT scan, instead of the X-ray. This CT scan is made the day after surgery, when the patient is still in clinic.

The postoperative CT scan will be used to determine the position of the tubercle after surgery. By measuring the difference between the postoperative and planned position, the agreement between the surgical planning and surgery can be established.

Intervention

-

Study burden and risks

The conventional postoperative X-ray will be replaced by a CT scan for patients included in the study. A CT scan is associated with an increased dose of ionising radiation. A normal X-ray is associated with 0,6 µSv, a CT scan with 0.020 mSv, the increase in dose is trivial compared to natural background radiation (2mSv in the Netherlands).

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* 16 years
Recurrent patellofemoral intability
Indication for tubercle transfer surgery
Insufficient benefit from conservative treatment
Signed informed consent

Exclusion criteria

Pregnancy
Prior surgery to affected knee

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-08-2018
Application type:	First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL66094.091.18