Measuring joint stressing magnitudes when performing knee arthroscopies

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Therefore, the study goal is to measure quantitative magnitudes and variation of joint stressing forces in vivo during arthroscopic knee surgery.

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

Summary

ID

NL-OMON34116

Source
ToetsingOnline

Brief title
Knee joint stressing

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
meniscal lesion, soccer knee

Research involving
Human

Sponsors and support

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

Intervention

Keyword: arthroscopy, knee, magnitude, stress

Outcome measures

Primary outcome

Primary study parameter is the magnitude of knee joint stressing force. The expected end point is the analysis of the magnitude and variation of the joint stressing forces and the comparison with a theoretical maximum stressing force to set up a guideline for safe stressing. These safety levels will be used to implement force feedback in the arthroscopic simulators. As a result, residents will experience enhanced training, start their first arthroscopy with a higher competency level, and potentially shorten their learning curve with repeated simulator training. Eventually, this contributes to an increase of patient safety and decrease of surgical errors.

Secondary outcome

nvt

Study description

Background summary

During arthroscopy of the knee joint, the available joint space is increased by stressing the lower leg. This way the surgeon has more manoeuvrability to inspect and navigate throughout the complete knee joint and to perform surgical treatment. This skill is considered as one of the five important arthroscopic skills a resident should ideally possess before he/she starts training in the operating room.
Training of these skills is preferably performed in arthroscopic knee simulator away from the patient. For adequate realistic training, feedback should be given to the resident indicating if he or she stays within stressing limits that prevent damage of knee ligaments. Data on these tolerable joint

stressing forces are unavailable in literature.

Study objective

Therefore, the study goal is to measure quantitative magnitudes and variation of joint stressing forces in vivo during arthroscopic knee surgery.

Study design

Patients receive an information letter at least four days before surgery and can decide on participation on the day of surgery. Preparations for the measurements are done before the patient entering the operating room. During surgery, synchronized measurements are performed of the stressing force with a load sensor attached to the surgeon, and video recordings of the lower leg to determine its posture and of the arthroscopic view.

Study burden and risks

No interventions will take place, the operation will be delayed for a maximum of 2 minutes and subjects are not disturbed other than to fill out the informed consent and measurement of their lower leg length and knee instability. There are no risks for the patients.

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

Patients should be scheduled for a routine knee arthroscopy at the daycare centre.
Patients should have an age 18 years or older
Patients should be able to read the patient informatio

Exclusion criteria

Knee arthroscopy that is not performed at the daycare centre
Age lower than 18 years

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2010
Enrollment:	21
Type:	Anticipated

Ethics review

Approved WMO
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	NL33847.018.10