Arthroscopic Optical Coherence Tomography in imaging of Trapeziometacarpal joint articular cartilage

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In-vivo visualization of TMC articular cartilage using intra-articular fiber-optic OCT during TMC arthroscopy.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON38039

Source
ToetsingOnline

Brief title
Optical Coherence tomography during Trapeziometacarpal arthroscopy

Condition

- Joint disorders

Synonym
degenerative joint disease with loss of cartilage, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Plastische Chirurgen AMC

Intervention

Keyword: Arthroscopy, Articular Cartilage, Optical Coherence Tomography, Trapeziometacarpal joint

Outcome measures

Primary outcome

To assess the feasibility of peroperative OCT as a clinical diagnostic tool in

patients with early stage OA of the TMC joint during TMC arthroscopy.

Secondary outcome

- Quantification of cartilage thickness and roughness of the articular surface

- Detection of pathologic cartilage tissue befitting early TMC OA

Study description

Background summary

Osteoarthritis (OA) of the trapeziometacarpal (TMC) joint is an important cause of pain and disability, affecting a large number of patients in society. Diagnosis is usually made on clinical symptoms and the radiograph-based Eaton-Littler classification. Recent research has shown that the interobserver agreement between radiologists and hand surgeons concerning staging of TMC OA based on radiographs is moderate at best. The same was observed for case-specific treatment choices between hand surgeons. Moreover, it is known that the articular cartilage, which cannot be visualized on radiographs, is the primary location where changes in early OA occur. Consequently, diagnosis of TMC OA is frequently made in a more advanced stage of the disease, which often comprises irreversible damage to the affected joint, rendering reconstructive surgery necessary. Advances in OA imaging of the TMC joint are needed to ensure a more solid foundation for choosing a therapeutic strategy. This study will focus the use of Optical Coherence Tomography (OCT) for visualization of TMC articular cartilage during TMC artroscopy in patients with clinical symptoms of TMC OA without radiological evidence supporting the diagnosis.

Study objective

In-vivo visualization of TMC articular cartilage using intra-articular

fiber-optic OCT during TMC arthroscopy.

Study design

A prospective observational study

Study burden and risks

During TMC arthroscopy, the thin fiber-optic OCT probe wil be introduced into the joint through (the readily made) TMC arthroscopy portals after which high-resolution images of the articular surface will be acquired. The OCT imaging system has been cleared for use on human subjects and is used in daily practice in cardiology and in research settings in urology. As such, the use of this imaging system and non-destructive imaging technique is considered safe. To accurately depict the intra-articular position of the OCT probe during the experiment, a 3D-RX scan of the TMC joint will be made (see document K5 for radiation advice). Extra manoeuvres taken in view of this study will lengthen the operative procedure with 15 minutes approximately.

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

- Over 18 years of age
- Clinical Symptoms of TMC OA
- Scheduled fo TMC joint arthroscopy
- No convincing radiologic evidence for TMC OA on plain radiographs (Eaton-Littler stage 0-1)

Exclusion criteria

- Not able to understand the written informed consent
- Contraindications for surgery
- Previous TMC joint surgery
- Under 18 years of age
- (Radiologically) Evident TMC OA (Eaton-Littler stage >1), rendering TMC arthroscopy an obsolete procedure.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	5
Type:	Anticipated

Ethics review

Approved WMO Date:	30-01-2014
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	NL47381.018.13