Retrospective comparison of tunnelwidening (TW) after anterior cruciate ligament reconstruction in two surgery techniques and two biocomposite interference screws.

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The aim of the study is to compare the radiological outcome of three different biocomposite interference screws (BIS) in two different ACL-reconstruction techniques with reference to TW, absorption and clinical follow up after three years.

Ethical review	Approved WMO
Status	Completed
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON43834

Source
ToetsingOnline

Brief title
(BIS) in (ACL) reconstruction

Condition

- Tendon, ligament and cartilage disorders
- Bone and joint therapeutic procedures

Synonym
Tunnelwidening

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Geen kosten verbonden aan dit onderzoek

Intervention

Keyword: ACL reconstruction, Biointerference screws, CT-scan, Tunnelwidening

Outcome measures

Primary outcome

Comparing the initial tunnel width drilled during the reconstruction and the

tunnel width 3 years postoperative. The primary endpoint will be the change in

width in (mm) during the follow-up of three years.

Secondary outcome

To evaluate clinical knee function, the Knee Osteoarthritis Outcome Score

(KOOS) and International Knee Documentation Committee (IKDC) are used. For the

level of activity we use the Tegner score. Standard clinical parameters will be

evaluated and compared between the groups.

Study description

Background summary

Bone tunnel enlargement or tunnel widening (TW) after anterior cruciate ligament (ACL) reconstruction is well documented in the literature8. Although many studies have described the presence of TW, none have shown this to be clinically relevant, with respect to the graft or increased failure rates.1-6, 10 (ref from protocol). Despite this, the presence of enlarged tunnels can complicate revision surgery. The exact etiology of TW is still unknown. Many factors have been described, which can be divided in two categories: mechanical and biological.
To get a better view of this mutifactorial problem, our purpose is to compare the extent of TW between three different biocomposite interference screws (BIS) in two different surgical techniques. We question whether differences in

material characteristics, composition of the screw materials and surgical technique can influence the occurrence of TW after ACL reconstruction.

Study objective

The aim of the study is to compare the radiological outcome of three different biocomposite interference screws (BIS) in two different ACL-reconstruction techniques with reference to TW, absorption and clinical follow up after three years.

Study design

165 Patients will be asked to visit the hospital to get a clinical evaluation and CT-images. They will also be asked to fill in specific questionaires to evaluate clinical knee function the Knee Osteoarthritis Outcome Score (KOOS) an International Knee Documentation Committee (IKDC). The Tegner score is used for the level of activity.

Study burden and risks

For the patients the benefits of this study are a free physical examination and evaluation of their complaints and CT-images.
Patients are asked to visit the hospital twice. If a patient is not mobile enough or cannot reach the hospital for other reasons we will ask to visit them at their home. Of these patients we will only be able to use the data from the clinical examination and questionairs.
Radiation produced by conventional CT-imaging used in the present study is negligible. Everybody living in a normal environment receives röntgen radiation on a daily basis. This is called background radiation and it is expressed in millisievert (mSv). There are potential risks related to radiation. Radiation can cause immediate direct damage to body tissues (such as radiation burns and hair loss), although usually only when given at higher doses. In this study only low dose CT-imaging will be performed. Besides that we keep two important keypoints in mind for medical radiation exposure: It has to be:
•*Justified* - exposure producing sufficient benefit to the exposed individual to outweigh the potential risk of exposing to radiation15.
•*Optimised* - procedures and techniques should be in place to keep radiation exposures as low as reasonably practical15.

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

ACL reconstruction
- Anatomical reconstruction
- Transtibial reconstruction
Used screw
- Arthrex BioComposite interference screw.
- Biomet ComposiTCP interference screw. (60 & 30)

Exclusion criteria

• Revision ACL reconstruction
• Graft other than hamstrings
• Removal of tibial screw

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-08-2017
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	07-09-2016
Application type:	First submission
Review commission:	METC Atrium-Orbis-Zuyd

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	NL54847.096.16