The Biocomposite properties of a poly96L/4D copolymer-bTCP interference screw at five years post-operative: A Pilot Study

Published: 19-05-2014
Last updated: 20-04-2024

Primary Objective: to determine the status of screw degradation, osseous replacement and host response of a biodegradable self-reinforcedTM poly 96L/4D lactide copolymer and βTCP biocomposite interference screw at five years after an ACL...

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

Summary

ID

NL-OMON40945

Source
ToetsingOnline

Brief title
long-term properties of an ACL reconstruction screw / MATRYX

Condition

- Tendon, ligament and cartilage disorders

Synonym
long-term absorption rate of the screw; anterior cruciate ligament reconstruction

Research involving
Human

Sponsors and support

Primary sponsor: ConMed

Source(s) of monetary or material Support: contract met Industrie

Intervention

Keyword: ACL reconstruction, biocomposite screw, degradation, osseous replacement

Outcome measures

Primary outcome

Primary study parameters / outcome of the study

• Standardized CT scan at a minimum of five years post-operative.

• Absorption using Housfield unit density (HU)

• Osteoconduction using Barber & Dockery Ossification Quality Score

• Biocompatibility

Secondary outcome

Secondary study parameters / outcome of the study (if applicable)

1. Clinical exam tests and measures (i.e. ROM, Lachmans, Drawer, pivot shift

test, etc.)

2. Functional tests (1 leg hop; jump; squat; etc.)

3. Patient satisfaction outcomes:

• Disease-specific: ACL-QOL

• Joint specific: IKDC

• General Health: SF-36

• Activy Score: Tegner

4. Intra-operative:

• Procedureal details (tunnel length, diameter, etc.)

• Adverse events

Study description

Background summary

The new generation of anterior cruciate liament (ACL) reconstruction interference screws combine bioabsorbable polymers with a ceramic component, such as beta tricalcium phosphate (bTCP), to create a biocomposite material. The bioabsorbable polymer degrades overtime providing structural support while the ceramic component promotes bony ingrowth. The process by which these polymers degrade is very complex and can result in considerable complication. There are a multitude of bioabsorbable polymers used in surgery, each with their own degradation profile. In order for surgeons to make evidence-based decisions, clinical data on a screws* long-term degradation profile and associated complications are needed. There is also a paucity of data on the in vivo osteoconductive properties of biocomposite screws. Pilot studies in human populations are needed to increase our understanding of these variables before large scale clinical trials can be conducted. The purpose of this research is to obtain preliminary data on the long-term bioabsorable and biocomposite properties of poly 96L/4D lactide copolymer and β-tricalcium phosphate (βTCP) interference screws in a human population.

Study objective

Primary Objective: to determine the status of screw degradation, osseous replacement and host response of a biodegradable self-reinforcedTM poly 96L/4D lactide copolymer and βTCP biocomposite interference screw at five years after an ACL reconstruction

Secondary Objectives:
1. to explore differences between femoral and tibial sites.
2. to obtain estimates of patient-reported outcomes as measured by disease specific, joint specific and general health questionnaires (ACL-QOL, IKDC and SF-36, respectively).
3. to report clinical and functional outcomes.

Study design

Pilot study - Retrospective case-series

Study burden and risks

Patients will be required to return to the clinic for a clinical examination, complete questionnaires and undergo a CT scan. The clinical exam will take approximately 30 minutes. The CT scan will take approximately 30 miniutes. The questionnaires will take approximately 15 minutes..

Patients are exposed to ionizing radiation during CT scan. Exposure is low and attempts will be made to reduce the time of exposure and, if possible, lower the radiation doses.

Benefits: detailed information will be revealed about the implanted screw and surrounding bone, patients will have a clinical exam of their knee stability and function, and the quality of life questionnaires will reveal how patients are coping 5 years after their surgery.

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

- graft fixation with a Matryx interference screw
- Age 18-50 years at time of surgery
- Male
- Primary ACL reconstruction with a single bundle ST or STG autograft
- Minimum 5years postoperative

Exclusion criteria

- Subsequent surgery on the affected limb after the index ACL surgery
- Failed ACL reconstruction: defined as meeting at least one of the following:
Lachman*s of 1+ or greater
Positive pivot shift
IKDC C and D
- Any condition that would exclude a patient from undergoing a CT scan
- Concomitant ligament or bone pathology at the time of index procedure or subsequently
- Double bundle/tunnel
- Smoker
- Diabetic
- Auto-immune conditions
- Elite Athletes
- Metastatic bone disease
- Female (note: excluded due to pregnancy possibility)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-12-2014
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Poly 96L/4D Copolymer-BTCP Interference Screw
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-05-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL48632.100.14