Difference in early postoperative stiffness and pain after arthroscopic rotator cuff repair: bio-absorbable versus non-absorbable titanium and PEEK implants

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1. To assess the correlation between the use of bioabsorbable anchors and the early postoperative rate of shoulder stiffness in comparison to the use of non-absorbable titanium and synthetic (PEEK) anchors in arthroscopic rotator cuff repair.2. To...

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

Summary

ID

NL-OMON41562

Source
ToetsingOnline

Brief title
Early stiffness cuffrepair: bio-absorbable vs 2 nonabsorbable implants

Condition

- Tendon, ligament and cartilage disorders

Synonym
lesion, shoulder tendon lesion, supraspinatus tendon

Research involving
Human

Sponsors and support

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

Intervention

Keyword: arthroscopic, bio-absorbable anchors, rotator cuff repair, stiffness

Outcome measures

Primary outcome

The difference between the three, previous described patient groups, with regard to: postoperative shoulder stiffness (ea. a 10* deficit in postoperative external rotation).

Secondary outcome

Postoperative outcome: functional (according to Oxford Shoulder Score and Range Of Motion), Tendon integrity (ultra sound).Postoperative pain (VAS). Patient satisfaction (very satisfied, satisfied, not satisfied, displeased). Total number of adverse reactions. Also record any side effects encountered.

Cost-effectiveness of the three different types of anchors used.

Study description

Background summary

Rationale: Rotator cuff lesions are not rare and can lead to unexplained pain and considerable disability, incidence varying between 10 to 35 %. Good to excellent results in arthroscopic rotator cuff repair are published but little has been said about complication rates, especially with regard to post operative stiffness and pain. In our clinic we experience a higher degree of postoperative pain and shoulder stiffness 3-6 months postoperative in patients undergoing arthroscopic rotator cuff repair using bio-degradable anchors compared to titanium or synthetic anchors. The aim of our study was to evaluate outcomes in early postoperative shoulder stiffness and postoperative pain in

patients undergoing arthroscopic rotator cuff repair, prospectively. The use of bio-degradable anchors may result in higher rate of postoperative shoulder stiffness and pain than is associated with the use of titanium or synthetic anchors in arthroscopic rotator cuff repair. We also want to evaluate cost-effectiveness of the three different types of anchors used.

Study objective

1. To assess the correlation between the use of bioabsorbable anchors and the early postoperative rate of shoulder stiffness in comparison to the use of non-absorbable titanium and synthetic (PEEK) anchors in arthroscopic rotator cuff repair.
2. To assess the postoperative rate of early shoulder stiffness following arthroscopic rotator cuff repair.
3. To assess success rate of operation (functional outcome and postoperative tendon integrity) and complication.
4. To asses differences in postoperative pain and patient satisfaction.
5. To asses cost-effectiveness of the three different types of anchors used.

Study design

Prospective, randomized, controlled study

Intervention

Supraspinatus lesions were repaired using a standardized arthroscopic approach and a double row technique. Patients were randomized to receive commercially available absorbable (n=30), titanium (n=30) or synthetic anchors (n=30).

Study burden and risks

The burden for the participants consists of normal outpatient visits of a proximal 5 minutes: pre operative, 1, 3, 6, 12 weeks, * and 1 year. All assessments are non-invasive nad standart to patients clinicaly treated before. To asses shoulder stiffness, pre and postoperative shoulder Range Of Motion (ROM) will be tested: pre-operative, 3, 6 weeks, 3, 6 and 12 months postoperative. Patients are asked to fill in the Oxford Shoulder Score a twelve question questionnaire: pre and 3 months postoperative.
This study does not impose more, peri and postoperative, risk to the patient than is seen in clinical performed arthroscopic rotator cuff repair. The study will not provide personal benefits participating patients but future patients might benefit from the results of the study performed.

Ultimately this will result in more insight in and less postoperative stiffness in patients undergoing rotator cuff repair

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

- Willing and able to participate in the study protocol
- Age > 18 years
- Diagnosed with a small to medium tear of the supraspinatus tendon, confirmed by ultra sound, symptoms persevering over 6 months despite conservative treatment including physiotherapy, possible subacromial infiltration with corticosteroids and anti inflammatory drugs.

Exclusion criteria

- Unable to give informed concent
- Language barrier

- Frozen shoulder
- Previous surgery to the shoulder or additional injury as in fractures
- Increased surgical risk(ASA >3)
- patients under 18
- diabetes mellitus

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2010
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	01-06-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	12-02-2013
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	10-01-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	24-04-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL29749.098.09