Glenohumeral translation and range of movement analysis in patients following surgical open and arthroscopic Bankart repair

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Evaluation of pre- and postoperative glenohumeral translation and function (especially exorotation) after open (modified) Bankart procedure versus arthroscopic stabilizing surgery for posttraumatic recurrent shoulder instability.

Ethical review	Not approved
Status	Will not start
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON34557

Source
ToetsingOnline

Brief title
Flock of birds Bankart

Condition

- Bone and joint therapeutic procedures

Synonym
shoulder instability; shoulder pain

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep

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

Intervention

Keyword: Bankart, Flock of birds, GH translation, RSA

Outcome measures

Primary outcome

- glenohumeral range of motion analysis (using the six degree-of-freedom electromagnetic tracking device *The Flock of Birds tm* (FoB) (Ascension Technology Inc., Burlington, VT, USA))

- glenohumeral translation measurement (in AP direction)

Secondary outcome

Function measured with Questionaires:

Constant score, Oxford instability score, DASH score, WOSI, Rowe, NSST, a VAS for pain and a single questioning reflecting satisfaction accompanied with the quality of life questionnaires (sf-12 and shoulder function assessment score).

Study description

Background summary

Dislocation of the glenohumeral joint (mostly in anterior direction) is the most common dislocation in human joints with a reported incidence of 1% to 2% in the general population. The prognosis of recurrence after an acute first-time anterior shoulder dislocation (AFASD) in young patients is reported to be between 17% and 96%. The best treatment of AFASD in young patients still remains a debated issue as most published studies have a short follow-up and a mixed population of patients and pathology.
Both open and arthroscopic repairs are reported successful in the short and midterm follow-up and both have specific pros and cons.
Open surgery has proven a long term success but may restrict external rotation and may lead to secondary osteoarthritis. Arthroscopic techniques were developed in an attempt to avoid the wide dissection with open procedures.

Their claimed advantages include reduced postoperative pain, earlier rehabilitation and less restriction of movement. Midterm results have however reported a slightly higher incidence of persistent instability and recurrence of dislocation.
Until now, mainly cadaver studies regarding the influence of stabilizing surgery for posttraumatic glenohumeral instability on the glenohumeral translation and ROM of the shoulder have been performed on various custom shoulder devices with simulated muscle forces. Clinical studies on GH translation during abduction and external rotation are scarce and variable.

Study objective

Evaluation of pre- and postoperative glenohumeral translation and function (especially exorotation) after open (modified) Bankart procedure versus arthroscopic stabilizing surgery for posttraumatic recurrent shoulder instability.

Study design

Patients will be enrolled from orthopedic out-patient clinic of the Leiden University Medical Center, Rijnland hospital, MCH and Reinier de Graaf Gasthuis, location Delft. All patients with recurrent posttraumatic glenohumeral instability that fulfil our inclusion criteria will be measured for Range of Motion (ROM) using a six-degrees-of-freedom tracking device (Flock of Birds®). Secondly postoperative glenohumeral postero-anterior translation during abduction and external rotation using RSA controlled fluoroscopy will be measured, together with the Range of Motion (ROM) analysis with the Flock of Birds device.
A total of 20 patients will be tested of which 10 will be treated with the open modified Bankart procedure followed by a standard Physiotherapy protocol and 10 will be treated using an arthroscopic Bankart technique also followed with a standard physiotherapy program.

Study burden and risks

Potential risks associated with placement of RSA and normal range of motion (analysis) of the shoulder joint are negligible. Pain caused by movement in the normal range of motion of the shoulder is prevented by accurate supervision of the clinical researcher, during all movement measurements.

Extra effort for patient:
Twice a visit to the Leiden University Medical Centre at the shoulder laboratory for range of motion analysis translation measurement glenohumeral in AP direction (once preoperatively and once postoperatively)

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

* clinically diagnosed: Posttraumatic glenohumeral instability
* age between 18 and 60 years
* Patients capable and willing of giving informed consent.

Exclusion criteria

* The individual is unable or unwilling to sign the Patient Informed Consent (PIC) specific to this study.
* Patients with an occupation or past-time which is likely to put unusual and extreme strain on the shoulder.
* tumor

* prior surgery
* arthrosis
* Ac pathology
* prednisone use

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Not approved

Date:	01-04-2011
Application type:	First submission
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	NL32965.098.10
Other	volgt