3D kinematic analysis after latissimus dorsi transfer

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

Summary

ID

NL-OMON44601

Source
ToetsingOnline

Brief title
3D kinematics after latissimus dorsi transfer

Condition

- Tendon, ligament and cartilage disorders

Synonym
defects of the shoulder tendons

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Teaching Hospital OVLG Amsterdam

Intervention

Keyword: cuff, kinematic, tendon, transfer

Outcome measures

Primary outcome

The following primary study endpoints will be obtained for both the patient group and the control group.

With the use of the Flock-of Birds method at the READE Centre, we will measure 3 actively performed ROM tasks: (1) elevation in the sagittal plane (forward flexion), (2) abduction in the scapular plane (elevation), and (3) internal and external rotation of the arm with 90° of abduction in scapular plane (axial rotation). Patients will be instructed to reach a maximal joint angle in each active ROM task.

In addition, patients will perform several ADL tasks, such as grasping a cup, combing their hair, and scratching their back. All ROM and ADL tasks will be performed twice, and at the subject*s own pace.

For each active ROM task, we will calculate 3 different motions: (1) the motion of the scapula relative to the thorax (ie, scapulothoracic motion), (2) the motion of the humerus relative to the thorax (ie, thoracohumeral motion), and (3) the motion of the humerus to the scapula (ie, glenohumeral motion).

All motions are expressed in joint angles defined using the International

Society of Biomechanics standardization proposal of the International Shoulder Group. The difference between the thoracohumeral and glenohumeral angles reflects the contribution of scapular motion to the movement of the arm.

Secondary outcome

The following secondary study endpoints will be obtained for both the patient group and the control group:

(1) Muscle activity of a selection of shoulder muscles will be recorded with the use of surface EMG (Delsys Trigno Wireless, Delsys Inc., Boston, USA). Muscle activation patterns will be quantified by EMG amplitudes (normalized by 1 kg isometric contractions) and relative timing of different muscles.

(2) Abduction and external rotation strength quantified in Newton will be measured with a hand-held dynamometer.

The following secondary study endpoints will be obtained for only the patient group:

(1) Amount of pain in the shoulder during the 3 actively performed ROM tasks will be noted and quantified according to VAS.

(2) All transfers, subscapularis and teres minor muscles will be visualized by MRI imaging. A musculoskeletal radiologist at the OLVG will evaluate these images and assess the degree of atrophy and fatty infiltration according the

classification of Goutallier.

(3) Ultrasound will be used to (a) assess actual movement of the LD transfer before and after the muscular interval through which the transfer is being pulled, namely between the teres major muscle and the long head muscle of the triceps, and (b) visualize the LD and the subcapularis tendon and assess its integrity and possible ruptures. These observations and classifications will be done by a musculoskeletal radiologist at the OLVG.

(4) A standardized X-ray of the operated shoulder will be made at the OLVG and will be classified according the Hamada classification for cuff tear arthropathy by the coordinating and principal investigator.

(5) Different shoulder scores and PROMS will be obtained: Constant Scores, Simple Shoulder Test scores, Oxford Shoulder Scores and the DASH.

Study description

Background summary

Transfer of the latissimus dorsi (LD) is gaining popularity as a treatment of patients with irreparable postero-superior rotator cuff tears without degeneration of the glenohumeral joint. LD transfer provides overall functional improvement and pain relief, but some patients do better than others. The working mechanisms to success or failure are not well understood yet. It is suggested that the LD after transfer primarily acts as a new external rotator and as a suppressor of the humeral head. Others claim that the transfer primarily provides a tenodesis effect, resulting in a more sufficient balancing of the glenohumeral joint while enabling other shoulder muscles to replace the dysfunctioning rotator cuff. Despite encouraging results, a return to full

normal active function or strength cannot be expected and some patients have poor results. Which ones do well and which ones do not, we do not know and both the mechanisms to success or failure are not fully understood.

Study objective

Considering the lack of consensus, we feel these mechanisms merit additional focus and research. LD transfer changes shoulder anatomy and thus affects the complex interplay in the glenohumeral and scapulothoracic joints. So far, no study has been performed to evaluate the kinematic pattern after LD transfer. Therefore, we propose this study that aims to gain insight in 3D kinematics and muscle activation patterns after LD transfer, that may explain its clinical improvements in patients >1 year after LD transfer. In addition, we aim to identify which anatomical and patient characteristics may contribute to the functional and clinical outcome of the LD transfer.

Study design

The study will be designed as an observational case-control study.

Study burden and risks

Risks and Burden

The burden for participants is to visit 2 different centres for non-invasive kinematic analysis (READE) and physical and radiological examination (OLVG). The control group will only visit the READE institution for Flock-of-Bird measurements. The additional radiation dose per shoulder X-ray (10µSV), that is to be made for inclusion purposes, is comparable to the background radiation that an average person receives on one normal day. Furthermore, as a result of the EMG measurements which are being applied to the patients shoulder regios with sticky patches, patients will be informed on possible skin irritation and muscle aches after the various measurements.

Our research objectives cannot be achieved without this specific group of patients who have undergone LD transfer.

Contacts

Public
Onze Lieve Vrouwe Gasthuis

Oosterpark 9
Amsterdam 1091 AC

NL
Scientific
Onze Lieve Vrouwe Gasthuis

Oosterpark 9
Amsterdam 1091 AC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients can be included if they underwent a LD transfer after massive postero-superior rotator cuff tears (ruptured infra- and supraspinatus) with no osteoarthritis with a minimal follow-up of 1 year.

Exclusion criteria

Patients are excluded from this study in case of severe osteoarthritis of the shoulder or if they underwent any shoulder surgery before the LD transfer in the past.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-03-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	12-05-2016
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	NL50263.100.16