

Postoperative deltoid EMG activity and function in patients after Reverse Total Shoulder Arthroplasty: A comparison of standard implantation technique and lateralization

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Study synopsis

Title:	Postoperative deltoid EMG activity and function in patients after Reverse Total Shoulder Arthroplasty: A comparison of standard implantation technique and lateralization
Background:	Reverse total shoulder arthroplasty (RTSA) is a well-established method to treat patients with irreparable rotator cuff tears and glenohumeral osteoarthritis. The biomechanical principle implies a medialization and distalization of the center of rotation (COR). Deficiencies in internal and external rotation constitute frequently encountered functional problems. Some studies showed reduced activation of the posterior deltoid in EMG measurements, which may explain the inability to compensate these movements. Lateralized prosthetic designs demonstrated increased external rotation through an alteration of the deltoid's lever arm.
Aim of the study:	The aim of the study is to investigate the impact of lateralization on functional outcome and deltoid EMG activity in comparison to a standard implantation technique.
Primary outcome:	pre- and postoperative maximal voluntary contraction of deltoid muscle on EMG
Secondary outcomes:	pre- and postoperative ROM of shoulder joint, pre- and postoperative clinical scores (Constant-Murley score, Quick DASH questionnaire, pASES and SVV) and pre- and postoperative radiographic humeral length, comparison of the two groups in all parameters
Study design:	randomized prospective single-center study with 4 follow-up investigations within a time interval of two years.
Subjects:	A total of approximately 130 subjects, who are scheduled either for standard or lateralized RTSA at the Department of Orthopedics and Trauma Surgery at Klinik Donaustadt
Methods:	The patients will be divided into two groups, standard RTSA and lateralized implant via randomization. Preoperative and at 4 follow-up controls, surface EMG measurements of the deltoid will be obtained and clinical scores (Constant-Murley score and Quick DASH questionnaire) will be assessed. As patient related outcome measures, pASES-S and SVV will be evaluated. Pre- and postoperative x-rays and CT scans for lateralization measurement and routine follow-ups for screening of complications will be performed.
Statistical analysis:	For group comparisons, categorical variables will be given as frequency and percentage, while continuous variables will be given as mean \pm standard deviation. Primary and secondary outcome parameters will be analyzed in both groups prior and after surgery. The Kolmogorov-Smirnov test will be applied to test for a possible normal distribution of the data. Group comparisons will be performed with <i>t</i> -test respectively Mann Whitney U-Test depending if normal distribution is given or not. Correlations between various parameters (preoperative

EMG and postoperative functional outcomes; radiographic humeral lengths and EMG respectively functional outcomes) will be investigated. IBM SPSS Statistics 25 will be used to perform group comparisons and correlations. A p -value ≤ 0.05 (two-tailed) is considered significant and correlation coefficients $> .30$ respectively $> .60$ are regarded moderate respectively strong. Other standard calculations using statistical tests may be added as needed.

Abstract

Introduction

Reverse total shoulder arthroplasty (RTSA) is a well-established method to treat patients with irreparable rotator cuff tears and glenohumeral osteoarthritis. The biomechanical principle is a medialization and distalization of the center of rotation (COR) to provide a compensatory role for the insufficient rotator cuff. Deficiencies in internal and external shoulder rotation constitute frequently seen functional problems. Some studies showed reduced activation of the posterior deltoid in EMG measurements, which may explain the inability to compensate these movements. Lateralized prosthetic designs implants demonstrated increased external rotation force through an alteration of the deltoid's lever arm.

Material and Methods

This study will be conducted as a monocentric randomized, prospective trial. Approximately 130 patients, scheduled for reversed total shoulder arthroplasty (RSA), will be enrolled. The patients will be divided into two groups depending on receiving RSA or a lateralized implant via randomization. Preoperatively and at 4 follow-up visits, a surface EMG (sEMG) of the deltoid muscle will be conducted and clinical scores (Constant-Murley Score and Quick DASH questionnaire) will be assessed. As patient related outcome measures, p-ASES-S and SVV will be evaluated. Pre- and postoperative x-rays and CT scans will be conducted for preoperative planning and measurement of achieved lateralization. Clinical and radiological complications will be routinely documented. Group comparisons and correlations will be performed to compare both groups pre- and postoperatively. The study's duration is scheduled for 2 years.

Aim of the Study

The aim of the study is to evaluate a possible difference in function and EMG activity between the two patient groups. Especially a different increase in external rotation range of motion and strength shall be investigated. Furthermore a possible connection between preoperative deltoid muscle activity and postoperative outcome shall be pointed out. Lastly, the impact of lateralization on functional outcome, shall be evaluated compared to the standard implantation technique.

Introduction

Reverse total shoulder arthroplasty (RTSA) is a well-established method to treat patients with irreparable rotator cuff tears and glenohumeral osteoarthritis (1). The biomechanical principle is a medialization and distalization of the center of rotation (COR) in the glenohumeral joint, which induces an elongation of the deltoid muscles' lever arm and therefore tensioning of the muscle (2,3). This in consequence increases deltoid strength, alters its moment arm in order to generate more elevation torque, which in turn provides a compensatory role for the insufficient rotator cuff (4,5). Although acceptable results could be achieved with the original Grammont prosthetic design (6), some serious issues arose with the original conception, such as acromial fracture, instability, dislocation and scapular notching (7–9). Furthermore, deficiencies in internal and external arm rotation constitute frequent functional problems (8–10). Concomitant altered lever arms of the teres minor and subscapularis muscles seem to play a key role in this matter (11). Some studies showed reduced activation of the posterior deltoid in EMG measurements, which may explain the inability to compensate these movements (5,12,13). To counter these drawbacks, newer, lateralized prosthetic designs have been introduced (7). In particular, lateralization restores tension in the remaining rotator cuff and improves efficiency of the posterior deltoid muscle (14). Several studies showed an improved range of motion for this type of prosthetic design, in particular regarding external rotation (15,16). The lateralization can be reached via different means, for example BIO-RSA, where a autologous humeral head bone graft is used or artificial glenoid augments, which are implanted above the base-plate (17). Evaluation of shoulder muscle condition can be performed via use of magnetic resonance imaging (MRI), but no information can be attained about dynamic muscle function (18,19). However, especially for the deltoid and adjacent upper trapezius muscles, surface EMG assessment is an easily applicable, non-invasive and cheap way to assess and objectify muscle function (5,12,13). A clinical improvement of the rotatory capability could already be shown for lateralized designs. The deltoid muscle is the key to functionality after reversed shoulder arthroplasty and the main muscle to undergo compensatory changes (12). The influence of preoperative deltoid activity on postoperative functional outcomes, as well as the altered muscle activation of a lateralized implant to a standard prosthetic design will be investigated in this study.

Material and Methods

Study design

The study will be conducted as a randomized, single-center, prospective trial at the Klinikum Donaustadt Vienna with a total of 4 (6 weeks, 3 months, 6 months, 1 year) follow-up investigations. Primarily, the patients will be asked for participation in the study and full written consent for the operation and the trial will be obtained. At the same visit, the preoperative surface EMG measurement will be undertaken and the preoperative clinical scores as well as patient related outcome measures (PROM) will be assessed. Furthermore an MRI scan for evaluation of muscle quality and a CT scan for preoperative implant planning will be scheduled. Patients will be randomized via sealed envelope technique. After surgery, all patients receive standardized postoperative mobilization treatment starting on the first postoperative day. Furthermore, pre- and postoperative x-rays will be obtained for measurement of reached lateralization. All patients will be provided with a standardized exercise regimen, which they will pursue in an outpatient physiotherapy setting. The patients will be examined for possible clinical or radiological complications at our outpatient clinic 6 weeks, 3 months, 6 months and 12 months postoperatively. During every outpatient follow-up visit, clinical scores, PROMs and standardized x-rays and a final CT scan will be obtained, and the EMG measurements will be undertaken according to protocol. The duration of the study is scheduled for 3 years.

Aims of the Study

- To evaluate deltoid muscle activity using surface EMG measurements in patients after implantation of a lateralized glenoid in comparison to a standard prosthesis (Univers Reverse, FA Arthrex).
- To assess differences in pre- and postoperative EMG activity of the deltoid muscle
- To evaluate the influence of preoperative EMG muscle activity on postoperative functional outcomes, i.e. shoulder range of motion and arm abduction strength
- To compare the clinical outcomes of lateralized to standard prosthesis
- To assess possible postoperative differences in EMG activity comparing lateralized and standard prostheses

- To evaluate the influence of the extent of deltoid lengthening and therefore lever arm increase on EMG activity and functional outcome

Main Hypothesis

- H1: Delta muscle activity in superficial EMG is higher in patients after lateralized glenoid than in patients treated with standard RTSA.

Secondary Hypotheses

- H2: Delta muscle activity in superficial EMG increases significantly in both groups when compared between pre-and postoperatively
- H3: The postoperative increase in delta muscle activity, especially of the posterior parts, measured via superficial EMG is significantly higher in patients treated with lateralized glenoid in comparison to patients after standard RTSA.
- H4: A higher preoperative delta muscle activity results in a higher postoperative muscle activity in superficial EMG measurements
- H5: Range of motion, especially in external rotation is significantly higher in patients treated with lateralized glenoid than in patients with standard RTSA.
- H6: The clinical outcome in objective (Constant score) and subjective (SVV, p-ASES, Quick-DASH) outcome scores is significantly higher in patients treated with lateralized glenoid in comparison to standard RTSA.
- H7: The lateralization via glenoid augmentation is achievable and measureable via radiological means (X-ray, CT scan)
- H8: The extent of lateralization correlates with the increase of delta muscle activity in superficial EMG measurements
- H9: The extent of lateralization correlates with the increase in range of motion, especially in external rotation
- H10: The extent of lateralization correlates with the increase in clinical outcome measures (Constant score, SVV, p-ASES, Quick-DASH)
- H11: There is no significant difference in the rate of surgical related complications between the two groups

Patients

Approximately 130 patients scheduled for Reverse total shoulder arthroplasty after failed conservative treatment will be included. Inclusion criteria: diagnosis of Cuff tear arthropathy (CTA), irreparable rotator cuff tear or severe osteoarthritis (OA), primary RSA, age 60-85, verified rotator cuff tear in preoperative MRI, absence of severe cognitive impairment. Exclusion criteria: previous muscle transfer, revision surgery, highly dysplastic glenoid, axillary nerve palsy, upper limb radiculopathy, cervical myelopathy, degenerative muscular disease, previous proximal humeral fracture, revision arthroplasty, rheumatoid arthritis.

EMG Measurements

For EMG measurements, a surface EMG set-up (FreeEMG, BTS, Italy) is used. Before attachment of the transcutaneous electrodes, the skin is cleansed with an alcoholic disinfectant to minimize impedance. The surface EMG electrodes are attached at specific muscle areas: the anterior, middle and posterior deltoid muscle according to SENIAM recommendations (<http://seniam.org/>). The measurements are recorded in 3 different motions: external/internal rotation, abduction and forward flexion/extension. The ratio between peak torque and EMG root mean square is quantified to assess neuromuscular efficiency (20).

Arm strength is evaluated using a spring balance dynamometer.

Surgical technique and postoperative care

The patients are implanted with the same reversed shoulder prosthesis (Univers Reverse + Universal Glenoid, FA Arthrex) according to a standardized protocol following the manufacturer's instructions. Surgery is performed in beach chair position via delto-pectoral approach in a cementless technique. Lateralization is reached via metal glenoid augment / lateralized glenosphere or a combination of both of at least 4mm, according to the manufacturer's protocol as well, when randomization demands it.

Standardized postoperative rehabilitation starts on the first postoperative day according to protocol. The patients are allowed free ROM in all directions adapted to pain from the early beginning of post-operative rehabilitation. All patients receive 3 months of outpatient physical therapy at our department of Physical medicine.

Radiological Measurements

Radiographs of the operated side are obtained pre- and postoperatively as true antero-posterior views of the entire humeral bone and glenohumeral joint in neutral rotation. According to the protocol by Greiner et al. the change in center of rotation (COR) is measured preoperatively from the center of the humeral head, and postoperatively as the distance from the center of the baseplate to the outer border of the acromion (21). In every patient the critical shoulder angle (CSA) will be measured at the a.p. radiograph (22). Humeral lengthening is determined postoperatively on the operated and non-operated side. The distance between the midpoint of the epicondylar line and a perpendicular line from the most lateral point of the acromion through the shaft axis is measured. The difference is considered humeral lengthening according to the protocol by Lädermann et al. (23). Preoperatively every patient will have to undergo a shoulder MRI for rotator cuff assessment and a CT scan for classification of the glenoidal bone stock and preoperative planning of the implant via Virtual Implant Planning (VIP, FA Arthrex) .

All measurements are performed twice by two experienced orthopedic surgeons. Intra- and inter-observer reliability is calculated.

Clinical outcome and additional measurements

Demographic data (age, sex, dominant side, height, weight, BMI, medication, comorbidities, especially osteoporosis) is obtained via the clinical information system. Active range of motion (ROM) of both shoulders in all standard directions is measured pre-and postoperatively as well as at every follow-up visit using a goniometer. At the same occasions, the absolute and relative (age adapted) Constant score, the self-reported QuickDASH, the p-ASES and the SVV will be assessed (24–27).

The Quick DASH (Disability of Arm, Shoulder, Hand) is a validated tool to evaluate upper extremity function. It consists of 11 questions, regarding complaints (pain, tingling) as well as activities of daily living.

The Constant score is a well validated tool for shoulder function assessment. It consists of four items: evaluation of pain, activities of daily living, range of motion and strength.

The p-ASES (patient assessment American Shoulder and Elbow Surgeons Score) is a validated patient related outcome measure (PROM) tool which consists of 11 questions and can be extended with a clinical assessment tool. The patient related part queries the parameters pain,

instability and activities of daily living. Moreover questions regarding pain medication and subjective instability are asked.

The Subjective Shoulder Value (SVV) is a simple, reproducible and validated question for a exclusively subjective evaluation of a patient's shoulder. The patient is asked to assess his/her shoulder from 0-100%, when 100% stands for a fully functional, pain free shoulder.

Statistics

All calculations will be made using SPSS® (Version 25.0, SPSS Inc., Chicago, IL, USA). Descriptive statistics, including means and standard deviations respectively frequency and percentage, will be performed for both groups and at pre- and postoperative time points. Primary and secondary outcome parameters will be analyzed in both groups prior and after surgery. The Kolmogorov-Smirnov test will be applied to test for a possible normal distribution of the data. In normally distributed values, the *t*-test will be applied to compare the continuous outcome parameters. If the values are not normally distributed, the Mann Whitney U-Test will be applied. Correlations between various parameters (preoperative EMG and postoperative functional outcomes; radiographic humeral lengths and EMG respectively functional outcomes) will be investigated.

A probability value of $p \leq 0.05$ (two-tailed) is considered significant. Correlation coefficients $>.30$ are considered moderate and $>.60$ strong. Other standard calculations using statistical tests may be added as needed.

Both groups (lateralization vs. standard reverse shoulder prostheses) are independent. The primary endpoint is a continuous variable (maximal postoperative voluntary contraction of the deltoid muscle in EMG) of the voluntary contraction of the deltoid muscle in EMG in the lateralization group. As there is no recent research about the topic of interest, we assume a medium effect, based on theoretical considerations as described in the introduction. Further information regarding the statistical considerations, including reference values for the Constant Score, Quick-DASH, ROM and external rotation can be found in Rienmüller et al (12). Reference values for ASES are proposed by Pegreff et al. (5). Li et al. (13) provides values of orientation for the muscle activity measurements. As the main hypothesis is directed, a one-sided analysis is appropriate (with an alpha error level of 0.025). Standard effect sizes (Cohen's *d* and *r*) will be provided to determine the clinical relevance of conducted analysis.

Assuming a medium effect with a power of 0.8 and an alpha error level of 0.025 for the main hypothesis the a priori calculated sample size results in 128 participants.

t tests – Means: Difference between two independent means (two groups)

Analysis: A priori: Compute required sample size

Input: Tail(s) = One
 Effect size d = 0.5
 α err prob = 0.025
 Power (1- β err prob) = 0.80
 Allocation ratio N2/N1 = 1

Output: Noncentrality parameter δ = 2.8284271
 Critical t = 1.9789706
 Df = 126
 Sample size group 1 = 64
 Sample size group 2 = 64
 Total sample size = 128
 Actual power = 0.8014586

Statistical Tests planned:

Note that in case of a significant result of the Kolmogorov-Smirnov test for the respective variables the calculations will be done with non-parametric tests.

In general the calculated for each variable as well as the two subgroups of interest (lateralization glenoid, RTSA) and the overall sample will be mean, sd, number of participants, as well as age. In case of non-normally distributed data median and range of the respective variables will be provided.

Hypothesis	Statistical Test	Variables
H1 (one-tailed)	Independent t-test	<p>Muscle activity after lateralized glenoid vs. Muscle activity RTSA</p> <p>Expectation: Significantly higher means of muscle activity in the lateralized glenoid group</p> <p>Multiple comparison correction: Bonferroni</p>
H2 (one-tailed)	Dependent t-test	<p>Muscle activity preoperative vs. Muscle activity postoperative for both groups (lateralized glenoid and RTSA)</p> <p>Expectation: Significantly higher means of muscle activity in the postoperative group.</p> <p>Multiple comparison correction: Bonferroni</p>

H3 (one-tailed)	Independent t-test	<p>Change in muscle activity lateralized glenoid vs. Change in muscle activity RTSA</p> <p>Change in muscle activity = Postoperative posterior muscle activity – Preoperative muscle activity</p> <p>Expectation: Significantly higher means of muscle activity in the lateralized glenoid group.</p> <p>Multiple comparison: Bonferroni</p>
H4	Correlation	<p>Preoperative muscle activity x Postoperative muscle activity</p> <p>Expectation: $r > .3$</p>
H5 (one-tailed)	Independent t-test	<p>ROM/external rotation lateralized glenoid vs. ROM/external rotation RTSA</p> <p>Expectation: Significantly higher means in the ROM/external rotation in the lateralized glenoid group</p> <p>Multiple comparison correction: Bonferroni</p>
H6 (one-tailed)	Independent t-test	<p>Constant Score lateralized glenoid vs. Constant Score RTSA</p> <p>SVV lateralized glenoid vs. SVV RTSA</p> <p>p-ASES lateralized glenoid vs. P-ASES RTSA</p> <p>Quick-DASH lateralized glenoid vs. Quick-DASH RTSA</p> <p>Expectation: Significantly higher mean scores in the lateralized glenoid group</p> <p>Multiple Comparison Correction: Bonferroni</p>
H7	Qualitative description	Subjective radiological ratings by experts
H8	Correlation	<p>Lateralization x muscle activity</p> <p>Expectation: $r > .3$</p>
H9	Correlation	Lateralization x ROM

		Lateralization x external rotation Expectation: $r > .3$
H10	Correlation	Lateralization x Constant Score Lateralization x SVV Lateralization x p-ASES Lateralization x Quick-DASH Expectation: $r > .3$
H11 (two-tailed)	Chi-Square Test	Complication rate (dichotomous) lateralization glenoid vs. Complication rate (dichotomous) RTSA Expectation: no significant differences in complication rates

Privacy

The original patient data will be accessible for authorized personnel only and will be worked on in a pseudonymised form.

The data is saved on working stations at the Department of Orthopedics and Traumatology in the Klinik Donaustadt. It is secured by password and cannot be accessed from anywhere else.

Time schedule

After positive ethic vote, enrolling the patients will start immediately. Recruiting phase will take approximately 2 year. The follow-up will take 1 year for every patient. Therefore a total duration of 3 years can be assumed. Finally there should be a phase of 6 months in which the paper should be written.

Risk Benefit Ratio

The included patients will not derive a direct benefit of this study. Hence to the planned examinations, there is no additional risks for the included patients, which surpasses the anyway existing common risk of surgery. The risk of leakage of patient data, will be minimized by pseudonymization of the data.

Working with patient related data will only be possible at working stations at the Department the Department of Orthopedics and Traumatology in the Klinik Donaustadt, password secured. Only authorized personnel will have access to original data, which consists of the involved authors mentioned above.

The collected data can be published for research purpose but only after strict anonymization. The results of these study will be used to generate further information about the impact of lateralization on postoperative function in patients after reversed total shoulder arthroplasty.

Insurance

According to legal requirements, a no-fault insurance – i.e. damage-based insurance with absolute liability will be arranged for every participant, in order to guarantee appropriate coverage of potential risks, which can arise while participating in the study.

The insurance will be made with Zurich Insurance Group.

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The maximum payment by the insurer is up to € 500.000 for each insured participant, but is limited to € 3.000.000 for all of the insured participants in total.

Period of insurance: 28.07.2023 – 01.09.2026, 0:00;

Policy Number: 25896093-9

Good Clinical Practice

All authors have carefully read and checked this document. They comply with the requirements and conditions specified therein and agree to perform the study according to the regulations of Good Clinical Practice (GCP). The requirements concerning original data and the auditings of the study will be observed. They accept that modifying the study protocol is only permitted by amendments, which have to be confirmed by the ethic review board in writing. They acknowledge that any infringement of these regulations can lead to termination. They agree to above mentioned time schedule.

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