The impact of conjoint tendon lengthening on functional internal rotation of the shoulder following reverse shoulder arthroplasty: A prospective, randomized clinical trial

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ABSTRACT

Introduction

Reverse total shoulder arthroplasty (RTSA) can reliably restore active forward elevation, abduction, and external rotation, which are often lost in patients with massive rotator cuff tears. However, functional internal rotation (i.e., functional movements of the hand behind the body) is often unsatisfactorily restored and/or lost after RTSA. This study aims to compare the standard surgical approach for RTSA to RTSA with conjoint tendon lengthening with the targeted metric being postoperative functional internal rotation.

Methods and analysis

This study will be a prospective, randomized-controlled clinical trial comparing standard of care RTSA to RTSA with conjoint tendon lengthening in 64 patients undergoing RTSA by a single surgeon. Participants and assessors will not be blinded to intervention. The primary outcome is postoperative functional internal rotation. Secondary outcome measures include VAS, ASES, SANE, PROMIS, and VR-12 scores, as well as forward elevation and external rotation at the side, and complications at any time point. Our null hypothesis is that patients who undergo conjoint tendon lengthening during RTSA will have significantly increased functional internal rotation and clinically significant improved above-mentioned scores compared to non-resected tendon patients.

Ethics and dissemination

This study is pending approval by the University of Missouri – Columbia Institutional Review Board Committee (2094589)

Discussion

Completion of this trial will provide evidence on the effectiveness of conjoint tendon lengthening for patients undergoing RTSA to improve functional internal rotation. If these patients have superior postoperative functional internal rotation, this trial has the capacity to change current clinical practice.

BACKGROUND

It is well known that internal and external rotation of the shoulder are often limited following reverse total shoulder arthroplasty (RTSA). RTSA can reliably restore active forward elevation, abduction, and external rotation, which are often lost in patients with massive rotator cuff tears. However, functional internal rotation (i.e., functional movements of the hand behind the body) is often unsatisfactorily restored or even lost after RTSA.[1–3] Limited internal rotation has been attributed to mechanical impingement of the humeral socket against bony structures or soft tissue. Various biomechanical studies have recently analyzed factors influencing functional internal rotation. These data suggest that lateralization of the center of rotation, inferior positioning of the glenoid component,[4–6] a decreased glenosphere size,[7] a more varus neck-shaft angle,[8] and less humeral component retroversion[9–12] are positively associated with improved internal rotation. However, it is not uncommon to observe limited functional internal rotation despite these measures. Limited internal rotation can be disabling for activities such as toileting, pulling up pants or shorts, or tucking in a shirt.[1–3,13] The authors' intraoperative observation suggests that limited internal rotation is caused by soft tissue restraints rather than impingement of the humeral socket against bony structures. This observation calls for further research.

METHODS

Study design

The following protocol has been developed per Standard Protocol Items: Recommendations for Interventional Trials guidelines. This study will be a prospective randomized-controlled clinical trial (RCT) comparing outcomes after either RTSA or RTSA with conjoint tendon lengthening. The trial will be conducted at a single high-volume academic center in Columbia, Missouri. Blinding in surgical trials is difficult, and neither surgeons nor participants will be blinded to treatment allocation. However, the independent statistician will be blinded to allocation groups.

Recruitment and consent

The study population will consist of participants undergoing RTSA. Eligible participants will be identified at the shoulder and elbow clinic, be invited to take part in the trial, and will be informed of study details and provided with written information along with a detailed explanation of the trial by a member of the research team. Once a participant agrees to participate, and meets all inclusion criteria, they will be enrolled and randomized into one of two groups.

Study participants

Inclusion criteria

- All patients undergoing primary RTSA

Exclusion criteria

- Revision RTSA
- RTSA for acute proximal humerus fracture or fracture sequela

Baseline measures

The following will be collected from all participants preoperatively:

- Age
- Sex
- Preoperative functional (operative) shoulder and contralateral shoulder range of motion if applicable
- Indication for RTSA
- Associated injuries
- Medical comorbidities
- Residence and ambulatory status

Treatment allocation

Individuals consenting to participate in the trial will be randomized to RTSA or RTSA plus conjoint tendon lengthening. Each patient will receive a study ID, and a computer randomization system will be used to allocate patients to receive either of two groups.

Intervention

All RTSAs will be performed by the attending surgeon (H.M.K) in a standard fashion through a deltopectoral approach. The skin will be incised with bovie electrocautery in standard fashion, and the dissection will be carried down through the subcutaneous tissue to the level of the shoulder. The subscapularis muscle will be incised and reflected to expose the shoulder joint. Following

surgical removal of the humeral head and reaming of the glenoid cavity, the Perform glenoid and humeral components of Tornier Stryker Reverse Shoulder system will be implanted. The sizes and offsets of the components will be chosen based on each patient's local anatomy which will vary among patients. Each of these surgical steps will be performed in all patients regardless of whether they are in the control or investigative group. Following final implant selection, the subscapularis tendon will be repaired using three transosseous nonabsorbable sutures whenever there is a reparable subscapularis tendon. After definitive implantation of the prosthesis is completed, and the subscapularis tendon is reattached, the investigative step will take place. In the control group, which is the group receiving a RTSA without conjoint tendon lengthening the subcutaneous tissue and skin will be closed in standard fashion. In the investigative group, prior to subcutaneous and skin closure, the conjoint tendon will be lengthened by approximately 2 cm. The conjoint tendon is comprised of the coracobrachialis and biceps short head tendon, which attach proximally to the coracoid process at the level of the shoulder. In the investigative group, as mentioned, the conjoint tendon will be released completely via a Z-shaped incision made at a level 2 cm distal to the coracoid process and sutured back in a lengthened position using #2 Ethibond suture for the patients assigned the conjoint lengthening group. Electrocautery will be used for the lengthening, and the underlying muscular portion of the conjoint tendon will be preserved. As mentioned above, the control group will not receive this conjoint tendon lengthening. Then, for the investigative group following lengthening and like the control group, the wound will be closed in layers, and the shoulder will be immobilized in an abduction sling.

Postoperative management

Postoperatively, patients will wear the sling for 4 weeks, after which supervised physical therapy will begin.

Outcome measures

The primary outcome will be functional internal rotation at six months. Functional internal rotation will be measured based on the highest anatomical level that the patient's thumb can reach:

- Side
- Ipsilateral buttock
- Lower lumbar
- Mid-lumbar
- Upper lumbar
- Thoracolumbar junction
- T10 and above

Additional secondary outcome measures and associated timepoints will include:

- Six weeks: pain VAS
- Three months: pain VAS, ASES, SANE, Forward elevation, external rotation at the side
- Six months, one year, and two years: pain VAS, ASES, SANE, PROMIS, VR-12, Forward elevation, external rotation at the side
- Complications at any time points: dislocation, severe pain, arm muscle cramping, implant loosening, infection, hematoma, medical complications, blood transfusions, non-union, mortality rate. Specific surgical complications include wound infections, intraoperative fracture, deep surgical infection, and periprosthetic fractures.

Follow-up
All participants were be surveilled per standard of care at our hospital for the targeted patient group. Patients will return for follow-up at two weeks, six weeks, three months, six months, one year, and two years. Plain radiographs will be taken at the immediate postoperative (anesthesia care unit) setting and at all scheduled follow-up visits. Radiographs obtained in clinic at the aforementioned follow-up intervals are standard of care and are not part of the research explicitly. For example, all patients regardless of whether they are in the control or investigative group will receive radiographs at the above intervals. A member of the research team will review participant outcome measures at each appointment.

Sample size calculation
To reject the null hypothesis that functional internal rotation is equal between groups, 32 subjects are needed per group with a power set at 80%, and with a Type 1 error probability of 5%.

Data collection and management, and risks
Data collection will primarily be electronically based. A breach of confidentiality and/or privacy is a risk of this study. To prevent this, all collected data will be stored electronically in password-protected files to protect patient identity and information. All information will be collected and reviewed by the research team only. Data will be maintained on a password-protected computer that will be accessible only to the study team. No patient identifiers will be maintained in the database. Every attempt will be made to minimize missing data. Multiple contact details will be taken at recruitment, and a system of reminders plus phone contact if applicable will be made to ensure patients make follow-up appointments. Additionally, there is an additional risk of being withdrawn from the Standard of Care treatment if they are randomized into the experimental condition. Benefits of this procedure included improved functional internal rotation following surgery and the potential to change clinical practice.

Data analysis
The primary outcome (i.e., functional internal rotation at six months) will be compared between the groups using Mann-Whitney U test. Other range of motion data (i.e., forward elevation and external rotation at the side), pain VAS, ASES, SANE, PROMIS, and VR-12 will be compared using either independent t-test or Mann-Whitney U test depending on the normality of data distribution of each variable. The correlations between functional internal rotation and all other variables will be analyzed using Spearman rank correlation or Pearson correlation.

Patient and public involvement
Patients who undergo RTSA often have limitation of functional shoulder internal rotation following surgery. However, there are no literature that discuss conjoint tendon lengthening as a possible therapeutic intervention. The current research question was developed to address this, and patients were not involved in the design, recruitment, or conduct of this study. The future results of this trial will be available through publication in a peer-reviewed journal, and at meetings if applicable.

ETHICS AND DISSEMINATION

Safety

While this trial compares a new surgical intervention technique with the current standard of care, serious adverse events are not anticipated, and therefore a data safety monitoring board will not be established at the commencement of this trial. Following conclusion of the trial, participant follow-up will follow local participating institute guidelines.

The potential risk of patients enrolled in this study stems from potential side effects of conjoint tendon lengthening, which has not been studied or reported previously to our best knowledge.

1. Although there are no published studies describing exactly the same procedure, there is one published study that showed good clinical outcomes with no complications following conjoint tendon release. Tashjian et al. reported significantly improved anterior shoulder pain with no complications following a conjoint tendon release procedure in patients who were experiencing anterior shoulder pain after RTSA [Tashjian RZ, Frandsen JJ, Christensen GV, Chalmers PN. Conjoint tendon release for persistent anterior shoulder pain following reverse total shoulder arthroplasty. JSES Int. 2020 Jul 31;4(4):975-978. doi: 10.1016/j.jseint.2020.07.005. PMID: 33345243; PMCID: PMC7738564].
2. Additionally, the Latarjet procedure is a procedure that the orthopaedic community has been doing for anterior shoulder instability for decades. This procedure involves cutting the coracoid process and moving it distally, which has essentially the same effect as a conjoint tendon release/lengthening. There have been no reports or my anecdotal experience of complications related to the conjoint tendon (e.g., biceps muscle cramping, loss of biceps or other muscle strength, etc) following this procedure. This can be indirect evidence that releasing/lengthening the conjoint tendon has no major or minor consequences.
3. Lastly, the PI (H. Mike Kim, MD) has been performing this conjoint tendon lengthening on his primary RTSA patients for last 6 months, and there has been no complications. There has been no decreased biceps muscle strength, biceps cramping pain, instability of the prosthesis, hematoma, neurovascular injuries, or infection. In fact, the patients seem to be outperforming in many aspects those patients who did not receive a conjoint tendon lengthening. For example, they seem to have better improvement of pain and range of motion especially in internal rotation.

Ethics

Any protocol modifications will be reported to the IRB, trial registry, protocol database, and individual participants. All adverse events will be reported to the IRB committee as well, and confidentiality of individuals involved in the trial will be maintained as discussed above.

Dissemination

The results of the study will be presented at national orthopaedic meetings and the results will be published in an orthopaedic, biomechanical, or surgical research journal following completion of the trial.

DISCUSSION

A recently study by Horchreiter et al.[14] found that active extension of at least 40° is a prerequisite for satisfactory functional internal rotation after RTSA, with an average loss of 16° of active extension following RTSA compared to the contralateral unaffected side. Our clinical and biomechanical observation is that the conjoint tendon becomes tight with extension, which appears to be the main limiting factor for extension and ultimately internal rotation after RTSA. Based on this observation and the study by Horchreiter et al., we hypothesize that the conjoint tendon is a factor limiting extension and internal rotation after RTSA, and that releasing/lengthening the conjoint tendon may increase extension and affect the prosthetic joint biomechanics. To this end, we proposed a prospective randomized clinical trial in which we will randomize patients who undergo primary RTSA into two groups, conjoint tendon lengthening group vs. control group, and compare various clinical outcome measures including functional internal rotation at multiple postoperative time points. We hypothesized that conjoint tendon lengthening will have significantly greater extension and functional internal rotation of the shoulder following RTSA compared to the control group. This trial has the capacity to find a safe and effective way to improve functional internal rotation after RTSA. If so, a novel surgical application of this concept may lead to a substantial improvement in the disabling limitation of internal rotation following RTSA. Limitations of this study include the lack of blinding of surgeon, participants, and research assessors who have access to operative notes. Blinding was not used in this study as it is impossible to blind the participating surgeon to operative technique.

Inclusion of participants into the trial will commence in January 2023, with data collection expected to be complete by the end of 2025. With follow up of two years, the data will be expected to be presented around 2026.

REFERENCES

1. Kim MS, Jeong HY, Kim JD, Ro KH, Rhee SM, Rhee YG. Difficulty in performing activities of daily living associated with internal rotation after reverse total shoulder arthroplasty. *J Shoulder Elbow Surg*. 2020;29(1):86-94. doi:10.1016/j.jse.2019.05.031
2. Rojas J, Bitzer A, Joseph J, Srikumaran U, McFarland EG. Toileting ability of patients after primary reverse total shoulder arthroplasty. *JSES Int*. 2020;4(1):174-181. doi:10.1016/j.jses.2019.10.104
3. Rojas J, Joseph J, Liu B, Srikumaran U, McFarland EG. Can patients manage toileting after reverse total shoulder arthroplasty? A systematic review. *Int Orthop*. 2018;42(10):2423-2428. doi:10.1007/s00264-018-3900-4
4. Liou W, Yang Y, Petersen-Fitts GR, Lombardo DJ, Stine S, Sabesan VJ. Effect of lateralized design on muscle and joint reaction forces for reverse shoulder arthroplasty. *J Shoulder Elbow Surg*. 2017;26(4):564-572. doi:10.1016/j.jse.2016.09.045
5. Lädermann A, Tay E, Collin P, et al. Effect of critical shoulder angle, glenoid lateralization, and humeral inclination on range of movement in reverse shoulder arthroplasty. *Bone Jt Res*. 2019;8(8):378-386. doi:10.1302/2046-3758.88.BJR-2018-0293.R1
6. Keener JD, Patterson BM, Orvets N, Aleem AW, Chamberlain AM. Optimizing reverse shoulder arthroplasty component position in the setting of advanced arthritis with posterior glenoid erosion: a computer-enhanced range of motion analysis. *J Shoulder Elbow Surg*. 2018;27(2):339-349. doi:10.1016/j.jse.2017.09.011
7. Langohr GDG, Giles JW, Athwal GS, Johnson JA. The effect of glenosphere diameter in reverse shoulder arthroplasty on muscle force, joint load, and range of motion. *J Shoulder Elbow Surg*. 2015;24(6):972-979. doi:10.1016/j.jse.2014.10.018
8. Lädermann A, Denard PJ, Boileau P, et al. Effect of humeral stem design on humeral position and range of motion in reverse shoulder arthroplasty. *Int Orthop*. 2015;39(11):2205-2213. doi:10.1007/s00264-015-2984-3
9. Gulotta LV, Choi D, Marinello P, et al. Humeral component retroversion in reverse total shoulder arthroplasty: a biomechanical study. *J Shoulder Elbow Surg*. 2012;21(9):1121-1127. doi:10.1016/j.jse.2011.07.027
10. Kontaxis A, Chen X, Berhouet J, et al. Humeral version in reverse shoulder arthroplasty affects impingement in activities of daily living. *J Shoulder Elbow Surg*. 2017;26(6):1073-1082. doi:10.1016/j.jse.2016.11.052
11. Jeon BK, Panchal KA, Ji JH, et al. Combined effect of change in humeral neck-shaft angle and retroversion on shoulder range of motion in reverse total shoulder arthroplasty - A simulation study. *Clin Biomech Bristol Avon*. 2016;31:12-19. doi:10.1016/j.clinbiomech.2015.06.022
12. Jassim SS, Ernstbrunner L, Ek ET. Does Humeral Component Version Affect Range of Motion and Clinical Outcomes in Reverse Total Shoulder Arthroplasty? A Systematic Review. *J Clin Med*. 2021;10(24):5745. doi:10.3390/jcm10245745
13. Triplet JJ, Kurowicki J, Berglund DD, Rosas S, Horn BJ, Levy JC. Loss of Functional Internal Rotation Following Various Combinations of Bilateral Shoulder Arthroplasty. *Surg Technol Int*. 2018;33:326-331.
14. Hochreiter B, Wyss S, Gerber C. Extension of the shoulder is essential for functional internal rotation after reverse total shoulder arthroplasty. *J Shoulder Elbow Surg*. 2022;31(6):1166-1174. doi:10.1016/j.jse.2021.11.006