**Research Plan:** Accelerated versus conservative rehabilitation following rotator cuff surgery to repair full-thickness supraspinatus tears: Clinical outcomes and recovery of muscle function.

### Background, Rationale and significance

Tendinopathy and tears of the rotator cuff tendon, namely the supraspinatus tendon, are very common, causing significant pain and restricted movement of the arm, compromising patients’ daily activities, participation in sport and exercise, and ability to work. The incidence of rotator cuff tears increases with age, with full-thickness rotator cuff tears present in approximately 25% of individuals in their 60s, and more than 50% in their 80s1,2. Arthroscopic rotator cuff repair is the most popular surgical treatment for rotator cuff pathology. In Australia, approximately 14,000 rotator cuff repairs are carried out each year, with an estimated cost of $A250 million3. While surgery is considered an effective treatment, high failure rates and recurrent tears at the insertion site are common, especially degenerative tears, which are frequently observed in the older population4,5.

Post-operative rehabilitation is a critical part of the treatment following rotator cuff repair. Specific exercises to improve mobility and strength of the rotator cuff are commonly prescribed after rotator cuff repair; however, debate and uncertainty currently exists regarding the period of post-surgical immobilization, the amount of load permitted at the repair site throughout the early post-operative stages, and when and how to safely graduate this progressive loading stimulus. In an animal model, it has been proposed that while immobilization is superior to mobilization for bone-tendon healing, immobilization combined with early passive motion was harmless to tendon-bone healing6.

Improvements in surgical techniques have also improved the possibility of an early or accelerated post-operative treatment protocol, yet a general consensus still does not exist. Traditionally, repairs have been managed with early passive range of motion followed by delayed active motion and, finally, strengthening exercises. However, as the incidence of repair failures grew, it was suggested that overly aggressive rehabilitation and excessive loading at the healing repair site may play a role. Subsequently, delayed rehabilitation involving an early period of immobilization became the norm. The rationale behind a delayed rehabilitation program stems from concerns that early repair site loading may negatively affect tendon healing; however, current evidence and expert opinion suggests that this period of immobilization may be too conservative, and in fact may potentially increase the risk of post-operative shoulder stiffness and delay the return of shoulder muscle function.

### 2. Statement of the Purpose and Aims of the Project

This is a prospective randomized controlled trial (RCT) investigating the benefit of an accelerated rehabilitation program, compared with the traditionally conservative regime, after arthroscopic rotator cuff repair. Furthermore, the recovery of muscle function in the shoulder musculature will also be assessed.

The general aims of this project are:

1. To compare the safety, efficacy and clinical outcomes of patients prospectively randomized to an early, accelerated rehabilitation protocol (based on earlier studies) or a conservative protocol following arthroscopic rotator cuff repair.
2. To investigate differences in muscular strength, rating of perceived exertion (RPE) and electromyographic (EMG) muscle activity of the rotator cuff and shoulder girdle musculature in “pathological” patients with rotator cuff tears, compared with healthy, matched controls.
3. To investigate differences in muscular strength, RPE and EMG activity of the rotator cuff and shoulder girdle musculature in patients 6 and 12 months following rotator cuff surgical repair (and undergoing either an early accelerated or conservative rehabilitation program), and healthy, matched controls.

### 3. Methods

3.1 Study population, informed consent and recruitment

This is a prospective RCT investigating two different post-operative rehabilitation interventions and, therefore, all patients undergoing arthroscopic rotator cuff repair with Mr Allan Wang (AW) that fit the below inclusion study criteria will be invited to participate in this trial. Participants will be invited to be part of the study after consultation with the surgeon (AW), having confirmed a full-thickness tear of the supraspinatus via clinical examination and magnetic resonance imaging (MRI), and being scheduled for surgery. At this time, the Patient Information Sheet (Appendix 1) and a verbal summary of the study and patient expectations, with particular reference to the two different rehabilitation pathways, will be presented to the patients. Patients willing to participate will then complete the Patient Consent Form (Appendix 1), and will then be randomized to one of the two rehabilitation arms of the study: conservative (CR) or accelerated (AR) rehabilitation. Ethical approval will be obtained from the St John of God (SJOG) Research Ethics Committee and the written, informed consent from each patient will be collected prior to surgery.

*Inclusion Criteria:*

* Male or female, between 35 and 75 years.
* Have been diagnosed with a full-thickness tear of the supraspinatus that is deemed repairable by the surgeon.
* Have failed conservative treatment (physiotherapy and corticosteroid injection) prior to surgery.

*Exclusion Criteria:*

* Have a supraspinatus tear > 2cm, or a partial thickness tear.
* Present with rotator cuff tears secondary to significant trauma (fracture, dislocation etc).
* Have received non-surgical treatment in the rotator cuff within the three months prior to surgery, including corticosteroid injection and platelet rich plasma (PRP) injections.
* Present with pre-existing conditions associated with upper extremity pain, including: arthritis, ongoing infection, carpal tunnel syndrome, cervical neuropathy or other nerve pathology.
* Are likely to have problems with follow-up (i.e. patients with no fixed address, report a plan to move out of town, or intellectually challenged patients without adequate support network).
* Do not read and speak English.
* The individual is unable or unwilling to follow the designated post-operative rehabilitation protocol.

*Withdrawal Criteria*

As outlined on the Patient Consent Form, patients will be free to withdraw from the study without prejudice or altered post-operative care.

*Sample Size Calculation*

A power analysis using G power software7 was performed to calculate the sample size required for this study. Assuming a 5% significance level and a power of 0.8, the minimal clinical important difference of 10.4 points between groups on the Constant Score8 and standard deviations from previous study9, generated a sample size of72 patients (36 per group).

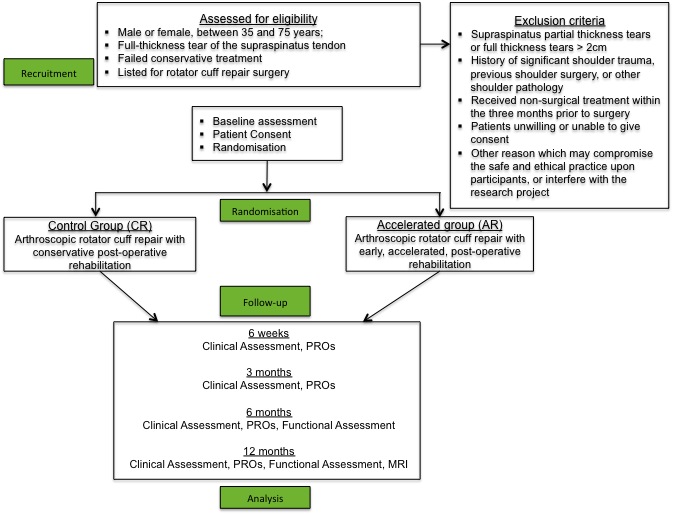
3.2 Procedures:

Once patient consent has been provided as outlined above, enrolled patients will be referred to St John of God Hospital prior to their scheduled surgery for an education session and initial assessment to record baseline data. Patients will be asked a series of standardized, introductory questions pertaining to previous injuries, medical history and demographics. All patients will be assessed clinically using validated subjective and functional assessment measures (detailed below). A summary of the study design is outlined in Figure 1.

*The Surgical Technique*

All surgery will be undertaken by a single orthopaedic surgeon (AW), and co-author of this research. All procedures will be performed under general anaesthesia with an interscalene nerve block. An initial diagnostic glenohumeral arthroscopy to confirm the presence of a full-thickness supraspinatus tear will be performed, followed by debridement of the bursal tissue and tendon margins. Tear type and size will be measured with a calibrated probe with 5 mm increments. Tears over 20 mm in the anteroposterior dimension will be excluded, as will partial tears. Supraspinatus tears associated with subscapularis or infraspinatus tears will also be excluded from the study. After acromioplasty, rotator cuff reconstruction will be performed. A double row suture-bridge repair with bioabsorbable anchors will be performed (Arthrex Bio-Corkscrew 5.5 mm–FT, Biocomposite Pushloc 3.5 mm; Arthrex). Concomitant shoulder injuries will be treated as clinically or radiographically necessary. Acromioclavicular joint arthropathy will be treated with arthroscopic excision of the lateral end of the clavicle, and long head of biceps tendinopathy will be treated with tenotomy.

**Figure 1.** Study flow chart

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*Post-operative Rehabilitation*

Patients assigned to the CR group will follow a conservative rehabilitation protocol which, for the first 12 weeks, will be self-managed at home. Patients will be required to attend an initial education session at 1-2 weeks post-surgery with an experienced Accredited Exercise Physiologist (AEP) for instructions on their post-operative exercise regime. CR patients will be placed in a sling for six weeks and instructed to adhere strictly to the activity restrictions outlined in Table 1 which has been developed based on current reported literature10,11. In the same session, patients will be instructed on performing activities of daily living (ADL) safely, in order to avoid adversely loading the repair site throughout the early post-operative time line. Following this initial education session at 1-2 weeks post-surgery, CR patients will return at 6 weeks post-surgery for the next supervised follow-up which will include the introduction of active-assisted ROM exercises. As mentioned, patients will be required to undertake these prescribed exercises independently at home. Competency and ongoing instruction in undertaking home exercises will be determined by the treating therapist, and will be developed and monitored via an online home-exercise software platform (Physitrack). Physitrack involves video-based demonstrations of exercise technique and dosage, and allows the therapist to monitor daily adherence and patient-reported pain. At the 12-week mark, patients will be required to attend supervised exercise rehabilitation twice per week for 6 weeks, along with daily home exercises which will again be delivered and monitored via Physitrack. Patients will be provided with a “training kit” consisting of Therabands and other simple equipment found in most homes to complete the prescribed exercises. Hard copies of the patient information sheet and exercise program will also be provided. The generic CR protocol is outlined in Table 2.

**Table 1.** Patient enforced restrictions on activities of daily living (ADL) and activity/sport following rotator cuff repair, to be followed by both the conservative (CR) and accelerated (AR) groups. Derived from Van der Meijden et al. (2012) and Long et al. (2011)10,11.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Patient Restrictions / Recommendations  Rotator Cuff Repair | | | | | | | | | | | | | | | |
| **Activities of Daily Living** | **Weeks** | | | | | | | | | | | | | | |
|  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 16 | 21 | 26 |
| Typing |  |  | | | | | | | | | | | | | |
| Eating / Drinking |  |  |  |  |  |  | | | | | | | | | |
| Dressing |  |  |  |  |  |  | | | | | | | | | |
| Washing / Showering |  |  |  |  |  |  | | | | | | | | | |
| Household duties |  |  |  |  |  |  | | | | | | | | | |
| Driving |  |  |  |  | | | | | | | | | | | |
| Lifting (< 2kg) |  |  |  |  |  |  | | | | | | | | | |
| Overhead activity |  |  |  |  |  |  |  |  | | | | | | | |
| Lifting (> 2kg) |  |  |  |  |  |  |  |  | | | | | | | |
| **Sport and Recreation** |  | | | | | | | | | | | | | | |
| Throwing |  |  |  |  |  |  |  |  | | | | |  | | |
| Overhead and Serving Sport |  |  |  |  |  |  |  |  | | | | |  |  | |
| Contact Sports |  |  |  |  |  |  |  |  | | | | |  |  |  |
| Swimming |  |  |  |  |  |  |  |  | | | | |  |  |  |

Patients allocated to the AR group will be placed in a sling for 6 weeks; however, they will also follow an early, accelerated rehabilitation regime, based on prior research and the outcomes of earlier studies that our group is currently undertaking. Similar to the CR group, patients in the AR group will also be required to attend an initial education session 1-2 weeks post-surgery with an AEP for instructions on their post-operative exercise regime. In this same session, patients will be instructed on performing passive ROM exercises and ADL safely. As per the CR group, AR patients will be required to undertake these prescribed exercises independently at home via Physitrack. Patients will be required to return at 4 weeks post-surgery for the next supervised follow-up session, and will subsequently undertake a supervised exercise session including active-assisted ROM exercises, and again at 6 weeks for a further supervised follow-up session. From 8 weeks post-surgery, patients in the AR group will be required to attend supervised exercise rehabilitation twice per week for 6 weeks, along with daily home exercises which will be delivered via Physitrack. Patients will be provided with a “training kit” consisting of Therabands and other simple equipment found in most homes to complete the prescribed exercises at home. Hard copies of the patient information sheet and exercise program will also be provided. A brief overview of activities, goals and treatment guidelines for the CR and AR groups is demonstrated in Table 2.

**Table 2.** Proposed conservative (CR) and accelerated (AR) rehabilitation protocols for the groups, following rotator cuff repair.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Phase | Goals | Treatment Guidelines | CR | AR |
| Phase 1: Immobilization | Protect repair site, manage pain & allow healing, gentle scapula exercises | * Complete immobilization * Cryotherapy * Scapular retractions, cervical ROM, elbow/hand ROM grip strengthening exercises | 0 – 6 weeks | 0 – 3 weeks |
| Phase 2: Passive ROM | Restore pain-free ROM, passive forward flexion >120°, passive internal/external rotation >75°, abduction >90°. | * Therapist-guided passive ROM: 'cradle the arm' and 'rock the baby', * Codman’s pendulum exercise, * Internal/external rotation ('open the gate') * Scapular retractions, cervical ROM, elbow/hand ROM grip strengthening exercises | 6 weeks | 0 – 3 weeks |
| Phase 3: Stretching, Active-assisted ROM & Active ROM | Restore full, pain-free active ROM, restore normal scapula control / kinematics | * Active-assisted ROM using uninvolved arm, overhead pulleys, wand/cane exercises, & TheraBands. * Active ROM: Spider crawl exercise (elevation/depression of hand up wall), elevation, fitball clocks, supine forward elevation / abduction → standing. * Scapular retractions, cervical ROM, elbow/hand ROM grip strengthening exercises | 6 weeks | 4 weeks |
| Phase 3: Strengthening | Continued glenohumeral ROM, rotator cuff strengthening, scapula strengthening | * Isometric rotator cuff exercises * Isotonic rotator cuff exercises, e.g. internal / external rotation using TheraBands, dumbbells * Isotonic scapula exercises, e.g. scapula retractions / protractions / shrugs using TheraBands, dumbbells * CKC stability exercises e.g. wall pushups, quadruped | 12 weeks | 8 weeks |
| Phase 4: Progressive strengthening & Sport-specific exercises | Advance upper limb strength, increase functional exercise, return to work / sport | * Continue phase 3 rehabilitation as required * Advanced isotonic rotator cuff exercises e.g. exercises in 45° - 90° abduction * Advanced isotonic scapula exercises e.g. unilateral rows / punches, push-ups * Rhythmic perturbation / stabilization exercises e.g. body blade, ‘statue of liberty’ * Plyometric exercises | 16 weeks | 12-16 weeks |

ROM = range of motion; CKC = closed kinetic chain exercises;

*Patient Evaluation*

The following measures will be undertaken following surgery at the designated time points.

1. *Patient-reported Outcome (PRO) Assessments*

Patients in both the CR and AR groups will be required to attend follow-up clinical assessments at 6 weeks, as well as 3, 6 and 12 months post-surgery. Four validated PROs will be employed to evaluate post-treatment outcomes. These will include the:

1. Oxford Shoulder Score (OSS);
2. Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH);
3. Simple Shoulder Test (SST);
4. EuroQOL five dimensions questionnaire (EQ-5D), and
5. Shoulder Activity Scale (SAS)

The patients’ subjective pain levels will be measured weekly using a visual analogue scale (VAS), as part of the rehabilitation protocol. The VAS is a scale from 1 to 10 and requires the patient to rate their pain along the scale; with 0 equating to no pain and 10 equating to the worst possible pain.

1. *Functional Patient Assessment*

Patients’ bilateral active range of motion (ROM) will be measured in all planes (abduction, flexion, extension, internal and external rotation) using a fluid inclinometer at 6 weeks, as well as 3, 6 and 12 months post-surgery. ROM will be measured within the patients’ pain tolerance to minimize any risk of injury or discomfort. The Constant Score is a shoulder-specific tool using a combination of subjective and objective components to assess shoulder function. The maximum score of 100 points consists of 35 points based on subjective assessments of pain and activities of daily living and 65 points based on examiner-derived measurements of shoulder strength and ROM. The higher the score, the higher is the quality of function. Strength in abduction will be measured via a strain gauge with the patient in a standing position with the arm in the scapular plane and 90° of elevation, with the hand and forearm pronated. The measurement should be pain-free and the highest value out of three is used.

1. *Electromyographic (EMG) Evaluation*

Electromyographic (EMG) data will be collected simultaneously from 11 shoulder muscles using a combination of surface and intramuscular fine-wire electrodes. Pre-gelled and self-adhering silver/silver-chloride bipolar dual surface electrodes will be used to measure the muscle activity of the following muscles on the participant’s right side: upper trapezius, anterior deltoid, middle deltoid and posterior deltoid. The surface electrodes are to be placed on the target muscles as described by Basmajian and De Luca12 over the belly of the muscle in line with the direction of the muscle fibres, with an inter-electrode distance of approximately 20 mm. Prior to application of the surface electrodes, the skin will be cleansed and shaved (if required).

Intramuscular electrodes will be used for muscles that underlie more superficial muscles (supraspinatus, upper and lower subscapularis), are thin and overlie other muscles (middle trapezius, lower trapezius), or for muscles that shift markedly with respect to the overlying soft tissue during shoulder movement (infraspinatus, serratus anterior and latissimus dorsi). An experienced investigator (SN) will insert all intramuscular fine wire electrodes via a sterile 30 mm, 27-gauge hypodermic needle with a pair of 0.051 mm, insulated, bent end Teflon coated stainless steel wires and 200 mm tail with 5mm bare-wire terminations (Chalgren Enterprises, USA), according to the protocol of Basmajian and De Luca12 and Boettcher et al.13. The insertion site will be prepared using an aseptic technique, via a chlorohexidine solution. Depth of the insertion will be determined using via ultrasound and confirmed by visualization of the EMG signal during maximal voluntary isometric contraction (MVIC).

Surface EMG electrode placement will be attained initially through surface palpation and isometric contraction, and confirmed through visualization of the EMG signal during MVIC (MYON m320® Telemyo system sampling at 2000Hz) during muscle-specific, manual muscle testing techniques. Two trials of 5-second MVICs will be performed, and will represent 100% EMG activity to be used as a standardized, within-subject reference for the data collected during the rehabilitation exercises. Verbal encouragement will be given during all trials. Electrodes will remain in place until the completion of the testing session. Passive, active and resisted movements will be performed to determine participant comfort and quality of EMG data as previously described14. Muscle activation magnitude will be captured with VICON® NEXUS software and post-processing will be filtered/normalized in MATLAB® software (The Mathworks, Natick, MS, USA). An additional surface electrode will be placed over the clavicle to serve as a reference electrode for all surface muscles and a large ground electrode will be used as a reference electrode for all intramuscular electrodes.

1. *Radiological Assessment*

Radiographic analysis will be performed via magnetic resonance imaging (MRI) pre-operatively as part of the diagnostic evaluation, and at 12 months post-surgery. All scans will utilize a 1.5-T unit (Sonata Maestro Class; Siemens) with 40 mT/m gradient power. Multiple images will be obtained in oblique coronal, oblique sagittal, and axial planes with both short-tau inversion recovery (STIR) and turbo spin echo (TSE) T1-weighted sequence. MRI assessment will be performed by an experienced musculoskeletal radiologist blinded to patient allocation to either group. A comprehensive MRI evaluation protocol described by Bauer et al.15 (Table 3) will be used to assess the integrity of the supraspinatus tendon at baseline and 12 months post-surgery, and compared between the respective treatment arms. This method of grading has shown excellent intra-observer and good inter-observer reliability15.

**Table 3.** Magnetic resonance imaging (MRI) scoring template for supraspinatus tendinosis and partial thickness tears (scored from 0-9).15

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Domain** | **Score = 0** | **Score = 1** | **Score = 2** | **Score = 3** | **Score = 4** |
| *Tendinosis* | Normal tendon | Focal tendinosis | Generalised tendinosis | N/A | N/A |
| *Tear thickness* | No tear | <25% tendon thickness | 25% - 50% tendon thickness | 50 – 100% tendon thickness | Full thickness |
| *AP tear size in mm* | No tear | <5 | 5 - 10 | > 10 | N/A |

3.3 Data handling, statistical analysis and reporting of results

Paper records will be kept under lock and key in a metal filing cabinet in the St John of God Hospital. Computer records will be stored in the assessor database and will be password protected. The patients consulting surgeon and the study investigators will only have access to hand written and electronic records. Records will be kept for 15 years after which, paper records will be shredded and computer records will be permanently deleted including back-up copies. The result of the research will be made available through medical journals or meetings, but all patient information will be de-identified and no private information will be identified outside the investigator office.

Statistical analysis will be performed using SPSS software (SPSS, Version 11.5, SPSS Inc., USA). A series of repeated measures analysis of variance (ANOVA) will be used to investigate primary and secondary clinical outcome measures between the two rehabilitation groups at baseline, and at 6 weeks and 3, 6, and 12 months post-surgery. Where a significant interaction effect is found, post-hoc independent t-tests will be used to determine time-points at which the two groups differ. Statistical significance will be determined at p ≤ 0.05.

Statistical significance of differences in EMG activity between operated and non-operated sides in each group will be assessed by the paired t-test at a significance of p ≤ 0.05. ANOVA will be used to test the significance of differences of the means among four groups (healthy, pathological, 6 and 12 month repaired), following which appropriate post hoc tests will be performed for multiple comparisons, using a significance level at p ≤ 0.05. Additionally, ANOVA will be used to compare differences in muscle activation between the two rehabilitation interventions (AR and CR) at 6 and 12 months post-surgery, following which appropriate post hoc tests will be performed, using a significance level at p ≤ 0.05.

### 4. References

1. Tempelhof S, Rupp S, Seil R. Age-related prevalence of rotator cuff tears in asymptomatic shoulders. *J Shoulder Elbow Surg*. 1999;8(4):296–299.

2. Yamaguchi K, Tetro AM, Blam O, Evanoff BA, Teefey SA, Middleton WD. Natural history of asymptomatic rotator cuff tears: a longitudinal analysis of asymptomatic tears detected sonographically. *J Shoulder Elbow Surg*. 2001;10(3):199–203. doi:10.1067/mse.2001.113086.

3. Wang T, Gardiner BS, Lin Z, et al. Bioreactor design for tendon/ligament engineering. *Tissue Eng Part B Rev*. 2013;19(2):133–146. doi:10.1089/ten.TEB.2012.0295.

4. Wu XL, Briggs L, Murrell GAC. Intraoperative determinants of rotator cuff repair integrity: an analysis of 500 consecutive repairs. *Am J Sports Med*. 2012;40(12):2771–2776. doi:10.1177/0363546512462677.

5. Huang T-S, Wang S-F, Lin J-J. Comparison of Aggressive and Traditional Postoperative Rehabilitation Protocol after Rotator Cuff Repair: A Meta-analysis. *J Nov Physiother*. 2013;03(04). doi:10.4172/2165-7025.1000170.

6. Zhang S, Li H, Tao H, et al. Delayed early passive motion is harmless to shoulder rotator cuff healing in a rabbit model. *Am J Sports Med*. 2013;41(8):1885–1892. doi:10.1177/0363546513493251.

7. Faul F, Erdfelder E, Lang A-G, Buchner A. G\*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods*. 2007;39(2):175–191.

8. Kukkonen J, Kauko T, Vahlberg T, Joukainen A, Aärimaa V. Investigating minimal clinically important difference for Constant score in patients undergoing rotator cuff surgery. *J Shoulder Elbow Surg*. 2013;22(12):1650–1655. doi:10.1016/j.jse.2013.05.002.

9. Keener JD, Galatz LM, Stobbs-Cucchi G, Patton R, Yamaguchi K. Rehabilitation following arthroscopic rotator cuff repair: a prospective randomized trial of immobilization compared with early motion. *J Bone Joint Surg Am*. 2014;96(1):11–19. doi:10.2106/JBJS.M.00034.

10. van der Meijden OA, Westgard P, Chandler Z, Gaskill TR, Kokmeyer D, Millett PJ. Rehabilitation after arthroscopic rotator cuff repair: current concepts review and evidence-based guidelines. *Int J Sports Phys Ther*. 2012;7(2):197–218.

11. Long JL, Ruberte Thiele RA, Skendzel JG, et al. Activation of the shoulder musculature during pendulum exercises and light activities. *J Orthop Sports Phys Ther*. 2010;40(4):230–237. doi:10.2519/jospt.2010.3095.

12. Basmajian JV, De Luca CJ. Muscles alive. *Muscles alive: their functions …*. 1985.

13. Boettcher CE, Ginn KA, Cathers I. Standard maximum isometric voluntary contraction tests for normalizing shoulder muscle EMG. *J Orthop Res*. 2008;26(12):1591–1597. doi:10.1002/jor.20675.

14. Kelly BT, Kadrmas WR, Speer KP. The manual muscle examination for rotator cuff strength. An electromyographic investigation. *Am J Sports Med*. 1996;24(5):581–588.

15. Bauer S, Wang A, Butler R, et al. Reliability of a 3 T MRI protocol for objective grading of supraspinatus tendonosis and partial thickness tears. 2014:1–8. doi:10.1186/s13018-014-0128-x.