**Research Plan:** Exercise rehabilitation and functional recovery following reverse total shoulder arthroplasty

### Background, Rationale and significance

Reverse total shoulder arthroplasty (RSA) is an end-stage surgical treatment option for patients with rotator cuff arthropathy and/or massive rotator cuff tears with who have significant difficulty in moving their shoulder and undertaking daily activities. RSA has demonstrated good success at relieving pain, improving range of motion, functional capacity and overall satisfaction,1,2 and with expanding indications and successful midterm outcomes, it is now being performed in a wider patient demographic, including younger patients.3,4 Return to sports and physical activity is increasingly being evaluated as a factor in judging orthopaedic surgical outcomes. An increase in patient activity intensity post-surgery may reflect greater function associated with clinical improvements in range of motion, strength, pain and / or overall physical function. Conversely, patients avoiding high intensity activities may represent deteriorating function associated with clinical impairments.5 A variety of different methods are routinely employed to assess patient function after RSA, such as self-reported questionnaires. Previous studies have demonstrated relationships between strength and self-reported activity and functional outcomes,6-8 however self-reported outcome evaluations are dependent on patient recall and perception of activity performance which do not inherently capture detailed functional movement data. Furthermore, within-clinic assessments fail to capture an accurate representation of upper limb function during activities of daily living in a patient’s natural living environment. The use of activity monitors in measuring function and limb use after injury to assess the impact of disease on movement, and the effectiveness of intervention in normalising limb use has grown to involve the upper extremity, including those scheduled for RSA.9 Using activity monitors in the upper extremity as an alternative method for evaluating patient function post-surgery, may allow for a more objective measurement of the frequency, duration, and intensity of shoulder function in patients after RSA.

Patient satisfaction is closely correlated with resumption of regular activities, and in the case of RSA, it has been shown that those who return to their pre-surgery physical activity and recreational sports after RSA, report greater levels of satisfaction post-surgery.4 Following RSA, patients with greater isokinetic shoulder strength participate in higher demand recreational or sports activity and report fewer difficulties with activities of daily living,10 and conversely, lower isokinetic shoulder strength is known to be a major factor in reduced range of motion (ROM),7 and is also associated with inferior clinical outcomes following RSA.7 Therefore a well-planned postoperative rehabilitation program, in combination with a correctly performed surgical procedure, is essential in optimising patient outcomes.8 While rehabilitation is generally recommended following RSA, these recommendations are based on expert opinion only,11 with no studies having investigated the effect of structured postoperative rehabilitation at an evidence level of 1 or 2. Furthermore, no study to date has evaluated the effect of a pre-operative strengthening program in patients with massive rotator cuff tears scheduled for shoulder surgery, in particular, RSA. Exercise rehabilitation has previously been shown to be effective in improving pain, strength and quality of life scores in patients living with massive rotator cuff tears,12-16 and a larger preoperative deltoid size has been shown to correlate with an improvement in outcomes after RSA.17 Therefore, an individually tailored exercise program before and after surgery may accelerate a patient’s return to normal activity, improve their postoperative outcome, and result in a higher level of postoperative satisfaction.

Therefore, this research aims to investigate the benefit of a structured, peri-operative exercise program in patients scheduled for RSA, compared with control subjects who receive the usual conservative course of management. Furthermore, this study will also investigate the effectiveness of using upper limb activity monitors to objectively capture upper extremity function in patients following RSA.

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

This research will comprise of two primary studies. The first part of this research is a prospective RCT investigating the benefit of a structured peri-operative exercise rehabilitation program in patients undergoing RSA. The purpose of this study is to investigate the capacity in which structured pre-surgery and post-surgery exercise programs can improve patient strength, active range of motion (AROM) and early functional recovery after RSA, compared with control subjects who receive the usual course of care.

Specifically, this study will examine:

* The extent to which patients with massive rotator cuff tears tolerate an exercise intervention prior to surgery.
* The value of a structured, peri-operative exercise program on the patient’s rate of improvement in strength, AROM and functional rehabilitation after surgery.
* The value of exercise rehabilitation on the participant’s rate of improvement in upper extremity function and other aspects related to quality of life after surgery
* The influence of exercise rehabilitation on patient satisfaction after surgery

The following research hypotheses will be tested:

* A four-week, individually tailored clinic plus home-based exercise program will be well tolerated by patients with massive rotator cuff tears who have been scheduled for RSA
* Participants in the exercise group will demonstrate improved pre-operative strength, AROM and upper extremity function following the preoperative exercise program
* The pain levels of patients who undertake the preoperative exercise program will remain either the same, or decrease pre-surgery.
* Patients in the EM group will demonstrate improved independence and higher quality of life scores immediately prior to reverse TSA (though after the pre-operative exercise intervention), and at 3, 6 and 12 months post-surgery, compared to the control group.
* Patients in the EM group will report higher levels of post-operative satisfaction at 3, 6 and 12 months post-surgery, compared to the control group.

The second part of this research will seek to evaluate the effectiveness of using upper limb accelerometers to objectively capture upper extremity function in patients after reverse shoulder arthroplasty and to a.) compare activity data between the operated and non-operated limb, b.) compare activity data between a surgical cohort and a control cohort, and c.) correlate this data with self-reported functional scores from common clinical questionnaires and satisfaction surveys across the postoperative timeline.

The specific aims of this study include:

* Evaluating upper limb function in patients with isolated massive rotator cuff tears scheduled for RSA using activity monitors worn on the upper limb, and comparing them to their uninvolved limb, as well as a separate healthy control group.
* Evaluating upper limb function in patients at 3-, 6- and 12 months’ post-RSA using activity monitors worn on the involved limb and comparing them to their uninvolved limb, as well as a separate healthy control group.
* Determining whether the level of activity, including volume and intensity, correlates with self-reported, perceived function post-RSA and subsequent rehabilitation.

The following research hypotheses will be tested:

* Overall functional limb use will be greater for the uninvolved limb compared to the involved limb in patients with rotator cuff tears
* Overall functional limb use will be greater in healthy controls compared to patients with massive rotator cuff tears
* Overall functional limb use will significantly improve in patients undergoing reverse shoulder replacement, from baseline to 3-, 6-, and 12 months’ post-surgery
* Significant limb asymmetries will exist between the involved and uninvolved sides of patients with massive rotator cuff tears, as well as healthy controls.
* Limb symmetry will progressively improve in patients undergoing reverse shoulder replacement from baseline to 3-, 6- and 12 months’ post-surgery
* Greater overall functional limb use / activity will correlate with greater self-reported physical activity and functional scores

### 3. Methods

**Study 1**

3.2.1 Study population, informed consent and recruitment

This is a prospective RCT investigating two different peri-operative management regimens in patients undergoing reverse TSR and, therefore, patients scheduled for reverse TSA 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 their surgeon having confirmed a massive, full-thickness tear of the rotator cuff 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: usual management (UM) group or the exercise management (EM) group. 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.

Patients meeting the following criteria will be eligible for inclusion in this study:

* Male or female, between 55 and 80 years and local to the Perth metropolitan area
* Patients with a massive rotator cuff tear, with or without arthropathy, subsequently scheduled for RSA
* Pseduoparalysis of the affected shoulder, including forward elevation <90 degrees

Patients with the following criteria will be excluded from participation:

* Require a revision shoulder arthroplasty
* Recent or previous fractures of the shoulder complex
* Previous shoulder surgery on the affected side or both
* Adhesive capsulitis
* Present with pre-existing conditions associated with upper extremity pain, including ongoing infection, carpal tunnel syndrome, cervical neuropathy or other nerve pathology
* Clinically verified polyarthritis, rheumatoid arthritis and/or fibromyalgia
* Failed medical clearance to participate in exercise
* 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 pre- and/or 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.

Ethical approval will be obtained from St John of God Human Research Ethics Committee and the written, informed consent from each patient will be collected prior to surgery.

*Sample Size Calculation*

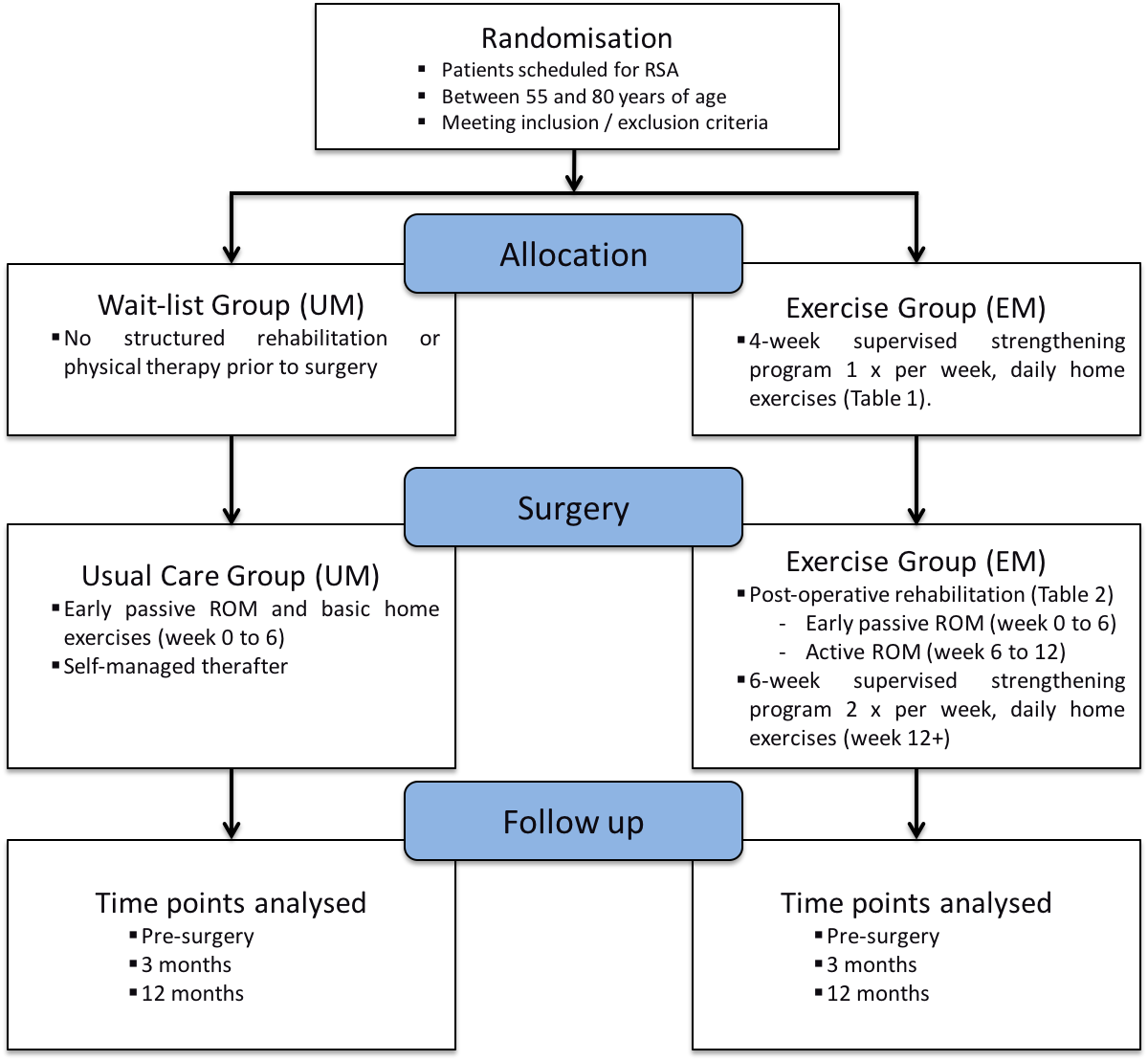
A power analysis using G power software18 was performed to calculate the sample size required for this study. Assuming a 5% significance level, a power of 0.8 a sample of 31 patients in each group was required to detect a 10-point difference in ASES scores19, To account for a 5% drop out rate, a total of 66 patients (33 in each group) has been proposed.

3.1.2 Procedures:

As outlined above, patients will first be seen at the private practice of Mr Allan Wang. Patients being offered reverse TSA that meet the inclusion criteria for this study will be invited to participate in the trial. The Patient Information Sheet and a verbal summary of the study and the expected participation will be presented to the patients. Those patients willing to participate will then complete the Patient Consent Form (Appendix 1) and will be randomized to either the EM or UM groups.

Once patient consent has been obtained as outlined above, enrolled patients will be referred to the adjoining clinical rehabilitation room in the rooms of Mr Wang at St John of God Hospital at least 4 weeks prior to their scheduled surgery for an initial assessment to record baseline data as well as introductory questions pertaining to previous injuries, medical history and demographics. For those randomised to the exercise group, familiarisation of the home-based exercise program and an education session will also take place. 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.

**Figure 1.** Study flow chart



*Pre-surgery Exercise Rehabilitation*

Patients assigned to the exercise group will be required to participate in a 4-week pre-surgery exercise program, scheduled following the baseline assessment and familiarisation session. The pre-surgery intervention program will consist of an individually tailored exercise program undertaken with an Exercise Physiologist twice per week, consisting of strengthening exercises addressing the deltoid for active elevation, active internal and external rotation and the scapula stabilisers, interspersed with moderate intensity cardiovascular exercise. On the days outside of supervised exercise, an individualised home-based exercise program will be required to be undertaken at least three times per week. Each participant will be provided with a training kit consisting of TheraBands as well as everyday objects useful for rehabilitation exercise. Written guidelines will be set out by the Exercise Physiologist will be provided to patients to use as a reference. Additionally, competency and ongoing instruction in undertaking home exercises will be ensured by developing a digital home exercise reference using Physitrack, which involves video-based demonstrations of exercise technique and dosage, and allows the therapist to monitor daily adherence and patient-reported pain. A brief overview of goals and exercises and guidelines for the EM group is demonstrated in Table 1.

**Table 1.** Proposed pre-operative rehabilitation focus for the Exercise Management (EM) group.20

|  |  |  |
| --- | --- | --- |
|  | Goals | Exercise Guidelines |
| Range of Motion (ROM) | Improve glenohumeral motion (forward flexion, abduction & external rotation), improve shoulder and thoracic posture | * Passive ROM (PROM) * Forward flexion, internal / external rotation * Pendulum exercise * Posture Shoulder shrugs Shoulder retraction * Active-assisted ROM (AAROM) * Wand exercises (elevation, abduction, adduction, internal / external rotation) * Pulley exercises (elevation) * Active ROM * Spider crawl, wall slides |
| Flexibility | Improve flexibility and reduce tightness of anterior and posterior capsule | * Anterior capsule stretch * Posterior capsule stretch * Trapezius stretch |
| Strengthening | Improve strength and conditioning of the anterior deltoid for shoulder elevation  Improve active external rotation strength  Improve strength of the scapular stabilizing muscles and dynamic scapular control | * Anterior deltoid strengthening e.g. supine → seated → standing shoulder flexion * External Rotation e.g. supine → seated → standing, 0° abduction (elastic resistance), side lying (dumbbell) * Scapula exercises e.g. prone scapula retractions → seated rows → standing rows; supine scapula protractions → wall protractions → wall push ups → standing presses |

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

*The Surgical Technique*

All patients will undergo RSA under general anesthesia in a semi–beach chair position with routine antibiotic prophylaxis. A deltopectoral approach will be used in all cases. The subscapularis tendon will be tagged and mobilised. A limited tenotomy of the superior edge of the pectoralis major tendon will be performed for mobilization of the proximal humerus and to improve exposure of the glenoid. RSA will be performed using the uncemented SMR Modular Shoulder System (Lima Corporate, Udine, Italy) in all cases. A 36-, 40-, or 44-mm glenosphere will be implanted as judged necessary to achieve satisfactory soft tissue tension and stability. All glenospheres will be eccentric in design. The humeral component will be implanted routinely in neutral version. In closure, the subscapularis tendon will be repaired as possible with No. 5 Ti-Cron (Ethicon, Somerville, NJ, USA) horizontal mattress sutures.

*Post-operative Exercise Rehabilitation*

Initially, all patients will be placed in an immobilisation sling for six weeks and instructed to adhere strictly to the activity restrictions outlined in Table 2, which has been developed based on current clinical practice and the reported literature. All patients will be educated on optimal management for reducing pain and/or swelling, as well as safely removing and fitting of the sling and clothing, and all contraindications and precautions. In-patient exercises will focus on safe passive range of motion (PROM) of the shoulder, as well as AROM of the hand, wrist and elbow. As mentioned above, these exercises will also be developed into a home exercise program (HEP) for patients to continue with in the comfort of their home, assisted by Physitrack which involves video-based demonstrations of exercise technique and dosage, and allows the therapist to monitor daily adherence and patient-reported pain.

Following hospital discharge, all patients will return to the SJOG Hospital 2 weeks post-surgery to consult with their surgeon to attend to the surgical wound, and then again at 6 weeks post-surgery for follow-up. Patients randomised to the UM group will have their immobilisation sling removed and continue without intervention, whereas patients assigned to the EM group will be referred to the SJOG clinical rehabilitation room for education and to advance their HEP and to remove the immobilisation sling. The new exercises will focus on progressing the current ROM exercises to more active exercises to restore full, pain-free AROM. Isometric strengthening of the anterior and posterior deltoid, and remaining posterior cuff muscles will also be initiated to advance active elevation and rotatory movement. Patients will be required to complete these home-exercises daily for a further 6 weeks with ongoing surveillance monitored via a phone call at 9 weeks to follow up on the exercises and progress further if needed. Patients will be asked to make reference to a “post-surgery home exercise guide” for instruction and guidelines, as well as Physitrack.

At 12-weeks, patients randomised to the EM group will again attend the SJOG hospital clinical rehabilitation room for further education as well as the first supervised exercise session. From 12 weeks, patients will undertake intensified strength and conditioning aimed at advancing deltoid and external rotator strength to improve functional elevation & active rotation, scapula stability training and cardiovascular exercise under the supervision of an Exercise Physiologist twice per week for 6 weeks. Patients will also be required to complete daily home exercises, which will again be referenced in the “post-surgery home exercise guide” as well as 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. A brief overview of goals, exercises and guidelines for the EM group is demonstrated in Table 2.

**Table 2.** Proposed post-surgery rehabilitation protocol for the Exercise Management (EM) group.

|  |  |  |
| --- | --- | --- |
| Phase | Goals | Treatment Guidelines |
| Phase 1: Early Passive ROM (Week 0 – 6) | Education, joint protection, passive ROM exercises, assistance putting on / taking of sling / clothing | * Education * Shoulder anatomy * Operative procedure * Patient and therapist expectations * Sling immobilization for 4 weeks * Precautions: * Cryotherapy * No shoulder AROM * No lifting objects * No internal rotation, adduction or extension beyond neutral * Self-managed home exercises * Supine flexion / elevation in scapular plane to 90 * Pain-free deltoid isometrics in scapular plane * Therapist-guided passive ROM: 'cradle the arm' and 'rock the baby', * Codman’s pendulum exercise, * Internal/external rotation ('open the gate') * Periscapular exercises, cervical ROM, elbow/hand ROM grip strengthening exercises, |
| Phase 2: AROM & Early Strengthening  (week 6 – 12) | Restore full, pain-free active ROM, restore normal scapula control / kinematics | * Completed self-managed at home, 3 x per day * 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 * Isometric rotator cuff exercises |
| Phase 3: Advanced strengthening (week 12+) | Advanced deltoid strengthening & active rotation, scapula strengthening. Progress functional tasks and ADLs | * Supervised rehabilitation twice per week & self-managed at home alternate days, 3 x per day * Isometric ER / IR * Active ER / IR using TheraBands, dumbbells * Isotonic scapula exercises, e.g. scapula retractions / protractions / shrugs using TheraBands, dumbbells * CKC stability exercises e.g. wall pushups, quadruped |

*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 EM and UM groups will be required to attend follow-up clinical assessments at 6 weeks, as well as 3, 6, and 12 months post-surgery. Five validated PROs will be employed to evaluate post-treatment outcomes. These will include:

1. The Oxford Shoulder Score
2. The American Shoulder and Elbow Surgeons Questionnaire (ASES)
3. The Simple Shoulder Test (SST);
4. The Short Form (36) Health Survey (SF-36), and
5. The Shoulder Activity Scale (SAS).
6. *Functional Patient Assessment*

Patients’ bilateral AROM will be measured in all planes (abduction, flexion, internal and external rotation) using a fluid inclinometer at 3-, 6- and 12 months post-surgery. AROM will be measured within the patients’ pain tolerance to minimize any risk of injury or discomfort. The Constant Score will also be evaluated, which 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.

All participants at 12 months post-surgery undergo evaluation of isokinetic shoulder strength using a Biodex System 3 Pro dynamometer (Biodex Medical Systems, New York, NY , USA). Three protocols of shoulder movement will be tested: internal and external rotation, abduction and adduction, and forward flexion and extension. For each protocol, patients will be tested within a locked range of motion predetermined by their limit of comfort. The isokinetic testing was performed with the dynamometer velocity set to 60°/s. Each protocol will consist of 1 practice motion to ensure comfort and technique. After 2 minutes of rest, 3 consecutive repetitions of the movement at maximum power will be performed and measurements will be recorded.

*C. Activity Data Assessment*

Functional limb activity will be measured using five ActiGraph GT9X+ Link (ActiGraph, Pensacola, FL) activity monitors secured bilaterally to the upper arms at the mid-biceps, the lower arms at the wrist, and on the waist of each participant, as per previous recommendations9. Activity data will be collected over three consecutive days preoperatively and at 3-, 6- and 12 months’ post-surgery in patients’ natural living environment, but not including time spent sleeping. The accelerometer sampling rate will be set at 30 Hz (as recommended by the manufacturer). The vector magnitude (VM) physical of activity counts from each accelerometer will be calculated with ActiLife software (ActiGraph, Pensacola, FL). The ActiLife VM physical activity counts will be exported to an Excel spreadsheet using 1-second epochs for every second during the entire data collection. The average activity for each limb segment will be determined each day by calculating the arithmetic mean of the epoch activity value within 1 day for each subject. A within-subject average activity value will subsequently be calculated for each limb segment over the 3 days of collection. Novel techniques used to determine limb asymmetries and activity intensities will also be applied.5,9

3.1.3 Data handling, statistical analysis and reporting of results

Paper records will be kept under lock and key in a metal filing cabinet in the SJOG 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.

At baseline, a series of one-way analyses of variance (ANOVA) will be performed to determine if initial differences exist between the two patient groups. To determine the efficacy of a pre-surgery exercise program, a series of one-way analysis of variance (ANOVA) will be performed in conjunction with post-hoc paired t-tests in the results obtained between the pre-intervention and pre-operative time points, and then again at 3-, 6-, and 12 months’ post-surgery. When comparing the effectiveness of the surgery plus the exercise intervention, against the surgery plus usual care, a series of two-factor ANOVAs (group and time) will be taken at pre-surgery, 3-, 6-, and 12 months’ post-surgery.

**Study 2**

3.2.1 Study population, informed consent and recruitment

Thirty patients from the same RSA cohort as described above will be recruited for this study, as well as a control group consisting of thirty “apparently healthy” participants.

All control group participants are required to have no upper extremity injury at the time of testing, no symptoms in either upper extremity, and no history of shoulder surgery to either arm. Individuals who did not meet all participation criteria will not be eligible for study enrollment. Ethical approval will be obtained from St John of God Human Research Ethics Committee and the written, informed consent from each patient will be collected prior to surgery

3.2.2 Procedures:

Functional limb activity will be measured using five ActiGraph GT9X+ Link (ActiGraph, Pensacola, FL) activity monitors secured bilaterally to the upper arms at the mid-biceps, the lower arms at the wrist, and on the waist of each participant, as per previous recommendations.9 Activity data will be collected over three consecutive days preoperatively and at 3-, 6- and 12 months’ post-surgery in patients’ natural living environment, but not including time spent sleeping. After activity data collection, patients will complete the Oxford Shoulder Score (OSS), the Simple Shoulder Test (SST), and the American Shoulder and Elbow Surgeons evaluation form (ASES). An activity participation questionnaire and a patient satisfaction questionnaire used in previous studies will be employed, as well and a Global Rating Scale for Perceived Function.[24](#_ENREF_24),[26](#_ENREF_26) Mean, minimum and maximum daily physical activity counts will be evaluated for the lower and upper arm between the patient group and the control group over the three days. Limb asymmetries and activity intensities assessing the amount of time participants are inactive, and engaged in low-intensity and high-intensity activity using previously described algorithms5,9 will be compared between the control and patient groups.

3.2.3 Data handling, statistical analysis and reporting of results

Between group differences will be evaluated for the lower and upper arm for minimum, mean, and maximum activity counts with a univariate ANOVA. A paired samples t-test will be applied to the asymmetry indices results to compare between the control and patient groups for the lower and upper arm separately. Between group differences were also evaluated for the time spent across activity bins. When statistical significance was achieved, post hoc testing will be performed using independent samples t-test to determine where differences were occurring. For all measures alpha will be set a priori at p≤0.05. Pearson correlation coefficients will be computed between patient-reported outcome scores and the accelerometer scores.

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