Title: Is Formal Physical Therapy Beneficial After Reverse Shoulder Arthroplasty? A Single-Blinded, Randomized Controlled Trial

Principal Investigators: Bryan M. Saltzman, Patrick Connor, Shadley Schiffern, Nady Hamid,

Purpose: The purpose of this study is to compare, in a randomized controlled trial, the effectiveness of an unsupervised home exercise program vs outpatient physical therapy in terms of restoring function for patients undergoing unilateral reverse shoulder arthroplasty.

Research Question (s):

1. What, if any, is the value of formal physical therapy after reverse shoulder arthroplasty surgery?
    a. Specifically, in evaluation of pain, functional outcomes, ROM, strength?

Type of Study: Prospective, single-center, 2-arm, parallel-group, randomized controlled trial

Treatment Group: Self-directed ("unsupervised") home exercise program based on a detailed PT manual that will be provided to patients prior to discharge.

Comparison (Control) Group: Formal outpatient physical therapy

Randomization: After obtaining informed consent, patients will be randomized by independent party to one of the two treatment groups. Patients will be randomized to either receive formal outpatient physical therapy of a self-directed, unsupervised home therapy regimen. A 1:1 randomization schedule will be followed. An Excel random number generator will be used to determine the allocation order using sequentially numbered sealed envelopes opened just prior to surgical intervention, at which time patients are informed of their group allocation. Separate individuals will complete the random allocation sequence, patient enrollment, and outcome assessment.

Inclusion Criteria

- Recruited from a single academic center (OrthoCarolina)
- Age between 60-85 years
- History and physical examination consistent with a diagnosis of primary rotator cuff tear arthropathy
- Scheduled Unilateral Reverse Shoulder Arthroplasty

Exclusion Criteria

- History of ipsilateral shoulder surgery (i.e. revision procedures)
- History of ipsilateral shoulder infection
- Requirement of discharge to an acute rehabilitation center, skilled nursing facility, convalescent home, or long-term care facility
- Autoimmune, neuromuscular, post-traumatic or inflammatory degenerative joint disease
- Inability to follow written directions in English

Primary Outcome Variable: Constant-Murley score and subgroups

Secondary Outcomes Variables

- ASES score
- DASH score
- Patient satisfaction
- VAS Pain
- Active Range of motion
    - Forward flexion in the scapular plane
    - External rotation with the elbow at the side
    - External rotation with shoulder abduction in the plane of the scapula
    - Internal rotation (how far up the spine the patient can reach with the thumb)... to facilitate statistical analysis, the spinal segment reached will be converted into a number (T1-T12 = 1-12; L1-L5 = 13-17; Sacrum = 18)

- Shoulder strength in 90 degrees of abduction (kg)
- Post Operative Complications

Independent variables/Covariates/Confounding Variables

- Preoperative PROs (VAS Pain, DASH, ASES, Constant)
- ASA classification
- Charlson Comorbidity Index
- Smoking status
- First and Last Name
- MRN
- Date of Birth
- Date of Death
- Sex
- Race
- Ethnicity
- Height
- Weight
- BMI (calculated)
- Durations of symptoms
- Date of Surgery
- Operative Details
- Operative Variables
    - Glenosphere size
    - Components
    - Glenoid fixation
    - Tenotomy vs. tenodesis of the biceps
    - Subscapularis condition
- Post Operative Visit Dates
- Radiology Dates
- Radiology Outcomes

Patient Selection and Identification:

Patient enrollment will be a single academic center (OrthoCarolina). Patients will be initially identified after workup and evaluation by staff physician and are diagnosed with rotator cuff tear arthropathy and determined to require reverse shoulder arthroplasty. All inclusion/exclusion criteria and patient demographics/medical history will be reviewed. After identification, interaction will be conducted with the patient, physician, and research staff to obtain written consent and authorization for participation.

A deltopectoral approach will be used with patients under general anesthesia in the beach chair position. Tenotomy or tenodesis of the long head of the biceps will be performed for all patients with an intact biceps tendon. The remaining subscapularis will be tenotomized, with refixation performed at the end of the procedure, whenever possible. All humeral stems will be uncemented, and positioned in 5-10 degrees of retroversion. After surgery, all patients will initially be placed in a shoulder immobilizer. Standardized perioperative protocols will be used for all patients in terms of analgesic medications pre- and postoperatively.

Postoperatively, the formal outpatient physical therapy will be initiated within 5-days postoperative, at a frequency of 2-3x/week for a total of 12 weeks postoperatively. This initially includes elbow, wrist, and hand ROM for the first two weeks. Use of home pulleys begin at the 2-week postoperative time point, and arm use for ADLs is initiated at the 4-week postoperative time point. The motion of internal rotation to reach behind the back begins at 10 weeks postoperative. These patients will additionally be provided with a list of suggested physical therapy exercises to be performed at home. The unsupervised, self-directed home exercise group will follow a 12-weeks unsupervised home exercise program based on a detailed physical therapy manual provided to patients prior to discharge, which will include images and written explanations for suggested exercises, which will be performed 3x/day and will be graduated from week to week in accordance with the progression of the other group. Exercises will also be demonstrated to patients prior to hospital

discharge. All patients will be provided a diary to keep a record of their daily therapy regimen and to promote compliance.

The primary outcome will be change in Constant-Murley score from baseline and assessed longitudinally at 6-weeks, 3-months, 6-months, and 1-year postoperatively. Additional patient-reported outcomes will be as above, including VAS Pain, DASH, ASES, and Patient Satisfaction. Range of motion and strength measurements will be recorded at the above time points as well. An independent examiner blinded to the group assignment at the OrthoCarolina institute will evaluate shoulder function and active range of motion. [3].

Patients who are unable or unwilling to return to the clinic for an office visit will be contacted by a study investigator or a member of the research staff using an IRB approved phone, email or mail script (or letter) and will be asked to complete any patient reported outcomes (PRO) questionnaires. A phone script with verbal consent will be used for this group. Therefore, a waiver of consent documentation is requested for this group.