Sensor-Monitored Compliance Following RCR and Effects on Postoperative Prognosis

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SENSOR-MONITORED COMPLIANCE FOLLOWING ROTATOR CUFF REPAIR
AND EFFECTS ON POSTOPERATIVE PROGNOSIS

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ABSTRACT

Rehabilitation in the immediate postoperative period after surgical rotator cuff repair is critical for long-term patient outcomes. This rehabilitation typically consists of six weeks of immobilization with a sling following surgery to optimize tendon-to-bone healing, but the benefit of this has been debated in recent years. The optimal immobilization period is difficult to determine because patient compliance with immobilization protocols varies. Subjective measures from patients regarding compliance are often unreliable, suggesting a need for a more objective approach. In this prospective cohort study, we will use temperature sensors to monitor sling wearing times and assess the effect of patient compliance with immobilization on tendon healing and functional outcomes following surgery. This objective measure of compliance will aid in clarifying the optimal immobilization period, which will help inform postoperative rehabilitation guidelines following rotator cuff repair and may reduce the burden associated with six weeks of immobilization for patients.
CHAPTER 1: INTRODUCTION

1.1 Background

1.1.1 Rotator Cuff Pathology and Anatomy

Nearly 50% of adults in the U.S. experience musculoskeletal conditions that cause acute or chronic pain and dysfunction, with shoulder pathologies representing a large proportion of cases.\(^1\) Estimates report that the lifetime prevalence of shoulder disorders is as high as 70%, making them one of the most common musculoskeletal ailments among the U.S. population.\(^2\) Pain caused by shoulder conditions, such as impingement syndrome, rotator cuff tendinopathy and acute or degenerative rotator cuff tears often persists longer than six months.\(^1\) Thus, individuals experience significant disease burden that negatively impacts employment, psychological well-being and overall quality of life.

A large number of pathologies can affect the shoulder, but rotator cuff tears are one of the most common and lead to significant restrictions in shoulder function.\(^3\) The rotator cuff is comprised of the subscapularis, supraspinatus, infraspinatus and teres minor muscles and their tendons, all of which directly overly the shoulder capsule and work together to provide active range of motion of the upper arms and stability across the glenohumeral joint.\(^4\) The subscapularis muscle is responsible for humerus adduction and internal rotation, while the supraspinatus aids the deltoid in shoulder abduction. Both infraspinatus and teres minor aid in external rotation of the shoulder.\(^4\) Because these muscles work in unison, and are responsible for substantial range of motion and dexterity of the upper extremities, any disruption or change in their integrity has the capacity to cause impairment in the functionality and strength of the arm.
Of the four tendons that comprise the rotator cuff, the supraspinatus is most commonly implicated in both acute and degenerative tears. Tendon tears can be described as being either small (<1cm), medium (1-3cm), large (3-5cm) or massive (>5cm), with large to massive tears usually involving multiple tendons. Additionally, they can also be described as being either partial-thickness or full-thickness, with full-thickness tears involving communication between the bursal and articular side of the rotator cuff.

1.1.2 Diagnosis of Rotator Cuff Tear

Practitioners utilize various methods for diagnosing rotator cuff tears. A detailed physical exam helps the clinician to identify any areas of focal tenderness, any gross deficits in range of motion and strength, and the function and integrity of the neurovascular system. Normal range of motion in the shoulder is approximately 150-180 degrees of forward flexion, 40-60 degrees of extension, 150-180 degrees of abduction, 60-90 degrees of external rotation and 50-70 degrees of internal rotation, which can be evaluated with the use of specific tests to target individual muscles. The subscapularis tendon can be targeted with the Gerber test, where the patient internally rotates their arm with elbow in the flexed position until the dorsum of the hand is resting along the back. If the subscapularis tendon is compromised, then the patient will be unable to lift their hand off of their back. The supraspinatus muscle and tendon can be evaluated with the Jobe or “empty can” test, where the patient’s arm is flexed to 90 degrees in the scapular plane with the forearm pronated and shoulder internally rotated. The clinician then applies downward pressure to the arm above the elbow which will result in pain or weakness if the tendon is compromised. Holtby et al. estimated the specificity of this test to be as
high as 90%, which is useful given the frequency with which the supraspinatus is implicated in rotator cuff pathology. The infraspinatus and teres minor muscles and tendons function to create external rotation of the proximal humerus and can be assessed with resisted external rotation with the patient’s arm adducted to their side, with a positive sign evidenced by pain or weakness. The hornblower sign, where the patient’s arm is passively abducted and externally rotated to 90 degrees, is used to assess the teres minor muscle and tendon. If the patient cannot maintain this position and there is a passive internal rotation observed, then pathology of these tendons are implicated.

Aside from patient history and physical exam findings, imaging has also shown to be a valuable modality in the diagnosis of rotator cuff tears. Liu et al. performed a systematic review analyzing the performance of Magnetic Resonance Imaging (MRI), Magnetic Resonance Arthrography (MRA) and Ultrasound (US) in the detection of rotator cuff tears. Across 144 studies and over 14,000 patients, they found that MRA had the highest sensitivity and specificity in the detection of full-thickness tears and partial-thickness tears, and that MRI was superior to US in the detection of any tear type. Though MRA was superior in their review, non-contrast MRI and US are the imaging modalities of choice because of their non-invasive nature. MRA is used primarily for assessment of rotator cuff pathology in the post-operative setting or when non-contrast studies are inconclusive. Additionally, MRI provides the ability to localize and define the extent of rotator cuff tears and is highly reproducible, compared to US which is more operator dependent.
1.1.3 Epidemiology

Rotator cuff tear prevalence increases with age, with up to 31% of individuals aged 70 years or older living with a partial or full-thickness tear.\textsuperscript{3} The combination of dysregulated homeostasis of muscular tissue and compromised vascularity in the tendons of elderly individuals leads to greater risk of tendon degeneration, and puts the individual at a higher risk of tear with acute trauma or falls. The majority of patients with degenerative tears present without a significant history of antecedent trauma.\textsuperscript{2} Additionally, individuals with chronic tears of the supraspinatus tendon often have a history of subacromial impingement syndrome, which is instigated by tendon overuse and overload, such as during repetitive overhead activities.\textsuperscript{2} Though rotator cuff tears do seem to be mostly an age-dependent, degenerative process, acute traumatic tears can also occur in the context of a shoulder dislocation or as avulsion injuries in throwing athletes.\textsuperscript{12} Regardless of the cause, untreated rotator cuff tears will more often progress in size over time, which can have negative implications for patients.\textsuperscript{13} Thus, management and treatment of both acute and chronic rotator cuff tears is important and aims to restore or improve range of motion and reduce patient pain.

1.1.4 Treatment Options

There remain several options for treatment of rotator cuff-related disease. Non-operative treatment is the mainstay for patients who have minor tears, who are not good surgical candidates or who are asymptomatic.\textsuperscript{12} Such treatment may involve physical therapy, with a particular focus on core and scapular muscle strengthening, which has been shown to significantly improve forward elevation and abduction as well as patient-reported functional assessments.\textsuperscript{14} Another common conservative treatment option is
subacromial injections with corticosteroids, such as methylprednisolone and betamethasone.\textsuperscript{12} Though corticosteroids often provide short-term relief, their use alone has not shown to improve long-term clinical outcomes.\textsuperscript{15} These conservative measures can be effective for some patients, however, patients with more severe disease, as evidenced by increasing pain and reduction in function, require surgery to halt disease progression and improve long-term outcomes.\textsuperscript{12}

For patients who remain symptomatic, have full-thickness tears, or who have acute bursal-sided partial thickness tears involving >25\% of tendon thickness, or partial articular-sided tears involving >50\% tendon thickness, surgical repair remains the best viable treatment option.\textsuperscript{16,17} Though rotator cuff repairs were historically performed via an open or “mini-open” technique, an arthroscopic approach represents the majority of repairs performed today and is popular among providers and patients because it is minimally invasive and reduces infection risk postoperatively compared to open procedures.\textsuperscript{18} Regardless of the surgical technique used, the specific objectives of surgery generally remain the same: 1) reattachment of the viable tendon(s) to the anatomic footprint on the humerus using anchors and sutures, 2) provide high initial fixation strength and 3) minimize gap formation during surgery.\textsuperscript{12,19} To accomplish these goals, surgeons utilize both single row and double row suture techniques, both of which have been shown to be effective in repairing the involved tendons.\textsuperscript{12} Additionally, studies have demonstrated that clinical outcomes are equivalent for single row and double row techniques, except in larger tears where a double row may be advantageous.\textsuperscript{20} While arthroscopic surgery has become a mainstay in the treatment of rotator cuff tears, surgical
success and clinical outcomes for patients are variable, though they can be assessed using various subjective and objective techniques.\textsuperscript{19}

1.1.5 Postoperative Monitoring

Assessing the function and strength of the arm as well as monitoring patient discomfort and pain is important in both preoperative and postoperative periods. Functional shoulder assessments are useful tools for achieving this, and help both physicians and physical therapists identify structural and biomechanical changes, and correlate them to a patient’s functional disabilities.\textsuperscript{21} Currently, there are over 30 validated functional assessment scales used across the world, which address components such as Activities of Daily Living (ADLs), pain, range of motion, strength, physical symptoms and patient satisfaction.\textsuperscript{21} For example, the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) is useful for patients suffering from shoulder instability, rotator cuff tears and shoulder pain. It consists of two sections which analyze components such as pain and instability, ADLs, range of motion and strength. The overall score is derived from a formula with a maximum score of 100 points.\textsuperscript{22} Similarly, the Constant-Murley (CM) score is useful for patients with subacromial pain, rotator cuff tears and shoulder instability. The CM score has 13 items divided into four components including pain, ADLs, range of motion and strength, with a maximum score of 100 points.\textsuperscript{23} In addition to the numerous shoulder assessments available for clinicians, MRI and US are also useful for clinical follow-up, especially in cases where a retear of a repaired tendon is suspected.\textsuperscript{24} The combination of imaging and functional assessments aid in the monitoring of patients in the postoperative period, where long-term outcomes are dependent on a multitude of factors.
Age, size of tear and occupation have all shown to affect post-operative outcomes for patients undergoing rotator cuff repair.\textsuperscript{19} Patients of older age have shown decreased rates of tendon healing when compared with younger patients. For example, Boileau et al.\textsuperscript{25} found that only 43\% of patients over the age of 65 had completely healed tendons over a 29 month follow-up period. Similarly, Namdari et al.\textsuperscript{26} reported that patients who identified as having labor intensive jobs were at higher risk for failed rotator cuff repair. Increasing tear size has also been implicated in numerous studies as a risk factor for failed healing. Studies, however, show large variation in their estimates for the correlation between tear size and healing outcomes, with failure rates ranging from 34-94\% with increasing tear size.\textsuperscript{19} Numerous other variables affect postoperative outcomes, including concomitant procedures, fatty infiltration, rotator cuff atrophy, muscle-tendon unit retraction and patient-related factors. However, considerable attention has been given to examining the relationship between post-operative rehabilitation protocols and long-term clinical outcomes for patients.

The postoperative rehabilitation period following rotator cuff repair is critical for the long-term integrity of the repaired tissue.\textsuperscript{27} The total rehabilitation period is estimated to be between four to 12 months, but conclusive, universal physiotherapy interventions and an optimal immobilization period have not been identified.\textsuperscript{28,29} Historically, a six week period of total joint immobilization with an abduction sling was recommended immediately following surgery, which was hypothesized to allow for tendon healing and prevention of retear at the repair site.\textsuperscript{30} However, providers have started to prescribe early, progressive rehabilitation instead of immobilization, which is thought to prevent postoperative stiffness and frozen shoulder, and may allow for greater range of motion.
long-term. Though heavily studied, there remains little consensus in the literature about which protocols are better, thus reducing the confidence with which providers prescribe post-operative rehabilitation to their patients.

1.2 Statement of the Problem

Despite the numerous studies exploring long-term outcomes of patients prescribed conservative versus progressive rehabilitation, few studies exist that have evaluated compliance with postoperative immobilization. The majority of previous research has either monitored compliance with sling immobilization with patient-completed questionnaires or simply assumed that patients were adherent. Thus, the true effect of immobilization cannot be readily identified because it is unknown if patients are actually wearing their slings and adhering to their providers recommendations. The more common recommendation is sling immobilization for six weeks for 22-23 hours per day, with gradual introduction to passive motion, stretching, active motion and strengthening. For patients, strict adherence to wearing a sling represents a significant burden in the postoperative period, especially for individuals who live alone or who need to return to work sooner. Therefore, a study that evaluates the effect of immobilization compliance on patient outcomes following rotator cuff repair would help to elucidate the utility of six weeks of immobilization and will further inform current rehabilitation guidelines.

1.3 Goals and Objectives

The goal of this study is to determine if patient outcomes following rotator cuff repair are affected by their compliance to postoperative immobilization protocols. This study will employ the use of temperature sensors to determine the frequency which patients wear their sling following surgery. Patients will be evaluated over the course of
one year to determine if their level of compliance affects 1) tendon healing and 2) the improvement or restoration of arm function. Results will help to inform postoperative rehabilitation guidelines following rotator cuff repair, clarify the necessity of a full six weeks of immobilization and may help to reduce the burden of the post-operative period for patients and their caregivers.

1.4 Hypothesis

Patients with lower rates of immobilization compliance will have increased rates of incomplete tendon healing or retear, and reduced scores on functional shoulder assessments when compared to patients with higher rates of compliance.
1.5 References

CHAPTER 2: REVIEW OF THE LITERATURE

2.1 Introduction

The literature review search was conducted initially in June 2022 and again six months later in December using PubMed and Ovid (Embase). MeSH terms for primary searches included combinations of the terms “Rotator Cuff”, “Shoulder”, “Immobilization”, “Restraint”, “Patient Compliance”, “Postoperative Period”, “Rehabilitation” and “Surgery”. Additional articles were also compiled from the references of relevant articles.

2.2 Review of Empirical Studies

2.2.1 Studies Examining Immobilization Periods: Animal Models

Numerous studies over the last decade have aimed to validate the best post-operative regimen for patients following rotator cuff repair, especially as researchers and clinicians have gained more insight into the various biomechanical properties at play in a healing tendon. Much of what was known initially was derived from animal studies that evaluated tendon-bone healing in rats, as it is known that the bony anatomy between rats and humans, especially as it pertains to the rotator cuff, is similar. Thomopoulos et al. used the rat rotator cuff model to investigate the role of immobilization on rotator cuff healing by testing a variety of loading conditions on newly repaired supraspinatus tendons. Rats were divided into three groups based on activity level: exercise, cage activity and immobilization in a cast. At eight weeks post-operatively they found that rats in the immobilized group had superior material properties, including better tendon organization and a higher type I to type II collage ratio as compared to rats in the exercise group.
Similarly, Gimbel et al.\textsuperscript{3} investigated the effects of length of immobilization and various activity levels on the mechanical properties of the supraspinatus tendons in rats. They found that decreased activity had a positive effect on the elastic properties of the healing tendons, with decreased disorganization of collagen in the lower activity group after four weeks (p < 0.01). They postulate that reducing activity in the postoperative period improves tendon to bone healing, which progresses by first increasing collagen organization with subsequent increase in the mechanical properties of the tissue. Using data derived from these studies and others, clinicians have aimed to improve clinical outcomes for their patients following surgery with control and optimization of the mechanical environment surrounding the newly repaired tendons. As such, the clinical practice of a period of immobilization and decreased activity following tendon repair has been widely practiced and accepted to minimize occurrence of retear.\textsuperscript{1}

\textbf{2.2.2 Clinical Evaluation of Immobilization and Rehabilitation Protocols}

As discussed earlier, clinical investigations examining different rehabilitation protocols have become more abundant, with hundreds of studies analyzing various clinical outcomes during the postoperative period. Considerable attention has been given to exploring various periods of immobilization and the optimal rate of therapy progression, with the goal to minimize postoperative retear without increasing the risk of developing frozen shoulder.

Sheps et al.\textsuperscript{4} evaluated early active motion versus sling immobilization in 206 patients undergoing rotator cuff repair. Half of the patients were randomized to an early motion group, who performed active range of motion exercises after weening themselves from sling, and half were randomized to an immobilization group, who wore a sling for
six weeks and did not perform active range of motion exercise. There were no significant differences in range of motion between groups over the 24-month follow-up period (p > 0.06). However, 30% of patients in the early motion group experienced a retear after 12 months compared to 33% of patients in the immobilization group, though the results were not significantly different (p > 0.8). This study had many participants, most of whom were retained for the entire study period. However, for the immobilization group, compliance was measured with the use of a questionnaire, so it is unknown if participants adhered to protocols as prescribed.

Tirefort et al.\textsuperscript{5} performed a similar study in which they evaluated clinical outcomes in 80 patients following rotator cuff repair. Forty patients were assigned to wear a sling for four weeks following surgery while another 40 patients did not wear a sling at all. Patients in both groups were instructed to perform passive mobilization five times per day, with the sling group instructed to remain in the sling at all other times. After 1.5 months, patients in the no sling group had greater mean external rotation (p = 0.017) and active elevation (p = 0.038), as well as greater internal rotation (p = 0.011) at three months compared to the sling group. After six months, there were no significant differences in tendon thickness anteriorly (p = 0.472) or posteriorly (p = 0.639), which is correlated to a low retear rate in both groups. Additionally, immobilized patients had lower Single Assessment Numeric Evaluation (SANE) scores and increased pain compared to patients who were not immobilized (p = 0.009 and 0.022 respectively). Though not significant, the authors discuss that the sample size available for evaluation at six months was small and may not be sufficient to determine statistical significance.
Additionally, patient compliance with sling immobilization was not evaluated at all, calling into question the internal validity of their study conclusions.

Arndt et al.\(^6\) followed 100 patients after repair of supraspinatus tendon tear who were randomized to be immobilized for six weeks and perform different therapy protocols following surgery. In the conservative therapy group, patients were placed into a sling following surgery and instructed to perform only pendulum exercises, while the aggressive range of motion group performed passive exercise three to five times per week while wearing a sling between sessions. Patients were followed for a minimum of 12 months and evaluated for changes in stiffness, range of motion, shoulder function scores and anatomy using Computed Tomography (CT). The aggressive range of motion group had significantly better external rotation (\(p = 0.011\)) and higher CM scores (\(p = 0.045\)) as compared to the conservative therapy group. There were no differences in retears between groups (\(p = 0.269\)). Strengths of this study include inclusion of patients who underwent concomitant procedures, such as biceps tenotomy and distal clavicle excision, and that retention of patients throughout the duration of the study was high, with only five patients lost to follow-up. However, it seems as though physical therapy activities were performed in the aggressive range of motion group based on the availability of the physical therapist, so it is hard to determine if all patients received the same level of care. Additionally, the authors make no mention of how compliance was monitored, if at all.

Cuff et al.\(^7\) followed 68 patients for one year after rotator cuff repair to evaluate differences between rotator cuff healing and range of motion in individuals assigned to perform early passive motion versus a delayed motion protocol. Patients were randomized following surgery, placed into a sling and instructed to wear them for six
weeks, with only the early motion group permitted to remove them during physical therapy. The early motion group performed therapy three times per week for six weeks, at which point they discontinued use of their sling and progressed to active range of motion by 10 weeks, followed by strengthening at 12 weeks. The delayed motion group remained in their sling for six weeks, performing only gentle pendulum exercises three times per day. After six weeks, they began formal physical therapy, which progressed to active range of motion and strengthening on a similar schedule as the early therapy group. After six months, the early range of motion group demonstrated greater forward elevation compared to the delayed motion group (p < 0.0001), with all other range of motion parameters being similar. After one year, there were no significant differences in range of motion, with early and delayed therapy groups achieving similar forward elevation (p = 0.06), external rotation (p = 0.67) and internal rotation (p = 0.99). Additionally, there were no differences in rotator cuff healing as determined by US between the two groups (p = 0.47). This study had unique inclusion and exclusion criteria compared to others evaluated thus far. For example, only patients with full-thickness crescent-shaped supraspinatus tears were included, with all other tear types, including those that were partial-thickness or involved infraspinatus or subscapularis, excluded. Achieving these metrics likely limited the number of patients who were eligible to participate in this study, which ultimately may have limited statistical power and interpretation of true associations. Additionally, the authors note that compliance between the two groups was not monitored at all, which could have led to discrepancies in range of motion or healing that were not readily identified.
Jenssen et al.\textsuperscript{8} performed a prospective randomized non-inferiority trial to determine if there were differences in postoperative outcomes for patients immobilized for three weeks versus six weeks. One hundred and twenty patients were randomized to either begin active range of motion exercises at three weeks (early) or six weeks (delayed). The early group wore a simple sling for three weeks while the delayed group wore an abduction pillow sling for six weeks. Patients were instructed to wear their sling at all times except when performing gentle pendulum exercises three times per day. Following the immobilization period, patients performed active range of motion with a physical therapist. After one year, there were no differences between the early group and the delayed group in Western Ontario Rotator Cuff (WORC) indexes, demonstrating that three weeks of immobilization was non-inferior to six weeks. Additionally, they also found that CM scores were similar between both groups after one year (p = 0.37) and that the quality of tendon healing for both groups was similar as determined by MRI (p = 0.97). Strengths of this study included the inclusion of patients with differing tear types and use of MRI for evaluation of retears. However, the primary outcome in this study, the WORC index, is comprised of mostly subjective questions regarding symptoms, function and emotion, which may inadvertently exclude objective information determined by a skilled provider. Additionally, compliance with post-operative protocols was patient-reported, adding to the subjective nature of this study.

Keener et al.\textsuperscript{9} followed 103 patients over a two year period to assess for differences in functional shoulder assessments, pain scores, strength and tendon integrity based on different rehabilitation protocols. Half of the patients were assigned to receive physical therapy starting the first week following surgery, while the other half were
assigned strict immobilization for six weeks. Both groups were placed in a sling, with those in the early therapy group permitted to remove them during therapy. During the first six weeks, those in the early group underwent therapist-supervised physical therapy, while patients in the immobilized group did not start therapy until week six. After three months, patients in the early therapy group had greater shoulder elevation ($p = 0.02$) and external rotation ($p = 0.05$) as compared to patients in the immobilized group, however, there were no retained differences after two years ($p > 0.15$ for each). Additionally, functional scores, such as the Visual Analog Scale (VAS) pain scores, ASES scores and CM scores, showed no significant differences between groups at any point during the two year follow up period ($p > 0.26$ for all). Lastly, healing rates as determined by US were similar between groups, with >90% of patients in each group having an intact repair after a minimum of 12 months ($p = 0.46$). Strengths of this study include the use of an independent examiner to collect clinical data throughout the duration of the study. Additionally, the study was powered at a level that was high enough to detect differences between groups. The authors do, however, disclose that compliance was only monitored based off of patient reporting, and no other means were implemented to determine if they adhered to treatment.

Kim et al.$^{10}$ evaluated 117 patients in the postoperative period to determine if early passive range of motion compared to strict immobilization during the first four to five weeks following surgery significantly affected shoulder function scores, pain scores and tendon healing. Both groups of patients wore slings, with the early mobilization group performing passive range of motion, including flexion, abduction and external rotation starting on day one following surgery. The immobilized group did not perform
passive range of motion until after at least four weeks of immobilization. After 12 months, there were no significant differences in forward flexion (p = 0.206), external rotation (p = 0.623), internal rotation (p = 0.854), ASES scores (p = 0.216) or CM scores (p = 0.854). Additionally, >80% of patients in each group achieved healing in their repaired tendon after one year as determined by CT or MRI, which was not significantly different between groups (p = 0.429). While this study analyzed a variety of objective and subjective outcome variables, researchers only included patients with small to medium sized tears and excluded those who had large tears. Despite this, their results may be generalizable to patients with those tear types. Lastly, they make no mention of any method to assess compliance during the period of immobilization following surgery.

Lee et al.\textsuperscript{11} evaluated early aggressive versus conservative rehabilitation in 64 patients undergoing repair of medium and large cuff tears. Individuals assigned to the early range of motion group started forward flexion and external rotation exercises on day one following surgery with the support of a therapist. Abduction slings were worn during all other times up to six weeks, at which point patients started active range of motion and strengthening exercises. The conservative group was instructed on the use of a continuous motion machine which allowed them to stretch up to 90 degrees and perform forward flexion. They were not allowed to perform external rotation. Patients in this group were immobilized at all other times up until six weeks when they began active assisted exercises. After the three month postoperative mark, patients in the early range of motion group had better forward flexion and abduction, though there were no differences in range of motion at one year (p > 0.13 for all). MRI scans demonstrated that 23% of patients in the early range of motion group had retears compared to 8% in the
conservative group, but there were no statistical differences (p = 0.106). Though the study population in this analysis is small, surgeries were performed by a single surgeon and study participants with specific tear types were targeted, reducing variability in surgical methods and homogenizing the participants. The authors acknowledge that confounders such as postoperative compliance and patient-specific factors were not evaluated and could have impacted the study’s internal validity.

Similar results regarding range of motion were demonstrated in a study by Sheps et al.\textsuperscript{12} who evaluated shoulder function and sling use in 189 patients with full thickness rotator cuff tears following open repair. Patients were instructed to perform passive range of motion exercises beginning on post-operative day one, but were assigned to either wear a sling at all other times up to the six week mark, or wear a sling only as needed for comfort. After six weeks, both groups underwent an identical rehabilitation protocol, the details of which were not disclosed. Patients assigned to the comfort group wore their slings significantly less than those assigned to the mandatory group (p < 0.001). Interestingly, only 83% of patients assigned to the mandatory group wore their sling compared to 8% assigned to comfort group. After six weeks, patients in the comfort group had greater abduction (p = 0.002) and scapular plane elevation (p = 0.006) compared to those in the mandatory group. However, there were no differences in range of motion after three months or afterwards (p > 0.51). Additionally, abduction strength, which was used as a surrogate marker for tendon integrity, showed no differences between groups (p = 0.84). This study was unique in that it was the first analyzed here that used an open repair technique as compared to an arthroscopic approach used by others. Though the authors included patients with varying tear sizes, the results may only
be generalizable to those undergoing this type of surgery. A large number of individuals were recruited for this study, with sufficient power to detect clinically important post-operative differences. Though compliance was assessed via patient reporting, it is uncertain if that data is reliable or meaningful here. Additionally, integrity of the repair after 24 months was assessed using strength testing, which may not be as accurate as MRI or US, but may be just as useful clinically.

Mazzocca et al.\textsuperscript{13} showed comparable outcomes in their analysis of 73 patients undergoing repair of a supraspinatus tendon tear. In their study, two groups of patients were immobilized with an abduction sling post-operatively and assigned to either begin range of motion exercises on day two following surgery or on day 28. The early motion group began active assisted exercises under the supervision of a therapist, including external rotation and forward elevation. The delayed motion group did not perform these exercises until after the four week mark. The primary outcome of this study was the WORC index, which showed no differences between groups after six months (p = 0.08). Additionally, there were no differences in retear rates between groups (p = 0.78). This study also measured patient-reported compliance, which demonstrated that 10 patients were non-compliant with their slings, with eight of those coming from the delayed motion group. Individuals who did not wear the sling also had higher rates of retear compared to those who were compliant (p = 0.05), though because compliance was monitored subjectively, the validity of that outcome is uncertain.

Clinical outcomes following different durations of immobilization were evaluated by Koh et al.\textsuperscript{14} in 88 patients in the postoperative period. Patients were randomly assigned to be immobilized in a sling for either four or eight weeks, during which time no
passive or active exercise were allowed, including pendulum exercises. After discontinuation of the sling after four or eight weeks, patients began gentle passive range of motion therapy, and progressed all the way to full activity as tolerated, which usually occurred around the six month postoperative mark. Patients were followed for a total of two years and various clinical outcomes were assessed at intervals during that time including range of motion, stiffness, functional assessments and retears. At the time of final follow-up, groups did not show significant differences in functional shoulder assessments ($p > 0.433$ for all) or range of motion ($p > 0.065$ for all), however, the eight week immobilization group showed significantly higher stiffness as compared to the four week group ($p = 0.038$). Additionally, there were no differences in retears between the two groups after six months ($p = 0.726$). The authors elucidate several limitations to the study, including compliance, which was only measured with subjective means, and therefore may not be accurate. Additionally, follow-up MRI’s were performed at an average of six months postoperatively, which may not provide good estimates of long-term clinical outcomes.

As discussed, there is large variability in the approach to the postoperative period following rotator cuff repair. There is evidence to suggest that shoulder function and adequate healing of the repaired tendon are dependent on a multitude of factors, with immobilization and rehabilitation playing a large role. Still, there is no definitive trend in terms of outcome with each rehabilitation approach, but what remains consistent is the lack of, or subjective nature, of compliance monitoring. To only assume that a patient is compliant, or to assess compliance based on patient reporting alone, may undermine the
results of the aforementioned studies. Patient compliance in medicine is not a new concern and has been evaluated across medical disciplines over the last few years.

2.2.3 Studies Examining Compliance Across Medical Disciplines

The World Health Organization (WHO) defines compliance as “the extent to which a person’s behavior, i.e. taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider.”\(^{15}\) This was adopted from the previous definition which read: “the extent to which the patient follows medical instruction”. As the provider-patient partnership has become more important, the former definition was deemed to be more fitting and captured that relationship well. Regardless, the magnitude of poor compliance in medicine is well recognized, especially in regard to chronic diseases, such as medication compliance in asthma and hypertension. There are an abundance of studies that have evaluated compliance across medical disciplines, which lends insight into the widespread nature of the problem as well as the methods available to measure it.

Ali et al.\(^{16}\) evaluated compliance with dietary changes, exercise and medication following coronary artery bypass grafting (CABG) in 265 patients. Patients were prescribed various postoperative protocols, including diet and exercise recommendations, and daily medication. Their compliance was measured with a questionnaire that also allowed the authors to make inferences about factors affecting compliance. After an average follow up time of six weeks, 45.3% of patients were non-adherent to dietary recommendations, 41.1% were non-adherent to exercise recommendation and 26% were non-adherent to taking prescribed medications. Various factors were also determined to be predictors of non-compliance, such as living alone and having a busy work schedule.
Despite using subjective questionnaires, this study still demonstrated that postoperative compliance was low, with numerous factors contributing to patient behavior. Because patients likely overreport compliance and introduce information bias, the estimates provided in this study may actually underestimate non-compliance. Additionally, patients were only followed for an average of six weeks after surgery, so it would have been interesting to see how behaviors changed over a longer time period.

In another study examining the postoperative period following CABG procedure, Paryad and Balasi\textsuperscript{17} examined compliance with smoking cessation in 94 patients. Telephone interviews were used to gather social information, ask questions regarding smoking habits and determine patient perception of illness. Six months following surgery, 26.6\% of patients began smoking again. The majority of patients in the study had good perception of their illness, which was not enough of a deterrence to avoid smoking for some. The use of a telephone interview to measure compliance is a straightforward and fairly easy tool to use to gather relevant data. However, as with a questionnaire, patients may underreport their compliance, which the authors in this study eluded to.

Direct patient interviews were also used by Raju et al.\textsuperscript{18} to measure compliance with wearing compressive stockings in patients diagnosed with chronic venous disease. During their six-year study, over 3,000 patients were interviewed and asked questions regarding use of physician-prescribed compressive stockings. Only 37\% of patients were found to have full or partial compliance, with 63\% not using them at all. Additionally, there was no difference in compliance between men and women ($p > 0.05$). If found to be non-compliant, patients were also given the opportunity to explain their reasons for non-
use. Among the most common responses were “unable to give a specific reason” (30%), “ineffective” (15%) and “discomfort” (13%). This study highlights the ease in asking direct questions about compliance, which can be added to the standard patient interview during routine follow-up. However, it is difficult to assess whether patients who identified as being compliant actually behaved in that manner, or whether or not they felt compelled to give a certain answer during their interview. For some patients, interviews may feel more invasive than a questionnaire completed in private.

Compliance has also been measured in patients following weight loss surgery, which was conducted by Dagan et al\textsuperscript{19} in their analysis of patients status-post laparoscopic sleeve gastrectomy. Seventy-seven patients were given postoperative dietary and lifestyle recommendations and were subsequently followed for one year. Various parameters such as physical activity and dietary intake were measured with questionnaires and food diaries respectively. Only a small proportion of individuals reported adequate protein intake according to the dietician recommended goal of >60 grams per day. At month three, 15.1% of patients met that goal, followed by 32.9% at month six and 40.3% at month 12. Similarly, patients who met the goal of >150 minutes per week of physical activity was also low, with 36.8% meeting it at three months, followed by 50.6% and 42.1% at six and 12 months respectively. Interestingly, the 77 patients who completed the entire study were older and more educated than the 23 who dropped out early (p = 0.015 and 0.032 respectively), which may lend insight into factors contributing to adherence with physician recommendations.

Turkoglu et al.\textsuperscript{20} examined compliance with cystoscopy follow-up in 126 patients who underwent resection of bladder tumors and compared that to assessment of their
health literacy using a questionnaire. Patients were also assigned either low risk or high-risk status based on the extent and severity of their tumors. Using this, the authors were able to show that low or high-risk status was a reasonable predictor of compliance rates ($r = 0.76$). In their analysis, they also demonstrated that patients with adequate health literacy had significantly higher treatment continuity rates compared to those with inadequate health literacy (80.5% vs. 56.5%, $p = 0.008$). Additionally, they found that individuals <65 years old had higher treatment compliance than those >65 years old ($p = 0.018$), which the authors explained as a function of cognitive decline. Though this study was only a single-center study, the data gathered was useful in that it used follow-up continuity as a measure of compliance. Attending follow-up appointments and undergoing tests is burdensome for some patients, and though it does not directly assess patient activities outside of the clinic, it demonstrates a patient’s willingness to adhere to a follow-up schedule, which is necessary to detect or prevent cancer reoccurrence in this particular patient group.

Methods to assess compliance have continued to evolve, especially as it pertains to monitoring patient use of medication. Methods have moved from subjective approaches, such as with a patient interview or with the use of a questionnaire, to more objective methods. Remaining dosage units, the medication event monitoring system (MEMS) and biochemical (serum) measurements have all been used to objectively monitor medication compliance, with each having their own efficacy and drawbacks. \textsuperscript{15} For example, Matsui et al.\textsuperscript{21} used remaining dosage units (i.e. pill counting) as a method to assess compliance with taking an oral iron chelator and found that counting inaccuracies were common and could result in over-estimation of adherence. Similarly,
Cramer et al.\textsuperscript{22} used MEMS to evaluate patient compliance with antiepileptic drugs, but found that patients often had difficulty using the system properly and widespread adoption of this system came at a significant financial cost. Vitolins et al.\textsuperscript{23} evaluated numerous medication compliance methods, such as serum drug level monitoring, which offered an effective means to measure therapeutic drug levels, but came with drawbacks such as varying rates of absorption and excretion between patients.

\textbf{2.2.4 Studies Examining Compliance in Orthopedics}

In the field of orthopedics, compliance monitoring is also important and helps to determine the efficacy of treatment. As with other medical fields discussed above, compliance in orthopedics has historically been measured with subjective means, which encounter the same issue of internal validity as previously described. Compliance has been studied extensively as it pertains to treatment of scoliosis, where adherence to bracing is necessary to halt curve progression.\textsuperscript{24} For example, both Lonstein and Winter\textsuperscript{25} as well as Wiley et al.\textsuperscript{26} evaluated brace wearing in the treatment of adolescent idiopathic scoliosis and made clinical recommendations based on the outcomes of their respective studies. However, compliance in both studies was measured with the use of a patient questionnaire. Similar conclusions can also be drawn in studies by Gurnham\textsuperscript{27} and DiRaimondo and Green\textsuperscript{28}, where patients reported brace-wearing time to a nurse. As with other medical fields, compliance monitoring in orthopedics has continued to evolve, with new technologies offering a more objective approach.

In a study evaluating brace-wearing compliance in patients with scoliosis, Takemitsu et al.\textsuperscript{24} compared patient-reported brace wearing times to data collected with temperature sensors installed in the braces. Sixty-one patients were given instructions for
wearing their brace, including the total time it was to be worn each day. At various clinical intervals, patients were asked by their physician to estimate their brace-wearing time since their last visit. Data was also downloaded from the embedded temperature sensor, which took recordings every 10 minutes and was capable of storing 225 days of data. Patients reported their overall compliance to be 85% of the total recommended wearing time, which was significantly higher than time recorded by the temperature sensor, which estimated compliance at 75% (p = 0.01). Additionally, age was a significant predictor of compliance, with younger patients demonstrating higher sensor-measured compliance compared to older patients (p = 0.025). This study was unique in that it demonstrated with clear, objective data what previous studies in other field have eluded to- that patient’s overreport their compliance. Though questionnaires or patient interviews offer a more convenient and inexpensive means to monitor compliance, this study highlights that self-reported bias must be recognized.

Morton et al. performed a similar study in which they evaluated compliance with brace-wearing in 124 adolescents with idiopathic scoliosis. Each of the patients was outfitted with a brace that had an embedded temperature sensor designed to capture readings every 15 minutes. Patients were prescribed daily wearing times of either 16 or 23 hours per day. They were also given a pre-treatment questionnaire where they evaluated the likelihood of brace-wear adherence throughout the study duration. Their reported wearing times were assessed at various clinical follow-up intervals. Pre-treatment questionnaires were positively correlated to actual adherence as monitored by the sensor (p < 0.001). Patients who thought their adherence would be low actually showed low adherence throughout the study duration. However, patients and their parents
significantly overestimated brace-wearing time when compared to actual wearing time via the sensor data (74% vs. 47% respectively, p < 0.001). These results are similar to the previously discussed study, where self-reported bias was evident. However, using a pre-treatment questionnaire as a simple means to predict compliance may allow physicians to forecast which patients need extra adherence incentive and education.

Karol et al.\textsuperscript{30} used findings from these previous studies in adolescent scoliosis to develop their own hypothesis regarding patient compliance with bracing- that patients would be more likely to wear their brace when they knew they were being monitored. Researchers divided 171 patients with scoliosis into two groups, all of which were outfitted with a temperature sensor inside of their brace that functioned in a similar manner as those described in previous studies. One group knew that the sensors recorded compliance data, and that data was shared with them during routine follow up as a means to counsel them about the importance of wearing their brace. The other group knew about the presence of the sensors, but were not informed that they measured compliance. After six months, brace wear in the counseled group averaged 15 hours per day compared to 12.5 hours in the non-counseled group (p = 0.0095). Brace wearing times were significantly different throughout the duration of the study, with patients from the counseled group averaging 13.8 hours per day and the non-counseled group averaging 10.8 hours per day (p = 0.002). Finally, researchers demonstrated that compliance counseling increased brace use by approximately 3.2 hours per day and decreased the number of patients requiring surgery by 11%. The conclusions drawn from this study were interesting in terms of how patient behavior changes when they know they are being monitored. The Hawthorne effect is not a new principle and has been described in other
studies examining adolescent scoliosis. However, it may offer clinicians more incentive to counsel their patients about treatment adherence in this field and others.

Compliance has also been studied postoperatively in patients undergoing foot and ankle surgery. Chiodo et al. enrolled 51 patients who underwent different foot and ankle procedures, but ultimately all required casting and strict non-weight-bearing status postoperatively. During the casting process, pressure sensitive film was placed between the stockinette and cotton, which captured any pressure exerted by the heel during walking. Patients were given instructions to remain non-weight-bearing during their follow up period. They were also informed about the presence of the pressure film but were not told explicitly that it monitored compliance. Casts were in place for an average of 24 days prior to pressure-film analysis, but patients were followed for a minimum of three months to assess post-operative complications such as pain and osseous non-union. Approximately 27% of patients were non-compliant with non-weight-bearing instructions, which was shown to be significantly influenced by warm outside weather (p = 0.04). Postoperative complications were reported in 42.9% of non-compliant patients and 29.7% of compliant patients, which were not significantly different (p = 0.51). This study again illustrates the tendency of patients to be less compliant with instructions that make their day-to-day lives more challenging. Ultimately, non-weight bearing protocols in this scenario were instituted to reduce post-operative complications, but these were not found to be influenced by compliance. However, the patients underwent various procedures, which could have been a confounding factor that was not explored thoroughly. Additionally, there were only 51 patients in the study, which reduced the statistical confidence in assessing postoperative complications.
Temperature sensors have also been used following foot and ankle surgery to monitor patient compliance with wearing compressive stockings, which are thought to help mitigate pain and swelling postoperatively. Grubhofer et al.\textsuperscript{33} evaluated 76 patients for pain, swelling and functional scores at various intervals following hindfoot and ankle procedures. Half of them were randomized to receive compressive stockings outfitted with temperature sensors, and given strict instructions regarding daily use. The other half of the patient cohort did not wear stockings at all. After six weeks, patients in the stocking intervention group had an average wearing time of 136 hours, which translated to a compliance rate of 65%. Interestingly, over half of the intervention group had an average compliance rate of 16%. Despite this, there were no differences in pain, swelling or functional scores between patients with high versus low compliance (\( p > 0.15 \) for all) or between patients in the intervention group and the control group (\( p > 0.22 \) for all) after 12 weeks. This study further demonstrates the issue of patient compliance, the reasons for which were not explored fully. There were no clinically significant differences in postoperative outcomes, but this could be attributed to the relatively short follow-up time of 12 weeks, or that multiple types of foot and ankle procedures were included in the study.

2.2.5 Compliance as it relates to the Shoulder

As discussed in previous sections, the significance of compliance with postoperative protocols following rotator cuff repair is poorly understood, some of which can be attributed to the lack of objective data available to clinicians and patients. Previous studies, such as the one conducted by Silverio and Cheung\textsuperscript{34}, evaluated patient adherence to postoperative restrictions with the use of a questionnaire following surgery. Fifty
patients underwent rotator cuff repair by a single surgeon and were placed in abduction pillow slings with instructions to wear them for 23 hours per day, coming out only to perform hygiene and simple pendulum exercises. At their six-week follow-up appointment, their compliance to sling immobilization was assessed with a questionnaire, the results of which were used to calculate compliance rates. Additionally, patients were followed clinically for 11 months to note changes in ASES scores, the University of California-Los Angeles scores (UCLA) and the Simple Shoulder Test (SST). Average adherence after six weeks was estimated to be 88% and was not significantly correlated to changes in ASES scores (p = 0.765), UCLA scores (p = 0.665) or SST scores (p = 0.141). Variables such as injury location, nature of injury, repair complexity, comorbidities, living status and employment status, were not significantly correlated with compliance (p > 0.061 for all), except in the case of smoking where non-smokers had lower reported compliance when compared to smokers (p = 0.004). Strengths of this study include using a single center, single surgeon approach, which likely standardized and reduced variability with surgical procedures and patient follow-up. However, it falls into the same category of other studies that have used subjective data, like a questionnaire, to monitor compliance. Furthermore, elucidating any correlation between surgical outcome and compliance is difficult to make in this study.

Ahmad et al.\textsuperscript{35} evaluated 125 patients in the postoperative period following rotator cuff repair to determine if factors such as compliance with rehabilitation protocols affected the integrity of the repaired tendon. Surgery was performed by a single senior orthopedic surgeon, who instructed patients to remain completely immobilized in a sling for two weeks after surgery, followed by four weeks of intermittent table exercises with
sling use in between. After six weeks, sling use was discontinued and patients were allowed to begin formal physical therapy, which included gentle passive and active-assisted movements. Compliance with the postoperative protocols was monitored by a nurse, who completed patient interviews every six, 12 and 26 weeks, and asked various open and close-ended questions regarding patient activity at home. US was performed at the same intervals after surgery to assess for tendon retear. The incidence of cuff retear at six, 12 and 26 weeks was 13.4%, 25.2% and 29.1% respectively. Percentage of patients deemed to have poor compliance with postoperative rehabilitation during each of the three time frames were 9.1%, 17.3% and 16.4% respectively, which were found to be significantly associated with cuff retears (p < 0.001). Other factors, such as tear size, tendon quality, cuff retraction and repair tension were also significantly associated with retear (p < 0.01 for all). Though not explicitly evaluated in this study, the authors suggest that two groups of non-compliant patients likely exist: those who do not comply with simply wearing a sling and those who do not follow more complex rehabilitation after sling removal. This highlights the importance of reinforcement and monitoring even after the sling is discontinued and patient compliance may be more likely to be compromised. Strengths of this study include the large number of patients evaluated and the standardized surgical technique performed by a single surgeon. Though a significant association was found between compliance and cuff retears, compliance may be underestimated because it was subjectively measured.

In an effort utilize a more objective means of compliance monitoring following rotator cuff repair, Sood et al.\textsuperscript{36} investigated the accuracy and utility of temperature sensors placed in shoulder slings. Sensors were placed in three different sling locations
along the wrist, elbow and abdomen of four healthy volunteers who were instructed to wear their slings as much as possible but were allowed to remove them to complete daily activities as needed. Volunteers were also instructed to keep detailed timetables of sling wear to compare to that measured by the sensors. Total sling wear time as estimated by the volunteers was 171.63 hours. The diagnostic accuracies of the sensors were 99.5%, 99.1% and 99.3% at the abdomen, elbow and wrist respectively, with no significant differences between locations (p > 0.05). This study illustrated that temperature sensors can accurately measure sling wearing times and are thus capable of being used to monitor compliance, which has been demonstrated in other orthopedic specialties discussed previously.

Grubhofer et al. employed this technique to compare self-declared brace wearing times to sensor-monitored wearing times and evaluate the long-term clinical effects associated with compliance behavior following rotator cuff repair. Fifty patients underwent repair of supraspinatus tendon tear and were outfitted with shoulder abduction braces, which had temperature sensors installed near the abdominal portion of the sling. Patients were instructed to wear the brace 23 hours per day for six weeks, or 966 hours total. One day after surgery, passive joint mobilization was initiated while patients remained in their sling. Active-assisted and active range of motion was allowed six weeks postoperatively, followed by light weight-bearing at 10-12 weeks and full weight bearing at 16 weeks. Patients were notified about their participation in a compliance study, but the sensor was not mentioned until their six-week follow-up appointment, at which point they could either agree or decline to remain in the study. After six weeks, patients estimated their compliance to be 96% of the recommended wearing time, which was
significantly higher than the compliance rate of 75% as measured by the sensors (p < 0.001). Additionally, only 48% of patients showed an objective compliance rate of >80%, with two patients in the low compliance group (<80%) abandoning their brace after two weeks. There were no correlations between compliance and gender, educational status, shoulder dominance, smoking, age or living status (p > 0.094 for all).

In their follow-up analysis, the authors consulted with 46 of the original 50 patients, who were available for US examination and for functional shoulder assessments including the CM score and the SSV. Using a Receiver Operating Curve (ROC), a cutoff value of 60% compliance was estimated for discriminating between intact versus retear groups. The Odds Ratio for having a retear with a compliance rate of <60% compared to >60% was 13 (p = 0.037). The overall retear rate was 8.7%, with three out of four retears coming from the low compliance (<60%) group. There were no differences in functional shoulder assessments between the two groups (p > 0.474 for all). Subgroup analysis of the four patients with retear versus 42 without retear revealed significantly lower rates of compliance in the retear group (47%) compared to the no retear group (79%) (p = 0.011). This study was the first to quantify the association between objectively measured immobilization compliance and long-term clinical outcomes following rotator cuff repair. It demonstrated the feasibility of such a study, where compliance is monitored for a short duration and simple clinical outcomes are assessed during the postoperative period. However, given that only 50 patients were included in the initial portion, with 46 retained for clinical follow up and only four in the final subgroup analysis, no definitive conclusions can be drawn. Additionally, patients with combination supraspinatus and subscapularis tears were excluded, which may affect the generalizability of the findings.
Thus, the need for a larger prospective study that includes a larger cohort of patients and does not exclude them based on tear type is warranted to determine the true association of compliance and long-term clinical outcome following rotator cuff repair.

2.3 Literature Review Conclusion

Upon reviewing the literature, it is evident that there are no definitive guidelines available for physicians or their patients for rehabilitation during the immediate period following rotator cuff repair. Optimal rehabilitation protocols have not yet been published, and the duration and necessity of immobilization continues to be debated. It is clear, however, that compliance with immobilization is a concern and must be evaluated to quantify the optimal period of immobilization. With new technology allowing the objective measure of compliance, a large prospective study is feasible and necessary to better inform postoperative rehabilitation guidelines following rotator cuff repair.
2.4 References

CHAPTER 3: STUDY METHODS

3.1 Study Design

This study design will be a prospective cohort study examining rotator cuff retears among varying levels of compliance.

3.2 Study Population and Study Site

This study will take place at the Yale-New Haven Hospital system. We will recruit patients from the Orthopedic Surgery Department where six fellowship-trained orthopedic surgeons perform rotator cuff repairs. All patients will be evaluated for eligibility after making their decision to have surgery. The population will be adults undergoing first time repair of rotator cuff tear.

Enrollment and surgeries will take place in the first six to 10 months of the study. Adults 18 years or older undergoing first time repair of rotator cuff tear are eligible for inclusion. Participants will have had clinical and/or MRI diagnosis of rotator cuff tear. There are no criteria for size, thickness or number of tendons involved. Additionally concomitant procedures performed at the time of repair, including biceps tenodesis, distal clavicle excision and decompression, will not exclude patients from participating. Exclusion criteria include any patient presenting with retear of a previously repaired tendon.

3.3 Recruitment

We will recruit patients via convenience sampling during their preoperative appointments in the weeks leading up to surgery. Consent will be obtained from patients for participation, and they will be informed that sensors will be placed inside of their abduction pillow slings as a means to monitor sling-wearing compliance after surgery.
Patients will be informed that there are no additional risks for participation in the study and that the data obtained will not change the course of their treatment.

3.4 Operative and Rehabilitation Guidelines

Operative Procedure: Patients consented for the study will undergo arthroscopic repair by the attending physician via either single row or double row suture technique. Concomitant procedures and characteristics of the repair, including size, thickness and tendon involvement will be recorded during surgery. Upon conclusion of the procedure, patients will be placed into shoulder abduction slings, with temperature sensors invisibly placed into the abdominal portion of the brace.

Sensor Information: The temperature sensor used in the study will be provided by Orthotimer®. They have the capacity to store the time, date, and temperature every 15 minutes with accuracy +/- 0.1°C. The sensor is operated by a Lithium dry cell battery that has a lifespan of 18 months or more. It measures 9x13x4.5 mm and stores data for up to 100 days. Data can be downloaded wirelessly with a reader that transmits patient wear times to Orthotimer® software for analysis.

Sling Wearing and Rehabilitation Guidelines: Patients will be instructed to wear their slings 22 hours per day for six weeks, or 924 hours total. They may remove them only for personal hygiene and for rehabilitation as indicated (~2 hours per day, 1 hour at a time). The rehabilitation schedule during the six months following surgery will involve one-on-one sessions with trained physical therapists who will help patients transition from passive range of motion exercises to stretching, active range of motion and finally strengthening (Appendix A). Assuming adequate tendon healing, patients can expect to resume regular activities six months following surgery.
3.5 Study Variables and Measures

Demographic Variables: Demographic variables measured will include age, sex, BMI, living status, hand dominance and employment status (type of work).

Assessment of Compliance Rate (Independent Variable): Compliance rate, or the time spent wearing the sling out of the total recommended time, will be calculated as follows:

\[
\text{Compliance Rate} \% = \left( \frac{\text{Total Time in Sling (hours)}}{924} \right) \times 100
\]

Patients will be separated into three groups based on their compliance rate: low (0-33.3%), medium (33.4%-66.7%) and high (66.8%-100%).

Primary and Secondary Outcomes (Dependent Variables): The primary outcome will be rotator cuff retear in the first year after surgery as determined by ultrasound (US), which will be considered a dichotomous variable. Secondary outcomes will include functional shoulder assessments including the Simple Shoulder Test (SST) score, Constant Murley (CM) scores and Single Assessment Numerical Evaluation (SANE) score, which are a combination of subjective and objective questions regarding pain, activities of daily living, range of motion and strength (see Appendix B).

Confounding Variables: Confounding variables assessed during the analysis include tendon involvement, size of tear and hand dominance.

3.6 Blinding

Blinding of Compliance Rate and Outcome: Completely blinding patients to our assessment of compliance will not be possible since they must agree to participate in the study and because they will be informed that the sensors monitor sling-wearing time. However, to reduce any effect that their knowledge of the study has on sling-wearing behavior, sensors will be hidden from plain sight. Physicians, physical therapists and
radiologists will be blinded to patient compliance level during routine follow-up and examination.

3.7 Data Collection

Demographic and confounding variables will be recorded pre or postoperatively as indicated. Compliance data will be downloaded from the sensors at postoperative follow-up appointments during week one, three and six. Based on data from previous studies, if a threshold value of 35°C is exceeded, then this will be interpreted as brace-wearing time. Patients will complete SST, CM and SANE evaluations pre-operatively and at follow-up intervals of three, six and 12 months. At the six and 12-month follow-up visits, patients will also undergo US by a radiologist to evaluate the integrity of the repair and assess for retear. Additionally, any patient that experiences recurrent pain or discomfort will be evaluated via US as needed.

3.8 Sample Size Calculation

Sample size calculations were estimated using data from a previous study by Lee et al.\(^1\) in their examination of post-operative rehabilitation protocols after rotator cuff repair. Because prior studies examining compliance in this particular field are limited, early aggressive rehabilitation was used as a marker for low compliance and conservative rehabilitation was used as a marker for high compliance. Data provided by Lee et al. show that the retear rate among individuals assigned to an aggressive rehabilitation group is 23\% versus 8\% for those assigned to a conservative rehabilitation group. We used the Power and Precision tool by Biostat Inc. to determine the sample size necessary to observe a 15\% effect size between each compliance group (Appendix C). With power set at 80\% and alpha at 0.05 for a one-tailed hypothesis, the calculated sample size was 70
people for the high compliance group, 120 people for the medium compliance group and 120 people for the low compliance group. After correcting for three confounders and losses to follow up, the total number of individuals needed was estimated to be 400.

3.9 Analysis

The primary outcome will be analyzed using the intention to treat protocol. A bivariate analysis using simple logistic regression will be performed to assess the association between the three compliance levels and rotator cuff retear. We will also use receiver operating characteristic (ROC) curves to determine the optimum cutoff value of compliance for distinguishing between 1) in-tact and failed repairs after one year and 2) normal range of motion and development of frozen shoulder using Constant Murley scores after one year. Additionally, we will perform multivariate analysis using multiple logistic regression to assess the association between compliance levels, retears and confounding variables (tendon involvement, size of tear and hand dominance).

Differences in demographic variables and secondary outcome variables between the low, medium and high compliance groups will be compared using Analysis of Variance and Chi-square test as indicated.

3.10 Timeline and Resources

The proposed study will take place over the span of two years, and we expect patients to be recruited and undergo operations prior to the one-year mark. Final data collection, including clinical follow-up and US, will be conducted up to month 20, with manuscript composition overlapping this period up to the end of 24 months.

Personnel needed for the study include six orthopedic surgeons and their accompanying clinical staff. Data will be collected at follow-up intervals by the
overseeing physician or research assistant. Additionally, trained physical therapists will be needed to institute rehabilitation in the weeks following surgery. One to two trained radiologists with expertise in US diagnosis of rotator cuff tear will also be required.
3.11 References

CHAPTER 4: CONCLUSION

4.1 Advantages and Disadvantages

This is the first study to objectively quantify compliance with postoperative sling immobilization in patients undergoing rotator cuff repair without excluding patients based on tendon involvement. Other studies have also used objective means to assess the relationship between compliance and long-term clinical outcomes, but the patient population was too small and homogenous to make definitive conclusions that would inform management for providers.\textsuperscript{1,2} We think that by including a larger number of patients with varying degrees of tendon involvement, and by comparing more than two levels of compliance in our outcome analysis that we have the opportunity to yield more generalizable information to a wider population of patients. Through our study design, we hope to elucidate the utility of postoperative immobilization, with enough study participants to achieve high statistical power, while also taking into account confounding variables. We hope to yield results that will inform optimal rehabilitation guidelines following surgery that are generalizable to all patients undergoing primary rotator cuff repair.

The proposed study does have limitations. For example, though physicians, assistants and therapists are blinded to patient compliance rate, it is not possible to completely blind patients to their intervention. From analysis of previous studies, the Hawthorne principle has been shown to introduce bias, which may not be escapable here.\textsuperscript{3,4} Though we hope that by installing the sensors discretely that we can reduce this. Additionally, for our secondary analysis, we have selected three tests to quantify shoulder functionality and range of motion: 1) the Subjective Shoulder Value, 2) the Constant
Murley Score and 3) the Single Assessment Numerical Evaluation. Though there are dozens more that exist and have shown clinical utility, we chose the most commonly used tests by Yale orthopedists and do not think that omitting others reduces the value of our study results.

4.2 Clinical and Public Health Significance

The field of orthopedic surgery has made considerable progress in terms of the minimally invasive arthroscopic approach to rotator cuff repair. Additionally, with the use of advanced imaging techniques such as MRI, the extent of a patient’s condition prior to their operation is known with near certainty. However, there still remains significant uncertainty with respect to immobilization during the early postoperative period, which is arguably the most important time frame for patients during their recovery. The results of this study will help to fill this knowledge gap with clear, generalizable data to help inform postoperative guidelines. Knowing the optimal period of immobilization, where the incidence of retear and the development of frozen shoulder are minimized, may improve long-term clinical outcomes for patients.

Because there remains considerable variation in the literature with respect to postoperative immobilization protocols, the confidence with which providers prescribe guidelines to their patients is limited. The true necessity of six weeks of immobilization is uncertain, but represents a long and difficult period for patients without the use of their extremity. This is especially difficult for patients with comorbid disabilities or those who have injured their dominant extremity and may reduce their ability to perform activities of daily living, such as personal hygiene or meal preparation. Patients with comorbidities who have access to adequate help at home may still be able to meet daily immobilization
requirements. However, patients who live alone without access to additional help may find an extended immobilization period to be burdensome and ultimately not feasible. Therefore, if our results demonstrate that a shorter period of immobilization provides better or equivalent long-term outcomes compared to six weeks, then the early postoperative period may prove to be less burdensome for patients and for their caregivers.

Patient compliance across medical specialties is a global problem, but technology to objectively monitor patients has continued to evolve. This study will not only illustrate the necessity of objective compliance monitoring, but the feasibility of using this method following rotator cuff repair to predict long-term outcomes. We hope to ultimately inform physicians, physician assistants and other providers so they can prescribe postoperative immobilization and rehabilitation protocols with confidence, and increase the long-term clinical success of their patients.
4.3 References


APPENDIX A: Postoperative Rehabilitation Protocol

Week 1:
1. No exercises done during the first week following surgery.
2. Patients to remain in sling at all times except while bathing.

Week 2 to Week 4:
1. Stitches to be removed during this week.
2. Patients will attend formal physical therapy sessions to begin PASSIVE range of motion exercises, including pendulums, external rotation and elevation.
3. Patients to remain in sling at all times except while bathing and attending therapy.

Week 5 to Week 6:
1. Patients to continue PASSIVE range of motion exercises as described above with the help of a physical therapist.
2. Patients may discontinue use of their sling after reaching their six week postoperative date.

Week 7 to Week 12:
1. Patients will begin ACTIVE-ASSISTED and ACTIVE range of motion exercises, including table-slides and wall-walking with the help of a physical therapist.
2. Patients should not lift, push or pull anything heavier than one pound, and should not do any overhead lifting.

3 Months Postop:
1. Patients may begin gentle strengthening exercises at this time, utilizing a resistance band to perform internal and external rotation.
2. Patients will continue performing range of motion exercises as described above.
3. Patients should not lift, push or pull anything heavier than five pounds, and should not do any overhead lifting.

4 Months Postop:
1. Patients will continue range of motion and strengthening exercises as described above.
2. Patients should not lift, push or pull anything heavier than 10 pounds, and should not do any overhead lifting heavier than five pounds.

5 Months Postop:
1. Patients will continue range of motion and strengthening exercises as described above.
2. Patients should not lift, push or pull anything heavier than 15 pounds.

6 Months Postop:
1. Patients may resume normal activities at this time as indicated.
APPENDIX B: Simple Shoulder Test, Single Assessment Numerical Evaluation, Constant Murley

SIMPLE SHOULDER TEST (SST): (Circle: Left Shoulder/Right Shoulder)

Circle the best description of your shoulder function:

1) Is your shoulder comfortable with your arm at rest by your side?
   a. Yes
   b. No
   c. Don’t Know

2) Does your shoulder allow you to sleep comfortably?
   a. Yes
   b. No
   c. Don’t Know

3) Can you reach the small of your back to tuck in your shirt with your hand?
   a. Yes
   b. No
   c. Don’t Know

4) Can you place your hand behind your head with the elbow straight out to the side?
   a. Yes
   b. No
   c. Don’t Know

5) Can you place a coin on the shelf at the level of your shoulder without bending your elbow?
   a. Yes
   b. No
   c. Don’t Know

6) Can you lift 1 pound (a full pint container) to the level of your shoulder without bending your elbow?
   a. Yes
   b. No
   c. Don’t Know

7) Can you lift 8 pounds (a full gallon container) to the level of your shoulder without bending your elbow?
   a. Yes
   b. No
   c. Don’t Know
8) Can you carry 20 pounds (a bag of potatoes) at your side with the affected extremity?
   a. Yes
   b. No
   c. Don’t Know

9) Do you think you can toss a softball underhand 10 yards with the affected extremity?
   a. Yes
   b. No
   c. Don’t Know

10) Do you think you can throw a softball overhand 20 yards with the affected extremity?
    a. Yes
    b. No
    c. Don’t Know

11) Can you wash the back of your opposite shoulder with the affected extremity?
    a. Yes
    b. No
    c. Don’t Know

12) Would your shoulder allow you to work full-time at your regular job?
    a. Yes
    b. No
    c. Don’t Know

**Scoring:** Percent of questions answered “Yes”, with 0 being the worst function and 100 being the best function.

**SINGLE ASSESSMENT NUMERICAL EVALUATION (SANE)**

How would you rate your affected joint as a percentage of normal (0-100% scale with 100% being normal)?
CONSTANT MURLEY (CM)

Patient Completed Portion

A. Pain (/15): Average 1 & 2
   1. Do you have pain in your shoulder with normal activities?
      a. No = 15 pts
      b. Mild pain = 10 pts
      c. Moderate = 5 pts
      d. Severe/Permanent = 0 pts

   2. If “0” means no pain and “15” is the maximum pain you can experience, please indicate where your level of pain in your shoulder is. (Points given are inverse to the scale. For example, a level 5 is equivalent to 10 points.)

B. Activities of Daily Living (/20): Total (1+2+3+4)
   1. Is your occupation or daily living limited by your shoulder?
      a. No = 4
      b. Moderate Limitation = 2
      c. Severe Limitation = 0

   2. Are your leisure and recreational activities limited by your shoulder?
      a. No = 4
      b. Moderate Limitation = 2
      c. Sever Limitation = 0

   3. Is your night sleep disturbed by your shoulder?
      a. No = 2
      b. Sometime = 1
      c. Yes = 0

   4. To what level can you use your arm for painless activities?
      a. Above head = 10
      b. Head = 8
      c. Neck = 6
      d. Xiphoid (sternum) = 4
      e. Waist = 2
      f. Below waist = 0
Physician Completed Portion

C. Range of Motion (/40): Total (1+2+3+4)

<table>
<thead>
<tr>
<th>Movement</th>
<th>Range of Motion (Degrees)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0-30</td>
</tr>
<tr>
<td>1. Flexion</td>
<td></td>
</tr>
<tr>
<td>2. Abduction</td>
<td></td>
</tr>
</tbody>
</table>

Flexion and abduction are recorded with a long-armed goniometer. Check one box to indicate maximum extent of pain-free movement.

3. External Rotation of both arms simultaneously but recorded for only the affected side. Indicate all that apply. Must be painless.
   a. Hands behind head, elbows forward (+2)
   b. Hands to the top of the head, elbows forward (+2)
   c. Full elevation of the arms (+2)
   d. Hands behind head, elbows back (+2)
   e. Hands to the top of the head, elbows back (+2)

4. Internal Rotation of only the affected arm. Patient should use their thumb to point to anatomic landmarks. Check one box for most advanced, painless movement.
   a. Lateral aspect of the thigh (+0)
   b. Behind the buttock (+2)
   c. Sacroiliac joint (+4)
   d. Waist (+6)
   e. 12th thoracic vertebra (+8)
   f. Interscapular level (+10)

D. Strength (/25): Measured with a dynamometer. Patient will stand shoulder width apart with arm abducted 90 degrees in the scapular plane. The wrist is pronated and elbow extended maximally. The dynamometer strap should be placed around the wrist. The patient should be instructed to push upwards for 5 seconds. The average of 3 attempts is recorded, with 25 being the maximum score.
   a. 1st attempt: __
   b. 2nd attempt: __
   c. 3rd attempt: __
   d. Average: __

Constant Murley Score (max 100 pts)
Sum of A, B, C, D = ______
### APPENDIX C: Sample Size Calculation

<table>
<thead>
<tr>
<th>Group</th>
<th>Proportion Positive</th>
<th>N Per Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Compliance</td>
<td>0.38</td>
<td>120</td>
</tr>
<tr>
<td>Medium Compliance</td>
<td>0.23</td>
<td>120</td>
</tr>
<tr>
<td>High Compliance</td>
<td>0.08</td>
<td>70</td>
</tr>
</tbody>
</table>

Rate Difference: -0.15  
Alpha: 0.05  
Tails: 1  
Power: 80%

Power and Precision, Biostat Inc.
BIBLIOGRAPHY


