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A RANDOMIZED CLINICAL TRIAL TO COMPARE THE OUTCOMES OF PATIENTS WHO UNDERGO AN ARTHROSCOPIC BANKART REPAIR WHO ARE IMMOBILIZED POSTOPERATIVELY IN EXTERNAL VERSUS INTERNAL ROTATION

Stephane Vlachos

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By

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The thesis by

Stephane Vlachos

entitled:

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ABSTRACT

Study Design: Randomized Clinical Trial

Objectives: To determine the effect of immobilization in external rotation (ER) compared to internal rotation (IR) following arthroscopic Bankart repair on: 1) range of motion (ROM) and 2) quality of life (QOL) and functional scores.

Background: Cadaveric and magnetic resonance imaging studies suggest ER more closely approximates the edges of the Bankart lesion and increases contact force between the glenoid labrum and the glenoid, which may allow repaired structures that are immobilized in this position to heal in more a "natural" anatomical position than with IR.

Methods and Measures: Participants were randomly assigned to an ER brace or an IR sling. ROM measures were taken along with QOL and function scores preoperatively and at two, four, six and twelve weeks postoperatively.

Results: ER ROM was significantly higher in the brace group compared to the sling group. There were no significant differences in forward flexion, abduction or Patient Reported Outcomes.

Conclusions: Further research that is adequately powered to test these hypotheses is required.

Key Words: Arthroscopic Bankart Repair, Immobilization, External Rotation.

EPIGRAPH

Failures are made only by those who fail to dare,
not by those who dare to fail.

- Lester B. Pearson

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Chapter 1

Introduction

Chapter 1 – Introduction

The shoulder is one of the most mobile joints in the body, allowing for a wide degree of functional range of motion in multiple planes. However, stability is compromised as a result of this freedom of motion, which makes the shoulder one of the most commonly dislocated joints in the body (1). Anterior traumatic dislocation is the most common injury of the shoulder, accounting for 96% of all glenohumeral dislocations (1). The treatment of an anterior glenohumeral dislocation has traditionally consisted of a period of immobilization in a sling with the arm internally rotated against the body. There is little consensus on the length of time of immobilization with different sources recommending periods ranging from as little as two days to as long as eight weeks, though clinically most patients are immobilized between two and four weeks (2-6).

Several studies have advocated surgical stabilization as the primary treatment for shoulder dislocation citing better functional outcomes and lower rates of recurrence when compared to nonsurgical treatment, particularly in a young active population (7-10). When performing a surgical stabilization, most surgeons prefer an arthroscopic approach to the more traditional open procedure, due to arthroscopy's improved cosmesis, superior intra-articular visualization, minimized disruption of anterior soft tissues and decreased morbidity (7, 8, 11-13).

Recent cadaveric and magnetic resonance imaging (MRI) studies have suggested that immobilization in an externally rotated position may result in better healing and functional outcomes (14-16) with the injured structures healing in a more "natural" position. Although there has been some evidence to suggest that immobilization in external rotation may be of benefit to patients following a traumatic anterior dislocation (17), research in this area is limited, has produced mixed results and has only involved patients undergoing conservative treatment (17, 18).

This study will examine the effect of immobilization position on range of motion and patient reported outcomes of quality of life and function, at six weeks postoperative in patients having undergone arthroscopic anterior stabilization for anterior dislocation with an associated Bankart tear. It is believed that immobilization in external rotation will lead to greater range of motion and improved patient quality of life and function, leading to a quicker return to sport for young active patients.

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Chapter 2

Literature Review

Chapter 2 – Literature Review

Anatomy

The glenohumeral joint is a ball and socket joint between the humeral head and the glenoid cavity of the scapula (Figure 2.1). The glenoid labrum is a fibrocartilaginous ring surrounding the glenoid cavity (Figure 2.2) adding depth to the joint (1) and improving its inherent stability. The anterior portion of the labrum serves as one of the primary passive anterior stabilizers of the glenohumeral joint (2). Anterior stability is also provided by the fibrous joint capsule (Figure 2.3), which surrounds the glenohumeral joint and attaches to the margin of the glenoid and the anatomical neck of the humerus (1). The glenohumeral ligaments are band-like thickenings of the anterior capsule and serve to strengthen it anteriorly (3). The inferior glenohumeral ligament (IGHL) is the most important of the glenohumeral ligaments in terms of providing passive anterior stability (2, 3), particularly in an abducted and externally rotated position (4, 5). At 90º of abduction, the anterior band of the IGHL is the principal structure blocking an anterior dislocation (4).

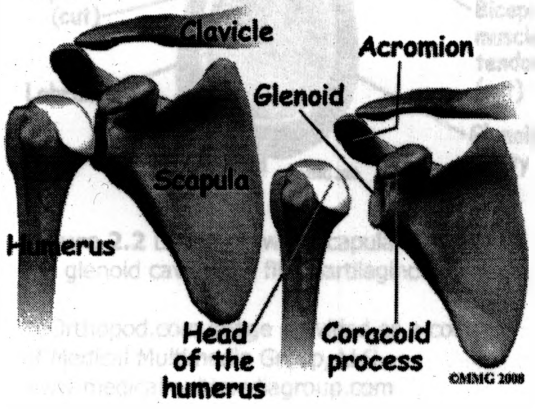

Figure 2.1 Bony anatomy of the shoulder joint.

*eOrthopod.com image provided as a courtesy of Medical Multimedia Group, LLC www.medicalmultimediagroup.com

The subscaplularis muscle of the rotator cuff also provides a degree of static stability to the anterior portion of the shoulder in the lower ranges of abduction (4). The subscapularis also provides dynamic stability for the shoulder joint, along with the remainder of the rotator cuff complex (4, 6). The long head of the biceps has also been identified as having a role in providing anterior stability to the shoulder by increasing torsional rigidity and resisting excessive external rotary forces that can lead to instability (5). It may also play a protective role by reducing the strain that is placed on the IGHL. Its effectiveness in providing anterior stability can be compromised, however, by the presence of a superior labrum anterior posterior (SLAP) lesion, which affects the long head of the biceps tendon's site of insertion resulting in decreased torsional rigidity and increased strain on the IGHL (5).

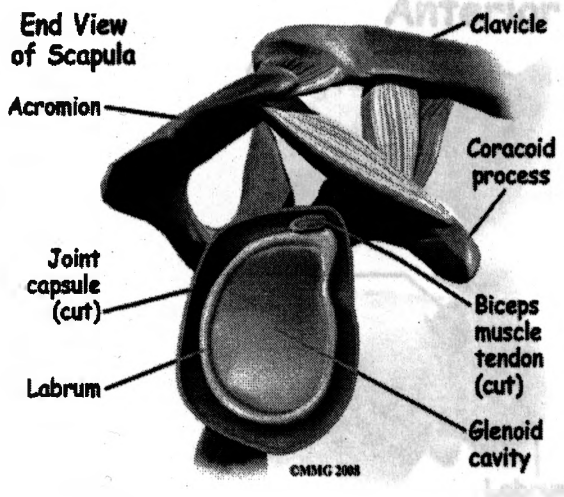

Figure 2.2 Lateral view of scapula displaying the glenoid cavity and fibrocartilaginous labrum.

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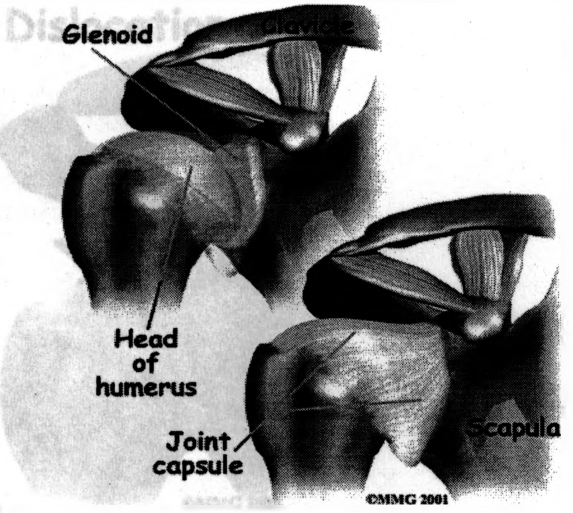

Figure 2.3 Anterior view of the shoulder joint displaying the fibrous joint capsule.

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Mechanism of Injury

An anterior dislocation of the glenohumeral joint usually occurs when excessive force is placed on the humerus while the shoulder is in an abducted and externally rotated position. The head of the humerus moves infero-anteriorly onto the inferior weak part of the joint capsule and results in the separation of the capsule and labrum from the anterior aspect of the glenoid (1) (Figure 2.4). The resulting avulsion of the capsule and anterior labrum is commonly referred to as a Bankart lesion (7) and is present in most patients who have sustained an anterior dislocation (2). Biomechanical studies have found that a Bankart lesion alone is insufficient to allow for a shoulder dislocation (8-10). By using cadaveric models and artificially creating Bankart lesions, Pouliart et al (9) concluded that anterior and/or posterior stabilizing structures needed to be compromised, in addition to a Bankart lesion, before a complete anterior dislocation would occur.

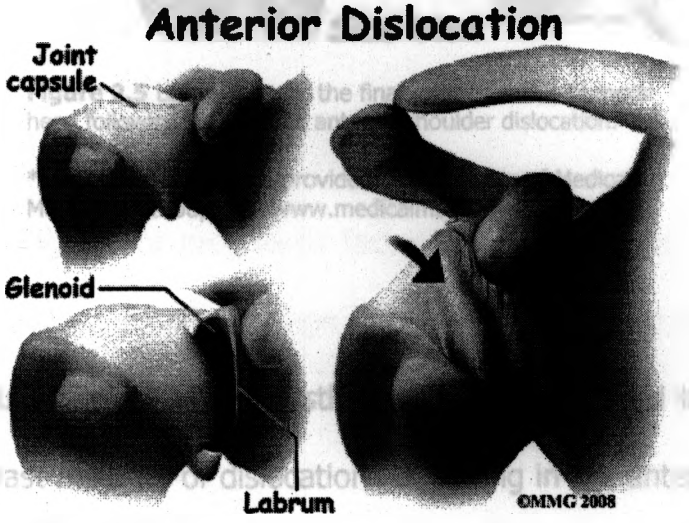

Figure 2.4 Movement of the humeral head infero-anteriorly, resulting in separation of the capsule and labrum from the glenoid.

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Once dislocated, the head of the humerus is usually pulled into the subcoracoid space by the strong flexor and adductor muscles (1) (Figure 2.5). The contact between the posterior surface of the humeral head and the anterior portion of the infraglenoid tubercle often results in a compression fracture referred to as a Hill-Sachs lesion. This fracture along with a variety of other injuries such as a greater tuberosity fracture, capsular stretching, SLAP lesions and rotator cuff tears can occur in conjunction with an anterior dislocation (2).

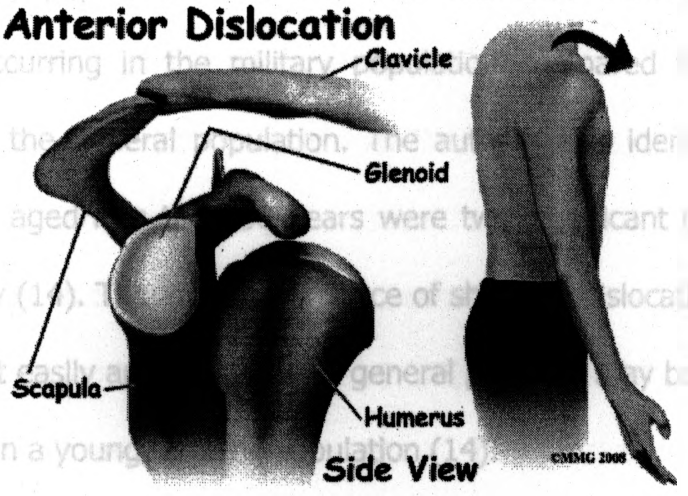

Figure 2.5 Lateral view of the final position of the humeral head following a traumatic anterior shoulder dislocation.

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Incidence

The shoulder joint is the mostly commonly dislocated large joint in the body with the vast majority of dislocations occurring in the anterior direction (2). In a study of the Swedish population involving over 2000 people, Hovelius et al (11) reported an incidence of 1.7% for people between the ages of 18 and 70

years, with males being three times more likely to dislocate. When examining a population of Swedish ice hockey players, the incidence was reported at 7% (12). Simonet et al (13) reported that a shoulder dislocation occurs at least 11.2 times per 100,000 person-years in a general North American population. This group had an incidence of 0.7% for males and 0.3% for females younger than 70 years of age.

Owens et al (14) investigated the incidence of shoulder dislocations in an American military population. The incidence was 1.69 dislocations per 1000 person-years occurring in the military population compared to 0.8 per 1000 person-years in the general population. The authors also identified that being male and being aged less than 30 years were two significant independent risk factors for injury (14). Though the incidence of shoulder dislocations in a military population is not easily applicable to the general public, it may be more reflective of an incidence in a young, athletic population (14).

Prognosis

The most significant prognostic factor for recurrent dislocation following an anterior shoulder dislocation is age at the time of first dislocation (15-19). Other factors such as gender, level of activity (athlete vs. non-athlete), and period of immobilization have also been investigated. Most researchers have identified the two years following the primary dislocation as the most crucial in terms of susceptibility of redislocation (15, 16, 18).

Simonet et al (19) followed 124 patients for an average of 4.63 years and found 33% of patients had a recurrence of dislocation. Patients younger than the age of 20 had the highest rate of recurrence (66%) while no patient above the age of 40 had any recurrence. Athletes had a much higher rate of recurrence (82%) compared to non-athletes (30%) (19). The group concluded that a six-week period of immobilization followed by an intensive rehabilitation program could improve overall prognosis in patients under the age of 30.

Hoelen et al (16) also noted the importance of age as related to prognosis. In a trial involving 166 patients, a 64% rate of recurrence was found with patients younger than 30 years of age. The recurrence rate within two years was 83%, and 98% within three years (16). Though overall men were more at risk of recurrence, in the younger age group men and women had similar rates of recurrence (65% and 57% respectively) (16). Athletes did not present with a worse prognosis compared to non-athletes and the period of immobilization was not shown to influence rate of recurrence in patients aged 30 years and younger (16). The presence of a Hill-Sachs lesion was not found to adversely impact the prognosis in younger patients, though some researchers have noted a higher rate of recurrence in older patients where a Hill-Sachs lesion was present (17).

In a prospective multicentre trial, Hovelius et al (17) followed 254 patients who had primary anterior dislocation treated by either immobilization for at least three weeks or early movement. At five years follow-up, two or more redislocations had occurred in 55% of patients 22 years or younger, while the

rate for patients 23 to 29 years old was 37% and for those between 30 and 40 years was only 12% (17). Surgical stabilization was scheduled or performed for 28% of the patients 22 years or younger, 18% of patients 23 to 29 years and 5% for patients between 30 and 40 years of age (17). In this study, the rate of recurrence was not influenced by either a three to four week period of immobilization or the level of athletic activity of the patient (17). The researchers did note that 19% of patients who had two or more recurrences within the first two years of follow-up had not experienced additional dislocations in the subsequent three years and were not considered at risk for further dislocations (17). Furthermore, the group stated that the presence of three or more dislocations should not be an unconditional indication for operative repair (17).

Hovelius et al (20) evaluated the same group of patients at a 10-year follow-up. Of the 255 patients at the five-year evaluation, 245 patients were also assessed at 10 years. No additional dislocations had occurred in 52% of the patients, while 4% had experienced one recurrence of dislocation (20). A surgical stabilization was performed for 23% of patients and the remaining 20% were classified as having recurrent dislocations, but had not undergone surgical treatment (20). At a 25-year follow-up evaluation, Hovelius et al (21) were able to evaluate 227 of the original 257 patients of their primary anterior dislocation cohort. No additional episodes of dislocation had occurred in 43% of patients, while 7% had one recurrence or subluxation. A surgical stabilization had been performed on 27% of the patients, while the remaining 22% who continued to

have recurrent dislocations had not been treated operatively (21). Given the length of follow-up of this population, Hovelius et al (21) concluded that approximately half of the patients treated nonoperatively for primary anterior dislocations had not sustained a redislocation or had become stable in the course of the 25 years following the primary anterior dislocation.

Nonoperative vs. Surgical Treatment

There has been some controversy regarding the most effective method of treatment for acute anterior shoulder dislocations. Traditionally, treatment for shoulder dislocations has followed a nonoperative approach involving a period of immobilization followed by a rehabilitative protocol. More recent research has suggested, however, that surgical stabilization in a more acute phase of the injury may result in better outcomes for the patient (22-26).

In a comparison of conservative treatment, consisting of a week of immobilization followed by a rehabiliation program, and primary open surgical repair followed by an identical rehabilitation program, Jakobsen et al (24) examined 76 patients between the ages of 15 and 39 years. Diagnostic arthroscopy was performed on all patients, who were subsequently randomized to conservative or surgical treatment. At two years follow-up, 21 of 39 patients (54%) in the conservative group had sustained a redislocation while only 1 of 37 (3%) had a recurrence in the surgical group (24). At 10 years follow-up, 24 patients (62%) treated conservatively had redislocated and 19 of these (80%)

required surgical stabilization. In the surgical group, a further two patients (9%) experienced recurrent dislocations with one requiring further surgical repair (24).

Arciero et al (22) conducted a similar study comparing nonoperative treatment with an arthroscopic surgical stabilization. The prospective cohort study included 36 cadet-athletes, between the ages of 18 and 24 years, from the United States Military Academy who had sustained an acute first-time anterior dislocation. This population was young, very active and unwilling to modify activity level. Due to the researchers' belief that arthroscopic stabilization represented an invasive treatment, they permitted participants to select their treatment groups (22). Those who selected nonoperative treatment were immobilized for four weeks followed by a supervised rehabilitation program centered on rotator cuff muscle strengthening. They were restricted from full activity for four months. The surgical group underwent arthroscopic Bankart repair and then followed the same rehabilitation protocol as the nonoperative group (22). Of the 15 patients in the nonoperative group, 12 patients (80%) developed recurrent instability with seven of those undergoing a subsequent open Bankart stabilization (22). In the surgical group, 3 of 21 patients (14%) developed recurrent instability though only one patient required an open surgical stabilization (22). The study reported an average follow-up of 32 months, ranging from 15 to 45 months.

Given the methodological issues and inherent biases of the study design utilized by Arciero et al (22), Kirkley et al (25) saw the need to conduct a

randomized clinical trial to compare nonoperative treatment to arthroscopic stabilization. The trial included 40 patients under the age of 30 years who had sustained their first traumatic anterior dislocation. Patients were randomly allocated to a nonoperative group, where treatment consisted of three weeks of immobilization followed by a rehabilitation program, or to an arthroscopic stabilization group, who received surgery within four weeks of the initial injury, followed by an identical immobilization and rehabilitation program (25). At 24 months follow-up, 9 of the 19 patients (47%) treated nonoperatively sustained a redislocation, of which seven patients elected to undergo a surgical stabilization. All patients who had surgery were found to have a Bankart lesion (25). In the surgical group, 3 of the 19 patients (16%) suffered a redislocation. One of these patients opted for a second surgery (25).

Additionally, quality of life was analyzed using the validated Western Ontario Shoulder Instability (WOSI) index and showed a statistically significant difference between the groups. Specifically, the average score on the WOSI was 69.8% in the nonoperative group and 86.3% in the surgical group at an average follow-up of 33 months (25). Range of motion was also measured and showed no significant difference between the two groups though a trend for limitation in external rotation was observed in the surgical group with a mean of 87% of the normal side compared to 99.7% of normal side in the nonoperative group (25).

In the long-term evaluation (79 months), 31 of the 40 original patients were available for follow-up and reported no additional dislocations. The mean

difference in WOSI scores between groups at 33 months follow-up was significant at 16% (95% CI, 1.6% to 33.2%); at the 79 month follow-up the difference of 11% (95% CI, -5.8% to 28.7%) was no longer significant (27).

Similarly, Bottoni et al (23) conducted a randomized clinical trial involving 24 patients between the ages of 18 and 26 years. The patient population consisted of active-duty military personnel and their families who were eligible for care in the military health care system. Patients were quasi-randomized (using the last digit of their social security number) into either a nonoperatively treated group or an operatively treated group (23). The nonoperative treatment consisted of four weeks of immobilization in a sling followed by a supervised rehabilitation protocol. The operative group underwent an arthroscopic stabilization, within 10 days of their injury, followed by four weeks of immobilization and the identical rehabilitation program. At four months postoperatively, patients were permitted to return to full active duty, including contact sports (23).

Of the 12 patients analyzed in the nonoperative group, nine (75%) developed recurrent instability with six of these requiring open Bankart repair. In the operative group, 1 of the 9 patients (11.1%) available for follow-up sustained a second anterior dislocation and subsequently underwent open Bankart repair (23). There was no statistically significant difference in loss of external rotation, as measured at six months following surgery or injury,

between the two groups. Upon magnetic resonance imaging (MRI) evaluation, all patients in the study had a Bankart lesion (23).

In a long-term evaluation of arthroscopic Bankart repair, Owens et al (28) followed a cohort of young patients for a mean follow-up of 11.7 years. A total of 39 patients of the original 48 were evaluated with an average age of 20.3 years at the time of surgery and 32.0 years at the time of follow-up (28). Six patients (14.3%) had sustained recurrent dislocations, while nine patients (21.4%) had reported experiencing subluxation events. A total of six patients underwent revision surgery, four for recurrent dislocations and two for subluxation events (28). Quality of life scores were also collected using the WOSI and the American Shoulder and Elbow Surgeons (ASES) questionnaire. The mean WOSI score was 371.7, or 82.3%, while the mean ASES score was 90.9 out of a possible 100 at the time of follow-up (28).

When examining the role of proprioception in athletic injuries, Lephart et al (29) highlighted the contribution of joint position sense and neuromuscular control to performing precise movements and muscular reflex, which help to provide dynamic joint stability. The combination of ligament trauma and proprioceptive deficits, leading to decreased neuromuscular control as well as mechanical and functional instability, can ultimately lead to further microtrauma or reinjury (29). A focus on regaining neuromuscular control in the unstable or postoperative shoulder should be included in the rehabilitation program in order to return to functional activity and improve functional outcomes for athletes

returning to sport (29). Following surgical treatment of shoulder instability, Potzl et al (30) found improved joint position sense in patients after a minimum of five years follow-up. Using a contact-free motion analyzing system, patients' ability to reproduce a given joint position in flexion, abduction and rotation in 90° of abduction without visual control significantly improved in the operative shoulder (30). Furthermore, when examining joint position sense in relation to middle and end range of motion, Janwantanakul et al (31) tested patients' ability to replicate joint positions at the 50^{th}, 75^{th} and 90^{th} percentile of their individual total shoulder rotation range as measured from full internal rotation. Patients were better able to accurately and consistently reposition the shoulder to the criterion joint position in the end range of motion compared to the middle range of motion (31).

Position of Immobilization

Historically, the standard method of treatment of acute shoulder dislocations was to immobilize the arm in an adducted and internally rotated position (19, 20). However, the literature suggests that the effectiveness of immobilization in this position is unproven (32). Several recent studies have suggested that immobilization of the shoulder in external rotation following an anterior dislocation may reduce the risk of recurrence and aid in the healing of Bankart lesions (33-37).

In a cadaveric study, Itoi et al (33) tested arm position in relation to the strain on the Bankart lesion. In specimens stripped of the surrounding musculature, they found that at 45° and 60° of flexion and/or abduction, the edges of the lesion were separated regardless of internal or external rotation. However, when the arm was adducted, the edges of the lesion were closely approximated in full internal rotation and up to 30° of external rotation, creating what the researchers called a coaptation zone (33). The authors found greater tension in the anterior soft tissues in external rotation and postulated that this position may be more beneficial in keeping the lesion approximated and lead to better healing than an internally rotated position (33).

Miller et al (36) examined the effect of external rotation on the contact force between the glenoid and the labrum in human cadaveric shoulders. They suggested that increased contact force at the site of injury might help to improve healing and reduce rates of recurrence (36). Only the deltoid muscle was removed from the specimens to maintain as much of the natural musculature as possible. No contact force was measured between the labrum and the glenoid at 60° of internal rotation. The contact force increased as the arm passed through neutral rotation and reached a maximum of 45° of external rotation (36).

Itoi et al (34) used MRI to study the position of Bankart lesions in live human patients with the arm in internal and external rotation. The trial included patients with a primary dislocation as well as those with recurrent dislocations, all of whom had Bankart lesions. The arm was held at the side of the body, and

positioned in internal rotation (average of 29°) then external rotation (average of 35°) (34). The separation and displacement of the anteroinferior portion of the labrum, as well as the approximation of the anterior part of the capsule to the glenoid neck were assessed. Separation and displacement of the labrum were both significantly less with the arm in external rotation. When primary dislocators and recurrent dislocators were examined separately, the same significant results were observed (34). The detached area of the capsule, the opening angle and the detached length, all of which were used to measure the degree of approximation of the anterior capsule, were all significantly smaller in the externally rotated position. The same result was observed when primary and recurrent dislocators were analyzed separately (34).

Similarly, Seybold et al (37) examined 34 patients with first-time anterior dislocations using MRI. A minimum of 10° of external rotation was used compared to full internal rotation as tolerated. In all patients, dislocation and separation of the labrum relative to the rim of the glenoid were significantly less in the external rotation position (37).

In a semi-randomized prospective study, Itoi et al (35) compared external rotation immobilization versus internal rotation immobilization as treatment following primary anterior shoulder dislocations. Forty patients were assigned, the first 10 patients alternately and the remaining 30 patients randomly, to three weeks of immobilization in internal rotation (IR) (20 patients) or external rotation (ER) (20 patients). At an average of 15.5 months of follow-up, the rate of

recurrence in the IR group was 30% (6 of 20 patients) and 0% (0 of 20 patients) in the ER group (35). For patients younger than 30 years of age, 45% (5 of 11 patients) had a redislocation and 0% (0 of 11) in the ER group. In patients who immobilized the shoulder for the full three weeks, 27% (4 of 15 patients) in the IR group and 0% (0 of 16 patients) experienced a redislocation. There was no significant difference in the compliance between groups (35). Although these findings are encouraging, the semi-randomized nature of this study and the relatively short follow-up compared to other studies examining immobilization and rates of recurrence limit the generalizability of the results (32).

A more recent randomized clinical trial by Whelan et al (38) compared sling immobilization in internal rotation to external rotation immobilization after primary anterior shoulder dislocation in a non-surgical population. Sixty-one patients were randomized (30 to IR sling and 31 to ER brace) at an average of four days following reduction of the dislocation. All the patients in the trial were less than 35 years of age (38). At an average follow-up of 18 months, 8 of 30 patients (27%) in the IR group and 7 of 31 patients (23%) in the ER group had experienced a recurrent instability episode. Compliance in both groups was excellent and loss-to-follow-up was minimal. The researchers concluded that immobilization in external rotation is of little added benefit compared to internal rotation immobilization in a high-risk population (38).

The recent research interest in the position of external rotation for immobilization has resulted in some brace and sling manufacturers developing

commercial immobilization devices. To evaluate four commercially available external rotation braces, Sullivan et al (39) tested the devices' ability to achieve and maintain external rotation in 12 healthy subjects. The DonJoy Ultrasling ER tested highest in patient comfort, maintenance of external rotation after activity and reapplication, and was among the least costly (39).

Range of Motion Measurements

The collection of range of motion (ROM) data by means of goniometry can be used to determine the presence or absence of impairment, research the effectiveness of therapeutic techniques and assess the successfulness of surgical procedures (40). Goniometry is also useful in developing treatment goals and evaluating the progress towards rehabilitative goals (40). Many studies have outlined the need for measurements of ROM about the shoulder to be reliable if they are to be applied in the clinical setting (40-43). In the evaluation of goniometric assessments, intra-tester reliability has been shown to be consistently greater than inter-rater reliability (42-45). Riddle et al (43) found high intra-tester intraclass correlation coefficient (ICC) values (0.87 to 0.99) for measures of passive horizontal abduction and external rotation. MacDermid et al (40) noted similar high intra-rater reliability when measuring passive lateral rotation of the shoulder (ICC values of 0.88 and 0.93).

Equally high measures of rater reliability were found when patients were tested in a supine position (42, 45). Some researchers have suggested this

position helps to stabilize the shoulder girdle while allowing the assessor to focus on proper alignment of the goniometer and control to the affected arm (42). The nature of the movement, whether passive or active, also has an effect on the reliability with active movements proving to be more reliable (45). This is likely a result of the examiner-related error introduced due to the variability of the force applied to move the arm and its effect on the passive ROM (42). Active ROM is also beneficial when assessing post surgical patients because it allows them to monitor their own pain and limitations.

Summary

Anterior shoulder dislocations are a common injury affecting a wide range of people. Age at the time of dislocation and level of activity are the most significant prognostic factors of recurrent dislocations. Treatment has traditionally consisted of a period of immobilization to allow the damaged tissues to heal, followed by a rehabilitation program to strengthen the supporting structures. There is little consensus on the length of time of immobilization, as well as its effectiveness in reducing redislocations. More recently, surgical trials have shown positive results in the treatment of young active patients with arthroscopic stabilizations gaining favour due to reduced morbidity and smaller losses in ROM (46). The position of immobilization has also recently been questioned, with some advocating that a position in neutral or external rotation is more conducive to healing and will reduce rates of recurrence. To date, no

research has been conducted to investigate immobilization in external rotation following a surgical stabilization or what the possible benefits may be to a young active population following anterior shoulder dislocation.

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Chapter 3

Objectives

Chapter 3 – Objectives

The primary purpose of this study was to determine if immobilization in an externally rotated position following arthroscopic anterior stabilization lead to greater range of motion about the shoulder as compared to the traditional internally rotated sling at six weeks post surgery when adjusting for baseline range of motion. We hypothesized that patients immobilized in external rotation would have greater range of motion scores.

The secondary objective of this study was to compare joint and disease specific quality of life questionnaire and functional index scores to determine if externally rotated immobilization following an arthroscopic anterior stabilization resulted in higher patient reported outcome scores compared to internally rotated immobilization at six weeks following surgery. It was hypothesized that immobilization in external rotation would yield higher quality of life and function scores at this time point.

The tertiary objective of this study was to examine a self-reported patient evaluation of: 1) the immobilization device in the areas of feeling of stability, helpfulness with recovery, and overall satisfaction at four weeks following surgery, as well as 2) the compliance for wearing the immobilization device at two and four weeks following surgery.

Chapter 4

Methodology

Chapter 4 – Methodology

Study Design and Participants

The current study was a prospective randomized clinical trial comprised of two treatment groups, both involving patients between 15 and 40 years of age who had undergone arthroscopic Bankart lesion repair (anterior stabilization). The University of Western Ontario Research Ethics Board approved the study (Ethics Review Certificate in Appendix I). Potential participants were identified from the practices of three orthopaedic surgeons at the Fowler Kennedy Sport Medicine Clinic (FKSMC) and screened by the surgeons for suitability for the study. Patients were not eligible if any of the following criteria were present: the patient 1) was undergoing revision for failed anterior stabilization; 2) had undergone previous surgery to the affected shoulder; 3) had a history of multidirectional or posterior instability; 4) had associated fractures (except Hill-Sachs or bony Bankart Lesions); 5) was unable or unwilling to comply with the rehabilitative protocol or required follow-up assessments; 6) had other upper extremity pathologies which would affect their ability to participate in the rehabilitative program, for example ; 7) had a medical condition that would preclude the patient from wearing a brace or sling; 8) was incompetent or unwilling to consent; or 9) was unable to read and speak using the English language. Patients with an associated superior labrum anterior posterior (SLAP) lesion were included in the study.

On the day of surgery, patients were presented with a letter of information (Appendix I) outlining the details of the study including risks and benefits related to the use of both devices as well as the randomization process. A study investigator answered any questions presented by the patient prior to obtaining written consent (Consent Form in Appendix I). Patients were also presented with a device information sheet (Appendix I), which included a description of both devices, instructions on how to remove the devices while maintaining their immobilization position as well as instructions on how to reapply them. Contact information for a research assistant, who was familiar with both devices, was also provided to help with any difficulties or questions specific to the devices. This allowed the study investigator, who was also an outcome assessor, to remain blinded to the treatment allocation of the patients while still providing patient support regarding the devices.

In order to obtain baseline data for each participant, preoperative measures of range of motion (ROM) were taken and patient reported outcomes (PRO), which included quality of life (QOL) questionnaires and a functional index, were collected. These measurements were completed on the day of surgery to satisfy the baseline time point and during follow-up visits at two weeks, four weeks, six weeks and twelve weeks postoperatively. Range of motion measurements and PRO were collected at every visit. To keep the outcome assessor blinded to the allocation groups, participants were instructed to remove their brace or sling prior to meeting with the assessor in their two week and four

week visits. They were also instructed not to relate which device they had been using.

During surgical investigation, the surgeon conducted an arthroscopic examination of the shoulder joint and surrounding structures to rule out associated pathologies that would exclude patients. A surgical evaluation form (Appendix I) was filled out to ensure relative standardization of the surgical procedure. Patients who were deemed unsuitable for the study or required changes to the standardized Bankart repair after surgical evaluation were excluded prior to randomization. These patients received the surgeon's current standard of care.

After surgery, participants included in the study were randomly assigned to one of the following treatment groups:

1. An external rotation brace group: all patients received an identical brace (DonJoy Ultrasling ER, DJO Inc., Vista, Calif.), which was applied and adjusted after surgery to position the affected upper extremity in 90° of elbow flexion, 5 to 10° of shoulder abduction and flexion, and 10 to 15° of external rotation at the shoulder (Figure 4.1).
2. A internal rotation sling group: all patients receive an identical sling (Procare Shoulder Immobilizer, DJO Inc., Vista, Calif.), which was applied and adjusted after surgery to position the injured upper extremity in 90° of elbow flexion, 0° of shoulder abduction and 80 to 90° of internal rotation at the shoulder (Figure 4.2).

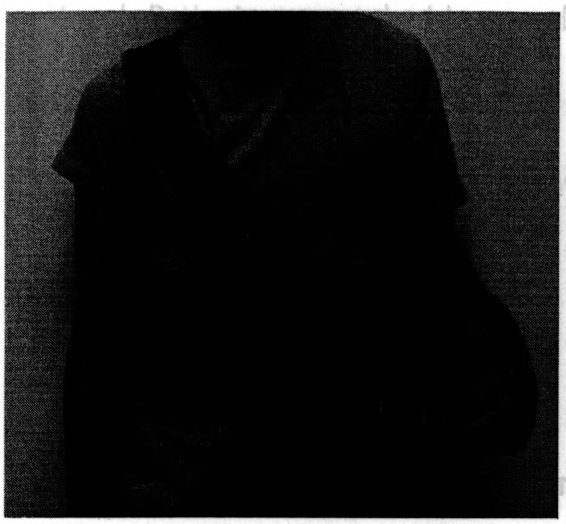

Figure 4.1 Immobilization of the shoulder in abduction and external rotation using a DonJoy Ultrasling ER Brace

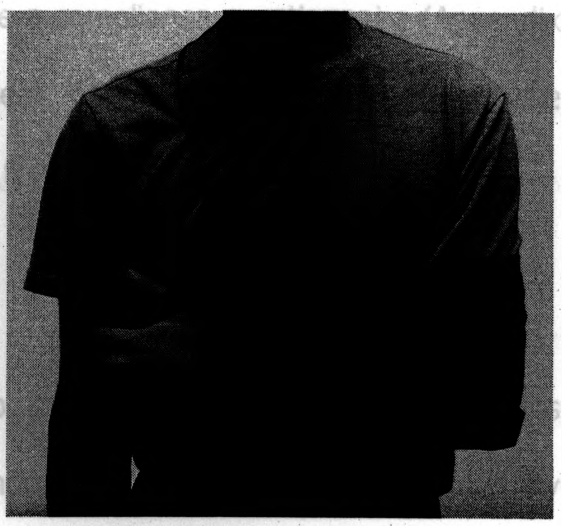

Figure 4.2 Immobilization of the shoulder in adduction and internal rotation using a Procare Shoulder Immobilizer sling.

This study used the standardized rehabilitation protocol currently employed at the FKSMC for patients having undergone arthroscopic Bankart repair (Appendix I). A copy of this protocol was provided to the patient in the prescription for outpatient physical therapy, along with a letter of explanation to the therapist (Appendix I) to be presented to their physical therapist at the first postoperative therapy session.

Both treatment groups were instructed to wear their device for a period of four weeks. During the first two weeks postoperatively, patients were told to wear the device at all times, with the following exceptions: during their physiotherapy, for brief removal while showering, or during hand, elbow and wrist exercises as prescribed in the rehabilitative protocol. Between two and four weeks postoperative, patients were gradually weaned off the device under the supervision of their physiotherapist within the guidelines of the rehabilitative

protocol. Patients were asked to complete a compliance questionnaire (Appendix II) at both the two week and four week postoperative visits and a device evaluation questionnaire (Appendix II) at four weeks postoperative.

Randomization

Participants were randomized to one of the two treatment groups according to a computer-generated randomization list that was stratified by surgeons and whether or not the patient underwent repair of a SLAP lesion at the time of stabilization, with permuted blocks sizes of two and four. Implementation and concealment of the allocation sequence was achieved by using randomization packages, which included an opaque sequentially numbered randomization envelope containing the treatment allocation, a surgical evaluation form and an inclusion/exclusion criteria sheet. Upon completion of the surgical procedure and inclusion of the patient by the surgeon, the randomization envelope was opened and the appropriate device was applied in the surgical recovery room.

Outcome Measures

Primary Outcome Measures

ROM measurements for active forward flexion, abduction and external rotation were collected. In the evaluation of goniometric assessments, intra-tester reliability has been shown to be consistently greater than inter-rater

reliability (1-4). Riddle et al (1) reported high intra-tester reliability for measures of passive horizontal abduction and external rotation. Similarly, MacDermid et al (3) noted high intra-tester reliability when measuring passive lateral rotation of the shoulder.

Rater reliability is enhanced when a consistent, well-defined measurement protocol is established to standardize the procedure (3), which includes planes of movement, patient position, bony landmarks, criteria for end of range and limitations. Therefore, an adapted version of Norkin and White's (5) shoulder ROM measuring protocol was developed with the help of a senior physiotherapist from the FKSMC (Appendix I). All ROM measurements were performed by a single outcome assessor, who was a graduate student conducting this study, using a standard universal goniometer (Figure 4.3) with patients placed in a supine position conducted active ROM measurements. The outcome assessor had received training specific to the ROM measuring protocol used in this study and practiced prior to the first patient being recruited under the supervision of a senior physiotherapist from the FKSMC.

Movements were explained and demonstrated to the participants prior to the measurement. For each movement, three trials were recorded and the average of these three measurements was used in the analysis. To minimize compensatory movements from the scapula, participants were instructed to gently retract the scapula, putting slight pressure onto the treatment bed. Participants were to maintain this position during each measurement with an

isometric contraction of the musculature surrounding the scapula. If physical therapy was scheduled on the same day as a follow-up visit, measurements were taken prior to the participant seeing the therapist to avoid confounding gains in ROM as a result of therapy.

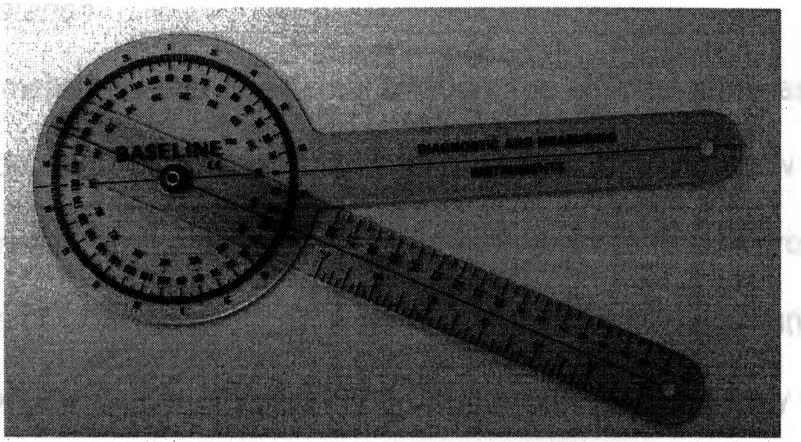

Figure 4.3 Standard Universal Full-circle Goniometer

Forward Flexion

For measurements of forward flexion, the affected arm was positioned in 0° of abduction, adduction and rotation at the side of the body. The forearm was placed in a neutral position so the palm of the hand was facing the body. The goniometer was positioned over the center of the head of the humerus (approximate center of the glenohumeral joint) on the lateral surface of the arm. The proximal arm of the goniometer was aligned with the midline of the thorax while the distal arm was aligned with the midline of the humerus using the lateral epicondyle as a reference. Participants were then instructed to lift their arm over the head, in line with the sagittal plane of the body, to the onset of discomfort indicating the end of ROM. End of range also occurred when

participants deviated from forward flexion by arching their lower back, allowing excessive scapular movement or abducting their arm. In these cases, range was measured at the point where the deviation occurred.

External Rotation

For measurements of external rotation, the affected arm was positioned in 0° of abduction, adduction and rotation with 90° of elbow flexion. The goniometer was centered about the olecranon process (the approximate center for the axis of external rotation). A dense foam pad was placed under the upper arm to allow the center of rotation on the goniometer to properly align with the olecranon process. The proximal arm of the goniometer was aligned parallel to the sagittal plane of the body while the distal arm was aligned with the midline of the ulna using the styloid process of the ulna as reference. Participants were then instructed to externally rotate their arm, parallel to the transverse plane of the body while avoiding abduction of the arm and keeping their elbow in the same relative position, until the onset of discomfort. During the two and four week follow-up visits, a limitation in external rotation of 30°, as prescribed by the surgeon, was observed. Participants who reached 30° of external rotation were instructed to stop, using the 30° as the ROM value for that trial. End of range also occurred when participants deviated from external rotation by arching their lower back, allowing excessive scapular movement or abducting their arm. In these cases, range was measured at the point where the deviation occurred.

Abduction

For measurements of abduction, the affected arm was again placed in 0° of abduction, adduction and rotation at the side of the body with a forearm neutral position while participants were supine. Participants were instructed to not allow for supination of the forearm during the movement as this would cause external rotation about the glenohumeral joint and violate the post-surgical external rotation limitation. The goniometer was positioned over the center of the head of the humerus (approximate center of the glenohumeral joint) on the anterior surface of the arm. The proximal arm of the goniometer was aligned with the midline of the thorax parallel to the sagittal plane of the body while the distal arm was aligned with the midline of the humerus using the insertion of the biceps in the bicipital fossa as a reference. Participants were then instructed to abduct their arm away from their body, in line with the coronal plane of the body, to the onset of discomfort. Participants were instructed to avoid scapular elevation to initiate abduction as well as during the movement. End of range also occurred when participants deviated from abduction by allowing excessive scapular movement or forward flexion. When deviations occurred, participants were permitted to correct their movement with another attempt. If the participants demonstrated an inability to perform the movement on the second attempt, the measurement was taken at the point where the deviation had occurred.

Secondary Outcome Measures

Using PRO, we measured quality of life using a disease specific tool, the Western Ontario Shoulder Instability Index (WOSI), and a joint specific tool, The American Shoulder and Elbow Surgeons Subjective Shoulder Scale (ASES), as well as function using the Upper Extremity Functional Index (UEFI).

The WOSI is a validated, reliable and responsive patient-reported 21-item questionnaire specifically designed to assess QOL in patients with shoulder instability (6). It is divided into four domains: physical symptoms (ten items), sports, recreation and work (four items), lifestyle (four items) and emotions (three items) (7). Detailed instructions to the patient are included as well as a supplement explaining each item. Specific scoring instructions are also provided. The best possible score is zero, which signifies no decrease in shoulder-related QOL for the patient, while a maximum score of 2100 indicates an extreme decrease in shoulder related QOL (6, 7).

The ASES is a validated, reliable and responsive outcome measure containing a patient self-report section and a section used by medical professionals to record physical findings when assessing shoulder pathologies (8). Only the patient self-report section was used in the present study. It consists of 11 items that are divided into two sections: pain (one item) and function (ten items). The pain item is marked on a 100-mm visual analog scale (VAS), which is anchored at both ends with verbal descriptors (7). In response to the question "How bad is your pain today?" a score of zero is indicative of "no pain at all"

while a score of 100 represents "as bad as can be". The 10 items of the functional section of the ASES include a range of activities of daily living (8, 9). Each item in the functional section has four response options ranging from zero (unable to do) to three (not difficult). Each section is equally weighed, with 50 points, for a total score out of a possible 100 points (8, 9).

The UEFI is a validated, reliable and responsive self-report functional measure for the upper extremity consisting of 20 items, which are scored on a five point scale of zero to four, and with adjectives of approximate equal interval properties (10). Total UEFI scores can range for zero, the lowest functional status, to 80 at the highest end of function of the upper extremity.

In addition to these validated questionnaires, we measured participant compliance with device use by means of a non-validated, patient-reported questionnaire where patients were asked to report the average amount of time per day they had been wearing their device over the two weeks since their last visit. The compliance questionnaire (Appendix II) presented participants with four response options, which included a verbal descriptor paired with a range of time (ie. Most of the time: 12 – 16 hours/day). Participants selected the option that best suited their compliance over the previous two weeks and could provide further written explanation to justify their choice.

Additionally, a device evaluation questionnaire (Appendix II), which was designed by the investigator for this study, also non-validated, was administered to describe participant satisfaction with the device. Participants were asked to

rate: 1) how stable their shoulder felt while wearing the brace/sling, 2) how helpful the brace/sling was in their recovery, and 3) their overall satisfaction with the brace/sling. The questionnaire used a 100mm VAS response format, where lower scores indicated greater stability, helpfulness and satisfaction. The questionnaire was administered at the four week postoperative visit to coincide with the completion of the immobilization period and disuse of the device. The questionnaire did not identify which device was being rated to ensure blinding of the outcome assessor to group allocation.

Statistical Analysis

Based on a comparison of two independent groups, a sample size of 62 participants per group was estimated to have sufficient power (beta = 0.2) to detect a moderate effect size (0.5) in ROM (2-sided alpha = 0.05). Assuming a loss-to-follow-up rate of approximately 20%, 150 participants (75 per group) were required.

The mean ROM scores and standard deviation for the brace and sling groups were calculated and the mean difference between groups for each ROM measurement with 95% confidence interval (CI) at six weeks postoperatively was provided. We used an analysis of covariance (ANCOVA) to make a statistical comparison of the means of each group after adjusting for baseline scores, where a two sided Type I error rate of 0.05 indicated statistical significance. A

similar analysis was conducted for all outcomes with a continuous scale (WOSI, ASES and UEFI).

To estimate the value of important group changes in goniometric measures of ROM, three physiotherapists with expertise in treating postoperative shoulder patients were surveyed. It was decided that an average within-patient change of 20° for forward flexion, 15° for external rotation, and 20° for abduction would be considered clinically significant. According to Goldsmith et al (11), the magnitude of a clinically important change for between-group means is approximately 40% of that of the important within-patient change. Therefore, a mean between-groups difference of 8° for forward flexion, 6° for external rotation and 8° for abduction was considered the minimal clinically important difference (MCID).

A between-group means difference of 20% (420 total points) was considered the MCID for WOSI scores based on previously published findings involving patients with shoulder instability (12). A within-patient change of 6.4 ASES points has been reported as an MCID (8), which can be converted to a between-group means difference of 2.6 points on the ASES as the MCID for this study. Due to the lack of published findings outlining a MCID using UEFI scores, this study utilized the within-patient minimal detectable change (MDC) of 9.1 points as an approximation for the MCID (10). After conversion to a between-group difference, the MCID for the UEFI scores was 6 points.

To account for missing data points, ROM and PRO data were treated separately for each participant. For missing end point data in participants who were lost-to-follow-up, the last outcome carried forward (LOCF) strategy was used. For missing mid-point data, a growth-curve analysis was used to compute the missing values. All analyses followed the intention-to-treat principle.

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Chapter 5

Results

Chapter 5 – Results

Participant Flow

The flow of participants through each stage of the trial is outlined in Figure 5.1. Of the 97 patients assessed for eligibility, 39 did not meet inclusion criteria, 16 required an additional procedure, 13 either had their surgery rescheduled or cancelled, or were missed by the investigators, and six declined to participate. As a result, 20 participants gave consent and were randomized. Eleven participants were allocated to the brace group and nine participants were allocated to the sling group. One participant was lost-to-follow up in the brace group at the 12-week postoperative visit and two participants were lost-to-follow-up in the sling group (one at the four week postoperative visit and one at the 12 week postoperative visit). The analysis included data from all 20 randomized participants, eleven in the brace group and nine in the sling group.

Baseline Demographics and Participant Characteristics

Participants' baseline demographics and characteristics were similar between groups in gender, age, affected arm, level of activity and smoking habits. Surgical characteristics were also similar between groups in regards to presence of a bony Bankart lesion and Hill-Sachs lesion as well as SLAP lesion repair (Table 1). The brace group had a longer time from injury to surgery (41.0 ± 38.2 months) compared to the sling group (26.4 ± 12.9 months) and had a

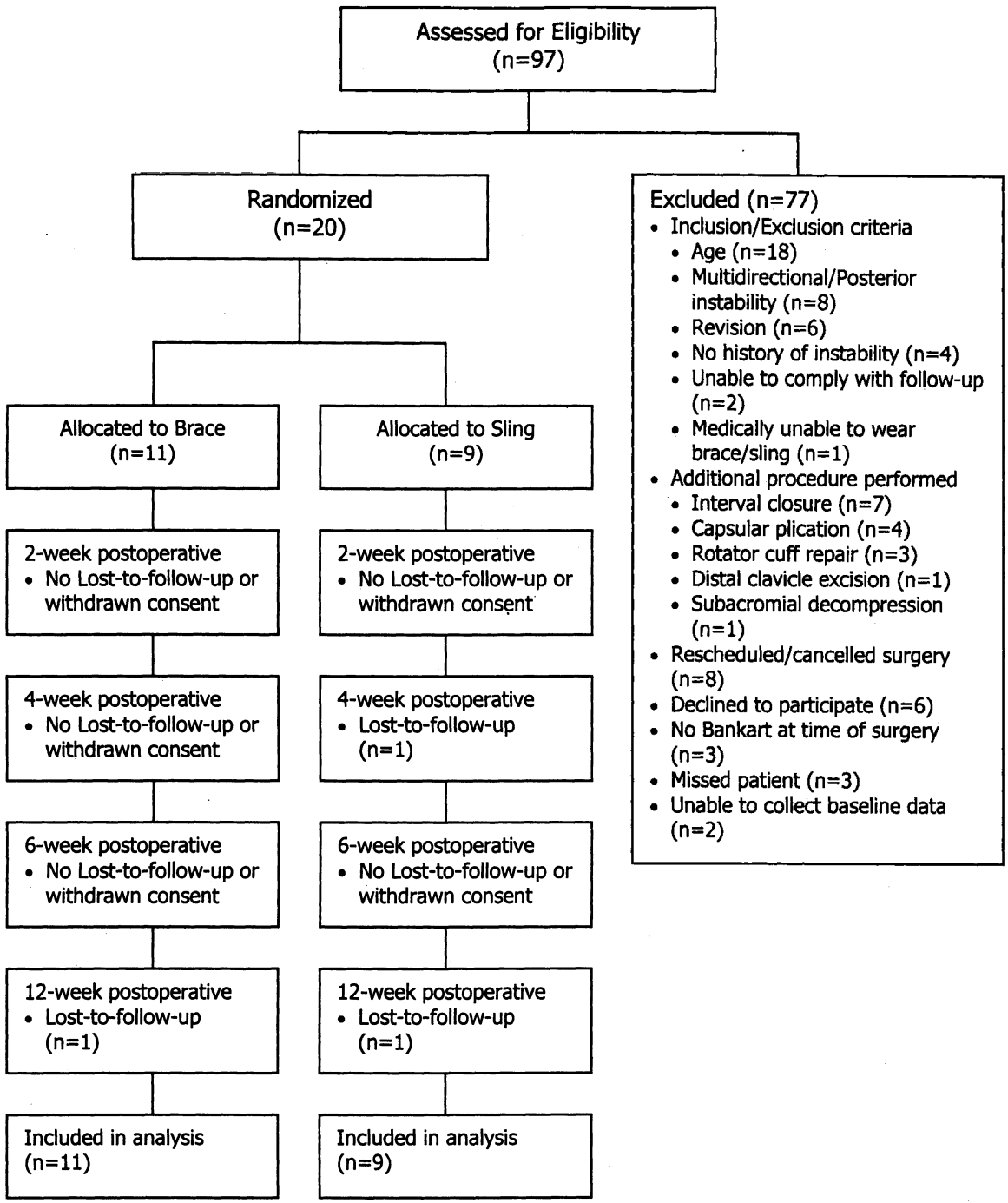

Figure 5.1 Participant Flow Through the Trial

higher percentage of participants competing in collision sports (81.8% in the brace group vs. 44.4% in the sling group). Of note, both groups had a high percentage of participants receiving physical therapy as a treatment prior to surgery (72.7% in the brace group vs. 88.9% in the sling group). No adverse events were reported during the course of this study.

TABLE 1
Baseline Demographics and Participant Characteristics

Characteristic	Brace (n=11)	Sling (n=9)
Sex, n (%)		
Male	10 (90.9)	6 (66.7)
Female	1 (9.1)	3 (33.3)
Mean Age ± SD, y	21.6 ± 5.84	21.9 ± 5.18
Mean Height ± SD, m	1.80 ± 0.08	1.78 ± 0.10
Mean Weight ± SD, kg	75.9 ± 16.7	83.2 ± 12.2
Mean Time from Injury to Surgery ± SD, months	41.0 ± 38.2	26.4 ± 12.9
Affected Arm, n (%)		
Right	5 (45.5)	4 (44.4)
Left	6 (54.5)	5 (55.6)
Dominant Arm, n (%)		
Right	9 (81.8)	7 (77.8)
Left	2 (18.2)	2 (22.2)
SLAP Lesion, n (%)		
Repaired	2 (18.2)	1 (11.1)
Normal or Not Repaired	9 (81.8)	8 (88.9)
Bony Bankart Lesion, n (%)		
Present	2 (18.2)	1 (11.1)
Absent	9 (81.8)	8 (88.9)
Hill-Sachs Lesion, n (%)		
Present	10 (90.9)	9 (100)
Absent	1 (9.1)	0
Level of Contact in Sport, n (%)		
Collision	9 (81.8)	4 (44.4)
Limited Contact	1 (9.1)	3 (33.3)
Non-Contact	1 (9.1)	2 (22.2)
Level of Activity, n (%)		
Varsity	4 (36.4)	1 (11.1)
Recreational	7 (63.6)	8 (88.9)
Non-Athlete	0	0
Employment Status, n (%)		
Student	8 (72.7)	6 (66.7)
Full-Time	3 (27.3)	3 (33.3)
Part-Time	0	0
Unemployed	0	0

TABLE 1 (continued)
Baseline Demographics and Participant Characteristics

Characteristic	Brace (n=11)	Sling (n=9)
Treatment Prior to Surgery, n (%)[a]		
Analgesics	8 (72.7)	2 (22.2)
NSAIDS	5 (45.5)	3 (33.3)
Corticosteroid Injections	1 (9.1)	0
Non-Steroid Injections	0	0
Physical Therapy	8 (72.7)	8 (88.9)
Smoking Habits, n (%)		
Never Smoked	8 (72.7)	6 (66.7)
Smoked, but quit	0	1 (11.1)
Smoke 1 pack/week	2 (18.2)	2 (22.2)
Smoke 1 pack/day	1 (9.1)	0
Smoke > 1 pack/day	0	0

Abbreviations: SD = Standard Deviation; SLAP = Superior Labrum Anterior Posterior; NSAIDS = Non-steroidal anti-inflammatory drugs.
[a] Participants were permitted to select more than one treatment. Percentages are not required to total 100.

Data Analysis

Descriptive statistics for all time points are presented in Table 2. To account for missing data points, ROM and PRO data were treated separately for each participant. In the brace group, one participant had a missing ROM mid-point value, which was imputed using a growth-curve method and one participant had a missing ROM end-point value, which was imputed by carrying the last outcome forward (LOCF). The sling group had two patients with missing PRO mid-point data, which were calculated using growth curve analysis, and two patients with missing ROM end-point data where the LOCF strategy was used.

Primary Analysis

Analysis of covariance (ANCOVA) indicated significantly higher external rotation ROM in the brace group (47.5 ± 3.61 degrees; adjusted mean ± standard error)

TABLE 2
Descriptive Statistics at all Time Points for Both Groups

Time	Outcome Measure	Brace (n=11)	Sling (n=9)
Baseline	Range of Motion, mean ± SD		
	Forward Flexion, deg	160.1 ± 16.7	155.9 ± 29.4
	External Rotation, deg	55.6 ± 9.07	52.1 ± 12.4
	Abduction, deg	152.6 ± 18.0	125.6 ± 43.3
	WOSI, mean ± SD score out of 100		
	Physical Symptoms	52.7 ± 24.9	67.3 ± 11.4
	Sports, Recreation and Work	47.3 ± 28.6	45.2 ± 13.8
	Lifestyle	55.0 ± 23.5	47.0 ± 19.1
	Emotions	27.0 ± 19.3	37.6 ± 20.0
	Total	48.5 ± 20.0	55.0 ± 10.2
	ASES, mean ± SD score out of 100		
	Total	76.7 ± 20.0	82.7 ± 8.95
	UEFI, mean ± SD score out of 100		
	Total	83.0 ± 11.3	86.4 ± 6.86
2-Week Postoperative	Range of Motion, mean ± SD		
	Forward Flexion, deg	119.7 ± 30.5	78.3 ± 58.7
	External Rotation, deg	24.4 ± 6.34	14.8 ± 7.61
	Abduction, deg	71.8 ± 30.6	54.9 ± 29.1
	WOSI, mean ± SD score out of 100		
	Physical Symptoms	35.6 ± 10.0	47.4 ± 19.1
	Sports, Recreation and Work	15.0 ± 14.2	11.2 ± 14.5
	Lifestyle	19.0 ± 13.7	31.8 ± 19.1
	Emotions	33.0 ± 14.1	42.2 ± 25.3
	Total	28.1 ± 10.1	36.8 ± 15.6
	ASES, mean ± SD score out of 100		
	Total	48.0 ± 16.7	50.3 ± 13.0
	UEFI, mean ± SD score out of 100		
	Total	34.1 ± 13.7	33.2 ± 17.8
4-Week Postoperative	Range of Motion, mean ± SD		
	Forward Flexion, deg	158.9 ± 21.2	159.7 ± 16.0
	External Rotation, deg	27.5 ± 3.74	19.4 ± 6.36
	Abduction, deg	116.4 ± 27.5	96.9 ± 19.6
	WOSI, mean ± SD score out of 100		
	Physical Symptoms	56.1 ± 13.9	60.8 ± 11.1
	Sports, Recreation and Work	24.8 ± 14.4	30.2 ± 16.2
	Lifestyle	38.6 ± 16.5	39.3 ± 19.7
	Emotions	44.4 ± 18.0	47.9 ± 25.4
	Total	45.1 ± 13.5	49.1 ± 13.0
	ASES, mean ± SD score out of 100		
	Total	66.6 ± 15.3	69.1 ± 9.08
	UEFI, mean ± SD score out of 100		
	Total	68.3 ± 15.0	62.4 ± 22.0

TABLE 2 (continued)
Descriptive Statistics at all Time Points for Both Groups

Time	Outcome Measure	Brace (n=11)	Sling (n=9)
6-Week Postoperative	Range of Motion, mean ± SD		
	Forward Flexion, deg	170.7 ± 22.8	168.7 ± 13.9
	External Rotation, deg	45.6 ± 13.4	27.2 ± 8.83
	Abduction, deg	140.5 ± 32.4	120.7 ± 17.9
	WOSI, mean ± SD score out of 100		
	Physical Symptoms	73.1 ± 16.1	73.6 ± 8.76
	Sports, Recreation and Work	47.3 ± 19.0	48.1 ± 24.1
	Lifestyle	55.8 ± 19.5	56.9 ± 20.9
	Emotions	58.7 ± 19.5	65.6 ± 19.9
	Total	62.8 ± 14.8	64.4 ± 14.0
	ASES, mean ± SD score out of 100		
	Total	82.0 ± 9.45	80.3 ± 12.0
	UEFI, mean ± SD score out of 100		
	Total	83.3 ± 9.85	79.2 ± 25.7
12-Week Postoperative	Range of Motion, mean ± SD		
	Forward Flexion, deg	176.9 ± 22.6	178.6 ± 10.8
	External Rotation, deg	56.0 ± 11.3	32.8 ± 9.75
	Abduction, deg	154.3 ± 24.5	140.6 ± 29.1
	WOSI, mean ± SD score out of 100		
	Physical Symptoms	87.7 ± 5.12	82.7 ± 10.3
	Sports, Recreation and Work	68.8 ± 14.6	56.2 ± 29.2
	Lifestyle	74.5 ± 14.1	70.3 ± 20.9
	Emotions	71.7 ± 18.8	76.9 ± 18.6
	Total	79.3 ± 7.61	74.5 ± 15.9
	ASES, mean ± SD score out of 100		
	Total	92.7 ± 4.94	89.0 ± 14.0
	UEFI, mean ± SD score out of 100		
	Total	94.4 ± 4.62	85.6 ± 27.6

Abbreviations: SD = Standard Deviation; WOSI = The Western Ontario Shoulder Instability Index; ASES = The American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; UEFI = The Upper Extremity Functional Index.

compared to the sling group (25.3 ± 4.00 degrees; adjusted mean ± standard error) with a clinically meaningful mean difference between groups (22.2 degrees [95%CI 10.8 to 33.7], $p<0.01$) at six weeks postoperatively (Table 3). External rotation was also significantly higher in the brace group at 12 weeks

postoperatively (56.1 ± 3.31 degrees vs. 32.6 ± 3.66 degrees) with a clinically important mean difference between groups (23.6 degrees [95%CI 13.1 to 34.0], $p<0.01$). No other ROM measurements were found to be significantly different between groups at either six weeks or twelve weeks postoperatively.

Secondary Analysis

In the brace group, one participant had missing PRO end-point data, which was imputed using LOCF. The sling group had three participants missing PRO data; one mid-point value, which was imputed using a growth curve analysis, and two end-point values where LOCF was used to impute the missing data. ANCOVA found no significant difference between the brace and sling group for any PRO measure at six weeks or twelve weeks postoperatively (Table 3).

Compliance and Brace/Sling Evaluation

Compliance with wearing the device at two weeks postoperatively was similar between groups. When asked, "In the past two weeks, how often did you wear your brace/sling?" both the brace and sling groups averaged a response of "All the time (as directed by the letter of information)" and were balanced between groups in the other three response categories. At the four week follow-up, results were equally distributed across all four response categories with no one category having a difference greater than one patient-response between groups.

TABLE 3
Between-Group Differences for Outcome Measures

Outcome Measure	6 Weeks Postoperatively			
	Brace (n=11)[a]	Sling (n=9)[a]	Difference (95% CI)	*P* Value
Range of Motion,				
Forward Flexion, deg	170.5 ± 5.96	168.9 ± 6.59	1.59 (-17.2 to 20.4)	0.86
External Rotation, deg	47.5 ± 3.61	25.3 ± 4.00	22.2 (10.8 to 33.7)	0.00*
Abduction, deg	136.3 ± 7.98	125.8 ± 8.90	10.5 (-15.8 to 36.9)	0.41
WOSI, Total score out of 100	62.6 ± 4.50	64.7 ± 4.98	-2.19 (-16.5 to 12.1)	0.75
ASES, Total score out of 100	82.1 ± 3.34	80.3 ± 3.70	-1.76 (-8.85 to 12.4)	0.73
UEFI, Total score out of 100	82.9 ± 5.77	79.7 ± 6.39	3.12 (-15.2 to 21.4)	0.73
	12 Weeks Postoperatively			
Outcome Measure	Brace (n=11)[a]	Sling (n=9)[a]	Difference (95% CI)	*P* Value
Range of Motion,				
Forward Flexion, deg	176.3 ± 5.24	179.3 ± 5.80	-3.06 (-19.6 to 13.5)	0.70
External Rotation, deg	56.1 ± 3.31	32.6 ± 3.66	23.6 (13.1 to 34.0)	0.00*
Abduction, deg	151.4 ± 8.28	144.2 ± 9.24	7.19 (-20.1 to 34.5)	0.59
WOSI, Total score out of 100	79.7 ± 3.73	74.1 ± 4.13	5.61 (-6.25 to 17.5)	0.33
ASES, Total score out of 100	92.6 ± 3.15	89.1 ± 3.49	3.58 (-6.42 to 13.6)	0.46
UEFI, Total score out of 100	94.1 ± 5.82	85.9 ± 6.44	8.22 (-10.3 to 26.7)	0.36

* Denotes statistically significance, $p < .05$

[a] Adjusted means ± standard errors, mean differences (95% confidence intervals [CI]), *P* values presented for comparisons at 6 weeks and 12 weeks postoperatively.

Abbreviations: CI = Confidence Interval; WOSI = The Western Ontario Shoulder Instability Index; ASES = The American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; UEFI = The Upper Extremity Functional Index.

At the four week follow-up, all eleven patients in the brace group and eight of the nine patients in the sling group completed the brace/sling evaluation. Feelings of stability while wearing the brace or sling were rated significantly higher in the brace group than in the sling group (3.00 ± 6.01 vs. 29.8 ± 7.05 [adjusted mean ± standard error], score out of 100 where lower scores indicate greater stability; mean difference = -26.8 [95%CI -46.3 to -7.21], p=0.01). Participants in both groups rated that the device helped with their recovery similarly (9.64 ± 3.54 vs. 9.25 ± 4.15 [adjusted mean ± standard

error], score out of 100 where lower scores indicate greater helpfulness in recovery; mean difference = 0.39 [95%CI -11.1 to 11.9], p=0.94), while overall satisfaction with the brace or sling tended to be rated better in the brace group (12.2 ± 5.34 vs. 21.3 ± 6.26 [adjusted mean ± standard error], score out of 100 where lower scores indicate greater overall satisfaction; mean difference = -9.07 [95%CI -26.4 to 8.29], p=0.29).

Chapter 6

Discussion

Chapter 6 – Discussion

This study was a randomized clinical trial comparing the effect of external rotation immobilization to internal rotation immobilization following an arthroscopic Bankart repair. Immobilization in external rotation following arthroscopic Bankart repair was postulated to result in greater range of motion (ROM) and patient reported outcome (PRO) scores of quality of life (QOL) and function at six weeks postoperatively. Using an external rotation immobilization brace following anterior arthroscopic stabilization resulted in significantly better external rotation ROM when compared to a traditional sling at six weeks and twelve weeks postoperatively. There was no significant difference in PRO scores between groups at the same time points. We observed a trend toward greater overall satisfaction and significantly higher ratings with respect to feelings of stability on subjective participant ratings in the brace group compared to the sling group as reported at four weeks postoperatively. Between weeks two and four following surgery, participants in both groups had a similar reduction in the length of time the devices were worn as physical therapy progressed, pain reduced and comfort increased.

When examining baseline patient characteristics, we observed a longer time from injury to surgery as well as greater participation in collision sports in the brace group compared to the sling group. In the brace group, two participants had a disproportionately longer period between the time of injury

and surgery compared to the rest of the group. The contribution of the two participants to the overall mean of the group exaggerated the average given the small group size. Greater participation in collision sports in the brace group was also observed, though this is of questionable prognostic importance since our primary outcome was ROM during the rehabilitation phase, during which participants would not be competing in sport. Involvement in collision sports would be of greater interest in a study examining rates of recurrence, as this is a significant risk factor for future dislocations.

When examining forward flexion and abduction ROM at six weeks and twelve weeks postoperatively, we found no statistically significant difference between the brace group and the sling group. The mean between-groups difference for forward flexion was small (1.59 degrees) while the difference for abduction was larger (10.5 degrees) however, examining the 95% CIs suggests that we cannot exclude or confirm the possibility that a clinically important difference exists between groups. We did find a statistically significant difference between groups for external rotation ROM at both six weeks and twelve weeks postoperatively in favour of the brace group. The mean between-groups difference at six weeks (22.2 degrees [95% CI 10.8 to 33.7], $p<0.01$) and 12 weeks (23.6 degrees [95% CI 13.1 to 34.0], $p<0.01$) postoperatively represented a clinically important difference on average and the lower boundary of the 95% CI excludes the possibility that the difference between groups is not clinically meaningful. This result suggests that immobilization in external rotation

following an arthroscopic anterior stabilization is of benefit in the recovery of external rotation ROM.

Disease specific QOL for shoulder instability, as measured by The Western Ontario Shoulder Instability (WOSI) index, presented no statistically significant difference at six and twelve weeks postoperatively. Given the range of the 95% CI at six weeks (-16.5 to 12.1) and twelve weeks (-6.25 to 17.5), the minimal clinically important difference (MCID) of 20% can be excluded at both time points. A similar pattern was found when analyzing the ASES and the UEFI; the mean difference was not statistically different, but in this case the 95% CIs were not conclusive.

The primary rationale for immobilization following an anterior shoulder dislocation is to allow the damaged structures to heal while protecting them from strain and further injury. Cadaveric and magnetic resonance imaging (MRI) studies have shown that external rotation more closely approximates the edges of the Bankart lesion and increases contact force between the glenoid labrum and the glenoid, which is believed to influence healing (1-3). This rationale also applies to surgical stabilization as external rotation may allow repaired structures to heal in more a "natural" anatomical position on the glenoid, rather than the shortened and anterior position that is believed to occur with internal rotation.

Recovery of functional ROM is a major goal of rehabilitation following an arthroscopic stabilization. The early phase of rehabilitation is focused on ROM prior to muscle strengthening, functional exercises and sport specific skills. If

immobilization in external rotation results in greater gains in ER ROM earlier in the rehabilitation process, patients should be able to progress through their physical therapy regiments more rapidly and return to sport sooner. This is of special interest to young active patients who are usually unwilling to modify their level of activity or participation in sport. Due to an insufficient sample size, this study was not able to conclusively show that immobilization in external rotation resulted in greater range of motion in the rehabilitation phase. However, the results of the present study suggest that some benefit may be expected for patients using an external rotation brace following an arthroscopic Bankart repair.

Research examining external rotation as a position of immobilization in the treatment of anterior shoulder dislocations is relatively new and limited. Most researchers have focused on rates of recurrence as the primary outcome (4-6); only one study included QOL scores as an outcome (6). No prior study had examined external rotation immobilization in a surgical population or reported its effect on range of motion in the rehabilitation phase of treatment.

Due to time constraints, the required sample of 75 participants per group was not achieved. As a result, this study does not have sufficient power to make definitive conclusions about the difference between treatment groups in ROM and PRO. Our ability to recruit patients into the study may have been improved by revising the eligibility criteria or stratification criteria to expand the breadth of patients who were eligible for the trial. Further, by expanding this study to

include multiple centers, we may have been able to accelerate patient recruitment and improve on the generalizability of the results.

In addition, the results of this study may be influenced by missing data; nine missing ROM points (six sling and three brace) and six missing PRO points (five sling and one brace). Because our study was small, it is possible that even a small proportion of missing data can influence the results, threatening the validity of the study. For example, one patient in the sling group was lost-to-follow-up at four weeks postoperatively resulting in his two week data being imputed for the remaining missing visits, a practice likely to underestimate his progress and decrease the average ROM for the sling group.

Further, data is rarely missing for trivial reasons and may be related to the treatment and/or the outcome. That data was missing disproportionately between groups is also of concern. Patients receiving a sling for immobilization may be less likely to fully commit to the study protocol knowing they have received the standard treatment. In this study, there was a greater proportion of missing ROM and PRO data from the sling group.

We did follow the intention-to-treat principle however, and analyzed patients within their allocated group whether or not they completed the prescribed treatment. This principle is meant to preserve the prognostic balance between groups provided through random allocation to treatment. Preserving the prognostic balance will help to minimize the risk of Type I error (finding a

significant difference when none exists). Prognostic balance had not yet been achieved in this study due to insufficient patient recruitment.

An additional limitation of this study is that we did not directly track participants' progress during physical therapy. Patient-reported journals could be used to capture rehabilitation milestones, though rehabilitation journals are dependent on the patient filling them out accurately and diligently to get a true record of their rehabilitation. Future research may consider implementing more frequent measurements during the first six weeks postoperative to comment on the rate at which each groups returned to a specific level of range of motion as well as the trajectory of change.

When measuring ROM, the outcome assessor did not vary the order in which the three planes of motion were measured, which can result in measurement order bias. By changing the order in which the movements are measured, we can reduce the possibility that the measurements conducted later in the sequence are influenced by those conducted earlier. In this way, the gains in ROM by the simple movements conducted during the measurements can be balanced by measuring in a varied order. Further, the time of day at which the measurements were conducted was not controlled in an effort to accommodate the participants' schedule. Similarly to the measurement order bias, movements performed later in the day may enjoy greater ROM due to greater laxity in the healing structures as a result of simple movements performed during the course of the day.

In the assessment of ROM, we did not measure internal rotation. This presented a major limitation in this study, as we were unable to comment on the effects of immobilization in ER on the patients' internal rotation ROM. Though patient self-reported QOL measures are designed to examine the impact of an injury on activities of daily living such as putting on a coat, washing one's back or managing toileting, a quantitative measure of internal rotation would have added a further dimension of comparison.

This study was conducted at a tertiary care center where the population of patients is elite. Patients that seek this level of care have often had prior treatment of various degrees and are now seeking a specialist. As a result, these patients are more apt to select surgical treatments and are usually more committed to the rehabilitation process that follows.

One of the strengths of this study was its design. We employed a randomization scheme utilizing permuted blocks and stratification for surgeon and superior labrum anterior posterior (SLAP) repair. Furthermore, we carefully adhered to established methodology and measurement protocol. With continued patient recruitment, the randomization will result in good prognostic balance between treatment groups. Valid and reliable outcome measures were used to assess PRO, and ROM data was collected by a single outcome assessor who was blinded to treatment allocation and used a standardized ROM measurement protocol to minimize variability. Finally, patient compliance to the immobilization protocol in this trial was excellent and similar between the two treatment groups.

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Chapter 7

Conclusion

Chapter 7 - Conclusion

For patients with anterior shoulder instability who undergo an arthroscopic Bankart repair, this study suggests that postoperative immobilization in an externally rotated brace provides greater external range of motion at six and 12 weeks postoperative then immobilization in an internally rotated sling. As a greater number of patients participate in this study, the certainty about this conclusion will improve.

Appendix I

Ethics Review Certificate

Letter of Information

Consent Form

Device Information Sheet

Letter to the Therapist

Physical Therapy Protocol

Range of Motion Measurement Protocol

Copyright Release

Western

Office of Research Ethics

The University of Western Ontario
Room 00045 Dental Sciences Building, London, ON, Canada N6A 5C1
Telephone: (519) 661-3036 Fax: (519) 850-2466 Email: ethics@uwo.ca
Website: www.uwo.ca/research/ethics

Use of Human Subjects - Ethics Approval Notice

Principal Investigator: Dr. R.B. Litchfield
Review Number: 13314 **Review Level:** Full Board
Review Date: May 15, 2007
Protocol Title: A Prospective, Randomized Evaluation of Externally Rotated Bracing Versus the Traditional Internally Rotated Immobilization of the Shoulder in Arthroscopic Bankart Lesion Repairs
Department and Institution: Orthopaedic Surgery, University of Western Ontario
Sponsor:
Ethics Approval Date: August 17, 2007 **Expiry Date:** April 30, 2008
Documents Reviewed and Approved: UWO Protocol, Letter of Information and Consent dated July 6, 2007, Device Information Sheet, Physiotherapy Letter of Information
Documents Received for Information:

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced study on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the UWO Updated Approval Request Form.

During the course of the research, no deviations from, or changes to, the protocol or consent form may be initiated without prior written approval from the HSREB except when necessary to eliminate immediate hazards to the subject or when the change(s) involve only logistical or administrative aspects of the study (e.g. change of monitor, telephone number). Expedited review of minor change(s) in ongoing studies will be considered. Subjects must receive a copy of the signed information/consent documentation.

Investigators must promptly also report to the HSREB:

a) changes increasing the risk to the participant(s) and/or affecting significantly the conduct of the study;
b) all adverse and unexpected experiences or events that are both serious and unexpected;
c) new information that may adversely affect the safety of the subjects or the conduct of the study.

If these changes/adverse events require a change to the information/consent documentation, and/or recruitment advertisement, the newly revised information/consent documentation, and/or advertisement, must be submitted to this office for approval.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

Chair of HSREB: Dr. John W. McDonald
Deputy Chair: Susan Hoddinott

Ethics Officer to Contact for Further Information		
✓ Jenniler McEwen	☐ Denise Grafton	☐ Grace Kelly (

cc: ORE File
LHRI

This is an official document. Please retain the original in your files.

LETTER OF INFORMATION

A Prospective, Randomized Evaluation of Externally Rotated Bracing Versus the Traditional Internally Rotated Immobilization of the Shoulder in Arthroscopic Bankart Lesion Repairs

The pronouns 'you' and 'your' should be read as referring to the participants rather than the parent/guardian who may be signing the consent form for the participant.

This study is being conducted at the Fowler-Kennedy Sport Medicine Clinic as part a master's thesis project by Stephane Vlachos, a graduate student at the University of Western Ontario, under the supervision of Dr. Robert Litchfield, M.D. F.R.C.S.C., and will involve 40 participants.

You are being invited to participate in a clinical trial (a type of research study), which will compare two different methods of shoulder immobilization following surgery for instability (arthroscopic Bankart lesion repair). The two treatments being compared are immobilization of the shoulder in a traditional sling or immobilization in an external rotation brace (your arm resting at 90 degrees to your body). Both are accepted methods of treatment of shoulder surgery.

Procedure

If you agree to participate, you will be randomly placed (like the flip of a coin) in one of the two study groups at the time of your surgery. You will have a 1 in 2 chance of being assigned to the traditional sling group or external rotation brace group. You will be provided with either a sling or an external rotation brace to be worn for a total of four weeks. All patients will receive an identical sling or brace, which will be applied and adjusted at the time of your surgery. Patients in both groups must wear their sling or brace at all times with the exception of physiotherapy sessions, showering or when doing hand, wrist and elbow exercises. In your week 2 and 4 assessments, you will be asked to remove your brace or sling prior to seeing the assessor to allow them to make measurements and conduct questionnaires without favouring a particular study group. After having removed the device, allow your hand to rest naturally at your side, so to not indicate your resting arm position while immobilized.

All subjects in the trial will be followed at 2, 4, 6 and 12 weeks after surgery to complete measurements of range of motion and quality of life questionnaires regarding the function of the shoulder. You will also be asked to complete a form regarding how often you've been wearing the brace or sling. These visits take place at regular follow-up evaluations requested by your surgeon at the Fowler Kennedy Sport Medicine Clinic. The 4 week evaluation is an additional visit required for participation in this study. At this visit, only measurements and questionnaires will be completed. Measurements and administration of questionnaires will take approximately 30 minutes.

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care. You do not waive any legal rights by signing the consent form. You will not incur any additional costs by participating in this study. If you are participating in another study at this time, please inform the study investigator or study doctor right away to determine if it is appropriate for you to participate in this study. If, during the course of this study, new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the investigator.

Confidentiality

You will not be identified personally in any publication or communication resulting from this study, and your records will be kept confidential. At the time of enrollment you will be assigned a unique study identification number. A master list of research participants with this number is kept separately from the data collected. This list assists with accurate data linkage for ongoing data collection and auditing of the study during your participation. This list will be destroyed upon completion of the study. The representatives of The University of Western Ontario Health Science Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.

Risks

The risks associated with this study are the same for both treatments and consist of those commonly accompanying immobilization of the arm after surgery. These include: stiffness of the elbow and forearm that may reach into the wrist, numbness or tingling in the arm and hand as well as loss of muscle resulting from lack of use of the arm. Patients in the external rotation group should also be aware of their arm position when moving around with the brace on to avoid contact with door frame, tables, chairs, etc.

Benefits

There are no known benefits associated with participating in the study, but your participation will help us get new knowledge that will benefit future patients undergoing arthroscopic shoulder surgery. If you choose not to participate in the study or withdraw before the study is complete, the alternative course of treatment will be the standard of care as prescribed by your attending physician.

If you have any questions, please contact Stephane Vlachos, at
or Dr. Robert Litchfield, at , or your surgeon. You will receive a copy of this letter of information and consent form should you choose to participate. If you have any questions about your rights as a research participant or the conduct of the study you may contact Vice President Research, c/o Lawson Health Research Institute

Consent Form

Re: A Prospective, Randomized Evaluation of Externally Rotated Bracing Versus the Traditional Internally Rotated Immobilization of the Shoulder in Arthroscopic Bankart Lesion Repairs

I, _____ have read the Letter of Information,
Patient Name
have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

_____	_____
Patient Signature	Date of Consent
_____	_____
Name of Parent/Legal Guardian*	Signature of Parent/Legal Guardian*
_____	_____
Name of Person Conducting Informed Consent	Signature of Person Conducting Informed Consent
_____	
Date	

**** Required if subject is less than 18 years of age at the time of consent.***

Device Information Sheet

A Prospective, Randomized Evaluation of Externally Rotated Bracing Versus the Traditional Internally Rotated Immobilization of the Shoulder in Arthroscopic Bankart Lesion Repairs

Dear Participant,

Thanks again for agreeing to be part of this study. The information gained by your commitment to this effort will be used to help other patients undergoing similar surgical procedures. In order to keep things equal between the two groups in the study, we ask that you follow the instructions of your doctors and physiotherapists as closely as possible.

Here are a few tips on how to get by with your new device:

Leave your arm in the sling/brace at **ALL** times. You should remove it only while doing physiotherapy, showering or occasionally as part of your hand, wrist and elbow exercises. Please record the times (when and for how long) your sling/brace is off. This will be helpful when completing your questionnaires.

FOR BRACE REMOVAL: Use only the quick release buckles to remove your device. Please DO NOT adjust the Velcro strapping as the positioning of the device is of importance.

FOR SLING REMOVAL: Only adjust one side of the Velcro strapping to minimize changes in the positioning of the device. Please ensure that arm position returns to the treatment position.

When showering, keep your arm in the position that it would be sitting in were your brace/sling still on. You may need some help with this. You may lift your arm to your side just enough to wash your armpit but don't do this excessively. If you are in the brace group, KEEP YOUR HAND IN FRONT OF YOUR BODY and try no to let your arm rotate toward your body. After you have dried yourself off, put your arm back in the device immediately.

For elbow and wrist exercises, always be sitting down. Again, keep your shoulder in the position it would have been in your device. Allow your elbow and wrist to fully extent and flex. You should do this at least 2-3 times a day to avoid stiffness in your arm.

If you have any questions regarding the adjustment or use of your device please contact Sharon Griffin at (519)

Sincerely,

Robert Litchfield, MD FRSC(C) Stephane Vlachos, B.Sc. M.Sc. (Candidate)

Physiotherapy Letter of Explanation

Re: A Prospective, Randomized Evaluation of Externally Rotated Bracing Versus the Traditional Internally Rotated Immobilization of the Shoulder in Arthroscopic Bankart Lesion Repairs

Dear Therapist,

This study is being conducted at the Fowler Kennedy Sport Medicine Clinic as part a master's thesis project by Stephane Vlachos, a graduate student at the University of Western Ontario, under the supervision of Dr. Robert Litchfield, M.D. F.R.C.S.(C). We are monitoring the progress of individuals after undergoing arthroscopic Bankart lesion repair. In particular, we are attempting to determine whether immobilization of the shoulder in an externally rotated position results is more rapid recovery of range of motion versus the traditional sling. We would appreciate your help.

We would like to standardize the outpatient physiotherapy protocol as much as possible. For that reason, we have provided patients with a copy of the Fowler Kennedy Sport Medicine Clinic rehabilitation protocol for arthroscopic Bankart lesion repair. Though this is a guideline, please follow it as closely as possible. Document any modifications to treatment or patient difficulties during the course of the rehabilitation on your report to the surgeon.

A suggested schedule for therapy is 2-3 sessions per week, for about 1 hour per session. If you have any concerns about a patient's compliance with the rehabilitation protocol, please include this information in your patient notes.

If you have any questions, please contact Stephane Vlachos, BSc. MSc. (Candidate), at (519) Dr. Robert Litchfield, Study Investigator, at .
We appreciate your help in this investigation. It would not be possible without your involvement.

Sincerely,

Robert Litchfield, MD FRCS(C) Stephane Vlachos, BSc. MSc. (Candidate)

Postoperative Rehabilitation Protocol

A Prospective, Randomized Evaluation of Externally Rotated Bracing Versus the Traditional Internally Rotated Immobilization of the Shoulder in Arthroscopic Bankart Lesion Repairs

0-2 Weeks

Wear sling at all times, with the exception of physiotherapy and showering.

Physiotherapy: Elbow, wrist and hand
Posture, scapular control
Modalities as indicated

2-4 Weeks

Wear sling for ADL, activities and sleep.
Able to remove sling for quiet times maintaining immobilization position

Physiotherapy: active-assisted ROM
ER to 30° (surgeon dependent)
-do not push ER, to return with function
Scapular control and strength
Humeral head control as needed
Incision mobilization as indicated
Mobilization within available ROM
Modalities as indicated

4-6 Weeks

Wean off sling

Physiotherapy: progress to active exercises
Add functional exercises
Mobilization as indicated
Modalities as indicated

6 Weeks

Commence strengthening
Continue with GHJ and scapular control exercises.
Add more functional exercises.

3 Months

Commence skills

External Rotation PostOp Study
Range of Motion Measurement Protocol

Resting Position

- Resting supine on firm treatment bed
- No pillow under the head
- End of Range occurs when:
    - Unable to lift arm up
    - Too painful to move through range of motion
    - Unable to hold end position for measurement
    - Unable to move while controlling humeral head position

Measuring Forward Flexion

- Gently palpate the head of the humerus to locate center
- Ensure that head of humerus is still, not moving anteriorly during movement
- Movement is to be conducted actively, holding the end position with the other hand while measurement is conducted.
- Position goniometer on lateral surface of the treated arm
- Landmarks:
    - Middle of the head of the humerus to lateral epicondyle on the lateral aspect of the arm
- Measurement:
    - Ensure the proximal arm of the goniometer holds its marked position from rest
    - Gently palpate the head of the humerus to monitor anterior movement, monitor scapula for excessive movement compared to normal side
    - Patient moves through range of motion
    - Measure range by aligning distal arm of the goniometer with the lateral epicondyle
    - Record measurement
- Repeat three times and take the average

Measuring External Rotation

- Ensure that head of humerus is still, not moving anteriorly during movement
- Movement is to be done actively
- Position patient arm at 90° of elbow flexion with forearm netural
- Ensure arm is perpendicular to bed, slightly elevated with cushion under elbow to allow for positioning of the center of rotation of the goniometer on olecranon
- Place goniometer on posterior surface of the lower arm
- Landmarks:
    - Center of olecranon process and ulnar styloid
- Measurement:
    - Ensure the proximal arm remains in its marked position from rest
    - Patient actively moves in external rotation while monitoring for movement of humeral head

    - Maximum of 30° when restricted by rehab protocol guidelines is to be observed
- End of range when:
    - Patient reaches limitation
- Repeat three times and take the average

Measuring Abduction

- Gently palpate head of humerus for movement
- Landmarks:
    - Center of the head of the humerus on the anterior surface and the insertion of the biceps tendon in the cubital fossa
- Measurement:
    - Allow patient to move through range of motion actively while monitoring for humeral head movement
    - Abduction movement will be limited with external rotation post operative limitation
    - Measure range and remove goniometer ensuring the angle is maintained in order to read measurement
    - Record measurement
- Repeat three times and take the average

From: Ann Campbell
Subject: **Re: eorthopod images**
Date: August 25, 2009 11:43:38 AM GMT-04:00
To: Stephane Vlachos
▸ 1 Attachment, 0.3 KB

Stephane - A formal release is not necessary for us. Your agreement to comply with our rules is sufficient - please print this email as your permission for one-time use of the five images listed below for your thesis (titled below). Good Luck!! Ann

Stephane Vlachos wrote:

> Ann,
>
> The fax number you can send the copyright confirmation too is: 519.661.4267
> Please include a cover page and address it to me. It's a communal fax for the research department. I would appreciate if you would send me an email after you've send the fax. I'll have to make a trip to the clinic to pick it up.
>
> Thank you very much for all your help. All the best.
>
> Stephane
>
> On 24-Aug-09, at 12:00 PM, Ann Campbell wrote:
>
> > include the web address please...Send the release via email - and a fax # I can return it to you. Permission will be granted for one-time use as stated below. Ann
> >
> > Stephane Vlachos wrote:
> >
> > > Ann,
> > >
> > > The title of my thesis is: "An RCT to compare the outcomes of patients who undergo an arthroscopic Bankart repair who are immobilized postoperatively in external versus internal rotation".
> > >
> > > I can comply to those regulations. I required a copyright release statement to include in the appendix. I would assume sending it via email would be easiest if that's possible. If it needs to be sent by fax, I can get a fax number you can send it to.
> > >
> > > Just to clarify. Should the note below the image include the web address or is the statement sufficient.
> > >
> > > Thank you very much for getting back to me so quickly.
> > >
> > > Stephane Vlachos

Appendix II

Patient Demographics Form

Surgical Evaluation Form

Range of Motion Data Collection Form

Compliance Questionnaire

Brace/Sling Evaluation Questionnaire

FOWLER KENNEDY
SPORT MEDICINE CLINIC

Date (dd/mm/yyyy): ☐☐/☐☐/☐☐☐☐

Patient ID#: ☐☐ - ☐☐☐☐☐

External Rotation PostOp Study – Patient Demographics

1. Date of Birth: ☐☐ ☐☐ ☐☐☐☐ (Day / Month / Year)
2. Operative Shoulder: ☐ Right ☐ Left
3. Do you have symptoms in your other shoulder? ☐ Yes ☐ No
4. Dominant Hand: ☐ Right ☐ Left
5. Gender: ☐ Male ☐ Female
6. Height: ☐ Feet ☐☐ Inches
7. Weight: ☐☐☐ lbs.
8. Date of Injury: ☐☐ ☐☐ ☐☐☐☐ (Day / Month / Year)
   ☐ Not Applicable/Gradual Onset – Please specify duration of symptoms in years ☐☐
9. Activity causing injury: ☐ ADL ☐ Work ☐ Sport
   ☐ Other (specify): _____
   ☐ No Specific Injury Recalled
10. If injury occurred during sport, please indicate what sport and level of contact: _____
    ☐ Collision (ie. Football, Hockey, Soccer, Wrestling)
    ☐ Limited Contact (ie. Baseball, Volleyball, Basketball, Skiing/Snowboarding)
    ☐ Non-contact (ie. Swimming, Tennis, Track & Field)
    ☐ N/A (Injury did not occur during sport)

Continued on next page →

11. Level of Activity: ☐ Varsity/High School ☐ Intramural/Recreational ☐ Non-Athlete

12. Occupation (specify): _____

13. Type of Employment: ☐ Full-time ☐ Part-time ☐ Retired ☐ Student

☐ Stay-at-home Parent ☐ Social Assistance ☐ Other (specify): _____

14. Have you had to reduce your hours of work because of your shoulder?

☐ Yes ☐ No ☐ N/A

15. Have you had to modify your duties at work because of your shoulder?

☐ Yes ☐ No ☐ N/A

16. Are you off work for a reason **unrelated** to your shoulder? ☐ Yes ☐ No

If you answered yes, please describe the reason: _____

_____

17. What previous treatment have you had on your shoulder? Please check all that apply.

☐ Pain Killers (ex. Tylenol)
☐ Anti-inflamatories (ex. Celebrex, Advil)
☐ Corticosteroid Injection
☐ Non-steroid Injections (ex. Synvisc)
☐ Physical Therapy
☐ Other (specify): _____

18. Smoking Habits:

☐ Never
☐ Quit Smoking — How long since you quit? _____
☐ 1 Pack per week
☐ 1 Pack per day
☐ More than 1 pack per day

Thank You for Completing the Questionnaire

External Rotation PostOp Study

Patient ID#: ☐☐ - ☐☐☐☐☐☐ **Date** ☐☐ ☐☐ ☐☐☐☐
DD MM YYYY

Surgical Evaluation

1. Anterior Labrum

1.1 Please describe the **anterior labrum** using the following descriptors

- ☐ Normal appearing labrum
- ☐ Degenerative
- ☐ Torn (soft tissue Bankart lesion)
- ☐ Bony Bankart lesion
  - ☐ <10% off of glenoid
  - ☐ 10-25% off of glenoid
  - ☐ >25% off of glenoid

2. Posterior Labrum

2.1 Please describe the **posterior labrum** using the following descriptors

- ☐ Normal appearing labrum
- ☐ Degenerative
- ☐ Torn (Reverse Bankart lesion)

3. Cartilage

3.1 Please describe the **glenoid cartilage** using the following descriptors

- ☐ Normal
- ☐ Grade I (mild cartilage fibrillation)
- ☐ Grade II (significant fibrillation but not to bone)
- ☐ Grade III (fibrillation to bone)
- ☐ Grade IV (exposed subchondral bone)

3.2 If not Normal, please describe the **size** of the lesion

Width ☐☐.☐ ☐ cm☐ mm
Length ☐☐.☐ ☐ cm☐ mm

3.3 Please describe the **humeral head cartilage** using the following descriptors

- ☐ Normal
- ☐ Grade I (mild cartilage fibrillation)
- ☐ Grade II (significant fibrillation but not to bone)
- ☐ Grade III (fibrillation to bone)
- ☐ Grade IV (exposed subchondral bone)

3.4 If not Normal, please describe the **size** of the lesion

Width ☐☐.☐ ☐ cm☐ mm
Length ☐☐.☐ ☐ cm☐ mm

3.5 Please describe whether there is a **Hill Sachs lesion**

- ☐ Present
- ☐ Absent

3.6 If **Present**, please describe the **size** of the lesion

Width ☐☐.☐ ☐ cm☐ mm
Depth ☐☐.☐ ☐ cm☐ mm

External Rotation PostOp Study

Patient ID#: ☐☐ - ☐☐☐☐☐☐ Date ☐☐ ☐☐ ☐☐☐☐ DD MM YYYY

Surgical Evaluation

4. Rotator Cuff

4.1 Please describe the **Supraspinatus/Infraspinatus** using the following descriptors

- ☐ Normal appearing tendon
- ☐ Tendinosis
- ☐ Partial thickness tear (intrasubstance)
- ☐ Partial thickness tear (bursal side)
- ☐ Partial thickness tear (humeral side)
- ☐ Full thickness tear

4.2 If a **full thickness tear** is present describe the size of the tear (articular side).

AP ☐☐.☐ ☐ cm☐ mm

ML ☐☐.☐ ☐ cm☐ mm

4.3 Please describe the **Subscapularis** using the following descriptors

- ☐ Normal appearing tendon
- ☐ Tendinosis
- ☐ Partial thickness tear (intrasubstance)
- ☐ Partial thickness tear (bursal side)
- ☐ Partial thickness tear (humeral side)
- ☐ Full thickness tear

4.4 If a **partial thickness tear** describe the size of the tear.

AP ☐☐.☐ ☐ cm☐ mm

ML ☐☐.☐ ☐ cm☐ mm

5. Superior Labrum Anterior Posterior Lesion

5.1 Please describe the **Superior Labral Biceps Complex** using thefollowing descriptors

- ☐ Normal
- ☐ Type I (fraying and degeneration labrum remains attac
- ☐ Type II (superior labrum and biceps complex stripped of the underlying glenoid)
- ☐ Type III (bucket handle tear)
- ☐ Type IV (bucket handle tear extending into the biceps tendon)
- ☐ Type V (Bankart + SLAP)

6. Biceps Tendon

6.1 Please describe the **Biceps Tendon** using the following descriptors

- ☐ Normal
- ☐ Subluxed
- ☐ < 25% torn
- ☐ < 50% torn
- ☐ > 50% torn
- ☐ Complete tear

External Rotation PostOp Study

Patient ID#: ☐☐ - ☐☐☐☐☐☐ **Date** ☐☐ ☐☐ ☐☐☐☐ DD MM YYYY

Surgical Evaluation

7. Other

7.1 Does the patient have synovitis?

☐ yes ☐ no

7.2 Does the patient have loose bodies?

☐ yes ☐ no

7.3 If yes, please provide the number

_____

8. Subacromial Space

8.1 Please describe the bursa.

☐ Normal

☐ Inflammed

8.2 Please describe the size of any RC lesions (bursal sided)

AP ☐☐.☐ ☐ cm ☐ mm

ML ☐☐.☐ ☐ cm ☐ mm

8.3 Please describe the Acromion using the following descriptors

☐ Normal

☐ Type I (flat)

☐ Type II (curve)

☐ Type III (hook)

8.4 Please describe the AC joint using the following descriptors

☐ Normal

☐ Inflammed

☐ Mild OA

☐ Significant OA

Primary Diagnosis: _____

_____

_____

_____

Secondary Diagnosis: _____

_____

_____

_____

_____

Other: _____

_____

_____

_____

☐	Baseline		
☐	2 wks post	☐	4 wks post
☐	6 wks post	☐	12 wks post

Date (dd/mm/yyyy): ☐☐/☐☐/☐☐☐☐

Patient ID#: ☐☐ - ☐☐☐☐☐☐

External Rotation PostOp Study - Range of Motion Form

1. Forward Flexion
(as per ROM Measuring Protocol)

Trail 1				.	
Trail 2				.	
Trail 3				.	
Average				.	

2. External Rotation
(as per ROM Measuring Protocol)

Trail 1				.	
Trail 2				.	
Trail 3				.	
Average				.	

3. Abduction
(as per ROM Measuring Protocol)

Trail 1				.	
Trail 2				.	
Trail 3				.	
Average				.	

n/a	Baseline		
	2 wks post		4 wks post
n/a	6 wks post	n/a	12 wks post

Date (dd/mm/yyyy): ☐☐/☐☐/☐☐☐☐

Patient ID#: ☐☐ - ☐☐☐☐☐☐

External Rotation PostOp Study - Compliance Questionnaire

When you received your shoulder brace/sling, you were asked to wear it at all times, with the exception of physical therapy, showering and to exercise your hand, wrist and elbow, for a period of four weeks after your surgery date.

In the past two weeks, how often did you wear your brace/sling?

Rarely (less than 6 hours per day) ☐

Sometimes (6 - 12 hours per day) ☐

Most of the time (13 – 18 hours per day) ☐

All the time (as directed in Letter of Information) ☐

If you answered other than 'All the time', explain.

_____

_____

_____

_____

_____

_____

_____

_____

FOWLER KENNEDY
SPORT MEDICINE CLINIC

Date (dd/mm/yyyy): ☐☐/☐☐/☐☐☐☐

Patient ID#: ☐☐ - ☐☐☐☐☐☐

BRACE / SLING EVALUATION QUESTIONNAIRE

To complete the following questions, place a slash across the line where best indicates your feelings about the question asked.

1. Did you experience discomfort as a result of wearing the brace/sling?

No discomfort ——— Extreme discomfort

2. Did you experience cramping in your arm as a result of wearing your brace/sling?

No cramping ——— Extreme cramping

3. Did you experience skin problems as a result of wearing your brace/sling?

No problems ——— Extreme problems

4. Did you experience problems with your brace/sling slipping?

No slipping ——— Extreme slipping

5. Did you find it hot to wear your brace/sling?

No difference ——— Extremely hot

6. Did you feel that your shoulder was more stable while wearing your brace/sling?

No problems ——— Extreme instability

7. Did you feel that wearing the brace/sling has helped in your recovery?

Definitely ——— Definitely Not

8. In general, were you satisfied with your brace/sling?

Very Satisfied ——— Very Dissatisfied