The Ottawa Hospital | L'Hôpital d'Ottawa

Title: A Multicenter Randomized Controlled Trial Comparing Single-Row With Double-Row Fixation in Arthroscopic Rotator Cuff Repair: Long-Term Follow-up

Clinicaltrials.gov NCT00253864

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A clinicaltrials.gov was created for the purpose of publication requirement.
We have included the protocol below for reference.

Single Versus Double Row Fixation for Arthroscopic Cuff Repair: A 8 Year Long Term Follow-up of a Randomized, Controlled Trial

1. Statement of Objectives

In a previous study, ninety patients undergoing arthroscopic rotator cuff repair were randomized to receive either a single-row or a double-row repair[33]. The primary objective was to compare the Western Ontario Rotator Cuff Index (WORC) score at twenty- four months (from June 2007 to June 2009). Secondary objectives included comparison of the Constant and American Shoulder and Elbow Surgeons (ASES) scores and strength between groups. Anatomical outcomes were assessed with magnetic resonance imaging (MRI) or ultrasonography to determine the postoperative healing rates.

The results of the study published in the Journal of Bone and Joint Surgery – JBJS (Volume 94-A. Number 14. July 18, 2012) are in agreement with other randomized clinical trials comparing single-row and double-row fixation. Our hypothesis that double-row fixation yields superior quality of life outcomes compared with single row lateral fixation was not supported.

No significant differences between the single-row and double-row groups were found in the WORC, ASES, or Constant scores or strength at any time point. However, a smaller initial tear size and double-row repair were associated with a greater healing rate.

The original RCT involved a two-year follow-up period. It is our hypothesis that a longer follow-up period would have been of value. At a mean of 8 years postoperatively, we will follow-up the patients involved in the original RCT and measure the same outcomes that were assessed at 2-years.

2. Background, Rationale, and Present state of Knowledge

Tears of the rotator cuff tendons are a very common entity. Uhthoff and associates(1) found a 20% incidence in a series of cadaver dissections. Lehman and associates(2) found an incidence of 17% in a large series of cadaver dissections with an incidence of 30% in those older than 60 years of age. Surgical repair of the rotator cuff is the preferred treatment with failure of conservative therapy. The results of open repair of the rotator cuff have shown that function and strength can be successfully restored, and that pain is effectively relieved.(3-6) Failure of open cuff repair can occur as a result of infection, failure of the deltoid muscle reattachment, and re-tearing of the rotator cuff.(7) Failure of the rotator cuff repair is the most frequently observed complication, and has been estimated between 20 and 68%. (8) Failure of the repair of the rotator cuff may occur secondary to poor tendon or bone quality, failure of suture or knots, inadequate fixation of tendon to bone, lack of tendon to bone healing, or inappropriate postoperative care.(9-11)

In the interest of minimizing the surgical morbidity associated with open rotator cuff repair, minimally invasive arthroscopic techniques have evolved. These techniques do not require detachment in the deltoid muscle, and thus deltoid detachment is not seen as a complication in arthroscopic cuff repair. Advantages of the arthroscopic method include smaller skin incisions, glenohumeral joint inspection, treatment of intra-articular lesions, and more rapid rehabilitation.(12) Weber and associates have shown that the rate of infection seen in arthroscopic cuff repair is lower than that of open repair: failure of the repair itself however does occur with arthroscopic methods.(13) Various reports have shown that a correlation exists between the anatomical integrity of the cuff as determined by various imaging modalities and the functional outcome following open repair.(5, 6, 14)

According to Gerber et al.(10), the principles of successful repair include strong tissue grasping, strong repair to bone, and little gap formation until healing. The two most popular methods of achieving these goals using arthroscopic technique involve the use of suture anchors, either in a single row or double row configuration.

Studies that examine pull-out strength allow for comparison of different techniques with respect to the strength of initial repair. However, as healing occurs, the repaired tendon relies less and less on initial fixation and more greatly on the innate strength of the tendon-bone junction. It is possible that a greater area of contact between the healing tendon and bone may result in increased strength. The surface area provided by different types of repairs has been studied by Apreleva et al.(15) The authors quantitatively studied the 3-dimensional area of the original supraspinatus insertion and compared this area to four different methods of reconstruction, in 10 human cadavera. The methods included transosseus simple suture, transosseous mattress suture, suture-anchor simple suture, and suture-anchor mattress suture. The authors concluded that transosseus simple suture reproduced the greatest area at 85% original surface area, and that the other three methods reproduced 67% of the original area only. If the anatomic rotator cuff insertion area not reproduced, results are likely to vary depending on the bone quality at the insertion site. This data has been used as the justification for adding a double row to arthroscopically repaired rotator cuffs.(16)

Dugas et al.(17) determined the insertion area of the rotator cuff tendons. The mean area of the supraspinatus insertion was 1.55 cm^2. The mean medial-to-lateral and anterior-to-posterior dimensions were 1.27 cm and 1.63 cm respectively.

In an effort to maximize contact area, the double row technique was described by Lo et al.(16) The first row is placed medially and sutures are threaded through the rotator cuff using mattress technique. The second lateral row is placed further laterally on the footprint. The authors suggest that a greater number of points of fixation and improved coverage may improve results.

Pullout strength of suture anchors has been shown to correlate with trabecular and cortical bone mineral density.(18) Load to failure was found to be greatest in the middle and anterior regions of the proximal greater tuberosity. However, other authors have found no correlation between suture anchor failure and overall bone mineral density, and higher load to failure with anchors in the posterior greater tuberosity.(19)

Kim et al. compared single row and double row fixation on nine pairs of cadaver shoulders.(20) The authors reported that double row repair demonstrated superior performance over single row repair. Gap formation, strain, repair stiffness and ultimate load to failure was superior in the double row repair.

Cummins et al. compared various configuration of suture anchors with transosseus sutures in an animal model.(21) Suture anchor repair was found to be comparable to transosseus repair in pullout strength. The weakest repair involved single-loaded sutures anchors applied through the cuff with simple stitches. Pullout strength improved two-fold with mattress sutures and double-loaded suture anchors, with the strongest configuration involving a double-row repair with mattress sutures.

Mazzocca et al. compared four arthroscopic repair techniques in 20 human cadaveric shoulders.(22) The authors compared single row with three types of double row fixation: diamond, mattress double anchor, and modified mattress double anchor. Footprint area,

displacement under cyclic loading and load to failure were examined. No difference between single row and double row fixation was found in cuff displacement or load to failure. A significantly larger cuff footprint area was found in all double row configurations over single row repairs.

Uhthoff et al.(23) have demonstrated in a rabbit model that the portion of tendon in contact with the bony trough influences the quality of healing. Fibrocartilage formed at sites where transected tendon was in contact with bone but not where the articular or bursal tendon surface contacted bone.

Gartsman et al. performed a prospective, randomized study in 93 patients to investigate the effect of subacromial decompression on arthroscopic rotator cuff repair.(24) The authors did not identify any difference between the interventions. Overall outcome for arthroscopic cuff repair with and without acromioplasty was 91.5 and 89.2 respectively using the ASES outcome measure.

In an earlier study, Gartsman et al. reported on the outcome of 73 patients with a minimum two year follow-up who underwent arthroscopic rotator cuff repair.(25) The authors reported a statistically significant improvement in all three rating scores (Constant, ASES and UCLA) from preoperative outcome scores. At final follow-up, 90% of patients rated their level of satisfaction as good or excellent.

Boileau et al. evaluated the outcomes and anatomical results in 65 patients who underwent arthroscopic repair of full thickness supraspinatus tears. The authors reported excellent by the outcome score of Constant in 77%, good in 15%, fair in 6% and poor in 2%. Overall, 88% achieved effective pain relief, and and 95% were either very satisfied or satisfied. MRI or CT-arthrogram was used to assess the integrity of the tendon a minimum of 6 months after repair. Complete healing was noted in 71% of shoulders, and partial healing in 5%. The incidence of tendon healing was similar with previously reported anatomical outcomes for open rotator cuff repair.(4-6, 26)

Smith et al.[36] Have demonstrated in rotator cuff repair with a double-row SutureBridge configuration, self-reinforcement is seen in repairs with and without medial-row knots. Self-reinforcement is greater with the knotless technique.

In a recently published retrospective study, the results of single row fixation was compared with double row fixation.(27) The authors reported on 80 shoulder with a mean follow-up of 35 months. The series included 39 patients who underwent repair with a single-row technique, and 41 patients who underwent a double-row repair. The functional outcomes based on UCLA and ASES scores were not significantly different in the two techniques. However, the incidence of re-tear in small tears was 13% in the single-row group compared with no defects in the double-row group, and for large and massive tears, 44% in the single row and 29% in the double-row group.

The principle investigator has performed bench testing to compare the surface contact area of the two techniques. Single row repairs were compared with double row repairs have a significantly smaller surface contact area. However, clinical evidence exists to suggest that the healed contact area for single repairs is similar or equal to that of double row repairs as healing occurs over the entire cuff footprint.(28)

The authors believe it is scientifically necessary to investigate the differences between single-row and double-row fixation for arthroscopic rotator cuff repair. As more surgeons are trained in the technique, it will be performed more frequently. Increased patient

awareness continues to lead to increasing demand for the minimally invasive approach. Double-row repair brings with it an increase in operative time and a significantly increased cost related to implants. Furthermore, a double-row reconstruction was found to be more economically attractive for larger rotator cuff tears (>3cm)[35].

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4. Research Design, Methods and Analysis

Primary research question
Do patients who underwent rotator cuff repair with arthroscopic technique using single row fixation have improved disease specific quality of life, as measured by the Western Ontario Rotator Cuff Index (WORC) at 8 years post-operatively compared with double row fixation.

Secondary Research Questions

1) What is the difference in anatomical outcome between double and single row fixation, as measured by US or MRI, at 8 years post-operative?
2) What is the difference in outcome as measured by the Constant score, and the ASES score, at 8 years post-operative?

Response variables
Our primary outcome measure is the disease specific Western Ontario Rotator Cuff Index (WORC)(29). The secondary outcome measures are the Constant Score(30), the American Shoulder and Elbow Society standardized assessment of shoulder function (ASES)(31). US or MRI evaluations will be carried out at 8 years post-operative to determine the healing status of the rotator cuff.

Null Hypothesis
There will be no significant differences in functional or quality-of-life outcomes (WORC scores) in patients who underwent single-row compared to double-row fixation techniques.

Why is a trial needed now?
As soft-tissue healing can be considered to be complete by twelve months, it seems likely that any further changes in healing status would be related to chronic intrinsic tendon pathology, which should be similar between groups. However, it is important to know the long-term results in terms of pain, function, strength, and patient satisfaction.

Give references to any relevant systematic review and discuss the need for your trial in the light of these reviews
An advanced search of the clinical database in Medline was undertaken.
There have been no systematic reviews or comparative studies and only a handful of case series. Favorable long-term results of case series have been reported demonstrating the efficacy of both single row and double row techniques. Hence the need for a randomized controlled trial comparing the two different types rotator cuff fixation.

How will the results of this trial be used?
The results of the trial will provide valuable information regarding the best technique for managing the rotator cuff via arthroscopic repair. The data obtained from quality of life measurements will enable the authors to suggest recommendations that will lead to maximizing function and quality of life in patients undergoing arthroscopic rotator cuff repair. The information will be presented at national and international shoulder meetings, and publications will be sought in major orthopaedics journals.

4.1 THE PROPOSED TRIAL

What is the proposed trial design?
Long term follow-up of a multicentred, randomized trial.

4.2 What are the planned trial interventions?

All patients have undergone a standard diagnostic arthroscopy using either single-row or double row fixation.

Single row fixation:
Single row fixation is defined as follows: fixation by way of bone anchors, located along a single row parallel to the sagittal axis of the rotator cuff footprint. The exact location of the anchors may occur either within that lateral margin of the footprint, or lateral to the footprint, over the edge of the tuberosity. Either simple or mattress sutures were used at the discretion of the surgeon.

Double row fixation:
Double row fixation is defined as follows: fixation by way of bone anchors, located along two rows. The lateral row is parallel to the sagittal axis of the rotator cuff footprint. The exact location of the anchors occurred either within that lateral margin of the footprint, or lateral to the footprint, over the edge of the tuberosity. Either simple or mattress sutures were used at the discretion of the surgeon. The medial row is parallel to the sagittal axis of the rotator cuff footprint. The exact location of the fixation occurred close to the bone/cartilage junction along the medial aspect of the footprint. Mattress sutures were used. An acceptable alternative method of fixation for the medial row consists of the Suretak II (Smith and Nephew). This device consists of a sutureless bioabsorbable implant and anchors the rotator cuff to the bone.

4.4 What are the proposed methods for protecting against sources of bias?
Blinding: Due to the nature of this surgical trial, the surgeon could not be blinded to the intervention. However, a trained independent assessor will carry out the follow-up assessments and will be blinded. This will minimize the potential for biases introduced by the examiner when performing the physical assessment and recording data. The assessor will not have access to the patient chart prior to the examination. The patient will also be blinded to the treatment assignment. To help reduce the potential for observer bias, the physical examination and the administration of study questionnaires are standardized.

4.5 What are the planned inclusion/exclusion criteria?

Patient Population
The target population is both men and women of any age that were randomized in the original double versus single row RCT.

Inclusion Criteria
1. Randomized in the double versus single row original RCT study

Exclusion Criteria
1. Excluded from the original study
2. Withdrew from original Study
3. Unable or unwilling to provide informed written consent

4.6 What is the proposed duration of treatment period?
All patients will come in for one clinic visit and will not be followed any further after all of the imaging and clinic data has been collected.

4.7 What is the proposed frequency and duration of follow-up?
Patients are assessed in the clinic by the blinded evaluators at 8 years post operatively. It is anticipated that at this clinic visit approximately 20 minutes will be spent with the assessor.

However, as in all doctors' clinics, some waiting can be anticipated and this can be variable depending on clinic loads and nature of cases.

Radiographic analysis will be done with an ultrasound or MRI at 8 years postoperative. Evaluation of the imaging will be performed by an independent investigator who is blinded to the patient's assigned treatment.

4.8 What are the proposed primary and secondary outcome measures? (see Appendix A)

PRIMARY:

The Western Ontario Rotator Cuff Index (WORC)(29) is a disease specific evaluation that has proven to be an accurate and valid assessment of function after rotator cuff repair. Because it is specific for rotator cuff disease of the shoulder, it is highly sensitive to small but clinically significant changes in patient function.

SECONDARY:

1) The American Shoulder and Elbow Surgeon's (ASES) score is a shoulder specific assessment tool developed by the American Shoulder and Elbow Society for use in all types of shoulder problems (Appendix A)(31). It consists of both patient self-assessment and physician assessment. The patient self-evaluation is divided into two sections: pain and activities of daily living (ADL). Pain is recorded on a visual analogue scale and ADL's are recorded on a numeric scale. The overall score is an equal weight of the two sections and produces a score out of 100. The higher the score, the better the outcome. The physician assessment is divided into four segments: range of motion, physical signs, strength and instability. The results of the physician assessment do not provide a score.

Europeans favor the Constant Score(30) (Appendix A). It has been validated, normalized in comparison to disease free patients and places greater emphasis on range of motion and strength The European shoulder society has adopted the Constant Score for functional assessment of the shoulder. The Constant Score records a variety of shoulder measurements including an objective test of strength using a spring loaded measuring device. The Constant Score reflects an overall clinical functional assessment. This instrument is based on a 100-point scoring system calculated from a self-assessment portion that evaluates pain and ability to perform tasks of daily living, and a clinical assessment which tests active range of shoulder motion and strength. The higher the score the better the outcome.

2) Further secondary outcomes which will be monitored during the post-operative course include: operative times of the two procedures, complications, and the incidence of revision surgery in each procedure.

The MRI or Ultrasound will determine the healing rates of both procedures. It is imperative to determine the relative healing rates as cuff integrity following surgery correlates with function and strength.

4.9 How will the outcome measures be measured at follow-up?

PRIMARY:

The patient will complete the WORC questionnaire at 8 years post-operatively. The research assistant will be available to answer any questions.

SECONDARY:

1) Patients will complete the ASES and Constant Scores at 8 years post-operatively. The research assistant will be available should the patient have any questions regarding the questionnaires. The patient is then examined by the blinded assessor for the physical

assessment portion of the constant score (Appendix A). The surgeon is the last person to examine the patient and is blinded to the results of the outcomes.

4.10 Details of planned analyses
Primary:
The primary analysis involves a comparison of the mean WORC scores between the two surgical treatment groups. This analysis is a two sample independent t-test to assess whether there is a statistically significant difference between groups for the mean WORC scores at 8 years post-operatively. The 5% significance level is employed. The underlying assumption for the WORC score data is that there is a normal distribution. If the sample distribution is determined to depart from normal, then a Wilcoxon rank sum test will be performed.

Secondary:
The secondary analysis involves a comparison of the secondary outcome measures between the two surgical treatment groups. The ASES, Constant Score, and imaging healing rates will be analyzed for differences between the two groups at 8 years. The planned secondary analyses are performed using a 5% significance level. No p-value adjustment is required for multiple outcomes, as treatment effectiveness is based only on the primary variable.

4.12 What is the proposed frequency of analyses?
The analysis will occur once all eligible patients have been recruited and all patient data has been collected.

4.13 What is the estimated cost and duration of the trial?
The duration of this trial will be 1 year. This study does not have any direct costs.

DETAILS OF TRIAL TEAM
Trial management:

What are the arrangements for day to day management of the trial?
The orthopedic research study coordinator is responsible for the day to day management of the trial. This includes: general administrative details, collecting, monitoring, tracking and analyzing data. The Study Research Coordinator (SRC) has experience in biostatistics, computer technology, epidemiology and study management. He/she is available to answer questions on a daily basis. **Quality Monitoring:** **Forms**: All forms are checked by the SRC for completeness, consistency and extreme values. **Appointments**: The SRC is responsible for monitoring participant visits **Equipment**: The scales used to measure power are calibrated. **Data Management:** is supervised by the study biostatistician. Data is collected on standardized Case Recording Forms (CRF). Any revisions to the CRF's are dated to maintain an audit trail of these changes. CRF's are signed and dated by the clinical investigator.

5. APPENDICES

Appendix A: Outcome Measures

WESTERN ONTARIO

ROTATOR CUFF INDEX

(WORC)©

A disease-specific quality of life measurement tool for patients with rotator cuff disease

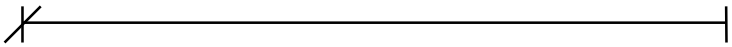
Patient Initials:_____

INSTRUCTIONS TO PATIENTS

In the following questionnaire you will be asked to answer questions in the following format and you should give your answer by putting a slash "/" on the horizontal line.

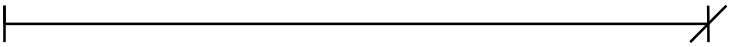
NOTE:

1. If you put a slash "/" at the left end of the line i.e.



then you are indicating that you have no pain.

2. If your put your slash "/" at the right end of the line i.e.



then you are indicating that your pain is extreme.

3. Please note:

a) that the further to the right you put your slash "/", the **more** you experience that symptom.

b) that the further to the left you put your slash "/" , the **less** you experience that symptom.

c) please do not place your slash "/" outside the end markers

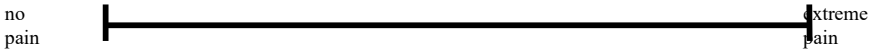
You are asked to indicate on this questionnaire, the amount of a symptom you have experienced in the past week as related to your problematic shoulder. If you are unsure about the shoulder that is involved or you have any other questions, please ask before filling out the questionnaire.

If for some reason you do not understand a question, please refer to the explanations that can be found at the end of the questionnaire. You can then place your slash "/" on the horizontal line at the appropriate place. **If an item does not pertain to you or you have not experienced it in the past week, please make your "best guess" as to which response would be the most accurate.**

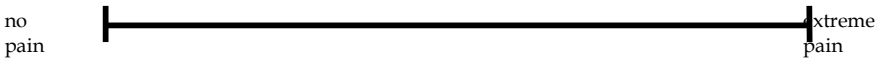
WORC
Section A: Physical Symptoms
INSTRUCTIONS TO PATIENTS

The following questions concern the physical symptoms you have experienced due to your shoulder problem. In all cases, please enter the amount of the symptom you have experienced in the last week. (Please mark your answers with a slash "/")

1. How much sharp pain do you experience in your shoulder?



2. How much constant, nagging pain do you experience in your shoulder?



3. How much weakness do you experience in your shoulder?

4. How much stiffness or lack of range of motion do you experience in your shoulder?

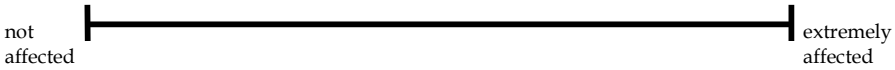
5. How much are you bothered by clicking, grinding or crunching in your shoulder?

6. How much discomfort do you experience in the muscles of your neck because of your shoulder?

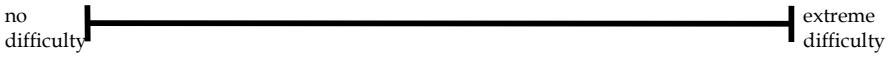
WORC
SECTION B: Sports/Recreation
INSTRUCTIONS TO PATIENTS

The following section concerns how your shoulder problem has affected your sports or recreational activities in the past week. For each question, please mark your answers with a slash "/".)

7. How much has your shoulder affected your fitness level?



8. How much difficulty do you experience doing push-ups or other strenuous shoulder exercises because of your shoulder?



9. How much has your shoulder affected your ability to throw hard or far?

10. How much difficulty do you have with someone or something coming in contact with your affected shoulder?

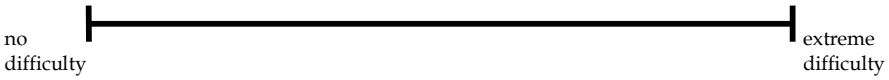
WORC

SECTION C: Work

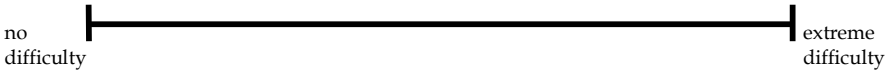
INSTRUCTIONS TO PATIENTS

The following section concerns the amount that your shoulder problem has affected your work around or outside of the home. Please indicate the appropriate amount for the past week with a slash "/".

11. How much difficulty do you experience in daily activities about the house or yard?



12. How much difficulty do you experience working above your shoulder?



13. How much do you use your uninvolved arm to compensate for your injured one?

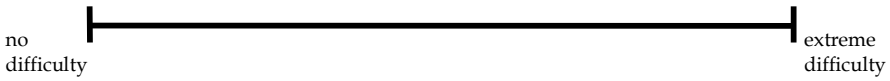
14. How much difficulty do you experience lifting heavy objects at or below shoulder level?

difficulty difficulty

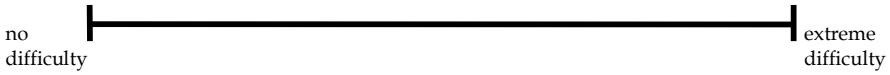
WORC
SECTION D: Lifestyle
INSTRUCTIONS TO PATIENTS

The following section concerns the amount that your shoulder problem has affected or changed your lifestyle. Again, please indicate the appropriate amount for the past week with a slash "/".

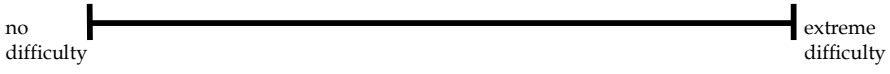
15. How much difficulty do you have sleeping because of your shoulder?



16. How much difficulty have you experienced with styling your hair because of your shoulder?



17. How much difficulty do you have "roughhousing or horsing around" with family or friends?



18. How much difficulty do you have dressing or undressing?

WORC
SECTION E: Emotions
INSTRUCTIONS TO PATIENTS

The following questions relate to how you have felt in the past week with regard to your shoulder problem. Please indicate your answer with a slash "/".

19. How much frustration do you feel because of your shoulder?

20. How "down in the dumps" or depressed do you feel because of your shoulder?

21. How worried or concerned are you about the effect of your shoulder on your occupation?

_____
_____
_____

THANK YOU FOR COMPLETING THE QUESTIONNAIRE

American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES): Patient Self-Report Section

1. Pain:

How bad is your pain today? (mark an "X" on the line)

|_____|

No pain at all — Pain as bad as it can be

2. Satisfaction:
Overall, what is your level of satisfaction with your shoulder?

|_____|

Poor — Excellent

3. Function: Circle the number in the box that indicates your ability to do the following activities:

0 = Unable to do; 1 = Very difficult to do; 2 = Somewhat difficult; 3 = Not difficult

	Activity	Right arm	Left arm
1.	Put on a coat	0 1 2 3	0 1 2 3
2.	Sleep on your painful or affected side	0 1 2 3	0 1 2 3
3.	Wash back/do up bra in back	0 1 2 3	0 1 2 3
4.	Manage toileting	0 1 2 3	0 1 2 3
5.	Comb hair	0 1 2 3	0 1 2 3
6.	Reach a high shelf	0 1 2 3	0 1 2 3
7.	Lift 10 lbs. above shoulder	0 1 2 3	0 1 2 3

8.	Throw a ball overhand	0	1	2	3		0	1	2	3
9.	Do usual work – List:_____	0	1	2	3		0	1	2	3
10.	Do usual sport – List: _____	0	1	2	3		0	1	2	3

CONSTANT SCORE		
Dominance left right	**Affected side** left right	**Normal side** left right
Pain		
severe 0, moderate 1-5, mild 6-10, none 11-15	/ 15	/ 15
Activities of Daily Living		
Work 0 (unable) – 4 (full w/o restriction)	/ 4	/ 4
Recreation/sport 0 (unable) – 4 (full activities)	/ 4	/ 4
Sleep 0 (grossly disturbed) – 2 (undisturbed)	/ 2	/ 2
Ability to work at the level: (check one)	_____ none _____ waist _____ xyphoid _____ neck _____ head _____ above head	_____ none _____ waist _____ xyphoid _____ neck _____ head _____ above head
Motion (passive)		
Forward flexion / elevation	Degrees	Degrees
Abduction	Degrees	Degrees
ER	Degrees	Degrees
IR	_____ Level	_____ Level
Motion (active)		
Hand behind head (elbow forward)	Yes / No	Yes / No
Hand behind head (elbow back)	Yes / No	Yes / No
Hand on head (elbow forward)	Yes / No	Yes / No
Hand on head (elbow back)	Yes / No	Yes / No
Full elevation from top of head	Yes / No	Yes / No
Active motion		
Dorsum of hand to: (check one)	____ lateral thigh (0) ER __ hand behind head with elbow held forward (2) ____ buttock (2) __ hand behind head with elbow held back (2) ____ lumbosacral junction ____ waist ____ 12th dorsal vertebra ____ interscapular region (T7)	____ lateral thigh (0) ER __ hand behind head with elbow held forward (2) ____ buttock (2) __ hand behind head with elbow held back (2) ____ lumbosacral junction ____ waist ____ 12th dorsal vertebra ____ interscapular region (T7)
Power		

1. trial	Lb	Lb
2. trial	Lb	Lb
3. trial	Lb	Lb