MASTER OF MEDICINE

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Long term follow up of rotator cuff Magnetic resonance imaging changes in patients who underwent acromioplasty without repair of full thickness supraspinatus tendon tears

BY

Dr DAVID CHIVERS

ORTHOPAEDIC REGISTRAR

GROOTE SCHUUR HOSPITAL

UNIVERSITY OF CAPE TOWN

SUPERVISORS: Prof. S. ROCHE

The research reported is based on independent work performed by the author. Neither the whole work nor any part of it has been, is being, or is to be submitted for another degree to any other university.

Dr D Chivers

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PART A RESEARCH PROTOCOL

Long term follow up of rotator cuff MRI changes in patients who underwent acromioplasty without repair of full thickness supraspinatus tendon tears.

I. Aim:

To assess the MRI pathoanatomical changes 10 years after unrepaired full thickness supraspinatus tears in a population of patients that had acromioplasty done for symptomatic impingement with a rotator cuff tear.

II. Background:

The supraspinatus muscle is the commonest of the rotator cuff muscles to tear and it usually tears in isolation. However associated tears of the subscapularis and biceps tendon occur in 16% of patients. The aetiology of these tears is multifactorial but can be classified into intrinsic or extrinsic causes. Bony impingement is the commonest extrinsic cause of supraspinatus tears. Intrinsic causes of rotator cuff tears due to tensile overload and age related muscle atrophy may occur with or without extrinsic causes such as impingement. An intrinsic or extrinsic cause of degeneration of supraspinatus muscle initiates a pathological cascade that can result in full thickness tears. Ozaki showed that 38% of cadavers over 60 had cuff tears, this figure rose to 80% in cadavers over 90 years of age. The prevalence of asymptomatic full thickness tears in the population aged 40 – 60 years is 4% according to an MRI study by Sher and Uribe. From this data it can be noted that

rotator cuff tears are relatively common and that not all patients with cuff tears present with a loss in function or pain.

Impingement syndrome as initially described by Neer, is the painful entrapment of the supraspinatous tendon, subacromial-subdeltoid bursa and/or the biceps tendon between the humeral head and the coracoacromial arch. Neer noticed that the anterior third of the acromium and its anterior lip seemed to be the offending structures in the concept of the impingement. Primary extrinsic impingement occurs when the space available for the rotator cuff is diminished, which may be due to subacromial spurring, acromial fracture, pathological os acromiale, or osteophytes off the undersurface of the acromioclavicular joint. This diminished space may lead to attenuation of the Rotator cuff.

The subacromial space and acromial morphology are important factors when deciding to do an acromioplasty. The acromial morphology was classified by Bigliani into three types:

Type 1: Flat undersurface of acromium

Type 2: Smoothly curved undersurface

Type 3: Hooked anterior inferior acromial undersurface.

Bigliani noticed that the type 3 acromion and a high incidence of rotator cuff tears due to impingement.

Neer classified impingement into 3 stages:

Stage 1 (Oedema and haemorrhage) typically occurs in the younger patient <25years, follows a clinical course of reversibility and treatment is conservative.

Stage 2 (Fibrosis and tendonitis), occurs in slightly older patients 25-40 years, follows a clinical course of recurrent pain, treatment includes bursectomy.

Stage 3(bone spurs and tendon rupture) occurs in patients >40 years results in progressive disability and treatment involves acromioplasty and/or rotator cuff repair. Therefore narrowing of the subacromial space due to bony pathology can lead to attritional changes of the rotator cuff and possible rupture. Based on the observations by Neer and Bigliani the recommended treatment for impingement syndrome is acromioplasty with or without rotator cuff repair.

More recently there are advocates for repair of all cuff tears. Yet we know that many patients who have a cuff tear are asymptomatic. We also know that in 80% of patients who have had repairs, but in whom the tendon has failed are also asymptomatic. Previously many patients were treated with a subacromial decompression without repair. The clinical results were surprisingly similar to patients treated with rotator cuff repair and decompression. There have been more recent papers looking at the natural history of rotator cuff tears suggesting there is progression of atrophy and fatty changes which are irreversible despite a successful surgical repair.

Computerized tomography scanning and Magnetic resonance scans have been used to document these fatty changes and atrophy. Goutallier developed a system of staging fatty infiltration of the supraspinatous muscle, which was later modified by Fuchs et al for MRI.

We would like to review the MRI changes in this group of confirmed rotator cuff tears who have least a 10 year follow up. To date this has not been done. There has been a short term follow up of patients who did not have surgery and were followed up

with MRI, but no long term studies. It may give us insight into the natural history of tears and the effect of a subacromial decompression on tear progression, fatty changes and atrophy. It will allow us to compare these with what we already know about repaired tendons and non-surgically treated rotator cuff tears.

III. Methods

A data base of patients that have had acromioplasty without rotator cuff repair in the last ten to fifteen years will be reviewed. Approximately 64 patients have been identified at Constantiaberg Mediclinic.

All patients have a confirmed full thickness tear at surgery and underwent a subacromial decompression without repair.

These patients will be contacted and asked if they are willing to partake in the study. If they are prepared to participate they will be asked to sign a consent form (see appendices). Patients shoulder function will be assessed using the Oxford and Constant shoulder scores. (see appendices) . They will be asked to have an MRI scan. The MRI images will be at no cost to them except for time, which will be approximately 45 min. The image series used by the previous studies will be once again used to document the fatty changes, atrophy and tear size. Two independent radiologists will be used and a statistician will be used to check the reliability and reproducibility of the scores The clinical score will be then used to see if there is a relationship to clinical outcome and MRI findings.

IV. Costs

Costs will include the telephone calls made to patients and the use of the MRI scan. Research funding has been arranged and confirmed through the department of

Orthopaedics. No further costs will be incurred. There will be no financial benefit to patients or authors of this study

V. Ethical concerns

The study will be a retrospective review of available data. No patients will be identified by name or number and every effort will be made to protect their privacy. There will be no immediate benefit to the patients involved but significant findings may contribute towards a better understanding of the natural history of rotator cuff tear pathoanatomy following acromioplasty without rotator cuff repair.

VI. Researchers

Principal investigator: Dr D Chivers

Co-investigators: Dr S Roche, Dr A Lambrechts, Dr B Vrettos, Dr R Dachs.

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PART B LITERATURE REVIEW

I. Objectives

1. Long term clinical assessment of patients that had subacromial decompression for impingement syndrome.

2. Assess the MRI changes of unrepaired full thickness tears of the rotator cuff following subacromial decompression.

3. Analyse and correlate both clinical and MRI data and justify the need to repair full thickness tears of the rotator cuff in the elderly population.

4. Research Question: There is controversy regarding the natural history of isolated tears of the rotator cuff and their management in impingement syndrome. Does acromioplasty alter the progression of unrepaired isolated full thickness supraspinatus tears?

II. Summary and interpretation of literature, and its implications for the Research

The reason for progression of isolated tears of the rotator cuff in impingement syndrome is multifactorial. Understanding the natural history of rotator cuff tears is important when evaluating whether acromioplasty has any effect on rotator cuff tear progression.

The article by Melis et al[10], that looked at the natural history of fatty infiltration and atrophy in tears of the supraspinatus muscle, suggests that tears progressed to stage 2 fatty infiltration by 4 years and severe fatty infiltration (stage 3 /4) by 6 years. Traumatic tears progressed faster and fatty infiltration of at least stage 2 was present at three years. Muscle atrophy was noted in all tear types and to occur at an average of 4,5years post symptomatic onset. This progression to fatty infiltration and atrophy is extrapolated to impingement syndrome, but as yet not been validated.

This assumption that all tears progress is now being disputed. Fucentese et al and Maman et al [11, 12] have both shown that small tears may get smaller and may even heal if they are isolated tears. These authors both quote figures of of 8-9 %[11, 12] healing rates in patients without impingement syndrome. One of the aims of this study was to investigate the possible protective effect of acriomiolasty on full thickness rotator cuff tears.

The aetiology of rotator cuff tears in impingement syndrome can be attributed to extrinsic, intrinsic and genetic factors. There is debate about the mechanisms of rotator cuff pathology in impingement syndrome. These mechanisms will influence management decisions and therefore need to be understood.

Acromial morphology as an extrinsic cause for rotator cuff tears and their progression is well described. A recent article [13] looking at relationship of radiographic acromial characteristics and rotator cuff diseases showed that the presence of an acromial spur is highly associated with a rotator cuff tears in the symptomatic and asymptomatic patient. In Bigliani's [4] description of acromial morphology, a type three acromion has a higher incidence of rotator cuff tears. However in the Maman[12] review there was no statistical correlation between acromial spur and rotator cuff tears. The presence of an acromial spur or abnormal

acromial morphology does not always correlate with clinical impingement symptoms. Therefore there has been the suggestion that intrinsic causes may be responsible for symptomatic impingement syndrome and rotator cuff degeneration.

The intrinsic theories of cuff degeneration and tears suggest that there is a zone of hypovascularity and relative hypoxia that may lead to apoptosis and rotator cuff damage.[14,15,16] This abnormal cuff is now dysfunctional which results in uncentered high riding humeral head which causes the acromial morphological changes.

Articular sided tears are also more common than bursal sided tears which may suggest intrinsic pathology. Ogata [17] showed that cuff degeneration and tears progress with age but acromial degeneration did not. Hyvonen[18] reported that open acromioplasty did not prevent tear progression in impingement syndrome as they found that tears may appear after acromioplasty in shoulder where no tear was present at time of surgery.

There have also been studies looking at surgical versus non-surgical or structured exercise regimes for the treatment of impingement syndrome, which have shown that long term outcomes are similar when comparing acromioplasty versus non-surgical interventions.[19,20,21]

A randomized controlled study performed by Kukkonen[1] demonstrated that operative treatment is no better than conservative treatment in the management of supraspinatous tears in impingement syndrome. Follow up was one year in this study. Kukkonen suggests that conservative treatment be the primary method of treatment.

These findings may support the theories that cuff degeneration is due to intrinsic mechanisms, and surgery may not alter the natural history of rotator cuff pathology in impingement syndrome.

There has been evidence to suggest that rotator cuff pathologies and symptoms may be genetic and there is a subset of patients that have increased genetic susceptibility in developing tears and subsequent tear progression. Harvie et al [22] has shown that siblings have a 2.42 relative risk of developing full thickness rotator cuff tears and a 4.65 relative risk of the tears being symptomatic.

The variability noted in the healing response of the rotator cuff in a cross section of patients is now being attributed to alterations in genetic expression. Genetic expression which controls cellular, vascular and extracellular matrix formation is controlled by biological and local mechanical factors at the tendon edge. It is postulated that surgical repair alters the biological environment at the tendon edge and therefore modulates gene expression [23]. Repair of the rotator cuff in sheep and rabbits however, has not shown to reverse fatty infiltration but early repair may result in partial recovery according to Kang et al. [14] The genetic expression of protein degradation genes which results in proteolysis and muscle degeneration is up regulated in massive rotator cuff tears [24]. This may explain the association with larger rotator cuff tears and significant fatty infiltration and atrophy.

The pathophysiology of fatty degeneration is related to unloading of the muscle due to its loss of insertion into bone, this result in changes in physiological structure and function of the muscle and ultimately atrophy [25, 26].This unloading of the muscle may ultimately be the reason that the larger tears progressed with respect to fatty

changes and atrophy. In smaller tears there is less unloading of the muscle and therefore less propensity to atrophy and degeneration.

The Rotator crescent and Rotator cable theory by Burkhart et al [3] describes two distinct areas of the rotator cuff with different load characteristics. The rotator cable which is relatively thicker and supports more load shielding the crescent area. Burkhart hypothesized that as people age there is progressive thinning of this relatively avascular crescent zone. This hypothesis has been recently supported by Kim et al [27] who has shown that most degenerative tears occur in a more posterior location near the junction of the infraspinatus and supraspinatus and not anteriorly as initially thought. The biomechanical relevance of this tear position is that the cable is still intact which has been shown in biomechanical studies by Meisha et al[28] to be the primary load bearing structure in the supraspinatus. Therefore tear position and not only tear size are important to consider when assessing the clinical effects of rotator cuff tears. A small full thickness tear within the rotator cable will not necessarily progress onto significant atrophy and fatty infiltration as it is protected from load by this hypothesised cable system. This load bearing structure will allow almost normal clinical functioning despite a full thickness rotator cuff tear being present. Norlin et al[29] concluded that small full thickness tears do well clinically post acromioplasty at 10 to 13 year follow up. Norlin did not have MRI correlation of tear progression but clinical data supports the fact that small tears may have an altered natural history when compared to larger tears.

The fibrogenic and adipogenic progenitor cells in muscle that are responsible for fatty change are normally inactive in healthy muscle. The activation and differentiation of these cells has been found to be initiated by aging, oxidative stress

and muscle degeneration. This fibroproliferative response in the older patient negatively affects the rotator cuff muscle's ability to regenenerate[25,26] The age of the patient is therefore important in assessing the healing capability of a rotator cuff tear and is of relevance in this study as we had an elderly patient cohort. Ozaki[30] showed that 38% of cadavers over 60 had cuff tears, this figure rose to 80% in cadavers over 90 years of age, where most of these tears were asymptomatic. The prevalence of asymptomatic full thickness tears in the population aged 40 – 60 years is 4% and patients over 60 years are 24% according to an MRI study by Sher and Uribe[31]. From this data it can be noted that rotator cuff tears are relatively common and that not all patients with cuff tears present with a loss in function or pain which might explain the good clinical outcomes in this age group.

III. Identification of gaps or needs for further research

Further research into the pathophysiology of impingement syndrome and the use of non-surgical management strategies. These management strategies could involve medical and genetic therapies to promote muscle regeneration.

Further understanding of the patients at risk by using genetic profiling and research into factors that predispose to muscle degeneration.

IV. Literature search strategy

Literature search was done online. Search engines, such as Google scholar (www.scholar.google.com) and PubMed (www.pubmed.gov) were used. The following key words were used: Acromioplasty, impingement syndrome, fatty infiltration, Oxford Score, Constant Score, Rotator cuff tear.

The quality of the articles was assessed based on the levels of clinical evidence. Meta-analyses and review articles were considered to be stronger evidence; studies with larger patient numbers carried greater weight than those with smaller patient numbers, and controlled trials with outcome-based results were sought out as the results of these might provide more significant clinical evidence

Articles before the year of 1960 were excluded.

V. Quality criteria

To ensure the quality of this study the following points were raised:

a. Context for the study

We describe a clear context for the study: The long term clinical and patho anatomical MRI outcomes of unrepaired isolated full thickness tears of the rotator cuff following acromioplasty

b. Aim of the study

The aims of the study and research tools are clearly defined: Clinical parameters as measured by the Oxford Score and Constant Score. Anatomical parameters measured on MRI using the Tangent sign (Described by Zanetti). And fatty Infiltration staging (described by Goutallier modified by Fuchs)

c. Data collection and analysis

All patient personal information was confidential. Patients were given a number and there data was stored in numerically. Outcomes of patient clinical and radiographic

investigations were recorded independently and analyzed independently as to avoid bias in interpretation of results.

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PART C: AIMS AND OBJECTIVES

I. Materials and Methods

The cohort consisted of patients from a single surgeon data base who had been operated on for symptomatic impingement syndrome without repair of a full thickness supraspinatus tear diagnosed at arthroscopy. Tears were categorized as C1(less than 1cm), C2 (between 1-1.9cm), and C3 (2-3cm) according to the Snyder classification.[2].

All C1 and C2 rotator cuff tears at arthroscopy were noted to be within the rotator cable as postulated by Burkhart. [3].

Imaging:

Patients did not receive an MRI on presentation to the primary surgeon as it was not clinically indicated at the time, but were assessed clinically and had x-ray confirmation of type 3 acromial morphology as described by Bigliani[4].

On follow up, all study participants had an MRI of both shoulders. The MRI images were assessed by an experienced musculoskeletal radiologist and a fellowship trained shoulder surgeon who had no information regarding the patient's clinical outcome.

Continuity or rupture was assessed on T2 weighted coronal imaging sequence. A tear was diagnosed if there was no continuity in the muscle fibres of the rotator cuff.

The quality and quantity of the rotator cuff was assessed on parasagital T1 weighted turbospin echo images taken parallel to the glenohumeral joint.

Fatty infiltration was assessed as described by Goutallier et al[5], modified by Fuchs et al[6] for MRI.

MRI Grading:

Goutallier modified by Fuchs et al for MRI:

Stage 0 normal muscle

Stage 1 some fatty streaks

Stage 2 muscle > fat

Stage 3 fat = muscle

Stage 4 fat >muscle

Figure 1: MRI Grading

Supraspinatus atrophy was determined using the tangent sign as described by Zanetti et al. [7]

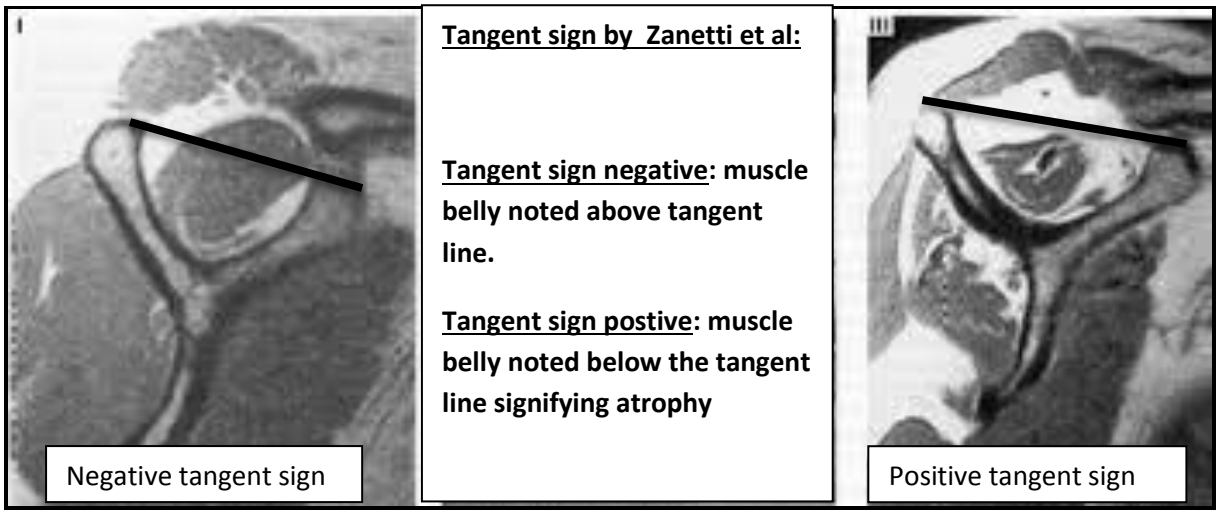


Figure 2: Muscle atrophy grading

Clinical assessment:

Clinical assessment was done according to a standardized technique using a hand held goniometer and dynamometer.

The Constant score [8] was recorded where a maximum of 100 points could be obtained. Shoulder range of movement was measured using a hand held goniometer as described by Constant and Murley[8]. Abduction strength was measured using a handheld dynamometer applied to the wrist. The arm was abducted in the scapular plane, elbow extended and forearm pronated. Three readings were taken and the average of the three readings was recorded.

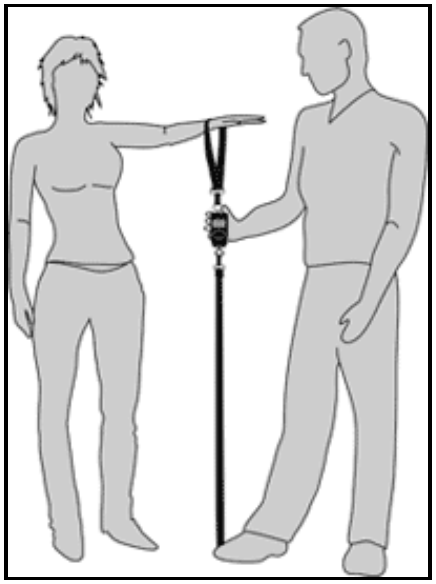


Figure 3: Representation of handheld dynamometer use

An Oxford score[9]was completed, by all patients examined, where a maximum score of 48 could be obtained.

II. Study location

MRI was done at Sport Science Institute in Newlands Cape Town. All clinical examinations were done in the medical examination room at the Sport Science Institute.

III. Study design

Analytical Retrospective Cohort study

IV. Study period

Data was collected over a period of six months, depending on availability of the MRI scan.

V. Study population

Elderly population from a single surgeon data base.

VI. Inclusion criteria

All patients had failed conservative treatment, and on examination had full active abduction, forward elevation and external rotation, minimal weakness of supraspinatus and full strength of infraspinatus and subscapularis.

Diagnosed impingement syndrome confirmed clinically and with radiographic imaging.

Diagnosed isolated full thickness tear of the supraspinatous muscle at arthroscopy.

VII. Exclusion criteria

Exclusion criteria were follow up less than five years, rheumatoid arthritis, diabetes, long term corticosteroid use and previous surgery to the shoulder

VIII. Data analysis

a) Clinical data

Completed Oxford and Constant scores were collated and stored in an excel spread sheet. The scores were then analysed and separated into the three groups of tears for statistical analysis.

Further analysis of the Constant score was done by looking at each clinical parameter measured and comparing this parameter between the three tear group sizes.

b) MRI data

The MRI scans were read by an experienced musculoskeletal radiologist and a fellowship trained shoulder surgeon. They had no access to patient clinical data and information. The fatty infiltration was staged as described by Goutallier modified by Fuchs for MRI. The stage of fatty infiltration was recorded and compared between groups. Muscle atrophy was classified as present or absent according to the tangent sign as described by Zanetti.

IX. Ethical considerations

Permission to conduct the study was obtained from the Research Ethics Committee of the Health Sciences Faculty of the University of Cape Town – see Appendix.
The protocol was accepted by Prof. M Blockman (Chairperson) on 02 October 2014.

PART D: RESULTS

I. Discussion of statistical analysis

The data was analyzed using Stata 13.0(Statacorp LP, 4905 Lakeway Drive, College Station, TX77845, USA) Categorical data between the groups was analyzed using the Chi-squared test or Fisher's exact test as appropriate. Normality of continuous data was assessed using the Shapiro Wilk test. Normally distributed data was summarized using means and standard deviations and compared using the Student's t-test. Skewed data was summarized using medians and ranges and groups compared using the Mann –Whitney test. Statistical significance was set at $p<0.05$ and all tests were two sided.

II. Discussion of results

There were 17 shoulders in 16 patients (9 females)

Mean follow-up was 7.2 years (range, 5-13 years). The mean age at surgery was 65.8 years (range, 50-82 years) and the mean age at most recent follow up was 73 years (range, 60-89years).

The patients were divided into three groups depending on size of tear at time of arthroscopy. In this study we had five C1 tears, eight C2 tears and four C3 tears.

C1 tears (n=5)

The average age at surgery was 60.4 years (range, 49-75 years).The average age of patients with C1 tears at most recent follow-up was 67.4years (range, 60-82 yrs).

The median Constant score was 86 (range 83-96) and median Oxford score was 47 (range 46-48).

Only one patient in the C1 tear group had significant fatty infiltration (grade IV) and a positive tangent sign indicating significant muscle atrophy.

C2 tears (n=8)

The average age at surgery was 65.3 years (range, 58-81 years).The average age of patients with C2 tears at most recent follow-up was 76.7 years (range, 69-81 years). The mean Constant score was 72.3 (range 62-98) and mean Oxford score was 45 (range 42-48).

Only one patient in this group had significant fatty infiltration (grade IV).

On MRI 2 tears in the group had regressed in size and were reported as partial thickness tears

C3 tears (n=4)

The average age at surgery was 69 years (range, 59-73 years).The average age of patients with C3 tears at most recent follow-up was 76.2 years (range, 72-83 years). The mean constant score was 72.3 (range 65-98). The mean Oxford score was 45 (range, 42-48).

On MRI all 4 patients had stage 4 fatty infiltration and a positive tangent sign.

(table 1)

	C1 tears	C2 tears	C3 tears
Age at surgery (range years)	60.4 years (49-75)	65 years (58-71)	69 years (59-73)
Age at follow up (range years)	67.4 years(60-82)	76.7years(69-81)	76.2 years(72-83)

Table 1. Comparison of tear size and age at surgery/follow up.

Comparison of Clinical parameters:

There was no significant difference between the three groups when comparing abduction strength Oneway ANOVA F= 2.28 (2 d.f) p=0.31), internal rotation (Kruskall-Wallis chi-squared = 0.517 (2 d.f.) p=0.8) and external rotation Kruskall-Wallis chi-squared = 0.596 (2 d.f.) p=0.7). There was however a statistical difference in range of motion when comparing forward flexion (Oneway ANOVA F= 4.23 (2 d.f) p=0.04) and lateral elevation (Oneway ANOVA F= 4.87 (2 d.f) p=0.04) between the three categories of tears.

(table 2)

	C1 tears	C2 tears	C3 tears	p value
Mean Abduction in kg (sd)	11.1 (7.5)	11.9 (7.1)	6.4 (3.3)	*p=0.4
Mean forward flexion Degrees (sd)	168.2 (7.5)	170 (7.8)	157,2 (7.2)	*p=0.04
Mean lateral elevation Degrees (sd)	171 (4.3)	170.8 (5.2)	162.8 (5.9)	*p=0.04
Median external rotation average (range) *** see key	4 (2-5)	5 (5-5)	4.5 (3-5)	**p =0.7
Median internal rotation Average (range) * see key	5(5-6)	5 (5-6)	5 (5-6)	**p =0.8

* Means were compared between the three categories using ANOVA

**Medians were compared between the three categories using Mann-Whitney U-Test

***External rotation: 1 hand behind head , elbow forward
2 hand behind head, elbow back
3 hand to top of head elbow forward
4 hand to top of head elbow back
5 full elevation

*** Internal rotation: 1 lateral thigh
2 buttock
3 lumbosacral junction
4 waist
5 T12 verterbra
6 interscapular T7

Table 2: Table showing the clinical parameters for the three categories of tear (N=17)

There was no significant difference in Oxford (Kruskall-Wallis chi-squared = 0.562 (2d.f) p=0.75) and Constant scores(Kruskall-Wallis chi-squared = 0.727 (2d.f) p=0.69) when comparing the three groups

(table 3)

	C1	C2	C3	p value
Median Oxford score (range)	47 (25-48)	45 (37-48)	45(42-48)	p=0.75
Median Constant Score (range)	86 (52-96)	72.3 (78-98)	72.3(65-86)	p=0.69

Medians were compared between the three groups using Kruskall-Wallis chi-squared test.

Table 3 : Comparison of Median Oxford and Median Constant scores by tear size (N=17)

Comparison of MRI findings:

When assessing the fatty infiltration, atrophy and tear size. The C3 tears did have a statistically higher chance of having fatty infiltration (Pearson chi –squared =16.75(Pr=0.033) p= 0.028) The C3 tears also had significant atrophy Pearson chi –squared =7.50(Pr=0.023) p=0.032) as indicated by the tangent sign.

(table 4, table 5)

	Stage 0 (%)	Stage 1(%)	Stage 2 (%)	Stage 3 (%)	Stage 4 (%)
C1 tears	40.0	20.0	20.0	20.0	0.0
C2 tears	0.0	62.0	25.0	0.0	12.5
C3 tears	0.0	0.0	0.0	0.0	100.0

Fischer's exact test p=0.028

Table 4: Comparison of tear size and proportion of muscle with fatty infiltration N=17.

	Tangent sign negative (%)	**Tangent sign positive (%)**
C1 tear	80.0	20.0
C2 tear	75.0	25.0
C3 tear	0.0	100.0

Fisher's exact test p=0.032

Table 5: Comparison of tear size and proportion atrophy

In the C2 group two of the full thickness tears were now reported as being partial thickness tears and smaller in dimension than reported on initial surgical assessment. This equates to 12% percent of the total number of shoulders assessed (CI: 1.4 -36.4)

The association between increasing age and atrophy Wilcoxon rank-sum (p=0.05) was also noted to be significant as well as age and fatty infiltration Wilcoxon rank-sum (p=0.008).

The comparison between fatty infiltration stages and abduction strength revealed that stage 0(n=2) had mean strength of 9, 4kg (4.8kg-14.0kg). Stage 1 (n=6) abduction strength mean 16,0kg (range 6,6kg -22.kg). Stage 2 (n=4) mean abduction strength was 10.4kg (range 5.3kg -15.3kg) Stage 3 (n=1) the abduction strength was 3.5kg and the stage 4 (n=4) abduction strength was 4,2kg (range 1.4kg-8,4kg). There was a statistically significant association between muscle atrophy and abduction strength, Spearman's Rho -0.6, p = 0.009

(table 6)

Fatty infiltration stage (Goutallier)	Stage 0 (n=2)	Stage 1 (n=6)	Stage 2 (n=4)	Stage 3 (n=1)	Stage 4 (n=4)
Mean Abduction strength kg (range kg)	9.4kg (4.8-14.0)	16.0kg (6.6-22)	10.4kg (5.3-15.3)	3.5kg	4.2kg (1.4-8.4)

Spearman's Rho -0.6, p =0.009

Table 6: Comparison of fatty infiltration and abduction strength

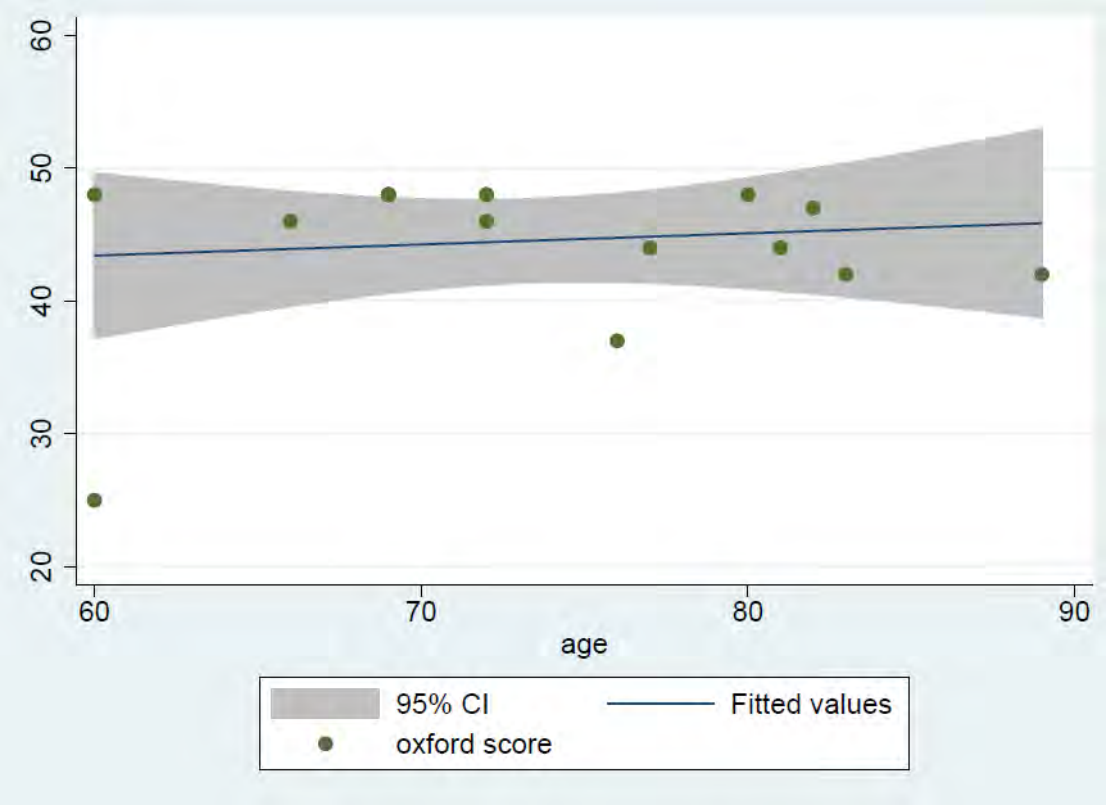


Figure 4: Graphical representation of Age and Oxford score

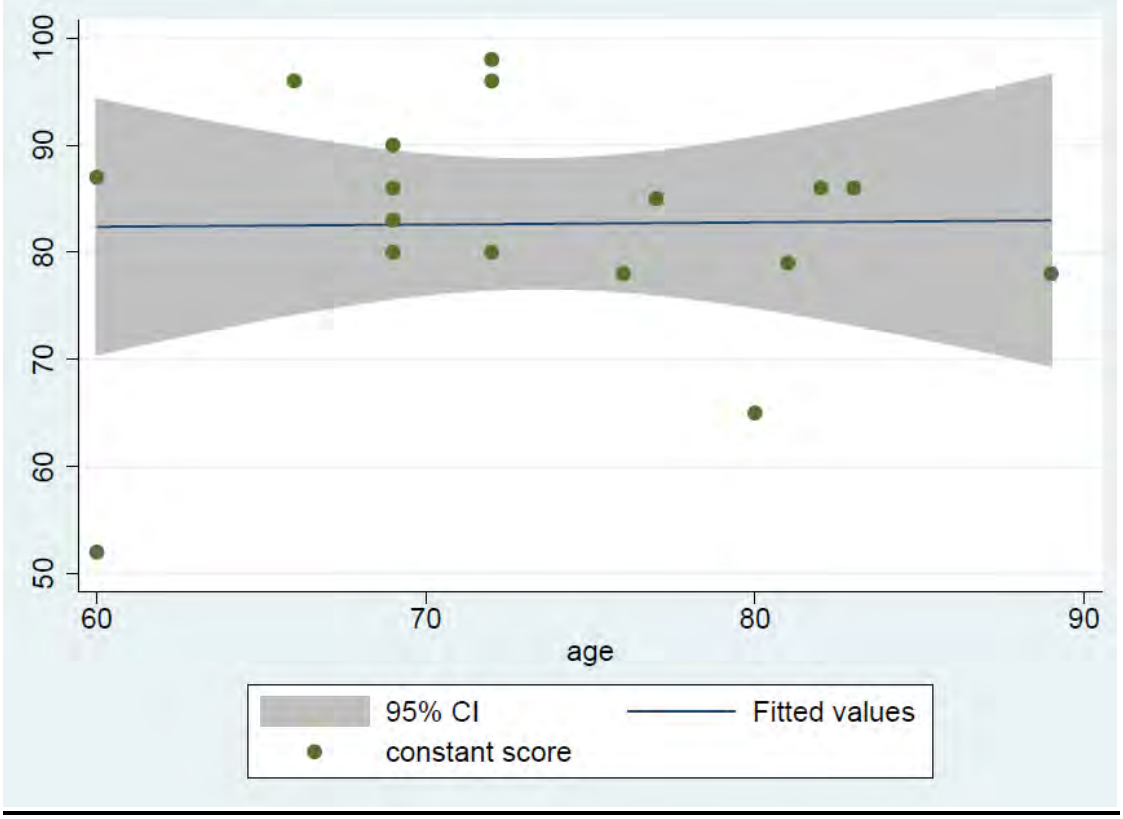


Figure 5: Graphical represenstation of Age Constant score

Figure 6: Graphical representation of Abduction Strength and stage of fatty infiltration.

III. Limitations of the study

The data presented herein is presented without any corrections being made. The weaknesses of our study are due to patient factors and initial presentation work up. The patient population we were dealing with was aged and so death and disability prohibited many patients from being included in the study. This meant that we had low study numbers. Patients on initial presentation to the surgeon did not have an MRI on presentation. This was not done as it was not clinically indicated at the time. All the patients had good functional range of motion and strength so further imaging was not required. The benefit of an initial MRI would allow us to compare the initial MRI images with the images on follow up.

PART E: CONCLUSIONS AND RECOMMENDATIONS

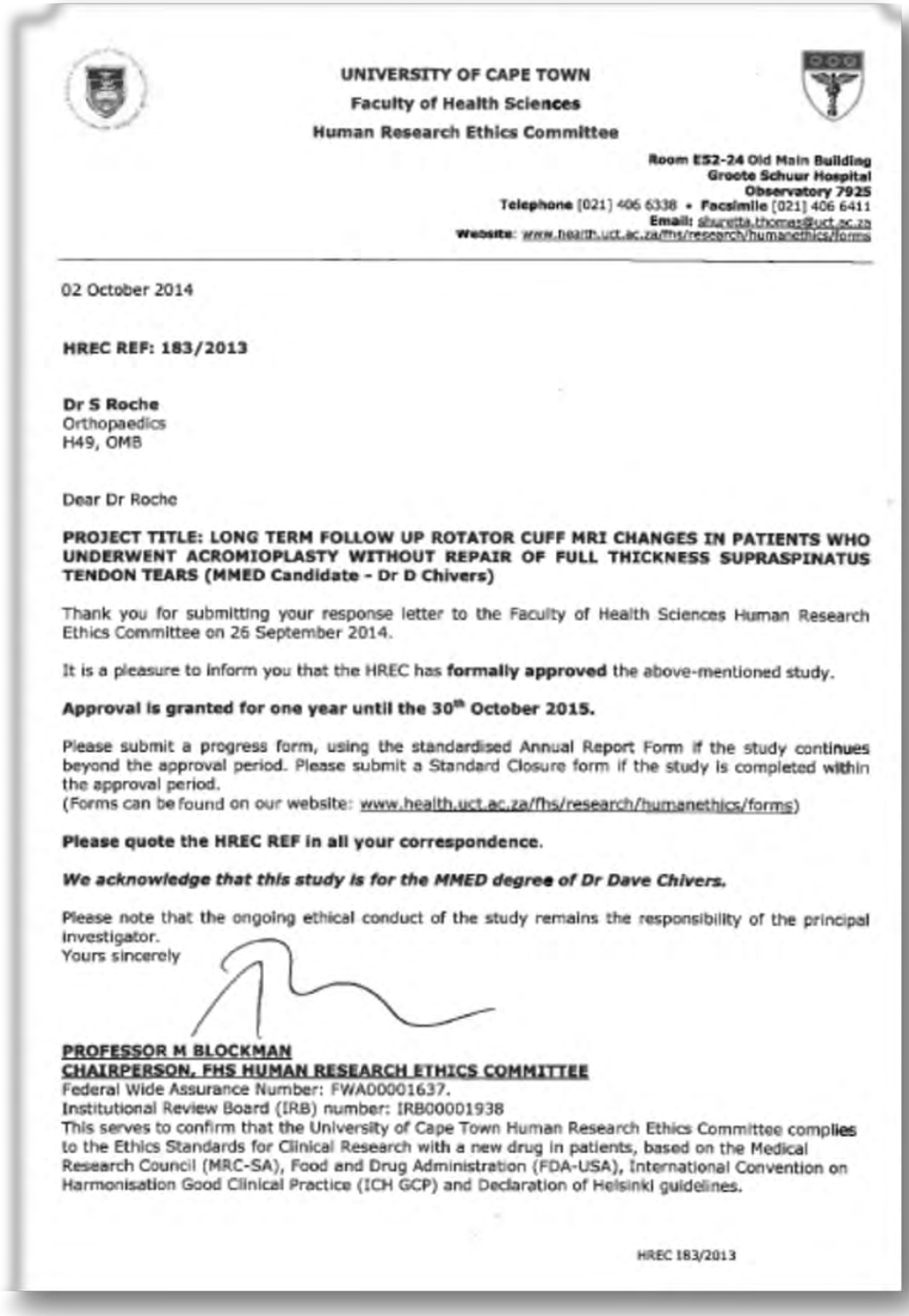
Currently this is the only long term MRI study of patients with full thickness supraspinatus tears that were not repaired at the time of acromioplasty.

This small cohort of patients had good long term clinical outcomes irrespective of tear size. It also showed that not all tears progressed to significant fatty change and atrophy in the long term. Small full thickness tears may progress or heal despite surgical intervention. The process of muscle regeneration or degeneration in the rotator cuff with a tear is influenced by local biological factors, genetic expression and tear location and therefore acromioplasty in isolation does not influence rotator cuff tear healing.

The recommendation that can be made from this study is that small tears within the rotator cable do not need to be repaired in an elderly population.

PART F: APPENDICES

I. Ethics approval



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • Facsimile [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

02 October 2014

HREC REF: 183/2013

Dr S Roche
Orthopaedics
H49, OMB

Dear Dr Roche

PROJECT TITLE: LONG TERM FOLLOW UP ROTATOR CUFF MRI CHANGES IN PATIENTS WHO UNDERWENT ACROMIOPLASTY WITHOUT REPAIR OF FULL THICKNESS SUPRASPINATUS TENDON TEARS (MMED Candidate - Dr D Chivers)

Thank you for submitting your response letter to the Faculty of Health Sciences Human Research Ethics Committee on 26 September 2014.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th October 2015.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that this study is for the MMED degree of Dr Dave Chivers.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.
Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

HREC 183/2013

II. Consent form

Patient information sheet and consent to participate in medical research

HREC REF: 183/2013.

Title: Long term follow up of rotator cuff MRI changes in patients who underwent acromioplasty without repair of full thickness supraspinatus tendon tears.

Authors: Dr D Chivers, Dr Steve Roche, Dr Basil Vrettos, Dr A Lambrechts, Dr R Dachs

Why is this study being done?

Impingement syndrome is the narrowing of the subacromial space in the shoulder which can result in damage or tears to the rotator cuff and pain. Impingement syndrome is treated with a subacromial decompression (acromioplasty) which removes excess bone in the subacromial space and allows more space for the rotator cuff to move. We are investigating the natural history and effect of subacromial decompression on the rotator cuff muscle. It will allow us to compare these results with what we already know about repaired tendons and non-surgically treated rotator cuff tears.

Why are you being asked to take part?

All patients seen by Dr Lambrechts that had an acromioplasty without rotator cuff repair in the last ten to fifteen years will be invited to take part in this study.

How many people will take part in the study?

We estimate that roughly 64 people will be invited to take part in this study.

What will happen if you decide to take part in the study?

All patients will have an MRI scan which will be at no extra cost to you. You will be asked to fill in a brief questionnaire, asking you specifically about the function of your shoulder and your ability to perform normal activities of daily living. Your shoulder will also be examined looking at range of movement and strength of the rotator cuff. All relevant clinical findings will be documented. We estimate that the MRI scan, examination questionnaire and physical examination will take 45 minutes.

What are the risks and discomforts of this study?

There is no risk associated in participating in this study.

Are there any benefits to you for being in the study?

Being part of this study will not influence your management in any way and therefore there is no benefit to you directly. The benefit however will be for us as doctors as information gained through this study may help us in understanding the natural history of rotator cuff tears in patients who have had acromioplasty. You will not be paid to take part in this study.

What other choices do you have?

It is completely your choice to take part in the study.

What will happen when the study is over?

Once you have had your MRI, completed the questionnaire and had the physical examination you will be finished with the study.

Will the results of the research be shared with you?

The overall results will be shared with you at the end of the study if you are interested. None of the personal details of any of the other people who were part of the study will be revealed.

Will you receive any reward (money or food vouchers) for taking part in this study?

You will not be paid for taking part in this study

Who will see the information which is collected about you during the study?

All the information collected for this study will be kept anonymous and confidential. All information will be kept on computers which will be protected by a password. Only the research team will have access to this information. Part of the study is that these results will be presented at congresses and in journals. No personal details of the patients from the study will be included in these presentations.

Who do I speak to (or contact) if I have any questions about the study?

You can speak to the surgeon directly (Dr A lambrechts or Dr Stephen Roche) or the study co-ordinator Dr David Chivers

Contact details: Dr David Chivers 082 903 7691/ megr@mweb.co.za

I, _____ hereby agree to participate in the research project investigating the natural history of rotator cuff tears in patients who underwent acromioplasty for impingement syndrome but did not have repair of the rotator cuff. I understand that my participation in this study is entirely voluntary and can be withdrawn at any stage and this will not jeopardize or change any further treatment if required. I understand there will not be any financial compensation involved for participation in this research.

I agree to the use of my medical records and that the data collected will be reviewed by the doctors involved with the study. I agree to have my shoulder examined and understand that this information will remain confidential but may be used for presentations and articles (on an anonymous basis.)

I understand that this research study has been approved by the Faculty of health Sciences Human Research Ethics Committee, University of Cape Town.
(Tel: 021 406 6492 or email: www.health.uct.ac.za/research/humanethics/)

_____ _____

Patient: Dr:

_____

Date

III. Questionnaires

a. Oxford Score

PROBLEMS WITH YOUR SHOULDER

During the past 4 weeks..... ✓tick one box for each question

1. *During the past 4 weeks.....*

How would you describe the *worst* pain you had from your shoulder?

None	Mild	Moderate	Severe	Unbearable
❑	❑	❑	❑	❑

2. *During the past 4 weeks.....*

Have you had any trouble dressing yourself because of your shoulder?

No trouble at all	A little bit of trouble	Moderate trouble	Extreme difficulty	Impossible to do
❑	❑	❑	❑	❑

3. *During the past 4 weeks.....*

Have you had any trouble getting in and out of a car or using public transport because of your shoulder?

No trouble at all	A little bit of trouble	Moderate trouble	Extreme difficulty	Impossible to do
❑	❑	❑	❑	❑

4. *During the past 4 weeks.....*

Have you been able to use a knife and fork - at the same time?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

5. *During the past 4 weeks.....*

Could you do the household shopping on your own?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

6. *During the past 4 weeks.....*

Could you carry a tray containing a plate of food across a room?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
❑	❑	❑	❑	❑

/P.T.O

During the past 4 weeks.....

✓tick **one** box for each question

7. *During the past 4 weeks.....*

Could you brush/comb your hair with the affected arm?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

8. *During the past 4 weeks.....*

How would you describe the pain you usually had from your shoulder?

None	Very mild	Mild	Moderate	Severe
❑	❑	❑	❑	❑

9. *During the past 4 weeks.....*

Could you hang your clothes up in a wardrobe, - using the affected arm?

Yes, Easily	With little difficulty	With moderate difficulty	With great difficulty	No, Impossible
❑	❑	❑	❑	❑

10 *During the past 4 weeks.....*

Have you been able to wash and dry yourself under both arms?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

11 *During the past 4 weeks.....*

How much has pain from your shoulder interfered with your usual work *(including housework)*?

Not at all	A little bit	Moderately	Greatly	Totally
❑	❑	❑	❑	❑

12 *During the past 4 weeks.....*

Have you been troubled by pain from your shoulder in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
❑	❑	❑	❑	❑

b. Constant Score

Constant Shoulder Score

Clinician's Name: _____ Patient's Name: _____

Answer all questions, selecting just one unless otherwise stated

During the past 4 weeks.....

1. Pain

- ☐ Severe
- ☐ Moderate
- ☐ Mild
- ☐ None

2. Activity Level (check all that apply)

- ☐ Unaffected Sleep
- ☐ Full Recreation/Sport
- ☐ Full Work

3. Arm Positioning

- ☐ Up to Waist
- ☐ Up to Xiphoid
- ☐ Up to Neck
- ☐ Up to Top of Head
- ☐ Above Head

4. Strength of Abduction [Pounds]

- ☐ 0
- ☐ 1-3
- ☐ 4-6
- ☐ 7-9
- ☐ 10-12
- ☐ 13-15
- ☐ 15-18
- ☐ 19-21
- ☐ 22-24
- ☐ >24

RANGE OF MOTION

5. Forward Flexion

- ☐ 31-60 degrees
- ☐ 61-90 degrees
- ☐ 91-120 degrees
- ☐ 121-150 degrees
- ☐ 151-180 degrees

6. Lateral Elevation

- ☐ 31-60 degrees
- ☐ 61-90 degrees
- ☐ 91-120 degrees
- ☐ 121-150 degrees
- ☐ 151-180 degrees

7. External Rotation

- ☐ Hand behind Head, Elbow forward
- ☐ Hand behind Head, Elbow back
- ☐ Hand to top of Head, Elbow forward
- ☐ Hand to top of Head, Elbow back -
- ☐ Full Elevation

8. Internal Rotation

- ☐ Lateral Thigh
- ☐ Buttock
- ☐ Lumbosacral Junction
- ☐ Waist (L3)
- ☐ T12 Vertebra
- ☐ Interscapular (T7)

The Constant Shoulder Score is: 0

Grading the Constant Shoulder Score

>30 Poor 21-30 Fair 11-20 Good <11 Excellent