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GLENOHUMERAL OSTEOARTHRITIS: PATIENT PROFILES AND OUTCOMES OF SHOULDER ARTHROPLASTY

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ABSTRACT

BACKGROUND AND PURPOSE: Part 1: To describe the profile of a typical patient diagnosed with glenohumeral osteoarthritis (OA) and identify predictors of total shoulder arthroplasty (TSA).

Part 2: To identify outcomes after undergoing a TSA due to glenohumeral OA.

METHODS: Part 1: A retrospective chart review was conducted of 127 patients with a diagnosis of glenohumeral OA from January 2011 to December 2013. Demographic data was collected.

Part 2: From the original sample, a convenience sample of 22 patients was selected who were at least one year post-TSA. Consent was obtained to perform a post-surgical functional evaluation in their homes or in the clinic based on patient preference. The measures obtained were strength and range of motion (ROM), as well as the subjective reports of the Simple Shoulder Test (SST) and the Shoulder Pain and Disability Index (SPADI).

RESULTS: Part 1: Of the 127 patients, average age was 70, and 55.9% were male. Surgical shoulder was the right shoulder in 52.8% of the subjects, left shoulder in 36.2% of the subjects, and bilateral shoulders in 10.2% of the subjects. The greatest predictor of undergoing a TSA was pain at rest (7.2). Part 2: There was no difference in ROM of shoulder flexion, abduction, internal rotation, and external rotation between surgical and non-surgical shoulders. Strength following a TSA was weaker in shoulder flexion and abduction, equal in rotation, and stronger in grip strength compared to the non-surgical shoulder. Average post-op pain was 1.1 compared to 6.2 pre-op pain which was statistically significant. There was a strong correlation between the SPADI and SST.

CONCLUSION: The most significant indicator for a TSA is pre-op pain at rest. Patients can expect significantly decreased pain, functional ROM and strength, and improved function following a TSA. Both SPADI and SST are effective outcome measures to assess shoulder pain and function.



The undersigned certify that they have read, and recommended approval of the research project entitled: GLENOHUMERAL OSTEOARTHRITIS: PATIENT PROFILES AND OUTCOMES OF SHOULDER ARTHROPLASTY Submitted by Lisa Carlson Katie Kruger Callie Larsen Kim Ruehlmann In partial fulfillment of the requirements for the Doctor of Physical Therapy Program

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Introduction

Osteoarthritis (OA), also known as degenerative joint disease, is an articular disease that gradually develops over time and typically originates in the cartilage of major joints in the body. It impacts the underlying bone and causes development of bony spurs and joint space narrowing, which can be diagnosed with radiographic imaging. Furthermore, it can be accompanied by significant pain, muscle stiffness and weakness, joint crepitus, tenderness, and misalignment. It most commonly affects the weight bearing joints of the hip, knee, and spine, but is also prevalent in the shoulder and hand. OA is present in 60% of men and 70% of women in people over age 65 years old, with an estimated affected number of people in the United States of 40 million. OA is the second leading cause of work disability in males over the age of 50 years old.^{1,2}

Treatment for OA is determined on an individual basis. It generally consists of a combination of both surgical and nonsurgical interventions. Strengthening exercise programs are generally the initial treatment for osteoarthritis.² Exercises focus on joint stabilization in order to prevent further joint degeneration. Patients with glenohumeral OA will likely be given exercises that focus on rotator cuff and shoulder strengthening. If conservative treatment is unsuccessful at reducing symptoms, surgical options are then considered. Surgery is typically only considered once pain has become severe and loss of function has begun to interfere with activities of daily living (ADLs). Less invasive surgeries such as lavage and debridement, abrasion arthroplasty, and laser or thermal chondroplasty may be performed in order to delay the necessity for a joint replacement.^{1,2} A total shoulder arthroplasty involves replacing both arthritic surfaces.



The head of the humerus is replaced with a metal ball with a stem that is pressed into the shaft of the humerus, and the glenoid is resurfaced with a polyethylene component.

A total shoulder arthroplasty is indicated in cases of OA and an intact rotator cuff.

Haines et al³ did a prospective clinical and radiological analysis of 124 shoulder arthroplasties carried out for osteoarthritis. The purpose of this study was to document which procedure is most appropriate to be performed relative to pain relief and increased functional mobility of the shoulder. All patients receiving shoulder arthroplasties by J.H. Haines or I. A. Trail between 1992 and 2002 were included in the study. The mean age was 66 years old with male: female ratio of 1: 3. Within the sample, 43 had a humeral head replacement and 82 had a total shoulder arthroplasty. The mean follow-up time after surgery was 5.1 years. Patients were assessed using the visual analogue pain scale, the American Shoulder and Elbow Surgeon score (ASES) and the absolute score of the Constant and Murley. Radiographs were obtained throughout the period of the study to look at humeral and glenoid components, and late glenoid erosion in the humeral head replacement. Pain and function scores improved significantly from each year up to eight years. However, there were 11 revision procedures due to persistent pain during passive and active ROM post initial surgery. ROM for shoulder abduction, flexion, and external rotation improved significantly (over 25 degrees in each direction) after the initial surgery, resulting in increased post-surgical functional mobility. They found that glenoid erosion and poor rotator cuff strength are related to poor results due to increased risk of joint loosening and should be taken into consideration before surgery.

Total shoulder arthroplasty is the gold standard therapy for several shoulder



conditions after conservative treatments have failed; however, there is very little research that evaluates long-term outcomes of patients who are post-TSA. Deshmukh et al⁴ set out to analyze these outcomes through survivorship analysis, quality of life patient questionnaires, and physical exam follow-up data. The study participants included 320 consecutive TSAs performed in 267 patients between 1974 and 1988. Diagnoses were variable, but the most common were rheumatoid arthritis (69%) and osteoarthritis (22%). Mean age at time of TSA was 60.3 +/- 13.7 years, and 78% of the patients were female. A subset of 80 patients were asked to return for a follow-up physical examination (minimum of 10 years post-TSA) and to complete the DASH questionnaire. Results revealed that 15 of the 80 patients contacted had required revisions due to loosening (mean 7.7+/-4.8 years post-TSA). There were 3 cases of deep joint infection, 4 cases of GH dislocation, and 8 cases of humeral fractures. Age and gender were not found to be significant predictors of whether or not a revision was indicated. The failure rate among patients with OA who underwent TSA was 8.5% (6/71). Subjects reported statistically significant improvement in pain level (92% felt "much better" or "better" after TSA) and shoulder ROM and strength. Survivorship analysis revealed that 93% have 10 year survivorship and 87% have 15 year survivorship. The results of this study reveal that ROM and strength improvements post-TSA are typically well maintained and patients are still benefiting from TSA greater than 10 years after surgery.

Carter et al⁵ performed a systematic literature review and meta-analysis to characterize the change in generic and shoulder-specific health-related quality of life measures from a TSA. 20 studies (ranging from 1989-2010 with a total of 1576



shoulders) met the inclusion criteria which were undergoing primary TSA, had surgical indications specified as glenohumeral arthritis, and reported pre-op and post-op health related quality of life outcome measures with at least 6 months of follow-up. They found an average patient age of 66.2 years and an average follow-up duration of 3.7 +/- 2.2 years. Significant improvements in physical function, physical role function, bodily pain, and the physical component summary were found. They concluded that TSA leads to significant improvements in scores for function and pain, but only modest improvements in overall health-related quality of life.

There is a significant amount of literature regarding OA impacting the hip and knee; however, shoulder OA is not as heavily represented in the research due to the lower prevalence. Since the shoulder is not a weight-bearing joint, it does not develop OA as frequently as other joints in the body. The lack of available literature that reports on surgical outcomes after TSA secondary to OA is what drove the researchers of this study to develop the project that will now be discussed.

There were several purposes of this research study. The first was to define the typical characteristics of a patient with glenohumeral osteoarthritis. The second was to identify the predictors for a patient's decision to undergo a total shoulder arthroplasty. The third was to determine the functional outcomes that a patient can expect after undergoing a total shoulder arthroplasty due to glenohumeral osteoarthritis. The fourth was to compare the Simple Shoulder Test to the Shoulder Pain and Disability Index and to determine if one is a better outcome measure than the other.

In part one, it was hypothesized that being a male over the age of 65 years old and having a high pain at rest rating would be predictors of the decision to undergo a total shoulder arthroplasty in patients with glenohumeral osteoarthritis.

In part two, it was hypothesized that there will be a difference in outcomes between the surgical and non-surgical shoulders following a TSA due to glenohumeral osteoarthritis. Strength, range of motion, and function will be different in the surgical shoulder compared to the nonsurgical shoulder after a TSA.

There are many outcome measures to assess upper extremity function. Angst et al⁶ assessed 43 patients (22 of whom had primary OA) in a cross-sectional follow-up examination 5-6 years after TSA to describe the health status and QOL of this population to norms using a comprehensive assessment approach. They aimed to find the functional outcome with excellent validity, excellent quality of data obtained, and high clinical feasibility. Deficits from norms were only observed in the shoulder-specific outcome measures and not in the SF-36 which is more generalized. The DASH, SPADI, and ASES showed high agreement in measuring specific symptoms and disabilities, with the highest correlation being between the DASH and the SPADI (0.93). The 22 OA subjects were less functionally impaired, had less comorbidities and were older than the 21 RA subjects and the SPADI and ASES were able to distinguish between the 2 conditions with a very high sensitivity and specificity. They concluded that these individual outcome measures did not always deliver unique information and in the future can be reduced based on responsiveness. This study guided the researchers to choose the Shoulder Pain and Disability Index (SPADI) for this study to assess shoulder outcome since it demonstrated good psychometric properties.



Furthermore, Roddey et al⁷ were interested in the psychometric properties of the outcome measures: SPADI, Simple Shoulder Test (SST) and the University of California-Los Angeles (UCLA) Shoulder Scale since no prior research had assessed the SST and UCLA. Roddey et al. had 192 patients, being seen for shoulder disorders at a private orthopedic surgeon office, fill out a questionnaire of demographic information and self-report sections of the three shoulder measures. Data analysis was run to determine the Cronbach alpha, SEM and Spearman correlation coefficients between the outcome measures. The Cronbach alpha was 0.96 for the SPADI total and the SEM with a 95% CI was +/- 9.3 points. The Cronbach alpha was 0.85 for the SST and the SEM with a 95% CI was +/- 22.8 points. A Spearman correlation coefficient of -0.80 was found between SPADI disability subscale and SST which happened to be the strongest. The UCLA function subscale was correlated with SPADI disability subscale of -0.64 and with SST of 0.60. Additionally, the SST and SPADI pain subscale found to have a 0.48 correlation. Since the SST was found to have good reliability, validity and be strongly correlated to the SPADI, the SST was chosen as an outcome measure as well.

Part One Methods:

A retrospective chart review was performed at St. Croix Orthopaedics of all patients with a diagnosis of glenohumeral OA. All patients included in the chart review had been seen by the orthopedic surgeons at St. Croix Orthopaedics during the time period between January 1st, 2011 and December 31st, 2013. Institutional review board (IRB) approval was obtained through St. Catherine University prior to beginning any data collection at St. Croix Orthopaedics. It was verified that all patients had signed

consent forms for medical disclosure at the time of their initial visits with the surgeons.

All information gathered from the charts guaranteed confidentiality by recording numbers in place of patient names or other patient identifiers. The data collected from patient charts included gender, age, body mass index, affected shoulder, dominant arm, pain rating at rest, pain rating at worst, whether or not the patient decided to undergo a TSA, and which physician performed their surgery. Statistics were run through SPSS and included paired t-tests, Pearson correlation, and regression analysis.

Part Two Methods:

The total number of patients from Part One of the study who underwent a TSA was 52 patients. Patients who underwent a reverse TSA or a hemiarthroplasty were not included. Since patients come to St. Croix Orthopaedics from the tri-state area, it was decided to take a convenience sample of patients within a 50 mile radius of SCO. Patients who were at least one year post-op, had sustained no new injuries since their TSA, and had unilateral surgery were included in the initial contact phase. Initially, 23 patients met the inclusion criteria. These potential patients were contacted by the HIPAA Privacy Specialist at St. Croix Orthopaedics and were asked if they would be willing to participate in the study. Only one patient declined and one patient was disqualified due to acquiring a new shoulder injury. This resulted in a sample of 21 patients to be included in Part Two of the research study. IRB approval was obtained prior to any data collection or patient interaction.

A \$550 grant was received from St. Croix Orthopaedic's Foundation of Orthopaedic Excellence to be able to offer \$25 gift card incentives to the participants.

The post-surgical functional evaluation was performed in the patient's home or at the St.



Croix Orthopedic clinic based on patient preference. The measures obtained were strength, range of motion, the Simple Shoulder Test, and the Shoulder Pain and Disability Index. Statistics were run through SPSS and included paired t-tests, Pearson correlation, and regression analysis.

Range of motion was measured using a goniometer in the standard testing position for shoulder flexion, abduction, and external and internal rotation. Goniometry has good intrarater reliability for all shoulder motions with ICC values ranging from 0.87-0.99. Interrater reliability for all shoulder motions ranged from 0.84-0.90.8 Therefore, all measurements were performed by one tester in order to maintain excellent reliability. Strength was measured using a Microfet hand-held dynamometer for shoulder flexion, abduction, external and internal rotation, elbow flexion, and hand grip. Hand-held dynamometry has excellent test-retest reliability (ICC = 0.97-0.98).9 Make tests were performed and all measurements were performed by one tester in order to maintain consistency.

Part One Results:

Demographic data was collected on a total of 127 patients. Of this sample, 55.9% was male, the mean age was 70, and the mean BMI was 29.9kg/m². Of the 127 patients, 85% of the patients were right-hand dominant, and 9.4% were left-hand dominant. Of the patients included in this chart review, 52.8% of them had OA symptoms in their right shoulder, 36.2% had OA symptoms in their left shoulder, and 10.2% reported bilateral symptoms.

Of the 127 patients, 41% elected to undergo a TSA. The average time between initial evaluation and the TSA was 5.2 months. Graph 1 depicts the average pre-op



pain at rest and pain at worst between patients who decided to undergo a TSA and those who did not. Pain rating on a scale of 0-10 is depicted on the Y axis. Pain at rest and pain at worst are on the X axis. There was a significant difference between the mean pain at rest between the two groups, with a p value of 0.018. No significant difference was found for mean pain at worst between those who underwent a TSA and those who did not.

Regression analysis was performed using SPSS software in order to determine which variables are predictors of whether or not a patient decides to undergo a TSA. Refer to Table 1 for detailed regression analysis of the following variables: dominant arm, gender, age, BMI, affected shoulder, and pain at worst. All were found to be insignificant for predicting TSA. The only significant predictor for if a patient would undergo a TSA was pain at rest, with a significant p-value of 0.028.

Part Two Results:

The graph in Figure 2 compares the mean range of motion for shoulder flexion, abduction, and external and internal rotation between the surgical and non-surgical shoulders. Degrees of ROM are on the Y axis, and the shoulder motions are specified along the X axis. None of these differences were significant, indicating that range of motion following a TSA is comparable to the non-surgical side.

The graph in Figure 3 compares the mean strength for shoulder flexion, abduction, external and internal rotation, elbow flexion, and hand grip between the surgical and non-surgical shoulders. On the Y axis is strength in units of pounds, and the different movements are along the X axis. The surgical shoulder was found to be significantly weaker than the non-surgical shoulder for flexion and abduction (p =0.001).

External and internal rotation and elbow flexion showed no significant differences between shoulders. Hand grip strength was stronger on the surgical extremity than the non-surgical extremity, although this difference was not significant. A Bonferroni correction was used in order to control for Type I error. Type 1 error is when the null hypothesis is rejected when it is true. The Bonferroni correction was found to be 0.01 which did not change the results.

The graph in Figure 4 depicts pre-operative pain and post-operative pain for the patients who underwent a TSA. On the Y axis is the pain number on the numerical scale of 0-10, and on the X axis is pre and post-op pain. There was a significant difference between pre-operative pain and post-operative pain (p = 0.001).

One component of the Simple Shoulder Test asks the patient to rate his/her ability to perform a certain task with his/her affected shoulder on a scale of 0 to 4, 0 being unable and 4 being normal. Thus, a higher number equates to higher function. There were a total of 15 questions in this section of the SST. These questions were divided into four different categories based on the task described: Lifting/Carrying, Functional Hygiene, Work Ability, and Shoulder Comfort. As shown in Table 2, patients reported an average of greater than 92.5% function in all four categories.

The SPADI provides a total score and two subscale scores, one for pain and another for disability. The higher the score the greater the pain and disability. As shown in Table 3, patients demonstrated very low scores on the SPADI as indicated in the chart, which means that patients were functioning between a 92 to 95% level of full function.



Table 4 shows the correlations between categories of the SST and the total SPADI score with certain strengths and ROMs. Flexion and internal rotation range of motion correlated with work ability. Internal rotation ROM also correlated moderately with functional hygiene and the total SPADI score. Flexion strength had a good correlation with the functional category of lifting and carrying from the SST. Insignificant findings were found in regards to the relationships between hand grip strength and functional hygiene, and hand grip strength and total SPADI. Finally, good to strong correlations were found between the SPADI total and the categories work ability, functional hygiene, and lifting/carrying of the SST.

As shown in Table 5 all affected shoulder and elbow strength measurements demonstrated significant and good to strong correlations with hand grip strength.

Part One Discussion:

The mean age of the 127 patients with glenohumeral osteoarthritis was 70 years, which is consistent with the literature. Brophy et al¹⁰ found an average age of 70.2 years, Moor et al¹¹ found an average age of 68.7 years, and Haines et al³ found an average age of 66 years for patients who underwent TSA. There were 56 females and 71 males in this study. This gender ratio was consistent with the findings of Brophy et al¹⁰ who published a study with a smaller sample size of 14 females and 26 males with glenohumeral OA. The gender ratio of our study was in contrast with the Moor et al¹¹ study which included 52 women and 40 men with glenohumeral OA. The existing literature is therefore inconsistent regarding which gender is more commonly affected by glenohumeral OA.



The pre-operative pain scores for these patients were comparable to the Haines et al study who found a mean pre-op pain of 7.4 in a sample size of 124 patients post-TSA. It was discovered that the average pain at rest was 5.78 and average pain at worst was 7.55 on a scale from 0 to 10. The only significant factor for predicting which patients will undergo a TSA was pain at rest, which supported one component of the Part One hypothesis. However, no evidence was found to support the gender and age components of the hypothesis. The results revealed that neither age nor gender are significant predictors for undergoing TSA. Even though age and gender were not significant predictors, the mean age of the patient population was over 65 years old, and the majority (55.9%) were male.

Part Two Discussion:

After analyzing the data, the main finding of this study was that post-operative pain was significantly decreased compared to pre-op pain. These findings are comparable to the previously discussed article by Haines et al³ who found pre-op pain to be on average 7.4 and post-op pain to be on average 2.4 in a sample size of 124 subjects. Overall, patients can expect functional ROM and strength, decreased pain, and increased function following TSA. These results are comparable to a systematic review by Carter et al⁵ who found that TSA leads to significant improvements in function and pain and modest improvements in overall health-related QOL in 1,576 subjects. In addition, Deschmukh et al⁴ reported significant improvements in pain, shoulder ROM and strength following a TSA in 267 subjects. The Fehringer et al¹² study concluded that post-op patients can expect to regain approximately two-thirds of their function based on a sample size of 102 patients.



Findings show that post-operative ROM is equal to that of the non-surgical shoulder. The patients demonstrated weaker flexion and abduction strength in their surgical shoulder, but equal shoulder rotation and elbow flexion strength between surgical and nonsurgical shoulders. Grip strength was found to be stronger in the surgical shoulder. Both the SPADI and the SST demonstrated low disability and high function in the patients tested

A strong correlation was identified between SPADI and SST. These results are comparable to Roddey et al⁷ who found a strong correlation of -.80 in their study of 192 subjects. A correlation was also found between grip strength and upper extremity strength. This is in contrast to the findings of Giampaoli et al¹³ who found grip strength to be a predictor of disability in 140 older men, however the results of this study did not identify a significant correlation between grip strength and function.

In summary, there were no differences between the surgical and nonsurgical shoulders in regards to ROM, pain, and function; therefore the null hypothesis was accepted for these outcomes. However, there were significant differences in flexion and abduction strength between surgical and nonsurgical shoulders, so the experimental hypothesis was accepted for these outcomes.

There were several limitations to this research. A convenience sample was used and our sample size was rather small. The surface for supine ROM measurements was inconsistent due to collecting some data in the patients' homes. No control group was used. Instead the nonsurgical shoulder was used as the comparison side. Lastly, there were no pre-op or post-op radiographic imaging available for analysis.

Future research is needed in order to continue to validate the results identified in



this article. A prospective study measuring preoperative ROM and strength with a larger sample size and control group would further strengthen the validity of the results. Patients could be followed through their care from the initial visit to their post-op appointments rather than performing part of the data collection retrospectively. This would better gauge individual functional improvements following TSA. Future studies should include radiographic imaging in order to analyze the extent of joint space narrowing and the severity of OA.

The next step in this project is to apply a measurement system to the X-rays of the 127 patients included in Part One with the assistance of a surgeon at SCO. Moor et al¹¹ hypothesized that a short acromion with an inferiorly inclined glenoid would be associated with glenohumeral osteoarthritis. From radiographs, Moor determined the critical shoulder angle (CSA) which takes into account both the tilt of the glenoid in the frontal plane and the acromion index. This study found that the mean CSA of the healthy shoulder was 33.3 and that CSA angles <30 degrees are likely to be osteoarthritic. They concluded that certain biomechanics are risk factors for developing degenerative joint diseases. Even though radiographs of patients prior to surgery are not always available in order to measure the CSA, it would still be important to look at the radiographic imaging of patients with glenohumeral osteoarthritis to analyze the severity of OA. This will determine whether or not degenerative changes on X-rays are predictors for TSA.

A study published by Kircher et al¹⁴ looked at the acromion index to see if there was a correlation between a low acromion index and shoulder osteoarthritis. This study included 282 patients, of whom 53 patients (mean age 31.62+/-11.80, 19 female) had



instability, 109 patients (mean age 48.2+/-8.01, 63 female) had calcifying tendonitis and 120 patients (mean age 66.43+/-9.74, 56 female with mean age 70.0+/-9.17, and 64 males with mean age 63.3+/-9.2) had diagnosis of shoulder osteoarthritis. A retrospective analysis of standardized x-rays were used to measure the acromion index at three levels in the anteroposterior view and axillary view. Two independent investigators took the shoulder measurements. The instability and calcifying tendonitis groups were used as controls as it was not healthy to x-ray unaffected shoulders due to radiation. Results showed the mean acromion index to be 0.64+/-0.07 mm for instability patients, 0.64+/-0.08 mm for calcifying tendonitis and 0.73+/-0.12 mm for shoulder osteoarthritis patients. From these results, there was no correlation between a low acromion index and shoulder osteoarthritis. Therefore, future studies looking at shoulder osteoarthritis do not need to include the acromion index as a precursor to the disease.

Conclusion:

In summary, the results show that the most significant predictor for TSA is a high rating of pre-operative pain at rest, but being male and over age 65 are not predictors. Patients can expect decreased pain, functional ROM and strength, and improved function after a TSA. After analysis of the SPADI and SST, it was determined that both are effective outcome measures to assess shoulder pain and function.

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Figures and Tables:

Figure 1: Pain rating comparison

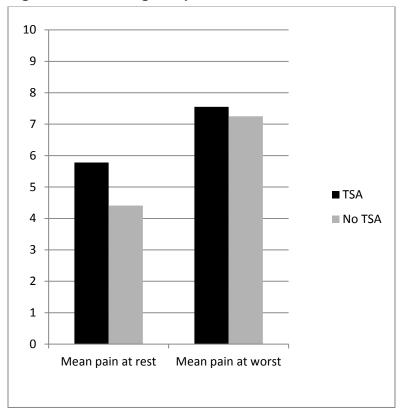
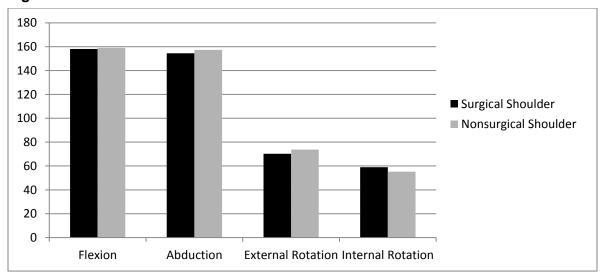


Figure 2: Mean ROM Results





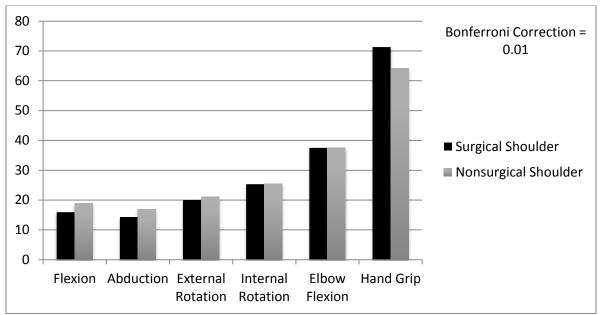
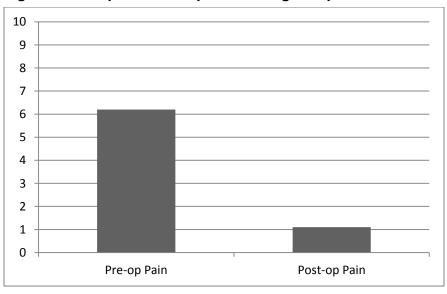


Figure 3: Mean Strength Results





p = 0.00

Table 1: Regression analysis

Variable	p-value
Dominant Arm	0.336
Gender	0.422
Age	0.458
BMI	0.997
Affected Shoulder	0.335
Pain at worst	0.586
Pain at Rest	*0.028

^{*}Denotes statistically significant result

Table 2: SST Results

Category	Score
Lift/Carry	11.5/12
	(95.8%)
Function/Hygiene	31.3/32
	(97.8%)
Work Ability	7.6/8
	(95%)
Shoulder Comfort	3.7/4
	(92.5%)

Table 3: SPADI Results

	Score
Pain	7.7
	92.3%
Disability	5.2
-	94.8%
Total	6.2
	93.8%

Table 4: Correlations

	Work Ability	Function/ Hygiene	Lift/Carry	SPADI Total
Flexion ROM	*p=0.034 .463 Mod			
Internal Rotation ROM	*p=0.017 .514 Good	*p=0.039 .453 Mod		*p=0.022 478 Mod
Flexion Strength			*p=0.010 .546 Good	
Hand Grip Strength		p=0.288 .243 Weak		p=0.243 266 Mod
SPADI Total	*p=0.017 526 Good	*p=0.000 761 Strong	*p=0.000 844 Strong	

^{*}denotes statistical significance for correlation

Table 5: Correlation between hand grip strength and shoulder/elbow strength

Shoulder/Elbow Strength	Significance	Pearson Correlation
Shoulder Flexion	*0.002	0.637 (Good)
Shoulder Abduction	*0.010	0.551 (Good)
Shoulder Internal Rotation	*0.001	0.687 (Good)
Shoulder External Rotation	*0.000	0.750 (Strong)
Elbow Flexion	*0.000	0.720 (Good)

^{*}denotes statistical significance



Glenohumeral Osteoarthritis: Patient Profiles and Outcomes of Shoulder Arthroplasty INFORMATION AND CONSENT FORM

Introduction:

You are invited to participate in a research study investigating the results of shoulder replacement surgery. This study is being conducted by Katie Kruger, Callie Larsen, Kim Ruehlmann, and Lisa Carlson, who are all physical therapy graduate students at St. Catherine University, under the supervision of Paul Niemuth, a faculty member in the Department of Physical Therapy. You were selected as a possible participant in this research because you have undergone shoulder replacement surgery or arthroplasty at least one year ago and are not having problems with your other shoulder. Please read this form and ask questions before you agree to be in the study.

Background Information:

The purpose of the research study is to measure the overall satisfaction, strength, range of motion, and pain ratings of patients who have had shoulder replacement surgery due to their shoulder arthritis. This information will be used to inform patients considering shoulder arthroplasty what they should expect. Approximately 25 people are expected to participate in this research.

Procedures:

If you decide to participate, you will be asked to partake in a one-time, 30-minute shoulder evaluation performed by one of our researchers. You will be asked to complete two brief questionnaires regarding your shoulder function and pain levels and also answer some questions about your shoulder. Each questionnaire should take less than five minutes to complete. You will be asked to lie down on your back and move your shoulders in several directions while we take measurements of how far you are able to move in each direction. We will take each measurement twice. If it is uncomfortable for you to lie flat on your back, we will take the measurements in a sitting position. Lastly, we will measure your strength by having you resist our pressure in different directions using a strength assessment tool while you are sitting. Again, we will take each measurement twice.

Risks and Benefits of being in the study:

The study has very minimal risks. Mild discomfort may be experienced due to the resisted muscle contractions that you will be asked to perform during the strength assessment. Some soreness may result but should be minimal and temporary in nature.

You will be helping the field of research in determining the most likely outcomes that patients who are undergoing shoulder replacement surgery should expect. This is important because you can help give future patients all of the information they need regarding their surgery in order to make the best informed decisions.



Compensation:

There is no compensation for participating in the study.

Confidentiality:

Any information obtained in connection with this research study that can be identified with you will be disclosed only with your permission; your results will be kept confidential. In any written reports or publications, no one will be identified or identifiable and only group data will be presented.

We will keep the research results in a locked file cabinet in Dr. Paul Niemuth's office on the Minneapolis campus of St. Catherine University and only the four graduate students performing this research and Paul Niemuth or other DPT faculty members will have access to the records while we work on this project.

We will finish analyzing the data by the end of December 2014. We will then destroy all original reports and identifying information that can be linked back to you.

Voluntary nature of the study:

Participation in this research study is voluntary. Your decision whether or not to participate will not affect your future relations with St. Croix Orthopedics or St. Catherine University in any way. If you decide to participate, you are free to stop at any time without affecting these relationships.

Contacts and questions:

Statement of Consent:

You may ask questions now, or if you have any additional questions later, the faculty advisor, Paul Niemuth at 651-690-7981, will be happy to answer them. If you have other questions or concerns regarding the study and would like to talk to someone other than the researcher(s), you may also contact Dr. John Schmitt, Chair of the St. Catherine University Institutional Review Board, at (651) 690-7739.

You may keep a copy of this form for your records.

You are making a decision whether or not to participate. Your signature indicates that you have read this information and your questions have been answered. Even after signing this form, please know that you may withdraw from the study at any time. I consent to participate in the study. Signature of Participant Date

Date



Signature of Researcher