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Effectiveness of Physical Therapy in Treating Atraumatic Full Thickness Rotator Cuff Tears. A Multicenter Prospective Cohort Study

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Abstract

Purpose—To assess the effectiveness of a specific non-operative physical therapy program in treating atraumatic full thickness rotator cuff tears using a multicenter prospective cohort study design.

Methods—Patients with atraumatic full thickness rotator cuff tears who consented to enroll provided data via questionnaire on demographics, symptom characteristics, co-morbidities, willingness to undergo surgery, and patient related outcome assessments (SF-12, ASES, WORC, SANE score, Shoulder Activity Scale). Physicians recorded physical examination and imaging data. Patients began a physical therapy program developed from a systematic review of the literature and returned for evaluation at 6 and 12 weeks. At those visits patients could chose one of three courses: 1.) *Cured* (no formal follow up scheduled), 2.) *Improved* (continue therapy with scheduled reassessment in 6 weeks), or 3.) *No better* (offered surgery). Patients were contacted by telephone at 1 and 2 years to determine if they had undergone surgery since their last visit. A Wilcoxon signed rank test with continuity correction was used to compare initial, 6 week, and 12 week outcome scores.

Results—The cohort consists of 452 patients. Patient reported outcomes improved significantly at 6 and 12 weeks. Patients elected to undergo surgery less than 25% of the time. Patients who decided to have surgery generally did so between 6 and 12 weeks, and few had surgery between 3 and 24 months.

Conclusion—Non-operative treatment using this physical therapy protocol is effective for treating atraumatic full thickness rotator cuff tears in approximately 75% of patients followed for two years.

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Level of evidence—Level IV, Case Series, Treatment Study

Keywords

Rotator Cuff Tear; Nonoperative Treatment; Physical Therapy; Prospective Multicenter Cohort; Outcomes; MOON Shoulder Group

INTRODUCTION

Rotator cuff tears are extremely common, affecting at least 10% of those over the age of 60 in the United States²⁸. Using 2010 United States census data this equates to over 5.7 million people³⁷. Industry estimates suggest rotator cuff surgeries are performed on between 75,000–250,000 patients per year in the United States^{21, 34}. These data reveal that fewer than 5% of patients with rotator cuff tears in the United States are treated surgically.

Interestingly in those that do have surgical repair of rotator cuff tears, the failure rate is between 25 and 90%^{4, 9, 10, 11, 12, 16, 24, 32, 42} yet patients whose repairs fail report satisfaction levels and outcome scores that are nearly indistinguishable from those whose repairs are intact³⁰. Because most patients in these studies do postoperative physical therapy, it is conceivable that the postoperative physical therapy may be responsible for the improvements in outcome. Finally, a number of retrospective case series¹ and one randomized controlled trial²⁵ have suggested that nonoperative treatment of full thickness rotator cuff tears may be successful in some patients.

These data lead to the hypothesis that physical therapy may be effective in treating patients with symptomatic atraumatic full thickness rotator cuff tears. In 2009, we published a systematic review on the effectiveness of exercise on treating rotator cuff impingement syndrome, and offered a synthesized physical therapy protocol¹⁸. The specific objectives of this multicenter prospective cohort study are to: 1) determine the effectiveness of this rehabilitation protocol in treating patients with atraumatic rotator cuff tears, with failure defined as patients electing to have surgery; and 2) determine the effect of this non-operative physical therapy protocol on patient reported measures of outcome.

MATERIALS AND METHODS

The MOON Shoulder Group is a team of 16 fellowship trained orthopaedic surgeons and research personnel from nine geographically dispersed sites within the United States, representing both academic and private practice patient environments. This group was formed to conduct large multicenter studies on conditions of the shoulder.

From May 2004 through October 2006 the MOON Shoulder Group met regularly to formulate research questions of interest, develop and standardize radiographic and MR imaging protocols, assemble validated behavioral and patient-oriented outcome assessment forms for data collection, and conduct validation studies on: MRI classification of rotator cuff tears³¹; rotator cuff tear classification based on arthroscopic videos¹⁹; and radiographic findings associated with rotator cuff disease².

In addition the group performed systematic reviews of the literature to: evaluate postoperative rotator cuff repair rehabilitation,³ summarize the literature regarding indications for surgical treatment of rotator cuff tears^{27, 39}; and determine the effectiveness of physical therapy in treating rotator cuff disease and develop a standard physical therapy protocol based on the evidence¹⁸.

With regard to atraumatic rotator cuff tears, the indications for surgery are not clear^{7, 27, 39}, and our research group could not develop standard indications for surgery by consensus. Therefore the group decided to conduct a prospective cohort study on the non-operative treatment of atraumatic full thickness rotator cuff tears using the physical therapy protocol derived from the systematic review¹⁸. We expected that some patients would be successfully treated and decline surgical intervention, while others would fail nonoperative treatment and undergo rotator cuff repair. By identifying features that distinguish these groups, we expect to have insight into appropriate indications for surgery. This manuscript documents the demographic data of this cohort, and reports on the success of non-operative treatment in the first 400 patients enrolled in this study who have follow up of at least 12 weeks.

IRB Approval

IRB approval was obtained at all participating sites before enrollment of the first patient.

Inclusion and Exclusion Criteria

All patients, age 18–100 with shoulder symptoms and MRI documented, atraumatic, full thickness rotator cuff tears were invited to participate. Any patient with a history of an injury leading to their presenting symptoms was excluded. Other exclusion criteria included pain related to the cervical spine, scapular pain, previous shoulder surgery, glenohumeral arthritis, inflammatory arthritis, adhesive capsulitis, previous proximal humeral fracture, bilateral rotator cuff tears, and dementia.

Protocol

All patients who met inclusion criteria were offered an opportunity to enroll in the study. At the initial visit, patients completed a questionnaire that detailed demographic data and included validated patient reported outcome measures (SF-12³⁶, ASES Score²⁹, WORC Index¹⁵, SANE Score³⁸, and the Shoulder Activity Scale⁵). Physicians performed a standard physical examination and reviewed radiographs and MRI images for each patient, and then recorded information on standard Teleform (Cardiff, Vista, CA, USA) data collection forms.

Physical Therapy Program

Patients were given two instructive rehabilitation books (Appendix 1)-one for physical therapists, and another for home-based physical therapy written in the 8th grade level with an accompanying DVD. This physical therapy program was derived from a systematic review of the literature that demonstrated exercise was effective in treating impingement syndrome¹⁸. The specific exercises included daily range of motion (postural exercises, active assisted motion, active training of scapula muscles, active range of motion); daily flexibility (anterior and posterior shoulder stretching); and three times per week strengthening (rotator cuff and scapula exercises). Therapists were instructed to provide manual mobilization exercises as needed, as there is evidence to support their use in impingement¹⁸, and to progress the patient to a home therapy program when ready. Heat and cold were recommended as modalities, but ultrasound was not. Patients completed a compliance diary regarding their physical therapy visits and the frequency of home therapy events.

Patients returned after performing the therapy program for six weeks. At that point, patients were given three options: 1.) If they considered themselves “cured”, no additional treatment or formal follow up was prescribed; 2.) If they were “improved” patients continued the

physical therapy program for another six weeks; 3.) If they were “no better” they could elect to have surgery. Patients could choose to have surgery at any time in the course of treatment.

Outcome Measures

Patient demographic information including age, gender, race, employment status, worker’s compensation or automobile claims, tobacco history, and co-morbidities were collected at entry into the study. Data on whether the patients had undergone surgery for their rotator cuff tear was collected at each follow up time point. The following patient related measures of outcome were collected at study entry, six weeks, 12 weeks, 1 year and 2 years: SF-12³⁶, ASES Score²⁹, WORC Index¹⁵, SANE Score³⁸, and the Shoulder Activity Scale⁵.

At the initial visit, physicians completed a data collection form that included findings from the physical examination, and interpretation of radiographs and MRI grading of the rotator cuff tear³¹. Physical examination data was also collected at six and 12 week visits.

Statistical Methods

Most epidemiologic data is presented as descriptive data in table form. Comparisons of patient related outcome scores were analyzed using a Wilcoxon signed-rank test with continuity correction. Failure of nonoperative treatment data is presented as descriptive data and was analyzed using a Kaplan Meyer survivorship curve. Statistical analysis was performed with free open source R statistical software (R Development Core Team. R: A Language and Environment for Statistical Computing. Vienna, Austria: R Foundation for Statistical Computing; 2010. Available at: <http://www.R-project.org/>).

RESULTS

Enrollment

The group saw 2233 rotator cuff tear patients during the enrollment period. Of this group, 1280 patients were excluded for the following reasons: acute tears (38%), previous surgery (11%), bilateral disease (8%), neck disorders (6%), frozen shoulder (2%), dislocation (3%), rheumatoid disease (1%) fracture (1%). Of the remaining 953 patients eligible to enroll in the study, 452 (47%) elected to do so. These 452 patients are followed as a prospective cohort with rolling entry into the study. Of this group 30 patients withdrew from the study. This report is based on 422 patients for whom we have follow-up data at a minimum of three months and up to two years for 90% of the cohort (N=381).

The average age of those who enrolled was 62, whereas the average age of those who did not was 58 ($p<0.001$). Equal numbers of males and females enrolled, where as of those who did not enroll, males predominated (63%). This difference was statistically significant ($p<0.001$).

Demographic Data for the Study Population

The average age of the study population was 62.6 years (range 31–90), with 206 (51%) male, and 194 (49%) female. The dominant arm was affected in 68% of subjects. The right arm was affected in 70% of subjects. With regard to tobacco use, 89.5% were nonsmokers. Other demographic features, including race, ethnicity, education level, and employment status are listed in Tables 1–4. Many patients had co-morbidities, with hypertension, back pain, and osteoarthritis most common (Table 5). Geographically, the patient mix was fairly well distributed (Table 6). Interestingly only 18% reported a family history of rotator cuff problems, whereas 60% did not. With regard to treatment before enrolling in the study, 23% had already tried some physical therapy, 40% had received injections, and 80% had tried NSAIDs.

MRI Features of the Rotator Cuff Tears

Superior humeral head migration was recognized on the MRI in 15% of patients. Tears involving only the supraspinatus were seen in 70% of patients (Table 7). Tear size was minimal in 48% of patients, and retracted to the mid humeral head in 33.5% of patients (Table 8).

Compliance with Physical Therapy Program

Overall 77.7% of patients submitted their physical therapy compliance diaries. In the first six weeks of treatment, most patients performed both supervised and home physical therapy. Patients averaged only 8 supervised physical therapy visits over the first six weeks. During the second six weeks of physical therapy, a higher proportion of patients did only home therapy, with a mean of 7 visits of supervised therapy over the six-week period (Table 9).

Improvements in Range of Motion

Average active range of motion progressively improved over the 12 weeks of treatment, notably for forward elevation, and abduction (Table 10).

Improvements in Patient Reported Measures of Outcome

Statistically and clinically significant improvements were noted over the 12 weeks of treatment for the ASES, WORC, and SANE scores (Table 11). No clinically important change was noted for the SF-12 domains or the Shoulder Activity Scale.

Failure of Nonoperative Treatment-Surgery Rates

This cohort of patients was collected over a three-year period, and this report is a cross sectional study of the cohort when all members of the cohort had reached 1 year follow up and 75% of the cohort had reached 2 year follow up. The data presented is a cross sectional evaluation of patients in the cohort based on different time points as of March 2012.

All patients in the cohort have reached the six-week time point (N=422). Of this group, we have data on 402 (95%) at six weeks. Of this group, 35 patients (9%) had elected to have surgery within six weeks of starting the physical therapy program (Figure 1).

All of the patients in the cohort have reached the 12-week follow up point, and we have complete data on 399 (95%). An additional 24 patients elected to have surgery between 6 and 12 weeks after starting the physical therapy program, as such the total number of patients who had decided to have surgery at 12 weeks was 59 (15%) (Figure 2).

All patients in the cohort have reached the one-year follow up point. We have data on 396 (94%). At one year follow up, 82 patients (21%) had elected to undergo surgery (Figure 3).

As of March 2012, 381 patients of the 422 in the cohort had reached the two-year follow up point (90%). Of this group data was available on 319 patients (84% follow-up). Of this group, 82 patients had decided to have surgery (26%) (Figure 4).

Kaplan Meyer survivorship analysis demonstrates that patients who elect to undergo surgery do so within 12 weeks. If a patient avoids surgery in the first 12 weeks, they are unlikely going to have surgery at a later time point, up to 2 years (Figure 5).

DISCUSSION

The key findings of this study are that physical therapy is effective in the nonoperative treatment of atraumatic full thickness rotator cuff tears as demonstrated by the surprisingly

low rate of surgery, and the significant improvements in validated patient related scores of outcome. It is interesting to note that most patients who failed nonoperative treatment did so within the first 12 weeks. It is also of interest that only approximately one supervised physical therapy visit per week was required during the typical 12-week course of treatment.

Limitations of this study include the potential for selection bias (e.g. patients who are less interested in surgery may be more inclined to participate, or the decision to have surgery may be influenced by the type of the insurance a patient may have); performance bias (some patients may have received medications, acupuncture or other pain relieving treatments that we did not examine); and generalizability may be limited as patients who presented with a history of trauma were excluded from the study. In addition, this report is a cross sectional study of the data as it stands today. The data could potentially change as the cohort continues to move through time.

Despite these potential limitations, our study included patients from multiple practices across the United States, has 400 subjects, and was performed as a prospective cohort study. As such, for atraumatic rotator cuff tears, the results of this study may be generalized to the United States population.

Substantial variation has been noted geographically in the frequency of rotator cuff surgery³⁵, and in orthopaedic surgeons' approaches to individual case scenarios⁸. As a result the indications for rotator cuff repair are not clearly defined or accepted^{27,39}. Patients who present with shoulder pain without a history of an injury and an MRI documented rotator cuff tear present a dilemma to physicians as there is little data to help make decisions regarding appropriate treatment.

Clearly larger tears were once small, and progression has been documented in some patients^{20,22,23,41,43}. It is known that asymptomatic tears may become symptomatic⁴¹ and that patients with bilateral rotator cuff tears where one is symptomatic and the other is not, the symptomatic tears is typically larger⁴⁰. This information would lead some surgeons to recommend surgery for all patients with rotator cuff tears. However, it is also known that progression can occur without the development of symptoms⁴¹. Unfortunately the literature does not identify the risks for progression of rotator cuff tear size or for predicting which patients will develop symptoms.

One randomized controlled trial compared rotator cuff repair to nonoperative treatment in patients with rotator cuff tears less than 3cm in size²⁵. In this study, the ASES and Constant Score at 12 months was significantly better in the surgery group (76.8 versus 66.8), however of the 51 patients randomized to their therapy group, only 9 patients (17%) failed and elected to have surgery. These data parallel the findings in our study and suggest that surgical treatment may not be necessary for many individuals.

Prevalence data supports this contention. Based on multiple cadaver and MRI studies, a conservative estimate would suggest that 10% of Americans over the age of 60 have full thickness rotator cuff tears²⁸. This would mean that nearly 6 million Americans have full thickness rotator cuff tears. A generous estimate of the number of rotator cuff repairs performed each year in the USA is 250,000²¹, which would mean that fewer than 5% of all of the full thickness rotator cuff tears that exist in the United States population are treated surgically.

Multiple case series report success rates with non-operative treatment to range between 59–85% however these studies are subject to selection bias, are retrospective in design, and in many studies include only those patients with massive tears in whom surgery cannot be performed¹. One prospective cohort study of 103 shoulders with rotator cuff tears treated

without surgery demonstrated lasting pain relief 13 years after diagnosis, and 72% of patients with no disturbance in activities of daily living¹⁴, however those that had pain or functional loss tended to be younger at the time of diagnosis.

Our prospectively collected data enrolling all patients with atraumatic rotator cuff tears suggests that physical therapy is highly effective at improving symptoms. Based on the prevalence data described above, the majority of patients with rotator cuff tears are either asymptomatic or have minimal symptoms, and it seems that the physical therapy program used in this protocol may bring patients to a relatively asymptomatic state.

This research has raised many questions. First, it would be important to know exactly what are the risk factors that would predict progression of known rotator tears or development of symptoms. Equally important would be information that allows us to predict which repaired tears are likely to fail. This information would certainly help surgeons and patients make informed decisions regarding surgery.

The nature of the patient's symptoms and the patient's expectations of treatment are important to appreciate when making decisions regarding surgery for rotator cuff tears. Most patients will present to the physician with pain as a chief complaint. Preliminary analysis of data from this study has demonstrated that the severity of the rotator cuff tear has no correlation with the severity of pain⁷ or the duration of symptoms³³. Interestingly, patients who have failed rotator cuff repairs report outcome scores that are not significantly different than patients whose repairs have healed^{6, 13, 16, 17, 26, 30}, unless the outcome score includes a large component for strength (e.g. the Constant Score), in which case healed repairs have better scores^{25, 30}.

The physical therapy program in this study was highly effective in alleviating patient symptoms despite the fact that patients continued to have tears in the rotator cuff. This leads one to believe that pain may not be the best indication for rotator cuff repair. Weakness or loss of function may be a better indication for surgery than pain. Further analysis of this cohort will be undertaken to identify those features that distinguish patients who decided to have surgery from those who did not. This data should provide some insight into the features that predict failure of nonoperative treatment, and should help clarify indications for surgery.

CONCLUSIONS

This large, multicenter prospective cohort study has demonstrated that a specific physical therapy protocol can be very effective in treating symptoms in patients with atraumatic full thickness rotator cuff tears. If failure is defined as patients electing to have surgery, then this program is successful in approximately 75% of patients at two-year follow-up. Interestingly, much of the physical therapy was done at home, with patients averaging slightly more than one physical therapy visit per week. Physical therapy is not ideal for all patients and some will elect surgery early. Others may be at risk for symptom or rotator cuff tear progression. Decisions regarding surgery should be made individually with each patient, but should include information that the physical therapy program used in this study is highly effective in alleviating symptoms.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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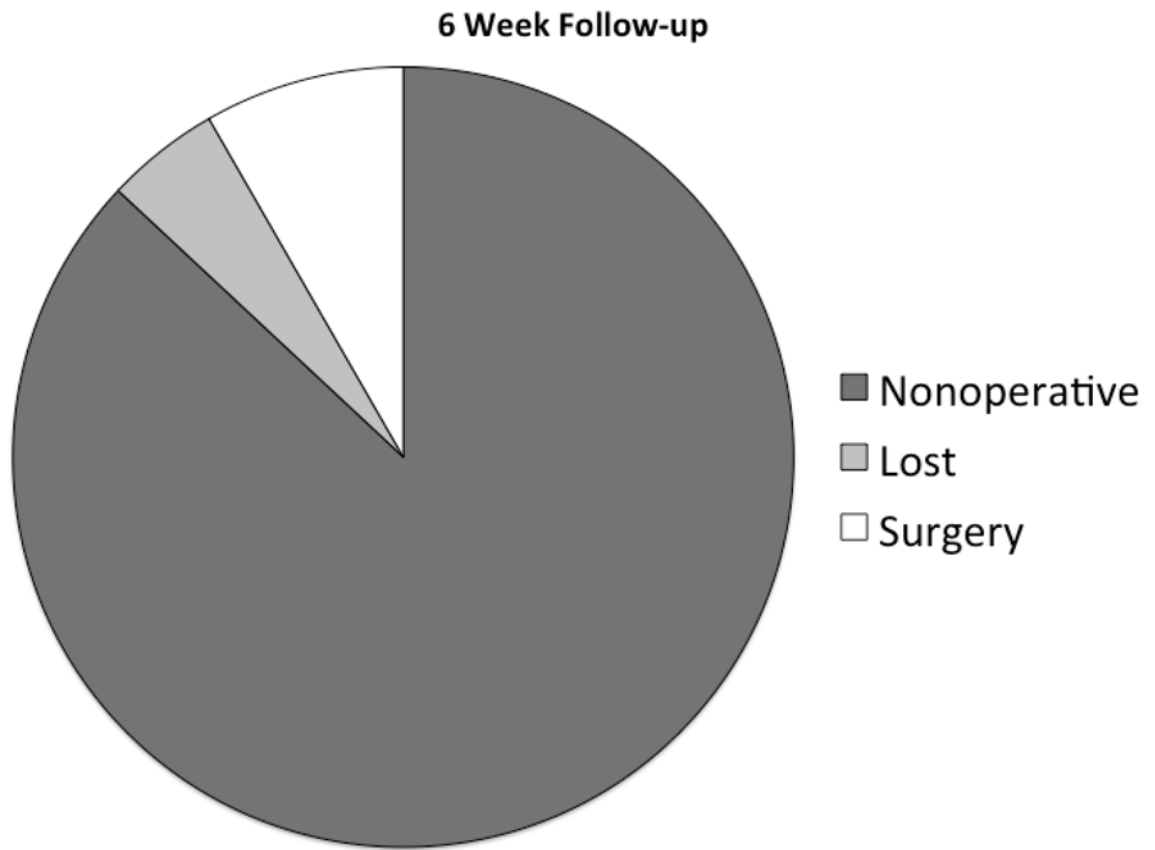


Figure 1. 6 Week Data

The entire cohort of 422 patients has reached the six week follow-up point. Of this group 20 patients (5%) were lost to follow-up. Of the 402 patients remaining, 35 had surgery (9%).

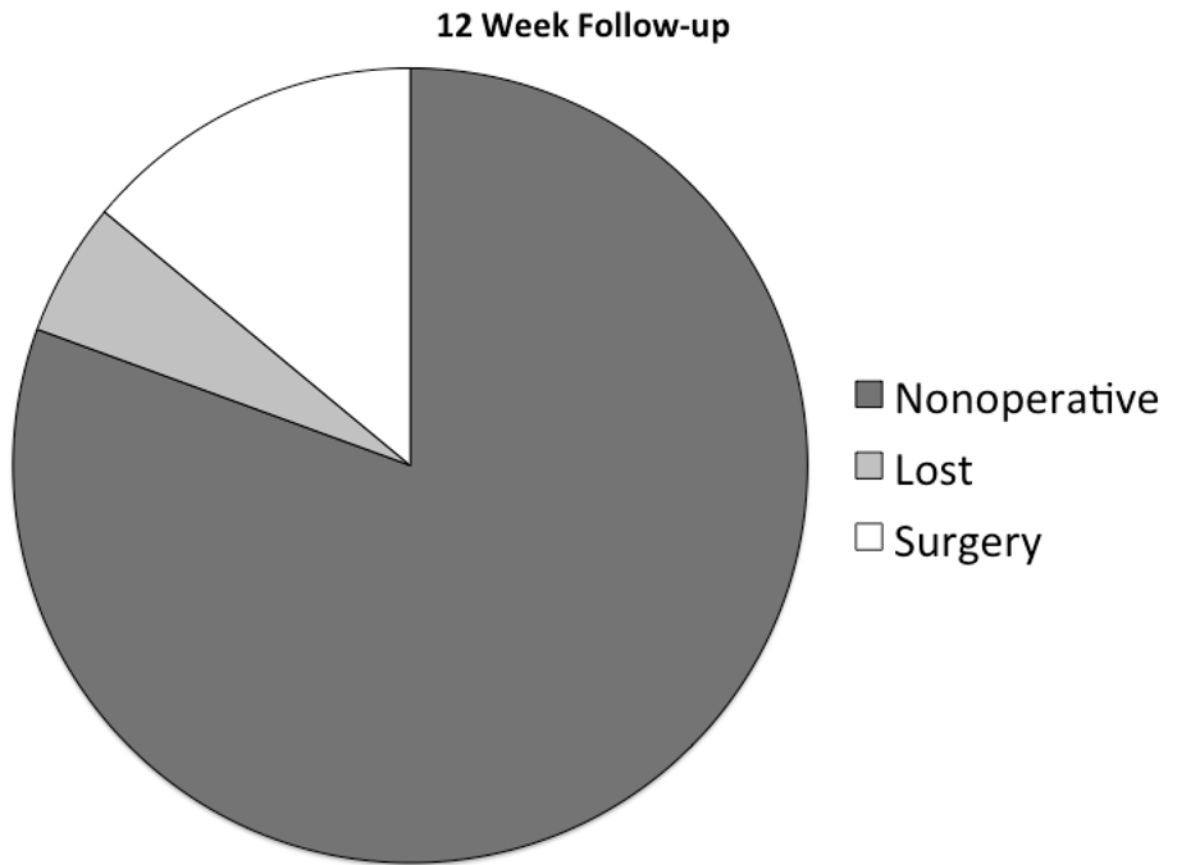


Figure 2. 12 Week Data

The entire cohort of 422 patients has reached the 12 week follow-up point. Of this group 23 (5%) were lost to follow-up. Of the 399 patients remaining, 59 had surgery (15%).

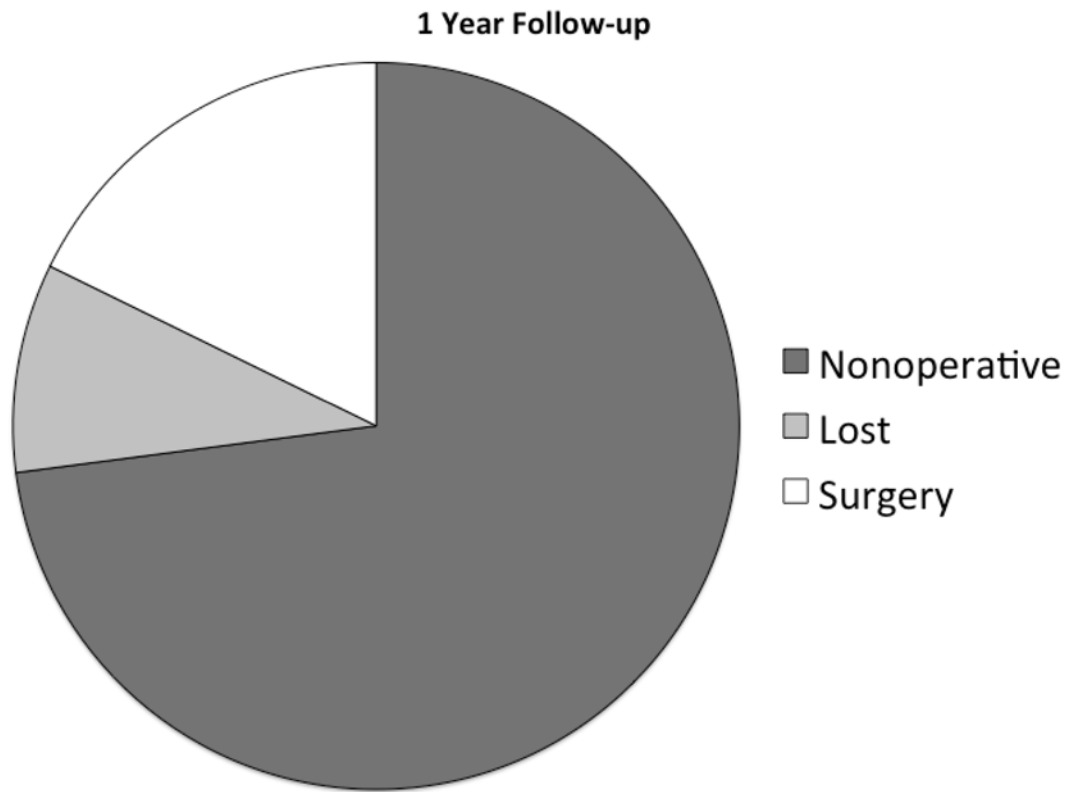


Figure 3. 1 Year Data

The entire cohort of 422 patients has reached the one year follow-up point. Of this group 26 (6%) were lost to follow-up. Of the 396 patients remaining, 82 had surgery (20%).

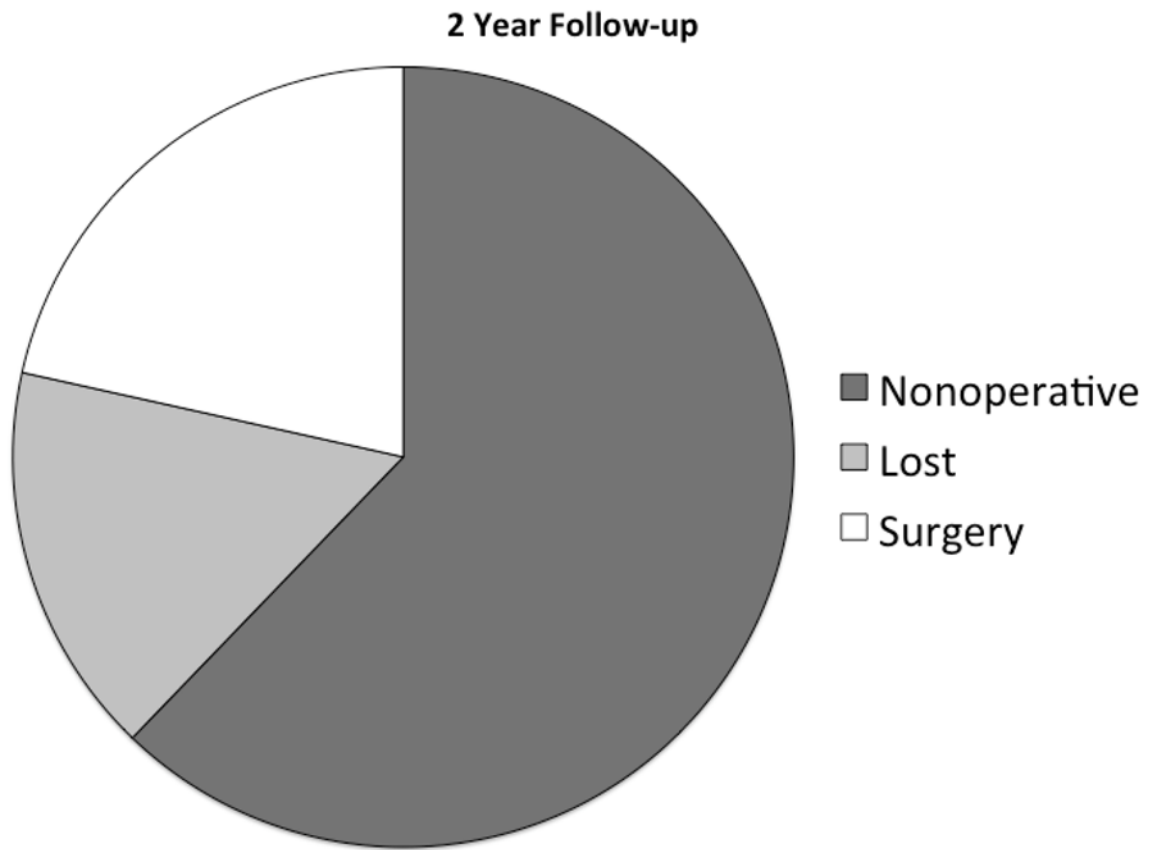


Figure 4. 2 Year Data

As of March 2012, 381 patients have been enrolled in the study for at least two years. Of this group, 62 (16%) were lost to follow-up. Of the 319 patients remaining, 82 had surgery (26%).

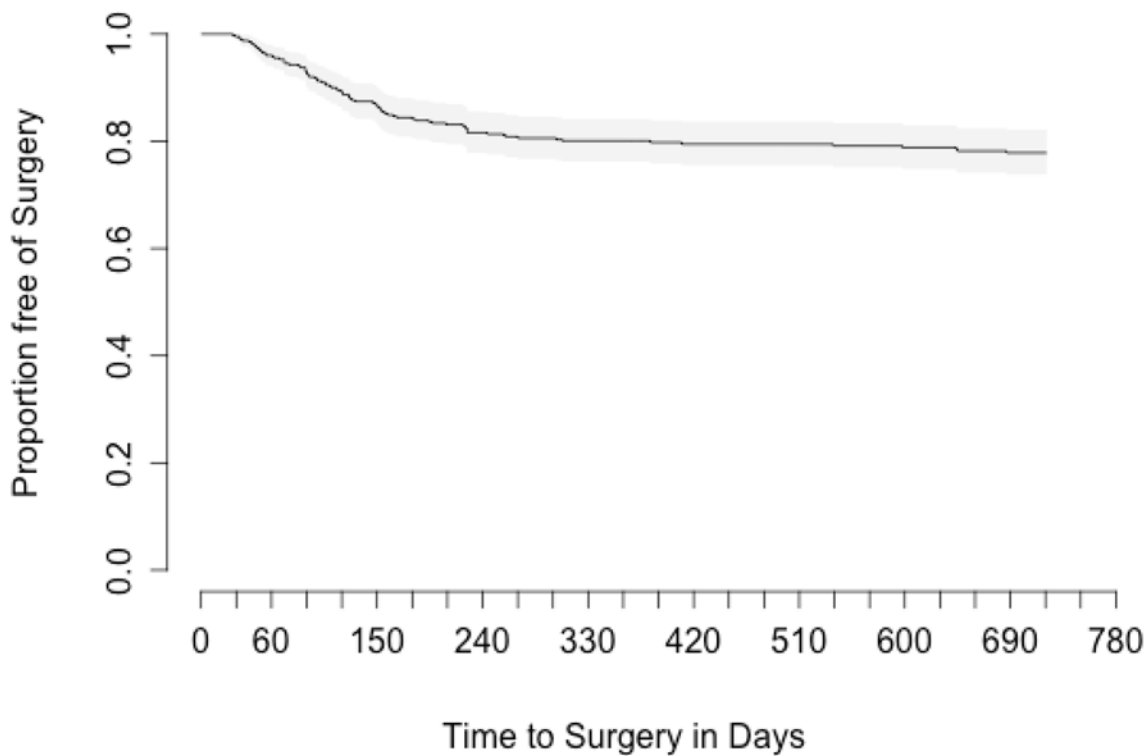


Figure 5. Kaplan Meyer Survival Analysis Curve – Failure of Physical Therapy as a Treatment for Atraumatic Rotator Cuff Tears

Note that most patients fail the physical therapy program and elect to have surgery between 6 weeks (42 days) and 12 weeks (84 days) after initiating the therapy program.

Table 1

Race Characteristics of the Study Population

Race	Number (%)
White	345 (86%)
Black	32 (8%)
Asian	12 (3%)
American Indian	6 (1.5%)
Hawaiian	1 (<1%)
No Answer	8 (2%)

Table 2

Ethnicity of the Study Population

Ethnicity	Number (%)
Hispanic	11 (2.5%)
Not Hispanic	319 (80%)
No Answer	70 (17.5%)

Table 3

Education Level of the Study Population

Education Level	Number (%)
No High School	14 (3.5%)
Some High School	15 (4%)
Graduate High School/GED	96 (24%)
Some College	85 (21%)
Associate Degree	20 (5%)
Bachelor Degree	77 (19%)
Graduate Degree	92 (23%)
No Answer	1 (<1%)

Table 4

Employment Status of the Study Population

Employment Status	Number (%)
Full Time	187 (47%)
Part Time	38 (9.5%)
Retired	130 (32.5%)
Homemaker	17 (4%)
Unemployed	6 (1.5%)
Disabled	21 (5%)
No Answer	1 (<1%)

Table 5

Co-Morbidities of the Study Population

Co-morbidities	Number (%)
Hypertension	197 (49%)
Back Pain	146 (36.5%)
Osteoarthritis/Degenerative Arthritis	133 (33%)
Other Medical Problems	102 (25.5%)
Depression	69 (17%)
Heart Disease	62 (15.5%)
Diabetes	54 (13.5%)
Rheumatoid Arthritis	32 (8%)
Cancer	30 (7.5%)
Ulcer/Stomach Disease	27 (7%)
Lung Disease	24 (6%)
Anemia/Other Blood Disease	20 (5%)
Kidney Disease	13 (3%)
Liver Disease	7 (2%)

Table 6

Geographic distribution of the Study Population

SITE	Number (%)
Vanderbilt University, Nashville, Tennessee	92 (23%)
The Ohio State University, Columbus, Ohio	84 (21%)
Washington University in St. Louis, St. Louis, Missouri	40 (10%)
Knoxville Orthopaedic Clinic, Knoxville, Tennessee	40 (10%)
Orthopaedic Institute, Sioux Falls, South Dakota	36 (9%)
University of California, San Francisco, California	36 (9%)
Hospital for Special Surgery, New York, New York	30 (8%)
University of Colorado, Denver, Colorado	27 (7%)
University of Iowa, Iowa City, Iowa	15 (4%)

Table 7

MRI size of tear based on number of tendons involved

Tendon Involvement	Number (%)
Supraspinatus only	281 (70%)
Supraspinatus and infraspinatus	83 (21%)
Supraspinatus, infraspinatus and teres minor	3 (<1%)
Subscapularis	2 (<1%)
Supraspinatus and subscapularis	20 (5%)
Supraspinatus, infraspinatus and subscapularis	7 (2%)
Unknown	4 (1%)

Table 8

Degree of rotator cuff retraction in coronal plane on MRI

Degree of Retraction	Number (%)
Minimal	191 (48%)
Midhumeral	134 (33.5%)
Glenohumeral	52 (13%)
Medial to the Glenoid	19 (5%)
Unknown	4 (1%)

Table 9

Compliance with Physical Therapy Program

	Number Returned	No Therapy	Supervised and Home	Supervised Only	Home Only	Ave No Supervised Visits
1-6 weeks	230/291 (79%)	4	180	5	41	7.99
7-12 weeks	143/206 (69%)	2	66	1	67	6.93

Table 10

Improvement in Active Range of Motion during Treatment

Active Motion	Baseline N=452	6 Weeks N=402	12 Weeks N=399
Forward Elevation	149.8	163.3	162.9
Abduction	136.8	154.9	154.7
External Rotation at Side	52.9	55.6	55.8
Internal Rotation at Side	56.7	56.9	58.3
External Rotation at 90 Abduction	74.75	80.33	80.86
Internal Rotation at 90 Abduction	45.32	46.36	52.27

Table 11

Patient Reported Measures of Outcome

Patient reported measures of outcome are compared to baseline scores with p-values.

Assessment Tool	Baseline N=452	6 weeks N=402	P value	12 weeks N=399	P value
SF-12 MCS	40.26	40.57	0.36	40.84	0.895
SF-12 PCS	35.34	35.64	<0.0001	36.05	<0.0001
ASES Score	54.47	77.98	<0.0001	83.67	<0.0001
WORC Score	47.16	62.52	<0.0001	69.67	<0.0001
SANE Score	46.6	62.73	<0.0001	70.27	<0.0001
Marks Activity Scale	9.89	10.15	0.096	10.01	0.47

MCS=Mental Component Score, PCS=Physical Component Score