The EFFICACY of ACUPUNCTURE in CHRONIC ROTATOR CUFF TENDINITIS: PROPOSAL of a PILOT RANDOMIZED CONTROLLED TRIAL

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RESEARCH QUESTION:

Do acupuncture treatments improve the Shoulder Pain and Disability Index scores of primary care patients in North America with chronic rotator cuff tendinitis in a randomized controlled trial?

OUTLINE of PROPOSAL:

(a) **INTRODUCTION**:

I. OBJECTIVE

To determine the efficacy of acupuncture in treating patients with chronic rotator cuff tendinitis.

II. RATIONALE:

Shoulder pain is the third most common problem presenting to the primary care physician office. Rotator cuff tendinitis is the most common type of shoulder problem. The greatest proportions of shoulder problems occur during the fifth and seventh decades of life. About 50% of the patients with shoulder problems complain to their physicians. The incidence in a Dutch general practice was estimated to be about 11.2 per 1000

patients per year. The National Morbidity Surveys in England and Wales reported the incidence per year to be 6.6 per 1000 patients.

Despite shoulder pain been such a common complaint, very little is known about the natural course of this condition. Shoulder pain can be either intrinsic or extrinsic to the shoulder. Intrinsic shoulder problems can be classified using the Cyriax methods. Cyriax's classification is well known and is used widely by physicians around the world. Shoulder pain is classified into rotator cuff tendinitis, subacromial bursitis, rotator cuff tear, adhesive capsulitis, bicipital tendonitis, acromioclavicular joint disorder, tumor, fracture, and arthritis. Although the classification is simple, these problems are sometimes clinically difficult to distinguish from each other. It is very difficult to distinguish between rotator cuff tendinitis and subacromial bursitis. Furthermore, due to the close proximity in which the four rotator cuff tendons attach, it is very difficult to isolate the complaint to one tendon. The bicipital tendon also traverses through that area making the diagnosis a challenge at times. Rotator cuff tendinitis is usually defined as shoulder pain especially with abduction of shoulder and one positive resistive test (resisted shoulder abduction, internal rotation, or external rotation).

It has been suggested that 90% of cases of rotator cuff tendinitis resolve with time and treatment. However, this idea contrasts with studies reporting response failures to local corticosteroid injection; thought to be the most effective treatment. The study by Chard et al in 1988 concluded that a quarter of patients continued to have chronic tendinitis for a prolonged period despite treatment. The patients in this retrospective study had pain persisting 2.5 years (mean of 19 months). Therefore, it does not appear that chronic shoulder tendinitis resolves spontaneously.

The use of non-steroidal anti-inflammatory drugs (NSAIDs) is common practice in primary care for rotator cuff tendinitis. According to a systematic review by Van der Windt in 1994, three trials with the highest methods scores demonstrated superior short term efficacy of NSAIDS in comparison with placebo intervention. Even through a significant proportion of patients do not respond to cortisone injection therapy, it appeared to be significantly more efficacious than NSAIDs. An updated Cochrane systematic review was done in 1999 on NSAIDS for shoulder pain. The pooled results of two studies looking at efficacy of NSAIDS in treating rotator cuff tendinitis suggested that NSAIDS may be superior to placebo in improving the degree of restriction in abduction.

In general practice, patients with the diagnosis of rotator cuff tendinitis fail to respond to NSAIDs, physical therapy is often recommended. Green et al. (2003) included 26 trials in their review of physiotherapy treatment of shoulder pain. For rotator cuff disease, exercise was effective for short term recovery (RR 7.74 (1.97, 30.32)), and had long term benefit with respect to function (RR 2.45 (1.24, 4.86)). In addition, mobilization combined with exercise resulted in additional benefit in comparison to exercise alone. Laser therapy was reported to be more effective than the placebo for adhesive capsulitis (RR 3.71 (1.89, 7.28)), but not for rotator cuff tendinitis. Ultrasound was more effective than the placebo for relieving pain in calcified tendinitis (RR 1.81 (1.26, 2.60)). However, there is no evidence to support or refute the effectiveness of ultrasound over exercise. Similarly, pulsed electromagnetic field therapy demonstrated some benefit in comparison to the placebo in providing pain relief for calcified tendinitis (RR 19 (1.16, 12.43)). The authors concluded that there is insufficient evidence to support or refute the

use of physiotherapy to treat shoulder pain. There is a need for more high quality studies in this area of research.

Corticosteroid injections are usually reserved for resistant cases to minimize the occurrence of potential adverse events. Buchbinder et al. (2003) included 26 trials in their review. Most RCTs had small sample sizes, heterogeneity issues, and were of variable methodological quality. Subacromial steroid injection was found to have a small benefit over placebo in some trials for rotator cuff disease. For adhesive capsulitis, one trial suggested short term benefit of intra-articular steroid injection over physiotherapy at seven weeks. Two other trials suggested an early benefit of intra-articular steroid injection over placebo. However, these two studies could not be pooled. The authors concluded that there is insufficient evidence to support or refute the use of corticosteroid injections for treating shoulder pain. Subacromial corticosteroid injection for rotator cuff disease and intra-articular injection for adhesive capsulitis may have some benefit, but their effect may be small and not well maintained.

Finally, surgery is sometimes indicated. Coghlan et al. (2008) included 14 RCTs consisting of 829 patients in their review of surgery for shoulder pain. Eleven trials included patients with impingement, two trials included patients with rotator cuff tear, and one trial included patients with calcified tendinitis. Due to heterogeneity, the studies were not pooled. Three trials compared either open or arthroscopic subacromial decompression with an active non-operative treatment (i.e. exercise, physiotherapy and/or education). No differences in outcome between groups were reported in any of these trials. Six trials that compared arthroscopic with open subacromial decompression reported no significant differences in outcome between groups at any time. However,

four trials reported quicker recovery and/or return to work with arthroscopic decompression. The authors concluded that there is insufficient evidence to support or refute the effectiveness or safety of surgery for rotator cuff disease.

In 2005, Green et al. published a systematic review on acupuncture for shoulder pain. Nine trials met the inclusion criteria, and studied various shoulder disorders including adhesive capsulitis (frozen shoulder), rotator cuff disease, and osteoarthritis. For all trials examined, the interventions were poorly described. Two trials assessed short-term success of acupuncture for rotator cuff disease. There was no significant difference in short-term improvement associated with acupuncture when compared to the placebo. However, acupuncture was more beneficial than the placebo in improving the Constant Murley Score (a measure of shoulder function) at four weeks (WMD 17.3 (7.79, 26.81)). In another trial, traditional and ear acupuncture plus mobilization was more beneficial in treating shoulder pain when compared to mobilization alone. The authors concluded that there is insufficient evidence to support or refute the use of acupuncture for shoulder pain, though it may provide short-term benefit with respect to pain and function. There is a need for more high quality trials in this area of research.

Beyond the studies reviewed by Green et al., Romoli et al. (2000) examined the following studies. Moore & Berk (1976) compared acupuncture to placebo acupuncture in 42 patients. The authors concluded that there was no significant improvement in shoulder discomfort between the two treatments for patients with chronic shoulder pain. A pilot study by Berry et al. (1980) compared five treatment groups of patients who received acupuncture, steroid injection plus NSAID, steroid injection plus placebo NSAID, physiotherapy in the form of ultrasound, or placebo NSAID plus placebo

ultrasound. All groups showed statistically significant improvement in shoulder pain and function at four weeks, but no differences were detected between the treatments. Lin et al. (1994) compared three treatment groups: electroacupuncture, regional nerve block, and a combination of the two methods. The combination of the methods showed significantly better pain control, longer pain relief duration, and longer improvement of shoulder mobility than did either of the two treatments alone.

After reviewing these three studies, Romoli et al. discussed design of an RCT involving 60 patients with unilateral shoulder pain. The patients were separated into three groups: acupuncture combined with mobilization, ear acupuncture combined with mobilization and mobilization alone (control). The researchers developed a protocol to examine the effectiveness of acupuncture on shoulder pain based on unpublished pilot study data, but never actually completed this protocol.

Additionally, Kleinhenz et al. (1999) treated 52 athletes with rotator cuff tendinitis in single blind RCT of acupuncture using their placebo needle design as the control. Patients had eight treatment sessions over the course of four weeks. Twelve acupuncture points were chosen from a list of 20. This combination was used over the course of four sessions. If there was no sign of clinical improvement, another examination was performed to choose alternate points for the next four sessions. Some local acupoints used (when tender) were TE 15, BL 44, TE 14, SI 12, SI 11, LI 15, LI 14, SI 14, SI 9, and Jianquan (extra). The distal acupoints chosen were along used the same meridians as the local acupoints used: LI 11, TE 3, SI 6, GB 34, and SI 3. The symptomatic point ST 38 was also used. The primary endpoint of the trial was the change in the modified Constant Murley Score from the baseline. Orthopedists assessed

treatment outcomes, but were not informed of the treatment allocation. Acupuncture was more effective than placebo acupuncture in the treatment of pain. The acupuncture group improved 19.2 Constant Murley score points (SD 16.1, range from -13 to 50) and the control-group improved 8.37 points (SD 14.56, range from -20 to 41), (P=0.014; C.I. 2.3; 19.4). Overall, the authors concluded that needling is integral to acupuncture's therapeutic effects in treating athletes with chronic shoulder pain.

In addition, Molsberger et al. (2004) reported a well-designed German study consisting of 424 patients with chronic shoulder pain. There were three treatment groups: acupuncture, sham acupuncture, and standard conservative orthopedic therapy. The primary endpoint was a 50% or greater improvement in the visual analog pain score. Three months after the cessation of treatment, 78% of the acupuncture group successfully achieved this endpoint, compared to 47% and 43% improvements found for the sham acupuncture and conservative groups, respectively. This outcome was statistically significant ($p<0.0001$) for the acupuncture group.

Although these results were positive, issues still remain regarding whether sham acupuncture is truly a placebo (discussed below). Also, none of the above studies compare needle acupuncture with laser acupuncture, which may be a more acceptable form of treatment in western societies. Furthermore, laser acupuncture would have fewer contraindications than needle acupuncture.

The present study is designed assess the efficacy of both needle and laser acupuncture in chronic rotator cuff tendinitis for the following reasons. Chronic pain patients (especially in the elderly population), pain levels and course of disease are usually relatively stable, so therefore, any recovery would be more likely due to

intervention rather than to the natural course of the disease. Therefore, a well design study is needed to compare the efficacy of needle acupuncture versus laser and sham laser acupuncture in chronic rotator cuff tendinitis, the most common shoulder complaint. This also allows determination of the efficacy of both metal and laser acupuncture needles.

Whether the results are positive or negative, they will influence the future of acupuncture practice for chronic rotator cuff tendinitis. A positive result for acupuncture intervention would confirm acupuncture's importance as a modality for pain relief in chronic rotator cuff tendinitis. If acupuncture can be demonstrated to improve disability and shorten recovery time in chronic shoulder tendinitis compared to conventional treatments, then acupuncture would have enormous beneficial economic impact on health care costs and would reduce unnecessary suffering in these patients. Otherwise, it is prudent that health policies be implemented to avoid unnecessary treatments and costs to patients.

b) **DESIGN ARCHITECTURE:**

This is an efficacy pilot study. The most appropriate design would be a double blinded randomized control trial. Moreover, a randomized controlled trial (RCT) would minimize some of the biases through proper sampling, randomized allocation, and blinding.

Three arms will be required in this study. These groups will receive advice and education about chronic rotator cuff tendinitis and asked to continue as needed use of analgesics such as acetaminophen or ibuprofen.

The cost of treatment of chronic rotator cuff tendinitis is relatively inexpensive if the economic cost for job absenteeism and drug complications are not considered. Thus, any new modality of treatment either has to be cheaper or has to improve the patient's physical function sooner than conventional treatment. Sham acupuncture has been extremely difficult to achieve in the past, either because superficial needling cannot be considered completely placebo or because "irrelevant" points could potentially also have some therapeutic effect. In chronic pain studies, sham acupuncture has been shown to be effective about 50% of the time compared to 75% for traditional acupuncture. From these studies, it appears that insertions of needles into the skin no matter how superficial or minimally stimulated exert a physiologic effect. Therefore, this method of sham acupuncture is not a true placebo. A better alternative to sham acupuncture is the use of sham laser. Therefore, another two groups using laser acupuncture are required to be certain that any improvement from the needle acupuncture treatment group is not due to the "placebo effect." The two additional groups will receive treatment by a machine that emits infrared laser beams via fiber optic cables at 50mw power. The laser machine has a "randomization" switch that allows for the front panel LCD display showing laser(s) activated and treatment timer to appear to be functioning normally regardless of whether the power to the LED laser emitter is present or not. With the fiber optic laser (Figure 1) placed in the cardboard applicator tube (Figure 2) that are used to hold the laser perpendicular to the skin over the chosen acupuncture point, the infrared laser beam is not visible to the machine operator or the subject. Hence, the randomization switch can allow the experimental protocol to blind both the person who is administering the treatment and the person who is receiving it as to whether the applied treatment is real

(powered laser) or placebo (sham laser). A research assistant who is not involved in either treatment or analysis of data will turn the switch on or off prior to each treatment according to the randomization protocol. All three groups will receive real or placebo treatments to the same set of points. These points will be determined by expert consensus.

C) **SAMPLE SPECIFICATION;**

I) **TARGET POPULATION**:

Adult patients with chronic rotator cuff tendinitis of over 6 months duration will be the targeted population.

II) **SAMPLE SELECTION**:

Patients will be recruited through orthopedists, primary care physicians, physiotherapists, chiropractors, and advertising. These patients will be recruited by two centers: Ancaster Sports Medicine Clinic in Ancaster, ON and Mayo Clinic Jacksonville in Florida. These centers are both affiliated with the respective universities, McMaster and Mayo Graduate School of Medicine.

A. Inclusion Criteria

1) Adult males and females between ages 18-70
2) Shoulder pain with abduction and aggravated by resistance testing (abduction, internal rotation, or external rotation)
3) Pain duration of 3 or more months
4) Willingness to travel to treatment centers and to be available for repeated follow-up phone calls

B. Exclusion Criteria

1) Receiving another treatment modality besides acetaminophen or NSAIDs
2) Patients who have contraindication to NSAIDs, such as ulcers, gastroesophageal bleeding, or chronic renal insufficiency
3) Pending medicolegal or worker compensation claims
4) Anti-coagulant therapy
5) Open skin lesions or cellulitis around the affected shoulder
6) Corticosteroid injections within the past 3 months
7) Clinical evidence of adhesive capsulitis
8) Serious cardiopulmonary or renal/hepatic co morbidities such as congestive heart failure, severe COPD, chronic renal insufficiency, or hepatic dysfunction

The inclusion criteria will include patients of both sexes to minimize the differences in treatment response between males and females. The age group 18 to 70 is chosen because chronic rotator cuff tendinitis occurs mainly in this age group.

This study is not a comparison study of acupuncture with other therapies. It is prudent to admit only those patients who are not receiving other treatments to the study. The contamination may reduce the treatment effect size of acupuncture. Lastly, it is important to eliminate factors that can affect treatment success or failure. If this study fails to show positive results, it should be because acupuncture has no or little effect on chronic rotator cuff tendinitis without any potential biases influenced by unsettled legal issues or worker compensation claims. This last exclusion criterion is justified since this is an efficacy study.

III) **SAMPLE SIZE;**

A convenient sample size of 30 participants in each arm (total of 90 participants) was chosen. Romoli (2000) suggested this sample size may even be large enough to provide statistically significant results.

IV) **DEMOGRAPHIC DATA**:

Demographic data including age, sex, occupation (if any), relationship (if any) to work injury, recreational activities (overhead sports like tennis), shoulder pain duration, and 0-10 visual analog scale (VAS) pain rating will be recorded.

d) **ALLOCATION CONCEALMENT:**

After recruitment, patient will be scheduled to the next available appointment. The time in between allows patients who are less seriously interested or potentially non-compliant to drop out before randomization. Informed consent will be obtained on the same day and patients will be randomly allocated into one of the three treatment groups. Closed envelopes will be prepared before the study that either allocates patients to group A, B or C equally. The letter either A, B or C will be placed inside an envelope and marked numerically. It will be opened in numerical order after recruitment of each patient. The envelopes will be prepared by a different person not involved in determining eligibility, administering intervention, or assessing outcome. Each center (the assistant at Mayo) will contact the coordinating center (McMaster Statistician) by telephone to receive the code either A, B or C.

A --Conventional treatment and metal needle acupuncture

B – Conventional treatment and real laser

C – Conventional treatment and sham laser

e) **BLINDING:**

Patients in the two laser groups and evaluators will be blinded. These patients will be seen individually at different times and will have no opportunity to meet. The treating acupuncturist/laserists (AJ,VB) shall be certified in acupuncture and will serve as experimental instruments only. Biases will be minimized by having the treating acupuncturist/laserists (AJ,VB) have minimal verbal contact with patients. Patients will only be asked relevant questions during the treatment such as "any pain with the needle?" The treating physician should also be asked to follow a standardized protocol for the metal needle acupuncture group in terms of how many times and how fast to twist the needle.

f) MEASUREMENTS of VARIABLES:

I) **VARIABLES**:

Independent variable: acupuncture treatment

Dependent variable: Primary Outcome: physical function and pain status

Secondary Outcomes: amount of analgesics consumed

II) **MEASUREMENT METHODS**:

1) The Shoulder Pain and Disability Index (SPADI)
2) VAS for average pain level
3) Medication Quantification Scale (Harden 2005)

The SPADI is a self administered questionnaire consisting of 13 items. It has two categories: pain and disability (see Appendix I). It takes approximately 2-3 minutes to complete. An MQS Score is calculated for each medication on the basis of a weight (1.1 to 4.5 in the 2005 iteration) multiplied by a score for dosage level, as stated in the drug

manufacturer package inserts or the *Physicians Desk Reference*, 1 for sub-therapeutic dose or occasional use, 2 for lower 50% of the therapeutic dose range, 3 for upper 50% of the therapeutic dose range, and 4 for supra-therapeutic dose. The MQS scores for each medication are then summed to yield a total MQS score for the patient at that point in time.

The change in range of motion on abduction is used widely in studies assessing shoulder pain. However, it is probably more sensitive as a measurement tool in patients with adhesive capsulitis (frozen shoulder) since patients with rotator cuff tendinitis do not usually experience limitation in the range of movement (especially abduction). These patients may however have a positive painful arc sign with abduction. That is, they experience pain typically from 60 to 120 degrees of abduction without any limitation to the shoulder range of motion. Therefore, the SPADI, rather than the degree of abduction will be used as a measurement tool in this study.

III) **RELIABILITY and VALIDITY OF QUESTIONNAIRE**:

The Shoulder Pain and Disability Index is a reliable and valid instrument to assess shoulder problems. Test re-test reliability of the SPADI total and subscale scores range from 0.6377 to 0.6552. Internal consistency ranged from 0.8604 to 0.9507. The SPADI total and subscale scores were highly negatively correlated with shoulder range of motion. This supports the criterion validity of the index. Principal components factor analysis with and without varimax rotation supported the construct validity of the total SPADI and its subscales. High negative correlations between changes in SPADI scores and changes in shoulder ROM indicated the SPADI detected changes in clinical status over short time intervals. Since the SPADI uses the visual analog scale on a plain

continuous line and the scores are converted back to a number from 0 to 11, the reliability and validity of the VAS needs to be examined as well.

Visual analog scales had been used extensively in the acupuncture literature mainly for pain intensity. VAS (Appendix II) has a high degree of reliability. The reliability was as high as 99 per cent in a group of rheumatological patients. The vertical VAS is slightly more reliable than the horizontal VAS. VAS is also more reliable in the literate group than the non-literate group of patients (reliability of 0.94 and 0.71 respectively). VAS was found to be more sensitive to changes in pain intensity than a verbal rating scale. It appears to be a valid instrument. VAS has a correlation of 0.6. to 0.63 in Melzack's McGill pain Questionnaire.

g) <u>METHODS</u>:

The patients' first examination and diagnosis of rotator cuff tendinitis will be made by the referring orthopedist (MB, CO at Mayo) or sports medicine specialist (WT at Mayo). Each patient will be subsequently seen by Dr Rizzo or Dorsher at Mayo or Dr Trinh or Bombin in Ancaster in consultation to confirm the diagnosis of chronic rotator cuff tendinitis and to determine if the subject meets inclusion/exclusion criteria of this study. Thus, each patient will be examined by two independent physicians to confirm accurate diagnosis of shoulder rotator cuff tendinitis prior to their entry into the study. Patients who are not considered to have rotator cuff tendinitis by referring and study physicians, or who do not meet the inclusion/exclusion criteria will be sent back to their referring physician for continuing care of their shoulder condition.

After providing informed consent, patients will be randomized according to the method described in the previous paragraph. Patients who meet the diagnostic criteria of

rotator cuff tendinitis as assessed by the two physicians will be selected to enter the study.

All subjects are then given education about Codman pendulum shoulder exercises (Appendix III) to prevent potential shoulder stiffness. Patients are strongly encouraged to continue to take ibuprofen 200 to 600 mg every 6 hours or acetaminophen 320 to 500 mg every 4 hours on an "as needed" basis. These instructions will be given by one of the evaluating physicians. Information on rotator cuff tendinitis (Appendix IV) will be provided to all patients entering the study.

The patients in all three groups will have ten sessions of metal needle, laser, or sham laser acupuncture treatments over a five week period by the same treating acupuncturist/laserist as described in the blinding section. Ten treatments are used because of previous systematic review suggests that this is the minimum number of treatments needed to produce sustained clinical effects.

Traditional Acupuncture Group (A):

Patients in this group will have needle insertion to a depth of 10-35 mm. Sterile, disposal 40 mm long, 0.2 mm diameter stainless steel acupuncture needles (Carbo) will be used. Acupoints treated will include distal points LI-4, GB-34, and ST-38 as well as 5 local shoulder points to include LI-15 and TE-14. The acupuncturist/laserist can choose among three other local points based on tenderness including LI-16, SI-9, SI-11, SI-12, SI-14, and TE-15. The needles will be manually twirled for 30 seconds or until patients feel a dull pressure and warmth feeling around the needle (*deqi*). The treatment sessions will last 20 minutes with needles manipulated at the 10 minute mark.

Laser groups (B and C):

The Weber Medical Laserneedle device (Gottingen Germany), an FDA approved multichannel low power ("cold") LED laser system, will be applied to the same set of eight body points with infrared laser at 50% power for 20 minutes for 20 Joules per point for subjects in cohort B. A randomization switch has been built into the machines accessible behind a locked panel behind the machine. This randomization switch when set to "C" cuts power to the LED laser though the machine's front panel LCD display still indicates to subject and treating physician that the machine is operating normally. In the "B" position the machine functions normally with the infrared lasers operative.

The acupuncturist/laserist will choose the eight points then affix the cardboard laser holders (Figure 2) to the skin at those points with hypoallergenic adhesive tape.

Treatments

An assistant not involved in the treatment or data analysis will room each subject after ensuring they have completed their SPADI/VAS/medication worksheets, placed these sheets in an opaque brown envelope identified only by study number and week/treatment session, and then instruct the subject to place the sealed envelope into a locked box as they enter the treatment room. After all these steps are done, the assistant will set up the laser machine to the proper treatment setting according to their randomization. The assistant will then set up the machine according to the randomization code: for "A" subjects the laser machine will be turned off, for "B" subjects the laser machine will be on with the randomization switch set to "B", and for the "C" subjects the machine will be on with the randomization switch set to "C". The machine back panel concealing the randomization switch will be closed and not visible to any person in the

treatment room, thus blinding the laserist/acupuncturist and subjects in groups B and C as to whether they are receiving true or sham laser treatments. Neither the subject nor the treating physician will be able to see the infrared laser beam if applied due to the physical properties of the beam.

The assistant will then summon the acupuncturist/laserist to the treatment room to initiate subject treatments as outlined above. The laserist/acupuncturist will apply the metal needles (group A) or the cardboard Laserneedle holders (groups B and C) as above then exit the room. The assistant will re-enter the room for groups B and C to insert the Laserneedles into the cardboard holders and tape the fiberoptic cables so that the shaft of each Laserneedle is perpendicular to the skin. The assistant will hit the "start" button on the machine front panel that starts the 20 minute treatment, and exit the treatment room. The subject will have a bell to summon assistance from the laserist/acupuncturist, who otherwise will only check on the subject every 5 minutes in the room while waiting nearby (and manually stimulate the needles at the ten minute mark for the metal needle acupuncture group).

At the end of each experimental day, the data sheets will be collected from the locked box in the treatment room and stored in a locked file cabinet by the assistant. Once weekly, the anonymized data will be transferred to the SPSS database for future statistical analysis.

The assistant will also contact the patients by phone at three and six months after completing their course of treatments to assess their longer term changes in shoulder pain, shoulder function, and use of ibuprofen and acetaminophen as measured by these

scales. The patient will also be queried regarding any adverse effects noted during their course of treatments at the 6 month mark.

h) ANALYSIS:

This is an efficacy trial. In this trial, metal needle and laser acupuncture are assessed under the most ideal conditions from the inclusion and exclusion criteria. The laserist/acupuncturist who are most respected in their acupuncture skills will perform the treatment. The study focuses on responsive events (pain and function measures), which are the intended outcomes of interest only. The patients who are most likely to comply with treatments are recruited.

I) STATISTICAL TEST:

There are three independent groups. For the primary outcome, the change of the mean score between pre-treatment and post 10 treatments will be compared between the three groups. Using the null hypothesis, there is no difference in the mean scores between the three groups. We will use regression analysis. The covariates that will be used include: baseline score, treatment group, and amount of analgesic medication used. Treatments will coded using two dummy variables: use of any laser acupuncture technique and use of true laser acupuncture. Laser acupuncture, sham laser acupuncture and metal needle acupuncture, will therefore be coded as 1, 1; 1, 0; and 0, 0 respectively.

Backwards stepwise regression will be used. A p-value of 0.05 will be used to keep a variable in the model. SPSS 15 will be used for the regression analysis. This analysis estimates the effects of laser acupuncture and the placebo effect of laser acupuncture independently.

II) INTENTION to TREAT PRINCIPLE:

Protocol violations cannot be assumed to occur randomly. The patients with the poorest prognosis are likely to drop out of the study and try another treatment. Therefore, they will be counted as a treatment failure and assigned scores the same as their entry SPADI scores.

i) MISSING DATA and PROBLEM CASES.

If subjects wish to withdraw from the acupuncture study protocol, they will be considered as a treatment failure, i.e. they will be assigned the same scores as their entry score or their last recorded score. Patients who have moved will be located by contacting their primary care or referring doctors to obtain updated contact information. All patients will be attempted to be accounted for by phone, email, or mail contact.

The problems areas anticipated are patients refusing to participate after randomization, lack of compliance with assessments, withdrawal from the study, receiving co-intervention such as manipulations, or receiving acupuncture from elsewhere.

j) FEASIBILITY:

It is feasible to do this clinical trial for the following reasons: The sample size is small enough that the large volume of rotator cuff injuries seen at both centers will allow for enough participants to be recruited; all laserist/acupuncturist and principal investigators are physicians qualified in acupuncture.

l) ETHICAL ISSUES:

In this study, the use of laser acupuncture is in the state of equipoise that a randomized controlled trial has to be done. It would be unethical to continue to practice laser acupuncture for shoulder pain without a well designed trial. As mentioned previously, laser acupuncture is widely used in North America. If there are no further advances in our clinical understanding of laser acupuncture, clinicians could potentially be wasting useful resources should acupuncture not prove to be an efficacious method of treating chronic shoulder pain. Thus, if the result is negative, it is prudent that health policies be implemented to avoid unnecessary treatments and costs to patients. Clinicians can then concentrate their energy and efforts on other modalities of treatment proven to be effective. If the result of this study is positive, it will guide further research of acupuncture in rotator cuff tendinitis. Hopefully, the results of future trials will confirm preliminary data that suggests laser acupuncture's importance as a modality to efficiently reduce pain and improve function in chronic rotator cuff tendinitis.

It is also unethical to subject patients through an experimental study that is poorly designed. Any study needs to be thoroughly designed and properly executed. In this study, it would be unethical not to offer patients any analgesic such as NSAIDs or acetaminophen (if intolerant to NSAIDs), even though the size of treatment effect for acupuncture may be greater in the treated groups as compared to the sham group. Patients will also receive conventional physical treatments such as Codman exercise in both groups in order to alleviate the theoretical concerns for shoulder stiffness due to inactivity. By having both groups receive conventional treatments, the control group

receiving the sham laser acupuncture is not deprived of treatment currently accepted as minimum standard of care.

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Figure 1. fiber optic laser "needles"

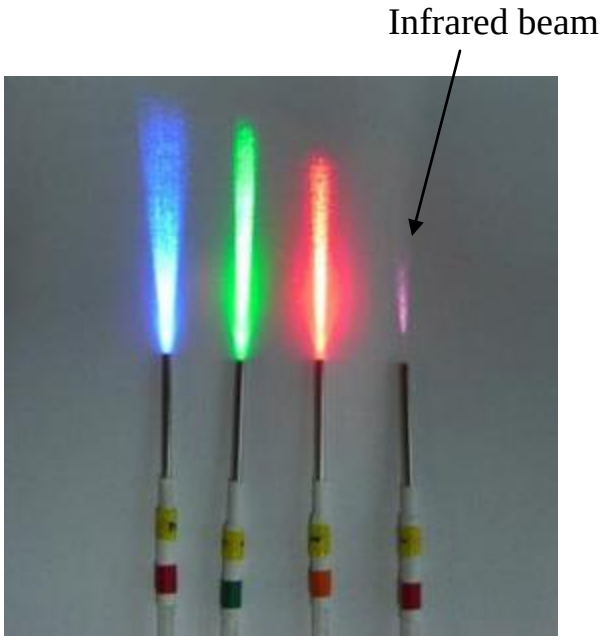
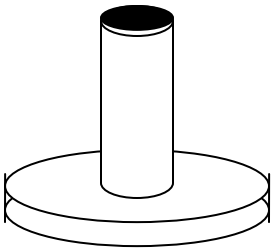


Figure 2. cardboard holders for fiber optic



Appendix I

Shoulder Pain Disability Index (SPADI)

Please place a mark on the line that best represents your experience during the last week attributable to your shoulder problem.

Pain scale

How severe is your pain?

Circle the number that best describes your pain where: 0 = no pain and 10 = the worst pain imaginable. At its worst?	0	1	2	3	4	5	6	7	8	9	10
When lying on the involved side?	0	1	2	3	4	5	6	7	8	9	10
Reaching for something on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Touching the back of your neck?	0	1	2	3	4	5	6	7	8	9	10
Pushing with the involved arm?	0	1	2	3	4	5	6	7	8	9	10

Disability scale

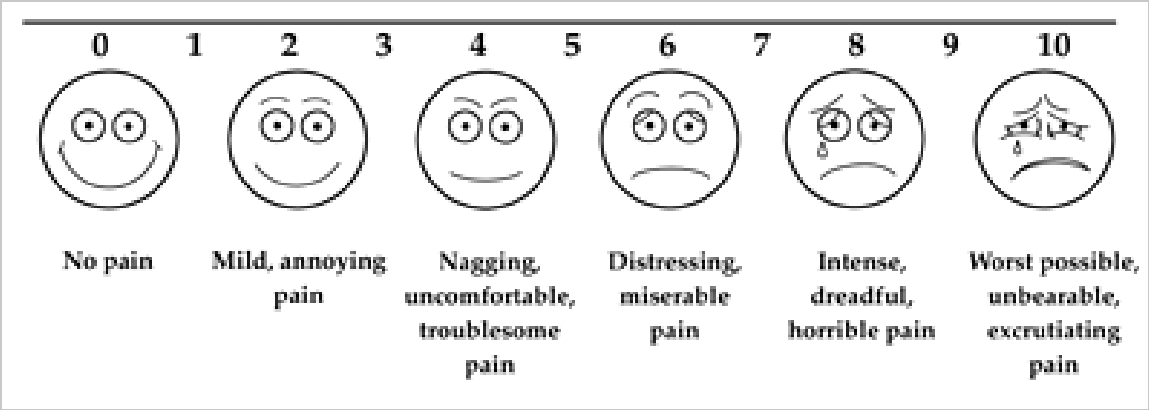
How much difficulty do you have?

Circle the number that best describes your experience where: 0 = no difficulty and 10 = so difficult it requires help. Washing your hair?	0	1	2	3	4	5	6	7	8	9	10
Washing your back?	0	1	2	3	4	5	6	7	8	9	10
Putting on an undershirt or jumper?	0	1	2	3	4	5	6	7	8	9	10
Putting on a shirt that buttons down the front?	0	1	2	3	4	5	6	7	8	9	10
Putting on your pants?	0	1	2	3	4	5	6	7	8	9	10
Placing an object on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Carrying a heavy object of 10 pounds (4.5 kilograms)	0	1	2	3	4	5	6	7	8	9	10
Removing something from your back pocket?	0	1	2	3	4	5	6	7	8	9	10

Appendix II

Visual Analogue Scale

How bad is your pain today? Place a vertical mark on the line below to indicate how bad you feel your pain today:



Medication

How much of the following medications did you use in the past week (average per day)?

Acetaminophen (Tylenol) _____ per day dose regular extra strength

Ibuprofen (Advil, Motrin) _____ per day dose 200mg 400mg 600mg 800 mg

Have you taken any other type of pain medication? _____ yes _____ no

If yes, please specify _____

Treatment Side Effects (at the 6 month mark of the study)

_____

_____

_____

Appendix III **Codmans's pendulum exercises**

pendulum side to side

BEND OVER AT THE WAIST AND LET YOUR ARM RELAX COMPLETELY. SLOWLY SWING YOUR ARM FROM SIDE-TO-SIDE AS ILLUSTRATED.
Repeat: 20 times
Sessions: 4 /day

pendulum side to side

BEND OVER AT THE WAIST AND LET YOUR ARM RELAX COMPLETELY. SLOWLY SWING YOUR ARM FROM SIDE-TO-SIDE AS ILLUSTRATED.
Repeat: 20 times
Sessions: 4 /day

Appendix IV **Rotator Cuff Tendinitis Information**

Rotator Cuff Tendinitis

Adapted From Mayo Clinic Web Information (www.mayoclinic.com/health)

Your rotator cuff is made up of the muscles and tendons in your shoulder. Four major muscles (subscapularis, supraspinatus, infraspinatus and teres minor) and their tendons connect your upper arm bone (humerus) with your shoulder blade (scapula), and help hold the ball of your upper arm bone firmly in your shoulder socket. The combination results in the greatest range of motion of any joint in your body.

Rotator cuff tendinitis is due to inflammation of your rotator cuff tendons. Rotator cuff tendinitis often results from overuse or overload, especially if you're an athlete who performs a lot of overhead activities, such as in tennis or racquetball.

Rotator cuff tendinitis symptoms may include:

- Pain and tenderness in your shoulder, especially when reaching overhead, reaching behind your back, lifting, pulling or sleeping on the affected side
- A sensation of shoulder weakness
- Loss of shoulder range of motion
- Inclination to keep your shoulder inactive

The most common symptom is pain. You may experience it when you reach up to comb your hair, bend your arm back to put on a jacket or carry something heavy. Lying on the affected shoulder also can be painful.

Common causes of rotator cuff tendinitis include:

- **Normal wear and tear.** Increasingly after age 40, normal wear and tear on your rotator cuff can cause a breakdown of fibrous protein (collagen) in the cuff's tendons and muscles. This makes them more prone to degeneration and injury. With age, you may also develop calcium deposits within the cuff or arthritic bone spurs that can pinch or irritate your rotator cuff muscles and tendons
- **Poor posture.** When you slouch your neck and shoulders forward, the space where the rotator cuff muscles reside can become smaller. This can allow a muscle or tendon to become pinched under your shoulder bones (including your collarbone), especially during overhead activities, such as throwing.
- **Falling.** Using your arm to break a fall or falling on your arm can bruise or tear a rotator cuff tendon or muscle.

- **Lifting or pulling.** Lifting an object that's too heavy or doing so improperly — especially overhead — can strain or tear your tendons or muscles. Likewise, pulling something, such as a high-poundage archery bow, may cause an injury.
- **Repetitive stress.** Repetitive overhead movement of your arms can stress your rotator cuff muscles and tendons, causing inflammation and eventually tearing. This occurs often in athletes, especially baseball pitchers, swimmers and tennis players. It's also common among people in the building trades, such as painters and carpenters.

What you can do for your shoulder tendinits pain

In the days before your appointment, you can make yourself more comfortable by:

- **Resting your shoulder.** Avoid movements that aggravate it and give you more pain.
- **Applying cold packs** to reduce pain and inflammation.
- **Taking pain medications**, if necessary. Over-the-counter nonsteroidal anti-inflammatory drugs (NSAIDs), such as aspirin, ibuprofen (Advil, Motrin, others) and naproxen (Aleve), may help reduce pain. Acetaminophen (Tylenol, others) also may help relieve pain.

If your tendinitis appears to be severe, he or she may recommend diagnostic imaging tests to better delineate your shoulder joint, muscles and tendons. These may include:

- X-rays
- A magnetic resonance imaging (MRI) scan
- An ultrasound scan

Most of the time, rotator cuff tendinitis heals on its own with self-care measures or exercise Your doctor or a physical therapist will talk with you about specific exercises designed to help heal your injury, improve the flexibility of your rotator cuff and shoulder muscles, and provide balanced shoulder muscle strength. Depending on the severity of your injury, physical therapy may take from three weeks to several months.

Other rotator cuff tendinitis treatments may include:

- **Steroid injections.** Depending on the severity of your pain, your doctor may use a corticosteroid injection to relieve inflammation and pain.
- **Acupuncture** The subject of the present study is to confirm European study results showing acupuncture improves shoulder tendinitis pain, and assess whether a painless form of acupuncture using low energy laser light can produce equally beneficial results.

Consent Form

Name and Clinic Number

To be completed by IRB office: Leave Blank Until Approved and Finalized
IRB # _____
Consent form approved _____;
This consent valid through _____;

1. General Information About This Research Study

Study Title: The Efficacy of Acupuncture in Chronic Rotator Cuff Tendonitis: Proposal of a Pilot Randomized Controlled Trial

Name of Principal Investigator on this Study: Peter T. Dorsher, MS, MD
and Colleagues

A. Study Eligibility and Purpose

You are being asked to take part in this research study because shoulder tendonitis is a common painful problem in adults, and acupuncture may offer long term relief of your pain with less discomfort and risks than usual interventions such as physical therapy, arthritis medications, and/or shoulder cortisone injections.
As you read this form describing the study, ask any questions you have. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you decide. If you decide to participate, you may stop participating at any time during the study. You may decide not to participate. If so, none of your current benefits or normal health care will be affected in any way. When you feel comfortable that all your questions have been answered, and you wish to take part in this study, sign this form in order to begin your participation. If you are agreeing for someone else, you need to sign this form. Your signature means you have been told about the study and what the risks are. Your signature on this form also means that you want yourself, or your child/relative/principal/ward to take part in this study.

B. Number of Participants

A total of ninety people will be recruited for this study.
The plan is to have 45 people take part in this study at Mayo Clinic Florida.

2. What Will Happen To You While You Are In This Research Study?

If you agree to be in the study, you will be asked to participate in the following:

You will be examined by two physicians to confirm you have shoulder tendonitis, and you will not be asked to change any medications you are taking for your shoulder pain.

Ten real or placebo (fake) acupuncture treatments (two per week over a five week period) will be provided to you at each of these visits by an acupuncturist participating in the research study. At each visit, research assistant will ask you questions and record your answers about the degree of pain you have from the shoulder tendonitis and how it affects your ability to use your arm.

You will be assigned to one of three treatment groups by chance (as in the flip of a coin). You will receive treatment to the shoulder joint with either traditional acupuncture with fine (hair-width) metal needles, laser acupuncture using light beams, or sham laser (laser power turned off). You will be able to go about your usual activities right away after receiving an acupuncture treatment.

This will help us determine which of these three treatments work, as well as which one works the best for treating shoulder pain.

If after the study ends, you still have shoulder pain and are determined to have received sham laser, then we will provide metal or laser acupuncture treatments to you at no charge (if metal and/or laser acupuncture are found tat the end of the study to have relieved shoulder pain).

3. How Long Will You Be in This Research Study?

You will be in the study for approximately 5 weeks (until you have completed ten acupuncture treatments.

4. Why You Might Want To Take Part In This Research Study

This study may not make your health better. However, we believe based on prior research studies that metal or laser acupuncture will improve your shoulder pain and improve your use of the shoulder with essentially no risk of pain or other harm. There is a one in three chance you might receive sham “fake” acupuncture with a laser. At the end of the study, if your shoulder pain is still present and it is found you received sham acupuncture, then we will provide ten sessions of real acupuncture to you at no cost if you wish to receive acupuncture for your shoulder pain.

5. What Are the Risks Of This Research Study?

This is a minimal risk study.

Metal needle acupuncture possible side effects

- Local bruising (less common, usually minimal and painless)
- Local discomfort (less common, usually minimal and lasting only minutes)
- Local infection (rare)
- Nausea (rare)
- Fainting (very rare)

Laser needle acupuncture possible side effects

- Fainting (very rare)
- Skin reaction/allergy to tape (very rare)

Before each treatment, you will be asked questions about your shoulder pain and ability to use the arm. If any of these questions make you feel uncomfortable, you may choose not to answer those questions.

Your doctor will discuss the risks of a simple shoulder exercise that you will be instructed in as part of your standard clinical care.

Pregnancy and Birth Control:

1) Will women of child-bearing-potential be allowed to participate in this study?

- Women of child-bearing-potential will be able to participate in this study because the risk to an unborn child appears to be very small
- Women who are pregnant, and/or nursing may take part in this study because the risk to an unborn or nursing child appears very small.
- The risk to an unborn child appears very small. Pregnant women are eligible to take part in this study.
- Men who are able to father a child are allowed to take part in this study.

Risk summary

The risks of this research study are minimal, which means that we do not believe that they will be any different than what you would experience at a routine clinical visit or during your daily life.

6. What Other Choices Do You Have If You Don't Take Part In This Research Study?

You do not have to be in this study to receive treatment for your condition. Your other choices may include physical therapy or cortisone injections in the shoulder. You should talk to the researcher and your regular physician about each of your choices before you decide if you will take part in this study.

7. Are There Reasons You Might Leave This Research Study Early?

Taking part in this research study is voluntary. You may decide to stop at any time. You should tell the researcher if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the researchers, or Mayo may stop you from taking part in this study at any time:

- if it is in your best clinical interest,
- if you do not follow the study procedures ,
- if the study is stopped.

8. Will You Need To Pay For Any Of The Tests And Procedures?

You will not need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- *metal needle acupuncture*
- *laser acupuncture*

However, you and/or your health plan will need to pay for all other tests and procedures that you would normally have as part of your regular clinical care.

If you have study related questions regarding billing, insurance or reimbursement, stop by or call:

Florida: The receptionist at the Registration Desk at the first floor, main lobby of the Davis Building or call (904) 953-7058

9. Will You Be Paid For Participating In This Research Study?

You will not be paid for taking part in this study.

10. What Happens If You Are Injured Or Ill Because You Were In This Research Study?

If you have side effects from the study treatment, you need to report them to the researcher and your regular physician, and you will be treated as needed. Mayo will bill you or your insurer for these services at the usual charge. Mayo will not offer free medical care or payment for any bad side effects from taking part in this study.

11. What Are Your Rights If You Are In This Research Study?

Taking part in this research study will not change your rights and benefits. Taking part in this research study does not give you any special privileges. If you decide to not participate in this study, or stop in the middle of the study, no benefits are taken away from you. Specifically, you do not have to be in this research study to receive or continue to receive medical care from Mayo Clinic.

You will be told of important new findings or any changes in the study or procedures that may affect you or your willingness to continue in the study.

12. What About Your Privacy?

Authorization To Use And Disclose Protected Health Information

Your privacy is important to us, and we want to protect it as much as possible. By signing this form, you authorize Mayo Clinic and the investigators to use and disclose any information created or collected in the course of your participation in this research protocol. This information might be in different places, including your original medical record, but we will only disclose information that is related to this research protocol for the purposes listed below.

This information will be given out for the proper monitoring of the study, checking the accuracy of study data, analyzing the study data, and other purposes necessary for the proper conduct and reporting of this study. If some of the information is reported in published medical journals or scientific discussions, it will be done in a way that does not directly identify you.

This information may be given to other researchers in this study, at McMaster University in Canada, or private, state or federal government parties or regulatory authorities in the USA and other countries responsible for overseeing this research. These may include the Food and Drug Administration, the Office for Human Research Protections, or other offices within the Department of Health and Human Services, and the Mayo Clinic Office for Human Research Protections or other Mayo groups involved in protecting research subjects.

If this information is given out to anyone outside of Mayo, the information may no longer be protected by federal privacy regulations and may be given out by the person or entity that receives the information. However, Mayo will take steps to help other parties understand the need to keep this information confidential.

This authorization lasts until the end of the study. The study does not end until all data has been collected, checked (or audited) and analyzed. Sometimes this can be years after your study visits have ended. For example, this could happen if the results of the study are filed with a regulatory agency like the Food and Drug Administration.

You may stop this authorization at any time by writing to the following address:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

If you stop authorization, Mayo may continue to use your information already collected as part of this study, but will not collect any new information.

If you do not sign this authorization, or later stop authorization, you may not be able to receive study treatment

13. What Will Happen to Your Samples?

No biological samples will be collected as part of this research study.

14. Who Can Answer Your Questions?

You can call …	At …	If you have questions or concerns about …
Principal Investigator: **Peter Dorsher MD**	Phone: **904-953-2823**	Questions about the study tests and procedures Research-related injuries or emergencies Any research-related concerns or complaints
Mayo Clinic IRB Research Subject Advocate: **Shari Brumm**	Phone: **507-266-4000** Toll-Free: **866-273-4681**	Rights of a research subject Use of Protected Health Information Any research-related concerns or complaints
Research Billing	Rochester: **507-287-1819** Florida: **904-953-7058** Arizona: **800-603-0558**	Billing / Insurance Questions

15. Summary and Enrollment Signatures

You have been asked to take part in a research study, at Mayo Clinic. The information about this study has been provided to you to inform you about this study.

- I have read the whole consent form, and all of my questions have been answered to my satisfaction.
- I am satisfied that I have been given enough information about the purpose, methods, risks, and possible benefits of the study to decide if I want to join.
- I know that joining the study is voluntary and I agree to join the study.
- I know that I can call the investigator and research staff at any time with any questions or to tell them about side effects.
- I know that I may withdraw from the study at any time.
- I will be given a copy of this completed form.

Please sign and date to show that you have read all of the above guidelines. Please do not sign unless you have read this entire consent form. If you do not want to sign, you don't have to, but if you don't you cannot participate in this research study.

_____ _____ _____

(Date / Time) (Printed Name of Participant) (Clinic Number)

_____

(Signature of Participant)

	Assistant Duties			**Acupuncturist/ Laserist Duties**	**Principal Investigator Duties**
Before Appointments →	Arrive to Clinic →	Treatment →	Post		
calls patient to remind of appointments	give patient SPADI and VAS forms	flip room lights on once forms in box and checklist done	greet patient after treatment	apply metal needle or laser holders to acupoints	collect data envelopes
	make sure forms are put in envelope with study ID#	notify treating MD to start treatment	query for issues and side effects of treatment	contact PI for patient/protocol issues	give envelope to secretary to put in locked file drawer
	forms in envelope put in locked box in treatment room		escort patient from room to elevator/exit		weekly make sure secretary enters data into SPSS database to store in share drive
	if A or B on study list (laser treatment) set switch to appropriate setting or turn off (if metal needle acupuncture)				address any subject concerns/problems
	complete checklist for form and switch completion				

Assistant's Worksheet

Week # of Study (1-5) _____

Mayo Clinic #	Study #	Switch Position (A,B,C)*	Treatment 1	Forms completed, in envelope, placed in locked box?	Switch Position Confirmed?	Treatment 2	Forms completed, in envelope, placed in locked box?	Switch Position Confirmed?
	1							
	2							
	3							
	4							
	5							
	6							
	7							
	8							
	9							
	10							
	11							
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	43							
	44							
	45							

* M=metal needle acupuncture, A= laser randomization switch "A" position, B= laser switch "B"

Shoulder Pain Disability Index (SPADI)

Please place a mark on the line that best represents your experience during the last week attributable to your shoulder problem.

Pain scale

How severe is your pain?

Circle the number that best describes your pain where: 0 = no pain and 10 = the worst pain imaginable. At its worst?	0	1	2	3	4	5	6	7	8	9	10
When lying on the involved side?	0	1	2	3	4	5	6	7	8	9	10
Reaching for something on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Touching the back of your neck?	0	1	2	3	4	5	6	7	8	9	10
Pushing with the involved arm?	0	1	2	3	4	5	6	7	8	9	10

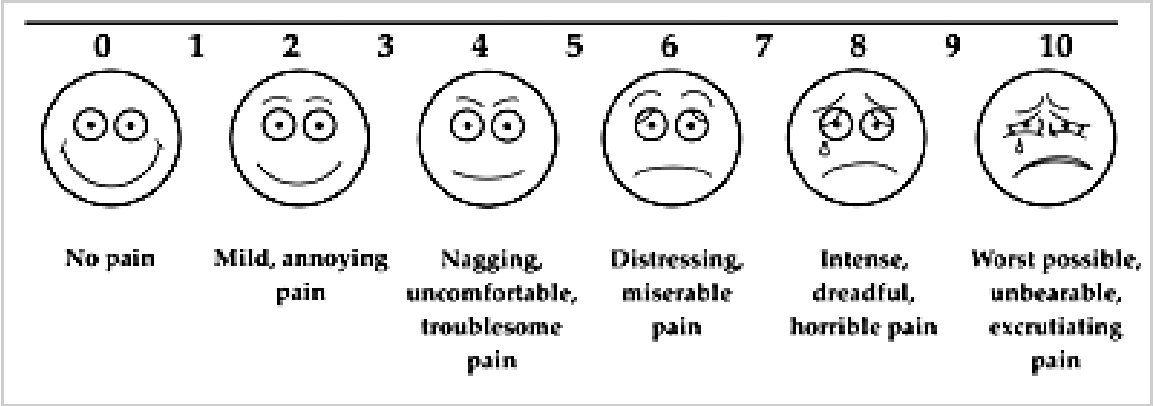
Disability scale

How much difficulty do you have?

Circle the number that best describes your experience where: 0 = no difficulty and 10 = so difficult it requires help. Washing your hair?	0	1	2	3	4	5	6	7	8	9	10
Washing your back?	0	1	2	3	4	5	6	7	8	9	10
Putting on an undershirt or jumper?	0	1	2	3	4	5	6	7	8	9	10
Putting on a shirt that buttons down the front?	0	1	2	3	4	5	6	7	8	9	10
Putting on your pants?	0	1	2	3	4	5	6	7	8	9	10
Placing an object on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Carrying a heavy object of 10 pounds (4.5 kilograms)	0	1	2	3	4	5	6	7	8	9	10
Removing something from your back pocket?	0	1	2	3	4	5	6	7	8	9	10

Visual Analog Scale

How bad is your pain today? Place a vertical mark on the line below to indicate how bad you feel your pain is on average today:



Medication Use

How much of the following medications did you use in the past week (average per day)?

Acetaminophen (Tylenol) _____ per day dose strength (circle): regular extra strength

Ibuprofen (Advil, Motrin) _____ per day dose strength (circle): 200mg 400mg 600mg 800 mg

Have you taken any other type of pain medication? _____ yes _____ no

If yes, please specify _____

Phone Follow-up at 3 months and at 6 months
Shoulder Pain Disability Index (SPADI)

Please report how your shoulder problem is now.

Pain scale
How severe is your pain?

Circle the number that best describes your pain where: 0 = no pain and 10 = the worst pain imaginable. At its worst?	0	1	2	3	4	5	6	7	8	9	10
When lying on the involved side?	0	1	2	3	4	5	6	7	8	9	10
Reaching for something on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Touching the back of your neck?	0	1	2	3	4	5	6	7	8	9	10
Pushing with the involved arm?	0	1	2	3	4	5	6	7	8	9	10

Disability scale
How much difficulty do you have?

Circle the number that best describes your experience where: 0 = no difficulty and 10 = so difficult it requires help. Washing your hair?	0	1	2	3	4	5	6	7	8	9	10
Washing your back?	0	1	2	3	4	5	6	7	8	9	10
Putting on an undershirt or jumper?	0	1	2	3	4	5	6	7	8	9	10
Putting on a shirt that buttons down the front?	0	1	2	3	4	5	6	7	8	9	10
Putting on your pants?	0	1	2	3	4	5	6	7	8	9	10
Placing an object on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Carrying a heavy object of 10 pounds (4.5 kilograms)	0	1	2	3	4	5	6	7	8	9	10
Removing something from your back pocket?	0	1	2	3	4	5	6	7	8	9	10

Visual Analog Scale (VAS)

How bad is your average daily pain now (0= no pain to 10= extreme)?

Medication Use

How much of the following medications do you currently use (average per day)?

Acetaminophen (Tylenol) _____ per day dose strength (circle): regular extra strength
Ibuprofen (Advil, Motrin) _____ per day dose strength (circle): 200mg 400mg 600mg 800 mg
Have you taken any other type of pain medication? _____ yes _____ no
If yes, please specify _____

Problems to Report

Please report any problems with the treatments you received

_____

_____

_____