Strengthening of the First Dorsal Interosseous for Thumb Carpometacarpal Osteoarthritis

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DETAILED PROTOCOL

I. BACKGROUND AND SIGNIFICANCE

Carpometacarpal (CMC) osteoarthritis is so common, particularly in women, that it should be considered as a normal part of the aging process. Overall radiographic prevalence of CMC osteoarthritis has been described to be as high as 91% in patients older than eighty years of age (1). The prevalence of CMC osteoarthritis increases steadily from the age of 41 years, more rapidly in women than in men (1). Another study, conducted in the Netherlands, showed that in a population of 55 years and older, 67% of women and 55% of men had radiographic signs of osteoarthritis of the hand (2). It also found that the distal interphalangeal (DIP) joints are most commonly affected (47%), followed by the CMC joint (36%). However, it has been reported that in symptomatic osteoarthritis, CMC osteoarthritis contributes more to pain and disability than arthritis of the interphalangeal joints (3). Psychosocial factors have been recognized as the strongest determinants of highly variable pain intensity and arm-specific disability (4-7). The pathophysiologic and psychosocial differences between patients who present to the doctor for treatment and those who do not are incompletely understood (1, 8). Most patients are able to adapt to symptoms of pain and disability, other patients might benefit from non-operative interventions; e.g. splinting, corticosteroid injections, pain medication, and multiple hand exercises.

The dorsal ligament complex is one of the components for stability of the thumb CMC joint. These ligaments specifically create stability for pinch and grip during the final phase of opposition (9). Both, the opponens pollicis (OP) and the first dorsal interosseous (FDI) play a key role in centralizing the metacarpal on the trapezium. A retrospective study showed that a dynamic stability modeled approach, including targeting the FDI, reduced pain and improved function in patients with thumb CMC osteoarthritis (10). Recently, another study demonstrated that reduction of radial subluxation - the thumb metacarpal versus the trapezium CMC joint – was achieved by contraction of the dynamic stabilizers of the healthy hand, specifically with the focus on the FDI (11).

More clinical research is needed to determine if there are efficacious (effective and low-cost) evidence-based exercise programs for pain reduction and functional improvement in patients with thumb CMC osteoarthritis. We are interested in the effect of FDI strengthening in patients with thumb CMC osteoarthritis. Therefore, we hypothesized that there is no difference in the change of lateral pinch strength at 12 weeks between patients treated with a splint versus patients treated with a splint and FDI strengthening for thumb CMC osteoarthritis. We also tested the same hypothesis for 3-point chuck strength, VAS for pain, and PROMIS UE CAT.

We propose a two-arm randomized (1:1) controlled trial to evaluate if strengthening exercises of the FDI in people who choose splinting as their treatment for CMC osteoarthritis have influence on the outcomes of strength, pain and function after a twelve week follow-up.

II. SPECIFIC AIMS

Aim:
To determine the effect of first dorsal interosseus strengthening in patients with thumb carpometacarpal osteoarthritis.

Primary Null Hypothesis:
There is no difference in the change of lateral pinch strength at 12 weeks between patients treated with a splint versus patients treated with a splint and FDI strengthening for thumb CMC osteoarthritis.

Secondary Null Hypotheses:

1) There is no difference in the change of 3-point chuck strength at 12 weeks between patients treated with a splint versus patients treated with a splint and FDI strengthening for thumb CMC osteoarthritis.
2) There is no difference in the change of Visual Analog Scale (VAS) for pain at 12 weeks between patients treated with a splint versus patients treated with a splint and FDI strengthening for thumb CMC osteoarthritis.
3) There is no difference in the change of PROMIS Upper Extremity (UE) CAT at 12 weeks between patients treated with a splint versus patients treated with a splint and FDI strengthening for thumb CMC osteoarthritis.

III. SUBJECT SELECTION

All English-speaking adult patients who elect splinting as their treatment for CMC osteoarthritis during their visit to one of the treating hand surgeons at the Orthopaedic Hand and Upper Extremity Service of the Massachusetts General Hospital will be asked to consider participation in this randomized controlled clinical trial if they eligible by the inclusion and exclusion criteria.

Inclusion criteria:

1. 18 years of age and older
2. English fluency and literacy
3. Clinical or radiological diagnosis of CMC osteoarthritis by MD
4. Choose splinting as option for treatment of CMC osteoarthritis

Exclusion criteria:

1. Patients with rheumatoid or post-traumatic osteoarthritis
2. Patients who also had an injection during the appointment for their thumb CMC osteoarthritis

All adult patients, satisfying all inclusion criteria, are eligible for enrollment in this study regardless of sex, race or ethnicity. Vulnerable populations will not be recruited.

IV. SUBJECT ENROLLMENT

The treating hand surgeon will introduce the study to the patient when a patient chooses splinting as treatment for thumb CMC osteoarthritis. A member of the study staff (PhD student, research assistant, research coordinator), not involved in the patient's care, will explain the study to the patient, review the study protocol in detail and address any questions the patient may have. If the patient is willing to participate, informed consent will be obtained by a member of the study staff. Subjects will be given a copy of the consent form, and will be informed that their participation is voluntary and that they can withdraw at any time during the study. As with all of our studies there will be no coercion. It will be emphasized that participation is voluntary and that they can withdraw at any time during the study. The hand surgeon and the member of the study staff will stress that not participating in this study will not affect patient's care now, or in the future. Subjects may take as long as they need to consider participation, given that they would still be eligible.

This study has an observational, randomized, prospective study design. At time of enrollment, demographic data will be collected as well as answers to questionnaires and strength measurements. The subjects will be randomly assigned to one of two different cohorts after informed consent has been obtained by a member of the study staff and all baseline measurements have been completed. During the follow-up visit twelve weeks plus or minus one week (time window of eleven to thirteen weeks) after enrollment part of the questionnaires and the strength measurements will be repeated. If participants are not able to come in to our office for this follow-up visit, follow-up questionnaires will be completed over the phone or via e-mail.

V. STUDY PROCEDURES

After informed consent is obtained, the subject will complete data sheets on demographic information and several questionnaires with the help of a member of the study staff who is not involved in the subject's care: 1) pain scale VAS (0-10); 2) PROMIS Upper Extremity CAT function score. In addition, 3-point chuck strength and lateral pinch strength will be measured by the treating hand surgeon. Questionnaires and measurements will take about 15 to 20 minutes.

After completing all baseline measurements, subjects will be randomized (1:1) based on a generated list of random numbers (Stata 13). They will be randomized into either the splint only cohort (cohort I) or the splint and strengthening exercises cohort (cohort II). The splints will be provided by an occupational therapist (OT) who will also explain the strengthening exercises to subjects randomized to cohort II. The first exercise is an exercise, in which the subject rests his or her hand flat on table, then the index finger is slided towards the thumb and the other hand is used to push the index finger back towards the middle finger. The index finger should resist this movement by holding it in place. This exercise is done for a count of 5 seconds and is repeated 10 times, three times a day. In the second exercise the hand is placed flat on the table with a rubber band around the index finger and middle finger. The index finger is slided away from the middle finger towards the thumb and held in this position for a count of 3 seconds, after this the index finger is slowly returned into the starting position. This exercise is also repeated 10 times, three times a day. Subjects of both cohorts will be scheduled for an OT

appointment at the day of enrollment. The treating physician will not know to what cohort the subject is randomized.

The final evaluation will occur during a follow-up visit after 12 weeks plus or minus one week (time window of eleven to thirteen weeks). Participation in this study does not increase the costs billed to the subject or the subject's insurance company for study related procedures. Subjects will complete the following questionnaires: 1) Pain score using VAS (0-10); and 2) PROMIS Upper Extremity CAT function score. In addition, grip and pinch strength measurements will be repeated by the treating hand surgeon. The total research time will be about 15 to 20 minutes. If for some reason the subject is not able to make it to the office for a follow-up appointment or if they miss their appointment, we will conduct the following questionnaires over the phone or via e-mail which will take about 5 minutes: 1) Pain score using VAS (0-10); and 2) PROMIS Upper Extremity CAT function score. Subjects will attempt to be contacted by their preferred method (phone or e-mail) first. If no response is received from the subject, a few days later the subject will be contacted again by phone call up to two more times. If we are still unable to contact the subject by the end of the follow up period (eleven to thirteen weeks), the subject will be considered lost to follow up. Subjects will provide permission to contact them by entering their information into the follow up contact form on REDCap. By doing this, subjects will be aware that we will follow up with them by phone and email if they do not come back in for another appointment within the 11-13 week follow up period.

Patients who are willing to participate in this study will get the same care for their CMC osteoarthritis as patients that decide not to participate in the study. An additional visit for follow-up is required for this study, but is usually part of usual care for thumb CMC arthritis. No additional radiographs will be taken. Subjects will not receive reimbursement of travel costs or refunds for their parking tickets.

VI. BIOSTATISTICAL ANALYSIS

Primary endpoint: Lateral pinch strength 12 weeks after enrollment.
Secondary endpoints: Strength on 3-point chuck scale, pain at rest or during activity and function 12 weeks after enrollment.

An a-priori sample size analysis using a two-tailed Unpaired Student's T test estimated the need to evaluate a sample size of 20 subjects with basal joint arthritis (N = 10 per group) will detect a meaningful difference in pinch strength between the two randomized intervention groups with an effect size of 1.3 with a type I error of 0.05 and 80% power. We anticipate that not all participants will return for follow-up at 12 weeks plus or minus one week and will have at least one missing value on the variables; we plan to enroll at least 80 subjects per group so that the sample size with complete data should remain at least 80 subjects (N = 40 per group).

The data will be assessed for normality with Kolmogorov-Smirnov and Shapiro-Wilk test. When the data are normally distributed (that is what we assume since we powered our study a-priori), parametric tests will be used, otherwise non-parametric tests. An unpaired Student t-test will be performed to determine the difference between continuous and dichotomous variables, if data are distributed normally; otherwise the Mann-Whitney-U test will be used. One-Way Analysis of Variance (ANOVA) will be

used to evaluate the relationship between continuous variables and categorical variables with more than two categories.

With the use of a paired two-tailed t-test or the non-parametric Wilcoxon Rank test, all scores (pain intensity, PROMIS UE CAT, 3-point chuck strength, and lateral pinch strength) at baseline will be compared to the scores at 12 weeks plus or minus one week. We will compare the mean difference of the baseline and 12-week plus or minus one week scores between the two groups using an unpaired two-tailed t-test. Change in scores between the two cohorts will also be analyzed using a linear mixed effects model. Because of the randomized study design, confounding factors will be equally distributed between the two groups. However, factors with a *P*-value below 0.05 or 0.10 will also be entered into the model to adjust for possible remaining confounders by chance. The level of significance will be set at $P < 0.05$.

Analysis will be done by the intention-to-treat principle: all subjects will be analyzed to their original allocation in the randomized controlled trial (RCT). There will be no correction for crossing over, or for subjects receiving additional treatment.

VII. RISKS AND DISCOMFORTS

Study participants will undergo usual care procedures for treatment of CMC osteoarthritis during their participation. Additional care is provided for subjects who are enrolled in the second cohort. An extra follow-up appointment is scheduled for both cohorts with their hand surgeon. Other follow-up appointments will be arranged by the treating hand surgeon as appropriate for each study patient's condition, regardless of whether patients decide to participate or not.

Subjects will be treated for CMC osteoarthritis by a splinting or by splinting and strengthening exercises in an RCT. It is not expected that the FDI strengthening exercises will lead subjects to experience additional risks in this study since the exercises are considered to be harmless. There are no additional risks for subjects in the control group since splinting is part of standard care for treatment of CMC osteoarthritis. The clinical care of subjects in this study might be slightly different from standard care in subjects in cohort II. However, the additional care might be beneficiary to these subjects because it might reduce their pain and improve their hand function as is suggested in the literature. Furthermore, subjects are not obliged to answer any questions they are not willing to and the subject's participation will not affect their medical care. Subjects are free to request changes in their treatment at any time and an intention-to-treat analysis will be used. Subjects can withdraw from the study at any time, study staff and the treating hand surgeon will emphasize that study participation is completely voluntary.

Study physicians will be readily accessible for consultation should a study subject experience increasing discomfort while completing questionnaires, or at any time during their study participation. In the extremely unlikely event that a subject has a severe adverse emotional disturbance while completing the questionnaire, we will contact the Acute Psychiatric Service and immediately take the subject to the Emergency Department for treatment. Subjects who are brought to the Emergency Department for additional psychological care will not be asked to complete the study and their study participation will be terminated.

All efforts are made to minimize the risks and loads for subjects, since it is needed to be proportional to the scientific value derived from the study. We do not foresee major additional risks for subjects participating in this study. Even though some subjects will receive additional FDI strengthening exercises we do not expect them to experience additional risks since the exercises are thought to be harmless and already used by some physicians to increase function in patients with CMC osteoarthritis. Nonetheless, the subjects who receive additional care may experience discomfort in the fact that they are asked to perform exercises three times a day. The interventions in both groups involve splinting of the thumb and exercises and are therefore entirely non-invasive. We therefore do not expect any major adverse events resulting from this study.

The greatest discomforts or inconveniences associated with participation in this study are the exercises performed by half of the study population and the additional follow-up visit in all the subjects. Furthermore, discomfort or inconvenience may be experienced during the process of filling out the questionnaires and performing the strength measurements at enrollment and the twelve-week follow-up plus or minute one week (eleven to thirteen weeks). Subjects are not obligated to answer questions or perform measurements when they do not want to. The measurements and questionnaires will require approximately 15 to 20 minutes at the time of enrollment and at the time of follow-up.

VIII. POTENTIAL BENEFITS

There may or may not be any direct benefits to the individual subjects. Subjects may benefit from the exercise intervention by experiencing reduced pain and improved function. It is also possible that the subjects will not directly benefit from the intervention, and their basal joint arthritis related pain will reduce under the standard care treatment outside of this research. Either outcome will contribute to the understanding of the role of FDI strengthening in the treatment of thumb CMC osteoarthritis.

IX. MONITORING AND QUALITY ASSURANCE

Study data will be collected and managed electronically using REDCap, an online research management tool. It enables researchers to create study-specific websites for capturing participant data securely. The questionnaires will be provided on an encrypted electronic device (e.g. computer, laptop, Ipad).

REDCap enables customization of item or instruments (e.g., format, randomization, skip patterns), storage of protected health information in a separate, secure database, automated accrual reports, real-time data export, among many other features. REDCap is well secured, effectively protected and an HIPAA compliant application which includes databases which store confidential, personal health information.

The PHI identifiers that will be collected through REDCap are: 1) Medical Record Number (MRN); 2) last name; 3) date of birth; and 4) email address. When no electronic medium (e.g., computer, laptop, Ipad) is available, we will collect the data through the paper version of the measurements (any PROMIS measure can also be downloaded for administration on paper), and afterwards enter the collected data into REDCap. The information collected during the study will not become part of the

subject's medical record unless deliberately requested by the subject. Hardcopies of study related data and forms will be filed in a locked cabinet in the research office, separate from medical file. Only the principal investigator and member of the study staff will have access to this information. Any electronic information or study data (which will be exported for analysis) outside of REDCap will be saved in an electronic folder on password-protected Partners' computers or encrypted laptops to which only investigators and members of the study staff will have access.

All subjects are given a participation number/code at time of enrollment. This code is kept on all data sheets instead of the subject's name and MRN, except for the inclusion/exclusion form which will include the subject's name and MRN. Subject information is only accessible by Partners authorized investigators and will not be shared with outside entities.

The full-time (premedical student) research coordinator and the principle investigator are responsible for adherence to all IRB rules and guidelines, and for the accuracy and completeness of all forms, entries, and informed consent.

The principle investigator will be responsible for monitoring outcomes. No independent monitoring will occur. All investigators and study staff will be responsible for reporting adverse effects to the principle investigator. All adverse events will be monitored in a data log. Our fulltime research coordinator will report adverse events to the IRB in accordance with the IRB adverse event reporting procedures under supervision of the principle investigator.

X. REFERENCES

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