LRTI versus InternalBrace for the Surgical Treatment of Thumb Carpometacarpal Arthritis: a Prospective Randomized Trial Pilot Study

Principal Investigator: Charles A. Goldfarb, MD

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A Introduction

A1 Study Abstract

Carpometacarpal osteoarthritis (CMC OA) is a prevalent and disabling disease. Trapeziectomy with ligament reconstruction and tendon interposition (LRTI), the most frequently performed procedure for CMC OA, requires prolonged postoperative immobilization which limits patients' abilities to perform ADLs and to work. Trapezium excision and internal brace (IB) stabilization is a largely unstudied novel alternative to LRTI which allows an expedited return to work/activity. In this feasibility and pilot grant application, our overall objective is to investigate critical questions to inform the planning of a definitive randomized controlled trial (RCT) comparing IB and LRTI for patients with CMC OA. Our central hypothesis is that a prospective RCT comparing LRTI and IB is feasible, and that IB will produce superior patient-reported outcomes to LRTI at 6 weeks and 3 months with an expedited return to work/activity. Our specific aims are to (1) establish feasibility of a definitive trial by determining the randomization rate and follow-up retention rate, (2) estimate effect sizes and variability in outcomes for planning a definitive RCT, and (3) characterize objective clinical outcomes (thumb range of motion, grip/pinch strength, radiographic outcomes, complications/need for additional surgery) and to identify differences in return to work/activity following IB and LRTI. To achieve our aims, we will randomize 50 patients as they present to the clinics of the 7 Washington University Orthopaedic Hand surgeons to LRTI (control) or IB (experimental). Patients will follow-up at 2 weeks, 4 weeks, 3 months, and 1 year post-operatively. Our primary outcome will be feasibility (randomization rate, follow-up retention rate). Secondary outcomes will be PROMIS and Visual Analog Scale Pain and Satisfaction scores at 6 weeks and 3 months, objective clinical outcomes (thumb range of motion, grip/pinch strength, radiographic outcomes, complications/need for additional surgery), and return to work/activity.

Upon completion of our aims, we expect to demonstrate that a prospective, randomized trial comparing LRTI and IB is feasible, and that patients who undergo IB will have superior short-term patient-reported outcomes to those who undergo LRTI. Furthermore, we will generate effect size and variability estimates for a definitive, subsequent RCT. Should the objectives for this study be successful, we expect to take an important first step in defining the role of the IB procedure in the treatment of CMC OA.

A2 Primary Hypothesis

Our central hypothesis is that a prospective, randomized trial comparing LRTI and IB is feasible, and that IB will produce superior patient-reported outcomes to LRTI at 6 weeks and 3 months with an expedited return to work/activity.

A3 Purpose of the Study Protocol

The purpose of our study protocol is to investigate critical questions to inform the planning of a definitive randomized controlled trial (RCT) comparing IB and LRTI for

patients with CMC OA. We expect to demonstrate that a prospective, randomized trial comparing LRTI and IB is feasible, and that patients who undergo IB will have superior short-term patient-reported outcomes to those who undergo LRTI. Furthermore, we will generate effect size and variability estimates for a definitive, subsequent RCT. Should the objectives for this study be successful, we expect to take an important first step in defining the role of the IB procedure in the treatment of CMC OA.

B Background

B1 Prior Literature and Studies and Rationale for this Study

Thumb carpometacarpal osteoarthritis (CMC OA) is a common disease, affecting up to 25% of women and 8% of men, and is increasing in prevalence with the aging population[1-3]. When symptomatic, loss of thumb function can impart up to 50% impairment to the upper extremity[13]. Nonoperative treatments for thumb CMC OA include activity modification, splinting, anti-inflammatory medications, and intra-articular corticosteroid injections[14]. When nonoperative treatments fail, surgery may be considered.

Surgeries for advanced thumb CMC OA all incorporate trapezium excision to eliminate painful bony contact. The majority of hand surgeons in the United States supplement trapeziectomy with suspension using the FCR tendon **(Figure 1)**[15]. This suspensionplasty is touted to reduce subsidence of the thumb metacarpal and improve pinch strength over simple trapeziectomy. However, LRTI using the FCR tendon increases surgical time, increases perioperative complications, and increases costs of surgery. Postoperatively, patients are typically placed in rigid immobilization for 4-6 weeks and require 3 months of healing prior to strengthening. Despite both the popularity and heightened direct/indirect costs, comparative studies have not demonstrated any long term benefit of LRTI over simple trapeziectomy and hematoma arthroplasty. Gangopadhyay et al[16] randomized 174 thumbs to trapeziectomy alone, LRTI, or trapeziectomy and palmaris longus interposition. Of the 153 thumbs with ≥5 years follow-up, 78% had good results and pain relief was durable, and there were no differences in pain, function (grip/pinch strength), or complications among the three groups. In their 2015 Cochrane Review, Wajon et al demonstrated no benefit to pain or function from LRTI compared to simple trapeziectomy, although they acknowledged that the evidence was of low quality[17].

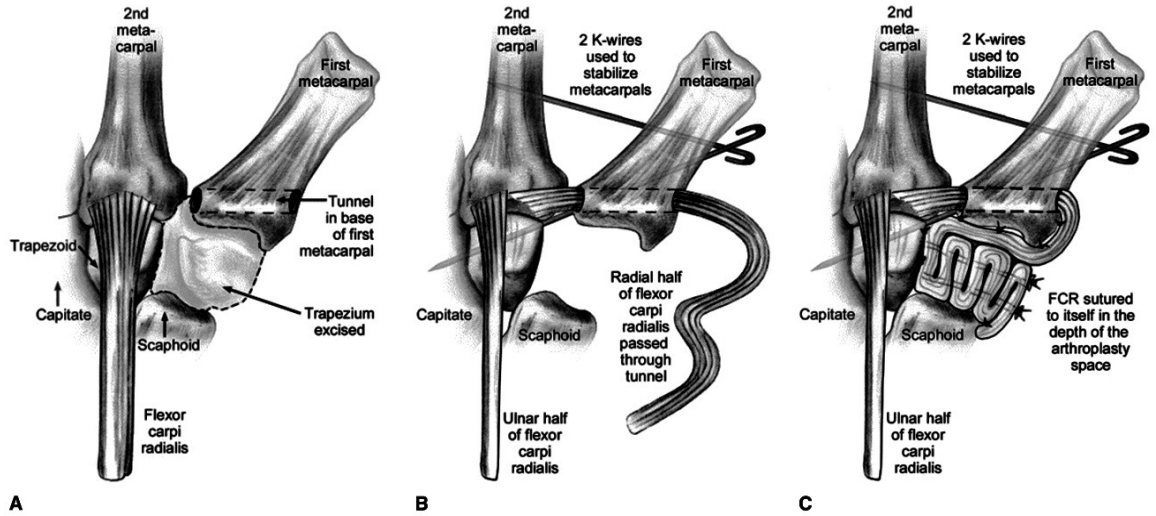


Figure 1[18]: Steps in trapeziectomy with LRTI. **A:** Trapeziectomy. **B:** Reconstruction performed with a LRTI using FCR tendon. Radial half of FCR tendon passed through a tunnel in base of first metacarpal. **C:** Tendon sutured to itself as a space-filling arthroplasty, augmented by Kirschner wire to prevent subsidence.

Hand surgeons, however, continue to perform LRTI secondary to the desire to provide mechanical support for the thumb metacarpal and to avoid the exposed Kirschner wires (K-wires) associated with simple trapeziectomy. Recently, techniques have been described that provide immediate internal suspension of the thumb metacarpal after trapeziectomy without requiring prolonged immobilization or painful K-wires[19-21]. Internal brace (IB, **Figure 2),** a technology used in ligament augmentation in lateral ankle instability, syndesmosis injuries, and scapholunate ligament reconstruction [22-24], has been used at our institution for thumb CMC OA with encouraging outcomes in the short-term (unpublished data). The IB procedure allows the patient to forego postoperative casting or K-wire pinning and return to all activities at 6 weeks.

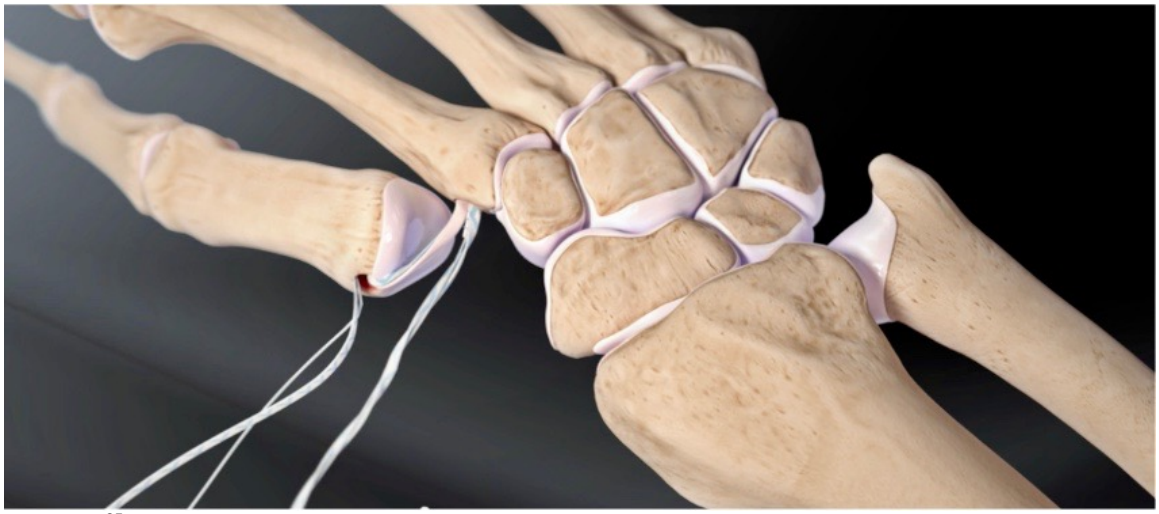


Figure 2[25]: Illustration of internal brace procedure. Trapeziectomy is performed in standard fashion. Longitudinal traction is applied to the thumb. A suture anchor with suture tape is inserted into a drill hole at the radial aspect of the thumb metacarpal base. A second suture anchor is inserted into a drill hole at the radial base of the index metacarpal such that the suture tape suspends the thumb at the natural groove. Thumb position and tension are then assessed.

To date, the literature lacks high level clinical evidence to define IB's role in the treatment of thumb CMC OA. A prospective, randomized controlled trial (RCT) is required to compare the procedure's effectiveness in relieving pain and restoring function against that of LRTI. **Therefore, we propose a pilot RCT comparing patient-reported outcomes following IB and LRTI to establish feasibility and generate effect size and variability estimates for a definitive, subsequent RCT (Aims 1 & 2). Recognizing that objective clinical measures such as thumb range of motion, grip/pinch strength, radiographic outcomes, and complications/need for additional surgery are critical in measuring IB's effectiveness against LRTI, we will characterize the two procedures with respect to these parameters along with return to work/activity (Aim 3).**

Upon successful completion of the proposed research, we expect to (1) demonstrate that randomization into a prospective RCT comparing IB and LRTI is feasible, (2) obtain estimates to inform the sample size and design of a future adequately powered prospective RCT, and (3) show that IB produces superior patient-reported outcomes at 6 weeks and 3 months to LRTI while offering an expedited return to work/activity.

C Study Objectives

C1 Study Aims and Rationale for Selection of Outcome Measures

Aim 1: Establish feasibility of a definitive trial by determining the proportion of eligible subjects who agree to randomized treatment and determining the follow-up retention rate. Rationale: To date, no studies have compared IB and LRTI for thumb CMC OA. Our study will assess the feasibility of a prospective RCT comparing outcomes of the two procedures. Hypothesis: A prospective RCT comparing outcomes of IB and LRTI is feasible, as defined by the ability to successfully recruit and randomize ≥50 patients over the course of 1 year with a follow-up retention rate of ≥90%.

Aim 2: Estimate effect sizes and variability in patient-reported outcomes for planning a definitive, two-arm RCT. Rationale: We will assess patient-reported outcomes (PROMIS UE/physical function, VAS pain, VAS satisfaction) following IB and LRTI. Effect size and variability estimates are required to inform the design of a future definitive trial. Hypothesis: IB will produce superior patient-reported outcomes to those of LRTI at 6 weeks and 3 months.

Aim 3: Characterize objective clinical outcomes (thumb range of motion, grip/pinch strength, radiographic outcomes, and complications/need for additional surgery) and to identify differences in return to work/activity following IB and LRTI at three months. Rationale: Objective clinical outcomes are important predictors of patient function after surgery for thumb CMC OA. IB offers an expedited return to work and activity by allowing patients to forego postoperative casting. Hypothesis: IB will produce similar objective outcomes to LRTI with a quicker return to work/activity.

D Study Design

D1 Overview or Design Summary

Our study has been registered on ClinicalTrials.gov. All facets of our study design, analysis, and interpretation will adhere to Consolidated Standards of Reporting Trials (CONSORT) guidelines. Data will be managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at our institution. REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

The research team will identify potential participants as they present to the clinics of one of our seven Orthopaedic Hand and Upper Extremity surgeons. The study population will consist of patients aged 50 years and older who are English-speaking and community-dwelling. These patients will have a confirmed diagnosis of isolated thumb CMC arthritis. Patients will not have carpal tunnel syndrome (to avoid outcome data confusion), rheumatoid/inflammatory arthritis, or a history of chronic opioid use. The research team will block randomize the participants into a control group (LRTI) and a comparison group (IB); block sizes will be 4, 6, and 8.

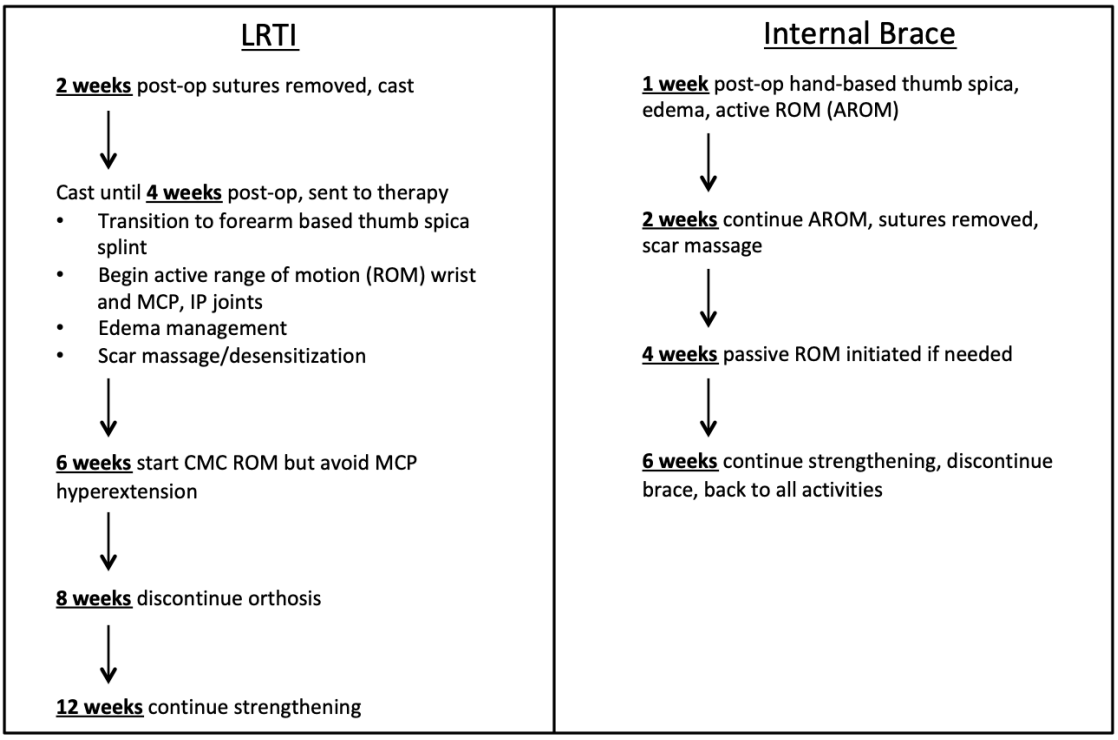
Study Aim 1

The team will review patients' medical records and radiographs to determine potential participants' eligibility. The team will recruit eligible individuals during their clinic appointments using an information form outlining the benefits and relative limitations of each procedure. Patients who are interested in participating in the study will undergo initial testing at their clinic appointment, at which time they can also provide informed consent. Feasibility will be recorded by means of randomization rate and follow-up retention rate throughout the enrollment process. In the event that a patient declines randomization into our study, we will record the patient's reason for declining.

Following the consent process, the study will proceed as follows:

1. Patient will undergo the surgery to which they are randomized, either LRTI or IB, performed by one of the seven Washington University orthopaedic hand surgeons.
2. All patients will follow-up in clinic 2 weeks, 4 weeks, 3 months, and 1 year post-operatively.

Patients will undergo a standardized postoperative recovery and therapy regimen:



Study Aims 2 & 3

PROMIS Physical Function and Upper Extremity scores will be collected at all clinic visits on iPad as per standard protocol for all patients presenting to a Washington University Orthopaedic Surgery clinic. Thumb ROM at carpometacarpal, metacarpophalangeal, and interphalangeal joints will be collected by a member of our team at 4 weeks, 3 months, and 1 year after surgery. Visual Analog Scale Pain and Satisfaction scores will be collected by a member of our team at 2 weeks, 4 weeks, 3 months, and 1 year post-op. Grip and pinch strength (3-point and lateral vs contralateral values and vs preoperative values) will be collected at pre-op visit and all post-op visits except the 2 week visit. Radiographic subsidence will be measured via C-arm radiographs at 3 months and 1 year post-op. Complications (mild, moderate, severe) will be recorded throughout the course of the study at all time points. Mild complications will be defined as those with minor clinical impact (i.e., scar tenderness or sensory disturbances). Moderate complications will be defined as clinically relevant with delay in patient recovery, but not severe enough to necessitate revision surgery and resolve by 12 months after surgery (i.e., mild CRPS type I, tendinitis, neuromas treated with steroid injections). Severe complications will be defined as those which result in revision surgery, pain at rest, or impaired hand function at 12 month exam (i.e., severe CRPS type I or tendinitis and neuromas that do not improve with corticosteroid injections and require surgery). We will document patient return to work/activity at each follow-up appointment.

Feasibility

This study will assess the feasibility of recruiting patients into a prospective RCT and will obtain estimates to inform the sample size and design of a future adequately powered clinical trial. Specifically, we will be assessing randomization rate as calculated by dividing the number of patients randomized by the number of eligible participants and we will record the patient follow-up rate. In addition to our prospective study, we are

currently performing a retrospective cohort study comparing patient-reported outcomes of patients who have undergone LRTI and IB over the past 2 years. We anticipate that this retrospective study will also be instrumental in informing the design and sample size of a definitive RCT.

Potential Pitfalls/Alternative Strategies
We are aware of several potential pitfalls which may present challenges to our study design, and we have developed alternative strategies to ensure that we achieve our aims in the event that these pitfalls occur. First, it is possible that patients will not consent to randomization into our trial at an acceptable rate. If, by 6 months into the enrollment period, we have not successfully randomized 25 patients, we are prepared to convert to a prospective cohort design. Second, it is possible that patients will not follow-up at all time points. This has not been our experience with this population[32]; however, should this occur, we are prepared to have patients complete PROMIS questionnaires remotely and obtain all other data over the phone.

D2 Subject Selection and Withdrawal

2.a Inclusion Criteria

The study population will consist of patients aged 50 years and older who are English-speaking and community-dwelling. These patients will have a confirmed diagnosis of isolated thumb CMC arthritis.

2.b Exclusion Criteria

Patients will not have carpal tunnel syndrome (to avoid outcome data confusion), rheumatoid/inflammatory arthritis, or a history of chronic opioid use.

2.c Subject Recruitment Plans and Consent Process

The team will review patients' medical records and radiographs to determine potential participants' eligibility. The team will recruit eligible individuals during their clinic appointments using an information form outlining the benefits and relative limitations of each procedure. Patients who are interested in participating in the study will undergo initial testing at their clinic appointment, at which time they can also provide informed consent.

2.d Randomization Method and Blinding

The research team will block randomize the participants into a control group (LRTI) and a comparison group (IB); block sizes will be 4, 6, and 8. The study will not be blinded.

2.e Risks and Benefits

The main risks of this study are the risks of the surgical procedures themselves. These include pain, stiffness, infection, damage to surrounding structures (nerves, tendons, blood vessels), and the possibility that the surgery would not work and necessitate revision surgery. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The patient will not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because we will obtain important information regarding surgery for thumb CMC OA.

2.f Early Withdrawal of Subjects and When and How to Withdraw Subjects

Patients may withdraw at any time by telling the study team they are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

2.g Data Collection and Follow-up for Withdrawn Subjects

In the event that a patient withdraws from the study, they will continue to follow-up at standard follow-up intervals as is practice for patients regardless of whether they participate in a study or not. PROMIS data will continue to be collected as is protocol for all patients presenting to Washington University clinics, but all other study-specific data will no longer be gathered.

E Study Procedures

E1 Screening for Eligibility

The team will review patients' medical records and radiographs to determine potential participants' eligibility. The team will recruit eligible individuals during their clinic appointments using an information form outlining the benefits and relative limitations of each procedure. An initial screening REDCap data collection form has been developed and will be used to this end.

E2 Schedule of Measurements, Visits, Safety and Adverse Events

Patients will undergo the surgery to which they are randomized, either LRTI or IB, performed by one of the seven Washington University orthopaedic hand surgeons. All patients will follow-up in clinic 2 weeks, 4 weeks, 3 months, and 1 year post-operatively.

PROMIS Physical Function and Upper Extremity scores will be collected at all clinic visits on iPad as per standard protocol for all patients presenting to a Washington University Orthopaedic Surgery clinic. Thumb ROM at carpometacarpal, metacarpophalangeal, and interphalangeal joints will be collected by a member of our team at 4 weeks, 3 months, and 1 year after surgery. Visual Analog Scale Pain and Satisfaction scores will be collected by a member of our team at 2 weeks, 4 weeks, 3 months, and 1 year post-op. Grip and pinch strength (3-point and lateral vs contralateral values and vs preoperative values) will be collected at pre-op visit and all post-op visits except the 2 week visit. Radiographic subsidence will be measured via C-arm radiographs at 3 months and 1 year post-op. Complications (mild, moderate, severe) will be recorded throughout the course of the study at all time points. Mild complications will be defined as those with minor clinical impact (i.e., scar tenderness or sensory disturbances). Moderate complications will be defined as clinically relevant with delay in patient recovery, but not severe enough to necessitate revision surgery and resolve by

12 months after surgery (i.e., mild CRPS type I, tendinitis, neuromas treated with steroid injections). Severe complications will be defined as those which result in revision surgery, pain at rest, or impaired hand function at 12 month exam (i.e., severe CRPS type I or tendinitis and neuromas that do not improve with corticosteroid injections and require surgery). We will document patient return to work/activity at each follow-up appointment.

E3 Study Outcome Measurements and Ascertainment

Study outcomes will be measured in clinic either on iPads (PROMIS) which is linked to our REDCap system, or entered into REDCap by the research coordinator or occupational therapists.

F Statistical Plan

F1 Sample Size Determination and Power

Various methods are identified in the literature for formulating a pilot study sample size. Julious[31] recommends a minimum sample size of 12 per group as a rule of thumb and justifies this based on rationale about feasibility and precision about the mean and variance. So as to align our study with these recommendations, we plan to enroll 50 patients total in our pilot/feasibility study.

Approximately 100 patients per year undergo surgical intervention (either IB or LRTI) for CMC OA at Washington University. Assuming a 50% randomization rate for this study, a sample size of 100 produces a two-sided 95% confidence interval with a lower limit of 0.404 and upper limit of 0.596 when the sample proportion is 0.5. The primary goal of the trial is to assess feasibility and to obtain estimates for planning a larger, more definitive study to detect meaningful changes in clinical outcome measures.

F2 Analysis Plan and Statistical Methods

Patient demographic and clinical characteristics will be summarized using means (standard deviation, SD) or median (25th, 75th) for continuous variables and frequency (percentage) for categorical variables. The recruitment rate (95% confidence interval) will be reported as the number randomized out of the total number of participants approached to participate in the study (screened). Reasons for not wanting to participate will be summarized and reported. The effect sizes and variability of the PROMs for each group will be reported and used to determine the sample size for a larger definitive trial. Differences in PROMs between LRTI and IB at 6 weeks and 3 months will be examined using a two-sample t-test and differences in categorical outcomes (return to work/activity, yes/no, at 3 months) using Pearson chi-squared test. Changes over time will be evaluated graphically to see the trajectory of change over follow-up and for assessing critical time points to inform future study design parameters. Objective parameters will be summarized for each group using descriptive statistics. The significance level will be 0.05 for all tests due to the exploratory nature of the study.

G Data Handling and Record Keeping

G1 Confidentiality and Security

Only the minimum necessary private information is collected for the purposes of the study. Any procedures or interventions conducted as part of the study will be conducted in private setting to the extent possible. Recruitment/consent will occur in a private setting. Participants will be able to ask questions in a private setting. All materials are stored in secured environment and access is limited to research team members only. Our data will be stored in REDCap.

H Study Administration

H1 Organization and Participating Centers

This study will be performed at Washington University/Barnes-Jewish Hospital. All patient encounters (clinic visits, surgeries) will take place at one of three sites within the Washington University Orthopaedics/Barnes-Jewish Hospital system. These sites are: Center for Advanced Medicine (St. Louis, MO), Center for Advanced Medicine – South County (St. Louis, MO), and Washington University/Barnes-Jewish Orthopaedic Center (Chesterfield, MO).

H2 Funding Source and Conflicts of Interest

An American Foundation for Surgery of the Hand Fast Track Grant ($5000) application was submitted for this study on 9/8/2019. Funding decisions will be announced in December 2019. The remainder of the study costs will be funded by the Washington University Department of Orthopaedic Surgery.

H3 Subject Stipends or Payments

Subjects will not receive compensation to participate in the study.

H4 Study Timetable

	6 months	12 months	24 months
Specific Aim 1	Patient enrollment, surgeries, data collection	Statistical analysis, manuscript writing and submission	Dissemination of study findings, future definitive RCT planning and execution
Specific Aim 2	Patient enrollment, surgeries, data collection	Statistical analysis, manuscript writing and submission	Dissemination of study findings, future definitive RCT planning and execution
Specific Aim 3	Patient enrollment, surgeries, data collection	Statistical analysis, manuscript writing and submission	Dissemination of study findings, future definitive RCT planning and execution

I Publication Plan

We plan to publish our study's findings in a major journal such as Journal of Bone and Joint Surgery or the Journal of Hand Surgery.

J Attachments

J1 Informed consent documents

Please refer to "Consent Documents & Other Attachments" section of IRB proposal for document entitled "LRTI IB Consent V1".

J2 Patient education brochures

Please refer to "Consent Documents & Other Attachments" section of IRB proposal for document entitled "2 Surgical Ooptions for Base of the Thumb Arthritis".

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