Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Ligament Reconstruction Tendon Interposition Versus Internal Brace for the Surgical Treatment of Thumb Carpometacarpal Arthritis: A Prospective Randomized Trial Pilot Study

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Research Team Contact: Dr. John C. F. Clohisy, MD

Clinical Trials Study Number: NCT03971188

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are going to undergo surgery for thumb carpometacarpal osteoarthritis (CMC OA), or arthritis of the thumb.

The purpose of this research study is to compare the outcomes of two surgeries performed to treat thumb CMC OA:

1. **Trapezium excision with ligament reconstruction-tendon interposition (LRTI):** This is the "standard" procedure. The trapezium, a bone on the thumb side of your wrist, is removed. After this, the thumb metacarpal bone (which goes from your wrist to the base of your thumb) is kept in position by taking a tendon from a small muscle in your arm and using it to fill the empty space left behind after the trapezium is removed.. Described more than 40 years ago, the basic procedure is unchanged. Most patients do very well for many years (10+) after this surgery with pain relief and get back to activities. This is the surgery that most hand surgeons in the United States perform for patients with your condition. However, it requires you to be in a cast for 4 weeks and can take up to 4-6 months to get back to all activities without worrying about your thumb.
2. **Trapezium excision with internal brace:** This is the investigational surgery. The trapezium bone is removed in this procedure, too, but instead of moving a tendon into the empty space to keep the thumb in position, a suture (stitch) is used to anchor the thumb metacarpal to the metacarpal of the index finger. A sling is created to support the thumb after bone removal. It is a simple surgery that allows you to get back to all activities by 6 weeks and is worn for one week. Since this is an investigational surgery there are no long-term data to say what happens after several years, but our early findings are positive.

Our study will compare the LRTI and internal brace procedures. Specifically, we are going to compare:

1. Patient Reported Outcomes Measurement Information System (PROMIS) scores. This is a scoring system which is used for many different medical conditions, including orthopaedic conditions.
2. Pain and satisfaction with your surgery.
3. Range of motion (i.e., how well can you move your thumb?).
4. Grip and pinch strength.
5. X-rays before and after your surgery.
6. Michigan Hand Questionnaire. This is a questionnaire that hand surgeons and researchers often use to measure patients' hand function.
7. Complications and need for additional surgery. Although rare, any surgery carries a risk of complications or the need for additional surgery. We will keep track of these if they occur, and compare them between the two procedures.
8. Return to work and activities (i.e., how quickly after your surgery did you return to your job and normal activity level?).

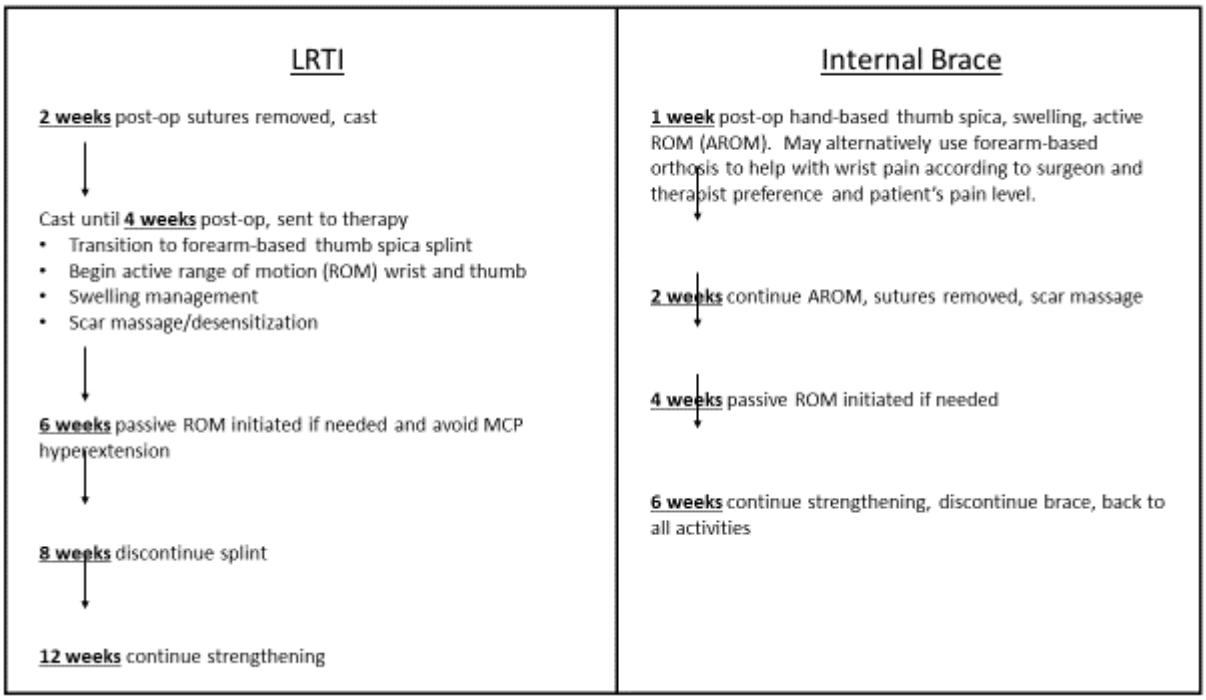
At this point, we believe that both surgeries are very effective in relieving pain and restoring function; however, there have not been any studies comparing the two surgeries. The researchers who are performing this study would like to better understand whether one surgery is more effective and viewed more favorably compared to the other, and whether patients in one of the groups returns to work and activities more quickly.

WHAT WILL HAPPEN DURING THIS STUDY?

Following your agreement to participate in this study, you will undergo initial testing at your clinic appointment which will include completing a questionnaire, obtaining X-rays, and undergoing range of motion and strength testing. You will be randomly assigned (like flipping a coin) to undergo either LRTI or the internal brace procedure by your Washington University Orthopaedic Hand and Upper Extremity surgeon.

Post-Surgery

After your surgery, you will follow-up in the clinic at 2 weeks, 4 weeks, 3 months, and 1 year. You will undergo a rehabilitation protocol as follows *(abbreviations: LRTI- ligament reconstruction tendon interposition, ROM- range of motion, MCP- metacarpophalangeal (the joint at the base of your thumb), IP- interphalangeal (the joint in your thumb), CMC- carpometacarpal (the joint between your wrist and the thumb metacarpal bone), AROM- active range of motion)*:



In summary: If you are in the **LRTI group,** you will be in a hard cast until 4 weeks after surgery. You will then begin working with therapy and gradually increase the intensity of the therapy. You will wear a splint until 8 weeks after surgery. You will continue therapy for as long as you need, which is usually until at least 3 months after your surgery. If you are in the **Internal Brace** group, you will be placed into a small splint shortly after your surgery and immediately begin therapy. You will be allowed to stop wearing the splint at 6 weeks after your surgery, and will continue therapy for as long as you need.

At all clinic visits, you will complete PROMIS (Patient-Reported Outcomes Measurement Information System) questionnaires, which is routine practice for ALL patients seeing a Washington University physician (not just those enrolled in this study). You will complete surveys asking about your Pain and Satisfaction at each post-operative visit. For all surveys/questionnaires, you are free to skip any questions that you would prefer not to answer.

Thumb range of motion, grip strength, and pinch strength will be measured at your first visit and at 4 weeks, 3 months, and 1 year after surgery. X-rays of your hand will be taken after you sign this consent form and at 3 months and 1 year after surgery. At each clinic visit after surgery, we will ask you if you have experienced any problems related to your surgery, if you have required any additional surgery, and when you returned to work and activities.

We will also record information from your chart, including both demographic (age, current and previous hand injuries or diagnoses, medical conditions, medications) and health related data. In addition, we will access your medical record to record information about any complications you may have.

Will you save my samples or research data to use in future research studies?
As part of this study, we are obtaining data from you. We would like to use this data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding thumb CMC OA, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the data.

We might remove identifiers from your private information and your data and then use the information and your data for future research studies or share them with other researchers for their future research. If this occurs we will not ask you for additional consent for these uses of your information or data.

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

HOW MANY PEOPLE WILL PARTICIPATE?
Approximately 50 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?
If you agree to take part in this study, your involvement will last for approximately 1 year after your surgery. The duration of the surgery itself will range from approximately 45 minutes to 1.5 hours. Each clinic visit (2 weeks, 4 weeks, 3 months, and 1 year after surgery) will be approximately 30 minutes in duration. In addition, we plan to conduct further research studies to compare long-term outcomes of the LRTI and internal brace procedures. For these studies, we plan to contact you via telephone and/or invite you to voluntary clinic appointment(s) at (and not limited to) 2 and 5 years after your surgery.

WHAT ARE THE RISKS OF THIS STUDY?
You may also experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The main risks of this study are the risks of anesthesia and the surgical procedures themselves. These include pain, stiffness, infection, damage to surrounding structures (nerves, tendons, blood vessels), the

possibility that the surgery would not work and we would have to perform the surgery again, permanent disability, and death. LRTI has the risk of pain or poor function associated with moving the tendon. The internal brace procedure has the risk of failure or malfunction of the suture used to keep the bone in place, which may cause pain or poor function. To date, we do not believe that either of these outweighs the other, or makes one procedure "better" than the other. Otherwise, to our knowledge, there are no other risks that are specific to one procedure or the other.

X-rays/Radiation Exposure
Regardless of whether or not you choose to participate in this study, you will have X-rays performed of the affected hand before and after surgery. The X-rays will be performed on the in-office C-arm (a type of X-ray machine) which uses a low dose of radiation and poses minimal risk for radiation-induced illnesses including cancer or skin irritation.

Questionnaires
You may become tired or bored while filling out the questionnaires. You may feel uncomfortable answering some of the questions. You are free to skip any questions you prefer not to answer.

Breach of Confidentiality
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled "How will you keep my information confidential?" for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may 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.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could receive non-operative treatments including therapy, bracing/splinting, corticosteroid injections, anti-inflammatory medications, or undergo the surgical treatment of your choice without being randomized (assigned) to LRTI or internal brace procedures.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The University and the research team are not receiving payment from other agencies, organizations, or

companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at (314) 305-6983 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Hospital or University representatives, to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will keep your data stored in a password protected database accessible only by members of the research team.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this

research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

your treatment or the care given by your health provider.
your insurance payment or enrollment in any health plans.
any benefits to which you are entitled.
However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
        - The research team may only use and share information already collected for the study.
        - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
        - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as

part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?
You may withdraw by telling the study team you 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.

Will I receive new information about the study while participating?
If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?
Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because the investigator has ended the study or the study is no longer felt to be important.

WHAT IF I HAVE QUESTIONS?
We encourage you to ask questions. If you have any questions about the research study itself, please contact our research team at (314) 305-6983. If you experience a research-related injury, please contact our research team at (314) 305-6983.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: N/A.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)