Study Title: 4DCT Imaging for Improved Diagnosis and Treatment of Wrist Ligament Injuries

NCT#: NCT03193996

Document Date: 15 February 2023

MAYO CLINIC

Name and Clinic Number

Approval Date: **February 15, 2023**
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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: 4DCT Imaging for improved diagnosis and treatment of wrist ligament injuries

IRB#: 17-001279

Principal Investigator: Kristin Zhao, Ph.D., and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

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CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Dr. Kristin Zhao **Study Team Contact:** Tyson Scrabeck	**Phone:** (507) 284-8942 (507) 538-8920 (pager) **Phone:** (507) 538-1016 **Institution Name and Address:** Mayo Clinic 200 1st St. SW Rochester, MN 55905	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Participant Advocate (The RPA is independent of the Study Team)	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** ResearchParticipantAdvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study
Patient Account Services	**Toll-Free:** (844) 217-9591	▪ Billing or insurance related to this research study

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Other Information:
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.

A description of this research study will be available on http://www.mayo.edu/research/clinical-trials. This Web site will not include information that can identify you. You can search this Web site at any time.

1. Why are you being asked to take part in this research study?

You are being asked to participate in this study because you will have surgery on your wrist to repair a ligament injury.

2. Why is this research study being done?

This study is being done to determine if a CT imaging technique, performed while moving the wrist, can be used to replace current invasive tests for diagnosing wrist ligament injuries and determining if surgeries are successful.

3. Information you should know

Who is Funding the Study?
The National Institutes of Health (NIH) is funding the study. The NIH will pay the institution to cover costs related to running the study.

4. How long will you be in this research study?

You will be in this study until 1 year post-surgery.

5. 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:

This study involves two visits to have five computerized tomography (CT) scans of your joint, without any iodine contrast injection. Four dimensional CT imaging is the same as a standard CT; however, we are able to image your joint while it is moving instead of in one fixed position.

The study coordinator will schedule your CT scans at a time which is convenient for you. One visit will be pre-surgical and the second visit will be approximately one year post-surgery. The study coordinator will contact you by telephone or email (your preference) to arrange your visit at one year post-surgery. Your CT scan appointment should take no longer than forty-five minutes.

When available, the CT scan will be performed on a newer scanner, which is still experimental and isn't approved by the U.S. Food and Drug Administration (FDA). The new scanner is quieter and has better resolution, but otherwise operates the same as our standard scanners.

The CT Technician will ask you to lie down on a table, which moves through a big donut-shaped machine that will then take x-rays of your joint. You will be instructed by the CT technician to move your joint during the CT scan. The CT scan will take several seconds to complete. You will have a total of five CT scans: one from hand to elbow performed while holding both your hands and arms still; and four of your wrists while moving as instructed (two scans on each arm independently).

Prior to, or after the end of the CT scanning, you will fill out two brief questionnaires, which will take no more than ten minutes. The study coordinator will escort you to the lobby area so you may continue with your day.

A radiologist (X-ray doctor) will then look at your joint CT scan for any unknown findings that your physician is not aware of. If any unknown findings are shown, that information will be communicated to your physician. The joint CT scan images and the radiologist's report will become part of your Mayo Clinic medical record.

Prior to your surgery, as part of your normal care for this kind of injury, you will have an arthroscopy – a small procedure in which an examination of the damage in your joint is conducted with a tiny scope through a small incision. The findings of the arthroscopy will be compared with the findings of the first 4DCT scan, and the two methods will be used together to

determine the appropriate surgery. Any wrist x-rays or MRIs you have had as part of your regular care may also be used in this comparison. A video recording from the arthroscope will also be stored for later analysis.

6. What are the possible risks or discomforts from being in this research study?

You will be exposed to x-ray radiation during the CT scan of your joint. The amount of radiation you will receive has a low risk of harmful effects.

The movements of your injured wrist requested by the CT Technician should cause little or no discomfort. However, if the requested movements become too painful, please inform the Technician and discontinue the movement.

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. What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

9. What are the possible benefits from being in this research study?

This study will not make your health better. It is for the benefit of research.

10. What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

11. What tests or procedures will you need to pay for if you take part in this research study?

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

- The CT scans of your joint.
- Questionnaires.
- Video recording of your wrist joint (but not the arthroscopy itself)

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, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

12. Will you be paid for taking part in this research study?

You will receive $50.00 for each study visit you complete. If you are able to complete the entire study, you will receive $100.00.

13. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Study data will be kept on secured servers, password protected, encrypted computers and file storage devices, and in secured files in the researchers' limited-access workspaces. Data sent externally for analysis will not include any direct identifiers linking it to you.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.
- Hospital for Special Surgery research staff involved in this study.

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With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

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

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Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: ResearchParticipantAdvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

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ENROLLMENT AND PERMISSION SIGNATURES

Your signature documents your permission to take part in this research.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

Signature