MAYO CLINIC

Name and Clinic Number

Approval Date: **February 4, 2022**
Not to be used after: **February 3, 2023**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Manipulation Under Anesthesia (MUA) to Treat Postoperative Stiffness after Total Knee Arthroplasty: A Multicenter Randomized Clinical Trial

IRB#: 15-009075

Principal Investigator: Dr. Matthew Abdel 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. Matthew Abdel **Study Team Contact:** Orthopedic Study Coordinator Staff	**Phone:** (507) 284-2511 **Phone:** (507) 538-3562 **Address:** Mayo Clinic 200 First Street 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 Subject Advocate **(The RSA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@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
Patient Account Services	**Toll-Free:** (844) 217-9591	▪ Billing or insurance related to this research study

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

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

You have exhibited a rare complication called postoperative stiffness that affects less than 5% of patients following a knee replacement surgery. While this complication is known, the cause and optimal treatment for this condition remains unknown.

2. Why is this research study being done?

Postoperative stiffness has been poorly studied. The best treatment option for this condition at this time is manipulation under anesthesia (MUA). While many patients regain range of motion not all return to optimal outcome.

It is thought that inflammation can contribute to postoperative stiffness. We would like to investigate if anti-inflammatory medications can limit scar formation, and improve knee function following MUA.

3. Information you should know

Who is Funding the Study?

A Knee Society grant is funding a portion of this multi-center study.

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

Your participation in this study will be for about 1 year following your MUA.

5. What will happen to you while you are in this research study?

If you agree to be in the study, you will be randomly assigned (like a coin toss) to receive MUA alone or MUA with anti-inflammatory medications, celecoxib and dexamethasone. You and the Principal Investigator can't choose your study group. You will have an equal chance of being assigned to either group.

If you are assigned to the MUA with anti-inflammatory medication group, an intravenous (into your vein) dose of dexamethasone will be given to you at the time of MUA. If in this group, you will also receive celecoxib. Similar to Advil (ibuprofen), this medication is a Non-steroidal Anti-inflammatory drug (NSAID) and decreases inflammation. It has fewer gastrointestinal side effects than typical NSAID's. You will be given a prescription to take to the pharmacy of your choice. You will be asked to take the medicine one time daily either at morning or night time with food and water for 2 weeks following MUA.

Whether you receive the anti-inflammatory medications or not, you will be followed throughout your routine follow up to assess your continued progress.

You will fill out questionnaires about your knee and quality of life. You will do this at the time you consent and at your 6-week and 1-year follow up visits. We hope that you will answer all of the questions, but you can skip any questions you don't want to answer. The questionnaires will take about 15-20 minutes to complete.

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

Risks associated with you participation in this study remain small.

Both celecoxib and dexamethasone are FDA approved to treat conditions of inflammation. Many people using either of these medications do not have serious side effects.

Side effects of an intravenous dexamethasone may include: nausea, vomiting, heartburn, headache, dizziness, trouble sleeping, appetite changes, increased sweating, acne, or pain/redness/swelling at the injection site. Additionally, this medication may make your blood sugar level rise, which can cause or worsen diabetes.

Celecoxib has potential side effects as well including: stomach upset or gas and rise in blood pressure. Some people have an allergy to NSAID's, which could cause severe headache, unexplained weight gain, and swelling of the hands or feet. Rarely, NSAID medications can impair the function of your kidneys and liver. However, the dose and duration of treatment used in this study would make either of these side effects exceedingly rare.

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop, and you will be advised whether any additional tests may need to be done for your safety. If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

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. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

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

The proposed benefits of this study would be to improve the treatment options for future patients experiencing your condition. While your knee may or may not benefit from this study, future patients may gain from the data collected in this study.

It is our hope that manipulation along with the use of anti-inflammatory medications will improve knee range of motion and knee function for patients experiencing postoperative stiffness.

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

You do not have to be in this study to receive treatment for your condition. Your other choices may include:

- MUA without anti-inflammatory medications
- No MUA, but continued physical therapy

Talk to your Principal Investigator or your doctor if you have any questions about any of these treatments or procedures.

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

You and/or your insurance will need to pay for all tests and procedures for this study as they are considered part of your clinical care.

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 not be paid to take part in this research study.

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. Data will be stored in electronic files and/or a cabinet, with access to study personnel as authorized by the investigator. The investigator will review the data on a regular basis (at least annually) to verify the validity of the data.

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.

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.

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.

- The sponsor(s) of this study and the people or groups it hires to help perform this 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

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@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.

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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.

ENROLLMENT AND PERMISSION SIGNATURES:

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

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

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.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature