Study Title: Postoperative Hip Bracing After Hip Arthroscopy

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UNIVERSITY OF WASHINGTON
CONSENT FORM

Project Title: A randomized controlled pilot trial of postoperative hip bracing after arthroscopic osteoplasty and labral repair for femoroacetabular impingement syndrome.

Researchers: Mia S. Hagen, MD (lead researcher) – Assistant Professor – (206) 598-3381
Christopher Y. Kweon, MD – Assistant Professor
Albert O. Gee, MD – Associate Professor
Carrie Wigton – Research Coordinator, Contact Person for Subjects (206) 598-3381
Department of Orthopaedics & Sports Medicine, University of Washington

24-hour emergency telephone number: Mia S. Hagen, MD – pager – (206) 993-3296

We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study before deciding whether or not you want to be in the study.

PURPOSE OF THE STUDY

This is a study to decide whether or not it is helpful to wear a hip brace after arthroscopic hip surgery. We are specifically looking at whether the hip brace helps patients with their pain after surgery. There is no agreement among doctors whether or a not a hip brace is helpful -- about 50% of doctors recommend them for their patients while the other 50% do not. About 75 patients will participate in this study.

STUDY PROCEDURES

If you agree to be in the study, you will be randomly assigned into one of two groups. Randomization means that you will be put into a group by chance. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

- Group A: After your hip surgery, you will wear a hip brace until your first postoperative clinic visit. You will be expected to wear the brace at all times except for toilet/shower. You will receive this brace at your preoperative clinic visit. This is the current standard of care that we require of all hip arthroscopy patients.
- Group B: After your hip surgery, you will not wear a brace.

The hip brace is made of metal and fabric and wraps around your waist and your thigh. It controls how much you can move your hip and supports the hip as you move around.

All other care is the same between groups – this includes the same type of surgery, same Physical Therapy protocol, and same follow-up care.

As is the current standard of care for your hip surgery, you will follow-up at Husky Stadium Sports Medicine Center at 2-3 weeks after surgery with the Physician Assistant, and you will see

Dr. Hagen at 6 weeks after surgery, 3 months after surgery, 6 months after surgery, and 1 year after surgery. Dr. Hagen will perform her standard physical exam of your hip in all visits. You will get X-Rays of your hip at the 6 week visit after surgery which is also the standard of care. These X-Rays are not a part of this study.

Dr. Hagen will not know which group you are placed in and you will be asked to not disclose this information to her. If you have any questions about hip bracing after you are in this study, you will please ask the Physician Assistant, Mahra. She will then refer these questions to Dr. Hagen in an anonymous fashion if she is not able to answer them on her own.

You will be asked to fill out a short survey at your preoperative office visit and then at your 6-week and 6-month postoperative visits. These surveys include basic questions about you, your current level of pain and how your hip is feeling. At the 2-3 week postoperative visit you will also tell us your current level of pain and if you were given a hip brace you will write down how often you used it. You may refuse to answer any question in any of these surveys. All information will be entered into our secure, encrypted database and kept confidential.

The study concludes at the 6- month visit after surgery but you will be asked to follow-up at 1 year as part of the standard of care at our institution.

Study Location: All office visits and surveys will be completed at the Husky Stadium Sports Medicine Center.

RISKS, STRESS, OR DISCOMFORT

Filling out the surveys may be inconvenient as they take a few minutes. There are no changes in current clinical practice with this study, so everything except for the surveys is considered standard of care.

Risks of randomization: You will be assigned to a “hip brace” or “no brace” group by chance, and the treatment you received may prove to be less effective or to have more side effects than the other study treatment. However there is no current proof that this is the case and that is why we are doing this study. If you are in the “no brace” group and you decide you later want a hip brace we will help you obtain the brace.

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. Your signed consent form will be added to your UW medical record. Therefore, people involved with your future care and insurance may become aware of your participation. The surveys will be part of your research record by will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you choose not to be in this study, you will instead receive the current standard of care in our institution. This means you will receive a hip brace and be expected to wear it at all times for the first 2-3 weeks after surgery (except for toilet/shower).

BENEFITS OF THE STUDY

The brace will be provided to you free of charge (it will be billed to insurance and any payment that you are responsible for will be covered by the study funding). Other than that, there will be no direct benefit to you from participating in this study. The study will help doctors learn more about whether or not hip braces are useful after surgery. We hope that this information will help in the treatment of future patients with hip problems like yours.

SOURCE OF FUNDING

This study is being sponsored by ***, which covers to costs of the hip bracing and research coordinator time. The lead researcher for this study, Mia S. Hagen MD, is receiving a small payment from the study sponsor for the time spent completing study-related duties outside of the surgical procedure.

There are no financial or proprietary interests in this study on the part of Dr. Mia S. Hagen or any of the other study personnel.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be confidential. It will be stored on a secure, encrypted database. The link between your identifiers and the research data will be destroyed after the records retention period required by state and/or federal law.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The University of Washington Medical Center

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm. Your participation in this study will be noted in your UW medical record. Your signed consent form will be added to your UW medical record.

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.

USE OF INFORMATION AND SPECIMENS

Returning Results to You

There are no anticipated clinically actionable individual results in this study and thus no plans to provide individual results of this study to participants. A summary of the overall results will be available at the website above.

Using Your Data in Future Research

The information and/or specimens that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that de-identified information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

The lead researcher, Dr. Hagen, may stop you from taking part in this study at any time if she believes it is in your best interest, if you do not follow the study rules or meet the study criteria, or if the study is stopped.

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, contact Dr. Hagen (lead researcher) and Carrie Wigton (research coordinator). They can be reached at (206) 598-3381 during work hours, or page Dr. Hagen at (206) 993-3296 if after work hours.

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call her at the number(s) listed at the top of this form. This number is monitored 24 hours a day.

If you are injured as a result of being in this study, necessary medical treatment will be offered at a UW Medicine facility.

The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. You may also call collect to the UW Human Subjects Division at 206-221-5940 if you do not otherwise have access to a telephone. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for

injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form. We will bill your health insurance for treating problems that result from your hip impingement or from standard clinical care. If you have no health insurance or your insurance refuses to pay, we will bill you.

Printed name of study staff obtaining consent* Signature* Date*

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

When subject is a minor:

Printed name of parent Signature of parent Date

When subject is not able to provide informed consent:

Printed name of representative Signature of representative Date

Relationship of representative to subject

Copies to: Researcher
Subject
Subject's Medical Record (if applicable)