Fraser Orthopaedic Research Society
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# PARTICIPANT INFORMATION AND CONSENT FORM

***Association between the direction of proximal humerus fracture dislocation and risk of avascular necrosis following open reduction internal fixation – An observational, cohort study***

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**Research Sites:** Royal Columbian Hospital
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**Study Coordinators:** (604) 553-3247 FORS@fraserhealth.ca

**Funding Support:** Unfunded

**Invitation:**
You are being invited to take part in this research study because you experienced a shoulder fracture that required surgical repair. Research studies are ways of finding out new information that might help other people with similar conditions or injuries to yours.

**Your Participation is Voluntary:**
Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education or other services to which you are entitled or are presently receiving.

Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts. You also need to know that there are differences between being in a research study and being cared for by your surgeon outside a study. When you participate in a research study, one of the goals is to learn things to help other patients in the future. Outside a research study, your surgeon's sole goal is to care for your health. Nevertheless, the researchers have a duty of care to all participants and will inform you of any information that may affect your willingness to remain in the study.

If you wish to participate, you will be asked to sign and date this form before any study related procedures can be started.

**Who is Conducting the Study?**

The study is being conducted by investigators within the Fraser Orthopaedic Institute. Although this is an unfunded study, researchers must serve the interest of the participant and also abide by their obligations. You are entitled to request any details concerning study compensation from the orthopaedic research office.

**What is the Purpose of the Study?**

The purpose of the study is to examine the rates of shoulder avascular necrosis in relation to the direction of the shoulder fracture dislocation. Avascular necrosis occurs when the blood supply is cut off to the bone and the result is that the bone tissue dies. This is one of the many risks of experiencing an injury such as yours. The study doesn't alter anything about your care as you have already received treatment for your fracture, consenting to the study means you are consenting to a singular visit and set of x-rays for the surgeon to assess and determine if you have any evidence of avascular necrosis. If present, the surgeon will discuss this with you at your visit.

Approximately 65 patients will be enrolled in this study from the Fraser Orthopaedic Institute. Your participation in the study will last approximately 1 visit date.

**Who Can Participate in the Study?**

**You may be able to participate in this study if*:***

(1) Age greater than or equal to 18 years of age

(2) Have a shoulder fracture that was surgically fixed at Royal Columbian Hospital between January 2011 – July 2021

**You will not be eligible to participate in this study if:**

(1) Previous, surgically fixed shoulder fracture in the injured limb prior to their treatment within the eligible window

(2) Inability to provide consent

(3) Inability to speak/understand or read English without a registered interpreter

**What Does the Study Involve?**

If you consent to participate in this study, you will be asked to come into your surgeon's private clinic for one visit. During this visit you will be asked to complete an x-ray, a short set of questionnaires (that can be done in the waiting room), and a discussion with your surgeon. The entire visit should take no longer than 1 hour, factoring in wait times in the clinic. The visit is designed to mirror the same type of clinical visit(s) that you performed previously, as per standard-of-care procedures. There are no special trips to the hospital for the purposes of the study.

The study team will consult your medical records to collect information such as your medical history and demographics (e.g., sex, age), treatment information, diagnostic testing, and take note of the relevant information (data) for this research study.

**Disclosure of Race/Ethnicity**

Studies involving humans now routinely collect information on race and ethnic origin as well as other characteristics of individuals because these characteristics may influence how people

respond to different treatments. You should be aware that providing this information is mandatory.

Your participation in the study will be over after your completion of the singular clinic visit.

**What Are My Responsibilities?**
As a participant in this study, you must:

- give correct and accurate information about your medical history and current medical conditions
- tell the research staff about any new or worsening health problems (adverse events) you have during the study
- come to the scheduled appointment and complete the questionnaires

**What Are the Possible Harms and Side Effects of Participating**?

You have already received treatment for your fracture, at which time all the possible risks associated with surgery were explained to you. If you choose to participate in this study, you will be asked to complete questionnaires that ask about your physical and mental health. There may be some emotional distress associated with answering the questions about your health. Although we would appreciate you completing the questions, you are not obligated to answer any questions you do not wish to or that you feel uncomfortable with. If new or worsening mental health is indicated in your answers to the questionnaires, your treating surgeon will ensure you follow up or are being supported by a general practitioner.

Although you should not expect to receive any direct benefit from participating in this study, your participation may help to improve the understanding between avascular necrosis and shoulder fracture dislocations in the future.

**What Are the Alternatives to the Study Treatment?**
You do not have to participate in this study. An alternative to the study procedures described above is not to participate in the study and continuing on just as you do now. Treatment is provided to you regardless of your involvement in this study.

**What if New Information Becomes Available That May Affect My Decision to Participate?**
We may learn new things during the study that you may need to know. We may also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information in a timely manner. You may also be asked to sign a new consent form discussing these new findings if you decide to continue in the research study.

**What Happens If I Decide to Withdraw the Decision to Participate?**
You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, the research team will have a discussion with you about what will happen to the information about you already collected. You have the right to request the

destruction of your information collected during the study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

If you choose to have the data collected about you destroyed, this request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let your study surgeon know.

Please note that although you may withdraw from participation of the research and ongoing evaluation, the procedures themselves cannot be undone.

**Can I Be Asked to Leave the Study?**
As a volunteer in this study, you may leave the study at any time. You may also refuse to answer any questions you do not want to answer and still remain in the study.

Your surgeon may stop your participation at any time, without your consent, if they feel it is in your best interest. You may be taken out of the study if you do not follow your study surgeon's instructions, if you experience a side effect that needs medical treatment, or if the study is stopped for any reason.

**Will Taking Part in This Study Be Kept Confidential?**
Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by the lead site or the Fraser Health Research Ethics Board for the purpose of monitoring/auditing the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., address, phone number, personal Health Number, SIN, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity (i.e. your name or any other information that could identify you) as a participant in this study will be kept confidential. Only your age at time of injury will be used. Information that contains your identity will remain only with the orthopaedic research office. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

All information that identifies you, both paper copy and electronic information will be kept confidential and stored and locked in a secure place that only authorized personnel will be able to access. Electronic files will be stored securely on hospital computers or securely on any portable electronic devices. All paper copies of study data will be securely stored in a locked office in the research office at the Royal Columbian Hospital. The data that is captured electronically is de-identified and entered into a secure electronic data capture system, only accessible to authorized personnel.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the lead site and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

**After the Study is Finished**

Once you have completed the study visit, your participation in this study will be concluded. The clinical care for your shoulder may continue at your surgeon's discretion. The results of this study may be presented at conferences, seminars or other public forums, and published in journals, but no information will be used in these presentations that would disclose your identity as a study participant. No information from this study will be released that would disclose your personal identity without your permission unless required by law. At the end of the study, if you so wish, you may contact the study staff to obtain results of this study.

**Future Contact**

We, the Fraser Orthopaedic Research Society (FORS) may wish to contact you later to participate in other studies or an extension of this study. Please respond below as to your agreement for future contact.

☐ **YES, I agree** to be contacted to participate in future/further research.

☐ **NO, I do not agree** to be contacted for future/further research.

**What Happens if Something Goes Wrong?**

By signing this form, you do not give up any of your legal rights and you do not release the study surgeon or other participating institutions from their legal and professional duties. There will be no costs to you for participation in this study. You will not be charged for any research procedures. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

**What Will the Study Cost Me?**

You will not receive any form of payment (compensation) for your participation in this study. You should not incur any expenses due to this study.

**Who Do I Contact If I Have Any Questions About the Study During My Participation?**

In you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact (weekdays from 7:00am-4:00pm);

The Fraser Orthopaedic Research Society: (604) 553-3247

**Who Do I Contact If I Have Any Questions or Concerns About My Rights as a Subject During the Study?**

If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, contact the Fraser Health Research Ethics Board (REB) Co-Chair by calling 604-587-4681. You may discuss these rights with the Chair of the Fraser Health REB.

**PARTICIPANT CONSENT TO PARTICIPATE**

***Association between the direction of proximal humerus fracture dislocation and risk of avascular necrosis following open reduction internal fixation – An observational, cohort study (PHF-D)***

Principal Investigator: Dr. F Moola
Co-Investigators: Drs. B Perey and J Murphy

I acknowledge that the research study described in the previous pages has been explained to me. By signing this consent form, I have indicated that I have read, understood and appreciate the information concerning the study. I understand that I do not give up any legal rights by signing it.

- I have had enough time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific objectives.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.
- I authorize access to my health record as described in this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

| Printed Name of Participant | Signature | Date |
|---|---|---|

| Printed Name of Person Obtaining Consent | Signature | Date |
|---|---|---|