FRASER
ORTHOPAEDIC
RESEARCH SOCIETY

403 - 233 Nelson's Crescent New Westminster, BC Canada V3L 0E4 | Tel: +1 604.553.3247 Fax: +1 855.946.1805 | Email: FORS@fraserhealth.ca | fraserortho.com

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)

Study Protocol
V.1.0
9 January 2023

Principal Investigators
Bert Perey, MD, FRCSC

Farhad Moola, MD, FRCSC

Justin Murphy, MD, FRCSC

Fraser Orthopaedic Research Society
Royal Columbian Hospital / Fraser Health Authority
233 Nelson's Crst
New Westminster, BC, Canada
V3L 0E4

403 - 233 Nelson's Crescent New Westminster, BC Canada V3L 0E4 | Tel: +1 604.553.3247 Fax: +1 855.946.1805 | Email: FORS@fraserhealth.ca | fraserortho.com

Study Personnel

Principal Investigators:

Bertrand Perey
MD, FRCSC
Clinical Associate Professor, University of British Columbia
#403 233 Nelson's Crescent
New Westminster, BC, Canada, V3L 0E4
Tel: 604-777-5577
Fax: 604-777-5644
E-mail: bperey@shaw.ca

Farhad Moola
MD, FRCSC
Clinical Associate Professor, University of British Columbia
#403 233 Nelson's Crescent
New Westminster, BC, Canada, V3L 0E4
Tel: 604-526-4646
Fax: 866-883-1615
E-mail: fmoola@me.com

Justin Murphy
MD, MSc, FRCSC
Clinical Fellow, Upper Extremity Reconstruction & Trauma
University of British Columbia
E-mail: jrmurphy@mun.ca

Project Manager:

Ella Spicer
Clinical Research Coordinator
Fraser Orthopaedic Research Society
Royal Columbian Hospital
#403 233 Nelson's Crescent
New Westminster, BC, Canada, V3L 0E4
Tel: 604-553-3247
Fax: 1-855-946-1805
E-mail: ella.spicer@fraserhealth.ca

403 - 233 Nelson's Crescent New Westminster, BC Canada V3L 0E4 | Tel: +1 604.553.3247 Fax: +1 855.946.1805 | Email: FORS@fraserhealth.ca | fraserortho.com

Table of Contents

403 - 233 Nelson's Crescent New Westminster, BC Canada V3L 0E4 | Tel: +1 604.553.3247 Fax: +1 855.946.1805 | Email: FORS@fraserhealth.ca | fraserortho.com

Introduction and Background

The incidence of proximal humerus fractures continues to increase and is among one of the more common fractures seen in the adult population[1]. Proximal humerus fracture dislocations, however, are less common. Despite the decreased prevalence, fracture dislocations have unique challenges with respect to obtaining an anatomical reduction and more frequently involve an open surgical reduction. In addition, depending on other fracture characteristics, there are various treatment options for the fracture itself. Some surgeons may try to preserve the native anatomy with a fixation construct, while others may opt for an arthroplasty procedure. One of the considerations for joint sparing versus replacement is the viability of the humeral head. Previous literature has examined patterns of proximal humerus fractures and have suggested predictable indicators that may lead to humeral head avascular necrosis (AVN)[2-4]. The study by Hertel et al. (2004) demonstrated various fracture patterns associated with an increased risk of AVN. Fracture dislocations were included in the study, however, specific details regarding direction of dislocation were not included. More recently, a large systematic review by Miltenberg et al. (2022), examined the functional outcomes, rate of revision, and short- and long-term complications for proximal humerus fracture dislocations treated with open reduction internal fixation[5]. While fracture dislocations ultimately lead to increased AVN and revision surgery, further discussion surrounding the direction of dislocation and how it may influence overall outcomes was not addressed.

Study Objectives

Primary Objective

The purpose of this study is to first to examine the rates of humeral head AVN in relation to direction of proximal humerus fracture dislocation.

Radiographic measures:

- Humeral head avascular necrosis – as classified by the Cruess classification system[6]
- Direction of the humeral fracture dislocation – characterized by the direction of humeral head in relation to glenoid. Simple objective measure base on A/P, Lateral, and/or Axillary Views.

Secondary Objectives

Secondarily, this study will address patient reported outcome measures with respect to direction of fracture dislocation.

Patient-reported outcome measures:
- Disabilities of Arm, Shoulder and Hand (DASH)
- Constant Score (CS)

403 - 233 Nelson's Crescent New Westminster, BC Canada V3L 0E4 | Tel: +1 604.553.3247 Fax: +1 855.946.1805 | Email: FORS@fraserhealth.ca | fraserortho.com

Study Design

The study will be an observational, cohort study. Participants will be pulled from a retrospective cohort of all patients with proximal humerus fracture dislocations who underwent operative fixation at Royal Columbian Hospital between January 2011 – July 2021. They will then be grouped by their dislocation directions to look at the development of AVN. Eligible patients will be given the option to consent to the study. This provisional consent will be obtained over the phone, in the form of a verbal agreement. During this agreement the patient will also receive an appointment time for them to come into the office. If agreeable, patients will be asked to come into the clinic to sign the Informed Consent Form, see their treating surgeon, and complete up-to-date radiographs and patient reported outcome measures (PROMs). These radiographs and PROMs will be used to assess AVN and overall function.

Study Population

Inclusion criteria

- Patients ≥18 years of age
- Patients who underwent operative fixation of proximal humerus fracture dislocation at Royal Columbian Hospital between January 2011 – July 2021
- Willing and able to consent and complete patient reported outcome measures
- Willing and able to follow the protocol and attend a follow-up visit
- Able to read and understand English or have an interpreter available

Exclusion Criteria

- Skeletally immature patients
- Patients with pathological fractures
- Patients who have had previous operative fixation of proximal humerus
- Patients treated non-operatively
- Patients presenting outside of the study duration window
- Participants treated by a non-participating surgeon
- Deceased patients
- Patients unable to complete patient reported outcome measures
- Patients declining to come back to the clinic for updated x-rays
- Dementia
- Incarceration

Methods

All patients deemed appropriate for study inclusion will be determined based on review of imaging conducted by an orthopedic attending, fellow, or resident to look for proximal humerus fracture dislocations. Patients eligible for study will be grouped based on direction of dislocation in one of four groups, anterior, posterior, varus and valgus. Both surgical and

403 - 233 Nelson's Crescent New Westminster, BC Canada V3L 0E4 | Tel: +1 604.553.3247 Fax: +1 855.946.1805 | Email: FORS@fraserhealth.ca | fraserortho.com

immediate postoperative protocols were left to discretion of attending surgeon, at the time of the initial surgery. However, the standard postoperative protocol included an initial follow-up for surgical site assessment and removal of sutures and/or staples. In addition, a period of restricted activity status was also left to discretion of attending surgeon.

Study Visit

Study participants will come back for one visit; this will be an observational visit to see how they are doing now. This exam will be conducted in the clinic at a minimum of 2 years postoperatively. Vascularity of the humeral head and union of the fracture will be assessed on anteroposterior and axial radiographs, while patient reported outcomes will be assessed using Constant and Disabilities of Arm, Shoulder and Hand (DASH) Scores.

The Constant Score (CS) is a 100-point scale (high scores = high level of function) composed of individual parameters looking at pain, activities of daily living (ADL), mobility, and measuring the strength of the affected shoulder.

The DASH is a 30-item questionnaire that looks at the ability of a patient to perform certain upper extremity activities. The DASH score ranges from 0 (no disability) to 100 (most severe disability).

Data Collection

Baseline

- Radiographs
  - Dislocation direction
  - Fracture type
- Patient Demographics (Chart Review)
  - Age
  - Gender
  - American Society of Anaesthesiologists (ASA) Score
  - Medical History
  - Social History
- Injury Characteristics
  - Side of injury
  - Mechanism
  - AO/OTA Classification

Surgical Treatment

- Radiographs
- Surgical Demographics
  - Date of surgery
  - Anaesthesia Type
  - Any Additional Procedures on the Injured Limb

Observational Visit

- Radiographs
  - AP, Lateral, and Axillary views
- Radiographic outcomes

403 - 233 Nelson's Crescent New Westminster, BC Canada V3L 0E4 | Tel: +1 604.553.3247 Fax: +1 855.946.1805 | Email: FORS@fraserhealth.ca | fraserortho.com

  - AVN Evidence
- Follow-up Demographics
  - Follow-up Period
  - Date of Last Follow-up
  - Quality of Reduction
  - Re-operations on the Injured Limb
- Patient reported outcomes (DASH, CS)

Outcomes

Primary Outcome Measure

The primary outcome measure is avascular necrosis of the proximal humerus, based on radiographic criteria. (Cruess Classification)

Secondary Outcome Measure

Patient-reported outcome measures will be collected at the one visit

DASH	Developed to asses single or multiple musculoskeletal disorders affecting the upper limb. The DASH is a very commonly used outcome measure that is fully patient-administered and contains 30-questions designed to quantify physical disability and symptoms in individuals with upper limb disorders.
CS	The constant shoulder score is one of the most commonly used outcome measures to asses shoulder disorders. It combines subjective and objective measurements in the form of: pain, activities of daily living, strength, and range of motion to provide you with a final score out of 100.

Radiographic Parameters

A/P, Lateral, and Axillary views.

Statistics

Sample Size

Out of a possible 70 participants we hope to enrol around 56 (with approximately 14 in each of the 4 dislocation groups). This accounts for 20% of the participants of the total to either choose not to enrol or be unavailable due to their morbidity status.

Data Analysis

As this is an observational study with limited patient population and no specific time points to reference, all participants will have the chance to complete the follow-up visit at their leisure. For this reason, we do not foresee needing to exclude any patients for missed appointments. At

403 - 233 Nelson's Crescent New Westminster, BC Canada V3L 0E4 | Tel: +1 604.553.3247 Fax: +1 855.946.1805 | Email: FORS@fraserhealth.ca | fraserortho.com

the follow-up visit each participant will be assessed for the presence of AVN in comparison to their dislocation direction. Descriptive statistics will be utilized and reported on and parametric analysis will be completed as appropriate.

Ethical Considerations

Potential Benefits

It is not known whether or not participants will gain any direct benefit from the study. It is possible that participants that come back may still be experiencing some pain or issues in their injured limb and want to see the surgeon to discuss potential management.

It is expected that the results of the study will contribute to the literature of shoulder fracture-dislocations and the development of AVN following this type of injury, and provide a possible indication for a large study in the future.

Potential Risks

As this is an observational cohort study there are no anticipated risks to participating in the study. Treatment has already occurred and all follow-up has been completed as per standard of care procedures. The only additional procedures that participants would need to take part in for the study are additional radiographs and the completion of one visit that includes completing PROMs.

As with all research that includes imaging there is a risk of incidental findings. However, this will be dealt with by the most responsible person, who in this case, will be the surgeon that is seeing the participant and assessing their radiographs.

Along with research there is also a risk of loss of confidentiality. Every possible step will be taken to ensure participant confidentiality.

Data Management

Data will be stored in a password protected excel spreadsheet on the FHA M-Drive. Participants will be de-identified and receive a unique study ID. There will be a separate, password protected excel spreadsheet that will house the participants name and their unique study ID. Only necessary study personnel will have access to it.

Confidentiality

All data will be identified using a unique number and letter system in the form of a participant number. This number (e.g. PHFD-001, PHFD-002, etc) will be the only identifiers used for identifying study participants. Most of the data will be electronic and housed in password protected servers in the FHA network on the remote drive. Any paper copies of the CRFs or consent forms will be kept secure in locked cabinets inside the locked research office. The project manager will authorize personnel to access the data only as necessary.

403 - 233 Nelson's Crescent New Westminster, BC Canada V3L 0E4 | Tel: +1 604.553.3247 Fax: +1 855.946.1805 | Email: FORS@fraserhealth.ca | fraserortho.com

Withdrawal

As the study consists of one study visit we do not anticipate the need for withdrawal. However, participants may choose to withdraw from the study at any time, without any affect to their care of treatment. Withdrawal will include the option to withdraw and still have their last radiograph assessed for the study, or they can choose to have a complete withdrawal (if they haven't completed the study procedures yet). If the participant has completed the study procedures and they choose to withdraw then a discussion will be had about what will happen to the information about them already collected. Participants have the right to request the destruction of their information collected for the study, or they may choose to leave the study and allow the investigators to keep the information already collected.

If participants choose to have the data collected about them destroyed, this will be respected to the fullest extend possible. However, there may be exceptions where the data is not able to be withdrawn, for example, where the data is no longer identifiable or where the data has been merged with other data. If the participant wishes to request the withdrawal of the data, they should let their surgeon and/or research team know.

Blinding

In order to maintain blinding in the study the initial x-rays, taken when the participant's presented to the emergency department, showing the dislocation direction, will be reviewed and assessed by a qualified individual that didn't perform the surgery. During the one-time follow-up visit the surgeon, who performed the participant's surgery, will assess the x-rays the participant had that day to look for any evidence of AVN. The surgeons will be blinded to the dislocation direction the participant experienced initially.

Ethics

The study protocol, case report forms, questionnaires, and the consent form will be submitted and approved by Fraser Health Research Ethics Board prior to study implementation.

The study will be conducted in accordance with the Tri-Council policy statement: Ethical Conduct for Research Involving Humans, the International Conference on Harmonisation Guidance E6: Good Clinical Practice E6: Consolidated Guidelines, applicable government regulations, and institutional research policies and procedures.

Publication/Presentations

Results from the study will be submitted for publication and presented at national conferences as fellow-ship research to influence future studies.

403 - 233 Nelson's Crescent New Westminster, BC Canada V3L 0E4 | Tel: +1 604.553.3247 Fax: +1 855.946.1805 | Email: FORS@fraserhealth.ca | fraserortho.com

References

1. Schumaier, A. and B. Grawe, *Proximal Humerus Fractures: Evaluation and Management in the Elderly Patient.* Geriatr Orthop Surg Rehabil, 2018. **9**: p. 2151458517750516.
2. Greiner, S., et al., *Humeral head necrosis rate at mid-term follow-up after open reduction and angular stable plate fixation for proximal humeral fractures.* Injury, 2009. **40**(2): p. 186-91.
3. Hertel, R., et al., *Predictors of humeral head ischemia after intracapsular fracture of the proximal humerus.* J Shoulder Elbow Surg, 2004. **13**(4): p. 427-33.
4. Boesmueller, S., et al., *Risk factors for humeral head necrosis and non-union after plating in proximal humeral fractures.* Injury, 2016. **47**(2): p. 350-5.
5. Miltenberg, B., et al., *Fracture dislocations of the proximal humerus treated with open reduction and internal fixation: a systematic review.* J Shoulder Elbow Surg, 2022. **31**(10): p. e480-e489.
6. Cruess, R.L., et al., *Aseptic necrosis following renal transplantation.* J Bone Joint Surg Am, 1968. **50**(8): p. 1577-90.