CLINICAL OUTCOMES FOLLOWING GLENOID NECK FRACTURE AS CORRELATED WITH QUANTITATIVE ASSESSMENT OF OSSEOUS INJURY

**Study Summary**

A significant subset of patients with scapula fractures also involves the glenoid neck (bone joining the shoulder joint the scapular body). There is little evidence pertaining to the best treatment or precise definition of these lesions. This study will be designed as a prospective, non-randomized cohort study that will collect outcome and radiological data on patients who have sustained a fracture of the glenoid neck (bone joining the shoulder joint the scapular body) for a period of 1 year. All patients who have sustained extraarticular scapula fractures (any fracture not involving the glenoid surface) will be considered. Information will be collected with respect to the radiographic characteristics of osseous injuries as well as functional outcome over time.

The goal is to determine if functional outcome correlates with the degree of bony injury. The null hypothesis is that once the fracture healing has occurred, forelimb function is not impacted by a fracture of the glenoid neck, regardless of radiographic osseous derangement. Specifically, we hope to compare outcomes following glenoid neck fracture against lesions of the scapular body to determine if significant osseous injury to this particular area impacts forelimb function to a greater degree than body fractures. The proposed study may serve as a pilot for a subsequent, multicenter effort, where mean and standard deviation data obtained will be used for a power analysis if future research involves any intervention.

**Background/Rationale/Purpose**

Extraarticular fractures (fracture not involving the glenoid articular surface) of the scapula (shoulder blade) have been traditionally managed nonoperatively. The logic for this course of treatment was based on the healing potential of the extensive muscular envelop of the scapula, the inherent mobility of the shoulder joint, and the difficulty in objectively assessing the degree of injury given its irregular osseous architecture.

Scapular fractures specifically involving the glenoid neck have the potential to significantly change the geometry of glenohumeral joint (shoulder joint) as well as affect the actions of muscles and nerves that act across it. Although most reports indicate patients sustaining glenoid neck fractures did well following nonoperative treatment, there was little use of validated outcome measures. Additionally, the context of severe trauma may have lead to an underestimation of functional recovery.

Advances in imaging technology combined with the evolution of internal fixation techniques have resulted in sporadic attempts at fixation of glenoid neck fractures, usually when they occurred in concert with bony injury to other members of the shoulder girdle, as in the "floating shoulder". However, in the absence of a universal canon of radiograph measurements, there are no current recommendations for operative versus non-operative management based on the characteristics of osseous injury as correlated with probable clinical outcome. Moreover, the common assertion that nonoperative management of scapular fractures leads to adequate functional outcome has not been rigorously examined in a prospective fashion, despite this being the standard of care nationally and at BMC.

Recent evidence suggests that nonoperative treatment may lead to significant decreases in strength and forelimb function despite the fact that the standard of care for the vast majority of these injuries does not involve surgery or reduction. The same may be true of glenoid neck fractures, as significant shortening or angulation of this metaphyseal isthmus may have a detrimental effect on the functional geometry of the glenohumeral (shoulder) joint. If so, surgical management may be indicated to restore a more physiologic geometry to the joint, and thereby give the best chance of recovery to a pre-injury level of function. It is our hope that these correlates of measurements and outcome will help codify an a priori set of radiograph evaluation criteria to help guide decisions for surgical versus non-operative management of glenoid neck fractures. The purpose of the study is to: 1) define the degree of forelimb dysfunction brought about by this specific injury and 2) the magnitude of osseous injury to the glenoid neck that can be tolerated before functional outcome is unacceptably impeded.

**Risk**

Category 1: Research involving less than or equal to minimal risk.

**Subjects**

Gender: Both

Age: Adult 18-85

Ethnicity: All Ethnic Groups

Languages: English

Groups to be recruited will include: Patients only

Vulnerable populations to be recruited as subjects: Emergency Department Patients, Women of child bearing potential

Patients will be evaluated by a trained research nurse or physician to determine eligibility. Once the clinical staff has determined that the patient is eligible for the study, the patient will be informed about the research study and asked if he/she wants to participate. Patients are informed of the risks and benefits associated with their participation. Patients willing to consider participating are asked to review a formal consent form and then are provided with the opportunity to have any additional questions addressed. Patients will be informed that their care will be the same regardless of their decision to participate. In order to enroll in the study, the Informed Consent Form will need to be signed by the time of their next standard of care appointment (2 weeks). Subjects will be assigned individual study ID numbers. Patient identifying information will be kept confidential following HIPPA guidelines.

English is the language chosen since the study design is using standard outcomes that are not available in languages other than English.

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Women of child baring potential are treated the same by the Radiology Department in or outside the study. The total exposure to radiation is no more for study patients than non-study patients. Pregnant patients are not eligible for the study.

**Design**

Design: Observational, prospective

This prospective, non randomized study will evaluate extraarticular scapula fractures involving the glenoid neck as compared to both non-glenoid scapular fractures and the uninjured contralateral shoulder girdle.

Patients will be initially identified by the PI and or designed staff for potential inclusion based on the aforementioned lesions being seen on radiographs, including plain x-rays and optional CT. Presenting radiographs will be assessed according to a tripartite measurement protocol specifically quantifying: 1) glenoid medialization, 2) glenopolar angle and 3) scapular shortening, each as either absolute values or a ratio to the contralateral scapula. Patients are not blinded or randomized.

Analysis: Patients sustaining glenoid neck fractures will be compared to those sustaining scapular body fractures to ascertain any functional difference owing to osseous lesion when the soft tissues are similarly traumatized. Then, the functional capacity of an extremity compromised by a glenoid neck fracture will be compared to the contralateral, uninjured extremity according to strength testing and the above outcome measures. Strength testing will be pursued using an objective measuring device such as a goniometer and range of motion data will be recorded. From these data sets pairing osseous injury and functional outcome, mean and standard deviation values will be extrapolated towards construction of a prospective multicenter analysis. A parallel analysis will concern the proposed radiograph measurements, as they will be objectively assessed for precision.

At the present time, the magnitude of difference that may be observed in both the outcome measures and radiographic characterization is unknown. Furthermore, there are no analogous studies in the literature from which to extrapolate an estimation of power. We plan to enroll 50 patients within the above-outlined context, with an enrollment horizon of a maximum of two years. With a scheduled follow-up evaluation period of one year, the proposed study timeframe is projected to be three years.

Inclusion criteria

1. Adults 18-85
2. Extraarticular scapular fractures
3. Scapular fracture is isolated or in concert with nondisplaced ipsilateral fractures of the clavicle, coracoid or acromion
4. Patient is free of preexisting neuromuscular or psychiatric dysfunction
5. Patient is free of previous upper extremity injury that would impede objective functional outcome evaluation\*

7. Patient is English speaking

1. Patient is signed the informed consent form

\* 6. Patient received a CT scan as part of their initial clinical care (Deleted from Inclusion

criteria. Original numbering system maintained.)

Exclusion criteria

1. Preexisting upper extremity injury or neuromuscular condition that impedes objective functional outcome
2. Displaced fractures of the ipsilateral acromion, clavicle, or coracoid
3. Concomitant injury to the forelimb or humerus
4. Patients mentally or physically unable to perform the function evaluation
5. Patient has concurrent injury that will impede objective functional outcome
6. Patients unwilling or unable to follow up for 1 year
7. Patients with poor propensity to follow up; drug, alcohol issues, etc.
8. Non English speaking patients
9. Patients currently or pending incarceration in prison

**Procedure**

Patients with a scapular fracture will be identified from radiographs by the PI or designees and then divided into two groups: those with a fracture involving the glenoid neck, and those with a fracture involving the scapular body. For the purpose of this study, the glenoid neck is defined as the metaphyseal isthmus extending from the subcondral bone of the glenoid fossa to a line perpendicular to the scapular spine, drawn through the syncline of the suprascapular notch.

Once the patient agrees to participate and signs the Informed Consent Form, the PI or designee will complete the Patient Demographic Form. Patients will follow-up at the 2, 6, 12, and 24 and 52 week clinic visits (standard of care). During each clinic visit, muscular strength and functional status will be assessed, the latter with validated outcome questionnaires included in the Patient Outcomes Form. Plain film radiographic assessment of the lesions will take place at 2, 6, 12, 24 and 52 week visits (standard of care). Films will be quantitatively assessed to catalog any interval change in the osseous derangement and document radiographic union. Patients will not be required to perform additional follow-up visits outside the standard of care for their fracture. Patients will complete the Patient Outcomes Form at each clinic visit. The Data Collection Grid easily highlights patient visits, data collection, and the x-rays series. The study does not involve any experimental or invasive interventions.

The three validated outcomes forms the patient will be required to complete are the DASH (Disability of the Arm shoulder and Hand), the SFMA (Short Musculoskeletal Form Assessment), and the ASES (American Shoulder and Elbow Surgeon's form). The ASES form is standard of care in approaching the immediate care and follow-up for scapular fracture patients, which includes both glenoid neck fractures and scapular body fractures. This validated outcome measure has been shown to have utility in evaluating changes in forelimb function over time. The DASH and SFMA are validated function outcome scores that will be part of the research protocol. They may be of value in determining the presence and/or magnitude of functional and quality of life differences between scapula fracture and glenoid neck fracture patients. These are more specific measures than the ASES and are frequently used in research protocols.

All measurements obtained from imaging will be based on radiographs that are necessary for standard of care. Following the standard of care follow-up appointments, radiographs will be scheduled for 2, 6, 12, 24 and 52 weeks as defined on the data collection grid and forms. Following standard of care, if there are radiographic signs of osseous union any remaining scheduled films will not be obtained at the follow-up appointments. For instance, a healthy person will likely heal their glenoid neck fracture by 12 wks. In this case, the scheduled films for 24 and 52 weeks will not be obtained. During the initial trauma work-up, optional CT scans and imaging of the affected regions will be obtained as per appropriate trauma protocol.

At the present time, the magnitude of difference that may be observed in both the outcome measures and radiographic characterization is unknown. Furthermore, there are no analogous studies in the literature from which to extrapolate an estimation of power. We plan to enroll 50 patients within the above-outlined context, with an enrollment horizon of a maximum of two years. With a scheduled follow-up evaluation period of one year, the proposed study timeframe is projected to be three years.

The following measures will be used by each site to enhance the likelihood of complete follow-up:

* The patient will provide the name and address of their primary care physician, and the name, address and phone number of two people at different addresses with whom the patient does not live who are likely to be aware of the patient’s whereabouts. The research coordinator will confirm that these numbers are accurate prior to the patient’s discharge from hospital.
* Participants will discuss in detail treatment of scapula fractures, complications and the potential treatment effects, and motivation for adherence with follow up visits and research protocols.
* Patients will receive reminders for upcoming clinic visits from local study personnel.
* Follow up schedules will coincide with normal clinic visits.
* Study personnel will contact patients no less frequently than once every three months to maintain contact and obtain information about any planned change in residence.
* If a patient refuses to return for a follow up assessment, his/her status will be determined by phone contact with the patient or the patient's family physician and outcome forms may be completed and returned.

**Sample Size**

Sample Size: 50

At the present time, there are no precedents in the literature from which to gauge a power analysis for either the radiographic measurements or functional outcomes. Therefore, this is in essence a pilot study.

Since this is a pilot study, we have no set expectation for the exact number of total patients to enroll. Based on our patterns of trauma experience, we believe that a total of 50 scapula fractures is a reasonable expectation. This total includes both body and glenoid neck fracture subgroups. We expect that more scapular body than glenoid neck fractures to present and be included in the study, again based on institutional experience.

**Data Analysis**

This is a prospective study for which there is no precedent outcome data in the available literature. The scapular fractures will thus be considered a cohort comprised of two a priori subgroups (scapular body and glenoid neck) which we believe may be functional different and thus we are leaving open the possibility that they will show a difference. We will analyze scapular fractures as a group for functional outcomes and compare the outcomes of scapular body against glenoid neck fractures. We will also attempt to correlate the degree of osseous derangement of a fracture as measured on radiographs with the scores on the 3 respective outcome measures and clinical extremity testing.

Direct measurement of radiographs will take place at the time of initial presentation and at the scheduled follow-up visits. The values will be recorded either as absolute values or ratios to the contralateral extremity. Patients will be evaluated for functional outcome via the DASH/SMF/ASES at scheduled follow-up visits.

Gross comparison of the degree of osseous derangement of the glenohumeral joint to functional outcome will take place. With multiple variables being examined on each side of the analysis, the first step will be to consider the existent data and define a single variable of interest. This will likely involve a separate consideration of the three radiographic injury parameters to the observed functional outcomes; the latter being considered as a continuous variable. Student-t, Chi-squared and analysis of variance will be used to evaluate continuous variables, proportions and multiple variables respectively. The glenoid neck injured group will then be compared in aggregate against those patients sustaining a scapular body fracture in terms of strength and validated functional outcome scores. Both cohorts will have the putatively uninjured contralateral extremity examined for strength.

**Potential Risks/Discomforts**

This is a prospective, observational study and the risks are the same whether or not the patient decides to participate. Shoulder pain and stiffness is a common discomforts associated with this injury. Follow-up care is recommended for this injury because of the possibility of long-term complications such as bursitis and posttraumatic arthritis.

Patients who decide to participate will be asked to complete three questionnaires that will take approximately 15 minutes to complete. These questionnaires will be required during initial hospitalization at the 2, 6, 12, 24 and 52 week follow-up visits.

The Data Safety Monitoring Plan (DSMP) will involve the PI and co-investigators to monitor adverse events and report on any safety findings patient enrollment is met. It is unlikely that any findings will cause the study to stop as all patients are being treated within standard of care for their injuries.

**Potential Benefits**

There is no direct benefit anticipated for participants. The benefit is directly related to future standard of care for glenoid neck fractures

There is potential benefit to society as baseline information on outcomes may identify a group of patients in whom we are currently not obtaining good results, potentially leading to improvement.

**Discuss the risk-to-benefit ratio.**

There is reason to believe that surgery may be beneficial to some patients with glenoid neck fractures that are currently being treated non-operatively. This study will help identify which patients (if any) may benefit from surgery. The data collected could also be used for a sample size calculation in an RCT. Because the risks to patients participation in this study are no different than those not participating, the benefits outweigh the potential risks.

**Recruitment**

Patients will be not be recruited, but rather, evaluated for eligibility as they present as trauma patients to our institution. Each scapula fracture will be evaluated, at time of presentation, against the inclusion/exclusion criteria using the criteria on the Inclusion/Exclusion Form. For instance, in patients with shoulder or arm fractures resulting in forelimb instability, surgery will be indicated and patient will not be eligible for inclusion. Patients meeting criteria will be approached as a potential study participant and given the Informed Consent Form.

**Consent Procedures**

Once the PI or designee has determined that the patient is eligible for the study and explained to the patient that the options for treatment, the patient will be informed of the possible procedures. Upon this review, the patient will then be informed about the research study examining the outcomes of their fracture and asked if he or she wants to participate. The common procedures are discussed and patients are informed that at this time a study is being done to more carefully evaluate the function outcome of this injury. Patients are informed that they are eligible to participate in this study and informed of the risks and benefits associated with their participation. Patients willing to consider participating are asked to review a formal Informed Consent Form. Patients are then given the opportunity to have any additional questions addressed. Patients will be informed that their decision to participate has no bearing on the course or quality of their care. Informed consent will be obtained by either the PI or designee prior to any study procedures being performed.

**Confidentiality**

The same strict adherence to ethical and legal confidentiality which is applied by clinicians treating patients with scapular fractures will be applied to the study patients. All data collected will remain confidential. Sources of protective health information (PHI) that will be used in this study include: hospital/medical records; physician/clinic records; radiology results; and interviews/questionnaires. Every effort will be taken to protect the names and PHI of the participants in this study. Patients will be required to give their authorization and sign an informed consent in order to participate. The research team will only use and share the information as it pertains to the study. Research data will be kept by the research coordinator or nurse who coordinates patient follow-up appointments. This data will be kept at the individual sites in accordance with their IRB approved procedures. De-identified data will be transferred to the data coordinating center (Harborview Medical Center, Seattle WA) Data will be transferred either via secured fax, secured email, or secured FTP accessible only to the data coordinating staff and the individual site. Data will ultimately be analyzed with a password protected computer program, but no identifying information will be included. Data will be stored for at least 3 years after the study closes. All data will be destroyed 3 years after the study closes unless the PI determines that the data needs to be kept longer for research/analysis purposes. If so, the PI will make the appropriate IRB amendment with justification.

No identifiable data will be available to anyone outside the local PI and study staff.

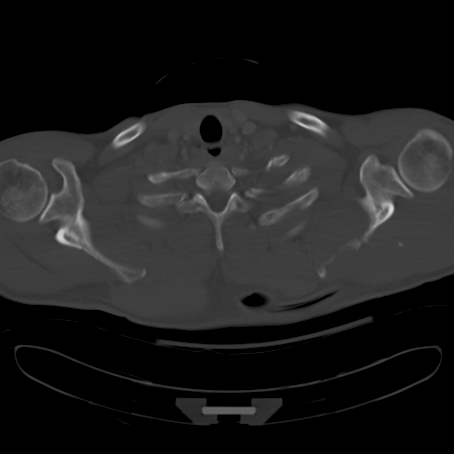
The patient demographics form is the only form that will contain identifiable information. This information is necessary to determine potential confounders (age, gender, etc.) and to provide information necessary for follow-up. This identifying information is maintained by the local site.

After the patient completes this form, the PI or research nurse will assign the patient a unique study ID (BMC001, BMC002, etc). This study number will be used on all subsequent forms. The master key to link ID with the demographics form will be kept in accordance with local IRB approved policy.

**Radiograph Measurement Protocol**

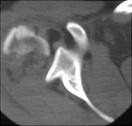
1. Glenoid medialization as measured on chest CT.

Taken as the distance from the lateral aspect of the base of the coracoid to the midline of the body on chest CT. The CT cut at the mid portion of the coracoid was found and used for measuring glenoid medialization, with each side being measured on different CT cuts if necessary. The distance between the anterior corner of the glenoid, where it joins the coracoid was identified. The perpendicular distance between this point and the midline of the body was measured for both the injured and non-injured shoulders. As shown below, the distance is measured as a perpendicular between the point identified at the tip of the arrow and the while line bisecting the midline of the body. Note that in this patient the distances for the right and left scapulae will be measured on different cuts.



2. Scapular shortening as measured on chest CT.

The distance from center of glenoid to medial border of scapula. The CT cut at the mid portion of the glenoid was identified for both scapulae, taking different cuts for left and right if necessary. The distance from the center of the glenoid on this cut and the medial corner of the scapular body, along the line of the scapula was measured. As shown below, this distance will be the distance indicated by the red line.



3. At designated follow-up visits, as stipulated on the Grid Form, both supine and standing plain radiographs of the affected extremity will be obtained in the AP plane (coronal) and the plane of the scapula (30 degrees off coronal). Glenoid medialization and/or displacement will be assessed in both positions.

4. Glenopolar angle as measured on AP shoulder radiograph in the scapular plane. The GPA is the angle between the line connecting the most cranial with the most caudal point of the glenoid cavity and the line connecting the most cranial point of the glenoid cavity with the most caudal point of the scapular body.

