

A MULTICENTER PROSPECTIVE COHORT STUDY OF SACRAL FRACTURES USING PATIENT BASED AND OBJECTIVE OUTCOMES.

Scientific Aims

There is wide variation in the current treatment of pelvic ring trauma. This divergence in practice patterns includes the use of either operative or non-operative care for the same fractures. Sacral fractures are the most commonly observed posterior pelvic ring injury and comprise up to 75% of cases reported at most institutions. The optimal and appropriate treatment of these fractures is vigorously debated despite the common goal of improving patient outcomes. While significant posterior pelvic displacement is universally considered an appropriate operative indication in healthy individuals, the threshold for “significant” is poorly defined and difficult to accurately measure. Further, lesser and minimal displacement patterns are currently being treated operatively and non-operatively, depending on the institution and the experience of the surgeon, and without adequate guidelines. This lack of consensus in the treatment of sacral fractures is due to a poor understanding of patient outcomes following operative and non-operative treatment, a poor understanding of how the morbidities associated with a specific treatment affect patient outcome, and a lack of data that allows any meaningful comparison of operative and non-operative treatment.

The purpose of this study is to define the patient-based and radiographic outcomes of sacral fractures based on injury pattern, fracture displacement, and treatment method. We anticipate that minimally displaced fractures will be treated non-operatively and significantly displaced fractures will be treated operatively by most centers. There will also be a group of patients with displacements that are treated operatively or non-operatively by different surgeons. We will document the outcomes for all three groups, and compare the outcomes of operative and non-operative management for the middle (overlap) group. This will aid the orthopaedist in determining the best treatment course for those patients based on displacement. Fourteen centers have agreed to participate with four already actively recruiting. The prospective evaluation will gather specific data points on mechanism of injury, displacements, position at union, and disease specific and general health outcomes.

Null hypothesis: We note that a null hypothesis is most effective with a comparison study. With the understanding that this is an observational cohort study, we have two purposes that we phrase as null hypotheses:

Hypothesis #1: Patient two year outcomes will demonstrate significant impairment compared with their initial baseline scores.

Hypothesis #2: In the group of patients with similar displacements, those treated operatively will have the same patient based outcomes as those treated non-operatively.

Background and Significance

Historically, neurologically intact patients with limited soft-tissue compromise and a stable pelvis have been treated non-surgically. Major functional limitations appear to be related to associated neurological, urological, and other injuries not directly attributable to the pelvic ring disruption. Some sacral fractures with minimal displacement may be subjected to an unnecessary

operative procedure while some unstable patterns may be erroneously treated non-operatively resulting in secondary displacement. Defining the natural history of subgroups of patients with apparently stable pelvic injury patterns will help to define the effect and appropriateness of interventions currently used in treatment of these injuries.

Aside from a retrospective study of Denis et al, long-term outcomes data are limited. The cohorts studied are small, with considerable selection bias, variable timing of surgery, and poor documentation of the neurologic injury (Kim). The incidence of infection for operatively treated fractures varies from 5 to 50%. Neurologic deterioration ranges from 2 to 5% and may result from compression of sacral fracture fragments. Fracture union is usually achieved in 85 to 90% of patients but residual pain is present in approximately 30% (Sabiston, Schmidek).

Templeman et al reviewed 30 patients with displaced sacral fractures and noted open reduction and iliosacral screw fixation leads to better reduction of the fracture than closed reduction and percutaneous fixation, the presence of a neurologic injury is the most important predictor of compromised outcome.

Zelle et al measured the effect of neurologic decompression on the extent of residual neurological injury. Patients were assessed at an average follow-up of 27 months. Patients undergoing surgical decompression had a significantly better neurological improvement as measured by the modified SOFCOT Index, and patients undergoing surgical decompression had a significantly better physical function than the patients that were managed without surgical decompression, as measured by the SF-36. The authors concluded that neurological decompression appears a useful part of treatment.

Totterman et al reported on 31 patients with displaced sacral fractures treated surgically. Fifteen months after injury, 65% of the patients had regained independence in functions pertaining to daily activities, 33% had returned to work. Polytrauma and impairments relative to voiding and sexual function had a detrimental effect on outcome. Fracture characteristics were not predictive of poor outcome.

Wright et al evaluated sexual and excretory dysfunction one year after pelvic fracture. Sexual limitations and excretory dysfunction were defined by the Functional Capacity Index. Health related quality of life was determined using SF-36. The relationship between specific fracture patterns and dysfunction along with the effect of dysfunction on quality of life in patients with pelvic fracture were evaluated. Of 1,160 eligible patients 292(26%) had pelvic fractures. Sexual dysfunction was reported in 21 vs. 14 % of those with vs. without pelvic fractures and bowel or bladder incontinence was reported in 8 vs. 4%. Men with sacroiliac fractures were at higher risk for sexual and excretory dysfunction. In women symphyseal diastasis was associated with sexual and excretory dysfunction. Of patients with pelvic fractures men with sexual dysfunction and women with excretory dysfunction had significantly worse quality of life than those without dysfunction.

Method

This project is a prospective observational cohort study of all unilateral sacral fractures seen across multiple centers. With comparisons of outcomes for similar injuries being performed a priori after the study is complete. To answer aim #1, we will report on the patient based and VAS scores of all patients over time. To answer aim #2, we will be seeking the overlap group of patients with the same displacements who were treated either operatively or non-operatively. We will compare radiographic and patient based outcomes for this group of patients. These will be compared using a T test with an alpha of 0.05 set as significant. Corrections will be made for multiple evaluations over time. All patients will follow the same postoperative protocol if possible based on additional injuries.

Radiographic data

The anatomic location of all fractures, the displacement of each injury on the three standard pelvic radiographs including ischial height to represent flexion, and the sacral displacement will be recorded. The initial CT scan will be used to record the specific sacral displacement in mm for anterior and posterior gapping and impaction, translation, and rotation (based on the quadrilateral surface). CT studies will be de-identified, and centralized at one location (University of Michigan Hospitals). Post injury measurements will be recorded through union. Injury CT's and plain films at union will form the basis of the anatomic outcomes. The initial displacements as measured on the CT's will be standardized by referencing from the S1 body to remove rotation and tilt as co-variables. See Appendix A for data collection instructions.

Patient based outcomes

Baseline information will be obtained during the initial hospitalization. The Majeed pelvic score, the SMFA, and a visual analog scale for pain will be utilized. The VAS will be obtained within the first 24 hours, at 1 week, at 3 weeks, and at 6 weeks in addition to all follow-ups. The validated outcome scores will be obtained at the initial hospitalization, the 3-month, 6 month, 12 month, and the 24-month follow-up. The 24 month follow-up is optional.

Follow-up clinical evaluation

A standardized physical exam will be obtained documenting assistive device use, walking ability, hip motion and strength at 6 weeks, 3, 6, 12, and 24 months. The 24 month follow-up is optional. The time to ambulation, defined as the ability of the patient to ambulate with or without assistive devices will be captured.

Sample Size

The long-term goal of the study will be to enroll and follow 1000 pelvic fractures. As approximately 75% of all pelvic injuries are minimally displaced, an a priori subgroup analysis of operative vs. non-operative treatment is possible. Although all scores including the VAS will be compared, data on VAS is not available to calculate the number needed to study. Using the Majeed score, assuming an average score of 87 (Majeed, 1989), and a standard deviation of 20, a two tailed alpha of 0.05 and a power of 80%, approximately 100 patients would be needed to see a 7 point difference in outcome. We are basing our analysis on this number for the subgroup analysis. We anticipate that less than half of the "minimally" displaced fractures will be treated operatively, thus we plan to enroll a minimum of 500 minimally displaced fractures in order to

reach the needed power. Additionally, the correction needed to define a difference in VAS, etc will be required due to multiple evaluations and greater numbers will aid in finding a difference if one exists. Finally, multiple trauma patients will be analyzed for homogeneity prior to including them in the overall results.

Outcomes will be reported separately for the various outcome scores. Comparisons will be made between “displaced” fractures and “minimally” displaced fractures, and within the “minimally” displaced group, operative and non-operative will be compared.

Inclusion criteria

Inclusion criteria will be all patients 18 - 80 years of age with unilateral sacral fractures.

Exclusion criteria

Patients unable to comply with outcome measures, prisoners, those with APC injuries, symphysis dislocations, or Zone 3 sacral fractures, displaced acetabular fracture those unable to comply with follow-up, and patients who were non-ambulatory prior to injury will be excluded.

Recruitment

Patients will be not be recruited, but rather, evaluated for eligibility as they present as trauma patients to each institution. Each sacral fracture will be evaluated, at time of presentation, against the inclusion/exclusion criteria using the criteria on the Inclusion/Exclusion Form. Patients meeting criteria will be approached as a potential study participant and given the Informed Consent Form. Patients who sign the consent form will be followed for 2 years (standard of care). A screening record from patients that do not meet criteria or patients that meet criteria but do not consent will be kept. There will be no PHI collected on this form and will be completely anonymous.

The following standard of care procedures will take place: Radiographic evaluation and physical examination will be recorded prospectively.

The following forms are research and may not be standard of care: Patient based outcomes: Baseline information on each awake and alert patient will be obtained during their initial hospitalization. The Majeed pelvic score, the short Musculoskeletal Functional Assessment (SMFA), and a visual analog scale for pain (0-10) will be used. The VAS pain will be obtained pre-treatment (retrospective pain), within the first 24 hours post-op for operative patients and the first 24hrs after diagnosis for the non-operative patients, at 7-10days, and at 21 +/- days (by mail or phone option) in addition to all scheduled follow-up visits. The validated outcome scores will be obtained at the initial hospitalization, the 3 month, 6 month, and 12 month, and if available, the 24 month follow-up visit.

The total study duration, including data analysis, will last 4 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 unilateral sacral 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.

Patient Population

Age range: 18-80

Sex: Male and Female

Ethnicity: Representative of site's patient population

Health Status: Representative of site's patient population

Confidentiality

The same strict adherence to ethical and legal confidentiality which is applied by clinicians treating patients with sacral 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 information 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.

Data Analysis

We plan to report descriptive data for all injuries based on initial displacement. A comparison will be done (student T) on the patient based outcome scores for the patients treated operatively vs. non-operatively given same displacements.

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. There are no findings that will cause the study to stop as all patients are being treated within standard of care for their injuries and the research component is limited to the patient outcome questionnaires.

Funding Source

OTA has provided funding for 138 patients. Subcontracts will be issued to all sites through the University of Washington.

Authorship

The PI at each site will be asked to identify one person who qualifies for authorship from that site. If the site PI feels that more than one person has met the criteria for authorship the site PI may apply to Dr. Tornetta for an additional site member to be listed as an author on any manuscript using this data.

Appendix A

Radiographic Evaluation Form

01. AP

- a. Iliac wing height difference
- b. Sacral height difference (vertical displacement)
- c. Sacral width difference
- d. Ischial height difference
- e. Injured side ring width
- f. Uninjured side ring width

02. Inlet

- a. Zone: Same
- b. Posterior displacement (sacrum)
- c. Posterior displacement (ilium)
- d. Injured width sacrum
- e. Uninjured width sacrum

- f. Injured width pelvic ring
- g. Uninjured width pelvic ring

01. Outlet

- a. Sacral displacement (superior)
- b. Iliac wing difference (superior)
- c. Ischial height difference (superior)

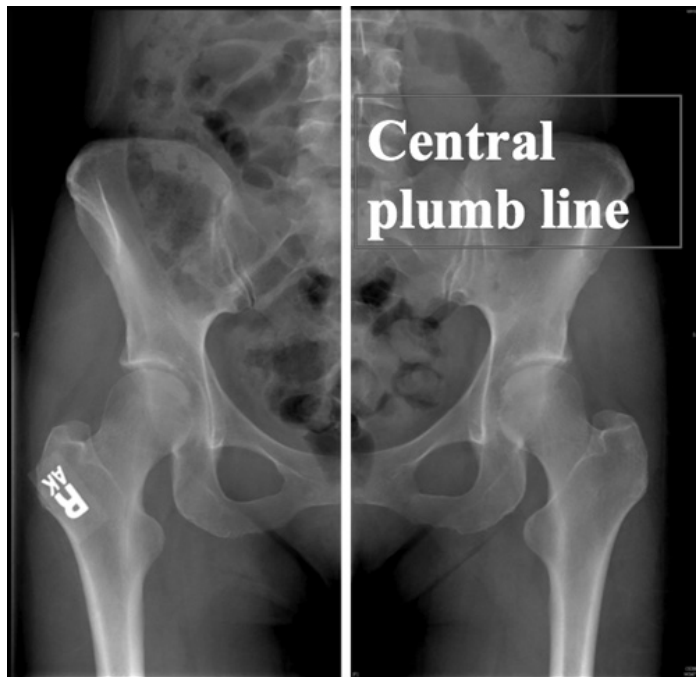
Plain Radiographs (AP, inlet, outlet)

The plain film radiographic evaluation data will be obtained from the AP, Outlet, and Inlet radiographs. From the AP view, the vertical displacement of the sacrum, the ischial height difference, and the injured and uninjured side ring width will be obtained. From the outlet view, the superior displacement of the sacrum and the ischial height difference will be recorded. From the inlet view, the posterior displacement of the sacrum, the posterior displacement of the ilium, and injured and uninjured width will be recorded. The Zone of the sacrum that was involved will be recorded on both the inlet view as well as the CT scan. Inlet and outlet at 6 months will be obtained only if change in reduction.

CT Scans

On the CT scan, the width of the injured side (measured from the midline to the lateral border of the sacrum) as well as the uninjured width should be recorded. The anterior cortex of the sacrum will be recorded as compressed, distracted, comminuted, or non-displaced. The posterior cortex of the sacrum will be recorded as incomplete, or complete and displaced or non-displaced. The translation (in the AP direction) will be recorded in millimeters. The A to P sacral depth at the narrowest portion of the sacrum will be recorded as well (this will allow future recording of a ratio). Finally, at the level of the quadrilateral surface of the acetabulum, the angulation of the acetabulum will be measured. This can be obtained on the PACS system or on a plain radiograph by correcting for any rotation of the patient in the scanner and measuring the relative rotation of the tangent of the quadrilateral surface and comparing this to a midline line (that is vertical). The number of degrees of internal or external rotation of each side is recorded.

To assist with the understanding of these lines, a sequential series of radiographs on the AP view will be demonstrated. First, a central plumb line is drawn that closely approximates the midline on a non-rotated AP view:



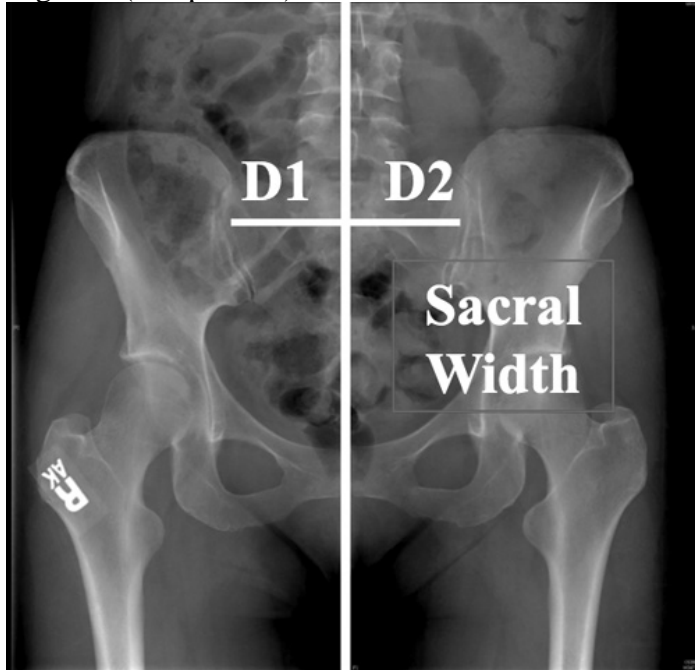
Next, a line is drawn perpendicular to this line at the top of the iliac wing on both the injured and uninjured sides. The difference between these two lines will be used to record the iliac wing height difference. Cephalad displacement will be positive, and caudal displacement will be negative.



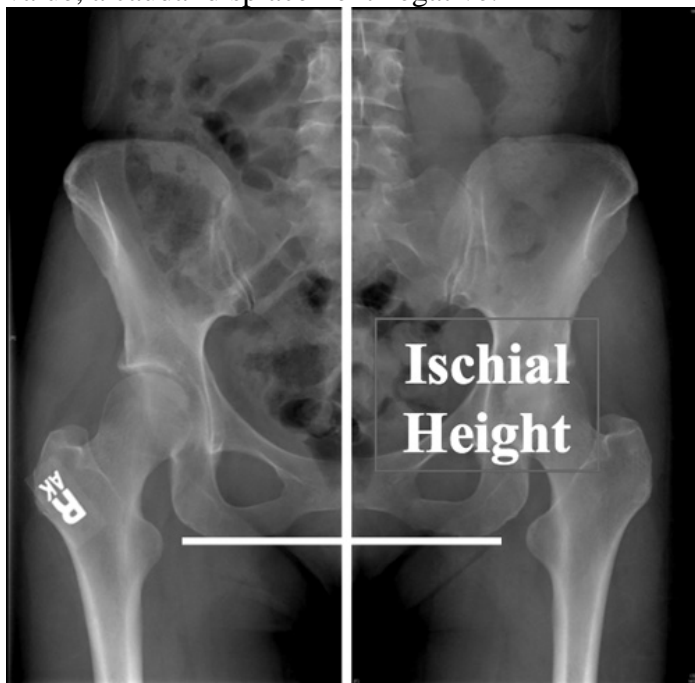
A line is then drawn perpendicular to the plumb line at the top of the sacrum on the injured and uninjured sides. The difference will be recorded as the vertical displacement of the sacrum. Cephalad displacement will be positive, and caudal displacement will be negative.



Next, the sacral width will be measured using lines perpendicular to the plumb line and extending to the widest portion of the sacrum. The difference between the two measurements will be used to calculate the sacral width. Increased values at the injured side (relative to the uninjured side) will be positive values (distracted), decreased values at the injured side will be negative (compressed).



Next, a line perpendicular to the plumb line along the lower border of the ischium will be used to calculate the ischial height difference. A cephalad displacement will be considered a positive value, a caudal displacement negative.



Finally, a perpendicular line will be drawn at the widest portion of the pelvis, corresponding to the pelvic brim proximal to the acetabulum. This will be used to calculate the injured and uninjured side ring width; both values will be recorded.



This is an example of all of the lines drawn on a AP view.



On the Inlet View: the posterior displacement of both the sacrum and ilium will be recorded and compared to the uninjured side. A posterior displacement will be positive, and an anterior displacement will be negative. The injured and uninjured width will be recorded at the sacrum (at the anterior SI joint) and of the pelvis (at the widest portion).



On the Outlet View: cranial displacement of the sacrum, the iliac wing, and the ischial tuberosity will be recorded. The sacrum will be measured at the lateral sacral ala. Again, cranial displacement if positive.



Background References:

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