University of Maryland, Shock Trauma Center
Department of Orthopaedics

The Effects of SI Screw Removal on Patient-Reported Pain and Functional Outcomes After Open or Closed Reduction and Internal Fixation of Pelvic Fractures

IRB Number: HP-00063838

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Safety Monitor: Andrew Pollak, MD

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PROTOCOL SUMMARY

Title	The Effect of SI Screw Removal on Patient-Reported Pain and Functional Outcomes After Open or Closed Reduction and Internal Fixation of Pelvic Fractures
Short Title	SI Screws
Type of Study	Observational outcomes study and prospective randomized control trial (if applicable based on participant pain at 6-month follow-up)
Primary Objective	To determine if removing SI Screws 6 – 9 months post SI screw stabilization surgery in pelvic fractures decreases patient reported pain at 12 months post SI screw stabilization surgery compared to the SI screws remaining in place
Secondary Objective	To explore associations between treatment and: 1. Patient reported pain up to 24 months post SI screw stabilization surgery 2. Narcotic use up to 24 months post SI screw stabilization surgery 3. Work productivity & activity impairment up to 24 months post SI screw stabilization surgery 4. Health related quality of life up to 24 months post SI screw stabilization surgery 5. Pelvic specific functional outcome up to 24 months post SI screw stabilization surgery 6. Surgical-related complications
Sample Size	We will recruit a sample size of 450 observational patients, of which, approximately 150 (75 per arm) will be enrolled in the randomized arm of the study with a 12 month follow-up for the primary outcome
Diagnosis and Main Inclusion Criteria	Pelvic fracture requiring SI screw placement in patients between the ages of 18 and 80 years of age, inclusive
Length of Follow-up	24 months

Study duration: We will recruit for two and a half years. Patients will be followed for 24 months. We estimate 6 years total.

Primary outcome measure: *Patient-reported pain* as measured by using the arithmetic mean of the four pain severity items on the patient-reported Brief Pain Inventory assessment (BPI) 12 months following the patient's injury.

Secondary outcome measures:. *Pelvic function* will be measured using the Majeed Pelvic Score.

Statistical analysis: We are interested in estimating the causal effect of removal versus non-removal of SI screws in pelvic fracture patients requiring the use of SI screws for stabilization. For all our analyses, we will report estimates of the causal effects, standard errors, and confidence intervals. We will also report the results of tests of null hypothesis of no causal effect.

KEY ROLES

Safety Monitor- Dr. Andrew Pollak will be responsible for overseeing patient safety for the study. Dr. Pollak will review the enrollment numbers, adverse events, and medical compliance annually for the duration of the study.

Principle & Sub-Investigators- Dr. Marcus Sciadini (PI) and the sub-investigators will be responsible for developing a detailed study protocol, providing oversight on study progress and act to correct deficiencies in the conduct of the study. The PI and sub-investigators will also draft the main publications related to the study, and assist with patient consent.

Research Coordinator- Haley Demyanovich, research specialists, are responsible for maintaining all study documentation, developing and maintaining the master IRB application and consent, circulating any changes to study documents including protocols, case report forms, and IRB materials to the research team members, providing daily oversight and management of study implementation, performing data quality control and analysis of study results, and conducting monthly reports for the study.

Research Team Members- The research team members are responsible for the conduct of the clinical study including patient enrollment, performing study procedures, data collection and conducting study follow-up visits.

BACKGROUND INFORMATION

Chronic pain following surgical stabilization of a pelvic fracture is very prominent and can have a major effect on a patient's quality of life. Persistent pain after radiographic evidence of fracture union commonly leads to implant removal. But, the routine removal of orthopaedic fixation devices after fracture healing remains an issue of debate. Many surgeons remember patients whose intractable, hardly explainable local symptoms and complaints resolved quickly after the procedure. However, implant removal requires a second surgical procedure in scarred tissue, poses a risk for nerve damage, infection and re-fractures, and is not a guarantee of pain relief.

Rates of implant removal vary based on anatomic location and implant selection. Many studies have introduced and assessed the outcomes of hardware removal in the ankle, tibia and femur. But, there is currently no controlled trial that assesses the benefits and harms of SI screw removal in pelvic fracture patients.

RATIONALE

Reports in literature are not consistent concerning the incidence of painful hardware and the outcome and pain relief after hardware removal. There is conflicting evidence that removing hardware decreases acute pain in ankle, tibia, and femur fractures but there is a need to explore the effect of SI screw removal in pelvic fracture patients. We propose to observe patients requiring SI screw stabilization surgery for 24 months. At 6 months post SI screw stabilization surgery, if the patient reports any pain associated with his/her pelvic injury, they will be asked to enroll in the randomized arm of the study that allows us to prospectively randomize patients to removal versus non-removal of SI screws and track which group has less pain and need for narcotic pain medications.

POTENTIAL RISKS

While the intake questionnaire and information gathered is of a sensitive nature (pain, narcotic use and medical history) and it might cause the patient some discomfort to answer truthfully, all information will be kept confidential and no identifiers will be used in publication.

While every attempt will be made to keep all information confidential and the master link between the patient study number and personal identifiers will be destroyed at the completion of the study, there remains a risk of

the potential for the loss/breach of confidentiality. This risk will be minimized by storing all paper questionnaires in a secure, locked location and all electronic data will be password protected.

If the patient enrolled in the randomized arm of the study and is randomized to the screw removal treatment, he/she will be exposed to all of the risks associated with surgery under a general anesthetic including but not limited to: prolonged intubation, heart attack, stroke and death. These risks are extremely rare and will be explained by the anesthesia team, and a separate anesthesia consent will be obtained. The risks of the surgical procedure are rare but include: infection, wound break down, re-fracture, and neurologic injury. A separate surgical consent will be provided to go into more detail of the risks of the procedure.

There may be risks in this study which are not yet known.

POTENTIAL BENEFITS

While there are no direct benefits to patients participating in the study (except for those that may accrue from closer clinical observation as a study patient), participation may help determine the best treatment for pelvic fractures requiring SI screw stabilization in the future. This study also provides a potential benefit of decreased pelvic pain levels.

PRIMARY OBJECTIVE

To compare 12 month assessments of patient reported pain of participants undergoing SI screw removal versus non-removal treatment following a pelvic fracture requiring SI screw stabilization. We hypothesize that there will be a decrease in the Visual Analog Scale (VAS) pain scores in the SI screw removal group as compared to the non-removal group at the patient's 12 month follow-up and beyond.

SECONDARY OBJECTIVES

To compare assessments of narcotic use up to 24 months post SI screw stabilization surgery of participants undergoing SI screw removal versus non-removal treatment following a pelvic fracture requiring SI screw stabilization. We hypothesize that there will be a decrease in the narcotic requirements in the SI screw removal group as compared to the non-removal group throughout the 24 month follow up and beyond.

EXPLORATORY OBJECTIVES

To explore associations between treatment and:

1. Work productivity and activity impairment up to 24 months post SI screw stabilization surgery
2. Health related quality of life up to 24 months post SI screw stabilization surgery
3. Pelvic specific functional outcome up to 24 months post SI screw stabilization surgery
4. Surgical-related complications.

DESCRIPTION OF THE STUDY DESIGN

The SI Screw study is an observational study in which patients will be asked to enroll during a clinical

appointment following a pelvic fracture requiring SI screw stabilization surgery. At 6 months post SI screw stabilization surgery, if the patient reports any pain associated with his/her pelvic injury, they will be approached at that time to consent in the randomized arm of the study that allows us to prospectively randomize patients to removal versus non-removal of SI screws. If the patient does not agree to randomization, the patient will continue to be tracked in the observational arm of the study and will choose SI screw removal or non-screw removal treatment for themselves based on personal preference and discussion with his/her surgeon.

A total of 450 patients will be enrolled in the observational arm of the study. Of the 450 observational arm patients, approximately 150 (75 per arm) will be enrolled in the randomized arm of the study. All patients will be recruited from University of Maryland, Shock Trauma Center.

A schematic representation of participant enrollment can be found in the figure below.

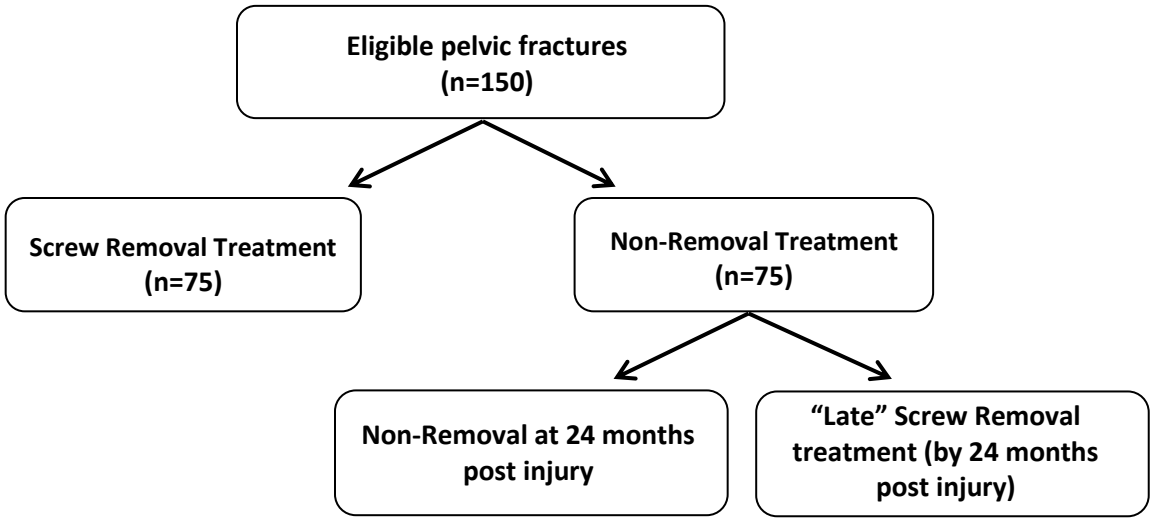

Figure: Participant Enrollment

At time of enrollment, participants will be asked to provide basic demographic information, health status and function prior to injury. Study injury characteristics will be obtained from the surgeon and the participant's medical record.

Participants will be prospectively followed at 6 months, 9 months, 12 months, 18 months, and 24 months post SI screw stabilization surgery. All follow-ups will occur in person at the hospital clinic follow-ups or over the phone and will consist of both a clinical examination (when applicable) and interview.

PRIMARY ENDPOINT

The primary endpoint is *patient reported pain severity* as measured by the Brief Pain Inventory assessment (BPI). The BPI is a 15-item questionnaire that assesses the severity of pain, the impact of pain on daily function, the location of pain, pain medications and the amount of pain relief. There is no scoring algorithm but the arithmetic mean of the four severity items can be used as a measure of pain severity and the arithmetic mean of the seven interference items can be used as a measure of pain interference. This assessment has been chosen because it is a short, reliable, patient reported assessment of pain that has been specifically designed for and validated in patients with pain from acute conditions such as postoperative pain.

SECONDARY ENDPOINTS

The secondary endpoints include:

1. *Patient reported pelvic function*. This will be measured using the Majeed Pelvic Score. The Majeed Pelvic Score uses five criteria chosen for functional assessment after major pelvic fractures: pain, standing, sitting, sexual intercourse and performance at work. Each of these clinical parameters is scored, the total being a maximum of 100 points for patients who were working before the injury and 80 points for those who were not. The five sections of the assessment are scored as shown in Table I and discussed below.
   Pain. Pain is an important sequel of major pelvic injury, and is given a score of 30 points, allocated according to the six grades listed in Table I. **Standing**. Weight-bearing in the erect position is given 36 points, in three main categories (aids, gait and walking ability), each of which has six grades. **Sitting**. Sitting is an important function in relation to the pelvis, but less so than gait or walking ability. A total score of 10 points is given in four grades. **Sexual intercourse**. For both men and women, four points are allocated for comfort during sexual intercourse. This does not take account of neurological or psychological impotence and is recorded in four grades. If, for any reason, sexual intercourse has not been attempted, a score of four points is given. **Work**. Work performance is allocated 20 points in five grades, ranging from no regular work to return to the same job as before injury with no loss of performance. A patient who was not working at the time of his injury is not scored; his overall assessment is then out of 80 points.

Table I. System for functional assessment after pelvic fractures

Pain – 30 points	
Intense, continuous at rest	0–5
Intense with activity	10
Tolerable, but limits activity	15
With moderate activity, abolished by rest	20
Mild, intermittent, normal activity	25
Slight, occasional or no pain	30
Work – 20 points	
No regular work	0–4
Light work	8
Change of job	12
Same job, reduced performance	16
Same job, same performance	20
Sitting – 10 points	
Painful	0–4
Painful if prolonged or awkward	6
Uncomfortable	8
Free	10
Sexual intercourse – 4 points	
Painful	0–1
Painful if prolonged or awkward	2
Uncomfortable	3
Free	4

Standing – 36 points	
A Walking aids (12)	
Bedridden or almost	0–2
Wheelchair	4
Two crutches	6
Two sticks	8
One stick	10
No sticks	12
B Gait unaided (12)	
Cannot walk or almost	0–2
Shuffling small steps	4
Gross limp	6
Moderate limp	8
Slight limp	10
Normal	12
C Walking distance (12)	
Bedridden or few metres	0–2
Very limited time and distance	4
Limited with sticks, difficult without prolonged standing possible	6
One hour with a stick limited without	8
One hour without sticks slight pain or limp	10
Normal for age and general condition	12

   The accumulative grading system is shown in Table II. This gives a breakdown into excellent, good, fair and poor for both working and non-working patients.

Table II. Clinical grade based on a score out of 100 points for working and 80 points for non-working patients (see text)

Working before injury	Not working before injury	Grade
>85	>70	Excellent
70 to 84	55 to 69	Good
55 to 69	45 to 54	Fair
<55	<45	Poor

2. *Surgical-related complications* will be determined by patient medical record review and surgeon recall following follow-up clinic appointments.

STUDY POPULATION

The study population will be patients aged 18-80 with a pelvic fracture that required SI screw stabilization.

Inclusion Criteria:

1. The patient is between 18 and 80 years of age, inclusive.
2. The patient has a pelvic fracture that required SI screw stabilization.
3. The patient has reached skeletal maturity.
4. The patient's pelvic fracture is a result of trauma (includes polytraumatized patients).
5. The patient is English-speaking.
6. The patient's surgeon agrees to randomization (the patient is amendable to either SI screw removal or non-screw removal treatment).
7. The patient's pelvic fracture was initially treated at Shock Trauma.
8. The patient is currently experiencing pain associated with his/her pelvic fracture.
9. The patient is able to be randomized between 2 and 8 months post SI screw stabilization surgery at an orthopaedic follow-up appointment.

Exclusion Criteria:

Patients who satisfy any of the following exclusion criteria will be ineligible for enrollment in the study:

1. The patient is non-ambulatory due to an associated spinal cord injury.
2. The patient was non-ambulatory pre-injury.
3. The patient is currently pregnant.
4. The patient is enrolled in another study that does not allow co-enrollment.
5. The patient is likely to have severe problems maintaining follow up.

CO-ENROLLMENT GUIDELINES

If allowed by the local IRB, participants in the SI Screws study may be co-enrolled in other research studies based on the following guidelines:

A. Regardless of whether the participant is enrolled in the randomization arm or the observational arm, the participant may be co-enrolled in any other observational study.
B. If the participant is enrolled in the randomization arm, he or she may only be co-enrolled in up to two additional randomized control trials prior to the completion of the intervention.
C. If the participant is enrolled in the randomization arm, he or she may co-enrolled in any other randomized control trial after the intervention is complete.

D. If the participant is enrolled in the observational arm, he or she may be co-enrolled in any other randomized control trial at any time.

RECRUITMENT

Approximately 150 participants will be enrolled in the study. Patients will be recruited during a standard of care clinic follow-up appointment between 2 and 8 months post SI screw stabilization surgery. Consenting procedures are described in detail in the Study Schedule and Informed Consent Sections of this protocol.

STUDY TREATMENTS

Both treatment options used in the study are within accepted practice and standard of care at this institution. The same resources (pain management, social work, physical therapy, etc.) will be available to study patients as to all trauma patients.

SI Screw Removal Treatment Group
Patients enrolled in the SI screw removal treatment group will be scheduled to undergo screw removal surgery between 5 – 9 months post initial SI screw stabilization. If additional surgery is required or other complications arise, this will be recorded within the study follow-up forms.

Non-SI Screw Removal Treatment Group
Patients enrolled in the non-SI screw removal treatment group will not undergo screw removal surgery. If complications arise and/or surgery is required, crossover will be allowed and recorded within study follow-up forms.

CLINICAL EVALUATION

A summary of the clinical evaluations is outlined below and can also be found in Appendix B.

Medical Record Review
At time of consent, information about the participant (medical history, height and weight, etc.) and the participant's injuries and hospital stay will be collected, including mechanism of injury, date and time of injury, presence of and severity of other orthopaedic and non-orthopaedic injuries, procedures done in the hospital, and SI screw surgery characteristics.

Assessment of Study Injuries
The following information will be obtained via medical record review and surgeon recall at the time of enrollment:

- Type of pelvic fracture
- Side of pelvic fracture
- SI joint displacement at time of SI screw stabilization surgery

Assessment of SI Screw Stabilization Surgery
The following information will be obtained via medical record review and surgeon recall at the time of enrollment:

- Type of fracture reduction
- SI screw placement characteristics

- Type of fracture fixation (if applicable)
- Acetabular fracture characteristics (if applicable)

Assessments at 6 months, 9 months, 12 months, 18 months, and 24 months Post SI Screw Stabilization Surgery

- Complications since last follow-up (type, severity, treatment)
- Assessment of fracture healing
- Weight bearing status and ambulation
- Use of ambulatory devices
- Pain assessment
- Narcotic use assessment

X-rays

AP and lateral x-rays at admission, post SI screw stabilization surgery, and at the 6 month, 9 month, 12 month, 18 month, and 24 month follow-ups will be obtained. These x-rays are obtained per standard of care.

PARTICIPANT INTERVIEWS

A summary of the participant interviews performed are outlined below and can also be found in Appendix D.

Enrollment Interview

At the time enrollment, participants will be asked about the following:

- Age, gender, race and ethnicity, and education
- Smoking history
- Previous injuries (specifically pelvis or back)
- Pain medication usage prior to pelvis injury
- Work and health status prior to pelvis injury
- General and pelvic function prior to pelvis injury

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Follow-up Interviews

At 6 months, 9 months, 12 months, 18 months, and 24 months post SI screw stabilization surgery, participants will be asked about the following:

- Any re-hospitalization or outpatient surgery since the last visit for any reason related to his/her pelvic injury
- Rehabilitation received
- Pain medication usage
- Work Status – Work Productivity and Activity Impairment
- Pain – Brief Pain Inventory
- Health Status – VR-12
- Pelvic Function – Majeed Pelvic Score

STUDY SCHEDULE

Screening and Consent

All patients between the ages of 18 and 80 (inclusive) with pelvic fracture that required SI screw stabilization surgery will be screened for eligibility by the research coordinator or research team members in close coordination with the surgeon investigators. Screening will typically occur at the time of SI screw stabilization surgery and patients will be tracked until valid enrollment period opens (2 to 8 months post SI screw

stabilization surgery). An eligibility checklist form will be completed on every potentially eligible participant and entered onto the electronic data capture system. The treating surgeon will be available via pager to answer questions regarding study eligibility. When the treating surgeon is not available, the study PI will be available to page. Contact information for the PI and alternate contact is available in Appendix A. In most cases, questions should be resolved at this level.

Once eligibility has been confirmed, the informed consent process will be completed by the research coordinator or research team member and attending surgeon. Patients will be approached about potential participation in the study at a standard of care clinic follow-up appointment between 2 and 8 months post SI screw stabilization surgery following determination of eligibility.

Enrollment
Once consented into the study, baseline data regarding participant characteristics, injury characteristics, fracture classification and medical history/co-morbidities will be collected. Characteristics about the hospital course and treatment received will also be collected. A brief interview will be conducted with the participant. All data will be recorded on the paper Case Report Form (CRF) and entered into the electronic data capture system.

Follow-up
Participants will return for follow-up visits at 6 months, 9 months, 12 months, 18 months, and 24 months post SI screw stabilization surgery. Participants will undergo a clinical evaluation by the treating surgeon and be interviewed by the research coordinator or research team member. These visits tend to mirror clinic visits per standard of care, however there may be some circumstances where patients are unwilling to return to the clinic. In these situations the research coordinator or research team member may obtain as much visit data as possible by phone and/or medical record review to prevent loss of important study information. All data will be recorded on the paper Case Report Form (CRF) and entered into the electronic data capture system.

Retention
Every effort will be made to retain participants in the study. We will keep participants engaged through use of study updates during non-study clinic appointments, and reminder calls/letters for upcoming appointment visit window timeframes.

Visit Windows
Each visit will have an interval of time surrounding the ideal date for the visit during which the visit may be completed and the data included in the trial database. This interval is approximately 2 weeks before or after the ideal date for a visit. Study data will still to be collected even if the visit falls out of the ideal window of time.

ASSESSMENT OF SAFETY

The study will monitor all complications and report adverse events to ensure participant safety. All local IRB requirements for reporting adverse events will be met.

The safety monitor (SM) is responsible for providing medical guidance and overseeing participant safety for the study. The SM participates in determining the course of action necessary to meet safety goals and objectives. This is achieved through the review of complications related or possibly related to study treatment, Serious Adverse Event (SAE) reports; resolving safety issues; and interacting with the Principal and Sub-Investigators at each site.

Reportable New Information (RNI)
The following information must be reported to the IRB within FIVE (5) business days of the investigator becoming aware of the information (please note that a separate RNI must be completed and submitted for each problem/event/report):

- Information that indicates a new or increased risk. For example:
  - New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk
  - An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
  - Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in the research protocol
  - Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
  - Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
  - Any changes significantly affecting the conduct of the research
- Any harm experienced by a subject or other individual which in the opinion of the local investigator is unexpected and at least probably related to the Human Research procedures and suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized
  - A harm is "unexpected" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population
  - A harm is "at least probably related to the Human Research procedures" if in the opinion of the local investigator, the research procedures more likely than not caused the harm (greater than 50% probability)
- Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance
- Failure to follow the protocol due to the action or inaction of the investigator or research staff
- Breach of confidentiality
- Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject
- Incarceration of a subject in a study not approved by the IRB to involve prisoners
- Complaint of a subject that cannot be resolved by the research team
- Premature suspension or termination of the research by the sponsor or the investigator
- Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused incidence in the investigational plan or application – including a supplementary plan or application – or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects)
- Audit, inspection, or inquiry by a federal agency
- Written reports of study monitors

Serious Adverse Event (SAE)
Serious Adverse Events may be discovered during regularly scheduled visits or though unscheduled participant contacts between visits. SAEs will be managed according to the medical judgment of the treating physician and source documentation will be maintained (e.g. laboratory and/or radiology reports, clinical notes, discharge summaries). The following are the categories considered for a serious adverse event and must be reported to the IRB during the continuing review process:

- Serious, unexpected, not related

  - Is unexpected, in terms of nature, severity, or frequency, given the research procedures that are described in the protocol and informed consent document and the characteristics of the participants eligible for the study
  - e.g. Death not due to study participation
- Serious, expected, related
  - Is related or possibly related to treatment/procedures under study; possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the study procedures or treatments
- Serious, expected, not related

Study patients who experience an SAE will be followed until resolution of the event and a final report will be submitted to the safety monitor and IRB. Please note that SAE's and RNI's may overlap and a single event may be classified under both conditions.

DATA ANALYSIS

We are interested in estimating the causal effect of removal versus non-removal of SI screws in pelvic fracture patients requiring the use of SI screws for stabilization. Our primary hypothesis is that the SI screw removal group will have lower VAS pain scores compared to the non-SI screw removal group during their outpatient follow-up period. For all our analyses, we will report estimates of the causal effects, standard errors, and confidence intervals. We will also report the results of tests of null hypothesis of no causal effect.

RANDOMIZATION

Eligible patients will be randomized in equal proportions to one of the two treatment groups: 1) SI screw removal, 2) non-SI screw removal. Allocation will be concealed using a centralized 24-hour computerized randomization system, www.randomize.net, that will allow Internet based allocation. The treatment allocation will be stratified on the following prognostic factors to ensure balance between the intervention groups: 1) patient SI joint displacement at the time of injury.

DATA MANAGEMENT

Data will be collected in real time by the study investigators, research coordinator, or research team members, directly on paper Administrative Forms (AFs) or Case Report Forms (CRFs) which will serve as source documents for the study. The study personnel will obtain the information necessary to complete the case report forms (CRFs) from several sources including but not limited to, the patient's medical record, clinical evaluations and patient interviews. These forms will NOT contain the patient's name, SSN, or hospital medical record number; they will be identified only by a unique patient-specific study number. All data requested on the AF or CRF must be completed. Source documents will be signed by the study team member that has reviewed the AF or CRF. An electronic data capture system, REDCap, will be used to store data electronically after paper AF and CRF collection. On the monthly basis, the research coordinator will make a visual check of the data and will query all missing data, implausible data, and inconsistencies.

The REDCap data entry screens will be similar to the paper AFs and CRFs. Data integrity will be enhanced by using the electronic data capture system through a variety of mechanisms for checking data at the time of entry including referential data rules, valid values, range checks, and consistency checks against data already stored in the database. Clinical site personnel will be able to view and modify data for participants recruited from their clinical site only. Each time data is submitted or modified, it will be validated by the research coordinator.

All AFs and CRFs must be kept secure in locked cabinets or other enclosures that are accessible only to study personnel. All electronic data must be password-protected and accessible only to study personnel. Study personnel will be responsible for backing up all electronically submitted data. Hard copy documents containing subject data and patient identifiers (and contact information) will be stored in secure document containers (file cabinets, lockers, drawers, etc.) in accordance with standard document management practices. Paper forms and the files containing personally identifiable data at each site will be destroyed within 5 years of study completion.

Quality control quality assurance procedures will be in place for the duration of the study. Ongoing data edits and internal audits will be performed to ensure collection of quality data. The continuous and timely flow of data from the AFs and CRFs to the REDCap electronic data capture system is an essential prerequisite for maintaining data quality.

Monthly performance reports will be completed by the research coordinator summarizing among other things: recruitment, status of follow up, data completion, and timelines of data entry.

MISSING DATA

As with most prospective studies, missing data will be unavoidable, even with excellent follow up. Since the informative nature of missing data cannot be verified from the observed data, we will adopt a sensitivity analysis framework for reporting results. We will analyze data under a variety of modeling assumptions regarding how strongly the missingness mechanism is related to outcomes. Regarding study conduct, we will:

1. Limit participant burden and inconvenience in data collection
2. Select high quality research team members
3. Monitor and report missing data rates during the study
4. Emphasize the importance of full participation in the study during the consent process
5. Collect information on the reasons for missing data
6. Actively engage participants in the study and educate them about the importance of their engagement
7. Collect surrogate information on participants who miss clinic visits
8. Hold regular meetings to discuss strategies for enrollment and engagement of participation

While these efforts will help to minimize missing data, we recognize that missing data is inevitable.

RESEARCH ETHICS APPROVAL

This protocol, DSMB plan, consent forms, the AFs, and the CRFs have been reviewed and approved by University of Maryland Institutional Review Board (IRB).

INFORMED CONSENT

Both a Randomized Control Trial (RCT) consent and Observational (OBS) consent has been prepared for the study and is attached in Appendix C. The consent form describes the purpose of the study, the procedures to be followed, and the risks and benefits of participation. Copies of the signed consent forms will be given to the patient, and this fact will be documented in the patient's record.

Eligible patients will be approached for their consent to participate. Informed consent will be obtained prior to treatment group assignment.

To encourage a high level of participation from eligible patients, the attending surgeon will be involved in the consent conversation. The conversation will be initiated by the research coordinator or research team member and the surgeon together. Patients will be informed of the risks and benefits of participation and what will be expected of them if they choose to participate. Consent will be obtained in accordance with principles of GCP and ICH guidelines.

The study should be presented as a randomized control trial upon initial consent conversation. If the patient declines to participate after full understanding of the trial, only then should the observational arm be presented.

VULNERABLE POPULATIONS

The study will not include children, pregnant women, or prisoners.

PARTICIPANT CONFIDENTIALITY

It is the investigator's responsibility to conduct the protocol under the current version of Declaration of Helsinki, ICH Guidelines, Good Clinical Practice, and rules of local IRBs. The investigator must ensure that the patient's anonymity be maintained.

Participants will be identified only by an identification code but not by their name, SSN, or hospital medical record number. The research coordinator will maintain a separate confidential enrollment log which matches identifying codes with patient names and addresses available only to research staff.

All study forms, reports, and other records that are part of the study data collection materials will be identified by coded number to maintain patient confidentiality. All paper records will be kept in locked file cabinets. All electronic records of study data will be identified by coded number. Clinical information will not be released without written permission of the patient, except as necessary for monitoring by the IRB or Safety Monitor. Consent procedures and forms, and the communication, transmission and storage of patient data will comply with the IRB and requirements for compliance with the Health Insurance Portability and Accountability Act (HIPAA).

STUDY DISCONTINUATION

Participants will be informed that they may discontinue the study at any time, for any reason. They will be assured that the medical care which they receive at the participating facility will not be affected should they elect to discontinue participation in the study.

REPORTS

The research coordinator will report queries on the monthly basis to ensure quality data collection and address missing data or visits at regular intervals.

STUDY RECORDS RETENTION

Study records will be maintained in accordance with current ICH guidelines. Data will be maintained for five years following the end of research-related activities. At the end of this period, paper forms will be shredded and the file containing personally identifiable data will be permanently deleted from local site computers.

SUPPORTING LITERATURE

Keating JF, Orfaly R, O'Brien PJ. Knee pain after tibial nailing. J Orthop Trauma 11: 10-13, 1997.
Pot JH, van Wensen RJA, Olsman JG. Hardware related pain and hardware removal after open reduction and internal fixation of ankle fractures. The Foot and Ankle Online Journal 4(5):1, 2011.

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APPENDIX A: STUDY CONTACT ROSTER

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APPENDIX B: DATA COLLECTION SCHEDULE

Assessment	Enroll-ment	6 month	9 month	12 month	18 month	24 month
Stratification Level (AF03)						
SI joint displacement (at time of injury)	X					
Patient Intake (CRF01)						
Demographics (age, gender, race/ethnicity, education)	X					
Smoking History	X					
Previous Injuries	X					
Pre-injury Pain Medication Usage	X					
Pre-injury Work Status (WPAI:SHP)	X					
Pre-Injury Health Status (VR-12)	X					
Pre-Injury Pelvic Function (Majeed Pelvic)	X					
Index Hospitalization - Clinical Intake (CRF02)						
Date/Time & Mechanism of Injury	X					
Height & Weight	X					
Medical History	X					
Narcotic Use	X					
SI Screw Surgery Characteristics	X					
Classification of All Injuries	X					
Study Injury Characteristics	X					
Patient Follow-Up (CRF03 & CRF04)						
Brief Pain Inventory (BPI)		X	X	X	X	X
Re-hospitalizations or Surgeries		X	X	X	X	X
Physical Therapy Tracking		X	X	X	X	X
Post-Injury Pain Medication Usage		X	X	X	X	X
Post-Injury Work Status (WPAI: SHP)		X	X	X	X	X
Post-Injury Health Status (VR-12)		X	X	X	X	X

Assessment	Enroll-ment	6 month	9 month	12 month	18 month	24 month
Post-Injury Pelvic Function (Majeed Pelvic)		X	X	X	X	X
Clinical Follow-Up (CRF05, CRF06, & CRF07)						
Ambulation & Weight Bearing Status		X	X	X	X	X
Pain Medication Usage		X	X	X	X	X
Fracture Healing Status		X	X	X	X	X
Complications (type, severity, treatment)		X	X	X	X	X
Treatment SI Screw Removal Surgical Characteristics (if applicable)			X			
Crossover SI Screw Removal Surgical Characteristics (if applicable)			X	X	X	X