

The MOI Open Tibia Study

Intramedullary Nailing versus External Fixation for OTA42 Open Tibia Fractures: a Randomized Control Trial in Dar es Salaam - Tanzania

Standard Operating Procedures

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Table of Contents

Key Study Contacts.....	3
1. Summary of Changes to Standard Operating Procedure	4
2. Background & Significance.....	6
2.1 Significance: Extremity Trauma as Global Epidemic	6
2.2 Innovation: Advancing Evidence Based Fixation of Severe Open Tibia Fractures	6
2.3 Preliminary Data.....	8
3. Specific Aims.....	8
4. Methods	9
4.1 Outcomes.....	10
4.2 Sample Size.....	11
4.3 Timeline	11
5. Study Procedures	12
5.1 Screening.....	12
5.2 Radiographs	14
5.3 Quality Control.....	15
5.4 Wound Measurement and Classification	15
5.5 Damage Control	16
5.6 Randomization	16
5.7 Definitive Treatment	16
5.8 Follow-up Schedule	17
5.9 Study Financial Coverage	18
5.10 Adjudication Review.....	19
6. REDCAP Procedures.....	21
6.1 Enrollment form – Screening and Consent.....	21
6.2 Intra-operative/Discharge Form.....	33
6.3 Baseline Image Upload	36
6.4 Post-Op Discharge.....	39
6.5 Follow-up Evaluation Form	43
6.6 Complications and Review Form.....	51
6.7 Follow-up Image Upload/Eval Form.....	56
6.8 Follow-up Scheduling.....	59
6.9 Uploading Images.....	65
References	67
Appendix and Supporting Documents.....	68
Appendix II: Informed Consent Form - Swahili version.....	77

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1. Summary of Changes to Standard Operating Procedure

February 3, 2016 (Max Liu)

Various items that required clarification arose after the first few weeks of the study. The following clarifications were agreed upon:

- **Damage Control:** Allowed (definitive treatment done within 2 weeks after first operation)
- **Exfix Pin-Care:** 2 weeks with dressing and BID pin wash with alcohol. Check at 2 week follow up. If dry, remove dressing. If discharge present, continue with dressing and additional evaluations before 6 weeks
- **Exfix Treatment:** 3 months then the following at surgeons discretion to be documented in eval form (1) removal, (2) removal with cast, (3) delayed exfix removal, or (4) other. Delayed exfix removal or other will be submitted for adjudication review
- **Antibiotics:** 3 options at surgeons discretion with (1) CTX, (2) CTX + gentamycin, (3) CTX + gentamycin + metronidazole
- **Weight Bearing Protocol (all patients):** 6 weeks toe touch then at surgeon's discretion
- **Nurses:** 2 per week (number of patients will increase next Saturday)
- **# IM Nail Interlocks:** 4 total on all nailed patients (2 prox, 2 distal)
- **Continue with study without interruption:** Yes
- **Cohort Study:** Will now include non-primarily closeable patients (we will attempt to contact the patients who came in since the start of the study)

There was also a patient "borderline" fracture who will be included and followed-up. We have made a note and can exclude during data analysis if necessary.

February 13, 2016 (Max Liu)

Following the presentation of an open tibia patient approximately 3 days after their injury, a discussion occurred regarding whether or not an upper limit would be set for patients in the cohort study who present >24 hours post-injury.

➔ It was decided that there would be no upper limit.

April 6, 2016 (Max Liu)

- ➔ It was decided that exfix patients who receive a cast will have the cast paid for by the study since it is a complication of their randomization (and not part of their typical treatment plan)
- ➔ Max will send out a revised budget

April 10, 2016 (Max Liu)

Kurt noticed during his site visit to MOI that there was underreporting of pin tract infections in the external fixation group. Previously, the question, "are the schanz pin tracts infected?" would only

appear if a surgical site infection was identified and reported under the question, “does the patient have any wound problems?” The underreporting may have been due to ambiguity in this question and the responses that were available.

In the scheme of things, this does not have too bad of an effect on the data because it was only for the first 40 patients. Some of these had wound infections so they saw the question and others might not have had pin tract infection. Thus we only missed those who did not have a wound infection but did have a pin tract infection in exfix group in first 3 months of the study.

- ➔ It was decided that the question “are the schanz pin tracts infected?” would appear for all external fixation patients regardless of the response to the question “does the patient have any wound problems?” Due to the difficulty of tracking at what time point patients get their external fixators removed, this question will appear at all follow-up visits even after the external fixator may have been removed. An option “N/A – the external fixator has already been removed” is provided in this situation.

April 13, 2016

- ➔ Amber stated that study related travel for Max (beyond his allotted Doris Duke funding) and others would be compensated under the study budget. Max will revise the budget accordingly.

April 22, 2016

In order to streamline where complications are recorded, the following recommendations were made by Saam and Dave:

- ➔ Infections and wound complications will be moved to the “Complications and Review Form”
- ➔ If a complication was previously recorded for a patient, a prompt will appear on subsequent follow-up forms asking the team to review the complications form and make any necessary updates

2. Background & Significance

2.1 Significance: Extremity Trauma as Global Epidemic

More than 75% of the global population lives in low and middle-income countries (LMICs) where rates of extremity injury average 2-5 times higher than high-income countries (HICs).¹ Higher mortality rates in LMICs have been directly linked to the expanding use of motorized transport within the context of underdeveloped trauma care systems.² As evidence of this growing epidemic, road traffic crashes are predicted to become the eighth leading cause of death and the fourth leading cause of disability worldwide by 2030.³

The World Health Organization (WHO) projects Africa's road trauma burden, currently the highest in the world (19.1-28.3/100,000), to increase by 80% between 2000 and 2020.⁴ On this continent better known for its battle with HIV, tuberculosis, and malaria, injuries account for more deaths among children ages 5-14 than all three infectious diseases combined.⁵

To shape the focus of our proposed study, we focused our efforts where the clinical need is greatest. Epidemiologic data indicate that open tibia and fibula fractures constitute the most common open long bone fracture encountered in orthopedic practice, and most often result from road traffic accidents.⁶ This data is consistent with the MOI experience, where 96.2% of patients enrolled in our pilot study suffered open tibia fractures resulting from motorcycle or motor vehicle accidents.

Tibia fractures constitute severe, potentially limb-threatening injuries. Sixteen percent of patients in our preliminary study sustained associated injuries (18.5% musculoskeletal, 9.3% Traumatic Brain Injury). This is consistent with prior research documenting the prevalence of multiple open fractures at 6.4%, an average injury severity score of 14 (Range 1-75), and more severe fractures associated with motorcycle accidents.⁷ Authors of the landmark Lower Extremity Assessment Project (LEAP) study which prospectively followed outcomes of patients with severe open diaphyseal tibia fractures found that nearly 33% of patients with Gustilo and Anderson Type 3 injuries available at 2 year follow-up underwent early amputation due to initial injury severity.⁸

Patients with open tibia fractures also suffer from high complication rates, as the bone's precarious blood supply and relative lack of soft-tissue coverage compromise the healing process. The LEAP authors reported high rates of infection (11% to 38%), nonunion (7% to 60%), and secondary operative procedures.⁸ In their seminal 1984 paper, Gustilo and Anderson demonstrated the correlation of infection rates with increasing severity of injury by roughly an order of magnitude, as measured by their eponymous classification.⁹ This finding was confirmed by Papakostidis et. al., in a systematic review of 30,260 open tibial shaft fractures published in 2011.¹⁰ Tibia fracture complications lead to high rates of functional disability due to the importance of the tibia to lower extremity alignment, stability, and strength.

Adding demographic insult to injury, road traffic accidents resulting in severe open tibia fractures predominantly impact young men. Patients in our preliminary study were largely male (77.8%) and averaged 34 years of age. Thus, these injuries disable the most economically productive demographic in developing economies. Lost income over the average 6-8 month time required for return to work has a devastating impact on home finances. The economic implications of these injuries cascade through communities generating cycles of debt, poverty, and family hardship. Additionally, these high acuity patients require vast curative resources, overburdening an already under-resourced health system.

2.2 Innovation: Advancing Evidence Based Fixation of Severe Open Tibia Fractures

The optimal method of surgical fixation for severe tibial shaft fractures continues to be a popular topic in the orthopaedic literature. Despite thirty years of global research comparing external fixation to intramedullary nailing, controversy on the subject persists. Of the more than ten comparative studies published in the literature, most utilized retrospective, non-randomized research designs. Authors of previous meta-analyses note widespread bias toward external fixation with increased fracture severity, despite good evidence supporting both fixation methods for Gustilo 3A (and even 3B) fractures. This bias further highlights the need for prospective, randomized treatment group allocation. Additionally, authors of the most comprehensive systematic reviews note that high rates of allocation group heterogeneity confound comparison of results across studies. To date, there has been no randomized, prospective, adequately powered trial evaluating external fixation versus undreamed intramedullary nailing and no comparative trial of external fixation with reamed nailing technique.^{11, 12}

Proponents of external fixators argue that these devices can be applied rapidly with relative ease without radiographic guidance, and entail limited insult to already traumatized soft tissues. A major additional advantage in Sub-Saharan Africa is their relative low cost, particularly considering bars and clamps are often cleaned and re-used. While union rates in large series were reported at 94%, difficulty of closed reduction raises potential for higher rates of malunion, reported at 20% and 33% in meta-analyses by Bhandari and Giannoudis, respectively.^{11, 13}

Intramedullary nails offer a similar union rate of 95% with the advantages of controlling segmental fractures (thus limiting malunion rates to approximately 10%), preserving joint motion, and permitting early weight bearing in polytrauma patients. Relative disadvantages include longer operative time, higher implant costs, higher rates of implant failure (12.4% vs 2.4% for external fixation), and prevalence of post-operative anterior knee pain. Rates of delayed union are somewhat equivocal between techniques, reported at 24% for external fixation and 22% for intramedullary nailing. Deep infection rates for both techniques are highly variable, with reported rates for external fixation ranging from 5.7 to 16.2% while rates for intramedullary nailing range from 2.4% to 7%.^{10, 11}

When treating severe open tibial shaft fractures, most surgeons in HICs now employ a “damage control” approach which draws from the relative merits of both methodologies. This strategy involves the application of an external fixator to the traumatized limb during the initial phase of care, followed by planned conversion to intramedullary nailing after the patient has been fully resuscitated and the wound thoroughly debrided.

Orthopaedic surgeons at MOI, and across Sub-Saharan Africa, are generally familiar with using both external fixation and intramedullary nailing techniques. However, there is little, if any, empiric evidence to guide the choice of treatment. Often, the operative plan hinges not on the surgeon’s experience or clinical judgment, but on the cost and availability of surgical implants. Economic scarcity necessitates careful resource allocation. Surgeons must often utilize external fixation for definitive care, rather than converting all patients initially managed with external fixators to intramedullary nails. The impact of other clinical factors, such as patient comorbidities, operative timing, availability of antibiotics, and surgeon competence remain unknown.

Despite the high prevalence of injury and disability throughout Sub-Saharan Africa, Africans rarely benefit from peer-reviewed research. In a recent review of articles published in four leading orthopaedic journals over three years, publications from Sub-Saharan Africa accounted for only 0.4% of the 3964 articles reviewed and 5.6% of the 265 articles with developing world authorship.¹⁴ OREF has already begun the work of reversing this trend. This study proposal aims to build on the success of a collaborative research partnership made possible by previous OREF funding which examined plating versus intramedullary nailing of femoral shaft fractures.

We propose to undertake a randomized, prospective trial which will generate Level 1 evidence concerning optimal fixation methods for the treatment of severe tibia fractures in Dar es Salaam, Tanzania. Clinical and functional outcomes data obtained from our study will inform practice patterns of surgeons throughout Africa, helping to reduce patient morbidity, limiting the economic impact of injury, and minimizing health system expenditures by preventing complications which

would necessitate reoperation. Results would prove useful to orthopaedic surgeons worldwide, who would have the highest caliber scientific evidence with which to advocate for funding needed from policy-makers and charitable donors to address the growing epidemic of global extremity trauma. Perhaps more importantly, we hope to break the widely held perception that austere environments present unsurmountable challenges to meaningful clinical inquiry.

2.3 Preliminary Data

Our Tanzanian colleagues conducted a preliminary study with similar research design over 12 months from March 2013 to February 2014. Fifty-four patients with Gustilo and Anderson Type 3A tibial shaft fractures were enrolled and randomly allocated to two treatment groups. Twenty six were treated with definitive external fixation, and 28 were managed with intramedullary nailing. Two patients were lost to follow-up from each group, leaving a total study population of 50 patients followed for 4.5 months.

As previously stated, the most common mechanisms of injury included motorcycle collisions (75.8%) and motor vehicle collisions (20.4%), followed by bicycle accidents and falls from height (combined 3.8%). Young men were most commonly affected. More than 60% of patients were treated within 16 hours from injury and 98% were treated within 24 hours from time of injury. Patients were treated according to standard open fracture protocols and randomized to two treatment groups undergoing either intramedullary nailing or external fixation.

We found no statistically significant difference in the rates of wound healing or incidence of deep infection (7.7% for IMN vs 12.5% for ex-fix). Twelve patients (46.2%) treated with external fixators developed superficial infection, none of which required implant removal. We observed a significantly faster time to callus formation in the intramedullary nail group (average 8.15 +/- 2.5 weeks, 92% at 10 weeks) when compared with the external fixation group (14.7 +/- 3.3 weeks, 25% at 10 weeks). Patients treated with intramedullary nails attained full weight bearing earlier than pts treated with external fixators. Malunion rates were also significantly lower in the intramedullary nail group, as two ex-fix patients (8.3%) were found to have significant post-operative limb length discrepancies and three (12.5%) were revised for angular or rotational malalignment, versus no malunions noted in the intramedullary nail group.

In summary, 9 patients (37.5%) treated with external fixation required re-operation (2 for deep infection, 3 for malalignment, 4 for delayed union) versus one re-operation (3.8%) for patients treated with intramedullary nailing. While early results from this pilot study predict a clinical advantage for intramedullary nailing over definitive external fixation, we feel the small sample size, limited follow-up, and lack of functional outcomes data warrant further empirical investigation. Most importantly, this pilot study, conducted by a Tanzanian primary investigator, demonstrates the viability of success for completing a larger randomized, prospective clinical trial in Dar es Salaam, Tanzania.

3. Specific Aims

Study Objective: To determine the optimal management of severe open tibial fractures in Sub-Saharan Africa in order to reduce long-term disability, limit the economic impact of injury, and avoid resource costs of reoperation.

Specific Aims

1) Compare the all-cause reoperation rate for AO/OTA Type 42 open tibial shaft fractures treated with initial intramedullary nailing versus external fixation at Muhimbili Orthopaedic Institute in Dar es Salaam, Tanzania.

- 2) Compare rates of secondary clinical endpoints including postoperative superficial and deep infection, clinical union, radiographic union, malunion, and health-related quality of life with minimum one year follow-up.
- 3) Identify prognostic factors related to the patient, injury, or management protocol that impact the reoperation rate, return to work, and health-related quality of life.

Study Null Hypothesis: There is no difference in the all-cause re-operation rate comparing reamed intramedullary nailing and external fixation for the initial treatment of OTA 42 Type 42 open tibia fractures

4. Methods

The proposed study will be a prospective, randomized trial conducted at Muhimbili Orthopaedic Institute (MOI) in Dar es Salaam, Tanzania. All skeletally mature patients presenting to the emergency department between December 2015 and December 2016 meeting inclusion criteria will be consented and enrolled in the study. Baseline clinical data will be obtained during enrollment. The patients will then undergo a standard wound debridement protocol (regardless of treatment arm) followed by intraoperative confirmation that the wound can be primarily closed. If so, the patient will be randomized using the REDCAP randomization module to one of two treatment arms: intramedullary nailing or external fixation. Primary and secondary outcomes will be measured prospectively during the postoperative period and at subsequent follow-up visits at 2wk, 6wk, 3mo, 6mo, and 1yr (Sections 2.6 and 2.7). Serious adverse events that occur during the study will be presented to all co-investigators (Section 3.2). Interim analysis will be produced and reviewed by all co-investigators every 6 months, with a final report generated within three months of the trials end (Section 2.9 and 3.3).

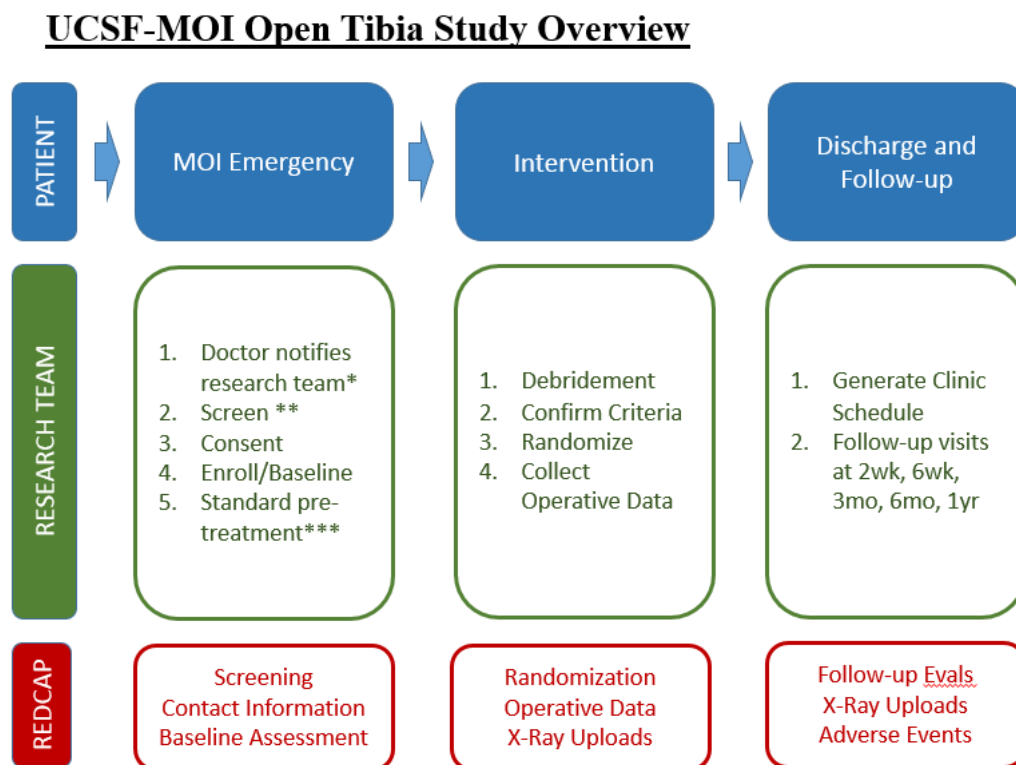


Figure 1: Timeline for patient enrollment and data collection

4.1 Outcomes

The primary outcome for our study will be composite, all-cause reoperation within one year of definitive skeletal stabilization, excluding bedside irrigation and debridement for superficial pin tract infections or planned ex-fix removal. The use of composite outcomes has been validated in a wide range of clinical trials.¹⁹ Primary events included in our composite outcome are detailed in the following table.

A participant who undergoes conversion from ex-fix to nail within six weeks of surgery will be analyzed according to the initial treatment that was assigned by randomization. Patients who undergo conversion from ex-fix to nail more than six weeks after the index procedure will be considered to have undergone a reoperation and will therefore count toward the primary outcome. Conversion from nail to ex-fix, regardless of time point, will be considered a primary outcome event.

Primary Events

Infection or hematoma	Repeat incision and debridement or drainage for superficial or deep infection or hematoma following initial wound healing.
Bone grafting	Bone grafting for patients > 6 months from index surgery. Bone grafting will be considered after 6 months in the case of delayed radiographic healing with > 2 months pain on attempted weight bearing.
Implant conversion (e.g. Ex Fix to IM nail) or implant exchange (e.g. exchange nailing)	Implant conversion or implante exchange > 6 months from index surgery to facilitate union.
Implant removal	1) For construct failure with appropriate clinical indication (broken hardware, half-pin failure at bone/pin interface). 2) Intramedullary nail removal to facilitate union. 3) Intramedullary nail removal due to patient reported pain or local irritation
Dynamization of intramedullary nail	To facilitate healing > 6 months from index surgery. * Note: Auto-dynamization without clinical indication for removal of broken component will not be counted as a primary event.
Osteotomy	To correct malalignment
Amputation	For limb salvage failure

Secondary clinical outcomes will include:

1. Post-operative compartment syndrome.
2. Superficial infection, as defined by CDC surveillance definitions, to include pin tract infections and cellulitis which resolves with use of antibiotics and local wound care.
3. Deep infection, as defined by CDC surveillance definitions, to include deep abscess or osteomyelitis.

4. Clinical union of fracture healing will be assessed by absence of movement at fracture site and time to painless weight bearing.²⁰ Non-union will be defined as fracture failure to heal beyond six months from date of injury.
5. Radiographic union will be assessed using rate of callous formation and visibility of fracture line as measured by the RUST score.²¹
6. Malunion. Post-operative malalignment will be defined as leg length discrepancy (>1 cm shortening), angular malalignment (> 5 degrees sagittal or coronal angulation referenced contralateral leg radiographs, if non-injured), or malrotation (>10 degrees, determined by Foot-Thigh Angle).
7. Implant failure will be defined as breakage or loosening of any implant component at bone-implant interface which necessitates re-operation.

Secondary functional outcomes will include:

1. Health-related quality of life as measured by EQ-5D.
2. VAS pain score.
3. Knee and ankle range of motion.
4. Functional testing to include walking speed and ability to assume full crouch.

4.2 Sample Size

Data from two preliminary studies at MOI inform our projection for requisite statistical power. Our pilot study showed a difference in reoperation rate comparing external fixation and intramedullary nailing of 38% versus 3.8%, respectively. However, with longer follow-up and more stringent criteria for reoperation, we estimate a more conservative effect size is needed for power analysis. Therefore, to achieve 80% power ($\alpha=0.05$) with a more conservative difference in the reoperation rate of 5% to 20%, the study would require 88 patients in each treatment group, or a total of 176 with completed follow up.

During the six month period from January to June 2012, MOI surgeons treated 238 patients presenting with open tibia shaft fractures, 50% (119) of whom suffered Gustilo Type 3A injuries - an incidence of approximately 20 patients per month. Our colleagues report the rate of open tibia fractures has continued to increase over the last two years and by current accounting, averages 25 patients with Gustilo Type 3A injuries per month. We therefore estimate an annual volume of approximately 300 qualifying injuries treated operatively at MOI. Assuming the majority meet inclusion criteria and a capture rate of 80%, we anticipate enrolling approximately 240 patients over a one year collection period. If the goal of 80% follow-up is met, a total of 192 patients will be included in our final analysis and we will achieve adequate statistical power. We will plan to conduct an interim analysis after six months to assess the accuracy of these initial estimates and determine whether the duration of the enrollment period should be altered.

4.3 Timeline

November 2015:	Training, refinement, and implementation of study protocol
December 2015:	Begin study enrollment
January 2016:	1 month evaluation and consideration for protocol changes
June 2016:	Site visit for 6 month interim analysis and progress report
December 2016:	End study enrollment and 1 year site visit/interim analysis/progress report
June 2016:	Site visit for 18 month interim analysis and progress report
December 2017:	Complete follow-up data collection
March 2017:	Final data analysis

5. Study Procedures

5.1 Screening

Screening for patients will begin on December 14, 2015 at 9am and end in approximately one year when the appropriate sample size has been reached. All open tibia fractures arriving at the MOI emergency room during the enrollment period will be screened for inclusion in the study. All patients, even those who are excluded, need to have their information recorded on REDCAP.

The orthopedics department has been directed to call the study phone whenever an open tibia patient comes in. The research coordinator is required to keep the study phone close with them at all times.

- If the patient arrives during normal business hours (7am to 5pm), the coordinator will go to the emergency room to assist the patient's physician with screening. The coordinator is also expected to periodically check the emergency room for any new open tibia patients in case the emergency staff fail to contact the study phone.
- The study coordinator on duty will remain at MOI until 9pm and periodically check the emergency room for any new open tibia admissions. If the patient arrives from 9pm to 11pm, the coordinator will screen from home using the study laptop. If the patient meets study inclusion/exclusion criteria, the coordinator will come to the hospital to consent the patient to enroll in the study.

Inclusion Criteria

1. Skeletal maturity
2. AO/OTA 42 open tibia fractures *
3. Wound primarily closeable (no flap or delay in closure due to contamination needed)
4. Palpable pedal pulses (no vascular injury sustained)
5. Presentation within 24 hours from injury **

Exclusion Criteria

1. Current injury is a pathologic fracture
2. Sustained bilateral tibia fracture
3. Sustained comminuted femur fracture
4. Sustained severe Traumatic Brain Injury (GCS<12) ***
5. Sustained severe spinal cord injury (lower extremity paresis/paralysis)
6. Sustained severe burns (>10% total body surface area (TBSA) or >5% TBSA with full thickness or circumferential injury)
7. Prior ipsilateral leg injury requiring surgery
8. Prior or current lower limb deformity or abnormality
9. Unable to complete follow-up visits

* See addendum for OTA42 subclassification schematic

** Patients who present greater than 24 hours after injury and/or have non-primarily closeable wounds but meet all other criteria are eligible for the cohort study (see below)

*** If at any point prior to the operation, the patients GCS score drops below 12, the patient will be excluded from the study. If the GCS score drops below 12 after the operation, the patient will remain in the study.

Cohort Study

Patients who meet all inclusion/exclusion criteria but present to MOI's emergency room beyond 24 hours after their injury and/or have non-primarily closeable wounds will be consented and included in a separate cohort study. These patients will be treated exactly the same way as an RCT patient with the same data collected except that they will not be randomized. Their primary surgeon will decide which operation is the most appropriate. The same consent form will be used, but the patient will be explained the details of the cohort study rather than the RCT study.

Informed Consent

All patients who remain eligible after clinical screening will be offered enrollment in the study. A written informed consent document will be provided to the patient and reviewed in detail by a trained research coordinator. This document will be provided in English or Swahili depending on the patient's preference. In cases where the participant is unable to provide consent, consent will be obtained from a legally acceptable representative. If the participant is unable to read, verbal consent will be provided in the presence of an impartial witness. The consent document should be signed and dated by the individual providing consent as well as the participant or their legally acceptable representative.

Signed consent forms should be kept in the SIGN Nail Office. A picture of the signature form should be taken and uploaded onto REDCAP.

If there is any concern from either the patient and/or the research coordinator that the patient will be unlikely to complete any follow-up visits (especially the 1 year follow-up visit), that patient will be excluded from the study. If the patient does not provide consent for any other reason besides an inability to complete follow-up clinics, the reason for not providing consent will be recorded.

Baseline Clinical Information

Once a participant has completed informed consent, the research coordinator will obtain baseline clinical information and record the information in REDCAP.

Antibiotics Administration

Antibiotics must be administered as close to admission as possible to minimize the risk of infection. The standard study antibiotic regiment is based on the estimated level of contamination. This depends on the clinical history and a visual assessment of the wound. It is up to the discretion of the treating surgeon which antibiotic regiment the patient will be placed on. It is recommended that the surgeon utilize one of the three regiments, but in cases where there is a compelling reason for the use of a non-study regiment, the surgeon is allowed to place the patient on a non-study antibiotic.

The breakdown of the antibiotic regiment only with details regarding whether or not the study will provide the antibiotics can be found below.

Contamination Level	Treatment	Provision Status
None or mild	Ceftriaxone 1g every 24 hr for 2 days	Provided for free

Moderate	Ceftriaxone 1g every 24 hr for 2 days + Gentamycin 80mg every 12 hr for 2 days	First dose gentamycin provided for free. If the patient cannot or is unwilling to pay to complete the regiment, the full course will be provided for free
Severe or high risk	Ceftriaxone 1g every 24 hr for 2 days + Gentamycin 80mg every 12 hr for 2 days + Metronidazole 500mg every 8hr for 2 days	First dose gentamycin and metronidazole provided for free. If the patient cannot or is unwilling to pay to complete the regiment, the full course will be provided for free

For patients who receive additional operations as part of their care (such as definitive treatment following damage control or reoperations), the antibiotics will be provided according to the same system as detailed in the table above.

There are three stages in the study where antibiotics can be administered:

1. Admission to MOI: all study participants will receive antibiotics at admission. The type of antibiotic to administer is based on a visual assessment of the wound as well as the clinical history provided by the patient. The decision to provide antibiotics should be done immediately following consent by the patient. A standard study antibiotic regiment should be administered unless another antibiotic is believed to be more suitable for the situation.
2. After surgical debridement: the study participant's surgeon may order additional antibiotics to be administered after further evaluation of the wound during surgical debridement. These may be standard study antibiotics or can be any other antibiotic that is available in the OR and that the surgeon believes is more suitable for the situation.
3. In the ward: the ward physician must continue the antibiotic regiments that have already been started in stages 1 and 2 and is also free to prescribe any additional antibiotics that may be necessary. These do not have to be from the standard study regiment. This applies primarily to patients who need to stay in the wards longer to recover from other associated wounds.

A system of recording which antibiotics were administered at each of the three steps has been built into REDCAP. The surgeon is allowed to stop a course of antibiotics at any point during the patient's treatment. If that is the case, the details of the situation will be recorded in REDCAP.

5.2 Radiographs

AP and lateral view x-rays should be taken at the following stages of the study: pre-op, post-op, 6 weeks, 3 months, 6 months, and 1 year. Research coordinators should try to be with the patient while these x-rays are taken to ensure that images of adequate quality are taken.

Radiographs are viewable through ClearCanvas enabled MOI desktops which are available in the radiology department, emergency department, and outpatient department.

A picture of the radiographs should be taken and uploaded onto REDCAP. The name of the patient should be visible on the picture taken. A reviewer from UCSF will review the baseline and follow-up x-rays within a reasonable timeframe after the pictures are uploaded.

Preoperative x-rays will be assessed for fracture classification. Follow up x-rays will be assessed for evidence of hardware failure and fracture union, as determined by the RUST score. In cases of disagreement, the reviewers will meet and achieve consensus. All data entry will be performed directly into REDCap.

5.3 Quality Control

To ensure quality of the x-ray, the radiology department has been notified to make sure that the x-rays include the fracture site and as much of the tibia as possible. For tall patients with long tibias, this may not be possible with the cassettes that are currently available for use by the department. If that is the case, 4 x-rays should be taken at each step of the patient's care: proximal tibia AP and lateral views as well as distal tibia AP and lateral views. However, this should be avoided when possible to minimize radiation exposure to the patients. The cost of the extra x-rays will be covered by the study. An option to upload additional x-rays has been built into REDCAP.

Post-op x-rays ideally are performed immediately after surgery. However, sometimes the x-ray department is backed up or the patient is uncooperative. If that is the case, try to notify the ward physician on duty to order the post-op x-rays. While it is under MOI policy that patients should not get discharged before getting post-op x-rays, sometimes this occurs immediately prior to discharge, making it difficult to ensure the quality of the x-ray.

In situations where the post-op x ray is found to be inadequate but the patient has already been discharged, it is permissible to retake the x-ray at the 2nd week follow-up visit and consider those x-rays as the control. While this situation is not ideal, it is an appropriate back-up option in case the immediate post-op x-rays are inadequate.

For further information on x-ray quality control, refer to the addendum at the end of this document.

5.4 Wound Measurement and Classification

A measurement of the wound is to be done in the operating room. Specifically, it should be taken after the patient receives anesthesia and the temporary splint/bandages have been removed but just before surgical debridement. The wound should be measured using a centimeter ruler (rather than visually approximated) and recorded onto REDCAP.

Only the maximum dimension of the wound (the longest length possible) needs to be recorded. This is irrespective of how the wound is oriented along the limb. The wound length should only include the part of the wound that is open (ignore any superficial abrasions that may be connected to the open part of the wound).

OTA Wound Classification

Classification of the wound is done using the OTA Wound Classification questionnaire (see REDCAP section). Wound classification is to be done after surgical debridement which allows the surgeon to fully assess the wound.

Wound Closure Status Check

After surgical debridement, the surgeon will assess the wound to see if the wound can be primarily closed. If the wound can be primarily closed, the patient will continue with the RCT Study.

If the wound cannot be primarily closed, the patient will be enrolled as a cohort study patient.

If the wound is found to be primarily closeable and came to MOI within 24 hours of injury, the patient will be funneled into the RCT study and randomized

5.5 Damage Control

After assessing the wound, the primary surgeon will need to determine if “damage control” using a temporary external fixator is necessary. This may be utilized in situations where the patient is hemodynamically unstable and needs quick stabilization of the tibia or requires another surgery that is more important. This option is available to the surgeon for both RCT and cohort patients. Furthermore, this option is available for RCT patients who are randomized to either a nail or an exfix.

If the surgeon decides to perform damage control, a temporary external fixator will be placed, and the patient will be allowed to recover in the ward with the definitive operation performed at a later date. The date of both the temporary exfix placement and the definitive operation will be recorded onto REDCAP. There is no set time limit or criteria for how long the temporary external fixator should remain on before the definitive treatment is to be conducted. The only standardized policy is that the definitive operation should take place in a timely manner after the clinical issue that warranted the temporary external fixator in the first place has been resolved.

5.6 Randomization

The following information applies only to patients who are eligible and enrolled in the RCT study. For cohort study patients, the primary surgeon is responsible for deciding which surgery is the most appropriate for the patient. This includes either nail or exfix and the number of proximal and distal interlocks or schanz screws.

After the surgeon has deemed that the patient’s wound can be primarily closed, the patient is ready to be randomized. Randomization will be done via the REDCAP module. The randomization allocation table utilizes a pseudo-random number generator from sealedenvelope.com and incorporates block randomization to maintain roughly equal distribution between the two groups throughout the study. The number of random allocations is set to 340 to account for additional patients beyond the 240 that is expected to be enrolled.

The patient will be randomized to receive either a hand-reamed SIGN intramedullary nail or locally available external fixator. Both modalities will be applied using standardized techniques.

5.7 Definitive Treatment

Nail: It is up to the surgeon’s discretion as to the appropriate size of the nail. A total of 4 screws will be placed – 2 proximal and 2 distal. These decisions will be recorded on REDCAP during the operation.

Exfix: Two Schanz screws will be placed proximally and two will be placed distally; only a single bar will be utilized. The patient will be instructed on proper pin-care procedures at the time of discharge which involves pouring methylated spirit (alcohol) directly onto the pins twice daily until the exfix is removed. The patient will be discharged with bandages covering the wound, but the pin insertion sites will be left open to allow for proper ventilation and pin-care. The patient will be discharged with dressing covering the wound and pin sites. The exfix will remain on for 3 months. At the 3 month follow-up, the decision will be made to (1) remove ex-fix, (2) remove ex-fix and replace with cast, (3) delay exfix removal, or (4) other. Delayed removal or other will be submitted for adjudication review.

Wound Protocol

If the wound is dry at the 2 week wound check, the dressing will be removed. If the wound is still wet at 2 weeks, the dressing will be changed and the patient will be instructed to periodically revisit the hospital to change the dressing until the wound becomes dry.

Weight Bearing Protocol

All patients will be advised to be on toe-touch status for the first 6 weeks. Afterwards, the patient will be instructed to bear weight as permitted by pain.

Summary of Treatment Options

Primarily closeable?	->	No	->	Cohort Study
	->	Yes (Cohort) (+ damage control)	->	Temporary exfix
	->	Yes (Cohort) (no damage control)	->	Definitive operation
	->	Yes (RCT): Nail (+ damage control)	->	Temp exfix (then nail)
	->	Yes (RCT): Exfix (+ damage control)	->	Temp exfix (then exfix)
	->	Yes (RCT): Nail (no damage control)	->	Nail now
	->	Yes (RCT): Exfix (no damage control)	->	Exfix now

5.8 Follow-up Schedule

Participants will be scheduled for follow up appointments at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year after the date of surgery. The 2 week visit is primarily a wound check to assess the wound and record any other surgical or medical complications that may have arisen since discharge. The remaining follow up appointments will include clinical evaluation, plain radiographs (AP and lateral views), and administration of the EQ-5D. The follow up schedule will be generated using the scheduling function in REDCap. All research clinic appointments will be conducted in a dedicated research clinic on Saturday afternoons. Every research clinic will be staffed by one of the study investigators (BH, EE), at least one research coordinator, and a research nurse.

Because the follow-up clinics occur on Saturdays, the following rounding system will be used to calculate which date the patient should come for a follow up visit:

- For patients that get operated on a Sunday, Monday, or Tuesday, the previous Saturday will be used to calculate the 2 week follow up date (and all other subsequent dates)
- For patients that get operated on a Wednesday, Thursday, Friday, or Saturday, the upcoming Saturday will be used to calculate the 2 week follow-up date (and all other subsequent dates)

Promoting Follow Up

The following strategies will be implemented in order to improve the rate of follow up:

1. Treating patients with a high level of hospital which involves:
 - a. Introducing the study participant to all members of the team
 - b. Advocating for timely and appropriate care of the patient
 - c. Clearly informing the patient about the steps of the study
 - d. Explaining the study to the contacts that the patient provided

- e. Protecting patient confidentiality
2. Calling the 3 contacts that the patient provides at the time of enrollment and notifying them of the patient's illness, their participation in the study, and the importance of helping them attend all follow-up visits.
3. Costs of follow up care will be free to study participants, including the consultation fees and cost of plain x-rays.
4. Saturday clinic will be separate from the general clinic and conducted in private clinic offices. This will make it easier for patients to come back to MOI, minimize waiting times, and ensure patients are able to see a specialist rather than physician in training.
5. All patients will be contacted on the Wednesday prior to the Saturday clinic by phone as a reminder of the appointment time. A second reminder will be sent by text message on the day prior to the clinic.

No cash incentives will be provided to compensate for travel and other expenses. However, at the conclusion of 1 year, all patients who have been lost to follow up will be contacted by study staff to encourage return to the clinic. In cases where cost of travel is the principal barrier, a telephone follow-up evaluation will be conducted. The patient will also be asked to go to the nearest hospital, take follow-up x rays, and send in a picture of the x-rays. A picture of the patient performing the squat and smile test will also be requested.

5. 9 Study Financial Coverage

The following summarizes what is and what is not financially covered by the study. Any items not mentioned here need to be approved by the study review committee.

Covered	Not Covered
<ul style="list-style-type: none"> - Ceftriaxone on admission - Ceftriaxone on subsequent surgeries that occur during the patient's first stay at the hospital - First dose of gentamycin * - First dose of metronidazole * - Consultation fees for follow-up clinics - Follow-up x ray images at 6k, 3mo, 6mo, 1yr - 2 week post-op control x-ray redo (if necessary) 	<ul style="list-style-type: none"> - Admission consultation and pre-op time - Cost of surgeries, implants ** - Post-op time in ward - Reoperations and all associated antibiotics and medications** - Exfix pin care methylated spirit - Knee brace - Physical therapy

* If the patient is not able to afford the remaining doses or has no relative who can purchase the antibiotics or will not be able to purchase the antibiotics in a timely fashion, these antibiotics will be provided for the patient at no extra cost

** While the study will not cover these items, the hospital may cover the cost if the patient is not able to afford

Study Steering Committee

The steering committee for the study will consist of David Shearer, Saam Morshed, Billy Haonga, and Edmund Eliezer. The steering committee will be responsible for performing adjudication review, evaluating interim data, and approving any sub-projects.

5.10 Adjudication Review

Review of the following study events will require review from the members of the study steering committee:

1. Death of a patient
2. Delayed external fixation removal
3. Surgical complications requiring reoperation

The review, comment, and voting process will occur on REDCAP. 3 steering members will need to evaluate each event that is put up for review. The steering committee members are responsible for providing the following inputs for each event:

1. Comments/opinions/justifications
2. Vote (yes or no): question varies depending on the event
 - a. Death event: question not applicable
 - b. Delayed external fixation: does the patient need to remain on external fixator for an extended length of time?
 - c. Surgical complications requiring reoperation: does the patient need a reoperation?
3. Vote (yes or no): is this event a primary outcome of the study?

Adjudication review will be conducted every 2 months.

Final Reporting

At the conclusion of the study there will be a principal manuscript reporting the findings of the primary study endpoints.

On-Duty Schedule and Responsibilities

A research coordinator is required to be on duty at all times. A person will remain on-duty for three consecutive days. The transition to the next person on duty will occur at noon or in the early afternoon after the person on-duty has finished the morning tasks. During the transfer, the person on duty should notify the next person on duty about any pending items that need to be completed. These items should be written down in the on-duty diary.

Scheduling of the person on duty is to be done on an excel form available in the dropbox. Substitutions are permitted as necessary. The form is to be maintained and updated should any substitutions occur.

The following need to be provided for the on-duty coordinator:

- ☐ Study Laptop and USB Modem
- ☐ Study Phone
- ☐ Battery charge bank and wire
- ☐ On-call diary
- ☐ SIGN office key
- ☐ Antibiotics
- ☐ Wound measurement ruler
- ☐ On-duty diary

- ☐ Extra forms: consent, OTA wound classification, EQ-5D

Daily tasks for on-duty

To do in the morning:

- ☐ Patients in ward: (1) create follow-up schedule and (2) make sure they receive their antibiotics
- ☐ Patients in emergency: periodically check to see if there are any new patients
- ☐ Check in emergency logbook if there were any missed patients
- ☐ Patients waiting for operation: wait and randomize in OR
- ☐ Get the unused antibiotics from emergency room from last night
- ☐ Fill in on-duty diary

To do at night before leaving:

- ☐ Check for any new tibia patients
- ☐ Leave ceftriaxone (3 boxes and 3 waters for injection) for emergency
- ☐ Instruct emergency staff about the purpose of the antibiotics
- ☐ Remind emergency staff to contact the study phone for any open tibia patients
- ☐ Upload any images such as consent forms, radiographs, etc.

Tasks specific to the person on duty on Wednesday:

- ☐ Call patients scheduled to come for follow-up clinic on upcoming Saturday
 - If appointment confirmed with patient, go to calendar in REDCAP and change appointment status to "Scheduled"
 - If not scheduled, call repeatedly during the week until they are aware of the appointment
- ☐ Send text reminder to all patients on Friday*

* This duty falls on the person on duty on Wednesday because that person is most familiar with the patients who will come on that Saturday

Tasks specific to the person on duty on Saturday:

- ☐ Prepare records of patients for Saturday Clinic
- ☐ Contact the physicians that should be present at Saturday Clinic
- ☐ Manage Saturday Clinic
- ☐ Send review committee an email notification regarding the events that have occurred that need to be reviewed

To do whenever a new patient enrolls in the study:

1. Record details on REDCap
2. Ensure antibiotics are given promptly
3. Assess quality of pre-op x-ray and redo if necessary
4. Call 3 phone numbers and notify patient contacts of the study

When calling patients to remind them of their follow-up clinic, please notify them of the following:

- ☐ The clinic is entirely free
- ☐ It is important for them to attend the clinic to ensure their recovery is properly managed
- ☐ It is important for them to come to clinic even if they feel normal and healthy
- ☐ If they have not yet finished paying their hospital bill, we will not force them to pay their bill

After discharge, patient records go to the accounts department so that the patient can complete their bill. The records should be received from the accounts department after the bill has been paid. The records should then be stored in the SIGN Nail Office until the completion of the study.

6. REDCAP Procedures

General Principles

- All dates are to be recorded in the format dd-mm-yyyy.
- A new record is only created when data is saved into that record
- A new form is created only when data is saved into that form
- **This is a key study question

Adding a New Record

A record is the same as a study participant. The Participant ID will be automatically generated by the REDCAP system in ascending numerical order. REDCAP does not allow you to change or manually input the participant ID.

1. Click on “Add/Edit Records” on the left panel



2. Click “Add new record”

A screenshot of the REDCAP form for adding a new record. It features a label "Choose an existing Participant ID" next to a dropdown menu with the text "-- select record --". Below the dropdown is a button labeled "Add new record".

Editing an Existing Record

1. Click on “Add/Edit Records” on the left panel



2. Click on the drop down menu and select the desired record. Wait for the record to load.

A screenshot of the REDCAP form for selecting an existing record. At the top, a yellow banner displays "Total records: 45". Below this is a label "Choose an existing Participant ID" next to a dropdown menu with the text "-- select record --".

6.1 Enrollment form – Screening and Consent

All open tibias will be screened during the enrollment study of the period. All included patients will be recorded in the same project and treatment arm on REDCAP regardless of whether or not they are in the RCT or Cohort study. Even those that will be excluded need to be reported on REDCAP.

1. Add a new record
2. Record Date of Screening, MRN, and First/Middle/Last Name
 - a. MRN is to be in the format BXXXXXXX as in all MRNs need to be led by a “B” followed by the appropriate number of blank zeroes. This is to maintain consistency with the MOI EMR and Clear Canvas
 - b. The first letter of each name should be capitalized

The screenshot shows a REDCAP data entry form with the following fields and labels:

- Participant ID**: A text input field with a red asterisk and the text "must provide value" below it.
- Date of Screening**: A date picker field with a calendar icon, a "Today" button, and a "D-M-Y" label. Below the field is the text: "Format is DD-MM-YYYY. Insert date manually, by clicking on the calendar image above, or press 'Today' if applicable".
- Medical Record Number**: A text input field with a red asterisk and the text "must provide value" below it.
- First Name**: A text input field with a red asterisk and the text "must provide value" below it.
- Middle Name**: A text input field.
- Last Name**: A text input field with a red asterisk and the text "must provide value" below it.

The next steps involve screening the patient for the appropriate inclusion/exclusion criteria. These should be performed with assistance from the patient’s surgeon.

3. Fill in inclusion criteria
 - a. Question1: OTA 42 refers to diaphyseal (mid-shaft) tibia fracture which must be confirmed by radiographic imaging
 - b. Question 2: Pedal pulses palpable is a clinical finding that confirms that the patient’s vascular system is intact
 - c. Question 3: Presentation time to MOI is defined as the time that they arrived at MOI’s emergency room (not Muhimbili National Hospital EMD)
 - d. Question 4: Skeletal mature is defined by closed physis as seen on radiographic imaging
 - e. Question 5: Primarily closable wound means that the skin is intact and that the contamination level is low enough for the patient’s wound to be fully closed at the time of surgery.

Matrix group: inc

Inclusion Criteria			
Variable: ota_42	yes	no	
Sustained diaphyseal open tibia fracture (AO/OTA 42) * must provide value	<input type="radio"/>	<input type="radio"/>	reset
Variable: inc_vasc			
Pedal pulses palpable (vascular system is intact) * must provide value	<input type="radio"/>	<input type="radio"/>	reset
Variable: inc_24hr			
Presentation to MOI within 24hr of injury * must provide value	<input type="radio"/>	<input type="radio"/>	reset
Variable: inc_mature			
X-ray's confirm skeletal maturity * must provide value	<input type="radio"/>	<input type="radio"/>	reset
Variable: inc_primary			
Wound can be primarily closed (no flap or delay in closure due to contamination needed) * must provide value	<input type="radio"/>	<input type="radio"/>	reset

4. Fill in Exclusion Criteria

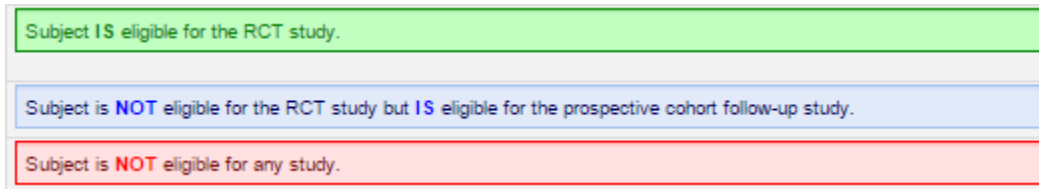
- Question 1: Pathologic fracture means a fracture which is due to weakening of the bone caused by an underlying bone disorder such as a tumor or osteoporosis.
- Question 2: Bilateral (meaning both legs) tibia fractures are excluded due to the difficulty in randomizing a patient with two open fractures and also the potential negative influence on outcomes that having two tibia fractures cause
- Question 3: GCS stands for Glasgow Coma Score. It is a rapid way to assess neurologic function. GCS < 12 means impaired cognitive function.
- Question 4: Paralysis means inability to use a particular body part
- Question 5: TBSA stands for Total Body Surface Area. Burns are calculated by assessing the percent of the skin they cover.
- Question 6: Prior ipsilateral leg injury means a previous injury in the same leg
- Question 7: This question is to rule out patients with physical or function leg deformities

Matrix group: exc

Exclusion Criteria			
Variable: exc_path	Yes	No	
Current injury is a pathologic fracture * must provide value	<input type="radio"/>	<input type="radio"/>	reset
Variable: exc_bilat			
Sustained bilateral tibia fracture * must provide value	<input type="radio"/>	<input type="radio"/>	reset
Variable: exc_femur			
Sustained comminuted femur fracture * must provide value	<input type="radio"/>	<input type="radio"/>	reset
Variable: exc_gcs			
Sustained severe Traumatic Brain Injury (GCS < 12) * must provide value	<input type="radio"/>	<input type="radio"/>	reset
Variable: exc_spine			
Sustained severe spinal cord injury (lower extremity paresis/paralysis) * must provide value	<input type="radio"/>	<input type="radio"/>	reset
Variable: exc_burn			
Sustained severe burns (>10% TBSA or >5% TBSA with full thickness or circumferential injury) * must provide value	<input type="radio"/>	<input type="radio"/>	reset
Variable: exc_ipsil			
Prior ipsilateral leg injury requiring surgery * must provide value	<input type="radio"/>	<input type="radio"/>	reset
Variable: exc_limb			
Prior or current lower limb deformity or abnormality * must provide value	<input type="radio"/>	<input type="radio"/>	reset

At the end of answering these questions, an automated message will be generated based on the answers provided.

5. Observe automated eligibility message
 - If all inclusion criteria are answer as “yes” and all exclusion criteria are answered as “no”, the patient is eligible for the RCT
 - If the patient (1) came to MOI 24 hours after injury, (2) has a non-primarily closeable wound, or (3) came to MOI 24 hours after injury AND has a non-primarily closeable wound, the patient will be eligible for the cohort study.
 - All other responses will result in exclusion for the study.



Subject IS eligible for the RCT study.

Subject is NOT eligible for the RCT study but IS eligible for the prospective cohort follow-up study.

Subject is NOT eligible for any study.

6. In situations where a patient is excluded for a particular reason, the only information that needs to be filled out on the screening form is the patients MRN, full name, and the one reason why the patient is excluded. It is not necessary to go through the other screening criteria if one criteria for certain excludes the patient. For excluded patients, a pop up box will appear. Record the exact reason for exclusion here.



Describe the reason for exclusion

* must provide value

Expand

7. Next, record whether or not the patient consents to the study.
 - a. If there is concern that the patient will not be able to be contacted for the 1 year follow-up visit, please choose that option. Note that this is one of the exclusion criteria.
 - b. If the patient is able to attend the follow-up visits but does not agree to participate in the study for any other reason, click “No” and record the reason why. It is important to record the reason why so that the study team can identify consistent reasons for not participating in the study.
 - c. If the patient provides consent, click “Yes” and confirm the study that the patient is enrolled in. This should match the study that the system automatically calculated. If it does not match, warning messages will pop up. Double check the screening questions to make sur the patient is enrolled in the correct study
 - d. If the patient was not identified before their operation but later found to have been eligible, record “missed patient”



Variable: consent_yn [Branching logic exists]

Has the patient agreed to be enrolled in the study?

**This is a key study question*

* must provide value

☐ Yes
☐ No
☐ Excluded because unlikely to attend all follow-up visits
☐ Missed patient (did not catch patient before surgery)

reset

The patient has been enrolled in the wrong study.

The patient IS eligible for the RCT but has been enrolled in the COHORT study.

Please double check the inclusion/exclusion criteria. Do not proceed until this error has been resolved.


The patient has been enrolled in the wrong study.

The patient IS eligible for the COHORT but has been enrolled in the RCT study.

Please double check the inclusion/exclusion criteria. Do not proceed until this error has been resolved.

Enrollment Form - Baseline Clinic Information

1. Record demographic information
 - a. If the exact date of birth down to the date cannot be provided, leave that field as empty and record in the text box an estimate of how old the patient is. When the patient's relatives come, please ask them for the exact date of birth
 - b. "Number of people in household" refers to the number of people the person shares a room/apartment/house with. These people may or may not be family members
 - c. "Number of people patient financially supports" refers to number of people the patient helps financially. These may or may not be family members
 - d. Insurance status refers to the type of insurance the patient has. If the patient buys insurance from a private company, check "Private". If the insurance the patient has is provided by the government, check "Public".

Demographics	
Date of Birth <small>* must provide value</small>	<input type="text"/>  <input type="button" value="Today"/> D-M-Y <small>Format is DD-MM-YYYY. Insert date manually, by clicking on the calendar image above, or press "Today" if applicable</small>
Gender <small>* must provide value</small>	<input type="radio"/> Male <input type="radio"/> Female <small>reset</small>
If the patient does not remember the date of birth, what is the patients age at time of injury (in years)	<input type="text"/>
Height (cm)	<input type="text"/> <small>This value is self reported</small>
Weight (kg)	<input type="text"/> <small>This value is self reported</small>
Highest level of education finished:	<input type="radio"/> None <input type="radio"/> Year 1 and 2 (Pre-Primary) <input type="radio"/> Standard I-VII (Primary) <input type="radio"/> Form 1-4 (Secondary Ordinary) <input type="radio"/> Form 5 and 6 (Secondary Advanced) <input type="radio"/> College <input type="radio"/> University <small>reset</small>
Number of people in household (including the patient):	<input type="text"/> ▼
Number of people patient financially supports (including the patient):	<input type="text"/> ▼
Insurance Status	<input type="radio"/> Private <input type="radio"/> Government <input type="radio"/> None <small>reset</small>

2. Ask about work status
 - a. "Formal Employment" refers to an official job with a contract such as a salaried health records technician at MOI. "Informal Employment" refers to people like boda boda drivers, etc.
3. Past Medical and Social History
 - a. Please individual ask the questions provided. Do not just say "do you have any other health problems"; if asked in this way, patients are more likely to forget to mention something
 - b. CD4 count refers to a lab test often given to people with HIV to check on their health status. Patients may or may not have been tested.
 - c. Smoking is a particularly important question because many studies on infection rates following open fracture repair cite smoking status as one of the contributors to an infection after surgery.





Past Medical and Social History	
Diabetes Status <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Decline to Answer <input type="radio"/> Unknown (Never Tested)
	reset
Additional comorbidities <small>* must provide value</small>	<input type="checkbox"/> None <input type="checkbox"/> Heart disease <input type="checkbox"/> Lung disease <input type="checkbox"/> Kidney disease <input type="checkbox"/> History of stroke <input type="checkbox"/> Tuberculosis <input type="checkbox"/> Other
HIV/AIDS Status <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Decline to Answer <input type="radio"/> Unknown (Never Tested)
	reset
Last known CD4 count AND DATE (if available)	<div style="border: 1px solid black; height: 80px; width: 100%;"></div>
	Expand
Answer only if patient has HIV/AIDS	
Other comorbidity	<input type="text"/>
Smoker <small>* must provide value</small>	<input type="radio"/> Current Smoker <input type="radio"/> Former Smoker <input type="radio"/> Non-Smoker
	reset
For how many years has the patient been smoking?	<input type="text"/>
About how many cigarettes does the patient smoke per day?	<input type="text"/>
For many years did the patient smoke?	<input type="text"/>
About how many cigarettes did the patient smoke per day when the patient was an active smoker?	<input type="text"/>
Does the patient drink alcohol?	<input type="radio"/> Yes <input type="radio"/> No
	reset
Number of drinks per WEEK	<input type="text"/>
	1 drink = 1 alcoholic beverage

4.

Past Medical and Social History	
Diabetes Status <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Decline to Answer <input type="radio"/> Unknown (Never Tested)
	reset
Additional comorbidities <small>* must provide value</small>	<input type="checkbox"/> None <input type="checkbox"/> Heart disease <input type="checkbox"/> Lung disease <input type="checkbox"/> Kidney disease <input type="checkbox"/> History of stroke <input type="checkbox"/> Tuberculosis <input type="checkbox"/> Other
HIV/AIDS Status <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Decline to Answer <input type="radio"/> Unknown (Never Tested)
	reset
Last known CD4 count AND DATE (if available)	<div style="border: 1px solid black; height: 80px; width: 100%;"></div>
	Expand
<small>Answer only if patient has HIV/AIDS</small>	

5. Injury Characteristics

- a. "Date and Time of Presentation to MOI" refers to the time they arrive at MOI's emergency room, not Muhimbili National Hospital emergency room
- b. "Outside Hospital" refers to any other hospital besides the hospitals in the Muhimbili Complex
- c. "Fall from standing height" means the patient was standing on the floor and then fell onto the floor (as in they did not fall off a roof)

Injury Characteristics	
Date and Time of Injury <small>* must provide value</small>	<input type="text"/>   <input type="button" value="Now"/> D-M-Y H:M <small>Insert date and time by clicking on the calendar image above</small>
Date and Time of Presentation to MOI <small>* must provide value</small>	<input type="text"/>   <input type="button" value="Now"/> D-M-Y H:M <small>Insert date and time by clicking on the calendar image above</small>
In which city did the injury occur?	<input type="text"/>
Was the patient referred to MOI from an outside hospital?	<input type="radio"/> Yes <input type="radio"/> No reset
How much time did it take to get to a hospital after the injury?	<input type="text"/>
Did the patient go from the injury site to the hospital by ambulance?	<input type="radio"/> Yes <input type="radio"/> No reset
Side of tibia fracture	<input type="radio"/> Left <input type="radio"/> Right reset
Mechanism of Injury	<input type="radio"/> Road Traffic Injury <input type="radio"/> Fall <input type="radio"/> Crush Injury (heavy object falling on leg) <input type="radio"/> Gunshot <input type="radio"/> Other reset
Was the patient a:	<input type="radio"/> Driver (car) <input type="radio"/> Passenger (car) <input type="radio"/> Driver (motorbike) <input type="radio"/> Passenger (motorbike) <input type="radio"/> Bicyclist <input type="radio"/> Pedestrian reset
Was the fall from standing height? ("Standing height" means they were standing on the floor and fell on the floor)	<input type="radio"/> Yes <input type="radio"/> No reset
How far did the patient fall? (meters)	<input type="text"/>
Describe "Other" mechanism of injury	<input type="text"/>

6. EQ-5D at Baseline

- a. The EQ-5D questions at this step of the study refer to the patient's health status just before the injury
- b. It is best to provide all the answer choices to the patient before allowing the patient to make a choice. This is how the original EQ-5D in English is tested and validated, and we should try to perform the EQ-5D as close as possible to the original way in which it was performed

Tafadhali onyesha maelezo yapi yanaelezea vizuri zaidi hali ya afya yako kwa leo.

<p>Uwezo wa kutembea</p> <p>* must provide value</p>	<p> <input type="radio"/> Sina tatizo katika kutembea <input type="radio"/> Nina matatizo kiasi katika kutembea <input type="radio"/> Siwezi kutembea kabisa </p> <p>reset</p>
<p>Uwezo wa kujihudumia</p> <p>* must provide value</p>	<p> <input type="radio"/> Sina tatizo kujihudumia mwenyewe <input type="radio"/> Nina matatizo kiasi katika kujisafisha au kuva mwenyewe <input type="radio"/> Siwezi kujisafisha wala kuva mwenyewe </p> <p>reset</p>
<p>Shughuli za kila siku (mfano: kazi, kusoma shuleni/chuoni, kazi za nyumbani, shughuli za kifamilia au starehe)</p> <p>* must provide value</p>	<p> <input type="radio"/> Sina tatizo katika kufanya shughuli zangu za kila siku <input type="radio"/> Nina matatizo kiasi katika kufanya shughuli zangu za kila siku <input type="radio"/> Siwezi kabisa kufanya shughuli zangu za kila siku </p> <p>reset</p>
<p>Maumivu / Kutojisikia vizuri</p> <p>* must provide value</p>	<p> <input type="radio"/> Sina maumivu au sina kutojisikia vizuri <input type="radio"/> Nina maumivu kiasi au najisikia vibaya kiasi <input type="radio"/> Nina maumivu makali au najisikia vibaya sana </p> <p>reset</p>
<p>Wasiwasi / mnyong'onyeo</p> <p>* must provide value</p>	<p> <input type="radio"/> Sina wasiwasi au mnyong'onyeo <input type="radio"/> Nina wasiwasi kiasi au mnyong'onyeo kiasi <input type="radio"/> Nina wasiwasi sana au nina mnyong'onyeo sana </p> <p>reset</p>
<p>Ili kuweza kukusaidia wewe kusema kama hali yako ya kiafya ni nzuri au mbaya, tumechora kipimo kinachofanana na kipima joto. Hali nzuri kabisa unayoweza kufikiria imewekewa alama ya 100 (mia moja) na hali mbaya kabisa unayoweza kufikiria imewekewa alama ya 0 (sifuri).</p>	
<p>Sasa tungependa utuambie sehemu katika kipimo hiki ambapo ungeiweka hali yako ya afya leo.</p> <p>* must provide value</p>	

- We will record at minimum 3 phone numbers. The first one will most likely be the patient's own phone number. Additional phone numbers can either be other phone numbers that the patient has or friends/relatives
- In the "Relationship to patient" question, a text box has been provided. Enter any description that will be useful when contacting that person such as "brother in law".
- After collecting 3 phone numbers, call the numbers and inform the people you call of the patient's injury and of their participation in the study. Also mention the importance of helping the patient attend all follow-up clinics. This is to encourage the contacts to take part in the patient's care and help them remember to attend the clinics.

Contact Information	
Primary phone number (most preferred contact) <small>* must provide value</small>	<input type="text"/>
Contact name (write "Self" if this is the patient) <small>* must provide value</small>	<input type="text"/>
Relationship to patient (write "Self" if this is the patient) <small>* must provide value</small>	<input type="text"/>
Secondary phone number <small>* must provide value</small>	<input type="text"/>
Contact name <small>* must provide value</small>	<input type="text"/>
Relationship to patient <small>* must provide value</small>	<input type="text"/>
Third phone number <small>* must provide value</small>	<input type="text"/>
Contact name <small>* must provide value</small>	<input type="text"/>
Relationship to patient <small>* must provide value</small>	<input type="text"/>
Were all three phone numbers successfully test called? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No
reset	
Save this form as "incomplete" until you are able to successfully test call all 3 numbers.	

8. Additional contact

- a. In situations where there is concern that the patient may be lost to follow-up, record additional phone numbers as back-up.
- b. "Describe where you live" is a free text box. Provide as much detail as possible so that it may be possible to find the patient later on if the phone numbers no longer work and they are lost to follow-up.

Additional Numbers	
Ward leader phone number (if available)	<input type="text"/>
Ward leader name	<input type="text"/>
Record additional phone numbers here. For each number, include the following: - Number - Name - Relationship (Self, Family, Friend, or Other)	<div style="border: 1px solid #ccc; height: 100px; width: 100%;"></div>
Expand	

Address

Describe where you live:

Expand

Describe where you plan to spend most of your time during recovery

Expand

Email

E-mail

If available


9. Antibiotics

- Once the patient has provided consent to participate in the study, they should receive antibiotics as quickly as possible if they have not yet.
- If the patient received antibiotics at another hospital but then came to MOI and was changed onto a study antibiotic regiment, choose "other" and record the details of all antibiotics given since the time of injury

Antibiotics

Date and time of first dose of antibiotics administered after the injury

* must provide value

 D-M-Y H:M
Insert date and time by clicking on the calendar image above

Was the first dose of antibiotics administered at MOI?

* must provide value

- ☐ Yes
☐ No

reset

What antibiotic regiment is the patient starting on at MOI?

* must provide value

- ☐ Ceftriaxone only
☐ Ceftriaxone + gentamycin
☐ Ceftriaxone + gentamycin + metronidazole
☐ Other

reset

If "Other", describe the following:

- Type of antibiotic
- Dosage
- Length of administration
- Reason of using a non-standard antibiotic

Expand

Standard Study Antibiotics Regiment

- None or Mild Contamination: Ceftriaxone (1g every 24hr for 2 days)
- Surface Contamination (not ground in): Ceftriaxone (as above) + Gentamycin (80mg every 12hr for 2 days)
- Severe or High-Risk: Ceftriaxone + Gentamycin (as above) + Metronidazole (500mg every 8hr for 2 days)

10. Tetanus prophylaxis

- a. All patients should have tetanus prophylaxis. This is usually in the form of a shot given in childhood with repeated shots every few years. If the patient does not remember or knows they have never received a tetanus shot, work with the National Hospital Emergency physicians to ensure the patients get the shot as soon as possible. This is most important for the patient's health, but also important for the study.
- b. Ward number refers to the ward that the patient will be sent to after the operation. This depends on the patient's insurance status.

Tetanus Prophylaxis	
Has the patient received tetanus immunization (either in the past or now)?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
reset	
Please check the patient's file or tell the physician to administer tetanus immunization	
Ward Number	
Which ward is the patient expected to go to after the operation?	<input type="text"/>

6.2 Intra-operative/Discharge Form

This form applies to both RCT and cohort patients. But for cohort patients, the randomization module will not appear.

1. Wound measurement

- a. A measurement of the wound should be performed after the patient receives pain medication and after all bandages and dressings have been removed. Take the maximum dimension of the portion that is open, ignoring superficial abrasions
- b. The measurement should be done in centimeters using a ruler rather than visually approximated. Be as precise with the measurement as possible

2. Surgical Debridement and Primary Closure status

- a. Whether or not the surgeon believes the wound can be primarily closed is done after surgical debridement. They will clean up the wound, manipulate the fracture, and see if there is enough skin to close the wound.
- b. If the surgeon believes the patient can be primarily closed, the patient passes the last exclusion criteria check and should remain in the study. If it is a cohort patient, it is up to the surgeon which operation the patient receives. If it is an RCT patient, proceed to the randomization module

Has the wound been surgically debrided?	<input type="radio"/> Yes <input type="radio"/> No	reset
* must provide value		
Does the surgeon believe this patient is primarily closeable?	<input type="radio"/> Yes <input type="radio"/> No	reset
This is a key study question		
* must provide value		

- c. If the surgeon believes the wound is not primarily closeable, the patient needs to be excluded from the study. This is considered an “intra-operative exclusion”. This is what the warning message looks like:

Subject is **NOT** eligible for the RCT study anymore.

This patient is considered an "intraoperative exclusion". Save the form as "Complete". Do not change any information that has already been collected.

Subject is **NOT** eligible for the cohort study anymore.

This patient is considered an "intraoperative exclusion". Save the form as "Complete". Do not change any information that has already been collected.

3. Randomization (RCT ONLY)

- a. If the patient is a cohort patient, the following reminder message will appear indicating the randomization module is hidden for these patient

Subject is a **PROSPECTIVE COHORT** patient. The randomization module will not appear. Please complete the remaining questions.

The patient has been enrolled in the wrong study.

The patient **IS** eligible for the RCT but has been enrolled in the **COHORT** study. Because of this, the randomization window module will not appear.

Please double check the inclusion/exclusion criteria. Do not proceed until this error has been resolved.

- b. For RCT patients, this is what the randomization module appears like. Click on randomize, confirm the warning message, and randomize the patient. The randomization module results are final. Once randomization has been performed, the patient must remain in the study and must receive that operation

Variable: random [Branching logic exists]

THIS IS THE RANDOMIZATION MODULE. ONCE YOU RANDOMIZE, THE RESULTS ARE FINAL

This patient has been randomized to receive:

* must provide value

Date and Time of Randomization

* must provide value

Insert date and time by clicking on the calendar image above

4. Damage Control

- a. If the patient believes that damage control using a temporary external fixator should be performed before the definitive operation that the patient has been randomized to (in the case of RCT patients) or that the surgeon has decided (in the case of cohort patients), then record “Yes”. Damage control is usually done in situations where the patient is not hemodynamically stable enough for a full surgery, but it is still better to temporarily fixate the fracture using an exfix.

Variable: random [Branching logic exists]

THIS IS THE RANDOMIZATION MODULE. ONCE YOU RANDOMIZE, THE RESULTS ARE FINAL

This patient has been randomized to receive:

* must provide value

Date and Time of Randomization

* must provide value

Insert date and time by clicking on the calendar image above

Will the surgeon perform "damage control" using an external fixator because the patient is currently too unstable?

☐ Yes

☐ No

* must provide value

reset

The patient will now receive a temporary external fixator and receive the definitive operation at a later date. This is allowed under our study protocol.

Please remember to record the dates of both operations in the post-op/discharge form.

5. At this time, additional antibiotics can be added or removed depending on how much contamination the surgeon believes there to be inside the wound

Does the surgeon believe additional antibiotics are required?

☐ + Gentamycin

☐ + Gentamycin + Metronidazole

☐ Other

☐ No

reset

If "Other", please describe the following:

- Type of antibiotic

- Dosage

- Timing

Expand

6. Wound Characteristics
 - a. Record the wound measurement details here in centimeters
 - b. OTA wound classification performed by surgeon

Wound Measurement	
Wound measurement length in centimeters (Measure the maximum dimension)	<input type="text"/>
<small>* must provide value</small>	
OTA Wound Classification	
Skin:	<input type="radio"/> Laceration with edges that approximate <input type="radio"/> Laceration with edges that do not approximate <input type="radio"/> Laceration associated with extensive degloving
	reset
Muscle:	<input type="radio"/> No appreciable muscle necrosis, or some injury with function intact <input type="radio"/> Loss of muscle but remains functional, or localized necrosis in injured area that requires excision <input type="radio"/> Dead muscle, loss of function, partial or complete compartment excision, complete disruption of muscle-tendon unit, muscle injury not approximatable
	reset
Arterial:	<input type="radio"/> No injury <input type="radio"/> Injury, no ischemia <input type="radio"/> Injury with distal ischemia
	reset
Contamination:	<input type="radio"/> None or minimal contamination <input type="radio"/> Surface contamination (not ground in) <input type="radio"/> Contaminant embedded in bone or deep soft tissues or high risk environmental conditions (barnyard, fecal, dirty water, etc.)
	reset
Bone Loss:	<input type="radio"/> None <input type="radio"/> Bone loss, but still some contact between proximal and distal fragments <input type="radio"/> Segmental bone loss
	reset

6. 3 Baseline Image Upload

Oftentimes, there are differences in how the patient's registration information is registered into the system. If it is not possible to find a patient using his last name, try using the middle or first names or using different spellings. It is also possible to search by MRN or date of x-ray. It is standard policy at MOI that all patients who will get operated at MOI receive x-ray imaging prior to and after the operation. This applies even if the patient arrives at MOI with x-rays taken at another hospital. Therefore, the x-rays should be in the system even if it is difficult to find the x-rays on the computer. Try different search criteria.

It is also of note that desktops in the radiology department immediately adjacent to the x-ray machine which are connected to the machines that digitally scan the x-rays have their images erased on a regular basis. ClearCanvas, however, stores the images on a server indefinitely.

If the x-rays need to be redone, a note should be made in REDCAP

1. The consent form, pre-op x rays, and post-op x-rays should be uploaded as soon as they are available.
 - a. There is an option to upload extra images if they are available. Check on the Extra Image #, describe the image, and upload it by pressing on the “Upload document” link
 - b. Upload any extra images that may be useful for UCSF during review

Baseline Image Upload	
Please upload the signed consent document here	+ Upload document
Upload PRE-OP AP view:	+ Upload document
Upload PRE-OP Lateral view:	+ Upload document
Upload POST-OP AP view:	+ Upload document
Upload POST-OP Lateral view:	+ Upload document
Check here for any extra images that need to be uploaded:	<input type="checkbox"/> Extra Image #1 <input type="checkbox"/> Extra Image #2 <input type="checkbox"/> Extra Image #3 <input type="checkbox"/> Extra Image #4 <input type="checkbox"/> Extra Image #5 <input type="checkbox"/> Extra Image #6
Describe what Extra Image #1 is:	<input type="text"/>
Upload Extra Image #1:	+ Upload document

2. The following questions will be used to evaluate the images at baseline
 - a. While the option “X-rays not adequate” has been provided, please refrain from using this answer choice as much as possible in order to maximize the amount of data obtained from the images.

Fracture Classification	
OTA Classification	<input type="radio"/> A1 Simple Spiral <input type="radio"/> A2 Simple Oblique ($\geq 30^\circ$) <input type="radio"/> A3 Simple Transverse ($\leq 30^\circ$) <input type="radio"/> B1 Wedge Spiral <input type="radio"/> B2 Wedge Bending <input type="radio"/> B3 Wedge Fragment <input type="radio"/> C1 Complex Spiral <input type="radio"/> C2 Complex Segmental <input type="radio"/> C3 Complex Irregular <input type="radio"/> X-rays not adequate
	reset
Location (continuous)	<div> <div>Proximal (0%)</div> <div>50%</div> <div>Distal (100%)</div> </div> <div> <input type="range"/> <input type="checkbox"/> </div> <div>Click bar above and then drag to set response</div>
	reset
Number of Cortices Proximally	<input type="text"/> "N/A" if x-rays not adequate
Number of Cortices Distally	<input type="text"/> "N/A" if x-rays not adequate
Coronal alignment	<input type="radio"/> < 5 degrees <input type="radio"/> 5-10 degrees <input type="radio"/> >10 degrees <input type="radio"/> X-rays not adequate
	reset
Degrees coronal angulation (Continuous)	<input type="text"/> "N/A" if x-rays not adequate
Direction of angulation	<input type="radio"/> Varus <input type="radio"/> Valgus <input type="radio"/> X-rays not adequate
	reset

Sagittal alignment	<input type="radio"/> < 5 degrees <input type="radio"/> 5-10 degrees <input type="radio"/> >10 degrees <input type="radio"/> Radiographs not adequate	reset
Degrees sagittal angulation (Continuous)	<input type="text"/> <small>"N/A" if x-rays not adequate</small>	
Direction of Sagittal Angulation	<input type="radio"/> Procurvatum <input type="radio"/> Recurvatum <input type="radio"/> X-rays not adequate	reset
Translation as percentage of shaft width	<input type="radio"/> 0-5 <input type="radio"/> 5-10 <input type="radio"/> 10-15 <input type="radio"/> >15 <input type="radio"/> X-rays not adequate	reset
Winqvist-classification	<input type="radio"/> Type I - Minimal or no comminution; if comminution is present, there is involvement of 25% or less of the bony circumference <input type="radio"/> Type II - Comminuted fragments involve up to 50% of the width of the bone <input type="radio"/> Type III - Comminuted fragment involves more than 50% of the width of the bone; leaves only a small area of contact between the proximal and distal fragments <input type="radio"/> Type IV - Comminution involves the entire bony circumference; no cortical contact <input type="radio"/> X-rays not adequate	reset
Bone loss?	<input type="radio"/> None <input type="radio"/> Bone missing or devascularized bone fragments, but still some contact between proximal and distal fragments <input type="radio"/> Segmental bone loss <input type="radio"/> X-rays not adequate	reset
Is the bone loss >50% of the circumference?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> X-rays not adequate	reset
Length of segment with bone loss	<input type="text"/> <small>"N/A" if x-rays not adequate</small>	

6.4 Post-Op Discharge

This form is to be filled out the morning after the patient's operation. This information is to be found in the patient's record which will be with the nurses in the ward.

1. Temporary Fixation using Damage Control

- a. Report whether or not temporary fixation was performed. If there is a mismatch between what was said about temporary fixation in the Intra-op/Randomize Form, warning messages will occur asking you to double check your answer.
- b. Note that if temporary fixation was not performed, the option to record the date of temporary fixation will not appear.

Temporary Fixation

Was damage control using a temporary external fixator performed?

☐ Yes
 ☐ No

* must provide value

reset

The intra-operative form indicates that the patient **DID** require temporary fixation. Please review the patient's chart. Contact Max if there is any confusion.

The intra-operative form indicates that the patient **DID NOT** require temporary fixation. Please review the patient's chart and contact Max if there is any confusion.

What date was temporary fixation performed?

00

31


Today

D-M-Y

* must provide value

Format is DD-MM-YYYY. Insert date manually, by clicking on the calendar image above, or press "Today" if applicable

2. Date of definitive treatment
 - a. This is a critical study question because the reports for follow-up visits is based on this question
 - b. If there is a mismatch between the type of definitive option stated in this form and what the patient was randomized to, a warning message will appear
 - c. The size of the interlocking screws does not have to be recorded.

Definitive Treatment	
Date of Definitive Operation	<input type="text"/>  Today D-M-Y <small>Format is DD-MM-YYYY. Insert date manually, by clicking on the calendar image above, or press "Today" if applicable</small>
This is a key study question <small>* must provide value</small>	
What type of definitive operation was performed?	<input type="text"/> ▼
This is a key study question <small>* must provide value</small>	
The incorrect operation was performed. Please notify the review committee immediately.	
The incorrect operation was performed. Please notify the review committee immediately.	
What is the size of the SIGN nail used?	<input type="text"/>
Number of proximal interlocking screws	<input type="radio"/> 1 <input type="radio"/> 2 reset
Number of distal interlocking screws	<input type="radio"/> 1 <input type="radio"/> 2 reset
What is the training level of the most experienced surgeon present for the operation	<input type="radio"/> Consultant <input type="radio"/> Specialist <input type="radio"/> Resident <input type="radio"/> Registrar <input type="radio"/> Intern reset

3. Operation duration times can be found in the patient's record. These have been recorded during the operation

Definitive Treatment Operation Duration	
Start of Preparation in OT	<input type="text"/>  Now H:M
Patient Arrival in OT	<input type="text"/>  Now H:M
Starting Time of Operation (Cut)	<input type="text"/>  Now H:M
End Operation Time (Bandage)	<input type="text"/>  Now H:M
End of Post-Op Preparation	<input type="text"/>  Now H:M

4. Associated Orthopaedic Injuries and Injury Severity Score
 - a. Review the information in the patient's record and note any other injuries that the patient has besides the open tibia fracture. If there are other injuries, check yes for the appropriate injury classification. A text box will appear. Record what the physician wrote word for word. It is best not to interpret what the doctor said.
 - b. If there is something you see that the patient has but the physician did not record the associated injury, notify the physician to confirm. If the physician agrees, record the information in the patient's record first, then record in REDCAP.
 - c. "Ipsilateral" means the same side of the body. "Contralateral" means the opposite side of the body. If a patient has a tibia fracture on the left leg, contralateral limb injuries refer to injuries on the right leg or arm

- d. The Injury Severity Score uses a formula that turns diagnoses into a severity, and calculates the score over the entire body. It is an overall measure of the patient's health after an injury.

Associated Orthopedic Injuries			
	Yes	No	
Other IP SILATERAL LOWER extremity injuries (besides the open tibia fracture)?	<input type="radio"/>	<input type="radio"/>	reset
Any CONTRALATERAL LOWER extremity injuries?	<input type="radio"/>	<input type="radio"/>	reset
Any IP SILATERAL UPPER extremity injuries?	<input type="radio"/>	<input type="radio"/>	reset
Any CONTRALATERAL UPPER extremity injuries?	<input type="radio"/>	<input type="radio"/>	reset
Describe other ipsilateral lower extremity injuries	<div></div>		Expand

Injury Severity Score			
	Yes	No	
Head/Neck (+ Cervical Spine)	<input type="radio"/>	<input type="radio"/>	reset
Face (+ Facial Skeleton, Nose, Mouth, Eyes, Ears)	<input type="radio"/>	<input type="radio"/>	reset
Chest	<input type="radio"/>	<input type="radio"/>	reset
Abdomen (+ Lumbar Spine)	<input type="radio"/>	<input type="radio"/>	reset
External	<input type="radio"/>	<input type="radio"/>	reset
Describe head/neck injuries	<div></div>		Expand

5. Antibiotics Check

- a. Record any additional antibiotics that were given in the ward and whether or not all the courses of antibiotics the patient was started on were properly completed (all doses were given on time)

Antibiotics Check	
Did the patient get started on any other antibiotics while in the ward besides the ones that have already been recorded?	<input type="radio"/> Yes <input type="radio"/> No
* must provide value reset	
What other antibiotics did the patient receive? - Type of antibiotic - Dose - Timing	<div style="border: 1px solid #ccc; height: 80px;"></div> <div style="text-align: right;">Expand</div>
Were all antibiotic courses administered on time and completed?	<input type="radio"/> Yes <input type="radio"/> No
This is a key study question * must provide value reset	
Describe which antibiotics were not administered on time or completed.	<div style="border: 1px solid #ccc; height: 80px;"></div> <div style="text-align: right;">Expand</div>
Standard Study Antibiotics Regiment - None or Mild Wound Contamination: Ceftriaxone (1g every 24hr for 2 days) - Moderate: Ceftriaxone (as above) + Gentamycin (80mg every 12hr for 2 days) - Severe or High-Risk: Ceftriaxone + Gentamycin (as above) + Metronidazole (500mg every 8hr for 2 days)	

- b. Pin care information should be given to patients who have an exfix. The protocol is to pour methylated spirited onto the pin 2x a day

Discharge	
Has the patient received proper exfix pin care information?	<input type="radio"/> Yes <input type="radio"/> No
<div style="border: 1px solid red; padding: 5px;"> Please instruct the patient on proper pin-care (pour methylated spirit onto the pin 2x a day) Afterwards, change the answer to the above question to "Yes". </div> <div style="text-align: right;">reset</div>	
Has a follow-up schedule been generated for the patient?	<input type="radio"/> Yes <input type="radio"/> No
* must provide value reset	
<div style="border: 1px solid red; padding: 5px;"> Please save this form as "Incomplete" and generate a follow-up schedule for the patient. Afterwards, change the answer to the above question to "Yes". </div>	
Time and Date of Discharge	<div style="display: flex; align-items: center;"> <input style="width: 100px;" type="text"/> <div style="margin-left: 10px;"> <input type="button" value="Now"/> D-M-Y H:M </div> </div> <div style="font-size: small; margin-top: 5px;"> * must provide value Insert date and time by clicking on the calendar image above </div>

6.5 Follow-up Evaluation Form

This form is intended for use at all of the follow-up evaluations. These evaluations can be the Saturday in-person clinics or the ones done over the telephone in situations where the patient cannot come to clinic.

1. Follow-up visit number and type
 - a. “Which follow-up evaluation?”: Even though REDCAP automatically generates a new Follow-up Evaluation form at each evaluation time point, this form asks again what evaluation visit number this form is for. This is important because the questions for a 2 week visit are different from the 6week to 1 year follow-up visit.
 - b. It is important to properly answer the “Type of Follow-up Evaluation” question properly because what you say determines the types of questions that appear. Certain questions such as Range of Motion evaluation can only be answer in person.

Follow-up Visit	
Which follow-up evaluation? <small>* must provide value</small>	<input type="radio"/> 2 Week <input type="radio"/> 6 Week <input type="radio"/> 3 Month <input type="radio"/> 6 Month <input type="radio"/> 1 Year reset
Record any reminders here to do for the patient during this follow-up visit:	<div style="border: 1px solid black; height: 80px;"></div> Expand
Date of evaluation <small>* must provide value</small>	<div> <input type="text"/> <input type="button" value="cal"/> <input type="button" value="Today"/> D-M-Y </div> <small>Format is DD-MM-YYYY. Insert date manually, by clicking on the calendar image above, or press "Today" if applicable</small>
Time from Surgery to Follow up	<input type="text"/> View equation
Type of Follow-up Evaluation **This is a key study question** <small>* must provide value</small>	<input type="radio"/> Patient attended Saturday clinic in-person <input type="radio"/> Telephone evaluation (missed clinic) reset
What is the reason for missing the appointment?	<input type="text"/>

2. Work

Return to Work

Has the patient been working at all since the last follow-up visit?	<input type="radio"/> Yes <input type="radio"/> No	reset
Has their health status prevented them from going back to work?	<input type="radio"/> Yes <input type="radio"/> No	reset
Has their health status prevented them from working at their usual level?	<input type="radio"/> Yes <input type="radio"/> No	reset
Is this the first time the patient has gone back to work since the operation?	<input type="radio"/> Yes <input type="radio"/> No	reset
Estimated date of return to work?	<input type="text"/> <small>date</small> 31 <input type="button" value="Today"/> D-M-Y	
What is the type of employment for the patient's main source of income?	<input type="radio"/> Formal Employment <input type="radio"/> Informal Employment	reset
What type of duty does the patient perform as his or her main source of income?	<input type="radio"/> Heavy manual labor <input type="radio"/> Mostly walking but not heavy lifting <input type="radio"/> Mostly sitting or standing	reset
Approximately how much did the patient make per WEEK (in Tanzanian Shillings)?	<input type="text"/>	
For approximately how many WEEKS did the patient work since the last follow-up visit	<input type="text"/> <small>Report in weeks (not days or months)</small>	

3. Pain assessment

- 10 is always worst imaginable pain. 0 is always no pain.
- The Tegner-Lysholm Knee Scoring System questions will appear only for patients who report anterior knee pain. It is best to read out the answer choices for the patient rather than asking them to provide the answer and interpreting their response. While some of the questions repeat questions that have already been asked, the knee scoring system needs to be completed in its entirety in order for a score to be calculated from the responses the patient provides.

Pain Assessment	
Mark all sites that are painful	<input type="checkbox"/> Knee <input type="checkbox"/> Fracture Site <input type="checkbox"/> Ankle/Foot <input type="checkbox"/> Other
Where in the knee is the pain the worst?	<input type="radio"/> Anterior <input type="radio"/> Posterior <input type="radio"/> Medial <input type="radio"/> Lateral reset
Current level of pain at the fracture sites?	<input type="text"/>
Specify other location of pain	<input type="text"/>
What is the patient's current level of pain today?	<input type="text"/>
Is there tenderness to palpation at the fracture site?	<input type="radio"/> Yes <input type="radio"/> No reset
Tegner-Lysholm Knee Scoring System: The following questions are specific to patients who have anterior knee pain.	
Is the anterior knee pain worse during weight bearing?	<input type="radio"/> Yes <input type="radio"/> No reset
Pain	<input type="radio"/> None <input type="radio"/> Inconstant during severe exertion <input type="radio"/> Noticeable during severe exertion <input type="radio"/> Noticeable after walking more than 2km <input type="radio"/> Noticeable after walking less than 2km <input type="radio"/> Constant reset
Does the patient have leg pain with weight bearing?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A (Not weight bearing yet) reset
Instability	<input type="radio"/> Never giving way <input type="radio"/> Rarely (during severe exertion) <input type="radio"/> Frequently (during severe exertion) <input type="radio"/> Occasionally (in daily activities) <input type="radio"/> Often (in daily activities) <input type="radio"/> Every step reset

Limp	<input type="radio"/> None <input type="radio"/> Slight or periodical <input type="radio"/> Severe and constant	reset
Support	<input type="radio"/> None <input type="radio"/> Stick or crutch <input type="radio"/> Weight-bearing impossible	reset
Locking	<input type="radio"/> No locking/catching sensations <input type="radio"/> Catching sensation but no locking <input type="radio"/> Locking occasionally <input type="radio"/> Frequently <input type="radio"/> Locked joint on examination	reset
Swelling	<input type="radio"/> None <input type="radio"/> On severe exertion <input type="radio"/> On ordinary exertion <input type="radio"/> Constant	reset
Stair Climbing	<input type="radio"/> No problems <input type="radio"/> Slightly impaired <input type="radio"/> One step at a time <input type="radio"/> Impossible	reset
Squatting	<input type="radio"/> No problems <input type="radio"/> Slightly impaired <input type="radio"/> Not beyond 90° <input type="radio"/> Impossible	reset

4. Imaging and Functional Testing

- These questions all require physical examination by the patient's surgeon. These questions do not appear for patients who are being evaluated over the telephone
- A squat and smile test will be conducted like in the femur study. Be sure to upload the image with a clear view of the entire body during the test.

Imaging and Functional Testing

Maximum knee extension	<input type="text"/>	▼
Maximum knee flexion	<input type="text"/>	▼
Maximum ankle plantar flexion	<input type="text"/>	▼
Maximum ankle dorsiflexion	<input type="text"/>	▼
Is there a leg length discrepancy greater than or equal to 1cm?	<input type="radio"/> Yes, the operated leg is shorter <input type="radio"/> Yes, the operated leg is longer <input type="radio"/> No	reset
How much is the leg length discrepancy in centimeters?	<input type="text"/>	
This should be measured with a ruler with the patient lying down rather than approximated or self-reported by the patient)		
Is the operative limb malrotated compared to the unaffected side?	<input type="radio"/> Yes <input type="radio"/> No	reset
Is the operated extremity internally or externally rotated?	<input type="radio"/> Internally rotated <input type="radio"/> Externally rotated	reset
How big is the difference in rotation (in degrees)?	<input type="text"/>	
Follow-up x-ray photos of operative site taken for this visit? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	reset
Is the patient able to go to a local hospital to take lateral and AP views of the operative site?	<input type="radio"/> Yes <input type="radio"/> No	reset

Please have the patient take x-rays of the operative site.

If, for some reason, no x-rays will be taken for this follow-up evaluation, please describe the reason here.

Expand

Is the patient able to send a picture of him performing the squat and smile test?

☐ Yes
☐ No

reset

Is the patient able to squat?

☐ Full squat (without pain)
☐ Full squat (with pain)
☐ Partial squat
☐ Unable to squat

reset

Squat and Smile Photo Taken?

☐ Yes
☐ No

reset

Please remember to upload the images on the image upload form.

Squat and Smile Comments

Expand

- c. The walking test will be administered according to the NIH 4 Meter Walking Test guidelines. Two tests will be conducted, and REDCAP will automatically calculate the average. Directions can be found online at the following link:
<http://www.nihtoolbox.org/WhatAndWhy/Motor/Locomotion/Pages/NIH-Toolbox-4-Meter-Walk-Gait-Speed-Test.aspx>

Is the patient able to perform the walking speed test?

☐ Yes
☐ No

reset

Walking Speed Test #1 (Seconds):

Time to walk 4 meters (in seconds)

Walking Speed Test #2 (Seconds):

Time to walk 4 meters (in seconds)

Averaged walking speed test time

View equation

5. Complications

- a. Properly recording complications is critical for the study because our end goal is to compare complication and reoperation rates between the two groups.
- b. Exfix patients will have additional questions appear related to schanz pin tract infections

Exfix Questions	
Has the patient been performing proper pin-care with spirit 2x a day?	<input type="radio"/> Yes <input type="radio"/> No
reset	
Please inform the patient about the importance of proper pin care	
What is the plan for the exfix? (Removal at 3 months with or without cast applied is standard procedure)	<input type="radio"/> Exfix removal at 3 months <input type="radio"/> Exfix removal AND a cast will be applied <input type="radio"/> Delayed exfix removal <input type="radio"/> Other (early removal, conversion, etc.)
reset	
This exfix plan is not standard. Please report this as a complication in the "Complications and Review" Form	
Are the Schanz pin tracts infected?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A (Exfix already removed)
reset	
How many pins are infected?	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4
reset	
Pin tract infection level (and corresponding treatment plan):	<input type="radio"/> 0 - Normal (requires weekly pin care) <input type="radio"/> 1 - Inflamed (requires daily pin care) <input type="radio"/> 2 - Serous discharge (requires antibiotics) <input type="radio"/> 3 - Purulent discharge (requires antibiotics) <input type="radio"/> 4 - Osteolysis (requires removal of pin) <input type="radio"/> 5 - Ring Sequestrum (requires debridement)
reset	
Since surgery is required to fix the schanz pin infection, please record the details on the "Complications" Form	

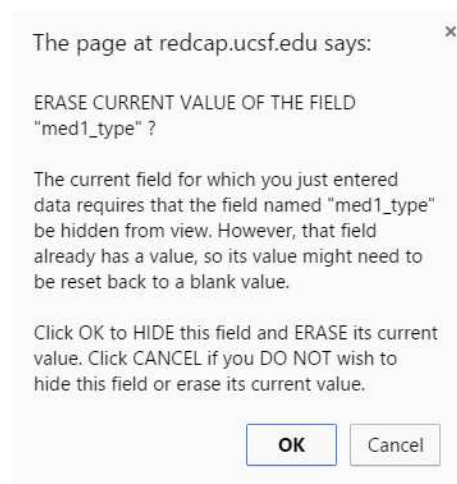
- c. If the patient has a medical or surgical complication, record "Yes" and proceed to the "Complications and Review" form. That is where additional information will be recorded.
 - i. A pop-up warning will appear if a patient has had a complication recorded and is coming back for follow-up. This is to enable us to be up to date with complications.

Complications	
Does the patient have any complications? These can include:	
- Infection - Wound problems - Nonunion/malunion - Hardware failure - Medical problems	<input type="radio"/> Yes <input type="radio"/> No
reset	
Please record the complication in the "Complications and Review" form	
This patient has previously had a complication recorded. Please update the 'Complications' form with any new events that may have occurred since.	

6.6 Complications and Review Form

This form is to be used to record all complications that occur in a patient throughout the entire time that the patient is in the study. There is only one form per patient (the form does not repeat). It can be used for complications that are caught during a follow-up Saturday clinic or when a patient reports a complication outside of a clinic.

1. Notes on how to use this form
 - a. The most important thing is to never uncheck an Event # checkbox that already has information stored in it. If this is done, a warning message will appear asking you if you want to delete the information or note. Press “OK” if your intention is to delete the information. If it was an accident, press “CANCEL” and then check the box that you accidentally unchecked. If any information is lost, leave the form and press “Leave and do not save record” when the warning message appears. If any information was accidentally deleted, please tell Max. He may have a backup of the data if the data was not reported very recently. If he does not have a backup, he may be able to contact REDCAP or UCSF to retrieve the data.



2. Overview
 - a. Whenever a new complication needs to be reported, check the appropriate checkbox in order to open the questions where information can be recorded. It is important to note that Event #2 does not refer to “report two events”, it refers to “report the second event”.


- b. Delayed exfix removal has its own types of questions and is listed separately. This is only for patients on exfix who need to stay on the exfix longer than 3 months.

Overview of Complications	
Has the patient died?	<input type="radio"/> Yes <div>reset</div>
Which MEDICAL complication do you want to report?	<input type="checkbox"/> Event #1 <input type="checkbox"/> Event #2 <input type="checkbox"/> Additional Events
Which SURGICAL complication event do you want to report? (Do not uncheck boxes of events that have already been reported)	<input type="checkbox"/> Event #1 <input type="checkbox"/> Event #2 <input type="checkbox"/> Event #3 <input type="checkbox"/> Additional Events <input type="checkbox"/> Delayed Exfix Removal

- 3. Mortality
 - a. To be used only if the patient has died
 - b. A query needs to be opened (See “Adjudication Review” Section)
- 4. Medical Complications
 - a. The most important thing to record for medical complications is whether or not the patient needed to be hospitalized.
 - b. Medical complications do not be reported unless there is concern that needs to be reviewed by the review committee
 - c. Any additional medical problems beyond 2 events need to be reported in free text entry in a text box. Number the medical complication events accordingly (Event #3...)

Medical Event #1

What day was the medical problem first diagnosed by the physician?

 Today D-M-Y

Format is DD-MM-YYYY. Insert date manually, by clicking on the calendar image above, or press "Today" if applicable

What kind of medical problem does this patient have?

* must provide value

- ☐ Stroke/Hemorrhage
- ☐ Heart Attack
- ☐ Pulmonary Embolism
- ☐ Pneumonia
- ☐ Deep Vein Thrombosis (DVT)
- ☐ Allergic Reaction
- ☐ Other/Multiple

reset

Describe the medical problem here

Expand

What kind of treatment did the patient receive?

- ☐ Treatment with hospitalization
- ☐ Treatment without hospitalization
- ☐ No Treatment

reset

Describe the treatment

Expand

Where was the patient hospitalized?

How many days was the patient hospitalized for?

Additional Medical Problems

Describe details of all other medical problems including:

- 1, Date of diagnosis
- 2, Type of problem
- 3, Treatment
- 4, Number of days hospitalized (if applicable)
- 5, Location of hospitalization (if applicable)




Expand


5. Surgical Complications


- a. If a surgical complication requires reoperation, record the estimated date and press "No" if the reoperation has not occurred yet. Patients who are awaiting reoperation will appear on the "Awaiting Reoperation" report.
 - i. Record "no" for the question "has this been reviewed yet". This will cause the complication to appear on the "Adjudication Review" report. Once the item

has been reviewed, Max will record “yes” which will remove the complication from the report.

- b. Once the patient has had their reoperation, change the answer to “Yes” and record the actual date of the reoperation.

Surgical Complication #1	
What day was the complication first diagnosed by a physician?	<input type="text"/>  Today D-M-Y <small>Format is DD-MM-YYYY. Insert date manually, by clicking on the calendar image above, or press "Today" if applicable</small>
What is the surgical complication? <small>* must provide value</small>	<ul style="list-style-type: none"><input type="radio"/> Superficial Surgical Site Infection<input type="radio"/> Deep Surgical Site Infection<input type="radio"/> Delayed Wound Healing<input type="radio"/> Nonunion/Delayed Union<input type="radio"/> Malalignment/Malunion<input type="radio"/> Hardware Failure (Non-infectious)<input type="radio"/> Missed Interlock<input type="radio"/> Compartment Syndrome<input type="radio"/> Other/Multiple <div style="text-align: right;">reset</div>
Describe the details of the complication <small>* must provide value</small>	<div style="border: 1px solid #ccc; height: 80px; width: 100%;"></div> <div style="text-align: right;">Expand</div>
Upload any relevant images here (if available):  Upload document	
Is reoperation being considered for this complication? <small>* must provide value</small>	<div style="display: flex; align-items: center;"><div style="flex: 1;"><input type="radio"/> Yes <input type="radio"/> No</div><div style="text-align: right;">reset</div></div>
Which hospital will the reoperation be performed at?	<input type="text"/>
ESTIMATED date of reoperation	<input type="text"/>  Today D-M-Y <small>Format is DD-MM-YYYY. Insert date manually, by clicking on the calendar image above, or press "Today" if applicable</small>

Has the reoperation been performed? <small>* must provide value</small>		<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> The patient no longer needs a reoperation	reset
<div style="border: 1px solid red; padding: 5px; color: red;"> This patient will now appear on the "Awaiting Reoperations" report. After the reoperation, change the answer to the above question to "Yes" </div>			
ACTUAL date of reoperation		<input type="text"/>  <input type="button" value="Today"/> D-M-Y	
Describe the reoperation that was performed:		<div style="border: 1px solid gray; height: 80px;"></div>	
		Expand	

Complication #1 Review			
Has this issue been reviewed? <small>* must provide value</small>		<input type="radio"/> Yes <input type="radio"/> No	reset
<div style="border: 1px solid red; padding: 5px; color: red;"> This issue needs to be reviewed. </div>			
Date of Review		<input type="text"/>  <input type="button" value="Today"/> D-M-Y <small>Format is DD-MM-YYYY. Insert date manually, by clicking on the calendar image above, or press "Today" if applicable</small>	
Results of Review <small>* must provide value</small>		<div style="border: 1px solid gray; height: 80px;"></div>	
		Expand	

- c. Additional surgical complications beyond the third event should be recorded in free text entry box. Label the event # accordingly (Event #4...)

Additional Surgical Complications

If the patient has had more than 3 surgical complications, describe them here. Include the following information:

1. Date complication first diagnosed by physician
2. Details of complication

If reoperation is being considered:

3. Type of surgery planned
4. Hospital
5. Estimated date of reoperation
6. Actual date of reoperation



Expand

Is reoperation being considered for any of these complications?

- ☐ Yes
☐ No

* must provide value

reset

Please send Max an email and he will manage the review of these reoperations.

Max's email: maxliu@stanford.edu

Have all reoperations been performed?

- ☐ No
☐ Yes
☐ The patient no longer needs a reoperation

* must provide value

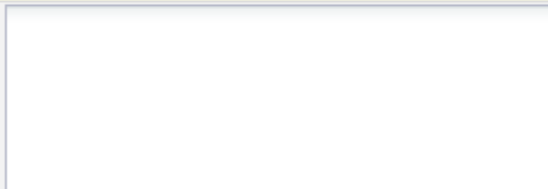
reset

This patient will now appear on the "Awaiting Reoperations" report. After the reoperation, change the answer to the above question to "Yes"

6. Delayed exfix removal
 - a. For patients who need to stay on exfix for longer

Delayed Exfix Removal (Exfix Patients Only)

Describe the reason for delayed exfix removal



Expand

Has the exfix been removed yet?

- ☐ Yes
☐ No

* must provide value

reset

This patient will now appear on the "Delayed Exfix" report. After the reoperation, change the answer to the above question to "Yes"

What day was the exfix removed?



Today

D-M-Y


Format is DD-MM-YYYY. Insert date manually, by clicking on the calendar image above, or press "Today" if applicable

6.7 Follow-up Image Upload/Eval Form

The same procedure for baseline evaluation images will be used for follow-up evaluation images. Note that if a patient is reported to not be able to perform the squat and smile and/or heel lift test, a flag will appear and the option to upload an image will not be present.

Image Upload	
Upload AP view:	+ Upload document
Upload lateral view:	+ Upload document
Upload squat and smile photo:	+ Upload document
<div style="border: 1px solid red; padding: 5px; color: red;"> The squat and smile upload box will not appear here because the patient reported that they cannot perform the squat and smile test. </div>	
Upload heel lift photo here	+ Upload document
<div style="border: 1px solid red; padding: 5px; color: red;"> The heel lift upload box will not appear here because the patient reported that they cannot perform the squat and smile test. </div>	
Check here for any extra images that need to be uploaded <div style="display: flex; align-items: center;"> <input type="checkbox"/> Extra Image #1 <input type="checkbox"/> Extra Image #2 <input type="checkbox"/> Extra Image #3 <input type="checkbox"/> Extra Image #4 </div>	

1. The following questions are used for image evaluation

X Ray Evaluation	
IM Nail breakage	<input type="radio"/> Yes <input type="radio"/> No
	reset
IM Nail interlocking screw breakage	<input type="radio"/> None <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4
	reset
IM Nail interlocking screw loosening	<input type="radio"/> None <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4
	reset
Exfix schanz pin loosening	<input type="radio"/> None <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4
	reset
Exfix schanz pin breakage	<input type="radio"/> None <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4
	reset
Coronal plane angulation	<input type="radio"/> < 5 degrees <input type="radio"/> 5-10 degrees <input type="radio"/> >10 degrees <input type="radio"/> X-rays not adequate
	reset
Coronal angulation (continuous)	<input type="text"/> "N/A" if x-rays not adequate
Coronal angulation direction	<input type="radio"/> Varus <input type="radio"/> Valgus <input type="radio"/> X-rays not adequate
	reset
 Variable: fu_sagittal_angulation	
Sagittal plane angulation	<input type="radio"/> <5 degrees <input type="radio"/> 5-10 degrees <input type="radio"/> >10 degrees <input type="radio"/> X-rays not adequate
	reset
Sagittal angulation (continuous)	<input type="text"/> "N/A" if x-rays not adequate
Sagittal angulation direction	<input type="radio"/> Procurvatum <input type="radio"/> Recurvatum <input type="radio"/> X-rays not adequate
	reset

2. The RUST Score questions will be used to evaluate quality of fracture healing

RUST Score	
Medial Cortex	<input type="radio"/> Fracture line, no callus <input type="radio"/> Fracture line, visible callus <input type="radio"/> No fracture line, bridging callus <input type="radio"/> X-rays not adequate
Lateral Cortex	<input type="radio"/> Fracture line, no callus <input type="radio"/> Fracture line, visible callus <input type="radio"/> No fracture line, bridging callus <input type="radio"/> X-rays not adequate
Anterior Cortex	<input type="radio"/> Fracture line, no callus <input type="radio"/> Fracture line, visible callus <input type="radio"/> No fracture line, bridging callus <input type="radio"/> X-rays not adequate
Posterior Cortex	<input type="radio"/> Fracture line, no callus <input type="radio"/> Fracture line, visible callus <input type="radio"/> No fracture line, bridging callus <input type="radio"/> X-rays not adequate
Squat and Smile Evaluation	
Squat and Smile	<input type="radio"/> Full squat without difficulty <input type="radio"/> Full squat with difficulty <input type="radio"/> Partial squat (< 90 degrees) <input type="radio"/> Unable to perform <input type="radio"/> Image not adequate

6.8 Follow-up Scheduling

Patients should be scheduled for follow-up using the REDCAP scheduling module

1. To generate the follow up schedule for the patient, click the “Scheduling” Link. To create a second viewing window, right-click “Scheduling” and choose “Open in new tab”. This will allow you to remain in the participant’s record and edit the schedule at the same time
2. Choose the “Create Schedule” tab
3. Choose the participant ID
 - a. If a patient does not have a schedule yet, they will appear on this list. If the patient has already been scheduled, they will appear on the list available under the “View or Edit Schedule” Tab



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The ITS Academic Research Systems

Open Tibia Study

Scheduling

[Create Schedule](#) [View or Edit Schedule](#)

The Schedule Generator will allow you to **generate a new schedule** defined on the [Define My Events](#) page. You may generate a schedule Date, which will be used as the starting point for projecting schedule view it on the [Calendar](#), after which, if desired, you may also perform record here while performing scheduling or you may choose a current

Offset that have been
ow by selecting a Start
cheduled, you may then
may create a new project
cheduled.

Add new Participant ID: OR

Start Date:

[Generate Schedule](#)

2 (Angle Lyimo)
3 (Ramadhan Seleman)
5 (Jacob Ndahani)
6 (Benny Mushumbusi)
7 (Meshack Mnanka)
8 (Salome Mushi)
10 (Amani Rowa)
11 (Anord Lyimo)
14 (Wilfred Munda)
15 (Meshack Mwangonji)
18 (Ladislau Massawe)
19 (Yona Mbuji)
20 (Richard Kibonde)
21 (Habibu Hassani)
22 (Mariam Kavishe)
23 (Ally Ally)
24 (Alex Mushi)
25 (Amina Mlembe)
26 (Waziri Luga)

[How to use the scheduling r](#)

1. Choose the "Start Date". This depends on the patient's date of operation. If the patient was operated on Sunday, Monday, or Tuesday, use the closest Saturday before the operation. If the patient was operated on a Wednesday, Thursday, or Friday, us the next closest Saturday.
2. Click "Generate Schedule"

Add new Participant ID: OR

Start Date:

[Generate Schedule](#)

Projected Schedule for "119" (NOTE: The dates below have NOT yet been scheduled.)

The projected schedule below was automatically generated for Participant ID "119" based on your pre-defined Events. You may change the value of any dates generated below simply by clicking inside the date box and selecting a new date. Any dates generated below that fall on weekends will be listed in red. Click the [Create Schedule](#) button to finalize this schedule, which will then be added to the Calendar.

Time (optional)	Date / Day of Week	Event Name
<input type="checkbox"/>	08/18/20 Saturday Range: 08/11/2012 - 08/25/2012	Initial Hospitalization
<input type="checkbox"/>	09/01/20 Saturday Range: 08/25/2012 - 09/08/2012	2 week follow up
<input type="checkbox"/>	09/29/20 Saturday Range: 09/15/2012 - 10/13/2012	6 week follow up
<input type="checkbox"/>	11/17/20 Saturday Range: 10/27/2012 - 12/08/2012	3 month follow up
<input type="checkbox"/>	02/16/20 Saturday Range: 01/26/2013 - 03/09/2013	6 month follow up
<input type="checkbox"/>	08/17/20 Saturday Range: 07/20/2013 - 09/14/2013	1 year follow up
<input type="checkbox"/>	09/01/20 Sunday Range: 09/01/2012 - 09/01/2014	Unplanned event

[Create Schedule](#) [Cancel](#)

- Delete the first line which is the "Enroll" Event
- If a patient knows they cannot come in on a particular Saturday ahead of time, you can manually change the follow-up date. This date must occur within a set range of dates. The allowed limits are found below. It is possible but not preferred to schedule a Saturday clinic outside of the allowed range.

	Event #	Days Offset	Offset Range Min / Max	Event Name
	1	0	-0/+0	Enroll
	2	14	-7/+7	2Wk Follow-up
	3	42	-14/+14	6Wk Follow-up
	4	91	-21/+21	3Mo Follow-up
	5	182	-21/+21	6Mo Follow-up
	6	364	-35/+120	1Yr Follow-up

- You must remember to Save the schedule by choosing "Create Schedule"

[Create Schedule](#)
[View or Edit Schedule](#)

The Schedule Generator will allow you to **generate a new schedule** based upon your Events and their Days Offset that have been defined on the [Define My Events](#) page. You may generate a schedule for a new or existing Participant ID below by selecting a Start Date, which will be used as the starting point for projecting schedule dates using your Days Offset. Once scheduled, you may then view it on the [Calendar](#), after which, if desired, you may also perform data entry for that calendar event. You may create a new project record here while performing scheduling or you may choose a currently existing one that has not yet been scheduled.

Add new Participant ID: OR [choose existing unscheduled](#)

Start Date:

[Generate Schedule](#)

✓ Successfully Scheduled "119"

Participant ID "119" was successfully scheduled for the dates and times below and has been added to the [Calendar](#). You may now edit this schedule or add more information, such as changing the status (e.g. "Cancelled", "Confirmed") or adding descriptive notes, by clicking the [View or Edit Schedule](#) tab above.

Schedule for "119"		
Time	Date	Event Name
	09/01/2012 Saturday	2 week follow up
	09/29/2012 Saturday	6 week follow up
	11/17/2012 Saturday	3 month follow up
	02/16/2013 Saturday	6 month follow up
	08/17/2013 Saturday	1 year follow up

4. It is possible to view the schedule you have created for a patient by clicking on the "View or Edit Schedule" tab. Choose the patient's record.
 - a. If a schedule has not yet been created, they will not appear on this list. Instead, they will be found under the list in the "Create Schedule" Tab

Scheduling
[VIDEO: How to...](#)

[Create Schedule](#)
[View or Edit Schedule](#)

To view or edit the calendar events of a previously scheduled Participant ID, select it from the drop-down menu below.




Select a previously scheduled Participant ID:
















-- select record --
 -- select record --
 1 (Samwel Masaki)
 4 (Abdallah Kingwana)
 9 (Faudhi Abeid)
 12 (Said Chatumu)
 13 (Jamali Simba)
 16 (Muthakwil Buchwa)
 17 (Job kanyaga)
 27 (Chande Chande)
 29 (Cosmas Kauku)
 31 (Juma Mwayahi)
 34 (Hamis Akuti)
 37 (Haji Said)
 40 (Adam Hussein)
 46 (Shabani Lyimo)


- b. Note that the dates of the visits are reported in mm/dd/yyyy
- c. If the date of a scheduled visit needs to be changed, click on the pencil icon and select the new date.
- d. If a new follow-up visit event needs to be created, click on the "Add new Ad Hoc calendar event on mm/dd/yyyy". The date is reported in mm/dd/yyyy (American style)
- e. If the schedule needs to be erased completely, click on the X for each event to delete the event. After all events are deleted, the patient will appear in the list in the "Create


Schedule” tab (as in the patient will no longer have a schedule). From there, you can create an entirely new schedule. They will no longer appear in the “View/Edit Existing Schedule” tab

View/Edit Existing Schedule for "1" (Samwel Masaki)

Below are the calendar events for **Participant ID "1"**. Dates that fall on weekends will be listed in **red**. You may edit any calendar event by clicking the  Edit icon, remove an event by clicking the  Delete icon, or view the full details of the event by clicking the  View icon. You may also add a new unscheduled event at the bottom of the table by selecting a date and clicking the *Add* button.

	Time	Date / Day of Week <small>M/D/Y</small>	Event Name	Status	Notes
  		01/02/2016 Saturday Range: 12/26/2015 - 01/09/2016	2Wk Follow-up	✔ Confirmed	
  		01/30/2016 Saturday Range: 01/16/2016 - 02/13/2016	6Wk Follow-up	☆ Due Date	
  		03/19/2016 Saturday Range: 02/27/2016 - 04/09/2016	3Mo Follow-up	☆ Due Date	
  		06/18/2016 Saturday Range: 05/28/2016 - 07/09/2016	6Mo Follow-up	☆ Due Date	
  		12/17/2016 Saturday Range: 11/12/2016 - 04/16/2017	1Yr Follow-up	☆ Due Date	

 Add new Ad Hoc calendar event on

 [Print Schedule](#)

Using the Calendar

1. Open the calendar from the left-side menu
 - a. You may view the calendar by day, week, or month. Alternatively, you can choose agenda to see a listing of all appointments for the month.

Project Setup

10 u

Project status: Development

Data Collection

Scheduling

- Generate schedules for the calendar using your defined events

Data Entry

Applications

Calendar

Data Export Tool

Data Import Tool

Data Comparison Tool

Logging

File Repository

User Rights

Graphical Data View & Stats

Data Quality

API

Report Builder

Reports

1) Stage 1: Registry Book Screening

2) Stage 2: Screened - Awaiting Surgery

3) Stage 3: Surgery Done, Awaiting Enrollment

4) Stage 4: Enrolled, Not Discharged

5) Stage 5: Enrolled, Discharged

6) All X-ray Screened Patients

7) Excluded patients (x-ray screening)

8) Excluded patients (clinical screening)

9) UCSF Radiograph Review Status

10) Follow up Status

Help & Information

Calendar

VIDEO: How to use this page (5 min)

The Calendar application can be used as a project calendar within this project to help organize your schedule and keep track of any upcoming events. It will allow you to add or modify calendar events and then view them either in a daily, weekly, or monthly format below. To add a new note or calendar event to any day, click +New at the top of that day's box to begin entering the information. Since you have already defined multiple events for this project, you may additionally [generate a schedule](#) using your pre-defined Events, which will then be added to the calendar.

Day

Week

Month

Agenda

August

2012

Print Calendar

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
			+ New 1	+ New 2	+ New 3	+ New 4 ★ 16 (2 week follow up) ★ 26 (2 week follow up) ★ 8 (2 week follow up) ★ 27 (2 week follow up)
+ New 5	+ New 6	+ New 7	+ New 8	+ New 9	+ New 10	+ New 11
+ New 12	+ New 13	+ New 14	+ New 15	+ New 16	+ New 17	+ New 18 ★ 33 (2 week follow up) ★ 59 (2 week follow up) ★ 60 (2 week follow up) ★ 51 (2 week follow up) ★ 56 (2 week follow up) ★ 9 (2 week follow up)
+ New 19	+ New 20	+ New 21	+ New 22	+ New 23	+ New 24	+ New 25

- 2) On the Wednesday prior to each follow up clinic, open the calendar
 - a. Choose the “month” tab
 - b. Click the patient’s participant ID for those that are coming in that Saturday to open the appointment window.
 - c. After calling the patient, change the status from “Due Date” to “Scheduled”. All successfully scheduled clinics will appear on the calendar as a yellow star. A white star means the patient has not yet been scheduled.

+ New

9

★ 27 (2Wk Follow-up)

☆ 29 (2Wk Follow-up)

☆ 31 (2Wk Follow-up)

☆ 34 (2Wk Follow-up)

☆ 37 (2Wk Follow-up)

☆ 17 (2Wk Follow-up)

- 3) After the patient’s visit has successful completed, change the appointment status to “Confirmed”, indicating that the visit has finished. These events will now appear as a green checkmark

Participant ID: **27** (Chande Chande) [view schedule](#)

Event Name: **2Wk Follow-up**

Status: ☆ **Due Date** [change status](#)









Date: **01/09/2016 (Saturday)**

Time: HH:MM

- + New 9
- ✓ 27 (2Wk Follow-up)
 - ☆ 29 (2Wk Follow-up)
 - ☆ 31 (2Wk Follow-up)
 - ☆ 34 (2Wk Follow-up)
 - ☆ 37 (2Wk Follow-up)
 - ☆ 17 (2Wk Follow-up)

6.9 Uploading Images

There are two ways to upload photos/images onto REDCAP. The first and easiest is to connect the phone to a laptop and upload onto the REDCAP website. The second is to use the REDCAP mobile app. Both will be mentioned here in case one modality no longer functions. In both situations, after the file has been successfully uploaded, the name and size of the file will appear in the upload document field. If you need to change the uploaded file, press “Remove file” and upload the other file.

Upload PRE-OP Lateral view:		20160105_105536[1].jpg (0.5 MB)
		 Remove file or  Send-It
Upload POST-OP AP view:		 Upload document
Upload POST-OP Lateral view:		 Upload document

Method 1 – Connecting Phone to Laptop

1. Take photo using phone
2. Connect photo using laptop
3. Open the patient’s REDCAP form and press “Upload Document”
4. Navigate to the phone’s memory, select the photo, and upload the document
 - a. The upload percent % complete will be viewable in the bottom left corner of the browser. If it is stuck, close the browser and try uploading again.
 - b. It is also possible to first transfer the photos onto the laptop (using the cable) and then navigating to the file in the laptop.

Method 2 – REDCAP Mobile App

There are two ways to use the REDCAP mobile app to upload images. The first is to take a photo directly in the app (this saves the photo into the app). The second is to first take a photo to save the photo into the phone, and then uploading the photo into the app. The second is preferred because you have a copy of the photo in the camera in case there is an issue with the mobile app.

#1 – Take photo in the app

1. Open the patient's REDCAP form
2. Press "Upload Document"
3. Press "Take Photo"
4. Confirm that the photo is adequate for upload

#2 – Take photo then upload into the app

1. Open the phone's camera
2. Take photo
3. Open the patient's REDCAP form
4. Press "Upload Document"
5. Press "Load photo from camera"
6. Select the file in the camera's memory that you have already taken

Explanation of REDCAP Mobile App

The REDCAP mobile app allows you to collect data on a phone or tablet and upload the files onto the REDCAP server. This is supported by both Apple and non-Apple products. This method is not a preferable method of data collection because the mobile app and REDCAP server are not live synced. This means that data on the phone is first collected and then it needs to be synced with the server. Conversely, any changes made on the server need to be downloaded onto the mobile app for it to appear. There is a risk of overriding or losing data during the syncing process, making this form of data collection very risk. Because of this risk, the steps for using the REDCAP mobile app will not be discussed in detail here. It may be explored as a data collection modality in the future if necessary.

One thing to note is that if the REDCAP mobile app is used, new records cannot be created using the mobile app even though the option appears. An error will occur when you try to upload the data. To work around this, create a new record on the REDCAP server, sync it to the mobile app by downloading the record on the mobile app, collect the data on the mobile app, and then sync the data back onto the server.

Data Management

Periodic evaluation and management of the data will be done to ensure that high quality data is being collected. This responsibility will fall to the protocol director. The following procedures will be performed on a bi-monthly basis on Sundays:

- Export all data as Excel CSV file with labels and store on encrypted laptop
- Create a backup of the project on REDCAP with everything except users
- Examine record status dashboard and notify team of any inconsistencies or remaining data to collect
- Execute all data quality checks

- Examine complications and review for patients from last 2 weeks and make sure adjudication review has been performed
- Close any data resolution queries
- Manage any open data queries that have not been completed by the review by date

References

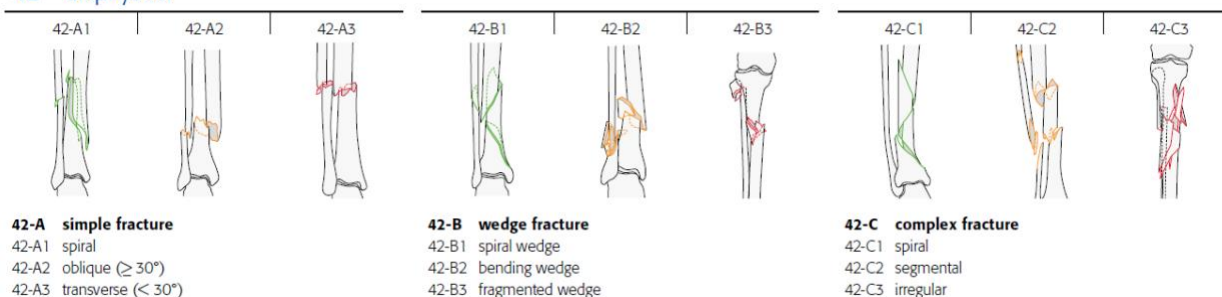
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OTA 42 Subclassification

Under the AO/OTA Fracture Classification system, tibia fractures are designed as either 41 (proximal), 42 (diaphyseal), and 43 (distal). The proximal and distal regions of the tibia are defined by the rule of squares.

All OTA Type 42 fractures (regardless of subclassification) are eligible for inclusion in the study.

42 diaphyseal



Antibiotics Supply

The following antibiotics were purchased from Dawa Plus Limited (Dar es Salaam, TZ). The order was coordinated by Ibrahim through a contact at the supplier. The ceftriaxone is a powder which needs to be reconstituted by sterilized saline water.

TRIXONE Ceftriaxone Sodium Injection USP 1.0g (1 vial)
Manufactured for: Abacus Pharma (A) Limited, East Africa
Registration No.: TZ15H0073
Storage: Store below 30C in a dry place. Protect from light
Cost per vial: 1300TSH

Super Amp Sterilised Water for Injections BP
Manufactured by: Claris Lifesciences Limited
Chacharwadi-Vasana, Ahmedabad-382 213, India
Mfg. Lic. No: G/28A/5372-A
B. No.: C250647
Storage: Store at a temperature not exceeding 30C

Gentamicin Injection BP 80mg
10x2ml ampoule
Each 2ml contains: gentamicin sulfate BP equivalent to gentamicin base (80,000 IU)
Manufactured by: Vital Healthcare Pvt. Ltd.
Works: Plot No. H-10, MIDC, Satpur, Nashik-422 007
Regd Off: 5/6, Shreyas, 2nd Hasnabad Lane, Santacruz (W), Mumbai-400 054. India

Cost per vial: we were given a sample box of 10 ampoules and used that. No additional ampoules were purchased.

Metris Metronidazole Injection USP (0.5% w/v) 100ml for IV use only

M.L: G/28DA/LVP/4-A

Manufactured by: Claris Lifesciences Limited

Chacharwadi-Vasana, Ahmedabad-283 213, India

Cost per bottle: 600TSH

The following were purchased from the MOI pharmacy. This was to replenish gentamicin from time to time. Not much gentamicin was used. In order to purchase antibiotics in this way, a prescription needs to be written. The maximum number of ampoules provided per prescription is 15.

Gentamicin Sulfate Injection 80mg/2ml

Reg. No.: TAN05, 468 J01K CHE

IV/IM 10 Ampoules/Box

Manufactured by: Sichuan Long March Pharmaceutical Co. Ltd.

Cost per vial: approximately 5000TSH for a box of 10 (500 TSH each)

X-Ray Quality Control

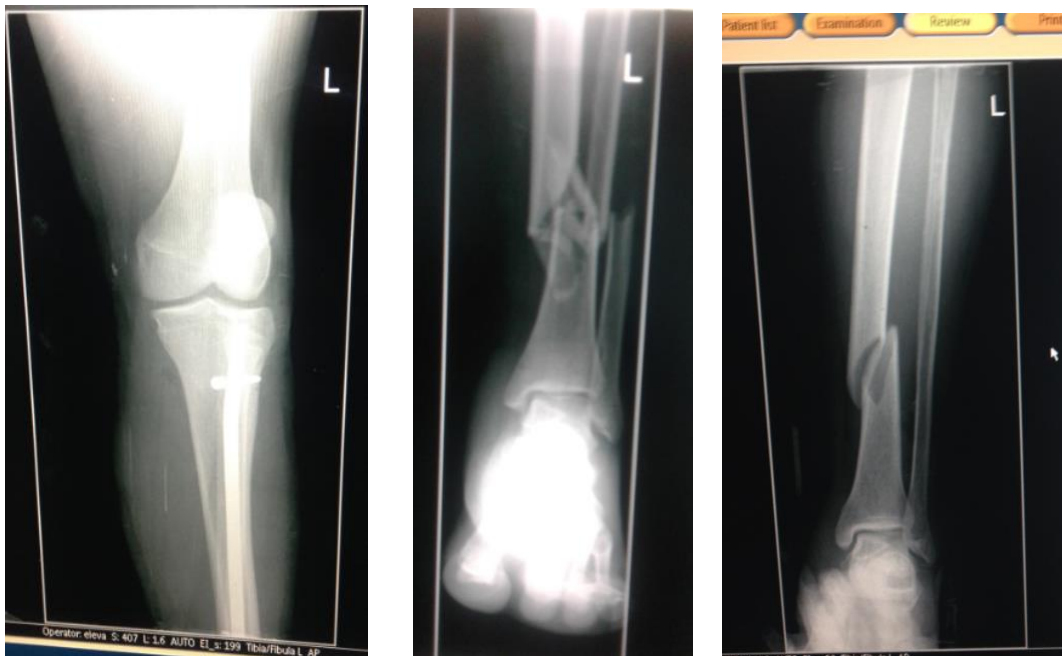
Good

These are examples of good quality x-rays. The majority of the tibia is seen along with clear identification of the fracture site.



Poor

An example of an inadequate x-ray is provided here. For the image on the left, notice that the fracture site as well as the distal portion of the tibia is missing. For the image in the middle, notice how the majority of the proximal tibia is missing. The image on the right suffers from both movement during the x-ray exposure and movement from the camera taking a photo of the image; however, enough of the tibia is exposed in the picture for it to be used.



How to Recharge the Airtel USB Modems

1. Purchase Airtel Vouchers or take from the study closet
2. Scratch the voucher
3. Turn off internet on the study phone
4. Dial *104*PIN# on the study phone to add money to the study phone
5. Send money to the USB modem
 - a. Dial *149*99#
 - b. Reply 3 for "Yatosha Intaneti"
 - c. Reply 2 for "Buy for a friend"
 - d. Reply with the phone number of the USB modem you are charging
 - e. Reply 3 for Monthly Bundle
 - f. Reply 1 for 3Gb
 - g. Reply 1 for enroll
6. Press *102# to check balance

Yatosha Intaneti is 3GB for 1 month = 15000TSH

*Add as much money as you need to buy the Yatosha Intaneti bundle you want

How to Recharge the Study phone with Airtime

1. Purchase Airtel vouchers or take from the study closet
2. Scratch the voucher
3. Turn off internet on the study phone
4. Dial *104*PIN# on the study phone to add money to the study phone
5. Purchase Yatosha airtime bundle
 - a. Dial *149*99#
 - b. Reply 1 for “Yatosha” (the name of the Airtel airtime bundle)
 - c. Reply 3 for Monthly Bundle
 - d. Reply 1 for 175 talk minutes
 - e. Reply 1 for enroll
6. Press *102# to check balance

The cheapest Yatosha Airtel Airtime is 10000TSH for one month

Study Numbers and Passwords

Joshua's Airtel USB Modem: 068-994-7943

Ibrahim's Airtel USB Modem: 068-325-4780

Justin's Airtel USB Modem: 068-994-6071

Study Phone Number: 068-994-7699 (Password is 696969)

REDCAP Mobile App: admin password is 696969. The username is moi (password 696969)

All study laptops have the password set to: igot (all lowercase)

Additional Information for the Blue HP Study Laptop (Ibrahim's Laptop)

McAfee Security

Email: tanzania.trauma.course@gmail.com

Password: Muhimbili1

Microsoft Office 365

Name: MOI Research Team

Email: tanzania.trauma.course@gmail.com

Password: Muhimbili

*Free for 1 year

DropBox Account:

First Name: MOI

Last Name: Research Team

Email: tanzania.trauma.course@gmail.com

Password: Muhimbili

Gmail Account

Email: tanzania.trauma.course@gmail.com

Password: Muhimbili

EQ-5D English Version

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

Self-Care

- I have no problems with self-care ☐
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

Usual Activities *(e.g. work, study, housework, family or leisure activities)*

- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☐
- I am unable to perform my usual activities ☐

Pain / Discomfort

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

Anxiety / Depression

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**Your own health
state today**

Best imaginable
health state

100

90

80

70

60

50

40

30

20

10

0

Worst imaginable
health state

UCSF-MOI Open Tibia Fracture Study – OTA Wound Classification

As part of the study, we are collecting data on the types of wounds that our study participants have. Please fill out this handout after the operation. Leave it in the patient's file after you have filled it out. If you have any questions, please contact the study phone at 06899-47699.

Patient Name: _____ MRN: _____

Wound measurement (take the maximum length): _____ cm

Skin

- ☐ Laceration with edges that approximate
- ☐ Laceration with edges that DO NOT approximate
- ☐ Laceration associated with extensive degloving

Muscle

- ☐ No muscle necrosis OR some injury with function intact
- ☐ Loss of muscle but remains functional OR localized necrosis in injured area that requires excision
- ☐ Dead muscle, loss of function, partial or complete compartment excision, complete disruption of muscle-tendon unit, muscle injury not approximatable

Arterial

- ☐ No injury
- ☐ Injury, no ischemia
- ☐ Injury with distal ischemia

Contamination

- ☐ None or minimal contamination
- ☐ Surface contamination (not ground in)
- ☐ Contaminant embedded in bone or deep soft tissue OR high risk environmental conditions (barnyard, fecal, dirt water, etc.)

Bone Loss

- ☐ None
- ☐ Bone loss, but still some contact between proximal and distal fragments
- ☐ Segmental bone loss

Patient Observation Chart

To be used post-op after patient is discharged to the ward:

Open Tibia Study Patient Observation Chart

Name: _____ MRN: _____ Ward #: _____

Antibiotic	Dose #	Date	Time	Time Given

	<u>Date to Check</u>	<u>Evaluation</u>			<u>Fixed</u>
Pre-Op	_____	<input type="checkbox"/> Good	<input type="checkbox"/> Missing	<input type="checkbox"/> Redo	<input type="checkbox"/>
Post-Op	_____	<input type="checkbox"/> Good	<input type="checkbox"/> Missing	<input type="checkbox"/> Redo	<input type="checkbox"/>

- ☐ Date of Birth (with day and month) recorded
- ☐ Contact information complete
- ☐ Follow-up schedule created

Standard Study Antibiotics Regimen

- None or Mild Contamination: Ceftriaxone (1g every 24hr for 2 days)
- Surface Contamination (not ground in): Ceftriaxone (as above) + Gentamycin (80mg every 12hr for 2 days)
- Severe or High-Risk: Ceftriaxone + Gentamycin (as above) + Metronidazole (500mg every 8hr for 2 days)

MOI Wifi Codes

The following wifi codes are for the MOI wifi. They differ depending on where you are in the hospital

2151298000

moi2151298

2151298moi

**MUHIMBILI ORTHOPAEDIC INSTITUTE IN COLLABORATION WITH THE
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO**

CONSENT TO BE IN RESEARCH

Study Title: Initial External Fixation or Intramedullary Nailing for Gustilo 3A Tibial Shaft Fractures: a Randomized Controlled Trial in Dar es Salaam, Tanzania

This is a research study, and you do not have to take part. The researchers from Muhimbili Orthopaedic Institute (MOI) will explain this study to you. The co-principal investigators are Dr. Billy Haonga and Dr. Saam Morshed. The investigators are from MOI and the University of California, San Francisco (UCSF). If you have any questions, you may ask the researcher.

You are being asked to take part in this study because you have a tibial fracture.

In this study, the researchers are collecting data to determine the outcome of various treatments for tibial fractures. The research is paid for by grant funding from the Doris Duke Charitable Foundation (DDCF), the Wyss Foundation, and UCSF Institute for Global Orthopaedics and Traumatology.

What will happen if I take part in this study?

If you agree to be in this study, you will be randomly assigned one of two well-established treatments for the treatment of open (Type3A) tibia fractures. The first treatment option is fixation of the fracture with a nail that goes inside the broken bone and the other is stabilization of the fracture with an external fixator. The nail is not typically removed, however, the external only stays on long enough for the bone to show signs of healing and is typically removed between 8 and 12 weeks after application. The initial treatment option involves thorough cleaning of all exposed tissues resulting from the open fracture and the need for further care of the wound (dressing changes or further surgery for wound care) will depend on the treating surgeon's interval assessments of the wound.

You will also be asked to share information about your current state of health and details of your injury. In addition, we will ask you to complete a short 5 question survey. The X-ray images that you took as part of your treatment plan will be made available to the research team.

You will also be asked to come back for routine follow-up visits at 6 weeks, 3 months, 6 months, and 1 year after the injury. At each of these visits, you will answer questions and complete the survey. You will also be asked to take plain film X-ray images of the fracture site.

We anticipate it will take about 30 minutes at the time of enrollment and at each follow up appointment to gather the information for the study. Your information will be recorded and shared with other researchers at MOI and UCSF.

Are there any risks to me or my privacy?

Your choice to participate in the study will not affect your treatment in any way. However, some of the questions may make you feel uncomfortable or raise unpleasant memories. You are free to skip any question at any point during the study.

We will do our best to protect the information we collect from you. Information which identifies you will be kept secure. Only a small number of researchers will have direct access to your identifying information. If this study is published or presented at scientific meetings, names and other information that might identify you will not be used.

Are there benefits?

There is no benefit to you in terms of the care you receive for your injury. The cost of all follow-up visits and x-rays obtained during the appointments required for the study will be paid for, and you will be allowed to bypass waiting lines at the clinic.

Can I say “No”?

Yes, you do not have to participate in the study. If you choose not to be in this study, there will be no consequences to the type of treatment or quality of care you receive for your injury.

Are there any payments or costs?

There will be no payments made directly to patients. However, the costs of the follow up medical care including clinic visits and X-rays will be provided for free at no cost to you.

Who can answer my questions about the study?

You can talk with the study coordinator about any questions, concerns, or complaints you have about this study. You may also contact the co-principal investigators directly:

Billy Haonga, MD, Muhimbili Orthopaedic Institute (bhaonga@gmail.com)
Edmund Eliezar, MD, Muhimbili Orthopaedic Institute (ndalama@yahoo.com)

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the National Institute for Medical Research at +255-22-2121400 or the UCSF Office of the Committee on Human Research at 1-415-476-1814.

CONSENT

PARTICIPATION IN RESEARCH IS VOLUNTARY.

You have been given copies of this consent form to keep.

If you wish to be in this study, please sign below.

Date

Participant's Signature for Consent

Date

Person Obtaining Consent

UCSF-MOI Open Tibia Fracture Study - Department Information Sheet

Please contact the study phone number highlighted below to reach whoever is on call.

068-994-7699

PATIENT ARRIVAL TIMES AND WHAT TO DO

Time of Day	What to Do	Screening	Antibiotics
7am to 5pm	Call study phone for all open tibias	Researcher will find you and assist you with screening	Researcher will provide for you to administer
5pm to 11pm	Call study phone for all open tibias	Researcher will assist with screening over phone and come to hospital if participant is a candidate	Antibiotics have been provided to emergency nurse on duty for you to administer
11pm to 7am	Push patients to morning and call study phone at 7am	Researcher will assist in the morning	Antibiotics have been provided to emergency nurse on duty for you to administer

STANDARD ANTIBIOTICS REGIMENT

Antibiotics should be administered AS CLOSE TO ARRIVAL AT MOI AS POSSIBLE.

Condition	Treatment
None or mild contamination	Ceftriaxone 1g every 24 hr for 2 days
Surface contamination (not ground in)	Ceftriaxone 1g every 24 hr for 2 days PLUS Gentamycin 80mg every 12 hr for 2 days
Contaminant embedded in bone or deep soft tissue OR high risk environmental conditions (barnyard, fecal, dirt water, etc.)	Ceftriaxone 1g every 24 hr for 2 days PLUS Gentamycin 80mg every 12 hr for 2 days

	PLUS Metronidazole 500mg every 8hr for 2 days
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RANDOMIZATION AND OTA WOUND CLASSIFICATION

Our researchers will randomize your patient to either nail or exfix after you have finished debriding the wound and ask you to classify the wound.

Other Contact Information:

Max Liu (Research Fellow):	0688633947 (maxliu@stanford.edu)
Joshua Ngayoma (Research Coordinator):	0714738989 (skandoj@yahoo.co.uk)
Ibrahim Sasillo (Research Coordinator):	0713480302 (namensah47@gmail.com)
Justin Kessy (Research Coordinator):	0718038645 (kessygasto53@yahoo.com)
Billy Haonga (MD):	0754563761 (bhaonga@gmail.com)
Edmund Eliezer (MD):	0753100500 (ndalama@yahoo.com)