

# Contents

[Contents 1](#_Toc38279385)

[Key trial contacts 3](#_Toc38279386)

[Synopsis 3](#_Toc38279387)

[1. Background and rationale 4](#_Toc38279388)

[2. Aims and objectives 5](#_Toc38279389)

[2.1. Aim 5](#_Toc38279390)

[2.2. Objectives 6](#_Toc38279391)

[3. Trial design 6](#_Toc38279392)

[3.1. Setting 6](#_Toc38279393)

[3.2. Eligibility criteria 6](#_Toc38279394)

[3.2.1. Inclusion criteria 6](#_Toc38279395)

[3.2.2. Exclusion criteria 6](#_Toc38279396)

[3.3. Interventions 7](#_Toc38279397)

[3.3.1. Routine physiotherapy advice 7](#_Toc38279398)

[3.4. Outcomes 7](#_Toc38279399)

[3.4.1. Primary outcome 7](#_Toc38279400)

[3.4.2. Secondary outcomes 8](#_Toc38279401)

[4. Sample size 10](#_Toc38279402)

[4.1 Participant recruitment 10](#_Toc38279403)

[4.2 Randomisation 12](#_Toc38279404)

[4.3 Data collection methods 12](#_Toc38279405)

[4.4 Follow up 12](#_Toc38279406)

[5. Data management 12](#_Toc38279407)

[5.1. Data entry 13](#_Toc38279408)

[5.2**.** **Data storage** 13](#_Toc38279409)

[5.2.1. Proposed time period for retention of relevant trial documentation 13](#_Toc38279410)

[5.3. Quality Assurance and Quality Control 14](#_Toc38279411)

[5.4.1. Statistical Analysis Plan 14](#_Toc38279412)

[5.4.3. Statistical analysis - main trial 14](#_Toc38279413)

[6. Harms 15](#_Toc38279414)

[6.1. Risks and anticipated benefits 15](#_Toc38279415)

[6.2. Informing potential trial participants of possible benefits and known risks 16](#_Toc38279416)

[6.3. Adverse event management 16](#_Toc38279417)

[7. Research ethics approval 17](#_Toc38279418)

[7.1. Protocol amendments 17](#_Toc38279419)

[7.2 Consenting 18](#_Toc38279420)

[7.2.3. Documenting consent 18](#_Toc38279421)

[7.3. Patient confidentiality 18](#_Toc38279422)

[7.4. Proposed action to comply with the medicines for human use (clinical trials) regulations 2004 18](#_Toc38279423)

[Declaration of interests 19](#_Toc38279424)

[Access to data 19](#_Toc38279425)

[Indemnity 19](#_Toc38279426)

[Dissemination and projected outputs 20](#_Toc38279427)

[References 20](#_Toc38279428)

# Key trial contacts

|  |  |
| --- | --- |
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# Synopsis

|  |  |  |  |
| --- | --- | --- | --- |
| Scientific Title | Assessment of bone healing time in tibial fractures; Static vs variable dynamization external fixation | | |
| Countries of recruitment | England | | |
| Health condition studied | Unilateral or bilateral isolated tibial fractures 41 A & B, 42 A, B &C and 43 A | | |
| Interventions | **Arm 1:** Traditional external fixator with static fixation either with hexapod struts or threaded rods | **Arm 2:** Variable dynamization external fixation using dynamizers (Orthofix, Verona). | |
| Key Inclusion and Exclusion Criteria | INCLUSION CRITERIA:   * Patients aged 16 years or older; * Isolated unilateral tibial shaft fractures * or bilateral tibial fractures 41 A & B, 42 A, B &C and 43 A * Where the treating surgeon believes the patient will benefit from surgical fixation.   EXCLUSION CRITERIA:   * Polytrauma * Prior failed fixation; * Pathologic fracture; * Patient is/would be unable to understand instructions for treatment * More than 28 days since injury * Pregnant | | |
| Trial Design | Parallel RCT | | |
| Planned Sample Size | 30 | | |
| Follow up duration | 2, 3 and 6 weeks, and 3, 6 and 12 months following external fixation removal. | | |
| Outcomes | Primary | | Secondary |
| Bone healing time (Radiographic images) | | * Olerud-Molander Ankle Score (OMAS) * Health related quality of life (EQ5D-5L) * Oxford Knee score * Complications * Secondary interventions |

# Background and rationale

Tibial fractures are the most common long bone injuries, with an incidence of 2 per 10,000 persons per annum. The most frequent etiology of tibial fractures is road traffic accidents, and nearly a third are sport injuries. Closed fractures consist of 76%, with an average patient age of 39.5 years. Incidence of non-union in tibial fractures is 7.37%, with higher rates in open fractures. Median cost to treat a non-union patient is considerably higher compared to those without; $25,555 and $11,686 respectively.

Tibial fractures are traditionally treated with either a plate, IM nail, or external fixator. All these devices, internal or external, are used in static mode (rigid fixation) until fracture heals. Recent reports suggest a static mode of treatment might be not ideal, as it ignores the mechanical conditions required for each natural biological phase of bone healing. Moreover, static devices cannot be manipulated to enhance bone healing in difficult fractures and fractures that are prone to non-unions. The concept of dynamization is a traditional treatment strategy that initially employs rigid stabilization, and once callus is formed the fixator is dynamized (made more flexible) to facilitate load sharing between the fixation device and the newly formed bony callus at the fracture site. However, this does not take into consideration the requirements for the natural phases of bone healing as described below.

Bone healing is divided into 3 phases:

* Granulation phase – a mobile phase with little risk of disruption of granulation tissue (i.e. stabilisation should allow for micromotion between the bone fragments to encourage robust callus formation).
* Cartilage phase – when soft cartilaginous callus forms, which gradually increases the stiffness of the callus tissue of healing bone and the stabilisation device. This phase potentially requires more frigid fracture stability of bone to prevent disruption of neovascularity.
* Remodelling phase – gradually increasing weight bearing and load sharing between bone and stabilisation device, potentially requiring more flexible fixation. However, at this point the mechanical properties of the stabilisation device (implant or fixator) contribute very little to the overall stiffness of the construct, because the majority of the loads are transferred through the newly formed bone and not in or around a fixation device.

In contrast to dynamization, Reverse Dynamization (RD) is a promising new treatment strategy that has recently been developed to accelerate bone healing. It is based on the hypothesis that a fracture initially stabilized less rigidly allows micromotion, and encourages vigorous cartilaginous callus formation. Once substantial callus has formed, the stabilization should then be converted to a rigid configuration (static mode) to prevent the disruption of neovascularization, and therefore accelerate bone healing and remodeling. Several studies in animal models support the RD regimen, and have demonstrated superior bone healing However, the optimal stiffness parameters of the fixation device and the timing as to when to change the fixation stability from a flexible (dynamic) to a more rigid (static) configuration are not yet clearly defined clinically.

Therefore, the aim of this study is to investigate whether tibial fracture healing can be accelerated using the Reverse Dynamization method. To do this, we will use an external fixation device, as it is currently the only option to change fixation stability from flexible/elastic to a static (rigid) configuration in an outpatient setting, without a secondary surgical intervention.

A pilot study in a small cohort of patients will be performed to determine initial fixator stiffness parameters, the amount of micromotion allowed by the dynamizers, and the timing as to when to change the stiffness from the elastic/flexible mode to rigid fixation. Based on a goat tibial fracture study (accepted in JBJS for publication), we anticipate that by 3 weeks robust fracture callus formation will be able to be confirmed by routine radiographs. In a different group of patients, fixator stiffness will instead be modified at 2 weeks post-operative, to determine whether the reverse dynamization method is able to further accelerate bone healing when there is only minimal callus mineralization visible on the radiographic images.

# Aims and objectives

## Aim

To determine whether bone healing can be accelerated using reverse dynamization as compared to traditional static fixation (rigid fixation) of tibial fractures.

## Objectives

1. A pilot study will be performed to identify the optimal timing to change fixator stiffness from the elastic/dynamic mode to the rigid/static fixation mode, as well as to define the preferred amount of micromotion of the initial fixation, which will later be incorporated into the main clinical trial.
2. To determine whether the optimal conditions identified in the pilot study can successfully accelerate bone healing and remodelling of tibial fractures.

# Trial design

The proposed study will be a multi-centre, randomised, controlled superiority trial with parallel groups.

## Setting

Hull University teaching NHS hospitals as main centre with involvement of Leeds teaching NHS hospitals and South Tees NHS hospitals.

## Eligibility criteria

We will include all adult patients (16 years or older) with 41 A & B, 42 A, B &C and 43 A tibial fractures who meet the eligibility criteria below.

### Inclusion criteria

* Patients aged 16 years or older
* Isolated unilateral or bilateral 41 A & B, 42 A, B &C and 43 A Tibial fractures
* Transverse fractures, short oblique and with fractures single butterfly
* Where the treating surgeon believes the patient will benefit from surgical stabilisation

### Exclusion criteria

* More than 28 days since injury
* Polytrauma – closed head injury, spinal fractures, pelvis/acetabular fractures, floating knee, femoral fractures, foot/ankle fractures or dislocations, knee dislocation or ligamentous injuries
* Comminuted and segmental fractures
* Previous failed fixation
* Pathologic fracture
* Patient is/would be unable to understand instructions for treatment
* Patient declines consent to participate

## Interventions

Eligible and consenting patients will be randomly allocated to either traditional static (Standard of Care, SOC) or variable Reverse Dynamization (RD) groups. Surgeons would be allowed to undertake external fixation as they perform the procedure routinely. Type (Ilizarov or hexapod) of fixator, number of pins and wires and frame configuration, would be left at the discretion of the surgeon for the duration of pilot study, although variables would be minimized. Fractures will be reduced as anatomically as possible and as soon as clinically reasonable; after the fixator is applied it is then managed under the SOC mode or under the RD protocol according to randomization.

### Routine physiotherapy advice

We will ensure that all patients randomised into the two groups will receive standardised, written physiotherapy advice detailing the exercises they need to perform for rehabilitation following their injury. Patients in both groups will be advised to move their toes, ankle, and knee joints fully within the limits of their comfort. Early weight-bearing will be encouraged, but the details of weight-bearing status will be determined by the treating surgeon. In this pragmatic clinical trial, any other rehabilitation input, including and beyond written physiotherapy advice (such as formal referral to physiotherapy), will be left to the discretion of the treating clinicians.

## Outcomes

### Primary outcome

The primary outcome is time to bone healing as determined by the Radiographic Union Score for Tibia (RUST) score, a validated score used to assess tibial fracture healing. Patients will undergo routine X-rays at 2 and 3 weeks at which time the fixation stiffness will be changed to a static mode, followed by a routine follow-up at 6 weeks, 12 weeks, and thereafter every 6 weeks until bone healing, with a final review at a minimum of 12 months. The RUST score assigns 1 – 3 points each for fracture line visibility and callus formation along the anterior, posterior, lateral, and medial cortices. Each fracture can have minimum of 4 (completely ununited) to a maximum of 12 (completely united) points. Fractures will be considered radiographically united with a RUST score of 9 or 9.

### Secondary outcomes

1. ***Olerud and Molander Ankle Score (OMAS):*** The OMAS is an established patient-reported outcome measure developed and validated score. It contains nine items: pain, stiffness, swelling, stair climbing, running, jumping, squatting, supports and work/activities of daily living. Item responses are each scored from 0 to 25, with 0 representing the most severe state. The scale scores representing each dimension are produced by summing the responses to each item within that dimension. Raw scale scores are then converted to a metric (0-100; 0=most severe). The OMAS will be collected once at baseline (patients will be asked to complete it while thinking about the week before their ankle fracture) and then at 6 and 12-months follow-up after frame removal.
2. ***EuroQol 5 Dimensions (5L) Score (EQ5D-5L):*** The EQ-5D-5L measures health-related quality of life in terms of 5 dimensions: mobility, ability to self-care, ability to undertake usual activities, pain and discomfort, anxiety and depression. Each dimension has five possible responses (no problems, slight problems, moderate problems, severe problems and unable or extreme problems). The EQ-5D-5L will be scored according to the user guide. EQ-5D-5L data will be collected at baseline: *i.e.* with regard to patient health related quality of life during the week before injury; then once each at 6, and 12 months.
3. **Oxford Knee Score (OKS)** – This is a validated self-administered 12 question knee specific patient reported outcome (PRO) score that is short and reproducible, and was designed and developed to assess knee function during the activities of daily living. The OKS was developed and validated specifically to assess function and pain after TKR, although it has also been used to assess pain and function in non-arthroplasty conditions.
4. ***Complications:*** Data on all further surgical procedures and other complications, e.g. deep wound infection (using Centres for Disease Control and Prevention definition), superficial infection, pin site infection (defined using the ‘Good, Bad and Ugly’ pin site grading system, rehospitalisation, blood clots, secondary interventions for non-union, and all other secondary procedures will be collected by research nurses using CRFs for infections and hospital records at 3, 6 and 12 months.

Non-union and mal-union. Non-union will be defined as the inability to heal using the RUST score (Table 1) as confirmed on X-rays/CT scans, or as any secondary intervention for failure to heal. Mal-union will be defined by a standard radiographic measurement undertaken at 12 months. More than 10 degrees of axial deviation in the sagittal, 5 degrees in the coronal plane, and >15 degrees rotation (internal or external) would be considered a malunion.

* 1. Routine standard radiographs at 2, 3, 6 weeks, and 3, 6 and 12 months; anterior-posterior and lateral tibia views, and/or when necessary a CT scan of the tibia and/or fibula, which will be taken at the time of bone healing and 12 months after the injury. Radiographic image assessment will be undertaken by the treating surgeon at the participating site, using a proforma which will then be returned to the coordinating centre.

1. ***Resource use and work impact:*** Data on resource use and work impact will be collected to inform the economic evaluation (e.g. length of hospital stay, rehospitalisation and return to work). This data will be gathered through a brief questionnaire administered to patients at 3, 6, and 12 months, and previous hospital records. Table 2 outlines the schedule of events.

Table 1: RUST Score

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Anterior | Posterior | Lateral | Medial | Score |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |
| 3 |  |  |  |  |  |
|  |  |  |  | Total Score |  |

Each tibial cortex (anterior, posterior, medial and lateral) was assigned a RUST score of 1 to 3 based on appearance.

* A cortex with a visible fracture line and no callus is given a score of 1.
* A cortex where callus and visible fracture line was present is scored as 2.
* A cortex with bridging callus and no fracture line visible within the callus bridge is scored as 3.

The scores of all cortices are then combined to give a minimum score of 4 (definitely not healed) and a maximum of 12 (completely healed).

Table 2: Schedule of events

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Time-point*** | **Baseline** | **3 months follow-up** | **6 months follow-up** | **12 months follow-up** |
| ***PROMS*** |  |  |  |  |
| EQ-5D – 5L | X | X | X | X |
| OKS | X | X | X | X |
| OMAS | X | X | X | X |
| Patient demographics | X |  |  |  |
| Resource use |  | X | X | X |
| Return to work/normal activities |  | X | X | X |
| Free text comments |  | X | X | X |

## 4. Sample size

To be determined after external pilot

## 4.1 Participant recruitment

Figure 1 outlines the tibia fracture treatment flowchart and how it fits into our recruitment plans for the trial. Potentially eligible patients will be recruited from orthopaedic trauma clinics or wards, intensive care units, and emergency departments. The research team will work closely with the direct care team at each centre to optimise the screening (i.e. identification of potential participants), and recruitment for their local circumstances. A member of the patient’s direct care team will first approach the patient about the study, then the research nurse/associate will provide information about the study including an information sheet. Patients will have the opportunity to ask questions of the surgeon and the local research team.

Figure 1: Tibia fracture treatment flowchart

Person sustains Tibial fracture

Patient approached about Trial

Patient accepts. Enrolled

Patient eligibility for Trial confirmed

Patient Declines:

Screened but removed from trial

Surgeon / research team identifies patient as eligible

## 4.2 Randomisation

## The process of randomisation will occur prospectively through a secure online system. The designated person will need to provide some basic descriptive information about the participant and confirm their eligibility criteria. After simple randomization, a study participant identification number and group allocation will be issued. Each patient will be individually randomized into treatment groups equally. If they have bilateral frames, they will be randomized twice.

## 4.3 Data collection methods

Data will be collected at recruiting sites or by post from patients, then returned to HTU for scanning and processing. All reporting of data collection will be undertaken in line with the Consolidated Standards of Reporting Trials (CONSORT) statement. Data will be collected at baseline, 3, 6, and 12 months post-randomisation.

Screening logs will be kept by participating centres throughout the trial. We will collect data on: number of eligible patients; proportion of eligible patients approached for consent; proportion of eligible patients not approached; proportion of patients approached who provide consent; proportion of patients approached who do not provide consent; proportion of patients providing consent who are randomised. We will also collect data on the proportion of patients randomised who do not receive the randomly allocated treatment, and the reasons why.

## 4.4 Follow up

Participants will be followed up at 3, 6, and 12 months post-randomisation. The primary follow-up point is 12 months post-randomisation. All follow-up will be undertaken through postal questionnaires. Follow-up data collection at 3, 6, and 12 months may also take place in NHS clinics where follow-up clinics form part of routine care, as necessary. Radiographs are those routinely used for these patients and for the follow-up of such patients following any intervention so that there will be no need to request any additional or special investigations.

A research nurse will keep track of participant recruitment and study status, as well as Case Report Form (CRF) returns. Data from CRFs will be processed by administrative personnel. Data will be verified through cross checking of the data against the hard copy of the CRF.

# 5. Data management

Study data will be recorded in a number of files for both the administration of the study and collection of patient data. All data will be completely anonymised for purposes of analysis and any subsequent reports or publications. For the purposes of ongoing data management, once randomised, individual patients will only be identified by trial numbers.

Imaging data is likely to be initially stored by participating centres using the Picture Archive and Communication System (PACS). All patient identifiable details will be removed from the imaging before being saved onto compact discs in a format such as Digital Imaging and Communications in Medicine (DICOM); or if necessary, securely transferred by email using nhs.net.

## 5.1. Data entry

The data collected by sites using paper CRFs will be mailed (original paper CRFs) to HTU to be entered/scanned into a secure drive. When necessary, a site can securely return the CRF electronically.

The staff involved in the trial (both at the sites and HTU) will receive training on data protection, and all staff will be monitored to ensure compliance with privacy standards.

## 5.2**. Data storage**

Each site will hold data according to the Data Protection Act 1998, and data will be collated in CRFs identified by a unique identification number (i.e. the Trial number) only. A trial enrolment log at the sites will list the ID numbers, and HTU will maintain a list of trial numbers for all trial patients at each site.

All HTU data recorded electronically will be held in a secure environment with permissions for access as detailed in the delegation log. The R&D department and HTU is based at the Hull University teaching hospitals, and have a backup procedure approved by auditors for disaster recovery. Full data backups are performed nightly using rotational tapes to provide five years-worth of recoverable data. The tape backup sessions are encrypted, and password protected, with tapes stored in a locked fire-proof safe in a separate, secured, and alarmed location. All study files will be stored in accordance with Good Clinical Practice guidelines. Study documents (paper and electronic) held at the YTU will be retained in a secure (kept locked when not in use) location for the duration of the trial. All essential documents, including source documents, will be retained for a minimum period of five years after study completion. The separate archival of electronic data will performed at the end of the trial to safeguard the data for the period(s) established by relevant regulatory requirements. All work will be conducted following the HUTH data protection policy.

### 5.2.1. Proposed time period for retention of relevant trial documentation

Essential trial documentation will be kept with the Trial Master File and Investigator Site Files. The Sponsor will ensure that this documentation will be retained for a minimum of five years after the conclusion of the trial to comply with the standards of Good Clinical Practice. Case report forms and electronic data will be stored up to 10 years after the conclusion of the trial.

## 5.3. Quality Assurance and Quality Control

Hull and East Yorkshire NHS Trust is the lead sponsor for this project and takes overall responsibility for the quality of study conduct. This study will be fully compliant with the Research Governance Framework and MRC Good Clinical Practice Guidance. A trial specific data management plan agreed to by the chief investigator, sponsor, and other study investigators will be drafted to provide detailed instructions and guidance relevant to database set up, data entry, validation, review, query generation and resolution, quality control processes involving data access and transfer of data to the sponsor at the end of the study, and archiving.

### 5.4.1. Statistical Analysis Plan

Full analyses will be detailed in a statistical analysis plan (SAP), which will be finalised prior to the end of data collection. This trial will be reported according to the CONSORT (Consolidated Standards of Reporting Trials statement) guidelines for clinical trials.

### 5.4.3. Statistical analysis - main trial

A flow diagram will be provided to display the flow of participants through the study (see Figure 2). The number of participants withdrawing from the trial will be summarised with reasons where available. Baseline characteristics will be presented by a trial arm for both the trial population as randomised, and for those patients for whom primary outcome data was available at 12 months follow-up. Statistical analyses will be on intention to treat (ITT) basis with patients being analysed in the groups to which they were randomised. Statistical significance will be at the 5% level. All trial outcomes will be reported descriptively by the trial arm at all time points at which they were collected. Outcomes will be illustrated graphically over time where appropriate, including confidence intervals.

The estimated treatment group differences at 12 months will be reported as the primary endpoint with 95% confidence interval and associated p-value. Secondary analyses of the primary outcome will include an estimate of treatment group differences at 3 and 6 months from the same model.

There will be an exploratory subgroup analyses of the primary outcome to assess the effectiveness of the different treatments across open vs closed fracture types. These interactions will be presented graphically, and the p-value of the interaction will be reported. While there is insufficient statistical power for these interactions, they may help inform further research.

Secondary continuous PROMS outcomes will be analysed by similar mixed effects regression analyses to the primary analysis model. Binary secondary outcomes of additional procedures and complications will be analysed by mixed effects logistics regression analyses.

Figure 2: Trial flow diagram

**5.5 Trial monitoring**

Trial monitoring will be undertaken by independent trial committee along with the trial sponsor.

# 6. Harms

## 6.1. Risks and anticipated benefits

Risks associated with this study are predominantly the same risks associated with the surgery: infection, bleeding and damage to the adjacent structures such as nerves, blood vessels, and tendons. Participants in both groups will undergo surgery and will potentially be at risk from any/all of these complications.

In this trial, surgeons will perform interventions which they undertake as part of routine practice and with which they are familiar. Measures taken by us, such as our emphasis on good practice and standardised protocols/care pathways throughout, are likely to reduce risk and may bring additional benefits. We will adhere to the Research Governance Framework/UK Policy Framework for Health and Social Care Research and MRC Good Clinical Practice Guidance. The participant information sheet for the study will be developed with the involvement of service users and will give a balanced account of the possible benefits and known risks of the interventions. It will state explicitly that quality of care will not be compromised if the participant decides to a) not enter the trial or b) withdraw their consent. We will make it clear that there is no obligation to participate. Written informed consent will be obtained from all participants after they have had sufficient time to read the study materials and ask questions

## 6.2. Informing potential trial participants of possible benefits and known risks

Informed consent will be obtained by the trained local research nurse or clinician using a patient information leaflet developed with the help of service users, which explains the risks and benefits clearly.

## 6.3. Adverse event management

Adverse events (AE) are defined as any untoward medical occurrence to a clinical trial participant which does not necessarily have a causal relationship with the treatment. We will only collect unexpected adverse event data related to the treatment for the original injury, and we will only collect adverse event data up until the 12 month follow up. Serious adverse events are defined as any untoward and unexpected medical occurrence that: 1) results in death; 2) is life-threatening; 3) requires hospitalisation or prolongation of existing inpatients’ hospitalisation; 4) results in persistent or significant disability or incapacity; 5) is a congenital anomaly or birth defect; 6) any other important medical condition which, although not included in the above, may require medical or surgical intervention to prevent one of the outcomes listed. A list of expected adverse events is given in Table 3.

Table 3: Expected adverse events

|  |
| --- |
| Wound complications (e.g. delayed healing) |
| Infection at the surgical site or adjacent joint |
| Pin site infection requiring pout pt. procedure/antibiotics |
| Damage to a nerve or blood vessel |
| Breakage of orthopaedic hardware |
| Thromboembolic events |
| Secondary operations for or to prevent infection, malunion, non-union, or for symptoms related to the metalwork. |
| Wire breakage and removal/exchange of wire |
| Partial/complete frame removal |
| Chronic Regional Pain Syndrome |
| Amputation |
| Procedure secondary to any non-musculoskeletal conditions |
| Acute admissions for all non-musculoskeletal conditions |
| Elective admissions to hospital |
| Abnormal blood results |
| Chronic medical conditions that have worsened due to either the progressive nature of the disease, or for other reasons |
| All malignancies |

All serious adverse events (SAE) will be entered onto the Serious Adverse Event reporting form and reported within 24 hours of the investigator becoming aware of them. Once received, causality and expectedness will be confirmed by the Chief Investigator. SAEs that are deemed to be unexpected and related to the trial will be notified to the Research Ethics Committee (REC) and sponsor within 15 days.

# 7. Research ethics approval

As the study is held England, an application for NHS ethical approval in England will be made. Local R&D will confirm the capacity and capability of centres to participate. We do not anticipate major ethical concerns with this study.

## 7.1. Protocol amendments

Any amendments to the protocol during the course of the trial will be submitted for approval by the REC as necessary.

Responsibility for recording and dating both oral and written informed consent or agreement will be with the investigator, or persons designated by the investigator, who conducted the informed consent discussion. Designated responsibility should be recorded on the site delegation log.

### 7.2 Consenting

Research nurses or attending clinician will invite the patient to consider joining the study. They will be provided with a participant information sheet and have the opportunity to ask questions of the surgeon and the local research team.

### 7.2.3. Documenting consent

The original signed consent form will be kept in the investigator site file. Three additional copies of the consent forms will be made; one held in the patient’s medical notes, one for the patient, and one copy to be returned to HTU. Throughout the entire study, screening logs will be kept at each site to determine the number of patients assessed for eligibility and reasons for any exclusion.

## 7.3. Patient confidentiality

The researchers and clinical care teams must assure that patients’ anonymity will be maintained and that their identities are protected from unauthorised parties. Patients will be assigned a trial number and this will be used on CRFs; patients will not be identified by their name in order maintain confidentiality.

All records will be kept in locked locations. All consent forms will be secured safely in a separate compartment of a locked cabinet. Clinical information will only be looked at by responsible individuals from the study team, the sponsor, the NHS Trust, or regulatory authorities; where it is relevant to the patient taking part in this research as he/she would have agreed to at the time of consent.

## 7.4. Proposed action to comply with the medicines for human use (clinical trials) regulations 2004

The techniques under investigation are well-recognized and internationally accepted surgical procedures using CE-marked implants and medical devices. We do not, therefore, require prior authorisation by the UK Competent Authority, or the MHRA under the Medical Devices Regulations (2002).

# Declaration of interests

* Professor H K Sharma: Paid Consultant for Orthofix and Biocomposites. Research Grant from Smith & Nephew, Dermol laboratories and BBraun.
* Mr. Paul Harwood: No Conflict of interest
* Mr. David Ferguson: No Conflict of interest
* Dr. Vaida Glatt: no conflict of interest.

# Access to data

A statement of permission to access source data by study staff, and for regulatory and audit purposes, will be included within the patient consent form with explicit explanation as part of the consent process and Participant Information Sheet. Once HTU has completed the analysis and published all intended scientific journals, the data will be made available for other researchers.

In principle, anonymised data will be made available for meta-analysis and where requested by other authorised researchers and journals for publication purposes. Requests for access to data will be reviewed by the chief investigator and study sponsor.

The investigator(s)/institutions will permit monitoring, audits, and REC review (as applicable) and provide direct access to source data and documents.

# Indemnity

This study will be sponsored by Hull and East Yorkshire NHS Trust. If there is negligent harm during the trial, when the NHS Trust owes a duty of care to the person harmed, NHS indemnity covers NHS staff and medical academic staff with honorary contracts only when the trial has been approved by the R&D department. NHS indemnity does not offer no-fault compensation, and is unable to agree in advance to pay compensation for non-negligent harm.

# Dissemination and projected outputs

Through the planned outputs, the study is expected to play a key role in providing the evidence on bone healing with static vs variable dynamization in tibial fractures.

We will produce the following outputs:

* The study protocol will be published in a peer-reviewed, open access journal..
* The results of the study will be presented at national and international surgical meetings such as the British Limb Reconstruction Society meeting (BLRS), British Orthopaedic Association Annual Congress, UK Orthopaedic Trauma Society meeting, the North American Orthopaedic Trauma Association, the European Federation of National Associations of Orthopaedics and Traumatology (EFFORT), Société Internationale de Chirurgie Orthopédique et de Traumatologie (SICOT), and the American Academy of Orthopaedic Surgeons.
* The findings will be published in peer reviewed medical and orthopaedic journals.

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