Study Protocol:

Streamlining Management And Rehabilitation with Technology for ankle fractures: The (SMART-Ankle) feasibility study

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Sponsor:

RBWH

CONFIDENTIAL

Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the Royal Brisbane and Womens Hospital Ethics Committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007), the Australian Conde for Responsible Conduct of Research, the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95) and the Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005).

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GLOSSARY OF ABBREVIATIONS & TERMS

Abbreviation	Description (using lay language)
RBWH	Royal Brisbane Womens Hospital
JTI	Jamieson Trauma Institute
SMART	Streamlining Management And Rehabilitation with Technology
GDPR	General Data Protection Regulation

SYNOPSIS

Full Title	Streamlining Management And Rehabilitation with Technology for Ankle Fractures
Short title	SMART Ankle Feasibility Study
Study design	Single group prospective cohort study
Sites	1
Expected sample size	12
Recruiting time period	6 months
Study aim	To evaluate whether patients can use these devices during rehabilitation and whether the data from the device enhances clinical outcomes
Inclusion criteria	18 years and older Ankle fracture as per protocol Charlson Comorbidity Scores of <4 Can stand and use crutches post operatively Can attend outpatient follow up visits at RBWH
Exclusion criteria	Charlson Comorbidity Index score ≥5

Primary objective	Feasibility for patients to use the Magnes device
Secondary objectives	Clinical relevance of the data from the device
Outcome measures	Weight bearing characteristics of patients who have undergone surgical fixation of their ankle fracture for 12 weeks EQ-5D 5L AFORM Questionnaire

1. Background

Ankle fractures is one of the most common lower limb fracture and lead to important limitations in activities and adverse events (1). Available trauma statistics for the period 2015 to 2020, show that 7570 surgeries related to ankle fractures were performed in Queensland, with a median cost of $20,653 per admission. Currently an average of 165 surgeries for ankle fractures take place in the Royal Brisbane Womens Hospital (RBWH) per year (for the same period - 2015 to 2020). While these injuries are common and costly, there is little consensus amongst clinicians regarding the best rehabilitation regime. The most recent Cochrane review drew on 38 studies with a total of 1896 participants to conclude there is limited evidence supporting early commencement of weight-bearing and the use of a removeable type of immobilisation to allow exercise during the immobilisation period after surgical fixation (1). That review also concluded that given the risk of adverse events, the patient's ability to comply with the use of a removeable type of immobilisation to enable controlled exercise is essential, and that there is little evidence for rehabilitation interventions and higher quality studies are needed.

Physiotherapists, orthopaedic surgeons and researchers at the RBWH and the Jamieson Trauma Institute (JTI) have recognised these problems and see the potential to improve the care of patients following surgery for ankle fractures, by streamlining and improving rehabilitation using digital innovations, such as smart orthotics to record weight-bearing, and smartphone apps to record pain scores, adherence to rehabilitation programmes and medication use. A number of these devices have been developed in recent years. For the purposes of this study the Magnes device (Magnes AG, Switzerland) will be used.

Studies to date evidence the important of early weight-bearing and mobilisation(2, 3) but identifying the optimal amount of weight-bearing exercise at different stages of rehabilitation is a recurring challenge in the rehabilitation of patients with ankle fractures (4). At present, clinicians do not have good evidence upon which to base their guidance about when to begin partial or full weight-bearing on their injured leg or other aspects of their rehabilitation protocols (3). As such, the best weight-bearing protocol following ankle fracture surgery, for optimal recovery, is currently unknown.

A further key challenge is that, currently, clinicians are able to monitor patient progress only during face to face or telehealth appointments, therefore gathering evidence of adherence with rehabilitation programs is based on patient recall of activities between appointments.

These challenges are consistent with the preliminary results of our systematic review (in progress) of postoperative rehabilitation of patients with ankle fractures, which shows a lack of evidence to guide decisions about rehabilitation intensity and timing of weight-bearing for optimal fracture healing and functional recovery.

Advances in technology present new opportunities for addressing these issues through remotely tracking patient progress and allowing the clinician to identify the optimal amount of weight-bearing exercise at different stages of rehabilitation, thus reducing reliance on patient recall. In the context of ankle fractures, smart devices may allow real-time gait data capture and in-depth analysis of weight-bearing throughout recovery.

It is anticipated that data gathered through the use of smart technology will help clinicians develop optimal rehabilitation protocols and may also allow for protocols to be delivered without the need for the patient to attend a physiotherapy clinic/specialist rehabilitation setting, offering the opportunity to reduce clinical costs and pressure on waiting lists.

Before a large study testing the added value of smart devices in rehabilitation programmes for those with ankle fracture, a feasibility study is needed to demonstrate that patients are able to use the smart device in their rehabilitation and that the device provides data in ways that can be accessed and potentially used in rehabilitation programmes. This feasibility study aims to evaluate whether patients can use these devices during rehabilitation and whether the data from the device enhance clinical practice. For the purposes of this study, the Magnes device will be used. It is anticipated that findings from this study will be used to inform a larger randomised trial to assess whether adding a weight-bearing and activity recording device during rehabilitation offers additional benefit when compared to standard rehabilitation protocols. In addition, it is anticipated that this feasibility trial will provide valuable insights into patterns of weight-bearing and general physical activity which will be used to help optimise rehabilitation protocols and improve functional outcomes.

2. Study Methods

2.1 Brief summary

The objective of this study is to evaluate the acceptability and feasibility of the Magnes device to monitor weight-bearing and gait characteristics during the rehabilitation phase following surgery for an ankle fracture, from the date of surgery to 12 weeks post-operatively. Alongside the clinical progress of the injured patient, the study will also examine:

1. The recruitment, screening and consent processes for eligible patients entering the study
2. The outcomes used to monitor patient progress up to 12 weeks post-operatively.
3. The acceptability and feasibility of the Magnes device to measure and record weight-bearing and gait characteristics following ankle fracture surgery, from both the patient and clinician perspectives.
4. The accuracy and usefulness of data collected by the Magnes device, for clinical decisions in practice.
5. The feasibility of conducting a future randomised clinical trial using smart devices, which can in turn support the development of new systems to streamline and improve care and outcomes.

It is anticipated that through this process valuable lessons will be learned concerning the methods and procedures above, which will help the development of a larger randomised controlled trial.

2.2 Study Design

This is a single group prospective cohort study, involving patients who have underwent surgical fixation of their unstable ankle fracture with data collection over a period of 12 weeks.

2.3 Interventions

The study will assess acceptance and interaction of patients and clinicians to implementation of a smart device to monitor weight-bearing during the rehabilitation phase following surgery of an unstable ankle fracture. Postoperative rehabilitation will be standardised for the initial 12-week rehabilitation period for all included patients, in accordance with current clinical practice. The patients' weight-bearing and activity will be recorded with the Magnes device.

This study does not examine the effectiveness of surgical or rehabilitation strategies. However, clinical outcomes will be recorded to allow exploration of the correlation between weight-bearing activities, clinical progress and adverse events. The future application of the Magnes device would allow to detect aberrant movement patterns early, hence avoiding complications following ankle fracture fixation.

2.4 Sample Size

A formal sample size calculation is not necessary for the purpose of this feasibility study. Based on the nature of this study, we target a sample size of n=12 patients (5).

2.5 Patient population

Patients will be recruited from the Orthopaedics department at the RBWH in Brisbane, Queensland, Australia. The Orthopaedics department at RBWH performs surgery, on average, on two ankle fractures per week. For the purposes of this feasibility study, it is envisaged that 12 patients will be an adequate sample.

2.6 Participant Recruitment

All patients with a unilateral unstable single malleolar, bi-malleolar and most tri-malleolar fractures requiring surgery, including those with syndesmotic/deltoid ligament injuries, will be approached, screened for contraindications and, if they meet the study inclusion and exclusion criteria (see below) and agree to participate, they will be asked to consent to participation to the study.

Patients will be recruited from the RBWH fracture clinic. The orthopaedic clinic staff will identify the type of fracture and the Charlson Comorbidity Index score before considering the patient for inclusion.

Suitable patients will be identified by the orthopaedics department and contacted by the research nurse in the preoperative phase, so that they are screened for eligibility, informed as to the nature of the study both verbally and by the study pack (which includes an invitation letter, information leaflet explaining the aims and objectives of the study and the consent form) and, if they are suitable for inclusion and agree to take part, sign an informed consent form.

Patients will be informed that they are free to withdraw from the study at any time and that their decision to withdraw will not affect their care in any way. Patients will be obliged to return the smart devices to the research team on completion of, or at the time of withdrawal from, the study.

2.7 Study Eligibility

Patients' eligibility to participate will be determined based on the following inclusion and exclusion criteria.

2.7.1 Inclusion criteria

Patients are eligible to participate in the trial if they:

- Are 18 years or older at the time of recruitment.
- Have suffered an ankle fracture that can be classified as tibia/fibula, malleolar segment (44) according to the AO Foundation-Orthopaedic Trauma Association (AO-OTA) Fracture and Dislocation Classification Compendium 2018 (6):
    - 44-A: infrasyndesmotic fibula injury
    - 44-B: trans-syndesmotic fibula fracture, and
    - 44-C: supra-syndesmotic fibula injury

  And, had ankle fracture surgery (fracture types include AO-OTA 44-A, 44-B and 44-C; single malleolar, bi-malleolar not extending into the tibial plafond and tri-malleolar with posterior fragment <20%).
- Have a Charlson Comorbidity Index score (7) of 4 or less. (Appendix 3)
- Can stand and walk with and without crutches when wearing the Aircast boot at the time of data collection.
- Can attend follow-up visits at the RBWH in person.

2.7.2 Exclusion criteria

1. A Charlson Comorbidity Index score 5 or higher
2. Foot or leg size incompatible with available Magnes shoes or Aircast boot
3. Comorbidities:
    a. concurrent or pre-existing injuries that impair the ability to use the orthosis as intended (e.g. neurological conditions including Multiple Sclerosis, brain injury, spinal cord injury);
    b. patients with any other disorders involving restriction of mobility, limited ambulation on forearm crutches, or conditions affecting the fracture healing process (e.g. joint disease, neurological disorder, amputation)
    c. BMI >35kg/m2
4. Require non-standard postoperative care
5. Not able to attend follow-up visits at the RBWH.
6. Have suffered any of the following fracture types:
    a. talus fractures
    b. pilon (tibial plafond) fractures
    c. calcaneal fractures
    d. stress fractures
    e. ankle fractures associated with ipsilateral (mid)foot fractures
    f. bilateral lower limb fractures
    g. concomitant upper limb fractures or injury
    h. Posterior malleolus fractures requiring posterior plating
    i. small and undisplaced fractures that can be managed non-operatively
    j. trimalleolar fractures with significant posterior involvement that are not suitable for early weight--bearing
    k. open (compound) fractures or fractures on both lower limbs.

2.8 Study Intervention

Current practice in the orthopaedic clinics of the RWBH includes fitting all patients operated for an ankle fracture with an Aircast AirSelect Standard walker boot (**Figure 1**A) in the operating theatre. As such, patients will be screened and consented in the pre-operative phase.

The Aircast Airselect Standard walking boot (hereafter referred to as the Aircast boot or Aircast) is shown in Fig. 1A. The Aircast is considered part of standard care for these ankle fracture patients. In clinical practice, the Aircast boot is utilised for fractures of the foot, ankle and distal tibia or fibula, high-grade ankle sprains and for postoperative immobilisation. It offers several advantages over traditional casts such as allowing easier access to the surgical wound, the ability to adjust the Aircast boot depending on swelling and improved durability when used as a walking device.

Those patients who consent to participate in the study will be fitted with the Aircast boot as per usual practice with the addition of a Magnes device attached to the boot, as shown in **Figure 1**A, in the operating theatre following surgical fixation.

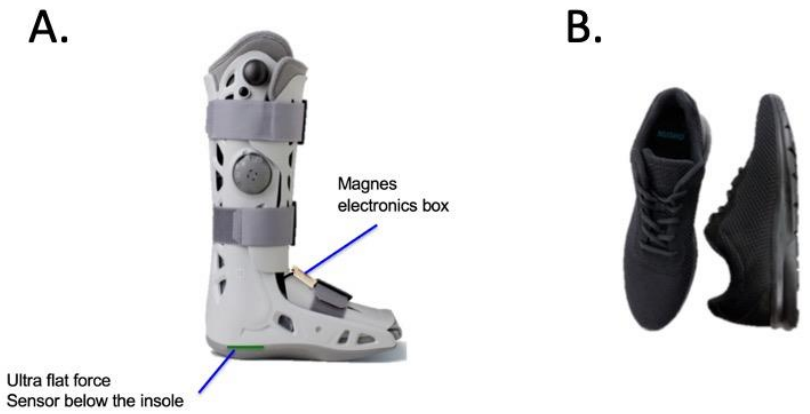

Figure 1: *The Aircast boot with the Magnes smart device (1A) and the Magnes NUSHU (1B) It has anterior and posterior semi-rigid outer shells that when tightened, using the three straps, immobilises and supports the ankle and provides protection. An inner lining protects the limb from skin irritation. The Aircast has two adjustable distal air cells within the shell that inflate to support the malleoli and provide compression to decrease swelling. The Aircast is available in sizes XS – XL, allowing a suitable fit for most patients.*

In addition, patients will receive a standard information and education leaflet designed for the study (Appendix 1). The information and education leaflet includes information about the smart devices and their care (smart device in the Aircast and the NUSHU shoe) and information on postoperative care (practical guide, weight-bearing, other activities and exercises). This leaflet will facilitate standardisation of the postoperative rehabilitation across patients. (Appendix 1).

Post-operatively patients will be offered up to 6 physiotherapy sessions in fortnightly intervals as per usual practice. (Appendix 2).

As the patients' rehabilitation progresses and restriction of movement is no longer necessary, patients will transition from the Aircast boot to the Magnes NUSHU. Typically, this will occur at

approximately 6 weeks post-operatively (**Figure 1**B). Patients will be asked to wear the NUSHU when they are no longer wearing the Aircast boot, for walking and other activities.

The Magnes NUSHU contains the same technology as the Aircast (it is fitted with a weight-bearing sensor, and records weight-bearing and activity data in the same way). Patients will be asked to wear the Magnes NUSHU shoes until the end of the study (12 weeks postoperatively).

2.9 Immediate postoperative care

As mentioned above, the Aircast boot will be applied in theatre, over the surgical dressings, without inflation, and is to be left on until the first Orthopaedic follow-up appointment at approximately 2 weeks. However, the Aircast boot is designed to make it easy to don and doff, so that circulation and wound healing can be assessed during routine postoperative care.

A physiotherapist will review each patient postoperatively, before the patient leaves hospital and give instructions about how the use of the Aircast boot, the maintenance of the Magnes device (charging, positioning etc), crutches and demonstrate, instruct and educate the patient with regard to the rehabilitation plan.

2.10 Use of Smart device during postoperative rehabilitation

The Aircast boot will be fitted with the Magnes smart device, removing the need for the patient to interact with the device for any other reason than to charge its battery. As mentioned above the Magnes smart device has a battery life of appx 16 hours. Patients will be advised to charge the battery every day and will be instructed on how to do this, before they leave the hospital.

The Magnes device has the capacity to automatically synchronise data when it is connected to the designated Hospital based WiFi network. Data will be downloaded from the Magnes device during each follow-up appointment (**Error! Reference source not found.**) and each physiotherapy appointment visit, every 2 weeks. The NUSHU shoe works in the same way as the Magnes smart device, and the same regime (regarding data download) will be followed.

3.0 Outcome measures

As this is a feasibility study the key outcomes to focus on are feasibility outcomes. As such the study will focus on the feasibility of the use of the Magnes device by the patient and the clinician.

3.1 Magnes Device specific Outcome Measures

The Magnes Device uses a lithium polymer battery and can collect approximately 16 hours of data on a single charge and can store data equivalent to 25 days of use. It can record gait parameters (i.e. step velocity, step length, swing time, step time, stance time) and the loading behaviour (i.e. peak load, average load, load duration, steps/day). Force is recorded in Newtons (N). The boot communicates to an iPhone/iPad application via Bluetooth low energy to start/stop data collection. The data are transferred to the smartphone/iPad via WLAN.

Aim 1:

The patient acceptability and feasibility of using this device in the Aircast boot during rehabilitation (week 1 to approximately week 6)

Feasibility

- Percentage of weight-bearing per week
- The correlation between instructed amount of weight-bearing and actual weight-bearing, in both intensity and total time.

Acceptability

- Ability to maintain charge in device
- Adverse events recorded relevant to the use of the Magnes smart device
- Open-ended /a semi-structured phone interview after Assessment 3 (12 weeks postoperatively) will be conducted and analysed to gain insight in the acceptability of using the Magnes smart device in the Aircast boot during postoperative rehabilitation. Every second participant will be selected to receive a phone call (participants 2, 4, 6, 8, 10, 12).

Aim 2:

The patient acceptability and feasibility of using the Magnes NUSHU during rehabilitation (from approximately week 6 to week 12)

Feasibility

- Time to fully weight-bear
- Percentage of weight-bearing per week
- The correlation between instructed amount of weight-bearing and actual weight-bearing

Acceptability

- Ability to maintain charge in device
- Adverse events recorded in regard to the Magnes smart device
- Semi-structured phone interview after Assessment 3 (12 weeks postoperatively) will be conducted and analysed to gain insight in the acceptability of using the Magnes smart device in NUSHU during postoperative rehabilitation.

Aim 3:

The clinician acceptability and usability of the data recorded by both devices (Magnes and NUSHU), for clinical decision-making

Feasibility

- Ability to upload data consistently during the exhibition phase

Acceptability

- A semi-structured interview will be conducted and analysed to gain insight in the usefulness of using data collected with the smart devices to inform clinical decision making.

The **clinical outcomes** of ankle rehabilitation will be evaluated using the AFORM questionnaire (8). This is a validated outcome measure for patients with ankle impairment and has been shown to possess high validity and reliability. It is a patient reported outcome measure, which is condition specific for use in clinical and research settings among patients who suffered an ankle fracture. The A-Form is comprising of 8 questions assessing activities of daily life and sporting activities. (Appendix 4)

Additional measurements will include health related quality of life measured using the EQ-5D 5L (EuroQol five-dimension health utility tool) which will be taken at all 3 points (at 2, 6 and 12 weeks post-operatively). The EQ-5D 5L is used to measure health utility and can be used to value health services in terms of quality-of-life improvement. It is not disease-specific and therefore enables

comparison across different diseases. Health utility measures are important for cost-effectiveness analysis and data from the EQ-5D 5L will enable economic evaluation of changes to health services as a result of introducing this new technology.

Data from the Magnes device will be downloaded at each fortnightly physiotherapy appointments (Appendix 2). The Magnes device provides data in force measurements (Newtons) which will be interpreted as weight-bearing and will be plotted to show the gradual increase through the period of rehabilitation and recovery.

Baseline measurement will be taken at the first postoperative appointment at 2 weeks post-surgery. Subsequent measurements will be taken at 6 and 12 weeks. If patients miss their follow-up appointments, the research nurse will call the patient and collect the outcome measures over the phone. Sensor data will be collected on the next visit of the patient to the clinic.

Objective measurements of ankle dorsiflexion, plantar flexion, eversion and inversion will be taken by the research physiotherapist using a goniometer as per standard clinical practice.

3.2 Baseline Assessment

At 2 weeks post-surgery, patients will attend orthopaedics and physiotherapy outpatient clinics to assess wound and fracture healing (**Error! Reference source not found.**).

Wound will be reviewed by the orthopaedic department/nurse. If wound healing is satisfactory, a tubular compression bandage will be applied. The Aircast boot will be reapplied.

Patients will be instructed on inflation of the Aircast boot, and will be provided a link to this video for future reference: https://www.youtube.com/watch?v=XnBm68oTDOw.

Patients will be instructed that the inflation of the Aircast boot may need to be adjusted as swelling reduces.

Patients will be given instructions, by the physiotherapist, about how partial weight-bearing, which can begin following the first follow-up visit. Additionally, their exercise protocol will be reviewed, and patients will be advised on an exercise regime. They will also be instructed in the charging of the battery of the Magnes device.

Measurements will be taken according to the schedule described in Table 2.

The Magnes device data will be downloaded for the first time since surgery, allowing for an evaluation of foot use and weightbearing activities since surgery.

3.2.1 Assessment 2

At 5-6 weeks post-surgery, patients will attend the orthopaedics and physiotherapy outpatient clinic for their second follow-up visit (**Error! Reference source not found.**).

At this visit and depending on the stage of healing of the fracture, the Aircast boot will be substituted by the Magnes NUSHU.

3.2.2 Final appointment

At 12 weeks post-surgery, patients will attend the orthopaedics and physiotherapy outpatient clinic for their third and final follow-up visit (**Error! Reference source not found.**) after which they will be discharged.

Outcome measures such as range of movement, AFORM and EQ-5D 5L questionnaires as well as downloading the data from the sensor will occur during these two follow-up visits.

4.0 Data collection

Data will be collected at 2 weeks post-surgery (baseline for this study), and at 6- and 12-weeks follow-up.Non identifiable baseline data, such as gender and age, will be recorded, in addition to non-identifiable health related data, for example, date of injury, injury cause, imaging reports and type of surgery. This information will be recorded on a secure, password protected Metro North REDCap server. See Appendix 5 for a pdf of the REDCap data dictionary. Range of movement, AFORM and EQ-5D 5L: measures will be taken at each follow-up visit.

Table 1: Outcomes to be recorded at patient follow-up visits

No.	Measurement	Description	When measured
Ability to use technology: insoles and iPad App			
1.	Data upload	Has the data been uploaded to the cloud successfully for the time period in question	2, 6, 8, 10 and 12 weeks
2.	Device charging and monitoring	How long each day did the patient wear the boot/shoe? Did the device remain charged (and able to record data) for the time period in question? Were there any problems related to keeping the battery charged?	2 weeks, 6 weeks, 12 weeks
3.	Other issues raised by the patient	Description of any other problems faced by the patient that limit their ability to use the device and capture data.	2 weeks, 6 weeks, 12 weeks
4.	Ownership of a smartphone	Patients will be asked if they own a smartphone (necessary as the future randomised trial will require this)	At recruitment
Patient Reported Outcome Measures			
5.	AFORM	Standardised questionnaire, filled in by the patient.	2, 6 and 12 weeks
6.	EQ-5D 5L: EuroQol five-dimension health utility tool	Standardised questionnaire, filled in by the patient.	2, 6 and 12 weeks
7.	Return to work	Has the patient returned to work? Is the patient able to return to work?	2, 6 and 12 weeks
8.	Medication review	Consumption of OTC and prescription analgesics	Daily for 12 weeks
Other clinical measures			
9.	X-ray ankle	XR ankle: WB out of cast – AP/lateral/mortise	6 weeks
10.	Wound review	Orthopaedic Department Nurse	2 weeks
11.	Weight-bearing	Magnes Sensor Data	2-6 -8*-12 weeks

No.	Measurement	Description	When measured
12.	Complications	Orthopaedic Department Nurse	Throughout the duration of the project
Range of Motion Measures			
13.	Ankle dorsiflexion (DF)	Measured using a standard goniometer	2, 6 and 12 weeks
14.	Ankle dorsiflexion (DF) (knee to wall)	Measured using a standard ruler	2, 6 and 12 weeks
15.	Ankle plantarflexion (PF)	Measured using a standard goniometer	2, 6 weeks, 12 weeks
16.	Ankle plantarflexion (PF) (knee to wall)	Measured using a standard ruler	2, 6 and 12 weeks
17.	Ankle range of motion (ROM)	Measured using a standard goniometer	2, 6 and 12 weeks

4.1 Data management

Information obtained from participants will be treated confidentially.

Files containing identifiable participant information will be stored on the Jamieson Trauma Institute server. These files and data are accessible via a Queensland Health computer at the Jamieson Trauma Institute and Research Centre, accessible only by the research team members. De-identified data will be stored on the Queensland Health password protected, secure server. Paper records will be stored in a locked fire-proof cabinet on a secure access floor of the Jamieson Trauma Institute, accessible by the members of the research team only.Patient data will be exported for analysis using SPSS (version 25.0, IBM, New York, NY, USA), and will be de-identified immediately, with each generated file password protected. If data needs to be sent between researchers and other team members in the analyses/reporting stage, these will be sent via Queensland Health email in password protected files. Data will only be accessed by and shared with researchers associated with the study. Publication of results/data will be de-identified so that the identity of participants in the study is not revealed. In line with Section 2 of the Australian Code for the Responsible Conduct of Research, research data will be retained for a period of 15 years from the date of publication. At the conclusion of this period, all the primary data will be deleted.

5.0 Withdrawal or dropout from study

Reasons for withdrawal or dropout from the study will be recorded by the research team, particularly as this information may be important for future work. Patients who withdraw or drop out of the study will be asked to return the smart devices to the research team, and no further data collection will take place.

6.0 Risks and Benefits

This study is not changing any aspect of standard clinical practice in the treatment and rehabilitation of ankle fractures so there is no additional risk from participating. The only additional burden is that the participant will complete two questionaries at three timepoints and they will be required to charge the Magnes device once a day. There will be no direct benefit to individuals as a result of participating in this study. However, they will indirectly contribute to advances in ankle fracture rehabilitation practices, and in streamlining aftercare in this population. Participants will not be reimbursed for their time.

7.0 Contacts and locations

Principal Investigators

Name	Organisation	Qualifications	Role
Dr Panos Barlas (Coordinating Principal Investigator)	Jamieson Trauma Institute	BSc (Hons), DPhil	Principal Research Fellow
Prof Michael Schuetz	Royal Brisbane and Women's Hospital	FRACS, FA(Ortho)	Orthopaedic Surgeon
Christopher Smith	Physiotherapy, RBWH	Bachelor of Physiotherapy	Physiotherapist
Esther Jacobson	Jamieson Trauma Institute	BSc (Hons)	Research Manager
Dr Jerry van der Pol	Royal Brisbane and Women's Hospital	MD, FRACS	Orthopaedic Surgeon
Dr Richard Hanly	Royal Brisbane and Women's Hospital	FRACS, FAOA, MBBS, BPhty (Hons)	Orthopaedic Surgeon
Peter Slattery	Rehabilitation Engineering STARS	Master of Engineering Science (Research), Bachelor of Engineering	Director
Prof. Ross Young	Jamieson Trauma Institute	BSc (Hons) MSc, Dip Clin Psych, PhD, MAPS	Professor of Rehabilitation
Dr Marlien Varnfield	CSIRO -	MSc - Odontology PhD - Epidemiology and Preventive Health	Mobile Health Systems Team Leader

Associate Investigator

Name	Organisation	Qualifications	Role
Michelle McGrath	Physiotherapy, RBWH	MSc Medical Engineering	Biomedical Engineer Magnes Data analyst

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Appendices

APPENDIX 1: Rehabilitation protocol

Ankle Fracture - Post operative Physiotherapy

The following is a guide only, please check for any changes or variances as indicated by your surgeon's post-operative plan.

(Excludes tibial plafond fractures and large posterior malleolar fractures)

0 to 2 weeks Gentle walking and elevation PWB

- Physiotherapy review post operatively for crutches
- Apply air-cast boot in theatre after surgery – No inflation
- **PWB (partial weight bear)** in air-cast boot with crutches is ok
  You may opt to NWB (non-weight bear) due to pain, this is ok too.
  After 3-5 days start to try and take some weight (<50% of your weight) on your foot with the boot
- Keep boot on at all times - leave on 24/7 but check your skin underneath by undoing daily to view your skin by removing the front panel
- Rest and elevate to allow for wound healing – aim to keep your leg elevated 23hrs/day
  - When sitting elevate your leg on a foot stool, chair or up on sofa
  - When lying down, you can elevate your leg on a single pillow
  - Don't walk too much, aim for essential walking within your home in the first week
- Do not get dressings wet – cover your lower leg in a cast bag for showering
- Leave dressings intact for 10-14 days - until the '2 week' follow up
- Around 2 weeks you will have dressing removed and wound reviewed by a doctor
- A tubi-grip will be applied and the air-cast boot re-applied
- Teach application of air-cast boot – **but not to inflate for first 2weeks** and until dressing removed
  Video demo: https://www.youtube.com/watch?v=XnBm68oTDOw

Crutches PWB = Partial Weight Bear

= <50% of your body weight

Boot on at all times

- Aim for ankle in neutral (90°)
- Can be refitted if needed to ensure heel down
  Or to check skin condition daily.

Walking with crutches:

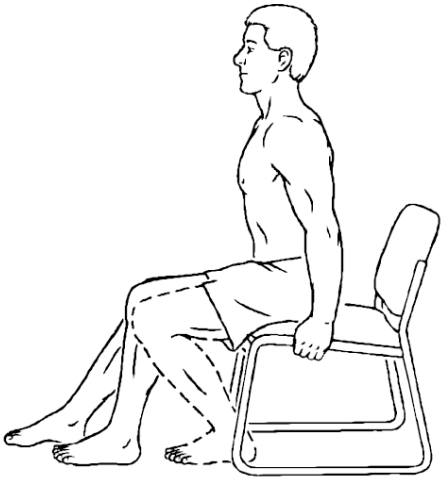
- Crutches in front first, boot foot next taking **Partial weight** as pain allows (**up to 50% of your body weight**), good foot follows stepping up to (not past) operated foot (can use scales to check weight you're

2 to 6 weeks **Progress more weight onto foot and start ankle movement** **WBAT**

WBAT (weight bear as tolerated = up to full weight) in air-cast boot with crutches, **boot inflated**

- Boot on for all walking using 2 crutches
- You may be able to manage with 1 crutch indoors (crutch in opposite hand to foot)
- If painful or limping continue with 2 crutches
- Aim for step-through gait – Physiotherapist to review and advise

- Boot can be removed at night, but needs to be reapplied if walking to toilet
- Foot can get wet in shower – remove boot and dressings, start tubigrip at 2 weeks
- Remove boot 3x daily to allow for ROM exercises (Exercises 1,2,3 as below)



Exercise 1 – Seated Heel slide stretch

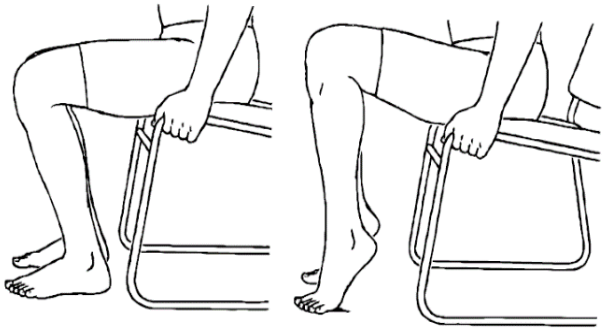
Sitting in a chair with boot off

Place foot on floor, heel flat

Slide foot backwards until stretch is felt

Hold for 10 seconds with heel on floor

Rest for 30 seconds and repeat stretch 5 times.

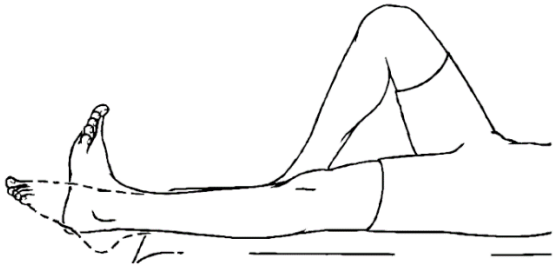


Exercise 2 – Seated Heel raises

Sitting in a chair with boot off

Raise heels up and down keeping toes flat

Repeat 20 times slowly, rest for 30 seconds and repeat 3 x 20.



Exercise 3 – Ankle back and forth

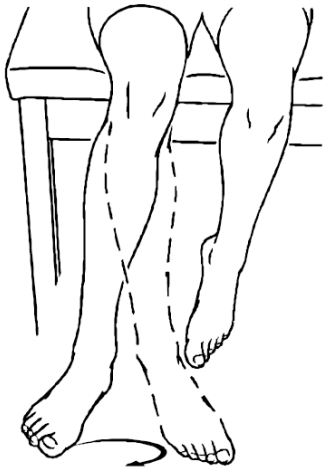
With boot off, move toes and ankle back and forth gently

Repeat 20 times slowly, rest for 30 seconds and

6 to 8 weeks Progress exercises and walking FWB

- Wean air-cast boot, **FWB (Full weight bear) out of boot with crutches**, then single crutch, then no crutches

- Wear boot when outdoors until 8 weeks, can remove boot at night and when walking inside
- Exercises - Progress to FWB ROM in standing with no boot as directed by Physiotherapist



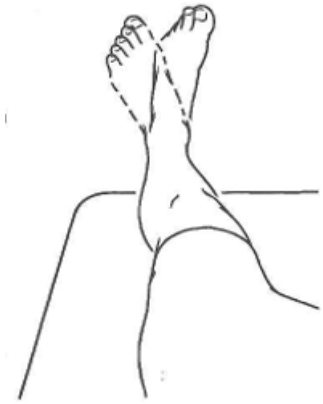
Exercise 4 – Ankle circles

Sitting with boot off

Move foot in circles, drawing circle with big toe

Both directions 10 times each = 20 circles

Rest 30 seconds and repeat 3 sets of 20 circles

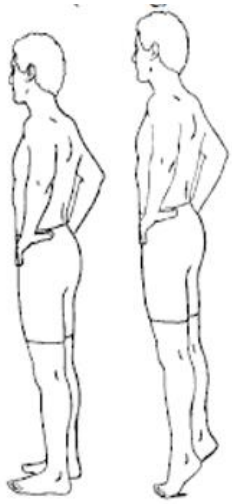


Exercise 5 – Ankle Eversion / Inversion

(Side to side movement)

Aim to turn sole of foot inward then outward

Both directions 10 times each



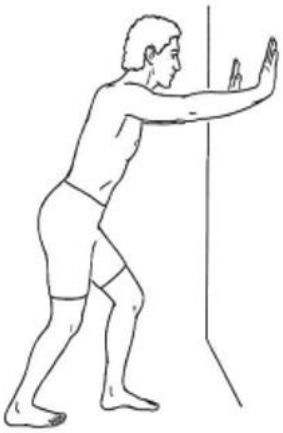
Exercise 6 – Standing heel raises – 2 feet

Start by holding onto wall, chair or bench for balance

Rise on balls of feet slowly

Repeat 10x

Rest and repeat 3 sets of 10



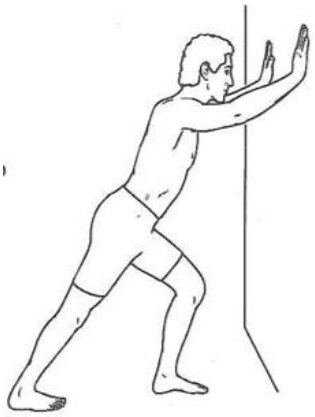
Exercise 7 – Standing Ankle stretch A

Stand with affected foot back

Both knees slightly bent

Lean into wall until stretch in lower calf

Hold for 10 seconds



Exercise 8 – Standing Ankle stretch B

Stand with affected foot back

Back leg straight keeping heel on floor

Foot turned slightly out

Lean into wall until stretch in calf

Hold for 10 seconds

Exercise 9 – Single leg balance

Attempt to balance on one foot, can hold onto wall, bench to start with

Aim to stand on one foot for 5 seconds, build up to 10 seconds

Other exercises your Physiotherapist may prescribe:

Sit to stand, Mini-squats, Lunge knee to wall, Slow stepping on spot

Seated bike - boot off from 6 weeks, careful with time and effort on bike, monitor for swelling, start with 2 x 5mins slow revolutions for weeks 6-8, increase as appropriate

12 weeks+ Return to full activities

watching for swelling and pain.

- Physiotherapist will guide you back to full activities and sport
- Jogging and running as per your Drs and Physiotherapist advice
    - Start with mini-tramp, flat grass, turning/cutting drills, jumping, hopping, ball drills
    - ankle strapping as indicated

Table 3: Rehabilitation Protocol

Exercise no.	Name	Description
1.	Seated Heel slide stretch	Sitting in a chair with boot off Place foot on floor, heel flat Slide foot backwards until stretch is felt Hold for 10 seconds with heel on floor Rest for 30 seconds and repeat 10 second stretch 5 times.
2.	Seated Heel raises	Sitting in a chair with boot off Raise heels up and down keeping toes flat Repeat 20 times slowly, rest for 30 seconds and repeat 3 times 20
3.	Ankle Dorsiflexion (pull toes back)	With boot off, move toes back and forth gently Repeat 20 times slowly, rest for 30 seconds and repeat 3 times 20 repetitions

Exercise no.	Name	Description
4.	Ankle circles	Sitting with boot off Move foot in circles, drawing circle with big toe Both directions 10 times each = 20 circles Rest 30 seconds and repeat 3 sets of 20 circles
5.	Ankle Eversion / Inversion (Side to side movement)	Aim to turn sole of foot inward then outward Both directions 10 times each Rest 30 seconds and repeat 3 sets of 20
6.	Standing heel raises (both feet)	Start holding on wall for balance Rise on balls of feet slowly Repeat 10 times Rest and repeat 3 sets of 10
7.	Standing Ankle stretch A	Stand with affected foot back Both knees slightly bent Lean into wall until stretch in lower calf Hold for 10 seconds Rest and repeat 3 times 10 second stretches
8.	Standing Ankle stretch B	Stand with affected foot back Back leg straight keeping heel on floor Foot turned slightly out Lean into wall until stretch in calf Hold for 10 seconds Rest and repeat 3 times 10 second stretches
9.	Single leg balance	Attempt to balance on one foot, can hold onto wall or bench to start with Aim to stand on one foot for 5 seconds, build up to 10 seconds When comfortable, can try this with your eyes closed
10.	Sit to stand	Sit on a standard chair with feet planted on the floor and stand in one movement. Repeat 6-10 times, rest for 2 minutes and repeat for a further two sets.
11.	Minisquats (both feet)	
12.	Lunge – Knee to wall	
13.	Slow stepping on spot	
14.	Seated bike	Boot off from 6 weeks (careful with time and effort on bike, look out for swelling, start with 2 times 5 mins slow revolutions for weeks 6 to 8, increase time watching swelling and pain.

APPENDIX 2: Rehabilitation timeline

Rehabilitation strategy

Patients will be followed up at 2, 6 and 12 weeks after their surgery (as per standard clinical care), at physiotherapy and orthopaedics department outpatient clinics at the Royal Brisbane and Women's Hospital (Brisbane, Queensland, Australia) (**Error! Reference source not found.**). Physiotherapy appointments will occur in fortnightly intervals from week 2 post-operatively. In total, patients will receive 6 sessions of physiotherapy treatment. Outcome measures will be recorded on the 1st, 3rd and 6th attendance of the patient for their physiotherapy and orthopaedic follow-up appointments (wks 2, 6 and 12 post-operatively).

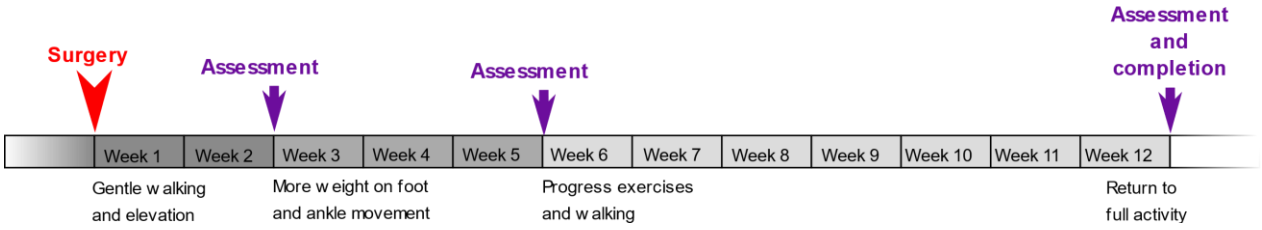


Figure 2. The patient's postoperative timeline, including assessment time points.

The rehabilitation exercises that patients will be instructed to do are described in APPENDIX 2. The information booklet provided to patients will include instruction sheets with cartoons showing how to perform each of the exercises (Appendix 1). Patients will advised as to their rehabilitation, pain relief and the Aircast boot according to the information in (Appendix 1). The wound dressings will be left intact until the first follow-up visit, 10 to 18 days after surgery.

Surgery date to 2 weeks post-surgery: Gentle walking and Elevation (Error! Reference source not found.**)**

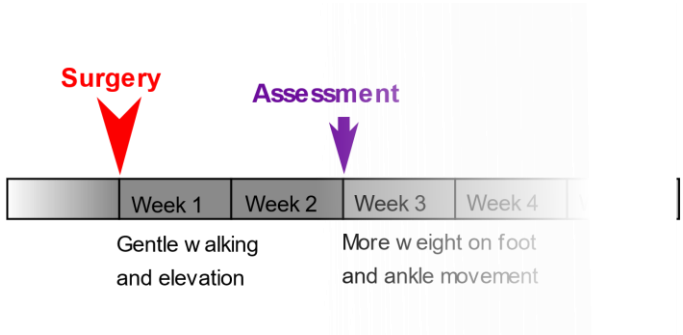


Figure 3. The patient's postoperative timeline from surgery to assessment 1.

Aircast boot

The Aircast boot should remain on at all times and ***should not be inflated during the first two weeks of the postoperative period***. During showering/bathing, the cast should be covered using a plastic bag, to ensure the boot and wound dressings do not get wet.

APPENDIX 3: Charlson Comorbidity Questionnaire

Charlson Comorbidity Index

Chart review version

Components of classical Charlson Comorbidity Index[1]

1. Has the patient had a myocardial infarction? (MI)
   ___ No
   ___ Yes

Criteria: Myocardial infarction includes patients with one or more definite or probable myocardial infarction. These patients should have been hospitalized for chest pain or an equivalent clinical event and have had electrocardiographic and/ or enzyme changes. Patients with electrocardiographic changes alone who have no clinical history are not designated as having had an infarction.

2. Has the patient been hospitalized or treated for heart failure? (CHF)
   ___ No
   ___ Yes

Criteria: Congestive heart failure includes patients who have had exertional or paroxysmal nocturnal dyspnea and who have responded symptomatically (or on physical examination) to digitalis, diuretics, or afterload reducing agents. It does not include patients who are on one of those medications but who have had no response and no evidence of improvement of physical signs with treatment.

3. Does the patient have peripheral vascular disease? (PVD)
   ___ No
   ___ Yes

Criteria: Peripheral vascular includes patients with intermittent claudication or those who had a bypass for arterial insufficiency, those with gangrene or acute arterial insufficiency, and those with a treated or untreated thoracic or abdominal aneurysm (6 cm or more).

4. Has the patient had a CVA or transient ischemic disease? (CVA)
   ___ No
   ___ Yes

Criteria: Cerebrovascular disease includes patients with a history of a cerebrovascular accident with minor or no residua, and patients who have had transient ischemic attacks. If the CVA resulted in hemiplegia, code only hemiplegia.

[1] Charlson, ME, Ales, KA, Pompei, P, MacKenzie, CR A new method of classification of prognostic comorbidity for longitudinal studies: development and validation J Chron Disease. 1987; 40(5): 373–383

16

5. Does the patient have hemiplegia? (PLEGIA)
   ___ No
   ___ Yes

Criteria: This includes patients with a hemiplegia or paraplegia, whether it occurred as a result of a cerebrovascular accident or other condition.

6. Does the patient have asthma, chronic lung disease, chronic bronchitis or emphysema? (COPD)
   ___ No
   ___ Yes

Criteria: Pulmonary disease includes patients with asthma, chronic bronchitis, emphysema, and other chronic lung disease who have ongoing symptoms such as dyspnea or cough, with mild or moderate activity. This includes patients who are dyspneic with slight activity, with or without treatment and those who are dyspneic with moderate activity despite treatment, as well as patients who are dyspneic at rest, despite treatment, those who require constant oxygen, those with CO_2 retention and those with a baseline PO_2 below 50 torr.

7. Does the patient have diabetes that requires treatment? (DM)
   ___ No
   ___ Yes

Criteria: Diabetes includes all patients with diabetes treated with insulin or oral hypoglycemic, but not diet alone. Diabetes during pregnancy alone is not counted.

7a. Does the patient have end organ damage from diabetes? (DMENDORGAN)
   ___ No
   ___ Yes

Criteria: This includes patients with retinopathy, neuropathy, or nephropathy attributable to diabetes.

8. Does the patient have moderate or severe renal disease? (RENAL)
   ___ No
   ___ Yes

Criteria: Moderate renal insufficiency includes patients with a serum creatinine >3 mg/dl. Severe renal disease includes patients on dialysis, those who had a transplant, and those with uremia.

9. Does the patient have a chronic liver disease? (MILDLIVER)
___ No
___ Yes

Criteria: Mild liver disease consists of chronic hepatitis (B or C) or cirrhosis without portal hypertension.

9a. Does the patient have moderate to severe liver disease? (SEVERELIVER)
___ No
___ Yes

Criteria: Moderate liver disease consists of cirrhosis with portal hypertension, but without bleeding. Severe liver disease consists of patients with ascites, chronic jaundice, portal hypertension or a history of variceal bleeding or those who have had liver transplant.

10. Has the patient had gastric or peptic ulcers? (ULCER)
___ No
___ Yes

Criteria: Peptic ulcer disease includes patients who have required treatment for ulcer disease, including those who have bled from ulcers.

11. Has the patient had cancer (other than basal cell skin cancer)? (CANCER)
___ No
___ Yes
If yes, which:
___ Lymphoma?
___ Leukemia?
___ Solid tumor (which?)_____

Criteria: Lymphoma includes patients with Hodgkins, lymphosarcoma, Waldenstrom's macroglobulinemia, myeloma, and other lymphomas. Leukemia includes patients with acute and chronic myelogenous leukemia, acute and chronic lymphocytic leukemia, and polycythemia vera. Solid tumor consists of patients with solid tumors without documented metastases, including breast, colon, lung, prostate, and a variety of other tumors.

11a. Has the patient had a metastatic solid tumor? (METASTASES)
___ Breast
___ Colon
___ Prostate
___ Lung
___ Melanoma
___ Other _____

Criteria: Metastatic cancer includes patients with metastatic solid tumors, including breast, lung, colon and other tumors

12. Does the patient have Alzheimer's, dementia from any etiology or any serious cognitive impairment? (DEMENTIA)
    ___ No
    ___ Yes

Criteria: Dementia includes patients with moderate to severe chronic cognitive deficit resulting in impaired function from any cause.

13. Does the patient have any rheumatic or connective tissue disease? (RHEUMATIC)
    ___ No
    ___ Yes

Criteria: Rheumatologic disease includes patients with systemic lupus erythematous, polymyositis, mixed connective tissue disease, rheumatoid arthritis, polymyositis, polymyalgia rheumatica, vasculitis, sarcoidosis, Sjogrens syndrome or any other systemicvasculitis

14. Does the patient have HIV or AIDS? (HIV)
    ___ No
    ___ Yes

Criteria: Acquired immune deficiency syndrome includes patients with definite or probable AIDS, i.e. AIDS related complex, and those who are HIV positive and asymptomatic.

Additional components of Charlson Comorbidity Index adapted to predict cost[2]

15. Does the patient have hypertension? (HBP)
    ___ No
    ___ Yes

Criteria: Hypertension includes patients who have systolic pressures >140 mm Hg and/ or diastolic pressures >90 mm Hg if without diabetes or renal disease, as well as controlled hypertensives; or patients with diabetes or renal disease who have systolic pressures >140 mm Hg or diastolic pressures >80 mm Hg.

16. Has the patient had decubitus ulcers, peripheral skin ulcers or repeated episodes of cellulitis? (SKINULCER)
    ___ No
    ___ Yes

Criteria: Partial thickness loss of skin over legs or back with open ulcers or two or more episodes of cellulitis requiring treatment with antibiotics, regardless of etiology.

17. Does the patient have depression? (DEPRESSION)
    ___ No
    ___ Yes

Criteria: Patients who are currently receiving treatment for depression, whether pharmacologic or psychotherapy, or cognitive behavioral therapy, or notes indicating that the patient has probable or definite depression.

18. Is the patient on warfarin or coumadin? (WARFARIN)
    ___ No
    ___ Yes

Conditions that are not assigned weights

- Angina includes patients with chronic exertional angina, those who had coronary artery bypass graft, and those initially admitted with unstable angina.
- Arrhythmia includes patients with chronic atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias requiring chronic treatment.
- Valvular disease includes patients with hemodynamically significant aortic stenosis and/or insufficiency, those with significant mitral stenosis and/or insufficiency, and those with prosthetic aortic or mitral valves, asymmetric septal hypertrophy requiring treatment, or tricuspid insufficiency.
- Other neurologic conditions includes patients with Parkinson's disease, uncontrolled seizures, or syncope without an identified cause or treatment.
- Other endocrine includes patients with hypopituitarism, adrenal insufficiency, and recurrent acidosis.
- Inflammatory bowel disease includes patients with ulcerative colitis or regional enteritis.
- Gastrointestinal bleeding includes those who have had bleeding requiring transfusions from causes other than ulcer disease.
- Coagulopathy includes patients with a circulating anticoagulant, or other coagulopathy.

Charlson Comorbidity Index
Scoring

Condition	Variable name	Points	Notes
Myocardial infarction	MI	1	
Congestive heart failure	CHF	1	
Peripheral vascular disease or bypass	PVD	1	
Cerebrovascular disease or transient ischemic disease	CVA	1	CVA only
Hemiplegia	PLEGIA	2	If hemiplegia, do not count CVA separately
Pulmonary disease/ asthma	COPD	1	
Diabetes	DM	1	DM only
Diabetes with end organ damage	DMENDORGAN	2	If end organ damage, do not count DM separately
Renal disease	RENAL	2	
Mild liver disease	MILDLIVER	2	
Severe liver disease	SEVERELIVER	3	
Gastric or peptic ulcer	ULCER	1	
Cancer (lymphoma, leukemia, solid tumor)	CANCER	2	Nonmetastatic cancer only
Metastatic solid tumor	METASTASES	6	If Metastatic, do not count cancer separately
Dementia or Alzheimer's	DEMENTIA	1	
Rheumatic or connective tissue disease	RHEUMATIC	1	
HIV or AIDS	HIV	6	
Hypertension	HBP	1	
Skin ulcers/ cellulitis	SKIN ULCER	2	
Depression	DEPRESSION	1	
Warfarin	WARFARIN	1	

APPENDIX 4: AFORM Questionnaire

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The A-FORM© (Version 1.0)

Ankle Fracture Outcome of Rehabilitation Measure

The following questionnaire is presented in two parts.
In the first part, for each question please tick the box that applies to you the most. Tick only one box per question.
In the second part, there are short statements with five numbers beside them. Please circle the number you the most. There are words at the top of each section to help you to decide which number to circle. I
(Please tick only the box that applies to you the most for each statement)

1) I feel pain in or around my ankle… *(Pick one response only☑)*
☐… all of the time, even when I am lying down
☐… when I try to stand or walk on my leg for only a minute or two
☐… after I have been standing or walking on my leg for around 20 minutes
☐… after I have been standing or walking on my leg for an hour or more
☐ OR: I do not feel any pain in or around my ankle

2) There is swelling around my ankle… *(Pick one response only☑)*
☐… all of the time, even if I put my legs up
☐… most of the time, but it goes down when I put my legs up
☐… occasionally, particularly if I have been standing on it for around 20 minutes
☐… occasionally, particularly if I have been standing on it for an hour or more
☐ OR: I do not have an swelling around my ankle

3) My ankle feels stiff… *(Pick one response only ☑)*
☐… all of the time
☐… most of the time, but will loosen up after I have used it for an hour or more
☐… most of the time, but will loosen up after I have used it for around 20 minutes
☐… occasionally, but will loosen up after I have used it for a minute or two
☐ OR: I do not have feel any stiffness around my ankle

PART TWO

(Please circle one number on each line)

4)	**How difficult do you find it (or do you think you would find it) when…**	**Not at all**	**A little bit**	**Moderately**	**Very much**	**Extremely**
4a)	…walking on a flat surface (e.g. footpath)	1	2	3	4	5
4b)	…jumping off both feet	1	2	3	4	5
4c)	…sprinting (running at fast speed)	1	2	3	4	5
4d)	…sleeping without waking up through the night	1	2	3	4	5
4e)	…getting back to sleep if you have woken up during the night	1	2	3	4	5
5)	**How restricted do you feel when…**	**Not at all**	**A little bit**	**Moderately**	**Very much**	**Extremely**
5a)	…trying to participate in activities that you need to complete to look after yourself *(e.g. showering, dressing, going to the toilet, preparing light meals)*	1	2	3	4	5
6)	**In general, are you currently feeling…**	**Not at all**	**A little bit**	**Moderately**	**Very much**	**Extremely**
6a)	…depressed	1	2	3	4	5
6b)	…fatigued	1	2	3	4	5
7)	**Specifically, are you feeling…**	**Not at all**	**A little bit**	**Moderately**	**Very much**	**Extremely**
7a)	…anxious about not being able to participate in your preferred health and fitness activities in the future	1	2	3	4	5
7b)	…anxious about not being able to wear your preferred footwear	1	2	3	4	5
8)	**Is your ankle fracture currently impacting…**	**Not at all**	**A little bit**	**Moderately**	**Very much**	**Extremely**
8a)	…the amount of extra work that others in your household now have to do	1	2	3	4	5
8b)	…your relationships with your extended family and friends	1	2	3	4	5

A-FORM data processing rules and summary score conversion

Each question is assigned a score from 5 (most severe impact response option) to 1 (least severe impact response option). The responses to each of the questions are then added to obtain a Raw Summary Score (with the exception of 7b, which is excluded from all summary scores). This gives a total between minimum of 14 (score of 1 on every question) and maximum of 70 (score of 5 on every question). Using Table 1 below, the Raw Summary Score is converted to the A-FORM Summary Score between a minimum of 1 and a maximum of 100. The A-FORM Summary Score is based on Rasch analysis and has appropriate measurement properties for use as a single representative score; and this is the summary score to report for the A-FORM instrument.

Table 1. Summary score conversion for the A-FORM (algorithm1.00)

Raw Summary Score	(converted) A-FORM Summary Score		Raw Summary Score	(converted) A-FORM Summary Score
14 or 15	**1**		35	**49**
16	**2**		36	**52**
17	**4**		37	**57**
18	**5**		38	**62**
19	**7**		39	**64**
20	**9**		40	**68**
21	**12**		41	**73**
22	**13**		42	**76**
23	**14**		43	**78**
24	**18**		44	**80**
25	**22**		45	**86**
26	**26**		46	**91**
27	**28**		47	**93**
28	**28**		48	**94**
29	**30**		49	**95**
30	**33**		50 to 52	**96**
31	**37**		53	**98**
32	**40**		54 to 62	**99**
33	**41**		63 to 70	**100**
34	**45**			

Note: Do not include Item 7b (footwear item) when summing the item scores. The converted A-FORM Summary Score is the summary score to report for the A-FORM instrument, this conversion is based on Rasch analysis reported in:

McPhail, S. M., Williams, C. M., Schuetz, M., Baxter, B., Tonks, P., & Haines, T. P. (2014). Development and validation of the ankle fracture outcome of rehabilitation measure (A-FORM). *Journal of Orthopaedic & Sports Physical Therapy*, 44(7): 488-499

APPENDIX 5 – REDCap Data Dictionary

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SMART Ankle Fracture Feasibility Study
Page 1 of 8

Demographics

Study ID	_____
Date subject signed consent	_____ (YYYY-MM-DD)
Age (years)	_____
Gender	○ Male ○ Female
Height (cm)	_____
Weight (kilograms)	_____
BMI	_____
Comments	_____

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SMART Ankle Fracture Feasibility Study
Page 2 of 8

Injury Details

Date of Injury	_____
Cause of Injury	○ Motor Vehicle Accident ○ Motorbike Accident ○ Bicycle Accident ○ Pedestrian Involved in Road Accident ○ Hit by Object ○ Fall < 2 metres ○ Fall > 2 metres ○ Sport Related Accident ○ Other
Details of cause of Injury if 'other'	_____
Imaging Reports (XR/CT/MRI) related to Ankle #	_____
Other Concurrent Injuries	○ None ○ Musculo-skeletal injury ○ Organ injury ○ Soft Tissue Injury ○ Traumatic Brain Injury ○ Spinal Cord Injury ○ Other
Details of other injuries (if applicable)	_____
Co-morbidities	○ None ○ Cardiovascular Disease ○ Lung Disease ○ Liver Disease ○ Kidney Disease ○ Cancer within the last 5 years ○ Infectious Disease ○ Mental Health Disorder ○ Other
Details of Comorbidities (if 'other')	_____
Charlson Comorbidity Index Score	_____

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SMART Ankle Fracture Feasibility Study
Page 3 of 8

Surgery and Other Treatments

Surgical Intervention	○ Yes ○ No
Surgery Date	_____
Surgery Description	_____
Other Treatments	☐ Physiotherapy ☐ Occupational Therapy ☐ Other
Details of Treatments if 'Other'	_____

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SMART Ankle Fracture Feasibility Study
Page 4 of 8

Week 2 Data

2 weeks post operatively	
Date of Week 2 visit	_____
AFORM Score	_____
EQ 5D 5L	_____
EQ 5D 5L VAS	_____
Knee to Wall measurement (in mm)	_____

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Week 6 Data

Week 6	
Date of Week 6 visit	
AFORM Score	
EQ 5D 5L	
EQ 5D 5L VAS	
Knee to Wall measurement (in mm)	

Week 12 Data

12 weeks	
Date of 12 Week visit	
AFORM Score	
EQ 5D 5L	
EQ 5D 5L VAS	
Knee to Wall measurement (in mm)	

Completion Data

Study Completion Information	
Has patient completed study?	○ No ○ Yes
Put a date if patient withdrew study	
Reason patient withdrew from study	○ Non-compliance ○ Did not wish to continue in study ○ Other
Date of study completion	
Was all equipment returned to RBWH?	○ Yes ○ No

General Comments	
Comments	

Adverse Event Report

Adverse Event Date	
Adverse Event Definition	○ Adverse Event ○ Serious Adverse Event ○ Suspected Unexpected Serious Adverse Reaction (SUSAR)
Adverse Event Description	
Serious Adverse Event Description	
SUSAR Description	