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| Midfix RCT – Does dorsal plating of Lisfranc injuries lead to better MOxFQ pain scores at 1 year compared to transarticular screw fixation? – A prospective randomized controlled trial |
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| **Statement of Compliance**This document is a protocol for a research project. This study will be conducted in compliance with all stipulations of this protocol, the conditions of the ethics committee approval, the NHMRC *National Statement on Ethical Conduct in Human Research (2007) – Updated 2018*, and the NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2018)*. If the project is a clinical trial, it will comply withthe *Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95)*. |

**STUDY INVESTIGATORS**

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| Principal Investigator: | Name: Dr John BilenkiInstitution: Gold Coast University HospitalDepartment: Orthopaedic SurgeryAddress: 1 Hospital Blvd, Southport, QLD, 4215Tel: 5687 4860Email: john.bilenki@health.qld.gov.auRole in Study: Principal investigator and study coordinator. I will be responsible for recruiting patients and ensuring the study’s protocol will be followed during management who are enrolled. I will additionally be responsible for data collection and final write up. |
| Co-Investigator: | Name: Dr Simon PlattInstitution: Gold Coast University HospitalDepartment: Orthopaedic SurgeryAddress: 1 Hospital Blvd, Southport, QLD, 4215Tel: 5687 4860Email: simonplatt@me.comRole in Study: As a foot and ankle specialist, he will be the primary surgeon carrying out the operations. With his years of knowledge and expertise, he has helped create the protocol for this study. Ultimately, he will be guiding the implementation of this study at the Gold Coast University and Robina Hospitals. |
| Co-Investigator: | Name:Institution:Department:Address: Tel:Email:Role in Study: |

**STUDY SYNOPSIS**

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| Title: | Midfix RCT – Does dorsal plating of Lisfranc injuries lead to better MOxFQ pain scores at 1 year compared to transarticular screw fixation? – A prospective randomized controlled trial |
| Short Title: | Midfix RCT |
| Study Sites: | Gold Coast University & Robina Hospitals |
| Study Aims/Objectives/Hypothesis: | To compare traditional transarticular screw fixation to more current dorsal plating techniques for fixation of Lisfranc injuries, using pain as scored by the MOxFQ. Secondary outcomes include function and quality of life scores, as well as need for metal work removal and arthrosis. The working hypothesis is that dorsal plating has improved pain, as well as improved secondary outcomes, compared to transarticular screws due to less iatrogenic joint trauma. |
| Study Design:  | Randomized Controlled Trial |
| Study Outcome Measures: | MOxFQ, EQ-5D scores, and AOFAS midfoot scores. MOxFQ scores are subdivided into pain, function, and social interaction measures; of which we are primarily concerned with pain and function. Need for further surgery secondary to metalwork failure, pain secondary to metalwork, or infection. Progression to arthrosis will be a tertiary outcome. |
| Study Population: | Patients over the age of 18 with Lisfranc injuries as documented on weightbearing radiographs or CT scan |
| Number of participants: | 98 |
| Translation to Clinical Practice: | Traditionally, transarticular screw fixation has been gold standard of treatment for Lisfranc injuries. More recently, with the development of dorsal plates, using dorsal plates for fixation has become more common, as they are thought to avoid damaging the cartilage between the midfoot joints. Early studies reveal better outcome scores and lower re-operation rate [11-13]. No RCTs exist comparing fixation methods. We hope this study will help determine which fixation method results in better patient outcomes. |
| Key Ethical and Safety Considerations: | Several surgeons may elect to take metalwork out at a specific time post fixation, regardless of whether pain or impairment of function exists. There is no clear evidence to support this practice in the literature at this stage. We will aim to monitor metalwork complications as part of this study and elect to take out metalwork, only if causing pain or irritation. This may lead to patients developing metalwork irritation that would not have if metalwork was removed routinely. This will however, not expose patients to potential risks of anaesthetic or surgery, many of whom we anticipate may not have any symptoms of metalwork irritation. |

## Glossary of Abbreviations, Terms, and Acronyms

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| Abbreviation, Term, Acronym | Definition (using lay language) |
| Open reduction internal fixation | Fixing fractures/dislocations by making a cut (opening), restoring alignment (reduction), and holding with metalwork (plates and/or screws). |
| Lisfranc injury | A lisfranc injury is a midfoot injury where a single or several metatarsal bones become displaced from their articulation with the rest of the tarsus (specifically between the medial cuneiform and the base of the second metatarsal). This injury involves rupture of ligaments, and at times fractures as well.  |
| Arthrosis | Joint osteoarthritis, as documented on radiograph by features of asymmetrical joint space narrowing, subchondral sclerosis, osteophytes, and subchondral cysts. |

## Background

Lisfranc injuries involve tarsometatarsal fracture dislocations and an interruption of the Lisfranc ligament complex. Incidence is relatively low with estimates of approximately one in 55,000 per year [1]. Research analysing the best method of fixation is comparably low. Post traumatic arthritis is an established consequence of the missed the Lisfranc injury [2]. Subsequent post-operative arthrosis is a common complication across fixation methods [2, 3, 4, 13, 14]. In efforts to improve pain and function post operatively, several studies have focused on comparing open reduction internal fixation to primary arthrodesis. These studies compared whether patient outcomes would be improved by reducing the joints anatomically with screw fixation across the joints or by directly fusing the involved joints, theoretically reducing risk of pain secondary to arthritis. The data has revealed mixed results between these methods with regards to both post-operative pain and return to function [5-7].

Efforts to minimize the added risk of arthritis, associated with Lisfranc injuries and their fixation, have led to dorsal plating techniques being more thoroughly described [9]. This involves insertion of a plate on the dorsal surface of the involved tarsometatarsal joints, held with screws into the involved bones. As a result, the dorsal plating technique has become a more popular method of fixation. Research directly comparing transarticular screws to plate fixation is limited. Biomechanical studies have demonstrated equal strength between these fixation methods [9,10]. Retrospective research has shown favourable outcomes with dorsal plating, leading to better anatomical reduction and functional outcome scores, when compared to transarticular screws [11,12]. Prospective research is scarce, but also illustrates several positives for dorsal plating techniques. Hu et al. demonstrated better short- and medium-term outcomes with dorsal plates, as well as a smaller re-operation rate, in their prospective comparative study [13]. Despite promising results through dorsal plating, no randomized controlled trial has been undertaken to compare dorsal plating with the more established transarticular screw technique. Stable anatomical reduction of the Lisfranc joint generally leads to better patient outcome scores [14, 15]. In theory, dorsal plating accomplishes this task, while minimizing further articular trauma. With no clear favourable method of fixation established through research, we seek to commence a randomized controlled trial comparing transarticular screw versus dorsal plating fixation for Lisfranc injuries.

Fixation with multiple types of metalwork for Lisfranc injuries can often lead to symptoms of pain and irritation. Eleftheriou *et al’s* review of the literature estimated symptoms secondary to metalwork fixation in up to 16% of cases requiring removal [4]. Ly reported a 19% rate of symptomatic metalware following arthrodesis, and 80% following open reduction internal fixation. In this study, metalwork was removed at an average of 6.75 months post-operatively, if symptomatic [7]. Some studies report routinely removing metalwork between 3 to 4 months [5]. Kirzner *et al* arranged for metalwork removal no earlier than six months post operatively, if required [11]. Multiple studies advocate for removal of metalwork only once full union is achieve or if metalwork becomes symptomatic [19-21]. No studies accurately document the rate of symptomatic metalwork in dorsal plating compared to transarticular screws. This study aims to compare rate of required metalwork removal between these techniques as a secondary outcome measure.

## Study Objectives

### Research Question and Aims/objectives

The primary purpose of this study is to further compare and analyse dorsal plate vs transarticular screw fixation in Lisfranc injuries through a randomized controlled trial. The primary outcome is improvement of pain post-operatively, as assessed by the MOxFQ pain score. Secondary outcomes include, MOxFQ function score, AOFAS midfoot scores, EQ-5D quality of life score, and need for further surgery, such as for fixation failure, pain secondary to metalwork and infection. Tertiary outcomes include monitoring for radiological signs of arthrosis. These outcomes have been selected to further examine the factors important to patient satisfaction, as well as the factors to likely require further surgery either acutely or in the future.

### Hypothesis

The null hypothesis is that there is no difference between dorsal plate and transarticular screw fixation. The alternative hypothesis is that dorsal plate fixation will improve subjective pain scores, as measured by the Manchester-Oxford Foot Questionnaire (MOxFQ). The MOxFQ consists of the three domains of walking/standing, pain, and social interaction. We additionally hypothesize that dorsal plating will lead to a better function score (MOxFQ walking/standing), EQ-5D, and AOFAS scores.

## Methods

### Methodological Approach

Individuals with a diagnosed Lisfranc injury as per weight bearing X-ray or CT scan, and consenting to operative fixation, will be recruited to participate in the study. Consenting participants will be randomized to receive fixation by either transarticular screws or dorsal plate via a single surgical team. Post-operatively, patients will be followed up at 6 weeks, then 3, 6, 12, 24 months. At each review, they will be asked to complete MOxFQ, EQ-5D, and AOFAS scores, which are frequently used to assess subjective pain and function. Several studies have validated their use in to assess subjective pain and function following foot and ankle surgery [16-18]. Both the MOxFQ and Progression to union, failure of fixation, and progressive arthrosis will be assessed radiologically with X-rays at each follow up and CT scan where deemed necessary. We seek to include approximately 100 people to obtain adequate study power (50 per treatment arm).

### Study Sites/Settings

This study will be a single-health service study, multi-centred, occurring at Gold Coast University and Robina Hospitals. Both of these hospitals operate under the service of Gold Coast Health, and under the care of a single orthopaedic surgery service. Patients will be grouped as if they are under once centre, as primarily they will be followed up in a single clinic and operated on by a single surgeon.

### Study Population

The study population includes adults (those over the age of 18), with a Lisfranc injury confirmed on weight bearing bilateral foot radiographs, or CT scan. This is diagnosed on weightbearing radiographs as a difference of greater than 2 millimetres of space between the distal lateral border of the medial cuneiform and the medial base of the second metatarsal, or greater than 1 millimetre difference as compared to the non-injured side. In patients who cannot weight bear, a non-weightbearing radiograph or CT is used for diagnosis. Signs indicating a Lisfranc injury include complete discontinuity of a line drawn from the medial base of the second metatarsal to the medial border of the middle cuneiform on AP radiograph; a bony fragment in the first intermetatarsal space (also known as fleck sign), indicative of an avulsion of the Lisfranc ligament; dorsal displacement of the proximal base of the first or second metatarsal on a lateral radiograph or sagittal CT sequence. Exclusion criteria include individuals with insulin dependent diabetes mellitus, pre-existing charcot arthropathy, pre-existing foot or ankle injury or pathology limiting mobility/function, multitrauma (more than one fracture location), those who cannot appropriately provide consent, or the inability to follow up in Gold Coast University Hospital for 18 months. Additionally, patients must be medically well enough to undergo surgery.

In order to obtain adequate enrolment to maximize study power, a minimal clinically important difference (MCID) of 4.55 and standard deviation of 25.09 was utilized from Dawson *et al’s* analysis [22]. Sample size groups of 49 individuals per group is required for a power of 0.80. It is expected that up to 110 to 120 individuals may require to be required to incorporate for those lost to follow up.

### Recruitment/ Selection

Patients with Lisfranc or suspected Lisfranc injuries are regularly encountered by referral from the emergency department for either immediate review or review through orthopaedic fracture clinic. If a Lisfranc injury is diagnosed via the criteria listed above, and inclusion/exclusion criteria are met, these patients will then be invited to participate in the trial.

In those individuals who meet selection criteria, operative fixation will be discussed. Operative fixation is the standard of care in Lisfranc injuries, as these injuries are commonly unstable [4, 20]. Nature of the injury will be discussed with patients with an orthopaedic registrar or consultant; as well as fixation methods, risks of operative versus non-operative management, recovery course, and nature of the study. Individuals will be asked to voluntarily enter the study and be randomized to a treatment modality. Those individuals who are willing to participate will sign a consent form, and will be made aware they are free to withdraw from participation at any point. Withdrawl may include that patients display a fixation method, although it is believed that this will be incredibly rare, or that they may wish to no longer complete the questionnaires or continue regular follow-up.

Randomization will occur through block randomization through Strata, using the ralloc command. Randomized outcomes will be inserted into individual opaque envelopes, each labelled with a trial number on the exterior. Once consent is obtained, an envelope with the next available trial number will selected. The treating surgical team will be notified to facilitate pre-operative planning.

### Consent

Consent will be obtained by each individual eligible for the study. The consent is both for participation and allowance for randomization. Consent will be obtained by an orthopaedic registrar or consultant, without any attempts to coerce or influence participation. Consent will apply for this study only. Individuals will have up until decision for surgery to decide if they would like to participate in the study.

### Risk Mitigation Procedures

As discussed in background, a Lisfranc injury is one which requires operative management to stabilize joints, minimize arthritis risk, and improve overall pain and function. In comparing two forms of fixation which are equipoise, as supported by the literature, there is no established risk of being randomized to one form of fixation over the other. There are inherent risks of having an anaesthetic for the surgery, as well as the surgery itself. Mitigation of risks will be broken up into pre-operatively, intra-operatively, and post-operatively. Pre-operatively, medically well patients, those with lowest anaesthetic risk, will be booked for surgery without formal anaesthetic review – as per current surgical practice. More medically complex patients, including those with documented respiratory, cardiac, or renal issues will be considered for an anaesthetics review based on severity of condition. Additionally, those with previous anaesthetic issues or complications will be referred for anaesthetic review pre-operatively. Patients with documented or suspected vascular issues will be considered for a pre-operative vascular surgery review. To further reduce risk of anaesthetic and operative complications (primarily infection), active smokers will be advised of the importance of smoking cessation, or at least reduction, pre-operatively.

Intra-operatively, risks will be mitigated by having a consultant foot and ankle specialist perform all surgeries. As per current practice, surgeries will be performed under sterile conditions. Patients will receive a single dose of intravenous antibiotics at induction.

Post-operatively, patients will be informed of the importance of elevation to reduce risk of wound breakdown secondary to swelling. Wounds will be checked in clinic at 10-14 days post operatively, and patients will be informed to return to clinic earlier than scheduled reviews if any concerns arise. Importance of elevation, non-weightbearing, and smoking cessation will be re-iterated at scheduled reviews and while an inpatient. Patients will receive enoxaparin while an inpatient. Need for venous thrombus embolism prophylaxis on discharge will be determined based on individual patient risk factors.

Any complications will be diligently documented in the study. Patients will receive most appropriate management, regardless of impact on the study. At any point, patients will be free to withdraw from the study without question or untoward pressure. More information on withdrawl procedures can be found below.

### Participant Withdrawal Procedures

Participants are free to withdraw from the study at any time without harassment or negative consequence from the department or investigators. Prior to surgery, if patients decide they have a preferred method of fixation different from their randomized method, they are free to discuss this with the treating surgeon. Surgeons will be specifically made aware that under no circumstances should they attempt to persuade a patient towards once fixation method or another (as no best fixation method is supported by the literature). Ultimately, if a patient and surgeon together decide to pursue a fixation method different from randomization, a patient can be taken out of the study without consequence and will be followed up as per standard post-operative procedure as per the treating surgeon. Once surgery is performed, fixation will not be changed. Post-operatively, patients can select to withdraw from the study, which would mean they would no longer require follow up or to complete regular questionnaires. Patients can alternatively select to withdraw from the study, but continue regular follow up otherwise. Additionally, if patients fail to attend 2 consecutive follow ups, they will be automatically withdrawn from the study. Once patients withdraw from the study, their information will be destroyed via shredding.

### Study Procedure

Patients meeting inclusion/exclusion criteria will be recruited to the study as previously described. Consent will be obtained on orthopaedic review in the emergency department or clinic, pre-operatively. Once patients have been recruited to the study, and randomized as previously described, foot swelling will be assessed in clinic and an operative date will be arranged within the first month after injury. Surgery will be completed by one of the foot and ankle specialists at either the Gold Coast University or Robina Hospitals. Patients will remain in hospital until they have medically recovered from anaesthetic, pain is controlled, and they are able to safely mobilize and non-weight bear on the affected limb – as assessed by hospital physiotherapists. Patients will have their wounds reviewed in the outpatient department at 10 to 14 days post operatively, at which point if required, sutures will be removed. Patients will subsequently be reviewed at 6 weeks, 3 months, 6 months, 12 months, and 24 months post operatively. At these reviews, the MOxFQ, EQ-5D, and AOFAS questionnaires will be administered. Radiographs will also be obtained to assess for union and signs of metalwork failure and arthrosis. If union is in doubt or there is concern for metal work failure beyond 3 months post operatively, a CT scan will be considered to further assess progression to union. Metalwork will not be routinely removed, practice which is supported by the literature [19-21]. However, should patients develop pain in relation to metalwork or signs and symptoms of infection, surgical metalwork removal will be arranged. Need for metalwork removal will be carefully documented, and patients will have their wounds reviewed 2 weeks following surgery to ensure healing and for removal of sutures. Following this, patients will continue with their scheduled follow-up appointments.

### Outcome Measures

The primary outcome measure will be comparing pain, as per the Manchester Oxford Foot and Ankle Questionnaire (MOxFQ) pain domains. Secondary outcome measures will be improvement in function, as assessed by the Mox-FQ function domains; quality of life, as assessed by EQ-5D; need for further surgery, including for infection, metalwork irritation or failure; non-union, as documented on follow-up X-ray or CT scan as indicated; and early radiological arthrosis, as documented on follow-up X-ray.

While the MOxFQ was originally validated for hallux valgus surgery, recent studies highlight its strength and suitability for assessing all foot and ankle surgery [24, 25]. As the MOxFQ can be divided into three domains (pain, walking/standing, social interaction), it lends itself to both an index score and subgroup analysis. As foot injuries can have a dramatic impact on individual’s ability to perform their daily activities, it is important to incorporate a quality of life score into the secondary outcomes. Both the MOxFQ index score (total score) and EQ-5D have been supported in the literature and will be utilized in this study [11, 13, 23, 25, 26].

As an additional outcome measure for comparison, we have also opted to include the AOFAS midfoot score. While some research has demonstrated reasonable validity of the AOFAS scores, much larger meta-analyses have failed to show reliability, validity and responsiveness of the AOFAS scores [27, 28]. As a large number of foot and ankle research comes out of the United States of America, many studies utilize this scoring measure [7, 11, 14, 17]. It is believed that the inclusion of this score will increase the reach of this study, by allowing the results to be directly compared to current data across a wide number of countries.

### Data Collection

Important data collection will be an initial patient questionnaire, to obtain patient demographics and ensure inclusion/exclusion criteria are met; initial and subsequent radiographs; and outcome measures. Radiographs and outcome measures will be taken at scheduled follow-ups of 6 weeks, followed by 3, 6, 12, and 24 months.

### Data Storage and Confidentiality

Data will be stored in a secured storage cabinet within Dr Platt’s office, which is also locked and only accessed via doors requiring swipe key access. This data will include all patient questionnaires completed through the course of the trial. All data will be retained for at least 15 years as per the guidelines. Should the information be discarded of in the future, it will only be done so through secure shredding to ensure no breach of patient confidentiality.

### Data Analysis and Statistical Considerations

Local biostatistician Dr Ian Hughes has been consulted for data/statistical analysis and will continue to be utilized following conclusion of data collection. Data analysis will be performed using excel and Stata15.

### Translation to Changes in Clinical Practice

Current best practice in the surgical management of Lisfranc injuries is unclear. As illustrated in the literature review, there is increasing evidence in support of dorsal plating techniques. To date, no randomized controlled trial comparing these techniques exists. As a result, there is no strong research to support one method of fixation over the other. This study aims to compare these methods in a randomized controlled trial, and incorporate several important secondary outcome measures often used in clinical decision making. As this study is taken place in a large tertiary trauma centre, Lisfranc injuries are commonly encountered through emergency departments and orthopaedic clinics. Results of this study are expected to directly impact our surgical management of these injuries moving forward. Additionally, co-investigator Dr Simon Platt, is heavily involved in foot and ankle surgery research. Following this study, we aim to publish our results in a prominent foot and ankle surgery journal, and present the results both domestically and internationally. In smaller hospitals, these injuries are often managed by orthopaedic generalists, where specialists are not available. We furthermore aim to present the results, not only at foot and ankle conferences, but also state and national orthopaedic meetings. Regardless of the results obtained, we expect them to have a large impact on current practice, providing further information on best management and advancing the discussion and research surrounding Lisfranc injuries.

### Timeline

Recruitment will begin as soon as ethics and SSA approval have been received. We expect to take approximately 2 years to recruit sufficient patients as per our power analysis. Afterwards, follow up with each patient is hoped for 18 months. A further 3-6 months is anticipated for collating and interpreting data, as well as write up and submission to orthopaedic journals. We anticipate a total time line of approximately 4 to 4.5 years to complete this trial.

### Funding and Resources

As this research does not strongly deviate from current practice, we do not anticipate any additional funds to conduct the trial. The only additional cost is that of printing/copying questionnaires for the trial. Once fully underway, we may recruit a medical student to assist with helping with distribution, completion, and questionnaires in clinic. This need will be assessed based on the amount of slowdown this may create with patient flow in clinic.

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