A DARFI Study
Into
Fractures of The Talus
(FACT-1)

Study lead: Mr Edward Gee

Protocol Version: 1.0.0

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Background

Study Management Group

Mr Edward Gee

Mr Abdul Rahman Gomaa

Mr Lyndon Mason

Mr Thomas Rogers

Mr Lyndon Mason (via the research fellow) will ensure that LUHFT's local research governance committee is regularly updated with the study's progress.

Final approval for new study sites to commence data collection and upload will be authorised by LUHFT's R&I once all site has issued confirmation of capacity and capability.

Scientific Advisory Group

Mr Donatas Chlebinskas

Mr Howard Davies

Mr Paul Fenton

Mr Edward Gee

Mr Abdul Rahman Gomaa

Mr Lucky Jeyaseel

Mr Dev Mahadevan

Mr Jitendra Mangwani

Mr Lyndon Mason

Mr Matt Philpott

Mr Andy Riddick

Mr Pete Robinson

Miss Mona Theadoraki

Mr Alex Trompeter

Mr Bobby Siddiqui

Study Delivery Timeline

From the point of launch:

4 months for data collection

6 months to preliminary data assessment

8 months to presentation

12 months to publication

Executive Summary

To ascertain the true risk factors for the management of talar fractures. By collecting a large population from multiple national centres treating this rare, complex injury we hope to accurately assess the risk factors for non-union, avascular necrosis, collapse, early arthritis and further surgery in the first 18 months post injury.

About DARFI

The Database of Atypical and Rare Fractures and Injuries (DARFI) is a collaborative platform for the study of atypical and rare fractures and injuries on a national scale to better understand their epidemiology and improve their outcomes.

Introduction

Talar fractures carry high rates of complications and morbidity, namely non-union, avascular necrosis, mal-reduction and early arthritis. These injuries often occur in a young, active population with significant impact on quality of life and morbidity. Complications pose a challenging clinical situation, and rates vary greatly between papers. Evidence is often underpowered due to this being a relatively rare injury. To combat this power is increased by performing met-analyses, systematic reviews or studying a cohort over a large time period, during which significant changes in management, techniques and implants may have rendered previous management strategies obsolete.

Study Aims

We aim to perform a multi-centre, retrospective review of talus fractures treated within the past 10 years using a national collaborative (FACT). This should enable a well powered study talus fractures with a variety of managements and complications. We aim to identify specific risk factors for current complication rates to guide best management.

Methods

The study will run from July 1st 2024 to November 1st 2024. Centres will enrol to be included in FACT1. Data will be collected by registrar or consultant level orthopaedic surgeons.

Data will be collected retrospectively by enrolled centres using their hospital's electronic notes system. Patients treated between January 1st 2013 and January 1st 2023 (minimum 18 month follow up) will be included. We aim for a study population of over 50 patients.

Patient details will be pseudonymised and centres will keep a list of which the pseudonymised number correlates to which patient locally. This list will be kept in a secure file locally by each site's PI.

Inclusion criteria

Any talar fracture in adult 16+ in past 10 years (between January 1st 2013 and January 1st 2023) with minimum of 18 month follow up

Exclusion criteria

Patients that are excluded via the National Data opt-out scheme

Less than 18 month follow up

Incomplete data

Children <16

Data Collection

Data will be collected using a central, electronic database with multiple choice options to gather the following information:

Demographics

Age

Sex

Geographical area and annual sun exposure and deprivation status score from postcode (postcode not recorded)

Smoking status

IVDU

Employed

Comorbidities stacked for number of comorbidities – Diabetes, steroids, BMI, osteoporosis

ASA grade

CEPOD grade

Previous injury to the talus

Previous surgery to the ankle

Fracture factors

Open fracture – Gustilo-Anderson Classification

Associated plastic surgery

Neurovascular injury

Hawkins classification (neck)

Talar body - Sneppen

High/low energy – RTC, fall over 3m

Polytrauma – ISS >15 on TARN database

Neck/body/head fracture/lateral process/dislocation without fracture

Comminution medial/comminution lateral/comminution both

Associated ipsilateral fractures – fibula, medial mall, plafond/Pilon, posterior mall, navicular, cuboid

Treatment factors

Initial reduction in ED

Initial open reduction

Cast or ex fix

Treated conservatively or surgically

Arthroscopy assisted

Approaches used - Lateral approach/Medial approach/dual approach/transligamentous/dorsal/Percutaneous

Implants used - PA screws 4-6mm / PA screws >6mm / AP screws 4-6 or >6 / medial plate / lateral plate

Time to reduction hours

Initial temporising procedure performed or straight to definitive surgery

Time to definitive fixation hours

Time of day for initial surgery

Time of day for definitive surgery

Malreduction on Xray or incongruence of ankle or subtalar joint.

Surgeon factors

MTC/TU/DGH

Grade of most senior surgeon

Grade of primary surgeon

Foot and ankle specialist surgeon

Initials of surgeon, how many done by that consultant in study period

Post op

Cast/boot

WB status post op – NWB 0-2, NWB 0-6, NWB >6

Mobilisation of ankle

Complications

Return to theatre

End Outcomes

AVN - collapse on radiograph

AVN sclerosis <1/3, 1-2/3, >2/3

Non-union – **Radiographs** Greater than 6 months, 3 months with no progression, no bridging callus on 2 views, pain at site of injury. **CT** less than 50% union

Time from date of injury to final xray

OA - Kellgren Lawrence scale for OA of ankle, subtalar, TNJ

Complications - The modified foot & ankle Clavien-Dindo complication classification

Infection

Wound

Metal removal

Further surgery

Revision

CRPS

Return to theatre – removal of metalwork, arthroscopy, infection debridement, other (free text)

Study Design

Retrospective date collection by national multi-centre collaborative using centralised electronic database.

Setting

Multi-centre collaborative. Registered consultants and single registrar per centre (for authorship purposes).

Project Timeline

Data will be collected using an encrypted, password protected Excel spreadsheet and stored on REDCap in line with DARFI's SOP.

The study will run from July 1st 2024 to January 1st 2025. Data will be collected retrospectively by enrolled centres using their hospital's electronic notes system.

We hope to finish data collection in January 2025.

Patient Eligibility

Inclusion criteria:

Any talar fracture in adult 16+ in past 10 years with minimum of 18 month follow up between January 1st 2013 and January 1st 2023 (minimum 18 month follow up) will be included. We aim for a study population of over 100 patients.

Exclusion criteria

Patients that are excluded via the National Data opt-out scheme

Less than 18 month follow up

Incomplete data

Children <16

Patient Identification

Patient identifiable data will be anonymised to a number on the centralised system and the list of these numbers and the patients they refer to will be kept locally.

Data Points

AVN - collapse on radiograph

AVN sclerosis <1/3, 1-2/3, >2/3

Non-union – **Radiographs** Greater than 6 months, 3 months with no progression, no bridging callus on 2 views, pain at site of injury. **CT** less than 50% union

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Return to theatre – removal of metalwork, arthroscopy, infection debridement, other (free text)

Follow Up

Minimum of 18 months follow up for each patient to ensure no late presentations of avascular necrosis.

End of Study

End of study will be defined as data collected by 1st January 2025.

Data Collection and Storage

Centres will enrol to be included in FACT1. Data will be collected by registrar or consultant level orthopaedic surgeons using local hospital systems. Data will be recorded onto a centralised electronic system.

Statistical Analysis Plan

The study will use convenience sampling since the national incidence of this injury remains unclear. Statistical analysis will be performed using SPSS 29.0.1 (IBM Corp, USA). Patient characteristics will undergo basic descriptive statistical analyses. The Kolmogorov–Smirnov test was used to test for normality of the data. The Mann–Whitney U test was used when comparing parametric data. Categorical data will be compared using a Chi-squared test. Univariate and multivariate logistic regression analysis were also performed to identify factors predisposing to the development of the relevant outcomes. Any factor which achieved significance on univariate analysis was included in further multivariate regression analysis. Furthermore, additional AI/ML algorithms (such as, but not limited to: LR, DT, RF, SVM, knn) may be used to explore predictive patterns that may otherwise not be identified using conventional statistical tests. A threshold for p-values less than 0.05 was deemed statistically significant.

Statistical analysis will be performed in association with statisticians from the research department in Liverpool University as well by lead authors.

Local Governance and Ethical Approval

Agreements are in place between Liverpool University Hospitals NHS Foundation Trust Research & Innovation Department and participating organisations, covering all associated DARFI studies.

Ethical approval for DARFI was obtained on 1st February 2024 from the NHS HRA South West - Central Bristol Research Ethics Committee (REC reference: 24/SW/0015, IRAS ID: 331288), covering all associated DARFI approved sub-studies. Permission is given via REC approval to collect this data retrospectively without individual patient consent.

Indemnity for this study is via the NHSLA.

Quality Assurance

Design: Meetings to consider previous literature and study design.

Data completeness: Spreadsheet utilised with drop down menus to ensure comparable data points.

Central monitoring will be conducted to ensure the validity of the uploaded datasets.

Authorship and Mini-teams

All scientific advisory group to be included on authorship.

One senior PI and one junior PI per centre for data collection.

Patient and Public Involvement

Patient and public involvement was undertaken throughout all stages of the design, development, and delivery of DARFI.

Expected Outputs

As a minimum we aim to produce 1 presentation and 1 publication from this study.

Ideally, we hope to produce 3 publications:

- Risk factors for complications of talar neck fractures
- Risk factors for complications of talar body fractures
- Outcomes of lateral talar process fractures

Acknowledgements

We thank the **Liverpool University Hospitals NHS Foundation Trust Research & Innovation Department** for kindly hosting DARFI on their REDCap servers.

Website: https://www.liverpoolft.nhs.uk/about-us/research

References

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