Open Fractures of the Tibia: A National, Regional and Individual Perspective

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By

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ABSTRACT

Introduction

Open tibial fractures are complex high energy injuries, associated with soft tissue loss and contamination; they are amongst the most severe injuries seen in orthopaedic practice. Modern practice demonstrates a tendency to reconstruct severely injured limbs; yet despite the use of aggressive protocols, recovery is often incomplete with long-term implications for patients. Robust research in this field is limited; much of the published work is based on single institutional experiences and hampered by poor study design. Ultimately, there will be a role for randomised controlled trials in determining the best interventions for these patients; although research questions in randomised controlled trials must be set on firm foundations with comprehensive work undertaken to understand current perspectives. These perspectives are currently not clearly outlined in the literature where; epidemiological patterns, the limits of established practice and patient views are all poorly represented. The aim of this thesis is to pursue answers to these questions, with an overall purpose of supporting the future development of high quality research in open tibial fractures.

Methods

A mixed-methods study with a sequential explanatory study design. Descriptive statistics, sensitivity analysis and generalised linear models were used to analyse data from two large datasets. The two datasets included data from the Trauma Audit Research Network (TARN); the national registry for trauma which contains comprehensive characterisation of patients and care-pathways; and a detailed local injury register from the East Midlands Trauma Centre which holds linked micro-costings and a cross-sectional patient-reported outcome measures (PROMS) dataset. A qualitative systematic review was performed using Joanna Briggs Institute methodology, and the results of these three studies were triangulated to inform the design of a qualitative study considering patient perspective. The qualitative study used semi-structured interviews with individuals who had sustained an open tibial fracture 12-72 months ago and were analysed using framework and cross-case analysis.

Results

Based on an analysis of 7994 cases from the TARN dataset, crude incidence rate of open tibial fracture was 2.85 per 100,000 persons per year. Injury occurred most frequently in males aged 25-30; however, incidence was 15% higher in patients aged over 65 when compared to the 15-39 age group (IRR: 1.15 (1.09-1.22). A fully adjusted model identified the mortality rate was two times greater in patients with comorbidities (OR: 2.34, CI: 1.60 – 3.42). In a further fully adjusted model including 2157 Gustilo 3B or 3C fractures, time to soft tissue coverage was related to wound complications. The proportion of individuals experiencing early inpatient wound complication increased by 0.3% per hour until definitive soft tissue cover (OR: 1.003, (CI: 1.001 - 1.004); other variables in this model relating to the injury or treatment were mostly not significant. The study highlighted the challenges of applying a research question to a dataset collected with a different aim.

The regional injury dataset included 212 individuals. The complication rate was 24% with mean time to revision surgery at 260 days. One year after injury, individuals reported a 26% ($p<0.01$) reduction in quality of life, and a 30% increase in disability ($p<0.01$). The mean cost of treatment was £27312, however, there was significant variation in cost dependant on injuries, treatment ($p<0.05$) and complications ($p<0.05$).

The qualitative study included 26 individuals who described recovery with parallel physical and psychological narratives. Regaining mobility was a priority for individuals who perceived this to be the gateway to returning to their former roles and responsibilities; whilst mobility was important, many symptoms were reported. The breakdown of routine and purpose that came after the accident was devastating and challenging to navigate. Hope was difficult to sustain due to unknown outcomes, although coping strategies such as goal setting and seeking personal support were important psychological mediators. Experience of recovery differed dependant on fixation strategy; with ring-fixators appearing more difficult to tolerate with broad social consequences. Age was also relevant; the gravity of these challenges was exacerbated for younger individuals, who did not

have the financial stability or social capital to endure this life-changing injury without long-term social ramifications.

Conclusion:

This thesis provides a clear national picture of the epidemiology, care pathways and costs associated with open tibial fracture, and provides insight into the implications of this injury for individuals. The thesis offers a case for improving surgical care for individuals with an open tibial fracture; but recognises that this will only be achieved with carefully planned research that adequately controls for variation in these injuries. In addition, modest restructuring of care-pathways to acknowledge the psychosocial implications of these injuries could dramatically improve patient experience with minimal cost.

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I am particularly indebted to my parents for giving me the opportunities and experiences that have helped with this and everything else. And, finally, I would like to thank Tom for never complaining about the amount of time I spent working and for somehow maintaining mine and his sense of humour throughout the last four years.

LIST OF ABBREVIATIONS

Acronym	Meaning
AIS	Abbreviated Injury Scale
BOA	British Orthopaedic Association
BOAST	British Orthopaedic Assessment Standards for Trauma
BPT	Best Practice Tariff
CI	Confidence interval
DRI	Disability Rating Index
GCS	Glasgow Coma Scale
HRA	Health Research Authority
HRG	Healthcare Resource Group
HRQOL	Health-Related Quality of Life
ICD	International Classification of Disease
IQR	Interquartile range
ISS/NISS	Injury Severity Score/New Injury Severity Score
JBI	Joanne Briggs Institute
JBI-QARI	Joanna Briggs Institute Qualitative Assessment, Review and Appraisal Instruments
KPI	Key Performance Indicator
LEAP	Lower Extremity Assessment Project
LRT	Likelihood Ratio Test
mCCI/CCI	Modified Charlson Comorbidity Index/ Charlson Comorbidity Index
METRC	Major Extremity Trauma Research Consortium
MTC	Major Trauma Centre
NUH	Nottingham University Hospitals
OR	Odds ratio
ORIF / IF	Open Reduction Internal Fixation / Internal fixation
PIS	Patient Information Sheet
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROMS	Patient-Reported Outcome Measures
QES	Qualitative Evidence Synthesis
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RTC	Road Traffic Collision
T&O	Trauma & Orthopaedic
TARN	Trauma Audit Research Network
TRISS	Trauma and Injury Severity Score
TSF / EF	Taylor Spatial Frame/External fixation
WALLTR	Wales Lower Limb Trauma Rating Scale
WOLLF	Wound Management in Open Lower Limb Fractures

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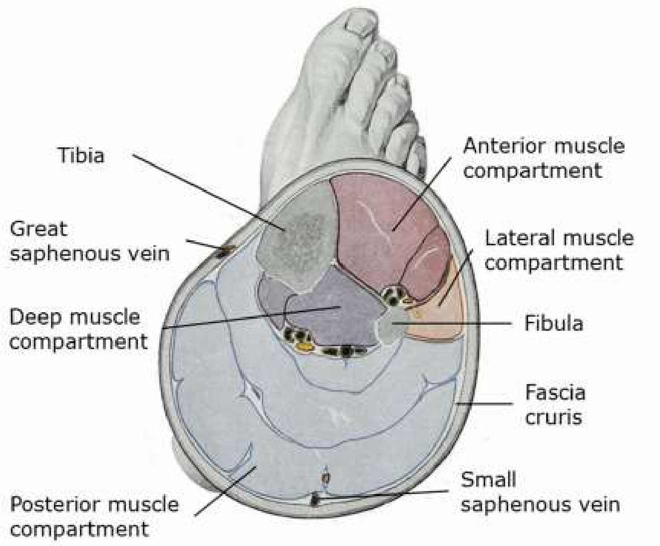
Chapter 1. Introduction

Open tibial fractures are a significant life changing injury that carry a large disease burden for around 1500 patients in the UK each year [1]. Recovery is long, with reported outcomes improving well over a year following injury [2]. Patients with comorbidities are known to have a particularly poor outcome [3]. This combined with the high financial costs [4], societal costs and known heavy psychological burden make this a priority area for musculoskeletal research.

1.1 Open tibial fracture: a definition

The tibia and fibula are two long bones located in the lower leg. The tibia, colloquially referred to as the shin bone, is the main weight bearing bone of the lower leg. The proximal tibia articulates with the femur to form the knee and the fibula to form the proximal tibio-fibular joint. Distally with the fibula and talus, the tibia forms the ankle joint. The tibia lies subcutaneously within the lower leg, medially. The lower leg consists of four osseofascial compartments; each compartment contains muscles, nerves and a blood supply that are separate from their neighbouring compartment. The tibia acts as the origin or insertion point for 11 muscles and the muscles control extension and flexion of the knee and ankle [5]. The nutrient artery and periosteal vessel provide the blood supply to the tibia [6]. The nerve supply to the tibia is shared with the surrounding muscle compartments and provides motor control and sensation below the knee [5]. Cross-sectional anatomy is shown in Figure 1-1.

Figure 1-1 Cross sectional anatomy of the leg midway between the knee and ankle, including muscles and neurovascular structures in each of the four leg compartments Adapted from Braus and Else, *Anatomie des Menschen: ein Lehrbuch für Studierende und Ärzte* [7]



An open fracture is a fracture associated with a break in the skin, which then exposes the underlying tissues to the external environment. Open tibial fractures are a heterogeneous group of injuries; with variation dictated by the mechanism of injury, but also variable by the co-morbidities of the injured person. The degree of openness is important, as openness increases risk of contamination and associated bone or tissue infection. Open tibial fractures are more common than other open long bone fractures due to the proximity of the bone to the skin [8]. Other important considerations when evaluating open tibial fracture severity include fracture contamination, location, extent of comminution and bone loss; presence and extent of muscle and soft tissue injury and neurovascular status. In the setting of an open tibial fracture; damage can be limited to a relatively simple fracture with a small soft tissue injury or can involve extensive injuries to all aspects of the lower leg [9]. Complexity of the injury dictates the likelihood of complications such as infection or non-union. The majority of these injuries can be repaired and rehabilitated to a certain degree with reconstructive surgery, but in the most severe cases the leg is not viable, and the limb is amputated. Reconstructive surgery has a spectrum of outcomes, and even when the treatment is successful, these surgeries are not usually restorative, and the individual is left with a limb that can be painful and have poor function [10].

1.2 Epidemiology and aetiology

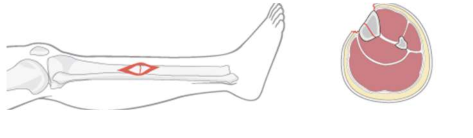
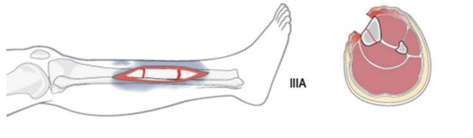
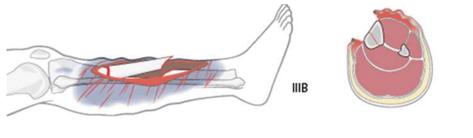
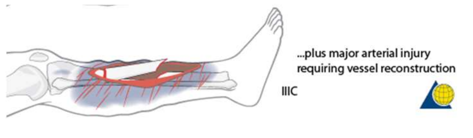
Open tibial fractures occur most commonly after exposure to a high energy direct force (such as an impact with a car bumper), but can occur in lower energy torsional injuries (such as skiing), or in simple falls where there is poor bone quality and frail soft tissues. Severe open tibial fractures are an important cause of devastating injury in military personnel. Due to the circumstances under which these injuries are likely to occur, open tibial fractures are rare injuries [11]. Two previous studies have identified an incidence of open tibial fracture between 2.3 and 3.4 per 100,000 person-years in Northern Europe [12, 13]; one a single-centred study from Edinburgh, the other a national registry study from Sweden. Both studies describe a greater frequency of injury in working-aged men; (75% male, mean age 43, where 18% were over 65) [13-15]. The higher frequency in younger people is relevant when considering the societal costs of these injuries. The global incidence in working-aged people will likely continue to increase over the next decade in response to industrialisation and improved transportation in lower-income countries, where safety measures are often not prioritised [16]. Within the United Kingdom there has been a recent focus on serious injuries in the older population. The UK population is ageing [17], and hospital data registries suggest incremental annual increases in the number of adults aged over 60 presenting with a serious injury to our hospitals [18, 19]. It is difficult to generalise these findings to the open tibial fracture population, and a better understanding of the contemporary national epidemiology would be useful for service planning and establishing how to target areas of clinical need.

1.3 Classification

The Gustilo classification [20, 21] is a widely adopted classification system for open fractures of all types. It is used routinely in clinical practice and is the reported classification system for most large clinical studies of open fracture [10, 22, 23]. The use of a classification system allows for characterisation of the injury and facilitates communication between clinicians. The Gustilo classification grades fractures in order of worsening prognosis in the context of infection based on certain injury characteristics; Table 1-1 presents the Gustilo classification in detail, reporting a 5 tier system. Type 1 injuries are low energy injuries with nominal soft tissue injury. Type 2 is a moderate energy injury with a larger soft tissue defect. Type 3 fractures are high energy injuries associated with complex fracture patterns and major soft tissue injury. Type 3 fractures are reported into three sub-tiers 3A, 3B and 3C; most easily differentiated by the treatment they require with 3B requiring flap coverage and 3C requiring vascular repair. The Gustilo system is a useful way of broadly presenting this heterogeneous group of fractures.

The Gustilo system has limitations with regards to validity and reliability. The system was developed as part of large case series first reported in 1976 [20] and later refined in 1984 [21]; the series included 1025 patients with open fractures, and the resulting system is still considered by many as the most practical algorithm for grading these injuries. Despite its widespread adoption, the methods used for developing the system are easily criticised. The study pooled retrospective and prospective data and measured only against a single outcome measure (infection), and categorisation is dependent on subjective terms such as "high energy" and "massive contamination" [24]. These methodological limitations have resulted in a system with poor inter-observer reliability, with only 60% agreement in published studies [25, 26]. These limitations have severe implications for the usefulness of this tool with regards to prognostication and have the potential to introduce error where used in a research setting.

Table 1-1: Summary of the Gustilo classification [20, 21]. Table describes defining characteristics of grades 1 to 3C. Images reproduced from Buckley, et al., *Principles of management of open fractures: AO Surgery Guide*. [27]

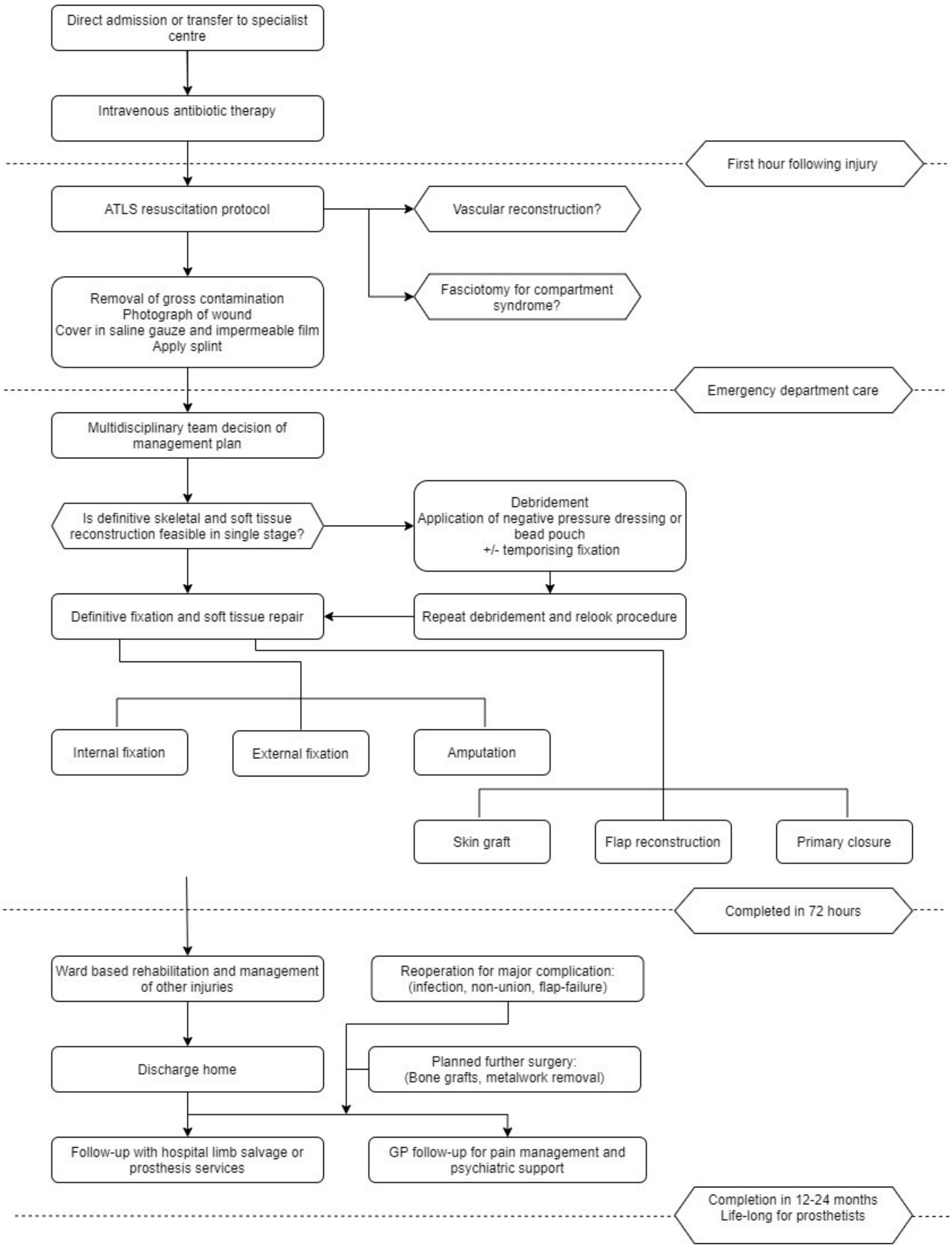
Gustilo Type	Image	Energy	Soft Tissue Damage	Contamination	Fracture Pattern	Periosteal Stripping	Skin Coverage	Neuro-vascular Injury
1		Low	Less than 1 cm	Clean	Minimal comminution	No	Local tissue cover	No
2		Moderate	More than 1 cm, but damage not extensive (no avulsion of soft tissues)	Moderate	Moderate comminution	No	Local tissue cover	No
3A		High	Extensive soft tissue damage, but adequate soft tissue coverage of bone	Extensive	Severe comminution or segmental fractures	Yes	Local tissue cover	No
3B		High	Extensive soft tissue damage, with large areas of exposed bone	Extensive	Severe comminution or segmental fractures	Yes	Requires free tissue flap or rotational flap coverage	No
3C		High	Extensive soft tissue damage, with large areas of exposed bone	Extensive	Severe comminution or segmental fractures	Yes	Not specified	Requires vascular repair

1.4 Management and BOA Standards for Trauma

Open tibial fractures require timely multidisciplinary management; within the UK, optimum strategies for management are outlined in published standards. The "British Orthopaedic Association Standards for Trauma in Open Fracture" (BOAST) are based on published literature and empirical guidance, they carefully negotiate the complex treatment pathway and outline the baseline expectations for treatment [28]. The guidelines are designed deliberately as audit standards and as such cover all aspects of auditable care. For completeness this guideline has been reproduced in full in appendix 8.1, and for brevity, the standard has been summarised below in Figure 1-2. The figure breaks the treatment pathway into four composite parts; pre-hospital and emergency department care which describes the first hours following injury; surgical planning and execution which should be completed within the first 72 hours of the hospital admission and a protracted phase of rehabilitation which occurs over many months or can be life-long. Pre-hospital and emergency department management is structured around resuscitation and stabilisation efforts, according to the Advanced Trauma Life Support (ATLS) [29] protocol. Unique to open fracture is the early administration of intravenous antibiotics and tetanus, and careful evaluation of the limb to assess injury severity and protection of the limb using splints and dressings to reduce potential for additional contamination. Surgical planning and execution is the source of much greater disagreement in the literature and will be discussed in more depth.

Modern practice demonstrates a tendency to surgically reconstruct mangled limbs. Before the development of current aseptic technique and standardised wound management; definitive treatment relied on amputation to reduce the risk of sepsis and death. Amputation in now rarely used as a primary treatment, as superior outcomes can be achieved through limb salvage. [30] Nonetheless; despite massive advancements in asepsis, technologies, and surgical techniques; reconstruction still presents significant challenges for surgeons and functional recovery is variable. Reconstructive practices are shaped around two core aspects, fixation of the fracture and reconstruction of damaged soft tissues which will be discussed in turn.

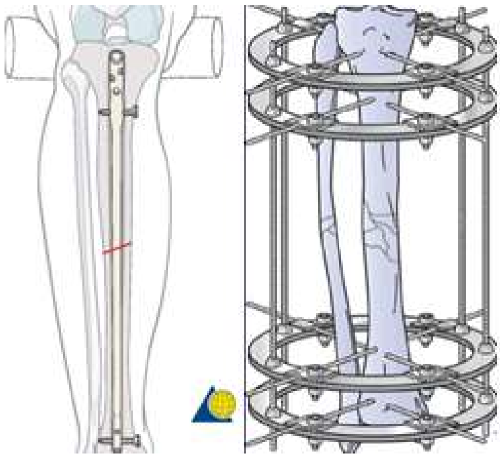
Figure 1-2: Schematic overview of the open fracture management pathway according to BOA guidelines [28]



1.4.1 Strategies for fixation

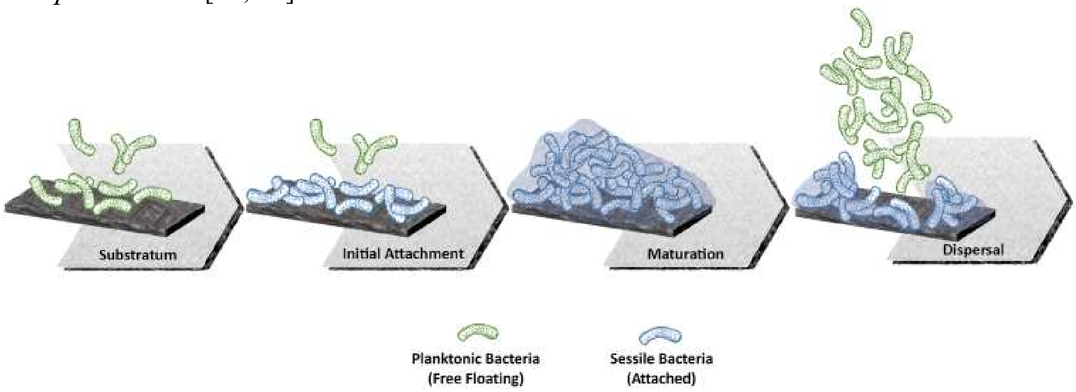
Strategies for fixation include both external and internal devices, which can be utilised as either temporising or definitive fixation (Figure 1-3). The choice of fixation device is grounded on core fracture fixation principles where management aims to achieve anatomical restoration through an adequately reduced and stabilised fracture [11]. Whilst these principles are the mainstay of fracture management, there are special considerations for an open fracture. The exposure of bone creates a contaminated environment increasing infection risk and has implications for the use of orthopaedic implants. In addition, the associated soft tissue injury and extensive bony injury impairs cortical blood supply and impacts bone healing [8]. Loss of too much bone (a critical defect) can result in a bone that will not heal [31]. This hostile environment must be appropriately managed to reduce the risk of complications.

Figure 1-3 Left intramedullary nail fixation in a tibia. Right: External ring fixator on a tibia. Figure obtained from, left: White and Camuso, *Tibial Shaft: AO Surgery Guide* [32], right: Tornetta, et al., *Rockwood and Green's Fractures in Adults* [9].



Internal fixation is the commonest surgery for tibial fracture. Internal fixation describes stabilising the fracture either by attaching a plate to the surface of the bone over the fracture site, or most commonly in tibial fracture, by placing a nail longitudinally through the bone, stabilised by screws at either end of the nail [27]. Whilst internal fixation is the preferred method of skeletal fixation in open fractures, high infection rates remain a concern. It is difficult to accurately estimate rate of deep infection after open tibial fracture, and estimates within the current literature range from 7 to 23%. [10, 20-23]. Despite this ambiguity the perception is that infection rates remain unacceptably high.

Figure 1-4 Schematic of the biofilm life cycle. Figure reproduced from Khatoon, et al., *Bacterial biofilm formation on implantable devices and approaches to its treatment and prevention* [33, 34]



As an avascular and inert object, implantable devices become contaminated at a considerably lower bacterial load (≈10,000 times less) than native tissue. Bacteria that are adhered to a surface (sessile state) behave differently to free-floating bacteria (planktonic state) (Figure 1-4). Protein-protein interactions, and changes in gene expression in sessile bacteria result in the production of an exopolysaccharide and other extra-cellular responses which result is a structured community of bacterial cells known as a biofilm. [35]. Biofilms mature and proliferate, and can disperse planktonic cells seeding infection to new areas; in addition, biofilms are resistant to the host's immune response and many anti-microbial agents [33, 34]. Therefore infections associated with orthopaedic devices are difficult to resolve. In the contaminated environment of an open fracture, the device is more vulnerable to contamination than in standard surgical settings which is reflected by the high infection rate. In this context there is a clinical need to manage infection risk and to seek alternatives to implantable devices to fix fractures.

External monolateral and ring fixators provide an alternative to internal fixation to definitively stabilise an open tibial fracture. Ring fixators involve the application of externally worn circumferential rings attached to the limb and bone via tensioned wires. The underlying principle developed by Ilizaroz [36, 37], conceptualised that placing gradual traction on callus stimulates new bone formation. For the ring fixator, routine adjustment of the struts allows progressive lengthening, correction, or compression in a minimally invasive setting. This confers benefit over internal fixation as they are dynamic and allow for adjustment, in a non-operative setting in response to emerging need during bone healing. In open fractures they have the advantage that the metalwork can be placed out of the zone of fracture and injury avoiding the risk of contaminated metalwork. [38] The technique has been widely used in orthopaedics, but less frequently in the setting of acute fracture, with studies limited to various case series [38-40]. Limitations of the technique include unique complications such as pin-site infections [41] and the need for the patient to engage and comply with a complex treatment regime which can be avoided with internal fixation. To reflect the additional burden on the patient, this technique is more likely to be reserved for patients with significant bone loss or contamination, although practice does vary between different surgeons. Existing studies comparing whether internal or external fixation should be used are hampered by poor methodological quality and the inclusion of older devices as an intervention which have since been shown to be unsuitable (such as Lottes and Enders intramedullary nails; older external fixator designs) [42]. There are no published contemporary trials, but there are several trials ongoing which consider internal versus external fixation for complex fractures of the tibia, which may provide guidance on the most appropriate method of stabilising these fractures [43-45].

1.4.2 Management of soft tissues

The role of soft tissue cover in open fracture is to protect the site from contamination and desiccation and to contribute to osseous healing by providing a vascular supply and growth factors to the site [46-48]. Overarching considerations include potential for flap failure (loss of blood supply to the flap resulting in flap death, necessitating further surgery to achieve soft tissue cover); donor site morbidity and eventual function and cosmesis of the limb [49]. The extent of soft tissue cover is dependent on the pattern and severity of soft tissue injury. The simplest open fractures can be managed with simple primary closure or use of skin grafts. Those with a more complex defect will require formal reconstruction with a tissue flap. There are multiple variations on tissue flap, but can be broadly described as either local or free flaps, and either fasciocutaneous or from muscle [50].

There is a preference for the use of muscle flaps in the setting of a large defect. Benefits of the muscle flap are that it provides a substantial blood supply to the area and can be easily contoured around large defects. Nonetheless, local tissue flaps are deemed versatile, technically less challenging to perform, and in recent studies seem to perform with similar outcomes [51, 52]. The evidence base regarding flap selection is weak and there would be benefit in further studies.

1.4.3 Surgical sequencing

Decisions relating to surgery are not dictated by the tibial injury alone, but also the physiological condition of the patient. Major trauma is associated with a systemic inflammatory response syndrome (SIRS) which occurs in response to bleeding and tissue damage. SIRS is driven by activation of the innate immune and complement system and can result in organ damage and sepsis; [53] therefore before surgery all physiological factors have to be considered. Decisions around surgical sequencing and temporal factors are challenging and an intricate question remains around their prognostic impact. Figure 1-2 outlines the various pathways available; with time to first debridement, use of temporising fixation and time to soft tissue coverage being three important considerations. Timely surgery is perceived to reduce contamination risk and restore blood supply to the limb. However, surgeons must be careful not to physiologically overwhelm patients shortly after injury.

Traditionally, urgent debridement of open tibial fracture was perceived to be fundamental to achieving good outcomes; however more recently best practice recommends that surgery undertaken by a surgeon with relevant expertise should be prioritised over immediate surgery. The previous dogma mandating urgent debridement, within 6 hours, was based on historic studies [54] but the value of urgent surgery has not been upheld in contemporary studies [10, 55]. Recent studies have instead identified a causal effect of experienced trauma centre care and reoperation rates or positive functional outcomes [10, 56]. Such findings compound a disciplinary perception that low volume surgery impacts on outcomes [57], and highlights the value of multidisciplinary care from orthopaedics, plastics and critical care. The BOA guidelines [28] were most recently updated in December 2017, and draw a specific impetus to the requirement for specialist care (within a major trauma centre (MTC)), as indicated above. There is therefore value in exploring the distribution of caseload within the UK to determine the impact of non-specialist practice.

Primary management of the fracture is also undertaken during the debridement surgery in order to support the soft tissues; this is often a temporising fixation with a mono-lateral fixator external fixator. Whilst definitive fixation can be achieved at the first surgery, this is dependent on soft tissues. Internal fixation without definitive closure risks infection; and placing a definitive ring fixator can limit access for definitive soft tissue surgery at a later stage. The definitive skeletal and soft tissue surgery should be planned and refined before and during the first debridement to optimise the surgical pathway. [28]

Modern strategies for soft tissue reconstruction allow for delayed coverage with temporising management supported by antibiotics beads or negative pressure wound therapy [22, 23]. Benefits of delayed coverage is that it allows time for soft tissue swelling and re-look procedures, acknowledges the physiological stress of major surgery, and can be convenient with regards to theatre staffing [22, 23]. However, delayed soft tissue cover is often contested with a view that changes in more chronic wounds; such as fibrosis, infection and venous stenosis; drive a high complication rate [58, 59]. The evidence base regarding this is particularly weak with methodologically limited studies [58, 59] consistently cited with a sense that practice is more guided by subjective experiences. The BOA guidelines suggest definitive soft tissue coverage in 72 hours, with an addendum that immediate flap protocols should be used where possible. [28] Early soft tissue reconstruction presents a series of infrastructure challenges for centres and can be difficult to achieve. More robust evidence would be useful to allow a better understanding of the relationship between surgical staging and complications; guiding centres to structure service aligned with good quality evidence.

1.4.4 Amputation

Salvage techniques, whether successful or not, can result in repeated surgeries, ongoing pain, infections, and possibly delayed amputation in a limb compromised by both the injury and surgery. Amputation still represents the best management strategy in individuals whose circumstances are particularly grave and clinicians have long sought guidelines or algorithms to support the decision making process [60]. Developing robust evidence in this area is particularly difficult as an randomised controlled trial (RCT) considering immediate amputation against salvage would be fraught with ethical issues; defining eligibility criteria that would create equipoise for both surgeon and patient would be an insurmountable task, and achieving an adequate sample size amidst these issues is likely unfeasible.

The LEAP study provides current best evidence; the study is a 569 patient prospective observational study considering amputation versus salvage in patients with severe limb injury; the cohort included 285 severe open tibial fractures [60]. Despite carefully adjusting for injury severity [61] and patient characteristics, the group found equivocal outcomes for reconstruction and salvage when measured with a general health score (the Sickness Injury Profile (SIP) [62]). Predictors of a worse SIP score following recovery were self-efficacy, social and economic factors, and the study concluded that the question of amputation versus salvage might not be worthy of such prevarication. Whilst this finding is interesting for considering the social determinants of health; the results of the study are at odds with much of the wider evidence base. Amputation is often associated with significant long term disability. Younger age and good health is a positive prognostic factor for prosthetic use; whilst older patients have less prosthetic use which results in muscle atrophy and bone loss [63-65]. Consideration needs to be given to longitudinal outcomes and whilst the LEAP study provides a rare example of an orthopaedic study reporting patient-reported outcomes in open tibial fractures, it highlights the importance of choosing appropriate outcomes measures for trials. The use of a general health score (SIP) as a primary outcome measure is unusual, with functional scores favoured in trauma studies as perceived more responsive [22, 66, 67]. In addition failure to capture longitudinal outcomes, or a surrogate for a longitudinal outcome, limits the extent to which the study can challenge the existing evidence base. This study had other limitations; it was not randomised and had broad eligibility criteria; whilst the study controlled for injury severity but this is not equivalent to clinical decision making and as a consequence there was residual confounding in the model reported. As a consequence, the study was not definitive regarding which injuries should be managed with primary ampuation and further work is needed to understand prognostic factors of these injuries. Amputation has often been associated with poor outcome although in this setting, demonstrated similar long-term functional outcomes for the individual; selection of outcomes that reflect the goals of the patient being treated is central to improving care.

1.5 Outcome

1.5.1 Definition of health and outcome

The international classification of functioning, disability and health (ICF) [68] provides a standardised, conceptual basis for communicating disability and health. In the ICF, health and disability are multi-dimensional concepts, relating to;

- “body functions and structures, and impairments thereof
- the activities of people, and limitations experienced performing them
- participation or involvement of people in all areas of life, and restrictions experienced
- environmental factors which affect these experiences”

Clinical outcomes are measurable changes in health or quality of life that result from receiving healthcare. A return to previous health status is normally the goal of any individual seeking healthcare intervention in trauma settings and healthcare professionals seek to support patients in meeting these goals through their clinical practice. In order to achieve this, it is important to understand what symptoms patients are likely to experience in illness and areas where recovery is likely to be incomplete.

1.5.2 Outcomes of importance in open tibial fracture

The METRC group have published a conceptual model for high energy lower limb injuries which documents major categories of outcome, and consider inter-relatability between those categories [69] (

Figure 1-5). The framework is based on the conceptual models of Wilson and Clearly [70]. It proposes a linear sequence of causal relationships that proceeds from injury, impairment, symptoms, participation and quality of life; recognising that the impact of each aspect can be modified by the individuals capacity to tolerate ill-health, their social environment, and their healthcare environment. For each component of the model METRC identified composite factors (i.e. secondary conditions could be either osteomyelitis or PTSD) and subsequently identified an instrument to measure each construct. Components of outcome outlined by METRC are shown in Table 1-2. This framework was developed using the data which emerged from the LEAP study [69] and provided a base for their subsequent programme of clinical trials.

Figure 1-5 METRC conceptual framework of outcomes following severe limb injury. Figure reproduced from Castillo, et al., *Measurement of functional outcomes in the Major Extremity Trauma Research Consortium (METRC)* [69]

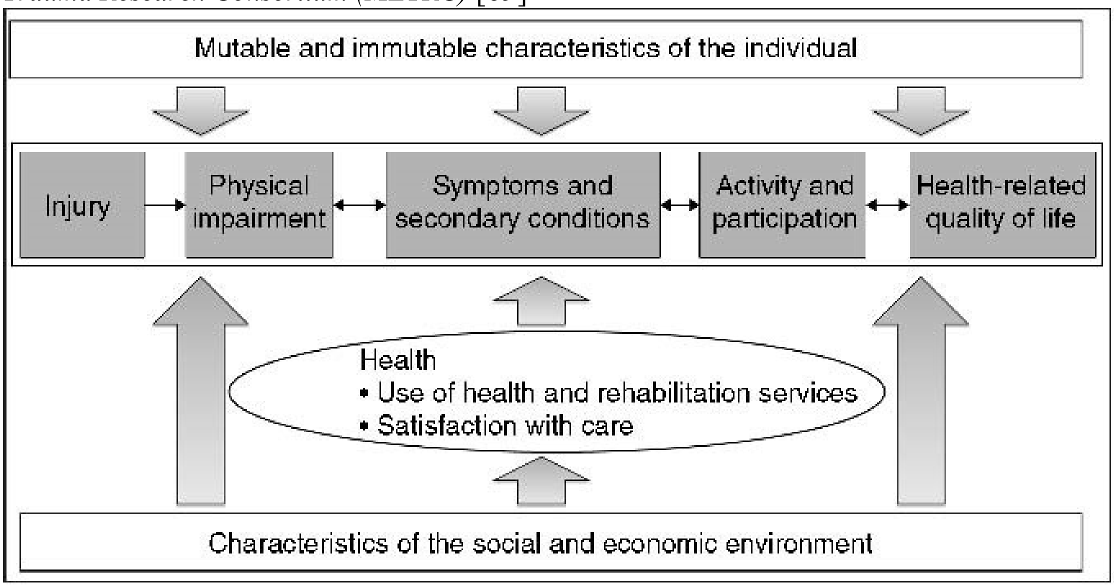


Table 1-2 Components of outcome relevant to major lower limb injury as proposed by the METRC Framework [69] of outcomes

Components of outcome
Physical impairment
Symptoms and secondary conditions
Major complication (infection, non-union)
Pain
Depression
PTSD
Activity and participation
Mobility
Functional limitation
Return to usual major activities
Participation in sports/leisure
Heath related quality of life
Patient satisfaction with care
Healthcare utilisation

The methodology used for identifying their outcome set is poorly documented, and probably fell short of gold standard methodologies [71, 72]; nonetheless the list of domains identified are aligned with both the LEAP study [10] and other recent important studies in open tibial fracture [22, 23]. Complications and residual symptoms are important outcomes following injury, and are frequently measured in clinical practice and research trials to evaluate effectiveness of an orthopaedic intervention. The next section explores some of the components of outcome identified by METRC in more depth, to further our understanding of the relevance of these aspects to open tibial fracture patients.

1.5.2.1 Major complication

A major complication is documented in recent studies as an event that requires the individual to undergo unplanned surgery [69, 73]. The most common complications following open tibial fracture are compartment syndrome, osteomyelitis, flap failure, non-union, infection and amputation; and it is not unusual for these events to occur simultaneously or sequentially in one patient [69]. The likelihood of occurrence of a complication is dependent on injury, patient, and surgical factors. Published complication rates for open tibial fracture are variable by the sampling frame for the study, and how a complication is defined. The two most frequently reported complications in studies are deep infection which is reported to occur 7-23% of cases [10, 20-23] and non-union reported in 8-29% of cases [10, 22]. All major complications have the potential to significantly impact the level of residual disability after recovery, and complications have often been used as primary outcome measures in clinical research

1.5.2.2 Healthcare utilisation and economic outcomes

Healthcare resources are inevitably limited by financial constraints, which need to be considered when developing technologies. Health economic evaluations are assessments which inform policy makers when allocating resource and making decisions on the adoption of certain technologies [74]. Such evaluations are an assessment of benefit versus cost. Benefit is measured by survival and health-related quality of life (measured by a utility score) presented as a “quality adjusted life year” (QALY). The QALY can be used to compare treatments. [75]. The NHS is willing to pay between £20,000 and £30,000 per QALY gained [76].

The best health economic data from a UK setting, relating to the treatment of open lower limb fracture is reported by Costa [77] reports average care costs of approximately £14,000 per patient; with similar estimates reported by small studies elsewhere in Europe [78]. Healthcare cost analysis was undertaken as part of the LEAP study within the American health system; which reported that early amputation is associated with a lower hospital cost than salvage [79]; yet the cost of lifelong management with a prosthesis is substantially higher than salvage. LEAP [4] reports lifelong costs of $509,275 and $163,282 in amputation and salvage, respectively. Indirect costs are not accounted for within these summaries but are significant and relevant; a separate paper [2] from the same trial reports that only 58% have returned to work by 84 months, and of those who returned to work 25% were limited in their work capacity. Indirect costs are not limited to the individual, and injury may affect family wide income due to care burden, although this has not been captured in the literature. The societal cost of these injuries when both direct and indirect costs are included must be substantial and as consequence of this, large interventional costs can potentially be justified.

1.5.2.3 Physical impairment

Reported functional outcomes following open tibial fracture are poor. LEAP [80] reported that at 7 years following injury, 50% of patients reported severe disability and only 34% of patients reported disability that was comparable to the general population. These outcomes were slightly worse than those recorded at 24 months following injury, suggesting the potential for progressive loss of function [81]. WOLLF [22, 23] measured disability as the primary outcome for the study; results were concordant with LEAP with patients reporting a 42% reduction in function at 12 months when compared to their reported baseline score. Functional outcomes are closely related to pain, depression and anxiety; targeting good functional outcomes is central to improving quality of life and reducing disability following trauma [11].

1.5.2.4 Pain

In the LEAP follow-up studies; 77% of patients reported chronic pain at 84 months and 25% reported that this pain interfered with daily living. Pain levels were comparable to those reported in specialist pain clinics for the back pain and headache population [82] which highlights the burden of pain on these individuals. Pain is associated with short long term anxiety and depression following severe limb injury; and reduction of severity or duration of pain is important in the context of both rehabilitation and return to previous activities [83]. It is unclear if pain drives depression or if depression makes pain appear worse, however the two are inextricably linked.

1.5.2.5 Psychological burden

Psychological outcomes following severe limb injury are poor according to several large studies. LEAP reported persistent psychological symptoms in medium and long-term follow-up [83]; and a large contemporary study in severe limb injury patients from the METRC group, reported symptoms of depression and PTSD in 38%

and 17% of participants, respectively [84]. A further study which included 2707 general trauma patients [85] found correlation between numbers of psychiatric disorders and increased functional impairment. The study also reported that patients with psychiatric disorders were three times more likely not to return to work a year after injury when compared to controls. There is evidence that psychological morbidity is common in trauma patients, and this morbidity has a significant impact on quality of life. Thus far we have broadly considered the physical aspects of recovery following open tibial fracture; although this review has indicated that the psychological impact of open tibial fracture is considerable and likely to be a component of a patient-orientated analysis; understanding the psychological narrative is important and will be discussed in the next section of this review.

1.6 Psychological aspects of recovery

Identifying and managing psychological problems are recognised as an important component of UK post-injury care for major trauma [86]; but the extent to which this support is accessible to the open tibial fracture population is very debatable. The literature does not discuss the psychological trajectory of injury and recovery after open tibial fracture; however, there is a wealth of broader literature related to psychological trauma following injury which will be introduced here to inform our analysis.

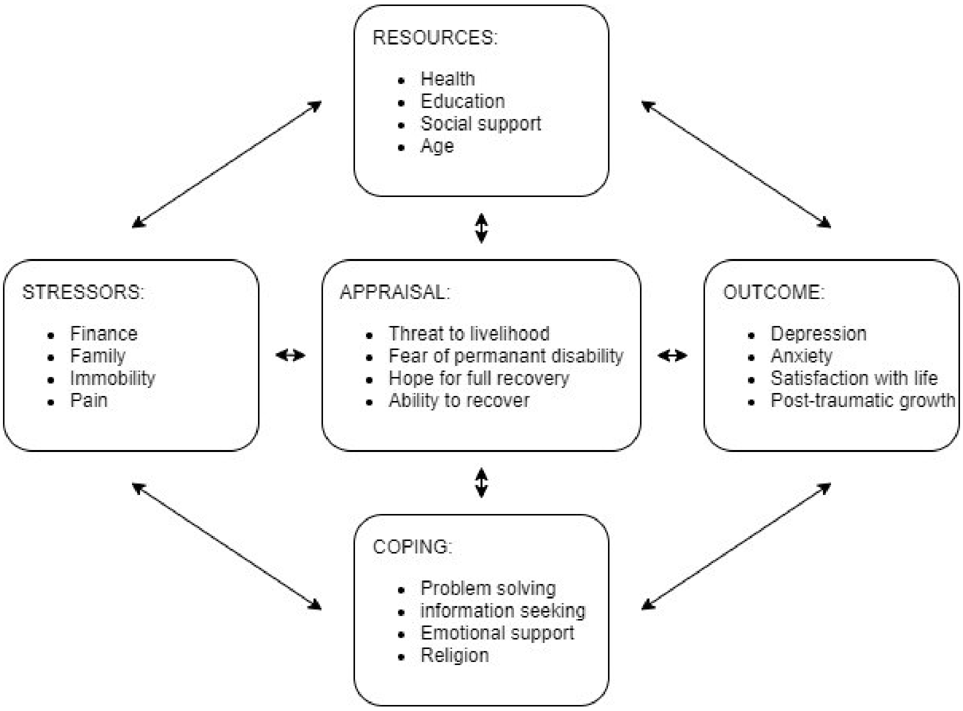
Sustaining major physical trauma causes a breakdown of the individuals existing routines, beliefs, values, relationships and sense of purpose, shattering pre-conceived perceptions of their self and the world. Psychological distress experienced in response to accidents can be attributed to this sudden derailing [87]. Recouping a sense of self requires the individual to adapt, finding new purpose and meaning in life that is within the constraints of newly acquired disability [88]. This reorientation is exceptionally challenging.

There have been multiple attempts to conceptualise the process of adaptation [89] following trauma. However, this study was guided by the "*stress, appraisal and coping*" framework, which is a contemporary evidence-based model and has been applied in the injury population [90, 91]. The model focuses on the individual's ability to cope with, and adjust to, life stress. It focuses on the relationship between environmental and personal variables; framing that 'appraisal' and 'coping' mediate the relationship between stressful life events (i.e. injury and immobility) and psychological adjustment (Figure 1-6).

Appraisal relates refers to the individuals' assessment of risk and hopes in recovery. Whilst coping strategies are cognitive and behavioural efforts to manage stressors. Coping strategies are often referred to as either problem focused or emotion focused. Problem-focused strategies are those where the individuals can practically manage the stress by making physical changes (such as installing a hand-rail), where emotion focused-strategies refer to psychological strategies (such as talking) for reducing stress. [91]. The process of appraisal and coping are dynamic and change over time in response to changes in the injury, personal or environmental factors. The effect is iterative, and differences in coping or appraisal strategies can also cause changes to stress, person or environment. Injury studies have found active coping strategies are more predictive of improved psychological outcomes than other factors such as age or time since injury [92]; with some correlation to improvement in functional outcomes. Hope has also been associated with better health outcomes [93, 94].

A qualitative study by Shauver [95] discussed coping strategies following an open tibial fracture. The study reported that coping techniques reduces stress, this leads to an increase in coping self-efficacy fostering further use of adaptive coping strategies; culminating in personal growth. It was reported that personal growth led to satisfaction with their limb despite poor functional and emotional outcomes. This study was used to explain the findings of the LEAP study [10] which found equivocal outcomes in individuals after severe limb injury; the study found that self-efficacy and not treatment after severe limb injury caused a difference in general health at two years. As adaptation is important to long term satisfaction, it would be useful to have further understanding into the role of appraisal and coping strategies used by individuals and whether any coping resource could be provisioned to support individuals during their recovery.

Figure 1-6 Figure adapted from Galvin and Godfrey, *The impact of coping on emotional adjustment to spinal cord injury (SCI): review of the literature and application of a stress appraisal and coping formulation*. [91]. Stress, Appraisal and Coping framework as a process of adaptation following trauma.



Favourable adjustment following trauma has been identified as a means of improving measurable health outcomes. Identifying and managing psychological problems are recognised as an important component of UK post-injury care for major trauma; but the extent to which this support is accessible to the open tibial fracture population is very debatable [86]. Alongside the physical narrative of recovery, this thesis will seek to outline to what extent the open tibial fracture population experience psychological trauma following injury, and what strategies they employ to help them.

1.7 Summary

This introduction has outlined why open tibial fractures represent a major and unique clinical challenge for orthopaedic surgeons and has outlined the problems faced by researchers seeking to evaluate clinical effectiveness. We have also portrayed the profound and severe impact these injuries have on individuals who sustain them. This introduction has provided a mandate for improvement, and identified a need for high quality research in these injuries.

Robust research in this field is limited; much of the published work is based on single institutional experiences and hampered by poor study design. The absence of high-quality studies impacts clinical decision making, service delivery, and prevents individuals from attaining the best outcomes from these devastating injuries. There is new enthusiasm amongst the orthopaedic community to reduce morbidity attributed to open tibial fracture, with a focus on delivering carefully considered research studies. There will be a role for randomised controlled trials in determining the best interventions for these patients, however RCTs cannot be performed without establishing where areas of equipoise are and where the uncertainty lies. Research questions in RCTs must be set on firm foundations with robust work undertaken to understand current perspectives. The scale of the problem, current clinical practice and outcomes, limitations of current clinical practice and what is important to individuals who sustain these injuries; are not clearly outlined in the literature. This work would be valuable to clinicians, patients and researchers seeking to understand these injuries. The purpose of this thesis is to pursue answers to these questions. To traverse the spectrum of topics from a variety of viewpoints and to respect the competing perspectives that are important in healthcare; a mixed-methods approach was adopted.

1.8 Aims and objectives

The overall purpose of this thesis is to support the future development of high quality research in open tibial fractures.

1.8.1 Aims

1. To use a national registry to evaluate epidemiological patterns and treatment trends in a large population of open tibial fractures; considering these in the context of death and clinical outcome within the UK trauma system. The thesis will also evaluate if registry research is able to answer specific clinical questions that are unsuited to prospective randomised clinical trial designs.
2. Use a comprehensive regional dataset to consider longer term clinical, patient centred and economic outcomes in an open tibial fracture cohort, to establish the longer-term results of competing treatment strategies and personal factors.
3. Identify and synthesise qualitative evidence on the experiences of open tibial fracture patients; to understand aspects of recovery most important to the individual and inform future qualitative research.
4. To understand what individuals who have recently experienced an open tibial fracture consider important when evaluating their recovery.

1.8.2 Objectives

1. Use a population registry to conduct a descriptive analysis of the incidence, baseline characteristics of the open tibial fracture population.
2. Explore the relationship between comorbidity and mortality in adult patients who have an open tibial fracture
3. Identify a national picture of treatment patterns and consider the relationship between key quality markers (i.e. time to definitive soft tissue closure or coverage) and short-term surgical complications.
4. Describe the demographics, injury characteristics and treatment of individuals admitted to a regional major trauma centre with open tibial fracture; consider generalisability of local practice to national picture.

5. Review major complications in the regional cohort and evaluate the relationship between key quality indicators and outcome.
6. Summarise patient-reported outcome following treatment for open tibial fracture.
7. Undertake a cost analysis to understand the average treatment costs for individuals with different treatments and different outcomes.
8. Conduct a systematic review of the literature to identify qualitative studies which consider experience of recovery after open tibial fracture.
9. Undertake a qualitative study to explore recovery from the perspective of individuals and also consider divergence in experience dependant on age and treatment.
10. Identify support strategies which would be useful to individuals with open tibial fracture, particularly in the context of coping, goal navigation and adaptation.

This thesis consists of varied methods and approaches, the aims and objectives are explored through 4 core chapters, each of which represents a separate study:

- Aim 1, and objectives 1 to 3 are addressed in “Chapter 2 A TARN Registry Study: the Epidemiology and Outcome of Open Tibial Fracture”
- Aim 2, and objectives 4 to 7 are addressed in Chapter 3 “A Local Evaluation of Service: Cost Analysis and Patient-reported Outcomes”
- Aim 3, and objective 8 is addressed in “Chapter 4 Recovery after Open Tibial Fractures: a Qualitative Evidence Synthesis”
- Aim 4, and objectives 9 to 10 are addressed in “Chapter 5 What is Important to Individuals with an Open Tibial Fracture: a Qualitative Study”

Chapter 2. A TARN Registry Study: the Epidemiology and Outcome of Open Tibial Fracture

2.1 Background

Registries provide a unique opportunity to access large volumes of consistent information regarding a condition, its care pathways, and their effectiveness; they are particularly useful when studying rare and difficult to access conditions. The Trauma TARN registry is the national trauma registry for England and Wales, and the largest of its kind in Europe. Use of this registry to study open tibial fracture will allow a better understanding of these injuries and treatments.

2.2 Aims and chapter plan

2.2.1 Aim

This chapter addresses aim 1: "To use a national registry to evaluate epidemiological patterns and treatment trends in a large population of open tibial fractures, considering these in the context of death and clinical outcome within the UK trauma system". The study will also evaluate whether registry research is able to answer specific clinical questions that are unsuited to prospective randomised clinical trial designs.

2.2.2 Chapter plan

This chapter begins with a methodology section which describes the limitations and advantages of registry research, and provides a description of the TARN registry which is the data source used in this chapter. This is followed by a methods section which describes how the data was received, processed and analysed. The methods section also includes some demographic analysis and includes a sensitivity analysis which was used to determine which data would be used in each analysis. The study aim will be achieved through a three stage analysis each addressing one objective, each analysis is outlined below:

Epidemiology of open tibial fracture.

Objective 1 was to use a population registry to conduct a descriptive analysis of the incidence and baseline characteristics of the open tibial fracture population. This analysis focuses on open tibial fracture epidemiology, exploring the relationship between age, gender, and mechanism on incidence and severity of injury. The impact of an ageing population on trauma incidence has recently received attention across the field [18], but this has not been explored exclusively in open tibial fracture. Incidence rates will be calculated for open tibial fracture stratified by demographics. These descriptive statistics will be utilised in relational analysis to elicit the relationship between the perceived causal factors (ageing and a high energy accident) and occurrence of injury, injury pattern and injury severity.

Relationship between comorbidity and mortality after open fracture

Objective 2 was to explore the relationship between comorbidity and mortality in adult patients who have an open tibial fracture, and will be addressed through this analysis. The increase in grey trauma [96] has significant clinical ramifications for treating open tibial fractures. Older patients have an increased risk of mortality after trauma when compared with younger patients, a relationship which is independent of injury severity [18]. Older patients are more likely to have complex medical needs, and it is important to understand the impact of this on outcome. This analysis will look at the relationship between comorbidity and mortality across our patient population, adjusting for other confounders of mortality such as age and injury severity.

Evaluation of national practice and impact on early outcomes

Objective 3 was to identify a national picture of treatment patterns and consider the relationship between key quality markers (i.e. time to definitive soft tissue closure or cover) and short-term surgical complications. National standards provided by the BOA [28] shape many of the treatment practices in the United Kingdom, but despite the existence of guidelines, there is significant variation in practice and the impact of this variance is unknown. This analysis looks at major points within the guidelines and considers compliance, and relationship with outcome. The analysis considers compliance with requirements for treatment within a specialist centre and the surgical strategies used most frequently across the UK stratified by injury severity. In addition, the analysis reviews compliance with the 72-hour target for time to definitive soft tissue closure or cover and considers the relationship between this target and early wound complications after surgery.

2.3 Methodology

2.3.1 National trauma registers

A trauma registry is a collection of uniform data collected from individuals who meet defined inclusion criteria usually based on the International Classification of Diseases (ICD). Data collected typically includes; demographics and comorbidity, the circumstance of injury, anatomy of the injury sustained (often coded to determine overall injury severity), physiological measurements, medical and surgical treatment pathways and outcome data. These registries are normally maintained by trained hospital personnel and predominantly relate to the acute stay. Trauma registries have been used in audit, service evaluation and quality improvement projects often directing national policy; registries are also a powerful research tool for epidemiological, clinical and outcomes research [97]. Trauma registries vary in design from surveillance registries as they focus on procedure during the peri-injury period rather than long term surveillance for survival of implant or patient. For this reason, trauma registries typically contain detailed demographic, process and treatment information, but limited information on medium and long-term outcomes.

The concept of categorising injuries, treatments and outcome is not new; the Edwin Smith Papyrus provides evidence that such strategies were employed by Ancient Egyptians to document practice [98]. Trauma registries in their current format emerged alongside the major trauma network system in the United States, initially with institutional registries but later regional and national registries. A pioneering registry study was the Major Trauma Outcome Study [99]; a retrospective descriptive study which reported data from 1982-1987 including 80,544 trauma patients, the study drew inferences on the drivers of mortality after severe injury. National trauma registries are not exclusive to the United States with developed and developing countries, also reporting registries [100-102]. The WHO first acknowledged registries as important in 2004 and in 2009 published guidance on quality improvement in trauma and stated the need for registries amongst this guidance [103]. Despite the recognised importance of registries in developing countries; registries in developed countries tend to be more likely to produce high-quality publications, and it is evident that the impact of a registry is linked to its core methodologies.

2.3.2 The strengths and pitfalls of registry research

Regarding arthroplasty registries; Bohler [104] suggested several key elements that are necessary for a successful registry which included:

- Integration of the registry within a national health care system.
- A centralised independent structure for data collection and storage.
- Understanding of information governance and data protection laws.
- Relevant specialists undertake interpretation and statistical analysis of data.
- Consultation with, and support of, professional medical associations.

There are some nuances between trauma and arthroplasty registries, although they are fundamentally similar with regard to their methodology and these suggestions are mirrored in the design of several successful trauma registries [101, 105, 106]. The value of a well-designed registry is that it reduces error systemically protecting from methodological weaknesses innate with registry research. It is important to understand the limitations of a research registry design, and we will discuss these in turn.

2.3.2.1 An inclusive approach or a convenience sample

A claimed strength of registry methodology is the inclusion of participants that would often be excluded from other study designs; however, meeting this benchmark of broad inclusion is difficult to achieve. The exclusion of participants – such as those lacking capacity – is encouraged in other trial designs to reduce variation in results and to circumvent ethical challenges [107]; however, this introduces a known bias which often prevents the generalisation of results to difficult to access populations. The use of sensitive inclusion criteria in a registry setting is philosophically appealing, although a difficult parameter to achieve in practice. Inclusion criteria for each registry can be grey when compared with carefully structured RCT inclusion criteria and are vulnerable to local interpretation which will impact the sampling frame. The greatest barrier to inclusion of patients within registries is resource; in RCTs there is ring-fenced funding for trial staff, whilst data-entry staff for registries are more likely to have competing priorities which impacts data submission. Central management of registries often control for missed data with uplift payments for data submission; and by quantification of missed cases by comparison with Hospital Episode Statistics (HES) data, coding or insurance data. Presented in this manner a registry is a convenience sample. Convenience sampling is a form of non-probability sampling which can introduce bias. The significance of this bias is questionable; it is the responsibility of those holding the data, and researchers analysing the data to scrutinise the data for missing cases evaluating for non-random error which will bias results.

2.3.2.2 Veracity in large data

The most frequently cited weakness of registry methodology is data quality. There are two broad sources of error within registry datasets; the first is misinterpretation of data by the data clerk, the second is the failure of the treating team to document data. The consequence of this is erroneous data being included in the registry, incomplete records or records being missed entirely. There are several examples where the accuracy of registry data has been challenged, one such example by Skinner [108] validated National Joint Registry (NJR) data against implant retrieval centre data. The study looked for homogeneity of component number on the NJR compared against the component number on the implant retrieved from the patient. The study identified a 6% error rate for components on the NJR, and further errors in the date of operation and demographics of the patient. Such examples have an impact on the perceived integrity of the data. Managing data quality within registries is challenging, and multiple strategies have been employed to improve veracity. Popular strategies of successful registries in the United Kingdom include providing financial incentives for compliance with registries [109], or utilising a minimum dataset to encourage clinician engagement [110]. In addition, data integrity is controlled centrally by the by use of validated databases, appropriate version control and involvement of key stakeholders in the design of the database.

2.3.2.3 Ethical considerations

Ethical requirements for research registries vary nationally, although within England the regulatory structure strikes a balance between protecting the data of individuals whilst not impeding access. Within England, HRA review (which includes ethics board review) is not required for the establishment of research databases if the data is anonymised [111]. However, if the research involves processing of identifiable patient data outside the normal clinical team without explicit consent, REC and confidentiality advisory group approval is needed as per Section 251 of the NHS Act 2006 [112]. Section 251 approval provides the statutory power to ensure that NHS patient identifiable information needed to support essential NHS activity can be used without the consent of patients. Medical research is an acknowledged medical purpose [60], and in the context of trauma registries, it is unfeasible to obtain consent from patients due to capacity limitations of the patient and infrastructure without affecting the sample frame. Criticisms of this approach are that the Section 251 process is complex, bureaucratic and long-winded which makes it inaccessible to many researchers; it also isolates the devolved nations who operate under different laws and are subsequently excluded from registry research. To make optimum use of large new data sources, there needs to be innovative approaches to the management of ethical issues in big data research, to allow this work to be conducted in a fair, legal but ready manner.

2.3.2.4 Outcome measure

Mortality is often the main outcome measure within a trauma registry; whilst useful for trauma risk modelling, mortality is less relevant in open tibial fracture patients. Mortality rates after open tibial fracture are reported at approximately 1% [3] and the

AIS [113] defines them as serious injuries that are survivable in isolation, although the combination of several injuries, comorbidity or age may alter this. In contrast, the goal for open tibial fracture recovery is a return to previous quality of life and current attitudes believe this is best measured using patient-centred outcome measures. The UK based TARN registry mirrors global patterns, relying on mortality and inpatient complications to evaluate the quality of care. The registry has made an attempt at collecting patient-reported outcome measures (PROMS), and has undertaken a 24 month pilot of PROMS data collection from TARN patients at 6 months after injury; however this data has not been published and is of unconfirmed quality. Successful PROMS collection from registry patients has been achieved in arthroplasty registries and in the trauma population elsewhere in the world [106]. High administration costs and a low linked return rates [114] are likely to act as a disincentive to wide adoption in the trauma registries, but failure to record such outcome measures, challenges the overall usefulness of a registry for research purposes.

2.3.3 The TARN registry

TARN [102] was initiated in the early 1990s after the work of Henry Champion highlighted the potential value of registries as a mechanism for change [99]. The TARN registry was initially led by emergency physicians who mirrored the methodology and datasets utilised in the successful North American Major Trauma Outcome Study (MTOS)to capture data on UK trauma patients. The MTOS methodology relied on comparing expected and observed outcomes in relation to mortality, termed the 'TRISS Methodology' [99]. Early major publications from the TARN database demonstrated that mortality rates for UK trauma patients were higher than their matched counterparts with large variation in care between units [115], with further studies identifying the importance of tertiary centres in the management of head injury [116] . Such evidence fostered momentum to continue and grow the registry with strong support within both participating hospitals and the Department of Health. From these promising foundations, TARN has continued to play a fundamental role in shaping clinical care and UK trauma policy by producing powerful meaningful statistics based on robust registry methodology [117].

The TARN registry today remains the largest trauma registry in Europe [97]. The aims of the registry have stayed consistent, with trauma risk scoring playing a central role. In addition, TARN remains a powerful service evaluation tool overseeing a series of key performance indicators, and importantly the TARN registry retains an interest in supporting research programmes. Compliance has improved in response to two measures:

1) The registry was adopted onto the Healthcare Quality Improvement Programme (HQIP) hosted the National Clinical Audit Programme, which mandates the submission of TARN audit data via the standard contract with trusts accountable via their quality accounts.
2) In April 2012, the Department of Health launched the Major Trauma Best Practice Tariff which provides MTCs with a per patient uplift payment of £1406 or £2819 for individuals with an ISS>8 or ISS >16 respectively. The Best Practice Tariff (BPT) is awarded when individuals meet a series of quality indicators reported to CCGs via the TARN platform. The introduction of BPT incentivises centres to submit all TARN cases in a timely manner to optimise funding received for these patients.

The TARN registry aligns itself well with the priorities set by Bohler [104]and presents an excellent example of good registry practices.

2.3.4 Can trauma registries be used for open tibial fracture research

Randomised controlled trials are ubiquitously referred to as the gold standard for evaluating interventions, as they minimise many of the potential selection and reporting biases common with other methodologies; nonetheless the methodology has limitations. Foremost RCTs are prohibitively expensive and time consuming. Limitations specific to open tibial fractures are that this injury is rare and there are legal and ethical challenges around research consent in an emergency setting, and thus recruiting enough participants to assess statistical differences is difficult. These limitations mean that trials often prove unfeasible, or funding is unavailable for pertinent research questions.

The 21st century has promised a “big data” revolution in healthcare; with anticipation that data collected for a different purpose (i.e. hospital charging) can be repurposed for research use. The value of big data is that it can be obtained quickly and in large volumes; the challenge is that the data is variable and sometimes of questionable veracity [118]. Nonetheless, there are examples where big data has been used successfully to provide insight into patterns of behaviour [119]. The term “big data” relates to a population with a sample size to overcome the variability in the data to allow meaningful conclusions to be drawn. There are obvious parallels between a conventional “big” dataset and a registry; however, registry data has less error as it is not repurposed data, but data collected for research purposes. This improvement in data quality is probably offset by the smaller sample sizes seen in registries when compared to other forms of “big” data. To an extent, error in registries can be managed with appropriate statistical techniques, these may include multiple imputation to correct for missing data and sensitivity analysis to explore for biases in the data.

Registry research presents an alternative methodology to evaluate clinical questions relating to the management of open tibial fracture. Registries have been identified as useful vehicles for studying rare conditions and the broad sampling frame allows for an inclusive approach to exploring these conditions. Whilst the methodology has limitations, there are also significant benefits when the challenges of alternative methods are considered. A focus of this thesis is to support the future development of high quality research in open tibial fractures. There are few comprehensive registry studies in open tibial fracture and an evaluation of these injuries which considers the utility of data and asks meaningful questions around demographics, injury characteristics, treatment, and outcomes, would provide a stand-alone contribution and allow insight into where future research should be targeted.

2.4 Methods

2.4.1 Ethical approval

This study was conducted under pre-existing ethical approvals held by TARN. As an audit function, TARN's governance structure is provided by Department of Health via HQIP; the audit is registered under the National Clinical Audit Programme and the Clinical Outcome Review Programme (NCAPOP). Certain activities conducted by TARN are outside of this governance structure and supported by the Health Research Authority (HRA) Approval. The HRA approval awarded to TARN includes section 251 approval [112] (further described in 2.3.2.3). The data transferred to Nottingham was issued within the constraints of TARN's existing HRA approval, which includes Section 251 and therefore no further permissions were required to allow completion of the project.

2.4.2 TARN research application process

Application for data was via a data request form; the form (project reference: 1175009) completed for this project is available in appendix8.2. The project was reviewed at an internal review board, composed of clinicians, managerial staff, and analysts. The project was evaluated for feasibility, ethical limitations and conflict with work being undertaken by other researchers. The positive outcome of the meeting was relayed to the research team and once both parties confirmed they were happy to proceed; this agreement was formalised through a data transfer agreement, which outlines the contractual obligations for researchers using TARN data. This agreement between the University of Manchester and the University of Nottingham is included in appendix 8.3. TARN data is routinely stored on encrypted servers at the University of Manchester; relevant fields were extracted into a csv. file and these data were transferred to the University of Nottingham via an encrypted data portal. Once received, the data was stored on the University of Nottingham encrypted server with access restricted to the lead researcher within a password-protected area in line with data protection regulations.

2.4.3 Overview of TARN fields

The TARN dataset includes demographics, injury details, comorbidities, physiological factors, medical and surgical care, inpatient-complications, length of stay, mortality, and discharge details. An additional dataset is captured to explore compliance with the BOAST open fracture guidelines, which provides comprehensive data on the injury of relevance to our research questions. A copy of the TARN data dictionary for the dataset is included in appendix 8.4.

Index

In the TARN data, each record represents a hospital attendance by a patient and patients who are transferred between hospitals have multiple records for their individual episode. The dataset is indexed and pseudonymised by a dual primary key; a submission ID which is unique to the hospital stay within the episode, and a case ID which is an overarching identifier for patient's entire episode. TARN exports are a 'flat export' providing each admission as a separate record. The dataset was reconstructed locally by merging all records under one case ID into a single record, to create a dataset indexed as one record per patient. This was achieved using an SQL statement with the case ID as the primary key and resulted in 16652 unique records; these records were sense checked to ensure no loss of data integrity.

Demographics

Age and gender are mandatory fields and always completed. Children were excluded from all analyses except for the incidence analysis, which was decided due to the profound differences in care pathways and outcomes between children and adults. More extended demographic data (i.e. geographic) was unavailable due to data protection constraints within TARN.

Mechanism of injury

Mechanism of injury is reported for all patients in the TARN dataset, mechanism is reported under one of nine headings; they include road traffic collision (RTC) and fall from more than 2 metres, but also more rare mechanisms such as shootings. These were generally reported separately, but where comparison between high and low energy injuries was needed, the variable was recoded as follows:

- High energy injury: RTC, Fall from more than 2m
- Low energy injury: Fall from standing
- Other: Blast, blow, crush, shooting and other

The category “other” were generally high energy injuries, but there was a degree of subjectivity, the variable was included and excluded from each analysis reporting mechanism to look for bias and effect from omitting these cases.

Hospital stay information

Admission dates, attendance at an MTC, transfer, reason for transfer and length of stay are all captured as part of the TARN dataset. For this study, records were considered as a superspell. A superspell acknowledges that some hospital episodes require admission to more than one hospital, this is particularly relevant here as many trauma patients were transferred between units, and it was important to consider events at both units. In cases where two sets of injury data were reported, data were used from the patient’s operating hospital.

Physiological data

This data was mainly captured in the emergency department and documented the patient’s baseline statistics and comorbidities. This data is important for trauma risk scoring within TARN and centres are strongly encouraged to supply this data. Missing data impacted the usability of some of the physiological data, and therefore this data was only utilised if the field was reported in most cases.

Glasgow Coma Scale

The Glasgow Coma Scale (GCS) is a neurological scale used to gauge consciousness and is composite of a triple criteria scoring system (best motor response, verbal response and eye response). A score of 15 indicates full consciousness, whilst a score of 3 is equivalent to a deep coma or death [120]. The scale is prognostic for acute brain injury, with lower scores indicating a worse prognosis [121]. Within TARN, a missing GCS reflects an intubated patient [122].

Charlson Comorbidity Index

Charlson Comorbidity Index (CCI) is a widely used and widely accepted comorbidity index frequently used in predictive models [123]. CCI uses weighted ICD-10 based diagnoses summed to give a score for each patient, the initial version of the score includes 17 comorbidities identified as being associated with an increased risk of mortality in hospitalised patients, the score has evolved over time and consequently there are various iterations of the index [124, 125]. TARN utilise a modified Charlson comorbidity index which was developed after a mapping exercise which considered both the existing ICD-10 codes used in the published CCI, and a broader comorbidity dataset which was collected by TARN [126]. This mapping exercise identified several additional comorbidities were relevant in predicting death in trauma patients, henceforth TARN developed a modified CCI (mCCI) for use in trauma-risk modelling. This iteration is used throughout our analyses. Table 2-1 includes a list of comorbidities identified as most prevalent in trauma patients and their weightings with regards to impact on mortality in a broader trauma population; those in bold are conditions included in the TARN mCCI, but not the CCI.

Table 2-1 Frequency of comorbidities, and weighting for mortality utilised to calculate the TARN mCCI. Conditions in bold are additional to the original CCI. Table reproduced from study by Bouamra [126].

Conditions	(N)	Weights
Liver disease	1312	13
Metastatic cancer	480	9
Renal disease	2293	6
Congestive heart failure	7435	5
Acute myocardial infarction	5111	4
Dementia	5903	4
Alcohol abuse	**9415**	**4**
Cancer	4167	3
Peripheral vascular disease	2201	2
Blood disease	**2312**	**2**
Cerebral vascular accident	5019	1
Not classified	3177	0
Other conditions	29723	0
Connective tissue disorder	10369	0
Diabetes	8993	0
Genito-Urinary diseases/peptic ulcer	3277	0
Pulmonary disease	13123	0
Paraplegia	199	0
HIV	176	0
Mental health	**49847**	**0**
Bone disease	**5453**	**0**
Neurological disorders	**4325**	**0**

Abbreviated Injury Scale and Injury Severity Score

Within TARN all injuries are abbreviated injury scale (AIS) coded [113]. The AIS is a severity scoring system that classifies each injury in every body zone according to its relative importance on a six-point ordinal scale. A score of 1 is equivalent to minor injury (i.e. superficial laceration), a score of 6 is an untreatable injury (i.e. C2 complete cord transection). An open tibial fracture is classified as a point 3 (serious) injury under the AIS system. All injuries within TARN are initially matrixed under an AIS diagnostic code; this is then converted into an AIS score, which can be used to draw assumptions about injury severity. The injury severity score (ISS) [127] converts AIS codes for each patient into a single score for each patient which has prognostic survival value in a clinical setting. An idiosyncrasy of the score that diminishes its predictive power is ISS only considers one injury per body zone; this is particularly relevant in orthopaedic trauma patients as there are frequently multiple limb injuries. A new injury severity score (NISS) [128] was introduced, which is the sum of squares of the patient's three most severe injuries, irrelevant of the site and is the one reported throughout this analysis as more representative of limb injuries.

Injury details

Extensive details around the injury were collected with high fidelity. A limitation of the AIS limb field is that it provides a singular score per patient and is a poor marker for evaluating the severity of orthopaedic injuries. There was interest in understanding the patterns of concomitant orthopaedic injury for each individual; this data was obtained from the injuries field which documented serial injuries in long text form. Data was parsed using SQL code and converted into multiple categorical variables, to allow more stringent analysis. An example of this is shown below in Figure 2-1.

Figure 2-1 Raw aggregate data was provisioned by TARN, this data was parsed locally, the orthopaedic injuries were matrixed into variables whilst non-orthopaedic injuries were just described using AIS code which was also provisioned by TARN. This figure shows how the data was processed, Top) shows raw data received from TARN. Left) Shows appearance of data after parsing. Right) show data after matrixed.

Raw data from TARN

Femoral Shaft fracture complex | Patella fracture NFS | Tibia Shaft fracture complex, Open | Fibula fracture above ankle joint, Weber C| Tibia Shaft fracture complex, Open | Fibula fracture through ankle joint, weber B| Ankle joint dislocation | Clavicle fracture NFS| | Ulna distal extra articular fracture | Pneumothorax NFS | Cerebrum injury, brain swelling, NFS| Brainstem injury involving haemorrhage| Pneumothorax NFS | | Cerebrum haematoma, intracerebral, petechial hemorrhage(s)| Subarachnoid hemorrhage NFS | Acromioclavicular joint dislocation | Maxilla fracture, LeFort III

Data after parsing

Femoral Shaft fracture complex

Patella fracture NFS

Tibia Shaft fracture complex, Open

Tibia Shaft fracture complex, Open

Ankle joint dislocation

Fibula fracture above ankle joint, Weber C

Fibula fracture through ankle joint, weber B

Clavicle fracture NFS

Ulna distal extra articular fracture

Acromioclavicular joint dislocation

Brainstem injury involving haemorrhage

Cerebrum haematoma, intracerebral, petechial hemorrhage(s)

Cerebrum haematoma

Subarachnoid hemorrhage NFS

Maxilla fracture, LeFort III

Pneumothorax NFS

Pneumothorax NFS

Matrixed variables		
Regrouped orthopaedic injuries from ICD-10 codes	Tibial fractures (n)	2
	Fibula fractures (n)	2
	Open fractures (n)	2
	Open tibial fractures (n)	2
	Patella fractures (n)	1
	Femoral fractures (n)	1
	Forearm fractures (n)	1
	Upperarm fractures (n)	1
	Upper limb soft tissue injury (n)	1
	Lower limb soft tissue injury (n)	1
	Open femoral fractures (n)	0
	Pelvic fractures (n)	0
	Rib fractures (n)	0
	Calcaneal fractures (n)	0
NISS	NISS	50
AIS score	Head AIS	5
	Face AIS	3
	Thoracic AIS	3
	Limb AIS	3
	Abdominal AIS	0
	Spinal AIS	0
	Pelvic AIS	0
	Other AIS	0

Tibial fracture

Information collected for the open tibial fracture allowed for documentation of site, intra-articular extension, and complexity (simple, wedge or complex), the dataset includes 13 different AIS descriptions for open fracture and captures Gustilo grade. The frequency in which each of these 13 criteria is used is described in Table 2-2. The current classification system for open tibial fractures in TARN was introduced in 2012 aligned with the introduction of BPT, prior to this fracture pattern and severity was reported in much less detail. Whilst the availability of 13 fracture descriptions at first appears useful, the application of the descriptions was inconsistent which limited their usefulness. One problem of note is that data entry personnel are not medically trained, and have the option of applying multiple classifications to one fracture, an example is as follows:

Classified by data-entry personnel as: *"Tibia Shaft fracture complex, open, Comminuted Distal Partial-articular, Gustilo 1"*

Surgeon record: *"ORIF Distal Tibial #Pilon Fracture of the Tibia Anterior incision lateral to Tib ant Plane between TA and EHL developed, arthrotomy, fracture heamatoma evacuated, joint washed out Extremely comminuted fracture with depressed articular fragments...."*

In this example, there is some conflict between what the surgeon has reported and the data-entry personnel, although it is impossible to determine whether the data entry is incorrect from this record. The challenge for the data-entry personnel is accurately coding the surgeon or radiologists diagnosis under the TARN definitions without introducing error; this is difficult in many scenarios, but particularly in the setting of open tibial fracture where there is huge variability. For this reason these sub-classifications were not used extensively in the analysis. One classification that was utilised in the analysis was Gustilo grade; the Gustilo classification is documented by the surgeon and not retrospectively classified by data-entry personnel thus reducing potential for error. In addition, Gustilo grade is a mandatory field for Gustilo 3B/3C fractures within the TARN dataset resulting in good completion rates.

Table 2-2 Open tibial fracture cases per ICD-10 code.

Cohort	(n)
Tibia Shaft fracture Open	562
Tibia Shaft fracture simple – Open	752
Tibia Shaft fracture Wedge – Open	17
Tibia Shaft fracture complex – Open	4459
Distal Tibia fracture -Open	969
Distal Tibia fracture extraarticular – Open	225
Distal Tibia fracture partial articular – Open (inc. Pilon fracture)	123
Distal Tibia fracture complete articular – Open	6
Tibia Fracture – Open	464
Proximal Tibia fracture – Open	178
Proximal Tibia fracture- extraarticular – Open	11
Proximal Tibia fracture- partial articular – Open	64
Proximal Tibia fracture- complete articular – Open	126
Total	7956

Management of bilateral injuries presented a final concern when considering the injury data. Within the dataset, 5% had bilateral open tibial fractures, in these cases, the patient was retained as one record, and the most severe injury was classified as the index injury. Where present, bilateral open tibial fractures were managed as a confounder in analyses.

Surgical procedures

A great limitation of the TARN surgical data is that it is not relational or linked. Therefore the surgery or procedure cannot be linked to the injury due to the way injuries and surgeries are recorded. Laterality of surgical procedure is not captured; therefore, you cannot determine the surgical treatment for an injury; which in turn invalidates much of the surgical data collected in TARN. This issue does not extend to patients eligible for the BOAST open fracture audit (Gustilo 3B/3C) as the BOAST eligible procedures are flagged as such, allowing the procedure to be linked to the injury. The example below (Table 2-3, Table 2-4) shows two records for different patients with multiple orthopaedic and soft tissue injuries; their treatment included two surgeries; one patient had a BOAST eligible fracture whilst the other patient was not eligible. From the below example, it is evident that the surgical data for the non-BOAST patient is less useful as the tibial fracture surgery cannot be identified. Because of this issue with data validity, analyses including surgical data were restricted to BOAST eligible patients who had BOAST flagged documented skeletal and soft tissue management.

Table 2-3: Surgical pathway for a none BOAST patient where it is difficult to identify the surgery for open tibial fracture

Parsed injury		Surgery 1		Surgery 2
Scalp contusion	→	Direct wound suture	→	Local muscle flap
Scalp laceration, minor		Primary Open Reduction and External Fixation		Internal Fixation to bone
Liver contusion (haematoma)		Internal Fixation to bone		Internal Fixation to bone
Humerus shaft fracture - complex		Skin Debridement		
Tibia Shaft fracture complex, Open		Skin Debridement		
Fibula fracture above ankle joint, Weber C		Skin dressing		
Pelvic ring fracture, incomplete disruption of post arch , blood loss <20%		Laparotomy		
Acetabulum Fracture - partial articular (involving one column)				

Table 2-4: Surgical pathway for a BOAST patient, with identifiable BOAST flag against procedures relevant to the open tibial fracture

Parsed injury		Surgery 1		Surgery 2
Carpal joint dislocation (distal radioulnar)	→	**Skin Flap - Local Random Pattern (BOAST4)**	→	Primary ORIF - Screw
Right Gustilo 3B (BOAST4), Tibia Shaft fracture complex, Open,		**Primary Open Reduction and External Fixation (BOAST 4)**		Skin dressing
Fibula fracture above ankle joint, Weber C		Manipulation of Joint		Skin suture
Scalp laceration, minor		Plaster cast		
		Skin Debridement		

The 3B/3C cohort provided a rich data source for analysis. The operative data includes surgeon grade, speciality, timing, procedures performed, and a narrative description extracted directly from the patient's record. The surgical procedures for BOAST audit fractures are based on the OPCS codes and are as shown in

Table 2-5 and Table 2-6 (fixation and soft-tissue cover respectively). It was felt that these definitions were too granular for this study, resulting in small groups unsuitable for regression modelling. In additional we were concerned about the ability of audit personnel to code to the level of detail required by these categories. As a consequence, for this study, broader groups were drawn to reduce error and help the statistical stability of the model. Once these broader terms were defined, the operation narrative was compared against the operative procedure for accuracy. This process identified 94% agreement between the operative procedure and the operative narrative; where possible coding was updated if there was a definite omission. As part of the case-by-case review, several additional variables were generated to support analysis; these included: number of surgeries on the tibia, number of re-operations, and whether the patient had staged soft tissue cover or definitive fixation.

Table 2-5 Number of fixation procedures recorded under each OPCS code for BOAST patients

OPCS code	(n)	Grouped	(n)
Primary Open Reduction and External Fixation (BOAST4)	638	External fixation	1662
Primary Closed Reduction and External Fixation (BOAST4)	483		
Application of Ilizarov Frame (BOAST4)	414		
Secondary open reduction and external fixation (BOAST4)	127		
Primary ORIF - Nail (BOAST4)	656	Internal fixation	1969
Primary ORIF - Plate (BOAST4)	391		
Primary ORIF - Screw (BOAST4)	288		
Secondary ORIF (BOAST4)	174		
Primary ORIF - unspecified (BOAST4)	136		
Primary ORIF - Wire (BOAST4)	107		
Primary ORIF - Pin (BOAST4)	76		
Primary Closed Reduction and Internal Fixation (BOAST4)	75		
Primary Open Reduction Fracture (BOAST4)	66		
Primary Closed Reduction Fracture(BOAST4)	24	Conservative	24
Acute bone shortening (BOAST4)	108	Cases verified	108
Amputation of Upper/Lower Limb	192	Amputation	192

Table 2-6: Number of soft-tissue procedures recorded under each OPCS code available for BOAST patients

OPCS code	(n)	Grouped	(n)
Free flap unspecified (BOAST4)	604	Free flap	822
Harvest flap - Gracilis muscle (BOAST4)	119		
Harvest flap - Latissimus dorsi (BOAST4)	39		
Muscle flap - Microvascular free tissue transfer (BOAST4)	34		
Harvest flap - Latissimus dorsi muscle and skin (BOAST4)	19		
Harvest flap - Serratus anterior (BOAST4)	3		
Harvest flap - Gluteus maximus and skin (BOAST4)	3		
Harvest flap - Tensor Fasciae Latae and skin (BOAST4)	1		
Harvest flap - Pectoralis and skin (BOAST4)	0		
Harvest flap - Rectus abdominis and skin (BOAST4)	0		
Harvest flap - Trapezius and skin (BOAST4)	0		
Harvest flap - Epigastric (Inferior) (BOAST4)	0		
Local fasciocutaneous flap (BOAST4)	228	Local flap	529
Harvest flap - Gastrocnemius (BOAST4)	60		
Local muscle flap (BOAST4)	58		
Harvest flap - Gastrocnemius and skin (BOAST4)	33		
Harvest flap - Soleus muscle (BOAST4)	30		
Skin flap - Local random pattern (BOAST4)	30		
Pedicle flap - Fasciocutaneous subcutaneous (BOAST4)	27		
Pedicle flap - Local fasciocutaneous subcutaneous (BOAST4)	25		
Harvest flap - Lower leg skin and fascia (BOAST4)	19		
Pedicle flap - Distant myocutaneous subcutaneous (BOAST4)	13		
Skin Flap - Distant random pattern (BOAST4)	2		
Harvest flap - Digitorum brevis (extensor) (BOAST4)	1		
Pedicle flap - Axial pattern local subcutaneous (BOAST4)	1		
Skin flap - Axial pattern distant (BOAST4)	1		
Skin flap - Local sensory (BOAST4)	1		
Skin flap - Neurovascular island sensory (BOAST4)	0		
Direct wound suture (BOAST4)	737	Suture	737
Skin graft – Unspecified (BOAST4)	631	Skin graft	1048
Skin autograft - Meshed split (BOAST4)	287		
Harvest Skin Graft - Other specified (BOAST4)	130		

Outcome data

Outcome data collected within TARN is of limited utility for those wishing to study open tibial fracture. The registry was initiated to model mortality risk (TRISS) as a performance indicator in victims of trauma. As such, the main outcome measure available for analysis within this dataset was mortality and was provisioned as a binary outcome measure, which confirms survival at 30 days following injury. The mortality data are not reported by individual hospitals but provisioned via linkage with the office of national statistics [17]. This methodology represents an accurate and holistic means of studying mortality rates, which circumvents issues with individual hospitals having to report mortality data even after the patient has left the hospital. Mortality is a rare event following open tibial fracture reported at 3.3% in this dataset; this analysis will consider risk factors for mortality with a focus on the role of comorbidity in mortality.

Beyond mortality, collection of outcome data by TARN is restricted to inpatient complications, length of stay data and number of surgical procedures. Whilst a series of 74 complications were captured, the most pertinent are shown in Table 2-7. One limitation is that complications are recorded against the individual and not the injury, site and laterality are not recorded, so it is not possible to determine which injury the complication has occurred in. An additional limitation of utilising inpatient complications is that whilst deep infection or osteomyelitis is recognised as a clinically significant complication, these infections tend to emerge beyond the acute stay window and thus cannot be measured by this dataset. Within the dataset early orthopaedic infection is reported at 1.8%, whilst in the wider literature deep infection is reported to occur in between 7 to 23% of cases [10, 20-23]. Furthermore, criteria or definitions of these complications are not provisioned by TARN, and is likely to be dictated by individual centres which will affect veracity. Whilst complication is an outcome measure within one section of the analysis, the above is acknowledged and the results interpreted with caution.

Table 2-7 outlines the complications that were considered for use in the analysis as these are all common complications following open tibial fracture. A decision was made to focus on infective complications as these are an established clinically relevant outcome measure after open tibial fractures [69]. From the 74 complications, the most relevant were: orthopaedic infection, graft infection and wound dehiscence. Each case reporting this complication was scrutinised for accuracy, and specificity to the tibial fracture. The outcome of this review was that wound dehiscence was normally not associated with the tibial fracture and therefore not used in the onwards analysis, however orthopaedic infection and graft infections was normally related to the tibial fracture and accurately reported. These two complications (orthopaedic infection and graft infection) were grouped under the heading “early wound complication” which was used as an outcome measure in 2.8.4.2.

Table 2-7: Occurrence of inpatient complications in patients with Gustilo 3B or 3C open tibial fracture reported by TARN

Complication	n (%)
Orthopaedic infection	38 (1.8)
Graft infection	16 (0.7)
Non union	2 (0.1)
Pulmonary embolism	8 (0.4)
Deep vein thrombosis	12 (0.6)
Wound dehiscence	6 (0.3)
Compartment syndrome	25 (1.2)
Total complications	92 (4.3)
Total patients	2157

TARN is funded to collect patient reported outcome measures (PROMS) from all patients included on their database and have ethical approval to share this data with researchers. An understanding of patient perspectives of outcome, measured by a validated PROM, was initially a primary focus of this project and is still deemed a relevant research question by the research team. Approval for use of this data was agreed as part of the data exchange contract and clearly documented. This approval was subsequently redacted and informally revised with a new instruction that PROMS data would only be released after TARN had utilised the data for Manchester led publications. Alternative methodology for collating outcome measures from patients was explored, but due to implications with information governance, these were deemed unfeasible and not pursued. Therefore, this analysis was limited to questions achievable within the available outcome measures.

Inclusion criteria for TARN

The inclusion criteria for the TARN registry aim to define a population who have sustained major trauma. This is defined based on two core criteria; individuals with an injury severity equal to or greater than 9 on the injury severity score.

1) All patients who have been admitted for trauma whose stay meets the following criteria:
    - length of stay is 3 days or more;
    - or is admitted to a High Dependency Area regardless of length of stay;
    - or deaths of trauma patients occurring in the hospital;
2) And whose injury severity score is equal to or greater than 9.

An open tibial fracture results in a minimum ISS of nine, with greater scores awarded in patients with multiple injuries; by default, these inclusion criteria force inclusion of all open tibial fractures sustained in patients in England and Wales.

2.4.4 Sensitivity analysis and data management

The dataset which was provisioned by TARN included the fields described above and are listed in full in appendix 8.4. The data was based on a select and extract query limiting results to records containing “*open*” AND “*tibia*” within a single field thus achieving a dataset which included all open tibial fractures on the registry. No limitations were placed on the search with regards to the patient population, and the search included all records from 1st January 1998 to 31st December 2017. The dataset provisioned to Nottingham included 16652 records. Whilst a complete dataset of 16552 records was received from TARN, this dataset was reviewed and reduced to improve the quality and control confounding.

Figure 2-2: Process of defining cohorts for analysis based on outcome of missingness assessment and sensitivity analysis.

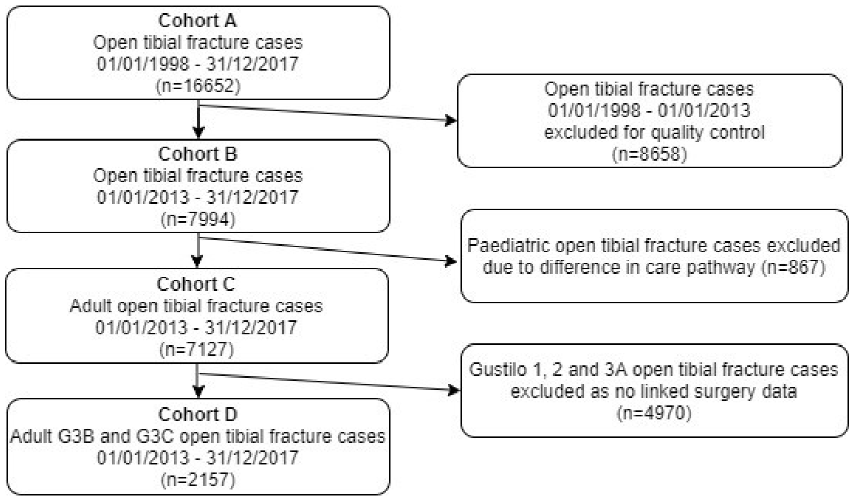


Figure 2-2 describes how cohorts were generated from the initial dataset of 16552 patients. Four cohorts (A, B, C, D) were outlined and differ by timeframe and inclusion criteria. Which cohort was used is outlined alongside each analysis. They are described below:

- Cohort A is the full cohort provided by TARN and included 16552 open tibial fracture cases admitted between 1st January 1998 and 31st December 2017. This cohort was not used in any analysis.
- Cohort B includes all open tibial fracture admissions between 01st January 2013 and 31st December 2017, and includes 7994 cases. The rationale for using a date limited cohort was the identification of directional bias which is explained in the sensitivity analysis below. The cohort was used in the incidence analysis where there was value in considering burden in children.
- Cohort C excluded paediatrics (<18). The cohort included all adult open tibial fractures admitted between 1st January 2013 and 31st December 2017, (excluding 832 paediatric cases) resulting in a 7127 patient cohort. This cohort was used in the comorbidity and mechanism of injury analysis.

- Cohort D was limited to Gustilo 3B and 3C fractures in adults admitted between 1st January 2013 and 31st December 2017. The cohort included 2157 cases. As described in 2.4.3 linkable surgery data was only available for Gustilo 3B/3C fractures, so in aspects of analysis where surgical data was needed unlinked cases were excluded to reduce error.

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [129] draw attention to the importance of acknowledging error within registry datasets, seeking to minimise it and reflecting on the impact of missing or erroneous data through sensitivity analyses. Table 2-8 summarises the demographics and missingness across the four cohorts outlined above and provided baseline insight into bias and missingness between the cohorts which was then explored further.

Table 2-8: Summary of demographics and missingness for the four cohorts outlined in above. Comparison of descriptive statistics for core cohorts allows for comparative analysis to consider bias in the dataset.

	Full cohort 1998-2017 (Cohort A)	Adult and paediatric 2013-2017 (Cohort B)	Adult 2013-2017 (Cohort C)	Adult G3B/3C 2013-2017 (Cohort D)
Age (mean, SD)	42.8 (22.4)	44.8 (22.8)	46.2 (21.0)	48.3 (20.4)
CCI (mean, SD)	1.01 (2.2)	1.1 (2.3)	1.21 (2.4)	1.22 (2.4)
GCS (mean, SD)	14.3 (2.2)	14.4 (2.0)	14.4 (2.1)	14.3 (2.2)
NISS (mean, SD)	18.5 (10.8)	18.5 (10.7)	18.7 (10.8)	20.6 (11.4)
>65 (%)	18.0	20.9	23.9	22.2
Gustilo 3B (%)	34.4	37.3	38.3	91.5
RTC (%)	53.7	50.8	49.1	52.7
Female (%)	31.5	33.7	34.7	27.2
Wound comp. (%)	1.8	1.3	1.4	2.6
Mortality (%)	3.0	3.1	3.3	2.2
Missing CCI (%)	11.2	7.0	7.0	5.8
Missing GCS (%)	7.0	4.7	4.5	3.5
Missing Gustilo (%)	39.4	22.4	21.2	0.0
	(n=16552)	(n=7994)	(n=7127)	(n= 2157)

The literature review in 2.3.2 outlined that financial incentives for registry compliance improves case ascertainment and missingness within records. Submission of data to TARN was not mandated, or incentivised (BPT), until April 2012 and we hypothesised that this change will have reduced error in the data. Annualised cases recorded on the registry are summarised in

Figure 2-3. The figure demonstrates large increases in annual cases until 2013 (intersect line) with a relative plateau beyond this; which indicates that introduction of BPT impacted case ascertainment. Of note, whilst BPT was introduced in April 2012 the number of admissions does not stabilise until 2013; the likely explanation for this is that audit requires significant training and resource, and the introduction of BPT does not embed as a change until 2013. Temporal trends were analysed to consider the impact of poor case ascertainment over time and are shown in Figure 2-4. The figure shows a generally stable dataset but there is an indication that older and sicker patients may have been omitted from the audit before mandated submission.

These temporal trends were tested statistically to explore bias due to poor case ascertainment. This was achieved by generation of an additional variable to compare the before-BPT group with a post-BPT group, continuous variables (age and NISS) were dichotomised. Odds ratios (OR) were obtained and found that the post-BPT group were significantly more likely to be female, older, have less severe injuries, and have a low energy injury mechanism, with odds ratios are reported Table 2-9. This difference is likely to exist as prior to mandatory audit participation, participation relied on local motivation and specialist interest. Specialist interest is more likely in referral centres which existed informally before the introduction of the MTC system; and as specialist centres they would receive more high energy cases leading to a directional bias in the data. After the introduction of mandated data entry centres complied with submission, thus reducing bias.

Table 2-9: Odds ratios for demographic differences before and post introduction of BPT. Odds ratios show that after BPT cases were less likely to be young, male, severely injured, or occur as the result of an RTC. 95% confidence intervals and p-value indicate that this finding is significant.

	Odds ratio	95% CI
Under mean age (42)	0.75	(0.70 – 0.80)*
Male	0.80	(0.75-0.85)*
NISS greater than mean (13)	0.89	(0.83- 0.96)*
Road Traffic Collision	0.85	(0.80 – 0.90)*
P<0.05		

Figure 2-3 Open tibial fracture cases recorded on TARN per annum, the dotted line indicates the first full year of BPT payments for data submission

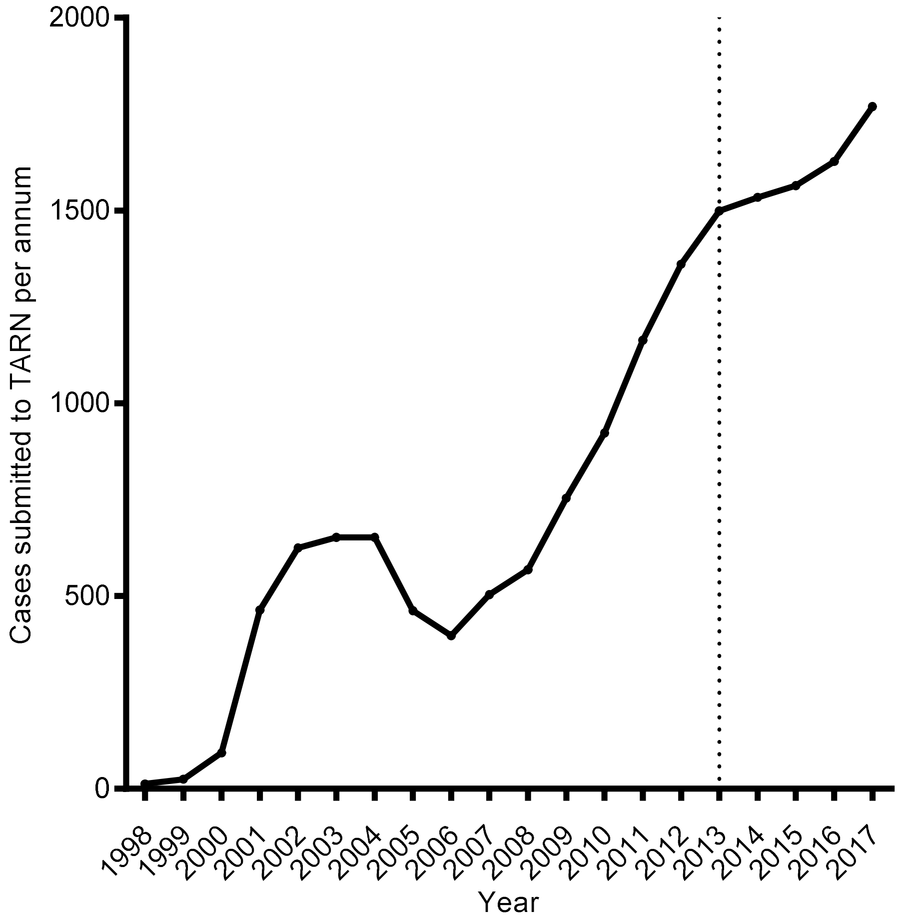
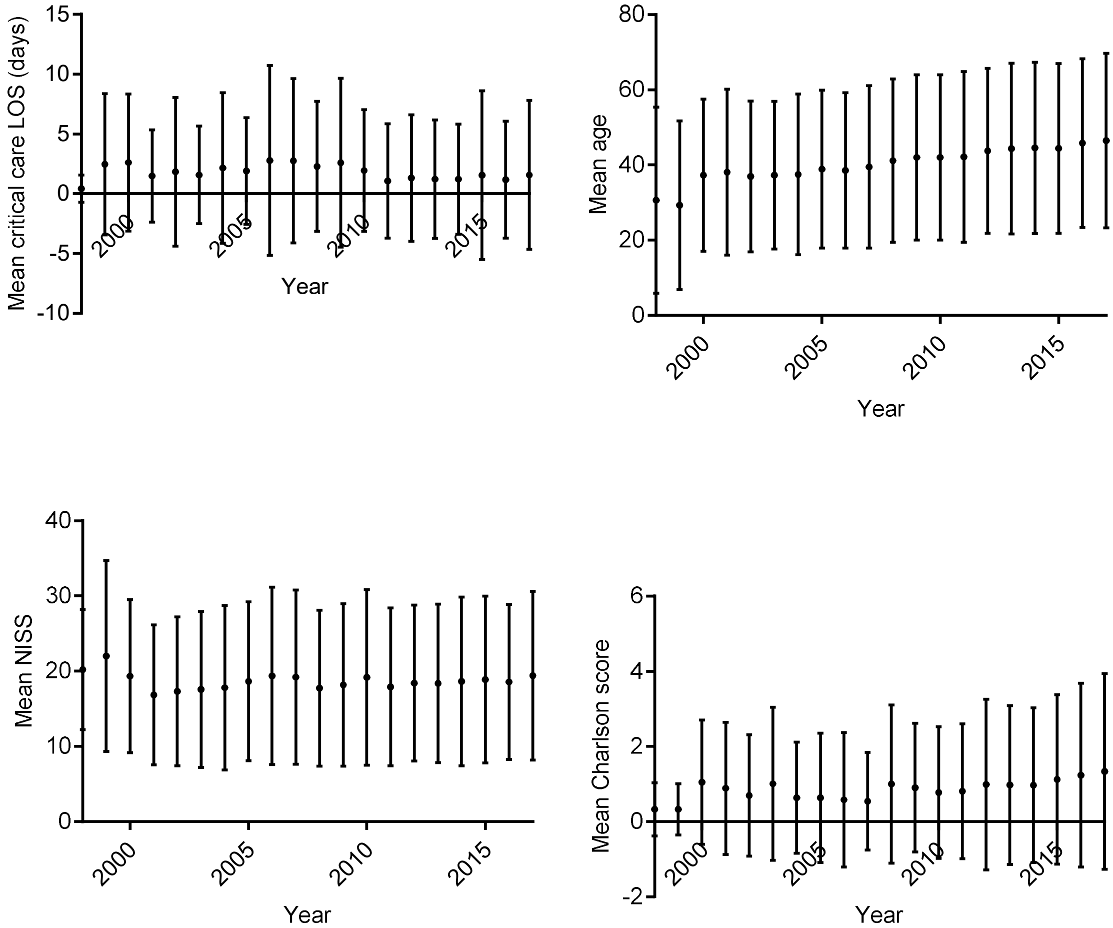


Figure 2-4 Top left) Mean critical care LOS. Top right) Mean age. Bottom left) Mean NISS. Bottom right) Mean Charlson score. Graphs shows mean and SD (shown on whiskers) of four core variables and change over time, analysis shows the presence of selection bias in dataset.



Version control also impacted the decision to restrict the dataset to a more contemporary window. The aims of TARN have evolved over time and with new demands the dataset has expanded, with fields such as Gustilo grade only being introduced into the dataset in 2012. Missingness is shown across the cohorts in as missingness is more prominent in the earlier data, exclusion of these records seemed appropriate. The conclusion from this analysis is that inclusion of data prior to 2013 is likely to introduce confounding and bias into the dataset and thus was considered unsuitable for onwards analysis. The datasets utilised are as pictured in Figure 2-2. Amongst the data retained, missingness within variables was still problematic in certain circumstances, percentage missingness for each variable was calculated for each cohort and where present the analysis included testing for bias as a consequence of missing data and is documented alongside the relevant analysis.

2.4.5 Statistical analysis

Each objective required tailored statistical techniques to reach substantive conclusions. An overview of these techniques is presented in this section, with specific details of the statistical methods employed presented alongside each analysis.

2.4.5.1 Descriptive analysis and normality testing

Descriptive statistics were used to summarise the baseline characteristics, clinical and patient-reported outcomes. Univariate analysis was used to explore the relationship between characteristics and outcome. Normality testing was used where deemed appropriate and guided onwards analysis.

2.4.5.2 Generalised linear models

Logistic and Poisson regression are used throughout this analysis; these models are useful for controlling the effect of confounding by including the confounder within the analysis. In generalised linear models, a transformation of the outcome variable is modelled, opposed to the outcome itself. For logistic regression, the linear model for the exposure variables is related to the outcome by the log odds function, for Poisson, it is the logarithmic function. Regression models were fitted using the maximum likelihood approach, and a standardised procedure [130, 131] was employed as described:

1) Descriptive analysis of the exposure and outcome variable was undertaken to explore the data; normality plots were conducted to explore distributions. Missingness within covariates was managed on a case-by-case basis, although standard approach was imputation of the mean paired with sensitivity testing to scrutinise for generation of bias in the results.
2) Crude odds ratios and their respective confidence intervals (CI) were calculated in isolation for each outcome and explanatory variable.

3) Influence of covariates in combination was explored using multivariable models.
4) Models were developed using a forward stepwise selection from the null model and then repeated using backwards regression from the full model to assess the effect of the direction of modelling on variables.
5) Inclusion in the model was determined by the amount of variation on the outcome variable they explained and their significance level. The threshold level for variation was a 10% change in the odds ratio; significance testing relied primarily on the Wald's test, and a threshold was set at $p<0.05$.
6) Potential multicollinearity was assessed for all variables (Pearson's correlation coefficient, Spearman's correlation coefficient, Pearson's contingency coefficient, variance inflation factor, as appropriate). Multicollinearity was assumed if the respective coefficients exceeded 0.4.
7) The linearity of log-odds was assessed for each continuous variable using design variables. Design variables were normally quartiles with three cut-points; however, a variation on this was used if it made clinical sense. To test whether the increase in effect on outcome was constant between successive levels of the variable, the model was tested, including either the continuous or categorical variable. The two models were compared using the likelihood ratio test (LRT). If there is a significantly better fit (LRT = $p<0.05$) when the variable is included as a categorical variable rather than the linear trend, the categorical variable will be retained in the final model as this result identified that the relationship between the exposure and the outcome is non-linear.

2.4.5.3 Statistical software

Microsoft Access was utilised as a data management tool to prepare data for analysis (Example SQL statements are included in appendix 8.5). All calculations were carried out with STATA version 15, College Station, TX: StataCorp LP (Example shown in appendix 8.6). Graphs were predominantly produced using both GraphPad Prism version 7 for Windows, La Jolla California USA.

2.5 Analysis

2.6 Epidemiology of open tibial fracture

2.6.1 Background

An open tibial fracture is recognised as a severe orthopaedic injury which is likely to have life-long implications for the individual; yet little is known about the epidemiology of this condition. The injury is frequently described as a “rare” injury although this conclusion is based on colloquial estimates; and the lack of basic information on frequency, incidence and mortality has implications for service planning and resource allocation. Previous estimates of incidence are based on data from an Edinburgh and Swedish registry [12, 13], the findings of these studies are discussed in more depth in section 1.2 where it was concluded that contemporary national data are lacking from the literature. To address this need, this study evaluates the incidence of open tibial fracture in England and Wales. This study utilises data from TARN to estimate the incidence of open tibial fracture between 2013 and 2017, stratified by age, gender and Gustilo grade. In addition, mechanism and patterns of concomitant injury were also evaluated.

2.6.2 Objective

This analysis addresses objective one: “To use a population registry to conduct a descriptive analysis of the incidence, baseline characteristics of the open tibial fracture population”.

2.6.3 Method

Crude incidence rates were calculated stratified by age, gender and injury severity, Poisson confidence intervals were also calculated. Poisson regression was used to model disease incidence rate ratios (IRR) from count data and as described in 2.4.5.2.

2.6.3.1 Census data

Population statistics were sought from census data overseen by the UK data service [132]. The UK data service project number for this study was 172930. Population statistics utilised were aggregated by age (5-year age band) and gender, and were based on data from the 2011 census.

For the incidence analysis the total population of England and Wales was used as the denominator.

2.6.3.2 Sensitivity analysis:

Selection of cohort: Three cohorts were included in this analysis. Cohort B (n=7994) was used in the incidence and frequency analysis to allow the inclusion of paediatrics. Cohort D (n=2157) was used to calculate incidence in Gustilo 3B/3C fractures. The rest of the analysis in this section used cohort C which includes all adult patients with an open tibial fracture (n=7127).

Gustilo Grade: Gustilo Grade is used in multiple points in this analysis. Missingness in this field is significant in cohort C (21%). To manage this; the impact of retaining and excluding the "Gustilo – not stated" on odds and frequencies was tested at each stage of this analysis and the outcome of testing documented alongside the analysis.

Mechanism of injury: To ascertain energy of injury, mechanism was categorised as per 2.4.3. Amongst the "other" category there is some subjectivity regarding the energy of injury. To manage this; the impact of retaining and excluding the "other" category on odds and frequencies was tested at each stage of this analysis and the outcome of testing documented alongside the analysis.

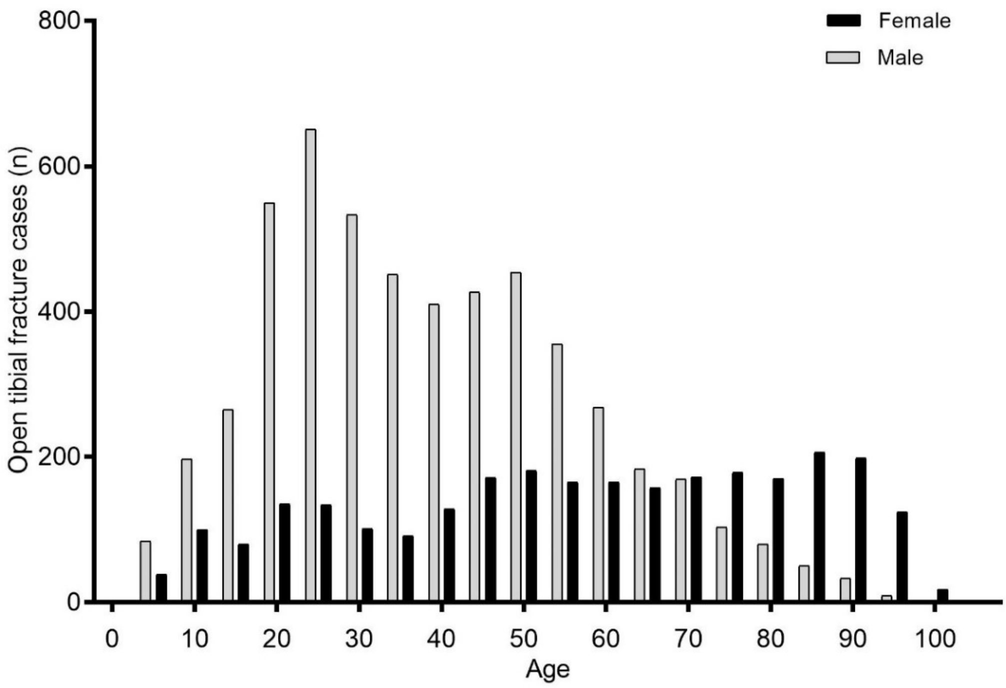
2.6.4 Analysis

2.6.4.1 Incidence of open tibial fracture

Seven thousand nine hundred and ninety-four patients were included on the TARN registry over a 5 year period ending on 31st December 2017. Crude incidence rate of open tibial fracture was 2.85 cases per 100,000 persons per year (CI 2.79-2.91). In men and women reported incidence was 3.83 (CI 3.72 – 3.93) and 1.91 (CI 1.84 – 1.98) cases per 100,000 persons per year, respectively for each gender. The mean age at presentation was 44.0 (SD 22.86).66.0% (n=5276) participants were male, and

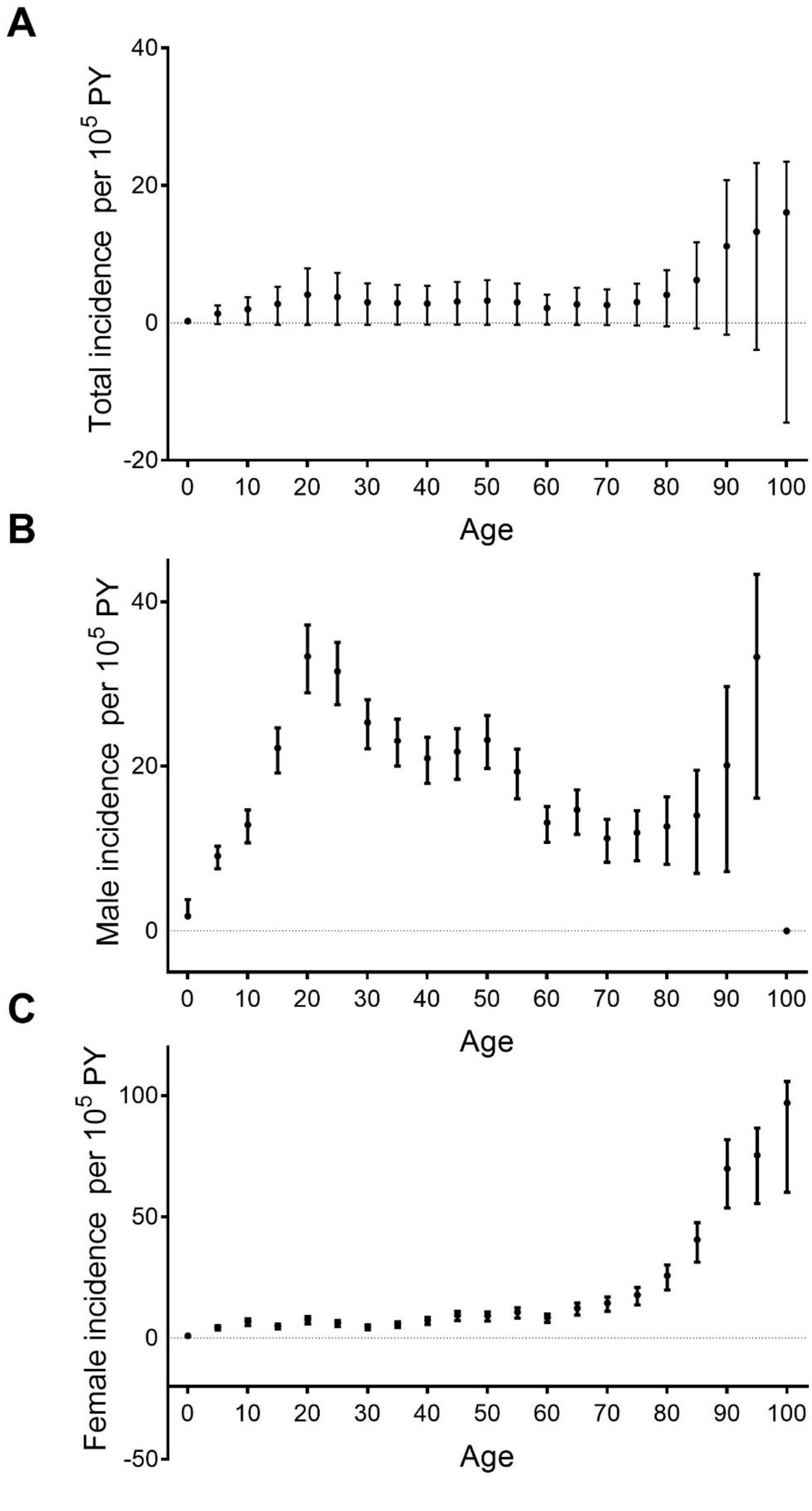
34.0% were female (n=2718). Frequency distribution in male patients is likely unimodal with a peak at 25 years with gradually declining frequency into older age, although debatably there is a second peak at approximately 50 years; the frequency in women is markedly less with a gentle positive correlation with increasing age and greater frequency in older women than older men, frequency distribution is reported as a histogram in Figure 2-5.

Figure 2-5 Age at presentation with open tibial fracture, grouped by gender



Incidence rate by age and gender is shown in Figure 2-6. Analysis of incidence highlights an important incidence in older patients, which is not apparent from the frequency graphs. The distribution of incidence in male patients is bimodal with the first mode around 20 years, and the second at 95 years; distribution in female patients show low and steady incidence until the age of 65 and a strong positive correlation with increasing age after this. Incidence by age when not stratified by gender is bimodal with a less significant peak at 20 years old and sequential increases beyond the age of 70 albeit in the setting of wide confidence intervals. Similar trends were observed when the analysis was limited to severe open fracture (Figure 2-12).

Figure 2-6: Variation in incidence rate (per 100, 000 person years) by age and gender (with Poisson CI). A) All incidence, B) Male incidence, C) Female incidence.



To provide additional oversight, these trends were analysed statistically in a mutually adjusted model using more clinically relevant age cohorts, this analysis supported the concept of a bimodal distribution with an incidence rate ratio of 0.35 (0.32-0.39), 0.87 (0.83-0.92) and 1.15 (1.09-1.22) for age groups of under 15, 40-65 and over 65 when compared to the 15-39.9 age category (Table 2-10).

Table 2-10 Poisson regression model of open tibial fracture incidence. All incidence rate ratios are mutually adjusted for all other variables in the table, the age category of 15-39.9 was used as the base category for age.

	Odds ratio	95% confidence interval
Sex (female)		
Male	2.04*	1.95 - 2.13
Age (15-39.9 years)		
<15	0.35	0.32-0.39
15-39.9	1	1
40–64.9	0.87	0.83-0.92
>64.9	1.15**	1.09-1.22

* $p<0.01$, ** $p<0.01$ for trend, $R^2 = 0.2$, n=7994

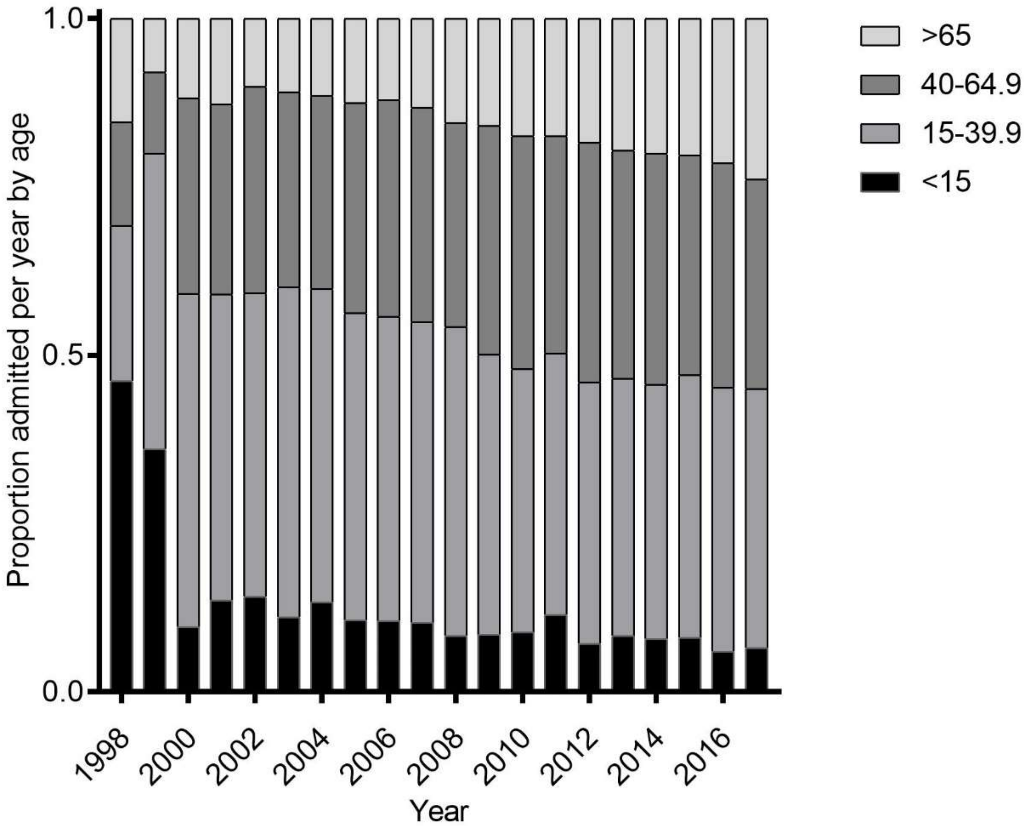
The literature identifies an increasing incidence of polytrauma in elderly patients, and would be an interesting question to ask of this dataset however longitudinal analysis is difficult due to questionable validity of data before 2013, which limits what can conclusions can be drawn. Nonetheless

Figure 2-3 outlined that case ascertainment has been relatively stable with good fidelity since 2013 supported by a firm infrastructure.

Figure 2-3 shows rapid growth in cases until 2013 which cannot be explained by epidemiology or public health; however, after data submission was mandated in 2013, there is a plateau with a small year on year increase in cases. Closer analysis shows this growth is within the older population (Figure 2-7), supporting the hypothesis of increased frequency of open tibial fractures due to a growing elderly population. Incidence was higher in the older patient group, and we would anticipate a correlation between an ageing population and the number of open tibial fractures.

This finding cautiously identifies a growing population of older patients with open tibial fracture, which has the potential to impact services.

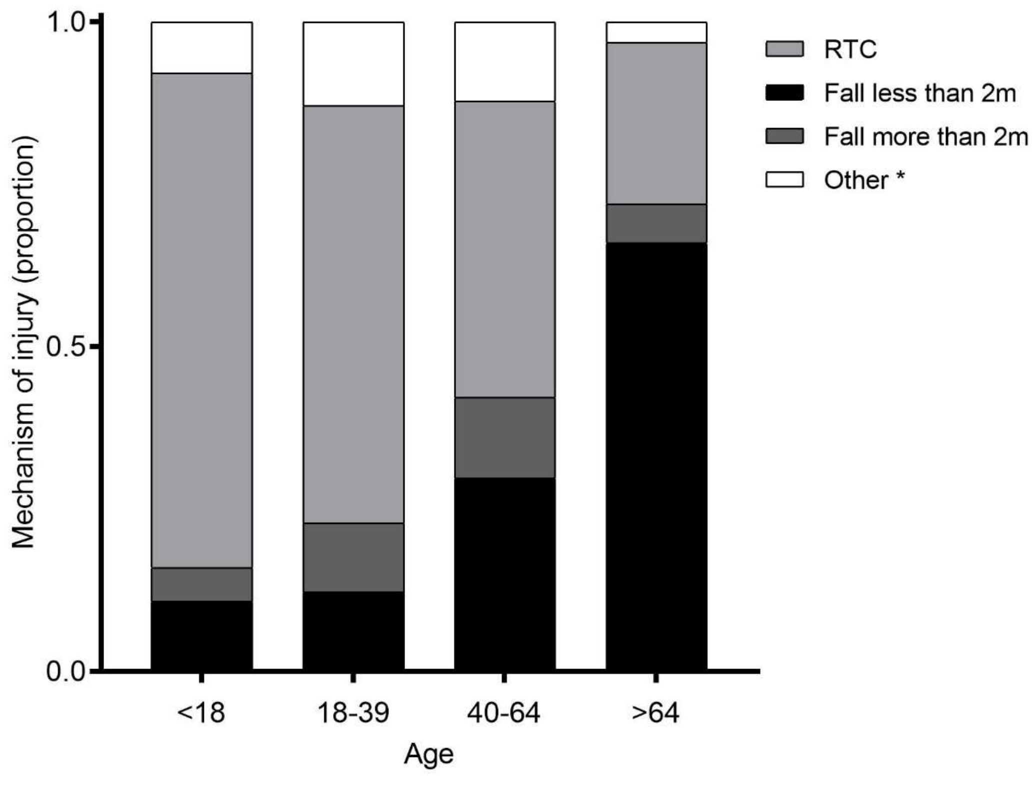
Figure 2-7 Open tibial fracture cases recorded on TARN per annum, grouped by age to consider the effect of an ageing population on the frequency and epidemiology of open tibial fracture



2.6.4.2 Mechanism of injury

RTC, fall from height and fall from standing height were the three most commonly reported mechanisms and the reported mechanism for 90.8% (n=7258) of injuries within the cohort of 7994 people. The remaining 10.2% (n=815) included a mix of blunt and penetrating trauma (including blow to the limb, crush injury and shooting) and are described as “other” henceforth). RTC was the reported mechanism in 58.2% and 24.8% in under and over 65s respectively, antithetically fall from less than 2m composed the next largest group and occurred in 20.3% vs 66.0% in under and over 65s respectively. High energy fall was more common in younger patients (10.5% vs 6.2%), as was the miscellaneous group (11.7% vs 3%). Mechanism of injury grouped by age is shown in Figure 2-8, this graph demonstrates the evolving patterns in mechanism with ageing, with a transition from more high energy mechanisms to low energy mechanisms in older patients.

Figure 2-8: Distribution of mechanism of injury by age, in patients with open tibial fracture presented as a proportion. *Other includes stabbing, shooting, blast, blow and crush .



Calculation of adjusted odds ratios to explore the relationship between age and mechanism was undertaken using logistic regression. The analysis showed that the adjusted odds of sustaining an open tibial fracture through a low energy fall was 12.53 times higher (CI 10.86-14.50) in individuals over 65 when compared with individuals aged 18-40, after adjusting for gender (1.13 (CI 1.12 – 1.13)). Patients aged 40-65 were also more likely to have a low energy injury when compared with patients aged 18-40, although this was only a ratio of 2.82 times greater (2.47 to 3.24). These findings are shown in Table 2-11 and support a hypothesis that in younger people these injuries are more typically associated with a high energy mechanism, but are also seen in older individuals generally as a result of a low energy injury.

Table 2-11 Odds ratios showing the relationship between aging and sustaining an open tibial fracture through a low energy mechanism, adjusted for gender.

	Odds ratio	95% confidence interval
Sex (male)		
Female	1.2	(1.08 - 1.34)*
Age group (18-39.9)		
40-64.9	2.82	(2.47-3.24)**
>64.9	12.53	(10.86-14.50)**

*p<0.01, **p<0.01 for trend, n= 7127

2.6.4.3 Patterns of concomitant injury

Figure 2-9 describes the patterns of injury according to the AIS. Based on the AIS, we identified that in 86.5% of cases the limb injury was the most severe injury sustained, although in a third of (29.3%) of cases an injury was sustained to an anatomical area other than limb highlighting the complexity of managing these injuries. The AIS does not reflect the impact of sustaining multiple injuries per body zone, relevant after high energy trauma where it is common to have multiple orthopaedic injuries. Instead this information is provided by NISS and the original diagnostic codes. The average ISS and NISS in this cohort was 9; higher NISS was associated with high energy injuries (Wilcoxon rank, z=-27.89, p<0.01, Figure 2-10). The coding which contributes to the NISS was studied and was used to aggregate data on long bone fracture and pelvic fracture which is reported in Table 2-12. This analysis identified that an open tibial fracture is an isolated fracture in 49.8% (n=3548) of cases. Concomitant tibial fractures are seen in 10.4% (n=743) of cases, and 5.0% (n=362) of patients have a bilateral open tibial fracture. 4.3% (n=306) of patients sustain a concomitant femoral fracture, 2.6% (n=187) are open. 8.5% (n=607) sustain an upper limb fracture, and 11.0% (n=818) experience a concomitant acetabular or pelvic fracture.

Figure 2-9 Patterns of concomitant injury based on AIS (%). The denominator is a cohort of 7127 adult patients who sustained an open tibial fracture.

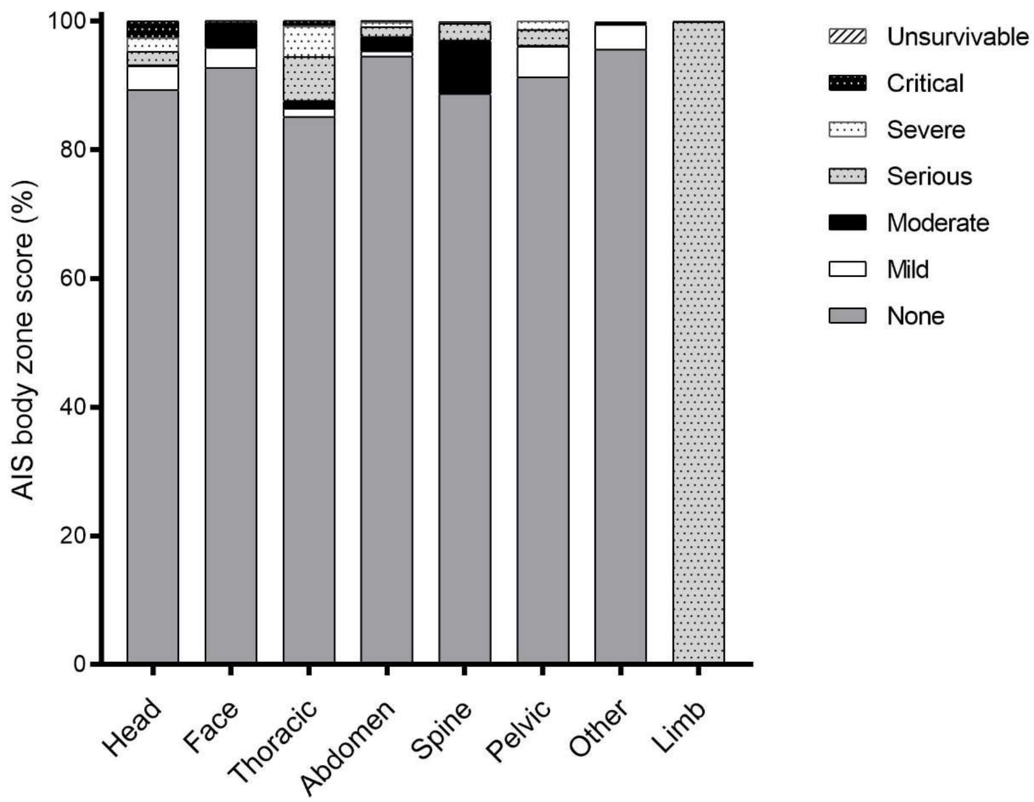
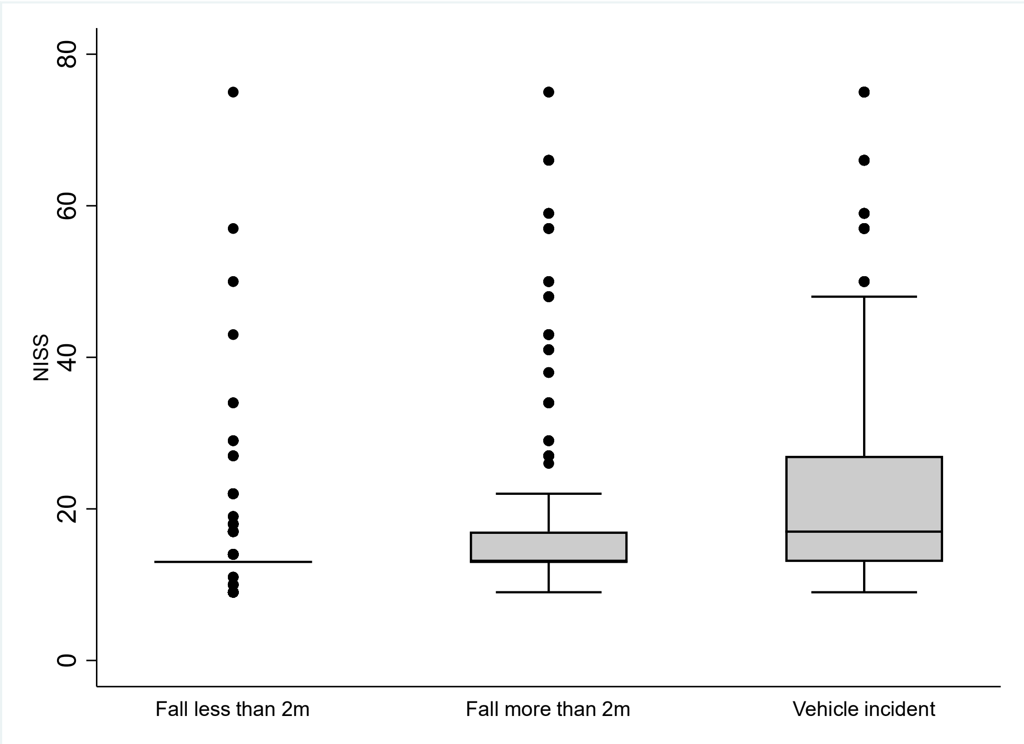


Table 2-12 Distribution of concomitant orthopaedic injuries, n (%)

Concomitant injuries recorded with open tibial fracture	
Tibial fracture	743 (10.4)
Closed	381 (5.3)
Open	362 (5.0)
Femoral fracture	306 (4.3)
Closed	119 (1.7)
Open	187 (2.6)
Upper limb	607 (8.5)
Humerus	258 (3.6)
Radius	349 (4.8)
Acetabular	248 (3.4)
Pelvic	570 (8.0)
Isolated tibial fracture	3548 (49.8)
Cohort	7127

Figure 2-10: NISS grouped by mechanism in adult patients with open tibial fracture. Plot shows IQR and median; whiskers show 95 and 5 percentiles.



2.6.4.4 Fracture severity based on Gustilo classification

Gustilo grade is used to document the severity of tibial injury. Figure 2-11 shows the frequency of graded cases and indicates greater frequency of grade 3 cases when compared with grade 1 and 2 fractures. Grade 3 fractures are associated with more extensive bony and soft tissue injury, this finding that more severe fractures occur at a greater frequency than grade 1 and 2 fractures allows for inferences with regard to the societal burden of these fractures. The odds of sustaining a Gustilo 3 fracture through a high energy mechanism was 75% higher (OR 1.75, CI 1.5-1.9) than low energy mechanisms. Patterns of age and gender incidence and frequency in high-grade Gustilo 3 fractures was similar to the picture presented for all open tibial fracture, although the incidence in the very elderly occurred at a lower rate in high-grade fractures (shown in Figure 2-12,

Figure 2-13).

Figure 2-11: Frequency of open tibial fracture per annum. Stacked bar shows spread of injury severity by Gustilo grade in 7994 patients

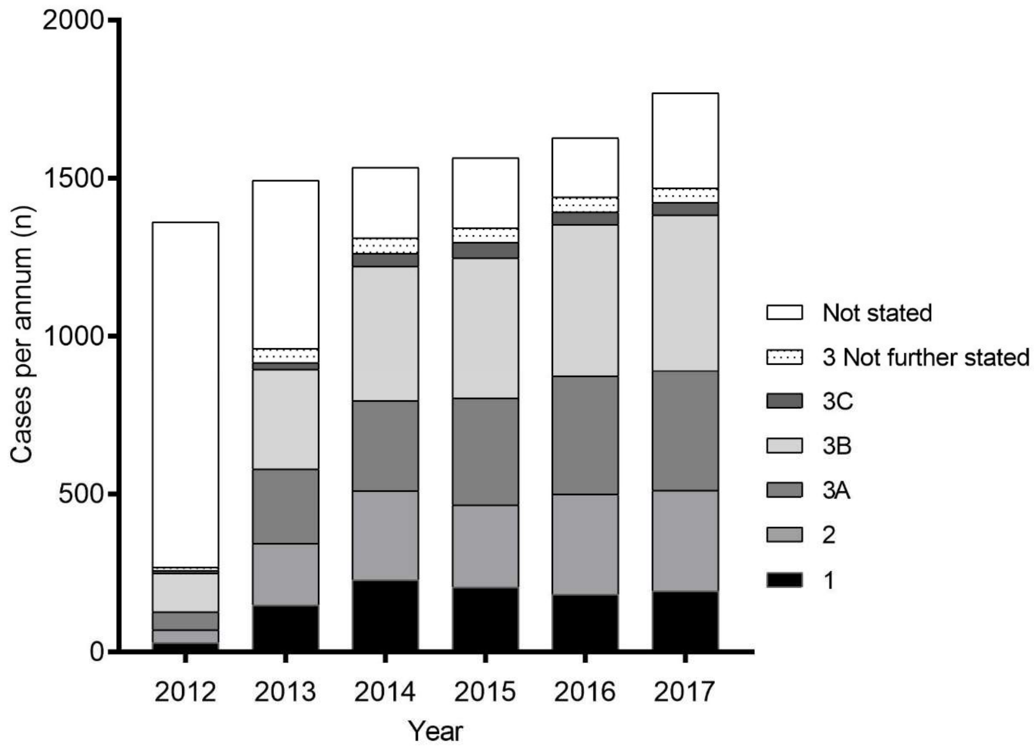


Figure 2-12 Incidence of Gustilo 3B/3C fractures (n=2157) (B) when compared to whole cohort (n=7994) (A). Incidence is per 100,000 person years (PY)

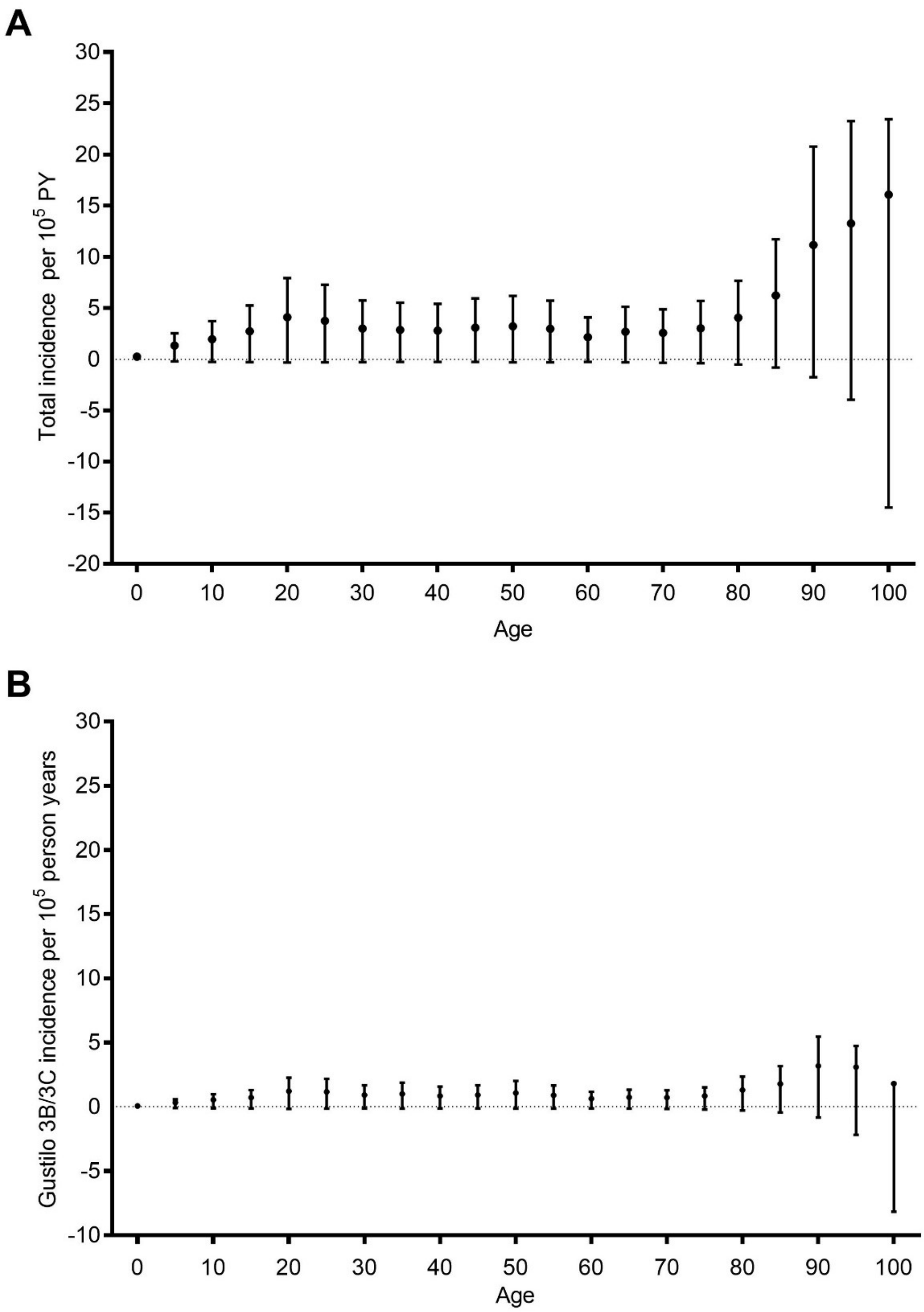
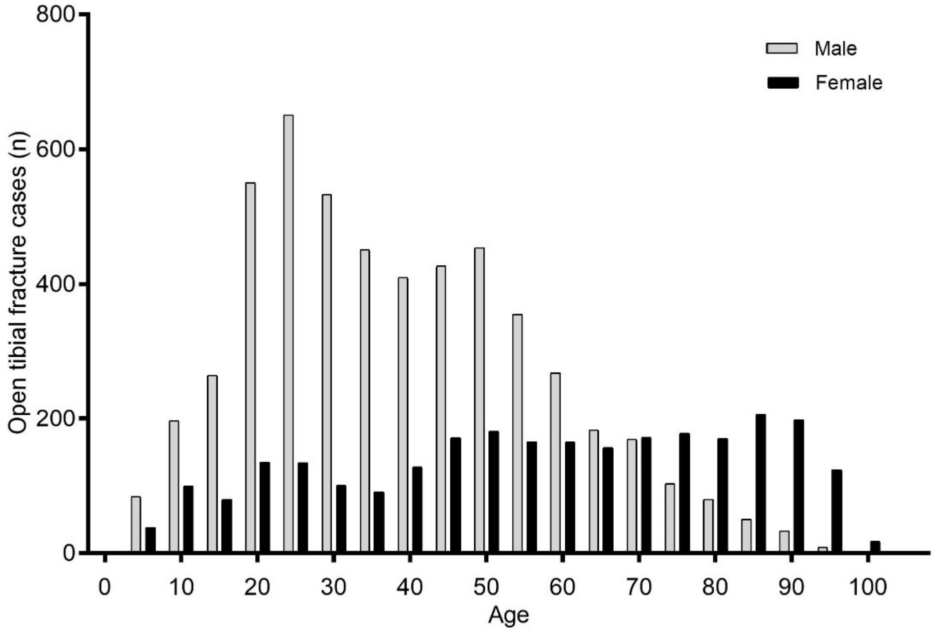
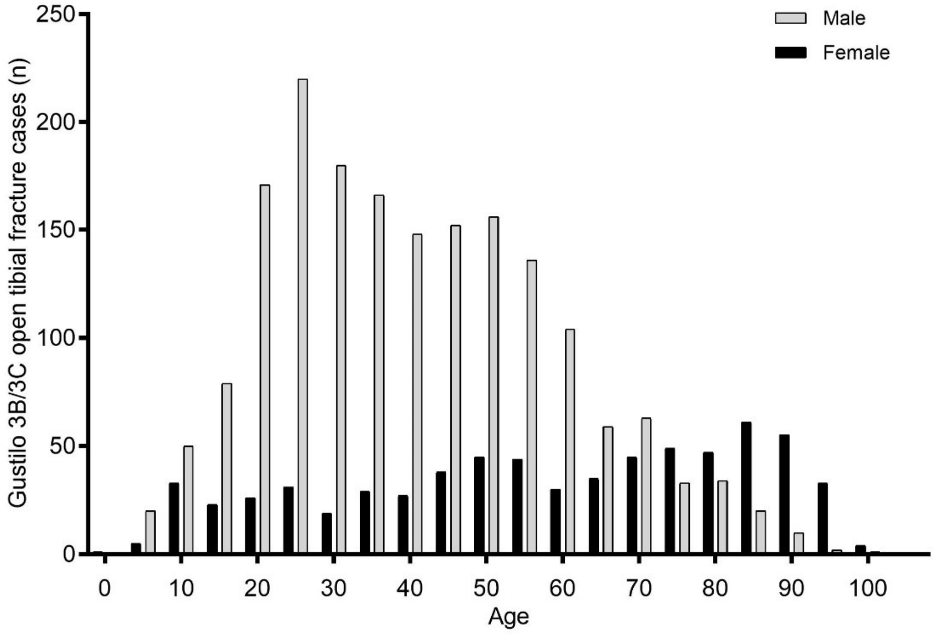


Figure 2-13 Frequency of Gustilo 3B/3C fractures (n=2157) (B) when compared to whole cohort (n=7994) (A).

A



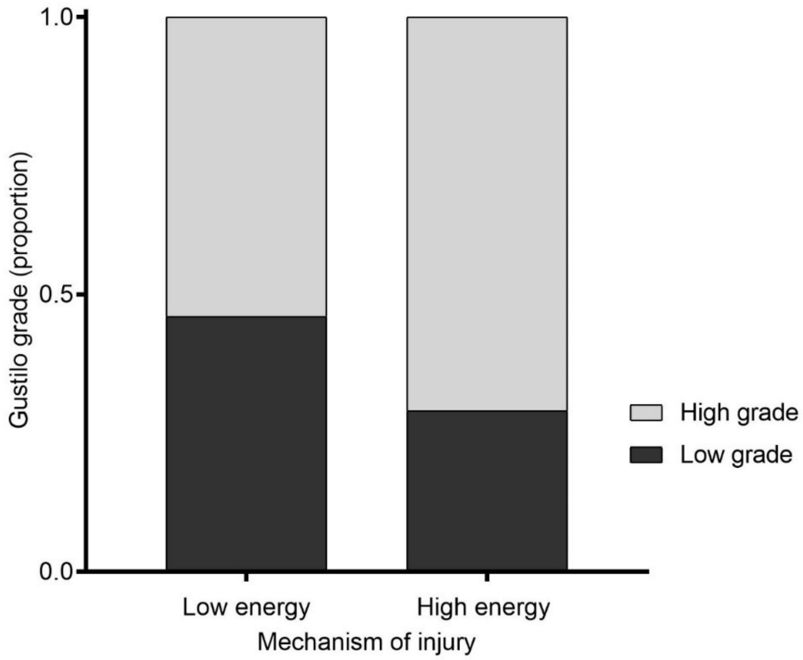
B



One of the defining characteristics of a Gustilo 3 fracture is a high energy mechanism. A theme of this analysis is injury burden in older people, whose fractures are typically associated with lower energy mechanisms. Amongst this inclusive dataset, we were interested in exploring whether the assumptions around high energy fractures and high Gustilo grade stood. To undertake this analysis, the energy of the injury were categorised as per 2.4.3 and sensitivity analysis was conducted to examine the impact of retaining and excluding the “other” group. Inclusion of the group had no impact on the overall odds, and there was no significant relationship between the “other” category and Gustilo grade (OR 1.09 (0.91- 1.31)). In addition, the impact of retaining and excluding cases with omitted Gustilo grade was checked; the “Gustilo – not stated” group was significantly different from the low grade and high grade Gustilo group, being more likely to be associated with a high energy mechanism than Gustilo 1 or 2 fractures (OR: 0.79, (0.66-0.89) but less likely to be associated with a high energy mechanism than Gustilo 3 fractures (1.44 (1.26-1.65). This suggests that whilst Gustilo grade is not missing at random; it is not a directional bias. For the analysis, those with Gustilo missing, or an “other” mechanism were excluded (n=812).

Those who sustained a Gustilo 3 fracture were 2 times more likely (OR 1.98, CI: 1.77-2.21), to do so through a high energy mechanism when compared with a low energy mechanism; this finding was retained when the analysis was limited to patients aged 65 or over (OR 1.86 CI 1.61 – 2.13). Whilst there was a relationship between Gustilo grade and energy of the injury there is significant crossover between the groups (show in Figure 2-14) which indicated that mechanism is not necessarily proportionate to soft tissue injury. This finding is consistent with the assumption that older patients with osteoporosis may sustain a greater bone and soft tissue injury with any given mechanism.

Figure 2-14 Proportion of low grade versus high grade Gustilo fractures in the setting of both low and high energy injuries.



2.6.5 Discussion

We estimate that the incidence of open tibial fracture is 2.85 cases per 100,000 persons per year. Incidence was significantly higher in men than women with 3.83 and 1.91 cases per 100,000 persons per year, respectively for each gender. When considering age; frequency was greatest amongst men aged 20 to 30, however incidence rate ratios indicated that incidence was significantly higher in those over the age of 65 (IRR 1.15) when compared to those aged 15 to 39.9. There was some evidence that incidence of open tibial fracture is increasing in the older population. Similar findings were apparent when the analysis was limited to Gustilo 3B and 3C fractures only. These rates indicate that whilst this injury predominantly affects individuals of working age, there is an important incidence in the older population. The mechanism of injury was different dependant on age group. Patients aged over 65 were 12 times more likely to sustain an open tibial fracture through a simple fall when compared to individuals aged 18 to 39.9. Younger patients were more likely to sustain injuries through car accidents, and higher energy mechanisms were associated with a greater NISS and Gustilo grade, likely to drive high disability after open tibial fracture in younger patients. Typically, a defining characteristic of the Gustilo 3 fracture is a high energy mechanism, yet this dataset demonstrates that fractures documented as Gustilo 3 were not exclusively high energy particularly amongst the older age group, and highlights the limitations of the Gustilo score particularly in an older population.

Existing epidemiological data for this injury is limited. Two previous studies have identified an incidence of open tibial fracture between 2.3 and 3.4 per 100,000 person-years in Northern Europe [12, 13]. One of these studies utilised the Swedish national dataset, whilst the second study was a single centre study originating from Edinburgh. Our findings of an incidence rate of 2.85 are complementary to previously identified incidence rates. The differences in reported rates are likely geographic; mechanisms of injury have regional differences and may also reflect differences in general health with known differences in life expectancy, healthcare organisation, and prevention strategies [133]. The Weiss study does report a frequency curve showing high frequency in the younger male population, but neither study presents age and gender-specific incidence rates for open tibial fracture. In a broader context, our findings are analogous with other recent studies which identify an older major trauma population who have not always previously been acknowledged [18, 134]. Within the existing open tibial fracture literature [10], interventional and cohort studies frequently exclude these patients due to the potential for confounding the data, and therefore they are to a degree under-reported. These patients represent an important subset of the open fracture population and strategies for management should be carefully considered in the context of an aging population.

The dichotomy between young and older patients was the focus of this study and the most interesting finding. The frequency was greatest in young men which is an important finding when we acknowledge that individuals have significant residual disability after these injuries. The predominant mechanism of injury in younger individuals was a RTC, risk-taking behaviours in young individuals reduce with age reflected in lower incidence in middle-aged adults [135] . Incidence of open tibial fractures in younger patients in the UK is likely to remain stable over the next decade. Improved road and workplace safety is likely to reduce serious accidents; however, these interventions and improving health systems may improve survivorship resulting in an increased number of these fractures requiring treatment, with an approximately stable picture overall. Globally there is forecast to be continued rises of RTCs secondary to industrialisation in developing countries.[16] Collectively these findings indicate a need to continue efforts to reduce serious accidents and also develop strategies to reduce disability after open tibial fractures in younger people. Whilst there is a clear burden associated with severe limb injury, it is also important to acknowledge rareness and the implications this has for optimising care. A difficulty of treating severe injuries successfully is the provision of specialist healthcare with a current focus on reducing low volume surgery [136]; in the setting of such a rare and complex injury, establishing and maintaining a dedicated specialist infrastructure will remain challenging.

Patients over 65 were significantly more likely to sustain an open tibial fracture than those in the 15 to 49 age groups who are most frequently associated with these injuries. The predominant mechanism for open tibial fracture in older people was a low energy fall, yet pathological processes result in a severe injury despite an insignificant force. Incidence increased incrementally with age, suggesting that muscle loss and fragility of soft tissues make older patients more vulnerable to open injury despite the low energy mechanism [15]. The findings from this study around the validity of the Gustilo grade are important. Gustilo [20, 21] defined Gustilo 3 as high energy, but there is significant crossover between the groups with many high grade injuries resulting from low energy mechanism. This reflects that much of what clinicians see is more complex than the energy of the injury and that mechanism is not necessarily proportionate to soft tissue injury. The Gustilo grade is the most widely used classification strategy in open fractures but has limitations.[24] The validity of the Gustilo grade in an older population has not been specifically addressed, this work suggests that where there is frailty the Gustilo grade is less useful for clinical communication and prognostication. Nationally the proportion of the population over 65 increases by 2.5% every 10 years [17] and based on limited analysis of secular trends our data suggests a degree of correlation between an aging population and the number of open tibial fractures reported. It is anticipated that in the next 20 years the size of the population aged over 85 will double [17]. As incidence appeared to be highest in this age group, this will correlate with an increase in the frequency of open tibial fracture in the absence of appropriate interventions.

This study presents a picture of the national epidemiology of open tibial fracture, grounded on reliable data from the census and a registry with an excellent track record of mandated case ascertainment, nevertheless there are several limitations. Longitudinal analysis was not possible due to poor case ascertainment prior to 2012. In addition, an anonymised dataset prevents geographical analysis and consideration of the social determinants of these injuries. A limitation of the method was that two datasets were not linked which introduced some error in the denominator. As with all registry methodology a small degree of classification error (i.e. ankle fractures coded as tibial fractures), and some relevant information (i.e. laterality of fractures) was omitted from the dataset which limited the analysis of concomitant injuries.

Prevalence estimates are used to understand societal burden of a condition and are often an expectation of an epidemiological analysis. Failure to provide them through this study is a limitation. Prevalence is the number of cases of a disease or condition present in a population at a given time. Prevalence estimates for this study would include all individuals who have ever had an open tibial fracture as most will experience some long-term or permanent sequelae; however defining prevalence in orthopaedic trauma is challenging as: “recovery” after trauma is poorly defined, trauma can recur, and trauma sequelae is cumulative. From TARN data, it was not possible to undertake a valid prevalence estimation so this was not attempted.

This study has presented several opportunities for future work. Further epidemiological studies to understand the secular trends of incidence would be beneficial to detect any reduction in the incidence of fracture amongst younger people and to observe increasing incidence amongst the older population. Spatial analysis to understand the geography of these fractures and their relationship to deprivation may also be of interest. Whilst ascertainment of prevalence estimates would provide useful insight into total societal burden. These analyses were not possible through TARN, but could potentially be achieved using the Clinical Practice Research Datalink (CPRD) which is a robust national primary care dataset. A limitation of the CPRD is that the coding held around open fracture is reportedly poor and this may limit the value of such an analysis [137]. The CPRD has previously facilitated linkage with other Department of Health registries, and a collaboration with TARN may be an opportunity for more extensive analyses [138].

This study presents novel data on the epidemiology of open tibial fracture in England and Wales in adults and children. The study confirms this is a rare injury which predominantly affects younger men involved in high energy accidents, but also identifies an important incidence in older patients which is likely to increase amidst an ageing population. The findings are relevant to those interested in designing clinical efficacy studies for open tibial fracture. Firstly, the rare nature of this injury has implications for the feasibility of any clinical trial and should be a consideration in power calculations and when defining eligibility criteria. Secondly, the high incidence of open tibial fracture in older individuals highlights an important research area, these individuals should not be excluded from clinical trials and finding best management strategies for older patients could warrant age-targeted trials.

2.7 Relationship between comorbidity and mortality after open fracture

2.7.1 Background

There is interest in exploring the risk factors for mortality after trauma, and in response to an ageing population, there is a focus on improving outcomes for older victims of trauma. The TRISS score [139, 140] is an established methodology for predicting the risk-adjusted mortality in a major trauma population and models risk based on Glasgow Coma Scale on admission (GCS), total anatomical injury (NISS), age and comorbidity (mCCI) [126]. The relevance of head injury and NISS in the open tibial fracture population is unclear, as there is a low incidence of concomitant head injury in this series and the orthopaedic injury predominantly drives the NISS. Our previous analysis identified an important older population who sustain these injuries, who are often not discussed within the literature and have been excluded from the larger trials [10]. There is a natural relationship between age and comorbidity, and we were interested in exploring the role of comorbidity in mortality after open tibial fracture.

2.7.2 Objective

This analysis addresses objective two: "Explore the relationship between comorbidity and mortality in adult patients who have an open tibial fracture".

2.7.3 Method

Univariate analysis and logistic regression modelling were used to analyse the data as described in 2.4.5.2.

2.7.3.1 Determination of variables

The TARN dataset includes multiple variables that could be perceived as confounders for mortality. The selection of variables for the model here was guided by TRISS, which is the most established mortality risk prediction model for trauma. In addition we tested variables specific to the limb, such as Gustilo grade, as these are potential confounders specific to open tibial fracture. Variables perceived to be of relevance were determined apriori. Variables tested included: age, gender, CCI, NISS, GCS, Gustilo grade, multiple open fractures and multiple lower limb injuries. These are described in greater detail in 2.4.3.

2.7.3.2 The linearity of independent variables and log odd

Several of the apriori variables were obtained as continuous variables (age, CCI, GCS, NISS). Linearity of log-odds was assessed for each continuous variable using design variables, as described in 2.4.5.2, point 8. There is a significantly better model fit (LRT = $p<0.05$) when we independently included age, CCI and NISS as a categorical variable rather than the linear trend. As a consequence, the categorical variables were retained in the final model as the relationship between the exposure and the outcome was non-linear.

There is a moderate positive relationship between age and comorbidity (correlation coefficient 0.34), although the interaction was independent enough not to breach collinearity assumptions.

2.7.3.3 Sensitivity analysis:

Selection of cohort: This analysis was completed using cohort C, a cohort of 7127 open tibial fractures in adult patients as described in 2.4.4. Paediatric patients were excluded, as they have very low morbidity, with different treatment approaches and different causes for and drivers of mortality.

Comorbidity index: The main explanatory variable for the study was mCCI. This variable reports 7.0% missing data. To manage missingness; an additional variable was generated, and simple imputation of the mean was used to populate missing data. Both variables were tested in the final model, and both models evaluated using a likelihood ratio test (LRT) to determine the impact of missing data on the final model.

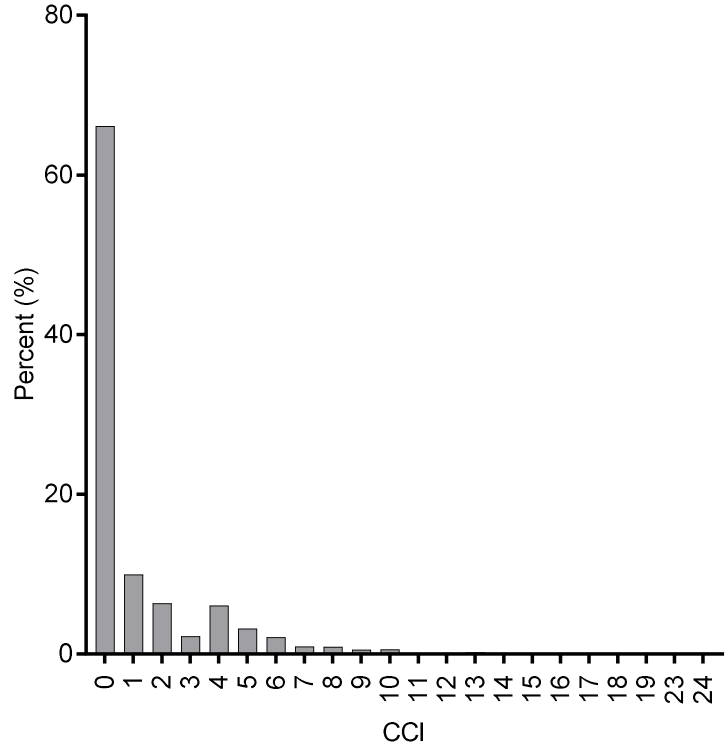
Glasgow Coma Scale: Missingness also impacted GCS score with 4.2% of scores missing. In the TARN dataset, it is anticipated that missing GCS reflects an intubated patient, and therefore imputation was not used to correct missingness; instead, the ordinal variable was converted to a categorical variable with intubated patients managed separately. Both the original variable and the categorical variable were tested in the final model with the most appropriate model retained based on goodness of fit.

2.7.4 Analysis

2.7.4.1 Relationship between comorbidity and mortality

The analysis included 7127 adult tibial fractures admitted between January 1st 2013 and December 31st 2017, broad demographics are as previously described in 2.4.4. The population is predominantly healthy male individuals who sustain a major injury through a high energy accident; however, 23.9% (n=1703) of this population consists of older people who are more likely to sustain low energy injuries and have additional medical problems which limit their capacity to recover from such a significant injury. CCI was 0 in 66.0 % (n=4703) of individuals, and only 10.3% (n=734) had a CCI of greater than 3. There is low frequency of comorbidity overall in these patients, but subgroup analysis shows that comorbidity tends to be associated with older patients (Figure 2-15). This is important in the context of an ageing population and an increased need to understand the trajectory of injury in this group.

Figure 2-15: Top) CCI in 7127 adult open tibial fracture patients (%). Bottom) Relationship between ageing and CCI in open tibial fracture patients



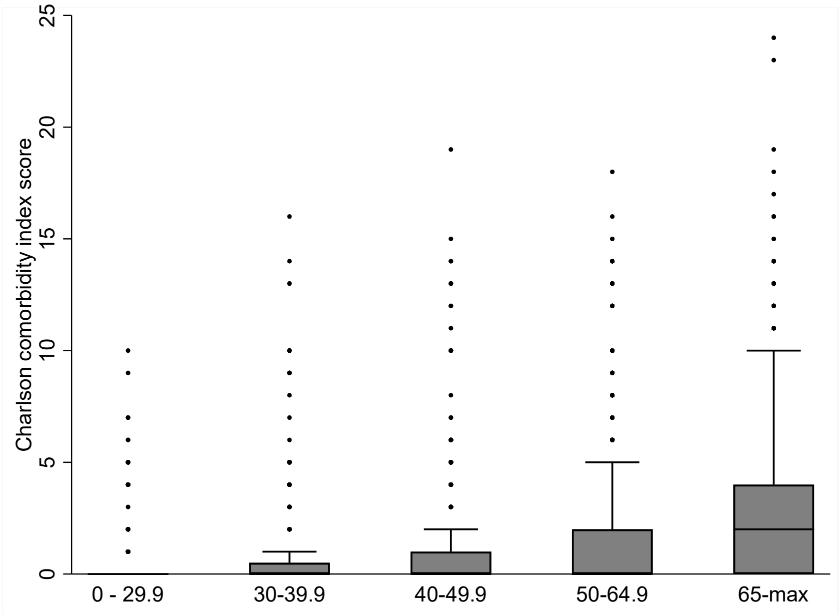


Table 2-13 Crude odds ratios (and confidence intervals) for mortality against patient and injury characteristics at 30 days in a cohort of 7127 adult open tibial fracture cases

	Odds ratio	95% confidence interval
CCI (0)		
1-2	0.95	(0.57 - 1.57)
3-24	2.34	(1.60 - 3.42)*
NISS (9-13)		
14-17	0.95	(0.56 - 1.58)
18-24	1.43	(0.80 - 2.57)
25-75	9.31	(6.69 - 12.95)*
Age (18-29.9)		
30-39.9	0.86	(0.46 - 1.58)
40-49.9	0.96	(0.54 - 1.71)
50-64.9	1.37	(0.83 - 2.25)
65-max	5.03	(3.37 - 7.51)*
Male sex		
Female	2.00	(1.54 - 2.59)*
GCS (13-15)		
Intubated	2.45	(1.30 - 4.61)*
9-12	6.97	(4.07 - 11.92)*
6-8	9.94	(5.35 - 18.4)*
4-5	26.26	(13.25 - 52.03)*
3	71.20	(47.59 - 106.59)*
Gustilo grade	1.19	(1.15 - 1.23)*
Open femoral fracture	4.25	(2.67 - 6.77)*
Bilateral open tibia	2.96	(1.85 - 4.72)*
p<0.01*, p<0.05**, n=7127		

Within our cohort, 3.29% (n=234) patients died within 30 days of admission. Variables perceived to be relevant in the context of mortality and comorbidity were determined apriori. Crude odds ratios were calculated for these factors and are reported in Table 2-13. All factors were significant. Amongst binary variables largest effect size was seen from a concomitant open femoral fracture, bilateral open tibial fracture and gender sequentially. Amongst discrete and continuous variable the largest effect size was apparent from GCS then NISS, age and comorbidity. 30 day mortality as a proportion amongst 5 of these variables is shown in Figure 2-16.

Figure 2-16 Crude mortality rate in 5 variables eventually significant in the fully adjusted model presented against 30 day mortality as a proportion of the 7127 patient population A) Age, B) CCI, C) Gender, D) GCS, E) NISS.

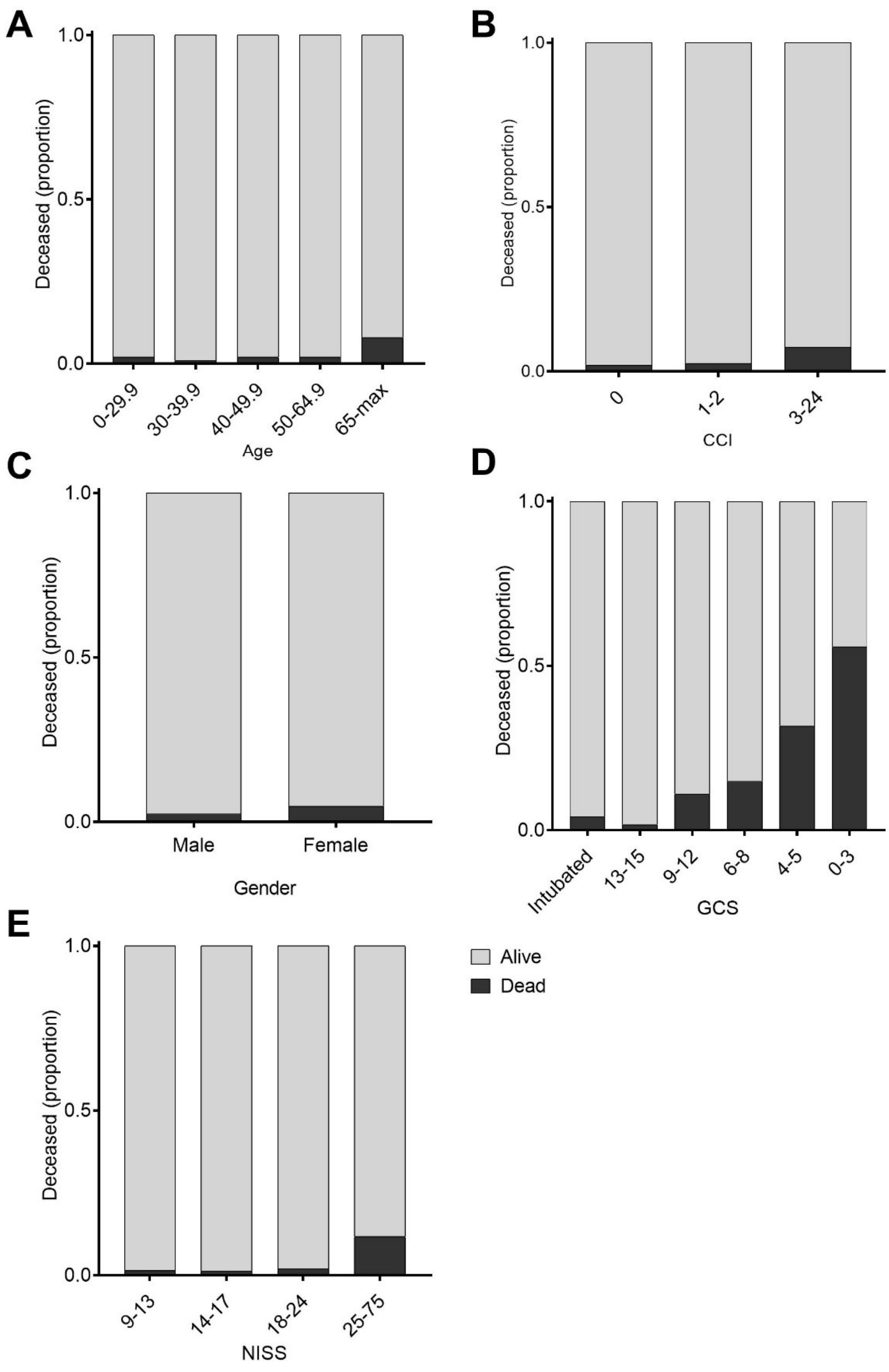


Table 2-14 Adjusted odds ratios and confidence intervals (final regression model) for 30 day mortality against patient and injury characteristics in a cohort of 7127 adult open tibial fractures

	Odds ratio	95% confidence interval
CCI (0)		
1-2	0.95	(0.57 - 1.57)
3-24	2.34	(1.60 - 3.42)*
NISS (9-13)		
14-17	1.12	(0.67 - 1.88)
18-24	1.81	(0.97 - 3.38)
25-75	4.99	(3.16 - 7.87)*
Age (18-29.9)		
30-39.9	1.00	(0.45 - 2.22)
40-49.9	1.46	(0.67 - 3.17)
50-64.9	3.08	(1.54 - 6.15)*
65-max	13.87	(7.27 - 26.50)*
Male sex		
Female	1.67	(1.15 - 2.42)*
GCS (13-15)		
intubated	2.19	(1.01 - 4.75)**
9-12	5.15	(2.54 - 10.04)*
6-8	9.07	(3.86 - 21.33)*
4-5	21.95	(8.43 - 57.15)*
3	71.70	(37.94 - 135-49)*

$p<0.01$*, $p<0.05$**, $R^2 = 0.34$, n=7127

Adjusted odds ratios (Table 2-14) obtained from a logistic regression model identified that a higher CCI was associated with increased mortality and that the odds of death were 2 times greater (OR 2.34, 1-60 – 3.42) in patients with a comorbidity score of greater than 3. The proportion of fatalities was also predicted by age; age did not significantly impact the odds of death in those aged under 50; however patients 50-65 and over 65 were three (1.54 – 6.15) and 14 (4.27 – 26.50) times more likely to die as a consequence of open tibial fracture than younger patients. NISS also increased odds of death in individuals with a NISS of greater than 25 (OR 4.99 CI 3.16 – 7.87); as did a GCS of less than 13 at time of injury and female gender (OR 1.67 CI: 1.15 – 2.42). Each retained factor adjusted the crude odds of CCI, although this was within 10% change. Several factors such as Gustilo grade, multiple open fractures and multiple lower limb injuries were tested for inclusion in the model but were not retained as were not significantly related in the adjusted model. The analysis identifies a relationship between comorbidity and mortality in open tibial fracture patients, yet also a complex relationship with multiple variables contributing to outcome.

2.7.5 Discussion

This analysis identifies a relationship between comorbidity and mortality after open tibial fracture and acknowledges that the causes of mortality after open tibial fracture are complex and multi-factorial. Individuals with greater comorbidity as measured on a mCCI were more than twice as likely to die than those with no or minimal comorbidities. The study utilised established risk factors for mortality after trauma to obtain an adjusted risk for comorbidity, and from this, we also understand that injury severity, reduced GCS, and age were also predictors of mortality.

The findings reported in this study are relatively novel. A study by Weiss [3] based on a Swedish registry of 3777 patients considered mortality after open tibial fracture; the study focused on 90 day and 2 year mortality and a mortality rate of 2% at 90 days is lower than the 3.2% reported in our study at 30 days. The study attempts to model risk factors for mortality, identifying mechanism, age, length of stay and amputation as predictors of death. The usefulness of this is limited as several factors (length of stay and amputation) are on the causal pathway, the authors acknowledge that being unable to access variables such as ISS and comorbidity is a limitation of their study; and no other studies were identified which considered the role of comorbidity in mortality after open tibial fracture. More relevant data comes in the wider trauma literature where comorbidity and age has previously been recognised as independently associated with mortality following trauma [141-145]. Work by the TARN registry identified the value of augmenting existing TRISS [139, 140] models with the CCI to improve outcome prediction and developed a modified CCI to include medical comorbidities prevalent in the trauma with adjusted weightings [126]. When compared with the broader trauma population, 30-day mortality in our analysis was lower, (3.2% versus 7% in [126]), but finding broad agreement regarding the relationship between comorbidity and mortality, is useful for the generalisability of this analysis.

This study has several limitations. We have endeavoured where possible to control for confounding factors, although it is likely that residual bias exists. The TARN database is an established and inclusive dataset for modelling mortality. However, there are criticisms of the TRISS methodology [139, 140] with regards to the discriminative ability of the model, and in some regards, the model is a crude appraisal when considering the drivers of mortality. In respect to the data collected, there is anticipated challenges with collecting comorbidity data in a trauma setting, and these figures may be to a degree under-estimated.

An additional limitation is that this study focuses only on 30-day mortality. This was a limitation of the dataset provided as TARN are unable to provide date of death as this is an identifiable characteristic. In the context of a question which focuses on mortality, one would anticipate a cox-proportional hazard model and associated survival analysis, which would allow for evaluation of the evolving risk of mortality over time. A shorter period of follow-up may increase the weighting of injury factors in outcome, whilst longer-follow-up may result in age having a stronger association [146, 147]. Our failure to provide these statistics limits the usefulness of these findings and longitudinal analysis of mortality would provide further insight into the patterns of mortality after open tibial fracture.

Considerations for further work could focus on different confounders previously demonstrated as relevant to trauma outcomes. The Nottingham Hip Fracture Score (NHFS) [148, 149] is an example of a score intended to risk model mortality in a trauma population; it has been validated yet presents a very different model to TRISS [139, 140]. TRISS was intended to be utilised in a non-selective high-energy trauma population, and likely underestimates the role of medical comorbidity and frailty in the outcomes of trauma. Extrapolation of the NHFS to an open tibial fracture population may provide greater insight and a useful clinical tool for those involved in the management of comorbid patients with open tibial fracture. This is a novel study which considers the impact of comorbidity in patients who sustain an open tibial fracture and identifies that these patients are at greater risk of mortality. There is scope for further studies which evaluate the impact of comorbidity on outcomes after open tibial fracture.

2.8 Evaluation of national practice and impact on early outcomes

2.8.1 Background

There is an identified need to improve outcomes for patients with open tibial fracture. The current BOA [28] guidelines for open fracture management consist of 19 standards based on best evidence which are intended to guide practice. It could be proposed that existence of these guidelines should result in improved outcomes for individuals via the Hawthorne effect [150]; however compliance with these guidelines and the impact of these on outcome has not been evaluated. Compliance with these indicators is measured by the TARN audit. The intention of this analysis is to summarise current practice in the UK and report this in the context of the BOA indicators, considering the relationship of these indicators to early outcome.

The quality indicators vary in their measurability and clinical significance, two quality indicators of particular interest were selected for onwards analysis:

- Standard 1: Open fractures of long bones should be taken directly or transferred to a specialist centre that can provide orthoplastic care.
- Standard 14: Definitive soft tissue closure or coverage should be achieved within 72 hours of injury if it cannot be performed at the time of debridement.

The BOA guidelines were most recently updated in December 2017 [28], and drew a specific impetus to the requirement for specialist care; the literature informing this guideline is reviewed within the introduction chapter (1.4). Whilst perceived to be of importance, the existing literature does not indicate to what extent this benchmark is being achieved within England. The TARN data is an ideal resource for exploring the distribution of caseload within the UK to determine the impact of non-specialist practice.

Management of soft tissue defects associated with a severe open fracture presents a clinical challenge and an important question remains regarding the prognostic impact of temporal factors. These were summarised within our introduction chapter (1.4.3). The BOA guidelines suggest definitive soft tissue cover in 72 hours, with an addendum that immediate flap protocols should be used where possible. Early soft tissue reconstruction presents a series of infrastructure challenges for centres and can be difficult to achieve. This analysis intends to explore compliance with the BOA guideline nationally, and the implications of non-compliance.

2.8.2 Objective

This analysis will address objective 3: "Identify a national picture of treatment patterns and considering the relationship between key quality markers (i.e. time to definitive soft tissue closure or coverage) and short-term surgical complications."

2.8.3 Method

Univariate analysis and logistic regression modelling were used to analyse the data as described in 2.4.5.2.

2.8.3.1 Determination of variables for descriptive analysis

Site of attendance and surgical data was utilised to obtain a descriptive analysis of practice in England and Wales. The TARN dataset includes detailed coding of surgical procedures, our approach to this data is as detailed in 2.4.3 (under surgical procedures). All other data utilised is outlined in 2.4.3.

2.8.3.2 Determination of variables for regression model

The TARN dataset includes many complications which could be utilised to assess early outcome, the usefulness of many of these is limited, and after close consideration "early wound complication" was the outcome measure selected for this analysis. An overview of complications, the rationale for choosing "early wound complication" and the data management process for this variable is described in 2.4.3 under the heading outcome data.

There are multiple variables that are confounders for treatment outcome and exposure. In the selection of variables for the model, various characteristics of the patient, injury, and treatment were included. Variables tested included: age, female gender, CCI, NISS, GCS, Gustilo 3C, bilateral open tibial fracture, open femur fracture, surgery in two hospitals, time to debridement, definitive external fixation, flap closure, delayed wound closure, definitive soft tissue cover within 72 hours and time to soft tissue cover. Where further clarification is required, greater detail is provided in 2.4.3.

2.8.3.3 Linearity of independent variables and log odd

Several of the apriori variables were obtained as continuous variables (age, CCI and, NISS). Linearity of log-odds was assessed for each continuous variable using design variables, as described in point 8 of 2.4.5.2. There was no significant difference in the better model fit (LRT = $p>0.05$) when we independently included age, CCI and NISS as a categorical variable rather than the linear trend. As a consequence, the continuous variables were retained in the final model.

The relationship between time to soft tissue coverage was explored as both a continuous, categorical variable (quintiles) and binary variable (72-hour cut-point). The value of three iterations of the variable was to explore the potential for a non-linear relationship and to recognise the importance of the 72-hour guideline when answering this question. There was no difference in fit between the of the continuous and quintile model (LRT $p>0.05$), so the continuous variable was retained in the final model. The final adjusted model was tested twice with both the binary and continuous variable for completeness. Tests for multi-collinearity indicated a low level of multi-collinearity.

2.8.3.4 Sensitivity analysis:

Selection of cohort: This analysis was conducted using a cohort of 2157 open tibial fractures which have are confirmed as having either a Gustilo 3B or 3C fracture. These were chosen due to the availability of linked surgery data.

Missing data within field: All fields were checked for missing data, missing data was handled through additional variable generation, and simple imputation of the mean to populate missing data. Both variables were tested in the final model, and both models evaluated using a likelihood ratio test to determine the impact of missing data on the final model. In some cases, it was hard to identify whether data were missing (i.e. where a trauma unit had failed to enter data, but some data had been entered by the MTC).

162 cases from cohort C failed to include the method or time of definitive closure or fixation. A further 179 cases had primary amputation and this data was purposely not captured. Some of the below analysis is specific to the reconstruction pathway, and where the aforementioned fields are necessary to the analysis cases were excluded and an adjusted denominator used.

2.8.4 Analysis

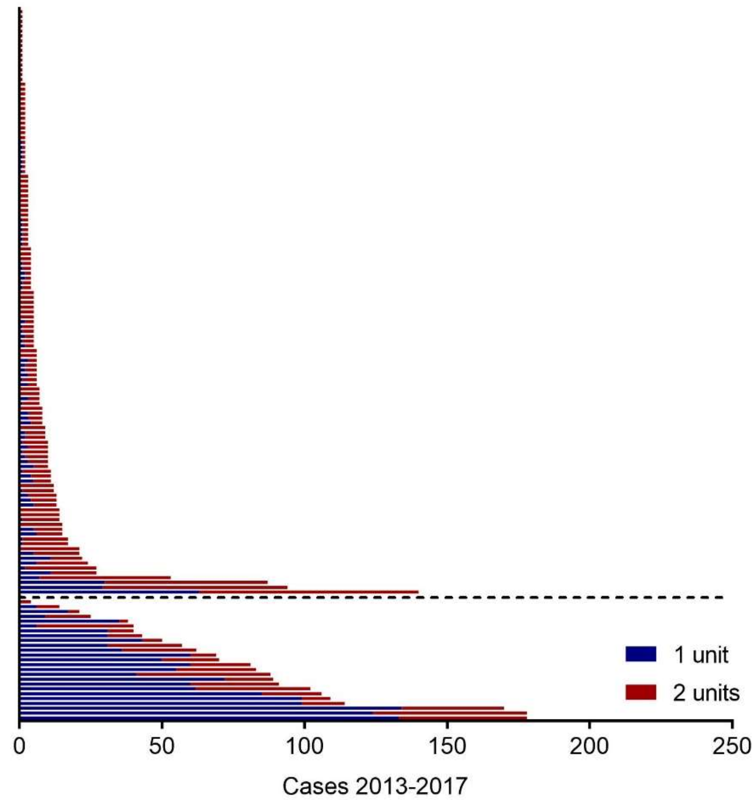
2.8.4.1 Standard 1: Open fractures of long bones should be taken directly or transferred to a specialist centre that can provide orthoplastic care.

This analysis was limited to 2157 patients who sustained the most severe injury to the tibia (Gustilo grade 3B and 3C injuries). The demographics of the patients were similar to our core cohorts, with a mean age of 46 (SD 20) and 27% of the population were female. Comorbidity affected 25% of patients and only 5% had a CCI of greater than 6. Average NISS was 11 (SD 11). This analysis was limited to individuals with at least one Gustilo 3B or 3C tibial fracture. Demographics are also described in Table 2-8.

148 units had reported data to TARN, 25 (16.8%) of which were major trauma centres, Figure 2-17 describes the distribution of caseload across England and Wales between 2013 and 2017. The majority of care was delivered in a MTC setting; over the period 88% of patients were admitted to an MTC at some stage of their care, whilst the remaining 12% were managed solely in trauma units. A small number of trauma units were unusual in that they had large caseloads compared to many MTCs. An explanation for this is that some large trauma units are appropriately equipped to deliver an orthoplastic service despite not being an MTC. A very low volume caseload was reported by a small number of trauma units. Despite clinical guidelines recommending early transfer, 10% of patients had surgery at two hospitals, surgery across two units prevents specialist input across the entire patient pathway and has perceived implications for the individual.

There was no significant relationship between sole management in an MTC and wound complications (OR: 0.73, CI: 0.42-1.29); similarly, surgery in multiple hospitals did not result in an increased incidence of complications (OR: 0.88, CI: 0.37 – 2.08). However, patients having surgery in multiple hospitals did have significantly more surgical procedures (Wilcoxon $z=-6.7$, $p<0.01$) and a significantly longer length of stay (Wilcoxon $z=-3.7$, $p=0.02$) when compared with individuals only having surgery at one hospital.

Figure 2-17: Caseload per centre between 2013 and 2017. Blue are cases managed in one unit, red cases involve a transfer. MTCs are shown below the line, trauma units are above the line.



In Gustilo 3B and 3C fractures nationally the most common definitive surgery was internal fixation (57.5% (n=1148). When divided into two separate groups, the most common surgery for 3B fractures was fixation (58.7% (n=1063)), whilst in 3C fractures the most common management strategy was amputation (47% (n=77)). Those with Gustilo 3C injury were 17% more likely (OR: 1.17, 1.09-1.25) to require an amputation than 3B injuries. These patterns are shown in Figure 2-18. With regards to soft tissue cover, a free muscle flap was used most commonly and in 36.8% (n=727) of cases, with local flaps being used in 20.5% (n=406) of cases. 33.7% (n=666) were managed with local coverage alone; this is reported in Table 2-15.

Figure 2-18: Distribution of definitive surgery. A) All Gustilo 3B/C fractures. B) Gustilo 3B fractures. C) Gustilo 3C fractures

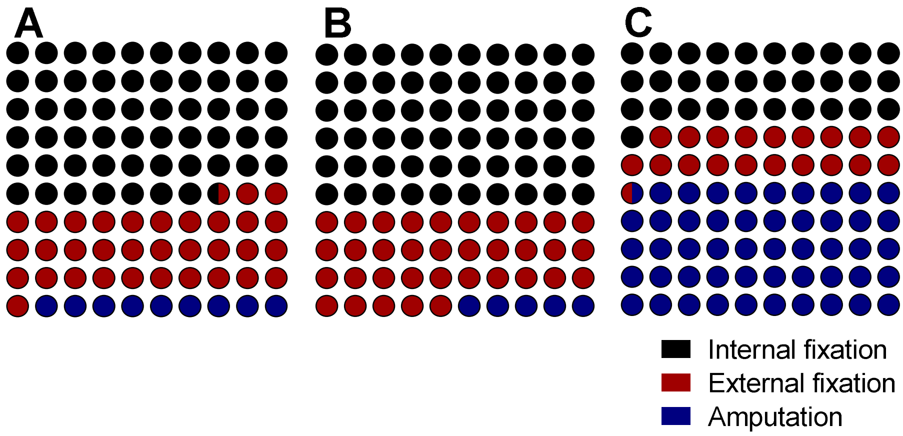


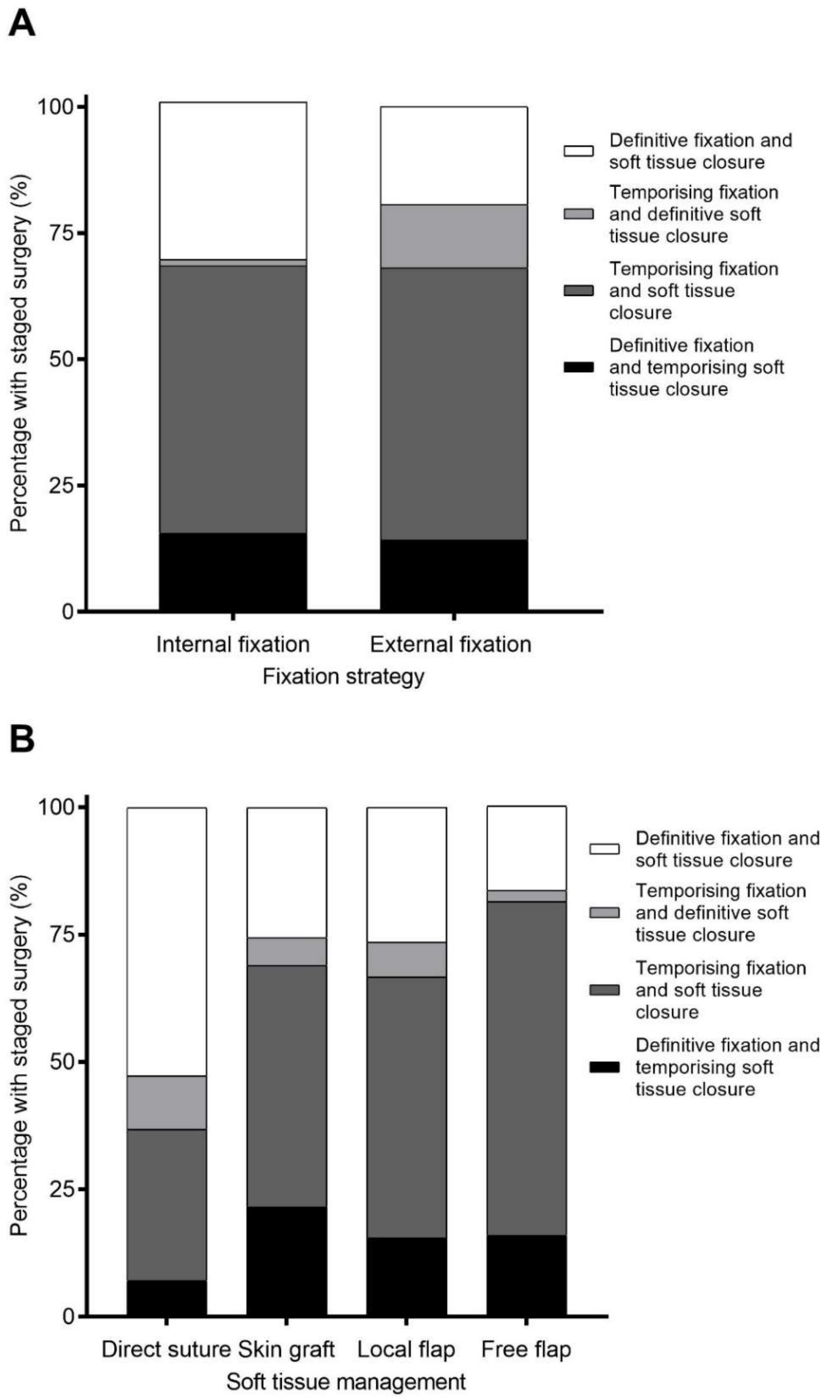
Table 2-15 Distribution of Soft Tissue closure or coverage strategies

Soft tissue cover, n (%)	n (%)
Direct wound suture	327 (16.5)
Skin graft	339 (17.1)
Local flap	406 (20.5)
Free flap	727 (36.8)
Amputation	179 (9.0)

While there is a target from the guidelines that soft tissue cover should be achieved in 72 hours, the guidelines do not provide guidance on surgical sequencing or number of procedures. This may explain some of the variation in practice identified between centres; with practice in some centres targeting single-stage surgery with definitive and soft tissue closure or coverage completed within the first surgery while others favour early but delayed soft tissue cover.

The BOA guidelines focus on the logistics of surgery and surgical sequencing. The median time to debridement was 9 hours with an interquartile range (IQR) of 4-17, and the median time to soft tissue cover was 59 hours with an IQR of 17-116 hours. The large IQR described above suggests there is variation both in and across centres for both administrative and medical reasons. With regards to surgical sequencing, this analysis identified that 27.1% (n=487) have definitive fixation and soft tissue coverage or closure at the first surgery, 15.6% (n=179) have definitive fixation and temporising soft tissue management, 5.3% (n=95) have definitive closure and temporising skeletal management, 53.9% (n=350) of individuals are managed with temporising fixation and temporising soft tissue management; this data is shown in Figure 2-19 for both fixation and soft tissue cover. Figure 2-19 A, shows no difference between staging of soft tissue reconstruction dependant on fixation strategy, although having definitive external fixation was more likely to be done as a staged surgery. Figure 2-19 B shows that those with direct suturing were far more likely to have single stage surgery (63%), those having a graft of local flap were half as likely to have single stage surgery (31% and 32% respectively), whilst those having a free flap only had single stage surgery in 18% of cases.

Figure 2-19 Shows percentage with staged surgery grouped by management strategy (skeletal fixation shown in A, soft tissue shown in B). Staging is reported as whether definitive surgery or soft tissue cover was achieved in the first surgery for the open fracture.



2.8.4.2 Standard 14: Definitive soft tissue closure or coverage should be achieved within 72 hours of injury if it cannot be performed at the time of debridement.

Early wound complications was defined as the development of an orthopaedic or graft infection during the index inpatient stay. Orthopaedic infection developed in 2.1% (n=38), whilst graft infection occurred in 0.9% (n=16). The combined early complication rate was 3.0% in 1816 patients having limb salvage following a Gustilo 3B or 3C fracture. This data is shown in Table 2-16.

Table 2-16: Occurrence of early wound complications in patients with Gustilo 3B or 3C open tibial fracture reported by TARN

Complication	n (%)
Orthopaedic infection	38 (2.1)
Graft infection	16 (0.9)
Total complications	54 (3.0)
Total patients	1816

Figure 2-20 Boxplot shows time to soft tissue closure (STC) in the group experiencing no wound complications against the wound complications group. Red line shows 72 hours.

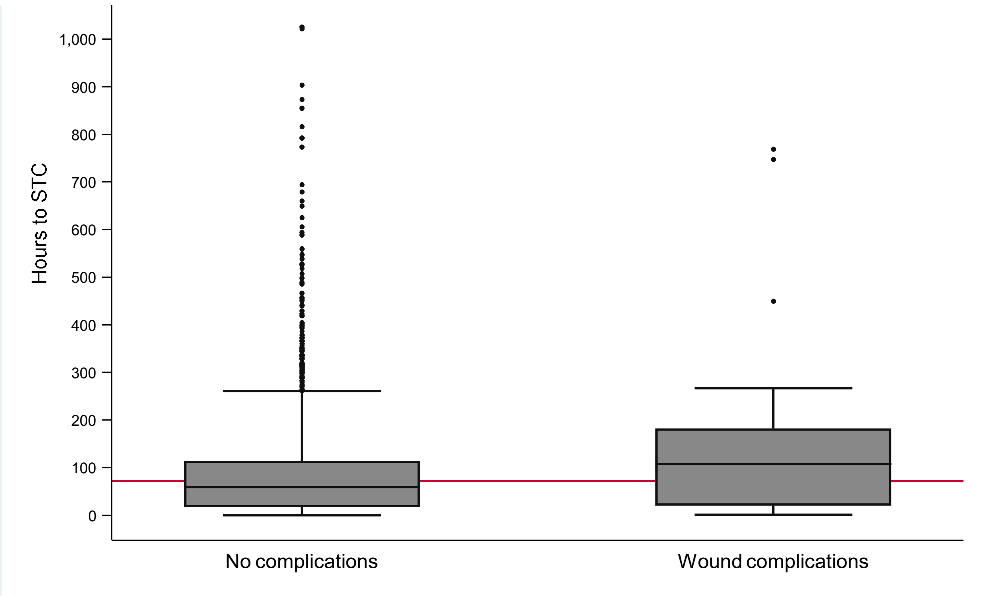


Figure 2-20 shows the crude relationship between time to soft cover and early wound complications,. The relationship between independent variables and wound complications were initially analysed using crude odds ratios (Table 2-17). The analysis identified that having a Gustilo 3C fracture (OR: 2.077 (CI: 1.002-4.304), an open femoral fracture (OR: 2.722 (1.137-6.515)) or flap closure (2.145 (1.077 – 4.271) was significantly related to occurrence of wound complications ($p<0.05$). In addition, the proportion of wound complications increased by 0.3% per each hour delay to soft tissue cover (equivalent to a 3% increase with every 10 hours elapsed). To mirror BOA guidelines, time to definitive cover was also included as a binary variable (cover within 72 hours), which identified that delay beyond 72 hours was twice as likely OR: 2.195 (CI 1.248-3.863) to result in complications when compared with early definitive closure.

Table 2-17 Crude odds of early wound complications after open tibial fracture in the context of patient and surgical variables in a cohort of 1816 3B and 3C open tibial fractures undergoing limb salvage

	Odds ratio	Confidence interval
Age	0.999	(0.986 - 1.012)
Female gender	0.780	(0.420 - 1.465)
CCI	1.040	(0.940 - 1.148)
NISS	1.014	(0.995 - 1.034)
GCS	0.985	(0.875 - 1.107)
Gustilo 3C	2.077	(1.002 - 4.304)**
Bilateral open tibial fracture	0.950	(0.293 - 3.085)
Open femur fracture	2.722	(1.137 - 6.515)**
Surgery in 2 hospitals	1.048	(0.444 - 2.470)
Time to debridement	0.996	(0.983 - 1.010)
Definitive - Ex-fix	1.013	(0.541 - 1.893)
Flap coverage	2.145	(1.077 - 4.271)**
Delayed wound closure	1.012	(0.776 - 1.319)
Definitive soft tissue cover > 72	2.195	(1.248 - 3.863)**
Time to soft tissue cover per hour	1.003	(1.001 - 1.004)*
p<0.01*, p<0.05**, n=1816		

An adjusted model to identify the relationship between time to soft tissue closure or coverage and early wound complications after acknowledging confounders is reported in Table 2-18. Several risk factors were not retained in the adjusted model as they were not significant. In the adjusted model the proportion of individuals experiencing wound complication increased by 0.3% per hour (CI: 1.001 – 1.004), the only other indicator of wound complication was a concomitant open femoral fracture and these individuals were 3 times more likely(OR: 3.175, CI: 1.091 – 9.241) to have wound complications than those without this simultaneous injury.

Table 2-18 Adjusted odds ratios for wound complications (final regression model)

	Odds ratio	Confidence interval
Hours to soft tissue cover	1.003	(1.001 - 1.004)*
Open femur fracture	3.175	(1.091 - 9.241)**
$p<0.01$*, $p<0.05$**, $R^2 = 0.35$, n=1816		

2.8.5 Discussion

This study presents a national appraisal of current practice in open tibial fracture and identifies a relationship between failure to meet established targets and wound complications. The overall picture was one of variation. The majority of patients were managed in a specialist centre, although there were exceptions. A range of surgical techniques were used, the use of temporising versus definitive procedures and the overall number of procedures per patient appeared quite random. Whilst temporal targets of 72 hours to soft tissue closure exist, this target seemed to be ambitious in the majority of settings and patients who had more complex soft tissue procedures were more likely to breach the 72-hour target. A secondary focus of our analysis was the relationship between time to soft tissue cover and wound complication. In the adjusted analysis, time to soft tissue cover was identified as a predictor of wound complication. This relationship was examined as both a binary categorical variable and linear trend, where the linear trend provided a better fit than using a 72-hour cut point, this finding suggest that whilst the 72-hour target is a pragmatic target any delay to surgery was important.

These findings provide further evidence to support the BOA guidelines [28], which advocate soft tissue closure or cover within 72 hours. This finding strengthens the existing evidence base, as these guidelines are founded on a small number of single-centred retrospective case series [59, 151-155]. Closer consideration of the evidence base gives rise to a more nuanced argument regarding the importance of the 72-hour target. Our study identified that individuals who wait longer for soft tissue cover are at greater risk of wound complications, irrelevant of the exact number of hours elapsed. Management of open tibial fracture is a complex intervention, and consistently achieving closure within 72 hours requires abundant resources and corroborated systems. There are multiple potential fault points in the pathway, and the variability in service levels was clear from our analysis. The pathway needs to facilitate direct admission to a trauma unit [56] with access to plastic surgeons with the appropriate skillset, [156] where a timely [59] and single staged joint orthoplastic approach is feasible where appropriate [155]. Failure to overcome these fault points has been associated with higher complication rates in the studies referenced [56, 59, 155, 156] and would also delay the patient in the surgical pathway. Our regression model included some of these variables as confounders, although they were not significant in the adjusted model. The differences between studies are likely to arise from the statistical approach, power and outcome measures utilised with limitations in each example across the various studies. The cumulative message is that early soft tissue cover reduces early infection, which may be directly related to temporal factors or secondary to the individual being in appropriate circumstances and environment which allow timely access to surgery.

A limitation of this study is the use of early wound complication as an outcome measure. Selection of an appropriate outcome measure is essential to study design and has an impact of the translatability of clinical efficacy research to practice. Within an RCT the prospective design allows for deliberation over the correct outcome measure, and often a spectrum of clinical and patient-reported outcomes measures are collated to allow triangulation and interpretation. A limitation of registry research is it retrospectively fits a research question to prospectively collected data, the TARN registry was initiated to model mortality risk following trauma and has not adapted to modern pressures to collate for longitudinal clinical outcome data. Capture of complications within TARN is limited to inpatient complications, of which early wound complication (flap and orthopaedic infection) appeared most relevant to our research question. There were two clear limitations with use of early wound complications as an outcome measure. The first is the definability of wound infection; TARN does not provide trusts with guidance unto what comprises an infection therefore it is subject to local interpretation which introduces variation and error into the dataset. The second limitation was temporal, TARN only detects infection if diagnosed within the acute patient stay, but in many cases these infections only emerge several months down the line with patient re-presenting as a readmission. This limitation is evident through our analysis which reports a complication rate of 2.5%, where studies with a more comprehensive approach to follow-up report deep infection in 7 to 23% of cases [10, 20-23]. As this study only reports inpatient complications it is difficult to draw any conclusion on the definitive impact of delayed soft tissue cover on infection which is an outcome of greater relevance.

There have previously been no formal validation studies using the TARN data, and it is difficult to quantify the extent to which error exists within the dataset. Our validation of the diagnoses and surgical data, was limited to considering to what extent the narrative surgical record agreed with the documented diagnoses and treatment. The value of this was limited as it relied on the full surgical record being included on the TARN dataset, this field was not mandatory and it was evident that certain centres were not inputting data in these fields which undermined the usefulness of the validation exercise undertaken for this study. It is therefore likely than there is uncaptured variability within the data.which results in residual confounding and limits what conclusions can be drawn. The research focus for open tibial fracture is not the development of novel technologies but improving prognostics and the appropriate targeting of established treatments; yet this study has shown that the TARN data does not allow these inferences to be made. Theoretically, TARN records surgical procedures in great detail; however it is unlikely that audit clerks will have sufficient expertise to code such a specialist operation without input from the surgeon, which is not specifically encouraged by TARN. It is also reasonable to suggest that use of OPCS codes alone does not provide sufficient granularity unto the intricacies of the surgical procedure. Certain arthroplasty registries utilise minimum datasets which are completed by the surgeon in theatre[157], this approach which allows for more detail to be collected with regards to the injury and surgery.

There are some further fundamental limitations regarding the way surgical and complication data is recorded. The database fails to record site and laterality of either the surgery or complication, and subsequently it becomes difficult to evaluate these factors in relation to a specific injury. Our findings identify that a concomitant open femoral fracture is a confounder for infection in both the adjusted and unadjusted model, this finding is reasonable due to the significance of an additional major injury and contaminated operative site. Antithetically having bilateral open tibial fractures showed a slightly decreased risk of infection with a wide confidence interval, which is an odd finding, difficult to explore further without further details around the injury, surgery or complication.

The recording of the injury is in itself limited to ICD code and Gustilo grade within TARN, which is likely insufficient for this setting. The Gustilo grade has been criticised as having low inter-observer validity [25, 26] which is likely a consequence of the use of highly subjective language within the definition of the classification. There is recent impetus to utilise different systems to classify open fractures. The OTA-OFC [158] was developed by an expert panel and subsequently validated [159] [160], identifying the relevance of skin injury, muscle loss, arterial injury, bone loss and contamination as prognostic for short-term clinical outcomes after open tibial fracture. A recent alternative comes from the OTS (Orthopaedic Trauma Society) [161] which is based upon objective descriptors of the open fracture and correlates with patient-centred outcomes in a large cohort of open fractures of the lower limb. These alternatives are gaining traction, with an increasing acknowledgement that having an appropriate and contemporary classification of these fractures in an important research question. The TARN data fails to capture many of the aspects deemed important by the OTA or OTS score, and does not capture either score directly. This uncaptured confounding within the data is likely to have impacted both the exposure and outcome variable; for example, those with severe muscle and bone injury may have waited longer for surgery due to the need for specialist resources and be vulnerable to complications; yet it is not possible to evaluate this within our analysis.

With regards to further work, there remains an opportunity for clinical effectiveness trials which evaluate established treatment protocols for open tibial fracture. Those wishing to conduct trials in this area should be cautious of the likely challenges of detecting an intervention signal in this complex pathway where there are numerous variables. In advance of these trials, there needs to be consensus on a contemporary classification system for open fractures to control for injury factors. In addition a trial testing an area of the treatment pathway (such as immediate versus early flap protocols) should attempt to control and measure other areas of the pathway (such as surgery in an MTC). Due to the phenomenal costs of RCTs and the associated limitations of accessing this treatment group, it is frustrating that these techniques cannot be tested utilising observational data. Thus, in addition to formalised trials, there is space for re-appraisal and re-design of established registries to allow these questions to be evaluated in a robust manner.

2.9 Conclusion

The chapter has provided new insight into the epidemiology, risks and treatment patterns associated with open tibial fracture. A known pattern of injury is that these injuries tend to occur in young working-age males, our epidemiological analysis identifies a significant incidence in older patients. We confirmed a relationship between comorbidity, age and mortality in this population; in the setting of an ageing population, these two aspects outline a requirement for clear and appropriate treatment pathways for open tibial fracture in the older population. In describing a national picture of treatment, we described great variation in the methods used to manage these injuries, although relational analysis identified an increased risk of early wound complications with every hour delay to definitive closure identifying clinical relevance for this target that may confer benefit to patients.

Limitations within the TARN dataset truncated what questions could be asked of the data. Failure to collect greater detail around the fracture, linked surgical data, and a relevant and valid outcome measure greatly reduces the usefulness of TARN for orthopaedic research. This study has done much to outline the potential value and pitfalls of a national registry as a research tool. The methodology remains valuable for researching this difficult to access population, and there would be great value in a registry explicitly designed to capture data on open tibial fracture. Methodologists are becoming more receptive of non-traditional trial designs, which promote statistical efficacy, with scope to embed RCTs within registries or extend RCT datasets with registry data. A well-designed open tibial fracture registry would be a valuable tool for observational research, and could potentially be used to facilitate RCTs in a novel statistical design.

This study has identified areas for future research. There needs to be further research into open tibial fracture in older patients; at least this should mean including older patients in trials, in addition, there is potential to conduct studies that are specific to the older population, particularly if the research priorities for these patients are divergent. A further research area may be targeted at evaluating different soft-tissue or fixation protocols, with an apparent lack of consensus nationally. Nonetheless, before undertaking expensive RCTs, further groundwork is needed to inform future trial designs. Defining eligibility criteria is difficult with limitations around characterising the fracture, reaching consensus on a validated fracture classification system would be a significant contribution to practice and research, providing a foundation for further studies. In addition, it is difficult to prioritise outcome measures based on the current evidence base, and having a better understanding of the priorities of patients would help determine the best outcome measures for future trials.

A national registry is useful over other forms of observational data as it reduces sampling bias, and the case volume reduces the impact of veracity. This has been demonstrated by TARN on a number of occasions by consistently delivering publications which change care [117]. Unfortunately, national registries are not a panacea, as this analysis has demonstrated. Fundamentally the limitations experienced through this analysis were driven by applying research questions to a dataset that was collected for a different purpose (modelling mortality risk after major trauma), which created a ceiling to our analysis. Acknowledging this limitation, we recognised the potential utility of regional orthopaedic trauma registries, which potentially lack statistical power and generalisability; but were designed specifically to evaluate pathways and outcome relating to orthopaedic trauma and as a consequence, these registries capture detail beyond what is available within TARN. As our purpose was to provide data that would facilitate the development of high-quality research, the use of a comprehensive and well-characterised registry to identify areas where future research became the focus of the next chapter.

Chapter 3. A Local Evaluation of Service: Cost Analysis and Patient-reported Outcomes

3.1 Background

The East Midlands Major Trauma Centre sits within the East Midlands Major Trauma Network and is the largest of its kind in Europe. The trauma centre was opened in 2012 with roll-out of services staged over two years, and the centre now supports six trauma units. The East Midlands MTC has a major trauma referral population of 4.7 million, with a district referral population of 800,000 [17]. The East Midlands includes a distinct mix of large cities (Nottingham, Derby and Leicester) but also large rural areas (the Peak District and the Lincolnshire Wolds), and this contrast of town and country shapes a unique trauma caseload. The region has some of the most dangerous roads and a strong agriculture industry; road traffic and industrial accidents are prevalent in working-aged individuals. This landscape is contrasted by a rural population who are increasingly elderly, and as a consequence, the Nottingham service is one of the biggest providers of fragility fracture care nationally. This diverse mix creates a high-volume caseload, and is also responsible for managing revision cases within the region. The casemix generates a challenging caseload for surgeons and the service.

Well-designed local audit registries can be powerful tools for service evaluation and quality improvement. The aims of an individual registry dictate its utility as a resource for asking meaningful questions; from the perspective of our research question, the greatest limitation of the TARN registry was that it was not designed for orthopaedic trauma research and thus was limited in scope. Nottingham hosts an orthopaedic trauma audit registry which has been carefully designed to measure the process of care and relevant outcomes. Patient reported outcomes, longer-term clinical outcomes and cost data were absent from our TARN evaluation of tibial fractures, yet these elements are important outputs of clinical efficacy research and it is important to have an understanding of these outcomes based on current routine practice to inform future research questions and study design. This chapter will endeavour to explore some of these elements to obtain a complete picture of open tibial fracture care and outcomes.

3.2 Aims and analysis plan

3.2.1 Aim

This chapter addresses aim 2: "Use a comprehensive regional dataset to consider longer-term clinical, patient-centred and economic outcomes in an open tibial fracture cohort, to establish the longer-term results of competing treatment strategies and personal factors".

3.2.2 Analysis plan

This analysis will utilise data from a collection of linked datasets, including, the Nottingham Trauma Registry and patient level clinical coding and costing data to address four main questions:

Demographic Profile:

This analysis will address objective 4:"Describe the regional demography of open tibial fracture and compare this to this previously described TARN dataset". This analysis serves to consider the differences between the national and regional epidemiology; helping us understand the generalisability of the regional data and will show how the demands of the regional population differs to total population in England. This analysis also considers aspects of epidemiology not available nationally such as ethnicity and deprivation.

Occurrence of major complication requiring surgery

This analysis addresses objective 5: "Review major complications in the regional cohort and evaluate the relationship between key quality indicators and outcome". It is important to understand the long-term clinical outcomes of individuals who are treated for open tibial fracture and the relationship of complications with certain treatment factors. This analysis serves to document the risk of certain complications in the open tibial fracture cohort and the temporal patterns associated with developing an infection after surgery. In addition; a regression analysis will look at variables that may be related to the development of complications; a TARN analysis identified delay to soft tissue cover as a confounder for early complications and this variable will be studied again in the smaller dataset.

A cross-sectional review of patient function and quality of life following open tibial fracture

This analysis addresses objective 6: "Summarise patient-reported outcome following treatment for open tibial fracture." Patient reported outcomes can provide a better picture of recovery than clinical measures; validated PROMS can measure the return to previous health state which is more closely aligned with the goals of patients and thus more relevant to clinical practice. The TARN data does not include PROMS, and it is challenging to understand recovery in the absence of this data. A cross-sectional collection of PROMS was undertaken for our cohort. We report on quality of life and function after sustaining an open tibial fracture.

Cost of hospital based treatment after open tibial fracture

This analysis addresses objective 7: "Undertake a cost analysis to understand the average treatment costs for individuals with different treatments and different outcomes." Understanding the costs of treatments is important to policy makers, practitioners and patients. Cost of therapy for open tibial fracture is poorly documented; mostly referring to US health costs or particular aspects of treatment for open tibial fracture. This analysis used hospital billing data to provide insight into micro-economic data, stratified by Gustilo grade, treatment and complications.

3.3 Method

The analysis includes three datasets, the Nottingham Trauma Registry, a PROMS dataset and a coding dataset. These are described in turn below.

3.3.1 Nottingham Trauma Registry

All patients admitted to Nottingham University Hospitals following orthopaedic trauma are audited and included on a local registry. The registry was initiated in 2003 with the intention of auditing factors associated with this population's morbidity and mortality; and includes demographic, physiological, operative, and clinical outcome data for each patient. Responsibility for data-entry is shared between the on-call registrar and an audit officer. Admission data for each patient is entered prospectively by the on-call registrar and this robust initial dataset is used to form the daily trauma MDT (multi-disciplinary team) list. Responsibility for maintaining the patient's audit record is handed over to the audit officer at the MDT. Audit officers have extensive coding experience and have undertaken GCP and HQIP training. The audit officer uses a range of sources to inform the audit including paper and digital health records, theatre management systems, radiography report data and microbiology reports. The audit officer reviews each inpatient daily until the point of discharge. Use of multiple sources and close monitoring allows for the collection of a complete and verified dataset. Whilst the database has not been formally validated the dataset is reconciled on a monthly basis against coding records to identify omissions in the data which may result in a loss of income for the trust, this reconciliation sets a baseline standard for data quality within the registry. Further verification of the data was undertaken during the data management process as has been outlined below. Microsoft Access is the platform used to host the database. The local database serves to manage data before uplift to national Audit platforms such as the TARN registry, but also is an essential tool for local quality improvement and service evaluation.

3.3.1.1 Data management

The registry was used to identify a cohort of individuals who had sustained an open tibial fracture between 1st January 2014 and 1st January 2019. Relevant data fields were agreed, and a limited dataset was provisioned in a csv. file. On provision of the extract, a case note review was undertaken for each record; this was conducted to achieve several additional aims:

- Firstly, case note review allowed for full validation of the data, ensuring completion and accuracy.
- Secondly, the review allowed for an extension of the dataset, the audit registry is not specific to open fracture and thus lacks detail in some areas of interest
- Thirdly, as the audit registry is restricted to inpatient data, review of outpatient clinic letters allowed for the collection of clinical outcome data, such as infection, non-union and death when these events occurred following the acute hospital stay.

Missing data within field: All fields were checked for missing data. Missingness was not a limitation amongst the exposure variables due to the ability to cross-reference with the clinical record. Missingness effected the clinical outcome variable for 23 patients due to repatriation; imputation was not used; these cases were included in the descriptive analysis but excluded from the regression models in 3.4.2.

3.3.1.2 Review of inpatient dataset

Demographic data: The dataset included core demographics such as age and gender, but also broader information such as ethnicity[162] , geographic, deprivation data (index of multiple deprivation [163]) and mortality. This demographic data is directly obtained from the trust hospital system, which is linked to NHS spine [164], which acts as a platform for demographic and mortality data. Index of multiple deprivation data is sought on an interim basis by linkage of postcode data to census data, and this data provides useful insight into deprivation with patients admitted.

Comorbidity data and injury data: The audit dataset includes comorbidity data and injury data collated by the registrar during medical clerking; the audit officer responsible for that record converts the verbatim history into a matrixed definition. Appropriate audit recording for an open tibial fracture would include the fracture site, laterality and grade of soft tissue injury. Comorbidities are collected according to the NHS standard for coding comorbidities [165]. The coded comorbidities were converted to CCI for analysis.

Surgical data: Surgical data collected by the audit team includes operation performed, time of surgery, and grade of surgeons' present. Classification of surgery performed by the audit clerk is based on agreed definitions documented in a local audit SOP which is guided by local practice and have been described below:

Definitive fixation: Recorded as either internal fixation, ring external fixation, palliative (plaster cast or temporising external fixator), or amputation. For the purpose of the regression model below, amputation and conservative management were excluded, reporting a binary variable of internal fixation versus external ring fixator.

Soft tissue coverage: Recorded as either, primary closure, skin graft, local flap, free flap or amputation. For the purpose of our regression model two groups were created of direct tissue closure (including primary closure and skin graft) or additional tissue cover (free flap and local flap).

Single stage surgery: This is documented as a categorical variable documenting temporising fixation and closure. For our regression, this was reported as either single stage surgery yes or no.

3.3.2 PROMS dataset

PROMS were deemed an important element of service evaluation but were not an embedded part of the dataset; as a consequence, these were sought separately from all patients in the cohort. Before approach, all individuals in the group were screened for inclusion. Exclusion criteria were shaped by practical aspects; individuals were excluded if they had a serious cognitive or neurological impairment, poor spoken English or no fixed address. Letters were not sent to addresses of deceased individuals. The survey was sent to individuals by post and included a cover letter which explained the voluntary nature of the survey, and its purpose (appendix 8.7). Individual returned the questionnaires to the trust via a pre-paid envelope and responses were collated and linked back to the audit data using an allocated survey number.

This data collection was undertaken over a period of 4 years, in an attempt to achieve a relatively uniform period of follow-up, letters were sent when patients were a minimum of 12 months after their injuries. The questionnaires asked individuals to confirm their current health state and recall a retrospective baseline health-state. Whilst vulnerable to recall bias, this approach was taken as a retrospective and prospective baseline have been shown to have high agreement in an orthopaedic population, and was deemed preferable to comparing data to population norms [166, 167].

3.3.3 Patient level clinical coding and costing data

Hospital billing data was requested for all individuals in the cohort who had a completed care spell and was provisioned by an appropriately designated individual within the trust finance department. Coding data provisioned included all Healthcare Resource Group (HRG) codes allocated to an individual, and their associated speciality and cost. The HRG code gives information on anatomical site, comorbidity, and complexity of procedure. Data provisioned included all inpatient and outpatient costs, excluding those related to radiology and prosthetics as these services are commissioned via different platforms. The data was reorganised to provide an over-arching cost of in-patient and out-patient costs per individual evaluated.

3.3.4 Selection of outcome measures

A series of outcome measure were selected that were considered to leave us best positioned to interpret and understand aspects of recovery that were important to patients. It was felt that a clinical outcome measure was needed as an objective measure of outcome. Still, it was decided this clinical outcome measure should be supplemented with patient-reported outcome measures to give further insight into patient function, and quality of life through recovery. Population-specific measures are felt to be more responsive in an orthopaedic setting [168], whilst a general health measure or HRQoL score provides useful holistic insight; neither were considered to be sufficiently valid in isolation, [169, 170]. Consequently, it was decided that a population-specific measure and a general health measure should be used to evaluate the patient-reported outcomes of this cohort, supported by a clinical outcome. These are described more specifically below.

3.3.4.1 Major complications

For the purposes of this analysis surgery for major complication was chosen as our clinical measure. Appropriate capture of complications is a critical component of evidence-based studies, but no standardised method exists for grading and reporting of complications in the setting of severe limb injury. The Clavien Dindo score [171] has been widely used in general surgery and adapted for use in some areas of orthopaedics, although it has not been used in orthopaedic trauma and the detail required for documenting the score requires prospective data collection by clinicians making it beyond the reach of registry based studies Use of all-cause revision surgery as an outcome measure follows the model utilised for LEAP [10] and METRC [69] studies. This approach was chosen as in a registry dataset grouping major complications reduces the potential for error in classification in cases where the underlying aetiology is unclear; particularly when the burden associated with various complications seems to be similar at an individual level.

3.3.4.2 The 5-dimensional EuroQol (EQ-5D-5L)

The 5-dimensional EuroQol (EQ-5D-5L) is an established measure of healthcare-related quality of life and utility [172]. The EQ-5D-5L variant was selected for use which measures five domains which include mobility, self-care, participation, pain, and depression. Individuals completing the questionnaire rank each domain as either not affected (1), slightly affected (2), moderately affected (3), severe affected (4) or extremely affected (5). Collected scores are converted to a value score [173] and reported as a scale of 0 to 1, with 0 representing a quality of life equivalent to death and 1 being perfect health. The EQ-5D was selected for use on this occasion due to its validity and brevity. Brevity was considered particularly useful in the setting of a postal questionnaire which requires patients to complete the documentation without support from researchers. With regards to validity, the EQ-5D is a widely adopted score which has been tested for validity and reliability in large population studies.

NICE recommends the use of the EQ-5D in its health technology appraisals to enhance comparability [76, 174], which has guided wide adoption, more so than other general health and utility questionnaires such as the Shortform-36 [175] and Health Utilities Index 3 [176]. Whilst the EQ-5D has broad validation for measuring health related quality of life, and has been shown to be valid in isolation in the hip fracture population [169], however some research groups have concluded that it is less relevant in specific populations due to the potential for floor and ceiling effects, [177] this concern resulted in the decision to use a panel of outcome measures opposed to using a utility score in isolation.

3.3.4.3 Condition specific outcome score

There is no consensus decision on a condition-specific outcome measure for open tibial fractures, although there are scores relevant to this population that have undergone various degrees of validation and reliability testing. In selecting our condition specific measure we were guided by best evidence at the point of selection; selecting the Disability Rating Index (DRI) [178] and Wales Lower Limb Trauma Recovery Scale (WALLTR) score [67] which have been utilised in the WOLLF study [22, 23].

The Disability Rating Index (DRI)

The Disability Rating Index (DRI) is a 12-item patient completed questionnaire which includes both simple (dressing and outdoor walking) and complex tasks (running or heavy work). Patients score their ability to complete each task on a scale of 0 (no impairment) to 100 (complete disability) [77, 178]. A mean average of each score is taken and reported which allows researchers to measure change in total disability. The DRI has undergone some validation in lower limb trauma [77], and has been used in multiple RCTs with demonstrated responsiveness [22, 23]. This DRI score was not intended initially for use in a trauma population but was designed to measure gross lower limb disability; thus, is a functional measure opposed to a condition-specific measure. It was selected for this study as the traits included in the DRI were particularly relevant to the open fracture population where severe disability is expected. Alternatives not selected were the Oxford knee score [179] and Olereud Molander Ankle Score [180]; these joint specific scores focus on joint function and achieving high levels of athletic demand which seemed less relevant.

The Wales Lower Limb Trauma Recovery Score (WALLTR)

The WALLTR score consists of 2 parts; the first being a 10 item questionnaire with an associated Likert scale where patients can rank their response from strongly disagree to totally agree; this is followed by an 8 item non-Likert questionnaire which collects data on use of mobility aids, work, driving, and financial implications of injury. The published score includes an algorithm which allows the researcher to calculate an overall score for the individual. WALLTR is a recently developed condition specific outcome score specifically designed to measure recovery from open lower limb fracture; the measure was derived using COSMIN methodology and has been validated in a broad population [66, 67]; but the questionnaire is yet to be widely adopted. Due to the robust methodology utilised to design the score, we were keen to use the measure in this study; however, this enthusiasm was partnered with caution as at the point of survey design, the WALLTR score was unpublished, and reports of its validity and reliability were anecdotal. Studying the DRI in tandem with WALLTR highlights these measures look at different traits, and thus it seemed acceptable to use these two scores together. This questionnaire is designed for use in a trauma population, without the use of a retrospective baseline and this format was followed for this study,

3.3.4.4 Cost

This study chose to use hospital billing data to evaluate costs. Use of macro costs based on NHS health reference standard tariff costings costs is a commonly applied tool for health economic analysis, however these techniques are limited in their value as the model chosen is theoretical and based on patient or clinician recall. Access to hospital coding data, offers the opportunity for more sophisticated analysis as this allows insights into the actually costs that commissioners incur for these injuries, and thus this technique was chosen.

3.3.5 Permissions

Permission to perform this service evaluation was sought from Nottingham University Hospital Trust Audit Department and was provisioned with an approval code (16-114c: appendix 8.8). This permission included using the registry for case identification and provision of limited data, review of patient notes to obtain a more comprehensive dataset, contacting patients to obtain PROMS, and linking this dataset to a coding dataset. The project was conducted in concordance with the Trust policy for audit and thus was fully compliant with trust governance procedures.

3.3.6 Statistical aspects

Statistical methods and software utilised followed the same broad methodology as described in 2.4.5 - 2.4.5.3.

3.4 Analysis

3.4.1 Demographic profile

3.4.1.1 Objective

This analysis addresses objective 4: "Describe the demographics, injury characteristics and treatment of individuals admitted to a regional major trauma centre with open tibial fracture; consider generalisability of local practice to national picture".

3.4.1.2 Analysis

Comparison with TARN data

Table 3-1 compares the demographics for adult open tibial fracture patients admitted to Nottingham against the demographics of those admitted nationally. The Nottingham cohort contained 211 patients, whilst the national cohort contained 7127. The timeframes differed by a period of 12 months (TARN: 2013-2017, Nottingham: 2014-2018). The Nottingham cohort included a more significant proportion of individuals with a Gustilo 3 fracture (n=156, 73.1%), when compared with TARN (n =3378, 49.5%); this finding is upstanding irrelevant of whether missing Gustilo grades within the TARN data are included or excluded from this comparison. The Nottingham cohort was generally younger and included a greater proportion of male patients than TARN. These differences would be in-line with expectations, as the major trauma status of Nottingham attracts a more complex case-mix.

Table 3-2 compares surgical data for the Nottingham cohort against the TARN cohort. The TARN data is limited to the 1995 cases of Gustilo 3B/3C fractures reported in that cohort. The Nottingham data is reported as all injuries (n=211), and 3B/3C fractures (n=94) to allow comparison with national data. Amongst severely injured patients' rates of a primary amputation are similar; there is a tendency to use external fixation for reconstruction more at Nottingham than nationally, which is likely to be case-mix related.

Table 3-1 Comparison of demographic profile and outcomes between regional and TARN dataset. TARN dataset includes 7127 adult open tibial fractures between 01/01/2013 and 31/12/2017, Regional dataset includes 211 adult open tibial fractures between 01/01/2014 and 31/12/2018.

		Regional cohort, n (%)	TARN, n (%)
Age			
	18-40	98 (46.5)	2832 (39.8)
	40-65	75 (35.6)	2622 (36.8)
	65>	38 (18.1)	1670 (23.5)
Gender			
	Female	49 (23.2)	2472 (34.7)
	Male	162 (76.7)	4655 (65.3)
Comorbidity			
	0 to 2	178 (84.4)	5498 (82.4)
	3 to 24	33 (15.6)	1172 (17.5)
Gustilo			
	1	30 (14.4)	853 (12.0)
	2	24 (11.5)	1224 (17.2)
	3A	62 (29.4)	1434 (20.1)
	3B	85 (40.7)	1928 (27.1)
	3C	9 (4.3)	169 (2.4)
	(NS)	0	1514 (21.1)
MOI			
	RTC	105 (50.5)	3424 (49.1)
	High velocity fall	33 (15.9)	727 (10.4)
	Low velocity fall	28 (13.5)	591 (8.5)
	Other	45 (20.2)	2230 (32.0)
30-day mortality (%)		6 (2.8)	234 (3.3)
Inpatient wound complication		9 (4.2)	54 (2.5)
Major complication		60 (28.4)	Not recorded
		n=211	n=7127

Table 3-2 Comparison of treatment pathways between regional cohort and TARN dataset. Descriptive statistics have been provided for the whole regional cohort, and the regional cohort limited to Gustilo 3B and 3C fractures to allow comparison with the TARN data.

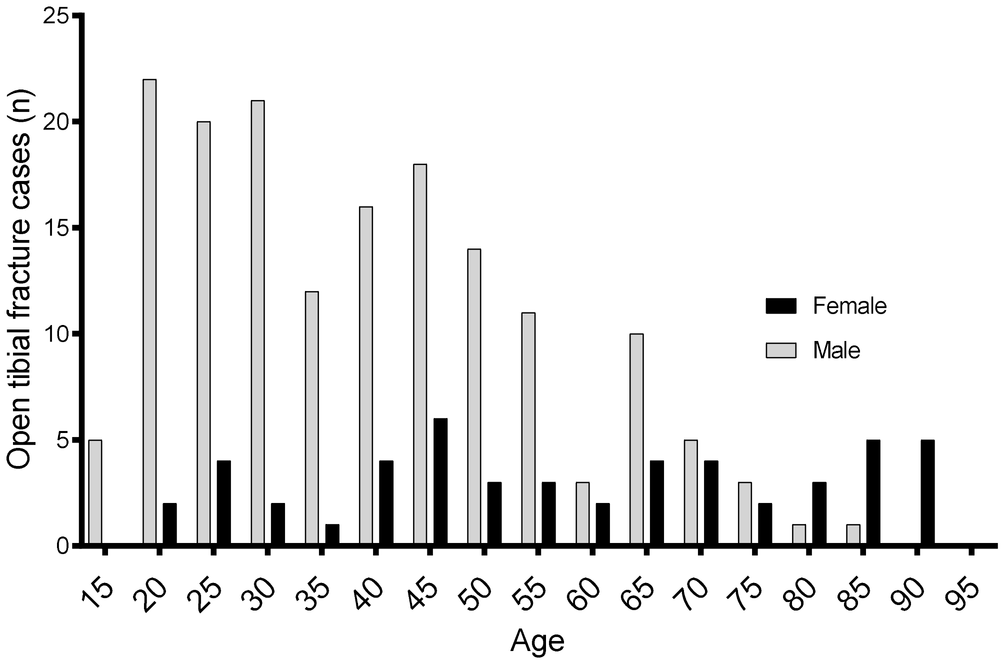
	Regional (All), n (%)	Regional (3B/3C), n (%)	TARN (3B/3C), n %)
Definitive treatment			
Palliative	8 (3.8)	0	0
Internal fixation	133 (63.0)	43 (45.7)	1148 (57.4)
Ring fixator	61 (28.9)	43 (45.7)	671 (33.6)
Amputation	9 (4.3)	8 (8.5)	179 (8.9)
Soft tissue closure			
Amputation	9 (4.3)	8 (8.5)	179 (9.0)
Direct closure	132 (62.4)	28 (29.8)	666 (33.7)
Tissue coverage	70 (33.3)	58 (61.7)	1133 (57.2)
	n=211	n=94	n=1995

Age and gender characteristics

The Nottingham cohort included 211 adult patients with open tibial fracture. Age and gender distribution is shown in

Figure 3-1. The mean age of the study population was 44 years, with a range between 18 years and 91 years. 76.7% (n=162) of our study population were male and the average age of injury in males was 39 years, female patients were older with a mean age of 58 years. The patterns of frequency were similar to what we identified in our national study; demonstrating that these injuries predominantly occur in men with lower frequency in women. Age patterns vary between gender with injuries occurring more frequently in working-aged men, but increasing frequency with age in women.

Figure 3-1 Frequency of adult open tibial fracture cases admitted to NUH 1st January 2014 and 31st December 2018 grouped by age and gender. (n=211)



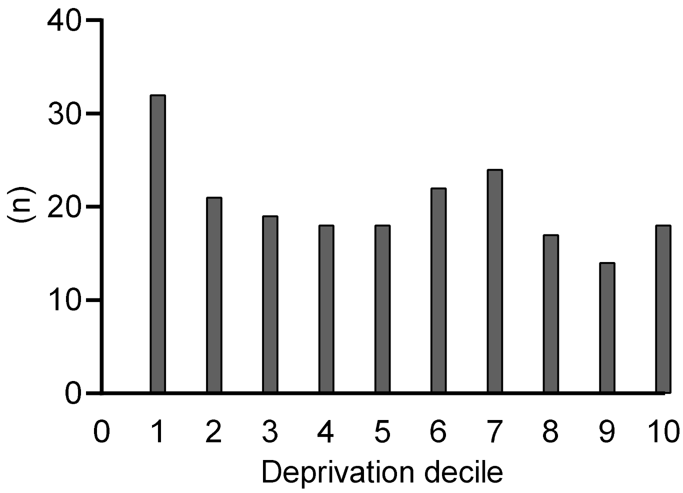
Ethnicity

Ethnicity data identified that most individuals 88.7% (n=187) included in the cohort were described as White British, 6.1% (n=13) were "other white", and 5.2% (n=11) were Black, Asian or Minority background. This is comparable to East Midlands statistics for ethnicity, which show a distribution of 85.4%, 3.9%, and 10.2% for White British, other White, and Black, Asian or Minority groups respectively. There is possibly a slightly higher frequency of injury in the "other white" group when compared to regional figures. [181]

Deprivation

Deprivation decile based on postcode data was available for all individuals within the dataset. Mean deprivation for our cohort as a whole was within the 5th decile (SD 2.9) with a range of 1 to 10, although there appeared to be a trend showing that deprived individuals were more likely to sustain these injuries (Figure 3-2

Figure 3-2 Frequency of open tibial fracture cases (n=211) admitted to Nottingham over a 4 year period, grouped according to deprivation decile. National deprivation deciles are based on postcode data, with 1 being most deprived and 10 being least deprived.



3.4.1.3 Discussion

This demographic study allows us to understand how this regional dataset compares to the national picture and provides further insight into the demographic profile of the open tibial fracture population. This cohort is comparable to the national registry in terms of broad demographics, although this regional population seems to include more high energy injuries which would be anticipated in a regional referral centre. This is a useful finding as it suggests that smaller well characterised datasets may be able to produce findings that are generalisable to a broader population.

It is also useful to consider the potential validity of both the TARN dataset and the local dataset. Neither dataset have had formal external validation. TARN routinely publishes dashboards which indicate HES linked case ascertainment; however this provides minimal indication of quality within records. This local dataset is subject to internal validation by the trust finance team and within the audit team, although these processes are to a certain extent informal and the additional verification of data undertaken for this analysis found errors within records. It is likely that several trusts undertake similar internal validation, which would positively impact on the quality of data within TARN, however it is likely that this is variable nationwide. Some national audits [157] within the UK mandate an annual data quality exercise for all participating trusts which formalises the process of internal validation. Replication of this process by TARN may serve to improve the quality within TARN and intermediary local trauma registries such as this one.

3.4.2 Occurrence of major complication requiring surgery

3.4.2.1 Objective

This analysis addresses objective 5: “Review major complications in the regional cohort and evaluate the relationship between key quality indicators and outcome”.

3.4.2.2 Analysis

Descriptive overview

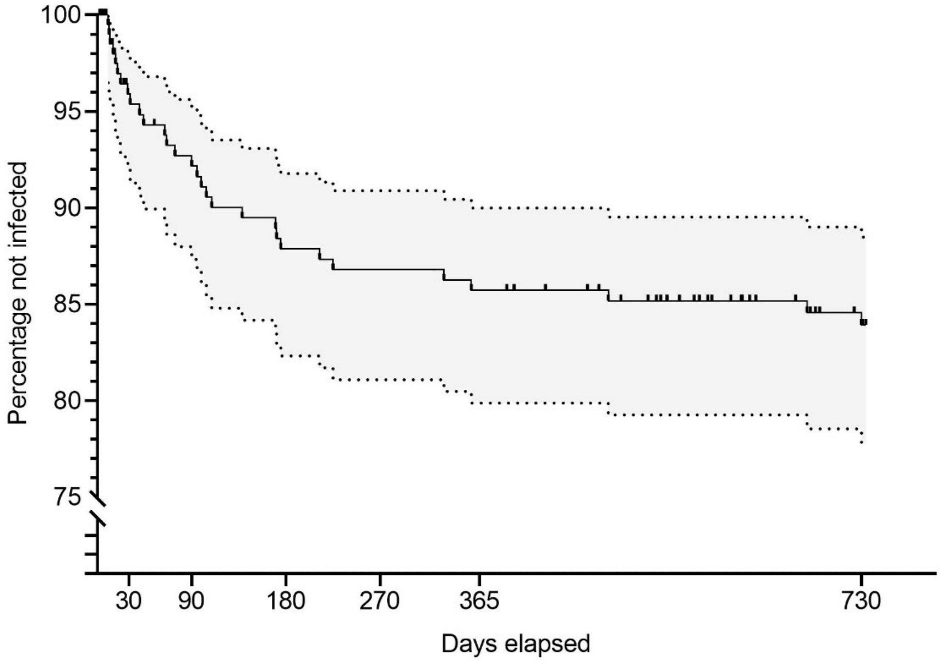
Revision surgery for complications following open tibial fracture is common. In this dataset, 28.4% (n=60) cases required revision surgery due to major complication, with infection being the most commonly cited cause for revision (n=30, 14.2%), and non-union the 2nd most common (n=22, 10.4%) Table 3-3. A further 6.3% (n=17) cases underwent elective revision, predominantly, for removal of symptomatic metalwork. 11.3% (n=24) patients had no follow-up at NUH; they were censored in Figure 3-3 but included in the denominator for Table 3-3.

Table 3-3: Frequency and percentage of complications in 211 adults with open tibial fracture admitted to NUH.

Complication	n (%)
Compartment syndrome	12 (5.7)
Flap failure	4 (1.9)
Infection	29 (13.8)
Non-union	22 (10.4)
Secondary amputation	4 (1.9)
Stump revision	3 (1.4)
Total	60 (28.4)

Mean time to revision surgery was 260 days (SD: 135 days). There were 29 infections in the cohort. Time to infection (days from injury to return to theatre for infection) was considered separately and is reported in Figure 3-3, which highlights that 51.7% (n=15), 86.2% (n=25), and 96% (n=27) of infections occur in the with the first 90 days, 9 months and first year after injury, respectively. The median length of stay in the TARN dataset was 13 days, extrapolated onto this dataset only 13.7% (n=4) of infections had developed within this period.

Figure 3-3 Kaplan-Meier estimator demonstrating percentage not infected over time including 211 patients with open tibial fracture over a 24 month period. Censor marks indicate point individual lost to follow-up. Confidence bands show 95% confidence interval.



Relationship between time to soft tissue cover or closure and revision for major complication

The relationship between time to soft tissue cover or closure and development of complications is a subject of interest in the literature; our earlier TARN chapter described this relationship, but a major limitation of the work was a short duration of follow-up. This cohort provides insight into longer-term outcomes, and thus the same question was asked of this data. This analysis was conducted using a cohort of 177 individuals with open tibial fractures irrespective of grade of injury. Individuals having primary amputation (9) or palliative management (8) were excluded due to the differences in pathway (soft tissues often not closed) or competing outcomes (mortality). Those with no outcome data were also excluded (23).

Several of the apriori variables were obtained as continuous variables (age, CCI). Linearity of log-odds was assessed for each continuous variable using design variables, as described in point 8 of 2.4.5.2. There was no significant difference in the better model fit (LRT = $p>0.05$) when we independently included age and CCI as a categorical variable rather than the linear trend. As a consequence, the continuous variables were retained in the final model. Tests for multi-collinearity indicated a low level of multi-collinearity.

The relationship between time to soft tissue closure was explored as both a continuous, categorical variable (quartiles) and binary variable (72-hour cut-point). The value of 3 iterations of the variable was to explore the potential for a non-linear relationship, to acknowledge the 72-hour guideline, and to deliver consistent methodology. There was a significant difference in fit between the continuous and quartile model (LRT $p<0.05$), so the quartile variable was retained in the final model. The 4th quartile point naturally sat at the 72 hour-threshold which released the need for examining the binary variable. The final adjusted model was tested twice with both the binary and continuous variable for completeness.

The relationship between independent variables and revision due to complications were initially analysed using crude odds ratios; these relationships are documented in Table 3-4.

Table 3-4 Crude odd ratios for developing a major complication against patient variables in a 177 patient cohort

	Odds ratio	95% CI
Age (18-40)		
40-65	1.20	(0.62-2.34)
65>	0.48	(0.18-1.31)
Gender		
Male gender	2.45	(1.05-5.68)**
Comorbidity	0.62	(0.25-1.56)
Ethnicity	0.41	(0.13-1.26)
Deprivation	0.92	(0.83-1.02)
Polytrauma	1.95	(1.04-3.63)
Gustilo grade		
2	1.92	(0.29-12.72)
3A	3.48	(0.72-16.75)
3B	12.43	(2.74-56.42)**
3C	15.33	(1.91-122.8)**
Definitive fixation (internal fixation)		
Ring fixator	4.44	(2.25-8.79)**
Soft tissue closure (direct closure)		
Additional tissue cover	4.83	(2.46-9.47)**
Surgical staging (temporising surgery)		
Single stage surgery	0.59	(0.47-0.74)**
Hours to soft tissue cover (0-9)		
10 to 21	0.79	(0.28-2.21)
22-72	1.09	(0.42-2.85)
73+	4.91	(1.99-12.09)**
Observations = 177, $p<0.05$*, $p<0.01$**		

The crude odds identified several variables to be significant predictors of need for revision surgery. Men were more 2.5 times more likely to require revision (OR: 2.45, CI: 1.05-5.68), and having polytrauma was also a significant predictor (OR 1.95, CI 1.04-3.63). Gustilo grade was a significant predictor variable as a trend, with individuals having a Gustilo 3B, or 3C being the strongest predictors (3B, OR: 12.43, (2.74-56.42); 3C, OR: 15.33 (1.91-122.8)); the wide confidence intervals are an indicator of heterogeneity and quite small groups.

Individuals who were treated with a ring fixator (OR: 4.44, CI: 2.25-8.79) or with additional tissue cover (OR: 4.83, CI: 2.46-9.47) were over 4 times more likely to require revision, whilst closure or coverage and fixation within a single surgery conferred a decreased risk of 40% (OR: 0.59, CI: 0.47-0.74). These findings were expected as ring-fixators and flap surgery are normally reserved for the most severe injuries due to treatment burden, and likewise, single-stage surgery is more frequently achievable in a less severe injury.

With regards to timing of soft closure, this was considered as a categorical variable and showed that patients waiting 3 days or more for soft tissue closure were 5 times more likely to require major revision surgery (OR: 4.91, CI: 1.99-12.09). We considered this figure to be subject to confounding and thus an adjusted model was constructed.

Table 3-5 Adjusted odd ratios to explore the relationship between time to soft tissue closure and developing a major complication

	Odds ratio	95% CI
Hours to soft tissue cover (0-9)		
10 to 21	1.02	(0.33-3.14)
22-72	0.69	(0.24-1.95)
73+	2.36	(0.87-6.36)
Gender		
Male gender	3.02	(1.15-7.91)*
Gustilo	1.91	(1.31-2.77)**
Observations = 177, R^2=0.18. p<0.05*, p<0.01**		

An adjusted model to identify the relationship between time to soft tissue cover and revision due to major complication after acknowledging confounders is reported in Table 3-5. Several risk factors were not retained in the adjusted model as they became non-significant after adjusting. In the adjusted model individuals waiting over 3 days (>72 hours), are more than twice as likely to experience complications, although this finding failed to reach significance (OR 2.36, CI: 0.87 – 6.36).

Variables that retained significance were Gustilo grade (OR: 1.19, CI: 1.3-2.77) and male gender (OR: 3.02, 1.15-7.91).

3.4.2.3 Discussion

We present a comprehensive overview of major complications in a population of open tibial fractures with long term follow-up from a regional dataset. The data presented identifies that almost one third (28.4%) of patients develop a complication which requires further major surgery, with infection and non-union being the most common complications. Temporal analysis determines that 86.2% of infections occur within 6 months of injury. When compared with our earlier TARN study, this study identifies a much greater burden from complications and highlights the difficulties of interpreting national audit data that does not include linked second episodes. The median length of stay in the TARN dataset was 13 days, extrapolated onto this dataset only 13.7% of infections had developed within this period, which provides significant insight into the sensitivity and limitations of using inpatient complications as an outcome measure.

This study considered the relationship between definitive soft tissue cover and longer-term complications to extend the analysis undertaken within our TARN chapter using a more robust outcome measure. The fully adjusted model identified Gustilo grade and gender as predictors of complication, whilst hours to soft tissue closure was not a relevant confounder which contrasts the finding of our earlier TARN work. Time to soft tissue cover or closure conferred increased risk in the unadjusted odds but was not significant after adjusting for other factors. Temporal factors often interact significantly with other aspects of the care pathways and other studies have found it challenging to pin-point the role of temporal factors in the treatment of these injuries as is discussed in our previous discussion on this topic (2.8.4.2) [56, 155, 156]. Crude odds ratios showed ring fixation and additional tissue cover as conferring increased risk for complication, whilst single-stage surgery offered reduced risk, adjusted odds ratios show that these factors were confounded by the severity of the injury. Gustilo grade provides information on injury severity, and it is therefore unsurprising that this was a significant factor for prognosis; Gustilo grade was not significant in our TARN model but was less relevant as the data was limited to Gustilo 3B and 3C fractures. The role of male gender is unclear, although it is possibly related to injury severity as this group are more likely to sustain high energy injuries and thus may have more complex fractures.

This study shares similar limitations to our TARN study from which it was clear that applying research questions to existing datasets collected for a different purpose can make it difficult to draw firm conclusions from the data. The ability to collect further data was useful for validity, but it was hard to extend the dataset as the medical notes often lacked details. Variation in the data is evident in the regression models reported in this chapter which appear to be hampered by residual confounding.

Nonetheless this analysis provides a useful contribution to methodologists, developing studies in this field. Determining length of follow-up to capture an outcome (such as complication) is a challenge for those designing research, and must be carefully considered during the feasibility stages. Methodologists must balance the costs associated with longer-term follow-up for researchers and patients against the risk of stopping data capture too early missing events in either arm, harming the integrity of the data. The infection rate of 14.2% and 2.1% in the regional and national cohort, particularly in the context of the differing results shown on the regression, highlight that capture of inpatient complication alone is likely to threaten the validity of a study. An infection rate of 14.2% in this study is concordant with other contemporary open tibial fracture studies reporting infection [10, 20-23]. The finding that 93.1% of infections occur in the first year provides appropriate backing data for those designing open tibial fracture research where length of follow-up was previously unclear.

3.4.3 A cross-sectional review of patient function and quality of life following open tibial fracture

3.4.3.1 Objective

This analysis addresses objective 6: "Summarise patient-reported outcome following treatment for open tibial fracture".

3.4.3.2 Analysis

Completed PROMS questionnaires were received from 81 individuals, flow of participants is shown in

Figure 3-4. From the initial cohort of 211 patients; 45 were excluded due to lacking capacity, 12 had no fixed address, and 17 were deceased. 166 patients were invited to complete the survey with a response rate of 48.8% (n=81). To consider the impact of missing data, a sensitivity analysis was undertaken and is reported in Table 3-6; the analysis identified that the demographics and treatment characteristics of those completing the PROM are similar. An odds ratio and confidence interval are also provided and indicate no significant difference between the PROMS and non-PROMS group.

Figure 3-4 Flow chart to demonstrate response to PROM survey

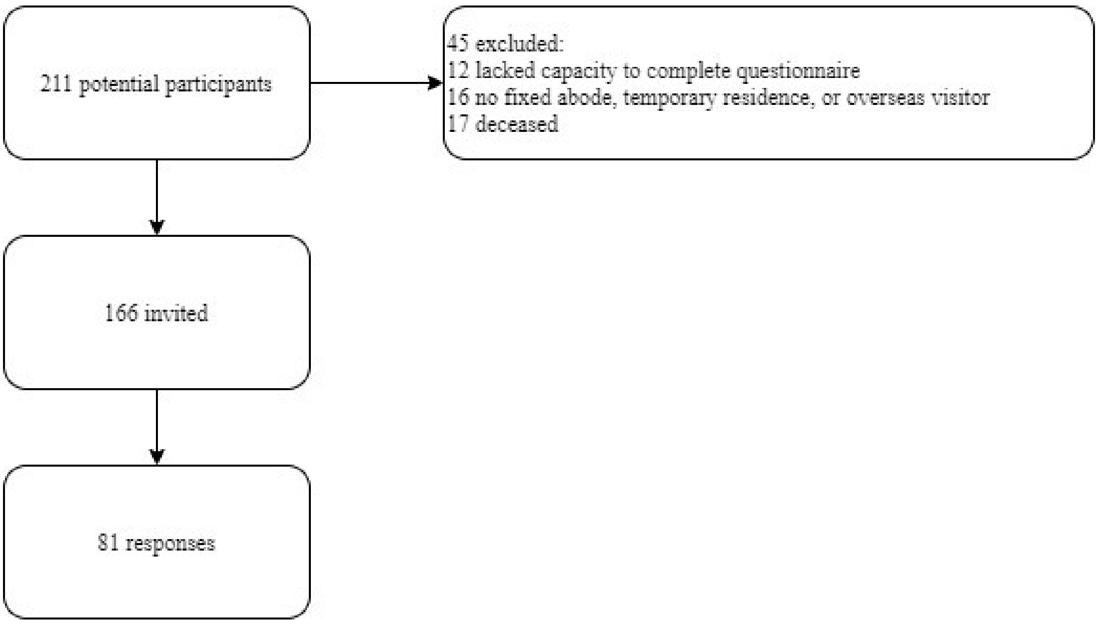
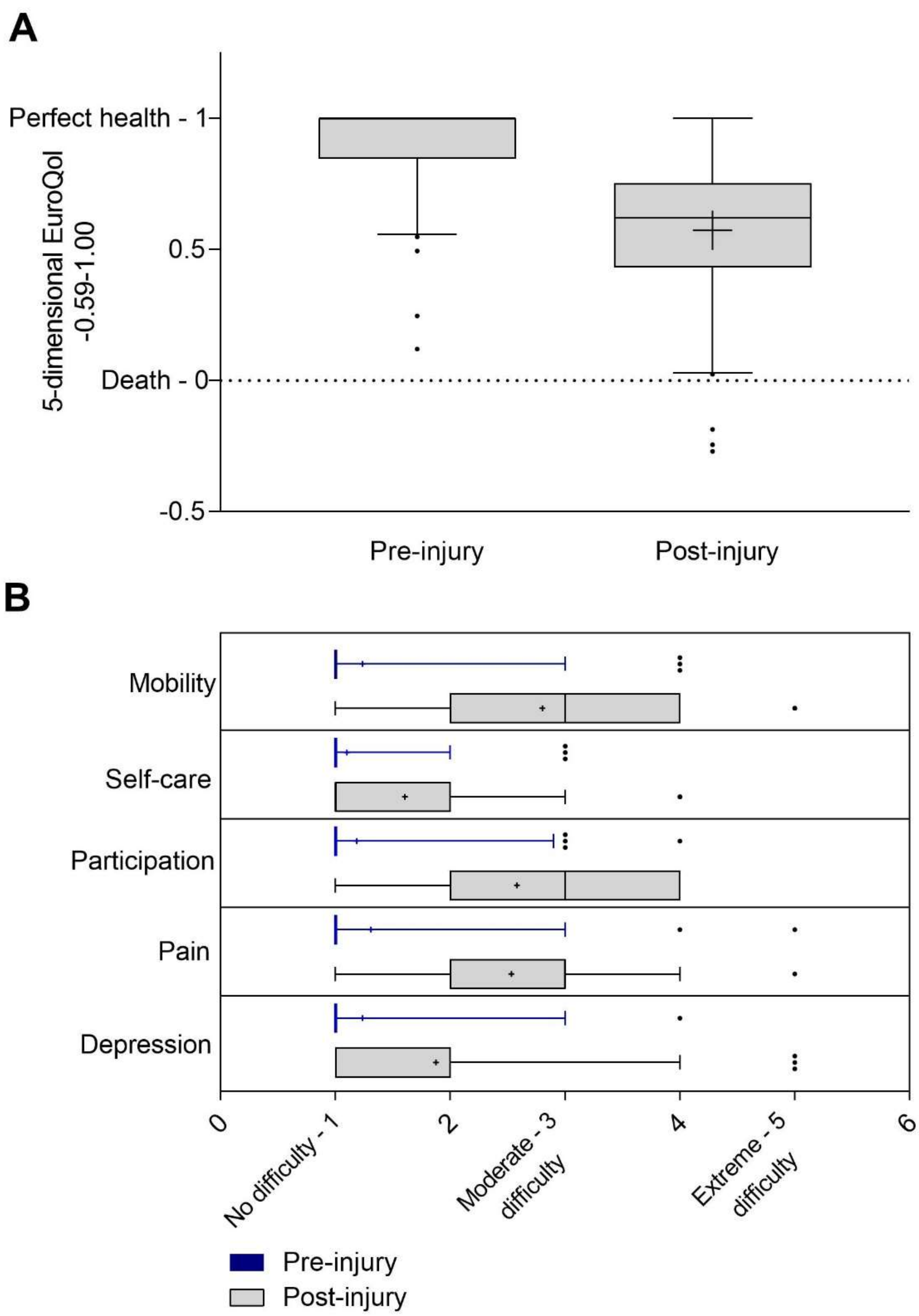


Table 3-6 Sensitivity analysis to assess response bias to PROMS questionnaire administered by post to 211 patients.

	PROMS unavailable	PROMS available	Odds ratio (95% CI)
Age			
18-40	66 (50.8)	32 (39.5)	1
40-65	43 (33.0)	32 (39.5)	1.53 (0.82-2.86)
65+	21 (16.0)	17 (21.0)	1.67 (0.78-3.59)
Gender			
Female	31 (23.8)	18 (22.2)	1
Male	99 (76.2)	63 (77.8)	1.09 (0.56-2.12)
Definitive			
Internal fixation	92 (74.1)	49 (60.5)	1
External fixation	32 (25.8)	31 (38.3)	1.61 (0.91-2.85)
Gustilo			
Gustilo 1/2	35 (26.9)	20 (24.5)	1
Gustilo 3	94 (72.3)	61 (75.2)	1.2 (0.84-1.84)
	n=130	n=81	

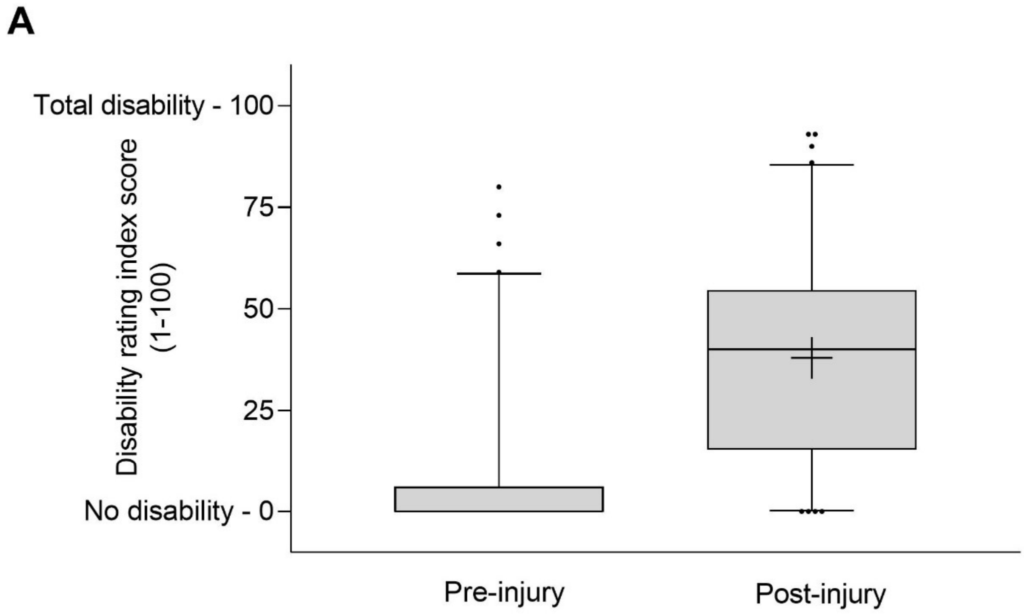
Figure 3-5 A) Mean EQ-5D index score before injury, and at least 1 year post-injury. Whiskers shows 5-95 percentile. + shows mean. B) Mean EQ-5D score by domain, before and at least one-year post-injury



A Wilcoxon matched-pairs test identified that there was a significant loss of health-related quality of life as a consequence of injury (Wilcoxon signed-rank z=7.6, p<0.01) which persisted for at least 12 months following injury; this significant difference is visible in Figure 3-5 and explained below. Before the injury, the median utility score for our patients was 1 (IQR 0.16) with values ranging 0.12-1.00; the results were skewed with 71.6% (n=58) patients of reporting no problems in any domain. Reference datasets for the EQ-5D in an age-matched population give an average utility score of 0.86 [182], and this comparison highlights that individuals who sustain an open tibial fracture are representative of the general population. Reported post-injury median utility was 0.63 (IQR 0.29) with values ranging from -0.56 to 1, the broad range and IQR suggests that extent of recovery is variable. The median loss of health following injury was 0.26 (IQR 0.36) with a range of -0.27 to 1. There is variation in improvement with some patients returning to perfect health, whilst others reported a health state of being worse than death. Response to injury on the domain level is documented in Figure 3-5. Prior to injury most patients reported no deficits in any domain, although there was a spectrum of responses within each domain. Following recovery, most patients reported moderate impairments in mobility, participation, and pain; slight anxiety or depression; but with no deficits in self-care. Domain level results highlight the multi-faceted nature of recovery, whilst the overall utility indicates the severity of these injuries.

Similarly, Wilcoxon matched-pairs tests identified that there was a significant increase in disability as a consequence of injury (Wilcoxon signed-rank z=7.7, p<0.01) which had persisted for at least 12 months following injury; this significant difference is visible in Figure 3-6 and explained below. Reported median DRI score before the injury was 0 (IQR: 5), median post-injury score was 40 (IQR: 40). There was a median difference of 30 points (IQR: 30). Most affected domains were running, heavy work, lifting objects and exercise/sports, whilst patients reported problems with dressing, sitting and standing to a much lesser extent; suggesting that by the later stages of functional limitations relate to high energy, complex tasks; opposed to more simple tasks.

Figure 3-6 A) Mean pre and post injury DRI scores. B) Post-injury subscale responses to DRI. Boxplots shows IQR, whiskers show 5/95 percentile.



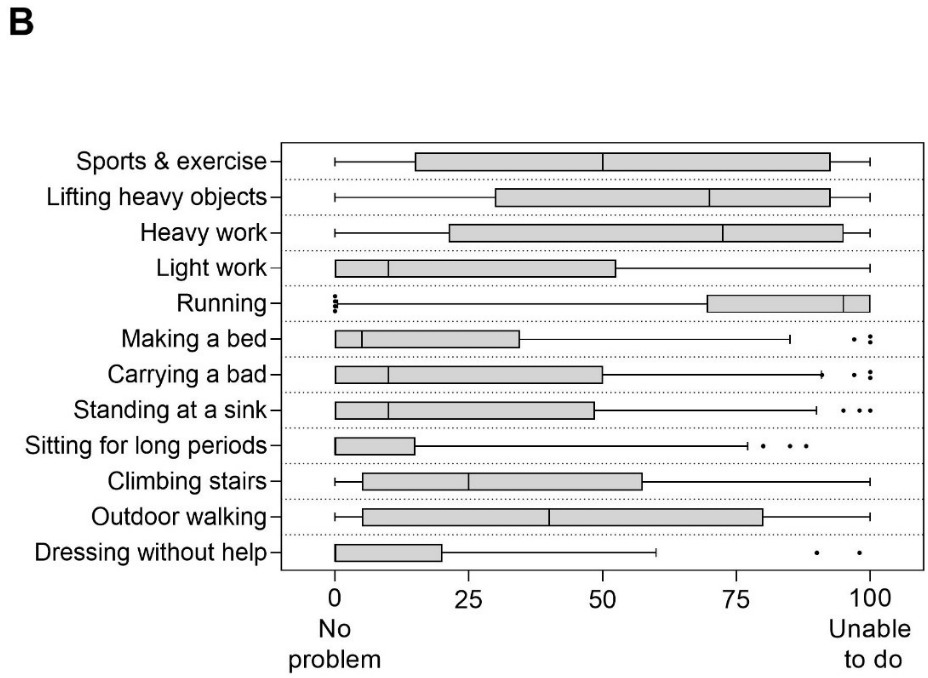
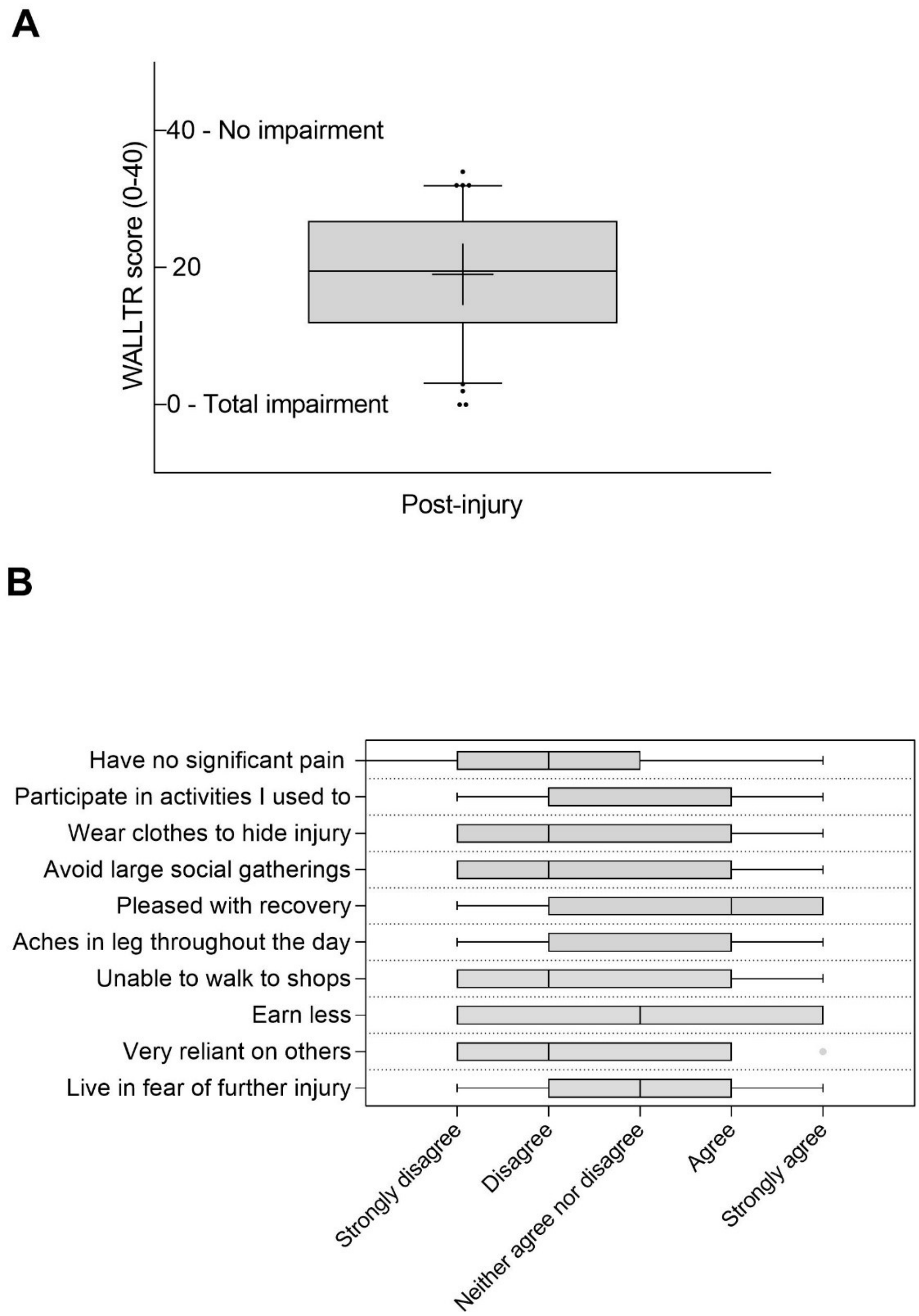


Figure 3-7 A) Mean post injury WALLTR score B) Post-injury subscale responses to WALLTR. Boxplots shows IQR, whiskers show 5 and 95 percentiles.



As with the measures of quality of life and disability, our injury-specific score indicated a significant deterioration in limb condition as a consequence of injury even after 12 months (Wilcoxon signed-rank = Z=7.8, p<0.01). Median post-injury WALLTR score was 20 (IQR = 14, range 0-34), demonstrating a 50% reduction in satisfaction with their limb; with pain and ability to perform previous activities being the most affected domains (Figure 3-7). Documented occupation at the time of completing the questionnaire is shown in Table 3-7; at the time of questioning 20% (n=17) were not working solely due to their injuries and only 27% (n=22) were able to work in the same capacity as before injury. 29% (n=24) of individuals were claiming sick-pay, and 25% (n=20) were involved in a litigation claim. 38% (n=6) of patients had been able to return to driving (if they had done previously). It was clear that the non-Likert section of the questionnaire had been poorly understood by patients and thus limited analysis has been performed.

Table 3-7 Occupation of participants, n (%)

Occupation (n (%))	(n (%))
Unskilled manual	24 (30)
Retired	18 (22)
Skilled manual	15 (19)
Unemployed	12 (15)
Unskilled non-manual	3 (3)
Skilled non-manual	3 (3)
Professional	3 (3)
Student	3 (3)

3.4.3.3 Discussion

Our findings illustrate that those who sustain an open tibial fracture report a 40% increase in disability and a 37% decrease in quality of life; at minimum 12 months after their injury first occurred. There was a significant impact on satisfaction with their limb and a long-term effect on the ability to work. The outcome from treatment varied; a small number of individuals reported a complete return to previous health states, whilst others reported complete disability and loss of quality of life.

Patient-reported outcome measures for open tibial fracture are seldom reported in the literature, although there are useful examples in severe limb injury. The LEAP study identified persistent pain, mobility issues, and depression at 1, 2 and 7 years after injury in individuals having both salvage surgery and amputation [2, 82, 83]. The WOLLF study [22, 23] utilised similar outcome measures to those used here reporting DRI and EQ-5D-5L at 12 months, the study outcome in our group was similar with participants in WOLLF reporting an average of 42% disability at 12 months, and a 45% loss in quality of life. The evidence from our cohort is supported by data from the wider literature that there is incomplete recovery from these injuries.

Patient reported outcome scores are often overlooked, and this data is consequently a useful addition; however, the data is limited in a couple of regards. The cross-sectional nature of the study has resulted in different lengths of follow-up and secondly there was a relatively low response rate to questionnaires. Sensitivity analysis demonstrated that the sample who returned the questionnaires were proportionate of the wider cohort. A cross-sectional overview of PROMS meant that it was impossible to draw comparisons between groups but was useful for over-arching insight into patient experience of open tibial fractures. Both of these issues could be improved by a prospective design with appropriate study management.

These findings show a long term impact of individuals as a consequence of injury, suggesting that treatments are not restorative and there is a need for long-term rehabilitation of these individuals to manage the physical, social, and psychological challenges likely to be experienced. Given the profound and lasting impact on the individual, PROMS should be prioritised an outcome measure in clinical trials to test whether that studies are delivering treatments that confer a meaningful improvement to the individual. It was evident that there was no consensus on the appropriate outcome measures to use in open tibial fracture trials and detailed work to develop a core outcome set would be a platform for delivering high quality RCTs in the future.

3.4.4 Cost of hospital based treatment after open tibial fracture

3.4.4.1 Objective

This analysis addresses objective 7: "Undertake a cost analysis to understand the average treatment costs for individuals with different treatments and different outcomes."

3.4.4.2 Analysis

Summary of costs

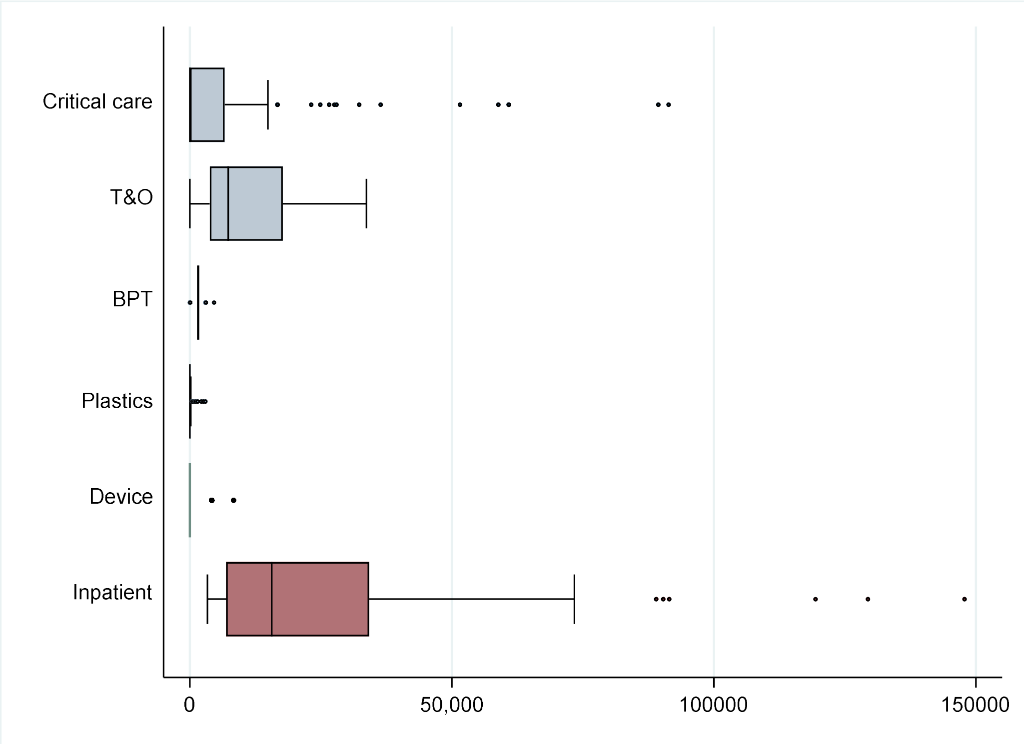
Inpatient and outpatient costs attributed to each speciality are shown in Table 3-8 and Figure 3-8. The mean per patient treatment cost was £27,312 (range £0-£147,996); per patient costs varied but in most cases Trauma & Orthopaedic (T&O) care was the most significant cost (mean inpatient cost £10,801). Application of a ring external fixator or pelvic reconstruction are specialist services and coded separately to reflect the additional associated costs. Critical care stay included stay on both intensive care and the level 1 trauma ward, only 41% required this degree of support at any stage and 75% had incurred a critical care cost of less than £9500. Critical care cost was dependant on number of organs supported and bed days, those with the highest cost had multiple concomitant injuries with significant risk to life. Some patients had separate charges for other injuries such as spinal surgery, general surgery or neuro-rehabilitation. 81 patients had BPT uplift. All patients had at least one A&E attendance.

Table 3-8 Inpatient and outpatient costs attributed to each speciality in patients with open tibial fracture, based on hospital coding data

(n=100)	% with cost	Mean (SD)(£)	Range (£)
Inpatient		25668.36 (27755.12)	(3320-137880)
Accident and Emergency	100	242.5 (99.3)	(0-646)
Critical care	41	8201.3 (17735.1)	(0-91329)
Trauma & Orthopaedic	91	10801.0 (9018.4)	(0-33660)
Ring external fixator	21	958.2 (1950.9)	(0-8332)
Plastics surgery	5	320.9 (1638.5)	(0-11643)
Pelvic reconstruction	2	304.6 (2142.7)	(0-15228)
General surgery	9	1509.8 (5630.2)	(0-29459)
Spinal surgery	3	545.2 (3467.3)	(0-30379)
Neuro-rehabilitation	8	1215.2 (7379.4)	(0-61675)
Best Practice Tariff	81	1569.8 (980.0)	(0-4560)
Outpatient		1644.4 (2231.03)	(0-9580)
Trauma & orthopaedic	87	961.5 (1051.4)	(0-4651)
Plastic surgery	26	217.2 (568.5)	(0-2954)
Orthopaedic rehabilitation	54	82.1 (190.8)	(0-1213)
Microbiology	13	427.6 (1415.1)	(0-8530)
Total	100.0	27312.8 (28176.17)	(3320-147996)

Inpatient costs

Figure 3-8 Boxplot of inpatient costs in 100 patients with open tibial fracture grouped by speciality and totals



T&O inpatient procedure costs were recorded under 89 different HRG codes, which provided detail on anatomical site (knee or ankle procedure, specific tibia codes were never used), procedure complexity (intermediate, major, very major, multiple (with intervention score) and complex procedures), and comorbidity (CCI). An additional 21 patients were coded as having a ring fixator. Procedure complexity was considered in the context of Gustilo grade (Figure 3-9) which highlighted heterogeneity in coding. How the difference in complexity corresponded to cost is shown in Table 3-9 and illustrates how heterogeneity may impact income. Procedure to repair open tibial fracture was most commonly recorded as major (38%) or multiple (46%) procedures; in less severe injuries, an intermediate code was used more frequently (38%). In addition to the base cost, 14 patients had charges for excess bed days (average £2466 (£7-£11,485). Whilst coding was to a very intricate level of detail, there were examples where veracity was questionable; for example, 21 patients were coded as having a ring fixator, whilst 35 from the cohort had a ring fixator during their care which would, in turn, have a significant impact on income.

Figure 3-9 Stacked bar chart shows HRG code attributed to each Gustilo grade as a proportion

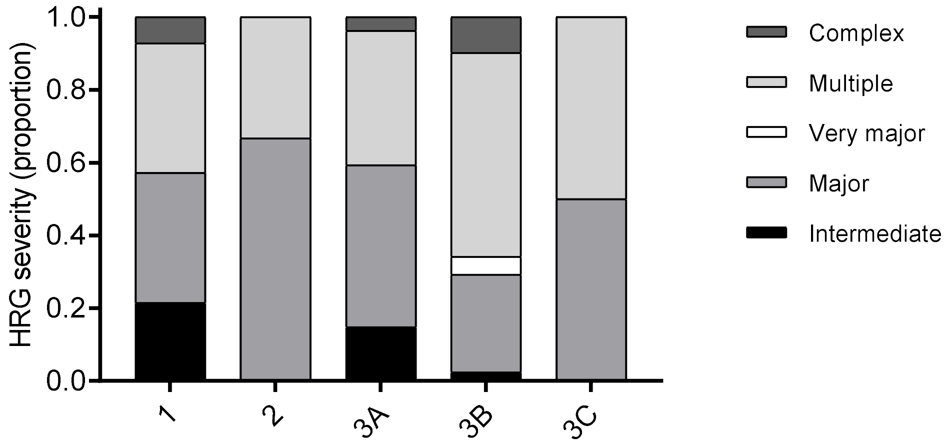
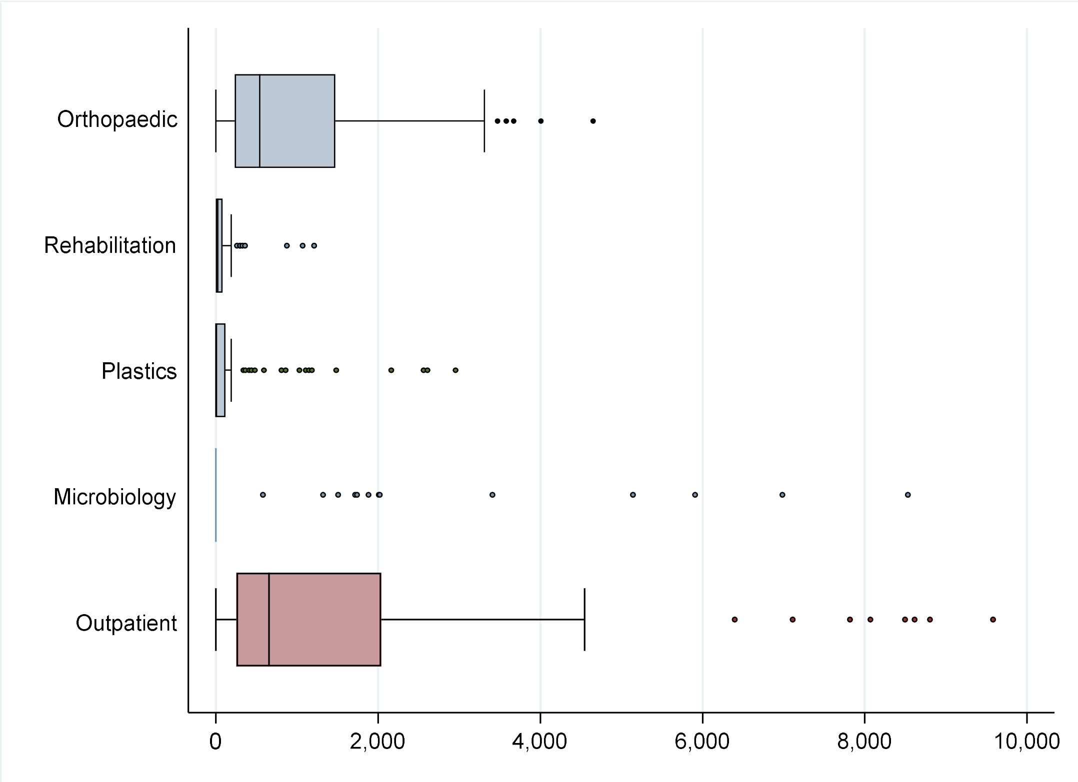


Table 3-9 Mean cost of inpatient HRG codes when grouped by procedure complexity

Procedure	Mean cost (SD)(£)
Intermediate	1625 (2302)
Major	2859 (4139)
Complex	8065 (9533)
Multiple	9028 (13600)

Outpatient costs

Figure 3-10 Boxplot to show overall outpatient costs for 100 patients with open tibial fracture, grouped by speciality



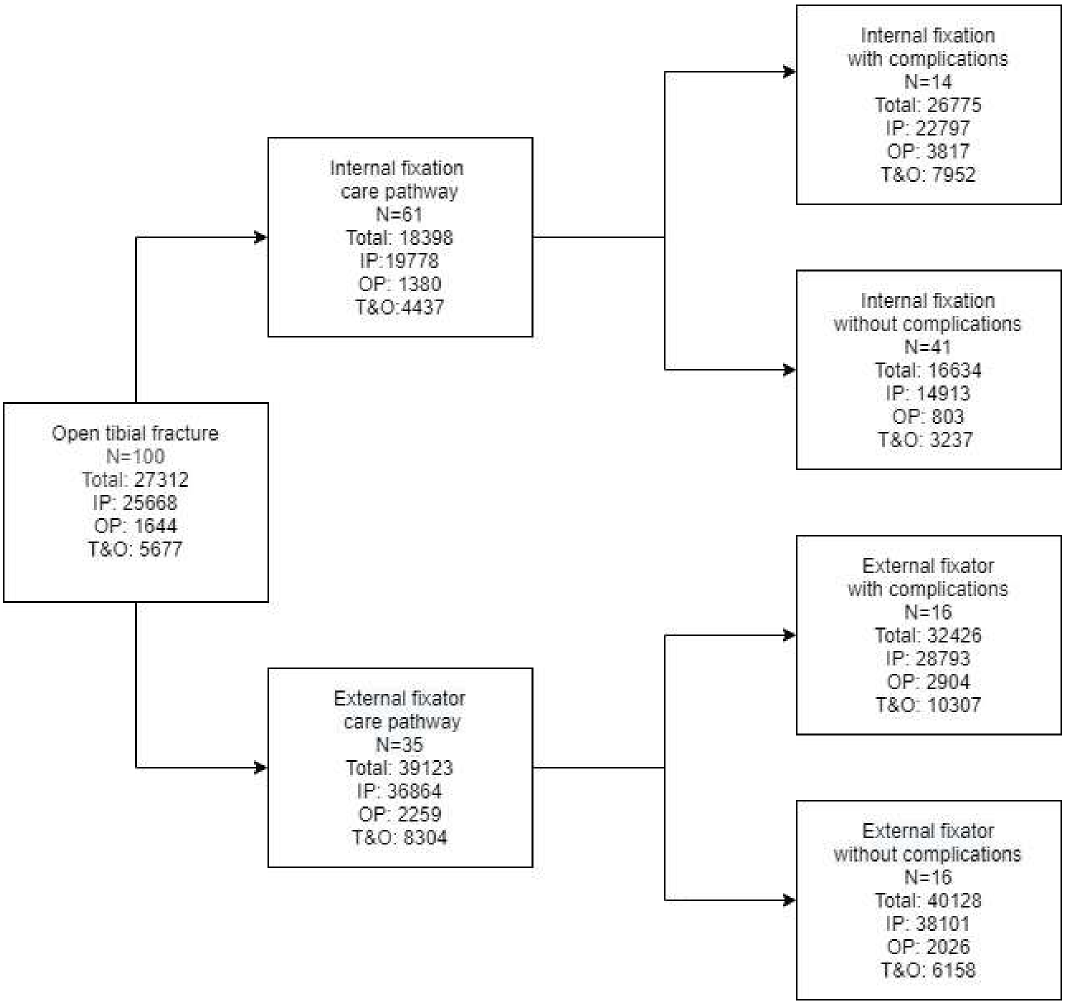
A summary of outpatient costs and breakdown by speciality are shown in Figure 3-10. Total mean outpatient cost per patient was £1644 ranging from £0-£9580. Outpatient appointments were charged at different rates; the first appointment was more expensive (mean cost: £217) than subsequent follow-ups (mean cost: £165), and a multi-professional appointment (mean: £218) was more expensive than those conducted by an individual consultant (mean: £146), the cost of the appointment varied between specialities. Outpatient charges also included procedures, on average these cost £166, but had a range of £120-£753. Average cost specifically for T&O outpatient care is shown in Table 3-10. The large range is explained by some individual's care being transferred to other centres following injury which results in zero cost, whilst high costs accumulate in those who have protracted follow-up and those who have had procedures in addition to consultations as part of their outpatient care.

T&O care formed a large portion of most patients' outpatients costs with an average of £961 of follow-up care, 87% used the T&O outpatient service. Rehabilitation services (occupational therapy, physiotherapy and orthotics) were accessed by 54 patients; the cost of physiotherapy was generally low, the average tariff price of one physiotherapy attendance was £23 and on average individuals attended two sessions (mean cost £84) with a range of 0 to 12. 13 individuals developed serious infections and required outpatient care from the infectious diseases team, the number of interactions with microbiology ranged from £2-£22, and the average cost of an outpatient appointment was £222, procedures and high-cost drugs resulted in a wide range of costs (£0-£8530). Some patients required outpatient input from plastic surgery (26%, mean £217).

Table 3-10 Trauma & Orthopaedic outpatient costs by appointment type in 100 patients with an open tibial fracture managed at a regional trauma centre.

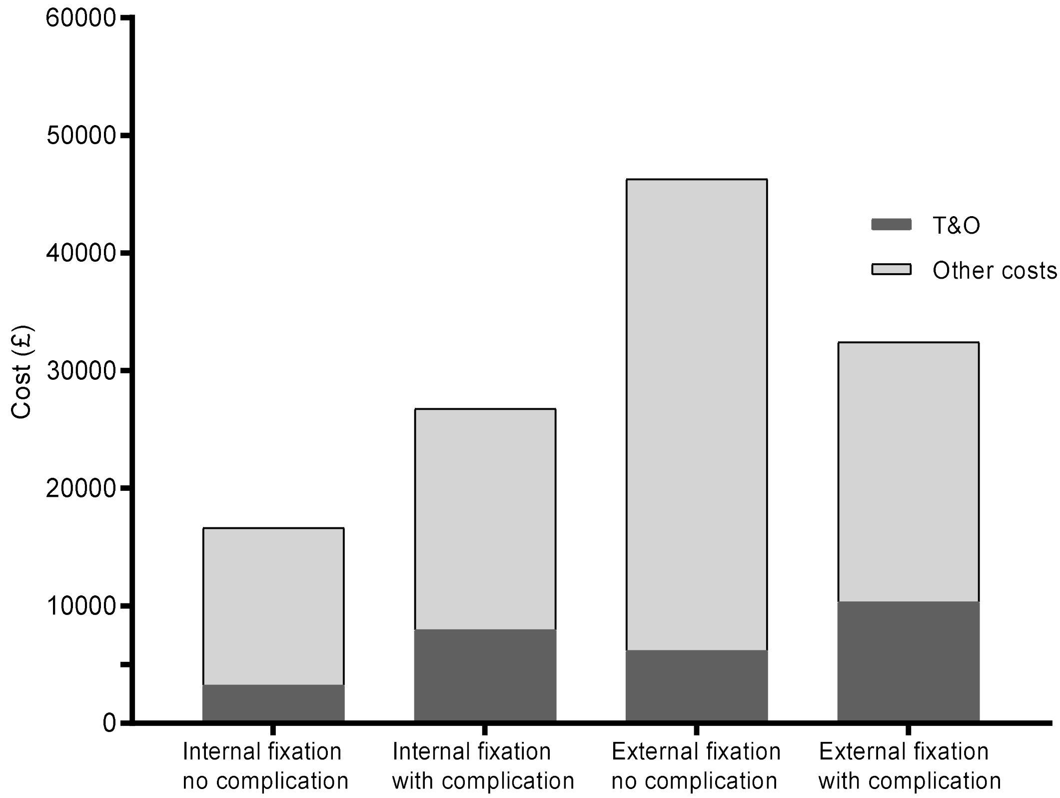
Appointment type	Mean cost (STD)(£)
Fracture clinic	90.67 (46.27)
First appointment, consultant led	
Single professional	128 (0.00)
Multidisciplinary team	142.67 (13.02)
Procedures	175.86 (98.56)
Follow-up appointment, consultant led	
Single professional	73.46 (9.74)
Multidisciplinary team	73.61 (6.06)
Procedures	128.23 (9.90)

Figure 3-11 Tree diagram shows breakdown of median costs across two central care pathways for internal or external fixation, with or without complications. Costs are reported as inpatient costs (IP), outpatient costs (OP), speciality cost (T&O) and an overall cost.



Fixation with internal or external fixation are the two main care pathways for open tibial fracture patients, differences in the median cost of each pathway were considered and are presented in Figure 3-11 and Figure 3-12. These figures show when considering the specific T&O cost that on average the cost of the ring fixator pathway (£8304) was almost twice that of the internal fixation pathway (£4437) (Wilcoxon rank, $z=-3.9$, $p<0.01$). In individuals that develop complications there is less cost variation between the two pathways, with ring fixator complications incurring a cost of £10307, and internal fixation costs at an average of £7952 (Wilcoxon rank, z=-1.5, p>0.05).

Figure 3-12 Costs presented in tree diagram, showing breakdown of costs grouped by care pathway and complications broken down by speciality



3.4.4.3 Discussion

Our evaluation utilised patient level costing data to summarise inpatient and outpatient costs and has identified several key findings with regards to hospital billing for these injuries:

1) There is vast heterogeneity in coding. Over 80 HRG codes were utilised to the describe procedures undertaken some attracting much higher tariffs despite the surgeries being similar in terms of indication and technique. This finding is important for hospital managers wishing to optimise income, and health care funders wishing to appropriately allocate resource.

2) The ring fixator care pathway was associated with significantly greater costs ($p<0.01$) than the internal fixation pathway; this would be anticipated as ring fixator treatment is usually reserved for more complex injuries. Still, it does provide insight into the additional burden that the use of this device places on services and individuals. Particular care should be taken to ensure these procedures are appropriately coded, and cost should be a factor in clinical decision making where there is equipoise.
3) The cost of complication was significant, with an average increased T&O care cost of £4000 per complication. This finding provides financial grounds to support work programmes which target reduced infection rate.

The data summarised through this study provide significant new insight as there are few examples of costing data in the literature; three studies were found. The first two focus on amputation [183] [4], whilst the most recent study was embedded within a Health Technology Assessment (HTA) trial considering the value of negative pressure wound therapy in open fracture [22, 23] [184]. Costa reports average care costs of approximately £14,000 per patient, which is significantly less than identified in our study where average cost is £27,312, the study also reports an average cost of complication £1950, which is lower than our average cost of £4215. There are limitations in the Costa study which may explain some of these differences. Firstly, the Costa study is limited to 12 months follow up which is likely to have impacted on the overall costs as many patient's care extended beyond 12 months. And secondly the Costa study relies on macro costing opposed to micro costings utilised in our study. There are limitation and advantages to the methodology applied in both our study and the Costa study, it is useful to draw comparisons between the two to obtain a more complete understanding.

Limitations of this study were mainly around the power of the study, whilst our regional open fracture cohort contained 211 patients, billing data was only available for 100 patients; as a consequence within groups analysis were small and vulnerable to confounding. A further limitation related to our ability to access all costing data from the individual's hospital spell, leading to potential under-estimations in costs;

for example data from the prosthesis service, and radiology is commissioned via a different system and thus data is not available. The use of billing data appeared to be a useful methodology in this short analysis. It would be a viable methodology in the setting of a linked RCT to robustly assess the costs of treatment, particularly when there is the appropriate quality of life data available.

3.5 Conclusions

This regional dataset has allowed us better understand the patterns of complication following injury, the patient perspective of how well they recover from the injury and the cost of these injuries to the NHS. The spectrum of outcomes collected and the availability of longer-term data, has provided a comprehensive overview of how well individuals recover from these injury and given an indication of the NHS and societal burden.

This chapter has provided greater insight into the descriptive outcomes of treatment, which makes a useful contribution to the evidence. This study has identified a high treatment cost for the health service following these injuries and their complications. Differences in the care pathways resulted in considerable variation; highlighting that there is a financial as well as a personal cost to using treatments where there is not a firm evidence base, which reiterates the research need in this population. This chapter also provided important information regarding outcomes of treatment; serious complications occurred in a quarter of patients. The study found that complications emerged up to one year after the injury, which is a useful finding for those designing future studies. Patient-reported outcomes showed that despite best treatment effort, many patients developed significant long-lasting disability, with a broader impact on quality of life; this highlighted that despite best treatment, recovery from these fractures is certainly incomplete. Further studies are needed to fully understand patient priorities with regards to patient experience and outcome.

This study shared methodologies with our TARN work, and consequently, limitations of this study were similar. Database studies apply research questions to previously collected data and thus is reliant on the existing content being appropriate to answer the research question. Whilst the TARN registry is well-powered and provides a national perspective; it was designed to study mortality in major trauma and thus lacked detail with regard to the injury, and fails to capture an outcome measure relevant to the cohort, these limitations curb overall usefulness. The regional dataset allowed us to access outcomes that were more important to both open tibial fracture patients and clinicians, but the cross-sectional approach limited the value of these. Similarly, whilst our registry was designed for orthopaedic trauma, injury characterisation was limited to Gustilo grade, which only provides limited prognostic information. This regional study identified that both injury severity and gender were significantly associated with complication rate but was not associated with time to soft tissue cover or any other aspects on the treatment pathway. It is important to understand why differences in the injury and care pathway are not represented in patient outcomes, a means of exploring this is qualitative research which will be the methodology employed throughout the latter half of this thesis.

Chapter 4. Recovery after Open Tibial Fractures: a Qualitative Evidence Synthesis

4.1 Introduction

Orthopaedic research almost always takes a quantitative stance to evaluate health technologies, with the RCT coveted as gold standard. This approach is not unique to orthopaedic research, and the culture of clinical research is positivistic in orientation. The positivistic stance relies on hypothesis testing; the hypothesis is based on apriori theory and tested using objective outcomes in an impartial manner, certain methodologies, such as randomisation and blinding; minimise bias. Traditionally, hypothesis based approaches are perceived to be the best methods of generating findings that are perceived to be reproducible beyond the population tested [185].

Qualitative methods are traditionally adopted by social scientists and deemed constructivist. The approach allows for multiple responses to a single question, acknowledging the importance of different perspectives. The approach utilises small sample sizes but provides rich descriptive accounts. The potential for bias is acknowledged and interpreted; the measures used are subjective and fluid. The approach is inductive, taking individual perspectives to develop broad patterns and ultimately understanding [186, 187]. When presented in this manner, positivistic and constructivist approaches seem incompatible; although in recent years there is increasing recognition that the differences between the two approaches are to an extent overstated. In healthcare research there is warming towards mixed-methods approaches, and the use of both qualitative and quantitative methods within a single research project is now supported by several funding bodies.[188]

Pragmatism is as an overarching philosophy which allows for qualitative and quantitative research methods to be used in a single study, stressing the primary importance of the research question rather than the methods. Pragmatism acknowledges the position of most mixed method researchers [189]; and encourages a practical and applied research philosophy in the absence of a forced choice-dichotomy between positivism and constructivism. The pragmatic approach accepts the needs to acknowledge both single and multiple realities, accepting hypothesis testing but acknowledging the need for individual perspective. The approach allows both deductive and inductive thinking, if this allows the researcher to further explore the research question [189].

The justification for using a mixed methods approach in this thesis is a practical one. The registry study provides a national perspective; that is objective and not influenced by the subjective experiences of individuals surgeons. The study provides new and important insight; however, the design of the TARN registry does not consider patient-centred outcomes which are essential for obtaining a holistic perspective. The long-term results after open tibial fracture are poorly documented; and existing studies in the field such as the LEAP study have failed to find differences despite vastly different interventions. This outcome from large observational studies, suggests that studies are either asking the wrong question, or failing to measure outcome correctly.

Positivistic, quantitative perspectives dominate orthopaedic research, and yet qualitative approaches are useful in settings, such as this, where there is a need to obtain more complete and corroborated results. Use of patient voice allows exploration of complex models of illness, providing information on outcomes that reflect the goals of the patient and are congruent with current perspectives that care should be patient orientated [190]. Sustaining major physical trauma has a profound effect on the survivor resulting in significant disability and a complex trajectory of recovery; people with open tibial fracture are diverse and will experience this injury differently dependant on their injuries and social position. Qualitative methods utilised here can provide a unique insight into the problems faced by patients.

The quantitative portion of this thesis has done little to evaluate or consider the existing qualitative literature. A search of literature failed to identify a qualitative evidence synthesis on recovery experience from open tibial fracture. A rigorous review and synthesis of the literature is needed to provide insight into the current qualitative evidence base for open tibial fracture.

4.2 Aims and objectives

This chapter addresses aim 3. Identify and synthesise qualitative evidence on the experiences of open tibial fracture patients; to understand aspects of recovery most important to the individual and inform future qualitative research.

Objective

The chapter will focus on a single objective, objective 8: "Conduct a systematic review of the literature in order to identify qualitative studies which consider experience of recovery after open tibial fracture".

4.3 Methods

The approach to undertaking a quantitative systematic review (SR) has broad consensus; yet this cannot be claimed for the qualitative counterpart. Systematic reviews are designed to minimise bias and collate evidence to answer a specific research question; there use has rapidly become a corner-stone of evidenced based practice and policy development [191]. Systematic reviews are often limited to RCTs or at least framed around the 'hierarchy of evidence'; whilst this approach is imperative to answering questions of clinical efficacy, there has been growing interest in the use of complementary qualitative methods to provide social context to questions around clinical efficacy and policy. Evidence synthesis in qualitative methods is considered valuable and has been used to shape several Health Technology Assessments (HTA); although identifying an appropriate methodology for this process has been challenging. One issue relates to whether the synthesis should follow the conventions of a quantitative SR, or whether the review should be analysed following the principals of primary qualitative research. Further complexities relate to the underlying philosophical assumptions of the primary research, and the observation that re-interpretation of the raw data under the constraints of a different paradigm may lead to misinterpretation and changed meaning [192].

Meta-aggregation is a widely adopted QES methodology; which was developed through a consensus approach and is aligned with the Joanne Briggs Institute (JBI) [193]. Meta-aggregation was founded on a pragmatist's perspective; and whilst sensitive to qualitative schools of thought the consensus work sought to identify processes analogous to those utilised in quantitative systematic reviews, thus rigorous enough to contribute to evidence based recommendations [192, 194]. The method characteristics of the method are as follows:

- Purpose: To collectively analyse all studies that meet pre-defined inclusion criteria
- Search strategy: Comprehensive with a documented search strategy.
- Critical Appraisal: Required use of a standardised tool
- Method of synthesis: Findings from selected studies are aggregated into sub-themes, sub-themes are then grouped into themes
- Outcome: Synthesised statements are presented as lines of action in the form of a standardised chart

Alternative methodologies exist and are not invalidated by the JBI approach; but are normally undertaken with a different purpose. For example meta-ethnography is undertaken to generate new knowledge; the search strategy seeks saturation and is not comprehensive and opposes any quality appraisal [195]; A further example is meta-study which employs a comprehensive search but intends to build new interpretations of the data [195]. Meta-aggregation was selected as the methodology for the review as it is supported by academic rigour and presents the best opportunity for a methodologically sound synthesis, it is aligned with our philosophical approach of pragmatism and is best-positioned to achieve our aim to identify and synthesise qualitative evidence on the experiences of adults with an open tibial fracture.

The aims and methodology for this review were determined apriori and are documented in a registered protocol on the PROSPERO database (CRD42018115884). The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Checklist [196] was followed. Methodological quality assessment and data extraction was undertaken using the Joanna Briggs Institute Qualitative Assessment, Review and Appraisal Instruments (JBI-QARI) [193], copies of each tool are included in appendix 8.9 .

4.3.1 Inclusion criteria

The current review considered qualitative papers that included adult patients who have received treatment for an open tibial fracture. Studies which reported severe limb injury but did not report open tibial fracture as a separate cohort were excluded; and mixed methods studies were only included where the qualitative findings are reported separately. Studies not published in the English language were excluded.

4.3.2 Search strategy

A systematic search was conducted using predetermined terms for open tibial fracture, related synonyms and truncations; combined using Boolean operators and database-specific syntax, an example of the search terms used in Medline is shown in Figure 4-1. A validated methodological filter for qualitative research designs [197, 198] adapted for specific databases was used to provide more concise search results. The search included papers from the earliest available year of indexing until October 2018.

Figure 4-1 Search strategy for identifying open tibial fracture in Medline, which was combined with a validated methodological filter

Search term
1. tibial fractures/
2. (tibia* adj4 (injur* or fractur*)).mp.
3. (open* adj4 (injur* or fractur*)).mp.
4. (open* adj4 tibia*).mp.
5. gustilo.mp.
6. ((lower limb* or lower leg* or lower extremit*) adj4 trauma).mp.
7. ((lower limb* or lower leg* or lower extremit*) adj4 fractur*).mp.
8. ((lower limb* or lower leg* or lower extremit*) adj4 injur*).mp.
9. exp Fractures, Open/
10. (compound* adj4 (injur* or fractur*)).mp.

The database search included MEDLINE, EMBASE, CINAHL, PsycINFO, SSCI, ASSIA, PEDRO, ProQuest dissertation and theses and Conference Proceedings Citation Index. The search was supplemented with a hand search of the reference list of retrieved studies to identify any further relevant citations. All citations retrieved were managed in Endnote and assessed for inclusion by two independent reviewers (JN and CD).

4.3.3 Quality assessment

Selected papers were initially reviewed by two authors for methodological validity using the standardised critical appraisal tool (JBI-QARI [193]). The checklist evaluates on congruity between paradigms, methodologies and methods but also considers bias and representation of participant's voice. JBI-QARI is the recommended quality appraisal tool for meta-aggregation studies, and a recent independent validation of the discriminative abilities of qualitative checklists to identify high quality research studies identified the checklist as the most appropriate to evaluate primary research studies [199]. The assessment will provide a baseline assessment of quality and all studies will be included irrespective of this; the decision not to exclude papers of low quality is supported by the recent literature [200] and was deemed appropriate given the subjective nature of the quality assessment.

4.3.4 Data extraction and synthesis

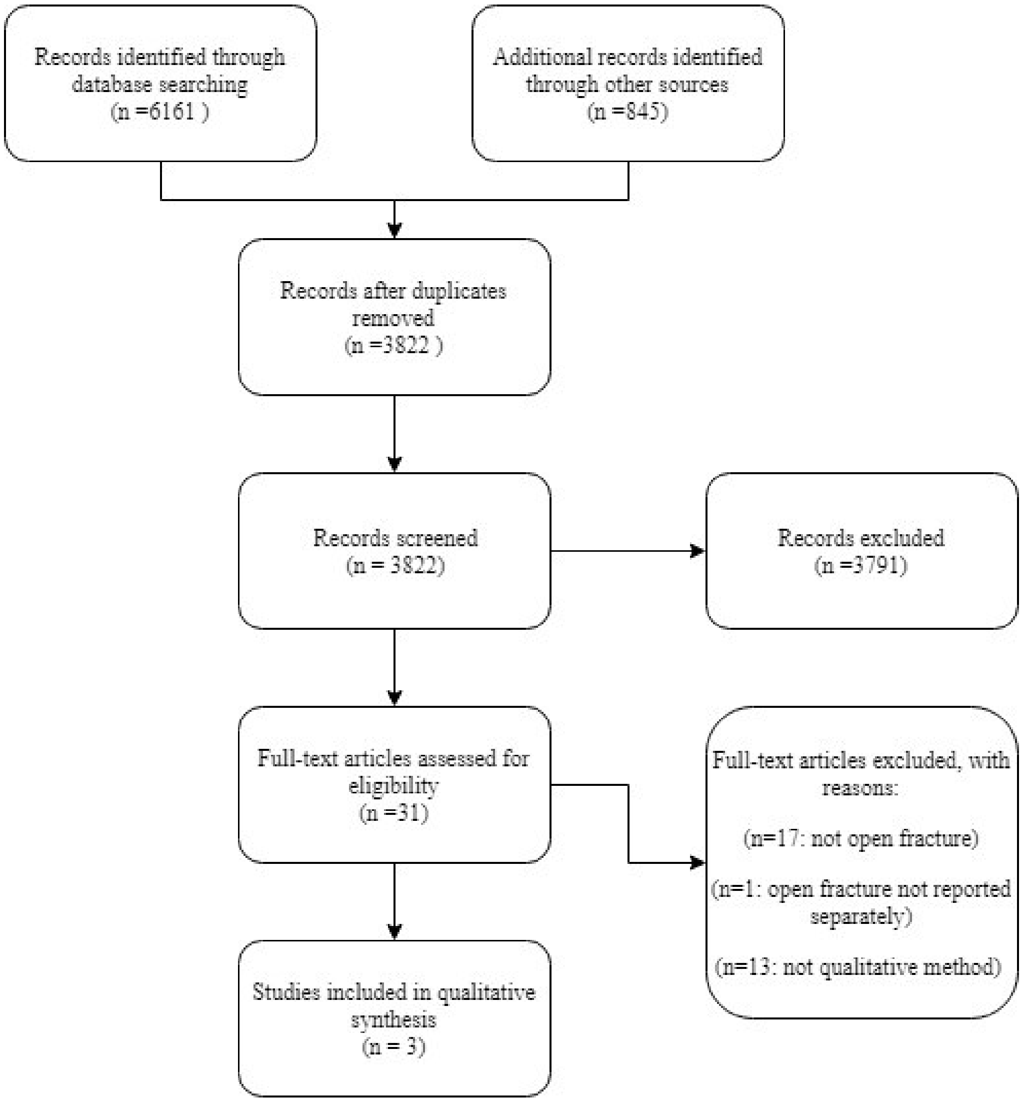
Extraction was guided by JBI methodology and utilised the JBI-QARI extraction template [193]. Extraction first focused on the characteristics of the study, collating data on methods, methodology, population, and phenomenon of interest; this process provides useful contextual information about each study included and assists interpretation. Secondly the extraction focused on the aggregation of findings and their associated illustrations. A "finding" is defined as a verbatim extract of the author's analytic interpretation of their results or data; an "illustration" is the direct quotation from the participant. Findings were identified within each included paper and rated according to credibility. Findings were assigned a level of credibility using the JBI levels of credibility, grading each as either unequivocal, credible or unsupported. Unequivocal findings are supported by evidence beyond reasonable doubt; credible findings present an interpretation of data although the finding is still plausible and unsupported findings are not supported by the data. After extraction data was organised into categories, the categories are de-novo and aggregate similar findings under a sub-heading that conveys the inclusive meaning of a group of similar findings. Categories were formed from unequivocal and credible findings; unsupported findings were not included. These categories were subjected to meta-synthesis, meta-synthesis describes the process of organising categories under a broad heading to produce synthesized findings. Any disagreements that arose between the reviewers during searches, quality appraisal or extraction were resolved by discussion amongst the review team.

4.4 Results

4.4.1 Study selection

The process of study selection is reflected in the PRISMA flowchart in Figure 4-2. The search initially yielded 3822 results for screening after duplicates were removed. Based on a search of title and abstract, 3790 records were excluded leaving 31 studies which required review of the full-text copy. Scrutiny of the 31 full text articles lead to 28 further exclusions. Exclusions were as follows: 17 studies reported limb injuries or conditions that were not open tibial fractures; 13 studies reported a quantitative methodology only; 1 study did not report open tibial fractures as a separate cohort. A total of 3 studies met the inclusion criteria and were included in the synthesis [66, 95, 201].

Figure 4-2:PRISMA flowchart.



4.4.2 Study characteristics

This systematic review is based on qualitative data reported in 3 papers. Table 4-1 summarises the main characteristics of each study included [66, 95, 201]. The number of participants in each study ranged from 8 to 20, with a total of 49 participants across all three studies. The average age of participants ranged from 35 to 44 years with all studies including both genders; this distribution is reflective of the anticipated demographic of this patient group [10]. There were differences with regards to the duration since injury amongst the studies, with one study [201] reporting acute experience (within one month of injury), one reporting 1-2 years post injury [66] and another reporting experiences of up to 12 years [95]; this difference results in three quite distinct studies as the focus within the acute experience is different to the chronic experience. All three studies [66, 95, 201] include a heterogeneous cross section of patients; the authors apparently mindful that the experiences of individuals will vary dependant on severity of injury, treatment received and complications. All studies were based in a western health setting. One of the studies was conducted in a ward environment [201], whilst the other two studies were conducted in university buildings by surgeons [66, 95]. The studies used a range of methodological approaches in the setting of a semi-structured interview, this is as would be anticipated in studies considering lived experience. Taken as a whole, these three studies [66, 95, 201] include a representative sample of patients that should reasonably reflect the experiences of individuals with an open tibial fracture who were managed in a western health setting.

Table 4-11 Characteristics of included studies (JBI-QARI)

	Trickett (2015) [66]	Shauver (2011) [95]	Tutton (2018) [201]
Method	Semi-structured interview, lasting about 1 hour	Semi-structured interview. 13-77 minutes per interview	Semi-structured interview, 25-86 minutes per interview
Methodology	Not stated (Mixed methods implied)	Grounded theory	Phenomenology (Heidigger)
Interventions	Using patient experience to develop a patient reported outcome measure	Recovery from open tibial fracture with focus on adaptive coping	Patient experience during acute care
Setting	Clinical research facility within the grounds of a trauma unit	University of Michigan, Level 1 trauma centre	Two UK major trauma centres, ward based
Geographical	United Kingdom	United States	United Kingdom
Cultural	Socioeconomic background not described	Socioeconomic background not described	Socioeconomic background not described
Participants	n=9, 29-62 years, 1-2 years from injury;	n=20, 23-68 years; 2-12 years following injury;	n=20, 20-82 years, 5-35 days from injury. Embedded within RCT.
	Gustilo 1-3B tibial fracture	Gustilo 3B/C tibial fractures	Gustilo 2-3 lower limb fracture
	1 amputation, 8 reconstructions (included internal and external fixation 4 complications)	23 fractures in 20 patients. 4 amputation 14 reconstructions 5 secondary amputations 22 major complications	All reconstruction
Data analysis	Conventional content analysis	Open coding	Coding

4.4.3 Critical appraisal

Each of the included studies [66, 95, 201] were critically appraised using a standardised quality appraisal tool [193] and Table 4-2 documents the quality assessment has below. Studies were not excluded due to perceived poor quality as the aim of this systematic review is to look for the lived experience and this is potentially still validly reported in despite methodological limitations [202]. Instead the quality assessment was utilised to obtain a formal baseline assessment of quality. Generally, the studies used methods, methodologies and interpretation methods that were congruent and did not impact on the interpretability of the studies. The studies do not labour on the setting and role of the researcher, although all studies have made documented attempts to manage any bias caused by the researcher. The Trickett and Tutton [66, 95, 201] studies support their themes with participant voice throughout the narrative and the relationship between voice, analysis and conclusion is self-evident; this is less true of the Shauver [95] paper which buries much of the interview data in tables making it difficult to relate their presented conclusions to the raw qualitative data. As previously discussed, all study findings were included in the synthesis, despite some quality limitations.

Table 4-2 JBI-QARI critical appraisal checklist. ✓) Yes, X) No, ?) Unclear

	Tutton [201]	Trickett [66]	Shauver [95]
Congruity between the stated philosophical perspective and the research methodology	X	X	X
Congruity between the research methodology and the research question or objectives	✓	?	✓
Congruity between the research methodology and the methods used to collect data	✓	?	✓
Congruity between the research methodology and the representation and analysis of data	✓	?	✓
There is congruence between the research methodology and the interpretation of results	✓	?	✓
Locating the researcher culturally or theoretically	✓	X	X
Influence of the researcher on the research, and vice-versa, is addressed	✓	X	X
Representation of participants and their voices	✓	✓	X
Ethical approval by an appropriate body	✓	✓	✓
Relationship of conclusions to analysis, or interpretation of the data	✓	✓	X

4.4.4 Type and classification of findings

Analysis of the 3 studies identified 47 findings. Findings were rated according to credibility; the majority of findings from our extraction were classified as unequivocal (n=11) or credible (n=29). Findings that are informed by participant voice are reported in detail in appendix 8.10; unsupported statements were not included in the synthesis. Unequivocal and credible findings were aggregated into categories of similar meaning; 11 de novo categories were defined. Categories were then brought together into 2 synthesised findings. Synthesised findings, categories and their findings are reported in the remainder of this section.

4.4.4.1 Synthesis one: The impact of pain, immobility, altered appearance and fear intrudes on all aspect of life; the impact lessens with time but never resolves.

This synthesis was generated from six categories reporting symptoms and the impact of these on participation. A summary of categories and their findings is reported in Table 4-3 and described below. Pain, immobility, altered appearance and vulnerability emerged as traits experienced after an open tibial fracture, which in turn were reported to impact on employment, finance, family-life, independence and social activities.

Findings relating to pain emerged from all studies included in the synthesis. It was apparent that the experience of pain evolves over time. Within an acute setting pain was reported as considerable but supported by the hospital environment. There is discussion around the evolution of pain to a more chronic pain; which was described by one individual as *''. . .like an ache, like toothache. . . not enough to need painkillers''* [66], the long term pain was sensitive to physical and environmental factors such as overuse and temperature.

Mobility was discussed in all three studies. Acutely, participants had to adapt to being suddenly immobile with a focus on the challenges of regaining very basic mobility, demonstrated by the following participant: *"to transfer from this to a wheelchair I'm absolutely exhausted and you've just got no trunk strength or virtually none"*[201].

Trickett [66] reported that with time patient's focused more on regaining the ability to walk or run, using weight-bearing status and return to a pre-injury level of activity to gauge their own recovery. Shauver [95] focuses on the residual mobility deficit faced long term reporting amputees reported had more difficulties long-term; this was illustrated with examples such as *"I can't walk"* [95] which emphasises the potential for permanent severe disability.

In all three studies there was strong reference to changes in appearance being a concern to individuals, but the founding for this varied. Reconstruction patients were concerned with the appearance of healing wounds, scars, and flaps whilst amputation patients appeared concerned with exposing prosthetics. In addition, two studies reported that patients raised concern about increase in body weight. The concern around cosmesis seemed to focus on unwanted *"attention from others"* [95] and a desire to avoid intrusive questions from strangers.

Fear and vulnerability was reported by individuals in all three studies. Vulnerability was most evident in a paper [201] which focused on acute admissions with patients describing experiences of being *"lonely and vulnerable"*. Apprehension continued throughout recovery, with fear being a theme which also emerged from Trickett's paper [66], fear was multi-factorial in aspects such as initial injury, pain, complications, further surgery or further injury. The impact of this vulnerability was profound and seemed to impact pace of recovery.

Symptoms were in many aspects inter-related, and it was difficult to tease apart the relative contribution of each aspect to impact on quality of life. Nevertheless, studies reported that the injury had impacted on employment, family-life, independence and social activities. Even within the acute setting and within the early stages of recovery there was an acknowledgement that reintegration into their previous normality would be difficult and there was anticipated challenges with regard to employment, social activities and family life (*"I would have thought after three months I would be back at work but after seeing the pictures there's no chance"* [201]). Individuals had reported difficulties in returning to their previous employment or indeed any form of employment, with significant financial implications; this was captured by one individual who stated that: *"[My old job] is the only thing I ever did. I don't really know how to do anything else."* [95]. There was a reported impact on social life due to challenges with leaving the house and an acknowledged impact on other family members who had adopted a caring role.

Table 4-3: Results of first meta-synthesis of qualitative research findings - The impact of pain, immobility, altered appearance and vulnerability intrudes on all aspect of life; the impact lessens over time but never resolves

Category	Findings
1.1) Body image: Change causes anxiety and prompts intrusive questions	The wound itself and the state of the injured leg created a real sense of panic; participants were reluctant to see the actual wound and had to be ready to do so. [201] .
	Appearance and cosmesis of the affected limbs were raised by many patients, both male and female, as something which they considered important. [66]
	The appearance prompted curiosity and questions from others. [66]
	20% of participants mentioned unwanted weight gain as a result of decreased activity. [95]
1.2) Mobility: Regaining ability to walk unaided	Participants had to learn how to cope with prolonged periods of bed rest and immobility; deal with the frustrations of limited mobility; accept the pace of recovery was dictated by healing; and move their bodies within the limits of their injuries. [201]
	Emphasised by patients was the importance of being able to weight bear as marking their own perception of recovery. Four patients described the progression to being able to run as a core component of their improving mobility and a significant stepping stone to normality. [66]
	Flexibility was a component of the patients' description of mobility in addition to the ability to move oneself from one place to another: [66]
	Participants who had undergone an amputation were more likely to relay a greater change than were patients who had only reconstructed limbs. [95]
1.3) Pain: Complex and severe, variable dependant on management	Pain was a source of concern to all participants. This was complicated by the variety of sources of pain, access to medication, and a reluctance to take medication. [95]
	Patients undergoing fine wire external fixation for their injury particularly emphasised this severe pain in the immediate postoperative period. [66]

	There was an observed transition from the initial pain following injury and surgery through to ache in the later stages. [66]
	Many of the patients describing 'ache' in contrast to 'pain' differentiated between them by describing their use of analgesics. 'Pain' required the use of analgesia whilst 'ache' often did not. [66]
	Changes in temperature were described as having a profound effect on symptoms including pain and stiffness. [66]
	Pain was characterized as "constant" or "almost always there" in 53% of cases; the remaining participants spoke of occasional pain, usually secondary to overuse. [95]
1.4) Vulnerability: Fear linked to injury and recovery	Participants expressed an emotional fragility that purveyed every aspect of their life. Some had only felt similar feelings before when a family member had died. [201]
	Fear was a prominent term used in all interviews and appeared to persist through to the final stages of recovery. [66]
	Patients reported fear of many separate circumstances, injury, pain, or complications, further surgery or further injury. [66]
	Fear was described as a barrier to recovery. [66]
1.5) Employment Impeded return to work and earning ability	Going back to work was difficult to visualize due to the uncertainty regarding the degree of functional recovery expected. Information on was gratefully received but participants felt clarity about timescales was unlikely due to the complex nature of their injury and individual recovery paths. [201]
	Only 4 participants were able to return to their previous positions, all desk-based jobs. [95]
	The inability to work had implications for many of the non-retired patients, with consequent financial implications. [66]
1.6) Social: Reliance on family and capped independence	The need to get home was overwhelming but as they progressed it was something they felt was more tangible and they could imagine what it would be like to go home. [201]
	The impact of the injury on others was recognised by patients as being important. The positive role that family had, as well as direct implications on others from having a severely injured family member. [66]
	Impact on others was reflected in alterations to social interactions. [95]
	Spouses were the most frequently mentioned source of support... perhaps indicating the importance of spousal support in the eyes of our participants. [95]

4.4.4.2 Synthesis Two: Adapting to changed circumstances requires great resource.

This synthesis was generated from 5 categories which embodied the physical, emotional, and social investment needed for recovery. A summary of categories and their findings is reported in Table 4-4 and described below. Each study is positioned at a different time point with regards to recovery; with studies reporting acute experiences, the experience of the first year of recovery and longer-term outcomes. The focus of adaptation is different in each paper and in some ways is difficult to synthesise.

The most acute paper [201] describes an experience of shock, vulnerability and becoming fragile in the immediate aftermath of injury. There is reference to experiences of detachment associated with phenomenal anxiety; and fragility as individuals attempted to process the significance of their experiences. An illustration of this is seen when considering amputation: *"The only time I actually felt detachment was when Jim [Surgeon] first mentioned the possibility, the extreme possibility of amputation*." [201] The Shauver and Trickett paper in comparison focus on the strategies employed to rebuild and overcome what they have lost as a consequence of injury.

Shauver focuses on coping [95]; hypothesising that adaptive coping techniques reduce stress and improve coping self-efficacy encouraging the use of further adaptive coping strategies resulting in personal growth; describing a positive feedback cycle. Shauver describes coping strategies used by patients as being either problem focused or emotion focused, which can either be adaptive (positive) or avoidance (negative) strategies; both strategies are further described as either. There are illustrated examples in the patient narratives:

- Approach coping: *"I don't take (motorized carts) when I go shopping, but do I go to places like Super Wal-Mart? No. I go to local grocery stores."* [95]
- Avoidance coping: *"People expect, 'Oh, I saw this guy runnin' the other day and he's runnin' 400s faster than Olympians.' Why can't I do that?"* [95]

Goal navigation and coping strategies are unique but overlapping processes. Within the setting of orthopaedic surgery where there is a strong impetus on the individual to engage with rehabilitation, attitudes towards goal setting are important and was identified by Trickett [66] as a theme emerging from their data. The study identified that goals could be identified by the healthcare professionals but were identified more often at the individual level; examples were *"making a cup of tea"* or *"getting out of the car"*. Meeting these goals was important to patients, and the opposite was a source of frustration.

Satisfaction with recovery was discussed in all three papers, with a general perception being that most people were satisfied with the outcome from their treatment. Within Tutton's paper [201] this satisfaction was regarding initially surviving a major accident interpreted as a gratitude towards health providers; the other two papers report general satisfaction with their eventual outcome. An important conclusion raised by Trickett was that there was a distinct "*discrepancy between normality, recovery and pre-injury functioning*." [66]

Table 4-4: Synthesis 2: Adapting to changed circumstances requires great resource.

Categories	Findings
2.1) Approach coping: Tackling and adapting to new stressors	Several participants reported modifications to their homes or vehicles and nearly every participant mentioned new ways to perform everyday tasks. [95]
	Recovery was accompanied by considerable changes, adaptation and coping strategies which were implemented both by the patient and those around him/her. [66]
2.2) Avoidance coping: Rejection of tasks that were previously easy	Participants were also horrified and shocked when, at some point in their recovery, they felt or were told that losing their leg had been or remained a possibility. [201]
	Alcohol was a method of coping with the circumstances surrounding the injury. [66]
	Participants reported engaging in problem avoidance, avoiding situations that are now too difficult or would highlight the participants' injury or disability. [95]
	Participants with amputations engaged in self-criticism, focused primarily on the perception from the popular media that many amputees are able to compete in athletics at a high level. [95]
2.3) Personal growth: Redefining self in the aftermath of trauma	Some of our participants seemed to be not only surviving their open tibial fractures, they were appearing to thrive, not in spite of the trauma they had been through, but because of it. [95]
2.4) Goal setting: Achievement of goals indicated progress	Often goals were set by the supervising healthcare professional but in many instances, goals were set by the patients themselves. Small steps were seen as important landmarks, indicating progress towards normality. [66]
	Failure to or delay in achieving goals was seen as a cause of frustration. [66]
2.5) Satisfaction with recovery and gratitude: Satisfaction despite limited function	There was a sense of being saved, being grateful that they had received such good care, and being lucky as the event could have been so much worse.
	Some patients deferred the decision regarding recovery to their surgeon. It is possible that this process was an act of seeking approval from an expert rather than a true abdication of responsibility. [66]
	There appeared to be a discrepancy between normality, recovery and pre-injury functioning. [66]
	Some patients defined a specific moment that signalled their full recovery. [66]
	Our patients reported satisfaction with their treatment outcomes and or/outcomes. [95]

4.5 Discussion

The results reflect the profound and devastating impact of an open tibial fracture on the lives of those who sustain them. Immobility, pain, cosmesis, vulnerability and the associated impact of these on ability to fully contribute to society were identified as outcomes of importance within the studies reviewed [66, 95, 201] These findings are well aligned with the quantitative evidence base and serve to embellish what was previously known regarding the outcomes of these injuries [10, 22, 69, 80, 82]. The inductive nature of qualitative research allows the priorities of patients to emerge independently of the framework created by a quantitative research design. The categories identified by this synthesis of outcomes are useful in directing practitioners and policy makers involved in the management of these injuries and may be used to provide impetus when allocating resource. It was evident from the synthesis that some aspects of outcome had been elucidated to but not explored. Further research in this area would serve to better consolidate the web of outcomes that have emerged as part of this synthesis.

Coping, goal navigation and adaptation following open fracture, or even orthopaedic trauma, is rarely discussed in the evidence base. This prevents researchers and healthcare professionals from drawing inferences on the strategies utilised by individuals in either the acute or chronic phrases of recovery. The studies presented in this review present inconsistent ideas regarding these strategies [66, 95, 201], but the emergence of these themes across the studies reviewed suggest that these strategies are important to patients and are likely to influence outcome. This has been demonstrated in other areas of disability and health research [203, 204]. Considerable potential exists to investigate this topic to better explore the relationship between coping, goals, and outcome with the scope to change practice.

Limitations and strengths of this review

This is the first synthesis to bring together the qualitative evidence base on open tibial fracture. The strength of this review is the use of rigorous methods which included a comprehensive literature search, and established methods to review, extract and synthesise findings; these methods emphasised transparency in the development of syntheses.

The syntheses elicited are limited by methodological flaws in the primary research studies. The JBI methodology includes a formal quality appraisal, although does not mandate how poor-quality studies should be managed [205]. In this example, all eligible studies were included in the synthesis irrelevant of "quality score"; yet all three studies presented some limitations with regards to quality, these were significant in two of the studies. Quality concerns related to poor documentation of methods and methodology and poor representation of participant's voice within the paper. These concerns cast doubt over the reliability of the findings as a representation of patient experience; it was reassuring that there was some overlap between themes, despite slight differences in the research question and approach.

A further limitation related to the sampling frame. There were notable temporal differences with all studies reporting different lengths of follow-up; time from injury effected symptom severity and coping impacting on the accounts given by patients. In addition, the cohort of patients included in the studies were heterogeneous, for example reconstruction patients were analysed alongside amputation patients despite the preconception that the experiences are not analogous. The consequence of this inclusive approach is that the themes become diluted and the studies lack analytic depth. This problem is compounded in the setting of a synthesis where there is loss of more marginal areas with a focus on core themes.

The main finding of this synthesis is the identification of a weak evidence base. This synthesis outlined a series of useful findings which elucidate to the experiences of those who sustain an open tibial fracture; however, the studies which inform the synthesis were of variable quality and depth which may have impacted the analysis. Acknowledging this, despite a thorough review of the literature, there is a paucity of studies which consider the narrative experiences of these patients and there is scope for further work that would contribute to the wider evidence base.

4.6 Conclusion

This qualitative synthesis identified two themes from a systematic review of the qualitative literature which identified only three studies:

- The impact of pain, immobility, altered appearance and fear intrudes on all aspect of life; the impact lessens with time but never resolves.
- Adapting to changed circumstances requires great resource

The symptoms reported by individuals were to an extent flat and it was hard to consider the impact that temporal, personal or management factors had on symptoms or experience. The studies touched on the concepts of adapting and coping following injury, but extensive analysis was limited to one study. The review highlights that patient voice is under-represented in the literature, with scope to apply or embed qualitative methods in different settings. In addition, this review identified patient concerns that are rarely considered in open fracture trials (such as cosmesis and fear), and would therefore be useful to those designing prospective studies in the context of both outcomes and intervention. To progress this thesis, the themes and subthemes identified here were used to inform the design a qualitative study considering what is important to individuals with an open fracture, which is the subject of the next chapter.

Chapter 5. What is Important to Individuals with an Open Tibial Fracture: a Qualitative Study

5.1 Introduction

Most of this thesis has taken a quantitative approach utilising large datasets to get a national and regional perspective of open tibial fracture. This work has achieved its aims in characterising who the injury affects, the clinical approach to managing these injuries and has obtained objective outcomes which describe how successful this clinical approach is. However, these investigations have not given the narrative perspective of individuals with an open tibial fracture; and what aspects of treatment and recovery were important to these individuals, has not been shown. The preceding systematic review allowed some insight into this; pain, immobility and psychological symptoms were relevant as these intruded on daily activities. Certain psychological strategies, such as adaptive coping mechanisms and goal setting, facilitated adjustment. The systematic review was limited by a narrow evidence base and concluded that there was scope for further research. Previous studies have not considered divergence of experience amongst cases; which is relevant in a setting when the epidemiology is diverse, and where there are competing treatment strategies; exploration of this would offer new insight into the experiences of having an open tibial fracture. The systematic review also indicated that the psychological impact of open tibial fracture is considerable and likely to be a component of a patient-orientated analysis. Although, in the limited available studies these aspects have not been explored in any depth. Coping strategies, goal navigation and adaptation; contribute significantly to physical and psychological outcomes; shaping overall satisfaction with injury. This study will consider which strategies individuals with open tibial fracture consider important to recover to consider whether the clinical services can support individuals in this manner.

5.2 Aims and objectives

5.2.1 Aim

This chapter addresses aim 4 and seeks to understand what individuals who have recently experienced an open tibial fracture consider important when evaluating their recovery.

5.2.2 Objectives

The chapter has two associated objectives first outlined in 1.8 and repeated here:

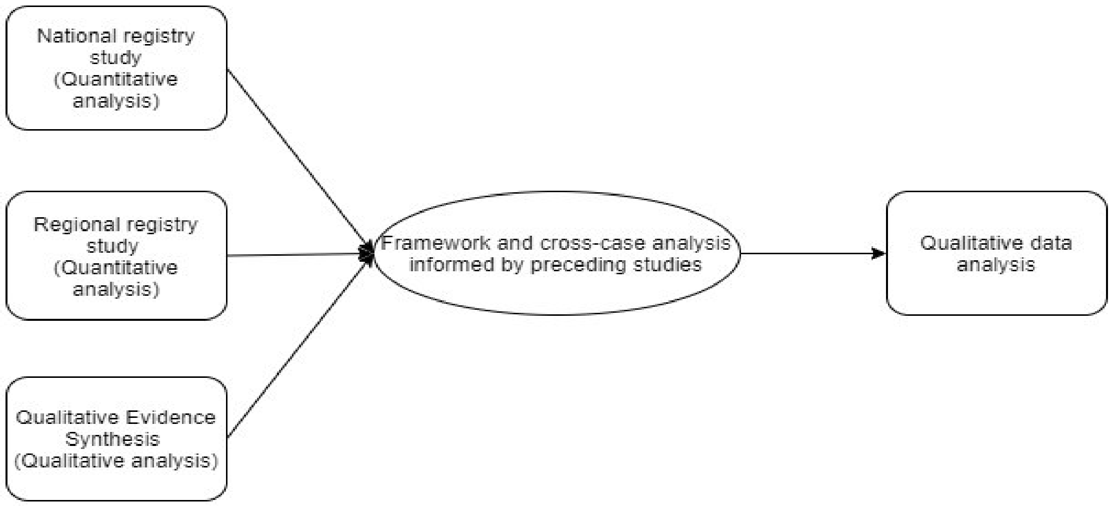
9) Explore recovery from the perspective of individuals and also consider divergence in experience dependant on age and treatment.
10) Identify support strategies which would be useful to individuals with open tibial fracture, particularly in the context of coping, goal navigation and adaptation.

5.3 Methodology

5.3.1 Mixed methods approach

The thesis is founded on a sequential explanatory design [189, 206, 207]; the first phase was quantitative providing insight into the demographics of the population, their treatments and the impact of these characteristics on complications and limb function. The qualitative data and its analysis will refine and explain those statistical results by exploring participants' views in more depth. The flow of data is shown in Figure 5-1; and the process of integration is explained thoroughly section 5.4.1.

Figure 5-1 Summary of explanatory sequential model used in this study, explaining how results from earlier chapters informed this study.



5.3.2 Rationale for using a Framework approach

The framework approach was developed specifically for applied or policy research and has recently become a popular approach in healthcare research [208] due to its systematic nature. The transparent and organised manner in which data is analysed and reported creates an audit trail providing objectivity often absent from other approaches to qualitative analysis [209]. In addition, the approach is efficient as it allows for a deductive analysis which focuses on prescribed areas. The systematic approach is amenable to use in multidisciplinary research teams, and the data can be presented alongside quantitative results. The systematic nature of this approach was reassuring to the research team who were mainly experienced in quantitative methods. Consequently, framework analysis was chosen as the method of analysis for this mixed-methods study [210].

The process of framework analysis consists of 4 stages: transcription, coding, charting and interpretation. The methods section below describes these stages in more detail and outlines how they were applied in this study.

5.3.3 Construction of interview guide

The method of data collection is a semi-structured interview. The interview guide was shaped by the data collected from our registry studies and our broader systematic review. These three studies have identified a series of themes and findings, and this study aimed to enrich the results of the earlier works. A copy of the interview guide is reported in appendix 8.11. The interview asked to what extent their leg impacted them at the point of interview, and how that compared to before their injury and during early recovery. The interview also asked what was important to them during recovery; asking about symptoms, strategies for managing limitations, pressures, and goals for recovery, and what they wished they had known at the start of recovery.

5.4 Methods

5.4.1 Eligibility criteria

Inclusion criteria

- Adult (over 18) patients with an open tibial fracture.

Exclusion criteria

- No recorded address or residing outside of England
- A prisoner under the custody of HMP
- Unable to provide consent due to language barrier or cognitive impairment
- Sustained a concomitant neurological injury requiring specialist rehabilitation
- Injury sustained over 5 years ago, but not within the last 12 months.

5.4.2 Recruitment

The departmental injury register (The Nottingham Trauma Registry introduced in 3.3.1) was searched to identify eligible cases; which were then discussed with the treating clinician to ask permission for the patient to be approached for research. Many of the cases identified were no longer under routine orthopaedic review as the time elapsed since injury and consequently, the preferred recruitment pathway was a postal approach; however, the protocol included permission to approach patients in clinic.

Process for postal contact: The recruitment pack was sent by the administrative staff of the clinical team. The pack included a cover letter, reply slip, Patient Information Sheet (PIS) (copies are included in appendix 8.12, 8.13, 8.14) and Stamped Addressed Envelope (SAE). Participants were invited to contact the research team if they wished to participate using the enclosed reply slip.

Process for recruitment in clinic: The clinical team were made aware of the study, and asked to introduce the study to patients who they felt were eligible. With the patient's permission, the clinical team referred the patient to the research team who would then approach the patient with the study information (PIS). Patients were allowed to discuss the study to decide whether they wanted to take part.

Consent: Written informed consent was taken before each interview and after the participant had time to ask questions. The consent form (appendix 8.15) was retained in the ISF with a copy issued to the patient

5.4.3 Ethics and regulatory approvals

Approval to conduct this study was given by the Health Research Authority (HRA). The study underwent proportionate ethical review by South Cambridge Ethical Review Board and also underwent a HRA assessment. The study was sponsored by Nottingham University Hospitals, who also provided capacity and capability. Copies of the relevant permissions are in appendices 8.16, 8.17 and 8.18.

5.4.3.1 Confidentiality

The below processes for maintaining confidentiality and their limits were discussed during the consent process. This study complied with the requirements of Caldicott Guardian Principles [211] concerning the collection, storage, processing and disclosure of personal information.

Participants were allocated a study number to protect confidentiality and anonymity. These identifiers were used throughout the interview, in all data, study materials and reporting. During the transcription process, patient and clinician identifying information were redacted. The results contain verbatim narratives and descriptive statistics, although the results do not contain any personal data that could allow identification of individual participants. Study numbers are provided in Participant demographics and background information, 5.5.3. Each quote within the text is labelled with the study number, participant age (10-year age band) and gender.

All electronic data was stored on NHS computers, and access was limited to delegated study members via usernames and passwords. Paper-based data was retained in a locked filing cabinet, in a key coded room within NUH. Audio recording equipment was encrypted, password-protected, with all data being removed from the equipment with each use. Personal and anonymised research data will be kept for 1 and 5 years respectively after the study has concluded.

5.4.3.2 Risk/Benefit

Distress: The potential for distress was discussed prospectively and participants were advised that they could stop the interview at any time. Various safeguards were put in place; such as having a list of local support groups and notifying the patient's GP of their participation on request. If more serious concerns arose, NHS safeguarding pathways were initiated for the individual.

Affiliation: Participants were reassured that involvement in the study would not affect their care in any way.

Researcher risk: Practical measures were put in place to ensure the safety of the researcher. These included only conducting the interviews within working hours, using university space to conduct the interviews, and making a colleague aware of the interview.

Benefit: No direct benefits were offered to the participants, although travel expenses were refunded on request.

5.4.4 Data collection and transcription

Participants were offered a face-to-face or telephone interview. Interviews were conducted by the lead researcher (JN) for the study and audio-recorded using an Olympus audio recorder. Interviews were normally held in a university meeting room to reduce any bias or intrusion from using a hospital setting. Demographics and attribute data were collected from medical records or directly from the patient.

Transcription was completed by JN. Each transcript was quality checked by the second coder (KS) against the audio file, which ensured the integrity of the transcript and assisted with familiarisation for the second coder. Transcription was supported by Dragon Naturally Speaking. Completed transcripts were imported into NVIVO for onwards processing.

5.4.1 Coding

Our provisional framework was derived deductively utilising the findings of both registry studies and the qualitative review; these studies and their findings are summarised in Table 5-1 below, alongside detail around how these informed the deductive framework.

The 37 codes identified apriori were derived as follows:

- Both registry studies failed to explain the impact of different treatments on outcome; yet it is likely, management strategies effect both experience and outcome. In this interview, individuals were asked for an opinion regarding the treatment they received; and any commentary around amputation, frames, nails, soft tissue surgery, and their associated complications were coded under specific codes.
- The results from the PROMS analysis have been scrutinised, and a list of symptoms/domains which seemed most sensitive to change have been extracted and used as codes in the deductive framework.
- The systematic review provided 11 categories which were used as codes in the first iteration of the deductively derived framework. There is overlap between some of the concepts in the registry studies and the QES.

Table 5-1 Summary of explanatory sequential model used in this study, explaining results so far and how these have informed this study.

Procedure	Outcome
National registry study, (n=16,652). Relational analysis considering: • Incidence • Factors in mortality • Factors in complication	Findings: • The injury occurs in the greatest frequencies in young male patients but occurs in the highest incidence in older female patients • Mortality is low, and therefore outcomes related to quality of life are important • Registry design impedes research into relationship between treatment and either clinical or patient-reported outcomes
Regional database study, (n=211). Service evaluation considering: • Complication rates • Functional outcomes • Quality of life • Cost of treatment	Findings • Major complications occur in a quarter of cases. • Extent of recovery is variable; most individuals have significant loss of function and quality of life even after completion of rehabilitation. • There is significant variation in treatment cost. • Gender and injury-severity, impact treatment outcome • Registry design impedes research into the relationship between treatment and either clinical or patient-reported outcomes
Qualitative Evidence Synthesis (n=49) Meta-aggregation considering: • Patient perspective of recovery	Findings: • Synthesis one: The impact of pain, immobility, altered appearance and fear intrudes on all aspect of life; the impact lessens with time but never resolves. • Synthesis two: Adapting to changed circumstances requires great resource
Deductive framework derived from quantitative results and qualitative synthesis.	Findings: • 37 codes defined apriori
Qualitative study (n=26) Considering: • Important aspects of physical recovery • Divergence amongst cases due to attributes • Role of coping strategies	Planned outcome; • Conceptual model of themes • Coding matrix

Coding was undertaken using both deductive and inductive approaches. The transcripts were coded against these pre-existing codes; however, open coding was used in tandem which allowed us to explore the data in more depth, having recognised limitations within the existing data. Each transcript was read and coded by two researchers. (JN and KS) (for coding example see appendix 8.19), with the two coders meeting regularly to discuss the evolution of codes.

5.4.2 Charting

The codes were charted into appropriate categories to generate a working matrix. Multi-disciplinary input (which included two surgeons, a frame nurse specialist and a senior qualitative researcher) was sought on the matrix at various stages during the analysis. Charts were fluid and recursive and retained a degree of plasticity until all data had been analysed in full. This process led to a matrix for the study, which indicates broad subject areas identified by patients, but also provides categories and codes which show more granular insight.

5.4.3 Interpretation

The matrix was used to describe our population and their experiences, in the context of our objectives. A cross-case analysis was used to assist in interpretation of the data. The cross-case analysis was structured using a case ordered descriptive matrix with cases ordered according to the variable being examined [212]. Cross-case analysis allows for closer consideration of cases, looking more holistically at an individual rather than dissecting their experiences into themes. Purely focusing on themes fails to capture that injury experience is different for different people; where cross-case analysis acknowledges variation exists between individuals and allows for these differences to be explored and documented.

5.5 Analysis

5.5.1 Study site characteristics

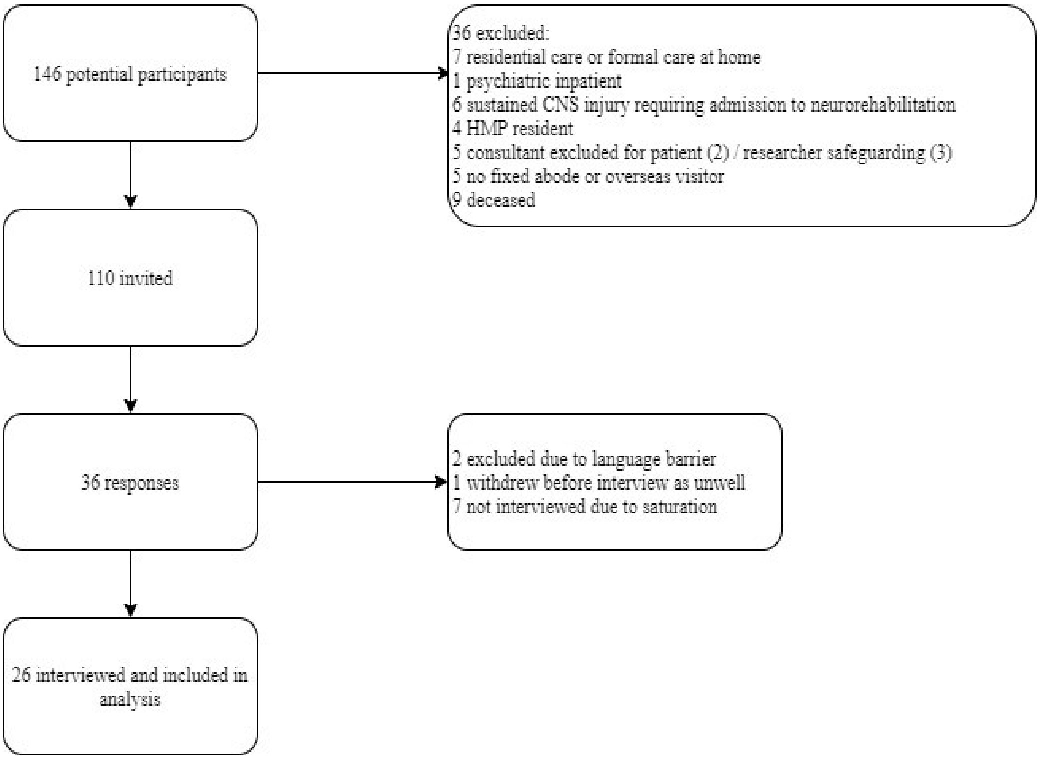
The study site was the East Midlands Major Trauma Centre and has been introduced earlier in the thesis (3.1, 3.4.1). The earlier analysis found that; Nottingham's open tibial fracture patients were slightly younger, had more severe injuries, and were more likely to be managed with external fixation, when compared with national data. These differences are expected for a specialist centre and have some relevance to the generalisability of the study. The hospital is commissioned to manage major injuries; therefore, individuals treated at Nottingham had access to specialist services not available to all trauma units nationally. The care pathway is as described in Figure 1-2. Patients are admitted under a specialist MDT onto dedicated trauma ward. On discharge, individuals attend a series of outpatient appointments; these appointments routinely include orthopaedic and plastic surgeons, and physiotherapy. Patients with ring external fixation (normally referred to as a Taylor Spatial Frame or frame, by patients) have access to a dedicated frame nurse to provide additional support with the device.

5.5.2 Interviews

In total, 26 individuals were interviewed. The majority agreed to attend in person, although some patients (n=5, 19.6%) chose a telephone interview; with work commitments and travel distance cited as the main reason for this. Interviews were on average 53 minutes long with a range of 22-103 minutes.

5.5.3 Participant demographics and background information

Figure 5-2 Flow chart of patient screening and recruitment



A recruitment flowchart is shown in Figure 5-2. The Nottingham Trauma database was searched for admissions between 1st January 2016 and 1st January 2019 with an open tibial fracture, identifying 146 potential participants. Following screening, 110 participants were approached and 36 agreed to take part; in total 26 took place. Participant demographics are presented in Table 5-2 and Table 5-3. The average age was 44 (range 21-80), and 20 participants (85%) were male; Figure 5-3 and Figure 5-4 shows the demographics and injury severity of injuries screened against recruited and shows good representation. The sample gave good representation to a range of mechanisms, polytrauma and working backgrounds. Internal and external fixation were well represented; 1 had a primary amputation. 12 (46%) had complications, which is slightly higher than was reported in the population screened, which likely reflects depth of experience. On average individuals sustained their injury 29 months ago (range 12 -44 months) and had 19 months treatment (range 4-41). Our population was representative of the cohort screened.

Figure 5-3 Stacked bar chart which shows proportion of Gustilo grade in the recruited population (n=26) against the population screened (n=146). Population screened for qualitative study included all open tibial fracture admissions between 01/01/2016-01/01/2019.

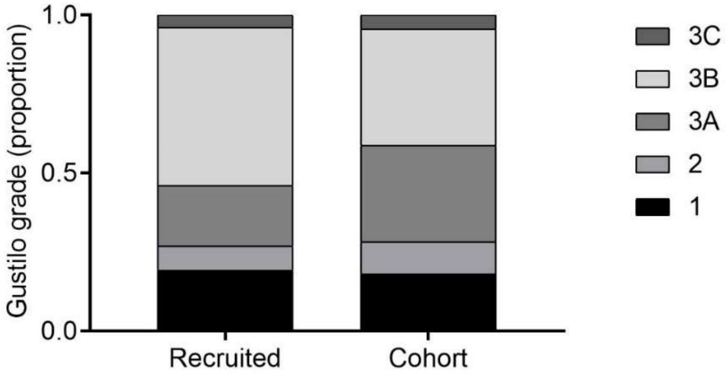


Figure 5-4 Frequency histograms which describe the age and gender of both the recruited and screened population. Left: Sample of population included in qualitative study. Right: Population screened for qualitative study which included all open tibial fracture admissions between 01/01/2016-01/01/2019.

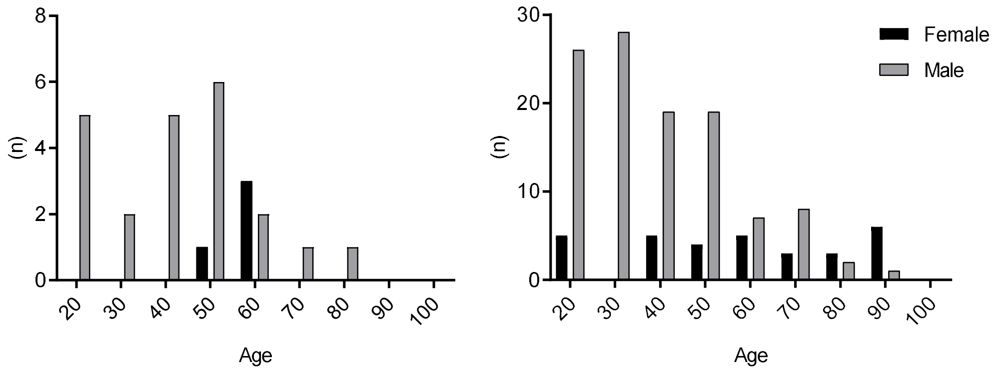


Table 5-2 Attributes of participant (part 1). IMD = Deprivation decile, ISS = Injury severity score, TSF = Taylor Spatial Frame (ring external fixator), IF= Internal fixation, BT = Bone Transport. Participants are referred to in the text by their participant ID, age, and gender (i.e. (1, M-40))

ID	Gender	Age	IMD	ISS	Gustilo	Mechanism	Definitive	Plastics	Complication	Revision	Treatment (m)	Time since injury
1	M	40-50	10	9	3B	RTC - Motorbike	TSF	Closure	Non union	IF	23	44
2	M	20-29	4	9	3B	RTC - Motorbike	IF	Local flap	Infection	TSF	20	21
3	M	30-39	4	>9	1	High energy fall	IF	Closure	None	None	7	36
4	M	70+	10	9	3B	Fall from standing	IF	Local flap	None	None	13	32
5	F	40-50	10	9	1	Fall from standing	IF	Closure	None	None	10	43
6	F	50-59	10	9	3A	RTC - Pedestrian	IF	Closure	None	None	8	45
7	M	20-29	8	9	1	Sport	IF	Closure	None	None	6	13
8	M	20-29	4	>9	3A	RTC - Motorbike	TSF	Closure	Compartment syndrome	Bone graft	15	15
9	M	40-49	2	9	3B	High energy fall	IF	Local flap	Infection	BT/TSF	36	36
10	F	50-59	9	9	3A	Domestic accident	IF	Closure	None	None	7	16
11	M	20-29	5	>9	1	RTC - Pedestrian	IF	Closure	None	None	11	32
12	F	50-59	4	9	3B	Domestic accident	IF	Free flap	Non union	TSF	32	32
13	M	40-49	9	9	3A	RTC - Pedestrian	IF	Closure	None	None	5	20

Table 5-3 Attributes of participants (part 2). IMD = Deprivation decile, ISS = Injury severity score, TSF = Taylor Spatial Frame (ring external fixator), IF= Internal fixation, BT = Bone Transport. Participants are referred to in the text by their participant ID, age and gender (i.e. (1, M-40)).

ID	Gender	Age	IMD	ISS	Gustilo	Mechanism	Definitive	Plastics	Complication	Revision	Treatment (m)	Time since injury
14	M	30-39	3	9	3B	High energy fall	TSF	Local flap	Infection	BT	33	33
15	M	50-59	1	>9	2	RTC - Motorbike	IF	Closure	None	None	12	33
16	F	50-59	10	9	2	RTC- Car	IF	Local flap	None	None	4	38
17	M	20-29	2	>9	3C	RTC - Motorbike	Amputation	Closure	None	None	18	18
18	M	50-59	4	9	1	RTC - Motorbike	IF	Closure	Infection	BT/TSF	41	41
19	M	50-59	8	9	3B	Industrial accident	TSF	Local flap	None	None	24	44
20	M	60-69	5	9	3B	High energy fall	TSF	Local flap	None	None	9	22
21	F	40-49	8	9	3B	Sport	TSF	Free flap	Non union	IF	15	15
22	M	20-29	5	9	3B	RTC - Bike	TSF	Local flap	Flap failure	Free Flap	12	12
23	M	20-29	6	9	3B	RTC - Bike	TSF	Local flap	None	None	15	15
24	M	30-39	10	>9	3B	RTC- Car	IF	Local flap	Infection	Amputation	38	38
25	M	60-69	10	>9	3A	High energy fall	IF	Closure	Infection	Metalwork removal	9	22
26	M	50-59	1	>9	3B	High energy fall	TSF	Local flap	Infection	BT	32	44

5.5.4 Review of themes

The final framework consisted of 111 codes, 23 subthemes and 5 themes. Subthemes and themes were allocated a title and are summarised below. (Table 5-4). The 5 themes identified were as follows:

- **Regaining mobility:** Individuals described a journey of recovery, which focused on recovering the mobility they had lost. Whilst the underlying restriction was mobility; this was presented in the context of their ability to return to responsibilities and recreations that had defined their previous normality. This theme describes the landmarks identified by the majority on the journey recovery.
- **Dealing with symptoms:** Impairments in mobility was the primary focus of individuals in this study, but they also reported a constellation of other symptoms which they had to live with and manage. This theme describes the symptoms in granular detail but also summarises them as broader domains.
- **The burden of surgery:** Whilst much of the impairment individuals experienced could be put on the injury itself; individuals attributed much of the burden they felt to the treatment they had. This burden, varied dependant on the treatment. This theme considers the challenges of each surgery.
- **Hope and expectation:** Open fracture is not a well-recognised condition on a societal level. Individuals who sustain one, quickly had to reconcile the severity of the injury, accept the uncertainty of an unknown prognosis and endure recovery. This theme explores how different patients process this and live with these uncertainties.

  Coping strategies: Recovery caused significant physical and psychological toll. Individuals had to find coping strategies to adjust to their injuries. This theme looks at the methods employed by individuals with an open tibial fracture to cope with their injuries.

Table 5-4 Framework matrix indicating theme and subthemes.

Theme	Subtheme description
Theme 1: Regaining Mobility	Accident and hospital experience Being housebound Able to travel Pressure to return to work despite ill health Return to pre-injury activities
Theme 2: Dealing with symptoms	Mobility Pain Body image Psychological burden
Theme 3: Burden of surgery	Treatment with a nail Treatment with a frame Amputation Living with complication Input into treatment decision
Theme 4: Hope and expectation	New threat to livelihood Hope for recovery Accepting a point of plateau
Theme 5: Coping strategies	Active coping, goal setting, information seeking Personal social support Professional social support Maladaptive coping strategies

5.5.4.1 Building the framework

Thirty-seven codes were identified deductively, which could have been placed under broad themes of “symptom-related”, “treatment-related” and “coping-related”. Broadly the “symptom-related” codes were derived from the PROMS analysis; the “treatment-related” codes were derived from outstanding questions on the regression analysis; and “coping related” codes were derived from the qualitative systematic review. Table 5-5 lists all of the apriori defined codes.

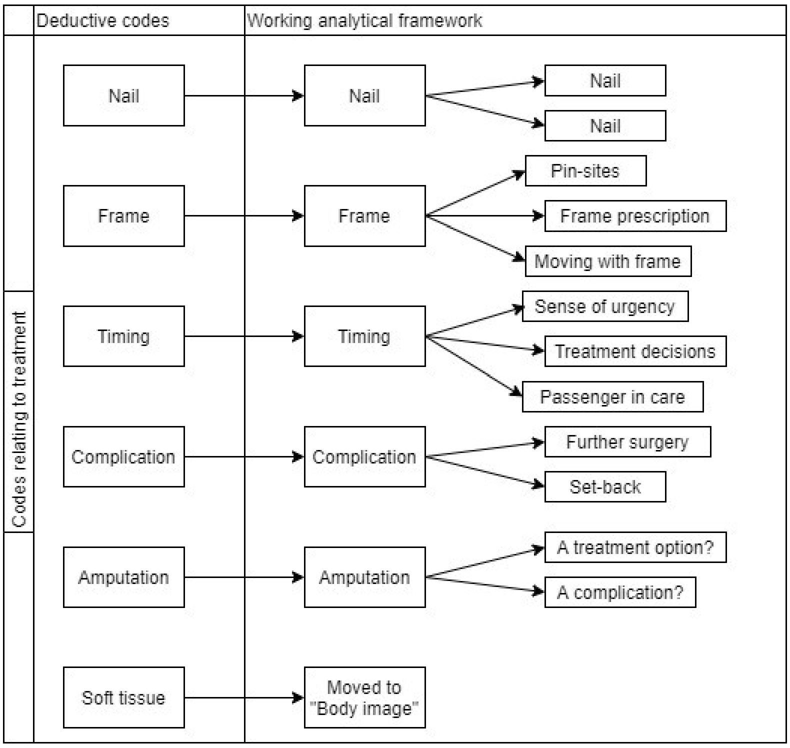
Table 5-5 Apriori defined codes derived from preceding quantitative work and systematic review

Symptom related	Treatment related	Coping related
Mobility	Nail	Active coping
Walking aids	Ex-fix	Avoidance coping
Walking	Amputation	Personal growth
Moving around house	Soft tissue	Goal setting
Lifting	Timing of surgery	Satisfaction with recovery
Shopping		
Light working		
Heavy working		
Running		
Sport		
Personal care		
Usual activities		
Work		
Unemployment		
Pain		
Chronic ache		
Mood-related		

Our working analytical framework was drafted after five interviews; in this iteration a sense of hierarchy was added as it was clear that some deductively derived codes operated better as sub-themes as individuals offered more granularity of experience. The deductively derived codes were positioned from a medical perspective; yet, this work needed to represent the voice of patients, so the title of the deductive codes were allowed to evolve to result in a more patient orientated analysis.

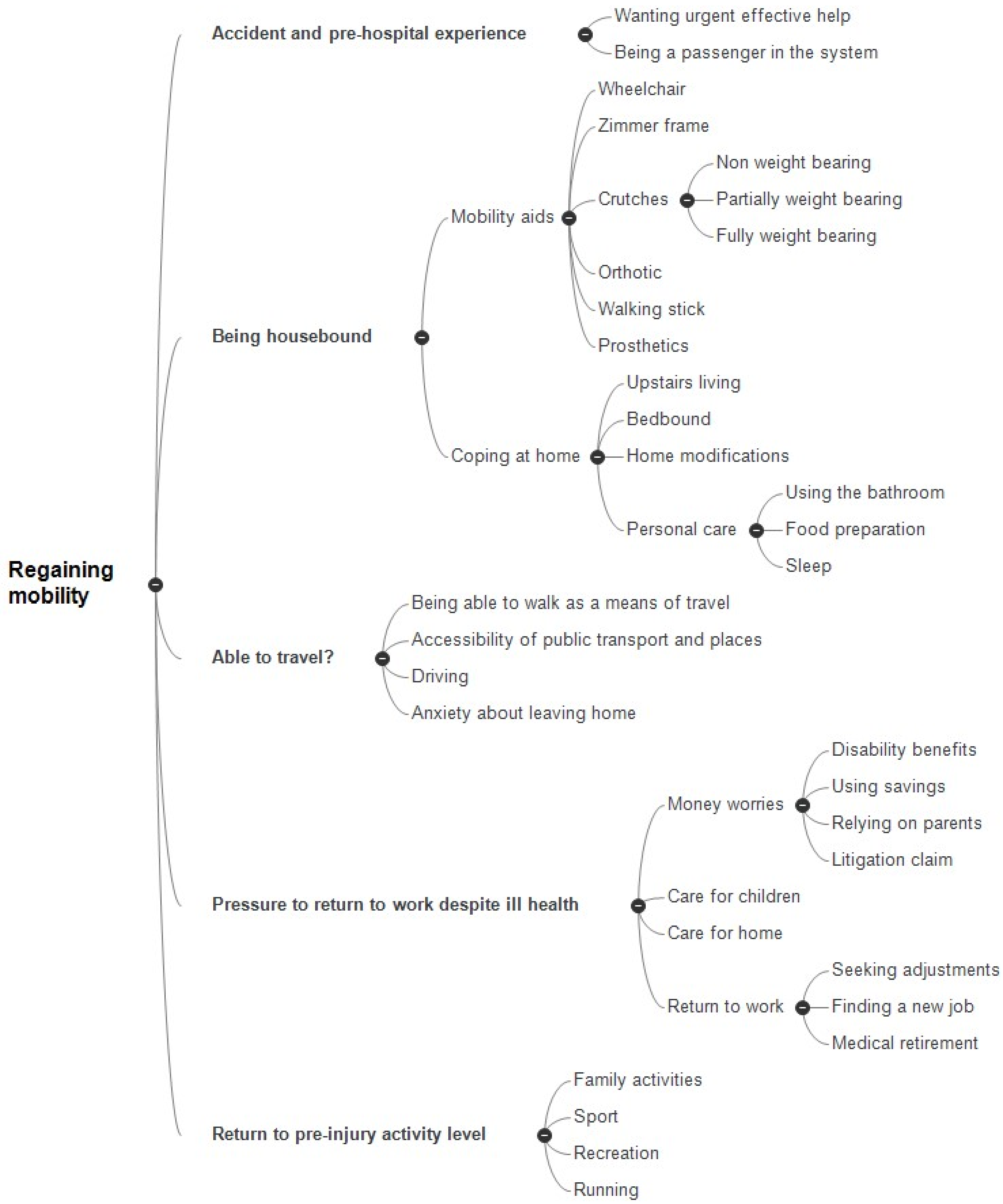
The framework developed at different rates across the themes. The codes, themes and subthemes under “dealing with symptoms”, “burden of treatment” and “coping strategies” emerged quickly (supported by the apriori codes) and the structure stayed consistent from early on in the analysis. The codes under “Regaining mobility”, were initially presented within “Dealing with symptoms” as from the deductively derived codes mobility lay flat against other symptoms, but during analysis it was clear that participants wanted the story to be framed around the battle to recover physical mobility and their personal normality; thus a standalone theme was introduced to represent this. “Hope and Expectation” was challenging to finalise; whilst most codes emerged consistently and densely, organising these codes, into sub-themes and themes that represented patient perspective was only fully achieved at the end of the analysis. Evolution of the framework is shown in appendix 8.20. To provide an example Figure 5-5 shows the apriori defined codes relating to treatment, these were used as a foundation point for the initial interviews, but were reorganised after 5 interviews to form a working analytical framework for the rest of the interviews.

Figure 5-5 The left hand column shows apriori defined codes relating to treatment, and how they evolved after five interviews as part of a working analytical framework



5.5.5 Regaining mobility

Figure 5-6 Matrix for Theme 1: Regaining Mobility. Figure shows theme, 5 subthemes, and underlying codes. Theme showed process of recouping physical mobility, with landmark points in recovery; such as being housebound, and returning to work.



The accident resulted in serious disability for individuals who had previously been fully independent; the journey of recovery was a slow, gradual improvement in mobility set in the context of trying to return to previous responsibilities and chosen activities. The responsibilities and activities varied between individuals, as did the level of impairment described, although landmarks in recovery were similar amongst everyone. Figure 5-6 charts the theme, its subthemes and codes.

5.5.5.1 Accident and hospital experience

Individuals recounted how events unfolded quickly at the scene of the accident, reflecting on how quickly they had lost normality. The prevailing sentiment was instinctive alertness; aware the accident would have long-term implications, yet due to incapacity, they were powerless to control the situation leaving them vulnerable. Normally conscious in the immediate aftermath of the accident, individuals were aware that their fractured bone was protruding through the skin and wanted urgent medical attention, the perception of most was that evacuation from the scene was slow and disorganised:

> *"It was a fiasco. They didn't come after the first call, so I rang them a second time. I impressed upon them that I can actually see the bones. At that point, they sent the air ambulance, but the air ambulance was unable to land, so then they sent a land ambulance".* ((ID 4, Male - aged 70) (4, M-70))

Patients struggled to recall their arrival at hospital due to either their injuries or painkillers. Individuals were often given ketamine in A&E and compared the experience of taking ketamine to like "*spinning through a wormhole*". (10, F-50).

Once on the ward patients described being a "*passenger"* (5, F, 40) in the process. They were relying on nursing and medical staff to protect them from complications and to make major treatment decisions for them; whilst some were comfortable with placing this much trust in the staff; others felt exceptionally vulnerable and remained very vigilant. The outcome of the accident was a significant loss of mobility, most marked during the early days during recovery. The period of hospital convalescence was challenging to tolerate, due to the combination of feeling both vulnerable and entirely dependent. The process, and emotions, were described by the participant below

> *"They kept coming to me, touching the leg to ask if I could feel it; I didn't realise at the time but there must have been a question mark as to whether they save it or not. ... The pain was almost unbearable. It was a very difficult few days. I didn't know what to expect from the second frame, and I was worried it would be as bad but it was better in comparison."* (20, M-60)

5.5.5.2 Being housebound

Individuals described being "*bedbound*" or "*housebound*" for months or years after the injury. Most were confined to their bed, one room or one floor for several months:

> *"I was laid in bed for months. I would only use the zimmer frame a couple of times a day to go to the toilet. We have a toilet downstairs, which was adapted slightly so I could just manage with that. I had a wheelchair, zimmer and crutches. There was a leg extension on the wheelchair, which made it difficult to leave the house because you couldn't move through tight spaces."* (9, M-40).

Mobility was very limited; relying on walking aids initially and gradually progressing to weight-bearing, it was often many months before they could stand normally.

> "*Well I was just completely bed bound. I couldn't sit-up…. I was still using a wheelchair until probably – Christmas – so 6 months, but I was using crutches more and more around the house."* (8, M-20)

Undertaking personal care or basic household tasks became exceptionally difficult, two examples are given below.

> *"When you are non-weight bearing you can't carry a cup of tea across the kitchen."* (1, M-40)

> *"I couldn't have a bath or shower for 15 weeks – I was just strip washing a gypsy shower, you know."* (19, M-50)

In the early stages of recovery, individuals described progressive improvements from being bedbound, to just housebound; initially requiring a wheelchair, but eventually managing with just crutches; requiring care from a spouse to being able to manage in the house alone. Each of these symbolised landmarks in a return to normality

5.5.5.3 Able to travel

Being able to travel, walking or driving, in company or alone, was central to regaining independence and being able to engage with some of their previous activities. This signalled a moving on from a dependant and housebound existence; and being able to walk outdoors, use public transport, motorbikes or cars was often a goal for many patients during their recovery. Endurance for walking developed over time, in a non-linear fashion. The initial focus was on being free from mobility aids and orthopaedic devices; as many of these aids were difficult to use outside the house, making individuals feel trapped at home. Initially, individuals worked on becoming confident at short trips outside the home, such as shopping, but worked up to longer distances, such as walking the children to school and building endurance for standing at work.

> *"Once I was home, well I'd want to walk to the end of the street, then the next street, my mum took me. Adding a little bit more every couple of days. Gradually increasing the distance I was walking, until how I am today."* (11, M-20)

Ability to use transport was important in returning to previous activity levels, circumventing many of the barriers created by injury-related immobility. Many patients relied on ambulance transport initially as they were unable to drive or sometimes sit in a car, and public transport was not accessible due to distance:

> *"The bus stops are too far to walk. But once I was able to walk to the car I could then get to the supermarket or whatever. With the blue badge system, you can get around most places you see."* (26, M-50)

Return to driving was dependant on advice from their clinical team, insurance and personal confidence. Still, many patients reported that they felt much more independent once they had regained the ability to drive. Individuals injured in motorbike accidents were particularly effected as through the crash they had lost their primary mode of transport; being unable to return to it due to either safety concerns, residual disability, or an inability to finance another vehicle.

5.5.5.4 Pressure to return to work despite ill health

Financial loss due to being unable to work was a significant source of stress common to all participants of working age and described by some as the *"worst thing"* (2, M-20) about the injury. Only two patients required less than six months off work, several patients had required several years off-work, and some patients were unable to return to work in any capacity. Three-quarters of participants lost their job because of their injury, but most were able to find employment elsewhere when further into their recovery. On returning to work, most patients had to seek adjustments to reduce the physical demands of their job role permanently. One participant described his experience of return to work as follows:

> *"I was off work for seven months and went back on a phased return. Starting with four hours a day and built up over a few months… I'm not desk-bound but I am not doing what I was doing previously"* (17, M-20)

Participants coped with the financial loss either by relying on government-funded disability payments (PIP), personal savings or family. Many found government funding difficult to understand, unfair and inadequate. Relying on family or savings for funds provided a source of relief for some, but it was obvious that they deemed this to be a burden and unsustainable.

> *"It was not being at work. That was the worst thing about it all. Statutory sick pay, it's 400 pound per month, 100 pound per week. 400 pounds is what I earn a week. So I lost about 16,000 – that's a huge amount of money."* (2, M-20)

Whilst financial aspects were important, an ability to work also signalled a return to normality for patients – described by one as *"helped in getting your back life on track"* (21, F-40). *A* desire to return to work and the toll of financial difficulties created a great pressure for patients, and thus return to work was a focal point for patients when describing a recovery journey.

5.5.5.5 Return to pre-injury activity level

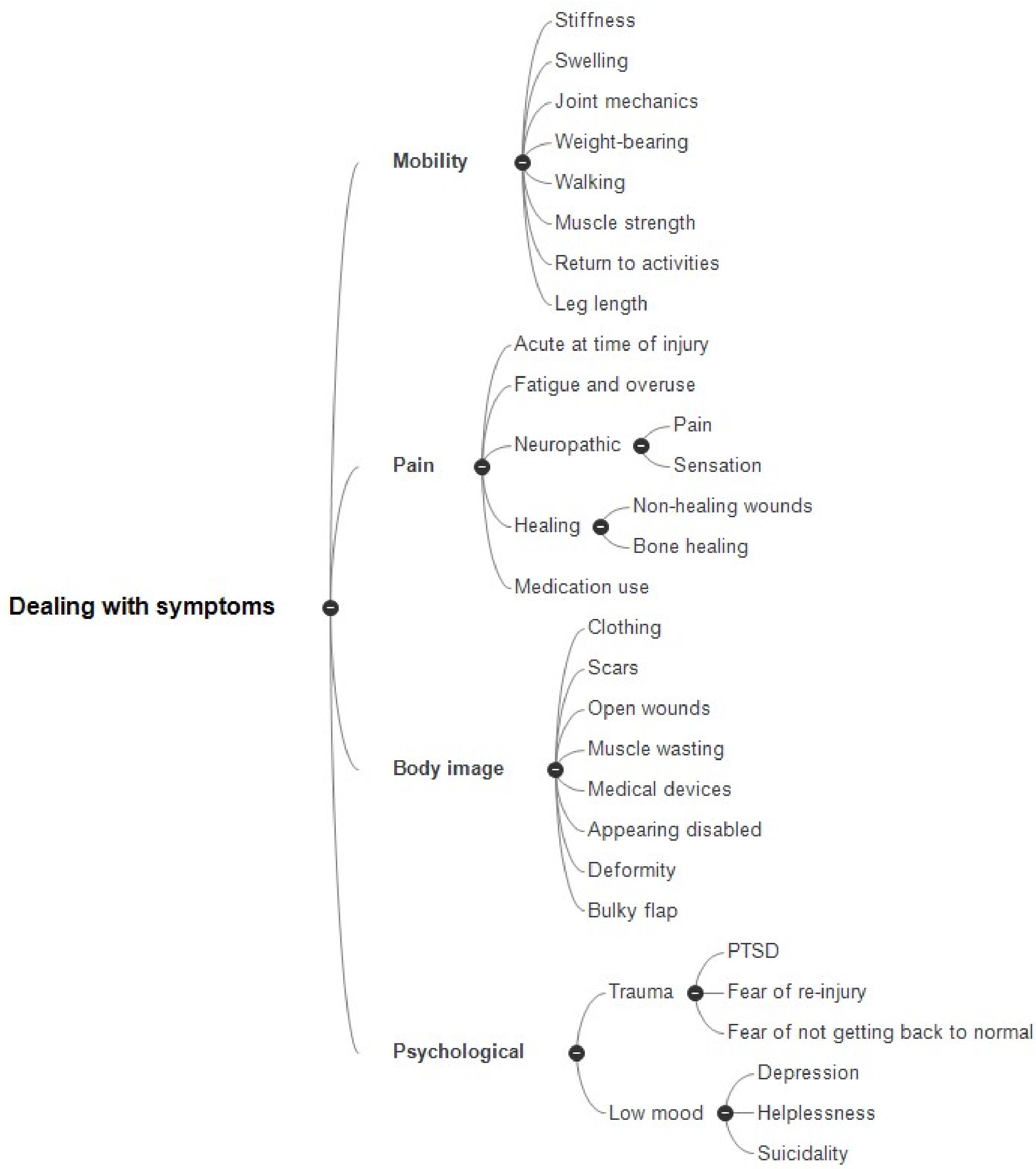
Individuals described their recovery, with an end target of "*getting back to normal"* (5, F-40). Most patients were accepting that they were likely to have some residual problems even after the injuries healed but wanted to get to a point where they could undertake their previous responsibilities and activities without major intrusion from their injury. Return to recreational activities seemed to be the final step in getting back to normal, although these activities were hugely variable dependant on the individual. Parents and grandparents wanted to spend time with children; others were desperate to return to sport, gardening or a busy social life. The other aspect in getting back to normal was relief from the psychological challenge of living with the uncertainty of recovery and the burden of regular hospital visits. Every person gave a bespoke example of their idea of getting back to normal, and some are below.

- *"Just want to get back to an active life… Get a job. Get back to swimming and sports and that. Before this I never sat down, I was always on the go. I'm just 23, and it's not right to be like this."* (8, M-20)
- *"My leg doesn't feel normal. I just want to get back to normal."* (5, F-40)
- *"My main hobby was photography, and I really miss that… Still got the stuff, so maybe I can get back to it."* (18, M-50)

- *"I just want to get out and do what I was doing before… I love doing my garden, but I can't do that because I can't kneel, or bend my ankle."* (26, M-50)
- *"Going to the hospital and being told I needed more surgery, I thought "what's this now", it seemed to never end."* (9, M-40)

5.5.6 Dealing with symptoms

Figure 5-7 Matrix for Theme 2: Dealing with symptoms. Figure shows theme, 4 subthemes, and underlying codes. Theme shows that an array of symptoms were experienced which impacted quality of life. Sub-themes were broad domains such as mobility, pain, body-image and psychological burden; codes were grouped under relevant domains and offered a more granular insight.



Whilst the focus of recovery was on mobility throughout the interviews, individuals reported a range of symptoms, which also impacted quality of life. Symptoms related to mobility, pain, body image and mood. Categories within the theme and associated codes are shown in Figure 5-7.

5.5.6.1 Mobility

Mobility was the prevailing component of recovery. Mobility was discussed in the context of tasks, reliance on mobility aids, but also how specific symptoms that prevented them from being mobile. Symptoms, which frequently caused immobility included muscle weakness (n=24), swelling (n=22), pain (n=6), stiffness (14), joint mechanics (n=4) and leg length (n=4). Patients described that their leg would fatigue quickly

- *"The more I walk the more I limp"* (2, M-20)
- *"When I walk the fluid goes down the leg and doesn't come back up, so it becomes stiff and swollen, slow and heavy, there's no pain*" (20, M-60).

Their symptoms would improve again with rest or using mobility aids. Symptoms that caused immobility improved with time as the fracture and soft tissues continued to heal, the degree of residual symptoms varied.

5.5.6.2 Pain

Most individuals were accepting of pain as an anticipated consequence of their circumstances, describing it as something they *"got on with"* (5, F-40). Several codes around pain were identified. Many patients talked about the unbearable pain caused by an unstable fracture, the wound, or as an impact of surgery. Once home pain became something that they managed and patients were guided by pain as a symptom of *"overdoing"* it, fatigue, or a problem. Pain lessened over time, but many patients did have chronic pain either from scarring, swelling, bones or nerves. Pain did impact patient's ability to meet rehabilitation goals and manage the psychological aspect of injury. The experience of pain was similar for many participants, and reported as follows:

> *"Ah, the pain was awful to start, unbearable at times. Now – well the leg aches all the time, and you know once you have done a certain amount as*

then it really aches. It was a long job and you expect a certain amount of this, that and the other." (25, M-60)

5.5.6.3 Body image

The appearance of the limb caused anxiety. Individuals were concerned whether the appearance of angulated limbs or prominent flaps would improve with time, and whether poor appearance correlated with poor outcome. Individuals also worried about how the public perceived their injuries and wanted to blend in despite mobility aids or wounds. Many patients had adapted clothing to cover the leg, citing dignity, warmth and hygiene as reasons for this:

- *"people are looking at your leg… like "ew god" – repulsed"* (22, M-20)
- *"I'm terribly nesh – it keeps it warm… and clean"* (21, F-40)
- *"It's just a bit unladylike to show your scars."* (16, F-50)

There were clear concerns, but most were pragmatic about the appearance, contextualising it as a minor inconvenience in the context of injury severity; as summarised below:

> *"It's just a bit of a mess left on the outside. It was like a tin of baked beans on the front of my leg at first, and you can still see the muscle fibres in the graft, and these dints from the pins; it's pretty skinny too. (*Researcher: Does the appearance bother you?*) I don't have much choice have I, but you know, it's my leg, not a prosthetic and it could be worse".* (2, M-20)

5.5.6.4 Psychological burden

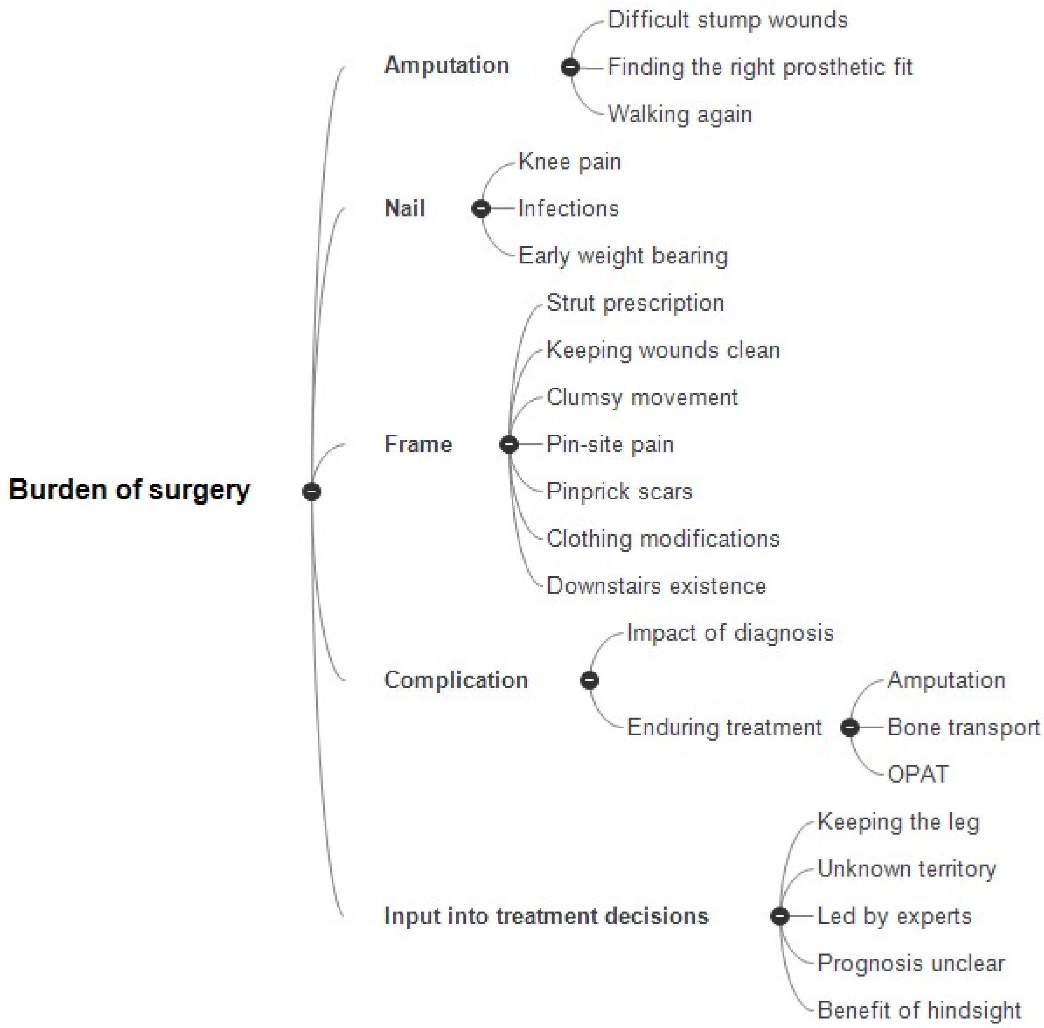
Many described *"low mood"*, *"feeling down"* or becoming *"depressed",* some had "*flashbacks*" and two reported being suicidal. Experiencing depression, was attributed to a sense of grief for the normality that they had lost, the stress of existing with an unknown outcome, the burden of their current circumstances or post-traumatic stress.

> *"There were weeks of suffering with so much pain and I thought I've had enough. You get very low, stuck in your bed for weeks with no-end in sight. I just thought I'd had enough, constantly to go back into hospital, having things done, I was fed up and you wonder whether there's a different way."* (26, M-50)

The degree to which participant's admitted or acknowledged psychological conditions varied, and many patients employed a range of coping strategies to help them cope with their circumstances which are discussed in 5.5.9.

5.5.7 Burden of surgery

Figure 5-8: Matrix for Theme 3: Burden of surgery. Figure shows theme, 5 subthemes, and underlying codes. Subthemes considered the challenges of specific management strategies and complications. Codes were specific problems and benefits grouped with their corresponding surgery.



Individuals in the study described their opinions on the surgery they received, pros and cons of each strategy, the experience of complication and the role they made in treatment choices. Matrix is shown in Figure 5-8. Cross-case analysis was used to investigate differences between competing treatment strategies by considering cases laterally. Three archetypal cases are presented in Figure 5.9.

Figure 5-9 Lateral summary of 3 archetypal cases, allowing comparison of internal fixation, external fixation and complication

Internal fixation: (13, M-40): Man in his forties who lived alone and works as a contactor in a professional role. He was a pedestrian who was hit by a car whilst running, he sustained an isolated injury which was repaired with an intramedullary nail. He felt the follow-up was a bit disjointed and would have preferred consultant-led follow-up, and better access to physiotherapy. He required a couple of months away from work but returned with reasonable adjustments after this. He focused hard on rehabilitation and was able to return to running after a year.

External fixation: (19, M-50): Man in his fifties, lived with his wife. Isolated injury sustained in an industrial accident treated with a TSF. His wife and children had been fundamental in helping him manage his recovery, during which he had been unable to wash, stand or sleep as he wanted. Work were unsupportive and he had to change jobs. He still had problems with nerve pain and swelling despite claiming a good recovery, he was no longer able to play with grandchildren, but he felt he had done well given the severity of his injuries.

Complication: (9, M-40): Man in forties, a retail manager who lived at home with his wife. Relatively low energy injury fixed with IM nail and closure but developed a devastating infection. He was in hospital for 3 months, with 14 operations and 36 months treatment; and spent years housebound, struggling to move beyond one room; his wife had supported him. He had lost his job through injury, but eventually found work elsewhere. Despite protracted recovery he was pleased with the endpoint, as he was eventually able to work and do some recreation (gardening, holidays etc). He had documented his recovery in a journal, and this had helped him retain some control and manage his circumstances closely, it also allowed him to recall positives and negatives about the recovery.

5.5.7.1 Treatment with internal fixation

Individuals expressed their surprise and relief at how effective and tolerable internal fixation was after having endured such a major injury. The surprise was mainly around not needing a cast or braces and in some cases were able to immediately weight-bear after surgery. Recovery was challenging and often individuals mentioned more physiotherapy or support would have helped; although they generally seemed to be relieved that they did not need a long period of "rest" and could progress with rehabilitation.

> *"I remember being amazed, that when I got up, I could put pressure on it straight away. Because it was such a big break, I was amazed that they said to get up, and use your crutches, but put pressure on at the same time. You know when you get a normal break, you get a cast, and you hold your leg up for six weeks. Crazy."* (11, M-20)

Long-term sequelae that were typical for internal fixation; was pain around the knee and screws; numbness; and development of arthritis in the distal and proximal joints. Generally, they had not had any major soft tissue reconstruction and subsequently did not report problems with these. Some were concerned about having metalwork in their leg for life; one said they felt the nail *"made the bone weaker"* (7, M-20), whilst another stated *"I quite like the idea of not having anything left in the leg. However remote the chance you always still think an infection will pop up"* (6, F-50). Of note, 30% of our internal fixation group had complications requiring further major surgery and this devastating event impacted on the story significantly (5.5.7.4); however, those with a complication-free recovery often seemed relieved at how well they had recovered set against the severity of the injury.

5.5.7.2 Impact of treatment with a frame

A frame is bulky and burdensome nature, putting a significant toll on those managed with one; the frame was stated to impact sitting, standing, sleeping, dressing and bathing. Progression to weight-bearing was challenging due to fear of re-injury or falling, this distrust and vulnerability were attributed to both the injury and the frame itself. The appearance of the frame was problematic, and made patients stay indoors to avoid stares; clothing modification were attempted to cover the frame, but this was difficult to achieve. This perspective is described below:

> *"You are worried about the leg, and the frame just gets in the way and makes all that worse. You cannot sit down or lie down as it gets in the way, it catches on clothing and bedding. When you can walk – if you can walk – it is weird to trust it with your weight, and it gets in the way."* (23, M-20)

Physical difficulties aside; the frame required the patients to be more involved with treatment and have more medical input, which included: weekly hospital reviews associated with long waits and transport difficulties; daily pin site hygiene and strut prescription administration; and seeking urgent help for pin-site infections:

> *"Well, it was like a Meccano kit. You had six struts; they came up with a plan, whereby you had to turn the nuts and adjust them yourself. My wife helped me with that because you can't reach it well enough to do it yourself."* (20, M-60)

Despite difficulties, individuals accepted the frame as a worthwhile treatment as it had helped to save their limb, often with a good eventual result. Frames were used either as the primary treatment or for some complications, the description of burden varied dependant on the specific individual; still, there was always a degree of morbidity associated with the frame itself.

5.5.7.3 Amputation

Two participants had an amputation; one was within the immediate days following injury, the other after developing complications a year after injury. Both participants felt that all other opportunities for salvage had been explored prior to the amputation and whilst devastating they had accepted this as the only option.

> *"They said there was no other option other than an amputation because of the extent of the damage to the vessels… they did try to save it but…. At the*

> *time - amputation you didn't want to even think about it, but on reflection Im glad I didn't have to go through that (*salvage surgery*) particularly to end up in the same position I'm in now."* (17, M-20)

> *"It was still infected and gaping open, and I had a contracture in my foot so I couldn't stand. My options were either surgery to try and correct the foot and the infection or amputation. I just wanted a route out I suppose."* (24, M-30)

The recovery experience from amputation was very different to salvage. In a similar manner to salvage surgery, there was frustration around the period of convalescence required. They were keen to learn how to use the prosthetics but were frustrated about the time spent waiting for the stump to heal, both patients had problems with wound healing. Care was under prosthetic rehabilitation services and delays with care perceptually limited progress and eventually both accessed prosthetic services privately

> *"The stump shrinks quite a lot, you need to go back quite a lot, because I had the private support, it meant I always had a leg that fitted. If you don't have private access you don't get that. A lot of people that had theirs through the NHS have struggled because of waiting times."* (17, M-20)

They reflected that in the context of their devastating circumstances amputation had represented the only treatment option, but one which had a rewarding outcome which they had no regrets about.

5.5.7.4 Living with a complication

Individuals with complications described the experience as a double insult, first accommodating the injury into their life, then realising they had developed a major complication that would significantly alter the trajectory of recovery. The complication resulted in repeat invasive surgeries, prolonged treatment, and immobility; importantly complications were perceived to open the door to a spectrum of outcomes not previously considered likely by these participants. Twelve (46%)

individuals in our study lived through a range of complications and their associated treatments. For patients with non-union, the focus was on the frustration of passively waiting for an end to treatment; this was difficult to accept as no treatment or behaviour would accelerate the process, and surgeons found it hard to provide a prognostic estimate.

> "*The response was always the same, it's not quite grown quite well enough, please go away and do a bit more walking, refocus, and we will assess again in five weeks… You do not really know what's really happening or what exactly they are waiting for - you are sort of in limbo."* (21, F-40)

Antithetically those with an infection were at times overwhelmed by the active need for them to participate in their treatment. The frames used were complex, hard to manage and stayed on for a long time; in addition to surgical management they often had intravenous antibiotics at home:

> *"I was having to give myself two injections, and the antibiotics through a line. Keeping the environment clean, using needles, storing things properly. I just didn't think I could do things like that."* (18, M-50)

What was clear from all these patients was a much greater sense of fear. The prognosis was much more unclear and having endured the early surgery, they were sensitised to the burden of further surgery and desperate to protect themselves from further adverse outcomes. The experience of being told they needed surgery to manage a complication is described by a participant below:

> *"When I was on the ward there were a couple of other people who'd been admitted again with infections - it seemed like what they gone through was really terrible. But I thought I'd be all right, that wouldn't happen to me. And then they came and told me that mine had an infection, I thought that's me now…I was in their situation. I'm now thinking, I've got the infection, what happens now, this is going to be a long process. Everything became a great unknown, the goalpost moved from "you will be home on Saturday and right*

in three months" to "you will be going home when this is right and we don't how long that's gonna' take." (9, M-40)

Complications added significant physical and psychological toll to individuals, and it should be an important consideration for clinicians and researchers considering the appropriateness of certain treatments.

5.5.7.5 Role of treatment decisions

Regarding early treatment preferences, participants had strong preferences towards salvage; they wanted a solution which gave them time to understand their circumstances better.

"They made it clear how severe the injury was that there was a risk of losing the leg. My input was "you can't take the leg off - what you going to do to make sure I don't lose my leg", but aside from that I didn't really have any input." (1, M-40)

This preference was unwavering for recovery without complications; noting the long rehabilitation was justifiable for a well-functioning limb. Those with complications had often given serious prevarication to amputation.

"I kept going back-and-forth about having an amputation - at this stage - I really wanted it, just to get to the end, the surgeon kept talking me around." (26, M-50)

For those who continued to pursue reconstruction despite complications, amputation was associated with more severe disability than a compromised salvaged limb. Articulating that amputation represented a series of foreign challenges, which included prosthetic use, stump problems and neuropathic pain.

"You know if I'd had an amputation, I imagine the pain would have still been there, maybe different but still there, and you have all the other problems, which go with it. You cannot undo what's done, so you want the best for what you have." (18, M-50)

They balanced these challenges against their current situation and their overall hopes for the outcome of treatment. Most who had salvage treatment were pleased with their limb at the end of treatment, but some speculated whether the right decision was made and whether they would ultimately need, or have benefitted from, an amputation.

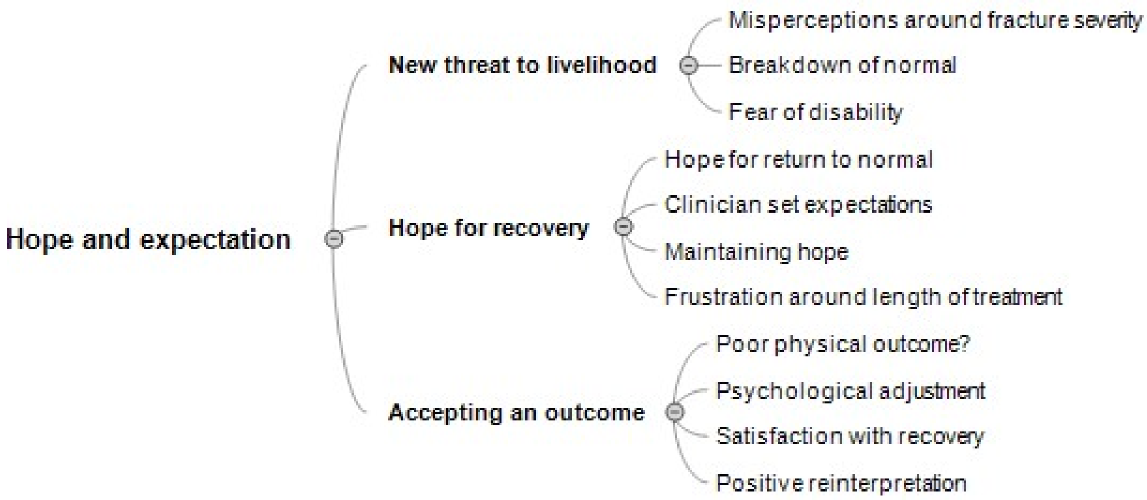
Most patients felt they did not need to have input into which fixation strategy was used but were grateful if they were kept informed about plans for further surgery and what the surgery involved. Most patients saw the situation from a position of neutrality and were happy to defer decision making to the treating surgeon.

> *"They did explain to me the steps of surgery and what complications could occur and why, they also explained why you needed the surgery. I wasn't offered any choice, they just told me what was going to happen, and that limited amount was exactly what I needed to know at that time."* (9, M-40)

Individuals with internal fixation were happy with the treatment and expressed that they didn't want to have external fixation unless unavoidable due to the burden associated with frames. Patients who had external fixation frequently viewed it as the only salvage option available for them and thus worth enduring, some patients liked not having retained metalwork in the leg after the completion of treatment.

5.5.8 Hope and expectation

Figure 5-10 Matrix for Theme 4: Hope and expectation. Figure shows theme, 3 subthemes, and underlying codes. Theme considered the psychological challenges faced by being newly injured. Subthemes considered hopes for recovery and trying to accept temporary or permanent disability



Interlaced with the story of physical recovery, was the attempt to psychologically reconcile what had happened to them and what it meant for their short and long-term future. Much of the psychological angst related to the uncertainty of how long their recovery would take and how complete it would be at the end. This theme (Figure 5-10) describes individual's hopes and expectations for recovery, following the shock of severe injury.

5.5.8.1 New threat to livelihood

Individuals described the injury as having "*torn*" (23, M-20) their life away from them; the injury led to an abrupt departure from their normal and they had to negotiate new threats. Individuals had limited preconception of open fractures in terms of the treatment they would have and the extent to which they would recover.

> *"I think it's hard, because the way I thought before was that if you had a broken bone, you put it in a cast, and it gets better. I thought that, and I think other people think that too. People think it's a short-term issue you had it, you use crutches for a bit, and that's that. You know, this has happened, you*

crack on with it, and it's sorted. That's what I thought really. The reality of this, hits you like a sledgehammer I suppose." (12, F-50, 3B-IF-C)

"I remember screaming at the accident. I was screaming I'm going to lose my leg…" (16, F-50)

With hindsight, participants could offer educated explanations about the fracture, its treatment, and complications; and the impact of each. Sustaining significant physical trauma had a major psychological impact; yet early misunderstandings around these rare injuries contributed to anxiety and isolation, as individuals battled with how to appraise the injury. Personal education seemed empowering and probably holds an important role in psychological support.

5.5.8.2 Hope for recovery

When asked to reflect on their initial hopes for recovery participants said that they hoped to "*get back to normal*" (10, F-50), clarified as wanting to return to their previous responsibilities and activities albeit with adaptations if necessary. A participant below described that he wanted to return to sport, and work; although the specific sport and job role had changed from before the injury.

"I'm at 0% still currently. But once I'm able to walk on my actual legs, I think things will be able to pick up again. I had a normal life before, I just want that back. Swimming for one. Working next, I'll work anywhere – it doesn't have to be the same job - ASDA will do." (22, M-20)

Whilst individuals were relatively clear in what their hopes had been for their recovery overall; hope was quite fragile and set-backs or delays in rehabilitation could affect the ability to look forward. Participants described these incidents as dark moments that they had struggled to recover from.

"I was crying. I was just overwhelmed, that first experience of walking. That hit me because it just felt like a huge step back, I had been so positive, I

> *thought well that's going to work, and it hadn't worked, so I'm back to square one."* (10, F-50)

Hope was an important motivator and seemed to help individuals get through difficult periods. Hope, or lack of hope, was an area where several participants seemed to display vulnerability. Interestingly, some said that they had tried not to hope or plan and did not ask their surgeon for prognosis as they felt this put undue pressure on all involved.

> *"Found it more valuable to look back and see the progress. I was able to see improvement, but I never looked forward. I thought it was unfair to ask surgeons or the nurses, how long this will take because they didn't know either."* (1, M-40)

Temporal aspects were also important, whilst participants wanted to recover well, they also wanted to recover quickly to help navigate the financial and social pressures inflicted by the injury. The recovery was described as taking "*much much longer than expected"* (1, M-40). Some thought that the clinical team had misled them, whilst others felt the clinical team were equally unsure and reluctant to speculate. Interestingly, many felt they were uncertain whether they would have wished to know the length of recovery prospectively, which mirrored earlier findings regarding participants not wanting to be overly involved in treatment decisions. An example of this dichotomy is below.

> *"One of my earliest memories of coming to group rehab and being asked "how long have they said you are going to have your frame on for then" and I said "about 4-6 months", and they said "oh well you can double that then and add a bit more". I was told three to six months and it was nine, so spot on really. I don't know whether you would be better off knowing upfront how long you was in this for. I don't know the answer to that one".* (21, F-40)

5.5.8.3 Accepting an outcome

Satisfaction with the completeness of recovery varied, one individual summarised the perspective of many by saying it was "*good enough*" (23, M-20). Patients who were satisfied, acknowledged that the damage was irreversible and whilst their limb was still compromised to varying degrees, they were able to do tasks that was important to them.

> *"I can use my motorbike again now. I'm hoping to still continue to get better, I think I'm still early days. I want to rebuild up the muscle in my leg and they said the bone would take another few years to harden off. Given the severity of it, and to think I could have lost the leg it's really actually quite good…."* (2, M-20)

Individuals less satisfied with recovery were more likely to have had complications resulting in debilitating chronic loss of function; with an outcome that correlated poorly with their expectations for recovery. It seemed whilst participants expected to have an incomplete recovery, this vision lacked granularity, and the reality was different from their expectation. The role of clinicians in this was not clear; yet, individuals speculated whether specific actions, tasks or treatments could have improved the degree of impairment at the end of treatment.

> *"It's just because, the injury was four years ago. I've had all the surgery I am going to get. I still need morphine, daily. I cannot walk more than 50 metres. And I won't ever work again. It makes you wonder if it was worth it. I am not sure what I imagined, but I thought it would be better on this."* (26, M-50)

Ability to adapt psychologically following injury impacts satisfaction with an outcome. Personal growth was not described universally but was most evident in those furthest from the injury and in younger patients. This could be as simple as acknowledging a personal emotional strength; but for the younger participants, it could be more complex; having been injured as a consequence of chaotic behaviours and changing life direction as part of recovery.

"I was told to take it easy on alcohol. I've never drank since. My life changed for the better because of the accident… When you decide to quit your life changes. All my social life was built around alcohol. A pub lifestyle. It's different now." (3, M-30)

5.5.8.4 To what extent is there variation in the recovery experience: Importance of age

The study included individuals from aged 21 to 80 and whilst individuals across the spectrum talked about similar themes, but purely focusing on themes fails to capture that priorities for recovery were different for different people. A case-ordered meta-matrix was used to examine the relationship between age and recovery experience. This analysis identified three age groups who differed in their approach to recovery; the groups were classified as early adults (aged below 40), middle adulthood (40 – 65), and late adulthood (over 65). Code density per age group is shown in Table-5-6. The youngest individuals were more likely to stress the financial and social loss experienced as a consequence of injury; the injury had often occurred at a point where they had just become independent from their parents and the injury was a major set-back. Older individuals were more financial secure and had patience and were less threatened by the period of convalescence. Those in "middle adulthood" carried some characteristics of both groups; still expressing financial and social pressures but general having more capacity to absorb the consequences of injury. Figure 5-11 presents condensed interview summaries of three cases perceived to be represented of their age group.

Figure 5-11 Lateral summary of 3 archetypal cases to highlight how age impacted the experience of recovery with one case per age group.

Early Adults: (22, M-20): Man in early twenties living with friends, an apprentice but also working casual hours elsewhere to make ends meet. He sustained an isolated tibial fracture through an RTA. The injury was repaired with local flap and a TSF, but the first flap failed requiring re-operation. He was still using crutches when interviewed but felt he just needed to recoup strength and was determined he would make a full recovery. To cope financially and physically he had moved in with a Grandparent who lived in a different county, he had to abandon his apprenticeship, and was isolated from his previous social circle. Through the accident he had lost his vehicle which was his main asset, and without a means of transport he was unsure how he would get back to work. He explained that after spending almost a year housebound he had lost much of what he'd spent his adult life working for. His main frustration was about the longevity of recovery, rationalising that his losses would have been less if recovery was shorter.

Older adults: (20, M-60) A retired gentleman, who is physically active and who lives with wife. He sustained the injury at home following a domestic accident, which required a TSF and he recovered without complications. He found the frame burdensome at the time, and felt the recovery phase had been long, but he felt that as a retired man he had time to recover without some of the stresses faced by other patients. He was pleased with his recovery as the leg doesn't limit him now as he can still do DIY, walk locally, drive, and go on holiday; he still develops swelling in the leg but he manages this by taking rest breaks to elevate the leg. He liked the frame despite the protracted recovery as he felt it reduced the risk of complication.

Middle adulthood: (21, F-40): A 40-year-old woman, injured in a sports accident. Had a TSF initially but required further surgery for non-union. She had paid sick-leave in the immediate aftermath of her injury, but was able to return to work within a few months after receiving appropriate adjustments and support with transport. Return to sport was a priority for her, and she managed to access specialist and frequent physiotherapy via a charity. She had relied on other patients for emotional support and had built good networks. She was concerned with the longevity of recovery, but also the extent to which she could recover and the long-term implications of the injury on her future health.

Table-5-6: Proportionate coding density for codes relevant to work, social activities/relationships and transport

	Age (%)		
	20-39 (10)	40-59 (13)	65+ (3)
Finance: Return to work	1.0	0.8	0.0
Finance: Benefits	0.7	0.6	0.0
Finance: Litigation	0.3	0.4	0.0
Finance: Private healthcare	0.1	0.2	0.0
Finance: Retirement	0.0	0.0	1.0
Finance: Education	0.3	0.0	0.0
Finance: Parents	0.9	0.0	0.0
Personal support: Parents	0.9	0.2	0.0
Personal support: Partner	0.2	0.8	1.0
Personal support: Family	0.9	0.9	1.0
Personal support: Patients	0.7	0.5	0.3
Personal support: Internet	0.6	0.5	0.3
Return to activities: Social life	0.9	0.3	0.0
Return to activities: Recreation	0.3	0.6	1.0
Return to activities: Sport	0.4	0.2	0.0
Return to activities: Child care	0.4	0.5	0.0
Able to travel: Public transport	0.2	0.2	0.3
Able to travel: Motorbike	0.4	0.1	0.0
Able to travel: Driving	0.2	0.8	1.0
Able to travel: Walking	0.9	0.8	0.7
Coping: Disengagement	0.6	0.2	0.0
Psychological: Low mood	0.7	0.5	0.0

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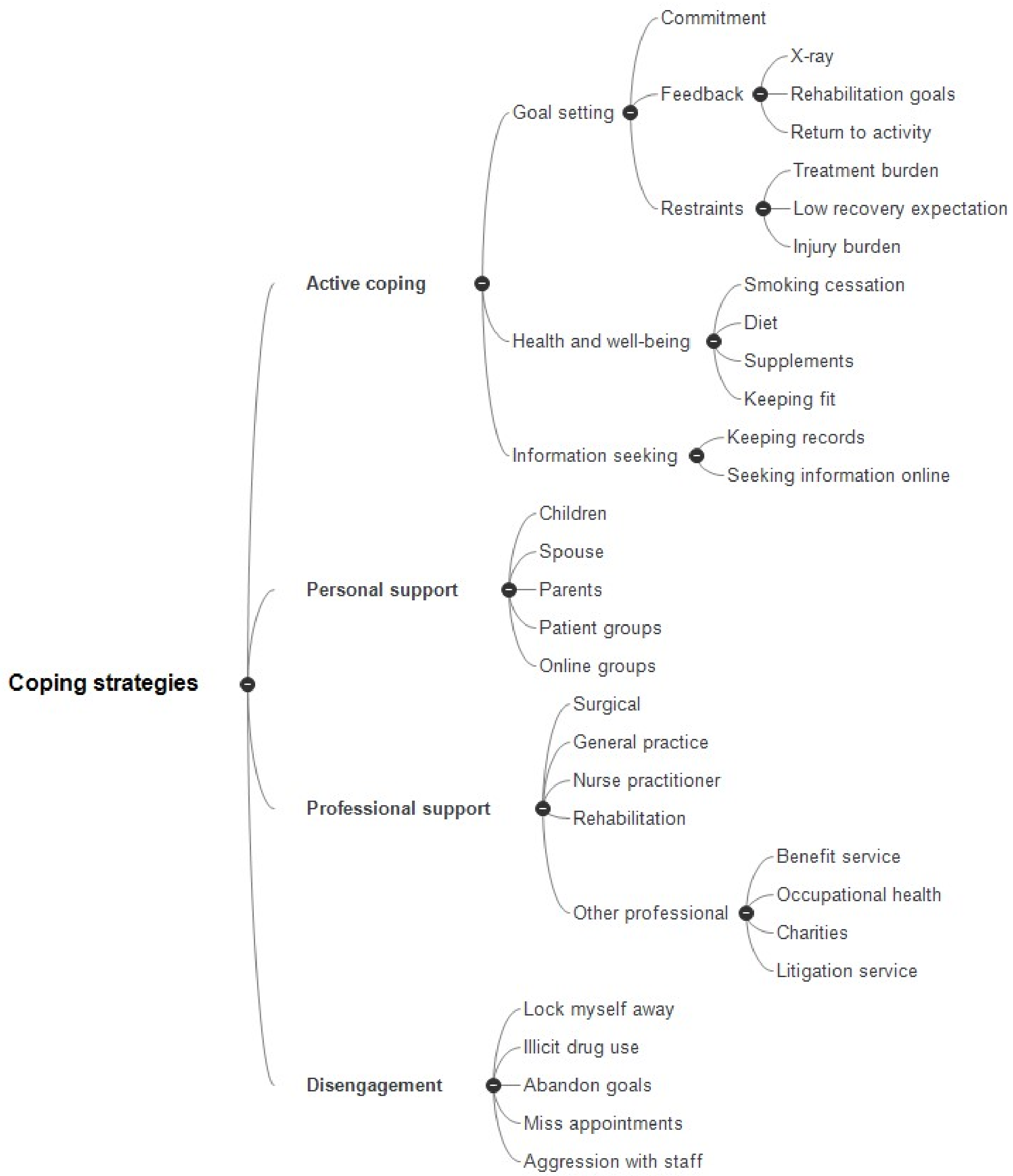
5.5.9 Coping strategies

Figure 5-12 Matrix for Theme 5: Coping strategies. Figure shows theme, 5 subthemes, and underlying codes. Subthemes considered coping strategies used by individuals, corresponding codes were specific examples of strategies used by individuals.



Individuals had to find strategies which allowed them to cope physically and psychologically with the impact of injury on their lives. Several different coping strategies were employed and are outlined in Figure 5-12.

5.5.9.1 Active coping, goal setting, information seeking

When asked what helped them to recover; personal motivation was a central concept and goal setting was important to most patients. Goals were typically around reducing mobility aid use and returning to specific activities; with progressive task complexity as recovery progressed. Participants relied on themselves to define goals but sometimes discussed them with practitioners to see how realistic the goals were to achieve. This process created a positive feedback cycle for individuals, and was what many attributed to be the driver of their successful recovery.

> *"What did I do…? I just set myself goals really. By this point I want to ditch my crutches, by this point I want to be back at work, by this point I want to be able to go outside… Setting a day where I could play sport… That kind of thing…"* (7, M-20)

Goals were not always around mobility and sometimes relied on health habits. There were several examples of patients taking action to change a behaviour in the hope that this would improve their treatment outcome:

- Improved diet: *"Paying attention to diet… I've focused on eating a paleo diet and cutting out processed food."* (22, M-20)
- Smoking: *"you should give yourself the best shot – so yea I did quit."* (2, M-20)
- Supplements: *"I was taking every multivitamin calcium supplement going"* (21, F-40)
- Keeping fit: *"I asked for dumbbells so I could work-out my arms from my bed."* (9, M-40)

Situational restraints were a barrier to achieving goals, but tasks could be adapted to be more achievable; for bone transport patients, goal setting was often compliance with and progression with the frame prescription. Interim x-ray reviews served as feedback, and bone growth on a scan was perceived as rewarding, encouraging continued compliance.

> *"In my head just kept thinking it's down to me to do this bone transfer. Had three rings to adjust with two clicks in the morning and two clicks at night. Focusing on getting it right each time and remembering to do it each time."* (18, M-50)

> *"I kept taking pictures on my phone. Every time I came into clinic, and that help me watch it progress, you could see it healing, or at least changing, it helps you feel like you were moving forward."* (19, M-50)

5.5.9.2 Personal Social Support

Strong personal networks were important. Younger patients who were living independently, typically moved back into their parental home after the accident recognising that multiple occupancy rental housing was not financially viable or physically practical. Older patients generally relied on a spouse to provide emotional, financial and instrumental support. Becoming a carer was a burden for family members; but typically was graciously undertaken to relieve pressure on the injured person.

"*And thank God, because in all of this, I don't think I would be how I am today, if it wasn't for my family, because they've been very supportive, very very supportive, and it goes a long way, doesn't it, that support".* (11, M-20)

The value of the personal support networks was most stark from talking to participants who did not have such networks. The study only included two individuals who lived alone through the recovery process and both described terrible isolation, hopelessness with regards to future prospects, and expressed suicidal intent.

"And I'm not married so I'm not doing it for them. So, who am I doing it for, why keep going with this. It's not like I don't want to do it but finding the motivation to get better for me it's hard you know. I've only got one room, it's about 3 metres squared. I've spent 2 years in one room, only had 6 nights out in two years. Hate it." (14, M-30)

There was a clear need for peer support. Isolation was caused by physical limits, but also the psychological impact of living with an injury which is poorly understood on a societal level. Peer support came via two routes; an NHS facilitated group clinic for TSF patients and digital resources such as patient support groups (on the social media platform, Facebook). These resources were accessed for both information and comradeship; patients talked extensively about the value of both resources. These resources were presented as a mechanism to access an "all hour's patient expert", examples given for this use of these resources were:

1) Clothing: *"My wife found a pattern to modify trousers online so they would fit over the frame".* (3, M-30)
2) Out of hours support: *"I thought about going to A&E, but someone was awake on the Facebook group and that got me through until the morning. When I could just ring clinic".* (22, M-20)
3) Overcoming psychological barriers around walking in a TSF: *"You would see others walking on their frame at the gym, and I thought why I can't. I realised I actually could, it was just in my mind."* (21, F-40)
4) Rehab motivation*: There are amputees who are a great source of motivation online, but also those very addicted to medication. It showed me paths I could go and where I wanted to be"* (17, M-20)

The second use was as a means of emotional support and reducing isolation, describing the trips to the TSF group as the "*highlight of the week*" (21, F-40). The group allowed them to meet those in similar circumstances, sometimes with contact extending beyond the prescribed appointment, via WhatsApp groups or meeting for coffee on the hospital site between appointments. Some patients did mention that they did not engage with the group as they found it difficult to see the success of other patients, whilst they were dealing with evolving complications. Generally, individuals highlighted peer support as a lifeline.

5.5.9.3 Professional support

Professional support came in many forms and ranged from the surgical team to more discrete roles such as claims advisors. Whilst professional support was predominantly instrumental, the attentive nature of specific practitioners reduced anxiety by providing a consistent support network. The extent of instrumental professional support was dictated by the severity of the injury and the programme of treatment. Most were very satisfied with the care they had received from the direct care team, although inconsistencies in care upset some.

Pain management following discharge was an area where individuals identified a gap in their care. GPs usually managed pain management, but patients felt they were given minimal support from either their surgical or community teams. Concerns focused on what medication should be taken and when it should be stopped; with an internal conflict around not being in pain balanced against concerns of addiction and side-effects. Even non-prescription medication caused confusion with patients being given contradictory advice from staff and other patients regarding ibuprofen use and whilst probably not worth such prevarication; these well-intended patients were upset that something this simple could have impacted outcome.

> *"It was the only thing that was done badly or could have been done better. No one had a conversation with me about pain and whether I wanted to start reducing painkillers, or at what point I was going to stop taking it. Taking painkillers that was left to me, I got to a point where I thought do I need to be taking this anymore, and I started to reduce it to see what happens".* (1, M-40):

5.5.9.4 Disengagement as a coping strategy

Social withdrawal, illicit drug use, aggression with staff and avoiding care were examples of maladaptive coping reported by individuals in the study. Social withdrawal was the most common:

> *"I'd lost all interest. I didn't want to go out and see them, it wasn't that I didn't want to see them just that I couldn't do anything with them and it frustrated me so much it was easier to shut myself away from it".* (21, F-40)

Another form of withdrawal was substance abuse. Several patients had sourced cannabis for pain management, which they greatly appraised but also admitted concern regarding the impact of this on bone healing:

> *"I've been smoking and that makes the infection worse, could be that... I smoke pot and I have done since I came off morphine. I need it to sleep. The pain is too bad when I sleep, and pot is the only thing that helps."* (14, M-30)

Finally, some patients had withdrawn from or refused medical care as they perceived the interaction to be pointless, or too intrusive.

> *"I've got wound up. The next thing, my Mums on the phone having a go at me because I've been effing and jeffing at the doctors."* (8, M-20)

Reflecting back at these moments, some patients felt that this would be a normal reaction for them in difficult circumstances and that these strategies were sometimes helpful in reducing more harmful behaviours. Others reflected that these behaviours were had been quite frightening and somewhat out of character; but were an example of the extreme stress caused by these injuries.

5.6 Discussion

5.6.1 Summary of key findings:

Individuals described a journey of recovery with physical and psychological narratives which evolved in parallel. The salient points have been summarised below:

- The accident resulted in a complete departure from the individual's normality and routines; they were thrust into foreign circumstances where they had become very dependent. The longevity of limitations varied and were sometimes permanent.
- The fracture resulted in severe immobility, pain, disfigurement and low mood. Regaining mobility was perceived as the gatekeeper to recovery for individuals
- The gravity of these challenges was exacerbated for younger individuals, who did not have the financial stability or social capital to withstand this life-changing event.
- Individuals who had an external fixator reported greater and prolonged dependence when compared with those with internal fixation. Participants were generally approving of their respective treatment.
- Complications acted as a double insult, and there was a clear sense of injustice for individuals who had to face such adversity twice.
  Hope was fragile and recursive throughout recovery dependant on tangible improvements. The unpredictable nature of open fracture made it difficult to find assurance about the future, resulting in persistent vulnerability.
  Goal setting was a means of addressing the physical rehabilitation but had great psychological benefits by giving control back to individuals.
  Instrumental and emotional support was also of great value to individuals, offsetting the vulnerability and isolation incurred as a consequence of their injuries.

5.6.2 Reflections of results

5.6.2.1 Physical

Individuals presented the process of regaining mobility against a background of gradually returning to responsibilities they were suddenly unable to do following injury. There faced an intensive period of hospital-based treatment followed by a housebound period with significance dependence on others. There was a gradual return to social responsibilities, such as driving, work and family commitments. Recreational activities were discussed but were relatively low priority. Mobility was a focal point, but pain, appearance and depression formed a constellation of symptoms, and cessation of these allowed gradual return to normality. The study builds upon similar exploratory studies in this field. Tutton reported patient experience at two timepoints [201, 213], the first was the within hospital stay and the second reflecting on residual disability at 2-4 years; the first paper focuses on vulnerability whilst the second focuses on striving to improve years after injury. Our study presented a similar picture but on a continuum; where early shock and loss, are reconciled and there is progression towards recovery but with an open-ended conclusion.

Trickett's [66] analysis was more symptom orientated identifying traits appropriate for use in a PROM. He determined pain and mobility as the most dominant features of recovery, acknowledging several other symptoms fall under these broad domains. This has complementarity with broad domains of mobility, pain, appearance, and psychiatric symptoms; identified through our study; where it was also challenging to dissect several inter-related symptoms reported by patients. Mapping of symptoms is useful in PROMs research and there are two additional pieces of consensus-based work are of note here; a currently ongoing COMET evaluation in open tibial fracture [214] and the METRC outcomes study [69]. The METRC outcomes framework was based on a surgeon led consensus approach and identifies key measurement domains of function, complications, depression, posttraumatic stress disorder, pain, activity and participation, health-related quality of life, patient satisfaction, and healthcare utilization. What comes across strongly from our work and is mirrored in the METRC framework is the priority put on mobility as a means of measuring improvement by participants; a finding relevant for future trial design and outcome measure research.

Previous qualitative work in open tibial fracture has not asked patients how they regarded their treatment, and no comparative analysis has been complete; thus, this work provides novel insight. Participants at the point of injury universally preferred salvage strategies; they were unfamiliar with the injury and unable to comprehend the necessity of amputation in that context. Whether this preference persisted depended on their outcome; with more equipoise for individuals who either had an amputation or complications following salvage. These preferences are interesting when we acknowledge that the most extensive study considering this found equivocal outcomes between salvage and amputation [10] and suggests that the quantitative approach has overlooked the nuances of the argument. Amputee experiences in chronic conditions, recognise mental preparedness before amputation as a factor in the ability to adjust; the stump was associated with pain, walking difficulty, impaired work capacity and stigma; but represented a health improvement when compared to pre-amputation [215-217]. The context presented by these studies provides insight into our study. The concerns of individuals facing early amputation following trauma, are very valid and are lived out in the realities of those who undergo amputation. Urgent amputation was not immediately acceptable to our participants; however, those who lived with severe and chronic limitations in their salvaged limb were more open regarding amputation. This highlights the difficulty and dichotomy faced by individuals with a catastrophic limb injury. It appeared in our study that amputation was only acceptable to individuals when they have determined all other options to be exhausted.

Studies comparing ring fixation against tibial nailing are currently topical, with several trials ongoing, some of which have an embedded qualitative study [43-45]; although there is presently limited literature available. Accounts of being house or bedbound were more common from participants with a frame; who rarely left the house for non-essential journeys due to accessibility challenges, and at home, they were more likely describe dependence on family for daily tasks. Sleep was interrupted by pain, immobility, and the device. Participants with a frame took more sick leave, and reports of financial difficulties and job losses were exclusive to this group. Those with internal fixation had similar early experiences, but within weeks were able to get into a car and use crutches to walk short distances and return to work was safer with internal fixation. Whilst often reliant of a partner for support, the burden seemed less. Complications were more common in the internal fixation group in this study, and where they occurred were devastating and significantly altered the trajectory of recovery. For infection, the situation evolved rapidly, and individuals were alarmed by increased risk of limb loss or permanent disability. All complications were associated with prolonged and intensive treatment which was difficult to tolerate as it prolonged the period of incapacity, at a point where individuals had depleted financial and social resources.

Individuals could articulate the challenges and value of both surgical strategies dependant on their perspective. Balancing a need to return to core responsibilities quickly, which appeared more achievable with internal fixation; against anxiety around infection which was perceptually more strongly associated with internal fixation. Actively engaging individuals in treatment decisions is strongly encouraged [218], albeit with acknowledged barriers [219]. When asked, participants were accepting that circumstance limited ability to engage in treatment discussions and were satisfied for decisions on their behalf if they were informed. However, as there were apparent differences in experience, all efforts must be made to support and engage individuals prospectively, with attempted discussion of different management strategies where appropriate. This point also stresses the need for further research into the surgical strategies for open fractures so that a valid evidence base can inform these discussions.

5.6.2.2 Psychosocial

As a consequence of their injuries, individuals were suddenly unable to participate in their everyday activities and had to adjust to accept new limitations rapidly. Individuals struggled with the realisation that recovery required multiple surgeries and then a prolonged period of waiting for their bodies to heal. The period of waiting was associated with incredible frustration, and the injury presented a threat to their livelihood; most were keen to recoup their previous normal, yet the spectrum of potential outcomes was difficult to reconcile. Our study had comparable findings to the recent publication by Rees [213] where they described the unendingness of recovery as the most challenging part of recovery. Expectations for recovery varied between and within individuals over time; some perceived that they would eventually be able to recoup the sense of "normality" with some adaptation.

A focus on age identified that recovery experience differed dependant on age, with different experiences from younger, middle and older adults. Older adults had time for convalescence, financial security and good social capital, and their circumstances reduced the burden of injury. Older participants in the study were still physically active, and their injuries were not due to profound frailty; the fall did not seem to perturb them from wanting to resume an active independent retirement once recovered. Unfortunately missing from our sample were care homes resident, who inevitably would have offered a different insight into the injury.

Before injury, the youngest adults were newly independent, forming careers, negotiating relationships and perhaps parenthood. They had relatively low earnings, yet were taking on financial obligations, with clear ambitions for careers and relationships. They were devastated that these energies and ambitions had been lost to a period of convalescence and isolation. Our younger adults whose injuries were more recent were unsure of how they could recoup these losses; interestingly those who were further into recovery demonstrated significant personal growth and could reflect positively on the events around the injury.

Amongst the middle adulthood group, there was still a need to regain normality, although the demands of these were generally less. They were more established in their family lives and employment and better equipped to find adaptations which helped to absorb the social impact of the injury. The injury was most devastating for those who became unemployed; as this group were financially independent and relied on savings or state benefits when unable to work; this was different to the younger group who turned to parents for financial support. This group were unique in that they were worried about the ramifications of the injury on their wider health, citing concerns such as osteoporosis and arthritis.

Age was identified as being a relevant factor in how individuals experienced their injuries, with younger individuals appearing to find the injury more challenging to reconcile. This was attributed to the instability and major life changes that occur in early adulthood and meant that the injury potentially held greater consequences for younger people. These findings are supported in the broader literature, which identifies younger adulthood as a transitional phase [220, 221]. The relevance of age and open tibial fracture has been outlined elsewhere in this thesis, and this study provides additional evidence of the importance of recognising distinct age populations in major trauma. Age-appropriate information, support and management should be available to allow individuals to navigate recovery.

Hope was fragile and should be protected by clinicians. Provision of prognostic information in major trauma patients by practitioners is particularly important in patients who are struggling with rehabilitation, reducing disengagement and loss of hope [222]. This was seen in the frame group who were motivated by feedback from weekly radiographs despite not making physical progress. A different study identifies the role of the clinician in facilitating ‘realistic hopefulness’ in managing the psychology of injury [223]. Managing anxiety around recovery is difficult for clinicians as outcomes are unpredictable, although certain psychological strategies have been shown to support individuals adapting to new circumstances. Managing hope is important; hope is related to positive coping and linked with improved psychological adaptation and functional outcomes [224]

Shauver [95] who first considered the role of coping strategies after open tibial fracture; concludes that the use of problem and emotion-focused coping strategies can lead to improved outcomes by fostering post-traumatic growth. This psychological adaptation allows individuals to see their injuries from a more optimistic perspective, which gives the perspective of an improved outcome; a finding is grounded elsewhere in the injury literature [224]. Shauver reported that individuals spoke of their coping strategies without specific prompting. Our study prompted individuals to talk about how they coped with injury, and participants provided lengthy responses around positive and negative coping strategies; focusing on the nuances of the strategy applied.

When asked about coping, use of active (or problem-focused) coping were most often discussed and included; rehabilitation-orientated goal-setting, holistic management of health (such as diet), and seeking information (documenting care and researching the injury). Goal setting was used as a mechanism for taking back control after a period of vulnerability and dependence. Control was maintained by using goals that were realistic and could be achieved in a short time frame. Physically, the use of goals gave individuals a tangible measure of recovery progression; psychologically goals were closely linked to hope and aspiration for recovery, achieving a goal motivated individuals to set new goals and continue with their attempts to return to normal.

The other predominant coping strategy reported was a reliance on social support; this related to both physical and psychological support. This support came from either a family member or another injured person and could be in-person or through digital resources. Increased reliance on a social network is quoted in several qualitative studies which focus on severe limb injury [95, 213, 225], and was also a central concept in this study. Evident from this study and not highlighted elsewhere are the difficulties faced by those with minimal community social support. These individuals often went hungry, missed hospital appointments, had long courses of care and poor function at the end of treatment. The motivation for recovery was low as without a family or employment; individuals lacked purpose.

Individuals cited the value of peer support to provide help with instrumental and emotional coping. Use of group clinics in NHS settings has become increasingly popular for those with chronic conditions or those needing regular access to services, with potential benefits to the patients and clinician. [226]. This approach seems to be successful in individuals with open tibial fracture amongst the small number who had access to this clinic and should be considered for more broad adoption as a means of providing psychosocial support to the most isolated individuals. Better facilitation of coping strategies may help patients tolerate their treatment and ease psychosocial burden. Providing evidence-based information around rehabilitation (i.e. diet, smoking or exercise) may support individuals with goal navigation and facilitating social interaction between patients.

5.6.3 Study strengths and limitations

5.6.3.1 Defining eligibility criteria

Eligibility criteria were deliberately broad to avoid restricting the recruitment pool in this difficult to access group. The exclusion criteria only omitted those unable to complete an interview and certain vulnerable populations. A cross-sectional approach was chosen as there was no apparent singular time-point for where the data-collection should be completed. Consequently, any time-point would have been arbitrary. The time point was selected to find individuals reaching the end of acute care, who could reflect on the acute recovery experience; most individuals are discharged at around 18 months, but this varied from 6 months to several years. The limitation was that individuals reflected differently on their injury dependant on the stage of rehabilitation and recovery; whilst this reflection was quite individual, having a fixed point may have created confidence with regards to variability and validity. The study may have been better suited to a longitudinal design as this would allow for evaluation of the impact of time.

5.6.3.2 Sampling

The process of recruitment intended to minimise bias and this was broadly achieved although there were some remnant concerns described as follows:

- The treating clinician had to provide permission to contact each patient, thus acting as gatekeepers and having some control over who was included in the study. The impact of this was minimised by explaining the study sought balanced views and individuals should only be excluded if participation would cause significant distress or researcher risk.

- Self-selection was more likely to introduce bias as individuals with certain attitudes were more likely to take part. The impact of this could be bi-directional, with individuals at opposite ends of the recovery spectrum likely be non-responders, for different reasons.
- The role of ageing and open tibial fracture is a theme of this thesis. The study included a proportionate number of older patients; however, these individuals were not frail and made a full return to independent living following their injury. Our study did not place an age limit or explicitly exclude individuals in residential care; however, a spectrum of factors meant that the older, frail patient (who require care for ADLs) have not contributed to this study.
- The study was single-centred, and experience may have been different at centres with varying care pathways.

Acknowledging these limitations in sampling the study also had several strengths with regards to sampling strategy. Recruiting a larger, balanced, sample, has added depth to the dataset which has allowed us to interrogate differences as well as similarities. This was achieved by careful communication with the clinical teams and using a multi-modal approach to recruitment. This is an achievement, as involving young men during times of personal hardship is notoriously difficult, and this population is under-represented in research.

5.6.3.3 Reflection

The position of a researcher in a clinical setting but without a clinical background helped build rapport with participants. The impartiality of the non-clinical researcher seemed to help patients to discuss both the positive and negative aspects of their care. Furthermore the position, encouraged patients to teach the researcher about their experience elaborating beyond what they would have done if they had perceived the researcher to be a clinical expert. As a consequence of this it was felt that the researcher gained a different insight than what may have been gained by a clinical researcher.

A major influence in analysing these interviews was the proceeding conclusions drawn elsewhere in the thesis. It was acknowledged that these was pre-existing biases, and these were best utilised to inform the interview schedule, structure of the framework and cross-case analysis and is likely to have directed the outcome of the study.

5.6.3.4 Use of Dragon Dictate to facilitate transcription

In the absence of formal funding, Dragon dictate was utilised to transcribe interviews with some success. Dragon dictate is an automated dictation software which can convert spoken words into editable text, reducing the administrative burden associated with interviews at a modest cost. The main limitation, related to the ability of the software to manage different users, their dialects and speech patterns. The software relies on deep learning to achieve maximum proficiency and improving the accuracy of the transcription depends on the user to "train" the software by correcting text and teaching dialect. This process of learning takes several hours of dictation and is better suited to a single user who is invested in using the software to facilitate long-term working. Consequently, Dragon dictate was not suitable for direct transcription of a live interview due to the guest speech. Nonetheless, the software was used successfully to transcribe retrospectively; by the interviewer repeating the audio recording back to the software. Once familiar with the software, this allowed for audio files to be converted rapidly to text files and therefore, despite limitations, Dragon Dictate may be a useful tool to facilitate transcription.

5.6.3.5 Framework and a mixed methods approach

The study was designed and presented as a sequential explanatory design; with this qualitative study informed by the preceding national and regional registry studies, and a systematic review. A mixed-methods approach was used with the intention of complementarity; deliberately seeking different perspectives, including those which are frequently overlooked in orthopaedic research. A challenge of using mixed methods design was the integration of the two methods and whether this could be achieved without weakening the messages from either study. The Framework

Approach was chosen as a means of achieving this; with the preceding studies informing a provisional deductive Framework guiding the qualitative analysis.

To what extent the analysis has stayed true to a Framework Approach is questionable. At the outset of this thesis, it was hoped that the TARN registry would be more dominant, delivering comprehensive and clear conclusions with further questions which would inform our Framework; however limitations in the registry resulted in a more conservative output. A systematic review also contributed to the Framework for this study; but carried a small number of findings, identifying inadequacies in the literature. As a result, the qualitative analysis began on a shallow foundation; and consequently, the qualitative analysis has an inductive character than was proposed, akin to a thematic analysis. By definition, Framework encourages the researcher to explore direct lines of inquiry, best suited to circumstances where there is a narrow research question; this is appropriate in many settings but was difficult to apply here as the preceding work lacked clear conclusions. The drift towards a more thematic analysis in this study is an acknowledgement that the stories of open tibial fracture provided through our interviews were rich and complex; and the analysis required flexibility and interpretation beyond what is normally achieved in a framework analysis. This drift was concordant with our pragmatic orientation which outlined that the methods should be malleable to fit the research question and is not necessarily a criticism of the work undertaken.

5.6.4 Recommendations for clinical practice and research

By asking individuals what was important for them regarding recovery, it has been possible to gain insight into the priorities for further research. There was evidence, to suggest that experience and outcome were not equivocal across difference treatments, which stresses the need for well-designed comparator studies; which capture patient-centred aspects of treatment. There were clear treatment preferences for salvage and internal fixation, although with hindsight salvage surgery was not a panacea, and infective complications were a concern for all individuals. Strong preferences towards internal fixation yet concerns regarding infection; indicates reducing infective complications associated with internal fixation should be a research priority, avenues for this is improving prognostication with existing technologies, evaluating technique, or considering new internal fixation technologies. The need for clinical trials in open tibial fracture has been identified elsewhere in this thesis, and studies such as this provide useful information for those designing these studies [227]. Outlining a relevant outcome set in open tibia has been a priority for several groups, and the information derived here could be useful for informing selection of outcomes or utilised in a PROM development setting.

The above recommendations focus on the physical aspects of recovery, yet from this research, it is possible to make several suggestions regarding where psychological care could be improved for individuals with an open fracture. Much of this analysis has focused on how individuals process their injuries; however, orthopaedic surgeons are not experts in mental health, and the fracture clinic environment does not facilitate discussions of this kind. Therefore, support needs to be provisioned via different avenues. Most individuals in the study did not want formal mental health support following their injuries; however, identified activities and environments which helped them psychologically, which could be facilitated by the NHS. Access to physiotherapy and nurse specialists was a great source of physical and psychological support but was only extended to about half of the individuals in the study. Group consultations were seen as a means of improving access with the additional benefit of access to peer support; and these consultations could be offered more widely as a tool for psychosocial support. Whilst the group consultation model was valued, individuals sought information beyond the scope of what be achieved by a group clinic environment where there are acute care needs to be addressed. Several individuals cited the value of digital resources in aiding their recovery and understanding. Consequently, there would be value in an online resource co-produced by the MDT for open tibial fracture care and patient experts. This website could advise on the injury, surgery, rehabilitation, holistic management, social care and financial support; which were identified as important issues to our patients. The service could include a forum which allowed individuals with similar care experiences to support each other.

Chapter 6. Conclusion

6.1 Statement of principal findings

The aim of this thesis was to undertake a detailed mixed methods analysis of the epidemiology, treatment, and outcomes of open tibial fractures from a national, regional, and individual perspective. The introductory chapter outlined that individuals who sustain open tibial fractures face permanent impairment and improving treatments for these injuries is of significant interest to the orthopaedic community. However, much of the work published so far is limited to single centre experiences, and the route forward for research is unclear. Our aims were achieved by using a mixed-methods approach which utilised the largest trauma registry in Europe (TARN), a detailed regional database, and a series of rich semi-structured interviews with participants who had sustained an open tibial fracture.

The results derived from the TARN registry identified a crude incidence rate of open tibial fracture was 2.85 x 10^5. These injuries occurred most frequently in young male patients (aged 25-30); however, the incidence was 15% greater in those over 65 when compared to the 15-39 age group (IRR 1.15 (1.09-1.22)). The incidence in the under 15 (IRR 0.35 (0.32-0.39)) and 40-65 (IRR 0.87 (0.83-0.92)) age group was significantly less than the incidence in the 15-39 age group, supporting the concept of a bimodal distribution. The study identified an increased risk of mortality (OR: 2.34, CI: 1.60 – 3.42) amongst patients with comorbidity (CCI > 3), after adjusting for other known risk factors including age, gender, NISS and GCS. Evaluation of surgical pathways was limited to 2157 patients who sustained Gustilo 3B or 3C fractures. Of these patients 1898 (88.0%) were treated in a major trauma centre, 1148 (57.4%), 671 (33.5%) and 179 (8.2%) were managed with internal fixation, external fixation, and amputation respectively. Inpatient (early) wound complications were reported in 60 patients (2.8%); in an adjusted model to explore the relationship between time to soft tissue cover and early wound complications the proportion of individuals experiencing wound complication increased by 0.3% per hour until definitive soft tissue cover (CI: 1.001 – 1.004). There were important findings related to the limitations of using TARN as a tool for orthopaedic research. The design of the registry prevents linkage of the injury to its treatment and outcomes; and furthermore the registry collects minimal outcome data, limited to mortality and inpatient complications. These limitation impact the usefulness of the data collected, and as a consequence, the registry allows for only limited analysis of the relationship between characteristics, treatment processes and outcome. The failure of national registries to collate relevant outcome measures highlights the importance of supplementing national level data with prospectively designed and high quality research, when making policy, funding decisions and national guidelines.

Our regional register provided substantive additional information to the national registry on the medium-term outcomes of these injuries; individuals reported a 26% ($p<0.01$) reduction in quality of life, and a 30% increase in disability ($p<0.01$) one year into their recovery, whilst one in four, required revision surgery within 12 months of injury. The average cost of treatment was £27312, but only £10801 was attributed to the orthopaedic injury, costs which seems relatively modest set against the devastating effect of the injury on the individual. The cross-sectional nature of the study and elements of retrospective data collection; introduced limitations and biases accepted with this study design; the subsequent qualitative work allowed for corroboration between methodologies reducing concern regarding such biases.

Open tibial fracture research has traditionally focused on surgical techniques, and the aspects of treatment and recovery that are important to the patient are poorly documented. Our qualitative study was based on a framework informed by a qualitative systematic review and service evaluation. Individuals described a journey of recovery and rehabilitation, enduring long periods of being housebound with a steady return to previous responsibilities. Regaining mobility, dealing with symptoms, burden of treatment, hope and expectation, and coping strategies were five themes identified from the data. Cross-case analysis, informed by the outcomes of our TARN study, found that treatment and age shaped the burden of injury with working-aged individuals struggling to endure the length of recovery due to societal pressures. Recovery from these injuries requires great investment from the patient and health service, and despite great effort, most individuals fail to return to previous activities.

6.2 Implications for clinical practice

This study outlined a series of research questions, and these questions have generated ideas for future research, which are outlined in the next section. However, they also have implications for current and future clinical practice, which is the subject of this section.

This thesis has outlined current epidemiology and practices for treating open tibial fractures a need for improved clinical practices. The high incidence of these injuries in older patients is a significant finding, and understanding the reasons for these observations is important. Guidelines for managing these fractures in the UK fail to acknowledge a bimodal distribution of incidence and guidance does not include any specific guidance for managing a frail or older patients (as is advocated for other injuries such as hip fractures). Our qualitative work recognised that older and younger patients had significantly different treatment goals and developing strategies for age-appropriate management is a necessity as not to disadvantage either group.

The TARN registry work identified several examples where individuals were not treated according to UK guidelines which provide the minimum expected standards for centres treating these patients, and identified a relationship between compliance and complications. Our qualitative study identified significant distress in individuals who had perceived delays in accessing care, highlighted that these guidelines play a role in patient experience as well as patient outcome. Given the severe nature of these injuries, their management should be a priority within regional trauma centres, with protected resources available to deliver timely specialist care where patient factors allow.

It is unlikely that there will be major changes in the technology used to manage open tibial fractures in the short-term, although existing technologies must be appropriately applied to secure the best outcome for the individual. Treatment for open tibial fracture is a complex intervention, and a challenge for clinical research is being able to detect a positive intervention signal. The widespread use of the largely invalid Gustilo classification in clinical practice as a surrogate for injury characterisation and communicating prognosis is likely to impact treatment planning, outcome and impairs the flow of information to the patient. Outside of direct clinical care, the classification system is used routinely in service evaluation and audit projects, and this in turn, impacts our ability to evaluate clinical practice. There are validated alternatives to the Gustilo classification although they do not seem to be widely adopted due to complexity and an unwillingness to devote time to documentation, a consensus-based approach to adoption of an appropriate classification scheme would be a positive next step in improving patient care.

This thesis has raised a question with regards to the usefulness of the TARN data collection platform for orthopaedic service evaluation particularly with regards to linking injuries, interventions and recorded outcomes. TARN is funded by the Department of Health, and hospitals receive significant funding from the government for perceived compliance with key performance indicators. In an era where central bodies are seeking to increase regulation of services, it is important that the orthopaedic communities campaign for a quality evaluation platform that utilises measures and outcomes which are likely to confer benefit to the patient.

Improving outcomes using surgical techniques is both challenging and expensive; however, our qualitative study identified that individuals placed significant value on instrumental and social support to shape their physical outcome and for psychological support. Psychosocial support systems are often considered outside of the NHS remit, yet according to our participants, a holistic approach to management conferred significant benefit. Detachment from their social circle and the health service was common, and it was clear that not all participants could seek support. Expansions of group consultation services and use of digital resources such as a website could act as a cost-effective means of providing information to patients. A web platform could be utilised to provide information about their injury, wellbeing, recovery, and rehabilitation, with signposting to charities and government bodies who will provide financial support; such a website could also include patient contributors and potentially an online community to reduce social isolation.

6.3 Recommendations for future research

Open tibial fracture is a nascent area for research and further work is clearly necessary, the following suggestion are outlined for future research.

This thesis has investigated the outcomes and epidemiology of open tibial fractures and outlines that patient needs are not being met by existing treatment options when applied according to UK guidelines. Since this thesis was proposed in 2016 several randomised controlled trials have been initiated in severe limb injury although very few published. Some of these studies are proving unfeasible as the eligibility criteria are so narrow there is an insufficient number of patients, which raises questions regarding the feasibility of trials in this patient population. Nonetheless there is scope for carefully designed randomised controlled trials within this patient population.

This thesis has outlined the limitations of observational research using existing registries, however randomised controlled trials also harbour limitations which are challenging to overcome in this patient population. A reasonable suggestion for further work would be initiation of a national registry which is specific to open tibial fractures that captures relevant information on the injury, surgery and collates patient centred outcomes; circumventing the problems associated with repurposing a trauma mortality registry. What comprises relevant information, could be determined through a Delphi exercise with contribution from both surgeons and patients. Such a resource would be valuable to evaluate competing treatment strategies which are currently standard of care within the NHS, and also appropriate for validating and developing classification systems with an aim of improving prognostics.

Our qualitative work identified parallel narratives of physical recovery and psychological endurance and adaptation. Importance was placed on the availability of relevant information to help them understand recovery, identify appropriate support, and enable rehabilitation. Development of an online platform was suggested, although as our understanding around how individuals cope with and adapt to recovery from open tibial fracture it would be reasonable to develop this as part of an action research study.

Chapter 7. References

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Chapter 8. Appendices

8.1 BOA Standard for Trauma in Open Fracture

British Orthopaedic Association

BAPRAS

BRITISH ORTHOPAEDIC ASSOCIATION & BRITISH ASSOCIATION OF PLASTIC, RECONSTRUCTIVE & AESTHETIC SURGEONS AUDIT STANDARDS for TRAUMA

DEC 2017

Open Fractures

Background and justification

Open fractures may require timely multidisciplinary management. The consequences of infection, can be great both for the individual patient and the community. Trauma networks and hospitals require the appropriate pathways and infrastructure, to manage these patients, to enable optimum recovery and to minimise the risk of infection.

Inclusions:

All patients with open fractures of long bones, hind foot or midfoot (excluding hand, wrist, forefoot or digit).

Standards for Practice

1. Patients with open fractures of long bones, hind foot or midfoot should be taken directly or transferred to a specialist centre that canprovide Orthoplastic* care. Patients with hand, wrist, forefoot or digit injuries may be managed locally following similar principles.
2. Intravenous prophylactic antibiotics should be administered as soon as possible, ideally within 1 hour of injury.
3. There should be a readily accessible published network guideline for the use of antibiotics in open fractures.
4. The examination of the injured limb should include assessment and documentation of the vascular and neurological status. This shouldbe repeated systematically, particularly after reduction manoeuvres or the application of splints. Management of suspectedcompartment syndrome should follow BOAST guidelines.
5. The limb should be re-aligned and splinted.
6. Patients presenting with arterial injuries in association with their fracture should be treated in accordance with the BOAST for arterial injuries.
7. In patients where an initial "Trauma CT" is indicated there should be protocols to maximise the useful information and minimise delay:
   - The initial sequence should include a head to toes scanogram. This should be used with clinical correlationto direct further specific limb sequences during that initial CT examination.
   - There should be a local policy on the inclusion of angiography in any extremity CT related to open fractures.
8. Prior to formal debridement the wound should be handled only to remove gross contamination and to allow photography, thendressed with a saline-soaked gauze and covered with an occlusive film. 'Mini-washouts' outside the operating theatre environmentare not indicated.
9. All trauma networks must have information governance policies in place that enable staff to take, use and store photographs of openfracture wounds for clinical decision-making 24 hours a day.
10. Photographs of open fracture wounds should be taken when they are first exposed for clinical care, before debridement and at otherkey stages of management. These should be kept in the patient's records.
11. The formation of the management plan for fixation and coverage of open fractures and surgery for initial debridement should be undertaken concurrently by consultants in orthopaedic and plastic surgery (a combined orthoplastic approach).
12. Debridement should be performed using fasciotomy lines for wound extension where possible (see overleaf for recommendedincisions for fasciotomies of the leg)
    - Immediately for highly contaminated wounds (agricultural, aquatic, sewage) or when there is an associatedvascular compromise (compartment syndrome or arterial disruption producing ischaemia).
    - within 12 hours of injury for other solitary high energy open fractures
    - within 24 hours of injury for all other low energy open fractures.
13. Once debridement is complete any further procedures carried out at that same sitting should be regarded as clean surgery; i.e. thereshould be fresh instruments and a re-prep and drape of the limb before proceeding.
14. Definitive soft tissue closure or coverage should be achieved within 72 hours of injury if it cannot be performed at the time ofdebridement
15. Definitive internal stabilisation should only be carried out when it can be immediately followed with definitive soft tissue cover.
16. When a decision whether to perform limb salvage or delayed primary amputation is indicated, this should be based on amultidisciplinary assessment involving an orthopaedic surgeon, a plastic surgeon, a rehabilitation specialist, the patient and theirfamily or carers.
17. When indicated, a delayed primary amputation should be performed within 72 hours of injury.
18. Each trauma network should submit appropriate data to the TARN, monitor its performance against national standards and audit its outcomes.
19. All patients should receive information regarding expected functional recovery and rehabilitation, including advice about return to normal activities such as work and driving.

*The BAPRAS/BOA group recommend that for clarity the narrative description of an Orthoplastic Service by NICE is broken into its component parts as follows: a combined service of Orthopaedic and Plastic Surgery Consultants; sufficient combined operating lists with consultants from both specialties to meet the standards for timely management of open fractures; scheduled, combined review clinics for severe open fractures; specialist nursing teams able to care for both fractures and flaps. In addition, an effective orthoplastic service will also: submit data on each patient to the national trauma database (TARN) and hold regular clinical audit meetings with both orthopaedic and plastic surgeons present. Please note: the definition of an Orthoplastic Centre was updated in November 2019.

Evidence base:

NICE Complex fracture guideline https://www.nice.org.uk/guidance/NG37/chapter/recommendations

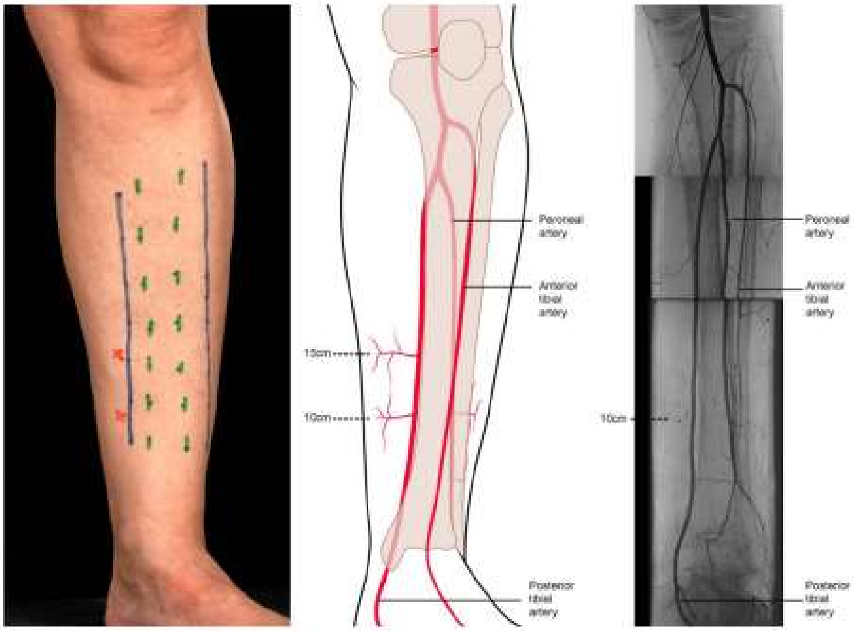

Figure showing recommended incisions for wound debridement and fasciotomies in the leg. The medial incision alone is usually sufficient for debridement and preserves the perforators arising from the posterior tibial vessels, which form the basis of local fasciocutaneous flaps. It also provides access to the posterior tibial artery and venae commitans when required as recipient vessels for free flaps. The lateral incision is used for decompression of the anterior and peroneal compartments in patients with compartment syndrome. (A) Margins of subcutaneous border of the tibia marked in green, access incisions marked in blue and perforators arising from the medial side as red crosses. (B) Line drawing depicting the location of the perforators, with approximate indicative distances from the tip of the medial malleolus. (C) Montage of arteriogram.

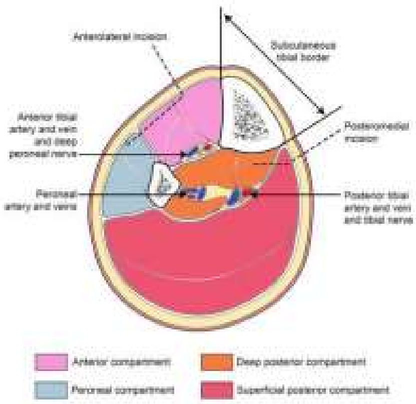

Figure showing cross section through leg showing incisions to decompress all four compartments

Figure reproduced from BOA: British Orthopaedic Association and British Association of Plastic Reconstructive and Aesthetic Surgeons, *British Orthopaedic Association Audit Standards for Trauma (BOAST): Open Fracture Management*. 2012 updated 2017, British Orthopaedic Association: London [28].

8.2 TARN data request application form

Research Request Form – The Trauma Audit & Research Network

Thank you for interest in conducting research with the TARN database.

Please provide us with your details below including your research hypothesis. Your research request will be discussed at the next meeting of the Research Management Team and you will be contacted with soon after with a decision.

Research Support Process
As part of the Research support process, any abstracts or manuscripts will be reviewed by the Research Management Team prior to submission to a journal or conference. This is applicable to both national and international publications/events.

Ref No (internal) 117509

Full Name

Jessica Nightingale

Job Title

PhD Student

Institution/Trust

University of Nottingham

Supervisor (if applicable)

Ben Ollivere

Research Hypothesis/Details & Requirements

Date Range of Analysis:

All

Is this analysis for (please underline –can be more than one):
Research Publication/Conference Abstract/Internal Trust Project/Other

Research Publication, Conference Abstract, Other (PhD thesis).

[Type text]

Aim: To investigate predictors of health related quality of life following severe open fracture using a cohort from the national trauma registry

Background

Management of severe open fractures of the tibia consists of either early amputation or reconstruction. Modern practice leans towards a tendency to reconstruct severely injured limbs; however this can give rise to multiple complications and associated costs. Defining reproducible criteria for lower limb salvage over amputation continues to be controversial, with little clarity on what clinical and patient factors drive positive outcomes following limb salvage procedures.

Best data in this field[1] concludes that patient coping strategies are a greater determinant of outcome than treatment strategies or certain clinical phenotypes. Whilst the study provides a wealth of information it usefulness in clinical decision making is limited. Epidemiological and outcomes analysis for these injuries is very limited. The TARN dataset captures an extended dataset for all patients admitted with limb threatening injury and use of this data would provide a unique investigation of fractures from a national perspective using one of the world's largest trauma databases.

Design

The project is a cross-sectional study of outcomes following severe open tibial fracture using data from the Trauma Audit Research Network (TARN), which is a national organisation that collects and processes data on moderately and severely injured patients in England and Wales. This will allow a robust and inclusive epidemiological analysis of incidence and risk factors for poor outcome defined by reduction in health related quality of life at 6 months following injury.

Study Population

Patients recorded on TARN who received treatment for open tibial fracture.

Inclusion Criteria

TARN: Cases to include all patients recorded on TARN who were admitted with a diagnosis of open lower limb fracture.

Analysis Covariates

Patient demographics
Injury characteristics
Treatment factors
Surgical factors
Outcome data - Re-operation/Readmission/LOS/Mortality/ EQ-5D data

Analysis Plan

The relationship between patient characteristics and quality of life will be modelled using multiple linear regression. Adjustment for covariates (age, gender, ISS) will be explored and factors that influence effect estimates will be retained in the model. The assumptions of multiple regression—linearity, homoscedasticity and multicollinearity—will be assessed.

1) MacKenzie, E. J. & Bosse, M. J. Factors Influencing Outcome Following Limb-Threatening Lower Limb Trauma: Lessons Learned From the Lower Extremity Assessment Project (LEAP). *J. Am. Acad. Orthop. Surg.* **14**, S205–210 (2006).

[Type text]

8.3 Fully Executed TARN Contract. Signature page and approved project proposal

CONFIDENTIAL

DATA TRANSFER AND USE AGREEMENT

THIS AGREEMENT is made as of the date of the final signature below, by and between

The University of Manchester with a business address at Oxford Road, Manchester, United Kingdom ("University")

and

University of Nottingham

with a business address of University Park Nottingham NG7 2RD ("the Recipient");

each a "Party" and collectively the "Parties"

WHEREAS the University is a leading UK teaching and research institution and holds data in the Trauma Audit and Research Network ("TARN"); and

WHEREAS the Recipient has an interest in access to such TARN Data and will use solely for the agreed Purpose (as defined below); and

WHEREAS the University is prepared to allow the Recipient access to certain TARN Data for the Purpose, to enable a specific research project; and

WHEREAS the Parties wish to clarify their respective rights and obligations in respect of the Recipient's use of such TARN Data and each Party's use of the results of such research project through entry into this Agreement.

NOW THEREFORE in consideration of the mutual promises and covenants set forth herein, and intending to be legally bound, the Parties agree as follows:

1. **Definitions**

1.1 "Purpose" shall mean use by the Recipient for academic research purposes in the specific research project detailed in Exhibit A, including (without limitation) the publication of the Results and the use of the Results for teaching, and no other purpose.

1.2 "Principal Investigator" shall mean the representative(s) of the Recipient named in Exhibit A responsible for the conduct of the research project.

1.3 "Results" shall mean the results relating to the research performed by the Recipient using the TARN Data including without limitation all analyses, calculations, algorithms and meta-data irrespective of format.

1.4 "TARN Data" shall mean the proprietary data of the University collected from participants in TARN and held at the University together with any additional information made available relating thereto.

Page 1 of 8

IN WITNESS WHEREOF the Parties have caused this Agreement to be executed by the hands of their duly authorized representatives as of the day and date first written above.

Signed on behalf of The Recipient		Signed on behalf of The University of Manchester - (The Trauma Audit and Research Network - TARN)	
Signed:		Signed:	A Edwards
Print Name:	Ryan Keyworth, Director, Research and Innovation, University of Nottingham	Print Name:	ANTOINETTE EDWARDS
Position:		Position:	EXECUTIVE DIRECTOR
Date:	30/10/18	Date:	26/10/20

Page 6 of 8 UoM Contracts Team – Dec'17

Exhibit A

Principal Investigator: Mr Ben Ollivere

means the representative(s) of the Recipient responsible for the conduct of the research project.

Purpose: shall mean use by the Recipient for academic research purposes in the specific research project as detailed below and no other purpose:

Recipient to insert description below of their project for which the TARN Data will be used.

Aim

This study intends to evaluate: When considering open versus closed fractures of the tibia, to what extent does the open attribute impact quality of life (QOL) at 6 months after injury? Additional objectives include conducting a robust analysis of national epidemiology, incidence and treatment pathways in the tibial fracture population.

Background

Trauma is the leading cause of death in those under the age of 44 and a significant cause of disability; open fractures represent a significant burden to trauma services and are associated with significant complications and impact on quality of life. Modern practice demonstrates a tendency to reconstruct severely injured limbs yet this can give rise to multiple complications such as infection and are associated with multiple readmissions, significant hospital costs and on occasion, delayed amputation.

Patient reported outcomes following open fracture are poor regardless of whether the limb is salvaged or amputated. The lower extremity assessment project is the largest prospective study reporting the outcome of 569 patients with severe limb injury. The study reported significant disability, ongoing pain and high incidence of psychiatric disorders in individuals who have sustained these injuries, even several years after the event. The evidence base regarding open tibial fracture is limited and often contradictory and there is value in conducting further studies to explore this.

Study population and inclusion criteria

Patients recorded on TARN who received treatment for either an open or closed tibial fracture. Cases to include all patients recorded on TARN who were admitted with a diagnosis of closed or open tibial fracture (including those with concurrent injuries). Whilst the study will focus on patients with QOL data, we are requesting a dataset which includes all patients and fields to allow evaluation of national epidemiology and incidence.

Analysis Covariates

Patient demographics, comorbidities, ISS, injury characteristics, Treatment factors, Surgical factors, Re-operation, Mortality, Patient reported outcome data.

Analysis Plan

The relationship between patient characteristics and quality of life will be modelled using multiple linear regression. Adjustment for covariates (age, gender, ISS, comorbidities) will be explored and factors that influence effect estimates will be retained in the model. The assumptions of multiple regression—linearity, homoscedasticity and multicollinearity—will be assessed.

8.4 TARN data dictionary

Field	Description
siteid	ID for site
mtc	MTC YN
SubmissionID	TARN ID
caseid	TARN case ID (conserved if patient is transferred)
Age	Age at injury
sex	Gender
arvd	Arrival date in hospital
arvT	Arrival time
arvdt	Arrival date/time
incd	Incident date
incT	Incident time
incdt	Incident date/time
mech	Injury mechanism
mechtype	Blunt / Penetrating
iss	Injury severity score
niss	New Injury Severity Score
issband	Common ISS bandings
gcs	Earliest ED GCS value
intubvent	Intubated ED or pre-hospital, 1 = Yes
ps14	Probability of survival
charl	PMC weight, -1 = not recorded
outtext	Outcome at 30 days
los	Length of stay
loscc	Length of stay in critical care
tteam	Trauma team activated
msen	Most senior ED doc
msendt	Most senior ED doc date
msentm	Most senior ED doc time
fstdoc	First ED doc
fstdocdt	First ED doc date
fstdoctm	First ED doc time
opDT	First operation date/time
ttop	Minutes to first op
op#	Number of operations
op_1	Procedures recorded in first op
op_2	Procedures recorded in second op
op_3	Procedures recorded in third op
ctDT	First CT date/time
ttCT	Minutes to first CT

Field	Description
ttype	Transfer status
head	Max AIS severity injury in the head
face	Max AIS severity injury in the face
thor	Max AIS severity injury in the chest
abdo	Max AIS severity injury in the abdomen
spine	Max AIS severity injury in the spine
pelv	Max AIS severity injury in the pelvis
limb	Max AIS severity injury in the limbs
other	Max AIS severity injury in other regions (burns etc)
msev	Most severely injured body region
wentED	Visited the ED
preAlert	Pre-alerted
triage	Triage status
prf	PRF number
rehabscript	Rehab prescription recorded
mtp	Massive transfusion protocol
arvmode	Mode of arrival
inreason	Transfer in reason
outreason	Transfer out reason
ward1	First ward
ward2	Second ward
ward3	Third ward
injuries	Text description of AIS codes assigned to patient
outdate	Discharge / death date
outtime	Discharge / death time
disdest	Discharge destination
died	1/0 variable for outcome at 30 days
blood6	Received blood in 6h Y/N
txaloc	Location first received TXA
txadt	Date/time first received TXA
knownoutcome	Final outcome of patient is recorded as part of this submission, 1 = Yes
ED_SBP	Earliest recorded value of observation in location
CriticalCare_OxygenSat	Earliest recorded value of observation in location
CriticalCare_RCT_R	Earliest recorded value of observation in location
ED_OxygenSat	Earliest recorded value of observation in location
CriticalCare_Pulse	Earliest recorded value of observation in location
PreHospital_OxygenSat	, recorded value of observation in location
CriticalCare_RCT_L	Earliest recorded value of observation in location
ED_RCT_L	Earliest recorded value of observation in location
PreHospital_RR	Earliest recorded value of observation in location

Field	Description
PreHospital_GCSVerbal	Earliest recorded value of observation in location
PreHospital_GCSMotor	Earliest recorded value of observation in location
ED_GCSEye	Earliest recorded value of observation in location
ED_RR	Earliest recorded value of observation in location
CriticalCare_SBP	Earliest recorded value of observation in location
PreHospital_SBP	Earliest recorded value of observation in location
PreHospital_GCS	Earliest recorded value of observation in location
PreHospital_RCT_L	Earliest recorded value of observation in location
CriticalCare_GCSMotor	Earliest recorded value of observation in location
ED_GCS	Earliest recorded value of observation in location
PreHospital_Pulse	Earliest recorded value of observation in location
CriticalCare_GCS	Earliest recorded value of observation in location
CriticalCare_GCSVerbal	Earliest recorded value of observation in location
PreHospital_GCSEye	Earliest recorded value of observation in location
PreHospital_RCT_R	Earliest recorded value of observation in location
ED_Pulse	Earliest recorded value of observation in location
CriticalCare_RR	Earliest recorded value of observation in location
CriticalCare_GCSEye	Earliest recorded value of observation in location
ED_GCSMotor	Earliest recorded value of observation in location
ED_GCSVerbal	Earliest recorded value of observation in location
ED_RCT_R	Earliest recorded value of observation in location
OperationDateTime_1	First op date/time
OperativeProcedure_1	First op procedures
SurgeonGrade_1	First op surgeon grade
SurgeonSpeciality_1	First op surgeon speciality
OperationDescription_1	Text description of first op
OperationDateTime_2	Second op date/time
OperativeProcedure_2	Second op procedures
SurgeonGrade_2	Second op surgeon grade
SurgeonSpeciality_2	Second op surgeon speciality
OperationDescription_2	Text description of Second op
OperationDateTime_3	Third op date/time
OperativeProcedure_3	Third op procedures
SurgeonGrade_3	Third op surgeon grade
SurgeonSpeciality_3	Third op surgeon speciality
OperationDescription_3	Text description of Third op
OperationDateTime_4	Fourth op date/time
OperativeProcedure_4	Fourth op procedures
SurgeonGrade_4	Fourth op surgeon grade
SurgeonSpeciality_4	Fourth op surgeon speciality
OperationDescription_4	Text description of Fourth op
OperationDateTime_5	Fifth op date/time

Field	Description
OperativeProcedure_5	Fifth op procedures
SurgeonGrade_5	Fifth op surgeon grade
SurgeonSpeciality_5	Fifth op surgeon speciality
OperationDescription_5	Text description of Fifth op
Coagulopathy (Other)	Treatment complications
Miscellaneous-Other	Treatment complications
MI	Treatment complications
Cardiovascular- Other	Treatment complications
Rhabdomyolysis	Treatment complications
Infection- Yeast	Treatment complications
Meningitis	Treatment complications
Hepatic/Biliary- Other	Treatment complications
Infection-Other	Treatment complications
Congestive Heart Failure	Treatment complications
Bowel Injury-Iatrogenic	Treatment complications
Loss Of Reduction/Fixation	Treatment complications
Cholecystitis (Acalculous)	Treatment complications
Haemorrhage	Treatment complications
Not Known	Treatment complications
None	Treatment complications
Readmission	Treatment complications
Unable To Intubate	Treatment complications
Empyema	Treatment complications
Anoxic Encephalopathy	Treatment complications
Cardiogenic Shock	Treatment complications
Pancreatic Fistula	Treatment complications
Necrotizing Fascitis	Treatment complications
Abscess (Excludes Empyema)	Treatment complications
Upper Airway Obstruction	Treatment complications
Ureteric Injury	Treatment complications
Alcohol Withdrawal	Treatment complications
Neurologic-Other	Treatment complications
Clostridium Difficile	Treatment complications
Neuropraxia-Iatrogenic	Treatment complications
Cardiac Arrest (In hospital)	Treatment complications
Infection-Orthopaedic Wound	Treatment complications
Aspiration	Treatment complications
Septicemia	Treatment complications
Hematologic-Other	Treatment complications
Disseminated Intravascular Coagulation	Treatment complications
Methicillin-sensitive	Treatment complications

Staphylococcus aureus (MSSA) infection	
Urinary tract infection	Treatment complications
Renal Failure/Acute Kidney Injury	Treatment complications
Ulcer-Duodenal/Gastric	Treatment complications
Infection-Graft	Treatment complications
Fistula	Treatment complications
GI-Other	Treatment complications
Resp Arrest Or Resp Failure	Treatment complications
Transfusion Complication	Treatment complications
Musculoskeletal/Integumentary-Other	Treatment complications
ARDS	Treatment complications
Seizure In Hospital	Treatment complications
Splenic Injury (Iatrogenic)	Treatment complications
Sepsis	Treatment complications
MRSA	Treatment complications
Pulmonary- Other	Treatment complications
Embolus (Nonpulmonary)	Treatment complications
Pleural Effusion	Treatment complications
Diabetes Insipidus	Treatment complications
Gangrene	Treatment complications
Nonunion	Treatment complications
Shock	Treatment complications
Small Bowel Obstruction	Treatment complications
Pulmonary Embolism	Treatment complications
Pneumonia	Treatment complications
Arrhythmia	Treatment complications
Unable To Start Iv	Treatment complications
Pericardial Effusion Or Tamponade	Treatment complications
Infection-Wound	Treatment complications
Pancreatitis	Treatment complications
Renal/Gu-Other	Treatment complications
Infection- Line	Treatment complications
Stroke	Treatment complications
DVT	Treatment complications
Peritonitis	Treatment complications
Anastomotic Leak	Treatment complications
Pulmonary Oedema	Treatment complications
Thrombosis	Treatment complications
Abscess-Intra-Abdominal	Treatment complications
Hydrocephalus	Treatment complications

Field	Description
Pneumothorax (Iatrogenic)	Treatment complications
Hepatitis	Treatment complications
Atelectasis	Treatment complications
Coagulopathy (Intraoperative)	Treatment complications
Dehiscence/Evisceration	Treatment complications
Decubitus (Open Sore)	Treatment complications
Metabolic	Treatment complications
Ileus	Treatment complications
Hemiplegia	Treatment complications
Ventriculitis-Postsurgical	Treatment complications
Compartment Syndrome	Treatment complications
Fat Embolism	Treatment complications
DU	Treatment complications
Multi organ failure	Treatment complications
PE	Treatment complications

8.5 Use of Microsoft Access to manipulate data

Example of data management in Access: Conversion of flat CSV file into split cohorts.

Aim	SQL statement
Converting multiple hospital admissions into a unified spell per patient	SELECT [1st Hospital].*, [2nd Hospital].* INTO Unified spell FROM [1st Hospital] INNER JOIN [2nd Hospital] ON [1st Hospital].[CaseID] = [2nd Hospital].CaseID;
Conversion of continuous admission date field into categorical variable.	UPDATE [Unified spell] SET [Unified spell].[Yearadm] = 1998 WHERE ((([Unified spell].arrivaldt) Between 1/1/1998 And 1/1/1999));
Exclusion of paediatric patients	SELECT [Unified spell].age, [Unified spell].* INTO Adults spells FROM [Unified spell] WHERE ((([Unified spell].age)>17.99));
Generation of 2013-2017 cohort	SELECT [Unified spell].[Yearadm], [Unified spell].* INTO Cohort FROM [Unified spell] WHERE ((([Unified spell].[Yearadm]) Between 2013 And 2017));
Generation of surgical cohort	SELECT [Adults].[tib_frac], [Tibia Details 3].* INTO Adults3B3C FROM [Adults] WHERE ((([Adults].[tib_frac]) Like "*BOAST*"));

8.6 Example of STATA coding

Coding utilised for regression model in **Error! Reference source not found.**. A similar model was utilised for all logistic regression models

```
** Obtain descriptive statistics (niss)**
sum niss, detail
hist niss, frequency
twowayscatter niss charl
graphbox niss, over (mort)

** Management of missing data **
sort sort
tab gcs
sum gcs, detail
gen gcscat = gcs
recode gcscat = 16 if (gcs = .z)
recode gcscat min/3.99=0 4/5.99=1 6/8.999=2 9/12.999=3 13/15.99=4
16/max=intubated
label define gcscat 0 "0-3" 1 "4-5" 2 "6-8" 3 "9-12" 4 "13-15" 5 "intubated"
fvset base 4 gcscat

** Converting continuous to categorical variable, LRT**
sum age, detail
twoway scatter age charl
graphbox age, over (mort)
xtile agecat = age, nq(4)
tab agecat, summarize (age)
gen agecat2 = age
recode agecat2 min/29.999=0 30/39.999=1 40/49.999=2 50/64.999=3 65/max=4
logistic dm i.agecat2
est store model1
logistic dm agecat2
lrtest model1

**Forward regression model testing**
logistic dm i.ccicat i.nisscatquin i.agecat2 sex i.gcscat
logistic dm i.ccicat i.gcscat
logistic dm i.ccicat i.gcscat i.nisscat
logistic dm i.ccicat i.gcscat i.nisscat i.agecat
logistic dm i.ccicat i.gcscat i.nisscat i.agecat openfem
logistic dm i.ccicat i.gcscat i.nisscat i.agecat blopentib
logistic dm i.ccicat i.gcscat i.nisscat i.agecat gustilo
logistic dm i.ccicat i.gcscat i.nisscat i.agecat sex
```

8.7 Service evaluation letter

Nottingham University Hospitals NHS
NHS Trust

Mr B J Ollivere
Associate Clinical Professor
Consultant Orthopaedic Trauma Surgeon

Enquiries via:
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Trauma and Orthopaedics
Audit and Research Office
C Floor, West Block, QMC
Nottingham University Hospitals
Derby Road
NG7 2UH
Jessica.nightingale@nuh.nhs.uk
0115 9249924 (#67502)

Survey of patients following severe limb injury

Nottingham University Hospitals are carrying out an audit of patients who have received treatment for a severe tibial fracture in the past two years. This survey is being undertaken to allow the hospital to assess the quality of care delivered to NHS patients from the patient's perspective, ensure we continue to provide high quality care and improve care for others in future.

The questionnaire should only take about 5 minutes to complete. A stamped addressed envelope (SAE) is also enclosed. Please take care to ensure that all the questions have been answered.

Participation in the survey is entirely voluntary. If you decide not to take part in the survey it would be helpful if you could return the uncompleted questionnaire in the SAE provided. If you wish to have a face to face meeting to help with completion of the questionnaire please contact us at the above address.

Please be assured that any information you supply will be treated in confidence. Thank you for your consideration.

Yours Sincerely

Mr BJ Ollivere MD FRCS(Orth)
Associate Clinical Professor
Consultant Orthopaedic Trauma Surgeon

8.8 Permission to conduct service evaluation

Figure 8-1 Trust Audit Approval for a Service Evaluation of Severe Limb Injury at Nottinham University Hospitals

Jessica Nightingale

From:	Turner Helen (Corporate) <Helen.Turner2@nuh.nhs.uk>
Sent:	28 November 2016 11:06
To:	Nightingale Jessica (Musculoskeletal & Neurosciences)
Cc:	Ollivere Ben (Trauma & Orthopaedics)
Subject:	Project registration - limb injury
Attachments:	Audit Review Form (with conclusions) v2.docx

Dear Jess

Thank you for submitting your clinical audit registration form.

Having reviewed the registration form, it appears that the requirement is to simply log your project with no further support required from the clinical audit function. This has been approved as a baseline audit.

Your project number is: 16-114c

Please complete and return the attached review form to myself once you have finished your project (actions have been implemented).

If you need to view your registration then please follow the link:
http://nuhnet/medical_director/integrated_governance/clinical_audit/Lists/AuditProjects/AllDivisions.aspx

Many thanks and regards

Helen Turner
Clinical Audit Officer (Surgical Division)
Clinical Quality Risk and Safety team
Above James Unit
City Hospital Campus
(Tuesday, Wednesday and Thursday)
Extension: 54057

C Floor
West Block
Queens Medical Centre Hospital campus
(Monday and Friday)
Extension: 66035

8.9 JBI systematic review tools

Figure 8-2 JBI-QARI Critical Appraisal Checklist

JBI Critical Appraisal Checklist for Qualitative Research

Reviewer________________________________Date________________________

Author ________________________________Year________Record Number______

	Yes	No	Unclear	Not applicable
1. Is there congruity between the stated philosophical perspective and the research methodology?	☐	☐	☐	☐
2. Is there congruity between the research methodology and the research question or objectives?	☐	☐	☐	☐
3. Is there congruity between the research methodology and the methods used to collect data?	☐	☐	☐	☐
4. Is there congruity between the research methodology and the representation and analysis of data?	☐	☐	☐	☐
5. Is there congruity between the research methodology and the interpretation of results?	☐	☐	☐	☐
6. Is there a statement locating the researcher culturally or theoretically?	☐	☐	☐	☐
7. Is the influence of the researcher on the research, and vice- versa, addressed?	☐	☐	☐	☐
8. Are participants, and their voices, adequately represented?	☐	☐	☐	☐
9. Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?	☐	☐	☐	☐
10. Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

Figure 8-3 JBI QARI Extraction Tool - Part A

JBI QARI Data Extraction Tool for Qualitative Research

Reviewer ______________________ Date ______________________

Author ______________________ Year ______________________

Journal ______________________ Record Number ______________________

Study Description

Methodology

____

Method

____

Phenomena of interest

____

Setting

____

Geographical

____

Cultural

____

Participants

____

Data analysis

____

Authors conclusions

____

Comments

____

Complete Yes ☐ No ☐

Figure 8-4 JBI QARI Extaction Tool - Part B

Findings	Illustration form Publication (page number)	Evidence		
		Unequivocal	Credible	Unsupported

Extraction of findings complete Yes ☐ No ☐

8.10 QES List of study findings

Trickett, R.W., et al., A qualitative approach to recovery after open tibial fracture: the road to a novel, patient-derived recovery scale. Injury, 2012. 43(7): p. 1071-8.

Finding	Illustration
Appearance and cosmesis of the affected limbs were raised by many patients, both male and female, as something which they considered important during their recovery.(RT)	''Well, I wouldn't wear shorts. I wouldn't, I know I'd die if I had to go in my shorts to a party or a do."(C)'
Whilst the appearance of the leg was clearly important, it was sometimes the fact that the appearance prompted curiosity and questions from others, rather than embarrassment of exposing the injured limb (RT)	''The appearance doesn't bother me because I'm 63 and I am lucky that I have got my leg, so I am quite happy about that. But when you see other people looking and they say what's happened and you tell them and you know. But if I had a stocking on and you couldn't see the scar then I'd just say I've pulled a muscle. It's simple and that's that, that's what I do.'' (C)
Diet and weight (RT)	"I've gained about 50 pounds, I hate to say. 45 or 50. I stayed right around 120 pounds, so this has been the biggest the adjustment for me: my weight." (C)
Emphasised by patients was the importance of being able to weight bear as marking their own perception of recovery. Four patients described the progression to being able to run as a core component of their improving mobility and a significant stepping stone to normality.(RT)	''[Have you recovered?] Yes it's over and done now. I can run.''(C)
Flexibility was a component of the patients' description of mobility in addition to the ability to move oneself from one place to another: (RT)	''. . .the deciding factor. . . [that indicates recovery]. having a little bit, a lot more movement. . .'' (C)
Patients undergoing fine wire external fixation for their injury particularly emphasised this severe pain in the immediate postoperative period (RT)	''Oh my God, well the nurse she just literally lifted my leg and twisted it and I sort of hit the ceiling then. But after that she sort of knew how painful it was.'' (U)
There was an observed transition from the initial pain following injury and surgery through to ache in the later stages. (RT)	''I took tramadol. . . because the pain. . . the pain there was awful, in my leg'' …… ''I have a constant throbbing and ache.'' (C)
Many of the patients describing 'ache' in contrast to 'pain' differentiated between them by describing their use of analgesics. 'Pain'	''. . .like an ache, like toothache. . . not enough to need painkillers' (C)

required the use of analgesia whilst 'ache' often did not: (RT)	
Changes in temperature were described as having a profound effect on symptoms including pain and stiffness. (RT)	"'I wear the leg warmer all the time because if my leg goes cold then it pains. . .'' (U)
Fear was a prominent term used in all interviews and appeared to persist through to the final stages of recovery. (RT)	''Fear. More fear I would say, that if I put my foot on the floor it was going to go'' (C)
Patients reported fear of many separate circumstances, injury, pain, or complications, further surgery or further injury (RT)	''I'm frightened to do anything'' (C)
Fear was described as a barrier to recovery (RT)	"Fear is the main thing that stops you doing stuff' (C)
The inability to work had implications for many of the nonretired patients, with consequent financial implications. (RT)	''I claim £85 a week for disability. But I'm about £228 a week worse off than if I had been working, you know. We are financially alright so I don't worry about the money, no, we don't have to scrimp and save or be penny pinching.'' (C)
The impact of the injury on others was recognised by patients as being important. This reflected both the positive role that family had during recovery as well as the more direct implications on others from having a severely injured family member. (RT)	''. . .between the two of us it was getting to her if you know what I mean, but we've sorted that out now. [It's not easy?] No, for her and that's why we go away and take her on holiday more than anything for her benefit rather than mine, but we got over that because it was getting to her and I couldn't see it, but I did in the end, alright we are fine now.'' (U)
Impact on others was reflected in alterations to social interactions. (RT)	''. . .I probably didn't go to the pub for about 4 months.'' (U)
Recovery was accompanied by considerable changes, adaptation and coping strategies which were implemented both by the patient and those around him/her. (RT)	''I learned to adapt it's like I had a pair of leggings made that were sort of Velcro on the side and things like that, wearing clothes wasn't a problem.'' (U)
Alcohol was a method of coping with the circumstances surrounding the injury. (RT)	''Every Friday we go out to the bowling club, my wife's secretary of the bowling club and I go with her and I have two units, two pints and a whisky, three or six units or whatever and I don't take the pills because I'll be well, you know" (C)
Often these goals were set by In many instances the goals were set by the supervising healthcare professional but in many instances the goals were set by the patients themselves. These small steps were seen as important landmarks, indicating progress towards normality and in turn	"You know like, you could see that you are going well like, you know, getting stronger. It wont' be long, you know they tell me" (C)

independent markers of recovery. (RT)	
Failure to or delay in achieving goals was seen as a cause of frustration. (RT)	‘‘It frustrates me because I think, it’s something I want but I can’t, you know.’’ (U)
Some patients deferred the decision regarding recovery to their surgeon… It is possible that this process was an act of seeking approval from an expert rather than a true abdication of responsibility. (RT)	‘‘[with regards to completeness of recovery] when they signed me off and said that’s it’’(C)
There appeared to be a discrepancy between normality, recovery and pre-injury functioning, (RT)	“It stiffens up but that is normal, I am stiff” (C)
Some patients defined a specific moment that signalled their full recovery (RT)	“I suppose when I was running again”. (C)

Tutton, E., et al., *A qualitative study of patient experience of an open fracture of the lower limb during acute care.* Bone and Joint Journal, 2018. **100-B**(4): p. 522-526

Finding	Illustration
The wound itself and the state of the injured leg created a real sense of panic; participants were reluctant to see the actual wound and had to be ready to do so. The visual look of the wounds often left participants feeling shocked and sick. (ET)	“Oh God, I never saw anything as foul looking in all my life. The only way I could describe it was somebody had got a fillet steak, a nice thick fillet steak and slapped it on the side of my ankle, that’s just what it looked like. I said to them how can you say that looks good when it’s not good?” (U)
Being constrained: Participants had to learn how to: cope with prolonged periods of bed rest and immobility; deal with the frustrations of limited mobility; accept the pace of recovery was dictated by healing; and move their bodies within the limits of their injuries. (ET)	“Yes, the strength in my legs is so reduced it’s quite incredible and so you can imagine a few more weeks like this and it’s going to take a while to get my strength back,it’s your core strength. If I transfer from this to a wheelchair I’m absolutely exhausted and you’ve just got no trunk strength or virtually none.” (U)
Being in pain: Overall pain was a source of concern to all participants at some point in their recovery. This was complicated by the variety of sources of pain, access to medication, and a reluctance by patients to take medication. (ET)	“Yes there are days that the pain is bad and there have been days where I can’t bear the pain. I’ve been asking for pain killers and I’ve curled up […] to try and deal with the pain. It does have its days of coming and going, the pain […] It’s not always just pain, it’s like itching where it’s healing and I can’t itch it which is annoying. There’s aching, itching, pain, throbbing, there’s a burning pain like when you’ve got sunburn, it feels like that on my legs where they took the skin grafts from.”(C)
Being a person with strong emotions: The participants expressed an emotional fragility that purveyed every aspect of their life. Some had only felt similar feelings before when a family member had died. (ET)	“[…]it wasn’t until I got right down to the anaesthetics room that the penny dropped and then I was like a big girl’s blouse because I didn’t have the wife there or anybody there just two strangers and I felt lonely and vulnerable and basically my life is in their hands.” (C)
Being at work: Going back to work was difficult to visualize due to the uncertainty regarding the degree of functional recovery expected. Any information on this aspect was gratefully received but participants felt clarity about timescales	“I would have thought after three months I would be back at work but after seeing the pictures there’s no chance I would be back at work at three months but it’s nice to know that I can inform my boss and everything and get all of that out of the way, yes it’s really

was unlikely due to the complex nature of their injury and individual recovery paths (ET)	helped with planning for future jobs and things, it's useful, very useful." (U)
Being at home: The need to get home was overwhelming but as they progressed it was something they felt was more tangible and they could imagine what it would be like to go home (ET).	""It's really hard and it sickens me the thought of losing my bikes but it's a small sacrifice. If I want to live another thirty years on this planet and I want to walk these beautiful girls down the aisle, then it's a small price to pay." (P)
Participants were also horrified and shocked when, at some point in their recovery, they felt or were told that losing their leg had been or remained a possibility. (ET)	"The only time I actually felt detachment was when Jim [Surgeon] first mentioned the possibility, the extreme possibility of amputation. When another surgeon came in and mentioned it again I almost felt like I was in heaven and just detached slightly. I was listening to him and thought blimey I've completely disconnected from this, that's when I feel detachment when that gets raised, I'm not consciously, it's not a decision to detach but it just seems to happen because it's something that even though I'm aware of it I don't really want to have to consider it right now." (U)
There was a sense of being saved, being grateful that they had received such good care, and being lucky as the event could have been so much worse. These notions were repeated throughout their interviews: (ET)	"I've just got to go with what happens really but at the same time I've still got to harp back to the fact that in the first place I was lucky. I could easily have died in that incident so you've got to think about relative situations really haven't you and the injury that I eventually sustained…" (U)

Shauver, M.S., M.S. Aravind, and K.C. Chung, *A qualitative study of recovery from type III-B and III-C tibial fractures.* Annals of plastic surgery, 2011. **66**(1): p. 73-79.

Finding	Illustration
Our patients reported satisfaction with their treatment outcomes and or/outcomes (MS)	"I told them, I said, 'Well, I want a leg that will work for me.' And he said, 'You're going to get a leg that will work for you.' And they did! This is the same [prothesis] that I've had since day one." (C)
Problem-focused approach coping: Several participants reported modifications to their homes or vehicles, and nearly every participant mentioned learning new ways to preform everyday tasks or changes. (MS)	"I don't take [motorized carts] when I go shopping, but do I go to places like Super Wal-Mart? No. I go to local grocery stores." (C)
Emotion-focused approach coping is characterized by the expression of emotion and need for social support….very few participants discussed the actual expression of emotion… But spouses were the most frequently mentioned source of support. (MS)	"We went through some really tough times. Pretty good building block for a relationship and marriage when you go through s tuff like this. Talk about for better or for worse." (C)
Problem focused avoidance coping: Several participants reported engaging in some degrees of problem avoidance, by avoiding situations that are now too difficult or that would highlight the participants' injury or disability. (MS)	"I have to have a really good reason to get up and move around now; either my kids, doctors appointment or something I have to do. Otherwise I don't wanna mess with it 'cause there's a possibility of injuring myself." (C)
Emotion focused avoidance coping: Three participants with amputations engaged in self-criticism, focused primarily on the perception from the popular media that many amputees are able to compete in athletics at a high level. (MS)	"People expect, 'Oh, I saw this guy runnin' the other day and he's runnin' 400s faster than Olympians.' Why can't I do that?" (C)
Personal growth: Some of our participants seemed to be not only surviving their open tibial fractures, they were appearing to thrive, not in spite of the trauma they had been through, but because of it. (MS)	"I'm no longer a drunken idiot, so this helped. This helped me realize that things couldn't stay the same. And, it was a sign, I think." (C)
All participants indicated that their physical	"I can't walk, can't run, can't go up stairs

functioning had changed to varying degrees since their injury Participants who had undergone an amputation were more likely to relay a greater change than were patients who had only reconstructed limbs. (MS)	without help, can't do yard work. I can't have a job unless I'm sitting down, and I can't stand for more than 40 minutes." (C)
Pain was characterized as "constant" or "almost always there" in 53% of cases; the remaining participants spoke of occasional pain, usually secondary to overuse (MS)	"On a daily basis I have pain, whether it hurts minimal or extreme." (C)
70% of participants responded that they had noticed a reduction in their everyday energy level, when compared to their pre-injury level. (MS)	"I feel like it takes twice as much energy to do stuff that I did before. And not even do it as good as before." (C)
Only 4 participants were able to return to their previous positions, all desk-based jobs (MS)	"I was able to do the same work, but I cannot stay in certain positions for long, so I've just got to move." (C)
7 of 11 participants who underwent only reconstructive surgery said they were embarrassed or uncomfortable with the scars on their legs. 3 of 9 participants with amputations expressed discomfort with exposing their prothesis. 20% of participants mentioned unwanted weight gain as a result of decreased activity. (MS)	"I've gained about 50 pounds, I hate to say. 45 or 50. I stayed right around 120 pounds, so this has been the biggest the adjustment for me: my weight." (C)

8.11 Interview guide

Interview structure: Aim is to get your point of view, and really my purpose is just to enable you to get your point across. I will ask questions to facilitate that and maybe to clarify and build on ideas

Discuss digital recording of the interview and confidentiality / can stop at any time – anticipate 1 hour.

PIS and consent form. Give a copy to participant

QUESTIONS

- How much does your leg effect you today
- How does that compare to before your accident
- How does it compare to immediately after the accident
- How did that change throughout your recovery
- What symptom was most important to you
- What was it important to get back to
- What strategies were important to you throughout your recovery
- Who was important to you throughout your recovery
- What information do you wish you had known that you would like to have had day 5.

PROMPTS:

- Is there any more you want to say about…..?
- Why was that important to you?
- What was the significance of …. for you?
- What difference, /effect has this made /had
- What effect if any, has this had
- **Informed consent prompt:** Are you ok/happy to continue?

8.12 Patient Information Sheet

Nottingham University Hospitals NHS
NHS Trust

Mr Ben Ollivere
Consultant Orthopaedic Surgeon
Clinical Associate Professor
Queens Medical Centre
Department of Trauma & Orthopaedics
Derby Road
Nottingham
Enquiries via Miss Jessica Nightingale
07810326600
Jessica.nightingale@nottingham.ac.uk

Participant Information Sheet

The experience of recovery following severe tibial fracture

Principle Investigator: Mr Ben Ollivere

Thank you for taking the time to read this leaflet. You are being invited to take part in a research study, which is being undertaken as part of a PhD project at the University of Nottingham. We have invited you to join as you are over the age of 18 and have been treated for a severe limb injury within Nottingham Major Trauma Centre during the last few years. Before you decide whether or not to take part, please take time to read the below so you understand what is involved and why I am asking you to take part.

Please read the following information, discuss it with others if you wish, and take time to decide whether or not you want to take part. We would be very happy to explain anything that is not clear.

What is the purpose of the study?
An open fracture is a rare and difficult injury to treat. Recovery often requires extensive surgery and a long period of recuperation. Often the outcome for people who have recovered from these injuries is incomplete; with people suffering varying degrees of physical, social and often financial loss.

Due to the emergency, traumatic and rare nature of these injuries, little research has been done in this area. We would like to know more about how best to treat these injuries to meet the needs of this group.

The purpose of this research study is to explore the factors that impact recovery from these injuries. We hope to achieve this by interviewing those who have sustained these injuries to gain their perspective on their recovery.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If at any time after agreeing to take part in the study you change your mind you can withdraw without giving a reason.

What will happen to me if I take part?
We are asking you to share your experiences of your injury and subsequent recovery. This would be achieved through an interview with us. The interview will take place on a one-to-one basis, with a local researcher.

The interview would be carried out at a time which is convenient for you and would be conducted at Queens Medical Centre, Nottingham. The interview will be explained to you before commencing the interview and you would have the opportunity to ask questions. Prior to starting the interview, we would also ask you to sign a consent form to show that you have agreed to take part in the study and you would be given a copy to keep. The interview will be audio recorded to provide an accurate record of the experiences you share.

During the interview the researcher will ask you questions, which allow you to tell the story of your injury and recovery. This may include for example:

- The circumstances of your injury
- Your experiences of hospital care
- Your experiences of recovery after discharge from hospital

The interview would be expected to last for one hour. Refreshments will be available throughout the interview. If you wish to take a break or to finish the interview at any point, you would only need to tell us and would not need to give a reason for stopping the interview.

You will not offered formal payment for participation in the study but all travel expenses incurred can be refunded. We will discuss this with you, and arrange payment on the day of the interview.

Interviews and recalling what may be challenging experiences can be emotionally tiring. You may wish to have a family member or friend with you during the interview, or someone to talk to afterwards. We would be able to offer you contact details of local support organisations and discuss other means of support if you would find this helpful. With your permission, your GP will be notified that you are taking part in this study; we will only contact your GP if you provide permission for us to do so, on the consent form. Our details are given at the end of this information sheet should you wish to contact me after the interview has taken place.

As part of the study we will identify your injury pattern and treatment through accessing your patient records. Your medical records will be used for this purpose alone.

Would my taking part in this study be kept confidential?
The study has the necessary ethical approval and anything you say would be treated as confidential. All information collected would be kept in the strictest confidence. You would be allocated a code which would be used as a unique identifier for all the information you have shared. The name/code master list would be kept securely, separate from the interview information and only accessible to the research

team. Your name would not be recorded anywhere else and no individual would be identifiable from the published results, however anonymized quotations may be included in the results.

What happens after the interview?
The transcription of the interview will be analysed. The study is being conducted as part of a doctoral (PhD) thesis and the findings of the study will be reported as part of this thesis. The results of the study may also be used as part of other academic publications or conference presentations.

If you choose, we will send you a summary of the research at the completion of the study.

How will my part in this study be kept confidential?

If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper and electronically at your treating hospital under the provisions of the 1998 Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be allocated a trial number, which will be used as a code to identify you on all trial forms.

Your records will be available to people authorised to work on the study but may also need to be made available to people authorised by the Research Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. A copy of your consent form may be sent to the Research Sponsor during the course of the study. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

The information collected about you may also be shown to authorised people from the UK Regulatory Authority and Independent Ethics Committee; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.

If you withdraw consent from further study involvement all data collected about you to that time point will still be used in analyzing the results of the study.

The audio-recording will be taken on an encrypted device, and subsequently retained on a secure computer network. In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made.

Who is organizing, funding and reviewing this study

The Nottingham University Hospitals NHS Trust will act a sponsor the research.

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the NHS by Cambridge Research Ethics Committee.
The study has also been reviewed and approved by the Research & Innovation department of Nottingham University Hospitals NHS Trust.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. The lead doctor for the trial, Mr. Ben Ollivere, or researcher, Miss Jessica Nightingale can be contacted on 0115 924 9924 (#67502). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital or you can contact PALS (Patient Advice and Liaison Service) telephone 0800 183 0204

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

You are encouraged to ask further questions.

If you decide you would like to take part, please return the reply slip and our researcher will contact you to discuss the study further and arrange an interview time. Alternatively, you can contact us by phone to arrange an interview time.

If you would like to discuss anything or have further questions at any time, please contact, Jessica Nightingale, the researcher who will be conducting the interviews, using the contact details below.

Miss Jessica Nightingale
Trauma & Orthopaedic Audit Office
Queens Medical Centre, C-West
Derby Road
Nottingham
NG7 2UH
Jessica.nightingale@nottingham.ac.uk
07810326600

8.13 Invite letter

Nottingham University Hospitals NHS
NHS Trust

Ms Jessica Nightingale
Trauma & Orthopaedic Audit Office
Queens Medical Centre, C-West
Department of Trauma & Orthopaedics
Derby Road
Nottingham
0115 924 9924 (#67502)
Jessica.nightingale@nuh.nhs.uk

INSERT Patient ADDRESS BLOCK

Dear INSERT Patient name

Re: Research study being undertaken at Nottingham University Hospitals

We are contacting you to ask you to consider participation in a research project currently being undertaken at Nottingham University Hospitals. The research study aims to find out more about the injury and recovery of people who have experienced a severe leg fracture. The study intends to achieve this by conducting one to one interviews with a series of patients who have sustained these injuries. As a person who has sustained such an injury, we would be grateful for your participation.

The full details of this study are discussed in the Participant Information Sheet which is enclosed. I would be grateful if you would read this information before deciding whether you would be willing to participate in this research. The Information Sheet also outlines what your role in the research would be, if you agree to participate.

So we are aware of your decision regarding participation in this study, please could you contact Jessica Nightingale, the lead researcher conducting the study. You can do this either by email or phone, using the contact details above, or by returning the enclosed reply slip by post. We would be grateful if you could reply within 28 days. On receiving your response, we will contact you to make the necessary arrangements. If we do not receive a response from you within 28 days, we will assume that you do not wish to take part, and we will not contact you again.

If you have any further questions regarding the study, which you would like to discuss before you make up your mind, the research team are more than happy to discuss these with you and can be contacted using the contact details at the top of this letter.

Thank you for taking the time to read this letter.

Kind regards

[signed]
Consultant Orthopaedic Surgeon
Enclosed:
Pre-paid envelope
Participant Information Sheet

The experience of recovery following severe tibial fracture
Participant Invite Letter Version 1.1, 23/10/2017
PI: Ben Ollivere
IRAS: 228080

1 NUH03004S

8.14 Reply slip

Nottingham University Hospitals NHS
NHS Trust

Mr Ben Ollivere
Queens Medical Centre
Department of Trauma & Orthopaedics
Derby Road
Nottingham
Enquiries via Miss Jessica Nightingale
0115 924 9924 (#67502)
Jessica.nightingale@nuh.nhs.uk

The experience of recovery following severe tibial fracture

REPLY SLIP

I am willing to be contacted to discuss inclusion in the study "The experience of recovery following severe tibial fracture".

Name:

Contact telephone number:

And/or

Email address:

Preferred contact time/method:

Please return the completed for in the envelope provided. Alternatively feel free to pass on these details by phone or email using the contact details above.

The experience of recovery following severe tibial fracture
Reply Slip Version 1.0, 23/10/2017
PI: Ben Ollivere
1 NUH03004S

8.15 Consent form

Nottingham University Hospitals NHS
NHS Trust

Participant Consent Form
Version: 1.1 Date: 27/10/2017

The experience of recovery following severe tibial fracture

Principal Investigator: Mr. Ben Ollivere

Patient Study ID: …………………… Initials: ………………

Patient initial each box

1. I confirm that I have read and understand the information sheet dated ___________ (version _______) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. ☐
3. I understand that my medical records may be looked at by authorised individuals from the Sponsor for the study and the UK Regulatory Authority in order to check that the study is being carried out correctly. ☐
4. I understand that even if I withdraw from the above study, the data collected from me will be used in analysing the results of the trial. ☐
5. I consent to the use of audit recording with the possible use of anonymised quotes. ☐
6. I agree to take part in the above study ☐

Optional:

1. I am happy for my GP to be notified about my involvement in the above study. ☐

Name of the patient *(Print)*	date	Patient's signature
Name of person taking consent *(Print)*	date	Signature

Original to be retained and filed in the site file. 1 copy to patient, 1 copy to be filed in patient's notes,

Participant Consent Form
PI: Mr. Ben Ollivere
The experience of recovery following severe tibial fracture
V1.1 27/10/2017

NUH03004S

8.16 Letter of HRA Approval

NHS
Health Research Authority

Mr Ben Ollivere
Associate Clinical Professor, Trauma
WC1388
Queens Medical Centre
Derby Road
Nottingham
NG7 2UH

Email: hra.approval@nhs.net

08 November 2017

Dear Mr Ollivere

Letter of HRA Approval

Study title:	**The experience of recovery following severe tibial fracture**
IRAS project ID:	**228080**
REC reference:	**17/EE/0372**
Sponsor	**Nottingham University Hospitals NHS Trust**

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

Page 1 of 8

IRAS project ID	228080

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application

IRAS project ID	228080

procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **228080**. Please quote this on all correspondence.

Yours sincerely

Kelly Rowe
Assessor

Email: hra.approval@nhs.net

Copy to: *Ms Natalie McGregor, Nottingham University Hospitals, Sponsor contact*
Jessica Nightingale, Nottingham University Hospitals, Student

IRAS project ID	228080

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	Version	Date
Covering letter on headed paper		23 October 2017
GP/consultant information sheets or letters [GPRecoveryexperiencesV1200517]	1	20 May 2017
Interview schedules or topic guides for participants [INTERVIEWSCHEDULERecoveryexperiencesV120052017]	1	20 May 2017
IRAS Application Form [IRAS_Form_02112017]		02 November 2017
Letters of invitation to participant [REPLY Recovery experiences V1 200517]	1	20 May 2017
Letters of invitation to participant [INVITE Recovery experiences V1.1 231017]	1.1	23 October 2017
Participant consent form [CONSENTrecoveryexperiencev11 27102017]	1.1	27 October 2017
Participant information sheet (PIS) [PISRecoveryexperiencesV11 23102017]	1.1	23 October 2017
Referee's report or other scientific critique report [Peer review form]	1	10 August 2017
Research protocol or project proposal [PROTOCOLRecoveryexperiencesV120052017]	1	20 May 2017
Summary CV for Chief Investigator (CI) [2016 10 Oct SUMMARY]	2	01 October 2016
Summary CV for student [Jess Nightingale CV]	1	01 January 2017
Summary CV for student [Sarah Cooper - Support letter (2)]	1	17 August 2017
Summary CV for supervisor (student research) [2 Page CV BJO]	1	01 January 2013

IRAS project ID	228080

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Ms Natalie McGregor
Tel: 01159249924
Email: researchsponsor@nuh.nhs.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	Single site NHS sponsored study, no additional agreements expected.
4.2	Insurance/indemnity arrangements assessed	Yes	NHS indemnity will apply. Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the

IRAS project ID	228080

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	No external application for funding has been made; study will be undertaken as part of a PhD.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	REC FO dated 08/11/2017
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

IRAS project ID	228080

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
There is one participating NHS site, study activities will be conducted as per protocol. If this study is subsequently extended to other NHS organisation(s) in England, an amendment should be submitted to the HRA, with a Statement of Activities and Schedule of Events for the newly participating NHS organisation(s) in England. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.
This is a single site study sponsored by the site. The R&D office will confirm to the CI when the study can start.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
The CI will also act as PI at site. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
As site is also sponsor, it is anticipated that existing contractual arrangements are in place.

IRAS project ID	228080

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

8.17 Letter of REC Approval

NHS
Health Research Authority

East of England - Cambridge South Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

08 November 2017

Mr Ben Ollivere
Associate Clinical Professor, Trauma
WC1388, Queens Medical Centre
Derby Road, Nottingham
NG7 2UH

Dear Mr Ollivere

Study title:	**The experience of recovery following severe tibial fracture**
REC reference:	**17/EE/0372**
IRAS project ID:	**228080**

Thank you for your letter of 2 November 2017, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Covering letter on headed paper		
GP/consultant information sheets or letters [GPRecoveryexperiencesV1200517]	1	20 May 2017
Interview schedules or topic guides for participants [INTERVIEWSCHEDULERecoveryexperiencesV120052017]	1	20 May 2017
IRAS Application Form [IRAS_Form_02112017]		02 November 2017
Letters of invitation to participant [REPLY Recovery experiences V1 200517]	1	20 May 2017
Letters of invitation to participant [INVITE Recovery experiences V1 200517]	1.1	23 October 2017
Other [Jess Nightingale 2015 GCP]	1.0	01 December 2015
Other [BenGCP]	1.0	01 January 2012
Other [Consent recovery experience v11 27102017 (tracked)]	1.1	27 October 2017
Other [Invite recovery experiences v11 23102017 (tracked)]	1.1	23 October 2017
Other [PIS Recovery experiences v11 23102017 (tracked)]	1.1	23 October 2017
Participant consent form [CONSENTrecoveryexperiencev11 27102017]	1.1	27 October 2017
Participant information sheet (PIS) [PISRecoveryexperiencesV11 23102017]	1.1	23 October 2017
Referee's report or other scientific critique report [Peer review form]	1	10 August 2017
Research protocol or project proposal [PROTOCOLRecoveryexperiencesV120052017]	1	20 May 2017
Summary CV for Chief Investigator (CI) [2016 10 Oct SUMMARY]	2	01 October 2016
Summary CV for student [Jess Nightingale CV]	1	01 January 2017
Summary CV for student [Sarah Cooper - Support letter (2)]	1	17 August 2017
Summary CV for supervisor (student research) [2 Page CV BJO]	1	01 January 2013

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our RES Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

17/EE/0372	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Leslie Gelling
Chair

Email: nrescommittee.eastofengland-cambridgesouth@nhs.net

Enclosures: *"After ethical review – guidance for researchers" [SL-AR2]*

Copy to: *Ms Natalie McGregor*

Ms Natalie McGregor, Nottingham University Hospitals

8.18 Confirmation of Capacity and Capability

Jessica Nightingale

From:	Mcgregor Natalie _Inactive (Research & Innovation) <Natalie.McGregor@nuh.nhs.uk>
Sent:	09 November 2017 13:02
To:	Benjamin Ollivere; Nightingale Jessica (Trauma & Orthopaedics)
Subject:	IRAS 228080 Acknowledgment of NUH Study Participation at Nottingham University Hospitals NHS Trust

Dear Dr Ollivere,

RE: IRAS 228080 Acknowledgment of NUH Study Participation at Nottingham University Hospitals NHS Trust
R&I Ref: 17OR010
Full Study Title: The experience of recovery following severe tibial fracture
Sponsoring organisation: NUH

This email confirms that Nottingham University Hospitals NHS Trust acknowledge participation in the above study to be conducted in accordance with the HRA approval (8 November 2017).

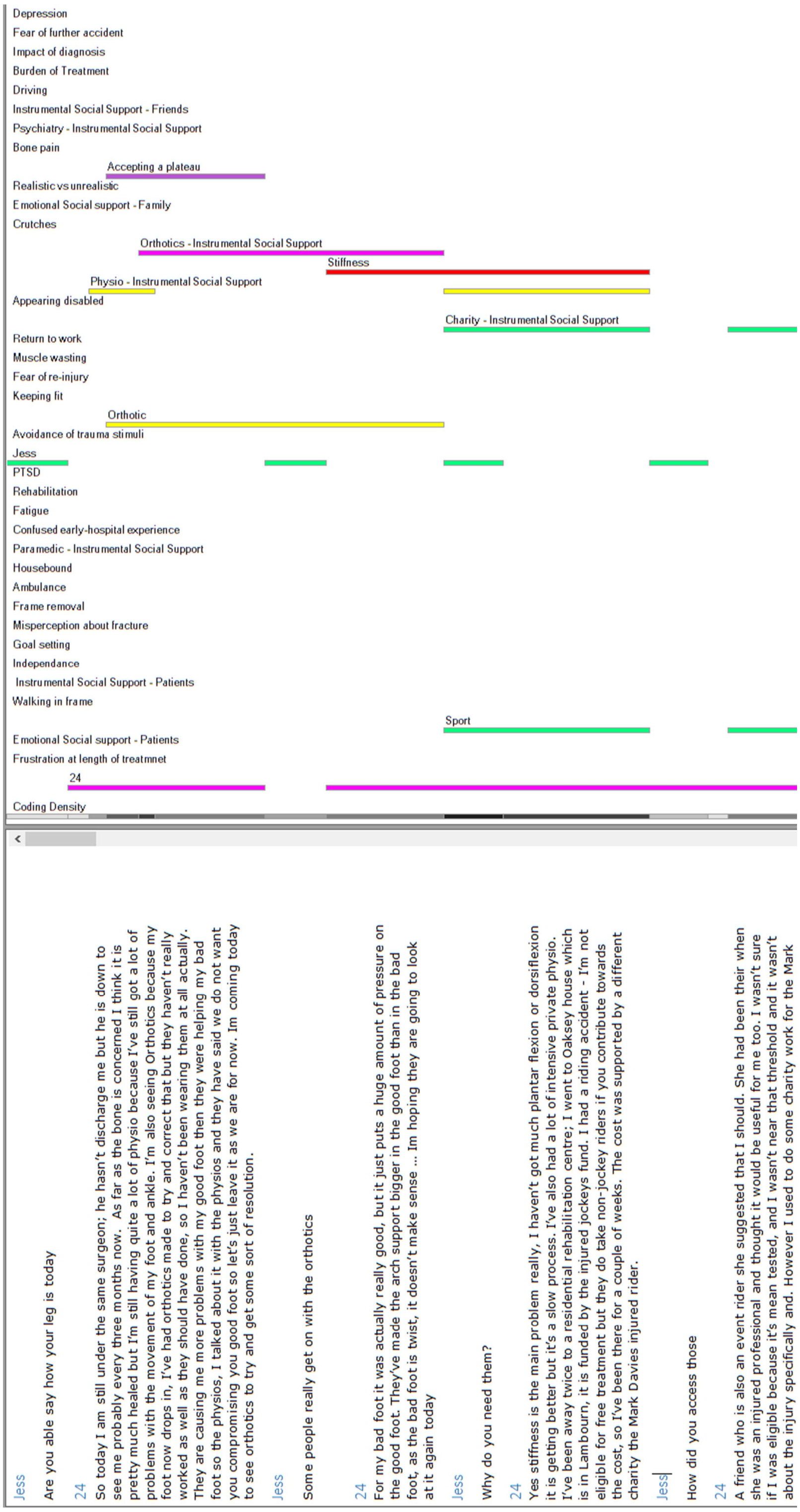
If you wish to discuss further, please do not hesitate to contact me.
Kind regards

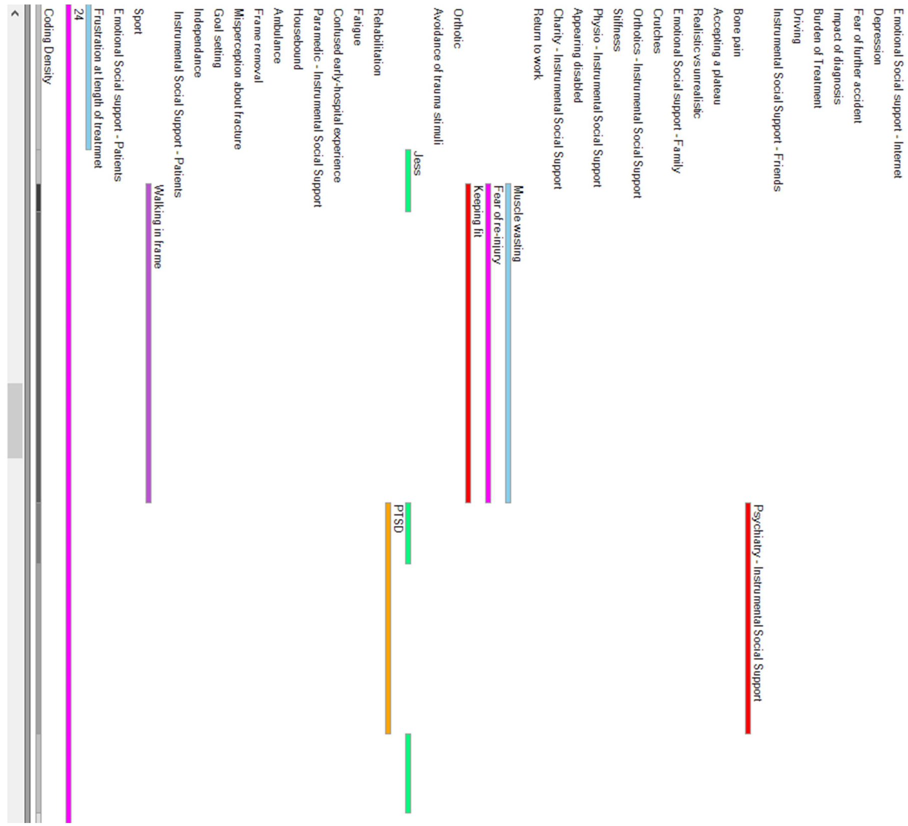
Nottingham University Hospitals NHS Trust

Dr Maria Koufali
Deputy Director Research and Innovation
Please note that the R&I department maintains a database containing study related information, and personal information about individual investigators e.g. name, address, contact details etc. This information will be managed according to the principles established in the Data Protection Act.

1

8.19 Example of qualitative coding in NVIVO





sometimes you would see a consultant or one of their registrars. The response was always the same, it's not quite grown quite well enough, please go away and do a bit more walking, refocus, and we will assess again in five weeks. After five weeks when there wasn't much improvement again, you would be sent away again with the same advice. You as an individual - do not really know what's really happening or what exactly they are waiting for - you are sort of in limbo. Your life is suspended, not quite knowing what that next five weeks is going to bring and that next five weeks may not bring anything, it may just bring another five weeks.

Jess

And what was going on at home during those five weeks

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Well you do improve, because you adapt. The frame will hold your weight and the only thing that stops you walking on that is your own mindset. You do improve because you get braver... You meet other people who are going through it as well. I remember saying to one other lad wearing a frame, that I wished I could walk like you can and he just said that I could, but it was all in my your head, he said the only thing that is stopping me walking was my demons about it - it's just in your mind. I thought you know what you're probably right and because he'd said that to me that gave me that drive that push to go home and get sorted - we aren't talking early days here where they do stop you walking on it, it was further down the line when really there are no physical barriers it's all mental. At that stage you are weight bearing is tolerated and it is your responsibility to do as much as you can. I suppose now looking back my biggest regret is not doing more, because now my legs completely wasted away and I have no muscle, I've lost all my fitness, and I have no upper body strength; I've regained the weight I lost before my accident. You just feel like everything's got to start again from scratch, with hindsight I think if only I'd tried a bit harder to keep fit when I'd got my frame on.

Jess

You are quite hard on yourself

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Emotionally it's massive. I had EMDR therapy which was brilliant, it works by using eye movement whilst you recall the trauma as sort of a densensitisation. Apparently it is similar to REM sleep... It's all a bit weird and I'm not sure how works but it certainly worked. My doctor... I was in quite a dark place referred me to some sort of counselling. They did an assessment and felt I had PTSD, they said that EMDR was the best treatment. For me - it was the best thing I could have done at the time and not I actually think Im braver than I was before my accident... I'm not sure but I think its dealt with anxieties that were underlying.

Jess

Psychological therapies for patients – in my experience the feedback varies. Interesting that you found it a very positive experience.

8.20 Evolution of final framework

Theme	Subthemes	Codes	Registry derived	QES derived	Working framework after Interview 5	Working framework after Interview 15	Final Framework	Notes around code evolution
Theme 1: Regaining mobility								
	Accident and hospital experience							
		Wanting urgent help						Code initially named "surgical timing"
		Passenger in system						Code merged with input into treatment
	Being housebound							
		Mobility aids						Multiple mobility codes merged under mobility aids
		Upstairs living						Code initially named climbing stairs
		Bed bound						
		Home modifications						
		Using bathroom						Code initially named personal care
		Not sleeping						Code initially named personal care
		Preparing meals						Code initially named light work
	Able to travel							
		Walking as travel						Code initially named outdoor walking
		Access to public transport						
		Driving						
		Anxiety over leaving home						
	Pressure to return to work despite ill health							Code initially named work
		Childcare						
		Managing home						

		Money worries	
		Claiming Benefits	
		Relying on savings	
		Parental financial support	
		Litigation claim	
		Return to work	Code initially named work
		Adjusted working	Code initially named heavy work
		Medical retirement	
		Finding a new job	
	Return to pre-injury activities		Code initially named usual activities
		Sports	
		Recreation	Code initially named heavy work
		Running	
Theme 2: Dealing with symptoms			
	Mobility		
		Stiffness	
		Swelling	
		Joint mechanics	
		Weight bearing	
		Walking	
		Muscle strength	
		Return to activities	
		Leg length	
	Pain		
		Unstable fracture	
		Fatigue & overuse	

		Neuropathic pain	
		Bone healing pain	
		Non-healing skin wounds	
		Pain Medication use	Moved and merged into professional support
	Body image		
		Clothing	
		Scars	
		Open wounds	
		Wasted muscles	
		Bulky flap	Moved from treatment burden
		Visible devices - TSF/prosthetic	
		Deformity	
		Appearing disabled	
	Psychological burden		
		PTSD	
		Fear of re-injury	
		Fear of not getting back to normal	
		Depression	
		Helplessness	Code initially named vulnerability
		Suicidality	
Theme 3: Burden of surgery			
	Amputation		
		Stump wounds	
		Prosthetic fit	
		Walking on prosthetic	
	Treatment with a nail		

- Anterior knee pain
- Infections
- Early weight bearing on nail

Treatment with a frame

- Frame strut prescription
- Pinsite management
- Walking with bulky frame
- Pinsite pain
- Pinprick scars
- Modifies clothing
- Downstairs living

Living with complication

- Impact of complication diagnosis
- Treatment for complications
- OPAT
- Bone transport
- Amputation after infection

Role of treatment decisions — Moved from Expectations for recovery

- Keeping the leg
- Unknown territory
- Led by experts
- Prognosis unclear
- Benefit of hindsight

Theme 4: Expectations for recovery

	New threat to livelihood		
		Misperception around fracture severity	
		Breakdown of normal	
		Fear of disability	
	Hope for recovery		
		Hope for return to normal	
		Clinician set expectations	
		Maintaining hope	
		Frustration with length of treatment	
	Accepting an outcome		
		Poor physical outcome?	
		Psychological adjustment	
		Satisfaction with recovery	
		Positive reinterpretation	
Theme 5: Coping strategies			
	Active coping, goal setting, information seeking		Code initially named problem-focused approach coping
		Goal setting	
		Keeping well and healthy	
		Information seeking	
	Personal social support		Code initially named social reliance
		Spousal support	
		Parental support	
		Support from children	
		Support from patients	
		Online support groups	

Professional social support						
	Surgeons					
	GPs					
	Specialist nurses					
	Rehabilitation					
	Counselling					
	Litigation advisors					
	Charities					
Positive reinterpretation						Code moved to accepting an outcome
	Finding strength					Collapsed under positive reinterpretation
	Improving chaotic behaviours					Collapsed under positive reinterpretation
	New health habits					Collapsed under positive reinterpretation
Maladaptive coping strategies						Code initially named avoidance coping strategy
	Abandoned goals					
	Social withdrawal					
	Rejecting healthcare					
	Substance abuse					