The treatment of segmental tibial fractures: does patient preference differ from surgeon choice?

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The treatment of segmental tibial fractures: does patient preference differ from surgeon choice?

ABSTRACT

INTRODUCTION: Segmental tibial fractures are complex injuries with a prolonged recovery time. Current definitive treatment options include intramedullary fixation or a circular external fixator. However, there is uncertainty as to which surgical option is preferable and there are no sufficiently rigorous multi-centre trials that have answered this question. The objective of this study was to determine whether patient and surgeon opinion was permissive for a randomised controlled trial (RCT) comparing intramedullary nailing to the application of a circular external fixator.

MATERIALS AND METHODS: A convenience questionnaire survey of attending surgeons was conducted during the United Kingdom's Orthopaedic Trauma Society annual meeting 2017 to determine the treatment modalities used for a segmental tibial fracture (n=63). Patient opinion was obtained from clinical patients who had been treated for a segmental tibial fracture as part of a patient and public involvement focus group with questions covering the domains of surgical preference, treatment expectations, outcome, the consent process and follow-up regime (n=5).

RESULTS: Based on the surgeon survey, 39% routinely use circular frame fixation following segmental tibial fracture compared to 61% who use nail fixation. Nail fixation was reported as the treatment of choice for a closed injury in a healthy patient in 81% of surgeons, and by 86% for a patient with a closed fracture who was obese. Twenty-one percent reported that they would use a nail for an open segmental tibia fracture in diabetics who smoked, whilst 57% would opt for a nail for a closed injury with compartment syndrome, and only 27% would use a nail for an open segmental injury in a young fit sports person. The patient and public preference exercise identified that sleep, early functional outcomes and psychosocial measures of outcomes are important.

CONCLUSION: We concluded that a RCT comparing definitive fixation with an intramedullary nail and a circular external fixator is justified as there remains uncertainty on the optimal surgical management for segmental tibial fractures. Furthermore, psychosocial factors and early post-operative outcomes should be reported as core outcome measures as part of such a trial.

Keywords: tibia, segmental, fracture, surgeon, preference, trial

INTRODUCTION

Segmental tibial fractures account for up to 12% of tibial shaft fractures and typically affect young adult males. They are complex, high energy injuries that are characterised by distinct fractures at two or more levels creating a separate intercalary diaphyseal fragment of bone. They are typically associated with a wide zone of soft tissue damage [1]. Compartment syndrome occurs in up to half of all cases and over 50% present as open fractures. Complications such as nonunion and infection are more common compared to simple tibial shaft fractures due to the severity of both soft tissue and osseous injury. Non-operative treatment is not indicated for these fractures as the outcome is poor [2]. Surgical options include plate osteosynthesis, intramedullary nailing and circular external fixation. Reamed intramedullary nailing and circular frame external fixation are the most commonly used surgical modalities for treating these fractures [3].

Complex fractures of this nature with a wide zone of soft tissue injury require a multidisciplinary approach with early stabilisation and soft tissue reconstruction. Failure to achieve union may result in revision surgery and limb reconstruction with a prolonged period of rehabilitation. Sustained periods of recuperation for a young, working population results in a fiscal impact to health services as well as impacting on their capacity to work [4]. Improving the quality of care given and reducing unjustifiable variation in practice associated with the treatment of these complex fractures is essential to ensure a more efficient quality driven treatment pathway.

The current literature is dominated by level IV evidence in the form of case series and poorly matched cohort studies [3]. Currently there is no good evidence showing superiority of one surgical modality over another in providing the best outcome for patients [3]. There is a trend towards better outcomes with reamed intramedullary nailing in closed segmental tibial fractures, and with circular frame external fixation in open segmental tibial fractures, but current studies are of insufficient quality to draw any firm conclusions [3]. Current studies report significant complication rates with treatment including infection, compartment syndrome, malunion, further surgery and amputation all of which signify a significant treatment burden to patients and have a significant cost implication to the health service provider [3]. Plate osteosynthesis has a higher rate of deformity compared to intramedullary

nailing or circular frame and a similar infection rate, and is performed less frequently [3]. This indicates that the two comparators for a future study are likely to be intramedullary nailing and circular frame fixation.

The complexity of segmental tibial fractures results in the majority being treated in Major Trauma Centres within the United Kingdom (UK) Major Trauma Network, with a specialist interest in limb reconstruction. This indicates that a multicentre randomised controlled trial (RCT) is a feasible method of determining the best method of fixation would be possible within the National Health Service in the United Kingdom. RCTs are difficult to perform in a trauma setting due to the difficulties encountered with consent, blinding and adherence to protocol requirements [5,6]. Prior to designing a RCT it is therefore important to determine the clinical equipoise of the treatment of segmental tibial fractures by clinicians and patients [6]. Clinical agreement has been defined in the literature by a number of different studies. Wright et al [7] proposed agreement as >90% of respondents agreeing on a survey, Marx et al [8] defined clinical agreement as >80% of surgeons answering similarly and Tierney et al [9] have suggested >60% agreement indicates general agreement and >95% indicates strong agreement.

The purpose of this paper was therefore to report the findings of a national survey of surgical preference towards the management of segmental tibial fractures to determine the level of clinical agreement within the surgeon's surveyed and establish whether community equipoise exists. The results of the survey were then compared to the conclusions drawn from a patient and public group to determine if patients agreed with surgeons as to which treatment produced a better outcome.

MATERIALS AND METHODS

Surgeon Survey

A questionnaire was developed by a multidisciplinary panel consisting of two trauma surgeons, a research methodologist and a physiotherapist to quantify surgeons' opinions regarding the treatment of segmental tibial shaft fractures. The questionnaire included both demographic questions and case scenarios. The questionnaire was pilot tested with four trauma surgeons before surveying a convenience sample of trauma surgeons at the United Kingdom's Orthopaedic Trauma Society annual meeting on the 13th January 2017.

Surgeons were asked whether they worked in a trauma unit or major trauma centre. Data were collected pertaining to their surgical practice to demonstrate their experience in treating segmental tibial fractures. To determine surgical preference to management strategies, surgeons were asked their opinions on five hypothetical case scenarios, with four questions on factors that might affect their surgical decision making. These cases included a 35-year old healthy male with a closed segmental fracture of the tibia, a 40-year old male smoker with diabetes and an open segmental tibial fracture, a 25-year old obese female with a closed segmental tibial fracture, a 45-year old female with a closed segmental tibial shaft fracture and compartment syndrome and finally a 29-year old female footballer with an open fracture**.** For each case respondents were asked if they would use a nail or frame, if partial weight-bearing would be commenced at day one, if full weight-bearing would be commenced at day one and if full weight-bearing would be commenced at six weeks. Responses were collapsed onto a two point Likert scale (yes or no). For the purposes of the study, clinical agreement was defined as >90% agreement according to the criteria used by Wright et al [7]. Responses were collected and analysed using Excel spreadsheets (Microsoft, Seattle, USA).

Patient and Public Involvement Exercise

A patient focus group was formed of four patients who had sustained five segmental tibial fractures. The patients consisted of three males, one female with a mean age of 46 (range 26 to 56) years and duration from injury ranging from two weeks to three years. There was also one patient partner to

determine together with the patients the perceptions of treatment for a segmental tibial fracture. Of the five segmental fractures, three were managed using a frame, two with an intramedullary nail. The one bilateral case was managed with a frame on one leg and a frame converted to a nail on the contralateral tibia. The focus group was chaired by a research methodologist and physiotherapist who were not involved in the patients' treatment. A narrative record was kept of the session. The exercise discussed topics including patient perception of the surgeon's decision on treatment, recovery time, and the effect of their fracture and recovery on their outcome from a biopsychosocial perspective, and RCT design features (if one was indicated).

RESULTS

Surgeon Preference Survey

Sixty-three surgeons responded to the survey from a convenience sample of 84. Of these, 52% worked in a trauma unit and 44% worked in a major trauma centre. Seventy-seven percent of the respondents were consultants, 14% in a non-training grade post and 8% trainees.

As illustrated in ***Figure 1***, 92% of respondents regularly used reamed intramedullary nails for the treatment of tibial fractures. Of these, 10% performed more than 25 a year, 38% performed 10 to 25 per year and 51% performed less than 10 tibial nails per year. Of respondents, 39% reported regularly using a circular external fixator for the treatment of tibial shaft fractures, whilst 61% did not. Of those surgeons who routinely used a circular external fixator, 5% applied more than 25 frames per year, 14% applied 10 to 25 frames per year and 51% applied less than 10 frames per year.

In case scenario one, a closed segmental fracture in a 35-year old healthy male closed segmental tibial shaft fracture, 81% of respondents opted for an intramedullary nail and 17% opted for a frame. In case scenario two, a 40-year old male smoker with diabetes and an open segmental fracture, 73% opted for a frame and 21% a nail. In case three, a 25-year old obese female with a closed segmental tibial fracture, 86% opted for a nail and 13% a frame. In case four, a 45-year old female with a closed segmental tibial fracture and compartment syndrome, 57% opted for a nail and 25% a frame. In case five, a 29-year old female footballer with an open segmental tibial fracture, 70% opted for a frame and 27% a nail.

There was no firm agreement over when to allow full weight-bearing in patients treated with an intramedullary nail. Fifty-two percent advocated full weight-bearing immediately after a nail, whilst 48% would recommend not immediately full weight bearing. By six weeks following a nail, 93% would advocate full weight-bearing and 7% would not. With a frame, 66% advocated immediate full weight-bearing and 34% did not. By six weeks, 96% advocated full weight-bearing after a frame and 4% did not.

Patient and Public Preference Exercise

The patient focus group reported that, in their view, it would be important to better understand why patients received nail or frame fixation. There appeared considerable variability of recovery profile within the patient group. Whilst all felt that their outcome was a success, those who received frame fixation consistently reported greater anxiety and a slower recovery compared to those who underwent nail fixation. Current perceived challenges associated with circular frame fixation included risk of pin site infection, limited knowledge around frame care post-discharge, particularly when discharged to more rural settings, and anxieties around the appeared social stigma related to a circular frame whilst it was in situ. In contrast, whilst the nail fixation was perceived as addressing many of these challenges, there were great concerns regarding knee range of motion.

When asked about trial conduct and design, there was agreement amongst the group that cosmetic appearance and pain were not important core outcomes. Sleep and difficulties associated with sleep, and functional outcomes on activities of daily living within the first three months post-injury were the key outcome measures identified by the group. The risk of adverse events and complications were also of importance but secondary to sleep and functional impairment. The group universally agreed that clear and shared decision-making on the surgical options should be considered when deciding definitive treatment. In the group's experiences, there was limited information provided on goals or expectations of treatment, and this should also be considered during the early consultations prior to definitive surgical management. Finally, approach for trial recruitment was discussed, feeling that an early approach i.e. within the first two days post-injury may not be appropriate, with all suggesting that they were either too unwell or in too much shock to be able to make an informed decision on trial enrolment.

DISCUSSION

The findings of this study indicate that there is currently a clear difference of opinion in the clinical community as to whether segmental tibial fractures (irrespective of the type of case) should be surgically managed using a frame or intramedullary nail. The need to address this clinical question further supported by patient and public recommendations that this is an important question, and better understanding to improve surgical decision-making in such cases, is essential. The findings also provide valuable insights into what outcome measures may be perceived as being important to patients following this injury.

The conclusions drawn from the surgical preference survey indicate some variability regarding how surgeons manage the same patient following a segmental tibial fracture based on their own decision-making. Whilst there was a high level of agreement for the use of an intramedullary nail (86% of respondents) for the patients with a closed segmental tibial fracture, all other instances were variable. Based on this, expertise and surgeon preference will need to be considered in the design and particularly the eligibility criteria for a future trial.

The findings from the recent systematic review by McMahon et al [3] reported faster union time following intramedullary nail fixation, but at the expense of a higher risk of deep infection. The overall quality of the current evidence-base is also of 'poor' quality [3], providing a reason for why clinicians may not base their clinical decision-making strongly on the research. Whilst we acknowledge that this will not be the sole reason, this does provide justification for investigating the effectiveness of frame versus intramedullary nail fixation following segmental tibia fracture. At the basis of each prospective RCT, there must be a foundation of equipoise within the surgical community, where the researchers are unsure whether a new treatment or intervention being studied is either superior or inferior to standard care [10]. This equipoise can be influenced by personal experience, anecdotal evidence or a poor evidence-base [11]. The findings in this paper suggest that not only are individuals uncertain as to the superior intervention for segmental tibial fractures, but

both the clinical and patient community are also uncertain, indicating ‘community equipoise’ which are essential criteria to justify a future clinical trial to answer this question [12].

In addition to surgical decision-making, the surgeon preference survey indicated variability in to post-operative weight-bearing status, most notably on the timing of full-bearing for both frame and intramedullary nail fixation. Variability in weight bearing is represented throughout the literature for tibial fractures [13-16]. Given the paucity of evidence regarding the advantages and disadvantages on the timing of weight-bearing, such uncertainty may be expected. However, as the patient and public preference exercise identified, early recovery and restoration to normal activities of daily living, particularly within the initial three post-operative months, is important which may provide further justification to investigate the feasibility of early commencement of weight-bearing. This highlights a further consideration which should be made when developing clinical trials in fracture management which has arguably been neglected within the evidence-base.

The patient and public preference exercise identified that sleep quality was consistently felt as an important measure for people following frame fixation. A study by McKee et al [17] using the Nottingham Health Profile showed a significant improvement in sleep following frame removal in 22 patients treated with a circular external fixator for post-traumatic deformities of the lower limb. The group felt that whilst the frame fixation was in situ, this, and perceived social stigma around the appearance of a frame, and how to dress with a frame fixation, were paramount measures. Whilst such concerns were not evident for those who underwent nail fixation, this was still perceived as a valuable measure to differentiate between the adoption of frame verses nail fixation. Assessing such domains as ‘life impact’ and ‘pathophysiological manifestations’ are in agreement with the current OMERACT [18] and COMET [19]. Unexpectedly, later-stage cosmetic appearance was felt as less important across the cohort, with fracture union and function more highly considered. This is reflective in the literature where fracture outcomes and the aesthetic appearance associated with malrotation are causes of litigation and complaints, more so than the appearance of skin or soft-tissue defects [20]. Nonetheless this provides valuable insights when considering what should be incorporated when

designing a study involving these treatments. These issues also emphasise what needs to be included in any core outcome set developed for trauma patients.

Whilst this paper provides valuable findings to provide the rationale and inform the design in trials for people following segmental tibia fracture, it presents with some limitations. Firstly, the surgeon preference survey provides data from 63 out of 84 surgeons who attended a meeting hosted for clinicians with a special interest in trauma. Accordingly, this may be a self-selecting group of surgeons and therefore their preferences may not necessarily be reflective of the UK as a whole (or internationally). Secondly, the patient and public preference group provided valuable experiences of nail and frame fixation, but these participants all derived from surgical experiences from one major trauma centre. It therefore remains likely that other experiences of surgical management and rehabilitation, geographic or socioeconomic circumstances or patient characteristics have been under-represented in this sample. Therefore, whilst providing a valuable 'signal' to inform trial design, these limitations mean that the findings should be not considered a consensus view on this topic and qualitative data collection, from a broader sample, should also form part of a future trial.

CONCLUSION

This paper has provided a rationale to undertake further study comparing meaningful clinical outcomes for people following segmental tibia fracture who are managed with a frame fixation method compared to a tibia nail. Recommendations on quality of life and psychological measures have been made. There remains variability in respect of which patients receive what treatment based on surgeon preference and what the resulting early recovery pathway is in respect to weight-bearing following either fixation method. Based on these findings, further exploration is now warranted to better understand what factors are important to design a definitive trial of frame versus nail fixation for people following this complex injury.

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Figure

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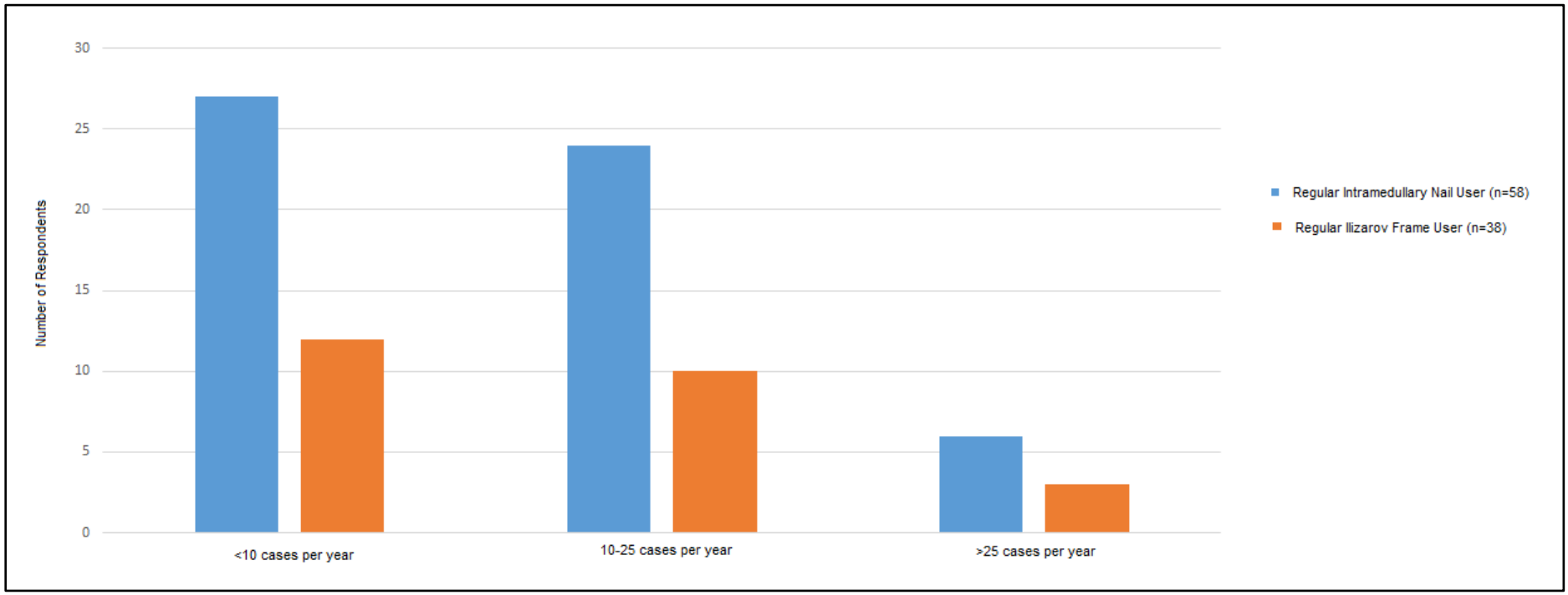
Figure 1: Bar chart to illustrate the frequency to which intramedullary nail and circular external fixators are used per year by surgeons who perceived themselves as regular users of these fixation methods for segmental tibial fractures.



CONFLICT OF INTERESTS:

Toby Smith has received institutional funding (research grants) from Smith & Nephew. No conflict with this work.

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Badri Narayan – no conflict of interest

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