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Unattainable equipoise in randomized controlled trials

STAFF VIEWS OF A FEASIBILITY STUDY OF SURGICAL TREATMENTS FOR SEGMENTAL TIBIAL FRACTURES

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Aims

To explore staff experiences of a multicentre pilot randomized controlled trial (RCT) comparing intramedullary nails and circular frame external fixation for segmental tibial fractures.

Methods

A purposeful sample of 19 staff (nine surgeons) involved in the study participated in an interview. Interviews explored participants' experience and views of the study and the treatments. The interviews drew on phenomenology, were face-to-face or by telephone, and were analyzed using thematic analysis.

Results

The findings identify that for the treatment of segmental tibial fractures equipoise was a theoretical ideal that was most likely unattainable in clinical practice. This was conveyed through three themes: the ambiguity of equipoise, where multiple definitions of equipoise and a belief in community equipoise were evident; an illusion of equipoise, created by strong treatment preferences and variation in collective surgical skills; and treating the whole patient, where the complexity and severity of the injury required a patient-centred approach and doing the best for the individual patient took priority over trial recruitment.

Conclusion

Equipoise can be unattainable for rare injuries such as segmental tibial fractures, where there are substantially different surgical treatments requiring specific expertise, high levels of complexity, and a concern for poor outcomes. Surgeons are familiar with community equipoise. However, a shared understanding of factors that limit the feasibility of RCTs may identify instances where community equipoise is unlikely to translate into practice.

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Introduction

Individual equipoise is a genuine uncertainty on the part of the clinical investigator regarding the comparative therapeutic merits of each arm in a trial.[1] It is one of the most challenging barriers to randomized controlled trials (RCTs) of surgical interventions.[2-4] If surgeons do not have equipoise, they may feel unable to enter patients into a trial. Lack of equipoise is often based upon surgical skill, experience of the interventions, and concerns about patient safety.[3,4] A lack of equipoise can result in insufficient recruitment or influence surgeons' interpretation and application of the eligibility criteria. This can bias the study results and undermine the usefulness of the study results for clinical practice.[3,5]

Where there is difficulty with individual equipoise, strategies such as expertise-based designs and community equipoise may be used. Expertise-based designs, where patients are randomly allocated to an intervention that is delivered by a surgeon with expertise in that procedure, are recommended for trials where the procedures are substantially different and are routinely delivered by different

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surgeons.[6] Acceptance of community equipoise, that is genuine uncertainty within the expert medical community regarding the comparative therapeutic merits of each arm in a trial,[7] could also facilitate recruitment. This is where surgeons proceed with their less preferred intervention by accepting the community does not know which intervention is best.[3] RCTs of traumatic orthopaedic injuries encounter further challenges due to patients' urgent needs and their lack of capacity.[8]

Segmental Tibial fractures, reamed Intramedullary nailing versus circular Frame external Fixation - a Feasibility study (STIFF-F) was a multicentre pilot RCT that aimed to assess the feasibility of comparing intramedullary nails (nails) and circular frame external fixation (frames) for segmental tibial fractures. The study was pragmatic and both interventions were routinely available in participating centres. Due to the differences between the two interventions, it was likely that surgeons would 'randomize to expertise'. The study opened for recruitment in six major trauma centres in England in May 2019 and closed in February 2020. During the recruitment period four centres screened 11 patients and three were randomized, one of whom died before surgery. Recruitment was difficult due to the rarity of the injury in the participating sites and staff highlighted this as the main barrier to the study. Good screening methods are important in rare injuries,[3] but less is known about recruitment to studies of two very different treatments. In order to understand the factors affecting this study, qualitative interviews were undertaken with staff involved in STIFF-F.

The research question was "what are staff views or experiences of STIFF-F, a study of a rare injury where treatments are substantially different?" The question was broad in order to capture what was most important to staff. The concept of equipoise featured explicitly and implicitly throughout their accounts of the study.

Methods

A total of 19 staff involved in STIFF-F participated in an interview between November 2019 and April 2020. Nine were consultant surgeons and the remaining ten, referred to as 'staff' to protect anonymity, included nurses, physiotherapists, and members of the trial team.

All staff involved in the study were eligible. Purposeful sampling was undertaken to gain participants with a range of roles, experience, and from a range of recruiting centres. Four participants were known to the researcher. The methodology drew on phenomenology to gain the lived experience of participants[9] as used in other studies of injury.[10] Interviews were lightly structured to explore participants' experience of the study and treatments and their views on what would have happened if there had been more patients with segmental tibial fractures. Open-ended questions such as "what is your experience of setting up and recruiting to STIFF-F?" were used to elicit what was most important to participants. Prompts including "can you tell me more about that?" and follow-up questions were used to gain detail. For example, a statement by a participant about being unable to include all patients with a segmental tibial fracture in the study was followed up with the question "what are the things that stop you putting patients in the study?"

Interviews were conducted face-to-face or by telephone. Participants provided written or verbal informed consent. Interviews lasted a mean of 38 minutes (20 to 70) and were conducted by an experienced qualitative researcher (ET). Ethical approval was granted by Berkshire Research Ethics Committee (reference 19/SC/0073, 20th February 2019).

Interviews were audio-recorded and transcribed verbatim. NVIVO 11 (QRS International, Warrington, UK) was used to manage the data. Two experienced qualitative researchers (EP, ET), with backgrounds in Health Sciences, conducted the analysis using a reflexive approach to thematic analysis.[11] This involved familiarization with the data, line-by-line coding to group sentences together based on meaning, and grouping similar codes into categories and themes. Analysis was iterative, with codes evolving through discussion and as more data were added. Participants chose not to have a copy of their transcripts.

Rigour was achieved through immersion in the data, reflection upon the process of interpretation, and regular discussion throughout analysis. Surgeons and nurses identified resonance with the findings. To enable transferability of findings a detailed description of the context and methods are provided. Quotes are presented to illustrate our interpretation. In the results, 'staff' refers to all participants.

Results

This study identified the overarching theme of unattainable equipoise. Unattainable equipoise occurred as the complexity of the patient, severity of injury, and current service provision led one treatment to be considered more appropriate for a patient than the other. This was conveyed through three themes: the ambiguity of equipoise, where multiple definitions of equipoise and a belief in community equipoise were evident; an illusion of equipoise, created by strong treatment preferences and variation in collective surgical skills; and treating the whole patient, where the complexity and severity of the injury required a patient-centred approach and doing the best for the individual patient took priority over trial recruitment. Figure 1 demonstrates the themes and categories within unattainable equipoise.

Ambiguity of equipoise. Multiple definitions of equipoise featured within staff accounts of STIFF-F. Among these,

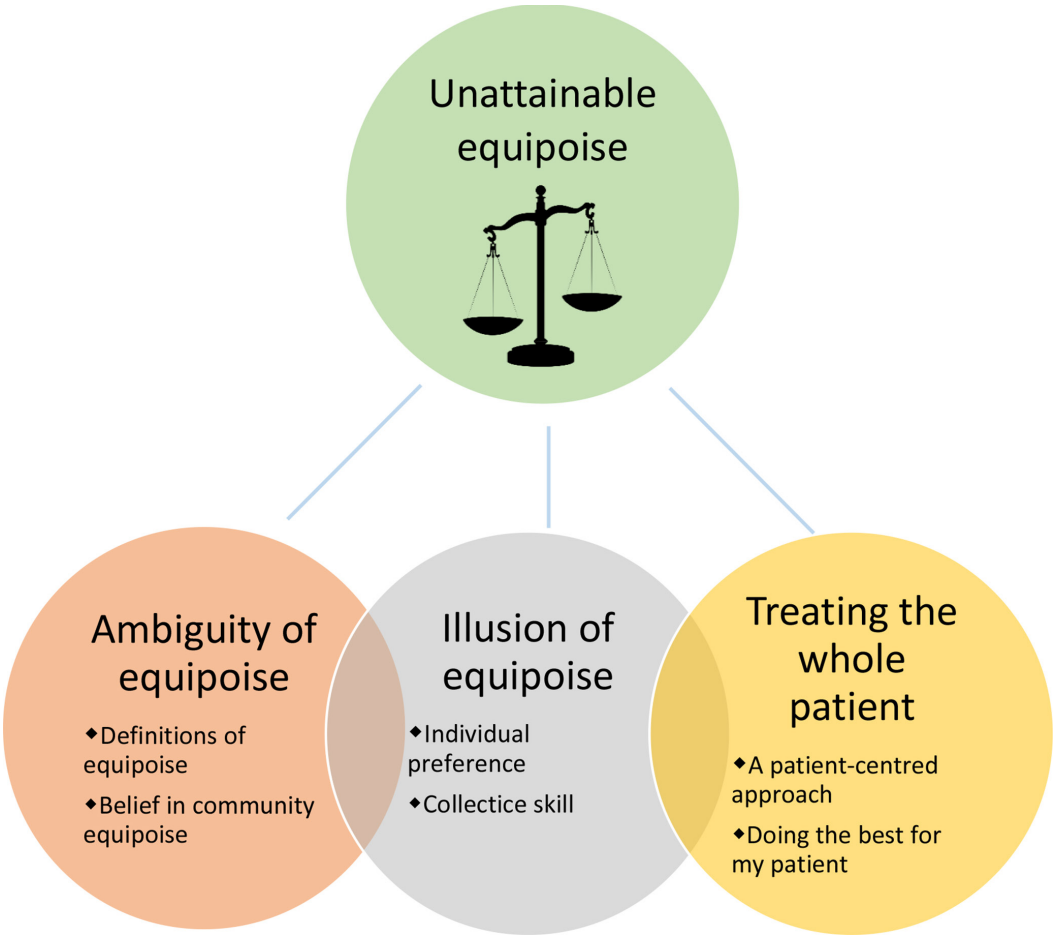

Fig. 1
Themes and categories within unattainable equipoise.

there was a belief in the presence of community equipoise for the treatment of segmental tibial fractures.

Definitions of equipoise. Five definitions of equipoise, as defined within the literature, were evident within staff accounts of STIFF-F. Staff described the challenges of individual, collective, community, clinical, and theoretical equipoise. These definitions are presented with examples in Table I.[1,3,7] A key challenge was that theoretical equipoise did not always translate into practice. In clinical practice with a patient in front of them, surgeons felt they would have a treatment preference.

> As a profession we might be able to sit in a room and say this one could either have a nail or a frame but on an individual patient basis there tends to be things that push people in one direction or another. So I wouldn't feel perhaps as comfortable that each individual orthopaedic surgeon would have equipoise about the individual patient in front of them.
>
> Staff 18 (surgeon)

Belief in community equipoise. There was a belief in the presence of community equipoise for the treatment of segmental tibial fractures. Although community equipoise did not translate into practice, it provided justification for the study and reinforced the importance of the research question. Staff expressed a need for evidence to inform the treatment of future patients which continued after the study failed to recruit.

> I think it's a valid question in that it's not something we have an answer to currently. I don't think you could get consensus from surgeons that would be universal to say, yes these patients would definitely do better with this type of treatment or this type of treatment.
>
> Staff 18 (surgeon)

Staff tended to agree about the risks and merits of each treatment. However, despite preferences, or thoughts about which intervention is best for an individual patient, staff struggled to weigh up which intervention is best overall. Living with a frame was considered challenging and restrictive but a deep infection from a nail could be devastating. Some staff were unsure which they would choose if it happened to them.

> It's hard because I wouldn't want metal in my leg all the time but I also don't know whether I want to hobble around with a frame and cleaning pin sites for an hour every day with a pair of tweezers picking scabs.
>
> Staff 15

Table I. Challenges of equipoise featured within STIFF-F, based upon the data and definitions within the literature.[1,3,7]

Theoretical A state of genuine uncertainty regarding the comparative therapeutic merits of each arm in a trial for a given disease/injury	Staff 18 (surgeon): Yes and I think that is quite a difficult one to tease out because I think you could sit people in a room with a set of scenarios and it would be easy for people to look at things on a screen and go yes I could go that way or they could have this, yes both would be very reasonable. But we are also making human decisions for real life people and I think there are more factors that come into that. Staff 5 (surgeon): Yes and also I think when you're in set up, you look at the feasibility of a study and you've probably looked through log books and say we get X amount of segmental fractures per year and so we can extrapolate that's how many we think we'll get into the study but you don't look at the granularity of the patients and what other injuries they might have had which may have meant that they wouldn't have been included in the study.
Community A state of genuine uncertainty within the expert medical community regarding the comparative therapeutic merits of each arm in a trial	Staff 18 (surgeon): I think it's a valid question in that it's not something we have an answer to currently. I don't think you could get consensus from surgeons that would be universal to say, yes these patients would definitely do better with this type of treatment or this type of treatment. Staff 12 (surgeon): I think that's what you'd expect if you talked to a group of framers and so they'll have their own opinions as to what is wrong with a nail. If you talk to a group of nailers they'll tell that you have infections rates in frames, everyone get infected, and you will get apocryphal stories from either side.
Collective A state of genuine uncertainty within a group or team regarding the comparative therapeutic merits of each arm in a trial	Staff 1 (surgeon): Most MTCs will have fifteen people on their on-call rota that can nail a tibia but may only have three people that can frame a tibia. You're immediately biased by the nature of the fact that there is a complete difference in the balance on people's views in terms of just sheer numbers . Staff 12 (surgeon): I think here at the moment we're actually quite well served and fairly split and so that the other study of plates versus frames for the other end of the tibia we can actively recruit because there's enough of us to do either and some of us who are quite happy to do both.
Clinical A state of genuine uncertainty regarding the comparative therapeutic merits of each arm in a trial for a specific patient	Staff 8 (surgeon): That's another thing that could potentially bias whether someone is more appropriate for nailing or framing. Potentially if someone needs a flap coverage certainly sometimes it makes a frame more appropriate or less appropriate depending on when the flap is going to go on. Staff 5 (surgeon): So with a simple segmental fracture you'd look at it and say I can nail and again that might push you towards nailing it rather than wanting to recruit it into the study and randomize it and similarly, if you have a very complex fracture with lots and lots of pieces you'd probably say that's better for a frame rather than for a nail and again that might push you towards framing it without recruiting it into the study.
Individual A state of genuine uncertainty on the part of the clinical investigator regarding the comparative therapeutic merits of each arm in a trial	Staff 11: I believe they weren't suitable for a nail and they would have to go through bone grafting and so the surgeon didn't have equipoise. Staff 8 (surgeon): I think personally I had equipoise regarding segmental fracture treatments, in this scenario. Having said that there's an intrinsic bias if you only intend to do one or other treatment, you naturally believe the treatment that you can provide is better. Staff 19 (surgeon): The next question is, have I got equipoise and the answer is probably not, but it would depend on the fracture.

MTC, major trauma centre.

An illusion of equipoise. The presence of strong preferences for these two different treatments within the community of surgeons and variation in the collective skills of surgeons in each team created an illusion of equipoise that did not translate into clinical practice.

Surgeon preferences. There was a lack of individual equipoise with surgeons' preferences based upon their skills, training, and patients' experience of the interventions. There was an inherent bias towards nails as frames required specialist training and expertise.

Preferences were reinforced by surgeons' experience and how they weighed up the risks and benefits of each treatment. Nails were often described as kinder for patients, less invasive, hidden, and with fewer psychological consequences such as stigma and less follow-up. Frames were often considered burdensome, torturous, and difficult to live with but resulting in fewer complications, deep infections, and deformity. Some staff thought the negative perception of frames could result from a lack of experience of them.

> I think a lot of our frame surgeons think it's worth the higher level of disability you get from the period of being in a frame because in the long term you get less deformity.
>
> Staff 6

> People care about, can the patient get up and walk and get back to their normal life ASAP [as soon as possible] and the nail is so clearly better at that I think compared to a frame because it's internal. There's no stigma attached to it. If you get a complication then of course the nail is a disaster compared to the frame but the rate of complications is still relatively low.
>
> Staff (surgeon) 1

Surgeons' experience of complications and limited knowledge of patient's long-term recovery could reinforce preferences.

> I think the truth is that people know what they feel comfortable doing but do they know what those patients are like two years after or three years afterwards because the healing time for a nasty segmental fracture is long... they would probably only be familiar with the complications there have been so people come back infected or if the fixation fails.
>
> Staff 12 (surgeon)

Collective skill. Treatment for a segmental tibial fracture was often a group decision, influenced by the skill within the group. Some centres have a strong group preference for one treatment and were unlikely to have achieved sufficient collective equipoise to participate in this study, while others have expertise in both treatments.

> You can go to some Trusts and everything gets framed and you go somewhere else and everything gets nailed and so then it becomes just a little bit more difficult discussing it with any patient because the whole ethos of the place is that you do it one way.
>
> Staff 12 (surgeon)

The ideal was for surgeons to randomize to expertise but this may have been more difficult than anticipated. The number of surgeons with a preference to nail was thought to almost always outweigh those with a preference to frame, potentially biasing the discussion and decision. There were occasions where there was an eligible patient but no framer in the trauma meeting. When this occurred, it could be difficult to achieve equipoise as staff believed it is not in the patient's best interests to wait for a frame when they could be fixed sooner with a nail.

> When you've got the issue of well there's no framer in the building today and this man's got a broken leg and I can nail his tibia this afternoon, I think that's a real issue. If you broke your tibia on a Friday and there's no-one around at the weekend what are you going to do? Are you going to think is it really fair to leave them for three days with a badly broken leg or shall we just get on and fix it this weekend?
>
> Staff 1 (surgeon)

In addition to expertise, centres needed resources to support patients with frames during recovery. Support included frame clinics, nurses and physiotherapists with experience of frames, psychological support, and help with pin site care. Due to resources required, some staff described a need to be cautious of the number of frames used.

> There's pressure as well on how many frames you do. They have a lot of follow-up and so they use a lot of resources, the frame patients and we have to be a bit reserved.
>
> Staff 6

Treating the whole patient. A patient-centred approach was needed to treat segmental tibial fractures as multiple factors could influence the optimal treatment. Doing the best for patients took priority over the trial due to the severity of the injury.

Patient-centred decision-making. A patient-centred approach to treatment was needed where surgeons consider the whole patient including their living situation, psychological wellbeing, employment, and confidence to care for pin sites and cope with a frame.

> Patients, from what I know, struggle with having a circular frame, generally, but I think it's the duration of time that they have to be in it which is quite challenging. Again, because it is bulky it is difficult to put clothes on, showering, thinking about their job as well.
>
> Staff 16

The complexity of the injury could influence treatment. Patients may have multiple fractures, open fractures, pelvic or head injuries, and require urgent treatment, time in intensive care, or multidisciplinary care.

> There's a reasonable chance that someone with a segmental tibial fracture may also have had a head injury, they might not be in a position to discuss entering into a trial. There may be a case of them being whisked straight to theatre for emergency surgery and getting an external fixator temporarily applied to the leg, potentially they will then sit in ITU for a period of time and it then becomes inappropriate to nail them because of the risk of infection and so on. So sometimes these sicker patients can steer themselves into a particular route of being treated one way or another.
>
> Staff 8 (surgeon)

Staff described fractures that surgeons might exclude from the study, emphasizing the degree of discomfort with the study and a lack of consensus as to which injuries should be included.

> I think what people will look at is how big the proximal and distal fragments are as to whether they feel they can be adequately controlled by a nail.
>
> Staff 12 (surgeon)

> If I had quite a serious high energy type 3B injury or Type A with contracture I would be concerned about including in recruitment.
>
> Staff 3 (surgeon)

> The more comminuted and open the fracture the more likely it would be to have a frame and if there's any bone loss as opposed to a nail... I think if it's got an intra-articular component they're more likely to frame.
>
> Staff 5 (surgeon)

Doing the best for the patient. Surgeons needed to do their best to achieve the best outcome for their patient, who took priority over this study.

> I think they just prefer to do what they know best to look after the outcome for that individual patient rather than thinking about a research trial and what may be and improving the evidence base, it's more about just making sure that one individual is safe.
>
> Staff 6

The severity and complexity of the injury made this study riskier than other studies, as there was more that could go wrong for patients. For some surgeons support from their team may help them include patients but for others the responsibility was solely their own.

> Ultimately, you're going to be held responsible if something goes wrong and while everyone else might decide that's the best treatment it's your name on the piece of paper saying you're responsible.
>
> Staff 5 (surgeon)

> Your eligibility criteria includes open segmental tibial fractures which are really high risk for amputation and the more risk that you're asking surgeons to commit to when you're asking them to randomize a patient I think the more responsibility they feel and the more uncomfortable they feel with it.
>
> Staff 6

Staff understood the difficulty this study posed for surgeons and accepted surgeons' decision to exclude patients that they did not feel were appropriate.

> Ultimately the patient's care lies in their hands and so you have to respect that [excluding patients from the study] and move on.
>
> Staff 9

Discussion

The findings of this study reveal the unattainable nature of equipoise through the themes, ambiguity of equipoise, illusion of equipoise, and treating the whole patient. Individual and clinical equipoise were unattainable for this study despite evidence of community equipoise,[12] as community equipoise was theoretical and did not translate into practice. Key factors contributing to unattainable equipoise were that segmental tibial fractures were rare at the study sites, the two treatments were substantially different and the risk of complications or poor outcomes were considered to be high. In addition, staff identified severity of injury, complex patient factors, resources, the delay waiting for a framer, individual treatment preferences, and variation in skills within clinical teams as factors that influence equipoise.

The findings suggest that investigating individual and collective equipoise and distinguishing clinical from theoretical equipoise may be helpful when designing future studies for rare injuries. This study shows that even when community equipoise[7] is present: surgeons can still have strong reservations about a study; equipoise can be theoretical and does not always translate into clinical practice; and collective equipoise is important for treatments where there are variations in local practices.

This study suggests that there are contexts where expertise-based designs[6] may be unable to overcome strong surgeon preferences. In this study, the presence of strong preferences for two treatments for segmental tibial fractures within the community of surgeons created an illusion of equipoise that did not translate into practice. Other studies of injury have shown that surgical skill influences a surgeon's treatment preferences and willingness to include their patients in RCTs.[3,8] This study, however, shows that surgical skill is just one of the factors involved in the decision.

These findings suggest severity and complexity of injury are factors that impede recruitment and show that, decisions about enrolling patients into RCTs are shaped by multiple factors in addition to surgical skill including surgeons' obligation to achieve the best possible outcome for their patient. Segmental tibial fractures were considered severe, with a burdensome recovery and a high risk of devastating complications. Surgeons can experience guilt, responsibility, anxiety, and frustration when their patients experience postoperative complications or adverse events leading them to adopt risk-averse approaches in the future.[13-15]

The sample comprised staff involved in the STIFF-F study. Increased opportunity to recruit to the study may have provided alternative perspectives. A broader range of staff, including those at sites that focused mainly on nailing or framing, may differ in their view. Additionally, interviews with staff involved in other RCTs of rare injuries might identify further factors that influence equipoise. Our sample included surgeons, research, and clinical staff. While surgeons make the decision to include patients into the trial, experienced research and clinical staff provided an additional perspective from which to consider the challenges of this study and were well placed to consider how surgeon equipoise influences trials. All participants, surgeons, and other staff contributed to the themes. Saturation of the themes, where no new themes and categories arise, was achieved.

Equipoise persists as one of the most difficult barriers for recruitment to RCTs of surgical interventions. Surgeons are familiar with the concept of community equipoise. However, this study shows that strategies such as acceptance of community equipoise and expertise-based trial designs may not always be sufficient to overcome a lack of individual equipoise. Greater understanding of surgeons' views and experience may help distinguish theoretical from clinical equipoise and may help identify instances where community equipoise is unlikely to translate into practice. This would be valuable when considering the feasibility of future trials for rare injuries.

Take home message

- Individual and clinical equipoise can be unattainable in randomized controlled trials of surgical interventions for complex and severe rare injuries with known complications and poor outcomes.
- In these circumstances, expertise-based designs and acceptance of community equipoise may only partially overcome a surgeon's concern about including their patients.

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- E. E. Phelps: Designed the study, Analyzed the responses, Drafted the initial manuscript, Made iterative changes to develop the final manuscript.
- E. Tutton: Designed the study, Collected and analyzed the responses, Drafted the initial manuscript, Made iterative changes to develop the final manuscript.
- M. Costa: Designed the study, Made iterative changes to develop the final manuscript.
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