Intramedullary nail fixation versus locking plate fixation for adults with a fracture of the distal tibia: the UK FixDT RCT

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Scientific summary

The UK FixDT RCT

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Scientific summary

Background

The tibia is the most commonly broken major bone in the leg. Injuries require hospital admission, usually require surgery and result in prolonged periods away from work and social activities. The treatment of displaced, extra-articular fractures of the distal tibia (lower third) remains controversial. These injuries are particularly difficult to manage because of the limited soft-tissue cover, poor vascularity of the area and proximity of the fracture to the ankle joint. Infections, non-union and malunion of the fracture are well-recognised complications.

Surgical treatment options include intramedullary (IM) nail fixation, 'locking' plate and screw fixation and external fixation. External fixators may be beneficial in selected cases but, in the UK, the IM nail and locking plate options are most commonly used for extra-articular fractures. Mid-shaft fractures of the tibia are generally treated successfully with locked IM nails. However, in the more distal metaphyseal region of the tibia, the fixation may be less stable. The bolts or screws that are inserted into the nail may break, malalignment of the bone may occur and there is a risk that the nail will penetrate into the ankle joint. The development of locking plates, in which a thread on the head of the screws locks into the holes in the plate to create a 'fixed-angle' construct, has led to a recent increase in the use of locking plate fixation. However, locking plates are not without risks and they require greater soft-tissue dissection, which carries a risk of infection, wound breakdown and damage to the surrounding structures.

The UK Fixation of Distal Tibia Fractures trial was designed to compare IM nail fixation with locking plate fixation for adult patients with a displaced, extra-articular fracture of the distal tibia.

Methods

All of the centres involved in the trial were UK NHS acute trauma centres. All of the centres provided definitive surgical fixation of this type of fracture in their hospital as part of routine clinical practice.

Inclusion criteria

The inclusion criteria for this trial were that the patient:

- was aged ≥ 16 years
- had any fracture that involves the distal tibial metaphysis, which was defined as a fracture extending within 2 Müller squares of the ankle joint
- would, in the opinion of the attending surgeon, benefit from internal fixation of the fracture.

Exclusion criteria

The exclusion criteria for this trial were that:

- there is, in the opinion of the attending surgeon, a contraindication to IM nailing: the presence of total knee replacement OR that the medullary canal is too narrow OR there is a pre-injury deformity of the medullary canal OR it is not possible to achieve fixation of four cortices with screws distal to the fracture
- the fracture is open
- there is a contraindication to anaesthesia
- there is evidence that the patient would be unable to adhere to trial procedures or complete questionnaires
- the fracture extends into the ankle joint (i.e. intra-articular fracture).

Interventions

Each patient had the allocated surgery according to the preferred technique of the operating surgeon. However, as there were a large number of centres and a large number of surgeons at each of these centres, no individual surgeon was expected to perform more than a handful of the procedures. Therefore, the effect of the surgeon and their learning curve would be minimal in this particular trial.

Intramedullary nail fixation

The IM nail is inserted at the proximal end of the tibia and passed down the hollow centre (medullary canal) of the bone in order to hold the fracture in the correct (anatomical) position. The reduction technique, the surgical approach, the type and size of the nail, the configuration of the proximal and distal interlocking screws and any supplementary device or technique was left at the discretion of the surgeon as per standard clinical practice.

Locking plate fixation

A locking plate is inserted at the distal end of the tibia and passed under the skin onto the surface of the bone. Again, the details of the reduction technique, the surgical approach, the type and position of the plate, the number and configuration of fixed-angle screws and any supplementary device or technique were left to the discretion of the surgeon. The only stipulation was that fixed-angle screws must be used in at least some of the distal screw holes; this is standard practice with all distal tibia locking plates.

Outcomes

The primary outcome was the Disability Rating Index (DRI), a validated scale that assessed patients' rating of their own disability. The DRI contains 12 items and provides an overall score from 0 to 100 points, in which 0 points represents no disability and 100 points represents complete disability. The secondary outcome measures in this trial were the Olerud–Molander Ankle Score (OMAS), the EuroQol-5 Dimensions (EQ-5D) health-related quality-of-life questionnaire score and complications at 3, 6 and 12 months postoperatively. Resource use was collected to inform the health economic evaluation.

Randomisation

A minimisation algorithm was used to allocate participants. Following informed consent, the method of fixation was allocated using a secure, centralised, web-based randomisation service, delivered by an accredited Clinical Trials Unit (Warwick Clinical Trials Unit). The allocated treatment was reported to the research associate, who informed the treating surgeon. Stratification by centre helped to ensure that any clustering effect related to the centre itself was equally distributed in the trial arms. Stratification on the basis of age was used to discriminate between younger patients with normal bone quality sustaining high-energy fractures and older patients with low-energy (fragility) fractures related to osteoporosis.

Blinding

The type of fixation determines the site of clearly visible surgical scars. Specifically, the insertion of an IM tibial nail requires a surgical incision at the knee. Therefore, the patients could not be blind to their allocated treatment. In addition, the treating surgeons were also not blind to the treatment but did not take part in the postoperative assessment of the patients. The functional outcome data were collected via patient questionnaires and entered into the trial central database by a research assistant or data clerk in the trial central office. The radiographs were reviewed by an independent assessor who was not involved in any other data collection or analysis.

Statistical analysis

The main analysis investigated differences in the primary outcome measure, the DRI score, at 3, 6 and 12 months on an intention-to-treat basis. The primary outcome end point was at 6 months.

Health economic evaluation

An economic evaluation was conducted from the recommended NHS and Personal Social Services (PSS) perspective. An incremental cost-effectiveness analysis was performed, which is expressed in terms of incremental cost per quality-adjusted life-year (QALY) gained.

Results

Patients

A total of 321 patients took part in the trial between April 2013 and May 2016 at 28 UK acute trauma centres. Over 80% of participants provided follow-up data at each time point and data were 88% complete for the primary outcome measure at 6 months.

Primary outcome measure

There was no statistically significant difference in DRI score at 6 months [IM nail fixation group, mean 29.8 points, 95% confidence interval (CI) 26.1 to 33.7 points; locking plate group, mean 33.8 points, 95% CI 29.7 to 37.9 points; adjusted difference 4.0 points, 95% CI –1.0 to 9.0 points; $p = 0.11$]. There was a statistically significant difference in DRI score at 3 months in favour of IM nail fixation (IM nail fixation group, mean 44.2 points, 95% CI 40.8 to 47.6 points; locking plate group, mean 52.6 points, 95% CI 49.3 to 55.9 points; adjusted difference 8.8 points, 95% CI 4.3 to 13.2 points; $p < 0.001$), but not at 12 months (IM nail fixation group, 23.1 points, 95% CI 18.9 to 27.2 points; locking plate group, 24.0 points, 95% CI 19.7 to 28.3 points; adjusted difference 1.9 points, 95% CI –3.2 to 6.9 points; $p = 0.47$).

Conclusions from the secondary per-protocol (per-treatment) analysis of the DRI did not differ from those of the primary intention-to-treat analysis.

Secondary outcome measures

The secondary patient-reported outcome measures showed the same effect and the same pattern over time as the DRI score. Each measure showed a statistically significant difference in favour of IM nail fixation at 3 months, which gradually reduced at 6 months and then 12 months after the injury. There was a statistically significant difference in the OMAS at 6 months (mean difference –6.0 points, 95% CI –11.2 to –0.7 points; $p = 0.026$) in favour of the IM nail fixation group. Similarly, there was a statistically significant difference in the EQ-5D health-related quality-of-life index at 6 months (mean difference –0.063 points, 95% CI –0.12 to –0.01 points; $p = 0.033$) in favour of the IM nail fixation group.

In terms of 'complications local to the distal tibia fracture', 14 (9%) patients in the IM nail fixation group and 21 (13%) in the locking plate group were treated with antibiotics for a wound infection in the first 6 weeks after surgery. Revision of the internal fixation was uncommon in both groups: two patients (1%) in the IM nail fixation group and five patients (3%) in the locking plate group ($p = 0.283$). However, removal of metalwork was required in 11 (7%) patients in the IM nail fixation group and 14 (9%) in the locking plate group. Other local complications were rare in both groups. There was no evidence of a difference in 'systemic complications related to the injury or its treatment' or in the number of 'unrelated adverse events'.

The health economic evaluation showed that patients who were allocated to the IM nail fixation group experienced a small increase in QALYs in the base-case analysis (0.01 QALYs, 95% CI –0.03 to 0.06

QALYs) over the 12-month follow-up and mean NHS and PSS costs were significantly lower in the IM nail fixation group (–£970, 95% CI –£1690 to –£260; $p = 0.05$). The difference in cost was driven by the lower number of outpatient visits and the lower rate of further surgery in the IM nail fixation group. Therefore, the incremental cost-effectiveness ratio indicates IM nail fixation is the 'dominant' procedure, as average costs for this intervention were lower and average benefits were greater than in the locking plate group. The probability of cost-effectiveness for IM nail fixation exceeded 90% regardless of the value of the cost-effectiveness threshold.

Discussion

This trial provides strong evidence that IM nail fixation and locking plate fixation provide similar outcomes at 6 and 12 months following an extra-articular fracture of the distal tibia. However, patients receiving IM nail fixation reported less disability, better ankle function and improved health-related quality of life at 3 months. The economic evaluation showed that IM nail fixation provided slightly higher quality of life in the 12 months after injury and at a lower cost and, therefore, it was cost-effective compared with locking plate fixation. The probability of cost-effectiveness for IM nail fixation exceeded 90%, regardless of the value of the cost-effectiveness threshold.

In conclusion, among adults with an acute fracture of the distal tibia randomised to IM nail fixation or locking plate fixation, there were similar disability ratings at 6 months. However, recovery across all outcomes was faster in the nail fixation group and costs were lower.

Trial registration

This trial is registered as ISRCTN99771224 and UKCRN 13761.

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