■ TRAUMA

Five-year outcomes for patients with a displaced fracture of the distal tibia

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Aims
To report the outcomes of patients with a fracture of the distal tibia who were treated with intramedullary nail versus locking plate in the five years after participating in the Fixation of Distal Tibia fracture (FixDT) trial.

Methods
The FixDT trial reported the results for 321 patients randomized to nail or locking plate fixation in the first 12 months after their injury. In this follow-up study, we report the results of 170 of the original participants who agreed to be followed up until five years. Participants reported their Disability Rating Index (DRI) and health-related quality of life (EuroQol five-dimension three-level questionnaire) annually by self-reported questionnaire. Further surgical interventions related to the fracture were also recorded.

Results
There was no evidence of a difference in patient-reported disability, health-related quality of life, or the need for further surgery between participants treated with either type of fixation at five years. Considering the combined results for all participants, there was no significant change in DRI scores after the first 12 months of follow-up (difference between 12 and 24 months, 3.3 (95% confidence interval -1.8 to 8.5); p = 0.203), with patients reporting around 20% disability at five years.

Conclusion
This study shows that the moderate levels of disability and reduced quality of life reported by participants 12 months after a fracture of the distal tibia persist in the medium term, with little evidence of improvement after the first year.

Cite this article: ***Bone Joint J*** **2023;105-B(7):795–800.**

Introduction
Surgical treatment options for extra-articular fractures of the distal tibia include intramedullary nail fixation, plate and screw fixation, and external fixation. External fixators may be beneficial in selected cases, but the nail and plate options are most commonly used for extra-articular fractures. Mid-shaft fractures of the tibia are generally successfully treated with locked intramedullary 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 may occur, and there is a risk that the nail will penetrate into the ankle joint.[1-4] The development of 'locking' plates, with fixed-angle stability, has led to an increase in the use of plate fixation. However, locking plates require greater soft-tissue dissection, which carries a risk of infection, wound breakdown, and damage to the surrounding structures.[5]

The FixDT trial was designed to compare intramedullary nail fixation with locking plate fixation for adult patients with a displaced fracture of the distal tibia. A total of 321 participants aged 16 years or over with an acute, extra-articular fracture of the distal tibia were recruited from 28 hospitals in the UK. A distal tibial fracture was defined as a fracture extending within two Müller squares of the ankle joint.[6] Patients were excluded if the treating surgeon recommended nonoperative treatment, the fracture was open (Gustilo & Anderson score > 1),[7] the fracture extended into the ankle joint, or there was a contraindication to intramedullary nailing. Further details of the fractures, surgeons, and surgical interventions are available in the National Institute for Health and

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doi:10.1302/0301-620X.105B7.BJJ-2022-1419.R1 $2.00

Bone Joint J 2023;105-B(7):795–800.

Table I. Base demographics and pre-injury scores for the 12-month follow-up (main study), and this subsequent five-year follow-up study.

Characteristic	Main study	LTFU		p-value
		No	Yes	
Total, n	321	151	170	
Mean age, yrs (SD)	45.1 (16.3)	42.7 (16.4)	47.2 (15.9)	0.013*
Mean BMI, kg/m^2 (SD)	27.7 (6.5)	27.2 (6.6)	28.1 (6.5)	0.206*
Mean DRI score (0 to 100) (SD)	10.0 (18.7)	12.9 (21.9)	7.4 (15.1)	0.008*
Mean EQ-5D-3L score (-0.594 to 1) (SD)	0.87 (0.22)	0.84 (0.26)	0.91 (0.18)	0.004*
Age group (yrs), n (%)				0.030†
< 50	194 (60)	101 (67)	93 (55)	
≥ 50	127 (40)	50 (33)	77 (45)	
Sex, n (%)				0.251†
Female	124 (39)	53 (35)	71 (42)	
Male	197 (61)	98 (65)	99 (58)	
Fracture side, n (%)				0.999†
Left	142 (44)	66 (44)	76 (45)	
Right	177 (55)	83 (55)	94 (55)	
Previous problems on injured side, n (%)				0.792†
No	243 (76)	115 (76)	128 (75)	
Yes	76 (24)	34 (23)	42 (25)	
Injury mechanism, n (%)				0.114†
Contact sports injury	25 (8)	10 (7)	15 (9)	
Crush injury	11 (3)	8 (5)	3 (2)	
High-energy fall	51 (16)	19 (13)	32 (19)	
Low-energy fall	172 (54)	79 (52)	93 (55)	
Road traffic collision	37 (12)	23 (15)	14 (8)	
Other	23 (7)	10 (7)	13 (8)	
Smoker, n (%)				< 0.001†
No	215 (67)	81 (54)	134 (79)	
Yes	103 (32)	67 (44)	36 (21)	
Alcohol (units/week), n (%)				0.299†
0 to 7	173 (54)	76 (50)	97 (57)	
8 to 14	52 (16)	22 (15)	30 (18)	
15 to 21	50 (16)	29 (19)	21 (12)	
> 21	40 (12)	20 (13)	20 (12)	
Diabetes, n (%)				0.999†
No	306 (95)	143 (95)	163 (96)	
Yes	13 (4)	6 (4)	7 (4)	

Where numbers do not add up to the column totals, this indicates that data were missing for a number of the study participants.
*Independent-samples *t*-test.
†Fisher's exact test.
DRI, Disability Rating Index; EQ-5D-3L, EuroQol five-dimension three-level questionnaire; LTFU, long-term follow-up; SD, standard deviation.

Care Research Journals Library.[8] Length of stay and intervention costs are described in the associated health economic analysis.[9] The trial showed that intramedullary nail fixation provides faster recovery for patients in the first 12 months after a fracture of the distal tibia, and costs less than locking plate fixation.[10] This paper reports the outcomes of the FixDT trial participants who agreed to take part in five-year follow-up of the trial.

Methods

At 12 months after their fracture, the 321 participants in the FixDT trial were asked for written informed consent to enter this study and 170 (53%) agreed to longer-term follow-up (LTFU) of 60 months (five years). Outcome data were collected by postal questionnaire annually, with telephone follow-up of non-responders as required. Patient-reported complications were verified with the recruiting centre where possible.

Outcomes. The primary outcome was the patient-reported Disability Rating Index (DRI).[11] The DRI provides a 100-point score, where zero represents normal function and 100 complete disability, with a minimum clinically important difference of eight points.

Secondary outcomes were health-related quality of life using the EuroQol five-dimension three-level questionnaire (EQ-5D-3L),[12,13] and complications related to the fracture. EQ-5D-3L responses were converted into an overall utility score that ranged from 1 (best possible) to -0.59 (worst possible), where 0 represents the quality of life associated with death, and a visual analogue scale (EQ VAS) for overall health state with a range from 0 to 100, where a score of 0 indicates the lowest level of health. Complications were grouped under the following headings: further surgery for removal of symptomatic metalwork, further surgery for nonunion, further surgery

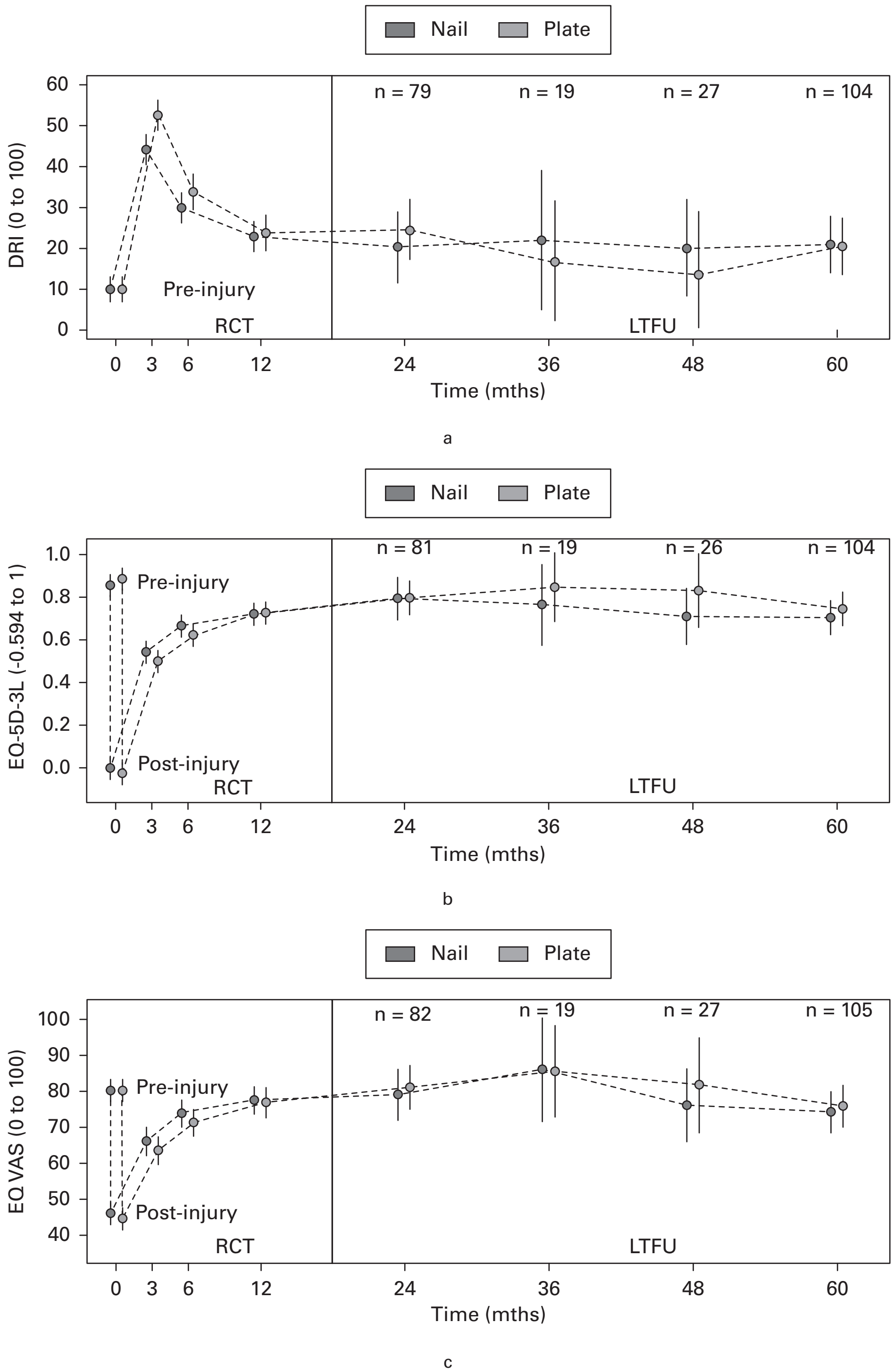

Fig. 1

Five-year outcomes for patients with a displaced fracture of the distal tibia. Temporal trends for a) Disability Rating Index (DRI), b) EuroQol five-dimension three-level questionnaire (EQ-5D-3L), and c) EuroQol visual analogue scale (EQ VAS) scores during the main randomized clinical trial (RCT) and longer-term follow-up (LTFU) by RCT intervention group (nail and plate); plotted as means and 95% confidence intervals.

for revision/augmentation of fixation, and further hospital treatment categorized as 'other' (e.g. physiotherapy related to the fracture).

Statistical analysis. Baseline characteristics were compared between FixDT trial participants who consented to follow-up at five years and those who did not consent. Continuous outcomes

Table II. Results of reported complications during five-year follow-up. Dashes represent instances where the number of results gathered were too small (e.g. 0, 1, 2) to conduct meaningful analysis.

Variable, n (%)	Total (n = 170)	Nail (n = 83)	Plate (n = 87)	Odds ratio (95% CI)	p-value*
Metalwork removal	16 (5.0)	10 (6.2)	6 (3.8)	0.54 (0.15 to 1.74)	0.299
Bone healing surgery†	2 (0.6)	2 (1.2)	0 (0.0)	-	-
Additional metalwork	3 (0.9)	2 (1.2)	1 (0.6)	-	-
Other further treatment	24 (7.5)	13 (8.1)	11 (6.9)	0.78 (0.30 to 2.03)	0.662

*Fisher's exact test.
†i.e. further surgery for nonunion.
‡i.e. augmentation of the fixation.
CI, confidence interval.

(e.g. age, baseline DRI) were summarized by means and standard deviations (SDs) and independent-samples *t*-tests were used to compare the groups. Categorical outcomes were summarized using cross-tabulations with associations assessed using Fisher's exact tests.

To model temporal changes in outcomes (DRI, EQ-5D-3L, and EQ VAS) during LTFU, we used a mixed-effects linear regression analysis, with participant included as a random effect and fixed terms for baseline demographics (e.g. age, sex, mechanism of injury, smoking, diabetes, previous injury) and pre-injury score. The random effect for participants was included to model the natural clustering (correlation) in outcomes in the time course of measurements (two, three, four, and five years) for the individual participants. Temporal changes in outcome scores during follow-up were approximately linear (i.e. increasing or decreasing at a fixed rate) for DRI, EQ-5D-3L, and EQ VAS, so follow-up time was also included in the model. Interaction terms, between treatment groups ('nail' (intramedullary nail) and 'plate' (locking plate) fixation), were also tested in the model to assess whether the rate of change in outcome score was modified by the treatment group allocation. Model selection and testing was via F-tests from single term deletions,[14] with confidence intervals (CIs) for fixed-effects constructed by bootstrapping and z-tests for significance testing and p-values.

Complications were summarized based on the total numbers of participants reporting each event during the study, with odds ratios and Fisher's exact tests used to quantify associations between the numbers of events and the treatment groups. All tests were two-sided, and significance was assessed at the 5% level. All analyses used complete-case data and were implemented in the statistical package R (R Foundation for Statistical Computing, Austria), using packages lme4 and lmerTest.[14,15]

Results

Participants. Of the 170 participants in this follow-up study, 83 (48.8%) were from the nail group and 87 (51.2%) were from the plate group. Table I shows the baseline demographics of the participants who consented to provide LTFU data compared with the 321 original participants who provided data up to 12 months. Those participants who consented to take part in this five-year follow-up study were marginally older (p = 0.013, independent-samples *t*-test), with a mean age of 47.2 years (SD 15.9) compared to 42.7 (SD 16.4) in the group who declined to take part in the follow-up study. They also had marginally better baseline (pre-injury) DRI and EQ-5D-3L scores; difference in DRI -5.6 (95% CI -9.7 to -1.4; p = 0.008, independent-samples *t*-test); and EQ-5D-3L 0.072 (95% CI 0.024 to 0.121; p = 0.004, independent-samples *t*-test).

Patient-reported outcomes. Figure 1 shows a summary of changes in DRI, EQ-5D-3L, and EQ VAS scores during the five years of follow-up. There were limited three- and four-year data available for all the scores, as the study focused its efforts mainly on the more important (extreme) two- and five-year time-points, but all 170 participants provided at least one outcome score during the five-year follow-up.

The primary mixed-effects model for DRI showed no evidence that scores changed between two and five years (p = 0.502, F-test for goodness-of-fit) and that the type of fixation (nail vs locking plate) did not influence the longer-term outcome.

A secondary analysis, to look at early changes in DRI in the 170 participants as a whole, confirmed that there was no difference between 12- and 24-month scores for DRI (difference 3.3 (95% CI -1.8 to 8.5); p = 0.203, paired *t*-test). Similarly, there was no evidence from mixed-effects models that EQ-5D-3L (p = 0.181) and EQ VAS (p = 0.058) scores changed during the LTFU, or that the choice of fixation influenced these outcomes.

DRI, EQ-5D-3L, and EQ VAS scores during the five-year follow-up were, however, correlated with participant's pre-injury scores. For DRI, a participant's pre-injury DRI score (p < 0.001, z-test for mixed-effects model coefficient) and previous problems on the injured side (p = 0.037, z-test for mixed-effects model coefficient) were significantly associated with DRI scores during the five years of follow-up. This was a strong association. A one-point change in pre-injury DRI score changed the DRI score during five-year follow-up by 0.75 points (bootstrapped 95% CI 0.54 to 0.94), and a previous injury on the same side as the index fracture reduced the DRI score by 7.8 points (95% CI 0.7 to 15.2); i.e. pre-fracture problems with the injured leg had a strong influence on post-fracture outcome.

Health-related quality of life scores were also modelled in an equivalent manner to DRI, with models showing that EQ-5D-3L scores during five-year follow-up were higher when the pre-injury EQ-5D-3L scores were higher (p < 0.001), were lower for smokers (p = 0.029) and diabetic patients (p = 0.009), and increased as BMI scores decreased (p = 0.001). Also, EQ VAS scores during follow-up were higher when the pre-injury EQ VAS scores were higher (p < 0.001); none of the other demographic data were associated with EQ VAS during the five-year follow-up.

Pre-injury DRI scores (mean 10.0 (SD 18.7), n = 317) were statistically significantly (p < 0.001, paired *t*-test) lower than five-year DRI scores (mean 20.6 (SD 25.2); n = 104); estimated difference 12.2 (95% CI 8.2 to 16.2), for 103 participants with pre-injury and five-year scores.

A similar analysis for EQ-5D-3L indicated that pre-injury EQ-5D-3L scores (mean 0.874 (SD 0.222); n = 316) were statistically significantly ($p < 0.001$, paired *t*-test) lower than five-year EQ-5D-3L scores (mean 0.725 (SD 0.323); n = 104); estimated difference -0.173 (95% CI -0.226 to -0.120), for 103 participants with pre-injury and five-year scores. Also, pre-injury EQ VAS scores (mean 80.5 (SD 17.6); n = 305) were statistically significantly ($p < 0.001$, paired *t*-test) lower than five-year EQ VAS scores (mean 73.4 (SD 23.0); n = 105); estimated difference -7.5 (95% CI -11.2 to -3.7); for 103 participants with pre-injury and five-year scores. These analyses indicated that participants had not recovered to pre-injury function or quality of life at five years.

Complications. Overall numbers of complications were relatively small, and there was no evidence that the rate of complications differed between nail and plate fixation (Table II).

Discussion

The FixDT trial showed that intramedullary nail fixation provides faster recovery than locking plate fixation for patients in the first six months after a fracture of the distal tibia, but that there was little difference by 12 months. This follow-up study confirms the findings of the original report, showing no evidence of a difference in patient-reported disability between the treatments out to five years. There was also no evidence of a difference between the treatment groups in terms of health-related quality of life, or complications related to the fracture or its treatment.

Reviewing the overall outcomes of the 170 participants in this five-year follow-up study provides an insight into the recovery of patients with an extra-articular fracture of the distal tibia.[16] Unlike patients with intra-articular fractures or open fractures of the lower limb,[17,18] the recovery trajectory of extra-articular fracture patients reaches a plateau in the first 12 months, with no evidence of improvement in disability rating or health-related quality of life after 12 months from the fracture. Although patients do not return to their pre-injury status after these extra-articular injuries, the longer-term deficit is relatively modest compared with these other types of lower limb fracture; there was only a 12-point difference between pre-injury disability rating and disability rating at five years (0 to 100 point scale). A history of pre-fracture injury to the ipsilateral leg was the strongest predictor of poor outcomes in the longer term.

The strengths of this study include the reporting of patient-centred outcomes, as well as surgical complications, in a well-defined patient population with high rates of follow-up at five years. However, there are several limitations. The patients who consented to take part in this longer-term follow-up study were self-selected from the larger group of participants in the FixDT trial up to 12 months. Participants in this study were a mean 4.5 years older than patients who declined to join the longer-term follow-up. This reflects the findings in previous mid-term follow-up studies that older patients are more likely to agree to longer-term follow-up in studies of acute fractures than younger patients.[18,19] There was also a small but significant difference in the baseline pre-injury DRI reported by patients who agreed to participate in longer-term follow-up compared with those who did not agree. The mean DRI score was 5.6 points lower (indicating less pre-injury disability) in those who agreed to take part. Since the number of participants who consented to take part in this mid-term follow-up study was less than the number in the original one-year report, the confidence intervals around the difference between the interventions is higher, i.e. this study did not have the same statistical power to detect subtle differences in outcome as the original trial report.

In conclusion, this five-year follow-up study found no evidence of a difference in disability, quality of life, or complications between patients treated with intramedullary nail compared with locking plate fixation for patients with an extra-articular fracture of the distal tibia. This contrasts with the early phases of recovery, where patients treated with a tibial nail showed less disability and improved quality of life at three and six months. Compared with patients suffering intra-articular and open fractures of the lower limb, patients with this extra-articular fracture can expect good outcomes within 12 months of their injury, although not a complete return to their pre-injury status.

Take home message

- This five-year follow-up study found no evidence of a difference in disability, quality of life, or complications between patients treated with intramedullary nail compared with locking plate fixation for patients with an extra-articular fracture of the distal tibia.
- Compared with patients suffering intra-articular and open fractures of the lower limb, patients with this extra-articular fracture can expect good outcomes within 12 months of their injury, although not a complete return to their pre-injury status.

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Funding statement:
The authors disclose receipt of the following financial or material support for the research, authorship, and/or publication of this article: this project was funded by the NIHR HTA Programme (project number 11/136/04) and was supported by the NIHR Oxford Biomedical Research Centre. The views expressed in this article are those of the authors and not necessarily those of the NHS, the NIHR, or the UK Department of Health.

Data sharing:
The data that support the findings for this study are available to other researchers from the corresponding author upon reasonable request.

Acknowledgements:
Data and safety monitoring committee: Dawn Teare (chair); Richard Gibson; and Smitaa Patel.
Trial steering committee: James Mason, (chair); Simon Donell; Tim Chesser; Suzanne Jones Griffith.
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Susie Hennings, Nafisa Boota, and Mandy Maredza (University of Warwick); Melina Dritsaki (University of Oxford); Jonathan Young, Tom Wood and James Masters (University Hospital Coventry and Warwickshire); Alan Johnstone (Aberdeen Royal Infirmary); Andrew Carrothers (Addenbrookes Hospital); Mike McNicholas (Aintree University Hospital); Nigel Rossiter (Basingstoke and North Hampshire Hospital); Nikhil Kharwadkar and Anna Chapman (Heartlands Hospital); Tim White (Royal Infirmary of Edinburgh); James Murray (Frenchay Hospital); Mark Blyth (Glasgow Royal Infirmary); Shivkumar Gopal (Hull Royal Infirmary); Ian McMurtry (James Cook Hospital); David Noyes (John Radcliffe Hospital); Adel Tavakkolizadeh (Kings College Hospital); Peter Giannoudis (Leeds Teaching Hospital); Aradhyula Murty (North Tyneside General Hospital and Wansbeck General); Ben Ollivere (Nottingham University Hospitals); Mark Westwood (Derriford Hospital); Mark Farrar (Poole Hospital);Charlotte Lewis (Queen Alexandra Hospital); Andrew McAndrew (Royal Berkshire Hospital); Benedict Rogers (Royal Sussex County Hospital); Andrew Gray and Stephen Aldridge (Royal Victoria Infirmary); Paul Dixon (Sunderland Royal Hospital); Caroline Hing (St Georges Hospital); John Kendrew (University Hospitals of Birmingham); Ashwin Kulkarni (University Hospitals of Leicester); Gorav Datta (Southampton General Hospital); Kevin Smith (Royal Stoke University Hospital).

Ethical review statement:
This study was approves by UK NHS Research Ethics 12/WM/0340.

Open access funding:
The authors confirm that the open access fee for this article was funded by NIHR HTA 11/136/04.

Trial registration number:
ISRCTN99771224

This article was primary edited by M. Hossain and first proof-edited by G. Scott.