

Cost-effectiveness of intramedullary nail fixation versus locking plate fixation in treatment of adult patients with extra-articular distal tibia fractures

Sub-title: Economic evaluation based on the FixDT trial

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Abstract

Aim

To estimate the cost effectiveness of intramedullary nail fixation in comparison to 'locking' plate fixation for the treatment of extra-articular fractures of the distal tibia.

Methods

An economic evaluation, from the UK National Health Service (NHS) and personal social services (PSS) perspective, was conducted based on evidence from the Fixation of Distal Tibia Fractures (UK FixDT) multicentre, parallel trial. Data from 321 patients were available for analysis. Costs were collected prospectively over the 12-month follow-up period using trial case report forms and participant-completed questionnaires. Cost-effectiveness was reported in terms of incremental cost per quality adjusted life year (QALY) gained and net monetary-benefit. Sensitivity analyses were conducted to test robustness of the cost-effectiveness estimates.

Results

Mean NHS and PSS costs were significantly lower for patients treated with nail fixation over those treated with locking plate (-£970, 95% CI: -1685 to -256; $P=0.05$). There was a small increase in QALYs gained in the nail fixation group (0.01, 95% CI: -0.03 to 0.06; $P=0.56$). The probability of cost-effectiveness for nail fixation exceeded 90% at cost-effectiveness thresholds as low as £15,000 per additional QALY. The cost-effectiveness results remained robust to several sensitivity analyses.

Conclusions

This trial-based economic evaluation suggests that nail fixation is a cost-effective alternative to locking plate fixation.

Clinical Relevance of Paper

- The paper adds important evidence on the cost-effectiveness of alternative treatment options for extra-articular fractures of the distal tibia.

Introduction

Optimal management of extra-articular fractures of the distal tibia remains disputed. Although plates and intramedullary (IM) nails represent two viable approaches to internal fixation of these fractures, each possesses distinct disadvantages. The bolts or screws that are inserted into the nail may break, mal-alignment of the bone may occur, and there is an increased risk of anterior knee pain ^[1]. Whilst tibial plating with 'locking' plates can achieve accurate reduction, the need for greater soft tissue dissection increases the risk of infection, wound breakdown and damage to the surrounding structures ^[1, 2].

Evidence from previous meta-analyses and systematic reviews comparing nailing versus plating treatment modalities have been inconclusive. Mao *et al* reviewed 1863 extra-articular fractures of the distal tibia ^[3]. They reported that rates of deep infection, delayed union and removal of instrumentation were similar for patients undergoing nail and plate fixation, but nail fixation was associated with significantly more mal-unions. In contrast, Zelle *et al* found that mal-union rates were similar between the two treatment groups ^[4]. However, the studies included in the meta-analyses had heterogeneous study designs and the randomised controlled trials lacked methodologic rigour ^[3].

The prolonged recovery and rehabilitation following a distal tibia fracture, along with complications associated with treatment choice, have important economic consequences. These injuries not only generate direct treatment costs but indirect costs, including income losses due to work absences. Given rapidly escalating health care costs, and the need to allocate finite health care resources more efficiently, the costs associated with nail and locking plate fixation should be considered alongside the clinical benefits. Data comparing the clinical and cost-effectiveness of intramedullary nail and locking plate management of distal tibial fractures are currently limited. Available data are based on assessments of intramedullary nails alone ^[5], different plates for fixation alone ^[6], or compare nail fixation with interventions other than locking plates.

We present a prospectively-conducted health economic evaluation from a multi-centre randomised controlled trial of intramedullary nail fixation versus locking plate fixation for the treatment of adult patients with a displaced fracture of the distal tibia.

Patients and methods

Trial background

Data from the Fixation of Distal Tibia Fractures (UK FixDT) trial formed the basis of the economic evaluation ^[7]. Briefly, patients were eligible for the trial if: (i) they had a fracture that involved the distal tibial metaphysis; (ii) were aged 16 years or over; and (iii) the treating surgeon believed that they would benefit from internal fixation of the fracture. Participants were recruited from 28 UK Trauma Hospitals between April 2013 and February 2016 and followed-up for one year. They were randomly allocated to either intramedullary nail fixation or locking-plate fixation. All surgery was performed according to the preferred technique of the operating surgeon. A sample size of 320 was required to detect, with 90% power at the 5% level, a difference of 8 points in the primary clinical outcome, namely the disability rating index (DRI). Full details of the trial protocol are available in open access ^[1], and the clinical results are presented elsewhere ^[7].

Study Perspective and Time Horizon

The primary analysis was undertaken from the perspective of the UK National Health Service (NHS) and Personal Social Services (PSS) as recommended by the National Institute of Health and Care Excellence (NICE) ^[8]. The time horizon for the economic evaluation followed the 12-month follow-up period of the trial, and therefore no discounting of costs and benefits was required.

Measurement and valuation of resource use

Estimation of the costs associated with the interventions included the cost of the initial surgery and the broader health and PSS resource inputs, plus, for the

purposes of a sensitivity analysis, personal costs and broader societal resource inputs. All costs were expressed in £ sterling and valued in 2014-15 prices. Where appropriate, costs were inflated or deflated to 2014-15 prices using the NHS Hospital and Community Health Services Pay and Prices Index [9].

Cost of distal tibia fixation

The initial surgical costs (intervention costs) were based on the initial hospital stay and associated operative costs as reported in table I. Unit costs were estimated using NHS reference costs, and the Healthcare Resource Groups (HRG) tariff for 'major knee procedures for trauma'[10]. Based on this tariff, distal tibia fixation costs the NHS £5315.47 if a patient stays in hospital an average of 5 days. Costs of the initial surgery were derived for each patient using the mean length of stay reported in the patient records. An excess bed day value of £327.00 was used to adjust the surgery costs of patients who stayed in hospital longer than 5 days. We assumed that treatment costs were disproportionately weighted towards the first 3 days of each initial hospital admission. Thus, the cost to the NHS of a patient who stayed in hospital for 3 days was calculated as £5315.47 – (2x£327), i.e. the 5-day tariff minus the bed day cost of £327 per each day not spent in hospital. The numbers of implants used during the surgery were derived from patient records. Unit costs for these implants were provided by the University Hospitals of Coventry and Warwickshire NHS trust finance department.

****Table I****

Broader resource use

Broader resource use over the 12-month follow-up period was captured via follow-up postal questionnaires, which were completed at 3-, 6- and 12-months post-randomisation. For the 3-month data, the recall period was since hospital discharge whilst at other time points, it was since completion of the previous questionnaire. The questionnaires captured the number, duration and type of hospital re-admissions following initial surgery, number and type of hospital outpatient visits and diagnostic tests, number and type of community health and social services, and the use of

medications, aids and adaptations. Furthermore, respondents provided information on direct non-medical costs (including travel expenses) incurred by themselves and their caregivers, and reported number of days off work and gross loss of earnings, attributable to their health state or contacts with care providers. Resource use values were converted into costs by applying unit costs obtained from national databases such as the Department of Health's National Schedule of Reference Costs ^[10], the PSSRU Unit Costs of Health and Social Care compendium,^[11] and the British National Formulary (BNF) ^[12]. Table II summarises the unit cost values and data sources for broader resource inputs.

****Table II****

Measurement and valuation of health outcomes

In line with the NICE reference case, the primary health outcome for the economic evaluation was the quality-adjusted-life-year (QALY) ^[8], which combines impacts on both health-related quality of life (HRQoL) and length of life ^[13]. HRQoL was assessed using the EQ-5D-3L questionnaire (EQ-5D for brevity) ^[14] at baseline and at 3, 6 and 12 months post-randomisation. The EQ-5D comprises five dimensions: 'mobility', 'self-care', 'usual activities', 'pain/discomfort' and 'anxiety/depression'. Responses in each dimension have 3 levels: (1) no problems; (2) moderate problems; and (3) extreme problems. EQ-5D health states can be converted into a single summary index by applying a utility algorithm, which attaches values to each permutation of responses to the EQ-5D descriptive system. We applied utility values for EQ-5D health states elicited from a general population sample in the UK using the time-trade-off method ^[15]. Utility values generated through this method range from -0.59 to 1.0; where 0 represents death, 1.0 represents full health and values below 0 indicate health states worse than death. QALY values for each patient were estimated by calculating the area under the baseline-adjusted utility curve, and were calculated using linear interpolation between baseline and follow-up utility scores.

Missing data

For the baseline analysis, multiple imputation under chained equations (MICE) ^[16] was used to model missingness for those cases where resource use or HRQoL data were unavailable, based on the tested assumption that data were missing at random. Regression models were used to impute unobserved costs and QALYs at each time point, and by treatment allocation, using age and gender as explanatory variables. Costs and EQ-5D utility scores at each time point contributed as both explanatory and imputed variables. The imputation was run 50 times following the rule of thumb that the number of imputations should be similar to the percentage of incomplete cases^[16]. Fifty datasets were generated using predictive mean matching. Each imputed data set produced was independently analysed with bivariate regressions using a seemingly unrelated regression model to estimate the costs and QALYs in each treatment group over the 12-month trial horizon. Estimates from each imputed dataset were combined using Rubin's rule to generate overall mean costs and QALY estimates and their standard errors ^[17].

Analyses of resource use, costs and outcome data

Resource use items were summarised by treatment group and follow-up period and differences between groups were analysed using t-tests for continuous variables and chi-squared tests for categorical variables. Means and standard errors (SEs) for values of each cost category were estimated by treatment allocation and follow-up period and statistical differences in mean costs by treatment allocation were assessed using t-tests. Mean total costs by treatment allocation and follow-up period were also estimated. Statistically significant differences in the mean total costs were assessed using non-parametric bootstrapping, based on 10,000 replications.

For each of the five dimensions of the EQ-5D, we calculated the proportion of patients reporting sub-optimal function (moderate or extreme problems) and assessed differences between groups using chi-squared tests.

Cost-effectiveness analysis

Cost-effectiveness results were expressed in terms of an incremental cost-effectiveness ratio (ICER) and calculated by dividing the difference between treatments in mean total costs by the mean difference in total QALYs. The ICER represents the additional cost required to gain a QALY and in our case indicates whether investing additional resources on a particular type of fixation is cost-effective. As a general rule, NICE considers interventions costing the NHS less than £20,000 per QALY gained cost-effective ^[18]. To determine the level of sampling uncertainty around the ICER, we conducted non-parametric bootstrapping, generating 50,000 estimates of incremental costs and benefits ^[19]. The bootstrap replicates from the non-parametric bootstrapping were used to populate cost-effectiveness scatterplots. We calculated the net-monetary benefit (NMB) of using nail fixation versus locking plate fixation across three cost-effectiveness thresholds: £15,000 per QALY, £20,000 per QALY and £30,000 per QALY ^[20]. A positive incremental NMB indicates that the intervention is cost-effective compared with the alternative at the given cost-effectiveness threshold. Furthermore, cost-effectiveness acceptability curves (CEACs) were generated based on the proportion of bootstrap replicates with positive incremental net benefits. The CEACs indicate the probability that nail fixation is cost-effective relative to locking plate fixation across a range of cost-effectiveness thresholds.

Sensitivity and sub-group analyses

Several sensitivity analyses were undertaken to assess the impact of parameters with a degree of uncertainty on cost-effectiveness outcomes. These included: 1) restricting the analyses to complete cases (i.e. those with complete cost and outcome data over the 12-month follow-up period); 2) adopting a wider societal perspective that included private costs incurred by trial participants and their families, productivity losses and loss of earnings due to work absences; 3) estimating the cost-effectiveness under a per-treatment analysis; and 4) additionally adjusting the baseline analysis for pre-injury HRQoL, which was assessed using the EQ-5D at baseline.

Sub-group analyses were also conducted for the main cost-effectiveness results to explore heterogeneity in the trial population. These were conducted by: (i) age group (<50 and ≥50 years) and (ii) gender (male, female).

Results

Between April 2013 and February 2016, 321 patients were recruited and randomised (nail fixation = 161; locking plate = 160). Three patients did not complete the baseline questionnaires. A total of 276 patients completed the 3-month questionnaire whilst 284 and 258 patients returned questionnaires at the 6- and 12-month follow-up time points, respectively. Overall, the follow-up rate was greater than 80% at all time-points. Table III shows the volume of missing health economic data by treatment allocation and follow-up time point. The missing data pattern was non-monotonic since several individuals with missing data at one follow-up time point completed subsequent questionnaires.

****Table III****

Resource use

Resource use was generally higher for participants allocated to the locking plate group compared to those allocated to nail group, but this was not always statistically significant (Table A1; Appendix). The exceptions, which showed statistically significant differences, were the mean total inpatient stay between 3-6 months (0 (nail) vs. 0.11 (locking plate) days), and mean total outpatient care contacts between 3-6 months (3.64 vs. 4.78 contacts). The differences in outpatient care appear to be driven by increased physiotherapy contacts in the locking plate group (1.84 vs. 2.53 visits).

Costs

The mean intervention costs from admission until discharge were £5460 for nail fixation compared to £5600 for locking plate fixation; the mean difference of £140

(CI: -684.24 to 262.61; $P=0.19$) (table IV) The mean length of the initial hospital stay was 3.87 days (SE 0.34) for nail fixation vs. 3.85 days (SE 0.33) for locking plate fixation. The mean total NHS and PSS cost throughout the first 6 months post-randomisation was £5876 for nail fixation and £6814 for locking plate fixation; the mean cost difference of £939 was statistically significant at the 5% significance level ($P=0.04$). The mean total NHS and PSS cost for the entire 12-month follow-up period was £6107 for nail fixation and £7102 for locking plate fixation; the mean cost difference of £995 was statistically significant at the 10% significance level ($P=0.05$). Productivity losses to employers through sickness absences appeared higher in the locking plate arm, and the difference for the entire follow-up period was statistically significant at the 10% level. Overall societal costs, for the entire follow-up period, were on average £3396 higher in the locking plate group; this cost difference was statistically significant at the 5% level ($P=0.01$) (table V)

****Table IV****

****Table V****

Health-related quality of life outcomes

Table A2 (Appendix) summarises the number and proportion of reported problems for each level for each dimension of the EQ-5D. The proportion of trial participants reporting suboptimal function is also indicated for each dimension and the difference between the two treatment arms shown using p-values. With the exception of mobility at 3 months (81% nail vs. 89% locking plate), which was statistically significant at the 10% significance level, there were no significant differences in the proportions of individuals reporting sub-optimal function within dimensions between the two arms at each time point.

The EQ-5D utility scores pre-injury, post-injury (baseline) and at 3-, 6- and 12 months post-randomisation are shown in table VI and figure 1. Both groups showed improvement in HRQoL from baseline to the last follow-up point. The most notable difference was observed at 6 months post-randomisation with a higher utility value observed for the nail fixation group ($P=0.03$).

The mean total QALYs (imputed) over the 12 months for IM nail and locking plate fixation were 0.55 and 0.54 respectively, but the difference was not statistically significant (0.01 QALYs, 95% CI: -0.03 to 0.06; $P=0.56$).

****Table VI****

****Figure 1****

Cost-effectiveness analysis

The baseline economic evaluation, using imputed attributable costs and QALYs and covariate adjustment, indicated that intramedullary nail fixation was associated with significantly lower mean NHS and PSS costs (-£970 (95% CI: -1685 to -256) and a non-statistically significant increase in QALYs (0.01 QALYs, 95% CI: -0.03 to 0.06) over the entire 12-month follow-up period (table VII). Uncertainty surrounding the ICER estimates are represented graphically in the cost-effectiveness plane (figure 2), which shows that most simulated ICER values fall in the south-east quadrant, indicating that nail fixation is on average less costly and more effective (produced more QALYs). The probability of cost-effectiveness given the uncertainty surrounding the mean ICER value is visually displayed in the CEAC. The probability that nail fixation is cost-effective ranged between 94-98% across cost-effectiveness thresholds of £15,000-£30,000 per QALY (table VII; figure 3). The net-monetary benefit for IM nail, for the base case, was positive (incremental NMB values >£1200).

****Table VII****

****Figure 2****

****Figure 3****

Sensitivity and sub-group analyses

Most of the sensitivity analyses undertaken (complete case, societal perspective, and imputed attributable costs and QALYs additionally controlled for pre-injury utility) supported the base case finding (table VII). However, the per-treatment analysis showed a slightly different pattern for QALY outcomes. The results for that analysis indicated that participants in the nail fixation arm, on average, experienced slightly worse HRQoL outcomes. However, the result was not statistically significant.

Moreover, the cost difference remained in the same direction as that for the base case analysis. The results of the sub-group analyses indicate that in the sample of patients below the age of 50, nail fixation was the dominant intervention; it lowered costs and moderately increased QALYs on average (table VII). In patients over the age of 50 years, nail fixation was associated with lower costs and lower benefits compared to locking plate fixation. However, the 95% confidence intervals for both the costs and QALY estimates suggest considerable uncertainty surrounding the effects of intramedullary nail fixation for this older group of patients.

Discussion and Conclusion

This study shows that nail fixation ‘dominates’ locking plate fixation in health economic terms. This conclusion is driven by the finding that there was a modest QALY gain in the nail group over the 12-month time horizon of the trial and costs were significantly lower in the nail group. In addition, there was a high probability that nail fixation is cost-effective across cost-effectiveness thresholds recommended by decision-makers, a finding that remained robust to several sensitivity analyses.

To our knowledge, this is the first trial-based economic evaluation to compare the cost-effectiveness of these two surgical procedures for the treatment of distal tibia fractures. Previous studies have compared two types of intramedullary nails (reamed vs. unreamed) in treating closed and open tibia fractures; however, they did not compare intramedullary nails to other interventions ^[5]. Busse and colleagues reported costs associated with treatment of low-energy tibial fractures with either casting, casting with therapeutic ultrasound, or intramedullary nailing (with and without reaming) by use of a decision tree model ^[21]. The results of that analysis indicated that intramedullary nailing was the treatment of choice for closed and open grade I tibial shaft fractures; however, impact on HRQoL was not assessed. Kao et al conducted a cost-effectiveness analysis comparing conventional buttress or dynamic compression plates and locking plates for treating displaced distal tibial fractures, but did not conduct a comparative assessment with intramedullary nails ^[6].

Strengths of the current economic evaluation include data collected from a prospective randomised trial with frequent assessments over a 12-month follow-up period and minimal loss to follow-up. This enabled a trial-based economic evaluation that was rigorous, with effectiveness and cost measures (including indirect patient-reported costs) collected prospectively, and the direct measurement of utility scores from our study participants to calculate QALYs [22]. Furthermore, the economic evaluation was conducted according to nationally agreed design and reporting guidelines [23].

Limitations of this trial-based economic analysis include that long-term cost-effectiveness beyond the 12-month follow-up period was not assessed. However, preliminary analysis of the HRQoL outcomes of the trial participants using extended follow-up data for this trial indicates that EQ-5D utility scores for the nail fixation and locking plate groups remain similar at 24 months post-randomisation (extended follow-up data will be reported in due course). The indication, therefore, is that the benefits of nail fixation are very likely to be concentrated in the first year that follows the treatment of displaced, extra-articular fractures of the distal tibia. Furthermore, our systematic search for external studies that compared plate and nail fixation did not find any good quality evidence on differences in functional outcomes and HRQoL beyond 12 months post-surgery. The available studies were either based on short follow-up periods,^[24] small sample sizes,^[2,25,26] non-randomised studies that relied on retrospective reviews or case series which tend to suffer from selection biases,^[2, 27] or a combination of these factors. A second potential limitation is that we used NHS tariffs to estimate total cost of the surgical treatment, which some have argued do not fully capture the cost of orthopaedic procedures and may not take into account varying operating theatre times^[28, 29]. However, in our case, it is unlikely that a different costing approach would have shifted results in favour of the locking plate as the mean operating theatre times were the same (124mins) for both procedures and the cost of implants represented a relatively minor component of total costs.

In conclusion, our study provides a comprehensive assessment of the cost-effectiveness of two commonly undertaken treatments for distal tibia fractures with obvious implications for the orthopaedic community. Notwithstanding the limitations

of within-trial analyses, this study provides robust evidence that over the first year that follows surgery, nail fixation is a cost saving intervention without detriment to health-related quality of life outcomes. Given these results, there is economic justification for recommending nail over locking plate fixation for the management of extra-articular distal tibia fractures.

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Table I: Unit costs (£,2014-15 prices) associated with initial operative procedures and initial hospital stay for intramedullary nail and locking plate fixation

| Item | Unit Cost | Source |
|---|------------|---|
| Surgery Costs¹ | | |
| Average surgery cost of distal tibia fracture fixation (based on mean length of stay of 5 days ²) | £ 5,315.47 | National schedules of Reference Costs year 2014-15 - 'Major Knee Procedures for Trauma, 19 years and over, with CC Score 0'- HT23D ^[10] |
| Cost per excess bed day | £ 327.00 | National schedules of Reference Costs year 2014-15 - 'Major Knee Procedures for Trauma, 19 years and over, with CC Score 0'- HT23D ^[10] |
| Implants: Intramedullary nail fixation | | |
| Guide wire 3.2x300 | £43.11 | UHCW ³ |
| Reaming rod 2.5x1000 | £63.47 | UHCW |
| Distal bolts | £45.88 | UHCW |
| End cap | £37.93 | UHCW |
| Blocking Screw | £29.80 | UHCW |
| Nail | £265.53 | UHCW |

¹HRG Code for distal tibia fracture fixation is similar for both intramedullary and locking plate fixation

² Surgery cost from NHS Reference Costs is based on assumed mean length of stay of 5 days for this category of patients; adjustments were made for all patients who stayed in hospital for a period less than 5 days; detailed methodology explained in-text.

³ UHCW denotes University Hospitals Coventry and Warwick NHS Trust Finance Department

Table II: Summary of unit cost values (£, 2014-15 prices) and data sources

| Resource item | Unit cost | Unit of analysis | Source of unit cost |
|---|-----------|--|---|
| Subsequent inpatient care | | | |
| <i>Orthopaedics (your leg)</i> | | | |
| Cost per average LoS ⁴ of 1 day | £1,780.34 | per procedure | NHS Reference Costs 2014-2015, 'Minor Knee Procedures for Non-Trauma, 19 years and over' - HN25A ^[10] |
| Day Case | £1,349.10 | per procedure | |
| <i>Orthopaedics (any other bones)</i> | | | |
| Cost per average LoS of 4 days | £2,648.56 | per procedure | NHS Reference Costs 2014-2015, 'Other Muscle, Tendon, Fascia or Ligament Procedures' - HN93Z ^[10] |
| Day Case | £965.19 | | |
| Adjustment per day \pm avg. LoS (excess bed days) | £278.52 | per day | NHS Reference Costs 2014-2015, 'Other Muscle, Tendon, Fascia or Ligament Procedures' - HN93Z ^[10] |
| <i>Other Inpatient</i> | | | |
| Rehabilitation Unit | £335.00 | per session | NHS Reference Costs 2013-2014, 'Rehabilitation for other trauma', V636Z ^[30] |
| Outpatient Care | | | |
| Orthopaedics | £112.50 | per session | Reference Costs 2014-2015 ^[10] |
| Blood tests/ Phlebotomy | £3.00 | per test | Reference Costs 2014-2015 ^[10] |
| X-rays | £30.23 | per test | Reference Costs 2014-2015 ^[10] |
| MRI scan | £146.00 | per test | Reference Costs 2014-2015 ^[10] |
| CT scan | £111.00 | per test | Reference Costs 2014-2015 ^[10] |
| Hospital Physiotherapist (NHS) | £38.00 | per session | PSSRU 2015 pg.217 ^[11] |
| Physiotherapist (private) | £70.00 | per hour | http://www.thephysiocentre.co.uk/how_much/ |
| Emergency department (orthopaedics & trauma) | £112.50 | per session | Reference Costs 2014-2015 ^[10] |
| Emergency department other | £140.59 | | Reference Costs 2014-2015 ^[10] |
| Primary and community care | | | |
| General Practitioner surgery consultation | £225.00 | per hour | PSSRU 2015 pg. 178 ^[11] |
| General Practitioner home visit | £5.20 | per home visit | PSSRU 2010 pg. 167 ^[31] |
| General Practitioner phone call | £27.00 | per telephone consultation lasting 7.1 minutes | PSSRU 2015 pg. 178 ^[11] |
| Practice nurse | £56.00 | per hour of face-to-face contact | PSSRU 2015 pg. 174 ^[11] |

⁴ LoS denotes length of stay

| Resource item | Unit cost | Unit of analysis | Source of unit cost |
|---|-----------|----------------------------------|--|
| District nurse | £67.00 | per hour of patient related work | PSSRU 2015 pg. 169 ^[11] |
| Community Physiotherapist | £36.00 | per hour of consultation | PSSRU 2015 pg. 179 ^[11] |
| Occupational therapist | £44.00 | per hour | PSSRU 2015 pg. 191 ^[11] |
| Personal Social Services | | | |
| Meals on wheels (frozen, daily) | £46.00 | per weekly meal | PSSRU 2014 pg. 127 ^[32] |
| Meals on wheels (hot, daily) | £44.00 | per weekly meal | PSSRU 2014 pg. 127 ^[32] |
| Laundry services | £4.55 | per load | North Yorkshire Country Council http://www.northyorks.gov.uk/article/23988/Paying-for-social-care-services-in-the-community |
| Social worker contacts | £42.00 | per hour | PSSRU 2015 pg. 95 ^[11] |
| Care worker contacts including help at home | £24.00 | per hour | PSSRU 2015 pg. 192 ^[11] |
| Aids and Adaptations | | | |
| Crutches | £5.06 | per unit | NHS supplies catalogue 2015/16 ^[33] |
| Stick | £3.94 | per unit | NHS supplies catalogue 2015/16 ^[33] |
| Zimmer frame | £35.99 | per unit | NHS supplies catalogue 2015/16 ^[33] |
| Grab Rail | £1.61 | per unit | NHS supplies catalogue 2015/16 ^[33] |
| Dressing aids | £1.66 | per unit | NHS supplies catalogue 2015/16 ^[33] |
| Long handle shoe horn | £1.66 | per unit | NHS supplies catalogue 2015/16 ^[33] |
| Productivity losses | | | |
| Median wage rate (full-time males) | £567.00 | per week | Annual survey of hours and earnings (ASHE, 2015) ^[34] |
| Median wage rate (full-time females) | £471.00 | per week | ASHE, 2015 ^[34] |
| Median wage rate (part-time males) | £156.00 | per week | ASHE, 2015 ^[34] |
| Median wage rate (part-time females) | £171.00 | per week | ASHE, 2015 ^[34] |
| Median earnings (self-employed) | £10800.00 | per year | https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/500317/self-employed-income.pdf |

Table III Number and proportion of individuals with missing health economic data by treatment allocation

| Variable | Description | Missing values: N (%) | | |
|----------|---|-----------------------|-----------------------|-----------|
| | | Nail (N=158) | Locking Plate (N=160) | Total |
| eq5db | EQ-5D index score pre-injury | 1 (1%) | 1 (1%) | 2 (1%) |
| eq5d0 | EQ-5D index score post-injury | 2 (1%) | 3 (2%) | 5 (2%) |
| eq5d1 | EQ-5D at 3 months | 23 (15%) | 19 (12%) | 42 (13%) |
| eq5d2 | EQ-5D at 6 months | 16 (10%) | 18 (11%) | 34 (11%) |
| eq5d3 | EQ-5D at 12 months | 43 (27%) | 42 (26%) | 85 (27%) |
| c0 | Operative costs (surgery cost including initial hospital stay + implants) | 0 (0%) | 0 (0%) | 0 (0%) |
| c1 | Total resource use baseline - 3 months | 54 (34%) | 54 (34%) | 108 (34%) |
| c2 | Total resource use between 3- 6 months | 30 (19%) | 31 (19%) | 61 (19%) |
| c3 | Total resource use between 6- 12 months | 60 (38%) | 58 (36%) | 118 (37%) |
| c4 | Total resource use between 0- 6 months | 67 (42%) | 62 (39%) | 129 (41%) |
| c5 | Total resource use between 0- 12 months | 88 (56%) | 82 (51%) | 170 (54%) |

Table IV NHS and personal social service costs for cases with complete data by trial allocation, study period and cost category (£, 2014-15 prices)

| Cost category by period | Nail Mean (SE) Cost | Locking Plate Mean (SE) Cost | Mean Difference | P Value ^a | Bootstrap 95% CI ^b |
|---|-------------------------|------------------------------|-----------------|----------------------|-------------------------------|
| 0-6months (n = 189 total; n= 91 IM; N=98 LP) | | | | | |
| Initial operation cost | 5460.04 (137.92) | 5600.11 (137.92) | -140.07 | 0.19 | (-684.24 to 262.61) |
| Subsequent inpatient care | 40.73 (29.35) | 313.14 (187.55) | -272.41 | 0.08 | (-648.97 to 104.13) |
| Outpatient care | 218.66 (11.46) | 249.01 (19.49) | -30.35 | 0.09 | (-75.00 to 14.31) |
| Community care | 106.91 (28.42) | 601.69 (371.42) | -494.78 | 0.10 | (-1233.98 to 244.42) |
| Medications | 37.73 (10.18) | 38.83 (14.28) | -1.11 | 0.47 | (-35.73 to 33.52) |
| Personal social services | 0.52 (0.52) | 0.98 (0.59) | -0.46 | 0.28 | (-2.02 to 1.10) |
| Aids and adaptations | 10.97 (2.30) | 10.45 (1.61) | 0.52 | 0.58 | (-5.02 to 6.06) |
| Total costs throughout first 6 months | 5875.56 (124.85) | 6814.22 (425.71) | -938.66 | 0.04* | (-1795.46 to -83.62) |
| 0-12months (n = 160 total; n= 70 IM; N=78 LP) | | | | | |
| Initial operation costs | 5428.47 (112.00) | 5528.72 (114.25) | -100.26 | 0.53 | (-671.23 to 298.66) |
| Subsequent inpatient care | 234.91 (92.68) | 596.25(237.18) | -361.34 | 0.16 | (-848.35 to 211.12) |
| Outpatient care | 268.94 (16.90) | 299.14 (26.25) | -30.20 | 0.34 | (-100.29 to 27.88) |
| Community care | 107.09 (23.30) | 588.22 (410.64) | -481.13 | 0.25 | (-1401.81 to 361.51) |
| Medications | 58.14 (19.60) | 78.45(35.95) | -20.31 | 0.62 | (-111.91 to 62.76) |
| Personal social services | 0.32 (0.32) | 0.91 (0.64) | -0.59 | 0.40 | (-2.16 to 0.88) |
| Aids and adaptations | 9.45 (2.08) | 10.77 (1.89) | -1.28 | 0.65 | (-7.90 to 2.03) |
| Total costs throughout first 12 months | 6107.32 (158.56) | 7102.46 (485.18) | -995.14 | 0.05 | (-2069.63 to -74.93) |
| ^a P value calculated using student t-test, 2 tail unequal variance | | | | | |
| ^b Non-parametric bootstrap estimation using 1,000 replications | | | | | |

Table V: Societal costs related to distal fracture fixation for cases with complete data by treatment arm (£, 2014-15)

| Cost category by period | Nail Mean (SE) Cost | Locking Plate Mean (SE) Cost | Mean Difference | P Value ^a |
|---|----------------------------|-------------------------------------|------------------------|-----------------------------|
| Follow up-period: 0 – 6 month | | | | |
| NHS and PSS costs | 5875.56 (124.85) | 6814.22 (425.71) | -938.66 | 0.04 |
| Private costs | 16.36 (8.02) | 12.46 (3.74) | 3.90 | 0.65 |
| Cost of lost productivity | 3901.13 (759.48) | 5351.80 (814.56) | -1450.67 | 0.20 |
| Societal costs | 9793.05 (761.66) | 12178.48 (1003.33) | -2385.43 | 0.07 |
| Follow-up period: 0 – 12 months | | | | |
| NHS resource use costs | 6107.32 (158.56) | 7102.46 (485.18) | -995.14 | 0.05 |
| Private costs | 49.52 (35.72) | 24.65 (7.80) | 24.87 | 0.48 |
| Cost of lost productivity | 3333.28 (649.45) | 5758.62 (1032) | -2425.34 | 0.05 |
| Societal costs | 9490.12 (658.07) | 12885.73 (1174.33) | -3395.61 | 0.01 |
| ^a P value calculated using student t-test, 2 tail unequal variance | | | | |

Table VI Mean EQ-5D index scores at the baseline and follow-ups: nail vs. locking plate for distal tibia fixation

| | Intramedullary Nail | | Locking Plate | | Difference (95%CI) | | |
|--|---------------------|-----|----------------|-----|--------------------|----------------------------|---------|
| Time point | Mean (SD) | n | Mean (SD) | n | Raw | Adjusted* | p-value |
| Post-injury | -0.003 (0.334) | 158 | -0.024 (0.311) | 156 | -0.021 | -0.030 (-0.09 to 0.03) | 0.331 |
| 3 months | 0.546 (0.273) | 134 | 0.499 (0.302) | 142 | -0.047 | -0.058 (-0.12 to 0.00) | 0.067 |
| 6 months | 0.670 (0.265) | 143 | 0.622 (0.275) | 141 | -0.048 | -0.064 (-0.12 to -0.01) | 0.029 |
| 12 months | 0.722 (0.278) | 128 | 0.731 (0.246) | 130 | 0.009 | -0.018 (-0.07 to 0.05) | 0.525 |
| *Mixed effects regression model based on intention to treat analysis approach. Fixed effects were allocated treatment group, age group, baseline pre-injury score and gender, and recruiting site was a random effect. | | | | | | | |

Table VII: Cost-effectiveness, cost/QALY (£, 2015): intramedullary nail fixation compared to locking plate fixation

| | Incremental cost (95% CI) | Incremental QALYs (95% CI) | ICER * | Probability of cost- effectiveness | | | Net monetary benefits | | |
|---|------------------------------|-------------------------------|---------------------------------|---------------------------------------|----------------|----------------|---------------------------|---------------------------|---------------------------|
| | | | | P ¹ | P ² | P ³ | NMB ¹ (95% CI) | NMB ² (95% CI) | NMB ³ (95% CI) |
| Base Case | | | | | | | | | |
| Imputed attributable costs and QALYs, covariate adjusted | -970 (-1685 to -256) | 0.01 (-0.03 to 0.06) | Dominant | 0.98 | 0.97 | 0.94 | 1204 (43 to 2465) | 1273 (-82 to 2689) | 1410 (-385 to 3190) |
| Sensitivity analyses | | | | | | | | | |
| Complete case attributable costs and QALYs, covariate adjusted | -1791 (-3986 to -225) | 0.04 (-0.02 to 0.09) | Dominant | 0.99 | 0.98 | 0.98 | 1429 (146 to 2818) | 1558 (118 to 3069) | 1818 (36 to 3626) |
| Societal perspective | -2230 (-4626 to 167) | 0.014 (-0.03 to 0.06) | Dominant | 0.97 | 0.97 | 0.96 | 2423 (-26 to 5173) | 2493 (-93 to 5337) | 2626 (-270 to 5706) |
| Per treatment analysis – imputed attributable costs and QALYs, covariate adjusted | -875 (-1725 to -26) | -0.01 (-0.06 to 0.04) | 172857 (south-west quadrant) | 0.92 | 0.88 | 0.81 | 923 (-347 to 2353) | 909 (-570 to 2508) | 872 (-1032 to 2861) |
| Imputed attributable costs and QALYs, additionally controlling for pre-injury utility | -1188 (-2266 to -110) | 0.02 (-0.02 to 0.06) | Dominant | 0.99 | 0.99 | 0.98 | 1518 (212 to 2940) | 1633 (180 to 3194) | 1862 (66 to 3738) |
| Subgroup analyses | | | | | | | | | |
| Base Case: age <50 | -1468 (-3547 to -291) | 0.08 (0 to 0.17) | Dominant | 0.99 | 0.98 | 0.98 | 1730 (207 to 3320) | 1953 (166 to 3804) | 2402 (55 to 4830) |
| Base case: age ≥50 | -821 (-2760 to 1110) | -0.022 (-0.09 to 0.05) | 60000 (south-west quadrant) | 0.71 | 0.67 | 0.62 | 709 (-1960 to 3480) | 630 (-2320 to 3610) | 473 (-3065 to 3930) |
| Base Case: males | -1651 (-5042 to -682) | 0.05 (-0.07 to 0.17) | Dominant | 0.71 | 0.68 | 0.62 | 745 (-1945 to 3612) | 670 (-2305 to 3741) | 520 (-3043 to 4075) |
| Base Case: females | -1193 (-5243 to 102) | 0.02 (-0.05 to 0.10) | Dominant | 0.71 | 0.68 | 0.62 | 746 (-1950 to 3643) | 673 (-2307 to 3781) | 529 (-3049 to 4157) |
| *ICER: Incremental cost-effectiveness ratio; dominance indicates average costs were less and average benefit greater for intramedullary nail vs. locking plate fixation P ¹ , P ² , P ³ : probability cost-effective if willing to pay £15,000/QALY, £20,000/QALY or £30,000/QALY, respectively | | | | | | | | | |

NMB¹, NMB², NMB³: net monetary benefit if willing to pay £15,000/QALY, £20,000/QALY or £30,000/QALY, respectively

Figure 1 Overall trend in EQ-5D utility score means and 95% confidence intervals by treatment arm

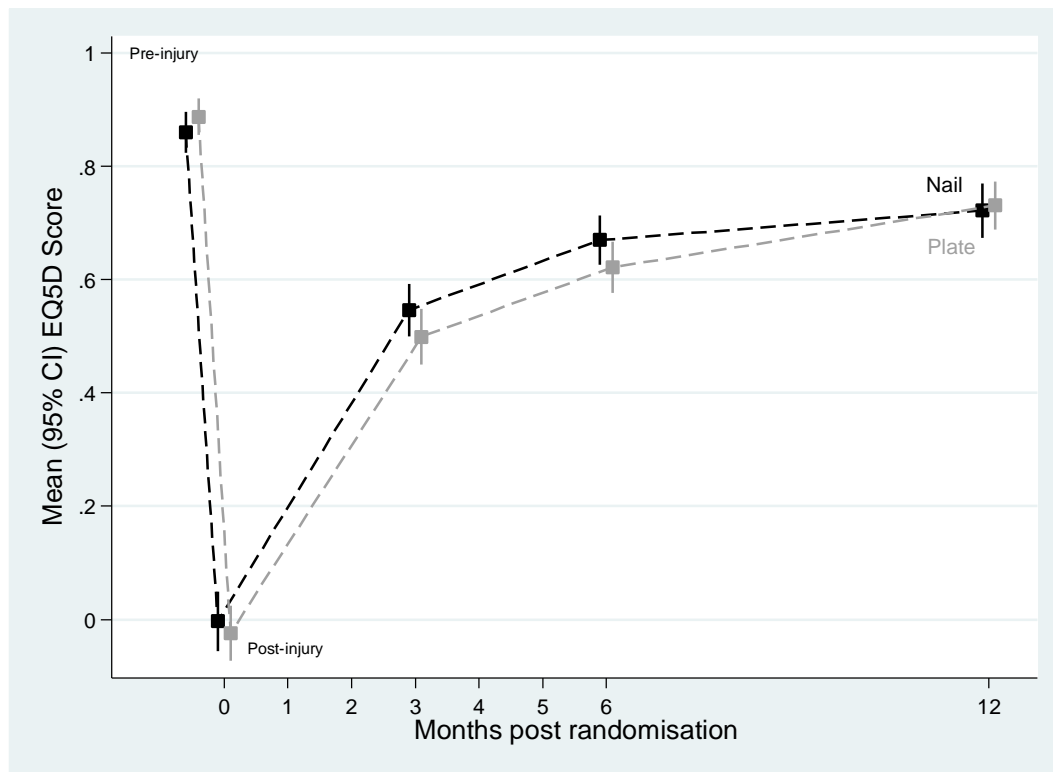


Figure 2 Graph showing cost-effectiveness plane generated from bootstrapped mean cost and quality adjusted life years (QALYs) differences over 12 months for base case (NHS and personal social service perspective, imputed, intention-to-treat analysis)

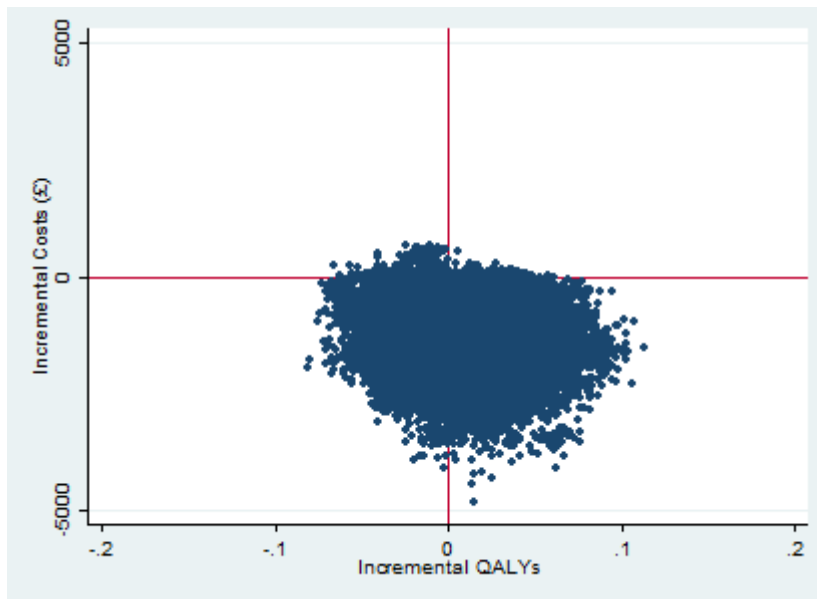
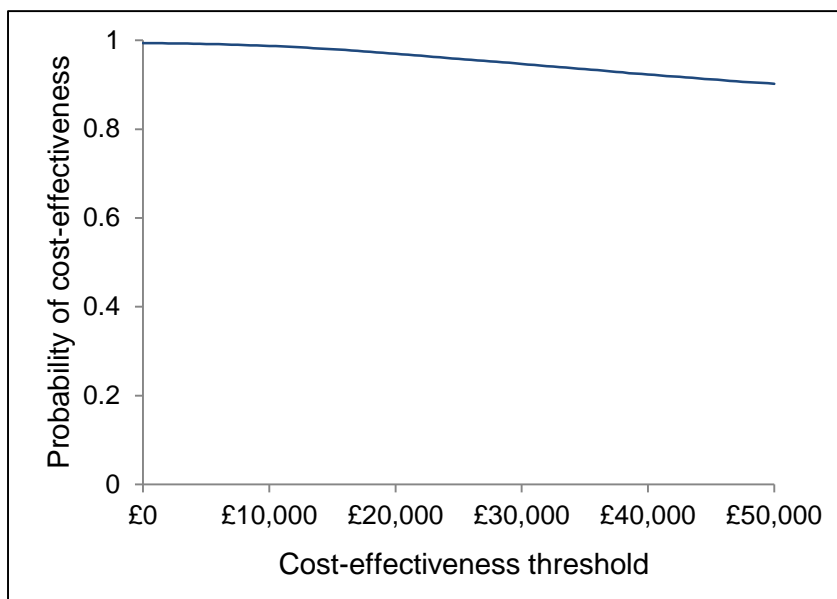


Figure 3 Graph showing the cost effectiveness acceptability curves at 12 months



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Contribution of authors

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S. Petrou: Economic evaluation study design, supervision of data analysis, writing the manuscript

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Appendices

Table A1 Use of health care resources related to distal fracture fixation by each follow-up period and treatment arm (complete cases)

| | IM Nail | Locking plate | Difference: p-value of t-test |
|--|--|--------------------|-------------------------------|
| Six-week follow-up | | | |
| Inpatient care | Mean length of stay in days (SE) | | |
| Intensive care | 0.11 (0.06) | 0.41 (0.39) | 0.45 |
| Acute trauma | 5.78 (0.36) | 5.83 (0.35) | 0.92 |
| Rehabilitation | 0.55 (0.30) | 0.19 (0.09) | 0.26 |
| Other | 0.17 (0.07) | 0.21 (0.12) | 0.78 |
| <i>Total inpatient care use</i> | <i>6.61 (0.47)</i> | <i>6.64 (0.39)</i> | <i>0.62</i> |
| | | | |
| | Proportion of participants prescribed antibiotics at 6 weeks (SD) | | |
| Antibiotics | 0.14 (0.35) | 0.13 (0.03) | 0.69 |
| | | | |
| Three-month follow-up | | | |
| Subsequent Inpatient care | Mean length of stay in days (SE) | | |
| Orthopaedics (leg) | 0.09 (0.05) | 0.18 (0.12) | 0.25 |
| Orthopaedics (other bones) | 0 | 0 | |
| Rehabilitation unit | 0 | 0.09 (0.09) | 0.16 |
| Other surgery | 0.03 (0.03) | 0.11 (0.11) | 0.24 |
| Other non-surgery | 0 | 0.01 (0.01) | 0.16 |
| <i>Total inpatient care use</i> | <i>0.12 (0.06)</i> | <i>0.38 (0.24)</i> | <i>0.16</i> |
| | | | |
| Outpatient care | Mean no. of contacts (SE) | | |
| Orthopaedics | 1.66 (0.12) | 1.93 (0.15) | 0.09 |
| Pathology | 0.07 (0.03) | 0.08 (0.03) | 0.85 |
| Radiology X-Rays | 1.26 (0.21) | 1.38 (0.11) | 0.21 |
| Radiology MRI Scan | 0.01 (0.01) | 0.03 (0.01) | 0.09 |
| Radiology CT scan | 0 | 0.03 (0.01) | 0.02 |
| Physiotherapy NHS | 1.82 (0.21) | 1.69 (0.19) | 0.67 |
| Physiotherapy Private | 3.59 (3.26) | 0.16 (0.10) | 0.86 |
| Emergency Department (fracture –related) | 0.10 (0.03) | 0.08 (0.03) | 0.66 |

| | IM Nail | Locking plate | Difference: p-value of t-test |
|--|--|--------------------|-------------------------------|
| Emergency Department (other reasons) | 0.02 (0.01) | 0.03 (0.02) | 0.25 |
| Other | 0.06 (0.02) | 0.08 (0.03) | 0.30 |
| <i>Total outpatient care use</i> | <i>8.59 (3.25)</i> | <i>5.50 (0.33)</i> | <i>0.83</i> |
| | | | |
| Community health care | Mean no. of contacts (SE) | | |
| GP Visits (surgery) | 0.92 (0.13) | 0.97 (0.16) | 0.39 |
| GP (home visits) | 0.14 (0.06) | 0.11 (0.05) | 0.62 |
| GP (telephone contacts) | 0.36 (0.10) | 0.46 (0.10) | 0.24 |
| Practice nurse contacts | 0.64 (0.19) | 0.39 (0.10) | 0.88 |
| District nurse contacts | 2.61 (0.92) | 1.13 (0.49) | 0.92 |
| Community physiotherapy contacts | 0.59 (0.15) | 0.71 (0.18) | 0.31 |
| Occupational therapy contacts | 0.29 (0.13) | 0.26 (0.11) | 0.56 |
| Other | 0.10 (0.10) | 0.22 (0.17) | 0.27 |
| <i>Total community health care use</i> | <i>5.64 (0.97)</i> | <i>4.25 (0.56)</i> | <i>0.89</i> |
| | | | |
| Aids and adaptations | Mean count (SE) | | |
| Crutches | 1.05 (0.09) | 1.21 (0.10) | 0.11 |
| Stick | 0.12 (0.03) | 0.06 (0.03) | 0.91 |
| Zimmer frame | 0.20 (0.04) | 0.34 (0.06) | 0.03* |
| Grab Rail | 0.12 (0.04) | 0.09 (0.04) | 0.70 |
| Dressing aids | 0.33 (0.24) | 0.11 (0.08) | 0.80 |
| Long-handle shoe horn | 0.03 (0.02) | 0.01 (0.01) | 0.81 |
| Other | 0.70 (0.10) | 0.68 (0.10) | 0.57 |
| <i>Total use- aids and adaptations</i> | <i>2.55 (0.30)</i> | <i>2.51 (0.18)</i> | <i>0.65</i> |
| | | | |
| Medicines | Proportion of participants prescribed each class of drug (SD) | | |
| Analgesics | 0.58 (0.35) | 0.56 (0.37) | 0.60 |
| Antibiotics | 0.08 (0.19) | 0.13 (0.0.28) | 0.34 |
| Anti-inflammatories | 0.14 (0.0.21) | 0.16(0.0.27) | 0.24 |
| Anti-coagulant | 0.05 (0.16) | 0.03 (0.14) | 0.84 |
| Anti-inflammatory gels | 0.01 (0.06) | 0 (0.04) | 0.74 |
| Other | 0.15 (0.29) | 0.11 (0.25) | 0.82 |
| <i>All medicines</i> | <i>1.00</i> | <i>1.00</i> | <i>0.98</i> |
| | | | |

| | IM Nail | Locking plate | Difference: p-value of t-test |
|--|---|--------------------|-------------------------------|
| Personal social services (PSS) | No. of contacts (SE) | | |
| Laundry services | 0 | 0 | |
| Social worker contacts | 0 | 0.01 (0.01) | 0.16 |
| Care worker/home help | 0.43 (0.43) | 0.74 (0.56) | 0.33 |
| Other | 0.60 (0.42) | 0 | 0.92 |
| <i>Total PSS use</i> | <i>1.02 (0.60)</i> | <i>0.75 (0.56)</i> | <i>0.63</i> |
| | | | |
| Productivity losses | No. of days off work | | |
| | 46.12 (4.21) | 54.46 (3.72) | 0.07* |
| | | | |
| Six-month follow-up | | | |
| Subsequent Inpatient care | Mean length of stay in days (SE) | | |
| Orthopaedics (leg) | 0 | 0.08 (0.08) | 0.04 |
| Orthopaedics (other bones) | 0 | 0 | |
| Rehabilitation unit | 0 | 0 | |
| Other surgery | 0 | 0.03 (0.03) | 0.16 |
| Other non-surgery | 0 | 0.01 (0.01) | |
| <i>Total inpatient care use</i> | <i>0</i> | <i>0.11 (0.06)</i> | <i>0.03**</i> |
| | | | |
| Outpatient care | Mean no. of contacts (SE) | | |
| Orthopaedics | 0.71 (0.10) | 1.17 (0.25) | 0.04 |
| Pathology | 0.05 (0.02) | 0.02 (0.02) | 0.89 |
| Radiology X-Rays | 0.53 (0.09) | 0.71 (0.10) | 0.1 |
| Radiology MRI Scan | 0.01 (0.01) | 0.01 (0.01) | 0.5 |
| Radiology CT scan | 0.02 (0.01) | 0.02 (0.01) | 0.5 |
| Physiotherapy NHS | 1.84 (0.28) | 2.53 (0.36) | 0.07* |
| Physiotherapy Private | 0.27 (0.12) | 0.12 (0.06) | 0.88 |
| Emergency Department (fracture –related) | 0.02 (0.01) | 0.01 (0.01) | 0.72 |
| Emergency Department (other reasons) | 0.02 (0.01) | 0.07 (0.05) | 0.18 |
| Other | 0.16 (0.09) | 0.13 (0.06) | 0.59 |
| <i>Total outpatient care use</i> | <i>3.64 (0.35)</i> | <i>4.78 (0.53)</i> | <i>0.04**</i> |
| | | | |
| Community health care | | | |
| GP Visits (surgery) | 1.09 (0.18) | 0.89 (0.25) | 0.74 |

| | IM Nail | Locking plate | Difference: p-value of t-test |
|---|--|--------------------|-------------------------------|
| GP (home visits) | 0.06 (0.04) | 0.11 (0.08) | 0.30 |
| GP (telephone contacts) | 0.18 (0.09) | 0.14 (0.08) | 0.62 |
| Practice nurse contacts | 0.06 (0.04) | 0.07 (0.05) | 0.43 |
| District nurse contacts | 0.18 (0.13) | 0.43 (0.43) | 0.29 |
| Community physiotherapy contacts | 1.70 (0.59) | 1.04 (0.38) | 0.82 |
| Occupational therapy contacts | 0.15 (0.09) | 0.46 (0.43) | 0.24 |
| Other | 0.15 (0.10) | 0.54 (0.37) | 0.16 |
| <i>Total community health care use</i> | <i>3.58 (0.61)</i> | <i>3.68 (0.67)</i> | <i>0.46</i> |
| Aids and adaptations | | | |
| Crutches | 0.16 (0.04) | 0.19 (0.05) | 0.32 |
| Stick | 0.09 (0.03) | 0.05 (0.02) | 0.91 |
| Zimmer frame | 0.02 (0.01) | 0.04 (0.02) | 0.26 |
| Grab Rail | 0.06 (0.04) | 0.01 (0.01) | 0.90 |
| Dressing aids | 0.03 (0.03) | 0 | 0.84 |
| Long-handle shoe horn | 0.01 (0.01) | 0 | 0.84 |
| Other | 0.09 (0.04) | 0.13 (0.04) | 0.24 |
| <i>Total use - aids and adaptations</i> | <i>0.47 (0.12)</i> | <i>0.41 (0.09)</i> | <i>0.65</i> |
| | | | |
| Medicines | Proportion prescribed each class of drug (SD) | | |
| Analgesics | 0.51 (0.45) | 0.56 (0.46) | 0.32 |
| Antibiotics | 0.08 (0.24) | 0.13 (0.34) | 0.50 |
| Anti-inflammatories | 0.07 (0.23) | 0.02 (0.10) | 0.79 |
| Anti-coagulant | 0.01 (0.08) | 0.01 (0.05) | 0.50 |
| Anti-inflammatory gels | 0.06 (0.23) | 0.04 (0.18) | 0.68 |
| Other | 0.27 (0.42) | 0.25 (0.39) | 0.58 |
| <i>All medicines</i> | <i>1.00</i> | <i>1.00</i> | |
| | | | |
| Personal social services | No. of contacts (SE) | | |
| Laundry services | 0 | 0 | |
| Social worker contacts | 0 | 0 | |
| Care worker/home help | 2.43 (1.75) | 0.71 (0.71) | 0.82 |
| Other | 0 | 0 | |
| <i>Total PSS use</i> | <i>2.43 (1.75)</i> | <i>0.71 (0.71)</i> | <i>0.82</i> |
| | | | |

| | IM Nail | Locking plate | Difference: p-value of t-test |
|--|---|---------------------|-------------------------------|
| Productivity losses | No. of days off work | | |
| | 24.59 (5.22) | 32.80 (5.89) | 0.15 |
| | | | |
| Twelve-month follow-up | | | |
| Subsequent Inpatient care | Mean length of stay in days (SE) | | |
| Orthopaedics (leg) | 0. 16 (0.10) | 0.15 (0.09) | 0.95 |
| Orthopaedics (other bones) | 0 | 0 | |
| Rehabilitation unit | 0 | 0 | |
| Other surgery | 0.01 (0.01) | 0.10 (0.08) | 0.28 |
| Other non-surgery | 0 | 0 | |
| Total inpatient care | 0. 17 (0.11) | 0.25 (0.15) | 0.71 |
| | | | |
| Outpatient care | Mean no. contacts (SE) | | |
| Orthopaedics | 0. 46 (0.13) | 0. 71 (0.18) | 0.28 |
| Pathology | 0. 13 (0.07) | 0. 27 (0.17) | 0.46 |
| Radiology X-Rays | 0.38 (0.09) | 0. 30 (0.08) | 0.50 |
| Radiology MRI Scan | 0 | 0.03 (0.01) | 0.08 |
| Radiology CT scan | 0. 75 (0.46) | 0. 11 (0.06) | 0.17 |
| Physiotherapy NHS | 0.55 (0.22) | 0. 70 (0.28) | 0.67 |
| Physiotherapy Private | 0.07 (0.05) | 0.07 (0.05) | 0.97 |
| Emergency Department (fracture –related) | 0.03 (0.02) | 0. 17 (0.16) | 0.36 |
| Emergency Department (other reasons) | 0. 01 (0.01) | 0. 03 (0.03) | 0.38 |
| Other | 0.10 (0.03) | 0. 31 (0.21) | 0.33 |
| Total outpatient care use | 2.47 (0.71) | 2. 70 (0.58) | 0.80 |
| | | | |
| Community health care | Mean no. contacts (SE) | | |
| GP Visits (surgery) | 0.91 (0.26) | 1. 64 (0.37) | 0.11 |
| GP (home visits) | 0. 06 (0.04) | 0 | 0.16 |
| GP (telephone contacts) | 0.91 (0.75) | 0. 03 (0.03) | 0.25 |
| Practice nurse contacts | 0.09 (0.07) | 0.42 (0.20) | 0.14 |
| District nurse contacts | 0 | 0 | |
| Community physiotherapy contacts | 0.69 (0.33) | 1.11 (0.59) | 0.54 |
| Occupational therapy contacts | 0 | 0. 89 (0.68) | 0.20 |
| Other | 0. 09 (0.09) | 0. 28 (0.22) | 0.45 |

| | IM Nail | Locking plate | Difference: p-value of t-test |
|---|--|--------------------|-------------------------------|
| Total community health care use | 2.75 (0.95) | 4.36 (1.02) | 0.25 |
| | | | |
| Aids and adaptations | Mean no. of items (SE) | | |
| Crutches | 0.13 (0.05) | 0.06 (0.03) | 0.30 |
| Stick | 0.03 (0.02) | 0.07 (0.02) | 0.13 |
| Zimmer frame | 0 | 0.02 (0.01) | 0.58 |
| Grab Rail | 0.01 (0.01) | 0.02 (0.01) | 0.10 |
| Dressing aids | 0.02 (0.02) | 0 | 0.32 |
| Long-handle shoe horn | 0 | 0.02 (0.01) | 0.16 |
| Other | 0.14 (0.05) | 0.10 (0.04) | 0.53 |
| Total use – aids and adaptations | 0.35 (0.09) | 0.27 (0.07) | 0.45 |
| | | | |
| Medicines | Proportion prescribed each class of drug (SD) | | |
| Analgesics | 0.55 (0.43) | 0.47 (0.42) | 0.73 |
| Antibiotics | 0.08 (0.24) | 0.05 (0.14) | 0.66 |
| Anti-inflammatories | 0.20 (0.34) | 0.19 (0.35) | 0.42 |
| Anti-coagulant | 0.03 (0.11) | 0 | 0.84 |
| Anti-inflammatory gels | 0.08 (0.24) | 0 | 0.91 |
| Other | 0.08 (0.24) | 0.29 (0.43) | 0.03** |
| All medicines | 1.00 | 1.00 | |
| | | | |
| Personal social services | Mean no. of contacts (SE) | | |
| Laundry services | 0 | 0.02 (0.02) | 0.16 |
| Social worker contacts | 0.01 (0.01) | 0.04 (0.04) | 0.24 |
| Care worker/home help | 0 | 0.01 (0.01) | 0.16 |
| Other | 0 | 0.01 (0.01) | 0.16 |
| Total PSS use | 0.01 (0.01) | 0.08 (0.05) | 0.09* |
| | | | |
| Productivity losses | Mean no. of days off work | | |
| | 12.99 (5.84) | 15.59 (4.91) | 0.73 |

Table A2 EQ-5D descriptive measurements by trial allocation, study period and EQ-5D dimension

| | EQ-5D level: n (%) ^a | | | | | | | | | | | | |
|-----------------------------------|---------------------------------|----------|-----------|------------|-----------------|----------|-----------|------------|--------------------|----------|----------|------------|-----------|
| | Level 1 | Level 2 | Level 3 | Suboptimal | Level 1 | Level 2 | Level 3 | Suboptimal | Level 1 | Level 2 | Level 3 | Suboptimal | |
| Baseline : IM (N=157); LP (N=158) | Mobility | | | | Self-Care | | | | Anxiety/Depression | | | | |
| | IM | 3 (2%) | 44 (28%) | 110 (70%) | 154 (98%) | 19 (12%) | 109 (69%) | 29 (18%) | 138 (88%) | 64 (41%) | 74 (47%) | 18 (11%) | 92 (59%) |
| | LP | 2 (1%) | 41 (26%) | 115 (73%) | 156 (99%) | 19 (12%) | 109 (69%) | 30 (19%) | 139 (88%) | 76 (48%) | 70 (44%) | 12 (8%) | 82 (52%) |
| | P-Value | 0.65 | | | | 0.98 | | | | 0.94 | | | |
| | Usual Activities | | | | Pain/Discomfort | | | | | | | | |
| | IM | 5 (3%) | 28 (18%) | 124 (79%) | 152 (97%) | 6 (4%) | 92 (59%) | 59 (38%) | 151 (96%) | | | | |
| | LP | 4 (3%) | 29 (18%) | 124 (78%) | 153 (97%) | 11 (7%) | 103 (65%) | 44 (28%) | 147 (93%) | | | | |
| | P-Value | 0.73 | | | | 0.12 | | | | | | | |
| 3 months: IM (N=135); LP(N=141) | Mobility | | | | Self-Care | | | | Anxiety/Depression | | | | |
| | IM | 25 (19%) | 107 (79%) | 3 (2%) | 110 (81%) | 96 (71%) | 38 (28%) | 2 (1%) | 40 (29%) | 71 (53%) | 58 (43%) | 7 (5%) | 65 (48%) |
| | LP | 15 (11%) | 125 (89%) | 1 (1%) | 126 (89%) | 92 (65%) | 49 (35%) | 0 | 49 (35%) | 76 (54%) | 53 (38%) | 12 (9%) | 124 (88%) |
| | P-Value | 0.07 | | | | 0.34 | | | | 0.42 | | | |
| | Usual Activities | | | | Pain/Discomfort | | | | | | | | |
| | IM | 12 (9%) | 99 (73%) | 25 (19%) | 124 (92%) | 21 (16%) | 104 (77%) | 11 (8%) | 115 (85%) | | | | |
| | LP | 6 (4%) | 102 (72%) | 33 (23%) | 135 (96%) | 16 (11%) | 107 (76%) | 18 (13%) | 125 (89%) | | | | |
| | P-Value | 0.12 | | | | 0.31 | | | | | | | |

| | EQ-5D level: n (%) ^a | | | | | | | | | | | | |
|---|---------------------------------|----------|----------|------------|-----------------|-----------|-----------|------------|--------------------|----------|----------|------------|-----------|
| | Level 1 | Level 2 | Level 3 | Suboptimal | Level 1 | Level 2 | Level 3 | Suboptimal | Level 1 | Level 2 | Level 3 | Suboptimal | |
| 6 months : IM (N=142); LP (N=142) | Mobility | | | | Self-Care | | | | Anxiety/Depression | | | | |
| | IM | 64 (45%) | 77 (54%) | 1 (1%) | 78 (55%) | 116 (82%) | 26 (18%) | 0 | 26 (18%) | 81 (57%) | 52 (37%) | 9 (6%) | 142 (43%) |
| | LP | 57 (40%) | 85 (60%) | 0 | 85 (60%) | 114 (80%) | 28 (20%) | 0 | 28 (20%) | 85 (60%) | 50 (35%) | 7 (5%) | 142 (40%) |
| | P-Value | 0.401 | | | | 0.762 | | | | 0.72 | | | |
| | Usual Activities | | | | Pain/Discomfort | | | | | | | | |
| | IM | 53 (37%) | 77 (54%) | 12 (8%) | 89 (63%) | 34 (24%) | 98 (69%) | 10 (7%) | 108 (76%) | | | | |
| | LP | 41 (29%) | 85 (6%) | 16 (11%) | 101 (71%) | 29 (20%) | 108 (76%) | 5 (4%) | 113 (80%) | | | | |
| | P-Value | 0.13 | | | | 0.28 | | | | | | | |
| 12 months: IM (N=116); LP (N=118) | Mobility | | | | Self-Care | | | | Anxiety/Depression | | | | |
| | IM | 73 (63%) | 43 (37%) | 0 | 43 (37%) | 98 (84%) | 18 (16%) | 0 | 18 (16%) | 77 (66%) | 35 (30%) | 3 (3%) | 38 (33%) |
| | LP | 71 (60%) | 46 (39%) | 1 (1%) | 47 (40%) | 105 (89%) | 13 (11%) | 0 | 13 (11%) | 82 (69%) | 31 (26%) | 5 (4%) | 36 (31%) |
| | P-Value | 0.66 | | | | 0.31 | | | | 0.55 | | | |
| | Usual Activities | | | | Pain/Discomfort | | | | | | | | |
| | IM | 61 (53%) | 51 (44%) | 4 (3%) | 55 (47%) | 37 (32%) | 73 (63%) | 6 (5%) | 79 (68%) | | | | |
| | LP | 68 (58%) | 43 (36%) | 7 (6%) | 50 (42%) | 41 (35%) | 72 (61%) | 5 (4%) | 77 (65%) | | | | |
| | P-Value | 0.44 | | | | 0.87 | | | | | | | |
| ^a n (%) are the absolute number and percentages of participants in each EQ-5D dimension and ordinal level. Rating of health care was self-reported | | | | | | | | | | | | | |

