■ HIP

Effect on health-related quality of life of the X-Bolt dynamic plating system versus the sliding hip screw for the fixation of trochanteric fractures of the hip in adults: the WHiTE Four randomized clinical trial

X. L. Griffin, J. Achten, H. M. O'Connor, J. A. Cook, M. L. Costa, on behalf of the WHiTE Four Investigators

From University of Oxford, Oxford, UK

Aims

Surgical treatment of hip fracture is challenging; the bone is porotic and fixation failure can be catastrophic. Novel implants are available which may yield superior clinical outcomes. This study compared the clinical effectiveness of the novel X-Bolt Hip System (XHS) with the sliding hip screw (SHS) for the treatment of fragility hip fractures.

Methods

We conducted a multicentre, superiority, randomized controlled trial. Patients aged 60 years and older with a trochanteric hip fracture were recruited in ten acute UK NHS hospitals. Participants were randomly allocated to fixation of their fracture with XHS or SHS. A total of 1,128 participants were randomized with 564 participants allocated to each group. Participants and outcome assessors were blind to treatment allocation. The primary outcome was the EuroQol five-dimension five-level health status (EQ-5D-5L) utility at four months. The minimum clinically important difference in utility was prespecified at 0.075. Secondary outcomes were EQ-5D-5L utility at 12 months, mortality, residential status, mobility, revision surgery, and radiological measures.

Results

Overall, 437 and 443 participants were analyzed in the primary intention-to-treat analysis in XHS and SHS treatment groups respectively. There was a mean difference of 0.029 in adjusted utility index in favour of XHS with no evidence of a difference between treatment groups (95% confidence interval -0.013 to 0.070; p = 0.175). There was no evidence of any differences between treatment groups in any of the secondary outcomes. The pattern and overall risk of adverse events associated with both treatments was similar.

Conclusion

Any difference in four-month health-related quality of life between the XHS and SHS is small and not clinically important. There was no evidence of a difference in the safety profile of the two treatments; both were associated with lower risks of revision surgery than previously reported.

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Introduction

Hip fractures are one of the greatest challenges facing the medical community. In 2000, there was an estimated global incidence of nine million osteoporotic fractures, of which 1.6 million were hip fractures.[1] These fractures constitute a heavy socioeconomic burden worldwide. The cost of this clinical problem is estimated at 5.8 million disability adjusted life years lost, 1.75% of the total healthcare burden in established market economies.[1]

Approximately half of all hip fractures lie outside of the joint capsule and the great majority of these are trochanteric fractures—those in the region

Correspondence should be sent to X. L. Griffin; email: x.griffin@qmul.ac.uk

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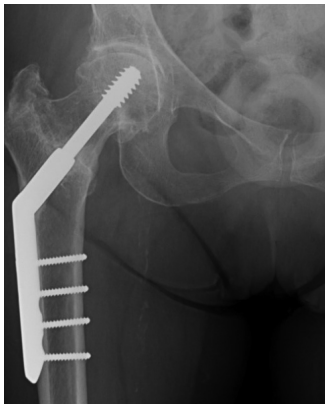

Fig. 1

Anteroposterior radiograph of sliding hip screw fixation of a right trochanteric fracture.

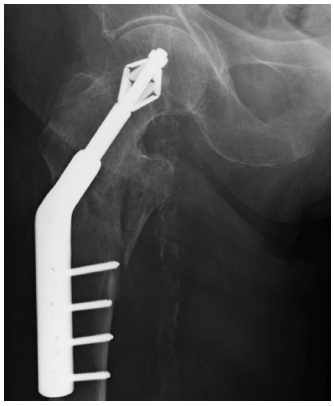

Fig. 2

Anteroposterior radiograph of X-Bolt Dynamic Hip Plating System fixation of a right trochanteric fracture.

between the greater and lesser trochanter that can be typically treated with fixation rather than replacement.[2]

The sliding hip screw (SHS) is well established in the treatment of these fractures and in many patients is effective at allowing controlled collapse of the fracture with consequent mechanical stability leading to successful bone healing (Figure 1).[3] However, in some people fixation strength is compromised due to porotic cancellous bone, making fixation difficult, risking implant cut out, when there is insufficient bone at the fracture to share the load on the limb with the fixation device. Rather than controlled collapse along the line of the screw, the screw may cut out from the hip leading to failure of the fixation and damage to the hip joint.[4] Revision surgery, to either re-fix or replace the hip, is complex and the outcomes are very poor in this frail group of patients with inpatient mortality approaching 50%.[4]

The X-Bolt Dynamic Hip Plating System (XHS; X-Bolt, Dublin, Ireland) builds on the successful design features of the SHS; it only differs importantly in the nature of the fixation in the head of the femur. Expanding flanges are deployed to engage and compress the surrounding cancellous bone improving fixation in cadaveric and biomechanical studies (Figure 2).[5] Biomechanical testing has demonstrated that the XHS has improved cut out strength compared with the SHS, the principal means of implant failure in the treatment of these fractures.[6] There is also improved rotational control and better torsional stability at the fracture site.[7] Our randomized pilot study, Warwick Hip Trauma Evaluation (WHiTE) One, has indicated that there is a trend towards a reduced risk of revision using the XHS compared with the SHS.[8] The aim of this trial was to quantify the comparative clinical effectiveness of the XHS and the SHS for the treatment of fragility hip fractures.[9]

Methods

Trial design summary. This was a multicentre, multi-surgeon, two-arm, parallel-group randomized controlled trial. Full details of the protocol have been published previously.[9] The West Midlands NHS Research Ethic Committee gave ethical approval on 5 February 2016 (WM/16/0001).

Eligibility. Patients were screened in ten acute NHS hospitals in the UK. Patients were included who presented with trochanteric fracture of the hip, determined by the treating surgeon using the AO/OTA classifcation,[10] and who in their opinion would benefit from SHS fixation. Patients were excluded who: were younger than 60 years of age; had a sub-trochanteric fracture; or who were managed nonoperatively. Overall, 2,105 patients were potentially eligible for entry into the trial between June 2016 and April 2018 at the ten study sites (Figure 3). Overall, 1,128 were randomized and consented into the trial. Twelve participants were randomized in error; of whom eight had the wrong type of fracture and received a non-trial intervention, and four were randomized twice. Three participants (XHS = 2, SHS = 1) withdrew immediately post-randomization for whom no data are available. Baseline demographic data were similar in both treatment groups (Table I). Participants had a median age of 86 (IQR 79 to 91) years, 825 participants were female and pre-injury median EuroQol Five-dimension Health Status and Index (EQ-5D) utility index was approximately 0.7 (0.4 to 0.8).

Standardized treatment pathway. Diagnosis of a hip fracture was confirmed as per routine clinical care. Routine investigations, anaesthetic assessment, antibiotic, and venous thromboprophylaxis were used as per local policy.

Anaesthesia was achieved in accordance with local policies. Perioperative analgesia was achieved by combining a local anaesthetic nerve block, periarticular anaesthetic infiltration, intravenous paracetamol 1 g intravenous infusion, and opiate analgesia as clinically indicated.

Internal fixation with either device was performed following the manufacturer's guidelines; the positioning of the participant, surgical approach, and wound closure was determined by the operating surgeon. Postoperative analgesia was prescribed by the responsible clinical teams as appropriate. In the postoperative period, as per standard of care, participants in both groups underwent an initial physiotherapy and occupational therapy assessment. An initial treatment plan was devised, aiming to mobilize participants through early, active, full weight-bearing. Participants were discharged from the acute Orthopaedic Trauma Ward at the earliest safe opportunity to the most appropriate discharge destination.

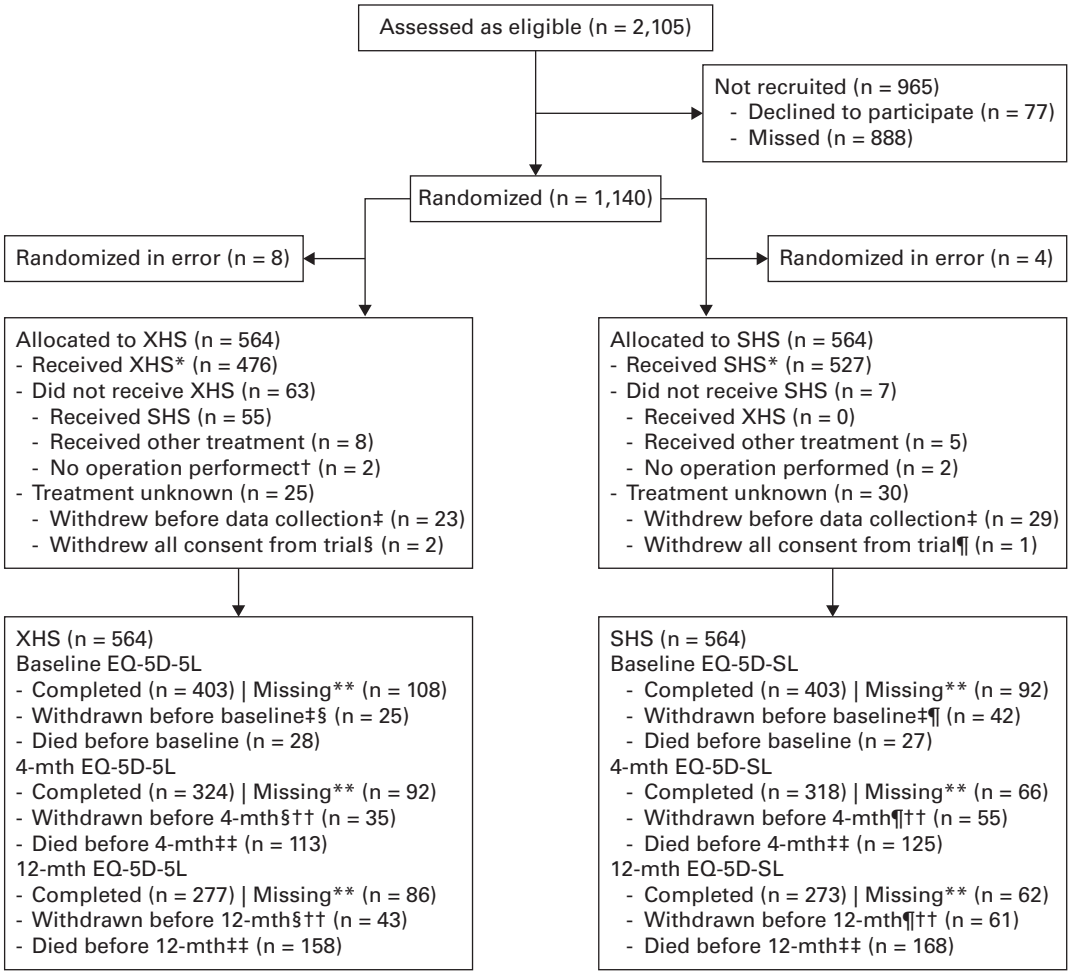

Fig. 3

CONSORT flow diagram. *Derived using operative data; †Participants died before operation performed; ‡Where patients withdrew before baseline data collection, hospital information and operative details will not have been collected; §Includes two participants who received treatment but subsequently withdrew and removed all consent for data to be used in trial; ¶Includes one participant who received treatment but subsequently withdrew and removed all consent for data to be used in trial; **Includes participants who did not complete this information on their questionnaire, who have consented to routine data collection only, or who have not returned their questionnaire; ††Includes all participants who have withdrawn prior to this timepoint; ‡‡Includes all participants who have died prior to this timepoint.

Allocated treatments. Participants were randomly allocated to one of two groups: SHS or XHS. The allocation sequence was generated with a 1:1 ratio using randomly permuted blocks of varying size by the trial statistician, stratified by trial centre. Allocations were assigned using secure, online randomization via a distant computer-generated system administered by Oxford Clinical Trials Research Unit, University of Oxford. Participants were enrolled by a member of the site research staff and were assigned to their treatment allocation before surgery.

SHS. Fixation was with a SHS and standard lag screw. Briefly, the fracture was reduced by closed means under image intensifier guidance. A wire was passed from the side of the femur into the centre of femoral head and then a channel opened to allow the passing of a large diameter cannulated screw over the wire and across the fracture. The screw was then mounted into a barrel attached to a side plate of a length determined by the operating surgeon. The use of any supplementary fixation such as wires, cables, lag screws, and trochanteric stablization plate attachments was permitted at the surgeon's discretion.

XHS. Fixation was with an XHS, a very similar device to the SHS with side plate, barrel, and lag screw but equipped with an expanding bolt to gain fixation within the femoral head. Similar to the SHS group, the fracture was reduced closed under fluoroscopic guidance, a wire was passed across the fracture into the centre of femoral head and a channel opened with a reamer over the wire. The wire was then removed to allow the passing of the narrower but solid X-Bolt implant with associated flanges. The X-Bolt was then mounted into a barrel attached to a side plate of a length determined by the operating surgeon. The use of any supplementary fixation such as wires, cables, lag screws, and trochanteric stablization plate attachments was permitted at the surgeon's discretion.

Consent. It is recognized that patients with a hip fracture are a clinical priority for urgent operative care,[11] with a preference to be treated on the next available trauma operating list. Most

Table I. Baseline characteristics of participants according to treatment groups.

Characteristic	XHS (n = 562)*	SHS (n = 563)*
Median age, yrs (IQR)	85.8 (80.3 to 90.6)	85.6 (78.8 to 90.9)
Female sex, n (%)	401 (71.4)	424 (75.3)
Diabetic, n (%)†	69 (16.0)	78 (18.0)
Smoker, n (%)‡	40 (9.5)	48 (11.2)
Weekly alcohol consumption, n (%)§	**421 (74.9)**	**423 (75.1)**
0 to 7 units	373 (88.6)	371 (87.7)
8 to 14 units	24 (5.7)	20 (4.7)
15 to 21 units	11 (2.6)	13 (3.1)
> 21 units	13 (3.1)	19 (4.9)
Pre-fracture mobility, n (%)¶	**540 (96.1)**	**534 (94.8)**
Freely mobile without aids	197 (36.5)	186 (34.8)
Mobile outdoors with one aid	111 (20.6)	99 (18.5)
Mobile outdoors with two aids or frame	98 (18.1)	102 (19.1)
Some indoor mobility but never goes outside without help	120 (22.2)	134 (25.1)
No functional mobility (using lower limbs)	5 (0.9)	8 (1.5)
Unknown	9 (1.7)	5 (0.9)
Residential status, n (%)**	**315 (56.0)**	**335 (59.5)**
Own home/sheltered housing	247 (78.4)	260 (77.6)
Residential care	41 (13.0)	46 (13.7)
Nursing care	21 (6.7)	25 (7.5)
Rehab unit (hospital bed in current trust)	1 (0.3)	1 (0.3)
Rehab (hospital bed in another trust)	1 (0.3)	0 (0)
Rehab (NHS-funded care home bed)	0 (0)	1 (0.3)
Acute hospital	4 (1.3)	2 (0.6)
Median preoperative AMTS (IQR)††	8 (3 to 10)	8 (4 to 10)
Median pre-injury EQ-5D-5L (IQR)‡‡	0.7 (0.4 to 0.8)	0.7 (0.4 to 0.8)
Median pre-injury EQ-5D-5L VAS (IQR)§§	70 (50 to 80)	70 (50 to 80)
AO/OTA fracture type, n (%)¶¶	**539 (95.9)**	**532 (94.5)**
31A1	222 (41.2)	204 (38.3)
31A2	303 (56.2)	307 (57.7)
31A3	14 (2.6)	21 (3.9)

*Does not include three participants who withdrew under "No data, no contact" (X-Bolt XHS = 2, SHS = 1).
†Diabetes data not available for 131 XHS participants and 129 SHS participants.
‡Smoking data not available for 140 XHS participants and 136 SHS participants.
§Alcohol consumption data not available for 141 XHS participants and 140 SHS participants.
¶Pre-fracture mobility data not available for 22 XHS participants and 29 SHS participants.
**Residential status data not available for 247 XHS participants and 228 SHS participants.
††Retrospective preoperative AMTS data not available for 31 XHS participants and 39 SHS participants.
‡‡Retrospective pre-injury EQ-5D-5L score not available for 161 XHS participants and 161 SHS participants.
§§Retrospective pre-injury EQ-5D-5L VAS not available for 161 XHS participants and 162 SHS participants.
¶¶Fracture type data not available for 23 XHS participants and 31 SHS participants.
AMTS, abbreviated mental test score; EQ-5D-5L, EuroQol five-dimension five-level questionnaire; IQR, interquartile range; SHS, sliding hip screw; VAS, visual analogue scale; XHS, X-Bolt hip system.

patients with a hip fracture are in pain and receive opiate analgesia. Accordingly for many patients the initial period in hospital is confusing and disorientating. Similarly, patients' next of kin, carers, and friends are often anxious at this time and may have difficulty in assimilating large amounts of information that they are given about the injury and plan for treatment. The initial focus is on obtaining consent for surgery, where possible, and informing the patient and any next of kin about immediate clinical care. It is often not possible for the patient or relative/carer (consultee) to review trial documentation, consider the information, and communicate an informed decision about whether they would wish to participate. The consent procedure for this trial reflected that of the surgery, with the clinical team assessing capacity before taking consent for the surgical procedure. This capacity assessment was then used to decide on the proper approach to consenting to the research study. An appropriate method, in line with the Mental Capacity Act 2005, was then used to gain either prospective or retrospective consent from the participant, or appropriate consultee, by a Good Clinical Practice-trained,[12] appropriately delegated member of the local research team.

Objectives. The primary objective of the trial was to quantify and draw inferences on the observed differences in participants' health status between the trial treatment groups at four months post-surgery.

Secondary objectives were to quantify and draw inferences on the observed differences in: participants' health status between the trial treatment groups at 12 months post-surgery; participants' mortality within the first year post-surgery between the trial treatment groups; participants' functional status between the trial treatment groups at 12 months post-surgery; participants' residential status between the trial treatment groups at 12 months post-surgery; the risks of revision surgery within the first year post-surgery between the trial treatment groups; and the risk and distribution of complications within the first year post-surgery between the trial treatment groups.

Outcomes. The primary outcome was at four months post-surgery with longer-term follow-up at 12 months post-surgery. Outcome data were collected through questionnaires and review of the medical record; participant questionnaires were completed face-to-face at baseline and over the telephone by a member of the trial team or via post at both four and 12 months follow-up.

Primary outcome measure. The primary outcome measure was health-related quality of life (HRQoL) at four months. The EuroQol Five-dimension Health Status and Index (EQ-5D) is a validated measure of HRQoL, consisting of a five dimension health status classification system and a separate visual analogue scale.[13] An updated version of the EQ-5D with five response levels (EQ-5D-5L) has recently been developed to enhance the responsiveness of the instrument to changes in patient health. The measurement properties of the EQ-5D in this patient population have been extensively investigated and is currently the best measurement tool available.[14,15] This outcome was obtained through telephone interview with the participant or consultee. EQ-5D-5L index values were derived by mapping EQ-5D-5L descriptive system data onto the EQ-5D-3L valuation set using the Crosswalk Index Value Calculator.[16] Using this value set the scale ranges from -0.594, indicating the worse possible heath state, to 1.0, and is anchored at 0 and 1.0 indicating a health state equivalent death and perfect health respectively.

Table II. Type of surgery received presented by treatment group

Characteristics	XHS (n = 562)*	SHS (n = 563)*
Surgery received, n (%)†	**539 (95.9)**	**534 (94.8)**
X-Bolt XHS	476 (88.3)	0 (0)
SHS	55 (10.2)	527 (98.7)
Received other treatment	8 (1.5)	5 (0.9)
No operation performed	0 (0)	2 (0.4)
Additional fixations, n (%)‡	**546 (97.2)**	**552 (98.0)**
Screws	49 (9.0)	38 (6.9)
Wires	3 (0.5)	5 (0.9)
Trochanteric plates	15 (2.7)	23 (4.2)
None§	479 (87.7)	486 (88.0)
Grade of operating surgeon, n (%)¶	**539 (95.9)**	**532 (94.5)**
Consultant	196 (36.4)	172 (32.3)
SAS	22 (4.1)	22 (4.1)
ST3+	282 (52.3)	304 (57.1)
Below ST3	22 (4.1)	22 (4.1)
Associate specialist	0 (0)	2 (0.4)
Staff grade/Speciality doctor	3 (0.6)	0 (0)
Unknown	14 (2.6)	10 (1.9)

*Does not include three participants who withdrew under "No data, no contact" (X-Bolt XHS = 2, SHS = 1).
†Surgery received data not available for 23 XHS participants and 29 SHS participants.
‡Additional fixations data not available for 16 XHS participants and 9 SHS participants.
§Includes participants where "None" was selected and where "No" has been recorded against each additional fixation option (XHS = 7; SHS = 14); this includes two SHS participants who did not have an operation performed and one XHS participant missing information on operation performed.
¶Surgeon grade information not available for 23 XHS participants and 31 SHS participants.
SHS, sliding hip screw; XHS, X-Bolt hip system.

Secondary outcome measures. HRQoL was also similarly measured at 12 months using the EQ-5D-5L. Mortality was obtained from participant's medical notes, information from carers, and the NHS Digital Spine, an information technology infrastructure linking widely used healthcare IT systems.[17]

Functional status was assessed on an ordinal scale: freely mobile without aids; mobile outdoors with one aid; mobile outdoors with two aids or a frame; some indoor mobility but never goes outside without help; and no functional mobility (using lower limbs). Data were obtained prospectively through participant and carer telephone interviews.

Residential status was assessed on an ordinal scale: own home/sheltered housing; residential care; nursing care; rehabilitation unit – hospital bed in the current trust; rehabilitation unit – hospital bed in another trust; rehabilitation unit – NHS-funded care home bed; and acute hospital. Data were obtained prospectively through participant and carer telephone interviews.

All-cause revision surgery was obtained from participant's medical notes, participant and carer telephone interviews, and review of the index hospital digital medical imaging record. Complications were obtained from the participant's medical notes and participant and carer telephone interviews. Radiological outcomes were collected from any radiographs taken as part of routine clinical follow-up during the first 12 months post-surgery, as planned in the protocol, but will be reported elsewhere.

Sample size. The best available evidence we had from data collected during the WHiT (Warwick Hip Trauma) and WHiTE studies suggests that the SD for EQ-5D at four months post-surgery is approximately 0.3 points.[14] The best available evidence for what constitutes a minimal clinically important difference for EQ-5D, which is important to detect, was estimated to be 0.075.[18] Using a conservative estimate of the SD (0.33), this suggested a standardized effect size of approximately 0.24; a 'small to moderate effect' based on Cohen's criteria.[19]

Assuming that the EQ-5D derived utility at four months post-surgery would have an approximate normal distribution, which was reasonable,[14] and a 1:1 allocation ratio, then if the true difference between the experimental and control group EQ-5D means was 0.075, for 90% power, we required 338 participants in both the experimental group and in the control group. Based upon a similar trial in this population we expected considerable loss to follow-up, due to death, increasing frailty and cognitive decline, and post-randomization withdrawals in participants who declined ongoing follow-up, so we assumed that only 60% of recruited study participants would be available at the definitive outcome at four months.[20] Conservatively, we aimed to recruit 1,128 patients to ensure 90% statistical power based upon these assumptions.

Blinding. In order to negate bias in the self-reported HRQoL outcome measures, participants were blinded to the treatment allocation; other outcomes were assessed by blinded research associates. The operating surgeon could not be blinded to the allocation, but took no part in the assessment of the trial outcomes. Participants were kept blinded until the completion of the trial when the blind was broken. There was no formal analysis of the success of the blinding.

Statistical analysis. Descriptive analyses of participants' baseline characteristics and intervention were summarized as means and SDs for normally distributed variables, as medians and interquartile ranges (IQRs) for non-normally distributed continuous variables, and as frequencies and percentages for binary and categorical variables. The main analyses of the primary and secondary outcome variables were conducted on an intention-to-treat (ITT) basis; including all participants with consent to use their data in their randomized groups, with no imputation for missing data.

Multivariate linear regression was used to investigate the primary outcome. The model included four-month EQ-5D-5L score as the dependent variable and treatment group as the main independent variable adjusted for centre, age, sex, and cognitive impairment at baseline. A zero value was imputed for the EQ-5D Index for all those participants who had died prior to the collection timepoint; this is the recommended approach based upon empirical studies exploring options for handling death in these analyses.[21] Cognitive impairment was assessed using the Abbreviated Mental Test Score (AMTS) and dichotomized by defining an AMTS of 7 or less as abnormal cognition and 8 or more as normal cognition.[22] The model was replicated for EQ-5D-5L scores reported at 12 months post-surgery to assess for longer-term differences between treatment groups.

A generalized linear model (GLM) approach was used to analyze secondary outcomes. Mortality and all-cause revision surgery were analyzed with logistic regression, and functional status was analyzed with ordinal regression.[23] The number and proportion of participants reporting each type of complication one or more times over the 12

Table III. Results from multivariate regression for primary and secondary outcomes by allocated treatment.

Outcome	XHS		SHS		Treatment effect	
EQ-5D Index	**n**	**Mean score (SD)**	**n**	**Mean score (SD)**	**Adjusted difference (95% CI) ***	**p-value**
4 month EQ-5D-5L †	437	0.345 (0.355)	443	0.320 (0.359)	0.029 (-0.013 to 0.070)	0.175
12 month EQ-5D-5L	435	0.312 (0.364)	441	0.293 (0.361)	0.026 (-0.016 to 0.068)	0.232
Secondary outcomes	**n**	**Events, n (%)**	**n**	**Events, n (%)**	**Adjusted OR (95% CI) ***	**p-value**
Mortality	454	161 (35.0)	456	170 (37.0)	0.873 (0.647 to 1.176)	0.371
All-cause revision surgery	522	14 (2.7)	502	11 (2.2)	1.260 (0.563 to 2.820)	0.573
	n	**Median (IQR)**	**n**	**Median (IQR)**	**Adjusted OR (95% CI) ***	**p-value**
Functional status	327	3 (2 to 4)	320	3 (2 to 4)	0.991 (0.748 to 1.313)	0.952
	n	**Median no. events (IQR)**	**n**	**Median no. events (IQR)**	**Adjusted IRR (95% CI) ***	**p-value**
Complications	470	0 (0 to 1)	470	0 (0 to 1)	0.936 (0.784 to 1.117)	0.461

*Primary model including EQ-5D index, treatment, centre, age, sex, and cognitive impairment with SHS as the reference treatment group.
†Primary outcome.
CI, confidence interval; EQ-5D-5L, EuroQol five-dimension five-level questionnaire; IQR, interquartile range; OR, odds ratio; SHS, sliding hip screw; XHS, X-Bolt hip system.

month follow-up period were explored and the count of the number of types of complications reported by each participant was analyzed using Poisson regression. As per the primary outcome, the regression models for the corresponding secondary outcomes included treatment as the main independent variable, adjusting for centre, age, sex, and cognitive impairment.

Radiological outcomes will be presented in a descriptive analysis elsewhere. Due to unexpectedly high volumes of missing data, residential status was also considered unsuitable for statistical analysis and only descriptive baseline data have been presented.

The sensitivity of the primary outcome analysis to assumptions made was assessed. The health state of participants prior to entry into the trial was accounted for by extending the main analysis to further adjust for retrospective baseline EQ-5D-5L score. The impact of the analysis population was evaluated using a per-protocol analysis, where participants who did not receive the treatment allocated to them were excluded, and Complier Average Casual Effect (CACE) analysis, where the adherence to treatment allocated is accounted for without exclusion. The imputation of zero for the EQ-5D-5L index values of participants who had died was investigated by repeating analyses solely among living participants. To ensure that any skew in the EQ-5D-5L data was not impacting the outcome, bootstrapping using normal approximation and 10,000 iterations was adopted to estimate the confidence intervals (CIs) for the treatment effect. Finally, the sensitivity to departures from the missing at random assumption was evaluated using a pattern-mixture model, in which data and missingness are modelled jointly.

Treatment effects were summarized using 95% CIs alongside a prespecified two-sided 5% significance level. Analyses were conducted using Stata v. 15.1 (StataCorp, College Station, Texas, USA).

Results

Data on the type of surgery received were available for 95% of participants (1,073/1,128; Table II). A total of 55 participants allocated to XHS received SHS (10%); there were no crossovers from SHS to XHS. The reasons for crossover were surgeon choice (20), clinical decisions (9), fracture characteristics (8), implant and equipment issues (11), and unknown (7). Of the participants, 15 received treatments not described in the protocol, for example an intramedullary nail, and 998 participants were operated on by a surgeon who was consultant or senior trainee grade.

Table IV. Reasons for all-cause revision surgery by treatment received.

Reason, n (%)	X-Bolt XHS (n = 401)	SHS (n = 493)
All cause revision	**11 (2.7)**	**13 (2.6)**
Failure of fixation	7 (1.7)	9 (1.8)
Excess femoral neck collapse	2 (0.5)	2 (0.4)
Femoral head cut-out	4 (1.0)	5 (1.0)
Plate failure	1 (0.2)	2 (0.4)
Periprosthetic fracture	3 (0.7)	2 (0.4)
Revision malreduction	0 (0)	1 (0.2)
Infection	1 (0.2)	1 (0.2)

*One participant who underwent revision surgery did not receive either trial treatment so is excluded from this total; data may not match other tables.
SHS, sliding hip screw; XHS, X-Bolt hip system.

Including participants who died, EQ-5D-5L data were available for analysis for 78% of participants at both the primary endpoint (four months; 880/1,128) and longer-term follow-up (12 months; 876/1,128) (Table III). There was no evidence of a difference between treatment groups in mean EQ-5D index for either the primary outcome (adjusted difference 0.029; 95% CI -0.013 to 0.070; XHS mean 0.345 (SD 0.355); SHS mean 0.320 (SD 0.359)). The 12-month outcome result was similar with adjusted difference 0.026 (95% CI -0.016 to 0.068; XHS mean 0.312 (SD 0.364); SHS mean 0.293 (SD 0.361)). A full breakdown of the responses provided to each domain of the EQ-5D-5L are reported in the Supplementary Material (Supplementary Tables i to iii). The longitudinal changes were similar between the treatment groups.

Pre-specified sensitivity analyses, including a per-protocol analysis and a CACE analysis, supported the findings of the primary analysis (Supplementary Table iv anf Figure a) and produced adjusted treatment effects consistent with that of the ITT analysis. Excluding participants who died increased the absolute EQ-5D index in both groups, reduced precision of the estimate, and remained non-significant. Pattern-mixture modelling demonstrated that the modelled treatment effect was not sensitive to missing data either at the primary outcome timepoint (Supplementary Figure b) or for the 12 months outcome (Supplementary Figure c).

Functional status data were available for 57% of participants (647/1,128) with the median score for both groups of 3 (IQR2 to 4), representing being mobile outdoors with two aids or a frame (Table III). There was no statistical evidence of a difference between treatment groups in the odds of declining functional mobility (adjusted odds ratio (OR) 0.991, 95% CI 0.748 to 1.313).

Less than 3% of participants receiving XHS (11/401) and SHS (13/493) reported any type of revision surgery during follow-up period (Table IV). There was no statistical evidence of a difference between treatment groups in the odds of requiring revision surgery in the 12-month post-intervention period (adjusted OR 1.260; 95% CI 0.563 to 2.820); Table III). Overall complications were reasonably well balanced between treatment groups (SupplementaryTable v) and there was no statistical difference in the reporting of complications across the 12-month follow-up period (adjusted OR 0.936; 95% CI 0.784 to 1.117) or in the odds of dying (adjusted OR 0.873; 95% CI 0.647 to 1.176).

Discussion

The findings of this trial provide strong evidence that any difference in the HRQoL between patients treated with XHS or SHS at any timepoint in the year following hip fracture surgery is small and not clinically important. All sensitivity analyses of the primary outcome were concordant with the principal finding.

The finding of the primary analysis of HRQoL at four months was maintained at long-term follow-up at one year. Mortality, functional, and residential status outcomes were also not different between the treatment groups. There was no evidence of a difference in the overall safety profile of both treatments, with all-cause revision surgery risk and complication profiles that were similar. The findings of this definitive trial do not support the inferences of superiority of the XHS based upon the findings of earlier biomechanical and pilot clinical investigations.[6-8]

We observed a comparatively low risk of revision surgery, lower than reported in previous smaller studies.[24] This may be associated with changes in co-interventions in clinical practice such as an increased prioritization of hip fracture surgery on operating lists or improved supervision of training surgeons associated with the implementation of best practice tariff.[25] It is likely that the patients' recovery following hip fracture is only moderately influenced by the selection of the surgical implant.

This was a large, pragmatic, multicentre, multisurgeon, randomized controlled trial. The strengths of this study are those inherent to the design—a randomized study nested within a cohort, a low risk of confounding, and findings that we believe to be generalizable. In addition, the sample was very large, including a wide variety of trochanteric fracture types and participants, attrition was relatively low given the population, and the outcomes measured were those most relevant to the patients and clinicians involved in their care.[26]

The attrition rate in the trial was anticipated but nevertheless considerable (13.1% at four months and 19.4% at 12 months) but this was reasonably balanced between groups and less than the planning assumptions reported in the protocol. Patients sustaining hip fracture are frail with a high mortality and often increase their level of care following the fracture. Approximately 10% of the participants allocated to the XHS did not receive this intervention; however, the primary ITT and sensitivity PP and CACE analyses produced similar findings. The revision risk was much lower than that reported most commonly in randomized and non-randomized comparative studies of extramedullary implants (e.g. XHS and SHS). We used a threefold approach to collecting these data—participant/carer self-report, hospital medical records, and review of all participants' available clinical imaging at 12 months. It is possible that participants underwent revision in hospitals outside of those included in the trial, although the vast majority of patients return to their index hospital if complications occur. It is also possible that this finding is due to potential centre effects, and hospitals participating in the trial may not reflect wider UK practice.

In conclusion we have found no evidence of any difference in HRQoL among patients with trochanteric hip fractures treated with either the XHS or SHS. This is despite biomechanical data to support the XHS and an indication of an improved revision risk in our previous pilot study.[8]

Take home message

- There was no statistically significant difference in the health-related quality of life at four and 12 months between X-bolt Dynamic Plating System and the sliding hip screw.
- The findings suggest no clinically meaningful difference between the novel and standard implants in the treatment of trochanteric hip fractures.
- Revision surgery risks are low in UK practice; current national recommendations for surgical care of these fractures should remain unchanged.

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Animation

An animation is available alongside the online version of this article and at vimeo.com/480824150.

Supplementary material

A summary of each of the dimension scores of the five-level EuroQol Five-dimensions Health Status and Index provided by respondents and the prespecified sensitivity analyses which support the primary analysis.

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Author information:
X. L. Griffin, PhD, Professor of Trauma and Orthopaedic Surgery, Honorary Consultant Trauma and Orthopaedic Surgeon, Department of Trauma and Orthopaedic Surgery, Barts and The London School of Medicine and Dentistry, Queen Mary University of London, London, UK; Barts Health NHS Trust, London, UK.

J. Achten, PhD, Scientific Officer
M. L. Costa, PhD, Professor of Orthopaedic Trauma Surgery
Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK.

H. M. O'Connor, MSc, Statistician
J. A. Cook, PhD, Lead Statistician
Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Centre for Statistics in Medicine, University of Oxford, Oxford.

Author contributions:
X. L. Griffin: Guarantor, Prepared and reviewed the manuscript, Designed the study.
J. Achten: Reviewed the manuscript, Designed the study.
H. M. O'Connor: Conducted the statistical analysis, Reviewed the manuscript, Designed the study.
J. A. Cook: Conducted the statistical analysis, Reviewed the manuscript, Designed the study.
M. L. Costa: Reviewed the manuscript, Designed the study.

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The West Midlands NHS Research Ethic Committee gave ethical approval on 5 February 2016 (WM/16/0001).

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