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HIP

The tip-apex distance in the X-Bolt dynamic plating system

M. A. Fernandez, A. Aquilina, J. Achten, N. Parsons, M. L. Costa, X. L. Griffin

Oxford Trauma, NDORMS, University of Oxford, Oxford, United Kingdom

Objectives

The Sliding Hip Screw (SHS) is commonly used to treat trochanteric hip fractures. Fixation failure is a devastating complication requiring complex revision surgery. One mode of fixation failure is lag screw cut-out which is greatest in unstable fracture patterns and when the tip-apex distance of the lag screw is > 25 mm. The X-Bolt Dynamic Hip Plating System (X-Bolt Orthopaedics, Dublin, Ireland) is a new device which aims to reduce this risk of cut-out. However, some surgeons have reported difficulty minimising the tip-apex distance with subsequent concerns that this may lead to an increased risk of cut-out.

Patients and Methods

We measured the tip-apex distance from the intra-operative radiographs of 93 unstable trochanteric hip fractures enrolled in a randomised controlled trial (Warwick Hip Trauma Evaluation, WHiTE One trial). Participants were treated with either the sliding hip screw or the X-Bolt dynamic hip plating system. We also recorded the incidence of cut-out in both groups, at a median follow-up time of 17 months.

Results

There was a significantly increased tip-apex distance with the use of the X-Bolt (mean difference 3.7mm (95% confidence interval 1.58 to 5.73); SHS mean 17.1 mm, X-Bolt mean 20.8; p = 0.001. However, this was not associated with an increased incidence of cut-out at a median follow-up time of 17 months, with three cut-outs (6%) in the SHS group and 0 (0%) in the X-Bolt group.

Conclusion

The X-Bolt is a safe implant with no increased risk for cut-out. Concerns about minimising the tip-apex distance may be justified but do not appear to be clinically important.

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Keywords: Tip-apex distance, Hip fracture, X-Bolt

Article focus

- The X-Bolt Dynamic Plating System is a new device which aims to reduce the risk of implant cut out in trochanteric hip fractures.
- Some surgeons have observed increased tip apex distances associated with the X-Bolt.
- This is a comparative analysis of the tip apex distance and risk of cut out measured from intraoperative radiographs of patients randomised to either the X-Bolt or Sliding Hip Screw as part of the WHITE ONE trial (Warwick Hip Trauma Evaluation).

Key messages

- Concerns about minimising the tip apex distance of the X-Bolt are justified but do not lead to increased risks of implant cut out.

Strengths and limitations

- Randomised controlled trial with pragmatic inclusion criteria.
- Small sample size from a single centre.

Introduction

The Sliding Hip Screw (SHS) is a well established fixation device for treating intertrochanteric fractures of the proximal femur.[1] In stable fracture patterns, this device has proven to be successful in allowing controlled collapse of the fracture. However, in the unstable fracture patterns where comminution exists, the fracture may collapse into varus and the device may fail, resulting in 'cut-out' of the screw

M. A. Fernandez, MBBS MRCS PhD, Clinical Research Fellow in Orthopaedic Trauma, University of Oxford, NDORMS, John Radcliffe Hospital, Oxford OX3 9DU and Specialty Registrar, Trauma and Orthopaedic Surgery, University Hospital Coventry, Clifford Bridge Road, Coventry, CV2 2DX, UK.
A. Aquilina, BSc MBChB (Hons) MRCS, Doctoral candidate,
J. Achten, MSc, PhD, Research Manager,
M. L. Costa, PhD, FRCS(Tr&Orth), Professor of Orthopaedic Trauma,
X. L. Griffin, PhD, FRCS(Tr&Orth), Associate Professor of Orthopaedic Trauma, University of Oxford, NDORMS, John Radcliffe Hospital, Oxford OX3 9DU, UK.
N. Parsons, MSc, PhD, Statistician, Statistics and Epidemiology Unit, Warwick Medical School, University of Warwick, Gibbet Hill Road, Coventry CV4 7AL, UK.

Correspondence should be sent to M. A. Fernandez; email: miguel.fernandez@ndorms.ox.ac.uk

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from the femoral head. The reported incidence of SHS cut-out is variable but most recent studies report failures in up to 5% of cases.[2-6] In 1995, Baumgaertner et al[2] described the measurement of tip-apex distance and found that amongst a number of risk factors, a tip-apex distance > 25 mm was most strongly predictive of cut-out.[2]

The X-Bolt Dynamic Hip Plating system (X-Bolt Orthopaedics, Dublin, Ireland) is a device which builds on the SHS and seeks to improve fixation in the femoral head with the aim of reducing the risk of 'cut-out'. It does this with the use of expanding flanges which engage and compress the surrounding cancellous bone in the femoral head and thereby improve fixation.[7] It is not yet clear if the same biomechanical advantages from a tip-apex distance of less than 25 mm apply to the X-Bolt. However, anecdotally, some surgeons report difficulty with minimising the tip-apex distance when implanting the X-Bolt and find that the device "backs out" as the expanding flanges are deployed. This may lead to an increased incidence of cut-out and implant failure.

In this work we compare the radiological measurements of the tip-apex distance and incidence of cut-out for two groups of patients with unstable trochanteric hip fractures treated with the SHS or X-Bolt as part of the Warwick Hip Trauma Evaluation (WHiTE) One trial.[8]

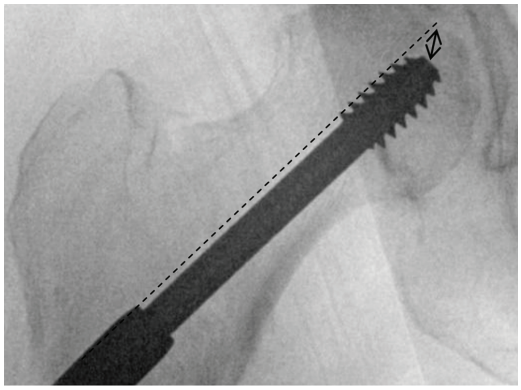

Fig.1a

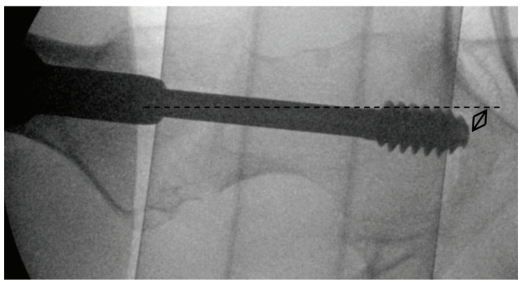

Fig.1b

Intra-operative radiographs showing measurement of the tip-apex distance for SHS in antero-posterior (a) and lateral (b) views. The apex of femoral head was defined as the intersection of the central axis of the femoral neck (dashed line) with subchondral bone. Double headed arrows showing tip-apex measurement.

Patients and Methods

We examined the intra-operative radiographs of participants in the WHiTE One study.[8] WHiTE One was an embedded pilot randomised controlled trial to investigate the clinical effectiveness of the X-Bolt compared with SHS (Depuy Synthes, Warsaw, Indiana) fixation of unstable pertrochanteric hip fractures.[8,9] Ethical approval was received on 6 November 2012 from the National Research Ethics Service Committee West Midlands – Coventry and Warwickshire (12/WM/0352). The method of Baumgaertner et al[2] was employed to determine the tip-apex distance which is the sum of two measurements, in millimetres, from the tip of the lag screw to the apex of the femoral head in two orthogonal plain radiographic projections (anteroposterior and lateral).[2] The apex of the femoral head was defined as the point at which a line drawn in the centre of, and parallel to, the femoral neck intersects with the subchondral bone on both the anteroposterior and lateral views (see Figs 1 and 2).[2] The magnification of radiographic images was corrected for by calibrating our measurement instrument against the known diameter of the shaft of the lag screw (8 mm for the SHS and 9 mm for the X-Bolt). Both the SHS and X-Bolt were four-hole 135° dynamic barrel-plate implants. In addition to the tip-apex distance, we also recorded the position of the lag screw in the femoral head and the quality of fracture reduction.[2] The position of the lag screw in the femoral head was recorded by dividing the femoral head into nine zones[10,11] resulting from the combined permutations of the lag screw position on the AP (superior, centre, inferior) and lateral (anterior, centre, posterior) radiographs. To define the boundaries of the nine zones, the femoral head was divided into thirds on both the AP and lateral views. The quality of fracture reduction was judged as good, acceptable, or poor according to the criteria originally described by Baumgaertner et al.[2] We recorded baseline demographic data and the incidence of screw 'cut-out' at a median follow-up time of 17 months.

Unpaired *t*-, Fisher's exact and chi-squared tests were used for significance testing of the differences between tip-apex distance, lag screw position and quality of reduction in the SHS and X-Bolt groups on a per protocol basis using GraphPad Prism 6.00 for Mac OS X (GraphPad Software Inc., La Jolla, California). Survival analyses were performed to determine the hazard ratio for lag screw cut-out with log rank test of significance between the SHS and X-Bolt groups. A p-value of < 0.05 was considered to be statistically significant.

Results

A total of 93 radiographs (44 X-Bolt and 49 SHS) were available for analysis. The mean age in the X-Bolt group was 83.6 years (range 60 to 96) and 84.8 years (range 63 to 96) in the SHS group.[8] The predominant fracture type was AO 31-A2. In the X-Bolt group there were 40 A2, and 4 A3 type fractures, compared with the SHS group in which there were 41 A2, and 8 A3 fractures.

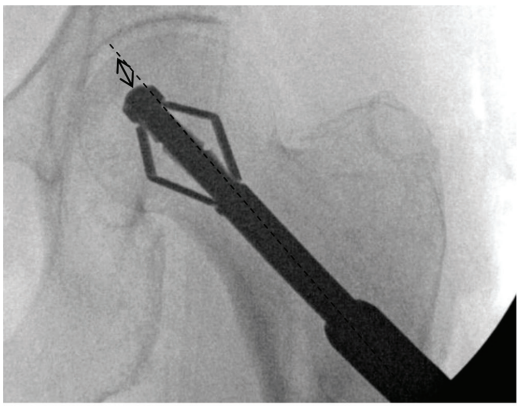

Fig. 2a

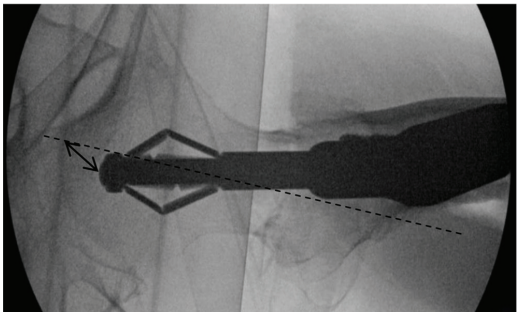

Fig. 2b

Intra-operative radiographs showing measurement of tip-apex distance for the X-Bolt dynamic plating system in anteroposterior (a) and lateral (b) views. The apex of femoral head was defined as the intersection of the central axis of the femoral neck (dashed line) with subchondral bone. Double headed arrows showing tip-apex measurement.

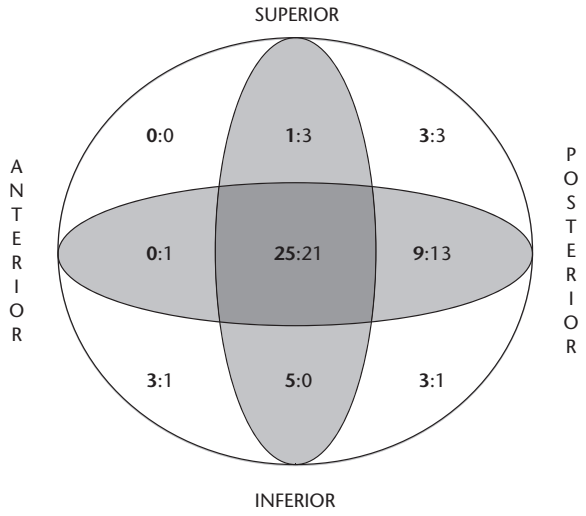

Fig. 3

The distribution of lag screw positions in the femoral head. Ratios of Sliding hip screw (in bold) to X-Bolt are given in each zone. Note: One X-Bolt had an inadequate lateral radiograph, and so its position could not be determined.

Table I. Mean tip-apex distance for the Sliding Hip Screw (SHS) and X-Bolt. Mean difference in tip-apex-distance = 3.7mm (95% confidence interval 1.58 to 5.73, p=0.001)

	SHS	X-Bolt	p-value
Number of participants	49	44	-
Mean age in yrs (range)	84.8 (63 to 96)	83.6 (60 to 96)	0.77*
Mean tip-apex distance in mm (range)	17.1 (9.2 to 27.3)	20.8 (9.4 to 32.6)	0.001*

*unpaired *t*-test

The majority of the lag screws were implanted in the centre-centre or centre-posterior positions in both the SHS and X-Bolt groups (Fig. 3). There was no significant difference between the proportions in each of the nine zones (Fisher's exact test p values: Superior anterior/centre/posterior, 1.00/0.34/1.0; Centre anterior/centre/posterior, 0.47/0.84/0.23; Inferior anterior/centre/posterior, 0.62/0.06/0.62).

There was no significant difference in the proportion of fractures with good or acceptable reductions between the two groups (SHS 90% *versus* X-Bolt 91%, p = 0.85, chi-squared test).

The mean tip-apex distance differed significantly between the two groups (Table I). The small number of participants precludes meaningful analysis of the tip-apex distance within each of the nine zones of the femoral head. However, in the centre-centre and centre-posterior positions, where most of the lag screws were positioned, the mean tip-apex distance was 14.6 mm in the SHS group and 17.7 mm in the X-Bolt (p = 0.014) for the centre-centre position, and 18.3 mm in the SHS group (6%) and 23.1 mm in the X-Bolt group (p = 0.004) for the centre-posterior position.

There were three lag screw cut-outs in the SHS group at seven months, 13 months, and 16 months post-operatively. The tip-apex distances for these failures were 23.3 mm, 16.6 mm, and 16.2 mm, respectively, and all occurred in A2 fracture types. The lag screw positions were centre-posterior, centre-centre, and centre-centre, respectively. The quality of fracture reduction in these failures was acceptable, poor and acceptable, respectively. The survival analyses revealed no significant difference in cut-out (Fig. 4) between the SHS and X-Bolt groups. The hazard ratio for cut-out was 6.87 (95% confidence interval 0.71 to 66.17) at a median follow-up time of 17 months. There were no lag screw cut-outs observed in the X-Bolt group.

Discussion

Our analysis has shown a significantly increased mean tip-apex distance when implanting the X-Bolt compared with the SHS. This difference, although statistically significant, does not appear to be clinically important and has not resulted in an increased incidence of screw cut-out. The increased tip-apex distance seen in the X-Bolt group may be multifactorial. The device is blunt-nosed and cannot advance beyond the reamed tunnel depth, unlike a lag screw, which may be advanced a little further into unreamed bone. Similarly, at the bone compactor step prior to implanting the X-Bolt, if the instrument is not at the tip-apex point when being deployed, this will result in a final X-Bolt position with an increased tip-apex distance. Recently, the manufacturer has updated the design of the bone compactor to help surgeons achieve optimum deep placement.[12]

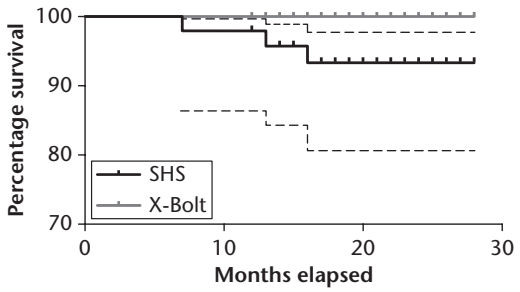

Fig. 4

Kaplan-Meier survival analysis for lag screw cut-out. No significant difference was found between SHS and X-Bolt (log rank test p = 0.09). Hazard ratio = 6.87 (95% CI 0.71, 66.17). The censored observations are shown by the check marks on the solid lines. Dashed lines correspond to the 95% confidence interval.

Baumgaertner et al[2] studied 198 fracture fixations using a variety of angled plates (130°, 135°, 140°, 145°, 150°) where the mean tip-apex distance was 25 mm (9 to 63) and the overall incidence of cut-out at three months (excluding 150° side plates) was 4%. The mean tip-apex distance in those fractures for which cut-out occurred was 38 mm (28 to 48). Most surgeons are guided by Baumgaertner et al's[2] seminal paper and now take steps to minimise the tip-apex distance in their intra-operative fixation. Consequently, our cohort of hip fracture patients looks very different from that in Baumgaertner et al's study, and with a mean overall tip-apex distance of < 20 mm it is likely that the incidence of cut-out will be less than 4%. Indeed, at 12 months' follow-up we observe 2% cut-out in the SHS group (one out of 49 fixations) *versus* 0% with the X-Bolt (number needed to treat = 1/absolute risk reduction = 1/0.02 = 50). At this rate, we would require 1228 participants (with 90% power and 5% type I error) to resolve a significant difference between the groups or 608 participants at the 4% level quoted by Baumgaertner et al.[2] The small sample size in this pilot study clearly represents the major limitation of this work and precludes any firm conclusions regarding the risk of cut-out. The strength of this study comes from the pragmatic nature of the inclusion criteria in WHiTE One.[8] All patients > 60 years of age with an unstable pertrochanteric fracture, including those with cognitive impairment, were included. Surgery was carried out by the on-call trauma team (consultants with a variety of subspecialty interest and training registrars) at the time of admission, a model which is common practice in the United Kingdom. The measured tip-apex distances are therefore likely to be representative of standard United Kingdom NHS practice. We do not believe that there was a significant learning curve associated with the use of the X-Bolt since both the surgical approach and device implantation do not differ significantly from the SHS.

We observed two late failures (> one year post surgery) in the SHS group. These two implant failures had tip-apex distances of 16.6 mm and 16.2 mm, which are significantly below the 25 mm threshold suggested by Baumgaertner et al[2] as strongly predictive of failure. It is likely that worsening bone quality and general frailty will have contributed to these late failures. It is not clear from the literature what the incidence of late failure is for the SHS in order to make a comparison or draw conclusions from this observation.

The main findings from this study are that the X-Bolt is a safe device with no increased cut-out when compared with the SHS, despite the observed increase in tip-apex distance with the X-Bolt. Surgeon concerns about minimising the tip-apex distance when implanting the X-Bolt compared with the SHS are justified but do not appear to be clinically important.

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Author Contributions

- M. A. Fernandez: Study inception, data collection and analysis, drafted the manuscript.
- A. Aquilina: Data collection and analysis, manuscript preparation.
- J. Achten: Study inception, manuscript preparation.
- N. Parsons: Review of statistical methods, manuscript preparation.
- M. L. Costa: Study inception, manuscript preparation.
- X. L. Griffin: Study inception, manuscript preparation.

ICMJE Conflicts of Interest

- None declared