Biomechanical Study Comparing Cut-out Resistance of the X-Bolt® and Dynamic Hip Screw at Various Tip-Apex Distances

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ABSTRACT

Background: Bone quality in hip fractures is poor and there is a need to not only correctly position metalwork within the femoral head, but also for implants to resist cut-out. New implant designs may help to reduce metalwork cut-out, leading to fewer failures of fixation. This study compared the cut-out strength of a Dynamic Hip Screw (DHS) to that of an X-Bolt® (X-Bolt Orthopaedics, Dublin, Ireland) implant in an osteoporotic Sawbones® (Sawbones, Vashon Island, WA) model.

Methods: An unstable fracture model (AO 31-A2) was created using low-density 5 pound per cubic foot (pcf) Sawbones®. The DHS and X-Bolts® were inserted into the Sawbones® femoral head at Tip-Apex Distances (TAD) of 10mm, 15mm, 20mm, 25mm, 30mm and 40mm. A cyclic-loading Instron® machine (Instron Corp., Norwood, MA) pushed the bone at a compression rate of 5mm per minute at a 20-degree angle to the axis of the implant with an upper force limit of 4000N. Maximum force reached and load to failure, defined as movement of the implant by 5mm, were recorded. Four implants were used per group to give a total of 48 tests between the two groups.
Hip fracture is a significant cause of morbidity and mortality; it carries a 7.1% mortality rate within 30 days of injury and nearly a third of patients die within one year following injury.1 According to the Annual Report of the National Hip Fracture Database, hip fracture was responsible for significant costs of over £1 billion per year for the UK Health Service in 2018.1 This figure can double with the addition of medical and social care costs. Hospitals plan for a fractured hip for every one thousand people in their catchment area,2 and this number can be expected to rise as the population ages; globally, the number of people aged over 60 is estimated to exceed 2 billion by 2050.3 It is well-recognised that complications are extremely costly and increase the risk of mortality. In a study of 2360 cases of proximal femoral fracture, Thakar et al.4 found that the mean cost of treatment in patients with complications was £18,709 (£2606.30 to £60827.10), compared with £8610 (£918.54 to £45601.30) for uncomplicated cases (p < 0.01), with a mean length of stay of 62.8 (44.5 to 79.3) and 32.7 (23.8 to 35.0) days, respectively. The probability of mortality after one month in these cases was significantly higher than that in a control group, with a mean survival of 209 days, compared with 496 days for the controls. Therefore, reducing complication rates by even a small amount could have enormous financial benefits, reduce mortality and prevent an increased length of stay.4–6

A well-established method for the treatment of pertrochanteric, extra-capsular femoral fractures that have minimal comminution and sufficient lateral buttress is the Dynamic Hip Screw (DHS).7 The DHS was introduced by Clawson in 1964 and is synonymous with the compression hip screw or sliding hip screw (SHS).8 Sliding at the screw-plate interface allows collapse of the fracture site. In cases of weak, osteoporotic bone, fixation with preservation of the blood supply must be observed, thus permitting early mobility. However, the bone around the device often fails. This same weakened bone that led to the fragility fracture in the first place is subsequently required to provide the metalwork anchorage for operative fixation. The failure of this device is most often related to cut-out of the lag screw from the femoral head as it collapses into the varus. Generalised failure of fixation can occur in up to 10% of cases.9 Additional reasons for complications include infection, non-union leading to metal fatigue failure, femoral shaft fracture, and lateral wall fracture leading to shortening and symptomatic hardware.10,11 Baumgaertner described the “Tip-Apex Distance” as a tool for assessing the placement of a DHS within the femoral head.12 This measurement is calculated by adding the distance from the tip of the hip screw to that of the apex of the femoral head on antero-posterior (AP) and lateral views (Fig 1). Correction is made for magnification by using a known distance, the diameter of the lag screw shaft. The target maximum distance was set at 25mm, as the authors reported no failure of fixation due to “cut-out” of the hip screw.

Results: The X-Bolt® demonstrated a superior average maximum total load push-out force compared to the DHS group for all of the TAD configurations tested. The maximum force reached in the X-Bolt® group was significantly higher than that in the DHS group at a TAD of 10mm (X-Bolt® 3299.25N vs. DHS 2843.75N, P<0.029) and 30mm (X-Bolt® 2908.25N vs. DHS 2030N, P<0.029). The X-Bolt® also had a higher load to failure than the DHS group at all of the TAD values tested.

Conclusions: The X-Bolt® implant gave superior performance compared to the standard DHS, as reflected by a greater push-out force in an osteoporotic Sawbones® model.

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INTRODUCTION

Hip fracture is a significant cause of morbidity and mortality; it carries a 7.1% mortality rate within 30 days of injury and nearly a third of patients die within one year following injury.1 According to the Annual Report of the National Hip Fracture Database, hip fracture was responsible for significant costs of over £1 billion per year for the UK Health Service in 2018.1 This figure can double with the addition of medical and social care costs. Hospitals plan for a fractured hip for every one thousand people in their catchment area,2 and this number can be expected to rise as the population ages; globally, the number of people aged over 60 is estimated to exceed 2 billion by 2050.3 It is well-recognised that complications are extremely costly and increase the risk of mortality. In a study of 2360 cases of proximal femoral fracture, Thakar et al.4 found that the mean cost of treatment in patients with complications was £18,709 (£2606.30 to £60827.10), compared with £8610 (£918.54 to £45601.30) for uncomplicated cases (p < 0.01), with a mean length of stay of 62.8 (44.5 to 79.3) and 32.7 (23.8 to 35.0) days, respectively. The probability of mortality after one month in these cases was significantly higher than that in a control group, with a mean survival of 209 days, compared with 496 days for the controls. Therefore, reducing complication rates by even a small amount could have enormous financial benefits, reduce mortality and prevent an increased length of stay.4–6

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Results: The X-Bolt® demonstrated a superior average maximum total load push-out force compared to the DHS group for all of the TAD configurations tested. The maximum force reached in the X-Bolt® group was significantly higher than that in the DHS group at a TAD of 10mm (X-Bolt® 3299.25N vs. DHS 2843.75N, P<0.029) and 30mm (X-Bolt® 2908.25N vs. DHS 2030N, P<0.029). The X-Bolt® also had a higher load to failure than the DHS group at all of the TAD values tested.

Conclusions: The X-Bolt® implant gave superior performance compared to the standard DHS, as reflected by a greater push-out force in an osteoporotic Sawbones® model.
from the femoral head in patients with less than this distance. In that study, there was no consideration of the variation in bone quality and no comment on the fact that TAD might need to be adjusted based on the size of the femoral head, which can vary significantly between sexes.

The risk of failure also increases with an unstable fracture configuration, inadequate reduction and poor bone quality.\(^{10}\)

The technique has been repeated by several authors.\(^{13-16}\) A logistic regression in 937 patients demonstrated that TAD was the most important factor for the risk of cut-out.\(^{11}\) A 24-fold increase in the risk of screw cut-out has been demonstrated in patients with a TAD in excess of 25mm, in comparison to those with less than 25mm.\(^{15}\) The method has also been described in the use of cephalomedullary screw placement, where failure rates were reduced with lower TAD.\(^{16,17}\)

Although the importance of aiming for a TAD >25mm is well-recognised, this is not always achieved. Modification of the implant design may affect fixation and the cut-out of implants,\(^{18}\) and various screw designs have been investigated, including blades and the X-Bolt\(^{®}\) (X-Bolt Orthopaedics, Dublin, Ireland). In comparison to a simple screw, these designs may allow compression of the surrounding bone instead of cutting-out of the bone as with a normal screw design. This may be particularly important in osteoporotic bone, where bone density is reduced. A design that uses the principle of compressing surrounding bone to the greatest extent is the X-Bolt\(^{®}\).\(^{19}\)

With cut-out representing an important clinical issue, this study was performed to determine whether the X-Bolt\(^{®}\) can anchor more tightly into weakened bone and thus reduce cut-out in an osteoporotic Sawbones\(^{®}\) (Sawbones, Vashon Island, WA) model compared to the DHS, the conventional fixation method, using various TAD configurations.

We hypothesised that the X-Bolt\(^{®}\) cut-out rate would be significantly lower for all TAD values and thus more forgiving for less-favourable TAD compared with the gold-standard DHS. We aimed to develop a standardised, repeatable osteoporotic model for testing.

<table>
<thead>
<tr>
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<th>Mechanical properties of 5 and 10 pcf Sawbones(^{®})</th>
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<tr>
<td>Density</td>
<td>Strength</td>
</tr>
<tr>
<td>(pcf)</td>
<td>(g/cc)</td>
</tr>
<tr>
<td>5</td>
<td>0.08</td>
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<tr>
<td>10</td>
<td>0.16</td>
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**Materials and Methods**

An unstable fracture model (AO 31-A2) was created using low-density surrogate bone (5 pounds per cubic foot (pcf), Sawbones\(^{®}\), Sawbones, Vashon Island, WA). Solid Rigid Polyurethane Foam (SRPF) with a density of 5 lb/ft\(^3\) exhibits material properties and characteristics comparable to those of osteoporotic bone,\(^{20-22}\) as shown in Table I. In a study of mechanical properties of cancellous bone, Li and Aspden found a Young’s modulus (E) of 247 E(MPa) (range 50 – 410), a yield strength of 2.5 MPa (0.6 – 5.8) and an energy absorbed to the yield point of 16.3 kJ/m\(^3\) (2 – 52) in 17 cadaveric femoral heads (13/4 female/male), which are comparable to the values for Sawbones\(^{®}\) models.\(^{21}\)

A cyclic-loading Instron\(^{®}\) machine (Instron Corp., Norwood, MA) was used to compare push-out at a 20-degree angle to the axis of the implant, to replicate the weight-bearing axis through the femoral head between the DHS screw (Smith & Nephew Inc., Memphis, TN) and an X-Bolt\(^{®}\) at different TAD values. Displacement and force exerted were recorded until the device had moved, signifying instability and progression to cut-out of the implant. For the purpose of this study, the implant was defined to be loose when it had moved \(\geq 5\) mm.\(^{22}\) The Sawbones\(^{®}\) models were individually machine-milled to give a smooth hemispheric head much like the femoral head. The stock material was 40mm thick and milled 45mm wide, representative of a small femoral head according to the literature.\(^{23}\) These were uniformly produced and then placed in a metal housing for mechanical testing. Once the DHS and X-Bolt\(^{®}\) was inserted, the base of the screw was inserted into a metal block where it was rigidly locked using screws. The plate on which the device sat was clamped to the Instron\(^{®}\) table, so that the only motion would be at the screw-Sawbones\(^{®}\) interface, as in Fig. 2.

The X-Bolt\(^{®}\) and DHS implants were tested with six screw positions in the 5pcf Sawbones\(^{®}\) to give the following TAD values for mechanical testing: 10mm, 15mm, 20mm, 25mm, 30mm and 40mm.

Four implants were tested in each group to ensure reproducibility, for a total of 48 tests between the two devices. We used 12 X-Bolt\(^{®}\) devices and eight DHSs.

The Instron\(^{®}\) machine was programmed to give a pre-load of 5N and then compress the sample at a rate of 5 mm/min up to a maximum force of 4000N.

For each of the Sawbones\(^{®}\), a small hole was drilled at the centre of the Sawbones\(^{®}\) to ensure there was no eccentric metalwork positioning that would increase shear forces in this model of the “femoral head”. Once the
screw was positioned centrally, the devices were inserted and a depth measure was used to confirm the distance of the metalwork from the tip to control the TAD, as seen in Fig. 3.

The DHS was inserted to the desired position after drilling with an 8mm drill bit as per routine surgical technique as part of the triple reamer. Figure 4 shows the DHS used (red square) as part of the complete device configuration for clinical use.

The X-Bolt® was deployed according to the manufacturer’s guidelines. The X-Bolt® is an expanding bolt with a central drive shaft comprised of threads in opposite directions. It has wings that deploy perpendicularly to compact the surrounding cancellous bone, which the manufacturer claims to improve anchorage (Fig. 5).

After wire insertion, the 9mm reamer was then inserted to the desired TAD and then a bone crusher was used to compact the surrounding bone through an arc of 180 degrees. The X-Bolt® was then expanded using a screwdriver with the Sawbones® anchored in a clamp to prevent rotation and to ensure full deployment of the wings.

All statistical analyses were performed using SPSS (version 17; IBM Corp., Armonk, NY). We used statistics based on non-parametric data. Due to the low number of subjects in each group, we could not assess normality. The Mann-Whitney U test was used to identify significant differences between the devices at various TADs. P-values of less than or equal to 0.05 were considered statistically significant.
RESULTS

The X-Bolt® demonstrated a superior average total load compared to the DHS group in all TAD configurations, as seen in Table II; this difference was significant at TAD of 10mm (P = 0.029) and 30mm (P = 0.029). By averaging the mean forces across the groups, we see the difference depicted in Fig. 6. With the X-Bolt®, significantly higher average forces were required to achieve failure, defined as movement of ≥5mm, for all TAD values, as shown in Table III (P = 0.029).

Macroscopically, the DHS group had more varus positioning of the screw, as seen in Fig. 7.

DISCUSSION

In this study, we compared a new technology, the X-Bolt®, to a well-established technology, DHS, in a push-out test using a standardised Sawbones® model. Cut-out is due to multiple factors, and the ability of various devices to anchor to weakened bone has not been extensively tested. We found that, in a 5pcf osteoporotic Sawbones® model, the X-Bolt® could resist a greater average force than the DHS in all TAD configurations.

The X-Bolt® also required greater force to move the device 5mm and this difference was statistically significant. This suggests that the compaction of weak cancellous bone with the use of X-Bolt® enables the device to anchor more firmly into weak bone. Another potential reason why the DHS moves at lower applied forces is that it has a sharp cutting tip instead of a blunted nose like the X-Bolt®, which prevents the latter from migrating into unreamed bone. These results are consistent with those presented by Gibson et al.,25 who tested the same devices on an Instron® machine with cyclic loading in a 5pcf Sawbones® model. They noted that the X-Bolt® demonstrated superior resistance to cut-out and withstood greater loading than a SHS, but did not explore the effect of TAD on cut-out. This is an important point because changing the TAD may have compromised the X-Bolt®’s ability to fully open. We showed that this was not the case, and the X-Bolt® gave superior results in all TAD positions. A pilot clinical study published by Griffin et al. 26 did not show any significant difference in EQ-5D or any secondary outcome measures. Although the study was not powered to report failures, interestingly, of the total 100 patients randomised, 3 in the DHS group and none in the X-Bolt® group required revision.

<table>
<thead>
<tr>
<th>TAD</th>
<th>X-Bolt 1 (N)</th>
<th>X-Bolt 2 (N)</th>
<th>X-Bolt 3 (N)</th>
<th>X-Bolt 4 (N)</th>
<th>Average (N)</th>
<th>DHS 1 (N)</th>
<th>DHS 2 (N)</th>
<th>DHS 3 (N)</th>
<th>DHS 4 (N)</th>
<th>Average (N)</th>
<th>P Value average differences</th>
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<td>3601</td>
<td>3532</td>
<td>2948</td>
<td>3116</td>
<td>3299.25</td>
<td>2805</td>
<td>2790</td>
<td>2850</td>
<td>2930</td>
<td>2843.75</td>
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</tr>
<tr>
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<td>3323</td>
<td>3148</td>
<td>3020</td>
<td>3231.25</td>
<td>3150</td>
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<td>3020</td>
<td>3250</td>
<td>3172.50</td>
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<td>2640</td>
<td>3220</td>
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<td>2915</td>
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<td>3388</td>
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<td>2300</td>
<td>2100</td>
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</table>

Table II

Maximum forces reached according to TAD in the two test groups

![Figure 6. Average maximum force for all TAD values.](image-url)
Surgeons aim for a TAD of ≤25mm. Although this may not always be achieved, the present results show that, even with a higher TAD, the X-Bolt® holds more firmly than a DHS. This correlated with the results of a clinical study that reported that the X-Bolt® functions well in less-favourable TAD configurations and may resist varus cut-out.19-26

Limitations
To simulate cut-out, a push-out compression model was used which, while not representative of the cyclic loading that is experienced by the native hip, is nonetheless an acceptable, validated model.27-29 This study only looked at TAD at a 20-degree angle to the axis of the implant. However, implants may fail in other modes, including torque. Gosiewski et al. demonstrated that the X-Bolt® was superior in terms of torque compared to DHS.30 An increase in the number of Sawbones® may allow a significant difference to be observed at all TADs. Because of the small number of implants available, the implants were re-used for each test. However, the SRPF material was very weak, mimicking osteoporotic bone, and this should have had no significant detrimental impact on the implants.

Failure was defined as movement of 5 mm, but this value is arbitrary and people may consider the device to be loose at different thresholds. It is unclear how this would translate to a clinical setting.

Further work is needed to examine these TAD configurations in Sawbones® models with various densities to replicate not only osteoporotic and osteopaenic bone, but also to see how the devices perform in higher-density material. It would also be useful to see how these devices perform when the metalwork is placed eccentrically, rather than centrally, in the femoral head model, by using the nine Cleveland zones of the femoral head.31

Conclusion
An ageing population can be expected to lead to an increasing number of hip fractures, which would place a large financial burden on the health system. Although failure rates are generally low (less than 10%), due to the large numbers involved (over 65,000 hip fractures in the UK per year), this represents a large clinical problem.

This study demonstrated the utility of a relatively new technology in a Sawbones® model which may be beneficial for anchoring to weakened bone, as demonstrated by a greater push-out force compared to a DHS.30

<table>
<thead>
<tr>
<th>TAD</th>
<th>X-Bolt 1</th>
<th>X-Bolt 2</th>
<th>X-Bolt 3</th>
<th>X-Bolt 4</th>
<th>Average</th>
<th>DHS 1</th>
<th>DHS 2</th>
<th>DHS 3</th>
<th>DHS 4</th>
<th>Average</th>
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<tr>
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<td>550</td>
<td>556</td>
<td>508</td>
<td>531.5</td>
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<td>175</td>
<td>220</td>
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<td>502</td>
<td>428</td>
<td>464</td>
<td>445</td>
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<td>211</td>
<td>220</td>
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<tr>
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<td>605</td>
<td>450</td>
<td>491</td>
<td>300</td>
<td>364</td>
<td>350</td>
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<tr>
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<td>492</td>
<td>496</td>
<td>496</td>
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<td>307</td>
<td>295</td>
<td>240</td>
<td>201</td>
<td>260.75</td>
</tr>
<tr>
<td>30mm</td>
<td>313</td>
<td>460</td>
<td>506</td>
<td>424</td>
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<td>180</td>
<td>264</td>
<td>164</td>
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<td>384</td>
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<td>169</td>
<td>218</td>
<td>219</td>
<td>208</td>
<td>203.50</td>
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</table>

Figure 7. The models after testing. The arrow indicates varus deformation in the DHS Sawbones® model.
**AUTHORS’ DISCLOSURES**

AG is a consultant for X-Bolt Orthopaedics (Dublin, Ireland). The authors declare that there are no other conflicts of interest.

**ACKNOWLEDGMENTS**

X-Bolts® (X-Bolt Orthopaedics, Dublin, Ireland) and Sawbones® (Sawbones, Vashon Island, WA) were provided by X-Bolt Orthopaedics. DHS was provided by Smith & Nephew Inc. (Memphis, TN).

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**REFERENCES**