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The efficacy of rotational control designs in promoting torsional stability of hip fracture fixation

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Objectives

Fractures of the proximal femur are a common clinical problem, and a number of orthopaedic devices are available for the treatment of such fractures. The objective of this study was to assess the rotational stability, a common failure predictor, of three different rotational control design philosophies: a screw, a helical blade and a deployable crucifix.

Methods

Devices were compared in terms of the mechanical work (W) required to rotate the implant by 6° in a bone substitute material. The substitute material used was Sawbones polyurethane foam of three different densities (0.08 g/cm³, 0.16 g/cm³ and 0.24 g/cm³). Each torsion test comprised a steady ramp of 1°/minute up to an angular displacement of 10°.

Results

The deployable crucifix design (X-Bolt), was more torsionally stable, compared to both the dynamic hip screw (DHS, $p = 0.008$) and helical blade (DHS Blade, $p = 0.008$) designs in bone substitute material representative of osteoporotic bone (0.16 g/cm³ polyurethane foam). In 0.08 g/cm³ density substrate, the crucifix design (X-Bolt) had a higher resistance to torsion than the screw (DHS, $p = 0.008$). There were no significant differences ($p = 0.101$) between the implants in 0.24 g/cm³ density bone substitute.

Conclusions

Our findings indicate that the clinical standard proximal fracture fixator design, the screw (DHS), was the least effective at resisting torsional load, and a novel crucifix design (X-Bolt), was the most effective design in resisting torsional load in bone substitute material with density representative of osteoporotic bone. At other densities the torsional stability was also higher for the X-Bolt, although not consistently significant by statistical analysis.

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Article focus

- To assess the rotational stability of three different fracture fixation device design principles: Screw (DHS – Dynamic Hip Screw), helical blade (DHS Blade), and deployable crucifix (X-Bolt).
- Undertaken using bone substitute material simulating three bone densities.

Key messages

- The deployable crucifix design (X-Bolt) was more torsionally stable, compared with both the screw (DHS, $p = 0.008$) and helical blade (DHS Blade, $p = 0.008$)

- designs in osteoporotic bone substitute material (0.16 g/cm³ polyurethane foam).
- The torsional stability of all three designs increased with density of the bone material.

Strengths and limitations

- The use of bone substitute material results in consistent material properties but may be less clinically relevant.
- Results are consistent with other publications.
- Limitations: small sample size and reuse of implants.

Introduction

Hip fractures are a serious condition most affecting the elderly, as this population is prone to falls and osteoporosis. The composition of modern society is changing worldwide, with estimations of the global number of people over 60 exceeding 2 billion by 2050.¹ The incidence of hip fractures is also increasing, with the annual number of fractures in 2050 estimated to be 6.3 million.² Over a 12 month period (1 April 2012 to 31 March 2013) the UK National Hip Fracture Database recorded more than 61 500 cases, with a 30-day mortality rate of 8.2%.³ The effectiveness of the procedure is also important, as a recent study has shown the median cost of treatment in patients with complications is £18 700 compared with £8600 for cases without complications.⁴ Leal et al⁵ estimate the annual cost in the United Kingdom associated with hip fractures at £1.1 billion; one of the most expensive conditions treated by the NHS.

One of the standard treatments for stable intertrochanteric fractures with minimal comminution and sufficient lateral buttress is fixation using a compressive sliding hip screw design. This type of fixation is referred to as the Dynamic Hip Screw (DHS), which was first used in 1964 by Clawson.⁶ It has undergone significant developments since its initial introduction.⁷ Cephalomedullary nails have also become popular and produce comparable results with respect to complications and residual pain.⁸

Rotational stability is a highly desirable characteristic of an effective hip fracture fixation device. A contributor to failure of fracture fixation is avascular necrosis (AVN).⁹ This may occur when the femoral head rotates axially relative to the neck, damaging the remaining vascular supply, and preventing revascularisation from taking place.¹⁰ A recent clinical study using radiostereometric analysis (RSA) to quantify the stability of an undisplaced femoral neck fracture post fixation, has shown a mean rotation of 5.5° (-3.6° to 14.0°) at four months follow-up, when using a DHS or three cannulated hip screws.¹¹ Torsional instability of an implant system is a predictor of the most common failure modes, including cut-out.¹²

The hip screw has undergone evolution to address rotational stability, and new design philosophies have emerged. The helical blade design (DHS Blade; Synthes GmbH, Zuchwil, Switzerland) was partially driven by the requirement for improved rotational stability. In addition to the design changes to the DHS, alternative approaches to improve rotational stability have emerged. One such approach is the deployable crucifix design (X-Bolt; X-Bolt Orthopaedics, Dublin, Ireland). The distinguishing feature of this design is a crucifix expansion system for obtaining fixation; this method of fixation is claimed to directly enhance the rotational stability. Whilst studies have compared this fixation device in terms of cut-out,¹³ no investigation has comparatively assessed the rotational stability of these design strategies.

The aim of the current study was to assess and compare the rotational stability of three torsional control philosophies.

Materials and Methods

Implant and sample preparation. Torsion tests were carried out using a bone substitute material, Solid Rigid Polyurethane Foam (SRPF; Sawbones, Vashon, Washington). Previous studies have shown that SRPF with a density of 0.16 g/cm³ is representative of the material properties and characteristics of osteoporotic bone.¹⁵⁻¹⁷ In the current study the effect of bone quality was included by performing additional tests with SRPF of 0.08 g/cm³ density, representing highly osteopenic bone and SRPF of 0.24 g/cm³ representing mildly osteopenic bone.¹⁶

The use of SRPF bone substitute material was adopted to provide standardised and repeatable test conditions; this is now well accepted in the literature for experimental studies¹⁷ and by standards organisations.¹⁸ Cadaveric material has highly variable mechanical properties which often makes meaningful comparisons difficult; it is also costly, and requires biohazard precautions that are not necessary with a non-biological analogous material.

The SRPF was supplied in 40 mm thick slabs, which were cut into 47 by 47 by 40 mm blocks. The dimensions were selected based on the average diameter of a female femoral head, which has been reported to be 47 mm.¹⁹ The single gender analysis represents the worst case scenario, as females generally have lower femoral head diameters and higher incidence of osteoporosis. Each block was pre-drilled using a pillar drill to a pre-set depth of 35 mm, and the implants inserted following the manufacturers' surgical technique.

The implants tested to represent each torsional control philosophy were the DHS (Synthes GmbH), the Dynamic Hip System Blade (DHS Blade) and the X-Bolt. The DHS is considered to be conventional and has been described previously.⁶ The DHS Blade comprises a head and shaft, and has a locking system allowing the relative rotation between the two to be adjusted. The head consists of helical blades with a large surface area, which were introduced to enhance rotational stability. The X-Bolt is a more recently developed dynamic hip fracture fixator. The opposite facing threads of the drive shaft compress and deploy the expandable wings perpendicularly to the shaft, to a diameter of 24 mm. Clockwise and anticlockwise rotation of the hexagonal screw located within the shaft, deploys and retracts the wings respectively (Fig. 1).

Torsion test. The distal end of the implant was rigidly fixed to the actuator of a bi-axial testing machine (Zwick Amsler HBT 25-200; Zwick Testing Machines Ltd., Leominster, United Kingdom), and each SRPF block was rotationally constrained in the plane perpendicular to



Fig. 1a

Fig. 1b

Images showing a) X-Bolt undeployed, b) X-Bolt deployed.

the rotation axis using custom-made brackets clamped to the testing machine baseplate (Fig. 2). Pure rotational stability was tested; no axial load was applied to the samples. The implants were rotated at constant ramp of 1° per minute up to an angular displacement of 10° to allow comparison with results published by O'Neal et al¹⁵ who used this methodology. A sampling frequency of 10 Hz was used to log the torque and angle data. The control and data acquisition was performed using Workshop 96 (Zwick Testing Machines, Version 6.00). A total of 45 tests were completed (three implant types, five tests per implant, in three densities of SRPF, Table I). The number of times each specific implant was reused (Table I) was determined by availability: five X-Bolts; two DHSs; and two Blades. Tests were performed using first the lowest density of foam, then the middle density and finally the highest density.

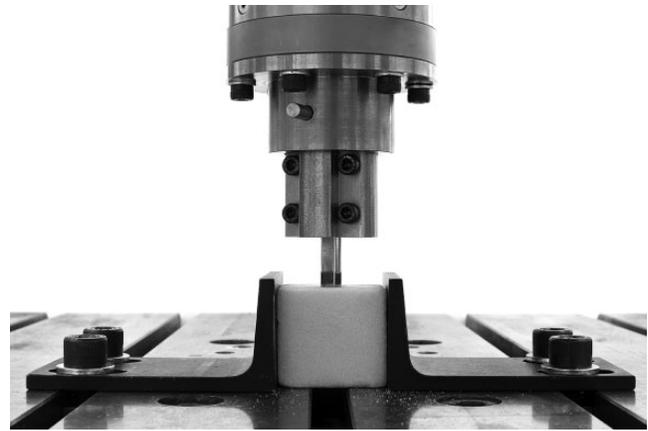


Fig. 2

Image showing the customised test rig used for the torsion testing. The implant was rigidly fixed to the bi-axial actuator. The bone substitute material was rotationally constrained in the axial plane, and was not in contact with base plate.

Signal processing and outcome measure. The testing machine torque output was digitally filtered using a zero-phase lag, fourth order Butterworth filter with 0.05 Hz cut-off frequency (MATLAB, Version R2011b; MathWorks Inc., Natick, Massachusetts). The primary outcome measure was the work done (W , measured in joules (J)) to rotate the implant by 6° and the secondary outcome measure was the peak torque (T , measured in newton meters (Nm)).¹⁵ The specific value (6°) of the angular displacement was selected to enable direct comparison with previous research by O'Neil et al.¹⁵ The work done was calculated by using the trapezium rule to estimate the area under the torque-angle graph (MathWorks Inc.).

Statistical analysis. All statistical analyses were performed using SPSS software (version 20; IBM Corporation, Armonk, New York). Non-parametric tests were used, as normality could not be assessed due to the relatively small number of samples in each group. Comparisons (Kruskal-Wallis) were made between the values of W for each implant across the range of SRPF densities, and for each density across the range of implants. If a significant difference was detected, a Mann-Whitney test was used post-hoc to determine between which pairs of values a significant difference lay. The Spearman correlation coefficient (r_s) was used to determine the relationships between the density SRPF with W and T separately, initially for the entire dataset and then for each implant. It was considered that p-values of less than or equal to 0.05 were statistically significant. The interquartile range (IQR) was used as a measure of data spread, with higher values of IQR an indication of larger variability.

Results

All the implants were intact after each test. There was visible yield on all of the torque-angle plots as the tests were completed, due to the SRPF being loaded beyond the elastic limit (Fig. 3).

Table I. A list of each implant unit and the number of tests at each density

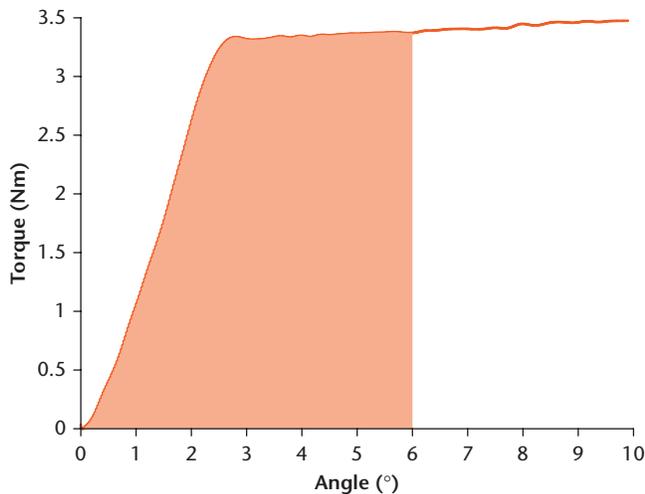
Design	Sample	Solid rigid polyurethane foam density			Tests (n)
		0.08 g/cm ³	0.16 g/cm ³	0.24 g/cm ³	
X-Bolt (X-Bolt Orthopaedics, Dublin, Ireland)	1	1	1	1	15
	2	1	1	1	
	3	1	1	1	
	4	1	1	1	
	5	1	1	1	
DHS Blade (Synthes GmbH, Zuchwil, Switzerland)	1	3	3	3	15
	2	2	2	2	
DHS (Synthes GmbH)	1	3	3	3	15
	2	2	2	2	
Totals		15	15	15	45

DHS, dynamic hip screw

Table II. Median values of work done (W) and peak torque (T) for all densities and fixation devices

SRPF Density	Median (IQR), work done (J)			Median (IQR) peak torque (Nm)		
	DHS	DHS Blade	X-Bolt	DHS	DHS Blade	X-Bolt
0.08 g/cm ³	0.03 (0.026 to 0.034)	0.10 (0.06 to 0.14)	0.10 (0.08 to 0.12)	0.49 (0.39 to 0.59)	1.3 (0.9 to 1.7)	1.6 (1.4 to 1.7)
0.16 g/cm ³	0.06 (0.05 to 0.07)	0.15 (0.13 to 0.18)	0.25 (0.23 to 0.27)	0.75 (0.56 to 0.94)	2.0 (1.9 to 2.1)	3.7 (3.5 to 3.8)
0.24 g/cm ³	0.15 (0.12 to 0.18)	0.15 (0.13 to 0.18)	0.22 (0.19 to 0.25)	1.8 (1.4 to 2.3)	2.2 (1.8 to 2.6)	3.5 (3.2 to 3.8)

SRPF, Solid Rigid Polyurethane Foam; IQR, Interquartile Range; DHS, dynamic hip screw

**Fig 3**

Graph displaying representative output – torque (Nm) versus angle (degrees) for the DHS in 0.24 g/cm³ foam. Area shaded in orange represents work required to rotate the implant by 6°.

In the lowest density SRPF, the DHS Blade exhibited the highest variability in the values of the primary outcome W (IQR = 0.06 to 0.14 J) and the DHS the lowest variability (IQR = 0.026 to 0.034 J) (Table II).

In low density SRPF (0.08 g/cm³) there was no significant difference in W between the X-Bolt and the DHS Blade (Mann-Whitney, $p > 0.999$). However, they both

performed significantly better than the DHS (Mann-Whitney, $p = 0.008$ and $p = 0.016$ respectively, Fig. 4).

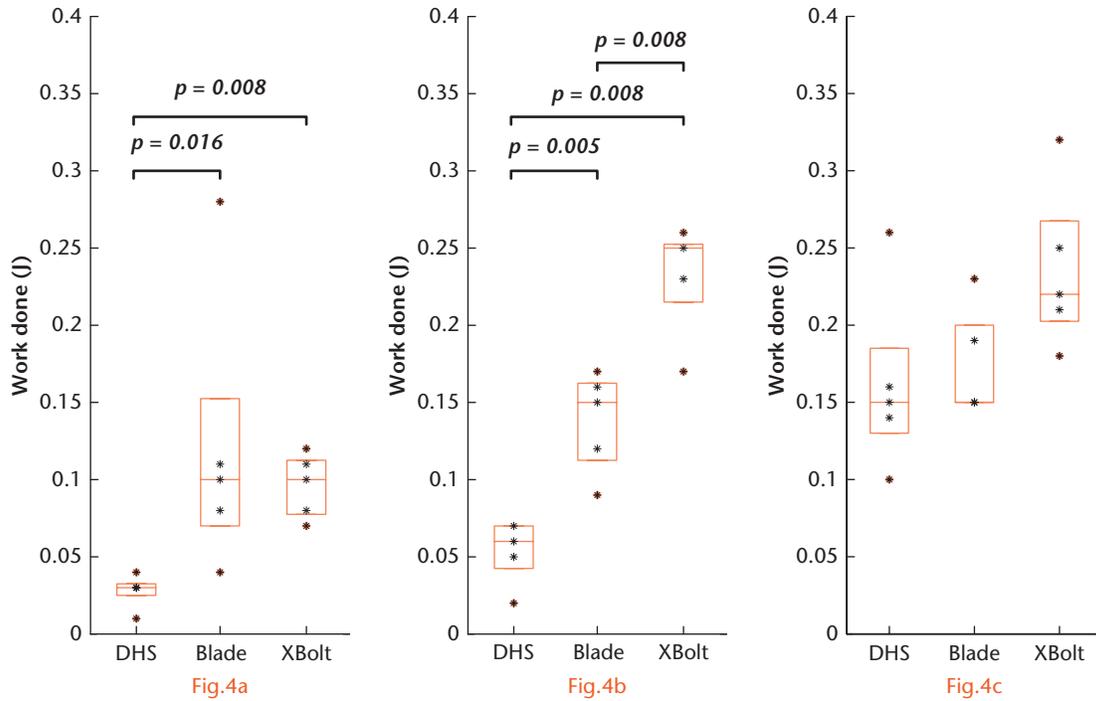
For the medium density SRPF (0.16 g/cm³) the values of W were significantly higher with the X-Bolt implant compared to the DHS Blade (Mann-Whitney, $p = 0.008$), and for both the values of W were significantly higher than that for the DHS (Mann-Whitney, $p = 0.008$ and $p = 0.005$, Fig. 4).

For the high density SRPF (0.24 g/cm³) no significant differences in the values of W were found between the three implants (Kruskal-Wallis, $p = 0.101$, Fig. 4). For the same density SRPF, the secondary outcome measure values (T) were significantly higher with the X-Bolt implant compared to the DHS Blade (Mann-Whitney, $p = 0.008$, Fig. 5).

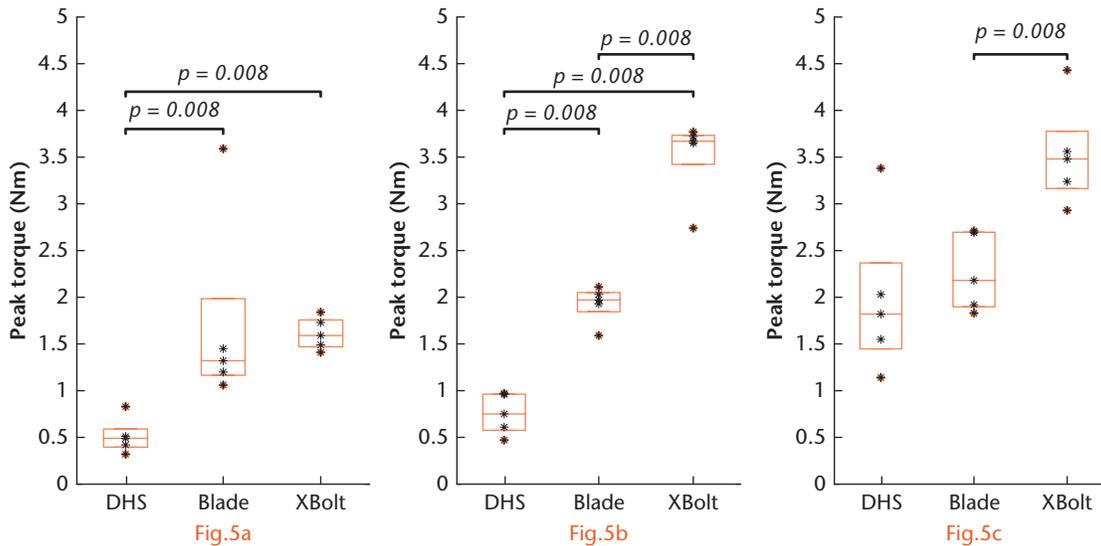
There was a positive correlation between W and the density of SRPF, across the entire dataset ($r_s = 0.58$, $p < 0.001$). A stronger relationship was found for the DHS ($r_s = 0.87$, $p < 0.001$) and X-Bolt ($r_s = 0.70$, $p = 0.004$), with a weaker relationship for the DHS Blade ($r_s = 0.51$, $p = 0.052$). A similar trend was observed between the peak torque (T) and the density of SRPF for the entire dataset ($r_s = 0.51$, $p < 0.001$) and also the individual implants (DHS: $r_s = 0.85$, $p < 0.001$; DHS Blade: $r_s = 0.51$, $p = 0.052$ and X-Bolt: $r_s = 0.64$, $p = 0.010$).

Discussion

Poor rotational stability is linked to most common failure modes of a hip fracture fixation device. The primary



Boxplots showing median and interquartile range for all data points of work done (W), for all densities and fixation devices; a) density, 0.08 g/cm³; b) density, 0.16 g/cm³; c) density, 0.24 g/cm³. Statistical significance between groups is stated where p < 0.05 (Mann-Whitney).



Boxplots displaying median and interquartile range for all data points of peak torque (T), for all densities and fixation devices; a) density, 0.08 g/cm³; b) density, 0.16 g/cm³; c) density, 0.24 g/cm³. Statistical significance between groups is stated where p < 0.05 (Mann-Whitney).

objective of this study was to compare the rotational stability of three different design philosophies in three different densities of polyurethane rigid foam. The key outcome measure was W, the work required to rotate the implant by 6°.

It is important to point out the study limitations. The number of implants was relatively small, and the implants were reused for each test. It was assumed that, due to the relatively low density of the bone substitute SRPF material,

this had no detrimental effect on the performance of the implants. To further minimise this risk, the tests were carried out in ascending order of SRPF density. Despite the small numbers, significant differences were found. Another limitation of this study is the size of the foam blocks combined with the clamping method. The relatively low density blocks, when fixed with the clamps, are likely to have undergone a small amount of compression, which could have had an impact on the density of the sample. This

Table III. A comparison of the mean values of work done (W) and peak torque (T) with the study of O'Neill et al¹⁴

SRPF Density (g/cm ³)	Mean (sd), work done (J)				Mean (sd), peak torque (Nm)			
	DHS		DHS Blade		DHS		DHS Blade	
	Current Study	O'Neil et al ¹⁵	Current Study	O'Neil et al ¹⁵	Current Study	O'Neil et al ¹⁵	Current Study	O'Neil et al ¹⁵
0.08	0.03 (0.01)	0.04 (0.01)	0.12 (0.09)	0.11 (0.03)	0.51 (0.19)	0.53 (0.13)	1.70 (1.10)	1.95 (0.37)
0.16	0.06 (0.02)	0.13 (0.03)	0.14 (0.03)	0.22 (0.05)	0.75 (0.22)	1.90 (0.56)	1.90 (0.20)	3.60 (0.59)

SRPF, Solid Rigid Polyurethane Foam; DHS, dynamic hip screw

factor needs to be considered however it is unlikely to have had a major impact on the study, as it would have affected all the devices in a similar manner.

A strength of the present study is that the torsional load was applied directly through the hydraulic actuator of a bi-axial testing machine, whereas previous studies have used a tensile testing machine combined with an adapter to translate the linear motion into angular motion.⁷ A complex arrangement to convert linear motion into angular motion introduces the possibility of further experimental error, which was avoided in the current study by the application of rotation to the device.

O'Neill et al.¹⁵ performed similar torsion tests of the screw and helical blade in 0.08 and 0.16 g/cm³ Sawbones bone substitute material. The results from this previous study correlate well with those obtained in the present study (Table III), particularly for the 0.08 g/cm³ bone substitute. The similarity of the work, W, and peak torque, T, in the DHS and DHS Blade in the present study compared to the literature suggest that the testing protocol was an appropriate way to compare the torsional stability of hip fixation devices, and emphasises the importance of the new data concerning the X-Bolt that were completed as part of the present investigation.

A trend was observed of W increasing with increasing density of the bone substitute material ($r_s = 0.58$, $p < 0.001$). This is likely caused by the increased resistance in a more dense material, therefore higher resistance to torsion. Another significant observation made was that the screw design consistently had the lowest value of W. This was confirmed by the statistical tests in all but the 0.24 g/cm³ density where the data was more scattered. It is not clear why the scatter was the largest in the highest density material, but the reuse of implants may have played a role. From the outside the samples appeared to remain intact during testing. The implants rotated relative to the cuboid substrate, compressing the internal material in the direction of motion. There was bulk failure of the substrate in compression, which was only apparent upon inspection post implant retrieval. The final observation worth highlighting from Figure 4 is the outlier for the helical blade design at the 0.08 g/cm³ density. This is the second highest value of W for the entire data set, yet it was measured at the lowest density. The same was observed for the T data (Fig. 5) and reason for this outlier is also unknown.

The fact that the deployable crucifix performed the best out of the three designs in the 0.16 g/cm³ bone substitute is particularly relevant, as this density is most representative of osteoporotic bone.¹⁶ The superior torsional resistance at the lower densities of the blade and crucifix fixation methods, compared to the screw design, was likely to be due to the geometry of the implants. The crucifix when fully deployed has a span of 24 mm, which provides a long moment arm to resist rotation around the main axis of the implant. The screw and helical blade designs both have an outer diameter of 13 mm. However, the helical blades provide a large surface area perpendicular to the direction of rotation, also providing high resistance torsion. The screw does not perform as well in axial rotation because the nature of the thread is that it can be unscrewed out as easily as it has been screwed in.

An important issue raised by this research was that the sliding hip screw design, which is one of the most commonly used treatments, had the lowest resistance to torsion in all but the 0.24 g/cm³ density bone substitute material. It is important to remember that the present study tested the implants in pure torsion, which although is a crucial failure mechanism of femoral fracture fixators, does not represent true physiological loading. The measured differences in the performances of the implants may well be influenced by application of axial load. Future research should address this, as also indicated by a clinical pilot trial by Griffin et al²⁰ comparing the X-Bolt with the sliding hip screw fixation system. Griffin et al²⁰ found the X-Bolt had fewer failure rates and the clinical performance was equivalent to the sliding hip screw.

The present study found that the crucifix design was the most torsionally stable proximal femur fixation device in bone substitute material representative of osteoporotic bone (0.16 g/cm³ polyurethane foam), compared to the screw and the helical blade design philosophies. At other densities the torsional stability was also higher for the X-Bolt, although not consistently significant from a statistical standpoint.

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Author Contribution

- J. D. Gosiewski: Substantial contributions to research design, acquisition, analysis and interpretation of data, drafting and critically revising paper.
- T. P. Holsgrove: Substantial contributions to data acquisition, photography, critically revising paper.
- H. S. Gill: Substantial contributions to research design and interpretation of data, critically revising paper.

ICMJE COI Statement

- Professor Gill is a member of the Editorial Board of The Bone & Joint Journal, and a member of Executive Committees of the British and European Orthopaedic Research Societies.

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