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Evaluation of Cyclic Cut-Out Failure in Intramedullary Nails: A Comparison Between Single Lag Screws and Integrated Interlocking Screws

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Introduction

Intramedullary nails that use a single sliding lag screw have become a preferred treatment for inter-trochanteric fractures of the femur. Despite their success, these devices have been associated with complication rates as high as 23% [1]. One of the most common causes of these complications is cut-out of the lag screw through the femoral head [2]. A recent study by Moroni, et al. has shown an average reduction of the femoral neck-shaft angle of six degrees in fractures treated with a sliding lag screw. This loss of anatomical reduction was seen even in patients with a final reduction rated "good" or "acceptable" [3]. A new lag screw configuration with two integrated interlocking screws has been designed to provide increased resistance to cut-out. More specifically, the integrated interlocking screws have a non-circular cross section that is intended to reduce rotational cut-out. The purpose of this research is to compare cut-out of this new screw configuration to that of a single lag screw or helical blade under dynamic loading.

Figure 1. INTERTAN° screws

Methods

Three single lag screws (IMHS screw, Smith & Nephew, Inc., Memphis, TN), three helical blades (TFN, Synthes, Inc., Paoli, PA) and three integrated interlocking screws (INTERTAN screws, Smith & Nephew, Inc., Memphis, TN) (Figure 1) were evaluated using a model based on the work of Sommers, et al. [4].

Custom-made 50mm femoral head surrogates of polyurethane foam (36 MPa compressive modulus) were confined in a 5mm thick polished stainless steel shell to allow for loading. The screw(s) were inserted using the appropriate instruments to a depth of 40mm, yielding a 12.2mm distance between the implant tip and the femoral head apex. Lag screws were inserted with a 7mm posterior offset parallel to the femoral neck axis, representing sub-optimal surgical placement. The screw shafts were rigidly fixed to a custom base fixture in a test frame at 149° to the horizontal plane. A 5mm thick steel back plate was mechanically fixed to the steel shell. The back plate rested against a Delrin® support so that the head surrogate was free to move in varus collapse, but lateral translation was prevented. Rotation of the foam surrogate was not constrained. The test setup is shown in Figure 2.

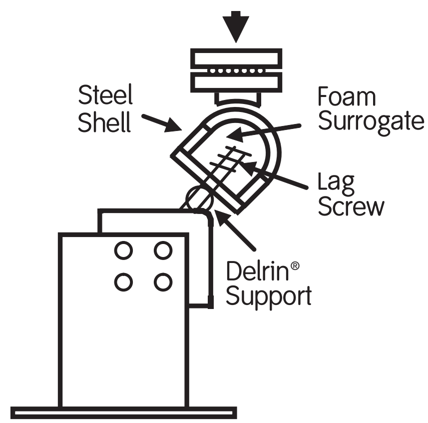


Figure 2. Experimental setup for fatigue cut-out

A compressive load was applied to the steel shell using a horizontal bearing and a polyethylene meniscus to ensure only axial forces. A sinusoidal cyclic load of 755 N (170 lbf) was applied at three cycles/sec up to 100,000 cycles. MTS TestStar IIm recorded the total number of cycles to cut-out, as well as peak/valley axial displacement vs. cycles. The value for cycles to cut-out was defined as the inflection point at which the slope rapidly approaches zero after an initial displacement (See Figure 3 for a representative graph).

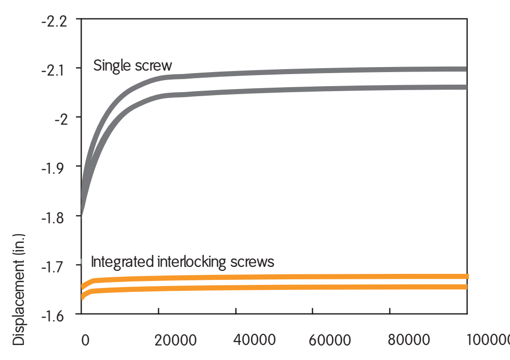


Figure 3. Representative displacement vs. cycle graph

After completion of fatigue testing, the foam bone surrogates were examined visually for evidence of screw cut-out, which was defined as penetration of the screw(s) to the foam/shell interface.

Results

Table 1 shows the cycles to cut-out for each design evaluated. The single screw constructs averaged 15,233 (SD = 12,593) cycles to cut-out; the helical blade constructs averaged 26,433 (SD = 22,527) cycles to cut-out; while all integrated interlocking screw constructs completed 100,000 cycles without cut-out (Figure 4). Upon visual inspection, the single screw and helical blade constructs showed evidence of both varus collapse and rotation about the long axis of the screw (or blade). While the integrated interlocking screws did not exhibit cut-out, slight rotation in the foam surrogates was visible. Figure 5 shows cross-sectional views of the foam surrogates after loading.

	Single Lag Screw	Helical Blade	Integrated Interlocking Screws
Sample 1	4100	9500	Did not cut out
Sample 2	28900	52000	Did not cut out
Sample 3	12700	17800	Did not cut out
Average	15233	26433	N/A
Std. Dev.	12593	22527	N/A

Table 1 – Cycles to cut-out

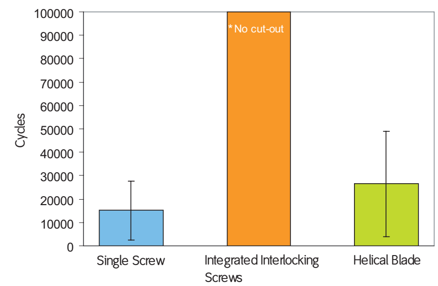
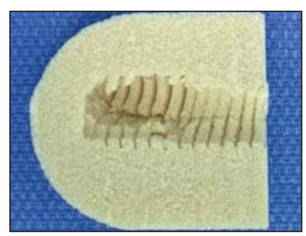


Figure 4 – Cycles to cut-out

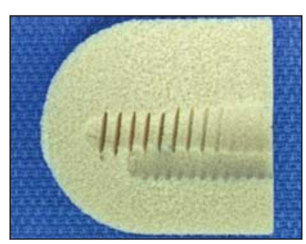
Discussion

The new lag screw configuration with two integrated interlocking screws exhibited increased resistance to cut-out. Visual evidence showed that the non-circular cross section reduces rotation of the screws in the femoral head surrogate compared to the single lag screw or the helical blade. This dynamic model for cut-out failure was previously shown to correlate well with clinical observations of cut-out [4]. Our results indicate that a device that uses two integrated interlocking screws may offer increased resistance to cut-out compared to a device that uses a single lag screw or helical blade.



Single Screw

Helical Blade



Integrated Interlocking Screw

Figure 5 - Cross-sectional views of the foam bone surrogates

References

[1] Baumgartner, M. et. al., *J Bone Joint Surg Am*. 1995.
[2] Yoshimine, F. et. al. *J Orthop Trauma*. 1993.
[3] Moroni, A. et. al. *J Bone Joint Surg Am*. 2005.
[4] Sommers, M. *J Orthop Trauma*. 2004.

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