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**DISTAL STEM FEATURES IMPROVE THE TORSIONAL RESISTANCE OF LONG STEM
CEMENTED REVISION HIP STEMS
AN *IN-VITRO* BIOMECHANICAL STUDY**

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Revision, hip, arthroplasty, replacement, torsion, torsional stability, stem, design

Abstract

When proximal bone stock is compromised at revision hip arthroplasty, distal fixation is often relied upon for stability of the femoral component. In such circumstances, torsional forces can result in debonding and loosening. This study compared the torsional behaviour of a cemented, polished and featureless (plain) stem with cemented, polished stems featuring fins or flutes.

The finned stem construct was found to be significantly stiffer than the fluted stem. The maximum torque of the finned and fluted stems was significantly higher than the plain stem; with no difference between the finned and fluted stems.

Distal stem features may provide a more reliable and greater resistance to torque in polished, cemented revision hip stems. Finned stem features may also increase the stiffness of the construct.

Introduction

The hip joint is subjected to high levels of loading in everyday living activities [1, 2]. These include combinations of axial, bending and torsional loads on the implants. The torsional loads, in particular, are associated with posteriorly directed forces acting on the femoral head during activities such as walking, rising from chair or negotiating stairs. Studies using instrumented implants with telemetry have shown that torsional moments in the hip joint can reach 37Nm [3].

One of the major long term complications in total hip replacement is aseptic loosening which is frequently associated with significant loss of bone stock associated with wear debris and osteolysis [4]. Revision surgery for aseptic loosening is a demanding procedure particularly in the presence of this loss of bone stock. In the case of the femur the loss is typically in the proximal femur [5-8]. Revision hip stems are often used in such cases to bypass the deficient proximal femur resulting in a significant component of the load transfer occurring through the distal stem. Due to the shape and diameter of the distal femur these revision stems typically do not have a geometry that offers optimal resistance to torsional loading. In uncemented revision stems the distal stem often has a roughened surface sometimes incorporating a bioactive coating to enhance osseointegration and provide stability; some include distal stem features such as flutes that enhance torsional stability. One of the most successful cemented total hip implants, the Exeter hip, is a collarless, polished design, double-tapered over its whole length. This surface finish and geometry allows the implant to subside within the cement mantle, the movement being accommodated by cement creep. As a result of this movement the cement and interfaces along the tapered section of the stem are primarily loaded in compression and are protected from shear stresses. One of the limitations of long stem cemented revision hip prostheses is that the polished, featureless, cylindrical distal section of the stems cannot load in compression and offers little resistance to torsional loading.

Distal stem features have been shown to influence torsional stability. Nunn et al demonstrated an increase in stem rotational displacement in the case of a smooth round stem when compared to one with protruding ridges in an uncemented setting [9]. However, this study also found that a smooth round cemented stem outperformed either of the uncemented designs. Kendrick et al showed a fluted distal stem design to be significantly more stable in torsion than a porous round stem in the uncemented setting, with finned and slotted stems falling in between [10]. Again a comparison with a plain round cemented stem showed this to be torsionally stiffer still than any uncemented stem design tested. Thus the

limited results from existing studies do suggest cemented stems provide superior torsional stability when compared to uncemented counterparts, at least initially before bony ingrowth has occurred.

Work on differing cemented stem designs is largely lacking. Only a single study by Kedgely et al provides data comparing different cross sectional shapes of distal stem in the cemented setting, but not distal stem features [11]. They found a rectangular stem with sharp edges to provide most resistance, a round stem least. In the context of revision hip stems, the distal shape of the stem is somewhat limited by the shape and diameter of the femoral diaphysis into which the stem must be implanted, and certainly commercially available cemented revision stems tend to have a round cross-section. In an ideal situation the proximal tapered part of the cemented revision femoral component will confer torsional stability but for this to happen there must be good proximal support of the stem and adequate fixation of the proximal cement-bone interface. Alternatively, where the technique of impaction grafting has been used, good anterior and posterior support of the femoral component with constrained impacted allograft must have been established [12]. Where proximal support of the stem is not adequate distal fixation of the stem becomes more important. In the revision scenario remarkably little literature exists examining the effect of stem features on torsional stability. To the best of our knowledge, no studies exist currently looking at these features in a cemented setting.

The aims and objectives of the study reported in this paper were to examine the torsional resistance associated with features on the distal section of a cemented polished revision hip stem and compare these to a plain featureless stem.

Materials and Methods

Models of the distal stem of a femoral revision hip prosthesis were produced to examine torsional resistance as a function of stem features. The distal stem models were of a fixed shaft diameter in order to mimic revision implants that are commonly used to bypass defects in the proximal femur. These implants have a longer constant diameter distal section in comparison to primary stems, and are usually round in cross-section to fit the shape of the bony diaphysis. It is this distal section which may be relied upon for torsional stability where there is proximal bone loss.

Three stems were produced by Stryker (Stryker BG, France). The cross-sectional geometry was plain, fluted or finned. The stems were machined from the same Orthinox® stainless

steel as that of the Stryker Exeter stem. All the stems were polished. The stems had a shaft diameter of 9.6 mm, based on the area of constant cross-section in the long stem Exeter revision prostheses. Each stem was 60 mm in length, with an additional length for fixation into the testing machine. The fins and flutes extended along the last 55 mm of the distal end of the stem. The finned/fluted stems had six fins/flutes, each 1 mm in radius and equally spaced 60° around the circumference of the shaft (Figure 1). These stem features resulted in the fluted stem having a minor diameter of 7.6 mm, and the finned stem having a major diameter of 11.6 mm. This geometry was such that the second moment of area, and therefore the stiffness, would be highest in the finned stems, then the plain stems and the stiffness of the fluted stems would be lowest. However, the testing method was such that the stiffness of the stem and cement construct was measured to allow comparison of the in-vivo situation.

The surface finishes of the stems were accurately measured to analyse whether or not there was a significant difference between the surface finish of the three stem types. If no significant difference was found, it could be assumed that only the geometry of the stems was being compared. The measurements were made using a ProScan 2000 (Scanton Industrial Products Ltd., UK) using a chromatic sensor with a resolution of 0.1 µm. Twelve readings were taken at locations 10, 20, and 30 mm from the distal end of each stem. Measurements were taken along the axial length of the stems. Each reading was taken over 2 mm using 2000 steps. The mean surface roughness (Ra) of the plain, fluted and finned stems, with the standard deviation shown in brackets was 1.74 (0.67) µm, 1.46 (0.63) µm and 1.58 (1.47) µm respectively. One-way ANOVA was completed using SPSS software, which suggested that there was no significant difference between stems ($F=0.712$, $p=0.493$).

A steel cylinder was manufactured to represent the cortical bone of the femur. The inner wall of the cylinder was left roughened after machining to ensure that the cement would bond securely, and thus prevent rotation of the cement within the tube, mimicking the femoral diaphysis. The inner-diameter of the cylinder was 16 mm, giving a cement mantle thickness of 3.2 mm.

In order to reduce the stem end-effect to a minimum, an insertion and testing jig was produced. This involved using a nylon spacer between the steel cylinder and the base plate during cementing. This spacer had an internal diameter of 12 mm, so as to fit closely around the stem. When the cementing process was complete the base and the nylon spacer were removed. A steel spacer with an internal diameter of 16 mm was used for testing so that the

end of the stem was not in contact with the internal wall of the steel cylinder (Figures 2 a & b).

Surgical Simplex P (Stryker Howmedica Osteonics) bone cement was used in all testing. The Summit Medical HiVac cement mixing system was employed (Summit Medical Limited, UK). The cement was mixed under a vacuum of 67.7 kPa for one minute. The plunger that operates the paddle in the mixing cylinder was moved at a rate of approximately 1 Hz during the mixing process. Each upward and downward movement of the plunger resulted in a rotation of the paddle of approximately 270°. The ambient temperature was maintained throughout preparation at $18\pm 1.0^{\circ}\text{C}$. The cement was injected in a retrograde fashion 3 minutes after initial mixing had begun.

The stem was inserted into the steel cylinder using a Zwick Amsler HBT 25-200 hydraulic testing machine (Zwick Testing Machines Ltd., UK) to a depth of 50 mm at approximately 10mm/sec. The stem was held in place using the Zwick testing machine for 15 minutes until the cement had fully polymerised. The stems were then cured in air overnight at $37.5\pm 0.5^{\circ}\text{C}$ before the torsion testing was completed.

Previous pilot study results were used to perform a power calculation, which predicted that for a power of 0.95 a sample size of 9 tests per stem would be required. This would detect an effect size of 0.638.

A Zwick Amsler hydraulic testing machine was used for the torsion tests. The stem was screwed into the actuator and a lock-nut tightened to a minimum of 50 Nm. Fixtures were used to constrain the square base plate in torsion only. Tests were completed in angular displacement control at a rate of $0.05^{\circ}/\text{sec}$ over a range of 10° using Zwick Workshop software (Zwick Testing Machines Ltd., UK). The quasistatic testing speed was chosen so as to reduce the inertial effects of the testing machine to a minimum. Clinical failure has been reported to be equated to 5° of stem rotation [11]. A torque limit of 35 Nm was imposed on the testing as pilot studies had showed that the fluted stem started to yield above 40 Nm. Load and position data for each test was acquired at 100 Hz.

Results

The stiffness and maximum torque were calculated from the torque and angle data that was recorded for each test. The stiffness was measured from the linear region of the torque/angle graph prior to any failure/debonding/yielding. After a failure or yielding was

detected, the test was continued until either 10° of rotation, or the torque limit of 35 Nm was reached. In those tests that were stopped due to reaching the 35 Nm limit, the maximum torque was taken as that acquired from the data (approximately 35 Nm), even though a higher maximum may have been possible. Any settling in of the sample at the beginning of a test, due to slack in the torsional clamps, was not used in the calculation of the stiffness. In one test using the fluted stem, the cement failed at the cement/tube interface. This test was rejected, not included in the results, and the test repeated to achieve the sample size of nine.

All the plain stems failed during the 10° of rotation. Two fluted stems failed, three reached the maximum torque of 35 Nm, and four yielded, two of which did so at a relatively low torque (15-20 Nm range). Three finned stems reached the maximum torque of 35 Nm, one of which had just yielded. The remaining six all yielded between 20-35 Nm. Only one finned stem demonstrated a significant failure, which occurred after yielding. It then immediately continued to transfer the pre-break torque of just over 30 Nm. The stiffness and maximum torque values are shown in Table 1 and the means and standard deviations in the box plots in Figure 3.

A comparison of the data was made using an ANOVA test with a Games-Howell post-hoc test using SPSS software. It was found that there was no significant difference between the torsional stiffness of the construct using the plain stem and either the fluted or finned stem ($p=0.446$ and 0.207 respectively). However, there was a significant difference between the fluted and finned stem in torsional stiffness ($p=0.000$). There was a significant difference between the maximum torque using the plain stem and both the fluted and finned stems ($p=0.000$ for both comparisons). There was no significant difference in maximum torque between the fluted and finned stems ($p=0.855$).

Discussion

Despite various studies investigating distal stem features in cementless hip stems, and a number of commercially available cementless stems with stem features being available to the revision hip surgeon, there is a lack of similar evidence in regard to cemented hip revision stems. Work has been carried out on torsional stability in the uncemented setting, and these studies suggest that features increased stability in cementless stems, but that plain, featureless, cemented stems have an even greater stability than those cementless, and featured stems [9, 10]. This study has demonstrated that distal stem features can provide improved torsional stability in polished cemented distal stem designs.

The stiffness was measured in the linear region of the torque/angle graph prior to any debonding or failure. The maximum torque measurement allowed the stem design that resisted the highest torque regardless of any failure in the cement or interface to be identified.

The finned stem provided significantly higher torsional stiffness than a fluted stem. The plain stem showed a large variability and as such no significant difference was found between this stem and those with features. The variability in construct stiffness with the plain stem might be considered reason enough to use a stem with features.

The mean maximum torque applied to both stems with features was approximately 30 Nm, which was significantly higher than the mean of 10 Nm that the plain stem was able to withstand. The variability of maximum torque was also greatest in the plain stem. Other studies have shown somewhat similar magnitudes to our results providing some validation [10, 13], however the great number of variables between methods between studies prevents any detailed comparison. The most comparable existing literature comes from Kedgely et al [11]. They achieved lower magnitude of torque at failure than in this study, their best performing stem failing at a mean of 21.9Nm. This difference may be explained by the work of Nunn et al [9] who showed that resisted torque relates to depth of potting' of stem specimens. In Kedgely's study stems were potted to a depth of just 16mm, compared to 50mm in our study. In the clinical scenario the length over which stem features can be applied is limited by the design of the stem. The aim of this study was focused on the effect of different stem features, rather than the length over which they were applied.

All tests used for the analysis failed at the stem/cement interface. One test with a fluted stem resulted in failure at the cement/tube interface, and this was discounted and the test repeated. All tests using the plain stem and two with the fluted stem showed a sudden drop in torque. This was likely to be the debonding of the stem and cement, or the fracture of the cement mantle. Following this event with the plain stems the torque remained low and reasonably constant (Figure 4). It is likely that the torque that was applied was due to friction as the stem rotated in the cement. In the case of the fluted stem, the torque did increase again after the drop, though not to the previous level (Figure 5). The only similar case using the finned stem occurred once yielding had already occurred and the torque quickly returned to the pre-drop level of approximately 30 Nm (Figure 6). This suggests that the debonding of the plain stem constitutes a failure of the construct, whereas the fluted and finned stems achieved at least some secondary stability, albeit within a fractured mantle. The fluted stem

could withstand some torsional loading after mantle damage and the finned stems appeared to resist torsion equally well before and after cement mantle damage. In either case fracture of the cement mantle in the clinical scenario is likely to herald progression to failure of fixation of the implant.

Investigation of the yielding pattern that occurred in four of the tests with the fluted stem and seven tests using the finned stem did not appear to be attributed to the stems, steel tube, base plate, or clamps. It was estimated from available materials data that the fluted stem, which had the lowest second moment of area of the three stems, would not yield until approximately 45 Nm. This was observed in the pilot study, albeit using a different grade of steel. The locknut was tightened beyond the level of torque applied during testing and the torque would increase if it was to tighten further, which was not the case, as the post-yield torque was always relatively constant. As the baseplate of the outer tube was constrained in torsion only, yielding of the constraining fixtures would have resulted in permanent deformation of the bolts that held the fixture in place. This was not observed. This suggests that there may have been some plastic deformation of the cement. Such a situation could lead to adverse outcomes in-vivo, due to the permanent rotation of the femoral component within the femur.

There are some limitations associated with this study; the stems were not subjected to axial or cyclic loading, which may shed more light on the interaction of the stability of different stem designs on torsional stability. Thomson and Lee recently demonstrated that the torsional stability of a cemented, polished, collarless, and tapered stem (like that of the Exeter design) increased as a compressive axial load increased. This was not true of matt-finish or collared stems [14]. However, in hip revision situations where a long stem revision component is used, the distal stem is not tapered due to the geometric constraint of the mid-femur medullary cavity. Therefore it is unlikely that axial loading would affect torsional resistance.

Care must also be taken in applying this information to the clinical setting and the effect these features could have on cement over a longer period of cyclical loading. Likewise, the clinical setting is likely to present complications such as a non-uniform cement mantle, which may well affect the torsional stability when features are present more than when a plain, circular cross-section is used. These limitations and applications in the clinical setting suggest that whilst this study has demonstrated possible advantages to distal stem features in cemented revision hip stems, further research is necessary in order to fully understand the load transfer characteristics, and failure modes of such stems.

Conclusions

This study has shown that distal stem features can provide a more reliable and greater resistance to applied torque in polished cemented revision stems. Furthermore, using finned stem features increases the stiffness of the construct. Flutes, whilst not providing as stiff a construct as fins, are able to withstand the same maximum torque and machining flutes into a stem may well be more cost effective than manufacturing stems with distal fins.

This knowledge should help guide implant design in the future, and may be applicable not just in the context of revision hip arthroplasty where distal fixation is often crucial, but in other settings in which torsional stability is required and comes from stem fixation, such as revision knee, primary shoulder and elbow arthroplasty.

Tables

Table 1: Stiffness and Maximum torque results

	Stiffness (Nm/deg)			Maximum (Nm)		
	Plain	Fluted	Finned	Plain	Fluted	Finned
Mean	17.70	13.20	24.39	10.31	29.19	30.47
S.D.	10.55	0.85	2.19	6.57	5.89	4.13

Figures

Figure 1: The three polished stems, from left to right: plain, fluted, finned.

Figure 2: The apparatus used for stem cementing (a) and torsional testing (b)

Figure 3a: Results showing median, interquartile range, range excluding outliers, and outliers (circles) for stiffness

Figure 3b: Results showing median, interquartile range, range excluding outliers, and outliers (circles) for maximum torque

Figure 4: Example results using the plain stem

Figure 5: Example results using the fluted stem

Figure 6: Example results using the finned stem

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