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1	DIST	AL STEM FEATURES IMPROVE THE TORSIONAL RESISTANCE OF LONG STEM					
2		CEMENTED REVISION HIP STEMS					
3		AN IN-VITRO BIOMECHANICAL STUDY					
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45	Keyw	vords					
46 47 48	Revis	ion, hip, arthroplasty, replacement, torsion, torsional stability, stem, design					

49 Abstract

50

51 When proximal bone stock is compromised at revision hip arthroplasty, distal fixation is often 52 relied upon for stability of the femoral component. In such circumstances, torsional forces 53 can result in debonding and loosening. This study compared the torsional behaviour of a 54 cemented, polished and featureless (plain) stem with cemented, polished stems featuring 55 fins or flutes.

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57 The finned stem construct was found to be significantly stiffer than the fluted stem. The 58 maximum torque of the finned and fluted stems was significantly higher than the plain stem; 59 with no difference between the finned and fluted stems.

60

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.

- 65 Introduction
- 66

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].

73

74 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 75 osteolysis [4]. Revision surgery for aseptic loosening is a demanding procedure particularly 76 77 in the presence of this loss of bone stock. In the case of the femur the loss is typically in the 78 proximal femur [5-8]. Revision hip stems are often used in such cases to bypass the 79 deficient proximal femur resulting in a significant component of the load transfer occurring 80 through the distal stem. Due to the shape and diameter of the distal femur these revision 81 stems typically do not have a geometry that offers optimal resistance to torsional loading. In 82 uncemented revision stems the distal stem often has a roughened surface sometimes 83 incorporating a bioactive coating to enhance osseointegration and provide stability; some 84 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, 85 double-tapered over its whole length. This surface finish and geometry allows the implant to 86 subside within the cement mantle, the movement being accommodated by cement creep. As 87 a result of this movement the cement and interfaces along the tapered section of the stem 88 are primarily loaded in compression and are protected from shear stresses. One of the 89 90 limitations of long stem cemented revision hip prostheses is that the polished, featureless, 91 cylindrical distal section of the stems cannot load in compression and offers little resistance to torsional loading. 92

93

Distal stem features have been shown to influence torsional stability. Nunn et al 94 95 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, 96 this study also found that a smooth round cemented stem outperformed either of the 97 98 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 99 100 slotted stems falling in between [10]. Again a comparison with a plain round cemented stem 101 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.

105

106 Work on differing cemented stem designs is largely lacking. Only a single study by Kedgely 107 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 108 109 provide most resistance, a round stem least. In the context of revision hip stems, the distal 110 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 111 revision stems tend to have a round cross-section. In an ideal situation the proximal tapered 112 part of the cemented revision femoral component will confer torsional stability but for this to 113 114 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 115 been used, good anterior and posterior support of the femoral component with constrained 116 117 impacted allograft must have been established [12]. Where proximal support of the stem is 118 not adequate distal fixation of the stem becomes more important. In the revision scenario 119 remarkably little literature exists examining the effect of stem features on torsional stability. 120 To the best of our knowledge, no studies exist currently looking at these features in a 121 cemented setting.

122

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.

126

127 Materials and Methods

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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.

136

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

139 steel as that of the Stryker Exeter stem. All the stems were polished. The stems had a shaft 140 diameter of 9.6 mm, based on the area of constant cross-section in the long stem Exeter 141 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 142 of the stem. The finned/fluted stems had six fins/flutes, each 1 mm in radius and equally 143 spaced 60° around the circumference of the shaft (Figure 1). These stem features resulted 144 in the fluted stem having a minor diameter of 7.6 mm, and the finned stem having a major 145 diameter of 11.6 mm. This geometry was such that the second moment of area, and 146 147 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 148 stiffness of the stem and cement construct was measured to allow comparison of the in-vivo 149 150 situation.

151

The surface finishes of the stems were accurately measured to analyse whether or not there 152 was a significant difference between the surface finish of the three stem types. If no 153 154 significant difference was found, it could be assumed that only the geometry of the stems 155 was being compared. The measurements were made using a ProScan 2000 (Scanton 156 Industrial Products Ltd., UK) using a chromatic sensor with a resolution of 0.1 µm. Twelve 157 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 158 2 mm using 2000 steps. The mean surface roughness (Ra) of the plain, fluted and finned 159 stems, with the standard deviation shown in brackets was 1.74 (0.67) µm, 1.46 (0.63) µm 160 and 1.58 (1.47) µm respectively. One-way ANOVA was completed using SPSS software, 161 which suggested that there was no significant difference between stems (F=0.712, p=0.493). 162 163

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.

169

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).

177

Surgical Simplex P (Stryker Howmedica Osteonics) bone cement was used in all testing. 178 179 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 180 operates the paddle in the mixing cylinder was moved at a rate of approximately 1 Hz during 181 the mixing process. Each upward and downward movement of the plunger resulted in a 182 rotation of the paddle of approximately 270°. The ambient temperature was maintained 183 throughout preparation at 18±1.0°C. The cement was injected in a retrograde fashion 3 184 minutes after initial mixing had begun. 185

186

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±0.5°C before the torsion testing was completed.

192

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.

196

A Zwick Amsler hydraulic testing machine was used for the torsion tests. The stem was 197 screwed into the actuator and a lock-nut tightened to a minimum of 50 Nm. Fixtures were 198 199 used to constrain the square base plate in torsion only. Tests were completed in angular displacement control at a rate of 0.05°/sec over a range of 10° using Zwick Workshop 200 software (Zwick Testing Machines Ltd., UK). The quasistatic testing speed was chosen so as 201 202 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 203 204 the testing as pilot studies had showed that the fluted stem started to yield above 40 Nm. 205 Load and position data for each test was acquired at 100 Hz.

206

207 Results

208

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

212 detected, the test was continued until either 10° of rotation, or the torque limit of 35 Nm was 213 reached. In those tests that were stopped due to reaching the 35 Nm limit, the maximum 214 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 215 216 test, due to slack in the torsional clamps, was not used in the calculation of the stiffness. In 217 one test using the fluted stem, the cement failed at the cement/tube interface. This test was 218 rejected, not included in the results, and the test repeated to achieve the sample size of nine. 219

220

221 All the plain stems failed during the 10° of rotation. Two fluted stems failed, three reached 222 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 223 224 of which had just yielded. The remaining six all yielded between 20-35 Nm. Only one finned 225 stem demonstrated a significant failure, which occurred after yielding. It then immediately 226 continued to transfer the pre-break torque of just over 30 Nm. The stiffness and maximum 227 torque values are shown in Table 1 and the means and standard deviations in the box plots 228 in Figure 3.

229

230 A comparison of the data was made using an ANOVA test with a Games-Howell post-hoc 231 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 232 (p=0.446 and 0.207 respectively). However, there was a significant difference between the 233 fluted and finned stem in torsional stiffness (p=0.000). There was a significant difference 234 between the maximum torque using the plain stem and both the fluted and finned stems 235 (p=0.000 for both comparisons). There was no significant difference in maximum torque 236 237 between the fluted and finned stems (p=0.855).

238

239 Discussion

240

Despite various studies investigating distal stem features in cementless hip stems, and a 241 242 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 243 244 revision stems. Work has been carried out on torsional stability in the uncemented setting, 245 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, 246 and featured stems [9, 10]. This study has demonstrated that distal stem features can 247 248 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.

254

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.

259

The mean maximum torque applied to both stems with features was approximately 30 Nm, 260 which was significantly higher than the mean of 10 Nm that the plain stem was able to 261 withstand. The variability of maximum torque was also greatest in the plain stem. Other 262 studies have shown somewhat similar magnitudes to our results providing some validation 263 264 [10, 13], however the great number of variables between methods between studies prevents 265 any detailed comparison. The most comparable existing literature comes from Kedgely et al 266 [11]. They achieved lower magnitude of torque at failure than in this study, their best 267 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 268 specimens. In Kedgely's study stems were potted to a depth of just 16mm, compared to 269 50mm in our study. In the clinical scenario the length over which stem features can be 270 applied is limited be the design of the stem. The aim of this study was focused on the effect 271 of different stem features, rather than the length over which they were applied. 272

273

274 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-275 repeated. All tests using the plain stem and two with the fluted stem showed a sudden drop 276 in torque. This was likely to be the debonding of the stem and cement, or the fracture of the 277 278 cement mantle. Following this event with the plain stems the torque remained low and 279 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 280 again after the drop, though not to the previous level (Figure 5). The only similar case using 281 282 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 283 the plain stem constitutes a failure of the construct, whereas the fluted and finned stems 284 285 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.

290

291 Investigation of the yielding pattern that occurred in four of the tests with the fluted stem and 292 seven tests using the finned stem did not appear to be attributed to the stems, steel tube, 293 base plate, or clamps. It was estimated from available materials data that the fluted stem, 294 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 295 steel. The locknut was tightened beyond the level of torque applied during testing and the 296 297 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 298 torsion only, yielding of the constraining fixtures would have resulted in permanent 299 300 deformation of the bolts that held the fixture in place. This was not observed. This suggests 301 that there may have been some plastic deformation of the cement. Such a situation could 302 lead to adverse outcomes in-vivo, due to the permanent rotation of the femoral component 303 within the femur.

304

305 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 306 stem designs on torsional stability. Thomson and Lee recently demonstrated that the 307 torsional stability of a cemented, polished, collarless, and tapered stem (like that of the 308 Exeter design) increased as a compressive axial load increased. This was not true of matt-309 310 finish or collared stems [14]. However, in hip revision situations where a long stem revision 311 component is used, the distal stem is not tapered due to the geometric constraint of the mid-312 femur medullary cavity. Therefore it is unlikely that axial loading would affect torsional resistance. 313

314

315 Care must also be taken in applying this information to the clinical setting and the effect 316 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 317 318 may well affect the torsional stability when features are present more than when a plain, 319 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 320 in cemented revision hip stems, further research is necessary in order to fully understand the 321 322 load transfer characteristics, and failure modes of such stems.

324 Conclusions

325

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.

331

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

334 settings in which torsional stability is required and comes from stem fixation, such as revision

knee, primary shoulder and elbow arthroplasty.

337 Tables

338

339 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







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











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