Fracture of the hydroxyapatite-ceramic-coated JRI-Furlong femoral component

BODY MASS INDEX AND IMPLICATIONS FOR SELECTION OF THE IMPLANT

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We describe three cases of fracture of the titanium JRI-Furlong hydroxyapatite-ceramic (HAC)-coated femoral component. We have examined previous case reports of failure of this stem and conclude that fracture may occur in two places, namely at the neck-shoulder junction and at the conical-distal cylindrical junction. These breakages are the result of fatigue in a metallurgically-proven normal femoral component. All the cases of failure of the femoral component have occurred in patients with a body mass index of more than 25 in whom a small component, either size 9 or 10, had been used.

In patients with a body mass index above normal size 9 components should be avoided and the femoral canal should be reamed sufficiently to accept a large femoral component to ensure that there is adequate metaphyseal fixation.

The first JRI-Furlong (Joint Replacement Instrumentation Ltd, London, United Kingdom) hydroxyapatite-ceramic (HAC)-coated femoral prosthesis was implanted by Furlong in 1985.1 Manufactured from wrought titanium alloy, its surface was completely covered with plasma-sprayed hydroxyapatite (HA)-coating applied in a vacuum. It had four parts comprising the neck, a rectangular proximal third with a small lateral fin and a medial collar abutting the calcar femorale, an intermediate conical section and a cylindrical distal stem. This design gave good primary fixation sufficient for immediate weight-bearing.

The published results were excellent. There was a survivorship of 99% at 12 and 13 years in primary total hip replacement (THR).2,3 In younger patients undergoing THR, survivorship of 100% and 95% at ten and 13 years respectively, was described.4,5

There have been no published series discussing fracture of the femoral component. However, there are two case reports in which there was a fracture of the neck6 and distal stem.7 In addition, two cases of fracture of the distal stem were noted by Bhatia and Edge8 in a series of 562 patients, who were treated for proximal femoral fracture using the JRI-Furlong HAC hemiarthroplasty system. In this series the stainless-steel alloy (ISO 5832-9) version was used which had a similar geometry to that of the titanium implant. The authors highlighted the risk of failure in the very active patient or when small sizes were used.

We report three more cases of fracture of the titanium-alloy JRI-Furlong femoral component which necessitated revision. Combining a review of these cases with those previously described, we make recommendations relating to the selection of the implant in patients with a high body mass index (BMI).

Case reports
Case 1. A 70-year-old man whose weight was 90 kg and height 1.74 m underwent a left THR for primary osteoarthritis. A JRI-Furlong size 9 femoral component was used and recovery was uncomplicated. Three years later he developed sudden pain in his left hip and was unable to bear weight. There was no history of trauma. Radiographs showed a fracture of the prosthesis at the neck-shoulder junction (Fig. 1).

At revision, the proximal part of the stem was found to be loose, but the distal cylindrical portion was securely fixed. Attempts at removal of the stem using flexible osteotomes were unsuccessful. A Wagner longitudinal transfemoral osteotomy9 was therefore used to remove the stem. Revision thereafter was uncomplicated. Five years later, he remained active and free from pain.

Metallurgical analysis of the failed femoral component was undertaken at the Materials and Engineering Research Institute (Sheffield Hallam University, Sheffield, United Kingdom). Using a combination of plain microscopy, scanning electron microscopy (SEM) and mass spectrometry, it was concluded that the
elemental composition, mechanical properties and microstructure of the stem were normal and in keeping with manufacturing standards (BS 7252-Part 3). Therefore, no underlying cause of the failure could be found except that it had resulted from fatigue because of high stresses on the neck over a long period of time.

Case 2. A 61-year-old man whose weight was 122 kg and height 1.82 m underwent right THR for primary osteoarthritis. Whilst reaming the femur, an undisplaced fracture was noted in the anterior femoral cortex extending 5 cm distally from the site of resection of the neck. Reaming was completed and a JRI-Furlong size 9 femoral component was inserted. The site of the fracture was reinforced with two cerclage wires. The patient was allowed to mobilise fully weight-bearing from the outset and recovery was uncomplicated. Three years later he presented with a history of worsening pain in his right thigh for six weeks and was only able to partially bear weight. There was no history of trauma. Radiographs showed a fracture of the femoral component at the junction of the conical and distal cylindrical portions (Fig. 2).

At revision, the proximal part of the stem was found to be loose and was removed with ease. The distal cylindrical portion was securely bonded circumferentially to bone, was impossible to remove using flexible osteotomes and the distal section was removed using the JRI revision system trephine.

Photographs of the implant immediately after removal showed the site of fracture of the stem and the distal circumferential osseous integration with artifactual marks produced by the trephine system. There was a relative paucity of formation of bone around the proximal aspect of the implant (Fig. 4).

Metallurgical analysis of this retrieved stem was undertaken at the Materials and Engineering Research Institute in Sheffield. Plain microscopy, SEM and mass spectrometry once again concluded that the elemental composition, mechanical properties and microstructure of the stem were normal and in keeping with manufacturing standards (BS 7252-Part 3). Failure of the component had resulted from nucleation and propagation of a fatigue crack with initiation at the posterior aspect of the cone of the stem. No evidence of a surface anomaly or defect at the initiation site which could have instigated the fracture was found. The most likely underlying cause was thought to be overloading of the stem, combined with inadequate proximal bony ingrowth, resulting in suboptimal fixation after varus malalignment at the time of implantation and subsequent fatigue.
Fracture of the femoral component of cemented THRs is a recognised complication. The first was reported in 1968 and other studies have noted an incidence varying between 0.23% and 10.7%. Fracture of the stem in HAC-coated uncemented femoral stems is rare.

Two sites of failure of the JRI-Furlong femoral component have been identified, namely, at the neck-shoulder junction (two cases) and at the junction of the conical and cylindrical portions of the stem (five cases). With the former pattern of fracture Morgan-Hough et al were also able to obtain metallurgical analysis of their implant which, as in our cases, concluded that it had failed from fatigue with no other attributable abnormality. Both of these failures occurred in 1998. In 2001, JRI announced a change in forging technique, increasing the blend radius between the neck and shoulder of all femoral components. Subsequently, no further cases of failure at the neck-shoulder junction have been reported. Sharma et al were only able to obtain metallurgical analysis of one of their three cases of fracture at this site with the finding, as in all the other analyses, that failure resulted from fatigue with a site of initiation at the surface of the prosthesis in the absence of any other attributable cause. Only one failure in our series has been identified subsequent to the change in forging techniques.

In order to assess why these implants may have been subjected to such fatigue, a review of epidemiological data relating to each case was undertaken (Table I). In one case a proximal femoral fracture was identified at surgery although it is not thought that this had any bearing on the failure of the component. In a series of 100 cases, McNally et al reported minor per-operative fractures in 13 hips described as ‘yawning of the anterior femoral cortex’. Only one required a cerclage wire and all united uneventfully.

The patients’ data show that they all had a BMI ≥ 25 kg/m². A BMI of 25 kg/m² to 30 kg/m² is considered as pre-obese, of 30 to 40 as obese and of more than 40 as morbidly

**Discussion**

Fracture of the femoral component of cemented THRs is a recognised complication. The first was reported in 1968 and other studies have noted an incidence varying between 0.23% and 10.7%. Fracture of the stem in HAC-coated uncemented femoral stems is rare.

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**Fig. 3a**

Case 3 – a) anteroposterior and b) close-up radiographs showing fracture of the stem two years after insertion of a JRI-Furlong stem.

**Fig. 3b**

**Fig. 4**

Case 3 – photograph of the femoral component immediately after removal using the JRI trephine system.
obese.\textsuperscript{13} In addition, all femoral components used in these cases were of size 9 or 10. In 1997, Furlong, the surgeon and inventor, stated in reference to the use of the size 9 component that the overall size of the component should be controlled by the fit of the body into the metaphysis with the selection determined by the use of a template. In addition, he required diaphyseal reaming to produce a cavity 2 mm greater than the diameter of the component rather than the insertion of a smaller component with insufficient fixation in the metaphysis.\textsuperscript{12} This information was distributed by the manufacturer (Joint Replacement Instrumentation Ltd., London, United Kingdom) in January 1998. They had already advised caution in obese patients.\textsuperscript{14} Subsequently, the JRI-Furlong literature recommended that in patients weighing 114 kg or more, a programme of weight loss should be undertaken before a THR was to be performed.\textsuperscript{15}

The JRI-Furlong HAC-coated THR femoral component has been shown to perform excellently in the medium term. Fracture of the stem is very rare with only seven cases in total now reported in metallurgically normal prostheses. All cases of failure have been in patients with a BMI greater than normal when a small component, either size 9 or 10 has been used. The Medicines and Healthcare Products Regulatory Agency (Hannibal House, London, United Kingdom) were notified of all our cases. Trends analysis has not revealed cause for concern and each case has been formally closed. We recommend that in accordance with the manufacturer’s recommendations and warnings, size 9 components should be avoided in obese patients and that attempts should be made to use as large a femoral component as possible to ensure adequate metaphyseal fixation.

We wish to thank JRI for their assistance at all stages in the preparation of this manuscript and to the Materials and Engineering Research Institute, Sheffield Hallam University, Sheffield for assistance with all the metallurgical analyses performed.

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**Table I. Epidemiological data relating to seven cases of fracture of the titanium-alloy JRI-Furlong-HAC\textsuperscript{2} stem**

<table>
<thead>
<tr>
<th>Authors</th>
<th>Location of fracture in the prosthesis</th>
<th>Gender</th>
<th>Age at operation (yrs)</th>
<th>Time from operation to fracture (yrs)</th>
<th>BMI\textsuperscript{1} (kg/m\textsuperscript{2})</th>
<th>Size of implant</th>
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<tbody>
<tr>
<td>Morgan-Hough et al\textsuperscript{6}</td>
<td>Neck</td>
<td>M</td>
<td>59</td>
<td>5</td>
<td>25</td>
<td>9</td>
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<tr>
<td>Current series</td>
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<td>M</td>
<td>70</td>
<td>3</td>
<td>30</td>
<td>10</td>
</tr>
<tr>
<td>Sharma et al\textsuperscript{7}</td>
<td>Stem</td>
<td>M</td>
<td>66</td>
<td>8</td>
<td>28</td>
<td>10</td>
</tr>
<tr>
<td>Current series</td>
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</tr>
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\textsuperscript{2}HAC, hydroxyapatite-coated

\textsuperscript{1}BMI, body mass index

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**Supplementary Material**

A further opinion by Mr J. Edge is available with the electronic version of this article on our website at www.jbjs.org.uk

**References**

10. Fernando US. Test certificate: investigation of failed JRI Furlong 9mm H-A.C femoral stem. Materials and Engineering Research Institute, Sheffield Hallam University 2006/2.