■ **HIP**

Assessment of the equivalence of a generic to a branded femoral stem

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Aims
The aim of this study was to compare the design of the generic OptiStem XTR femoral stem with the established Exeter femoral stem.

Materials and Methods
We obtained five boxed, as manufactured, implants of both designs at random (ten in total). Two examiners were blinded to the implant design and independently measured the mass, volume, trunnion surface topography, trunnion roughness, trunnion cone angle, Caput-Collum-Diaphyseal (CCD) angle, femoral offset, stem length, neck length, and the width and roughness of the polished stem shaft using peer-reviewed methods. We then compared the stems using these parameters.

Results
We found that the OptiStems were lighter (p < 0.001), had a rougher trunnion surface (p < 0.001) with a greater spacing and depth of the machined threads (p < 0.001), had greater trunnion cone angles (p = 0.007), and a smaller radius at the top of the trunnion (p = 0.007). There was no difference in stem volume (p = 0.643), CCD angle (p = 0.788), offset (p = 0.993), neck length (p = 0.344), stem length (p = 0.808), shaft width (p = 0.058 to 0.720) or roughness of the polished surface (p = 0.536).

Conclusion
This preliminary investigation found that whilst there were similarities between the two designs, the generic OptiStem is different to the branded Exeter design.

Cite this article: *Bone Joint J* 2017;99-B:310–16.

There are over 80 000 total hip arthroplasties performed every year in the United Kingdom,[1] 300 000 in the United States[2] and almost one million worldwide.[3] Expenditure on orthopaedic implants place a large financial burden on health-care budgets. Several implants have a demonstrated durability and good function in patients over many years.[4,5] As manufacturers' patents expire it is understandable that cheaper generic copies will be considered.[3] This has occurred in the pharmaceutical industry for many years and has resulted in some cheaper drugs being available.[6]

Although there are approximately 260 proximal femoral stem designs,[1] many have similar design features including collarless polished tapers, blade designs and hydroxyapatite coated stems. These stems have undergone clinical evaluation through the standard process such as Conformité Européene marking, clinical trials and benchmarking to a known standard such as that performed by the Orthopaedic Data Evaluation Panel (ODEP).[7]

The Exeter (Stryker, Kalamazoo, Michigan) femoral stem is an ODEP 10A* rated implant, which in its first format was introduced in 1970, and now has several imitations including designs from Asian manufactures. More recently, a new company (Orthimo AG, Zug, Switzerland) has introduced the OptiStem XTR for which equivalence is claimed with the established Exeter design,[4] with an expectation of similar clinical outcomes.

There is currently no independent method of determining design equivalence between generic and branded orthopaedic implants. Retrieval analysis of failed implants has shown that variations in surface topography and geometry can play a significant role in the rate of mechanical wear and corrosion of the components,[8,9] and indeed, a recent study has shown that variations within tolerances of the same design can result in considerable differences in material loss.[10]

In this study, we used peer-reviewed methods to compare independently the surface
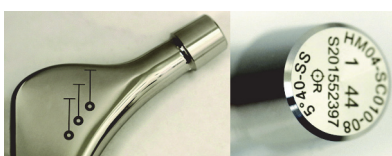
Fig. 1a   Fig. 1b

Fig. 1c

Images of the laser markings on the femoral shaft and trunnion of the new (a) Exeter and (b) OptiStem XTR branded stems. All markings were masked (c) in order to blind both examiners to the brand of stem being analysed.

topography and geometry of the generic OptiStem XTR femoral stem with the original Exeter stem.

Materials and Methods

We acquired ten boxed, as manufactured components consisting of the generic OptiStem XTR model (n = 5) and branded Exeter (n = 5) femoral stems. The five OptiStem XTR implants were all the same size (44), number 1 range and were donated by the manufacturer from a random selection. The Exeter stems were all size 44, number 1 and were purchased from the hospital stock of one of the authors and selected at random from different batches.

The identifying laser markings on the stem shaft and top of the trunnion (Fig. 1) were masked to anonymise the implants. Blinded analysis of the ten stems was then performed by two examiners (HH and ADL) independently. Figure 2 summarises the different parameters that were investigated.

Mass measurement. The mass of each stem was measured using Mettler PC 4400 (Mettler Toledo, Leicester, United Kingdom) digital scales. A total of three separate readings were taken by both examiners for each stem; the scales were zeroed before each measurement.

Stem volume. Micro-CT scans of each component were performed using an XTH-225-ST (Nikon Metrology NV, Derby, United Kingdom) scanner. A beam energy and current of 200 Kv and 55 µA respectively were used and the scan resolution was 95 µm. The raw scan data were imported into a 3D image processing package (Simpleware, Exeter, United Kingdom) and a greyscale threshold of 32 300 to 64 500 Hounsfield units was applied to isolate the stems. A 3D render of each stem was generated from which a measure of the volume of the component was obtained.

Stem dimensions. Each stem was placed on a flat surface within an imaging stand with a ruler (millimetres scale) aligned parallel to the stem shaft. A scale digitised image of each component was taken and imported into an open source image processing tool (ImageJ, Bethesda, Maryland). Using this we measured: the Caput-Collum-Diaphyseal (CCD) angle, defined as the angle between the longitudinal axes of the femoral neck and shaft; the femoral offset, defined as perpendicular distance between the long axis of the stem and the centre of the trunnion; the stem length, defined as the distance between the stem tip and shoulder; and the neck length, defined as the distance between the centre of the trunnion and point of intersection of the longitudinal axes of the neck and shaft. We used digital callipers to measure the width of the stems in their anteroposterior and lateral profiles at 2 mm, 50 mm and 100 mm from the stem tip (Fig. 2).

Surface topography. A Contour GT-K 3D optical profilometer (Bruker, Coventry, United Kingdom) was used to visualise the surface topography of the stem trunnions and to determine the height, the spacing and the roughness of the machined threads on their surfaces. A total of six measurement scans were taken along the trunnion surfaces, three each on opposing sides with the stem laid flat. The scan area was 1.256 mm × 0.942 mm using a 5× objective lens and 1× multiplier.

A backscan of 500 µm and length of 400 µm was employed with a threshold of 1%. The median of the distance between the peaks and troughs of the raw plots generated from the scans was used to determine thread height; the median of the distance between neighbouring peaks was used to determine thread spacing.

Following this, six additional scans (three on the front and back) were taken along the longitudinal axis of the shaft of each stem at 2 mm, 50 mm and 100 mm from the stem tip. A Gaussian regression filter was applied to the raw data and a measure of µm Ra roughness determined.

Trunnion analysis: roundness measuring machine. A Talyrond 365 (Taylor Hobson, Leicester, United Kingdom) roundness measuring machine was used to analyse the geometry and surface roughness of the trunnions. The trunnion was first centralised and levelled using on-board software. Following this a 5-micron diamond tipped stylus on a 90° cone was used to take a series of 180 vertical traces along the trunnion surface, capturing over one million data points.

The raw data were imported into a software package (Tribosol; Pontefract, United Kingdom) that is used for analysis of the geometry of the taper and trunnion of hip components; we have previously published our methods for this.[11] We used the scans to determine the cone angle of each trunnion and the changes in radius between the top and base of the trunnion. We identified a common value for the radius which was measured at the base of each of the ten trunnions; this radius was used to normalise the base radius values between the stems. A measure of the radius at a vertical distance of 7 mm from the same base radius was then performed.
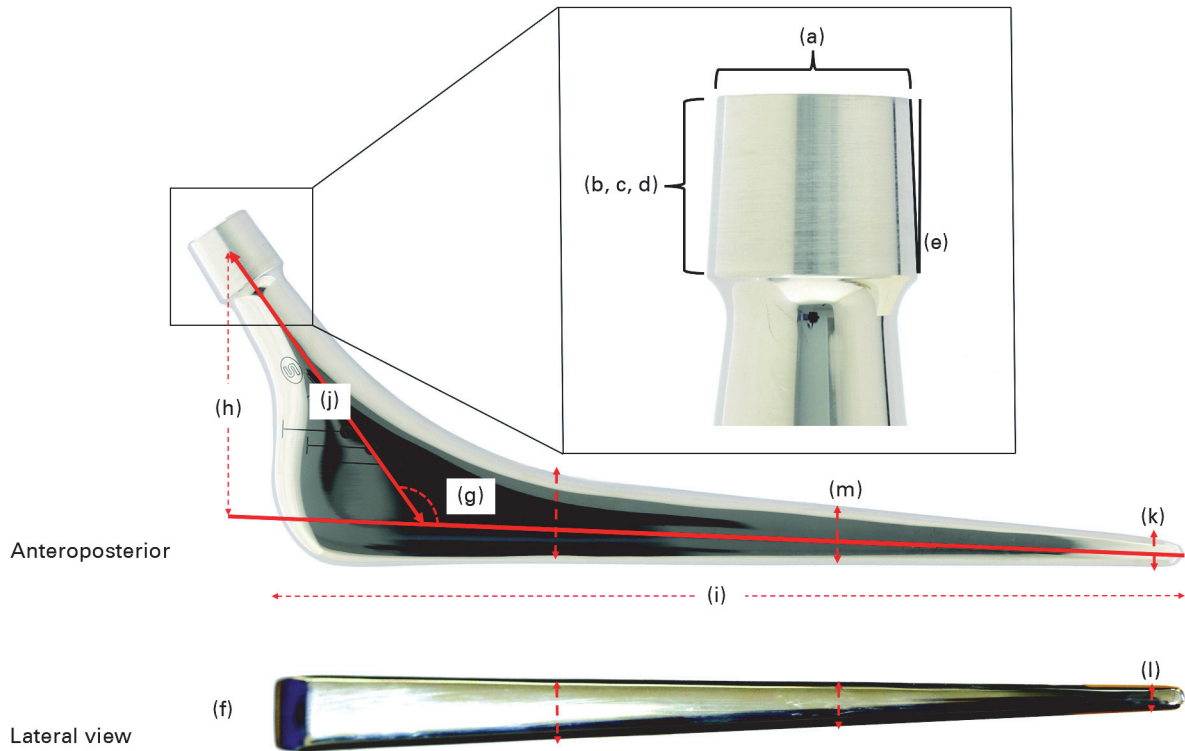
Fig. 2

Summary of the stem design parameters that were investigated: (a) trunnion diameter; (b) thread height; (c) thread spacing; (d) trunnion roughness; (e) cone angle; (f) stem mass and volume; (g) CCD angle; (h) femoral offset; (i) stem length; (j) neck length; (k) shaft width in an anteroposterior view at 2 mm, 50 mm and 100 mm from the stem tip; (l) width in lateral view at 2 mm, 50 mm and 100 mm from the stem tip; and (m) surface roughness at 2 mm, 50 mm and 100 mm from the step tip.

The raw measurement data were then imported into Talymap 7 (Taylor Hobson) to determine the surface roughness of the trunnions. From the 180 vertical traces that were taken, we selected four traces at a position of 0°, 90°, 180° and 270° from the starting point of the first scan trace. From these we extracted a measure of the roughness parameter (μm Ra).

Statistical analysis. We performed the Student's *t*-test to determine if there were any significant differences between the two stem groups in relation to the parameters investigated in this study. This analysis was performed using the statistical software package Prism (GraphPad, La Jolla, California) and throughout, a p-value < 0.05 was considered statistically significant.

We determined the strength of agreement in the data points generated by the two independent examiners for the thread spacing, thread depth, mass, trunnion roughness and stem shaft roughness parameters by calculating the intraclass correlation coefficient with 95% confidence intervals (CI); a coefficient close to 0 indicates poor agreement and close to 1 indicates good agreement. Paired *t*-tests were used to assess whether there were any significant dif-ferences in the measures of the cone angle, trunnion radius, CCD angle, femoral offset, stem length, neck length and stem shaft width determined by both examiners.

Results

Inter-examiner reliability. Statistical analysis of the raw data generated by both examiners revealed very good agreement, with an interclass correlation coefficient of 0.965 (95% CI 0.928 to 0.986), 0.942 (95% CI 0.868 to 0.984), 0.999 (95% CI 0.999 to 1.000), 0.995 (95% CI 0.981 to 0.999) and 0.782 (95% CI 0.653 to 0.982) for the thread spacing, thread depth, mass, trunnion roughness and stem shaft roughness parameters respectively. There were no significant differences between examiners for measurements of cone angle (p = 0.343), trunnion radius (p = 0.726), CCD angle (p = 0.793), femoral offset (p = 0.962), stem length (p = 0.253), neck length (p = 0.189) and stem shaft width (p = 0.596).

Mass and volume measurement. Figure 3 plots the mass of the ten stems with three repeat measurements for each. The median mass of the OptiStems was 160.50 g (interquartile range (IQR) 160.27 to 160.93), whilst for the Exeter stems it was 165.77 g (IQR 162.25 to 165.91) (p < 0.001).
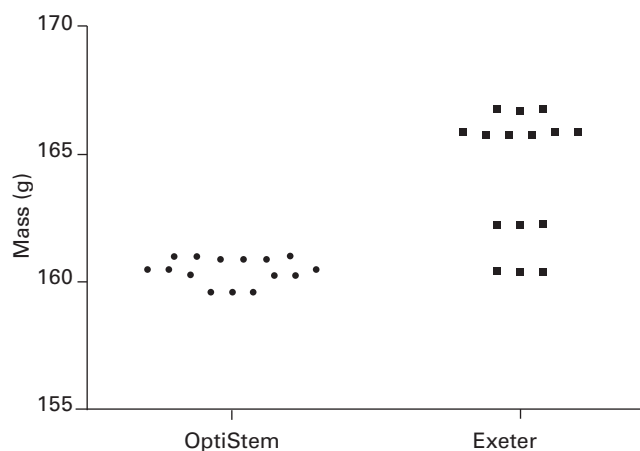
Fig. 3

Dot plot presenting the distribution of the mass measurements of the ten stems (measurements taken three times for each stem). The OptiStems (n = 5) had a lower overall mass than the Exeter stems (n = 5); there was no difference in the volumes of the two designs (*t*-test, p = 0.643).

The median volume measured for the OptiStem and Exeter stems was 22.00 cm^3 (IQR 19.92 to 22.71) and 21.90 cm^3 (IQR 21.47 to 22.23) respectively (p = 0.643).

Stem dimensions. The median CCD angles of the OptiStem and Exeter components were 125.41° (IQR 124.16° to 125.73°) and 125.55° (IQR 124.17° to 125.67°) respectively (p = 0.788).

The median measured femoral offset of the OptiStem and Exeter components were 44.29 mm (IQR 44.14 to 44.41) and 44.256 mm (IQR 44.19 to 44.45) respectively (p = 0.993).

The median stem length for the OptiStem and Exeter stems was 149.48 mm (IQR 148.67 to 151.07) and 149.32 mm (IQR 148.93 to 150.45) respectively (p = 0.808).

The median neck length for the OptiStem and Exeter components was 53.21 mm (IQR 52.88 to 53.76) and 52.89 mm (IQR 52.22 to 53.60) respectively (p = 0.344).

Table I summarises the median measurements of the stem shaft width in the anteroposterior and lateral profiles at 2 mm, 50 mm and 100 mm from the stem tip.

Surface topography. Figure 4 presents typical examples of the measurement scans captured for the ten stem trunnions. The median thread spacing for the OptiStem was 102.03 µm (IQR 102.02 to 103.99) and 38.21 µm (IQR 25.51 to 47.09) for the Exeter design (p < 0.001).

The median thread height for the OptiStem was 3.5 µm (IQR 3.4 to 3.5) and 1.4 µm (IQR 1.2 to 1.6) for the Exeter implants (p < 0.001).

The median stem shaft roughness for the OptiStem and Exeter designs was 0.022 µm Ra (IQR 0.021 to 0.034) and 0.024 µm Ra (IQR 0.018 to 0.035) respectively (p = 0.536).

Cone angle. The median measured cone angle of the Opti-Stem trunnions was 5.7° (IQR 5.69° to 5.72°), whilst for the Exeter devices it was 5.64° (IQR 5.63° to 5.64°) (p = 0.007).

Radius. We identified a common radius of 6.1 mm at the base of each of the ten trunnions. The median trunnion radius at a vertical distance of 7 mm from the base was 5.752 mm (IQR 5.750 to 5.752) for the OptiStem and 5.755 mm (IQR 5.750 to 5.752) for all the Exeter components (p = 0.007).

Trunnion roughness parameter. Figure 5 presents a measure of the roughness parameter, taken from four traces on each trunnion. The median value for the OptiStem trunnions was 0.924 µm Ra (IQR 0.919 to 0.931) and 0.274 µm Ra (IQR 0.248 to 0.287) for the Exeter implants (p < 0.001). Figure 6 presents a typical trace plot taken from the two stem designs.

Discussion

This study is the first independent investigation of the equivalence of a generic orthopaedic implant to its branded design. We compared five generic OptiStem femoral stems with five branded Exeter stems of supposedly matching sizes and found that the OptiStems were lighter, had a rougher trunnion surface with a greater spacing and depth of the machined threads, had greater trunnion cone angles and a smaller radius at the top of the trunnion. There was no difference in stem volume, CCD angle, offset, neck length, stem length, shaft width or roughness of the polished stem shaft.

This preliminary investigation found that whilst there were similarities between the two designs, the generic OptiStem is different to the branded Exeter design.

The impact of generic drugs has driven down healthcare costs in the pharmaceutical industry.[6] The desire to extend generic technology to orthopaedic implants is understandable. However, there are important differences between a generic drug and a generic implant. A drug has a unique chemical formula, chemical speciation and physical form. These parameters are measurable with mass spectrometers and radiographic analysis.[12] An implant has several physical and chemical parameters that can also be measured but there is considerable variation in material composition, material structure, and manufacturing process. We know that small changes have had a dramatic effect on the outcome.[13]

Several retrieval and laboratory based studies have demonstrated the importance of surface roughness as a contributing factor for mechanical wear and corrosion at the head-stem junction; a rougher surface leads to greater material loss.[9,10,14] The roughness parameter is calculated as the mean of the microscopic peaks and valleys of the surface. We found that the median µm Ra of OptiStem trunnions was more than three times greater than the Exeter trunnions. There is concern therefore that the OptiStem components are at greater risk of material loss at the taper junction when paired with cobalt chrome modular heads. This is due to a reduced contact area between trunnion peaks and the corresponding head taper surface, leading to increased localised contact stresses and more prominent

Table I. Summary of the median (interquartile range) measurements of the stem shaft width in the anteroposterior (AP) and lateral profiles at 2 mm, 50 mm and 100 mm from the stem tip. Comparison using *t*-testing

| | Distance from stem tip | | | | | |
| | 2 mm | | 50 mm | | 100 mm | |
	AP	Lateral	AP	Lateral	AP	Lateral
OptiStem	4.78 (3.59 to 4.96)	4.73 (3.94 to 5.60)	9.63 (9.26 to 10.21)	7.10 (6.81 to 7.56)	16.26 (15.73 to 16.65)	10.46 (10.00 to 11.08)
Exeter	4.21 (3.82 to 4.63)	4.49 (4.32 to 4.95)	9.59 (8.98 to 9.91)	7.12 (6.62 to 7.24)	16.40 (16.20 to 17.16)	10.07 (9.66 to 10.10)
p-value	0.696	0.72	0.495	0.455	0.243	0.058
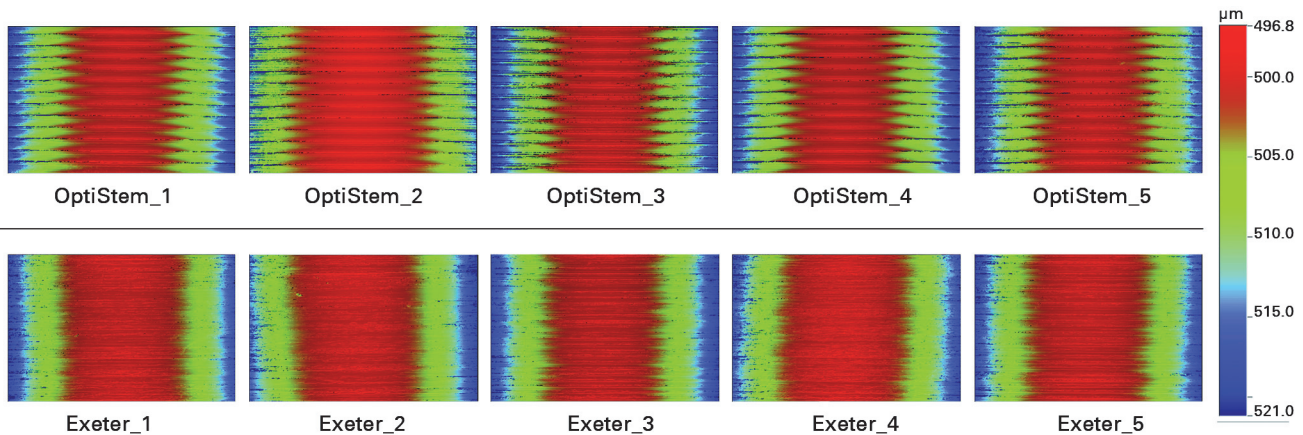
Fig. 4

Examples of the imaging scans generated by the optical profilometer for the ten stem trunnions. The OptiStem trunnions (top row) have a visibly more threaded surface topography than the Exeter trunnions; the depth is greater and the peaks are spaced a greater distance apart.
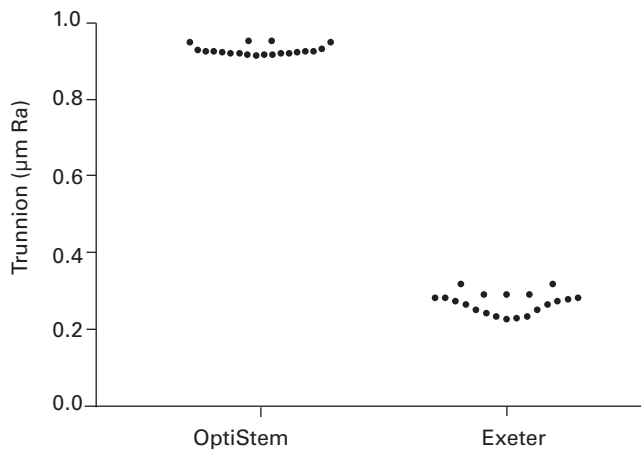

Fig. 5

Dot plot showing the distribution of the surface roughness measured from four different scan traces on each trunnion. The OptiStem trunnions had a median μm Ra that was over three times greater than the Exeter trunnions.

channels for fluid ingress to occur between the valleys of the trunnion thread and the taper surface, which could potentially lead to greater corrosion. The additional concern is that the OptiStem is designed to look like the Exeter, so an Exeter head may be inadvertently used with an OptiStem in cases such as acetabular component revisions.

Our finding that the OptiStem implants were lighter than Exeter stems despite there being no difference in their vol-

umes is of interest as this suggests that the material density of the OptiStem components may also be lower. It is not clear what the clinical significance of this finding may be. However, this is an indicator of possible differences in the manufacturing process between the two stem designs. Indeed, we noted a smaller range in the maximum and minimum measured values for the different parameters for the OptiStem compared with the Exeter components. This suggests a consistent manufacturing process for the OptiStems, but the difference in density between the two designs may be associated with differences in the microstructure of the alloys such as grain size or orientation. This may affect the mechanical properties of the component.

Optimal fit between a stem trunnion and head taper can be achieved if the angle of the trunnion and taper components are the same; a perfect fit creates a seal preventing fluid ingress from occurring. We found that the OptiStem trunnions had a greater cone angle than those of the Exeter stems and consequently the radius of the OptiStem trunnions was smaller. It is noted that the scale of the differences between the two designs for these two parameters are small. The measured values of the different parameters may be within the design tolerances of the Exeter component, however, we do not have access to these data to confirm or refute this. It is interesting that there is no overlap between the measurements and therefore the fit between the same femoral head and these two stems designs would be different. It remains
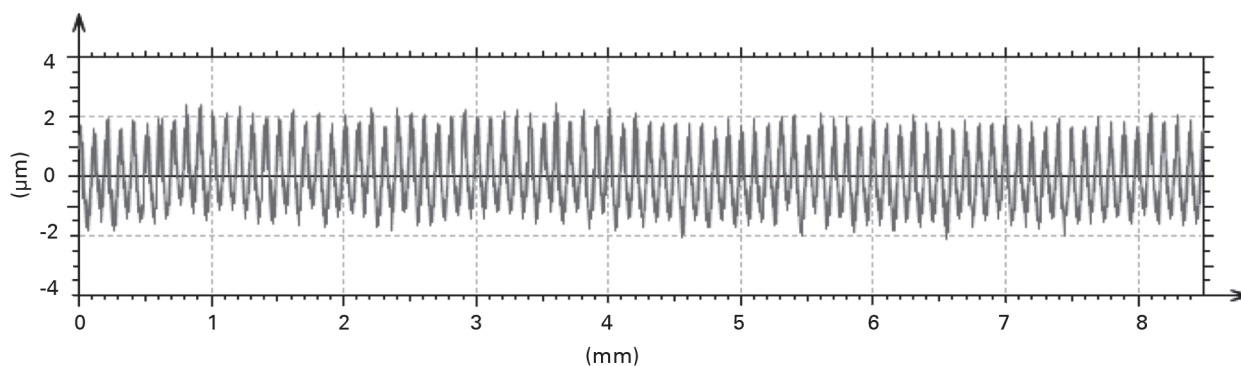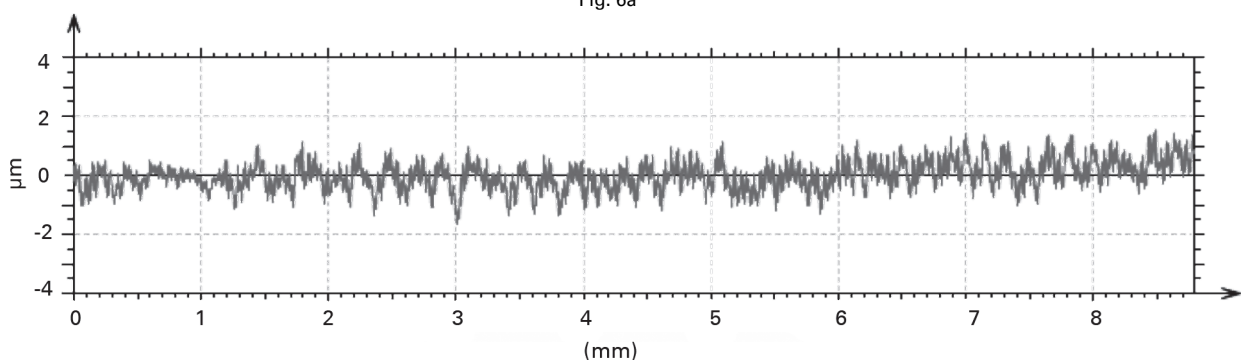
Fig. 6a

Fig. 6b

Example of a typical scan trace taken using the diamond probe on the roundness measuring machine from (a) the OptiStem trunnion and (b) the Exeter trunnion.

unclear what affect these parameters have on clinically relevant levels of material loss at the taper junction.[15] We note however that the manufacturer (Orthimo AG) supplies the OptiStem XTR with a femoral head design referred to as the OptiHead XTR. This study has not included analysis of this head design and we do not know if the effect of trunnion differences in the OptiStem would be mitigated by the design of the OptiHead, or if indeed they would be worsened.

Our study demonstrates the importance of independent verification of manufacturing finishes of orthopaedic implants. This is especially pertinent for generic implants that claim design equivalence to branded designs. There have been numerous examples in recent history of seemingly small changes in implant design resulting in large differences in clinical results.[16,17] Indeed, this was demonstrated with the Exeter stem which was associated with an increased incidence of loosening when a matt surface finish was used compared with the polished stem design.[16] The current study examined surface finish which confirmed that both designs were highly polished with no significant difference in their roughness. Another notable example is that of the 3M Capital hip (3M Healthcare, Oakdale, Minnesota) which was marketed as being a low-cost design emulating the established Charnley hip (DePuy Synthes, Warsaw, Indiana). This was however quickly discontinued following high incidences of early loosening[17]

which were thought to be due, in part, to the increased surface roughness of this design over the Charnley.

We acknowledge that there are other factors which may impact the performance of the stem which must be investigated in future studies. For example, it is important that the microstructural properties of the alloy used are fully characterised and features such as grain size and orientation are considered. Several other tests are possible, such as an examination of the method of manufacturing the stem, strength testing under load and testing the taper under load for debris generation. Future work should also consider any instruments that may be used with this generic design, which are known to play a large role in the performance of implants.

We found a difference in trunnion roughness, trunnion cone angle and radius, and implant mass when comparing the generic and branded stem designs. All implants require standard regulatory processes to be followed. It does not appear feasible that generic implants can be manufactured predictably to guarantee the same performance as generic drugs.

Take home message:
- The design of the generic femoral stem in this study is not the same as the branded stem on which it is based.

- It does not appear feasible that generic orthopaedic implants can be manufactured predictably to guarantee the same performance as generic drugs.

This article was primary edited by G. Scott.

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