

Correlation between inclination of the acetabular component and metal ion levels in metal-on-metal hip resurfacing replacement

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We examined the relationships between the serum levels of chromium and cobalt ions and the inclination angle of the acetabular component and the level of activity in 214 patients implanted with a metal-on-metal resurfacing hip replacement. Each patient had a single resurfacing and no other metal in their body. All serum measurements were performed at a minimum of one year after operation. The inclination of the acetabular component was considered to be steep if the abduction angle was greater than 55°.

There were significantly higher levels of metal ions in patients with steeply-inclined components ($p = 0.002$ for chromium, $p = 0.003$ for cobalt), but no correlation was found between the level of activity and the concentration of metal ions. A highly significant ($p < 0.001$) correlation with the arc of cover was found. Arcs of cover of less than 10 mm were correlated with a greater risk of high concentrations of serum metal ions. The arc of coverage was also related to the design of the component and to size as well as to the abduction angle of the acetabular component. Steeply-inclined acetabular components, with abduction angles greater than 55°, combined with a small size of component are likely to give rise to higher serum levels of cobalt and chromium ions. This is probably due to a greater risk of edge-loading.

Metal-on-metal resurfacing hip replacement¹⁻³ is becoming an increasingly common alternative to total hip replacement (THR), particularly in younger patients.⁴⁻⁸ It preserves femoral bone, has a lesser risk of dislocation and better wear characteristics than metal-on-polyethylene.^{2,6} The early to mid-term published results have been encouraging.^{4,9-12}

There are, however, a number of concerns about the metal-on-metal bearing. Although its wear rate is low,¹³ it still releases metal particles and ions into the body,^{14,15} particularly cobalt and chromium since most metal-on-metal bearings are made of a cobalt-chromium alloy (CoCr). The diameter of a hip resurfacing bearing is more than that of most THR components and theoretically, if the lubrication conditions are not ideal, may increase the amount of metal ions released.¹⁶ Several studies have reported increased serum concentrations of both Co and Cr after resurfacing hip replacement.¹⁶⁻²² The long-term consequences of increased levels of these ions in the body are not known. High concentrations of Co and Cr are toxic and are known to interfere with a number of biological functions.²³⁻²⁵ Willert et al²⁶ have described a soft-tissue reaction thought to be related to metal

sensitivity in patients with a metal-on-metal THR. There have also been recent reports of soft-tissue reactions with resurfacing hip replacement.^{27,28}

In the light of these concerns, it is important to examine factors which may influence the release of metal ions after resurfacing hip replacement. It has been reported that the position of the acetabular component will influence the bearing wear of a resurfacing hip replacement.²⁹ Further, it has been observed that large amounts of metallosis are found during the revision of steeply-inclined acetabular components.^{30,31} The relationship between wear and inclination angle in THR was examined by Brodner et al¹⁷ who showed that there was considerable variation in the measurements of metal ions, but no clear relationship between the abduction angle and the level of metal ions. The relationship between level of activity and the concentration of metal ions was studied by Heisel et al¹⁹ but no correlation was found between acute changes in activity level and the concentration of metal ions. Our aims in this study on a relatively large series of patients who had undergone resurfacing hip replacement were to determine whether a steeply-inclined

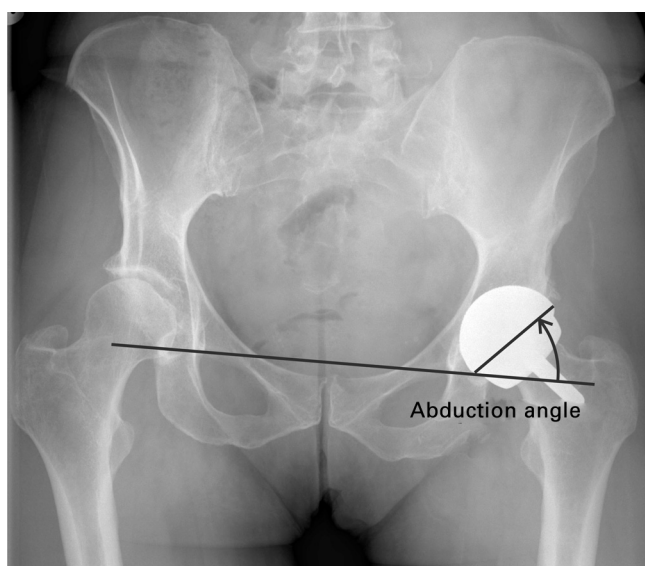


Fig. 1

Radiograph showing the measurement of the abduction angle on standard anteroposterior radiographs using ImageJ software.

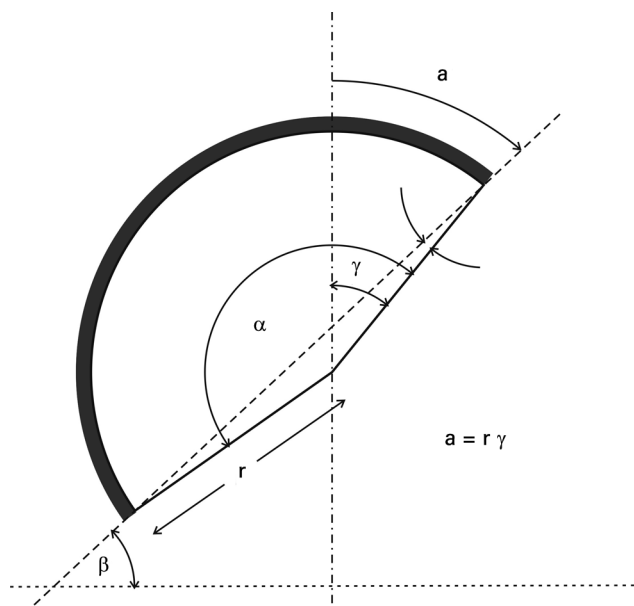


Fig. 2

Diagram showing the calculation of the arc of cover (a) using the equation $a = r \cdot \alpha$ (with α measured on the radiograph).

acetabular component would give rise to a higher concentration of metal ions and whether the latter was positively correlated with the level of activity.

Patients and Methods

There were 214 patients in the series: 125 men (58.4%) and 89 women (41.6%) with a mean age at the time of surgery of 50.5 years (13.9 to 72.2). The underlying diagnosis was osteoarthritis in 187 patients (87.4%), avascular necrosis in 15 (7.0%), dysplasia in five (2.3%) and rheumatoid arthritis, trauma or slipped upper femoral epiphysis in seven (3.3%).

Most of the patients (200) had been operated on by the senior author (KDeS) and the remainder by a group of nine surgeons. A variety of resurfacing devices had been used: 155 Birmingham Hip Resurfacings (BHR; Smith & Nephew, Memphis, Tennessee), 50 Conserve Plus (C+) (Wright Medical Technology, Memphis, Tennessee), eight articular surface replacement (DePuy, Warsaw, Indiana) and one Durom (Zimmer, Warsaw, Indiana). The BHR is made from a cast CoCr alloy, the C+ from a cast CoCr alloy which has undergone heat treatment, and the ASR and Durom devices from forged CoCr alloys. The diameter of the femoral component which was used was recorded in all patients. The mean diameter was 49.3 mm (38 to 59).

Blood samples were collected from all the patients at a mean time of 3.4 years (1 to 8.7) after surgery. These patients did not have any other metal implants at the time of measurement. The reason for the minimum one-year post-operative sample time was to avoid the confounding factor of higher levels of wear during the run-in period.^{13,18}

The samples were obtained using an intravenous catheter (Insyte-WTM; Becton Dickinson, Franklin Lakes, New Jersey). After the catheter had been introduced, the metal needle was withdrawn and the first 5 ml of blood were discarded to avoid possible contamination from the needle. A second 5 ml were collected using a vacuum tube (Venosafe VF-106SAHL; Terumo Europe NV, Leuven, Belgium).

Serum levels of Co and Cr were measured using inductive-coupled plasma mass spectrometry (ELAN DRC II; Perkin Elmer Life and Analytical Sciences, Shelton, Connecticut). The measurements were performed by the Laboratory of Clinical Biology at Ghent University Hospital, Ghent, Belgium. The laboratory quotes its quantification limit as 0.5 µg/l with a reproducibility of 5%.

At the time of collection of the sample, the patients were asked to complete a self-reported activity questionnaire, the UCLA activity score.³¹

Standardised anteroposterior (AP) post-operative radiographs (digitally recorded) were analysed using ImageJ software (National Institutes of Health, Bethesda, Maryland) to measure the abduction angle of the acetabular component (Fig. 1).

The patients were separated into two groups, steep and non-steep. Hips with an abduction angle $\geq 55^\circ$ were considered to be steeply-inclined while those with an angle of $< 55^\circ$ were considered to be not steeply-inclined. The value of 55° was chosen based on the previous work of Brodner et al,¹⁷ who reported higher levels of metal ions in patients with an abduction angle greater than 55° . There were 74 patients (43 men and 31 women) with steep components and 140 (78 men and 62 women) with non-steep components.

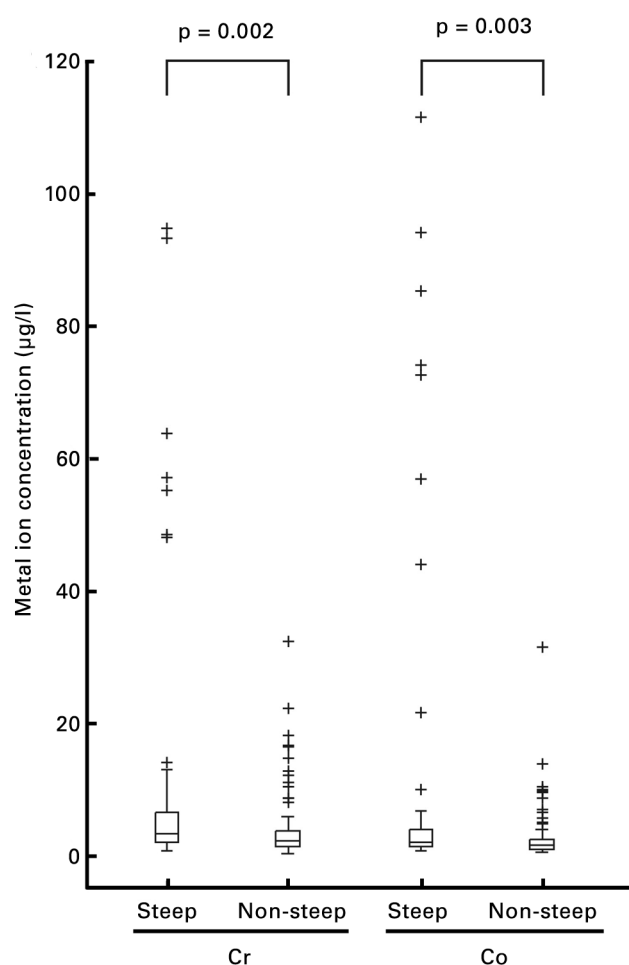


Fig. 3

Box plot showing the distribution of Cr and Co ions in the steep (component abduction $\geq 55^\circ$) and non-steep (component abduction $< 55^\circ$) groups.

We studied the differences between metal ion levels in men and women in both the steep and non-steep groups, while paying attention to the distribution of size of component. The latter and the abduction angle are both related to the amount of cover of the femoral component. Of particular interest was the cover of the proximal pole of the femoral component by the lateral edge of the acetabular component (Fig. 2), as this would indicate the risk of edge-loading. The circumferential portion of this cover in the frontal plane was termed the arc of cover (α), and was calculated assuming that the version of the acetabular component is neutral. The arc of cover is given by the product of the component radius (r) and angle (in radians) subtended between the vertical and the lateral acetabular component edge (γ) as follows:

$$\alpha = r\gamma$$

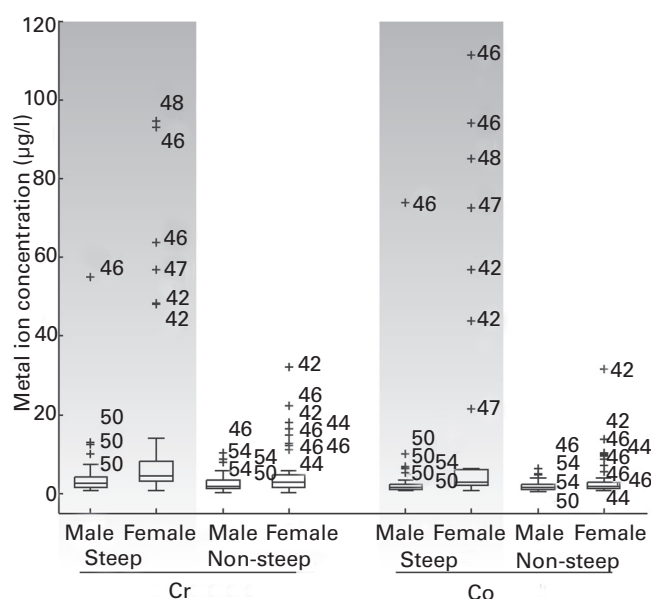


Fig. 4

Box plots showing the distribution of Cr and Co ions separated into the steep and non-steep groups. The number next to each outlier indicates the diameter of the femoral component in millimetres. For the steep group the differences between male and female subjects were significant for both Co ($p = 0.002$) and Cr ($p = 0.002$). Only Cr was significantly different between the genders for the non-steep group ($p = 0.023$); differences in Co levels were not significantly different ($p = 0.053$).

For the BHR the subtended acetabular component angle is 164° (Moore, Smith & Nephew, Birmingham, United Kingdom) and 170° for the C+ devices (Timmerman, Wright Medical Technology), since there were relatively large numbers of BHR ($n = 155$) and C+ ($n = 50$) devices, the arc of cover was calculated for each patient implanted with these devices and the correlation between the arc of cover and levels of metal ions were calculated. In addition, the differences in concentrations of metal ions between the BHR- and the C+-implanted patients were examined. These patients were divided into steep and non-steep groups.

The ion concentration data were also examined in relation to the level of activity given by the UCLA activity score.³¹

Statistical analysis. All statistical analyses were performed using SPSS version 15 (SPSS Inc., Chicago, Illinois). The level of significance was set at $p \leq 0.05$.

The data were not normally distributed so non-parametric statistical tests were used. We calculated a Pearson correlation coefficient for the levels of Cr and Co and also for ion levels and the length of time after surgery. Differences in Co and Cr concentrations between the steep and non-steep groups were examined using the Mann-Whitney U test. The distribution of component sizes between male and female patients was examined using the chi-squared test.

Results

There was a very high correlation between the concentrations of Co and Cr, with a correlation coefficient of

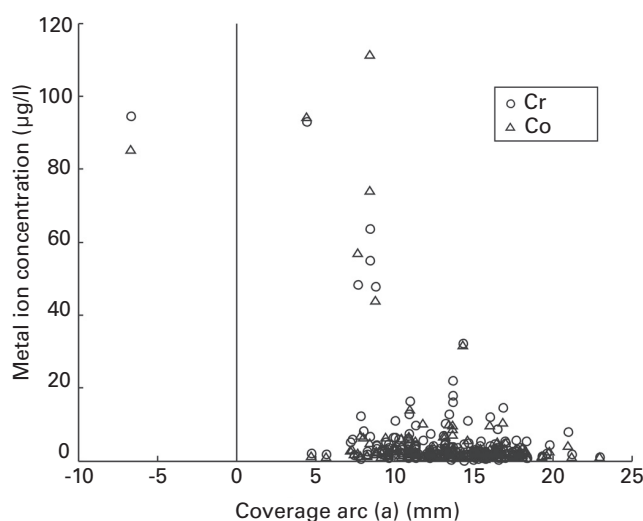


Fig. 5

Scatter plot showing the relationship between the coverage arc (a) and the metal ion concentration of Cr and Co.

0.957 which was highly significant ($p < 0.001$). No significant correlation between the levels of metal ions and the length of time from the initial surgery was found (Cr, $p = 0.26$; Co, $p = 0.22$).

The group with steep components had significantly higher concentrations of metal ions than those with non-steep components (Mann-Whitney U test, $p = 0.003$ for Co, $p = 0.002$ for Cr; Fig. 3). The mean values for Co were $9.8 \mu\text{g/l}$ (0.6 to 111.3; 95% confidence intervals (CI) 4.4 to 15.1) for the steep components and $2.4 \mu\text{g/l}$ (0.4 to 31.5; 95% CI 1.8 to 2.9) for the non-steep components. The mean values for Cr were $9.7 \mu\text{g/l}$ (0.6 to 94.6; 95% CI 5.3 to 14.1) for the steep components and $3.6 \mu\text{g/l}$ (0.2 to 32.2; 95% CI 2.8 to 4.3) for the non-steep components.

Most of the outlier values for the concentration of metal ions were in women (Fig. 4). In the steep category, women had significantly higher concentrations than men (Mann-Whitney U test, $p = 0.016$ for Co, $p = 0.010$ for Cr). In addition, the outliers within each group were from patients implanted with small components. The distribution of size was significantly different (chi-squared test, $p < 0.001$) between men and women, as women had smaller components.

There was a highly significant negative correlation between the arc of cover and the concentration of metal ions (Mann-Whitney U test, $p < 0.001$; Fig. 5). The correlation coefficients were -0.402 for Co and -0.442 for Cr.

The steep BHR patients ($n = 59$) had significantly higher concentration of metal ions than the steep C+ patients ($n = 13$) (Mann-Whitney U test, $p = 0.042$ for Co, $p = 0.048$ for Cr; Fig. 6). The mean ion concentrations for steep BHR compared with C+ implants were $10.2 \mu\text{g/l}$ (0.8 to 111.3; 95% CI 3.9 to 16.5) for Co and $10.4 \mu\text{g/l}$ (0.6 to 94.6; 95%

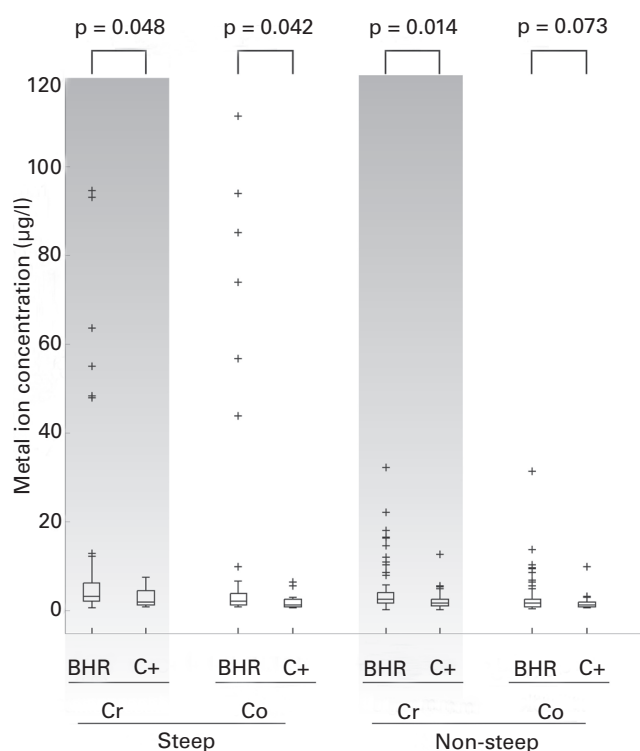


Fig. 6

Box plots showing the distribution of Cr and Co ions in the steep and non-steep in BHR- and C+ implanted patients.

CI 5.0 to 15.6) for Cr. For the C+ implant the mean Co ion concentration was $2.1 \mu\text{g/l}$ (0.6 to 6.4; 95% CI 1.0 to 3.3) and for Cr it was $3.0 \mu\text{g/l}$ (0.9 to 7.6; 95% CI 1.5 to 4.4). In the non-steep BHR patients ($n = 96$) and the non-steep C+ patients ($n = 37$) there was a significant difference only in the level of Cr (Mann-Whitney U test, $p = 0.014$), with the BHR patients having higher Cr concentrations.

There was no clear relationship between the level of activity and the metal ion concentration (Fig. 7a). The highest concentrations were observed in patients with UCLA scores of 7.0. This was the most frequently reported score (Fig. 7b).

Discussion

Our findings indicate that steeply-inclined acetabular resurfacing components give rise to higher concentrations of metal ions. The effect of the position of the component appears to be more important than the level of activity. A higher concentration of metal ions does not correlate with the level of activity.

The reason for a very high concentration of metal ions in some cases may be edge-loading which causes marked localised wear³⁰ and gives rise to elevated levels of ions.³² The more steeply-inclined the acetabular component, the more likely the occurrence of edge-loading. Our data show that the design of the implant and the size of the component are also important factors in the generation of edge-loading.

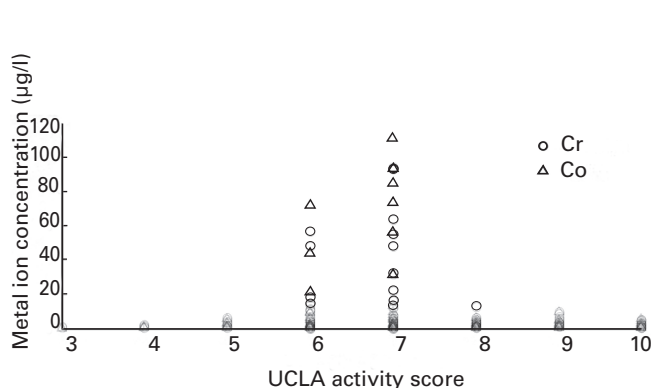


Fig. 7a

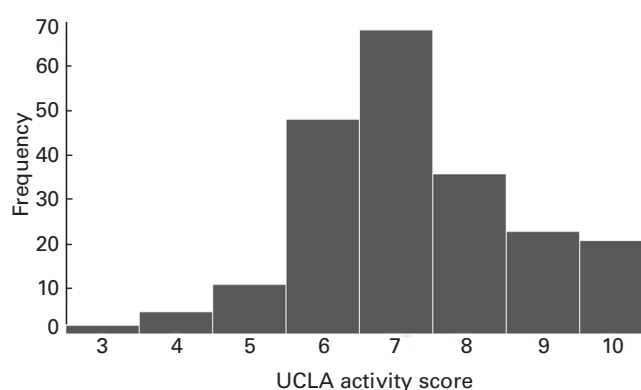


Fig. 7b

Scatter plot of University of California Los Angeles (UCLA) activity score against the metal ion concentration and b) Bar chart showing the distribution of UCLA activity scores.

What is not clear from the literature is the relationship between the level of metal ion and complications. It is clear, however, that a soft-tissue reaction to large quantities of particulate debris can result in fluid or mass formation with subsequent destruction of soft tissues^{19,28,33} as well as bone resorption leading to loosening of the implant or fracture of the femoral neck.²⁸

Overall, the level of metal ions tended to be higher in women than in men, particularly if the acetabular component was steeply-inclined. We found that 20% of women with steep acetabular components had ion levels above 30 µg/l, only 2% of men with steep components had ion levels above this amount. If the acetabular component was not steep, only 2% of women had ion levels above 30 µg/l and none of the men had such elevated levels. We therefore suggest that women who are found to have a steep acetabular component post-operatively should have their metal ion levels monitored. There are several reasons why women may generate higher levels than men, including differences in gait patterns. However, we believe that the tendency to have a smaller acetabular component is important, and this may explain why women have a higher risk of elevated levels. Our findings are in agreement with those of Vendittoli et al,³⁴ who reported that gender, size of the component and inclination are related to the level of metal ions for patients implanted with the Durom resurfacing hip replacement.

The combined effects of the size of the component and the abduction angle can be examined using the arc of cover. The size, abduction angle, and the arc angle (α) all influence the arc of cover of the acetabular component achieved in a given patient. We found a highly significant relationship between the arc of cover and the level of metal ions. This was a stronger correlation than those between the abduction angle and the level of metal ions and between the size of the component and the level of metal ions. Therefore, we concluded that there is a

relationship between cover and wear. If the cover was less than 10 mm, the chance of very high wear (ion levels > 30 µg/l) was 18%. The chance of high wear with cover greater than 10 mm was 0.6%. Cover appeared to be the most important factor explaining wear. It should be noted that our analysis does not take account of any anteversion of the acetabular component. A more accurate assessment of three-dimensional cover could be made using CT-based measurements as advocated by Cobb et al³⁵ and Barrett et al.³⁶

Another observation which supported the relationship between the arc of cover and the serum metal ion concentration was the tendency for higher ion levels to be associated with the BHR rather than the C+ replacement. It should be noted, however, that there were three times as many BHR-implanted patients as C+-implanted patients in the series. The main difference between the C+ and the BHR is that the articular surfaces of the acetabular components subtend different angles. Although both are less than a hemisphere, that of the C+ is approximately 170°, which is more than the 164° in the BHR. Therefore, for any given inclination angle and diameter of acetabular component, the C+ will have more cover than the BHR. We can re-arrange the relationship between the arc or cover and the design/implantation parameters to calculate the minimum values of α required to achieve a given amount of cover according to the equation:

$$\alpha = 2 \cdot (a/r + \beta)$$

Setting the desired minimum arc of cover (a) to 10 mm, we can calculate, for a range of sizes of femoral component and inclination angle, the minimum required values of α . We did so for femoral diameters ranging from 38 mm to 60 mm and inclination angles (β) from 40° to 60° (Fig. 8). There is less margin for error in the inclination angle when implanting a small component and when the value of α is

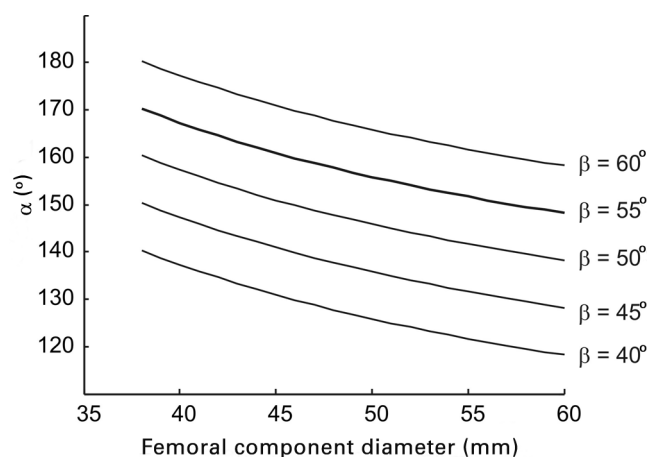


Fig. 8

Graph showing the calculated minimum values of the angle α needed to achieve a minimum arc of cover of 10 mm. These are plotted against the diameter of the femoral component for a range of inclination angles (β). Each separate line represents a given inclination angle.

less than 170° . Surgeons who implant resurfacing devices should be aware of the value of α for the implant which they are using and plan to ensure that adequate cover is achieved.

The positioning of the acetabular component seems to be much more critical in metal-on-metal resurfacing hip replacement than in conventional THR. This is in part because the acetabular component has a low profile to avoid impingement on the femoral neck, and in part because the wear associated with edge-loading has much more serious consequences. Edge-loading of metal-on-metal devices can disrupt the fluid film lubrication mechanism,³⁷ resulting in inadequate lubrication and increased wear.³⁸ Surgeons must therefore take great care to avoid edge-loading. This principle also applies to metal-on-metal THRs of larger diameter. The achievement of correct acetabular orientation is difficult for a number of reasons.³⁹ First, the position of the pelvis on the operating table is poorly defined and may alter. It is often very different from that perceived by the surgeon. Secondly, when the surgeon implants the acetabular component the estimate of its position relative to the patient is usually made by eye. This is likely to introduce errors. Thirdly, the appearance of the acetabulum at operation differs from that measured on the post-operative radiographs. When implanting the acetabular component, the surgeon considers the degree of opening to be the angle between the axis of the acetabular component and the sagittal plane, and anteversion the angle between the axis of the component and the coronal plane. When measuring acetabular inclination on radiographs, the angle between the axis of the acetabular component and the transverse plane is projected on to and measured in the coronal plane. Since the angles are measured in different ways they are profoundly different. If there is no acetabular component anteversion then that measured by the surgeon and that on the radiograph

are the same, but as the anteversion increases the inclination measured on radiograph also increases, even though the inclination at surgery does not. At resurfacing, surgeons tend to antevert the acetabular component substantially to prevent impingement, and this will therefore appreciably increase the inclination of this component.

In our study we have shown that high wear is very likely to occur in metal-on-metal resurfacings if the acetabular components are implanted steeply. This is a particular problem in women, in patients with a small acetabulum and in low-profile resurfacing acetabular components. The clinical message, therefore, is that surgeons need to be aware of the internal arc angle of the acetabular component which they are using and should ensure that these are never implanted more than 55° open. In order to achieve this, surgeons should probably aim to implant them less than 45° open. There is a need for improvement in instrumentation and possibly navigation in order to assist surgeons to achieve this aim.

Supplementary Material



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

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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