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A HIERARCHY OF COMPUTATIONALLY DERIVED SURGICAL AND PATIENT INFLUENCES ON METAL ON METAL PRESS-FIT ACETABULAR CUP FAILURE

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Abstract

The impact of anatomical variation and surgical error on excessive wear and loosening of the acetabular component of large diameter metal on metal hip arthroplasties was measured using a multi-factorial analysis through 112 different simulations. Each surgical scenario was subject to eight different daily loading activities using finite element analysis. Excessive wear appears to be predominantly dependent on cup orientation, with inclination error having a higher influence than version error, according to the study findings. Acetabular cup loosening, as inferred from initial implant stability, appears to depend predominantly on factors concerning the area of cup-bone contact, specifically the level of cup seating achieved and the individual patient's anatomy. The extent of press fit obtained at time of surgery did not appear to influence either mechanism of failure in this study.

Keywords

ORTHOPAEDIC SURGERY; CEMENTLESS ACETABULAR CUP; MODELLING; HIP REPLACEMENT; FINITE ELEMENT ANALYSIS

1. Introduction

Large diameter metal-on-metal (MoM) bearing couples were introduced to provide the twin benefits of reduced dislocation rate and durability, leading to a high volume of these implantations in the last ten years (in 2010, 10% of all primary hip replacements in England and Wales implanted a large diameter press-fit cup (NJR, 2010)). Recent registry reporting concerning inferior survivorship of these implant types (NJR, 2010), along with raised concerns regarding potential consequences of increased metal ions in patient blood (De Smet et al., 2008, Grammatopoulos et al., 2009, Hart et al., 2009) have brought into question the long term survival of MoM hip replacements.

Early reviews of MoM resurfacings reported premature failure, predominantly owing to femoral neck fracture (Shimmin et al., 2005). The higher incidence of fractures in women suggested that suitable patient selection, as well as correct surgical technique, were major

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factors concerning this failure mode (Mont and Schmalzried, 2008, Shimmin et al., 2005). The comparatively high revision rates on both hip resurfacings and total hip replacements involving a large diameter press-fit cup (NJR, 2010), indicated that the femoral component may not be the sole contributor to failure. Recent studies have reported a large percentage of revisions owing to acetabular cup loosening (Browne et al., 2010, Kim et al., 2008); and complications associated with metal component wear are suspected to be attributable to mal-positioned acetabular cups (Campbell et al., 2006, De Haan et al., 2008, Hart et al., 2009). Acetabular cup inclination angle has been correlated with component wear (indicated by blood metal ions) (Hart et al., 2009, Langton et al., 2008), supporting the theory, confirmed by *in vitro* experimental studies that high stresses associated with edge loading result in accelerated wear (Angadji et al., 2009, Mont and Schmalzried, 2008). Cup instability has also been associated with excessive wear (Sieber et al., 1999).

Obtaining a stable press fit of the acetabular component is a fundamental surgical skill and has been clearly linked to training and experience (Kim et al., 2008, Morlock et al., 2008a). The correct level of press-fit is device specific, with orthopaedic companies varying on their recommended level (Mont and Schmalzried, 2008). Full seating, which maximises the surface area in contact, may also be an important factor (Schmalzried et al., 1994), but as the majority of implanted MoM press-fit cups are monoblock and require no screw holes (NJR, 2010), the confirmation of full seating is difficult without an intra-operative radiograph. Correct cup orientation is similarly difficult, with a number of studies demonstrating the wide range of surgically achieved cup inclination and version angles (Kalteis et al., 2005, Lazovic and Kaib, 2005, Saxler et al., 2004), many outside of the 'safe zone' (Lewinnek et al., 1978). These surgical-related factors, along with many patient-specific attributes, all contribute to the potential success or failure of a MoM hip replacement.

The purpose of this research was to investigate the relative influence of different surgical factors, including cup positioning and fit, on the predicted survivorship of MoM press-fit cup implantation. We hypothesised that an investigation of acetabular component failure using a multi-factorial computational analysis approach, involving 112 simulated 'cases' representing different implantation scenarios might give more insight into the relative contributions of these variables to the success or failure of this bearing couple. The potential success of each of the 112 cases was analysed using finite element (FE) analysis. As the cases were created specifically for the study the isolated effects of each chosen input factor, and the interplay between them, could be explored.

2. Materials and methods

Five controllable factors were chosen which could potentially impact on the outcome of an implanted MoM acetabular cup: subject bone anatomy; cup inclination angle; cup version angle; level of press-fit; and cup seating, represented by a gap at the dome of the cup. The factors were varied depending on the scenarios which could realistically occur in a surgical situation. Combinations of all factor values were modelled in 112 FE models.

2.1 Full factorial analysis

The input factors included in the study (Table 1) were those which have been highlighted in the literature as having a potential effect on MoM acetabular cup failure (Isaac et al., 2006, Mont and Schmalzried, 2008, Morlock et al., 2008b). Certain input factors, such as microseparation (Nevelos et al., 2000) and bearing clearances (Rieker et al., 2005) were not included as these require modelling at a finer scale than the chosen factors, and therefore would have compromised computational efficiency and necessitated a reduction in the number of analysed cases. Impingement was also not considered, as femoral anatomy was not present in the simulations. Input factors two to five are explained in Fig. 1.

Each input factor was given a number of different values, which represent likely variations based on published studies (Table 1). Four hemi-pelvis bone geometries were chosen from an ethically obtained anonymised CT dataset of 14 candidates for hip surgery, collected from a range of different CT-scanners. Hemi-pelvises were selected from the dataset to reflect potential hip candidate range in anatomical acetabular inclination and version angles of 47.7-66.8° and 8.5-33.3° respectively (Murtha et al., 2008); patient details are listed in Table 2.

A full factorial analysis was carried out (Dar et al., 2002), including all combinations of all values of chosen input factors; this resulted in 216 ($4 \times 3 \times 3 \times 2 \times 3$) cases. Upon creation of the 216 models it became clear that certain combinations of input parameters were not realistic. It was found that the combination of a polar gap with any inclination angle other than 45.8° resulted in an extremely unstable cup which would not realistically be implanted as the instability would be apparent at the time of surgery. Such a combination was present in 96 models. It was also found that the highest inclination angle (55.8°) combined with the largest version angle (42.3°) caused a dislocation in one or more of the load cases, this was present in a further 8 cases. These models were subsequently disregarded, leaving 112 models remaining for analysis.

Excessive wear and implant loosening were taken as the two potential failure mechanisms; initial implant stability was taken as an indicator for future cup loosening (Pilliar et al., 1986). Implant loosening may occur as a result of symptoms other than excessive initial implant micromotion; these other bases for loosening are not considered in this study. The situation directly after implantation was taken as an indicator of long term success, as this has been shown to be valid for micromotion (Karrholm et al., 1994).

2.2 FE simulation

FE modelling was used as a tool to simulate the performance of each case. The methods used to generate the models have been experimentally validated in terms of strain and micromotion (Clarke et al., 2012). Subject specific hemi-pelvis meshes were segmented from CT scans using MIMICS (version 12.11, Materialise NV, Leuven, Belgium). The meshes comprised a volumetric trabecular mesh of around 180,000 linear tetrahedral elements, with a variable thickness cortical shell mesh of linear triangular elements applied to the exterior. Convergence studies were carried out to define the density of each mesh. Convergence was achieved when subsequent peak cup contact stress, micromotion and strain were all within 5% of the previous value. The element-specific variable cortical thickness was derived from the CT greyscale values, using an algorithm developed with the same logic as previous published work (Anderson et al., 2005). Appropriate subject-dependent trabecular stiffness was assigned on an element by element basis to the trabecular mesh using published techniques (Majumder et al., 2007) and the empirical density-stiffness relationship developed by Dalstra et al. (Dalstra et al., 1993). All material property assignments are listed in Table 3. Each hemi-pelvis model was orientated into the anterior pelvic plane using the contralateral hip for reference.

A reamed cavity was inserted into each mesh using RHINO (version 4.0, McNeel North America, Seattle, Washington). All four anatomical meshes were uniformly scaled so that they all had a reamed cavity with diameter of 52mm; this ensured that the same implant could be inserted into each acetabulum.

The linear scaled geometry of the ADEPT® cup (Finsbury Orthopaedics Ltd, Leatherhead, UK) was used to represent the MoM press-fit cup. The ADEPT® cup is geometrically similar to the BHR® (Smith and Nephew plc, London, UK), which is the most commonly implanted MoM press-fit cup (NJR, 2010). Algorithms were written to automate the

insertion of the cup in all combinations of inclination and version, including gaps at the dome of the cup. A 53mm cup was inserted to represent a 1mm press-fit, and a 54mm cup was inserted to represent a 2mm press-fit. An idealised bearing was represented with a spherical femoral head; and a 1mm thick, low stiffness 'fluid' layer between cup and head. The fluid layer allows an idealised pressure distribution at the bearing interface, removing potential pressure disturbances owing to mesh irregularities or point contact. Frictionless, free sliding was permitted at the bearing surface; and frictional sliding was applied at the cup-bone interface with a linear friction coefficient of 0.68 (Dammak et al., 1997). The model was rigidly fixed at the sacroiliac joint and pubic symphysis. The constructed model is shown in Fig. 2.

The implant was press-fitted into the reamed acetabulum by displacement driving the implant from a position outside the pelvis along a path perpendicular to the cup rim, into its final position in ABAQUS (version 6.8, Dassault Systemes Inc, Velizy-Villacoublay, France); the acetabulum was therefore pre-strained. Each model underwent a series of static loading scenarios, representing the peak loads associated with activities of daily living (Table 4) (Morlock et al., 2001). The hip joint contact force was taken from the averaged dataset measured by Bergmann et al. (Bergmann et al., 2001). Three activity cycles contained two distinct peaks (walking, walking upstairs, walking downstairs), which were both included in the static analysis. A total of eight load cases were therefore simulated. These load cases were taken to be the points of critical loading undergone on a frequent basis; a full loading regime of all frames in each activity cycle was not included and the resulting wear estimation is therefore not an accurate prediction of actual annual wear depth, rather an indication of relative wear between each implantation scenario.

The output parameters taken from the FE simulations were bearing contact stress and cup-bone micromotion. Wear was estimated by using the Archard wear model, which has been successfully applied to estimate wear depth from static models (Liu et al., 2008, Maxian et al., 1996). This estimates an idealised wear regime and does not include consideration of factors such as lubrication regime and other environmental effects present in vivo. This is appropriate in the case of a comparative study, such as this. As only critical loading scenarios were included, full annual wear depth could not be calculated. Instead, indicative wear depth was calculated from the contact stresses at the bearing interface and the joint sliding distances for each load case (Bergmann et al., 2001); using a material wear factor for cobalt chromium of $3 \times 10^{-6} \text{ mm}^3 \text{ Nm}^{-1}$ (Tipper et al., 1999), and proportionally summing together the load case combinations based on daily frequency (Morlock et al., 2001). No 'running in' period was included in the wear calculation. Cup-bone micromotion was taken as the maximum micromotion measured out of the eight load cases.

The results of the 896 simulations ($112 \text{ model} \times 8 \text{ load cases}$) were post-processed to calculate the indicative wear depth and maximum daily micromotion for each case. FE analysis can be used to predict absolute output values, but is more reliable as a tool for predicting relative outcomes. In this study the relative effect of different surgical factors were assessed. A Kolmogorov-Smirnov Z test was conducted for each input factor, assessing the sensitivity of the given output parameter to a change in input factor value. The resulting Z Value reports the largest vertical distance between two normalised cumulative frequency distributions. It is therefore independent of the unit of the output parameter, and allows direct comparison between different output parameters.

3. Results

An example FE output of contact pressure is presented in Fig. 3. All significant ($p < 0.01$) Z Values are reported between each input and output parameter (Table 5), along with the

maximum difference in medians caused by a change in each input factor. The input factors are ordered into a hierarchy in terms of their influence on the chosen failure mechanisms. Pie charts show the relative influence of the each input factors on the output parameter values derived from the FE outputs of the 112 cases (Fig. 4).

A comparison between cup inclination angle and indicative wear depth is shown in Fig. 5.

4. Discussion

The aim of this study was to highlight the relative effects of surgical error and patient variation on potential acetabular cup failure, producing a hierarchy of influencing factors. The analysis generated 112 models representing a variety of different potential implantation scenarios, and the resulting impact on cup failure. Chance of failure was deemed to be increased with an increase in indicative wear depth or micromotion. The results of this simulation demonstrated the multi-factorial nature of surgery, with both failure criterion showing sensitivity to different input factors. The results confirm the clinical data in that inclination angle error is the single most important factor (Table 5, line 1) when considering implant wear; a high inclination angle may cause accelerated wear (De Haan et al., 2007; Hart et al., 2009; Langton et al., 2008). Micromotion was most dependent on patient anatomy: a morphologically deficient acetabulum impacts upon initial cup stability (Table 5, line 2). The presence of a gap between the acetabulum and the dome of the cup, the result of not fully seating the cup, also had a significant effect on cup stability (Table 5, line 3). Version angle was shown to have a significant influence on wear; a larger version angle correlated with increased indicative wear depth (Table 5, line 4). The least important factor appeared to be the level of press-fit (Table 5, line 5). As a factorial analysis, the results presented here are highly dependent on the chosen range of values assigned to the input factors. Effort was made to choose input factor values which reflected reported incidences in the literature. Had a very low press-fit been included, e.g., 0.5mm, it is likely that this would impact on initial cup stability; but this was judged unlikely as this would be quite apparent at the time of surgery. Studies have also shown that a very tight press-fit can cause acetabular fracture (Kim et al., 1995, Sharkey et al., 1999, Zivkovic et al., 2010), or deform the thin-walled metal cup (Jin et al., 2006), possibly leading to edge loading (Ong et al., 2008). These failure mechanisms were not explored in this study.

The most striking influence was that of inclination angle on wear level. The indicative wear depth inside the cup was dominated by the inclination angle (Table 5, factor 2); but was not significantly affected by the subject bone anatomy (Table 5, factor 1). Version angle was also shown to influence wear (Table 5, factor 3), but to a lesser degree than inclination angle. Press-fit had a significant, but comparatively low impact on wear depth prediction (Table 5, factor 4). Indicative wear depth was calculated from the peak contact pressure output from the FE analysis. Contact pressures were elevated as the hip joint contact force was applied close to the rim of the cup. The results therefore indicate that the commonly achieved range in inclination angle has a higher impact in the location of the resultant force with respect to the rim, than the range in version angle. These findings are reflected in the many clinical observations of correlations between high inclination angle and high blood metal ions (De Haan et al., 2007, Hart et al., 2009, Langton et al., 2008), and the less frequently reported correlation with high version angle (Langton et al., 2008). The results of the current study show a non-linear relationship between inclination angle and indicative wear depth. Whilst wear is clearly at its highest under the steepest inclination angle, it is not at its lowest under the shallowest angle, as demonstrated in Fig. 5. There appears to be an optimum inclination angle in the region of 40-45°, as is clinically observed (Grammatopoulos et al., 2010) (although any clinical observations would also be affected by impingement).

The potential weak dependency of wear on subject bone anatomy (Table 5, factor 1) may contribute to the continued clinical observation of this trend. The data presented here clearly shows that the indicative wear depth is consistently low with an 'optimal' inclination angle, and consistently high with a steep inclination angle. Published clinical studies, however, show that some patients exhibit high blood metal ions with ideally placed cups, and others low blood metal ions with cups implanted at a steep inclination angle. This indicates that further factors, such as microseparation (Nevelos et al., 2000) and patient-specific activity levels and gait patterns (Glyn-Jones et al., 2009) also have a significant effect on wear. This simulation study was limited by the inclusion of an estimated joint reaction force, based on the averaged data from four instrumented prostheses (Bergmann et al., 2001). The reliance of the estimated wear on the direction of loading implies that subject-specific joint reaction forces would influence the indicative wear depth, which would be an interesting area for further work to ascertain the optimal orientation and its relationship to individual gait patterns.

The potential for cup loosening through initial implant micromotion appeared to be sensitive to different factors than those associated with indicative wear depth. Implant micromotions were heavily influenced by the subject anatomy (Table 5, factor 1) and the presence of a gap (Table 5, factor 5). Both of these factors affect the area of contact between the cup and bone, which in turn influences the stability of the cup within the bone. One subject (Subject C) clearly exhibited higher micromotions than all other subjects. Subject C had high inclination and version angles, which is likely to indicate a reduced potential area of contact between cup and bone. Whereas excessive wear might cause failure of an implant after prolonged use, initial implant instability might result in a particularly early revision. This was reported by Morlock et al., who observed that failures owing to cup loosening occurred at an average of 423.4 days after implantation, as opposed to failures resulting from other causes, which failed at an average of 722.15 days after implantation (Morlock et al., 2008b). They also observed that a substantial proportion of failures occurred within the first 50 implantations undertaken by a surgeon, indicating the influence of the learning curve on failure. In the present study, the presence of a gap between cup and bone, as a result of incorrect seating, had a high impact on initial cup-bone micromotions. The high dependency of micromotion on patient geometry suggests that there is inter-play between these two factors, indicating that significant surgeon experience may be required to achieve adequate stability in patients with relatively dysplastic acetabula.

The critical factors for the two failure mechanisms investigated in this study differ significantly. Cup orientation is shown to have a dominant effect on potential cup wear, but an insignificant effect on cup loosening. Conversely cup seating and patient anatomy are shown to have a significant effect on cup loosening, but a low effect on potential cup wear. The findings presented here are limited by the factors included in the study; further contributors to failure are likely to occur, as has been discussed. The results of this study aid the understanding of the mechanisms of two distinct failure types: early failure owing to loosening, and later failure owing to wear-related complications. To minimise their exposure to the risk of failure by these two mechanisms, it is essential that the chances of acetabular component misalignment and non-seating are minimised; this may be achieved with the use of technological aids, or be dependent on the surgeon's experience with metal on metal implantation.

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Figure 1.

A. Inclination angle (Inc.) is measured as the angle between a plane passing through the rim of the cup and the transverse plane. B. Version angle (Ver.) is measured as the angle between a plane passing through the rim of the cup and the sagittal plane. C. The level of press fit (P.F.) is the diametrical difference between the cup and the reamed acetabular cavity. D. The gap is the perpendicular distance between the cup and the reamed acetabular cavity, measured at the dome of the cup.

Figure 2.

Finite element model construction. Load is applied through the spherical femoral head, into the acetabular cup. The whole model is rigidly fixed in space at the sacroiliac joint and pubic symphysis.

Figure 3.
Example contact pressure distribution for peak loading during a 'Normal Walking' loading regime.

Figure 4.
Relative influence of each input factor on A., median wear depth and B., micromotion.

Figure 5.
Predicted wear depth versus cup inclination angle

Table 1

List of input factors input into the factorial study, with all factor values.

Input factor	Value 1	Value 2	Value 3	Value 4	Number of values	References
1 Subject bone anatomy	Subject A	Subject B	Subject C	Subject D	4	Murtha et al. (2008)
2 Cup inclination angle	35.7°	45.8°	55.8°	-	3	Kalteis et al. (2005), Lazovic and Kaib (2005), Saxler et al. (2004)
3 Cup version angle	12.3°	27.3°	42.3°	-	3	Kalteis et al. (2005), Lazovic and Kaib (2005), Saxler et al. (2004)
4 Level of press-fit	1 mm	2 mm	-	-	2	Adler et al. (1992), Curtis et al. (1992)
5 Gap at dome of cup	0 mm	1.2 mm	3 mm	-	3	Mackenzie et al. (1994)
Total number of cases (4×3×3×2×3)					216	
Removal of unrealistic cases (216-104)					112	

Table 2

Details of the four patient anatomies which were used in the study.

Subject	Gender	Age (years)	Anatomical inclination angle (deg.)	Anatomical version angle (deg.)
A	Female	33	71	10
B	Male	37	46	11
C	Female	50	64	22
D	Male	76	44	23

Table 3

Material property assignment to all meshes in the finite element models.

Mesh	Young's modulus (MPa)	Poisson's ratio	References
Cortical bone	17,000	0.3	Dalstra et al. (1993)
Trabecular bone	Element-specific	0.2	Dalstra et al. (1993)
Cobalt chromium cup	210,000	0.3	Davies (2003)
Cobalt chromium head	210,000	0.3	Davies (2003)
Fluid layer	0.1 (compression only)	0.4	n/a

Table 4

Peak loads and sliding distances for all daily activity loading scenarios included in the study (Bergmann et al., 2001 and Morlock et al., 2001).

Load case	Number of cycles per day	Force in the x direction (N)	Force in the y direction (N)	Force in the z direction (N)	Resultant force magnitude (N)	Sliding distance (mm)
Normal walking, first peak	3752	243	221	1921	2385	0.29
Normal walking, second peak	3752	165	-117	1701	1749	0.11
Going up stairs, first peak	57	169	498	2037	2704	0.26
Going up stairs, second peak	57	634	-312	1806	2128	0.13
Going down stairs, first peak	57	349	-357	2118	2110	0.17
Going down stairs, second peak	57	473	-875	1863	1461	0.37
Standing up	55	780	1171	739	2690	0.18
Sitting down	55	639	959	612	2210	0.14

Table 5

Hierarchy of Kolmogorov-Smirnov Z value sensitivities and difference in medians of each output parameter, depending on each input factor. Values are only reported if the Kolmogorov-Smirnov Z test demonstrated a significant ($p < 0.01$) difference between distributions.

Input factor	Wear depth	Micromotion Z value	Difference in medians	Z value	Difference in medians
2	Inclination angle	1	0.15 μ m	-	-
1	Subject bone anatomy	-	-	0.93	17 μ m
5	Gap at dome of cup	-	-	0.79	13 μ m
3	Version angle	0.71	0.025 μ m	-	-
4	Level of press-fit	0.41	0.0063 μ m	-	-