Margin-of-safety Algorithm Used with EOS Imaging to Interpret MHRA Warning for 46-48mm MOM Arthroplasty

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Abstract

The Medical Healthcare Products Regulatory Agency (MHRA June-2015) warned of higher risks with 46-48mm sizes of BHR hip resurfacing arthroplasty (HRA). The most common condemnation of adverse results in MOM bearings has been termed edge loading. We originally developed a margin-of-safety (MOS) algorithm to define edge loading of cups in simulator studies. This method integrated simulator wear-patterns with respect to cup diameters and cup designs. The algorithm's simplicity lay in the fact that with wear-patterns and rim-profile angles predetermined, the only input required was the cup inclination-angle. The algorithm demonstrated that the margin-of-safety decreased in smaller cups due to the tribo-mechanics of spherical CoCr bearings, a previously unrecognized feature. For the 46mm and 48mm cups highlighted in the MHRA alert, the critical cup inclinations where edge-wear became a risk occurred at 65-66°, revealing an insignificant difference with respect to diameters. The MOS-algorithm also indicated that lower lateral-inclination angles were particularly beneficial, i.e. a 46mm cup positioned at 50° inclination would exhibit a higher margin of safety than either 48mm or 50mm sizes positioned at 55° inclination. This evidence supported clinical studies that recommended BHR cup inclinations up to 50-55° and lower as optimal for reducing metal-ion concentrations. In a patient with normal spine mobility, our EOS imaging demonstrated that the inclination in the 46mm cup steepened by 9° from standing to the seated position while margin-of-safety was reduced by 50%. Our 2nd patient with a stiff spine sat with the same component orientations as in his standing posture. Thus MOM impingement and subluxation in different functional postures may also provoke rim-damage mechanisms. Here the combination of EOS imaging and the MOS-algorithm may aid understanding of such risks. Thus the margin-of-safety algorithm confirmed and helped explained the relative risks in the 46mm and 48mm cups highlighted

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by the MHRA. The algorithm's stratification by cup rim-profile, inclination angle and cup diameter may assist the surgeon determine which patients may be more at risk for edge wear with the smaller BHR cups. The ARC, CPR and MOS algorithms can be [downloaded here](#) (Excel file).

Keywords: BHR Resurfacing Arthroplasty, cup inclination, edge wear, MHRA alert, EOS, MOM

Level of Evidence: AAOS Therapeutic Level V

Introduction

Clinical studies of metal on metal (MOM) bearings used in hip resurfacing arthroplasty and total hip arthroplasty frequently described high rates of failure. [1-4] The most common condemnation of MOM performance has been termed "edge-loading". [1,5-12] Studies implicated small MOM diameters, sub-hemispherical cup designs, surgical positioning, and hip-joint excursion. Nevertheless the BHR resurfacing system continues to receive acclaim as very successful when applied correctly to young patients with the right indications, even in patients with the small BHR devices. [13-15] However, a recent Medical Device Alert by the Medical Healthcare Products Regulatory Agency (MHRA, June 2015, UK) singled out female patients and 46-48mm BHR devices as representative of unacceptable risks but with no guidelines provided (Fig. 1). Thus the surgeon may have a dilemma in determining

Fig. 2. Effect of cup inclination on wear-pattern (angle-A) and margin-of-safety (MOS), A) at 55° inclination the cup wear-pattern has a 58° arc and MOS has a 6° arc, B) adding 6° additional inclination reduces MOS to zero, and C) adding another 9° inclination reduces the cup wear-pattern to a 50° arc and edge wear presents. This edge-wear definition would be $EW = 9/58 = 16\%$.

which of his patients with smaller BHR devices may be at risk.

The key to assessing edge-wear lies in defining the 'margin for error' [9] or, as will be termed here, the 'margin-of-safety' (Fig. 2). During the bearing's run-in phase, the cup wear-pattern grows rapidly, typically to greater than 400mm² area. [16,17] As long as this habitual wear-pattern is separated from the cup rim by an adequate margin-of-safety (MOS), edge wear is unlikely (Figs. 2a, 3a). At a steeper angle the margin-of-safety decreases to zero and places the patient at risk for edge wear (Fig. 2b). At even steeper angles the cup rim will cross over the habitual wear-pattern area and edge wear ensues (Figs. 2c, 3b). This is believed to create severe stress-concentrations, compromise fluid-film lubrication, and thereby contribute to extreme wear. [6,10,11,18,19] The Petersen Tribology Laboratory of Loma Linda University (LLU) developed a margin-of-safety algorithm that integrated simulator wear-patterns with respect to cup diameters and cup designs. The

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Metal-on-metal (MoM) hip replacements - guidance on implantation and patient management

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- Do not implant BHR devices in:
 - female patients
 - patients requiring femoral heads sized 46mm or smaller
- Only use 48mm BHR heads in the specific circumstance of intra-operative downsizing from a pre-operatively templated 50mm to a measured 48mm at the time of surgery
- Return all unused BHR femoral heads sized 46mm and smaller and their corresponding acetabular and dysplasia cups to the manufacturer
- Follow up patients implanted with BHR hips that fall within the scope of this medical device alert ie:
 - all symptomatic patients
 - all female patients
 - all patients implanted with head sizes 46mm or smaller

Fig.1. Medical Healthcare Products Regulatory Agency (MHRA) issued a medical device alert (MDA-2015/024, 25th June 2015) identifying higher risks with BHR sizes 46-48 mm

Fig. 3. Wear-patterns (colored red for photography) in MOM retrieval studies showing, (a) margin of safety superior to central wear-pattern, and (b) wear-pattern juxtaposed to cup rim indicating edge-wear.

algorithm has been used to validate edge-loading in studies of steep cup scenarios. [20] While size of cup wear-patterns appeared to be an important parameter, this was not considered in prior studies. Clinical methods for assessing cup coverage have included the “Arc of Cover” distance [9] and the “Contact Patch to Rim” (CPR) distance. [1] These concepts measured the distance from the cup rim to either the vertical reference plane or to a 14° medially-directed axis, respectively (Fig. 4a). A third method termed “Contact Patch Edge to Rim” distance (CPER) combined a 14° medially-directed reference axis with a “contact patch” calculation (Fig. 4b). [6] While such measurements provided stratification of risk, [6,21-23] they did not provide the surgeon with the necessary details to assess risk of edge-wear directly.

Fig. 4. Schematic of methods used to describe cup coverage on antero-posterior images, a) “Arc of Cover” (ARC) [9] and “Contact Patch to Rim” (CPR) [1] distances, where ‘ARC’ defines a chord to be comparable to CPR-distance method, and b) “Contact Patch Edge to Rim” (CPER) [6].

There has also been little understanding of how patient postures change the position of artificial hip-joints. The majority of measurements have been made from radiographic or CT images taken with the patient in the supine position. However, hip dislocation is a frequent mode of failure and the sitting position is one where most impingements and posterior dislocations occur. At La Pitie Hospital (Paris, France), the orthopedic group developed EOS imaging (author JYL) to investigate various patient postures. The EOS™ imaging system is capable of simultaneously capturing two orthogonal antero-posterior (AP) and lateral images, thus typically providing full pelvic visualization in standing, sitting, and other positions. [24,25] The first objective of this report was to study the margins-of-safety (MOS) in 46-48mm diameter BHR mentioned in the MHRA warning. The conventional ARC and CPR methods were also compared (Fig. 4a). The second objective was to compare MOS and CPR data for standing and sitting positions in two patients, both with 46mm diameter MOM.

Methods

To avoid confusion with “contact patch” data and other commonly used terms (Fig. 4), the wear area produced in hip simulator studies will be defined as the Cup Area Pattern (CAP). CAP areas in MOM simulator studies typically ranged 411- 480mm² by the end of the 5-million cycle tests. [16,17,26] The corresponding wear-pattern angles (Fig. 2: angle-A) were calculated using standard equations for spherical geometry. These were plotted with respect to cup diameter and extrapolated by linear regression to cover the 36-60mm diameter range. The extent of cup rim-coverage is also believed to be an important parameter. [1,8-12] In this study we utilized the rim-profile angle (Fig. 5: P) to define loss of coverage in the load-bearing area of the cup. Cup-profile angles (P) were derived from published cup-face angles (F) provided for five MOM systems [6] and calculated using,

Equation-1 (Fig. 5):

$$2 \cdot P = 180 - F$$

The rim profile angles were extrapolated over the 36-60mm diameter range by linear-regression techniques. CPR and MOS data were calculated using the 14° medially-directed vector. [1] For a cup positioned with lateral-inclination L-angle (Fig. 5) the summation follows as,

Equation-2 (Fig. 5):

$$L + P + \text{MOS} + A/2 = 104^\circ$$

Fig. 5. Illustration of cup geometry defining inclination angle (L), rim-profile angle (P) and wear-pattern angle (A) with respect to a 14° medially directed load vector.

Note with resultant loading in simulator studies being in the vertical plane, equation-2 would simply be summated to 90°. The MOS-algorithm also provided a definition for edge-wear (EW), whereby,

Equation-3 (Figs. 2b, c):

$$\text{EW \%} = 100 \cdot (A - B) / A$$

The critical cup inclination angle (*L) with margin-of-safety diminished to zero can be determined by setting MOS=0 in equation-2,

Equation-4 Critical inclination (Fig. 2b):

$$*L = 104^\circ - (P + A/2)$$

Clinical studies of cup coverage have used varied criteria (Fig. 4) and therefore equation-2 can simply be extended as follows,

Equation-5 (Figs. 4a):

$$L + P + ARC = 90^\circ [9]$$

Equation-6: (Figs. 4a, 5):

$$L + P + CPR = 104^\circ [1]$$

Equation-7: (Fig. 4b):

$$L + P + CPER + C/2 = 104^\circ [6]$$

Using angles for margin-of-safety calculations greatly simplifies the analysis (Fig. 5). As required, MOS and CPR angles can be converted to 'distance' measurements,

Equation-8a:

$$\text{MOS distance (mm)} = \text{DIA} * \sin(\text{MOS}/2)$$

Equation-8b:

$$\text{CPR distance (mm)} = \text{DIA} * \sin(\text{CPR}/2)$$

A set of sample calculations are included for ARC, CPR and MOS indices (Table 1) - the template for ARC, CPR and MOS calculations can be [downloaded here](#) (Excel file). It is noted that the original equation for "Arc of Cover" calculated the distance along the cup surface, i.e. length of the circular arc. [9] In this study, the ARC distance (equation-5) defined the chord of a circle in order to be compatible with the CPR method (Fig. 4). The CPER innovation (equation-7) added contact-patch size, which reduced the rim-distance prediction compared to CPR data. However, following the run-in wear process, patient hip-function will have enlarged the wear-pattern area much beyond the size of the contact patch. [16]

The EOS imaging presents patients in various functional positions for analysis of pelvic and femoral rotations and for comparison of implant positions. Differences between standing and sitting postures were compared in two patients, one with normal spinal mobility and the second with considerable stiffness due to spinal pathology. Both had 46mm THA (Metasul™, Zimmer, Warsaw IN) with a 5° rim-profile angle (P). Cup inclination angles and CPR

distances were calculated and compared with the MOS-algorithm for sitting versus standing postures.

Results

The data from simulator studies demonstrated that wear-pattern angles decreased linearly with increasing cup diameter (Fig. 6). The wear pattern in a 36mm BHR-type cup had a 66.7° angle, which decreased to 58.2° in a 46mm cup and to 56.6° in a 48mm cup. The largest cup considered (60mm) had the smallest wear-pattern angle (46.4°),

Fig. 6. Trending of wear-pattern angles (A) derived from linear regression of data from hip simulator wear-patterns. [20]

Fig. 7. Trending of rim-profile angles (P) derived from data on cup-face angles (F). [6]

which compared to the 36mm cup, represented an overall reduction of 20.3° .

The rim-profile angle (P) defined how much hemispherical coverage was reduced in the load-bearing region (Fig. 7). These data will be labeled 'BHR-type' since some values may not reflect the vendor's actual specification (Table 1). The CORMET design provided the most coverage while the ASR provided least. The ADEPT and DU-ROM cups had constant profile angles whereas the ASR, BHR and CORMET profile angles decreased linearly with increasing diameter (Fig. 7).

Differences produced by wear-pattern and rim-profile angles were illustrated by comparing 46mm and 56mm cups (Fig. 8). Wear-pattern areas covered 418 and 458 mm^2 in the small and large cups, respectively. However the wear-pattern angle was larger (58.2°) in the small cup than in the large cup (49.8°). The rim-profile angle (P) was also larger in the smaller cup (9.7° vs 8.1°). The combined effect of these angles (Fig. 8) reduced the safety margin in the small cup (MOS= 15.2°) by 5.8° compared to the large cup (MOS= 21°).

Fig. 8. Comparison of wear-pattern angles (A) and margins-of-safety (MOS) produced in 46mm and 56mm cups at same inclination angle.

Comparing cups at 65° inclination the methods predicted that safety margins increased linearly with component size (Fig. 9a). The ARC and CPR methods had similar slope but differed in magnitude due to the 14° difference in their reference axes (Fig. 4). The CPER had the same reference axis as CPR method but subtracted the half-width of the contact patch, this reduction making it similar in magnitude to the ARC method. The MOS-algorithm revealed that 36-46mm diameter cups had edge-wear while the 48mm size achieved a safety margin represented by only 1.3° (Fig. 9a). The MOS trend showed the lowest magnitude but steepest slope due to the inclusion of simulator wear-patterns. The critical inclination angles (equation-4) were 65.2° and 66.3° for 46 and 48mm diameters respectively (Fig. 9b). Comparing MOM diameters and inclina-

Fig. 9a.

Fig. 9b.

Fig. 9c

Fig. 9. Comparisons of safety predictions in BHR-type cups, (a) ARC, CPER, CPR and MOS angles for 36-60mm diameter cups, all at 65° cup inclination, (b) Critical inclination angles (equation-4) predicted for 36-60mm diameter cups (c) Margins of safety predictions (MOS, angles) for small cups sizes 46-50mm versus the 56mm size and compared using cup inclinations 50, 55 and 60° .

tion angles, the 46mm cup at 50° inclination exhibited a greater safety-margin than the 48mm and 50mm cups at 55° inclination. At the same inclination, the 46mm cup exhibited a safety-margin only slightly lower than 48mm and 50mm sizes. The MOS-algorithm predicted that rim distances in 48 and 50mm cups would be 0.5mm and 1.1mm, respectively (Fig. 10). The CPR method produced 11.6-12.3mm distances for critical cup sizes 46-48mm, which as indicated were above the 10mm clinical threshold (Fig. 10).

Fig. 10. Comparison of safety margins (distances) predicted by four methods (ARC, CPER, CPR, MOS) for a cup inclination of 65°.

Fig. 11. EOS images for case with bilateral 46mm THA and good pelvic mobility in (a) standing and (b) sitting.

In standing posture, EOS imaging revealed that the cup in the right hip of patient-1 had a 53° lateral inclination that increased to 62° in sitting (Fig. 11). The CPR angles were correspondingly reduced from 51° to 42° and calculated MOS angles reduced from 16.6° to 8.1°. In contrast, patient-2 had essentially the same cup inclinations in both standing and sitting positions and thus CPR and MOS angles varied little (Fig. 12).

Fig. 12. EOS images for case with 46mm THA and stiff lumbo-sacral spine in (a) standing and (b) sitting.

Discussion

The margin-of-safety method appears to be the first to integrate wear-patterns and cup rim-profiles to define “edge-wear”. Its simplicity lies in the fact that using the predetermined wear-patterns and rim-profile angles, the only input required is cup inclination (Table 1). This algorithm revealed that critical cup inclinations, where edge-wear becomes a risk, were defined solely by cup-profile and wear-pattern angles (equation-4). The former represents the cup-design parameter while the latter represents tribo-mechanics of spherical CoCr bearings. For the BHR cups highlighted in the recent MHRA warning, the MOS algorithm predicted that the 46mm cup was most at risk at 65° and higher inclinations while the difference in safety margin between 46 and 48mm cups was represented by only 1.1°. Thus cup diameters appeared to be a relatively weak indicator of safety margin. The MOS-algorithm predicted that the margin of safety would actually be higher in a 46mm cup positioned with 5° lower inclination than in 48mm or 50mm size cups. Thus the margin-of-safety algorithm confirmed and explained the relative risks of 46mm and 48mm cups highlighted in the MHRA alert. Conversely, for a 46mm cup angled 5° higher than its critical incli-

nation (in Fig. 9b), the resulting definition for edge wear (equation-3) would simply show that $A-B = 5^\circ$ where angle- $A = 58.2^\circ$ (Table 1) and $EW\% = 5/58.2 = 8.6\%$.

The margin-of-safety algorithm has been validated in hip simulator tests. [20,27] However for clinical applications there are limitations to a mathematical depiction of edge-wear. The main assumption was that cup wear-patterns in hip simulators would be predictive of those in patients. It is to be anticipated that the CoCr tribo-mechanics in spherical bearings will be similar in vivo and in vitro. The major difference is that component positioning and hip functions are well defined in a simulator test and also non-variant. In contrast, surgical positioning of femoral and acetabular components and subsequent hip function represent a complex set of variables. In particular the head:neck ratios in the resurfaced hip joints may have variable effects such as impingement and subluxation. [28] In this regard our MOM retrieval studies documented that cup wear-patterns were much larger in failed MOM cases (Fig. 3b). [29]

Clinical studies of BHR cases recommended cup inclinations up to $50\text{--}55^\circ$ as optimal for reducing the metal-ion concentrations but also indicated that lower angles could risk anterior impingement. [1,30] The 46mm and 48mm BHR-type cups described here demonstrated critical cup inclinations at $65\text{--}66^\circ$ (equation-4). This evident shift of perhaps 10° may represent the difference between mathematical precision and clinical reality. The MOS-algorithm defined the proximity of the wear pattern to the cup rim at varied ‘inclination’ angles. Other mathematical methods integrated the angles of cup anteversion and lateral-inclination to provide a more complete component description. [6,23] However, all current methods were based on an assumption of a 14° reference axis for the hip-joint reaction

force (Fig. 4) - taken from a biomechanics study of patients in single-legged stance. [31] In reality we have little or no understanding of which patient posture(s) will produce an edge-wear condition. Thus while the MOS-algorithm can indicate the safety margin in that cup design and with that diameter, it is likely that this is representative of the ‘ideal’ patient (Fig. 3a). Thus mathematical treatments may underestimate the risk of edge-wear, particularly in young and active individuals (Fig. 3b).

The MOS-algorithm has provided the first demonstration that small cups inherently had the least margin of safety due to their wear-pattern angles being proportionally greater than in large cups. This tribo-mechanical effect was not intuitively obvious, considering that wear patterns increased in size with increased cup diameter. [29] However as shown by example, a 46mm cup featured a larger wear-pattern angle than a 56mm cup and thus the margin-of-safety was reduced accordingly (Figs. 6, 8). Adding to the risk was the reduced coverage in some design of small cups (Fig. 7). Thus smaller cups inherently have smaller safety margins, a fact which has become well identified in clinical and retrieval studies. [1,8-10,18]

The dilemma apparent is that steep-cup algorithms (Fig. 9, 10) are based only on a scenario of adverse edge-loading during gait, i.e. in the habitual load-bearing area of the cup (Fig. 4). However the apparent desirability of positioning cups with reduced lateral-inclination may result in other risks, such as posterior impingement, subluxation and anterior edge wear. [1,32] In our patient with normal spine mobility, EOS imaging demonstrated that cup inclination steepened by 9° in the seated position, with the margin-of-safety being reduced by 50%. Thus the risk is that MOM impingement and subluxation while in sitting

Diameter BHR-type	36mm	38mm	40mm	42mm	44mm	46mm	48mm	50mm	52mm	54mm	56mm	58mm	60mm
Inclination (L)	50	50	50	50	50	50	50	50	50	50	50	50	50
Angle (A/2)	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4
Angle (P)	11.3	11.0	10.7	10.3	10.0	9.7	9.4	9.1	8.7	8.4	8.1	7.8	7.4
L+P	61.3	61.0	60.7	60.3	60.0	59.7	59.4	59.1	58.7	58.4	58.1	57.8	57.4
P+A/2	44.7	43.5	42.4	41.1	40.0	38.8	37.7	36.5	35.3	34.1	33.0	31.8	30.6
L+P+A/2	94.7	93.5	92.4	91.1	90.0	88.8	87.7	86.5	85.3	84.1	83.0	81.8	80.6
MOS ($^\circ$)	9.3	10.5	11.6	12.9	14.0	15.2	16.3	17.5	18.7	19.9	21.0	22.2	23.4
ARC ($^\circ$)	28.7	29.0	29.3	29.7	30.0	30.3	30.6	30.9	31.3	31.6	31.9	32.2	32.6
CPR ($^\circ$)	42.7	43.0	43.3	43.7	44.0	44.3	44.6	44.9	45.3	45.6	45.9	46.2	46.6
MOS (mm)	2.9	3.5	4.1	4.7	5.4	6.1	6.8	7.6	8.5	9.3	10.2	11.1	12.2
ARC (mm)	8.9	9.5	10.1	10.8	11.4	12.0	12.7	13.3	14.0	14.7	15.4	16.1	16.8
CPR (mm)	13.1	13.9	14.8	15.6	16.5	17.3	18.2	19.1	20.0	20.9	21.8	22.8	23.7

Table 1. Sample calculations for BHR-type cups using 50° cup inclination as an example, where equation-2 indicates $MOS = 104 - (L+P+A/2)$, equation-5 has $ARC = 90 - (L+P)$, and equation-6 has $CPR = 104 - (L+P)$ and from. Angular data were converted to distances using equations 8a and b.

or other postures could provoke rim-damage mechanisms. [7,33,34] Such a release of large metal particles could then provoke an aggressive 3rd-body wear mechanism during gait. [20,34] These risks in implant orientation combined with patient positional variation are poorly understood. EOS imaging combined with the MOS-algorithm should help in the exploration of such postural variations.

In conclusion, the margin-of-safety algorithm demonstrated the risk factors inherent in 46-48mm BHR-type devices described in the June MHRA alert. The MOS-algorithm facilitated an understanding of how cup design, diameter and inclination affected the margin-of-safety. In patient studies the cup size and rim profile are pre-determined and thus the only input needed for ARC, CPR and MOS determinations is the cup's lateral inclination (Table 1). These data also indicated that cups with less steep inclinations (45-55°) effectively raised the available margin of safety, even in 46-48mm size cups. It is hoped the MOS-algorithm will provide surgeons with a suitable instrument to evaluate how the MHRA warning affects their clinical practice.

Disclosure Statement

One or more of our authors have disclosed information that may present potential for conflict of interest with this work. For full disclosures refer to last page of this journal.

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Glossary of Terms

A: Angle used to represent cup wear-pattern	CPR: “Contact Patch to Rim” chord distance from cup rim to a 14° medially-directed axis [1]
C: Angle used to represent size of contact-patch	CPER: “Contact Patch Edge to Rim” chord distance [6] measured from cup rim to edge of contact patch (as centered on a 14° medially-directed axis)
F: Angle describing the sub-hemispherical bearing surface	Edge wear: An adverse wear condition produced when the cup rim is able to cross the habitual wear-pattern in a MOM bearing
P: Profile angle representing loss of bearing surface in load-bearing region of cup	EW%: definition for edge wear in MOS-algorithm (equation-3)
L: Lateral inclination angle of cup	Margin-of-safety: A narrow region that can be present between cup rim and the edge of the wear-pattern
*L: Critical cup inclination (equation-4)	MOS: Margin-of-safety measurement (distance, angle: equations 2 and 8a)
ARC: Distance measured from cup rim to the vertical plane, analogous to the “Arc of Cover” [9]	Wear-pattern: Habitual wear zone produced by patient’s hip function
CAP: Area of cup wear-pattern produced in a hip simulator

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