Reconstructive REVIEW
An Open Access Journal

Volume 7, Number 3
September 2017

ORIGINAL ARTICLE http://dx.doi.org/10.15438/rr.7.3.190

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Simulator Study of MOM using Steep-cup Flexion - A Clinically Relevant Incorporation of Intermittent Edge-loading

Clarke I.C. [1], *Shelton J.C.* [2], *Bowsher J.G.* [3], *Savisaar C* [4], *Donaldson T* [5]

Abstract

Background: Adverse-wear phenomenon in metal-on-metal (MOM) arthroplasty has been attributed to "edge-loading" of the CoCr cups. Simulator studies of steeply-inclined cups run in the 'Anatomic-cup' model represented many variations in design and test parameters with no coherent rationale. We created an algorithm to synthesize MOM test parameters and noted that wear areas typically averaged only 10-15% of cup surface. In contrast, retrievals showed wear areas extending to 60% of cup surface. We hypothesized that MOM wear studies run in the orbital hip simulator with the 'Inverted-cup' model would, (i) differentiate normal-loading versus edge-loading, (ii) demonstrate cup wear areas x3.8-times larger than on femoral heads, cover 30% of cup surface, and (iii) double the wear-rates measured in prior Anatomic-cup study.

Methods: Edge-loading occurs when the cup rim is allowed to truncate the habitual wear area that provides optimal tribological conditions. A MOM algorithm was developed to synthesize relevant test parameters. The 60mm MOM bearings donated for this study were run in an orbital hip simulator using the Inverted-cup model. Tests #1 and #2 to one million cycles (1-Mc) duration assessed wear at peak cup inclinations 40° and 50°. Test #3 evaluated edge-loading with peak cup inclinations achieving 70° (5-Mc duration).

Results: Wear areas in Inverted-cups averaged 1663mm2 in tests #1 and 2, were fully contained within cup rims, and covered 30% of cup surface as predicted by algorithm. Test-3 with 70° cup inclination produced the predicted edge-loading with volumetric wear-rates averaging 2mm3/Mc, approximately 5-fold greater wear than prior Anatomic-cup study.

Discussion and Conclusions: Simulator studies of steep-cup mechanisms necessitate production of clinically-relevant wear-patterns such that the biomechanical and tribological functionality is respected. As an aid to steeply-inclined cup analyses, the MOM algorithm allowed integration of confounding test parameters. The algorithm successfully differentiated between "normal" and "edge loaded" cups and the MOM wear areas were as predicted for three cup inclinations. Also as predicted, wear-patterns in Inverted-cup model exactly reversed those of the Anatomic-cup model. Even with only intermittent edge-loading, Test-3 produced 5-fold greater wear than our prior Anatomic study.

Clinical Significance: The Inverted-cup simulator model successfully mobilized the cup to produce larger wear areas that were more representative of those in-vivo and therefore reproduced more realistic test conditions for studies of edge-loaded cups.

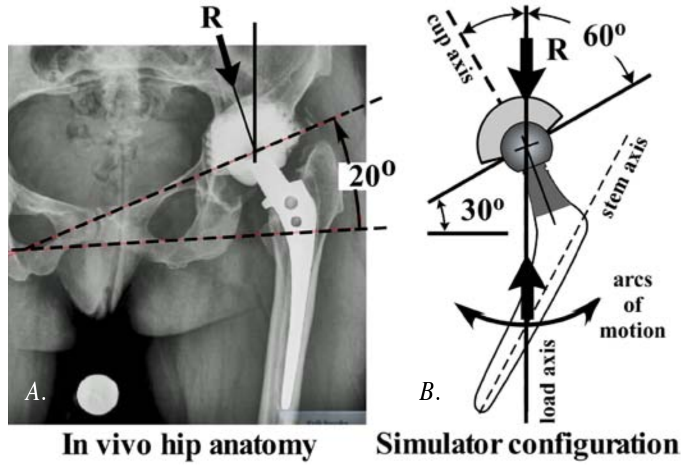
Keywords*: hip arthroplasty, MOM bearings, edge loading, simulator, wear*
Level of Evidence*: AAOS Therapeutic Level II*
Educational Value & Significance*: JISRF Level B*

Background

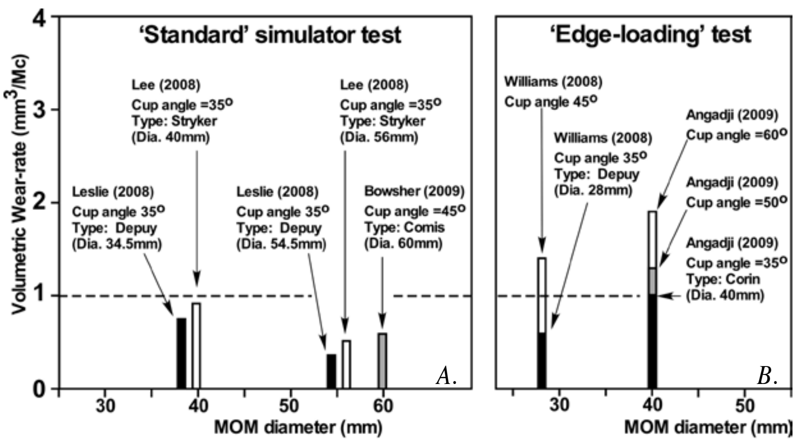
Laboratory wear predictions of total hip arthroplasty (THA) have come under frequent criticism, partially because they present only a limited simulation of many possible clinical conditions (Fig. 1A). For example, international guidelines [1] only specify one inclination for the acetabular cup (30°) in the hip simulator [Fig. 1B], this believed analogous to a 45° cup inclination in patients (Fig. 1A). This test configuration, referred to as the 'Anatomic' mode (Fig. 1B), represents an ideal wear model and has been the standard simulator test for almost 2 decades. Various studies demonstrated MOM wear to be satisfactorily low over the specified 5-million cycle test (Fig. 2A: 5-Mc test, cup inclination 35°). [2,3,4]

The revival of large MOM hip bearings began in the mid 1990's [5,6] and the first warnings of adverse wear with CoCr cups started appearing between 2006 and 2008 [7,8,9]. Subsequent clinical and retrieval studies demonstrated that steeply-inclined CoCr cups were particularly at risk for adverse wear, believed due to "edge loading" of the head against the rim of the acetabular cup [10,11]. Simulator studies then explored the effects of steeply-inclined cups. In one study of 38.5mm MOM run with 35° and 50° cup inclinations, wear-rates averaged 3.3 and 11mm^3/Mc, respectively [12]. In this 2-Mc test, the steeper cups demonstrated a 3.3-fold wear increase overall. In a similar study comparing 48mm MOM run with 35° and 65° cup inclinations, wear-rates averaged 2.5 and 19.5mm3/Mc, respectively [13]. Here the steeper cups presented a 7.8-fold increase over controls. However notable in two 5-Mc studies was that the wear with steeper cups appeared only double that of controls (Fig. 2B). [2,14] These exploratory studies included many confounding cup designs, diameters, metallurgy, and test parameters. Thus, no coherent theory was developed to explain such variations in wear performance of MOM bearings.

Using data from our prior 60mm MOM retrieval study [15], we developed an algorithm to integrate variations included in cup design, head diameter, and cup inclination. The key to the algorithm was an equation that defined size of wear-patterns on CoCr heads and cups. [16] In our prior Anatomic study, wear-patterns averaged 1668mm^2 on heads and 442mm^2 on cups, these data providing an experimental ratio of 3.77 for wear areas [17]. The theoretical wear-pattern ratio (x3.87) calculated using the cam design of the orbital simulator validated these data. It was also noted that the Anatomic simulator test produced cup wear-patterns that represented only 10-15% of the nominal hemispherical surface, defined here as the hemi-cup ratio (Table 1). [15] In contrast, retrieval studies showed hemi-cup ratios extended 50-60% in-vivo, i.e. were much larger than produced in contemporary simulator studies [15,18]. This difference would not be readily apparent in the standard simulator test (Fig. 1B) but would clearly be an important parameter when simulating edge-wear in steeply-inclined cups.



Figures 1A & B.

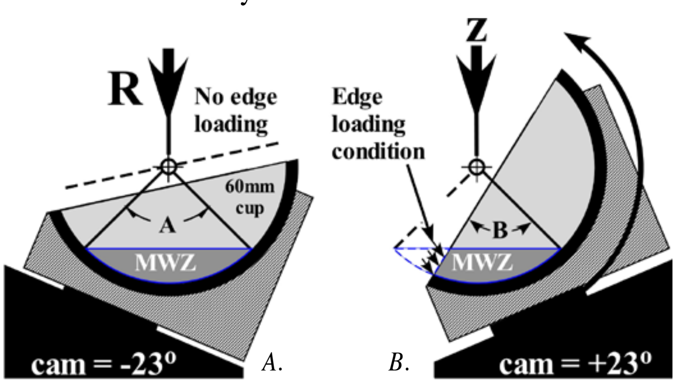


Figures 2A & B.

Table 1. Cup wear areas in simulators at 5-Mc (ISO-14242), ranked by MOM diameter.

Study	Diameter (mm)	Clearance (μm)	Hemi-area (mm^2)	Wear area (mm^2)	Hemi%
Leslie 2008	38.5	126	2328	429	18%
Lee 2008	40	400	2513	364	14%
Lee 2008	40	150	2513	383	15%
Leslie 2008	54.5	111	4666	474	10%
Lee 2008	56	400	4926	419	9%
Lee 2008	56	150	4926	416	8%
Bowsher 2009	60	245	5655	442	8%

Edge-loading occurs when the cup rim truncates what would be the normal, habitually worn area. Thus, a clinically relevant simulation of edge-wear effects necessitates a realistic wear pattern for the cup. Simulator mechanics creates the larger 'distributed' wear-pattern on the mobile bearing, this being the femoral head in the Anatomic test mode (Fig. 1B). The alternative 'Inverted cup' strategy would make the cup oscillate such that the larger wear-pattern would have a hemi-cup ratio of approximately 30% [15]. The first published studies of wear in 2nd generation MOM were run in this 'Inverted' test mode (Fig. 3) using MOM bearings of 28mm and 45mm diameter. [19,20] Although not measured in these early studies, distributed wear-patterns would have been produced in the cups. [21] The goal in this MOM simulator study was to demonstrate that steeply-inclined cups could be run successfully in "Inverted" test mode (Fig. 3). The hypotheses were that, (i) the MOS-algorithm would differentiate between "normal" and "edge-loading" conditions, (ii) wear patterns in 60mm cups run Inverted to 1Mc duration with no risk of edge-loading would be 3.8 times larger than on their mating heads, and (iii) cups run Inverted under edge-loading conditions to 5-Mc would double the wear-rates measured in the Anatomic study.



Figures 3A & B.

Methods

The hip simulator was identical to that used in our prior Anatomic study (Shore Western, Monrovia, CA) and our test methods duplicated that work. [17] Three tests were conducted with 60mm MOM bearings (*donated for research, DJO-Global, Austin TX*) with 1-Mc tests #1 and #2 run to assess the wear-pattern shifting with steeper cup inclinations but with no edge-loading (Table 2). Test #3 (N=4 MOM) was run to 5-million cycles with cup mounting-angle (L) set to 47° such that the cam mechanism created minimum/maximum cup inclinations of 24° and 70° (Fig. 3). Our prediction was that the cup wear-pattern would be truncated by 7.8°, this representing an edge-wear condition of 9% in test #3 (Appendix A).

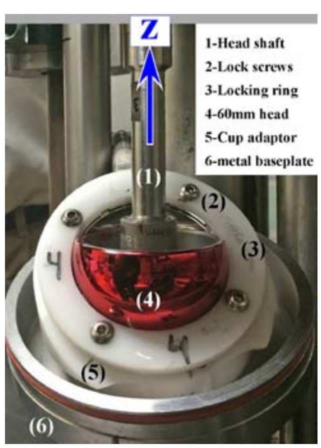


Figure 4.

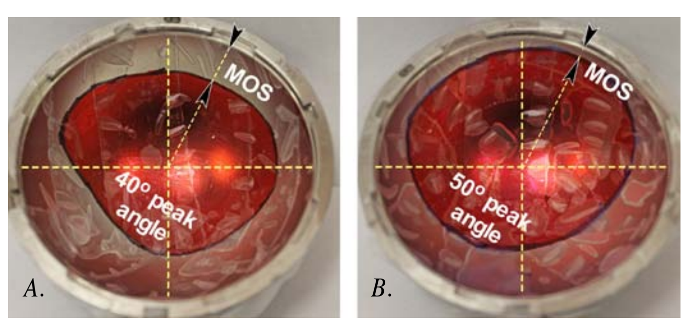
Table 2. Algorithm parameters for 60mm MOM.

#	Parameter	Test-1	Test-2	Test-3
1	Cup rim profile angle (P)	5.6	5.6	5.6
2	Angle subtending wear area (A)	90.4	90.4	90.4
4	angle (P + A/2)	50.8	50.8	50.8
5	Inclination angles (L)	17.0	27	47
6	Angle (L+P+A/2)	67.8	77.8	97.8
7	MOS angle	22.2	12.2	-7.8
8	Edge wear (EW%)	none	none	-9%

Cup adaptors were machined from Polyacetal with locking rings added to secure the steeply-inclined cups (Fig. 6). Each assembly was attached to a steel baseplate that housed a Plexiglas cylinder acting as lubricant chamber (450ml). Wear-patterns and weight-loss data were measured at 0.5-million cycle intervals to 5Mc duration. Areas of wear on heads and cups were identified visually and by light microscopy, stained red, and taped where necessary to minimize reflections during photography.

Results

Cup wear patterns in tests #1 and 2 were fully contained within cup rims as predicted by the MOS-algorithm and averaged 1663mm^2 and 1571mm^2 areas, respectively with < 3% variation about these means. The small MOS-angle in test-2 was difficult to measure, approximately 5.3° (Fig. 5B). The wear-patterns in study-1 (Fig. 5A) were selected as controls and demonstrated a 15.4° margin of safety (Table 3). Cup wear patterns were distinct and described by an included-angle of 90.2° (angle-A) subtended by a



Figures 5A & B.

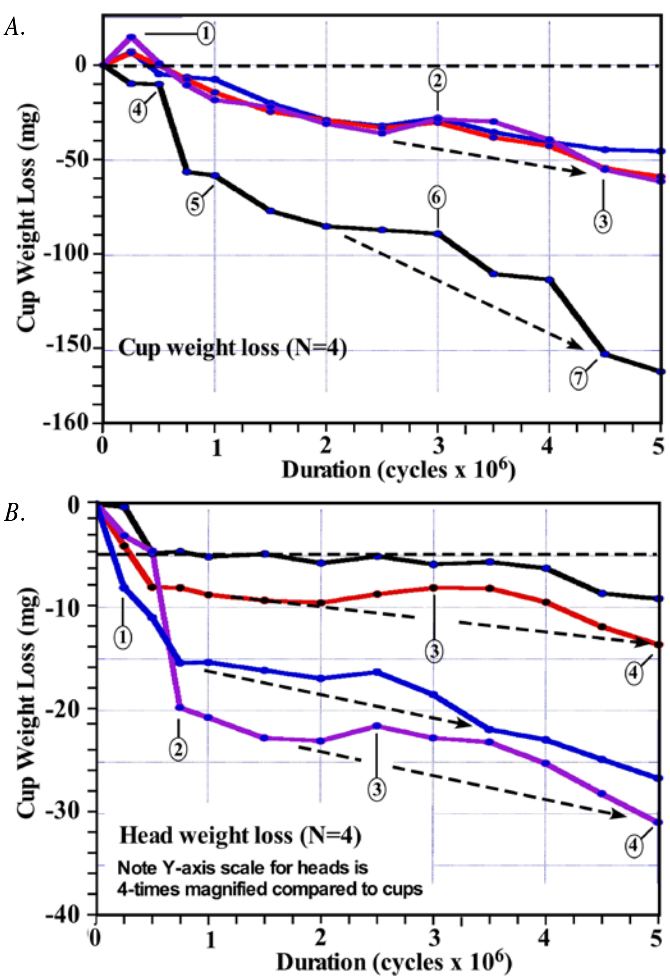
Table 3. Cup wear areas using 40° peak inclination (test-1: 1Mc).

Test-1	Cup-1	Cup-2	Averages
NWZ angle (N)	55.6	55.6	55.6
MWZ angle (A)	91.6	88.9	90.2
MOS angle (MOS)	14.0	16.7	15.4
Calculated MWZ area			1663
Hemi-area (60mm cup)			5655
Hemi-area ratio (%)			29.4%

wear area of 1663mm² with corresponding hemi-area ratio 29.4%. The femoral-head wear patterns at 1Mc duration were too indistinct to measure.

Cup weight-loss from wear over 5-Mc trended fairly linearly to beyond 50mg. Transient weight-gains were evident at 0.25Mc duration (Fig. 6A: flag-1, 15mg) and at 2.5-3Mc (flag 2). These fluctuations were due to build-up of protein contaminants inside the cups and were disregarded. Also noted was that cup #4 sustained damage at 0.75Mc and was not included in the analysis (flag–4: malfunction of simulator cam-bearing).

Head weight-loss trends showed run-in variations up to 0.75Mc (Fig. 6B: flags-1, 2). Transient weight-gains were also evident on heads (Fig. 6B: flags 3-4). Statistical analysis over 0.75 to 5Mc for heads favored a steady-state weight-loss averaging 0.9 mg/Mc. The corresponding steady-state cup trend averaging 10.5 mg/Mc was 11.7-fold greater than for heads. By 5-million cycles duration, the total weight-loss in heads and cups amounted to 11.2 and 71.1mg, respectively, i.e. 6.4-fold greater in cups (Fig. 7). The corresponding volumetric wear-rates for run-in and steady-state phases averaged 6mm3/Mc and 1.4mm3/Mc, respectively. These represented an overall wear-rate of approximately 2mm3/Mc.



Figures 6A & B.

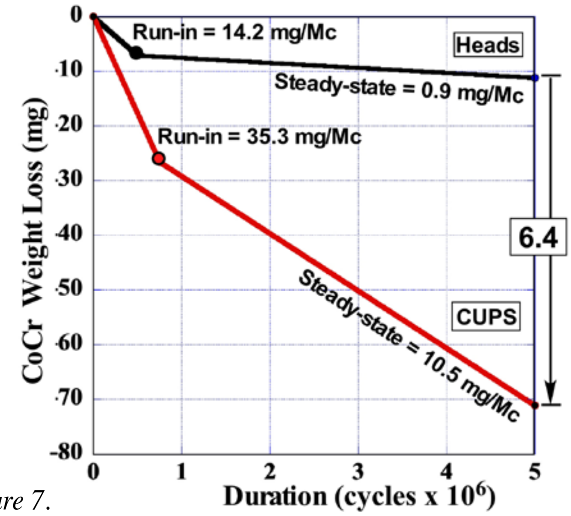


Figure 7.

Steep-cup test-3 (70° inclination) was predicated on truncating the normal wear-pattern by 7.8° to produce edge-loading in the cup. The main wear pattern (MWZ) clearly showed the effects of edge-loading produced (Fig. 8). Wear-patterns on femoral heads were faint, difficult to characterize and quite variable. Heads 1 and 4 were selected as the best representation at 2.5Mc duration, providing wear-pattern areas of 330mm² and 588mm² (approximated to 460mm²).

Discussion

This appears to be the first simulator study using a mathematical approach to define edge-loading in cups. The MOS-algorithm predicted that 60mm cups would have a ‘critical’ inclination angle of 62° (Appendix A). Tests 1 and 2 at 1Mc duration (peak inclinations 40° / 50°) showed wear patterns did not extend to the cup rims. In contrast, test-3 with 70° peak inclination produced edge loading as confirmed by the truncation of the wear patterns (Fig. 8). These data satisfied the first hypothesis that the MOS-algorithm would differentiate between “ideal” and “edge-loading” conditions.

There was no precedent for this simulator edge-loading study in ‘Inverted’ mode. The test validity was established by comparing areas worn in Inverted cups to those on heads run in ‘Anatomic’ test mode. Inverted cup areas (wear pattern =1663mm^2) corresponded almost exactly to Anatomic head areas (wear pattern =1668mm^2). This established our overall thesis, that running hip bearings in an Inverted test simply reversed the wear patterns produced in the Anatomic test. A governing criterion for steep-cup simulations is the cup wear-patterns should be representative of those in MOM retrieval studies. This study increased cup wear-patterns from a low of 8% in Anatomic mode to 29% in Inverted mode but this was still not as high as measured in retrieved cups. Possibly this reflects patients having much greater gait complexity compared to simulators using a fixed 45-46° flexion arc.

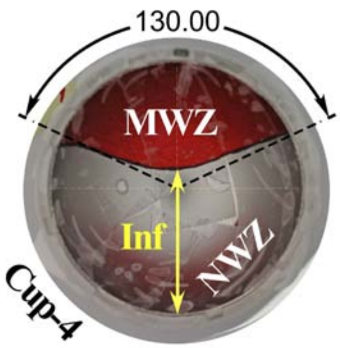


Figure 8.

MOM bearings typically show high wear during initial run-in phase, and then generally transition to a lower wear-rate within 1-million cycles. This occurs when head and cup wear-patterns enlarge enough to support optimal tribological conditions. Edge-loading produces truncation of normal wear patterns (compare Figs. 5 and 8) such that optimal conditions cannot be met and thus higher wear results. Even with Inverted cups experiencing edge-loading only intermittently in each cycle, test-3 produced 5-fold greater wear than our prior Anatomic study. This more than satisfied our 3rd hypothesis that MOM wear rates would be doubled under edge-loading.

Our 60mm MOM wear-rates (Inverted cups) averaged 2mm^3/Mc over 5-Mc test with a ratio of 86% cup to total MOM wear. The prior Anatomic test produced a cup wear ratio that varied from 68% in normal trending to 85% during “breakaway” wear trends [17]. The latter value was virtually identical to that in our edge-loaded test-3, likely signifying a trigger such as partial lubrication failure. There was also a dramatic correspondence of wear trends with 60mm Inverted cups run dynamically inclined over 5-Mc with 40mm cups in Anatomical mode and run at fixed 60° inclination. [14]. Clearly this could be coincidental due to the many experimental differences. However, our observation was that MOM bearings run under such edge-loading conditions did not provoke adverse wear as reported by others. Our data represented stable trends with wear-rates that did not turn lubricants black. These data suggest that additional conditions need to be present to provoke adverse wear, such as surgical and patient-related risks that may contribute to joint laxity, impingement, head subluxation, release of large metal particles, etc.

Appendix A

The size of head and cup wear patterns is produced by the simulator mechanics and this ratio is x3.87 for the orbital machines. Thus, in our prior 60mm Anatomic test, cup and head wear-patterns averaged 442mm^2 and 1668mm^2, respectively, giving the experimentally derived ratio x3.77. Knowing the angle subtended by the cup wear-pattern (45.6°) and cup flexion-angle (46° arc), the summated angle (91.6°) can be shown by spherical geometry to to be subtended by a head wear-pattern of 1712mm^2 area. The measured and calculated wear-areas on heads agreed within 44mm^2 (< 3% difference), revealing that wear patterns on hip bearings were predictable.

In our previous study, a MOS-algorithm was created to define sizes of cup wear-patterns and clinical risks of edge-loading. Equations governing edge loading in Anatomic test mode (Fig. A1) were presented as,

Equation-1: $\mathbf{L + P + MOS + A/2 = 90°}$

Equation-2: $\mathbf{2{*}P + F = 180°}$

Where,

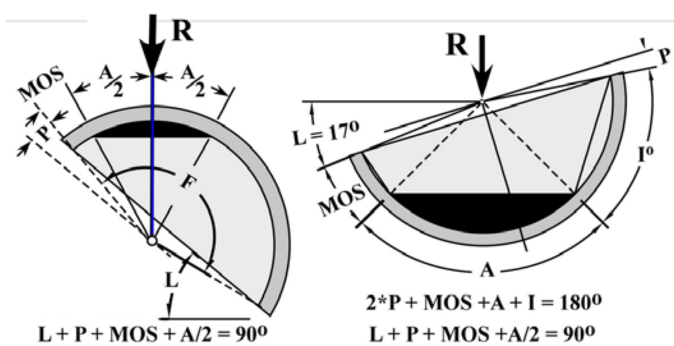
Angle (A) = wear-pattern angle from simulator data. [16]

Angle (F) = cup-face angle in sub-hemispherical cup.

Angle (L) = cup inclination in horizontal plane of simulator

Angle (MOS) = angle between cup rim and wear pattern

Angle (P) = rim-profile angle of sub-hemispherical cup



The critical cup angle (*L) can be defined as that inclination where the edge of the wear pattern becomes juxtaposed to cup rim, i.e. MOS angle = zero and given by,

Equation-3: $\mathbf{{*}L = 90° – (P + A/2)}$

Degree of edge-wear (Figure 3) can be defined as

Equation-4: $$\mathbf{EW\% = 100*(A - B)/A}$$

The notable difference between Inverted and Anatomic test modes is that in the former the cup inclination angle varies dynamically whereas in the latter the cup inclination is held fixed. However, analysis for edge-loading condition is essentially the same for both Inverted and Anatomic modes.

Acknowledgements

This project was supported by FDA contracts on preclinical (simulator) validation studies of Metal-on-Metal (MOM) Bearings (FDA-1090372 and 1119682).

SUBMISSION HISTORY

Submitted August 16, 2017
Reviewed September 14, 2017
Revised September 21, 2017
Accepted September 22, 2017
Published September 30, 2017

AUTHOR AFFILIATIONS

1 Ian Clarke, PhD
Professor in Research, Dept. Orthop., Loma Linda University Medical Center, 11406 Loma Linda Drive, Loma Linda University, Loma Linda, CA 92354 US
2 Julia Shelton, PhD
School of Engineering and Materials Science, Queen Mary University of London, London, UK
3 John Bowsher, PhD
Anterior Spine Devices Branch, FDA , Silver Springs, Washington, DC
4 Christina Savisaar, PhD
Orthopedic Joints Devices Branch, FDA, Silver Springs, Washington DC
5 Thomas Donaldson, MD
Donaldson Arthritis Research Foundation, 900 E. Washington Street, Suite 200 Colton, CA 92324 US

(Direct inquires to Ian Clarke, ithipgeek15@yahoo.com)

AUTHOR DISCLOSURES

The authors declare that there are no disclosures regarding the publication of this paper.

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