DEPUY INTERNATIONAL
RESEARCH AND DEVELOPMENT REPORT

REPORT NO: RDR 091_07	**PROJECT NO: A432**

TITLE: ASR wear study of 63mm diameter bearings to 5M cycles.

DESCRIPTION OF TEST PARTS OR MATERIALS:
ASR femoral components: 06_953, 06_954 & 60_957
ASR acetabular components: 06_1431, 06_1429 & 06_1427
Ultamet femoral components: 06_1242 & 06_1252
Ultamet acetabular components: 06_1278 & 06_1287

TEST PROTOCOL: DP 122

PASS/FAIL ACCEPTANCE CRITERIA:
The acceptance criteria was set such that ASR should wear at a similar or lower rate than the Ultamet 36mm bearings.

SUMMARY/ ABSTRACT:
Total mean volumetric wear of the ASR bearings over 5M cycles was 2.52mm^3, and 0.15mm^3 for the ultamet implants. Mean bedding in wear measured from 0 to 1.5M cycles, for ASR and Ultamet bearings was 1.96mm^3 and 0.11mm^3 respectively, while steady state wear from 1.5M to 5M cycles for ASR and Ultamet bearings was 0.24mm^3 and 0.02mm^3 respectively. These results are presented graphically in Figure 1, Figure 2 and Figure 3 on the following pages.

The current results for ASR do not meet the set acceptance criteria for this test. Therefore, a comparison was made with other currently used implants, in particular a 28mm wrought CoCrMo Ultima MOM bearing and a 39mm cast CoCrMo ASR MOM bearing to gauge the safety of the 63mm ASR bearing. Approximate mean wear of the ASR 39mm at 5M cycles is 4.0mm^3 and for the 28mm Ultima is 6.0mm^3. The wear levels for 63mm ASR therefore fall below the wear levels of both 39mm ASR and 28mm Ultima (Figure 4). 39mm ASR and 28mm Ultima are both currently used implants with a good clinical history, therefore it could be expected that the wear of 63mm ASR should pose no greater risk to the patient than is encountered with two other currently used, clinically successful bearings.

ASSOCIATED FILES: WR671E. Full results in:
L:\Applied_Research\test_dir_struct\lab_documentation\Work_requests\results\WR671 ASR IDE 510k simulator test

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VERIFICATION				
APPROVAL	**Approved for DHF use Yes/No**			
If not approved for DHF state reasons				

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ASR WEAR STUDY OF 63MM DIAMETER BEARINGS TO 5M CYCLES

Method

This report describes wear simulator results to 5M cycles for 3 x ASR 63mm bearings. alongside 2 x 36mm Ultamet unused bearings which were control samples. The 36mm Ultamet bearing is a currently used implant with a good clinical history. A significant number of previous in-vitro wear tests have been performed on this bearing, which have provided extensive information as to its typical wear behaviour. For these reasons it forms a good control sample for benchmark testing of newly developed implants.

Full details of the test method are documented in DP122. In summary, components were positioned in an anatomical position in a Prosim Hip Wear Simulator and subjected to repeated cycles representing walking, incorporating 25° flexion / 10° extension, ±10° internal / external rotation, and a twin peak Paul-type load profile with maximum and swing phase loads of 3kN and 300N respectively.

New-born 25% calf serum was used as lubricant, and lubricant was changed approximately every 250,000 cycles. Samples were gravimetrically assessed for wear every 500,000 cycles.

The acceptance criteria was set such that ASR should wear at a similar or lower rate than the Ultamet 36mm bearings.

Samples

All samples used were finished stock product, and were selected as far as possible to have similar clearances within each bearing type on test. All components were measured on a coordinate measuring machine accurate to 5µm, and results are presented in Table 1.

Bearing type		**ASR**	**ASR**	**ASR**	**Ultamet**	**Ultamet**
Cup	**Sample**	06_1431	06_1429	06_1427	06_1242	06_1252
	Diameter	62.601	62.603	62.607	36.117	36.114
Head	**Sample**	06-954	06-957	06-953	06_1278	06_1287
	Diameter	62.428	62.433	62.439	36.006	36.002
Bearing clearance		0.173	0.17	0.168	0.111	0.112

Table 1: Dimensions of components tested

Results

Total mean volumetric wear of the ASR bearings over 5M cycles was 2.52mm^3, and 0.15mm^3 for the ultamet implants. Mean bedding in wear measured from 0 to 1.5M cycles, for ASR and Ultamet bearings was 1.96mm^3 and 0.11mm^3 respectively, while steady state wear from 1.5M to 5M cycles for ASR and Ultamet bearings was 0.24mm^3 and 0.02mm^3 respectively. These results are depicted graphically in Figure 1, Figure 2 and Figure 3 on the following pages.

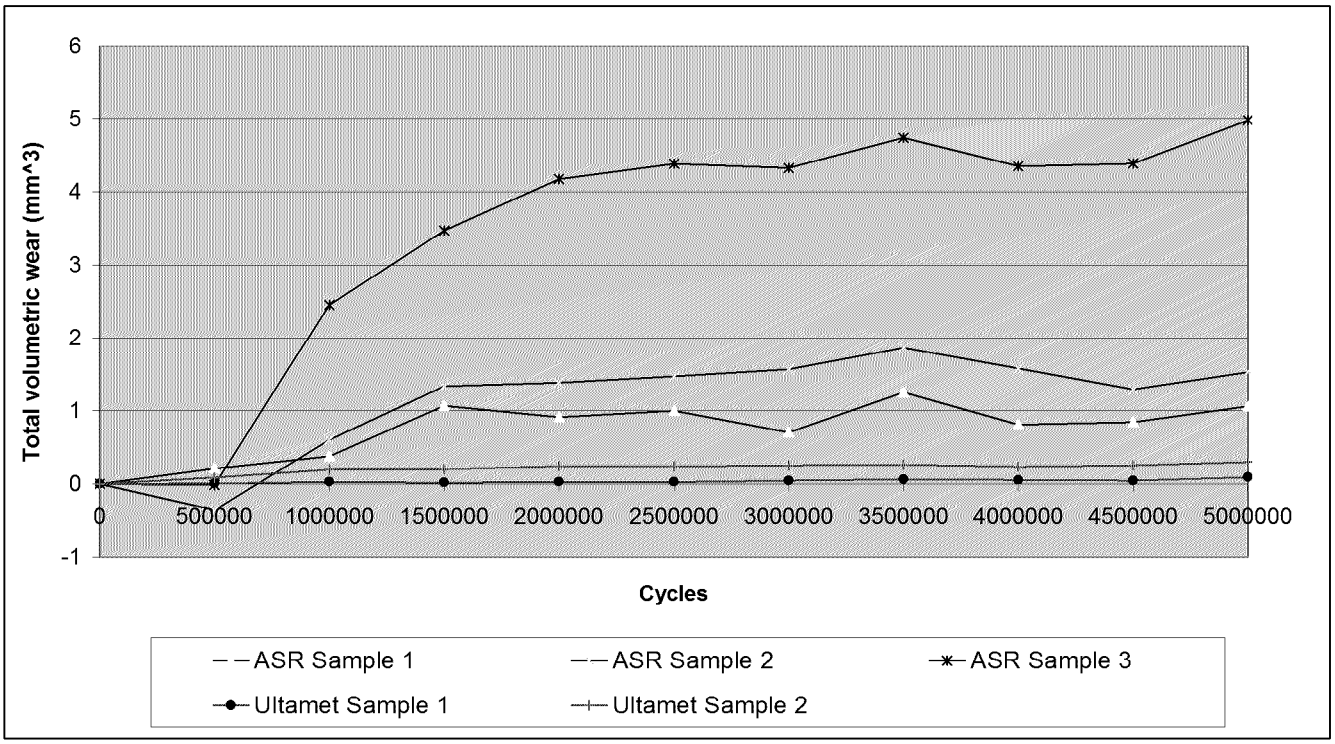

Figure 1: Total volumetric bearing wear for each sample tested

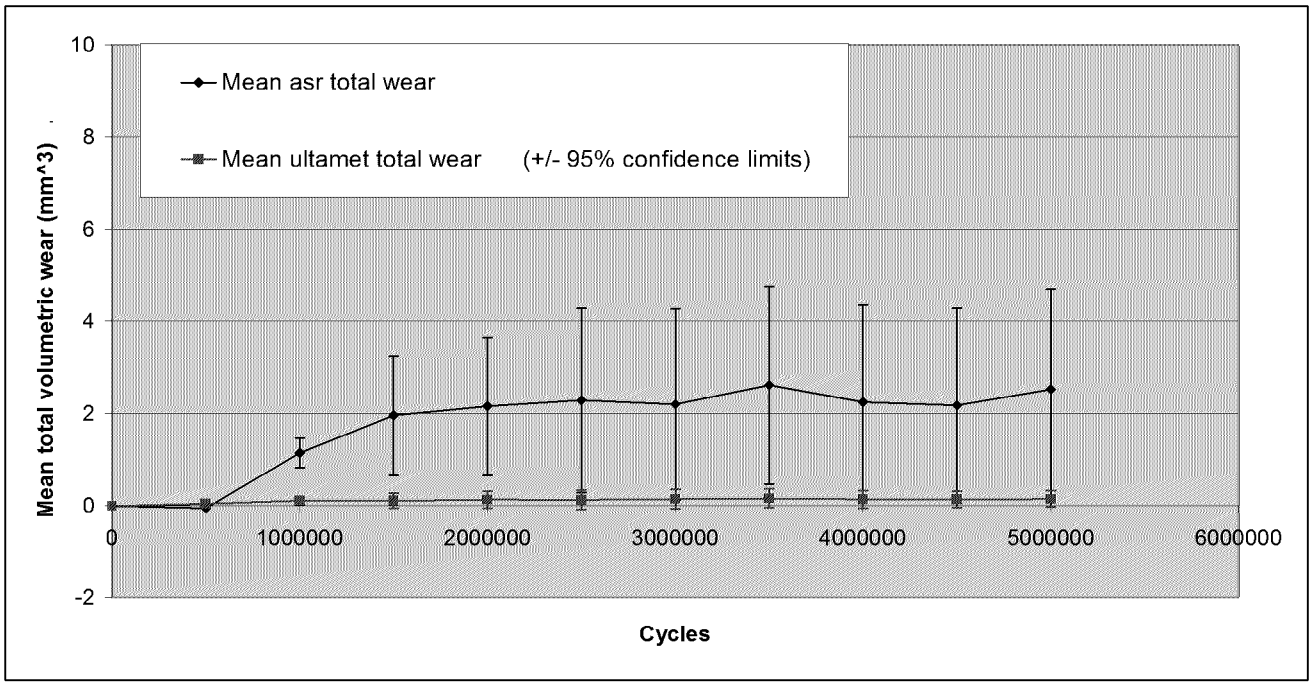

Figure 2: Mean total volumetric wear (± 95% confidence) by bearing type

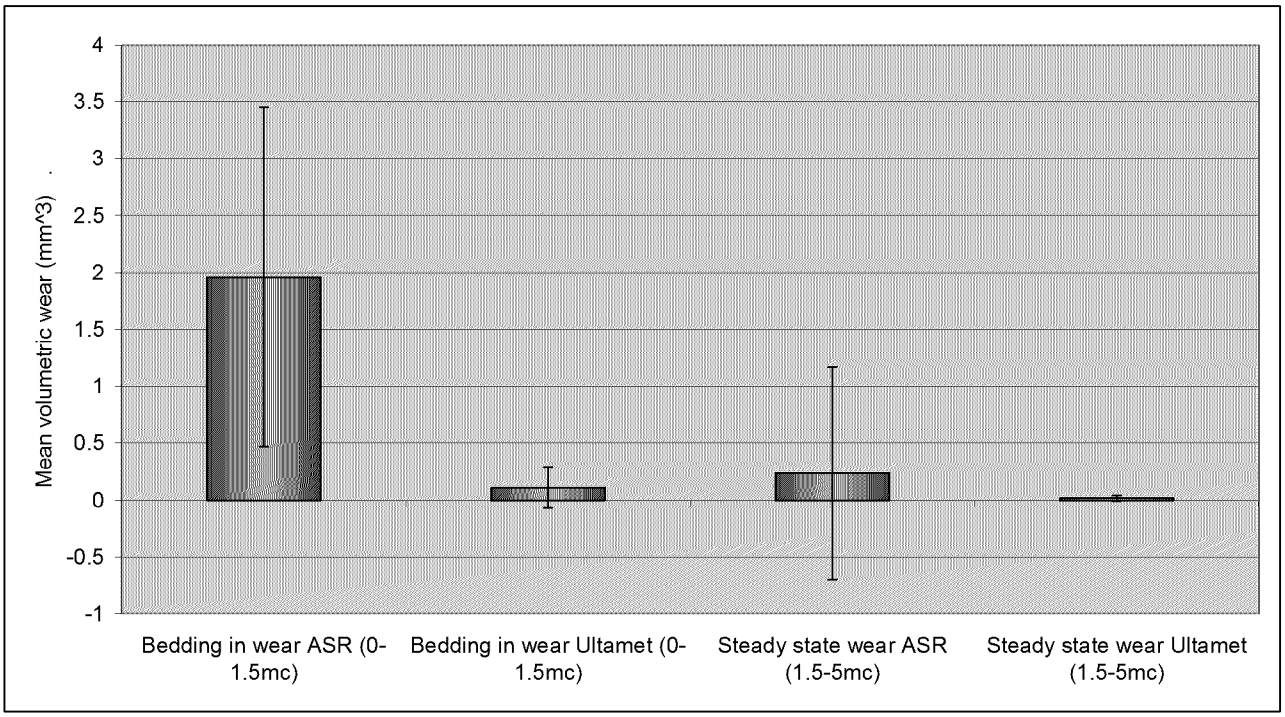

Figure 3: Mean bedding in (0-1.5mc) and steady state (1.5-5mc) wear rates by bearing type (± 95% confidence)

Discussion

The current results for ASR do not meet the set acceptance criteria for this test. Therefore, a comparison was made with other currently used implants, in particular a 28mm wrought CoCrMo Ultima MOM bearing and a 39mm cast CoCrMo ASR MOM bearing to gauge the safety of the 63mm ASR bearing.

The 28mm Ultima bearing was tested at DePuy International, Leeds, using the same protocol as the current study. The 39mm ASR bearing was tested at the University of Leeds, using a similar wear simulation machine from the same manufacturer as for the current study. The wear profiles used at both DePuy and the University of Leeds are very similar and are based on the standard protocol specified in ISO14242. Both protocols use the same motion parameters for flexion / extension, while the motion parameters for internal / external rotation are of the same magnitude but are applied 180˚ out of phase. This simply represents simulation of the opposite side leg, i.e. one profile mimics the left leg, the other the right. Both loading profiles are very similar in magnitude, however the DePuy load profile slightly lags the Leeds University profile by up to approximately 0.1 seconds. Full graphical representation of the two profiles is provided in Appendix 1.

Approximate mean wear of the ASR 39mm at 5M cycles is 4.0mm^3 and for the 28mm Ultima is 6.0mm^3. Therefore, the wear levels for 63mm ASR do fall below the wear levels of both 39mm ASR and 28mm Ultima (Figure 4 & Figure 5). 39mm ASR and 28mm Ultima are both currently used implants with a good clinical history, therefore it could be expected that the unexpected higher wear of 63mm ASR should pose no greater risk to the patient than is encountered with two other currently used, clinically successful bearings.

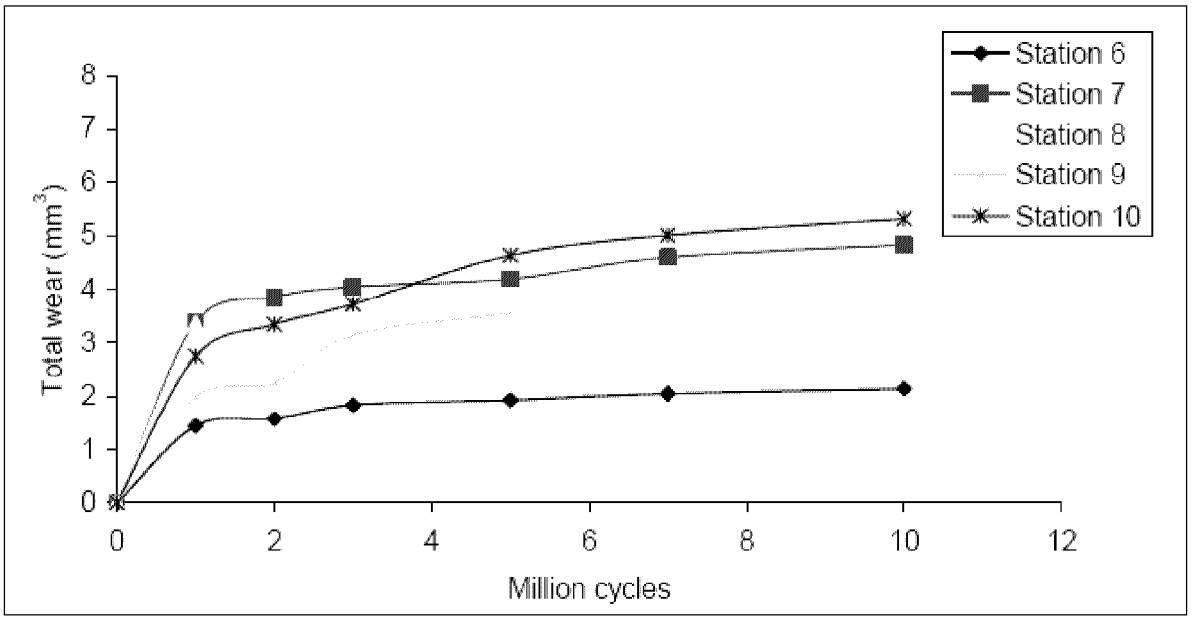

Figure 4: 39mm ASR (Measured at University of Leeds, report 0603-1-5)

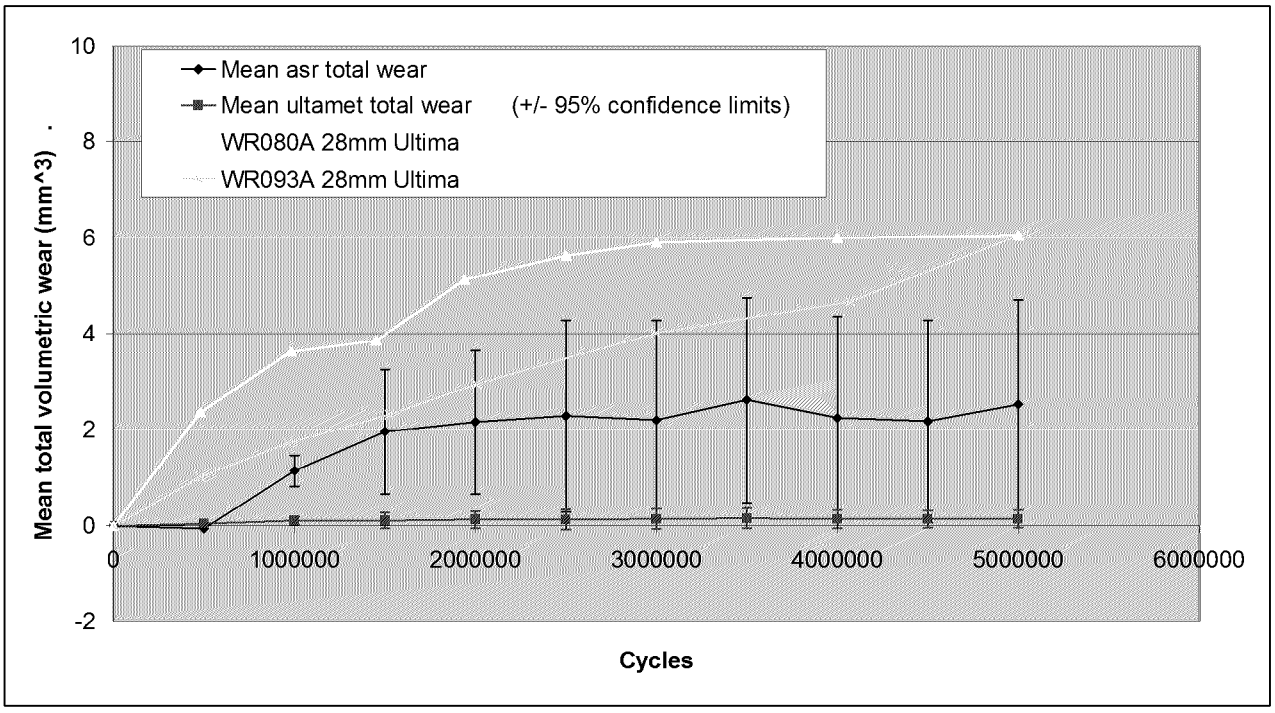

Figure 5: Data from the current study, compared with wear data previously obtained for Ultima 28mm in two separate studies using the same technique.

Appendix 1: Comparision of simulator protocols for DePuy and University of Leeds