The Safety and Efficacy of Large-Diameter Metal-on-Metal Total Hip Arthroplasty

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Summary
The proven clinical success of BIRMINGHAM HIP™ Resurfacing (Smith & Nephew Orthopaedics Ltd., Warwick, UK) has led to the resurgence of metal-on-metal bearing utilization in hip arthroplasty and the introduction of alternative hip resurfacing systems. In addition, large-diameter femoral head (LDH) bearings identical to those used in resurfacings have been adapted for use with standard total hip arthroplasty (THA) stems. LDH THA is a promising primary procedure for young and active patients who may not qualify for hip resurfacing. However, concerns have been recently raised that high wear from the taper junction between the head and stem can lead to highly elevated metal ion generation and increased failure risk in some LDH THA systems.

Following a comprehensive review of available safety and efficacy data, there is currently no significant evidence of high wear at the taper junctions, highly elevated metal ion generation, or reduced survivorship for BIRMINGHAM HIP Modular Heads (Smith & Nephew Orthopaedics Ltd., Warwick, UK) when coupled with Smith & Nephew stems. However, close monitoring of any patients presenting with elevated metal ion levels is recommended.

Introduction
The proven clinical success of BIRMINGHAM HIP Resurfacing (BHR™; Smith & Nephew Orthopaedics Ltd., Warwick, UK) initiated a contemporary resurgence in the utilization of metal-on-metal (MoM) bearings in hip arthroplasty [1-3]. To date, 93.5% and 96.0% survival has been reported for BHR patients at 10 and 13 years follow-up, respectively [4, 5]. For osteoarthritis patients under the age of 55 years, survival of 98% at 13 years is reported [5]. Further, BHR is the only Orthopaedic Data Evaluation Panel (ODEP) 10A rated resurfacing device on the market, demonstrating excellence in long-term clinical performance [6]. This evidence supports the previously reported benefits of MoM bearings, including reduced volumetric wear

*Disclaimer: This manuscript includes reference to the BIRMINGHAM HIP Modular Head, which is not approved for use in metal-on-metal total hip arthroplasty in the United States.
Recently, LDH total hip arthroplasty (THA) has become more common. During this procedure, an articulating surface identical to that of hip resurfacing is mated to a standard femoral stem via a tapered junction. LDH THA was initially introduced as a revision solution for hip resurfacing patients with failed femoral resurfacing components [15, 16]. However, the observed functional benefits have supported its use as a primary procedure. Specifically, LDH THA allows for an increased head-neck ratio, supporting optimal range of hip motion [16]. In addition, this procedure allows young and active patients with poor proximal femoral bone stock to take advantage of low-wear, low dislocation risk LDH MoM bearings [15]. While initial outcomes of LDH THA have been promising, two recent reports have raised concerns regarding excessive metal ion generation [17, 18]. Fretting corrosion is known to generate ions at all taper junctions [19-21]. Further, because LDH THA often includes two tapers at both the head-sleeve and sleeve-neck junctions, increased metallic surface area could result in additional corrosion [18].

In light of recent medical device alerts issued by the United Kingdom’s Medicines and Healthcare products Regulatory Agency (MHRA) [22, 23], in addition to a 2011 advisory publication from the British Orthopaedic Association (BOA) [24], it is appropriate to fully assess all available safety and efficacy data for specific LDH THA systems. This will allow the orthopaedic community to understand how specific design differences may be affecting metal ion generation and overall device survivorship.

Evidence of Increased Ion Generation in Specific LDH THA systems

There is emerging evidence of increased metal ion generation from LDH THA taper junctions. Garbuz et al [17] report the results of a randomized comparison of MoM hip resurfacing and LDH THA. Seventy-three (73) patients completed a minimum follow-up of 1-year. All procedures were performed with identical acetabular components (Durom™; Zimmer Inc., Warsaw, IN, USA). Forty-eight patients (48) received Durom hip resurfacing femoral components, while 56 patients received a large-diameter Metasul™ head (Zimmer Inc., Warsaw, IN, USA) mated to an M/L Taper™ (Zimmer Inc., Warsaw, IN, USA) Titanium stem via a Cobalt-Chrome alloy metal sleeve. Serum samples were analyzed using high-resolution sector field inducively coupled plasma mass spectrometry (HR-SF-ICPMS). Compared to the pre-operative baseline, median serum Cobalt (Co) and Chromium (Cr) levels were increased 3.9- and 5.4-fold in the hip resurfacing group and 46- and 10.7-fold in the LDH THA group, respectively. The relative increase in the LDH THA group was 10-fold higher for Co and 2.6-fold higher for Cr compared to the hip resurfacing group. Serum ions continued to increase at the 2-year review for the LDH THA group (Co: 5.38 µg/L; Cr: 2.88 µg/L). The authors conclude that ion generation from the current LDH THA taper junction is excessive, and recommend against its further use. These results are corroborated by Vendittoli et al [18], who report HR-SF-ICPMS whole blood ion levels for Durom and Metasul at 1-year. Significant postoperative increases were found for Cr, Co and Titanium (Ti), as compared to preoperative measures (p < 0.001). Relative ion increases of 1.9-, 20.1-, and 3.0-fold were noted for Cr, Co, and Ti, respectively. When compared to previously published Durom hip resurfacing ion data from the same authors, Co ions were found to be 3.3-fold higher for LDH THA [25, 26]. Further, in contrast with reported results for hip resurfacing, the authors note a positive correlation between bearing size and Co levels (r² = 0.257, p = 0.005), and a continual increase in ion concentrations between the 0.5 and 1-year intervals. Because ion generation can be utilized as a surrogate measure of in vivo device wear, increased ions following LDH THA could represent an increased risk of system failure [27].

Evidence of Increased Revision Risk in Specific LDH THA systems

The British Orthopaedic Association (BOA) recently issued a publication regarding the safety of LDH THA systems following its 2011 annual conference [24]. While there is generic reference to devices from multiple manufacturers, the BOA specifically notes a higher than anticipated early failure rate for the ASR XL™ system (DePuy Orthopaedics Inc., Warsaw, IN, USA). Specifically, ASR XL revision rates of 21% to 49% are re-
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Ion Generation in the BIRMINGHAM HIP™ Modular Head System

The BIRMINGHAM HIP Modular Head (BH Mod Head; Smith & Nephew Orthopaedics Ltd, Warwick, UK; Figure 1) LDH THA system features a MoM bearing metallurgically and geometrically identical to that of the clinically successful BHR hip resurfacing system in combination with a total hip replacement stem [2, 4]. Daniel et al [15] published the first metal ion analysis of BH Mod Head fixed to a monoblock (MB) uncemented stem through a 12/14 taper, as compared to a cohort receiving a 28-mm MoM Metasul™ total hip replacement (Zimmer GmbH, Winterthur, CH) [14]. The BH Mod Head MB THA system included all bearing diameters. At 1-year follow-up, whole blood ion differences between Metasul and BH Mod Head were not significant (Cr 1.7 vs. 1.4 µg/L; Co 1.7 vs 2.3 µg/L, respectively; p > 0.1). In addition, group differences in daily urinary output for both Cr and Co were also insignificant (Co 11.6 vs. 12.3 µg/24 h; Cr 3.7 vs. 4.1 µg/24 h; p > 0.5). The authors note that the functional advantages of LDH THA, coupled with only marginal, clinically insignificant increases in ion generation, support the transition away from small MoM bearings.

National joint registry reports may be referenced directly to further assess the performance of specific LDH THA systems. It may not always be possible to determine case specific reasons for revision from these sources. Specifically, data demonstrating which cases were revised for ARMD is unavailable. However, national joint registries do provide additional safety and efficacy data for the different designs of hip replacements, including the Durom and ASR XL LDH THA systems. The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) 2010 Annual Report provides revision data for both these LDH THA systems, coupled with stems which have a proven clinical track record when used in conjunction with smaller diameter non-MoM bearings [28]. To date, the results for 612 Durom acetabular components mated with Alloclassic™ femoral components (Zimmer Inc., Warsaw, IN, USA) are reported in the registry. For ASR XL, results for 2,888 and 1,118 procedures featuring the Corail™ and Summit™ (DePuy Orthopaedics Inc., Warsaw, IN, USA) femoral components are reported, respectively. Cumulative revision for the Durom LDH THA is currently 6.2% (CI 4.2, 9.0) at 5 years. In regards to ASR XL, cumulative revision is currently 6.4% (CI 5.3, 7.6) at 3 years for the Corail coupling, and 7.1% (CI 4.3, 11.5) at 5 years for the Summit coupling. Further, the AOANJRR has recently reported that revision rates for ASR XL are four times higher than those observed for other primary conventional THA procedures [29]. The reported revision rates for all three of these LDH THA-stem combinations currently exceed the 1% per year guidance limit from the National Institute for Health and Clinical Excellence (NICE) [30]. The fact that these stems perform better when used in conjunction with smaller diameter non-MoM bearings demonstrates that there is nothing inherently wrong with the stem design. For instance, the Corail stem used in conjunction with the Pinnacle cup has a 2.9% (CI 2.3, 3.7) revision rate at 5 years. The Corail-Duraloc combination has a 2.7% (CI 1.8, 4.0) revision rate at 5 years and 3.6% (CI 2.4, 5.3) at 7 years, which are within the NICE guidance limit for revision rates. These stems are only associated with high revision rates when combined with an ASR (XL) LDH bearing.

Figure 1: BIRMINGHAM HIP Modular Head (Smith & Nephew Orthopaedics Ltd, Warwick, UK).
The difference between the metal ion levels reported for the BHR™ Resurfacing System and those observed in the BH Mod Head system is not 10-fold increase as seen with the earlier reported Durom LDH THAs. The blood cobalt levels in both these BH Mod Head systems are higher than the levels observed for BHR (mean 1.2, median 1) by a factor of 2.0 to 2.3, while the blood chromium levels for BH Mod Head are lower than the levels for the BHR at the 1-year follow-up [31]. However, the BHR cohort included only male patients with only two head sizes (50mm and 54mm), while the THA system cohorts included all bearing diameters. Further, two thirds of the patients were women. Because bearing diameter is known to affect metal-ion generation, it is possible that group differences in diameter and gender can account for the modest elevation of metal ion generation in the LDH THA systems, as compared to BHR.

Finally, a report has been recently published that provides a relative comparison of ion levels between BH Mod Head and three additional LDH THA devices [32]. At a mean follow-up of 2 years, whole blood Cr and Co levels for BH Mod Head, coupled with an Anthology stem (Smith & Nephew, Inc., Memphis, TN, USA), were 1.86 and 1.9 µg/L, respectively. No BH Mod Head patients had excessively high ion levels. Of the remaining patients implanted with ASR XL, M2a-Magnum (Biomet, Warsaw, IN, USA), and Durom acetabular components, the highest relative ion levels were in the Durom group (2.68 µg/L; p = 0.001). While there were no group differences noted for Co, two patients implanted with the M2a-Magnum device did exhibit extreme Co levels of 11.6 and 16.5 µg/L at 3 months and at 1 year, respectively. However, the only reported incidence of ARMD was in one Durom patient, revised due to persistent groin pain (2 Year Co: 3.78 µg/L).

Revision Risk in the BH Mod Head system

Survivorship data for BH Mod Head is currently reported in the AOANJRR, and is available from the National Joint Registry of England and Wales (NJR UK) [6]. The AOANJRR 2010 Annual Report provides revision data for 1,979 BH Mod Head components mated with SYNERGY® femoral stems (Smith & Nephew, Inc., Memphis, TN, USA) [28]. Cumulative revision for the BH Mod Head is currently 2.2% (CI 1.3, 3.8) at a follow-up of 3 years, which is not different from the 3-year survivorship (2.3%, CI 2.0,2.7) of the SYNERGY stem-REFLECTION® cup combination with a smaller diameter non-MoM bearing in the Register. To date, NJR UK survivorship data is available for a total of 2,822 procedures. At a follow-up of 6.12 years, the survival probability of BH Mod Heads on all Smith & Nephew stems is
96.1% (Figure 3). It should be noted that 18 patients revised due to infection were excluded from this analysis. When the BH Mod Head is coupled with cemented Smith & Nephew stems, the survival probability is 94.1% at 5.89 years (Figure 4). Only one cemented patient was excluded due to infection. While revision risk does appear to be slightly higher in the cemented group, both survival probability values satisfy the safety requirements established by NICE [30].

It is important to note that Bolland et al [33] have reported outcomes for 199 LDH THA procedures featuring either BH Mod Heads or Adept resurfacing acetabular components (Finsbury Orthopaedics, Leatherhead, United Kingdom) coupled with a cemented collarless, polished, tapered stem (CPT; Zimmer, Warsaw, IN, USA). While the authors do report a relatively elevated cumulative revision rate of 7.6% at 5 years and evidence of significantly increased taper wear, it must be understood that combining acetabular and femoral components from different manufacturers is strictly contraindicated. At this time, there is no evidence of elevated revision risk when BH Mod Heads are combined with Smith & Nephew stems.

An additional comparison of interest from the NJR UK registry is hip resurfacing and LDH THA revision rates in patients under the age of 55 years. Survival probability for BHR™ patients is currently 94.9% at 7.5 years, as compared to 94.5% for BH Mod Head at 6.5 years. As noted previously, BHR may be particularly beneficial to young and active populations due to low observed wear at 10 years [4]. For relatively young patients that do not qualify for hip resurfacing, the current registry evidence suggests that LDH THA with the BH Mod Head may indeed serve as a safe and effective alternative.

Both the Durom and the ASR bearings were introduced as fourth generation MoM systems with reduced diametrical clearances. Although this attribute appeared beneficial in the laboratory studies performed by the manufacturers, clinical performance was never established. From the consistent higher failures observed with both these bearing systems, it now appears that reduced joint clearance could be one of the contributing factors to highly elevated metal ion generation and increased revision risk.

Figure 3: NJR UK Survival data for all BH Mod Heads coupled with all Smith & Nephew, Inc. stems. We thank the staff of all the hospitals in England and Wales who contributed data to the National Joint Registry. We also thank the staff of the NJR Centre for the collection of the data and for their support of the data linkage and analysis.
Reduced clearance is influenced more significantly by manufacturing tolerances and form variances, and from the possibility of in vivo circumferential cup deformation, which can occur either during implantation or under load bearing activities. An independent simulation study demonstrated that cup deformation, under the influence of the implantation-generated forces, effectively converts the initial low clearances in the Durom and ASR bearings into negative clearances [34]. This increases the risk of a clamping effect and high friction. In contrast, the higher initial clearance in the BHR bearing allows it to remain in low friction positive clearance mode, even after implantation-deformation [34]. This specific design feature may offer some explanation as to the performance differences of LDH THA designs, as the friction generated at the articulation surface can influence torque loads transferred down to the sleeve-stem taper, potentially exceeding the torque resistance strength of these taper junctions. Further, this torque can initiate micromovement at the stem/bone/cement interface, leading to fretting or mechanically-assisted corrosion and eventually to higher metal ion release and increased risk of implant failure.

**Monitoring Recommendations for LDH THA Patients**

There is reported evidence of elevated ion generation following implantation of the Durom and Metasul LDH THA [17, 18]. Further, there are reports of increased revision risk and ARMD in ASR XL patients [24]. Following review of all available outcome data for BH Mod Head and Smith & Nephew stems, there is currently no evidence of significantly elevated ion generation from the taper junction. In addition, survivorship for these devices currently meets NICE guidance standards [30].

While this evidence does support the safety and efficacy of BH Mod Head, close monitoring of potentially at-risk patients is strongly recommended. Smith & Nephew Ltd. has been notified regarding a relatively small number of case reports featuring BH Mod Head patients presenting with elevated ion levels (Dr. Steve Jones, University Hospital of Wales and Llandough, Wales, UK; Dr. B. Kuhnemann, Allamanda Hospital, Southport, AUS; Mr. J. Holland, Freeman Hospital, Newcastle, UK). These patients are being monitored closely for the presence of undiagnosed pain, swelling, or changes in walking ability that may be indicative of an ARMD response.

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**Figure 4: NJR UK Survival data for BH Mod Head coupled with cemented Smith & Nephew, Inc. femoral stems.**
Per MHRA guidance, patients with painful MoM hip implants should be further evaluated and where there is clinical or radiological concern of an adverse reaction metal ion analysis should be performed [22]. In the event that blood Co or Cr ions are persistently elevated above 7 parts per billion (ppb), MRI or ultrasound cross-sectional imaging should be performed to detect possible soft-tissue reactions, fluid collections, or tissue masses about the hip. If evidence of an adverse reaction is identified, revision surgery should be considered.

Conclusion

Recently developed LDH THA systems have built upon the clinical success of BHR™ by offering a low-wear, highly functional solution to patients that do not qualify for hip resurfacing. However, there is evidence that the combination of alternative designs and metallurgy, when associated with tapered sleeve junctions, could contribute to excessive wear, increased metal ion generation, localized adverse soft tissue reactions, and reduced survivorship. While anecdotal reports of high ions are being investigated, the safety and efficacy of BH Mod Head and Smith & Nephew stem combinations is currently supported. Further, Smith & Nephew is executing a series of wear tests to fully assess the potential for BH Mod Head taper wear, and to determine how specific design differences can adversely affect taper performance. The results of these tests will be communicated to the community as soon as possible.

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References


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