

Femoral side-only revision options for the Birmingham resurfacing arthroplasty

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Abstract

Background: The Birmingham Hip Resurfacing (BHR) system (Smith and Nephew) was developed as an alternative to conventional total joint replacement for younger, more active patients. Among other complications exists the risk for femoral component failure. The only marketed revision option for such a complication involves exchange of all components for a total replacement arthroplasty. This presents as a considerable and potentially unnecessary operative burden where revision of only the femoral prosthesis would suffice. We have analysed revision options for BHR in the context of periprosthetic femoral fractures with a stable acetabular component.

Methods: Technical details of dual mobility hip systems available in Australia were collated and analysed to assess for potential 'off label' use with an existing BHR acetabular component. These data were then compared with the custom-made Smith and Nephew dual mobility implant with respect to clearance and sizing.

Results: Two dual mobility articulation modalities from two companies were identified as appropriate for potential usage with four products analysed in detail. These two demonstrated acceptable sizing and clearance measurements.

Conclusion: Comparison between readily available dual mobility prostheses with custom-made implants showed off label dual mobility prosthetic use to be a viable alternative for femoral-only revisions with *in situ* BHR. Single component revision has several advantages which include: a less complex surgical procedure, shorter operative time, decreased blood loss and the expectation of resultant lower morbidity. Furthermore, this less complex revision surgery should give comparable results to that of primary total hip arthroplasty.

Introduction

Hip resurfacing arthroplasty (HRA) was initially popularized in the 1960s.^{1,2} Early implants, however, had a high failure rate due to accelerated wear and loosening (also a problem with conventional total hip replacement).^{3–5} Subsequent improvements in design, manufacturing and surgical technique led to a resurgence in use, until it declined once again when some metal-on-metal (MoM) hip articulations were found to cause clinical problems related to design flaws. Trunnionosis at the modular head-neck taper was also recognized as a problem with conventional MoM bearing hip arthroplasty, and has been abandoned as a current surgical option.⁶ Hip resurfacing with MoM bearings however continues to this day

(trunnionosis is not an issue), although its usage has declined. HRA in Australia now accounts for <0.8% of all hip arthroplasty procedures carried out.⁷

The most commonly used HRA in Australia remains the Birmingham Hip Resurfacing (BHR) currently owned and distributed by Smith and Nephew (Memphis, TN, USA). It was first implanted in England in the late 1990s and gained popularity in the United States in the mid 2000s.³

BHR was developed for use in younger, more active patients to allow femoral-sided bone preservation, easier revision options, greater hip stability (through large diameter heads in cups), reduced stress shielding and better hip proprioception secondary to preservation of the femoral head.^{3–5,8–13}

Patient selection is important with HRA and current indications and risk factors are well defined.^{3,14} Despite rigid adherence to indications, complications still occur (as in all surgical procedures).

Revision may become necessary to deal with femoral head loosening/lysis, avascular necrosis (AVN), metal-induced soft tissue hypersensitivity, periprosthetic fracture of the femoral neck, infection, pain, metallosis and dislocation.

Femoral-only revision may be considered for isolated femoral component aseptic loosening/AVN or femoral neck fractures. Risk factors that precipitate femoral neck fractures include poor bone density, older age, smaller femoral component, femoral neck osteo-necrosis and varus femoral component positioning.³

Previously, Smith and Nephew offered a large modular metal head that was compatible with the Birmingham cup for femoralonly revisions. This was discontinued by Smith and Nephew in mid 2014 due to taper wear problems and trunnionosis when used in MoM conventional total hip arthroplasty. As a result, the only present 'on label' femoral-only revision option is the Smith and Nephew custom-made dual mobility prosthesis (with a problematic 4–6 week manufacturing delay).

Other management options are to revise both femoral and acetabular components, or alternatively, to use an 'off shelf' dual mobility implant with compatible clearance and size (as compared to the custom-made Smith and Nephew option). 'Off label' usage avoids the 4-6 week delay required for custom-made implants, and offers surgical benefits of less operative time, decreased blood loss, shorter hospital stay and the potential for reduced morbidity when compared with a total revision procedure. Moreover, this procedure has demonstrated functional results in the literature comparable to that of primary hip arthroplasty.^{1,2} There are important considerations to be made when contemplating off label use; chief among them being the concept of clearance. Despite being labelled with the same diameter, a spherical femoral head will be slightly smaller than a liner so as to allow some eccentric movement. It is this eccentricity that is termed clearance and its value is relevant in the smooth lubrication and avoiding context of facilitating premature wear.

Methods

The Smith and Nephew Engineering team was contacted to provide clearance measurements for BHR MoM components as well as for their custom-made dual mobility prostheses. All other companies that manufacture and distribute dual mobility hip arthroplasty components in Australia were also contacted to provide technical specifications relating to inner and outer component diameters, clearance, polyethylene type used, manufacture process, sizing options and metallurgy. These data were then analysed to allow appropriate recommendations to be made.

Five companies were identified that provide dual mobility hip components: Smith and Nephew, Stryker (Kalamazoo, MI, USA), Zimmer Biomet (Warsaw, IN, USA), Global Orthopaedics and Lima-L (Udine, Italy). The last two companies were unable to provide relevant technical data for their dual mobility options and were thus excluded from the analysis. This left two off label options (Stryker and Zimmer Biomet), both of whom provide modular and monobloc acetabular options to match with dual mobility components. Those offered are the Modular Dual Mobility (MDM, modular) and Anatomic Dual Mobility (ADM, monobloc) (Stryker) and the G7 (modular) and Avantage (monobloc) (Zimmer Biomet). The dual mobility articulation insert systems associated with these acetabular options are named X3 (Stryker) and Active (Zimmer Biomet). The Zimmer Biomet system consists of two insert options, ArComXL and E1, both of which have the same design parameters with the E1 having vitamin E-impregnated polyethylene.

It is to be noted that all providing companies did not formally support the use of their prostheses in this off label manner (as expected) citing concerns that the components were not specifically designed for such application and the companies were not liable for any issues arising from component usage in this manner.

Available technical data for theses prosthetic systems were then analysed and compared with the Smith and Nephew custom-made dual mobility prosthesis (taken as the 'gold standard' option).

Results

Six dual mobility prostheses (including the Smith and Nephew custom-made option) from three manufacturers were assessed for potential use with the BHR acetabular shell. Of these, the Smith and Nephew 'Polar' system was considered inappropriate for use because clearance was significantly larger than the custom option when used with a BHR cup. This was due to the 'odd' rather than the 'even' progression in millimetres of Polar cup sizes. This left the options from Stryker and Zimmer Biomet. In either company's case, the monobloc shell is a sole dual mobility system, whilst modular options provide greater surgical flexibility with screw fixation options and applicability of dual mobility bearings as well as conventional fixed bearing surfaces. It is important to note that the dual mobility bearing surfaces remain identical across all sizes in each company. Thus, the ADM and MDM from Stryker utilize the same X3 dual mobility inserts. Similarly, the Avantage and G7 from Zimmer Biomet are used with the same Active dual mobility inserts.

Consideration should be given in situations where only the modular systems are utilized as not all insert sizes are required and may thusly not be available to the surgeon. This is because modular metal acetabular shell inner liners are manufactured to fit every acetabular shell size, but the same inner diameter may exist across a series of shell sizes.

Thus, with these offerings from Stryker and Zimmer Biomet, in addition to the Smith and Nephew gold standard, only three discrete dual mobility options were found that articulate appropriately inside a stable Birmingham shell to allow successful dual mobility femoral-only revision. Relevant to note is that whilst sizing availability remains brand specific and not all BHR cup sizes have an appropriate match when set against the modular acetabular systems, the provision of all monobloc insert options from the companies will facilitate matching with Birmingham shells in all cases.

Clearance measurements for the Smith and Nephew custommade prosthesis when matched for size with the BHR acetabular component is 330 μ m (within manufacturing tolerances). Clearances for the compatible off shelf dual mobility options were within the same range. Stryker's MDM/ADM clearance is manufactured at 314 μ m, whilst the systems from Zimmer Biomet have clearances of 300 μ m.

For appropriate matching, it is important to know the inner size diameter of the BHR cup *in situ* (each outer diameter has two available inner diameters), and/or the outer diameter of the resurfacing head being removed to ensure appropriate inventory available at the time of surgery.

The following combinations show appropriate compatibility for off label usage (Table 1):

Zimmer Biomet 'Active' dual mobility system

 ArCom XL and E1 inserts are manufactured for use with G7 and Avantage acetabular systems and show compatibility with all the available BHR shell sizes. If, however, only the inventory to go with G7 is requested, then 48, 52, 56 and 58 sizes are not included.

Stryker 'X3' Dual Mobility System

- The X3 insert has sizes as manufactured for use with MDM/ADM acetabular systems and show compatibility with the following BHR shell sizes as below. Furthermore, according to Stryker representatives, a size 38 X3 is not available for use with the ADM shell but is with the MDM. Conversely, if the inventory is only requested for MDM cups, then outer diameter X3 liner sizes 40, 44, 50 and 56 are not included.
- X3 inserts outer diameters are sized 40, 42, 44, 46, 48, 50, 52, 54, 56 and 58 and are able to match with 46, 48, 50, 52, 54, 56, 58, 60, 62, 64 and 66 BHR cups.

Discussion

Registry data from around the world suggest the 15-year BHR revision rate to be 9.6% in Australia whilst the UK registry demonstrates a 10-year revision rate of 8.85%. The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) annual report from 2016 demonstrates a cumulative revision rate for the BHR in patients younger than 55 years of

Table 1 Potentially compatible components

BHR shell 'size'	BHR ID	MDM/ADM incorporating X3 inserts	G7/AVANTAGE incorporating ArComXL and E1 inserts
44/46 46/48 48/50 50/52 52/54 54/56 56/58 58/60 60/62 62/64 64/66	38 40 42 44 46 48 50 52 54 56 58	38† 40‡ 42 44‡ 46 48 50‡ 52 54 54 56‡ 58	38 40 42 44 46 48§ 50 52§ 54 54 56§ 58§

†Denotes the size 38 X3 that is compatible and thusly available with the MDM shell but not with the ADM. ‡Denotes those insert sizes that are used as part of the ADM but not the MDM system due to design parameters. §Denotes those insert sizes that are not used/available as part of G7 system due to design parameters. ADM, Anatomic Dual Mobility; Avantage, Zimmer Biomet; BHR, Birmingham hip resurfacing (Smith and Nephew); G7, Zimmer Biomet; MDM X3, Modular Dual Mobility (Stryker).

1.1% at 1 year, 2.0% at 3 years, 2.9% at 5 years, 4.4% at 7 years, 6.8% at 10 years and 9.6% at 15 years.⁷ The most common indications for revision within the first 18 months are femoral neck fractures (0.9–1.1%), aseptic loosening, infection and metallosis.¹⁵ Haynes *et al.* discussed options when revision for fracture or component loosening becomes necessary. These included femoral, acetabular or total component revision. As stated earlier, advantages of femoral-only revision include shorter operative time, decreased blood loss, decreased risk of infection and a faster return to activity. Furthermore, the use of a large diameter head increases jump distance which theoretically reduces dislocation rate. Preservation of acetabular bone stock at revision is also cited as a significant advantage.¹⁵

Dual mobility prostheses as analysed in this paper were found to demonstrate appropriate compatibility for use with an existing BHR acetabular component. The clearance space between the off label outer polyethylene dual mobility insert and BHR shell combinations was found to match closely the Smith and Nephew custommade implant.

Dual mobility hip arthroplasty has been in use for many years and is believed to provide similar longevity to conventional total hip arthroplasty. The dual mobility concept was introduced as an additional articulation to reduce the risk of dislocation and impingement without increasing clinical failure secondary to wear or loosening. It has perceived benefits in preventing and treating instability in the setting of primary or revision arthroplasty.¹⁶ The goal of the dual mobility design is to achieve a stable environment throughout the greatest possible arc of motion whilst causing minimal component wear. It contains two articulations in its design, the first of which is between the femoral head and the outer polyethylene liner and follows the behaviour of a hard on soft bearing. The second articulation is between the outer polyethylene insert and the metallic acetabular shell. This articulation acts as a safeguard against impingement between the femoral stem and the fixed acetabular cup. The true acetabular shell can be impinged upon only in more extreme motion events. The head-liner construct theoretically functions as a large femoral head which increases the head-neck ratio and subsequent jump distance prior to dislocation.

Dual mobility components, however, are not without complications, which include intra-prosthetic dissociation as well as accelerated polyethylene wear secondary to the presence of two discrete articulations as a source of third body particulate wear. Mitigating against this problem has been the introduction of highly crosslinked ultra-high-molecular-weight polyethylene which possesses a higher resistance quotient against abrasive and adhesive wear. More recently introduced vitamin E-impregnated polyethylene may absorb free radicals and improve the wear characteristics even further. These developments have reduced volumetric wear in standard implants^{16–19} and have been integrated into dual mobility systems in an effort to deal with potential accelerated wear issues.

As discussed above, Stryker Orthopaedics offers two dual-mobility systems to the Australian market, those being the Restoration ADM and MDM although according to the company, the former monobloc option is barely utilized. Coupled to each of these is the X3 Mobile Bearing system. The MDM/ADM options offer the same dual mobility femoral-sided option with the clearance measuring 0.314 $\,\mathrm{mm.}^{20}$

The X3 insert for MDM/ADM is annealed polyethylene with cobalt chromium (CoCr) head options in 22.2 or 28 mm (CoCr and ceramic options in 28 mm). Both are utilized for the dual mobility shell and have sleeve options to facilitate offset adjustment depending on the femoral stem incorporated. The C-taper is optioned in -2.5, 0, +2.5, +5 and the V40 -2.5, 0, +4 variants.

Across its Active dual mobility range, the Zimmer Biomet group offers standard and vitamin E infused, highly crosslinked polyethylene inserts. Femoral head options with the 'Avantage' acetabular system come as 28 mm in cobalt chrome or ceramic, and taper sleeve options exist for length adjustment (-6, -3, 0, +3 and +6).¹⁹

The G7 system utilizes BIOLOX (Zimmer Biomet) delta ceramic (28 mm only) and cobalt chrome (22.2 or 28 mm) heads. Taper sleeve options include -5, -3 and Std for 22.2 mm, and -6, -3, Std, +3 and +6 for the 28 mm. As mentioned previously, there are fewer sizing requirements and hence less dual mobility sizing options available with G7 when compared with monobloc Avantage system.

The Zimmer system dual mobility prostheses all have 300 μ m clearance, as stipulated following consultation with the company engineers.

Between 30% and 45% of all resurfacing revisions are performed for fracture or avascular necrosis of the femoral neck/head.²¹ This represents a significant portion of revisions that would benefit from a femoral-only revision.

The literature has documented a number of revision surgeries managed with femoral-only revisions utilizing dual mobility constructs when stable *in situ* Birmingham acetabular shells are present. Sandiford *et al.* in 2010^1 discussed revision surgery for *in situ* hip resurfacing. They found only one loose cup in their series of 20 revisions. The other 19 acetabular cups (due to lack of available appropriate bearing surfaces) had to be extracted from surrounding bone in a more technically demanding procedure risking significant acetabular bone loss. By comparison, the revision of the femoral component was more straight forward and similar to that of conventional hip arthroplasty.

Gardofolo *et al.*²² reported good results in single-component revision of large-head MoM total hip arthroplasties and hip resurfacings using insert options from the Active or MDM dual mobility systems, when accurately matched to the acetabular shell *in situ*. They stated outcomes of isolated femoral revisions were comparable to those of total component revisions.

Pritchett²³ reported 14 MoM hip resurfacings with femoral head size greater than 44 mm that underwent femoral side-only revision with dual mobility components. There were no complications or further revisions in this group.

The concept of off label use was further explored by Renner *et al.* in 2015.²⁰ They retrieved a series of BHR and ADM acetabular shells and then assessed clearance with appropriately sized X3 dual mobility inserts. This allowed comparison of clearances measured from dual mobility X3/ADM constructs with off label dual mobility X3/BHR combinations.

The dimensions of the Birmingham components were measured using a validated artificial hip profiler to take measurements. Inner diameters of both the BHR and ADM shells were taken along with the outer diameters of the inserts. Clearances were then calculated with average values of 0.314 mm (0.246-0.375) for X3/ADM combination compared with 0.234 mm (0.163-0.304) for the X3/BHR shell combination. Renner *et al.*'s data²⁰ when summarized showed 88.9% of calculated clearances with X3/BHR constructs above the 'safe' 200 µm recommended clearance threshold proposed by Uddin. It should, however, be noted that only 30.9% of the X3/BHR combinations overlapped with the X3/ADM constructs with respect to clearance measurements. The authors determined that although clearances with the X3 insert inside BHR shells were on average reduced when compared with ADM shell, the majority of combinations appeared to be safe. Furthermore, this paper concluded that our measured clearances were above Uddin's safe value (200 µm). Limitations of Renner et al.'s study included possible deformation of the prostheses on insertion and later extraction, along with general wear and tear whilst in situ which may affect true clearance measurements.

Understanding these results requires an understanding of fluid film dynamics in the context of peripheral distances between the ball and insert/shell components or 'clearance' and an acknowledgement of the differences between a 'hard' MoM bearing (BHR) and a 'soft' dual mobility bearing. In 2005, Reiker *et al.* stated that the form of lubrication between components was related to the fluid film thickness ratio which itself is consequent upon the outer diameter of the femoral head and inner diameter of the acetabular shell. They proposed a lamba coefficient to define the lubrication mode and using a form of Ringer's lactate, that appropriated synovial fluid along with components of various clearances, stated that with values greater than 3, there was a complete fluid film with insignificant contact between head and shell whilst with those less than 3, there was some contact between components and some resultant wear.²⁴

Clearance recommendations for MoM are different to those for meta-on-polyethylene bearing surfaces (BHR MoM optimized 200–300 μ m/dual mobility 330 μ m as per discussion with engineers from Smith and Nephew). In addition, there is the potential for accelerated frictional wear when two articulations are utilized in a dual mobility construct (femoral head and insert as primary/insert and acetabular shell as secondary).

Uddin⁶ attempted to examine contact pressures in dual mobility environments to obtain his recommended 200 μ m as a reasonable cut-off value for clearances and noted that contact pressures were generally much lower in dual mobility bearings at the secondary insert/shell articulation when compared with the primary head/ insert articulation. This is clinically relevant to a dual mobility construct in a preexisting BHR cup.

Renner *et al.*'s and Uddin's findings were called into question by Reiker in 2017²⁵ who appraised a series of tribology studies and concluded that high rather than low clearances in MoM total hip arthroplasty led to increased volumetric wear and subsequent metallosis. This highlights the limits of current understanding regarding optimal clearance values.

This conflict in the literature is further accentuated by hip simulator biomechanical studies that have also shown larger sized head MoM prosthetic articulations with smaller clearances yielded better wear properties when compared with smaller heads and larger clearances. This was thought to be due to the protective effect of fluid film lubrication influenced by these two parameters.^{26,27} Clearance recommendations, however, must take into account the limitations in manufacturing tolerances as well as the potential for deformation on insertion of a press fit shell which may further alter clearance (even physiological loading may potentially cause prosthetic deformation and clearance reduction²⁸). It has been found that this can, in some instances, lead to equatorial contact through a negative clearance between the head and the shell, increasing friction and accelerating wear rates.²⁹ This increased frictional torque may even cause jamming and lead to acetabular loosening. High clearance on the other hand, may lead to an increase in contact pressures and a higher rate of volumetric wear, thereby increasing particulate debris and potential metallosis.²⁵

In summary, optimal clearance values are still not completely understood although the consensus is that they should be small enough to achieve elastohydrodynamic lubrication but not so small as to allow equatorial seizing. Furthermore, as mentioned above, it is important to note that large head dual mobility polyethylene on metal bearings behave differently to MoM articulations and the recommended clearance differences between these bearing surfaces reflect this fact. Suffice it to say that the dual mobility wear profile demonstrates sufficient promise to argue for its use in femoral component-only revisions in the setting of a previous BHR.

Conclusion

This paper suggests best off shelf implant options for off label use of dual mobility constructs when used in femoral componentonly revisions with BHR *in situ* cups. Either the Zimmer Biomet Active articulation dual mobility or the Stryker X3 dual mobility systems offer good clearance measurements and appropriate sizing options to allow use with the expectation of long-lasting functional outcome in revision total hip arthroplasty. Important considerations for the treating surgeon in the context of a retained BHR cup include appropriate acetabular shell positioning and stability, accurate knowledge of BHR cup size inner diameter and BHR head size to allow accurate size matching, and appropriate available dual mobility inventory to allow a durable and successful femoral-sided only BHR revision.

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Conflicts of interest

None declared.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Figure S1. A 56-year-old male patient with a well fixed and stable Birmingham shell that had to be removed after a fracture surrounding the femoral component occurred following a fall.

Figure S2. A 50-year-old male patient with a well fixed and stable Birmingham shell that had to be removed following failure only of the femoral component after multiple falls.