

Title Page

Authors: Gulraj S Matharu^{1,2}, Hemant G Pandit¹, David W Murray¹, Ronan BC Treacy²

Title: The future role of metal-on-metal hip resurfacing

Addresses for authors

1. Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences,
University of Oxford, Oxford, United Kingdom
2. The Royal Orthopaedic Hospital, Birmingham, United Kingdom

Corresponding author details: Mr Gulraj S Matharu

gsm@doctors.org.uk Telephone: +44 07949 921545 Fax: not available

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences,
University of Oxford, Oxford, United Kingdom

Abstract

Purpose

To assess the 10 to 15 year outcomes of metal-on-metal hip resurfacing (MoM HR) when performed at designing and independent centres, and make recommendations for the future use of MoM HR.

Methods

Studies reporting 10 to 15 year outcomes for modern MoM HR devices from both designing and independent centres were reviewed. Outcomes from these studies were assessed to allow the formulation of recommendations for the future use of MoM HR.

Results

Two MoM HR designs, the Birmingham Hip Resurfacing (BHR) and Conserve Plus, have outcomes reported at a minimum of 10-years. The BHR was the only device with outcomes reported at a minimum of 10-years by both designing (overall survival of up to 95.8% at 15-years) and independent surgeons (overall survival of 87.1% to 94.5% at 10-years). Implant survival in these seven BHR studies was influenced by the pre-operative diagnosis (primary osteoarthritis had better outcomes), gender (male patients had better outcomes), and femoral component head size (larger sizes had better outcomes). In contrast to independent centres,

designing surgeons reported acceptable outcomes in female patients undergoing BHR.

Conclusions

There remains a role for MoM HR in young active male patients with primary osteoarthritis, provided the surgeon has sufficient experience in the procedure, the implant has an established record, and the patient is aware of the potential risks associated with MoM bearings and HR. Very experienced HR surgeons may also consider this procedure in females provided they meet the refined inclusion criteria described (including femoral head sizes of above 46mm).

Key words

hip resurfacing; indications; metal-on-metal; outcomes; survival

Introduction

Over the last 15 years there has been a worldwide increase in the use of metal-on-metal (MoM) hip arthroplasty followed by a sharp decline. Between 2005 and 2006, 35% of all primary total hip replacements (THRs) implanted in the United States had a MoM bearing [1]. The use of MoM bearings for hip arthroplasty in young and active patients was initially an attractive concept due to low wear rates [2], greater range of hip motion, and a lower risk of dislocation [3,4]. This has largely been surpassed in recent years by concerns regarding the high short-term failure rates of a number of MoM hip designs due to adverse reactions to metal debris (ARMD) [5-11]. In England and Wales, MoM THR and hip resurfacing (HR) once accounted for 10.9% (in 2008) and 10.8% (in 2006) of all primary THRs performed respectively, but in 2012 they accounted for 0.1% and 1.3% respectively of all primary THRs performed [12].

Although the role of MoM bearings in hip arthroplasty has been considered over the last two years [13,14], a number of studies have recently been published which may assist in defining the future use of MoM bearings. The high failure rates of large-diameter (36 mm and above) MoM THRs [7,8] are well above those recommended for continued implant usage [15]. Registry data reports a cumulative 8-year survival of all uncemented MoM THRs of 84.5%, ranging from 56.7% to 88.9% depending on implant design [12]. It is clear these devices should not be used in the future, and patients with these implants should remain under regular clinical surveillance [16]. In addition, although some studies have demonstrated good long-term outcomes with 28 mm MoM THRs [17-19], it appears they provide no advantage over traditional bearing surfaces whilst still harbouring the potential for ARMD. By contrast, the future of MoM HR has been less clear. Although a number of studies reported promising

early clinical results following modern MoM HR [20-25], one of the designing surgeons acknowledged caution was needed with HR until long-term results were available [20].

The present article considers evidence from both designing and independent centres reporting outcomes at 10 to 15 years following MoM HR. In addition, recommendations are made for the future role of HR.

Outcomes of hip resurfacing at 10 to 15 years

Only two MoM HR designs have outcomes reported at a minimum of 10 years [26-33]; the Birmingham Hip Resurfacing (BHR; Smith & Nephew, Warwick, United Kingdom) and the Conserve Plus (Wright Medical, Arlington, Tennessee, United States of America). The BHR is the most commonly used MoM HR device with an estimated 125,000 implanted worldwide [34]. It is also the only device with outcomes reported at a minimum of 10 years by both designing [26,27] and independent surgeons [28-32] (Table 1). The 10 year survivorship of 88.5% reported by the designing surgeon of the Conserve Plus HR [33] is just below the acceptable limit for continued implant usage [15].

As observed with other orthopaedic implants [35], better outcomes have been achieved for the BHR by the designing surgeons (overall survival of up to 95.8% at 15 years) [26,27] compared to independent surgeons (overall survival of 87.1% to 94.5% at 10 years) [28-32]. However, these results from independent centres are encouraging with overall BHR survival in all studies [28-32] broadly within the acceptable limits for continued implant usage as

recommended by the National Institute for Health and Clinical Excellence (NICE) [15]. These young and active patients have traditionally experienced unsatisfactory long-term results with conventional THR [36-38]. Registry data at up to 10 years similarly supports the continued use of the BHR implant, but not most other HR designs [12,39].

A recent publication claimed there is no future role for MoM HR [40]. However, this work predominantly focused on registry data [40], and did not specifically consider the good outcomes achieved by independent surgeons when using an implant with an established record [28-32]. This is important given the outcomes for HR in registries can be significantly influenced by the results of poorly designed implants [9,12,39], which may result in the formulation of incorrect conclusions for the future role of MoM HR. What has become clear over recent years is that the indications for HR are actually narrower than originally described [41]. The main factors which appear to influence the outcome of HR are pre-operative diagnosis, gender, and femoral component head size.

Following a review of outcomes in 3095 BHRs McMinn *et al.* observed inferior 10 year survivorship in patients with a pre-operative diagnosis of developmental dysplasia of the hip (DDH) (94%) and avascular necrosis of the femoral head (93%) compared to all other indications for BHR (98%) [42]. In DDH it is important to appreciate the often complex hip anatomy and pay particular attention to combined component anteversion, as if this is excessive ($>45^{\circ}$) it may lead to edge loading, increased wear, and subsequent device failure [42]. The 10 year findings from McMinn *et al.* have recently been confirmed at 15 years following BHR, leading the authors to modify their indications for performing HR [27,42].

Another study from a designing surgeon demonstrated the best results were achieved in patients with primary osteoarthritis [26]. In this cohort nearly half of all revised hips were in patients with diagnoses other than primary osteoarthritis, although only 32% of all BHRs were implanted for these indications [26]. Independent reports similarly have observed the best results at 10 years following BHR are in patients with a pre-operative diagnosis of primary osteoarthritis [30]. In addition, HRs performed for hip dysplasia were associated with an increased risk of ARMD in one study [43].

The relationship between gender and femoral component head size to HR outcomes appears to be complex. Females have a number of risk factors for HR failure, but especially failure due to ARMD. These include a pre-operative diagnosis of DDH, the need for smaller HR components, large downsizing of the head-neck ratio, allergies to metal, and increased hip range of movement which can cause edge loading, impingement, or different gait patterns [4,43,44]. All studies reporting BHR outcomes at a minimum of 10 years observed that females and/or patients with smaller femoral component head sizes had significantly inferior outcomes [26-32]. On balance it would appear that femoral component head size is the most important factor for all modes of HR failure combined, with studies demonstrating gender is no longer a significant prognostic factor for HR outcome when femoral head size is controlled for [31,45,46]. However, given anatomical differences between sexes, it is recognised most patients with small femoral component head sizes will be female.

Recent reports from independent centres and registry data recommend against performing HR in females [11,28,30]. Although the designing surgeons have reported significantly inferior

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3 results in females compared to males at up to 15 years [26,27], these are still well within the
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5 acceptable limits recommended by NICE [15]. When performed by the two designing
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7 surgeons BHR survival in females was 91.2% at 14 years (109 hips with primary
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9 osteoarthritis) [26] and 91.5% at 15 years (335 hips with all diagnoses) [27]. By contrast, the
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11 10 year to 12 year survival in female patients reported for the BHR in five independent
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13 cohorts ranged from 73.9% to 89.1% [28-32]. These independent results in females are
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15 inferior to both the proposed revision rates from NICE for continued implant usage [15] and
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17 the results achieved with conventional THR in this patient subgroup [12,39].
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25 In addition to the advantages of MoM hip bearings, such as low wear and dislocation rates [2-
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27 4], and the good to excellent survival outlined for the BHR at up to 15 years [26-32], there
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29 are a number of other potential benefits of HR in suitable patients which must be considered.
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31 Studies have demonstrated that HR is associated with a more normal gait pattern compared to
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33 THR [47]. Patients with HRs also appear to participate in a greater degree and intensity of
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35 sporting activities than THR patients [48]. In addition, two independent analyses have
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37 established that patients undergoing HR have a significantly reduced mortality at up to 10-
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39 years compared to those undergoing either cemented or uncemented THR, even when
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41 adjustment is made for confounding factors [49,50]. Furthermore, some authors suggest that
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43 revision surgery for failed HRs is relatively straightforward with similar outcomes obtained
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45 to those following primary THR [51-53].
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54 These advantages of MoM HR must be balanced against the potential disadvantages of this
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56 procedure. This includes the unique modes of failure for HR compared to THR, such as
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femoral neck fracture and femoral head collapse [12,42]. Other authors have observed poor outcomes following revision of MoM HRs especially for ARMD, which is likely due to the significant soft-tissue destruction seen in a number of these cases [54]. Outcomes of HR revision therefore appear to be dependent on the specific indication [54] and components revised [55]. Furthermore, due to the potential risk of ARMD associated with all MoM hip bearings, HR patients require more regular follow-up compared to conventional THR patients (including blood metal ion sampling and cross-sectional imaging) if they develop symptoms [16].

Future role of hip resurfacing

In light of the present evidence regarding the medium-term to long-term outcomes following MoM HR it is possible to define the indications for continued use. It is recommended the BHR implant is used given its established results at a minimum of 10 years. Other designs may be considered in the future if similar outcomes are obtained at a minimum of 10 years by both designing and independent centres, though present registry data suggests this will not be the case for most HR designs [12]. The surgeon must have sufficient experience with implanting HRs given the procedure is more technically demanding than conventional THR [56]. The patient must meet the previously described indications for HR (young and active, with adequate proximal femoral bone quality, and no renal function impairment) [41], but also have primary osteoarthritis and adequate proximal femoral anatomy to allow the use of head sizes above 46 mm [26]. Surgeons can perform HR in eligible male patients, though very experienced HR surgeons may also consider females for the procedure provided they meet all the aforementioned selection criteria. On occasions experienced surgeons may also wish to consider older patients for HR provided they are active and meet all other proposed

indications. This is because chronological age was not originally cited as an absolute contraindication to HR [41], with good medium-term to long-term outcomes reported by experienced surgeons in patients aged over 60 years [27,57]. In addition, although there have been some case reports of adverse outcomes in patients receiving staged bilateral MoM HRs [58,59], medium to long-term outcome studies for the BHR suggest bilateral implantation in suitable candidates is safe [26,27,30,60]. Therefore patients with a well functioning HR can be considered for a contralateral HR provided they meet all of the selection criteria and are aware of the potential risks associated with MoM articulations. If there are any concerns in such instances, THR with an evidence-based bearing surface would be the most appropriate alternative.

All patients considered appropriate for HR must undergo thorough pre-operative counselling. This should include explanation of: (1) the unique complications of HR (such as femoral neck fracture and femoral head collapse), (2) the potential for wear related complications associated with MoM bearings requiring investigation with blood metal ion sampling and cross-sectional imaging with revision surgery needed in certain cases, and (3) the unknown potential long-term adverse risks of systemic metal ion exposure. Such comprehensive counselling will allow patients suitable for HR to make informed decisions regarding their treatment.

Further long-term clinical studies are required in patients undergoing HR, especially from independent centres. These studies should include the BHR, but also devices which have shown some promise such as the Conserve Plus [33], and should include patients with

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3 bilateral MoM bearings to assess if this influences outcomes at extended follow-up.
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5 Establishing survival and functional outcomes at over 15 years follow-up will assist in
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7 refining patient selection for HR. It will also identify what the late modes of implant failure
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9 are for HR, and whether these differ to those following THR.
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16 **Alternative arthroplasty options**
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20 Given the only future role of MoM hip arthroplasty is for a subgroup of patients meeting the
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22 refined selection criteria for HR, it follows that consideration is needed regarding the type of
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24 THR patients who would have previously undergone MoM hip arthroplasty should receive.
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26 Popular bearing surfaces include ceramic femoral heads with ceramic or highly cross-linked
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28 polyethylene liners or metal heads with highly cross-linked polyethylene liners. Although
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30 these THR bearing surfaces have promising outcomes at up to 10 years [61-65], they must be
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32 used with caution until long-term results are established given late modes of failure may
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34 occur which could alter the indications for bearing usage.
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42 If MoM hip arthroplasty has taught the orthopaedic community anything, it would be to base
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44 implant choices on the best available evidence and not to extrapolate the results of one
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46 implant design to another. Recently, the use of large-diameter ceramic-on-ceramic bearings
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48 has been recommended in place of poorly performing MoM THRs [10]. However, in light of
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50 concerns that taper junction failures seen in MoM articulations may occur in non-MoM large-
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52 diameter THRs [66], the widespread usage of large femoral head sizes is not recommended in
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54 this time of uncertainty. Similarly, although the concept of modular implants appears an
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56 attractive solution for dealing with complex proximal femoral anatomy, it is important to
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remember metal ion release and corrosion may also occur at these modular junctions resulting in ARMD [67-69]. Modular implants should therefore not be recommended for routine primary THR and used with caution if deemed absolutely necessary.

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Conflict of interest

The author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article. In addition, benefits have been or will be directed to a research fund, foundation, educational institution, or other nonprofit organisation with which one or more of the authors are associated.

Table 1 Outcomes of the Birmingham Hip Resurfacing at 10 to 15 years when performed by designing and independent surgeons

First author and year of publication	Number of hips (patients)	Overall survival (95% C.I)	Survival in males (95% C.I)	Survival in females (95% C.I)	Additional findings
<i>Designing surgeons</i>					
Matharu 2013 [26]	447 (393)	94.1% (84.9-97.3) at 14 years	100% (100-100) at 14 years*	91.2% (68.6-98.7) at 14 years*	- Females and smaller femoral head sizes were risk factors for failure
Daniel 2014 [27]	1000 (886)	95.8% (95.1-96.5) at 15 years	98.0% (97.4-98.6) at 15 years	91.5% (89.9-93.2) at 15 years	- Hip dysplasia and AVN were risk factors for failure
<i>Independent surgeons</i>					
Coulter 2012 [28]	230 (213)	94.5% (90.1-96.9) at 10 years	97.5% (92.4-99.2) at 10 years	89.1% (79.2-94.4) at 10 years	- Females had higher failure rates
Holland 2012 [29]	100 (90)	92.0% (86.7-97.3) at 10-years	94.6% (89.4-100) at 10 years	84.6% (70.7-98.5) at 10 years	- Smaller femoral head size was a risk factor for failure
Murray	646	87.1%	94.7%	73.9%	- Females and smaller

2012 [30]	(554)	(83.0-91.2) at 10 years	(92.0-97.4) at 10 years	(63.6-84.2) at 10 years	femoral head sizes were risk factors for failure
Van Der Straeten 2013 [31]	250 (232)	92.4% (90.8-94.0) at 13 years	98.7% (97.5-99.8) at 13 years	79.8% (76.4-83.2) at 12 years	- No difference in survival between males and females after adjusting for femoral head size
Reito 2014 [32]	261 (219)	91.0% (89.0-93.0) at 10 years	93.1% (91.0-95.2) at 10 years	86.0% (82.1-89.9) at 10 years	- Females had higher failure rates

AVN = avascular necrosis; C.I = confidence intervals

* Patients with primary osteoarthritis and aseptic revision used as the endpoint for survival analysis.