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Modular Dual Mobility clinical evidence

Modular Dual Mobility (MDM) clinical evidence

MDM clinical summary

Hip instability and dislocations continue to be major causes of revisions in total hip arthroplasty (THA) patients[1]. Registry data shows that in primary THA, dislocation is the second most common reason for revisions[2], and in revision procedures, dislocation rates range from 4% - 30%[3]. Revision arthroplasty may present an increased burden to the healthcare system, with an average length of stay over 6 days and cost upwards of $54,000 in the US[4]. Even when dislocation is successfully treated with closed reduction, a US based study reported that the average added cost was over 25% of the primary THA procedure[5]. Dual mobility constructs have demonstrated success in enhancing the stability of THA[3,6,7], therefore these designs have potential to reduce this burden.

This document aims to summarise current clinical evidence on Stryker's Modular Dual Mobility design (MDM, Stryker, Mahwah, NJ, USA).

MDM in revision THA

The rate of rerevision due to dislocation after revision THA has been reported to be in the range of 7.4%-14.4%[10]. With such high rates of dislocations, an implant like MDM has potential to make a significant difference. Abdel et al. reviewed a series of 355 THAs that underwent revision for any reason and received either a dual mobility construct (146 THAs) or a 40-mm large femoral head (209 THAs)[7]. The subsequent frequency of dislocation in the dual mobility construct group was less (3%) than the large head group (10%). Rerevision for dislocation in the dual mobility construct group was also less frequent (1% vs. 6%). The authors concluded, **"When compared with patients treated with a 40-mm large femoral head, patients undergoing revision THA who received a dual mobility construct had a lower risk of subsequent dislocation, rerevision for dislocation, and reoperation for any reason in the first several years postoperatively. Those findings were present despite selection bias in this study to use the dual-mobility construct in patients at the highest risk for subsequent dislocation."**

Due to the unexpected nature of dislocations, they are often treated by closed reduction in the emergency room. In cases where closed reduction is unsuccessful, a reoperation may be performed, resulting in added financial burden to the health care system. Abdel et al. conducted a healthcare economic study to understand the costs associated with revisions[8]. They investigated the costs of dual mobility vs. large femoral head (40 mm heads) constructs in revision THA from a US healthcare payer perspective. A Markov model was constructed to analyze costs of subsequent re-interventions in patients who underwent revision THA with dual mobility (n=126) or large femoral head (n=176) implants. Model states and probabilities were derived from prospectively collected registry data and Medicare costs were estimated as the weighted-average national Medicare payment for revision THA. Private payer costs were estimated by using a multiplier of Medicare costs. Probabilistic sensitivity analysis examined the effect of combined uncertainty across all model parameters. The authors found that over a 3-year period following revision THA, re-interventions were performed in 11 (9%) dual mobility patients and 34 (19%) large femoral head patients. The authors found the dual mobility constructs were less costly to Medicare compared to large femoral head implants ($960 vs. $2,495, respectively), resulting in a cost differential of $1,536. The authors also found that dual mobility constructs were less costly to private payers compared to large femoral head implants ($1,642 vs. $4,253), resulting in a cost differential of $2,611. They concluded that dual mobility constructs utilised in revision THAs were associated with a significantly lower absolute risk of re-intervention (~11% lower) and lower healthcare payer costs (saving $1,500-$2,500 per case) compared to large femoral head constructs. The relative costs to the US healthcare systems, as determined by Abdel et al., are presented in **Figure 1**.

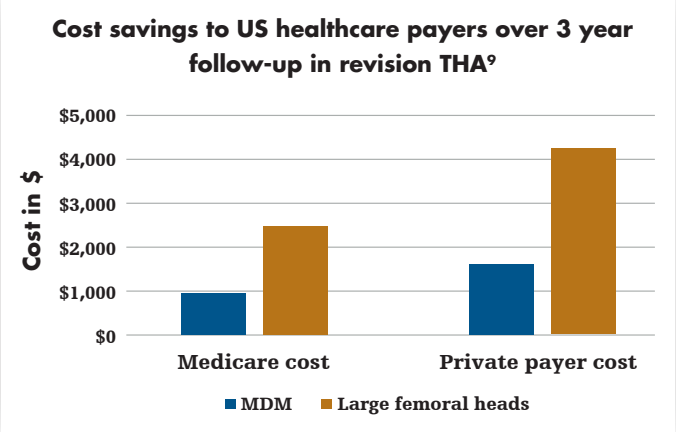

Figure 1: Comparison on cost savings between MDM and large femoral heads used in revision THA

As it is designed to enhance stability, MDM has also been used in revision patients that are at higher risk of dislocation. Sutter et al published data on the use of MDM as a revision THA construct to treat 64 patients mainly being revised for recurrent dislocation (42%), adverse local tissue reaction (25%) due to metal-on-metal THA, and re-implantations following infections (17%)[9]. At a 3-year follow-up within this patient population, of which 85% were considered 'high risk' for dislocation, there were only 2 instances of dislocation, which were treated nonoperatively. The results of this study led the authors to assert, **"in conclusion, these early results suggest that, in high-risk patients, this MDM component provided a low risk of dislocation and good overall survival".**

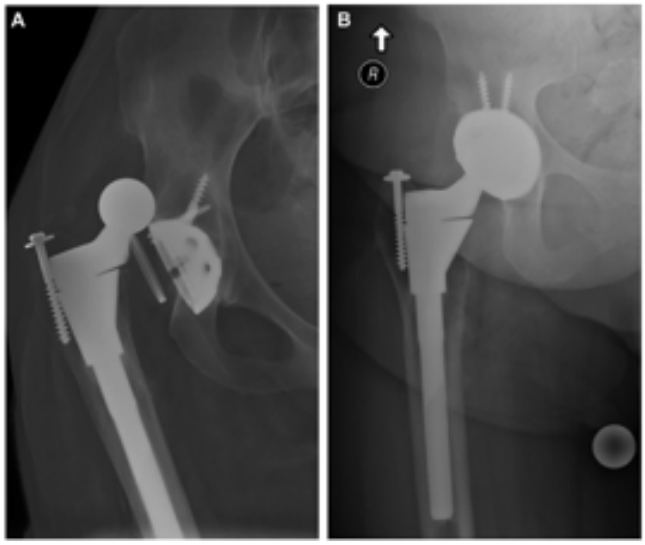

Figure 2: A) Radiograph demonstrating a 45-year-old woman with recurrent pain and instability following revision to a constrained liner and, B) the same patient status post revision to MDM acetabular components without pain or dislocation at 3-year follow-up.

MDM in primary THA

The rate of dislocation in primary THA patients is lower (0.5% - 4.8%)[10] than that reported in revision patients (7.4%-14.4%)[10]. Sotelo et al. reported that 63% of the dislocations were stable after closed reductions and only 37% required revision surgeries[5]. At their institution (Mayo Clinic, Rochester, MN), dislocation increased the cost of primary THA by 27% when closed reduction was successful, and by 148% when revision surgery was required[5]. Moreover, within primary indications, the dislocation rate may be higher in specific groups of patients. A meta-analysis found that THA patients with prior history of spinal fusion were at 2 times higher risk of dislocation and 3 times higher risk of subsequent revision[11]. Additionally, cognitive or neuromuscular disorder carry a dislocation risk of up to 13% while the literature has shown that the rate of dislocation in patients over 80 years of age was 9.2% at 1 year[10]. As MDM is designed to enhance joint stability, it has a potential to reduce the dislocation rate in these higher-risk patients. The key clinical results of dual mobility designs, both modular dual mobility (MDM) and anatomic dual mobility (ADM), in primary THAs are presented below.

In a multicentre study, Harwin et al published the results of using MDM in patients at higher risk of dislocation[1]. Older age (age ≥ 70 years), BMI ≥ 30 kg/m^2, a diagnosis of alcohol abuse, or neuro-degenerative conditions such as multiple sclerosis or Parkinson's disease were listed as high dislocation rate factors as shown in **Table 1**.

Table 1. Etiology of high risk for dislocation[1]

Age ≥ 70 years	112
BMI ≥ 30 kg/m2	190
Diagnosis of alcohol abuse	4
Parkinson's disease	4
Multiple sclerosis	2

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The survivorship to aseptic failure (n= 1) and all-cause (aseptic, n= 1; septic, n= 1) Kaplan-Meier acetabular component survivorships were 99.6% (95% confidence interval [CI], 99.1% to 99.9%) and 99.2% (95% CI, 98.5% to 99.9%), respectively **(Figure 3)**. One hip had impingement of an anteverted cup, resulting in neck notching, and required revision of the cup and stem. Another hip had a deep infection, which was treated with a two-stage revision procedure. There were no dislocations in this cohort. No progressive radiolucencies or component positional changes were seen on radiographic assessment. Patients reported a mean HHS of 92.5 (range, 47 to 100 points) at final follow-up.

The authors concluded, **"the reduced dislocation rates seen when comparing dual-mobility articulations have wide clinical application and may be of benefit to those who are at particularly high risk for instability, including patients aged 70 years or older, those with a BMI of 30 kg/m² or greater, those who have a diagnosis of alcohol abuse, or patients with neurodegenerative conditions."**

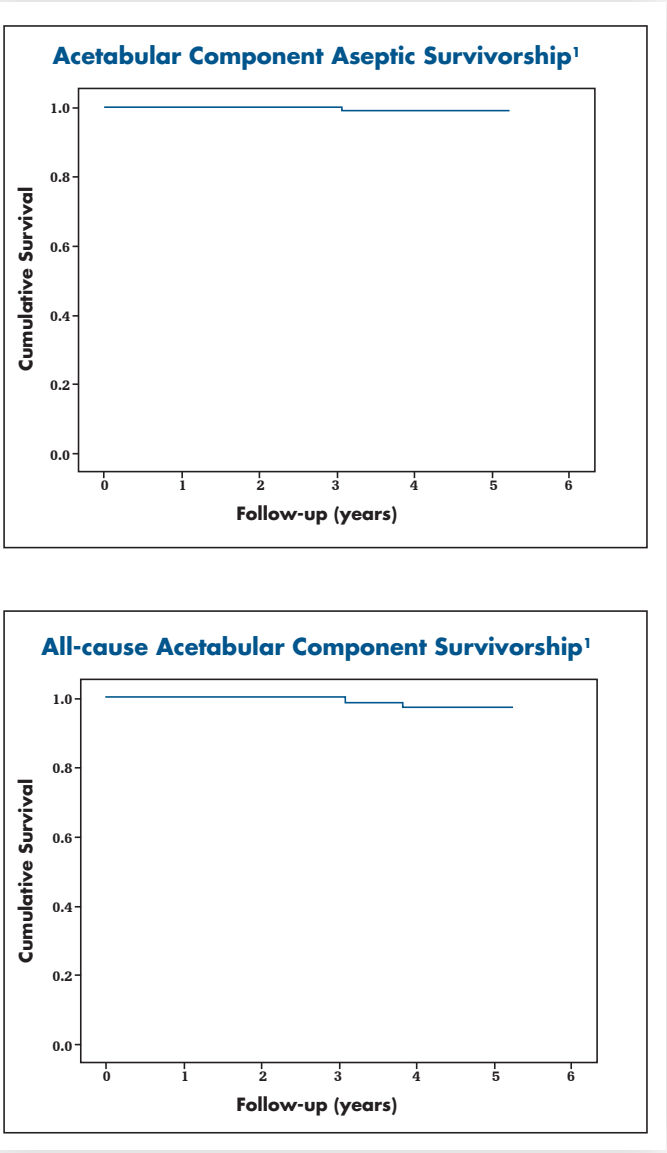

Figure 3: Aseptic and all-cause survivorship of acetabular components

In another study, Epinette et al. published the results of a prospective observational five year study across five centres in Europe and the US of 321 patients (MDM and ADM) with a mean age of 48.1 years[6]. Patients were assessed for causes of revision, hip instability, intra-prosthetic dissociation, Harris Hip Score and radiological signs of osteolysis. There were no dislocations and no intra-prosthetic dissociations. Kaplan Meier analysis demonstrated 97.51% survivorship for all cause revision and 99.68% survivorship for acetabular component revision at five years. Mean Harris Hip Score was 93.6. The authors concluded, **"contemporary annealed HXLPE DM demonstrate excellent early clinical, radiological, and survivorship results at five years of experience in a cohort of young patients that demand high performance from their implants."**

Rowan et al. published a matched cohort study of dual mobility and fixed bearing THA[12]. Each cohort had 136 patients with 3.2 and 3.4 years of follow up for dual mobility (DM) and fixed bearing (FB) groups respectively. Mean ages for DM and FB groups were 48.4 and 48.5 years respectively. The authors found that there were no dislocations or intraprosthetic dissociations (0%) in the DM group and 7 (5.1%) dislocations in the FB group (P = .01) at the mean follow-up of 3 years postoperatively **(Table 2)**. Two of the 7 unstable patients in the FB cohort were revised for recurrent instability (1.5%), and both eventually received a DM component. There was no difference in postoperative Modified Harris Hip Score between the DM (87.2 ± 16.6) and the control cohorts (87.9 ± 13.7; P = .78). In the discussion, the authors stated, **"These early results are encouraging for an active, high-demand set of patients and may mitigate concerns for instability in this patient population."**

Table 2. Patient details pertaining to those patients with fixed bearings that dislocated.[12]

Details	Patient #1	Patient #2	Patient #3	Patient #4	Patient #5	Patient #6	Patient #7
Gender	Female	Male	Female	Female	Female	Male	Female
Age at THA, y	46	41	54	47	51	44	48
Indication for THA	OA	Inflammatory arthritis	Dysplasia	AVN	OA	Post-traumatic	OA
Elevated liner used	No	No	No	No	No	No	No
Femoral head size, mm	32	36	28	32	36	32	32
Interval since THA, mo	20	24.5	1	0.03	25	1.5	24
Event leading to dislocation	Yoga	Fall	Bending	Fall	Bending	Bending	Bending
Direction of instability	Anterior	Posterior	Posterior	Posterior	Posterior	Anterior	Posterior
Shell inclination, degrees	57.53	49.11	43.18	49.37	45.94	43.19	49.45
Shell anteversion, degrees	28.57	11.89	16.51	25.31	17.29	28.16	15.82
Revised for instability	No	No	Yes	No	No	Yes	No

AVN, avascular necrosis; OA, osteoarthritis; THA, total hip arthroplasty.

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In the current healthcare environment, implant cost is an important consideration as well. Due to lower potential for dislocations[12], longer term benefits allowed for by dual mobility implants may translate into cost savings in primary THA. To that end, both European and US based researchers have investigated the cost effectiveness of dual mobility systems in primary THA.

Epinette et al. published a cost effectiveness model comparing dual mobility with fixed bearing designs for THA. They identified 80,405 THA patients and collected their outcomes over 4 years (2009–2012)[13]. Cost-effectiveness was assessed based on the costs of resources used for all consequences of prosthetic dislocation and paid for by the statutory health insurance system or other sources. The authors found that THA-DM was associated with a relative risk of dislocation of 0.4 versus THA-FB. This risk difference translated into 3,283 fewer dislocations per 100,000 patients with THA-DM **(Figure 4)**. The corresponding cost-savings for the 140,000 primary THA procedures done in France annually was 39.62 million Euros. A relative risk of 0.2 may yield annual cost-savings of 56.28 million Euros. In the probabilistic sensitivity analysis, THA-DM was the less costly option under all hypotheses, with potential maximum cost-savings of more than 100 million Euros per year in France. Although this study did not directly use MDM design, the cost savings were attributed to reduced dislocations with dual mobility designs.

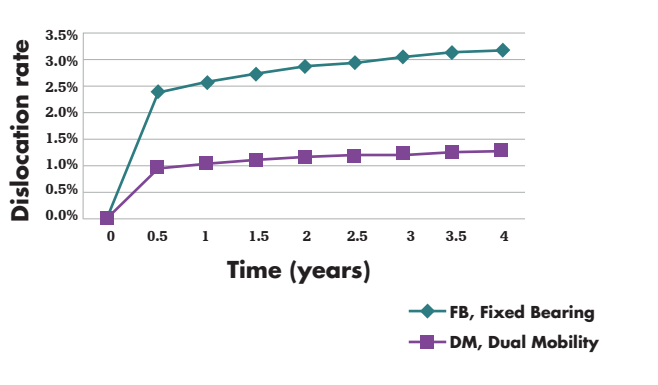

Figure 4: Dislocations with dual mobility vs. fixed bearing assuming a relative risk of 0.4 with the former[13]

In a US based study, Barlow et al. published their findings using Markov model analysis conducted from the societal perspective with use of direct and indirect costs[14]. Costs, expressed in 2013 U.S. dollars, were derived from the literature, the National Inpatient Sample, and the Centres for Medicare & Medicaid Services. Effectiveness was expressed in quality-adjusted life years (QALYs). The model was populated with health state utilities and state transition probabilities derived from previously published literature. In the base case, DM total hip arthroplasty showed "absolute dominance" over conventional total hip arthroplasty, with lower accrued costs ($39,008 versus $40,031 U.S. dollars) and higher accrued utility (13.18 versus 13.13 QALYs) indicating cost-savings. The authors found that DM total hip arthroplasty ceased being cost-saving when its implant costs exceeded those of conventional total hip arthroplasty by $1,023, and the cost-effectiveness threshold for DM implants was $5,287 greater than that for conventional implants. The authors concluded, **"This model determined that, compared with conventional bearings, DM implants can be cost-saving for routine primary total hip arthroplasty, from the societal perspective, if newer-generation DM implants meet specific economic and clinical benchmarks. The differences between these thresholds and the performance of other contemporary bearings were frequently quite narrow."**

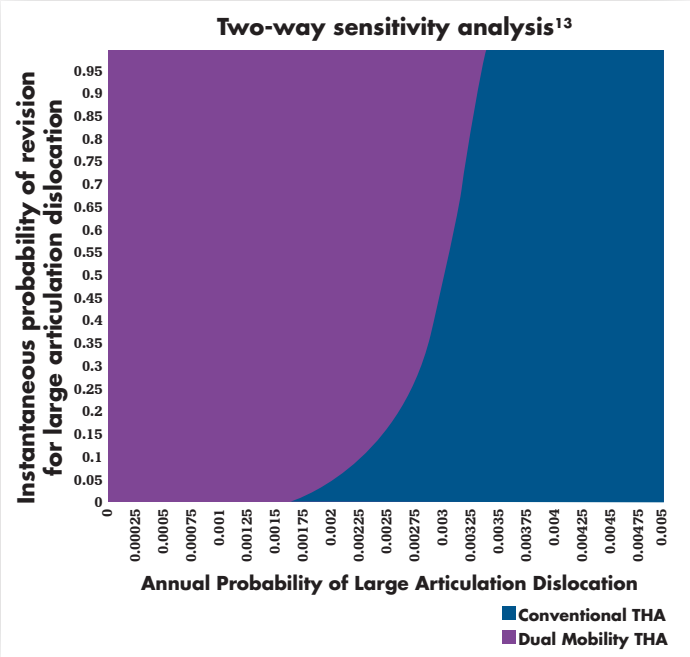

Figure 5: The chart shows results of the 2 way sensitvity analysis evaluating the probability of revision of DM in the setting of a large articulation dislocation compared with the probability of a large articulation DM dislocation. The blue area depicts the ranges of parameters for which conventional THA is preferred whereas the red areas depicts the parameters where DM is preferred.

MDM usage in femoral neck fractures

Displaced femoral neck fracture (DFNF) is a debilitating condition that is common in an elderly population. Surgical intervention is generally performed in these patients[12]. A variety of surgical treatment methods include internal fixation, bipolar hemiarthroplasty (BHA) and conventional THA[15]. Multiple clinical studies have demonstrated that arthroplasty results in better outcome in these patients when compared to internal fixation methods[15]. More recently, THA has been favoured over BHA in clinical literature[15,16]. Nonetheless, dislocation remains a concern in these patients. Blewitt et al. even reported a six-fold higher mortality rate of 65% within six months after BHA dislocation compared to a 10% mortality rate during the same period for those without dislocation[17]. These patients with higher dislocation risks may potentially benefit from a dual mobility construct.

Kim et al. conducted a retrospective cohort study with DFNF patients aged over 65 years who were treated either by BHA or dual mobility cups (DMC)[17]. After propensity matching, each group comprised 84 patients (168 patients in total) and was analyzed using peri-operative and post-operative parameters **(Table 3)**. Mean follow-up durations were 22.1 and 21.7 months in the BHA and DMC groups, respectively. The BHA group demonstrated significantly less intra-operative blood loss ($p = 0.001$) and a shorter length of operation ($p < 0.001$). However, there was no difference in one-year mortality ($p = 0.773$). The Harris Hip Score (HHS) was significantly higher ($p = 0.018$) in the DMC group. The dislocation rate was not different between the two groups ($p = 1.000$). The authors concluded, **"short-term observation showed DMC to be the preferred treatment over BHA with better clinical outcome, without disadvantages in mortality or dislocation rate."**

Table 3. Comparison between the two groups[17]

	BHA (n=84)	DMC (n=84)	p-value
Duration of follow-up (months)	22.1 ± 9.6 (12-48)	21.7 ± 10.4 (12-46)	0.829
Length of operation (minutes)	64.2 ± 22.4 (32-140)	77.3 ± 23.1 (45-143)	<0.001
Intra-operative blood loss (milliliters)	489.3 ± 189.7 (255-1010)	634.2 ± 337.2 (305-2050)	0.001
Harris hip score	79.3 ± 10.9 (35-99)	83.4 ± 11.5 (54-99)	0.018
Harris hip score subdomain pain	36.7 ± 4.7 (10-44)	39.7 ± 3.6 (20-44)	<0.001

Unfortunately, dislocations still occur in up to 10% of hemiarthroplasties performed for DFNF[18]. Furthermore, some studies report up to a 100% rate of acetabular articular cartilage and/or bony erosions from hemiarthroplasties, which can lead to progressive pain, dysfunction, and potentially acetabular bone loss **(Figure 6)**[18]. Conversion to THA with implantation of an acetabular component may be performed for the treatment of pain, as well as dislocations. Chalmers et al. reviewed conversion of 16 hemiarthroplasties to THAs with MDM construct compared with 13 conversions utilising large femoral heads (>36 mm)[18]. Survivorship free of revision was 100% in the MDM group compared with 92% in the large femoral head cohort at 2 years (P =0.7). One (8%) patient converted to a large femoral head underwent revision to a constrained liner for recurrent dislocations while no patients experienced a postoperative dislocation in the MDM group (P= 0.4). Harris Hip Scores improved from 54 to 82 (P < .01) in the MDM group, and from 52 to 86 in the large femoral head group (P < .01). The authors concluded, **"larger effective femoral heads used during conversion of hemiarthroplasties to THAs resulted in high survivorship free of revision, minimal complications, and excellent clinical outcomes at short-term follow-up."**

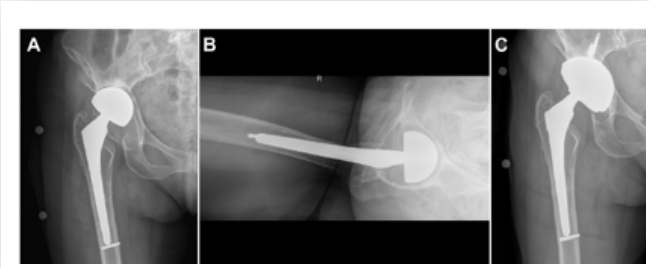

Figure 6: A 72-year-old female whom underwent a hip hemiarthroplasty at an outside facility for femoral head avascular necrosis 25 years before presenting at the author's with groin pain. She had significant acetabular bone loss (Paprosky Type IIB) with superior component migration as noted in the anteroposterior (A) and lateral (B) radiographs. She underwent a revision to a dual-mobility construct due to stability concerns. She remained stable at 5 years postoperatively (C).

Clinical data on MDM's modular junction

MDM allows for flexibility of acetabular shell options through the use of a modular cobalt chrome (CoCr) liner. Micromotion at modular junctions has been reported to cause fretting and corrosion at the femoral head and trunnion interface[19]. However, the magnitude of micromotion may be dependent on the locking mechanism which could be designed to minimise potential micromotion. There are several papers that have investigated the metal ion release in vivo as well as visual inspection in retrieved MDM liners.

Barlow et al. published a comparison of serum metal ion levels in well-functioning THA including both fixed and dual mobility bearings[20]. Serum cobalt (Co), chromium (Cr), and titanium (Ti) levels were measured in 80 non-consecutive patients with well-functioning unilateral total hip arthroplasty and compared among four bearing surfaces: ceramic-on-ceramic (CoC); ceramic-on-polyethylene (CoP); metal-on-polyethylene (MoP), and dual mobility (DM). The authors reported, **"No significant difference was found among serum Co and Cr levels between the 4 bearing surface groups (P =.0609 and P =.1577)."** **Figure 7** below illustrates serum metal ion levels in various bearing couples.

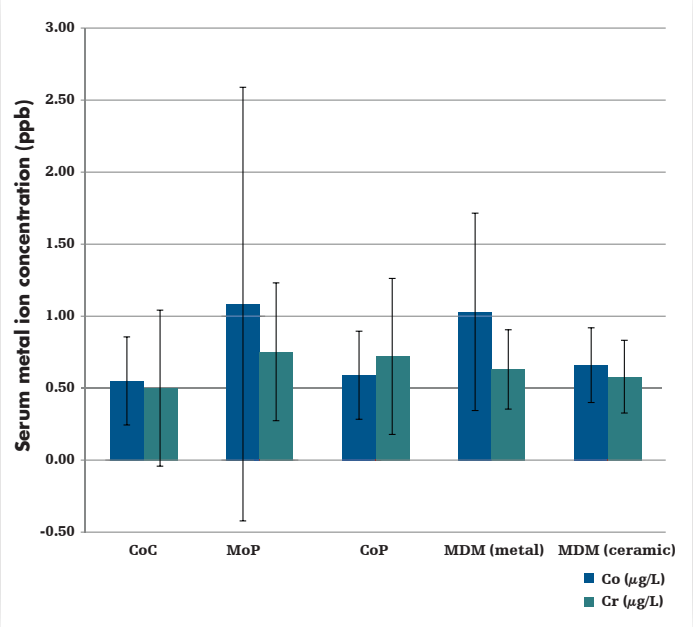

Figure 7: Bar graph of the mean serum Co and Cr metal ion levels for each bearing surface[20].

In another study, Markel and colleagues presented the study entitled, "Blood metal levels and leukocytes profiles in patients with modular dual mobility prosthesis" at the American Association of Hip and Knee Surgeons meeting in November 2017[21]. In this study, the change in Co and Cr metal ion levels, circulating subpopulation of monocytes and lymphocytes and

the cytokines profiles in MDM patients (n=41) at two years follow up were evaluated **(Table 4)**. They concluded that metal ion levels were within acceptable range at 2 years, and there was no evidence of an activated immune response as there was no increase of inflammatory monocytes or cytokines. The authors concluded, **"the modular mobile bearing implant should be considered safe relative to metal ion generation and inflammatory response. It presents an opportunity to use a large head and maintain a thick polyethylene-bearing surface. It is especially useful in revision or higher risk situations when added stability is desired and/or required."**

Table 4. Blood metal ion levels and circulating leukocyte profiles (n=41)[20]

Range	Mean ± SD, years
Chromium (Cr) (µg/L)	0.5 ± 0.-0
Cobalt (Co) (µg/L)	0.6 ± 0.21
CD3+ T cell (%)	71.44 ± 10.56
CD19+ B cell (%)	12.94 ± 9.50
CD4+ TN cell (%)	28.09 ± 16.97
CD45RA+ TCM cell (%)	21.53 ± 10.92
CD45 RA+ TEM cell (%)	41.44 ± 17.39
CD14+ T classical monocytes (%)	82.52 ± 5.83
CD16+ inflammatory monocytes (%)	9.30 ± 4.10

Tarity et al. have reported the findings of their retrieval study of MDM liners[22]. They assessed the backsides of 18 MDM components (LOI 15±23 months) for evidence of fretting and corrosion in polar and taper regions based on previously established methods. They collected and assessed 30 similarly designed modular inserts retrieved from MoM (66±34 months) total hip arthroplasties as a control. No specific pattern of fretting or corrosion was identified on the MDM inserts. The authors found both fretting and corrosion were significantly greater in the MoM cohort than the MDM cohort, driven by higher fretting and corrosion scores in the engaged taper region of the MoM inserts. The authors concluded, **"MoM components demonstrated more fretting and corrosion than MDM designs, specifically at the taper region, likely driven by differences in the taper engagement mechanism and geometry among the insert designs. The lack of significant fretting and corrosion observed in the MDM inserts are inconsistent with recent claims that this interface may produce clinically significant metallosis and adverse local tissue reactions."** The images in **Figure 8** show the differences between the liner types.

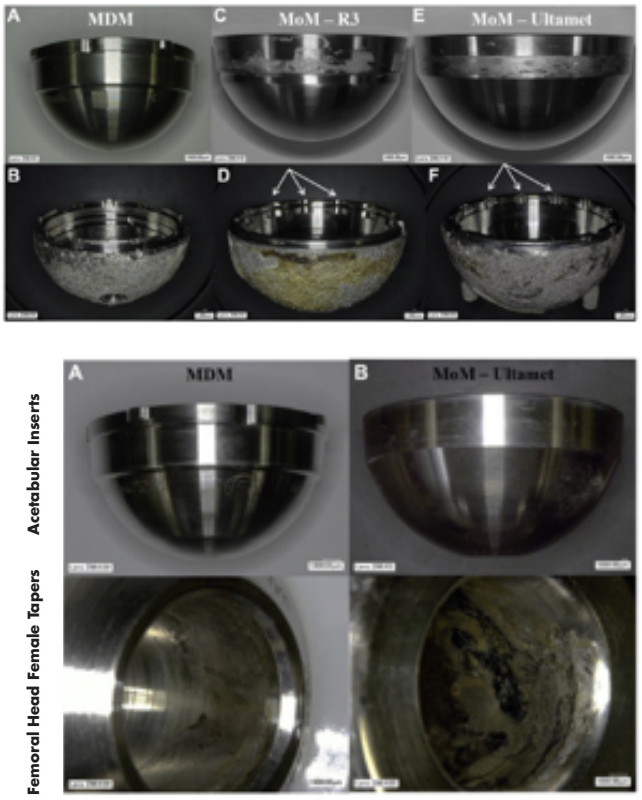

Figure 8: The top figure shows differences in fretting between MDM and MoM liners as well as differnces in the respective locking mechanisms. The bottom image shows that corrosion was significantly higher at the female taper of the femoral head than the backside of the corresponding CoCr insert for both (A) MDM (revised after 44 months in vivo for infection) and (B) MoM components (revised after 120 months in vivo for adverse local tissue reaction [ALTR])[22]

Summary

Since its launch in 2011, MDM has been used in over 150,000 patients[23]. The data presented on MDM indicates the potential to enhance stability in THA patients who possess a risk of dislocation. Cost-effectiveness data out of the US and France suggests that MDM may have the potential to be cost-saving by reducing the incidence of closed reductions, revisions, and re revisions as a result of dislocation.

Notes

Notes

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