stryker

Modular Dual Mobility
clinical evidence

Executive summary

Dual mobility constructs have demonstrated success in enhancing the stability of total hip arthroplasty (THA),[1,2,3] and their utilization continues to grow worldwide with 30.6% and 12.0% usage in revision and primary THA in the U.S., respectively.[4] With over **10 years of clinical history**, Modular Dual Mobility (MDM, Stryker, Mahwah, NJ, USA) has been implanted in **over 250K THA cases across 47 countries**[5] and is the most studied modular dual mobility implant in literature with over **50+ peer-reviewed publications**.[6]

This clinical and economic summary will review the design principles, clinical outcomes, indications and cost-effectiveness of Stryker's MDM design.

Clinical evidence

Contents

MDM design principles

The initial dual articulation system was based on the foundation of two orthopaedic concepts relating to total hip arthroplasty.[7] The following concepts are well-known and studied in the field:

Charnley low-friction arthroplasty

The Charnley low-friction arthroplasty (LFA) prosthesis has demonstrated both clinically and radiologically that smaller diameter heads produce lower torque forces in the shell and consequently less wear.[8]

With the dual mobility principle of two bearing surfaces, the inner 28/22mm head bearing and the polyethylene 'effective head,' the wear rates between dual mobility (DM) and 28mm fixed bearing (FB) are not statistically different.[9,10]

McKee-Farrar large diameter bearing theory

The large diameter bearing concept from McKee-Farrar recognized that a large diameter bearing is inherently more stable than a smaller diameter head.[11]

A potential advantage of dual mobility implants is that they can enhance hip stability by providing larger femoral head diameters that increase jump distance of the bearing, or the distance the femoral head must travel to dislocate from the implant (Figure 1).[12] This explains why there is a 59% greater jump height with MDM compared to a conventional THA with a 36mm head (Figure 2).[13] When compared against competitive designs in a benchtop analysis, Stryker's MDM achieved a 37% and 18% greater jump distance to Smith+Nephew OR3O™ and Zimmer Biomet G7® dual mobility, respectively.[14,15]

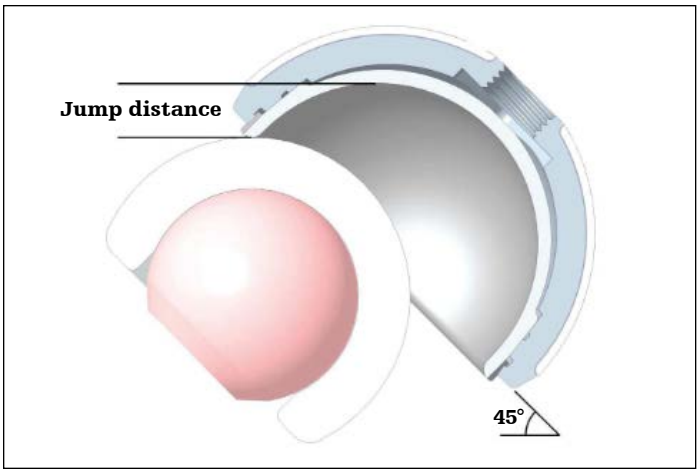
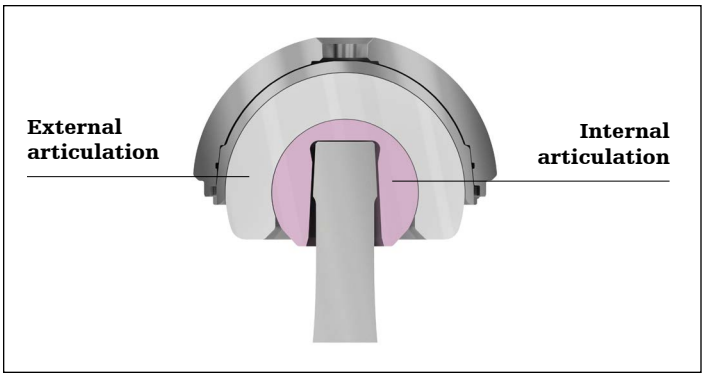


Figure 1.



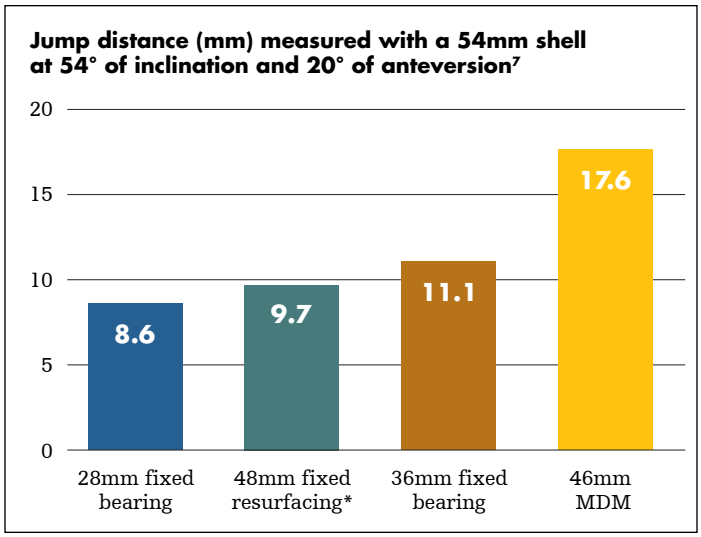


Figure 2. Jump distance comparison of MDM against fixed bearings and resurfacing shells

*Although resurfacing type shells have lower jump heights, they have the greatest ROM, which is needed when the native femoral neck is retained.

Outcomes

Minimum 7-year outcomes of dual mobility acetabular cups in total hip arthroplasty patients

Authors: Tarazi JM, Salem HS, Ehiorobo JO, et al.

Conclusion: At minimum of seven-year follow-up (7–8.5 yrs.), dual mobility acetabular cups contributed to excellent clinical outcomes and patient-reported outcomes with zero cup failures in a cohort of 143 patients.

Lack of early dislocation for dual mobility vs. fixed bearing total hip arthroplasty: A multi-center analysis of comparable cohorts

Authors: Dubin JA, Westrich GH.

Conclusion: Dual mobility demonstrated improved patient-reported outcome measures and lower rates of dislocation, readmission and revision at mean two-year follow-up in a 27-site multicenter study comparing 664 dual mobility to 218 fixed bearings as seen in Table 1.

Registry: Australian Joint Registry report [reported 4/24/2020]

Findings: The yearly cumulative percent revision for MDMs (all diagnoses) was 2.9% (2.1, 4.2) at five-and six-year time points for 289 and 109 MDMs, respectively. At the same time points, the yearly cumulative percent revision for all other primary total conventional hips was 3.3% and 3.6%, respectively (Figure 3).

	DM (N-664)	FB (N-218)	P value
Readmission within 30 days, n(%)	7 (1.05%)	6 (2.75%)	0.0992
Readmission within 60 days, n(%)	12 (1.81%)	6 (2.75%)	0.4098
Readmission within 90 days, n(%)	12 (1.81%)	6 (2.75%)	0.4098
Dislocation, n(%)	0 (0%)	2 (0.92%)	0.0609
Revision, deep joint infection, n(%)	2 (0.30%)	4 (1.83%)	NS
Revision, femoral component loosening, n(%)	1 (0.15%)		NS
Revision, femoral component subsidence, n(%)	1 (0.15%)		NS
Revision, perioprosthetic femoral fracture n(%)	5 (0.075%)	2 (0.92%)	NS
Revision, femoral impingement, n(%)	1 (0.15%)		NS
Revision, acetabular, n(%)	0 (0%)	0 (0%)	NS
Revision, femoral, n(%)	10 (1.51%)	6 (2.75%)	0.2452
Mortality	8 (1.20%)	5 (2.29%)	0.2471

Table 1. Postoperative complications and revisions in dual mobility (DM) to fixed bearings (FB)

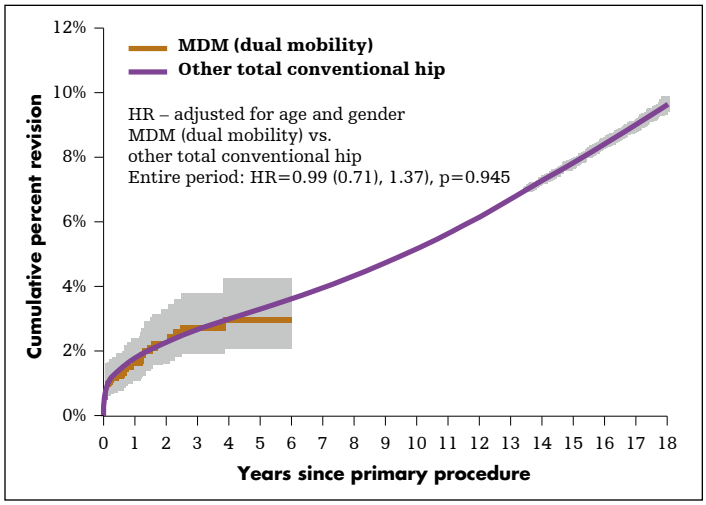


Figure 3. Cumulative percent revision rates between MDM and all other primary total conventional hips

Indications

Registry data shows that in primary THA, dislocation is the most common reason for revisions in the first five years, and in revision procedures, dislocation/instability is the most common reason for re-revision at 33.7%.[19] Moreover, within primary indications, the dislocation rate may be higher in specific groups of patients. This section aims to introduce complex cases that pose a high risk of dislocation. As MDM is designed to enhance joint stability, it has a potential to reduce the dislocation rate in these higher-risk patients.

Spine disease

Use of dual mobility cups in patients undergoing primary total hip arthroplasty with prior lumbar spine fusion

Authors: Nessler JM, Malkani AL, Sachdeva S, et al.

Conclusion: Zero dislocations were observed in a multicenter retrospective study of 93 primary hip patients implanted with dual mobility cups and with prior lumbar spinal fusions at mean follow-up of 2.7 years (Table 2).

Article	Type of construct	1° THA with prior LSF (n)	Dislocation (%)
Salib et al. 2019	Fixed bearing	97	5.2%
Malkani et al. 2018	Fixed bearing	1809	7.4%
Bedard et al. 2016	Fixed bearing	48	8.3%
Sing et al. 2016	Fixed bearing	9695	<3 levels, 4.26%
			≥3 levels, 7.20%
Nessler et al. 2019	Dual mobility	93	0%

THA = Total Hip Arthroplasty. LSF = Lumbar Spinal Fusion

Table 2. Dislocation rates following primary THA in patients with prior LSF

Neuromuscular disorder / Compliance risk

Dual mobility acetabular cups in primary total hip arthroplasty in patients at high risk for dislocation

Authors: Harwin SF, Mistry JB, Chughtai M, et al.

Conclusion: A multicenter study evaluating the performance of MDM in patients at a higher risk of dislocation reported 99.6% and 99.2% aseptic failure and all-cause Kaplan-Meier acetabular component survivorships, respectively. Older age (age ≥70 years), BMI ≥30 kg/m^2, a diagnosis of alcohol abuse or neurodegenerative conditions such as multiple sclerosis or Parkinson's disease were listed as risk factors associated with a high dislocation rate.

Displaced femoral neck fractures

Use of dual mobility acetabular component and anterior approach in patients with displaced femoral neck fracture

Authors: Jinnai Y, Homma Y, Baba T, Zhuang X, Kaneko K, Ishijima M.

Conclusion: In a retrospective study of 106 cases of femoral neck fracture, DM offered quick recovery of walking ability with no dislocation and low one-year mortality (Table 3).

	Year	Approach	Articulation	Age	12-month mortality rate (%)	Dislocation rate (%)	Follow-up period of dislocation (month)
Present study		DAA	DMC	81.0 (60-95)	5.7	0.0	12
Johnsson et al.	1996	Lateral	Single	80 (67-89)	N/A	8.7	24
Baker et al.	2006	Lateral	Single	74.2 (63-86)	N/A	7.5	41
Johansson et al.	2000	Dorsolateral	Single	84 (75-101)	26.0	22,0	24
Ravikumar et al.	2000	Posterolateral	Single	81.03	23.1	20.0	156
Bloomfeldt et al.	2007	Anterolateral	Single	80.5 (70.2-89.7)	6.7	0.0	12
Tarasevicius et al.	2010	Posterior	Single	74	21.4	14.3	12
Lim et al.	2016	Anterolateral/posterior	Single	70	6.0	7.0	N/A
Thurig et al.	2016	DAA	Single	75 (68-81)	16.7	2.3	20
Tarasevicius et al.	2010	Posterior	DMC	75	26.2	0.0	12
Bensen et al.	2014	Posterolateral	DMC	72.5 (43-98)	17.1	4.5	21.7
Nich et al.	2016	Posterolateral	DMC	86.7 (76.4-98.3)	19.0	4.4	24
Kim et al.	2018	Posterolateral	DMC	73.1 (65-90)	8.3	2.4	21.7

Table 3. Summary of the literature on the mortality and dislocation rates in different approaches and articulations.

Conversion of hip hemiarthroplasty to total hip arthroplasty utilizing a dual-mobility construct compared with large femoral heads

Authors: Chalmers BP, Perry KI, Hanssen AD, Pagnano MW, Abdel MP.

Conclusion: Conversion of 16 hemiarthroplasties to THAs with MDM construct compared with 13 conversions utilizing large femoral heads (>36 mm) resulted in 100% and 92% survivorship free of revisions at mean three-year follow-up in the MDM and large femoral head cohort, respectively.

Dual mobility hip arthroplasty provides better outcomes compared to hemiarthroplasty for displaced femoral neck fractures: a retrospective comparative clinical study

Authors: Kim YT, Yoo J, Kim MK, Kim S, Hwang J.

Conclusion: In patients over 65 years with displaced femoral neck fracture, short-term observation showed DM cups to be the preferred treatment over bipolar hemiarthroplasty with better clinical outcome, without disadvantages in mortality or dislocation rate.

Small anatomy / Dysplasia

Relative head size increase using an anatomic dual mobility hip prosthesis compared to traditional hip arthroplasty: impact on hip stability

Authors: D'Apuzzo MR, Nevelos J, Yeager A, Westrich GH.

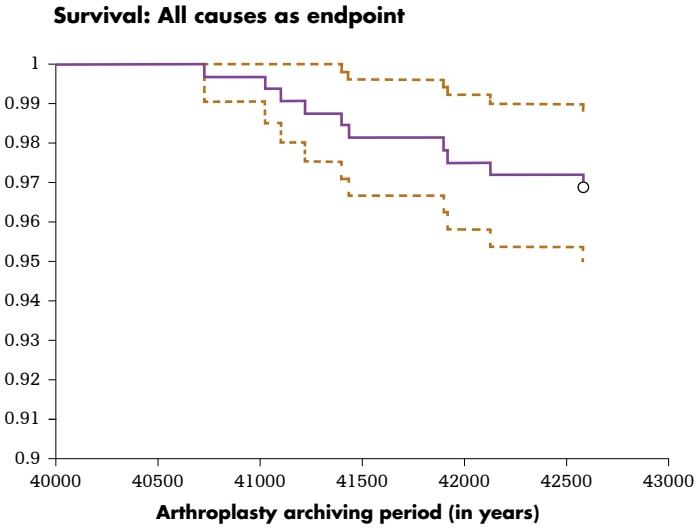
Conclusion: Computer modeling analysis evaluated two 78-patient matched cohorts (DM construct vs. fixed bearing prosthesis) for average head size and posterior horizontal dislocation distance (PHDD). The DM cohort had larger average head sizes and PHDD than the fixed bearing cohort by 11.5mm and 80% for cups ≤50mm, and 16.3mm and 90% for cups ≥58mm.

High demand / hyper-mobile

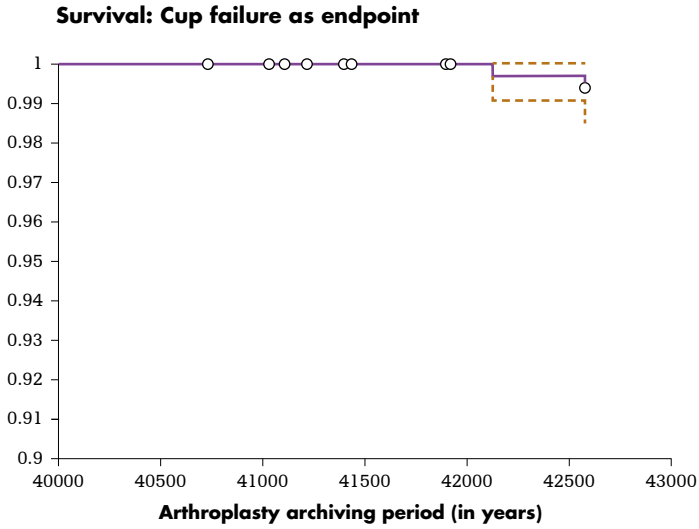
Early experience with dual mobility acetabular systems featuring highly cross-linked polyethylene liners for primary hip arthroplasty in patients under fifty five years of age: an international multi-centre preliminary study

Authors: Epinette J, Harwin SF, Rowan FE, et al.

Conclusion: No dislocations and no intraprosthetic disassociations at average 2.7-year follow-up were reported in a five-year multicenter study of 321 patients under 55 years of age. Kaplan-Meier analyses at five years demonstrated a 97.51% and 99.68% survival rate for revision due to any cause and DM cup-related failure, respectively (Figure 4).



Kaplan-Meier survivorship curve demonstrating 97.51% (0.958-0.992) DM THA survival at five years with revision for all causes as endpoint. y-axis: years.



Kaplan-Meier survivorship curve demonstrating 99.68% (0.985-1) DM THA survival at five years with revision due to DM cup-related failure as endpoint. x-axis: percent remaining. y-axis: years.

Figure 4. All cause and DM cup-related survivorship

Modular dual mobility total hip arthroplasty is a viable option for young, active patients

Authors: Barrack RL, Nunley RM, Lawrie CM.

Conclusion: At minimum five-year follow-up, modular dual mobility showed encouraging midterm survivorship with minimal concern for corrosion and metal ion release in a 43-patient cohort of young (18-65 years of age), active adult patients receiving primary THA treatment.

Dual-mobility vs fixed-bearing total hip arthroplasty in patients under 55 years of age: a single institution, matched-cohort analysis

Authors: Rowan FE, Salvatore AJ, Lange JK, Westrich GH.

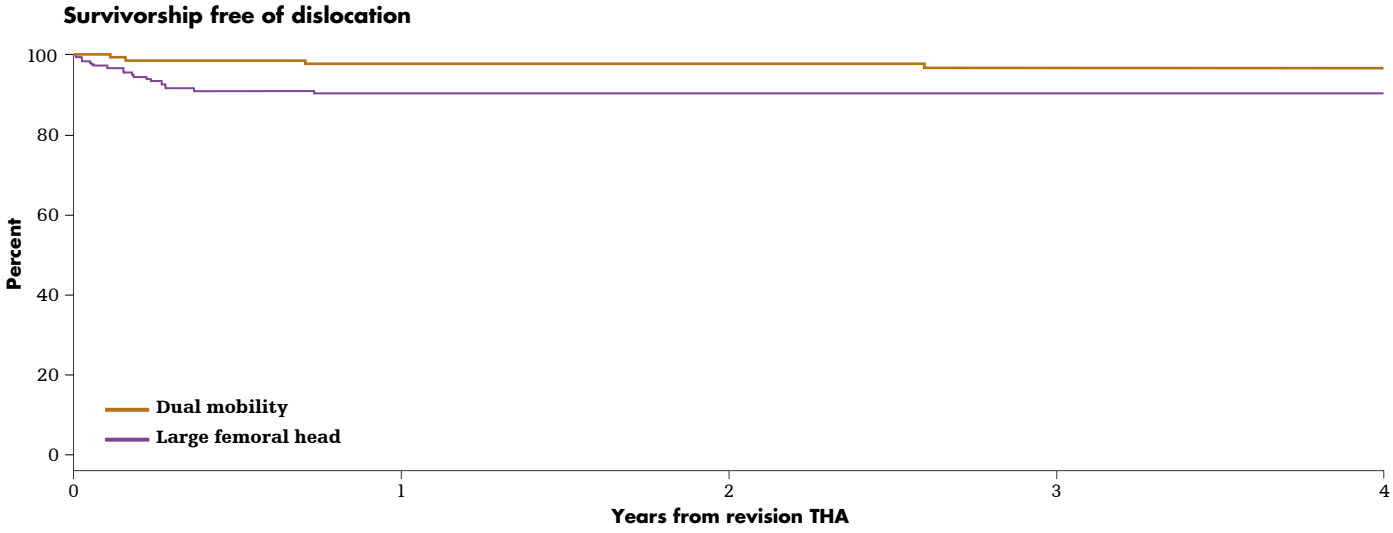
Conclusion: A matched cohort study comparing dual mobility and fixed bearing THA in a cohort of 136 patients found that there were no dislocations or intraprosthetic dissociations (0%) in the DM group and seven (5.1%) dislocations in the FB group (P = .01) at a mean follow-up of three years.

Revision THA

Otto Aufranc Award: Dual-mobility constructs in revision THA reduced dislocation, re-revision, and reoperation compared with large femoral heads

Authors: Hartzler MA, Abdel MP, Sculco PK, Taunton MJ, Pagnano MW, Hanssen AD.

Conclusion: A study of 355 revision THAs (146 MDMs vs. 209 40 mm large femoral heads) demonstrated a postoperative dislocation rate of 3% in the MDM cohort vs. 10% in the large femoral head cohort as seen in Figure 5.



Survival free of dislocation is demonstrated. The majority of dislocations occurred within the first year of re-revision.

Figure 5. Survivorship free of dislocation between THAs implanted with dual mobility and large femoral heads

Dual mobility bearing articulations result in lower rates of dislocation after revision total hip arthroplasty

Authors: Li WT, Kozick Z, Sherman M, Restrepo C, Smith EB, Courtney PM.

Conclusion: In a retrospective review of 267 patients who underwent revision, even with a selection bias of using dual mobility for patients at high risk of instability, patients who received an MDM bearing had a 4x reduced incidence of dislocation (2.1%, vs. 8.7% for conventional polyethylene single bearing, P=0.067) at the mean follow-up of 37.8 months.

Outcome of dual mobility constructs for adverse local tissue reaction associated abductor deficiency in revision total hip arthroplasty

Authors: Klemt C, Smith EJ, Oganesyan R, Limmahakhun S, Fitz D, Kwon Y.

Conclusion: At four-year follow-up, dual mobility had significantly lower dislocation rates compared to conventional articulations and constrained liners in 338 revision cases due to adverse local tissue reaction (ALTR).

Outcomes of modular dual mobility acetabular components in revision total hip arthroplasty

Authors: Sutter EG, McClellan TR, Attarian DE, Bolognesi MP, Lachiewicz PF, Wellman SS.

Conclusion: A retrospective review of 64 revision cases demonstrated three-year survival rates of 98% with failure defined as aseptic loosening and 91% with failure as any reason. No patient had a revision for dislocation.

Utilizing dual mobility components for first-time revision total hip arthroplasty for instability

Authors: Lange JK, Spiro SK, Westrich GH.

Conclusion: A study evaluating 40 patients for first-time revision THA for recurrent instability carried a re-dislocation rate of 5% and an all-cause re-revision rate of 10% at average three-year follow-up.

Modularity

Registry: Australian Joint Registry report [reported 4/24/2020]

Findings: There were zero revisions for metal-related pathology in 1608 MDMs at follow-up up to 7.9 years.

Dual mobility acetabular systems for total hip arthroplasty: a multicenter study and technique report

Authors: Salem HS, Harwin SF, Westrich GH, Delanois RE, Mont MA.

Conclusion: A multicenter study evaluating 941 primary and 381 revision THA cases with a dual mobility liner reported normal serum ion levels and no clinical complaints at five- and seven-year follow-up for both cohorts. Primary cases showed a 0.21% rate for both liner malseating and dislocation as seen in Table 4. The revision cohort exhibited no cases of malseating and a 1.3% dislocation rate.

Surgeon*	Malseating		Dislocation	
	Primary (n=941)	Revision (n-381)	Primary (n=941)	Revision (n-381)
Surgeon 1	0	0	0	0
Surgeons 2 and 3	0	0	1 (0.11%)	2 (5.2%)
Surgeon 4	2 (0.21%)	0	1 (0.11%)	3 (0.79%)

Table 4. Comparisons of malseating and dislocation with dual mobility implants in primary and revision THAs

*Some patients from each surgeon partially overlap with patients in previously published studies.

Uniformly low serum cobalt chrome levels after modular dual-mobility total hip arthroplasties with ceramic heads: a prospective study in high-risk patients

Authors: Chalmers BP, Mangold DG, Hanssen AD, Pagnano MW, Trousdale RT, Abdel MP.

Conclusion: No elevated Co levels were observed in a prospective study of 24 patients who received an MDM and ceramic femoral head in revision and complex primary THA at a mean of four years, including seven patients revised specifically for ALTR.

Modular dual mobility total hip arthroplasty is a viable option for young, active patients

Authors: Barrack RL, Nunley RM, Lawrie CM.

Conclusion: At minimum five-year follow-up, modular dual mobility showed excellent midterm survivorship with minimal concern for corrosion and metal ion release in a 43-patient cohort of young (18-65 years of age), active adult patients receiving primary THA treatment.

What are normal metal ion levels after total hip arthroplasty? A serologic analysis of four bearing surfaces

Authors: Barlow BT, Ortiz PA, Boles JW, Lee Y, Padgett DE, Westrich GH.

Conclusion: No significant differences in serum metal ion levels were observed at greater than one-year follow-up for MDM, ceramic-on-X3, metal-on-X3 and ceramic-on-ceramic in a study of 80 patients who underwent unilateral THA as seen in Figure 6.

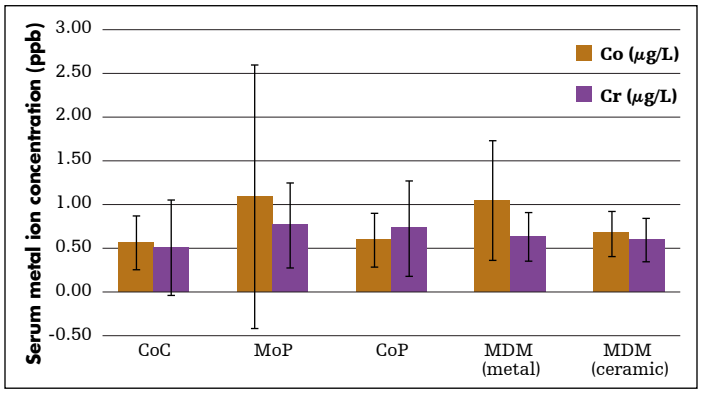


Figure 6. Bar graph of the mean serum Co and Cr metal ion levels for each bearing surface

Blood metal ion levels, leucocyte profiles, and cytokine profiles in patients with modular dual-mobility hip prosthesis: early results from a prospective cohort study

Authors: Markel DC, Bou-Akl T, Rossi MD, Pizzimenti N, Wu B, Ren W.

Conclusion: In a study of 39 patients with follow-up to two years, stable blood metal ion levels were observed with no reports of activated immune response (presence of elevated inflammatory biomarkers).

Fretting and corrosion at the backside of modular cobalt chromium acetabular inserts: a retrieval analysis

Authors: Tarity TD, Koch CN, Burket JC, Wright TM, Westrich GH.

Conclusion: In a retrieval analysis of 18 MDM liners and 30 metal-on-metal (MoM) inserts, there was no specific pattern of fretting/corrosion in MDM, and MoM showed statistically significantly higher fretting/corrosion.

A retrieval analysis of impingement in dual-mobility liners

Authors: Scott TP, Weitzler L, Salvatore A, Wright TM, Westrich GH.

A retrieval analysis demonstrated that DM liners significantly reduce the rate of impingement [21.5% (20/93)] when compared to fixed-bearing liners [77% (75/97)].

Modular dual-mobility liner malseating: a radiographic analysis

Authors: Chalmers BP, Dubin J, Westrich GH.

Conclusion: In a retrospective analysis of 305 MDM liner cases, no MDM liners disassociated, and no patients experienced a dislocation at one-year follow-up. MDM liner malseating was low at 1% with no short-term clinical implications (Figure 7).

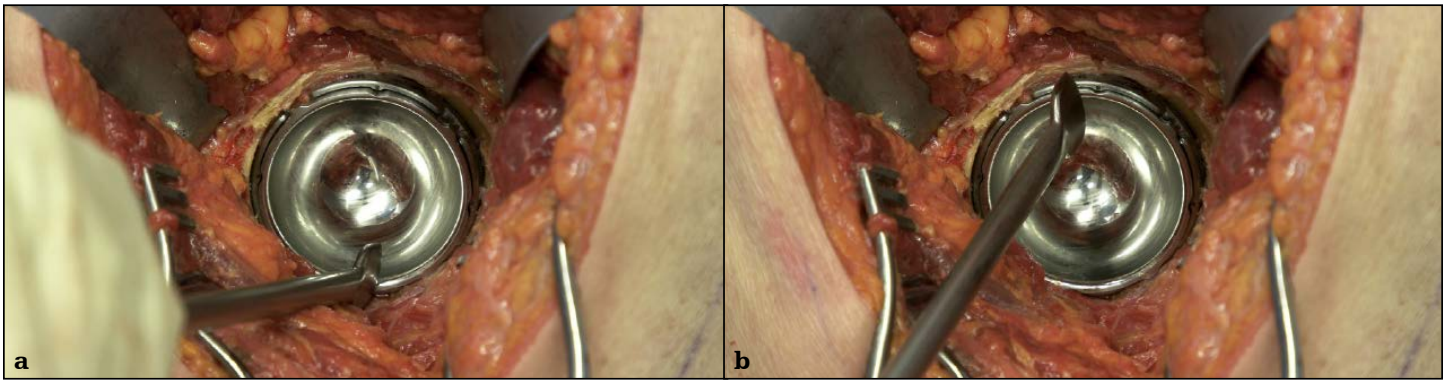


Figure 7. Photographs of the four-quadrant test performed intraoperatively to assess for any incomplete MDM liner seating. Using a cup rim impactor, the rim was firmly impacted at 6 o'clock (a), 12 o'clock (b), 3 o'clock and 9 o'clock, watching the opposite quadrant during impaction to ensure that the liner does not toggle

Cost-effectiveness

The cost-effectiveness of dual mobility implants for primary total hip arthroplasty: a computer-based cost-utility model

Authors: Barlow BT, McLawhorn AS, Westrich GH.

Conclusion: The authors noted that 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 quality-adjusted life years) indicating cost-savings in primary THA [surgeon-authored modeling using published outcomes data and established Medicare/Medicaid costs].

Cost analysis of dual-mobility versus large femoral head constructs in revision total hip arthroplasty

Authors: Abdel MP, Miller LE, Hanssen AD, Pagnano MW.

Conclusion: DM constructs utilized in revision THAs were associated with a significantly lower absolute risk of reintervention (~11% lower) and lower healthcare payer costs (saving approximately $1,500-$2,500 per case at year three post-revision) compared to large femoral head constructs [surgeon-authored modeling using published outcomes data and established Medicare/Medicaid costs].

Cost analysis of dual-mobility constructs in revision total hip arthroplasty: a European payer perspective

Authors: Abdel, M. Miller, L. Hull, S. Coppolecchia,A. Hanssen, A. Pagnano M.

Conclusion: European healthcare payers. At midterm follow-up, DM constructs used in revision THAs were associated with a significantly lower risk of reintervention, which translated to lower health care payer costs compared with LFH constructs among European healthcare payers.

Cost-effectiveness model comparing dual-mobility to fixed-bearing designs for total hip replacement in France

Authors: Epinette J, Lafuma A, Robert J, Doz M.

Conclusion: In a probabilistic sensitivity analysis comparing dual mobility with fixed bearing designs in 80,405 THA patients over four years, THA with a dual mobility cup was the less costly option under all hypotheses, with potential maximum cost-savings of more than 100 million Euros per year in France (Figure 8). Although this study did not directly use the MDM design, the cost-savings were attributed to reduced dislocations with dual mobility designs.

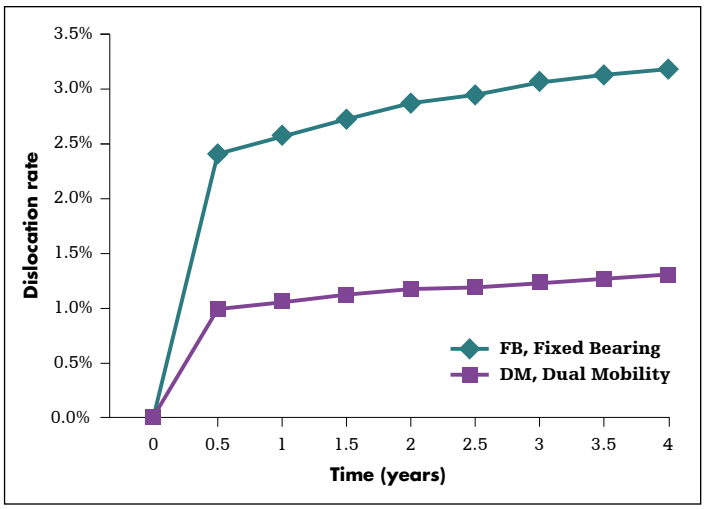


Figure 8. Dislocations with dual mobility vs. fixed bearing assuming a relative risk of 0.4 with the former

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