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Modular Dual Mobility Acetabular System

Design rationale

Addressing instability with dual mobility

Worldwide patient outcomes are affected by instability, which is a significant complication of total hip arthroplasty (THA).[1] National joint registries and meta-analyses indicate that hip dislocation is one of the most common causes of THA failure in both primary and revision procedures.[1-4] This has significant implications for future revision burden, especially with a growing number of THAs being performed on increasingly younger patients.[1]

Registry data shows that dislocation is the second most common reason for revisions of primary hip procedures,[5] and dislocation rates range from 4-30% in revision procedures.[3] The burden to the health economic system is higher when revisions occur, with an average length of stay over six days and cost upwards of $54,000 in the U.S.[6]

Constructs such as constrained liners and large femoral heads were designed to help address dislocation due to instability, but have had limited success in decreasing the postoperative dislocation rates.[2] Dual mobility constructs were developed in the 1970s and have demonstrated success in enhancing the stability of THAs.[1-4,7]

2019 Australian Orthopaedic Association National Joint Replacement Registry[5]

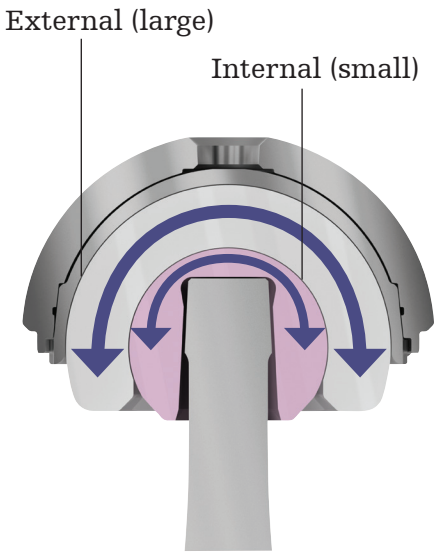
Reason for revision	Number	Percent
Loosening	3579	24.6
Prosthesis dislocation	3030	20.8
Fracture	3006	20.7
Infection	2647	18.2
Lysis	310	2.1
Pain	279	1.9
Leg length discrepancy	227	1.6
Malposition	209	1.4
Instability	192	1.3
Implant breakage stem	163	1.1
Implant breakage acetabular insert	131	0.9
Wear acetabular insert	121	0.8
Metal related pathology	120	0.8
Incorrect sizing	96	0.7
Implant breakage acetabular	92	0.6
Implant breakage head	45	0.3
Other	286	2.0
Total	**14533**	**100.0**

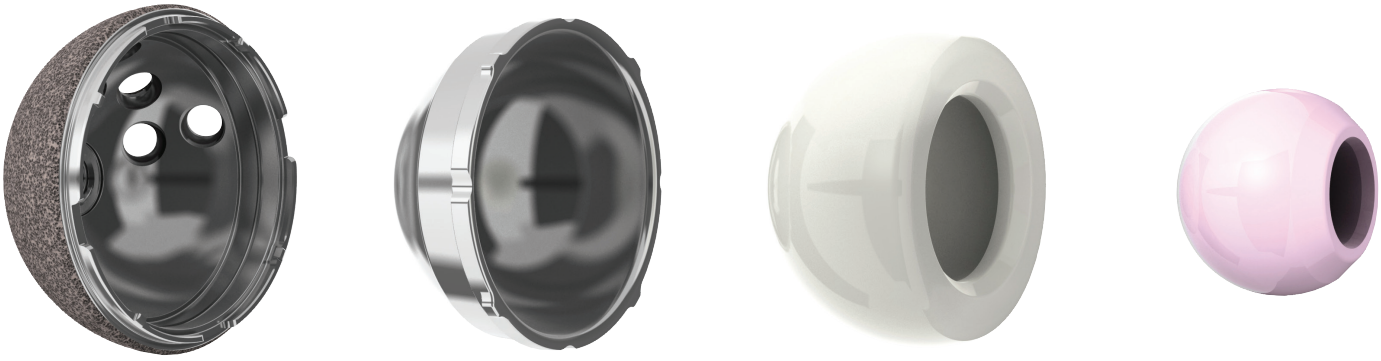
Modular Dual Mobility

Stryker's MDM consists of a modular cobalt chrome liner, a large diameter X3 polyethylene insert and a femoral head. The highly polished modular cobalt chrome liner can be assembled into any of Stryker's acetabular shells by using the Trident Locking Mechanism. X3 polyethylene has demonstrated annual in vivo wear of less than 10 microns per year, over 10 years, with no mechanical failures with conventional bearings.[8]

Together, these components result in a dual mobility device with two points of articulation – one between the X3 polyethylene insert and metal liner (external bearing), and the other between the X3 polyethylene insert and the femoral head (internal bearing). Primary motion occurs at the inner bearing while the outer bearing moves in cases of extreme range of motion, which may minimize wear,[9] reduce frictional torque[7] and increase stability.[7]

Two points of articulation





Clinical advantage of MDM:

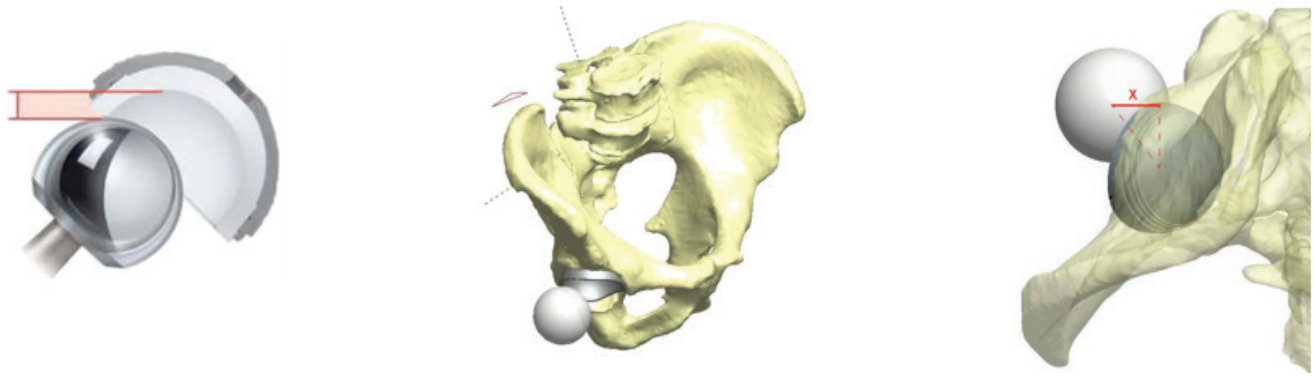
MDM offers stability[2-3,7] with:

- Versatility
- Clinical proof[1-4,10,11]
- Economic value[12]*

* Economic value and cost-savings based on U.S. data and indicative only. Cost-savings may differentiate across regions due to different healthcare systems, treatment plans and associated costs.

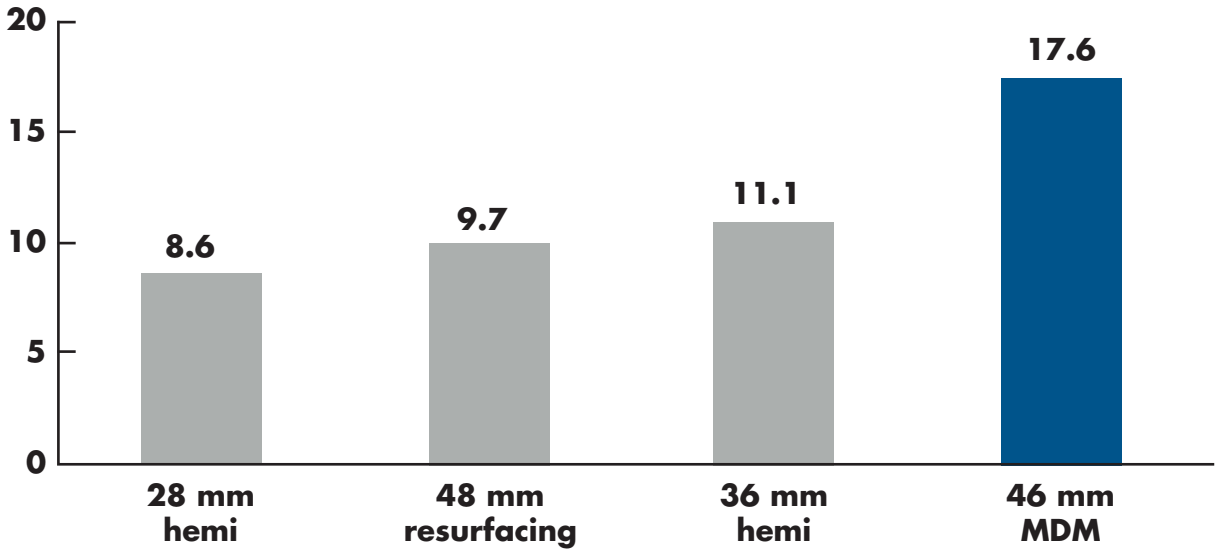
Stability:

- The X3 polyethylene inserts of the MDM system are available in large sizes offering increased jump distance – the distance the femoral head must travel to dislocate.[1] The greater the jump distance, the greater the stability of the hip.[13]
- Computer simulations of dislocation demonstrate that for a given shell size, the MDM design surpasses the jump height of a traditional fixed bearing.[7,14]
- When compared to a conventional THA with a 36 mm femoral head, MDM offers a 59% increase in jump distance.[7,14]



2D jump height (left) and 3D posterior horizontal dislocation distance: denoted X (center and right).[7]

Jump distance (mm) measured at 26° of pelvic tilt with a 54 mm shell at 45° of inclination and 20° of anteversion[7]



Measured in 3D posterior horizontal dislocation distance

Versatility:

MDM is a versatile bearing option, as its indications include both primary and revision cases.[1-4] It is a simple construct to use as it does not require a change in surgical technique and may be easily incorporated into a surgeon's practice.

MDM is versatile because it:

- May be used in primary and revision procedures
- Utilizes the Trident Locking Mechanism, allowing surgeons the flexibility to trial modular or fixed bearing options intraoperatively
- May be used with Trident, Tritanium, Trident II or the Restoration Anatomic Shell
- Offers the option to use cancellous bone screws

Potential applications for MDM

Revision:

- Dislocation

High-risk primary:

- Mental disability
- Neuromuscular disease
- Acute femoral neck fracture
- Spinal fusions
- Dysplastic hips
- Small acetabulums

Primary:

- High-demand patients

Clinical proof:

MDM launched in 2011, and has since had several studies published to show clinical success ranging from outcome data on stability to metal ion levels.

Stability

MDM has been shown to be clinically successful in preventing dislocations.[1-4]

The use of dual-mobility bearings in difficult hip arthroplasty reconstructive cases – Mont et al.

- In a revision setting, patients with dual mobility had lower dislocation and aseptic loosening rates compared to the control group.[2]
- MDM addressed stability in a wide array of indications, ranging from revisions to high-risk primary procedures.
- Authors of the study recommend the use of dual mobility in cases of recurrent dislocation, for revision arthroplasties or for patients at a high risk of dislocation in primary arthroplasty.[3]

Dual-mobility constructs in revision THA reduced dislocation, rerevision, and reoperation compared with large femoral head – Hatzler et al.

- Revision THA patients with a dual mobility construct had a lower risk of subsequent dislocation, lower risk of rerevision for dislocation, and lower risk of reoperation for any reason at 3.6 years of follow-up when compared to patients treated with a 40 mm femoral head.[4]
- Surgeons may consider expanding the role of dual mobility constructs in contemporary revision THAs as dual mobility constructs have shown to lower the risk of subsequent dislocation, rerevision and reoperation.[4]

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 – Epinette et al.

- The study evaluated dual mobility constructs in patients 55 years and younger and concluded that MDM demonstrated clinical data and may reduce stability and wear in the long run.[1]

Modularity

Modular junctions are a consideration with implant selection for reasons of strength, material performance and corrosion. In fact, clinical studies have demonstrated that the modularity of the MDM liner in terms of metal ion release have been shown not to be an issue,[10] and no difference has been shown in metal ion levels when compared to conventional constructs.[11]

Metal ion levels in patients with modular acetabular hip components, matching CrCo liners with titanium cups – Epinette, J.

- This two-year study demonstrated that modularity was not an issue with MDM, due to an optimal locking mechanism design.[10]

What are normal metal ion levels after total hip arthroplasty? A serologic analysis of four bearing surfaces – Barlow et al.

- This study compared metal ion levels across four bearing surfaces: ceramic-on-ceramic, ceramic-on-polyethylene, metal-on-polyethylene and MDM, which was divided into metal and ceramic heads. Results showed that there was no difference in metal ion levels across all bearing options.[11]

Economic value*:

In a Markov model analysis out of the United States, MDM exhibited "absolute dominance" with cost-effectiveness over conventional THA.[12]

Dual mobility implants are cost-saving for primary THA: A cost-utility analysis using direct and indirect costs – Barlow et al.

- This study compared outcomes of MDM and conventional constructs in the U.S., along with costs associated with the implants and the revisions.[12]
- MDM was shown to be more cost-effective when compared to conventional constructs, based on U.S. data.[12]

*Economic value and cost-savings based on U.S. data and indicative only. Cost-savings may differentiate across regions due to different healthcare systems, treatment plans and associated costs.

How may hospitals benefit when using MDM?

A study has shown that hip instability/dislocation and mechanical loosening are the most common causes for revision THAs in the United States.[6] For instance, the cost of treating dislocation has been estimated to represent $74,000,000 annually to the U.S. healthcare system.[15] Prevention of issues such as dislocation and loosening after hip arthroplasty is critical not only to minimize patient morbidity but also to maintain the cost-effectiveness of this surgical procedure.

The MDM system has been designed to help address the most common reasons for failure after THA,[1-4] which may help to minimize the overall expense to hospitals and the U.S. healthcare system.

How may surgeons benefit when using MDM?

MDM offers surgeons an alternative solution for addressing patients' individual needs. MDM is designed to offer orthopaedic surgeons increased versatility to allow them to address the wide breadth of reconstructive challenges that they face.

Operating room efficiency

- Single set of instrumentation to increase OR efficiency

Simplicity

- Surgical procedure is similar to conventional THA

Intraoperative versatility

- MDM uses a conventional acetabular shell offering the surgeon the intraoperative flexibility to utilize a conventional design or the MDM system

How may patients benefit when using MDM?

MDM is designed to allow for the potential for improved joint stability.[1-4] This bearing solution may be a suitable alternative for the changing needs of patients who require THA surgery – allowing surgeons to offer patients a solution to maintain their activity and lifestyle.

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