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Dual Mobility Total Hip Arthroplasty in Displaced Femoral Neck Fracture

Value Analysis Brief

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1. Executive Summary

1.1 Unmet Need

Femoral neck fracture is one of the most common types of hip fracture accounting for more than 50% of all hip fractures.[4,5] Approximately 70% of femoral neck fractures are categorized as displaced and require surgical treatment, typically with hip arthroplasty.[1, 2]

The number of hip fractures in Asia is expected to increase from 1.12 million in 2018 to 2.56 million in 2050, a 2.28-fold increase.[3] The direct cost of hip fracture in Asia is expected to increase from $9.5 billion United States dollars (USD) in 2018 to $15 billion USD in 2050, a 1.59-fold increase.[3]

The management of displaced femoral neck fractures has evolved to more patients receiving total hip arthroplasty (THA) over hemi-arthroplasty (HA), likely due to several evidence-based international guidelines supporting the adoption of THA in this cohort.[6-10]

The management of displaced femoral neck fractures has evolved to more patients receiving THA over HA, likely due to several evidence-based international guidelines supporting the adoption of THA in this cohort.

This value analysis brief provides health care professionals and policy makers with an overview of the evolution of displaced femoral neck fracture treatment from hemi-arthroplasty to dual mobility total hip arthroplasty based on registry data, clinical papers and governmental guidelines to improve the quality of life of patients.

1.2 Evidence Summary of Dual Mobility Hip Implants

The use of dual mobility THA in displaced femoral neck fractures appears to provide better patient quality of life outcomes relative to HA, without the increased risk of dislocation associated with a standard THA construct:

- A systematic literature review and meta-analysis by Lewis et al. (2019) concluded that, overall, THA appears to be superior to HA in displaced femoral neck fractures.[14] While THA was found to be superior to HA in terms of risk of reoperation and functional / quality of life scores, the risk of dislocation was greater with THA when compared to HA. The authors recommend THA for displaced femoral neck fractures in patients with a life expectancy >4 years and in patients younger than 80 years.
- A meta-analysis of dual mobility THA versus HA in displaced femoral neck fracture (six cohort studies, 983 patients) suggests there is a significantly lower likelihood of dislocation for dual mobility THA compared with HA.[15-20]

- Two recent meta-analyses demonstrated a significantly lower incidence of dislocation associated with dual mobility THA implants versus standard THA constructs in primary and revision THA.[21, 22]
- A recent matched-pair analysis comparing 4,520 hip fractures treated with dual mobility THA and 4,520 hip fractures treated with a standard THA found that the use of a dual mobility construct as primary treatment for hip fracture was associated with a lower risk of revision in general and due to dislocation in particular.[23]

1.3 G7® Dual Mobility Construct

From simple primary to complex revision arthroplasty, Zimmer Biomet's G7 Acetabular System is a modular system offering a comprehensive portfolio of shell, fixation and bearing options to establish a stable joint in THA. The G7 Dual Mobility construct is part of the G7 Acetabular System.

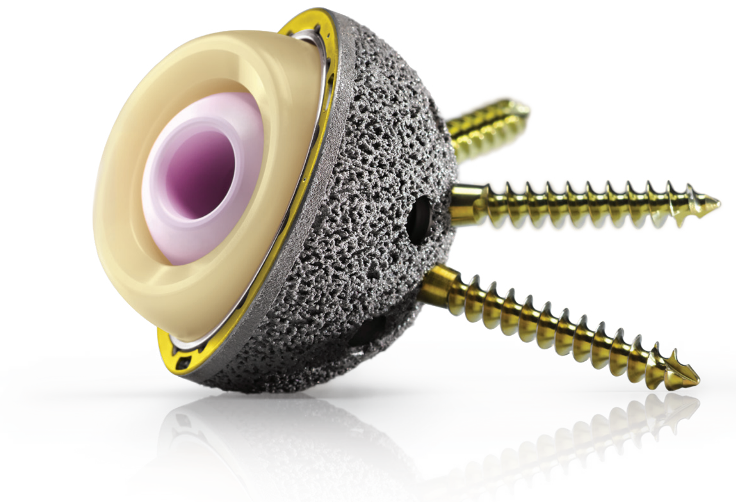

Figure 1: G7 Dual Mobility Construct

- The G7 Dual Mobility construct:
  - features an increased range of motion, which in turn increases the jumping distance and reduces the incidence of joint dislocation, making it a more forgiving system than a traditional THA implant.[11, 12]
  - offers dislocation resistance without the need to constrain the femoral head, providing stability and high range of motion for a variety of patient indications.[11, 13]
  - liners and bearings are compatible with all G7 acetabular cups, which are available in limited and multi-hole designs.[13]

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2. Background

Key Takeaways

Femoral neck fracture is one of the most common types of hip fracture accounting for more than 50% of all hip fractures.[4, 5] Approximately 70% of femoral neck fractures are categorized as displaced and require surgical treatment, typically with hip arthroplasty.[1, 2]

Hip fractures have devastating consequences for patients and their families, including an annual mortality rate of 30% and substantial impairment of independence and health related quality of life.[24]

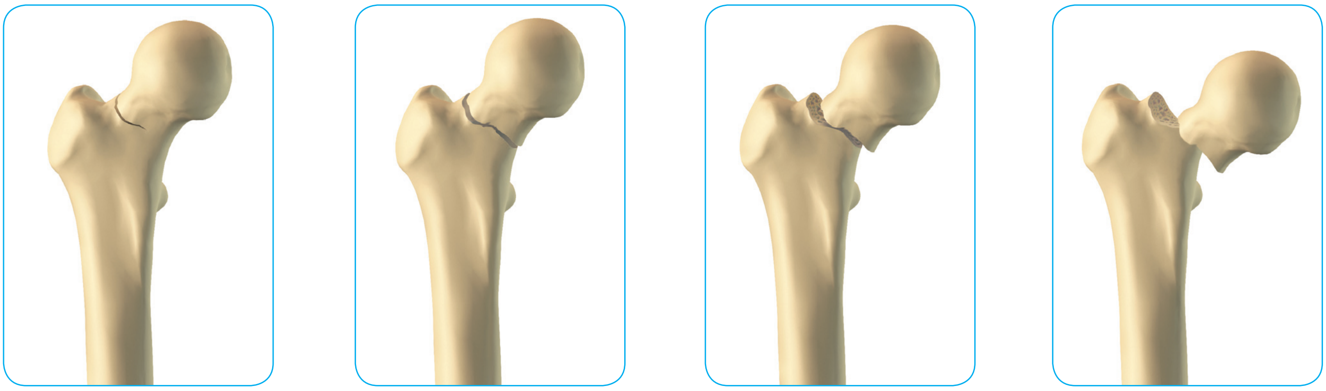
The number of hip fractures in Asia is expected to increase from 1.12 million in 2018 to 2.56 million in 2050, a 2.28-fold increase.[3] The direct cost of hip fracture in Asia is expected to increase from $9.5 billion United States dollars (USD) in 2018 to $15 billion USD in 2050, a 1.59-fold increase.[3]

The management of displaced femoral neck fractures has evolved to more patients receiving THA over HA, likely due to several evidence-based international guidelines supporting the adoption of THA in this cohort.[6-10]

2.1 Displaced Hip Fractures

A hip fracture is a break occurring at the proximal femur, near the pelvis. Hip fractures are either classified as intracapsular (i.e. at the femoral neck) or extracapsular (i.e. below the femoral neck). Due to their proximity to retinacular vessels, intracapsular fractures are associated with a higher risk of disrupting blood supply to the femoral head, which is a leading cause of avascular necrosis.[2]

For patients with femoral neck fractures, Garden's four-level classification system (Figure 2) is often used to determine the most appropriate treatment to manage the fracture.[25] Garden type I or II represents non-displaced or impacted fracture patterns, which are associated with minimal femoral neck displacement and a lessened risk of blood supply disruption to the femoral head. Conversely, Garden type III or IV fractures are categorized by greater displacement and substantially higher risk of blood supply loss; surgical treatment is recommended for these patients.[2, 8]



GARDEN I
Incomplete fracture
Minimally displaced
Valgus impacted

GARDEN II
Complete fracture
Non-displaced

GARDEN III
Complete fracture
Partially displaced

GARDEN IV
Complete fracture
Completely displaced

Figure 2: Garden Classification (intracapsular fractures)

2.2 Epidemiology

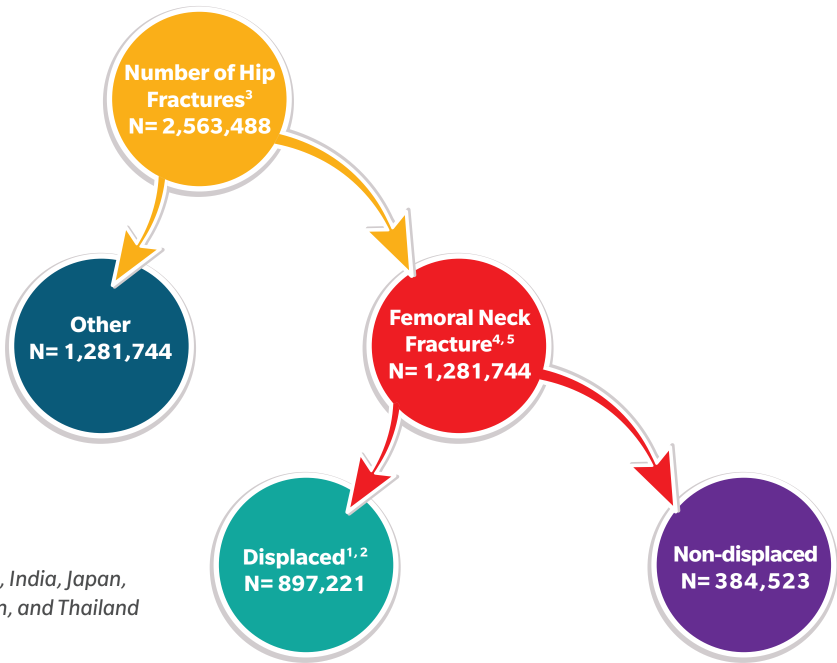
Femoral neck fracture is one of the most common types of hip fracture accounting for more than 50% of all hip fractures.[4, 5] Approximately 70% of femoral neck fractures are categorized as displaced and require surgical treatment, typically with hip arthroplasty.[1, 2]

Hip fracture is increasingly recognized as a growing problem in Asia.[3, 26] It is projected that Asian countries will contribute more to the pool of future hip fractures, with more than 50% of all osteoporotic fractures occurring in Asia by 2050, based on predicted changes in population demographics in Asian countries.[26] The highest incidence of hip fractures from Asia has been reported from Singapore. The increase in total number of hip fracture is expected to be highest in Malaysia.[26]

Asian countries will contribute more to the pool of future hip fractures globally with more than 50% of all osteoporotic fractures occurring in Asia by 2050.

Age is the main risk factor for hip fractures, with the incidence increasing exponentially with age in both genders, peaking at 75 – 79 years of age.[26, 27] Within countries, the age-standardized incidence of hip fractures in women is approximately double that noted for men.[28] Because of the increasing number of elderly people in the world, the total number of hip fractures in individuals 50 years and older will continue to rise.

Hip Fractures in nine Asia AFOS members*



** AFOS members: China, Hong Kong, India, Japan, Korea, Malaysia, Singapore, Taiwan, and Thailand*

Figure 3: Data on incidence rate of hip fracture for 9 Asian Federation of Osteoporosis Societies (AFOS) members. *(Adapted from Cheung, 2018)*[3]

2.3 Economic Burden

The number of hip fractures in the nine countries of the Asian Federation of Osteoporosis Societies (AFOS) is expected to increase from 1,124,060 in 2018 to 2,563,488 in 2050, a 2.28-fold increase (see Figure 3).[3] This increase is mainly due to changes in population demographics, especially in China and India. The direct cost of hip fractures is expected to increase from $9.5 billion United States dollars (USD) in 2018 to $15 billion USD in 2050, a 1.59-fold increase.[3]

The direct cost of hip fractures is expected to increase from USD 9.5 billion in 2018 to USD 15 billion in 2050.

The economic burden of treating hip fractures is substantial, particularly in Asian countries:

- **Singapore:** The cost of hip fractures in Singapore is expected to reach USD145 million in 2050 from USD17 million in 1998.[29] A retrospective analysis of 244 patients admitted to Tan Tock Seng Hospital in Singapore reported a mean cost of hospitalization of SGD 13,313.81.[30]

- **Malaysia:** The increase in total number of hip fractures in Asia is expected to be highest in Malaysia since the median age was 26.99 years in 2012.[3]

- **China:** Median hip fracture length of stay (LOS) has been reported at 22 days and costs are rising quickly -- the per-hospitalization episode and per-day costs of osteoporotic fracture increased rapidly (60% and 89%, respectively) between 2008 and 2010.[31] A study of 27,205 patients in 73 tertiary Chinese hospitals reported the mean treatment cost of all patients was ¥53,440 (SD=¥35,238), higher than the Chinese GDP per capita in 2014 (¥46,629) and 2.65 times of the disposable income per capita in 2014 (¥20,167).[32]

- **Japan:** The highest per case cost of hip fracture management is in Japan, where patients are allowed prolonged hospital stays (average LOS of approximately 34 days) until postoperative rehabilitation.[33, 34]

Currently, the direct cost of hip fracture implants makes up a small proportion of the total cost of care in Asia. The median proportion of surgical costs to the total cost of care in Asia has been reported at 24.54% (range 2.54–54.57%), while for implants it is 6.96% (range 1.93–25.93%).[33] These values are equivalent to 7.00% (range 2.05–16.93%) and 2.62% (range 0.41–9.66%) of GDP/capita, respectively.[33]

2.4 Clinical Burden

Hip fractures have devastating consequences for patients and their families, including an annual mortality rate of 30% and substantial impairment of independence and health related quality of life.[24] Hip fractures also account for more hospital days than any other musculoskeletal injury and represent more than two-thirds of all hospital days due to fracture.[24] Displaced femoral neck fractures, in particular, pose a higher risk of post-fracture healing complications such as avascular necrosis of the femoral head or non-union of the fracture.[2] Therefore, timely surgery for displaced femoral neck fractures remains the gold standard of treatment.[25]

The revision rate of THA and HA in displaced femoral neck fracture patients has been estimated at approximately 0.2% for THA and 1.8% for HA after one year.[35] Revision surgeries are associated with a poor prognosis and an increase in short-term mortality.[36] Patients undergoing revision surgery for hip fracture are at risk for infection, venous thromboembolic disease (VTE), dislocation, pulmonary embolism, and mortality.[37]

2.5 Treatment Pathways and Clinical Guidelines

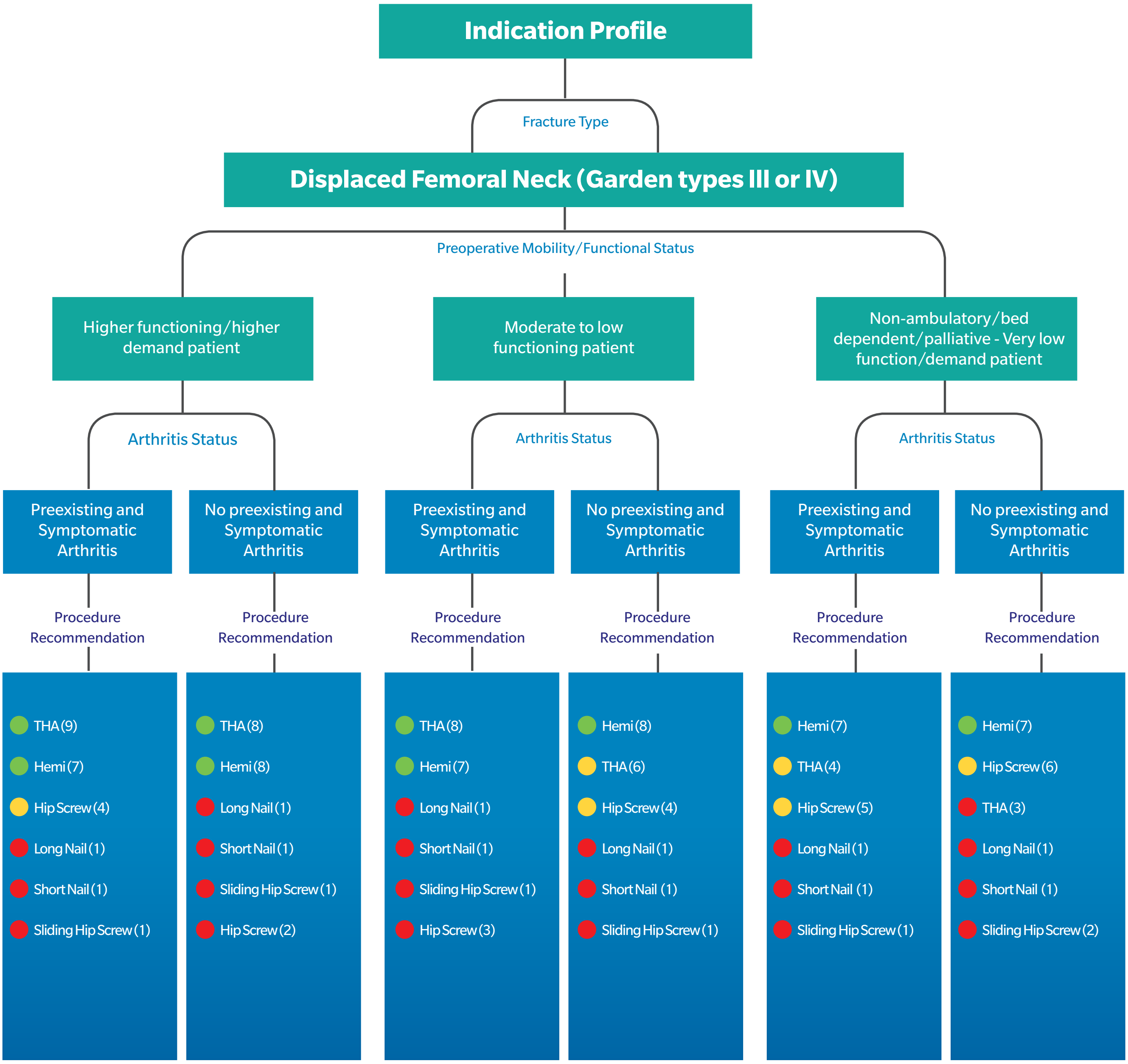
The management of hip fractures depends on individual patient factors (e.g. ambulatory status, age, cognitive function, comorbidities) and fracture factors (e.g. fracture location, type, degree of displacement).[14] Patients with displaced femoral neck fractures (Garden types III and IV) are at significant risk for osteonecrosis of the femoral head and fracture non-union. As such, displaced femoral neck fractures are usually managed with HA or THA.[38] HA is a less complex surgery and has been associated with reduced dislocation rates, reduced blood loss, and lower initial costs.[39] However, some patients treated with HA require conversion to THA due to complications such as acetabular erosion and aseptic femoral loosening.[14, 40]

THA on the other hand has been associated with superior patient satisfaction and better postoperative function, and has been increasingly used in recent years to manage displaced femoral neck fracture, especially in younger, more active patients.[14, 41] A systematic review and meta-analysis by Lewis et al. (2019) concluded that THA should be the recommended intervention for displaced femoral neck fracture in patients with a life expectancy greater than 4 years or in patients younger than 80 years old. The authors also concluded that HA is a reasonable intervention in patients with shorter life expectancy or patients greater than 80 years old.

The management of displaced femoral neck fractures has evolved to more patients receiving THA over HA, likely due to several evidence-based international guidelines supporting the adoption of THA in this cohort.[6-10]

- The National Institute for Clinical Excellence (NICE) in the UK published its guideline on the management of hip fracture in adults in 2011 and updated it in 2018 to emphasise the role of total hip replacement in displaced intracapsular hip fracture.[7]
  - The NICE guideline for hip fracture surgery states that THA should be offered to patients with displaced intracapsular hip fractures provided they pass the following criteria: 1) mobilise independently with the aid of no more than a stick; 2) are not cognitively impaired; and 3) are medically fit for anaesthesia and the procedure.[7]

- The American Academy of Orthopaedic Surgeons (AAOS) in the United States published its guideline on the management of hip fracture in adults in 2015.[8] The AAOS guideline states there is strong evidence supporting total hip arthroplasty for elderly patients with displaced femoral neck fractures. The guideline also suggests benefits from avoidance of reoperations in a frail patient population, which has implications on cost savings to society.



Appropriate Use Criteria - Hip Fractures for Elderly Patients: Acute Treatment

Appropriate with agreement · May be appropriate · Rarely appropriate

Figure 4: AAOS OrthoGuidelines - Hip Fractures in Elderly Patients *(Adapted from www.orthoguidelines.org/hipfxguideline)*

3. Evidence Summary

Key Takeaways

A systematic literature review and meta-analysis by Lewis et al. (2019) concluded that, overall, THA appears to be superior to HA in displaced femoral neck fractures.[14] The authors recommend THA for displaced femoral neck fractures in patients with a life expectancy >4 years or in patients younger than 80 years.

A meta-analysis of dual mobility THA versus HA in displaced femoral neck fracture (six cohort studies, 983 patients) suggests there is a significantly lower likelihood of dislocation for dual mobility THA compared with HA.[15-20]

Two recent meta-analyses demonstrated a significantly lower incidence of dislocation associated with dual mobility THA implants versus standard THA constructs in primary and revision THA.[21, 22]

3.1 Hemiarthroplasty Versus Total Hip Arthroplasty in Displaced Femoral Neck Fractures

The most recent systematic review and meta-analysis on the topic of HA versus THA in displaced femoral neck fractures, published by Lewis et al. (2019), included randomized and quasi-randomized clinical studies published between 1986 and 2018. 14 studies were identified through a systematic search of the MEDLINE, EMBASE, and Cochrane Controlled Trials databases. The meta-analysis was conducted following the PRISMA guideline and was registered in the PROSPERO database.

In total, 17 studies comprising 660 THA and 704 HA procedures were included. THA was found to be superior to HA in terms of risk of reoperation (risk ratio, 1.54 [95% CI, 1.01 to 2.35], P = .05), Harris Hip Score (HHS) (mean difference, 5.1 points [95% CI, 1.3 to 8.8], p = 0.009) and on the physical component summary (PCS) of the Short Form-36 (SF-36) (mean difference, 5.2 points [95% CI, 0.8 to 9.7 points, P = 0.02).[14] However, the 4-year incidence of dislocation was higher in the THA group (risk ratio, 0.37 [95% CI, 0.23 to 0.60], p < 0.001). No differences were found in terms of mortality and risk of infection. Furthermore, no statistically significant differences were found in terms of incidence of dislocation beyond 4 years.[14]

Lewis et al. (2019) concluded that, overall, THA appears to be superior to HA. Based on the scientific evidence, the authors recommend THA for displaced femoral neck fractures in patients with a life expectancy >4 years or in patients younger than 80 years. However, the authors found that both HA and THA are justified in patients older than 80 years or in patients with shorter life expectancy.[14]

3.2 Hemiarthroplasty Versus Dual Mobility Implants in Displaced Femoral Neck Fractures

Currently, there are no systematic reviews published comparing differences between hemiarthroplasty and dual mobility THA for the treatment of displaced femoral neck fractures. For the purpose of this value analysis brief, a meta-analysis was conducted. The meta-analysis included randomized controlled trials and cohort studies to examine the difference between hemiarthroplasty and dual mobility THA on clinical outcomes after hip arthroplasty for displaced femoral neck fractures. Full papers identified through a systematic search of the MEDLINE, EMBASE, and Cochrane Controlled Trials databases were eligible. Risk ratios for dislocation and the weighted mean differences for Harris Hip Score (HHS) were calculated. Fixed-effect (Mantel-Haenszel) models were employed. Stata 15.1 (StataCorp LLC, College Station, TX, USA) was used for statistical analysis.

In total, six cohort studies including 983 patients were identified.[15-20] After a mean follow-up of 2.0 (range, 1.4 – 3.0) years, there was a significantly lower likelihood of dislocation for dual mobility compared with hemiarthroplasty (risk ratio, 0.34 [95% CI, 0.20 to 0.59], $p < 0.001$).

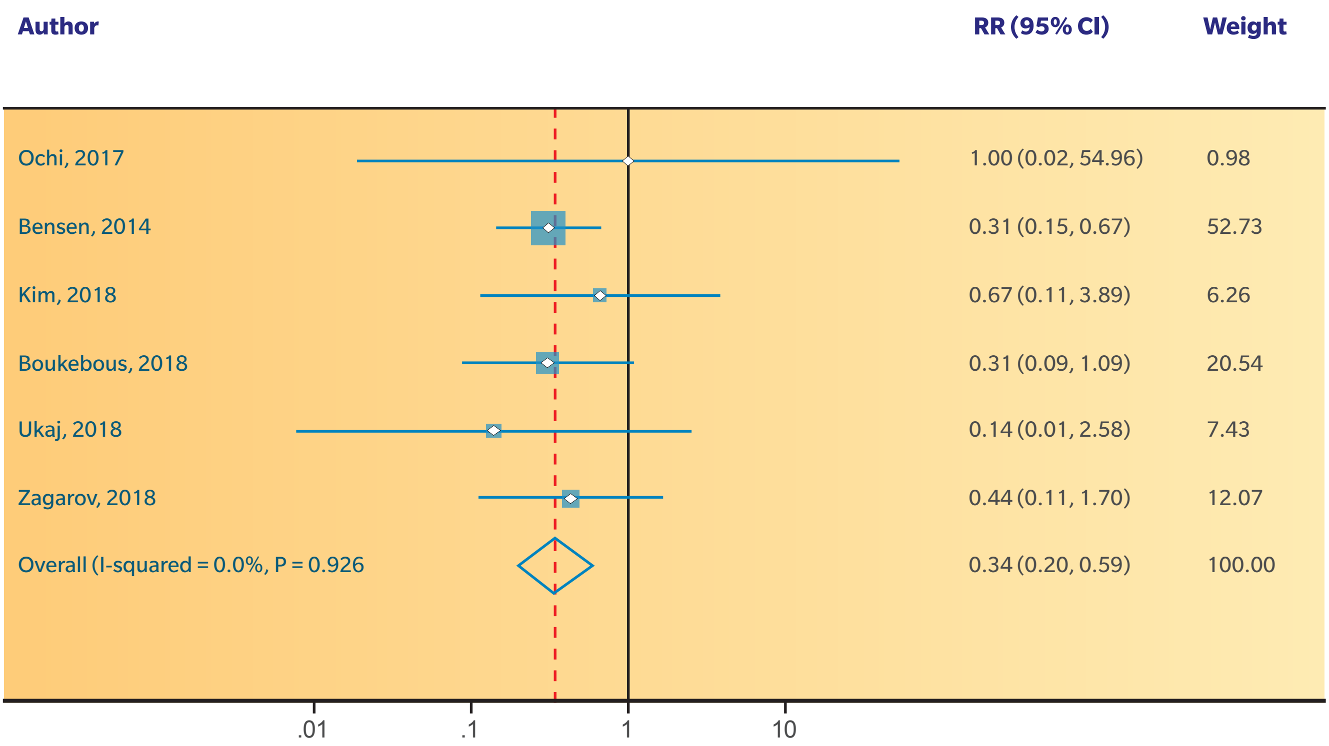


Figure 5: Dislocation Risk for Dual Mobility THA compared with Hemiarthroplasty in Patients with Displaced Femoral Neck Fractures

Two studies reported postoperative HHS in 231 patients.[17, 19] The weighted mean difference in HHS was 4.1 points (95% CI, 1.7 – 6.5 points, $p < 0.001$) in favour of the dual mobility THA group.

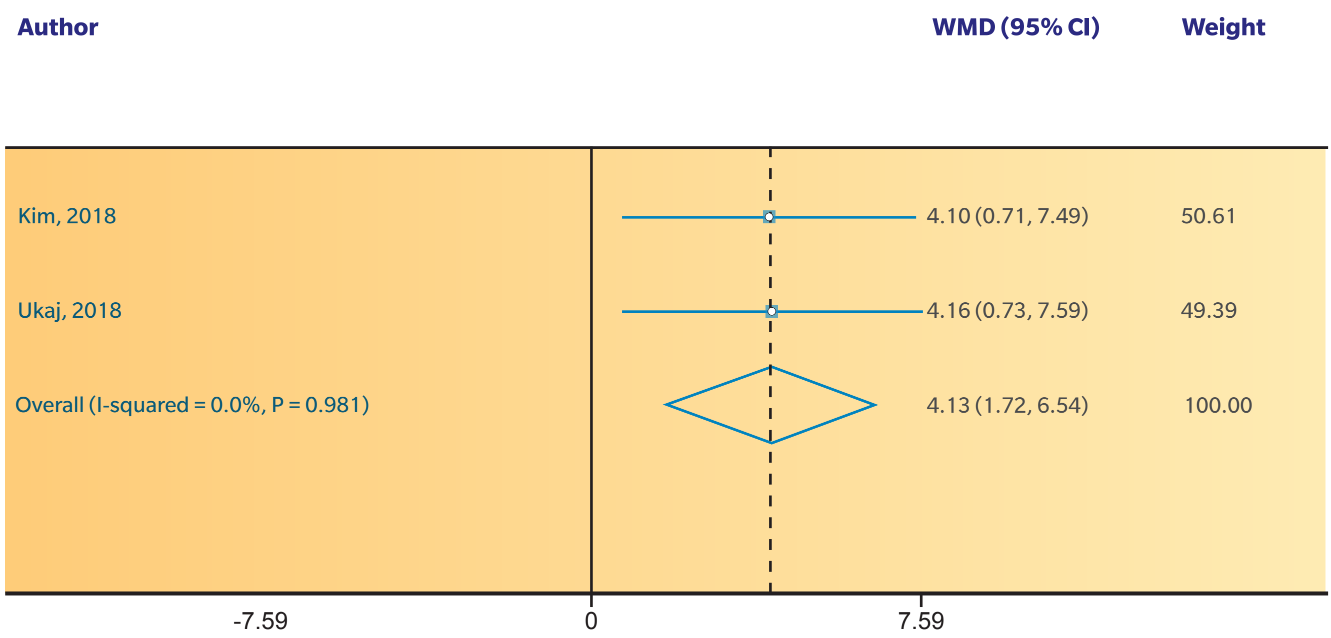


Figure 6: Harris Hip Score weighted mean difference between Dual Mobility THA and Hemiarthroplasty in patients with displaced femoral neck fractures

This meta-analysis of comparative studies revealed that dual mobility THA is associated with a lower rate of dislocation and a higher HHS score compared with hemiarthroplasty in patients with displaced femoral neck fractures.

3.3 Dual Mobility Versus Standard Implants in Total Hip Arthroplasty

The body of evidence for dual mobility versus standard hip implants consists of two recently published meta-analyses comparing clinical outcomes. Reina et al. (2018) conducted a systematic review and meta-analysis of prospective and retrospective studies that compared dual mobility constructs with controls for primary or revision THAs between 1986 and 2018.[21] The authors included five studies with primary THAs and six with revision THAs. In primary THA, at a mean follow-up of 7.6 years, an incidence of dislocation of 0.9% was found for the dual mobility implant group, compared with 6.8% in the standard implant group ($p < 0.001$). The odds ratios for the standard implant group to the dual mobility group were 4.1 (95% CI, 1.7 to 9.7, $p < 0.001$) for dislocation, 1.2 (95% CI, 0.2 to 9.5, $p = 0.87$) for revision, 3.0 (95% CI 1.0 to 9.3, $p = 0.04$) for revision due to dislocation, 1.7 ($p = 0.57$) for infection, 0.6 ($p = 0.53$) for fracture, and 1.2 ($p = 0.81$) for aseptic loosening.[21]

Similarly, in revision THA, an overall dislocation incidence of 2.2% was found for dual mobility, compared with 7.1% ($p < 0.001$) for standard bearings, at a mean follow-up of 4.1 years. The odds ratios for the standard implant group to the dual mobility group were 3.6 (95% CI, 2.0 – 6.4, $p < 0.001$) for dislocation, 2.5 (95% CI 1.6 to 3.8 ($p < 0.001$) for re-revision, 4.9 (95% CI, 2.2 to 10.6, $p = 0.007$) for re-revision for dislocation, 1.5 ($p = 0.32$) for infection, 1.2 ($p = 0.81$) for fracture, and 2.7 ($p = 0.003$) for aseptic loosening.[21]

This systematic review of comparative studies supports the efficacy of dual mobility constructs to minimize dislocation after both primary and revision THAs in addition to excellent mid-term survivorship compared with control constructs.[21] As with any meta-analysis, further evidence is needed to evaluate the long-term risks and benefits of dual mobility constructs in the primary and revision THA setting when compared with contemporary conventional implants.

A second meta-analysis was published by Romagnoli et al. (2019), which included 15 studies presenting the results of a total of 1218 dual mobility and 1190 standard hip implants. The meta-analysis showed a significantly lower incidence of dislocation associated with dual mobility THA implants (risk ratio, 0.2 (95% CI, 0.1 to 0.3, $p < 0.001$)).[22]

Interestingly, during the subgroup analysis, statistically significant differences in favor of the dual mobility group were also found for primary or revision arthroplasties, displaced femoral neck fractures, and elective procedures (i.e., diagnosis of osteoarthritis, avascular osteonecrosis or rheumatic arthritis). For fracture cases, a risk ratio of dual mobility to standard implants of 0.1 (95% CI, 0.0 to 0.7, $p = 0.02$) was found.[22]

Romagnoli et al. (2019) concluded that dual mobility acetabular components decrease the risk of post-operative instability in high-risk patients, both in primary and revision hip arthroplasties.[22] More high-quality studies are warranted to confirm the present data.

Dual mobility acetabular components decrease the risk of post-operative instability in high-risk patients, in both primary and revision hip arthroplasties.

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Study or Subgroup	Dual Mobility Events	Dual Mobility Total	Fixed Bearing Events	Fixed Bearing Total	Weight	Risk Ratio M-Hi, Fixed, 95% CI
OA, AVN, RA						
Bouchet et al. 2011	0	105	5	108	6.7%	0.09 (0.01, 1.67)
Calon et al. 2014	1	105	26	215	21.1%	0.08 (0.01, 0.57)
Epinette et al. 2015	0	143	7	130	9.7%	0.06 (0.00, 1.05)
Hernigou et al. 2016	5	85	13	85	16.1%	0.38 (0.14, 1.03)
Subtotal (95% CI)		438		538	53.6%	0.17 (0.08, 0.38)
Total events	6		51			
Heterogeneity: Chi^2 = 3.89, df = 3 (P = 0.27); 1^2 = 23%						
Test for overall effect: Z = 4.32 (P < 0.0001)						
Fracture						
Tarasevicius et al. 2013	0	42	8	56	9.0%	0.08 (0.00, 1.31)
Tarasevicius et al. 2010	0	58	5	67	6.3%	0.10 (0.01, 1.86)
Subtotal (95% CI)		100		123	15.3%	0.09 (0.01, 0.67)
Total events	0		13			
Heterogeneity: Chi^2 = 0.02, df = 1 (P = 0.89); 1^2 = 0%						
Test for overall effect: Z = 4.32 (P < 0.0001)						
Loosening, Infection, periprostetic fracture						
Chalmers et al. 2017	0	16	1	13	2.0%	0.27 (0.01, 6.23)
Gonzales et al. 2017	1	150	7	166	8.2%	0.16 (0.02, 1.27)
Hernigou et al. 2017	1	35	7	32	9.0%	0.13 (0.02, 1.00)
Jauregui et al. 2016	1	60	7	120	5.8%	0.29 (0.04, 2.27)
Perrin et al. 2017	1	24	5	25	6.1%	0.21 (0.03, 1.66)
Subtotal (95% CI)		285		356	31.1%	0.19 (0.07, 0.51)
Total events	4		27			
Heterogeneity: Chi^2 = 0.37, df = 4 (P = 0.98); 1^2 = 0%						
Test for overall effect: Z = 3.33 (P < 0.0009)						
Total (95% CI)		823		1017	100.0%	0.16 (0.09, 0.30)
Total events	10		91			
Heterogeneity: Chi^2 = 4.85, df = 10 (P = 0.90); 1^2 = 0%						
Test for overall effect: Z = 5.98 (P < 0.00001)						
Test for subgroup differences: Chi^2 = 0.45, df = 2 (P = 0.80). 1^2 = 0%						

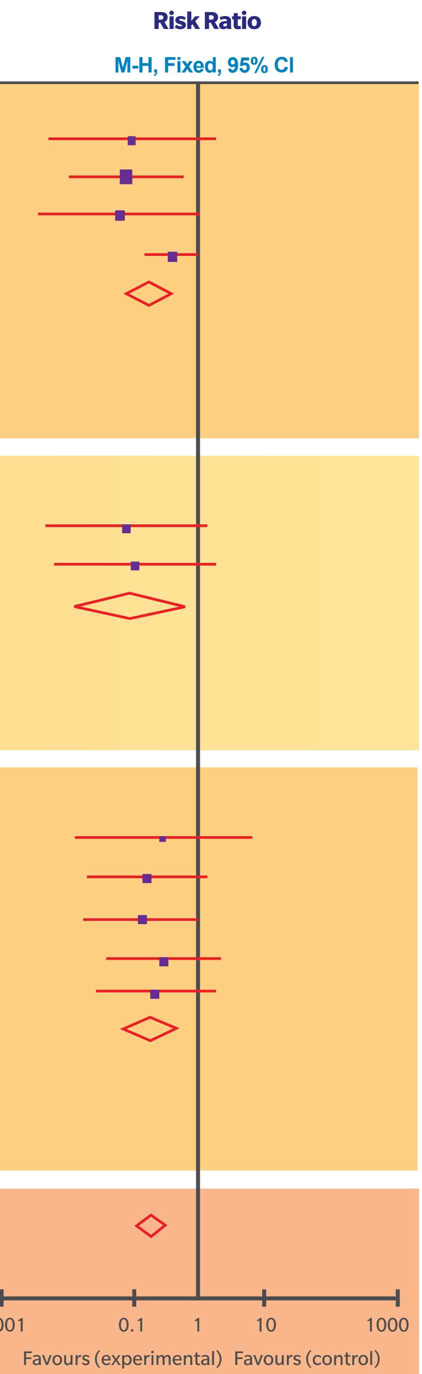

Figure 7: Dislocation Risk for Dual Mobility THA compared with Fixed Bearing THA according to Diagnosis

4. Implications of Dual Mobility Hips in Displaced Femoral Neck Fractures

With the incidence and cost of hip fractures in Asia set to increase drastically from now until 2050, solutions which reduce the number of subsequent revision surgeries and provide ample patient satisfaction will play a critical role in reducing the clinical and economic burden associated with hip fracture.3 Displaced femoral neck fracture patients treated with THA versus HA have better functional outcomes, including Harris and Oxford Hip Scores and walking distance.38, 42

Yet, a concerning factor for THA adoption has been that THA in displaced femoral neck fractures have a reported dislocation rate of approximately 10%, roughly five times higher than the dislocation rate in arthroplasty for osteoarthritis.[20] However, lower rates of revision and specifically, revision due to dislocation, have been reported with the use of dual mobility constructs in patients with displaced femoral neck fracture.[23] Additional longitudinal studies are needed to corroborate this evidence, but the early results are promising for the adoption of dual mobility constructs in this challenging patient cohort.

Dual mobility THA is associated with a lower rate of dislocation and a higher Harris Hip Score (HHS) score compared with HA in patients with displaced femoral neck fractures.

The economic implications of THA complications are staggering, with the cost of revision often exceeding 50,000 USD prior to consideration of additional costs such as post-acute hospital care.[51] The significantly reduced revision rates exhibited by contemporary dual mobility constructs suggest dual mobility may represent a far more cost-effective treatment compared to standard THA bearings.

In Epinette et al's study, using Markov modeling with determination of the incremental cost-effectiveness ratio (ICER), the direct healthcare costs of 80,405 patients in France who had undergone THA were analyzed over 4 years. Using a conservative relative risk of dislocation of 0.4 for dual mobility THA versus standard bearing THA, when considering the costs resulting from readmission and rehabilitation, the authors determined dual mobility constructs THA could be expected to save 283 Euros per patient. This result translates into a major economic impact, with an estimated cost-saving of nearly 39.62 million Euros if dual mobility THA was performed for all 140,000 primary THAs carried out in France annually.[52]

Moreover, in Barlow et al's Markov analysis of the lifetime cost-effectiveness of differing arthroplasty modalities, dual mobility THA demonstrated absolute dominance over standard bearing THA – with lower accrued costs (US$39,008 versus US$40,031) and higher accrued utility (13.18 versus 13.13 quality-adjusted life years).[53] Likewise, in patients with spinal deformity, Elbuluk et al illustrated that DM was cost-effective when dislocation rates were reduced to 0.9%, without including longer-term economic implications associated with dislocation such as revision surgery or loss of income.[51] Therefore, although longer-term financial analysis is required, early results suggest DM represents a cost-effective modality for primary THA.

5. Product Profile: G7 Dual Mobility Hip

The G7 Dual Mobility construct offers dislocation resistance without the need to constrain the femoral head, providing stability and high range of motion for a variety of patient indications.

Increased Range of Motion (ROM) with Dislocation Resistance

The Zimmer Biomet G7 Dual Mobility Hip offers dislocation resistance without the need to constrain the femoral head, providing stability and high range of motion for a variety of patient indications.[13, 44]

The basic construct (Figure 8) consists of a porous titanium alloy acetabular shell, CoCr alloy liner, polyethylene bearing and femoral head. The first motion occurs between the 22 or 28 mm femoral head and the concave surface of the polyethylene bearing until the neck of the femoral stem comes into contact with the bearing (Figure 9A). Secondary motion occurs between the polyethylene bearing and the metal liner when a larger range of motion is required (Figure 9B).

- Studies show femoral heads larger than 32 mm significantly decrease the risk of dislocation due to the increased distance required for the femoral neck to travel before impinging on the rim of the acetabular shell.[45, 46] In a dual mobility construct, the polyethylene bearing acts as a large diameter femoral head designed for the same purpose.
- The G7 Dual Mobility construct maximizes shell to bearing ratio, providing a 32 mm or larger bearing for all shell sizes to offer joint stability, high range of motion (up to 212°) and dislocation resistance to a greater number of patients.[12]

Figure 8

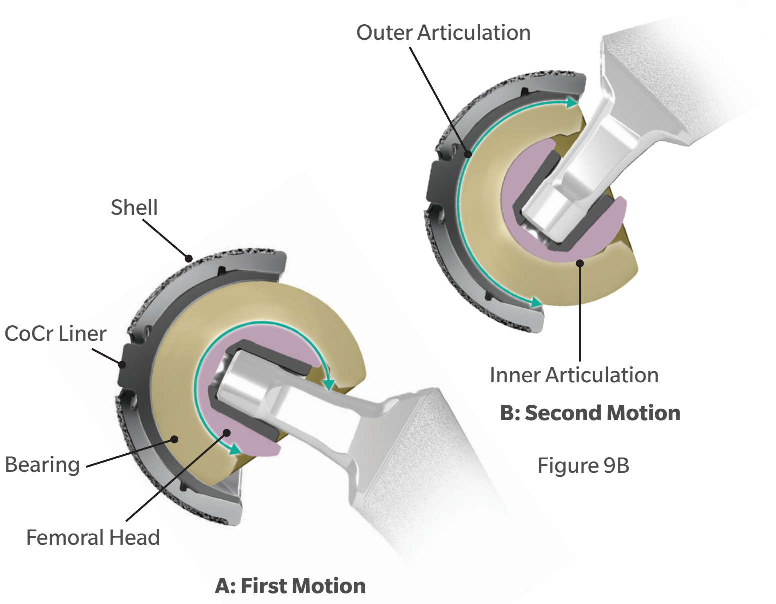

Figure 9A

Figure 9B

Strong Clinical Heritage

- Zimmer Biomet has over 10 years of clinical experience in dual mobility hip replacement with the Avantage® system. The Avantage system was developed in 1998 based on Professor Bousquet's philosophy and built on contemporary experience with early dual mobility designs. The Avantage system offers cemented and cementless shells to address surgical scenarios from primary through complex revision hip arthroplasty.

Table 1: Clinical results from the use of the Avantage system.

Reference	Details	Outcome
Bedencic K, Kavcic G, Tumpej J.[47]	Series of 1000 consecutive Avantage dual mobility cups used for THA in 901 patients for various pathologies (fracture of the femoral neck, osteoarthritis and avascular necrosis). There were 612 females and 289 males with a mean age of 76.8 years at the time of their operation (from 29 to 98). 808 patients with a total of 883 dual mobility cups were available for the final analysis.	No dislocations recorded at the mean follow-up of 8.9 years. There were also no cases of aseptic loosening (longest follow up 14 years). Harris Hip Score significantly increased for cases of osteoarthritis and avascular necrosis (from 44.9 to 90.4).
Fresard, P-L. et. al.[48]	134 THA were done between 1998 and 2002 with Avantage Press-Fit double mobility cup and ArCom® polyethylene. The mean age of patients was 74 ± 6 years (range 65–94 years). The mean follow-up was 5.4 years (range, 0.15–10 years).	No dislocation occurred in this series. Three revisions were documented for aseptic loosening. The overall survival rate at 7.2 years was 96.3 % (95 % confidence interval 92.2–100) using cup revision for aseptic loosening as the end point.
Semenowicz J. et. al.[49]	280 cementless Avantage and Avantage Reload cups were implanted in 260 women aged between 29 and 79 years (60.9 years on average) in the years 2004–2010. The follow-up period ranged from 2.7 to 9.7 years, 7.0 years on average.	None of the patients demonstrated postoperative prosthesis instability. Aseptic loosening was observed in 19 cups in 18 women (7.3%). The cumulative survival rate of the Avantage cup was 0.94 at 5 years and 0.86 at 8 years.
Graversen et. al.[50]	20 patients (18 females, 2 males) median age of 83 years (interquartile range 81–88 years), who were treated with the Avantage dual mobility cup (Biomet) due to an acute displaced (Garden type 3 or 4) FNF. All patients had a dementia diagnosis and were considered unable to follow the rehabilitation program with restriction of hip flexion and external rotation. The median follow-up time was 12.1 (0.4–47.6) months.	None of the patients experienced dislocation or received revision surgery in the follow-up period.

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