ZIMMER BIOMET
Your progress. Our promise.®

Dual Mobility Total Hip Arthroplasty in Displaced Femoral Neck Fracture

Value Analysis Brief

Contents

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]

Worldwide, approximately 1.5 million hip fractures occur per year, with roughly 340,000 in the United States in individuals older than 65 years. By 2050, there will be an estimated 3.9 million fractures worldwide, with more than 700,000 in the United States.[51] In the US a typical patient with a hip fracture spends over US $40,000 in the first year following hip fracture for direct medical costs and almost $5000 in subsequent years.[53] The total annual direct medical costs associated with all hip fractures estimated to be $5.96 billion annually ($25.3 billion by 2025), burdening the U.S. health care system.[54]

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]

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

The total annual direct medical costs associated with all hip fractures estimates to $5.96 billion annually ($25.3 billion by 2025), burdening the U.S. health care system.[54]

1.2 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.

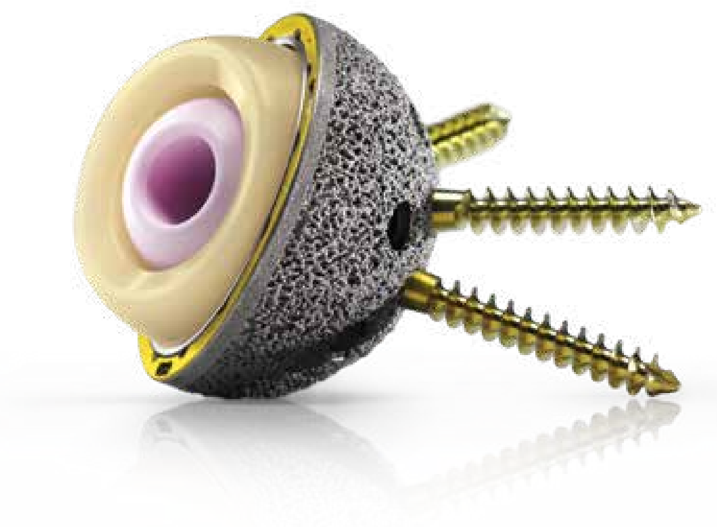


Figure 1: G7 Dual Mobility Construct

- The G7 Dual Mobility system 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]
- 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.[11, 13]
- G7 Dual Mobility liners and bearings are compatible with all G7 acetabular shells, which are available in limited and multi-hole designs.[13]

1.3 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]
- The use of dual-mobility THA in displaced femoral neck fractures thus appears to provide better patient quality of life outcomes relative to HA, without the increased risk of dislocation associated with a standard THA construct.

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]

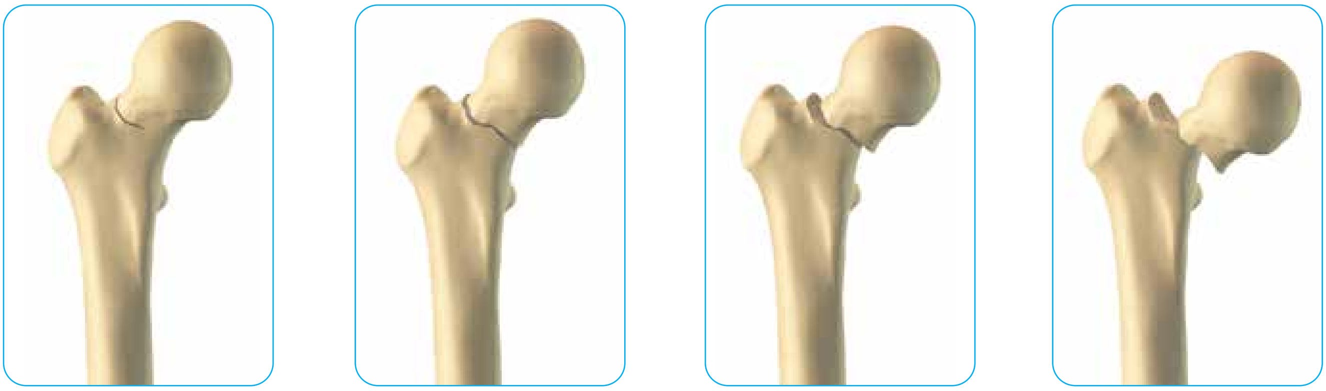
Worldwide, approximately 1.5 million hip fractures occur per year, with roughly 340,000 in the United States in individuals older than 65 years. By 2050, there will be an estimated 3.9 million fractures worldwide, with more than 700,000 in the United States.[51] In the US a typical patient with a hip fracture spends over US $40 000 in the first year following hip fracture for direct medical costs and almost $5000 in subsequent years.[53] The total annual direct medical costs associated with all hip fractures are estimated to be to $5.96 billion annually ($25.3 billion by 2025), burdening the U.S. health-care system.[54]

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]

As of 2014, the National Osteoporosis Foundation (NOF) estimated that 54 million American adults over 50 years of age present with osteoporosis and low bone mass, making this a high-risk population for hip fracture.[54]

Worldwide, approximately 1.5 million hip fractures occur per year, with roughly 340,000 in the United States in individuals older than 65 years. By 2050, there will be an estimated 3.9 million fractures worldwide, with more than 700,000 in the United States.[51]

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.

2.3 Economic Burden

Hip fracture rates have decreased for both men and women since 1995, however the number of fractures continues to rise as the population ages. Even though the incidence of hip fractures is relatively low, accounting for 14% of fractures, it has been estimated to account for 72% of total fracture costs.[52] The population of the US, according to projections, will retain its position as the second oldest region in the world in 2050 with 21.4 percent of the total population 65 and older.[55]

> ***In the US a typical patient with a hip fracture spends over US $40,000 in the first year following hip fracture for direct medical costs and almost $5000 in subsequent years.[53] The total annual direct medical costs associated with all hip fractures estimates to $5.96 billion annually ($25.3 billion by 2025), burdening the U.S. health care system.[54]***

In the US a typical patient with a hip fracture spends over US $40,000 in the first year following hip fracture for direct medical costs and almost $5000 in subsequent years.[53] The total annual direct medical costs associated with all hip fractures estimates to $5.96 billion annually ($25.3 billion by 2025), burdening the U.S. health-care system. Inpatient hospitalization and skilled nursing facility services jointly costed a patient $33,543 and $32,215 within the 90-day post-acute care period for intertrochanteric and all hip fractures, respectively.[54]

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 emphasize 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) mobilize 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.

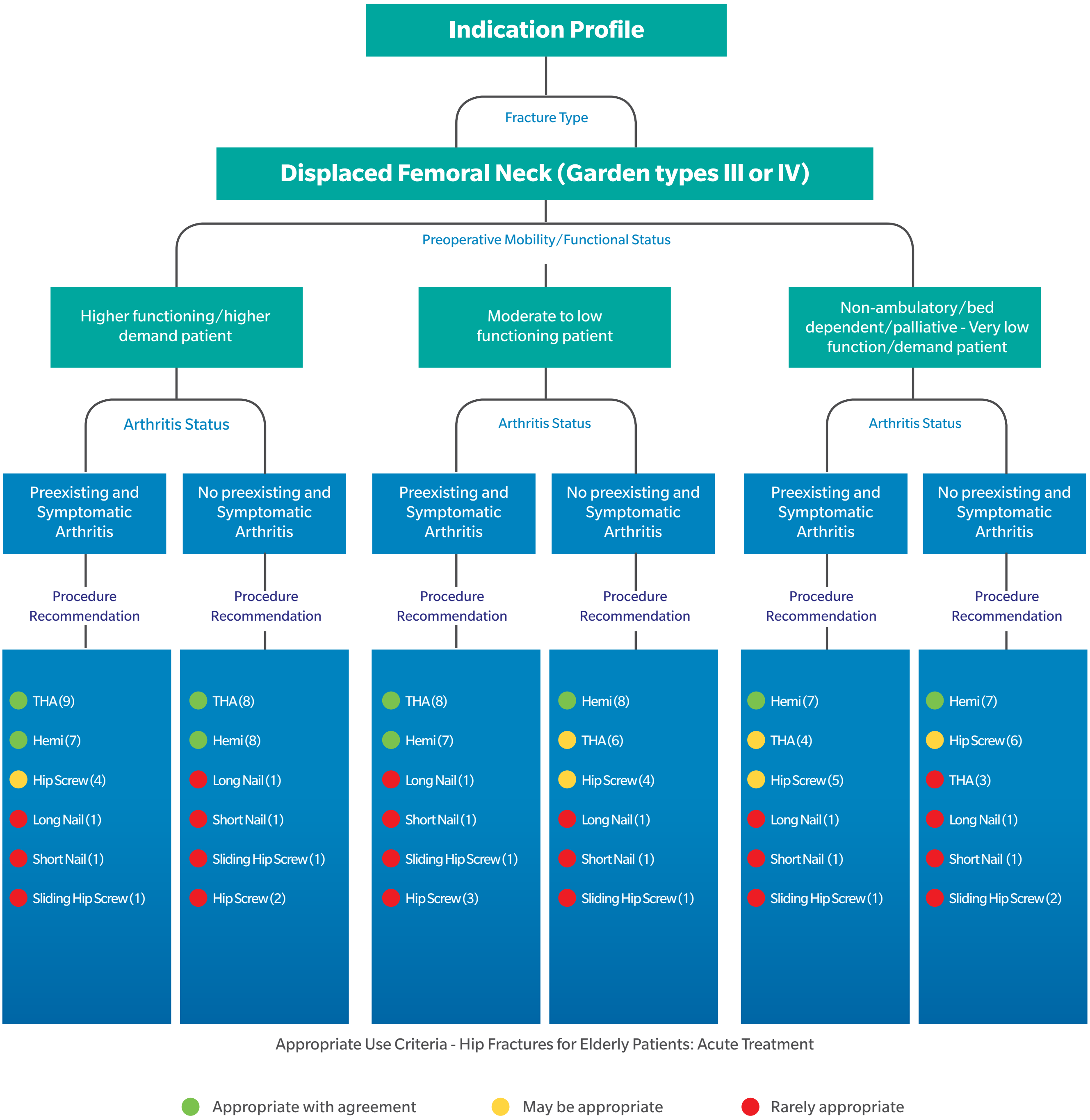


Figure 4: AAOS OrthoGuidelines - Hip Fractures in Elderly Patients *(Adapted from www.orthoguidelines.org/hipfxguideline)*

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], $p < 0.001$).

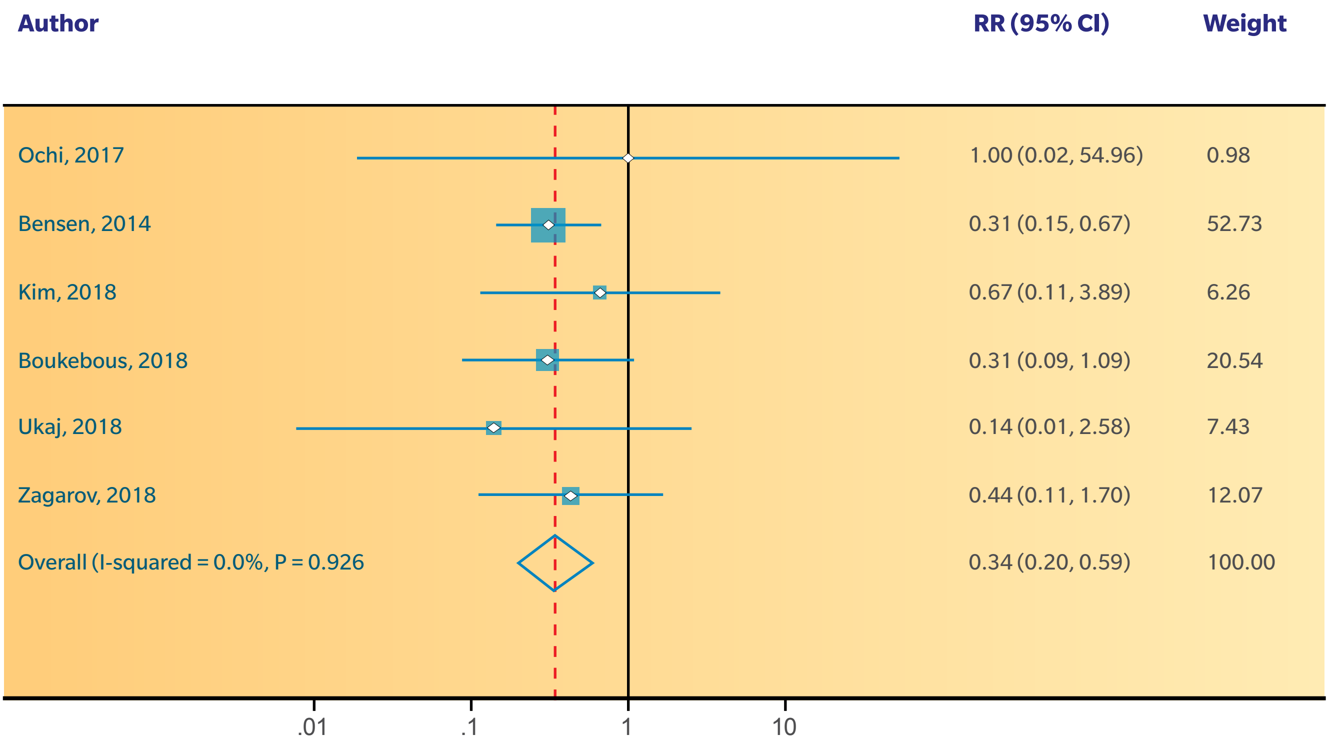


Figure 5: Dislocation Risk for Dual Mobility THA compared with Hemiarthroplasty in Patients with Displaced Femoral Neck Fractures

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.

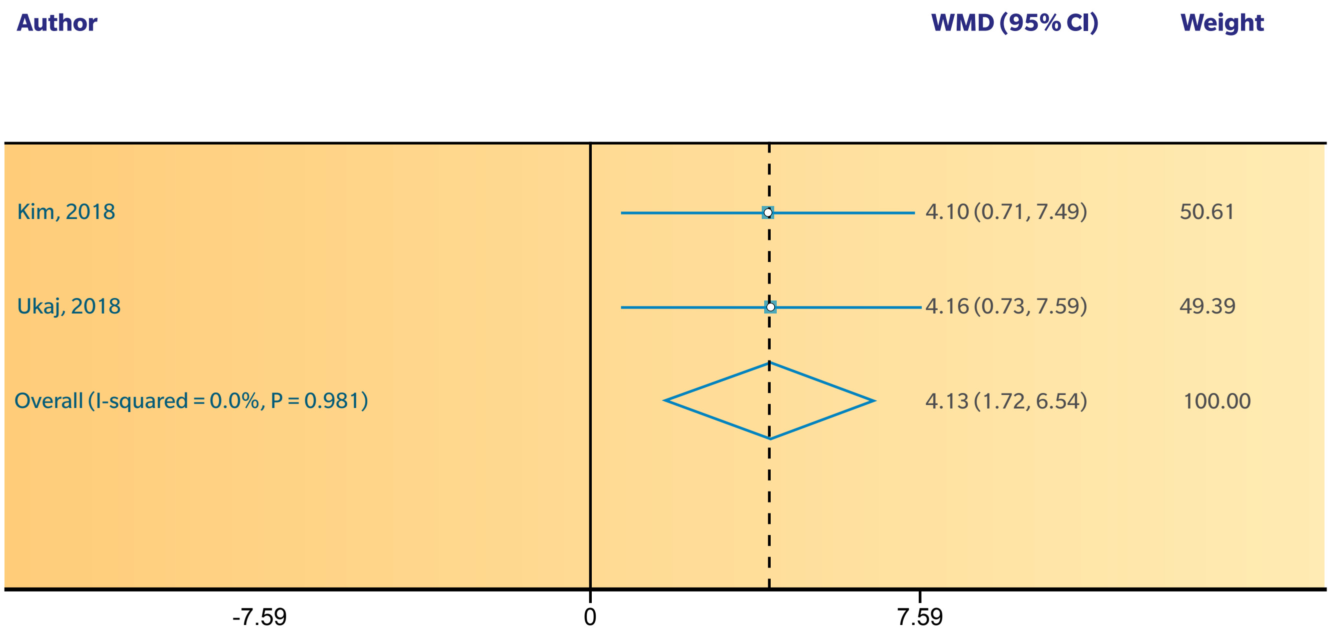


Figure 6: Harris Hip Score weighted mean difference between Dual Mobility THA and Hemiarthroplasty in patients with displaced femoral neck fractures

This meta-analysis of comparative studies revealed that dual mobility THA is associated with a lower rate of dislocation and a higher HHS 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.[22]

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); $I^2 = 23\%$						
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); $I^2 = 0\%$						
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); $I^2 = 0\%$						
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); $I^2 = 0\%$						
Test for overall effect: Z = 5.98 (P < 0.00001)						
Test for subgroup differences: $Chi^2 = 0.45$, df = 2 (P = 0.80). $I^2 = 0\%$						

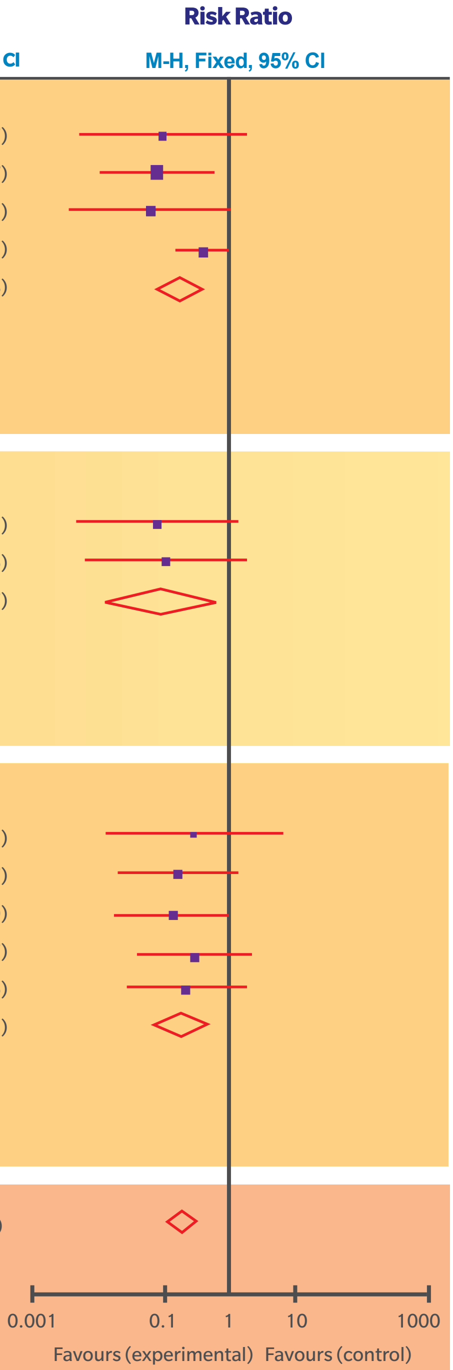


Figure 7: Dislocation Risk for Dual Mobility THA compared with Fixed Bearing THA according to Diagnosis

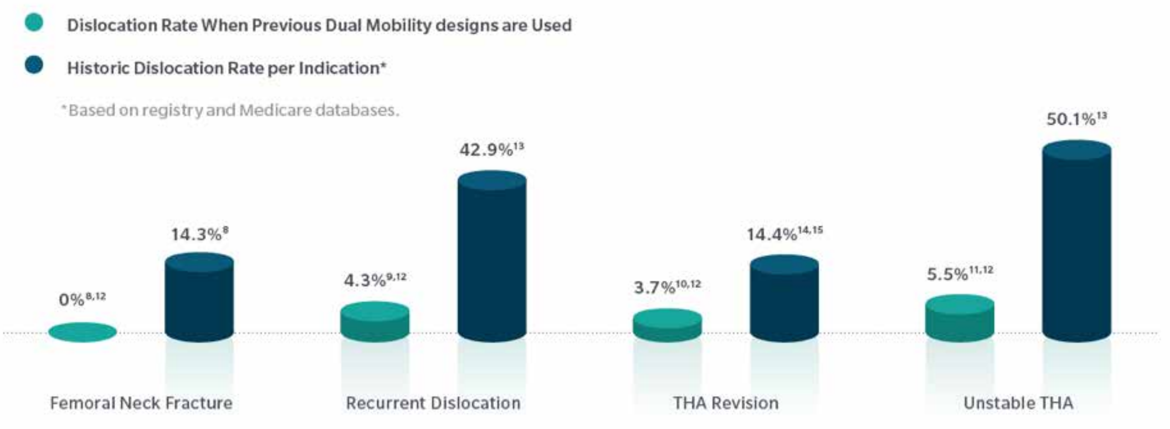
4. Implications of Dual Mobility Hips in Displaced Femoral Neck Fractures

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 major hurdle for THA adoption has been that displaced femoral neck fractures have a reported dislocation rate of approximately 10%, roughly five times higher than the dislocation rate in primary THA (Figure 5-1).[43] However, lower rates of revision and revision due to dislocation have been reported with the use of DMC (Dual Mobility Construct) 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 DMC in this challenging patient cohort.

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

Historical Dislocation Rates of Traditional and Dual Mobility Construct Designs

Dual mobility constructs have been used for over 30 years in a variety of patient types.[7–12]
The chart below highlights the clinical success of previous dual mobility designs compared to traditional constructs for patients with an increased risk of dislocation for reasons such as femoral neck fracture,[8] recurrent dislocation,[9] revision hip arthroplasty[10] and instability.[11]



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. [13,44]

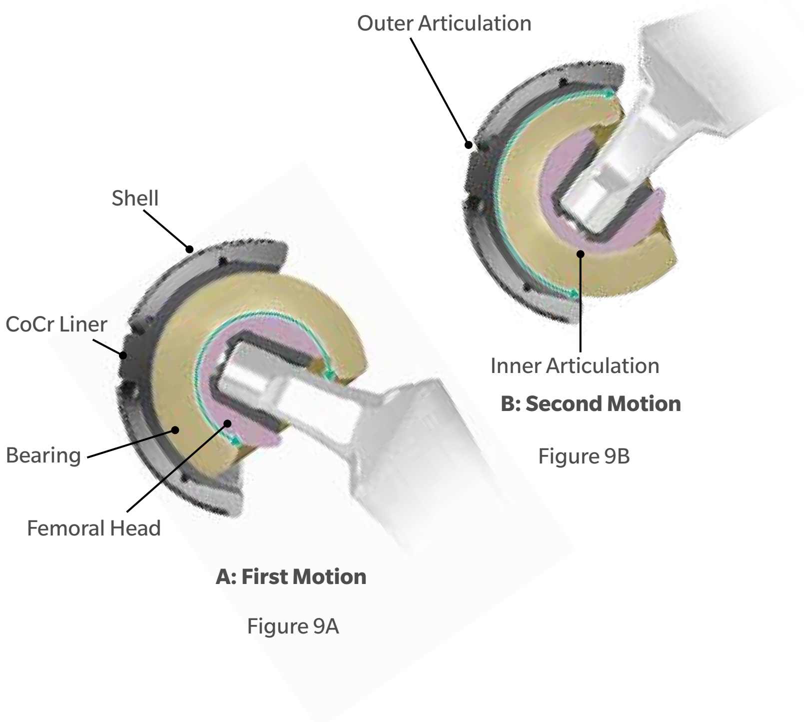
Increased Range of Motion (ROM) with Dislocation Resistance

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



A: First Motion

Figure 9A

B: Second Motion

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.

*Not available in the US disclaimer

6. References

1. Johansson T, Bachrach-Lindström M, Aspenberg P, Jonsson D, Wahlström O. The total costs of a displaced femoral neck fracture: comparison of internal fixation and total hip replacement. International orthopaedics. 2006;30(1):1-6.

2. Cauley JA, Lui LY, Genant HK, Salamone L, Browner W, Fink HA, et al. Risk factors for severity and type of the hip fracture. Journal of Bone and Mineral Research. 2009;24(5):943-55.

3. Cheung C-L, Ang SB, Chadha M, Chow ES-L, Chung Y-S, Hew FL, et al. An updated hip fracture projection in Asia: the Asian Federation of Osteoporosis Societies study. Osteoporosis and sarcopenia. 2018;4(1):16-21.

4. Gjertsen J-E, Baste V, Fevang JM, Furnes O, Engesæter LB. Quality of life following hip fractures: results from the Norwegian hip fracture register. BMC musculoskeletal disorders. 2016;17(1):265.

5. Filipov O. Epidemiology and social burden of the femoral neck fractures. Journal of IMAB–Annual Proceeding Scientific Papers. 2014;20(4):516-8.

6. Lee Y-K, Ha Y-C, Park C, Koo K-H. Trends of surgical treatment in femoral neck fracture: a nationwide study based on claim registry. The Journal of arthroplasty. 2013;28(10):1839-41.

7. Chesser T, Handley R, Swift C. New NICE guideline to improve outcomes for hip fracture patients. Injury. 2011;42(8):727-9.

8. Roberts KC, Brox WT, Jevsevar DS, Sevarino K. Management of hip fractures in the elderly. JAAOS-Journal of the American Academy of Orthopaedic Surgeons. 2015;23(2):131-7.

9. Chamberlain M, Pugh H. Improving inpatient care with the introduction of a hip fracture pathway. BMJ Open Quality. 2015;4(1):u204075. w2786.

10. Chehade M, Taylor A. Australian and New Zealand guideline for hip fracture care-improving outcomes in hip fracture management of adults. 2014.

11. Blakeney WG, Epinette JA, Vendittoli PA. Dual mobility total hip arthroplasty: should everyone get one? EFORT open reviews. 2019;4(9):541-7.

12. Data on file at Biomet. G7 Dual Mobility Range of Motion Study. April 2015.

13. Active Articulation Hip Bearings. IFU 01-50-1254 Rev B. April 2015.

14. Lewis DP, Wæver D, Thorninger R, Donnelly WJ. Hemiarthroplasty vs Total Hip Arthroplasty for the Management of Displaced Neck of Femur Fractures: A Systematic Review and Meta-Analysis. The Journal of arthroplasty. 2019.

15. Ochi H, Baba T, Homma Y, Matsumoto M, Watari T, Ozaki Y, et al. Total hip arthroplasty via the direct anterior approach with a dual mobility cup for displaced femoral neck fracture in patients with a high risk of dislocation. SICOT-J. 2017;3.

16. Bensen AS, Jakobsen T, Krarup N. Dual mobility cup reduces dislocation and re-operation when used to treat displaced femoral neck fractures. International orthopaedics. 2014;38(6):1241-5.

17. Kim YT, Yoo JH, Kim MK, Kim S, Hwang J. Dual mobility hip arthroplasty provides better outcomes compared to hemiarthroplasty for displaced femoral neck fractures: a retrospective comparative clinical study. Int Orthop. 2018;42(6):1241-6.

18. Boukebous B, Boutroux P, Zahi R, Azmy C, Guillon P. Comparison of dual mobility total hip arthroplasty and bipolar arthroplasty for femoral neck fractures: A retrospective case-control study of 199 hips. Orthopaedics & Traumatology: Surgery & Research. 2018;104(3):369-75.

19. Ukaj S, Zhuri O, Ukaj F, Podvorica V, Grezda K, Caton J, et al. Dual Mobility Acetabular Cup Versus Hemiarthroplasty in Treatment of Displaced Femoral Neck Fractures in Elderly Patients: Comparative Study and Results at Minimum 3-Year Follow-up. Geriatr Orthop Surg Rehabil. 2019;10:2151459319848610.

20. Zagorov M, Mihov K, Dobrilov S, Tabakov A, Gospodinov A, Nenova G. Dual mobility cups reduce dislocation rate in total hip arthroplasty for displaced femoral neck fractures. Journal of IMAB–Annual Proceeding Scientific Papers. 2018;24(2):2077-81.

21. Reina N, Pareek A, Krych AJ, Pagnano MW, Berry DJ, Abdel MP. Dual-mobility constructs in primary and revision total hip arthroplasty: a systematic review of comparative studies. The Journal of arthroplasty. 2019;34(3):594-603.

22. Romagnoli M, Grassi A, Costa GG, Lazaro LE, Presti ML, Zaffagnini S. The efficacy of dual-mobility cup in preventing dislocation after total hip arthroplasty: a systematic review and meta-analysis of comparative studies. International orthopaedics. 2019;43(5):1071-82.

23. Jobory A, Kärrholm J, Overgaard S, Pedersen AB, Hallan G, Gjertsen J-E, et al. Reduced Revision Risk for Dual-Mobility Cup in Total Hip Replacement Due to Hip Fracture: A Matched-Pair Analysis of 9,040 Cases from the Nordic Arthroplasty Register Association (NARA). JBJS. 2019;101(14):1278-85.

24. Bhandari M, Devereaux P, Tornetta III P, Swiontkowski MF, Berry DJ, Haidukewych G, et al. Operative management of displaced femoral neck fractures in elderly patients: an international survey. JBJS. 2005;87(9):2122-30.

25. Bhandari M, Swiontkowski M. Management of acute hip fracture. New England Journal of Medicine. 2017;377(21):2053-62.

26. Dhanwal DK, Dennison EM, Harvey NC, Cooper C. Epidemiology of hip fracture: worldwide geographic variation. Indian journal of orthopaedics. 2011;45(1):15.

27. Johnell O, Kanis J. An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. Osteoporosis international. 2006;17(12):1726-33.

28. Kanis JA, Oden A, McCloskey EV, Johansson H, Wahl DA, Cooper C. A systematic review of hip fracture incidence and probability of fracture worldwide. Osteoporosis international. 2012;23(9):2239-56.

29. Mithal A, Kaur P. Osteoporosis in Asia: a call to action. Current osteoporosis reports. 2012;10(4):245-7.

30. Tan LTJ, Wong SJ, Kwek EBK. Inpatient cost for hip fracture patients managed with an orthogeriatric care model in Singapore. Singapore medical journal. 2017;58(3):139.

31. Yang Y, Du F, Ye W, Chen Y, Li J, Zhang J, et al. Inpatient cost of treating osteoporotic fractures in mainland China: a descriptive analysis. ClinicoEconomics and outcomes research: CEOR. 2015;7:205.

32. Wang Y, Cui H, Zhang D, Zhang P. Hospitalisation cost analysis on hip fracture in China: a multicentre study among 73 tertiary hospitals. BMJ open. 2018;8(4):e019147.

33. Mohd-Tahir N, Li S. Economic burden of osteoporosis-related hip fracture in Asia: a systematic review. Osteoporosis International. 2017;28(7):2035-44.

34. Kondo A, Zierler BK, Isokawa Y, Hagino H, Ito Y, Richerson M. Comparison of lengths of hospital stay after surgery and mortality in elderly hip fracture patients between Japan and the United States–the relationship between the lengths of hospital stay after surgery and mortality. Disability and rehabilitation. 2010;32(10):826-35.

35. Ravi B, Pincus D, Khan H, Wasserstein D, Jenkinson R, Kreder HJ. Comparing Complications and Costs of Total Hip Arthroplasty and Hemiarthroplasty for Femoral Neck Fractures: A Propensity Score-Matched, Population-Based Study. JBJS. 2019;101(7):572-9.

36. Jones MD, Parry M, Whitehouse MR, Blom AW. Early death following revision total hip arthroplasty. Hip international : the journal of clinical and experimental research on hip pathology and therapy. 2018;28(4):400-6.

37. Badarudeen S, Shu AC, Ong KL, Baykal D, Lau E, Malkani AL. Complications After Revision Total Hip Arthroplasty in the Medicare Population. J Arthroplasty. 2017;32(6):1954-8.

38. Hopley C, Stengel D, Ekkernkamp A, Wich M. Primary total hip arthroplasty versus hemiarthroplasty for displaced intracapsular hip fractures in older patients: systematic review. Bmj. 2010;340:c2332.

39. Keating J, Grant A, Masson M, Scott NW, Forbes J. Displaced intra-capsular hip fractures in fit, older people: a randomised comparison of reduction and fixation, bipolar hemiarthroplasty and total hip arthroplasty. Health Technol Assess. 2005;9(41):1-65.

40. Sarpong NO, Grosso MJ, Lakra A, Held MB, Herndon CL, Cooper HJ. Hemiarthroplasty Conversion: A Comparison to Primary and Revision Total Hip Arthroplasty. J Arthroplasty. 2019;34(6):1168-73.

41. Hongisto MT, Pihlajamäki H, Niemi S, Nuotio M, Kannus P, Mattila VM. Surgical procedures in femoral neck fractures in Finland: a nationwide study between 1998 and 2011. International orthopaedics. 2014;38(8):1685-90.

42. Baker RP, Squires B, Gargan MF, Bannister GC. Total hip arthroplasty and hemiarthroplasty in mobile, independent patients with a displaced intracapsular fracture of the femoral neck. A randomized, controlled trial. The Journal of bone and joint surgery American volume. 2006;88(12):2583-9.

43. Iorio R, Healy WL, Lemos DW, Appleby D, Lucchesi CA, Saleh KJ. Displaced femoral neck fractures in the elderly: outcomes and cost effectiveness. Clin Orthop Relat Res. 2001(383):229-42.

44. Miller BJ, Callaghan JJ, Cram P, Karam M, Marsh JL, Noiseux NO. Changing trends in the treatment of femoral neck fractures: a review of the american board of orthopaedic surgery database. J Bone Joint Surg Am. 2014;96(17):e149.

45. Burroughs BR, Hallstrom B, Golladay GJ, Hoeffel D, Harris WH. Range of motion and stability in total hip arthroplasty with 28-, 32-, 38-, and 44-mm femoral head sizes: an in vitro study. The Journal of arthroplasty. 2005;20(1):11-9.

46. Beaulé PE, Schmalzried TP, Udomkiat P, Amstutz HC. Jumbo femoral head for the treatment of recurrent dislocation following total hip replacement. JBJS. 2002;84(2):256-63.

47. Klemen Bedencic, et al. (2019). A Way to Eliminate Luxation After Primary Hip Replacement - a Single Centre Experience with 1000 Cases of Dual Mobility Cups. CPQ Orthopaedics, 1(6), 01-07.

48. Fresard PL, Alvherne C, Cartier JL, Cuinet P, Lantuejoul JP. Seven-year results of a press-fit, hydroxyapatite-coated double mobility acetabular component in patients aged 65 years or older. European journal of orthopaedic surgery & traumatology : orthopedie traumatologie. 2013;23(4):425-9.

49. Semenowicz J, Mroczka A, Kajzer A, Kajzer W, Koczy B, Marciniak J. Total hip arthroplasty using cementless avantage cup in patients with risk of hip prosthesis instability. Ortopedia, traumatologia, rehabilitacja. 2014;16(3):253-63.

50. Graversen AE, Jakobsen SS, Kristensen PK, Thillemann TM. No dislocations after primary hip arthroplasty with the dual mobility cup in displaced femoral neck fracture in patients with dementia. A one-year follow-up in 20 patients. Sicot j. 2017;3:9.

51. Sterling RS. Gender and race/ethnicity differences in hip fracture incidence, morbidity, mortality, and function. Clin Orthop Relat Res. 2011;469(7):1913-1918. doi:10.1007/s11999-010-1736-3

52. Burge R, Dawson-Hughes B, Solomon DH, Wong JB, King A, Tosteson A. Incidence and economic burden of osteoporosis-related fractures in the United States, 2005-2025. J Bone Miner Res. 2007;22(3):465-475. doi:10.1359/jbmr.061113

53. Brauer CA, Coca-Perraillon M, Cutler DM, Rosen AB. Incidence and mortality of hip fractures in the United States. JAMA. 2009;302(14):1573-1579. doi:10.1001/jama.2009.1462

54. Adeyemi, Ayoade PhD1; Delhougne, Gary MS1 Incidence and Economic Burden of Intertrochanteric Fracture, JBJS Open Access: March 28, 2019 - Volume 4 - Issue 1 - p e0045 doi: 10.2106/JBJS.OA.18.00045

55. Bureau, U. (2018, October 29). The Population 65 Years and Older: 2016. Retrieved August 10, 2020, from https://www.census.gov/library/visualizations/interactive/population-65-years.html

This material is intended for health care professionals. Distribution to any other recipient is prohibited.

For indications, contraindications, warnings, precautions, potential adverse effects, and patient counseling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

ZIMMER BIOMET
Your progress. Our promise.®

3018.1-US-en-REV1020

Legal Manufacturer
Biomet Orthopedics
P.O. Box 587
56 E. Bell Drive
Warsaw, Indiana 46581-0587
USA