Hemiarthroplasty vs. tripolar total hip arthroplasty in the treatment of displaced femoral neck fractures in old-age patients

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Background

Displaced femoral neck fractures (DFNFs) are increasingly common in elderly patients. Hip arthroplasty, the recommended treatment of DFNF, consists of the total hip arthroplasty (THA) and hemiarthroplasty (HA). THA is superior to HA in younger patients. However, there are concerns whether the more substantial surgical trauma and higher dislocation rate would trade off the advantages of THA due to frailty and lower physical demands in the elderly over 75 years. **Objective**

This study was designed to compare the clinical score, dislocation rate, and functional outcome between the dual mobility total hip replacement and the bipolar hemiarthroplasty (BHA) in the treatment of FNFs and which of them is more successful.

Patients and methods

A comparative randomized prospective study was conducted on 50 patients with DFNFs. All cases were operated upon in Helwan University Hospitals, divided them into two equal groups: the first group was treated by total hip replacement with a dual mobility cup (DMC) and the second group was treated by BHA. Full analysis of history detailed examination and primarily samples are taken during the period study from February 2020 to April 2021.

Results

There is a statistically significant improvement in modified Harris hip score (MHHS) in the last follow-up at 9 months later in favor to DMC group compared with BHA group (P<0.001). The postoperative MHHS in the last follow-up of DMC ranged from 68 to 92 with the mean of 85.96±5.47, whereas in BHA group, ranged from 60 to 89 with the mean of 78.04±8.40.

Conclusion

THA may be a preferred management option for active elderly patients over 75 years, which can provide superior hip function and life quality with acceptable risks. Strict management should be followed to prevent dislocation after a THA, especially within the first 6 months.

Keywords:

DFNF, dislocation, dual mobility cup, hemiarthroplasty, modified Harris hip score, total hip arthroplasty

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Abbreviations: American Society of Anesthesiology, (ASA); bipolar HA, (BHA); Deep venous thrombosis, (DVT); Displaced femoral neck fractures, (DFNF); Dual mobility cup, (DMC); femoral neck fracture, (FNF); hemiarthroplasty, (HA); hip hemiarthroplasty, (HHA); total hip arthroplasty, (THA).

Introduction

The proportion of elderly people is increasing as the world's population ages, resulting in an expected rise in the incidence of osteoporotic hip fractures [1,2]. It is estimated that about 1.6 million hip fractures occurred in the year 2000 and the incidence of hip fractures is expected to increase to over 6 million worldwide by the

year 2050 [3,4]. About half of the hip fracture population has displaced femoral neck fracture (DFNF, Garden type III or IV) of the subcapital region; DFNFs can result in nonunion or avascular necrosis [5,6]. Moreover, these fractures are associated with impaired mobility, loss of function, and personal dependence as well as with global economic health costs, and are significant causes of mortality and morbidity in the elderly [7,8]. The optimal treatment of DFNF in the elderly is an ongoing

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scientific and clinical debate. Surgical treatment options for DFNF include internal fixation, which is not recommended in elderly patients, and arthroplasty [9,10]. Both hemiarthroplasty (HA) and total hip arthroplasty (THA) are widely accepted methods of hip replacement after DFNF [11,12]. Some evidence has suggested that THA leads to better functional outcome than HA; however, there are some advantages of HA compared with THA such as reduced dislocation rate, less complex surgery, shorter operation time, less blood loss, and lower initial costs [13,14]. The prosthesis and the acetabulum in HA can be articulated using a unipolar or bipolar prosthesis, and bipolar HA (BHA) provides good outcomes for elderly patients with DFNFs [15,16]. BHA after FNF has predictable and good medium- and long-term results. Even when compared with internal fixation or unipolar HA, BHA displays a later onset of acetabular erosion [15,17]. A review of data from national registries supports the continued use of BHA for FNF in the elderly, implying that BHA should be the preferred treatment for elderly patients with DFNF [18,19]. Elderly patients who receive BHA may also have a more favorable survival outcome compared with those who receive unipolar HA [20,21]. In addition, in elderly patients with FNFs who were fit and physiologically young, uncemented BHA seemed to achieve better functional outcomes. The clinical results from different groups cannot agree on whether to recommend BHA or THA [13,22]. Therefore, our study aimed to compare hemiarthroplasty vs. tripolar THA in the treatment of DFNFs in old-age patients.

Patients and methods

A comparative randomized prospective study was conducted on 50 patients with DFNFs. All cases were operated upon in Helwan University Hospitals, divided them into two equal groups: the first group was treated by total hip replacement with a dual mobility cup (DMC) and the second group was treated by BHA.

Ethical consideration

All participants were volunteers. All of them signed a written informed consent with explaining the aim of study before the study initiation. Approval of the study protocol was obtained by Ethical Scientific Committee for human research at Helwan University Hospitals and Om El Masreen General Hospital.

Inclusion criteria included patients older than 65 years at the time of injury, sustained an acute DFNF

(Garden III or IV), treatment with either BHA or dual mobility THA, and available follow-up records of at least 6 months postoperatively.

Exclusion criteria included severe cognitive dysfunction that may have hindered postoperative rehabilitation, absence of independent walking capability before trauma, implants, and/or surgical approach other than those specified in this study.

All selected women included in this study were subjected to the following: preoperative component that includes patient selection, patient counseling, and patient evaluation; clinical evaluation including history, general examination, and local examination; the American Society of Anesthesiology (ASA) system; modified Harris Hip Score scoring (MHHS); radiological evaluation; preoperative preparation of the patient. Local examination: complete local examination of the involved hip joint routine with particular emphasis on the following issues: limb length discrepancy, scars of operations, and neurovascular status. Operative technique: both lateral and posterior approaches were used in this study, details of lateral hip approach and details of the posterior hip approach. Postoperative component: patient transfer procedure: antibiotics, anticoagulants. recovery room, Hemoglobin level was checked in the first postoperative day, and also, wound condition, ambulation protocol, and radiological evaluation.

Statistical analysis

Results were collected, tabulated, statistically analyzed by IBM personal computer and statistical package SPSS version 25 (IBM Corp, 2013, Armonk, NY). Descriptive statistics included percentage (%), mean (x), SD and analytic statistics included χ^2 and Student's *t*-test. *P* value<0.05 was considered statistically significant.

Results

A total of 50 patients with DFNFs were included in our study, and divided into group I treated by total hip replacement with a DMC and group II treated by BHA. Results showed nonsignificant differences between DMC and BHA groups regarding age and sex (P>0.05), whereas body mass index (BMI) was significantly higher among DMC group than BHA group (P=0.006). In DMC group, the mean age of the studied patients was 68.64±6.88 years and the mean BMI was 29.08±2.42 kg/m². More than half of patients (52%) were males. In BHA group, the mean age of patients was 66.72 ± 5.57 years and the mean BMI was 26.69 ± 3.33 kg/m². More than half of patients (52%) were females (Table 1).

Also, there were no significant differences between DMC and BHA groups regarding dislocation, limb discrepancy, deep venous thrombosis (DVT), and infection (P>0.05). In DMC group, no dislocations occurred in all patients, limb discrepancy and DVT occurred in two patients (8%), and infection occurred in one patient (4%), whereas in BHA group, dislocations occurred in three patients (12%), limb discrepancy occurred in five patients (20%), DVT occurred in one patient (4%), and infection occurred in two patients (8%) (Table 2).

Blood loss, operative time, and the mean length of hospital stay were significantly higher among DMC group than BHA group (P<0.001). In DMC group, the approximate amount of calculated intraoperative blood loss ranged from 1000 to 2000 ml with mean of 1520.0±312.25 ml and the operative time ranged from 80 to 120 min with mean of 97.8±12.17 min. Also,

Table 1	Demographic	data of	DMC and	BHA groups
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mean length of hospital stay was 4.6 ± 0.87 days, whereas in BHA group, the approximate amount of calculated intraoperative blood loss ranged from 50 to 1200 ml with mean of 650.0 ± 292.97 ml and the operative time ranged from 50 to 90 min with mean of 62.2 ± 10.21 min. Also, the mean length of hospital stay was 4.04 ± 0.98 days (Table 3).

The mean duration of follow-up in the DMC and BHA groups was 9 months. There is a statistically significant improvement in pain score in the last follow-up at 9 months later in favor to DMC group (P<0.001). The postoperative pain score in the last follow-up of DMC ranged from 68 to 92 with the mean of 85.96±5.47, whereas in BHA group, it ranged from 60 to 89 with the mean of 78.04±8.40 (95% confidence interval [CI]=3.89–11.95 min, P<0.001) (Table 4 and Fig. 1).

The mean changes of MHHS were significantly higher in the last follow-up at 9 months later in favor to DMC group compared with preoperation (P<0.001) (Table 5 and Fig. 2).

	DMC (n=25)	BHA (<i>n</i> =25)	t	P value	95% CI	
					Lower	Upper
Age						
Mean±SD	68.64±6.88	66.72±5.57	1.084	0.284	-1.64	5.48
Range	60–80	60–81				
Sex	No. (%)	No. (%)	$\chi^2 = 0.08$	0.777	0.387	3.56
Male	13 (52.0)	12 (48.0)				
Female	12 (48.0)	13 (52.0)				
BMI						
Mean±SD	29.08±2.42	26.69±3.33	2.903	0.006*	0.74	4.05
Range	23–32	20.1-31.1				

BHA, bipolar arthroplasty; BMI, body mass index; CI, confidence interval; DMC, dual mobility cup; t, independent t test. *Significant.

Table 2 Radiological results among DMC and BHA groups

	DMC (n=25) No. (%)	BHA (n=25) No. (%)	χ^2	P value	95% CI	
					Lower	Upper
Dislocation						
No	25 (100.0)	22 (88.0)	3.191	0.074	0.345	0.635
Yes	0 (0.0)	3 (12.0)				
Limb discre	pancy					
No	23 (92.0)	20 (80.0)	1.495	0.221	0.502	16.477
Yes	2 (8.0)	5 (20.0)				
DVT						
No	23 (92.0)	24 (96.0)	0.335	0.552	0.041	5.652
Yes	2 (8.0)	1 (4.0)				
Infection						
No	24 (96.0)	23 (92.0)	0.335	0.552	0.177	24.615
Yes	1 (4.0)	2 (8.0)				

BHA, bipolar arthroplasty; CI, confidence interval; DMC, dual mobility cup; DVT, deep venous thrombosis; χ^2 , Pearson χ^2 test.

Table 3 Operation data of DMC and BHA groups

	DMC (n=25)	BHA (<i>n</i> =25)	t	P value	95% CI	
					Lower	Upper
Blood loss (ml)						
Mean±SD	1520.0±312.25	650.0±292.97	10.159	<0.001*	697.82	1042.18
Range	1000-2000	50-1200				
Time in min						
Mean±SD	97.8±12.17	62.2±10.21	11.204	<0.001*	29.21	41.99
Range	80–120	50–90				
Hospital stays/day	/s					
Mean±SD	4.6±0.87	4.04±0.98	2.143	<0.001*	0.03	1.09
Range	4–7	3–6				

BHA, bipolar arthroplasty; CI, confidence interval; DMC, dual mobility cup; t, independent t test. *Significant.

Table 4 MHHS score among DMC and BHA groups before and after operation

	DMC (n=25)	BHA (<i>n</i> =25)	t	P value	95% CI	
					Lower	Upper
Before operation						
Mean±SD	20.41±3.11	16.25±4.72	2.145	0.024*	10.12	18.5
Range	15–28	14–30				
1 month						
Mean±SD	50.96±8.29	38.28±7.36	5.717	<0.001*	8.22	17.14
Range	26–65	24–55				
3 months						
Mean±SD	61.52±5.38	49.44±8.63	5.939	<0.001*	7.99	16.17
Range	50-73	35–68				
6 months						
Mean±SD	72.68±5.13	63.04±7.55	5.282	<0.001*	5.97	13.31
Range	60–80	46–78				
9 months						
Mean±SD	85.96±5.47	78.04±8.40	3.949	<0.001*	3.89	11.95
Range	68–92	60–89				
Paired t test	839.829	405.32				
P value	<0.001*	<0.001*				

Comparison between the studied groups was done using independent *t* test, paired *t* test was used to compare between the patients in one group before and after treatment. BHA, bipolar arthroplasty; CI, confidence interval; DMC, dual mobility cup; MHHS, modified Harris hip score. *Significant.

Case presentations

Case 1 was a male ages 72 years with displaced left neck femur fracture and Garden type 3. His risk factors for dislocation were old age; MHHS at 6-month followup (94); pain improved from marked pain to slight occasional pain that does not compromise daily activity; gait: at last, follow-up patient can walk without support; activities: at last follow-up patient can climb stairs and put on shoes; operative details: acetabular reconstruction was done using cementless DMC and femoral reconstruction was done using cementless stem (Figs. 3–6).

Case 2 was a female ages 71 years with displaced left neck femur fracture and Garden type 4. Her risk factors for dislocation were old age; MHHS at 6-month follow-up (94); pain: improved from marked pain to pain free; gait: at last follow-up patient can walk without support; activities: at last follow-up patient can climb stairs and put on shoes; operative details: acetabular reconstruction was done using cemented DMC and femoral reconstruction was done using cementless stem (Figs. 7–11).

Case 3 was a female ages 75 years with displaced left neck femur fracture and Garden type 3. Her risk factors for dislocation were old age; MHHS at 6-month follow-up (92)' pain: improved from marked pain to pain free; gait: at last follow-up patient can walk without support; activities: at last follow-up patient can climb stairs and put on shoes; operative details: acetabular reconstruction was done using cemented

Table 5 Mean changes	of MHHS score among	DMC and BHA	groups before operation	compared with after operation

MHHS changes	DMC	(<i>n</i> =25)	BHA	(<i>n</i> =25)	P value
	Mean±SD	Improv. (%)	Mean±SD	Improv. (%)	
Before operation	_	_	_	_	_
1 month	30.55±5.20	149.68	22.03±2.64	135.67	<0.001*
3 months	41.11±2.27	201.42	33.19±3.91	204.25	<0.001*
6 months	52.27±2.02	256.10	46.79±2.83	287.94	<0.001*
9 months	65.55±2.36	321.17	61.79±3.68	380.25	<0.001*
P value	<0.	001*	<0.	001*	

Comparison between the studied groups was done using independent *t* test, paired *t* test was used to compare between the patients in one group before and after treatment. BHA, bipolar arthroplasty; DMC, dual mobility cup; MHHS, modified Harris hip score. *Significant.

Figure 1



Total pain data of dual mobility cup and bipolar hemiarthroplasty groups before and after operation.





Case 1a: preoperative anteroposterior left hip x ray.

Figure 2



Mean changes of modified Harris hip score among dual mobility cup and bipolar hemiarthroplasty groups before compared with after operation.

Figure 4



Case 1b: postoperative anteroposterior x ray.

Figure 5



Case 1c: anteroposterior view of left hip at 3-month follow-up.

Figure 6



Case 1d: anteroposterior view of left hip at 6 months.

DMC and femoral reconstruction was done using cemented stem (Fig. 12).

Discussion

DFNFs are increasingly common in elderly patients. Hip arthroplasty, the recommended treatment of DFNF, consists of the THA and HA [7]. THA is superior to HA in younger patients. However, there are concerns whether the more substantial surgical trauma and higher dislocation rate would trade off the advantages of THA due to frailty and lower physical demands in the elderly over 75 years [11]. In this study,





Case 2a: preoperative CT pelvis. CT, computerized tomography.

BMI was significantly higher among DMC group than BHA group, whereas there were no significant differences between DMC and BHA groups regarding age and sex. The mean age of the studied patients was 68.64 ± 6.88 and 66.72 ± 5.57 years in DMC group and BHA group with means of BMI were 29.08 ± 2.42 and 26.69 ± 3.33 kg/m², respectively. A total of 52% of patients were males in DMC group vs. 52% females in BHA group. In the same line, the study by Barışhan *et al.* [11] found that the most widely accepted surgical technique for the treatment of DFNFs in elderly patients is arthroplasty, and the clinical results of performing this type of surgery as THA or HA have been reported in the literature by Figure 8

Figure 9



Case 2b: preoperative 3D CT pelvis. CT, computerized tomography.

Figure 10



Case 2d: anteroposterior view of left hip of case 3 at 3-month follow-up.

Barışhan *et al.* [11], Thorngren *et al.* [22], Nather *et al.* [23], and Bekerom *et al.* [24]. Also, Hedbeck *et al.* [25] conducted a prospective randomized clinical trial examining the results of arthroplasty (HA, n=41; THA, n=42) performed in 83 patients aged >65 years. The authors found that although the results of both techniques were similar in the short-term period, the first-year follow-up results in the THA group were significantly better. Macaulay *et al.* [26] found that at the end of a 1-year follow-up, the Harris hip scores



Case 2c: intraoperative picture by fluoroscopy to left hip.

Figure 11



Case 2e: anteroposterior view of left hip at 6-month follow-up.

were 80 and 84, respectively, without a significant difference. Cadossi *et al.* [27] performed a study of patients with FNFs aged >70 years, 49 of whom underwent HA and 47 of whom underwent THA; at the 3-year follow-up, their Harris hip scores were 78 and 71, respectively, and this difference was significant. Liao *et al.* [28] found that patients who underwent THA had higher Harris hip scores at the 1-year postoperative follow-up, and this good outcome was





Case 3a: postoperative anteroposterior left hip x ray.

still present at the 2-year follow-up. Although the clinical differences obtained after arthroplasty surgery for the treatment of FNFs are reportedly due to patient-specific and surgeon-specific factors, additional studies with larger sample sizes and longer follow-up periods are needed to make more accurate assessments [29]. Our results agree with Liu et al. [17], who found that age and sex did not show any significant differences between the studied groups. Moreover, Liao et al. [28] revealed that as both groups went through propensity matching, age, sex, and ASA classification showed no significant difference, whereas there were significant differences between the studied groups regarding BMI.

In our study, no significant differences were found between DMC and BHA groups regarding dislocation and limb discrepancy. In DMC group, no dislocations occurred in all patients, whereas in BHA group, dislocations occurred in three patients (12%). Also, the study by Barishan et al. [11] revealed that two patients were treated uneventfully with abduction braces worn for 8 weeks, whereas one patient suffered two more recurrent dislocations after the initial reduction. Closed reduction after the third dislocation resulted in a dissociation of the bipolar cup from the femoral head, which consequently required revision. As there was no DMC option available in the institution at the period, the treatment was completed with a component exchange of the slightly overstuffed bipolar cup for a smaller component in addition to a longer neck. A thorough transosseous reattachment of the posterior soft capsule and tendons was performed followed by use of an abduction brace for 12 weeks. For the two dislocations in the DMC group, closed reduction was successful in all patients and no further dislocations took place after 5 weeks' application of abduction braces with no significant differences among studied groups in terms of dislocation. Dislocation is a devastating complication in hip arthroplasty. Blewitt and Mortimore [30] even reported a six-fold higher mortality rate of 65% within 6 months after BHA dislocation compared with a 10% mortality rate during the same period for those without dislocation. Compared with other etiologies such as osteoarthritis, fracture proved to be a more significant risk factor for postoperative dislocation in hip arthroplasty [31]. BHA still stands as the mainstay of treatment for DFNF due to its lower risk of dislocation compared with THA. In addition, Tarasevičius et al. [32] found that DMC was also shown to have a lower risk of dislocation than THA. Thus far only Bensen et al. [33] directly compared the dislocation rates of BHA and DMC for DFNF; BHA proved to be significantly more prone to dislocation then DMC with no significant difference, BHA did show a slightly higher dislocation rate.

In the current study, the mean duration of follow-up in the DMC and BHA groups was 9 months. Mean blood loss, operative time, and the mean length of hospital stay were significantly higher among DMC group than BHA group. In agreement with Barışhan et al. [11], the amount of intraoperative/postoperative blood loss and the number of transfusions were greater in the THA group. Also, Moretti et al. [34] found reduced hospitalization length in the hip hemiarthroplasty cohort. In accordance with our findings, Zhao et al. [35] reported that patients who underwent THR had a slightly higher blood loss than those in HA group (460 vs. 320 ml) and a litter longer mean duration of surgery in THR. Also, Hedbeck et al. [25] reported a smaller proportion of patients who had blood loss over 500 ml in the HA group (64.3% vs. 93.3%). Macaulay et al. [26] noted that more blood transfusion was needed in THR compared with HA (7.7 vs. 5.5 unit) and they observed longer mean surgical time in THR group. On contrary, Wang et al. [18] found no significant differences in outcomes including blood loss and length of postoperative hospital stay. Also, Iorio et al. [36], Chammout et al. [37], Ren et al. [38], and Sonaje et al. [39] found a significant benefit in favor of HA. The pooled analysis comparing THA with HA found a

mean difference of 21.7 min (95% CI=8.7-34.8 min, P=0.001), with high heterogeneity. In addition, Cadossi *et al.* [27] recently got an opposite result that more patients undertaking THR had blood loss of less than 500 ml. Also, they found a decrease the mean duration of surgery of 5.6 min in THR group. An important possible factor explaining this difference was that with the development of technique and prosthesis, the surgery of THR tended to be more convenient and time saving. Of course, individual differences could not be ignored too.

The present study demonstrated a statistically significant improvement in MHHS in the last follow-up at 9 months later in favor to DMC group. Also, the mean changes of MHHS score were significantly higher in the last follow-up at 9 months later in favor to DMC group compared with preoperation (65.55±2.36, with improvement of 321.17%). The postoperative MHHS in the last follow-up of DMC ranged from 68 to 92 with the mean of 85.96±5.47, whereas in BHA group, it ranged from 60 to 89 with the mean of 78.04±8.40 (95% CI=3.89 to 11.95 min, P<0.001). In agreement with our findings, Zhao et al. [35] favored the total hip replacement because hip function improved significantly compared with the HA group within 1 and 2 years after surgery. Also, Cadossi et al. [27] noted, from 3 months to 3 years postoperatively, the higher HHS transferred from HA to THR and the dominance of THR seemed to be increasingly evident. Similar result was reported by Hedbeck et al. [25], with the same duration of follow-up. Consistent with current findings, Yu et al. [40] and Burgers et al. [41] reported that the HHS was higher after THA compared with HA. Another agreement by Fahad et al. [42] showed that mean preoperative HHS for bipolar group was found to be 71.01, whereas for THA with DMC group, it was 73.52 with the difference being statistically insignificant. In terms of outcome variables, mean postoperative HHS for bipolar group was noted to be 68.82, whereas for THA with DMC group, it was 76.81. The difference was found to be statistically significant. With regard to postoperative complications, no significant difference was noted between both groups. In contrast, Avery et al. [43] showed that the functional score had declined in both groups between 3 and 9 years and the dominance in the THR group had also decreased 9 years after surgery as a result of the older age, prosthetic degeneration, and other complications. Also, Wang et al. [18] found that HHS after THA was not significantly different from that after BHA in each subgroup; however, it tended to be higher after THA. The subsequent results showed that the HHS in the THA group was better than that in the BHA group within 2 years, whereas the HHS was nonsignificantly higher in the THA group after 2 years. They suggested that even though THA might lead to better clinical outcomes, proper implants were of great importance for the patients. Moreover, heterogeneity was obvious between studies, which might also have influenced the validity of the pooled results. The explanation for the better hip function in patients managed with THA compared with HA due to acetabular erosion has been considered to be one important factor and, in previous reports, the rate of acetabular erosion has ranged from 2%14 to 36%15 for unipolar designs and from 0%14 to 26%16 for bipolar designs [25].

Strength of the study

The strength of this study is that much effort was taken to set the type of arthroplasty as the only variable. The two groups were operated by the same surgeon through the same approach, and even share the same femoral component, setting the acetabular procedure as the sole independent variable. Both groups were propensity matched in demographic data and the ASA classification to strengthen the analysis.

Limitation of the study

First, we included a small number of studies because of the strict inclusion criteria, and as a result, some essential data endpoints (average blood loss and long-term HHS) could not be analyzed. Second, we could only perform subgroup analyses according to age because of not enough data for the subgroup analyses based on comorbidities and ASA score. Third, there were much advancements in orthopedics, such as prosthetic equipment and hip function evaluation methods. Further research with an older population or subgroup analyses based on other factors reflecting patient frailty, such as comorbidities and ASA score, is needed.

Conclusion

Our study suggests that THA with DMCs may be a better alternative to BHA in treatment of displaced neck of femur fractures in elderly. First, the more extensive surgery of THA will not lead to detectable increases in mortality rate and general complications. Second, older patients, who have lower physical demand, can still benefit from THA in terms of hip function and quality of life. By changing our regimen of treatment from BHA to THA with DMC, we effectively reduced the number of dislocations in our population from 10% to 0%. DMC showed good clinical results as MHHS, ambulatory level, and lower limb discrepancy (LLD) in comparison with BHA. BHA showed statistical significance in less blood loss, operative time, and hospital stay in comparison with DMC. Further long-term studies are recommended to strengthen these results.

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Conflicts of interest

There are no conflicts of interest.

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