Dual-Mobility Versus Large Femoral Head in Revision Total Hip Arthroplasty: Interim Analysis of A Randomized Controlled Trial

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INTRODUCTION:

The purpose of this multicenter randomized controlled trial was to determine if dual-mobility bearings (DM) lower the risk of dislocation compared to large femoral heads (≥36mm) for patients undergoing revision total hip arthroplasty (THA).

METHODS:

146 Patients were randomized to a DM (n = 76; 46mm median effective head size, range 36-59mm) or a large femoral head (n=70; twenty-five 36mm heads, forty-one 40mm heads, four 44mm heads). All procedures were performed via a posterior approach. There were 39 both-component revisions, 78 single-component revisions (60 acetabular-only, 11 stem-only, and seven isolated head and liner exchanges), 24 reimplantation of THA after 2-stage revision, four conversions of hemiarthroplasty, and one revision of a hip resurfacing. The primary outcome was dislocation. Power analysis determined 161 patients were required in each group (power=0.8, alpha=0.05), assuming a reduction in dislocation rate from 8.4% to 2.2%. Descriptive and univariate statistics were performed, with alpha <0.05. RESULTS:

At a mean of 18.2 months (range, 1.4-48.2), there were three dislocations in the large femoral head group (all 40mm heads) compared to two in the DM cohort ([46mm and 51mm effective heads] 4.3% vs. 2.6%; p=0.67) at a mean of 5.0 months postoperatively (range, 0.5-12.5). One patient in the large head group and none in the DM group were successfully treated with closed reduction without subsequent revision (one DM patient required open reduction and was subsequently revised for periprosthetic joint infection; the remaining dislocations received head and liner exchanges). The effective head size was larger in the DM cohort vs. large head overall (46.0 ± 4.3 mm vs. 38.7 ± 2.2 , p<0.001) and in those that dislocated (48.5 ± 3.5 mm vs. 40.0 ± 0.0 mm, p=0.02).

DISCUSSION AND CONCLUSION: Interim analysis of a multi-center randomized trial found no difference in the risk of dislocation, although the rate of dislocation was lower than anticipated. Full enrollment and further follow up is required.

Variable	Large Head	Dual-Mobility	P-Value
Patients, n	70	76	
Mean age at surgery, years (SD)	68.4 (12.2)	66.8 (10.8)	0.38
Gender, n (%)			0.02
Male	39 (55.7)	29 (37.2)	
Female	31 (44.3)	49 (62.8)	
Mean BMI, kg/m2 (SD)	30.6 (6.9)	30.0 (6.7)	0.65
Laterality, n (%)			0.59
Right	40 (57.1)	48 (61.5)	
Left	30 (42.9)	30 (38.5)	
Smoking Status, n (%)			0.01
Never	43 (61.4)	31 (40.8)	
Former	17 (24.3)	39 (51.3)	
Current	8 (8.6)	5 (6.6)	
Not Assessed	4 (5.7)	3 (3.9)	
CCI Score, median (IQR)	3.0 (2.0, 4.0)	3.0 (2.0, 3.0)	0.12
ASA Score, median (IQR)	3.0 (2.0, 3.0)	3.0 (2.0, 3.0)	0.31
Mean albumin preoperatively (SD)	3.8 (0.7)	4.0 (0.5)	0.10
Mean follow-up, months (SD)	19.1 (10.8)	17.6 (11.2)	0.36

Criteria	Large	Dual-	P-	
	Head	Mobility	Value	
Both component revision, n (%)	21	18 (23.7)	0.77	
	(30.0)	' '		
Single component revision, n (%)	34	44 (57.9)	0.34	
	(48.6)	, ,		
Conversion of hip resurfacing to	0 (0.0)	1 (1.3)	> 0.99	
THA, n (%)				
Conversion of hemiarthroplasty to	3 (4.3)	1 (1.3)	0.34	
THA, n (%)	, ,			
Reimplantation of THA after 2 stage,	12	12 (15.8)	0.77	
n (%)	(17.1)	, ,		
1 stage procedure for PJI, n (%)	0 (0.0)	0 (0.0)		

Component	Large	Dual-	
	Head	Mobility	
Mean (effective) head size, mm (SD)	38.7 (2.2)	46.0 (4.3)	
Mean cup size, mm (SD)	58.7 (4.2)	58.3 (5.9)	
Mean liner size, mm (SD)	39.2 (3.4)	46.0 (4.4)	
Mean neck length, mm (SD)	2.9 (4.2)	3.3 (3.8)	

Туре	Large Head	Dual- Mobility	P- Value
Dislocation, n (%)	3 (4.3)	2 (2.6)	0.67
Median time to dislocation, months (IQR)	1.4 (0.9, 7.0)	5.4 (5.2 – 5.7)	0.80
PJI, n (%)	3 (4.3)	4 (5.3)	>0.99
Median time to PJI, months (IQR)	3.3 (2.0-4.6)	3.1 (2.7 – 3.5)	>0.99
Revision surgery, n (%)	4 (5.7)	8 (10.5)	0.31
Mean time to revision, months (range)	1.9 (1.0-3.5)	4.9 (2.3 – 5.9)	0.28
90-day readmission, n (%)	4 (5.7)	3 (3.9)	0.71
Fracture, n (%)	0 (0.0)	0 (0.0)	
Intraoperative, n (%)	1 (1.4)	1 (1.3)	> 0.99