Dual-Mobility Versus Conventional Bearings in Patients at High Risk of Dislocation: 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) reduce the risk of dislocation in high-risk patients undergoing primary total hip arthroplasty (THA) compared to conventional bearings.
METHODS:
248 Patients undergoing primary, posterior approach THA were randomized to a DM (n=120; 42mm median effective head, range 32-53mm) or a conventional bearing (n=128; two 28mm heads, twenty-three 32mm, seventy-seven 36mm, twenty-two 40mm, and four 44mm femoral heads). Three patients randomized to DM incorrectly received a conventional bearing. High-risk inclusion were: prior lumbar fusion, neuromuscular disorder, dementia, substance abuse, age ≥75, inflammatory arthritis, or preoperative combined flexion, adduction, and internal rotation ≥115°. Stratified randomization was performed: 1) patients with a history of spinal fusion (n=70) and 2) other inclusion criteria (n=178). The primary outcome was dislocation. Patient-reported outcome measures (PROMs) were collected at six weeks, one year, and two years. Power analysis determined 206 patients were required in each group (power=0.80, alpha=0.05), assuming a reduction in dislocation from 8% to 2%. Descriptive and univariate statistics (intention-to-treat and per-protocol) were performed, with alpha <0.05.
RESULTS:
There was one dislocation in the conventional cohort (0.8%; 36mm head) compared to none in the DM cohort (p=1.00) at mean follow-up of 15.5 months (range, 1.4-47.7). Revision surgery for any reason occurred in five patients in the conventional group (all for infection) vs. one DM patient (periprosthetic femur fracture; 3.9% vs. 0.8%; p=0.22). PROMs were not significantly different at all time points (p=0.10-0.96). There was no difference in intention-to-treat or per-protocol analyses. The effective head size was larger in the DM cohort vs. conventional (41.2±3.9mm vs. 36.0±3.0, p<0.001).
DISCUSSION AND CONCLUSION:
At interim analysis, DM did not decrease dislocation rates in high-risk patients undergoing primary THA, although the overall rate of dislocation was lower than expected. Continued enrollment and follow-up are required.

Table 1: Demographic information by randomization

Variable	Conventional	Dual Mobility	p-value
Patients, n			
Intention-to-treat	128	120	
Per-protocol	131	117	
Mean age, years (SD)	71.8 (10.5)	72.6 (11.4)	0.59
Gender, n (%)			0.57
Female	83 (64.8)	73 (61.3)	
Male	45 (35.2)	46 (38.7)	
Mean BMI, kg/m² (SD)	30.0 (6.6)	29.6 (6.0)	0.62
			0.85
Side, n (%)			
Left	55 (43.0)	53 (44.2)	
Right	73 (57.0)	67 (55.8)	
Smoking Status, n (%)			0.03
Never	60 (46.9)	61 (50.8)	
Former	56 (43.8)	57 (47.5)	
Current	12 (9.4)	2 (1.7)	
Mean CCI (SD)	3.9 (1.8)	3.9 (1.9)	0.98
Mean albumin (SD)	4.0 (0.4)	4.1 (0.4)	0.69
			0.54
ASA, n (%)			
1	2 (1.6)	5 (4.2)	
2	66 (51.6)	66 (55.0)	
3	59 (46.1)	48 (40.0)	
4	1 (0.8)	1 (0.8)	
Mean effective head size (SD)	36.0 (3.0)	41.2 (3.9)	<0.001

Table 2: PROMs and ROM from preoperative to postoperative by randomization (no difference in intention-to-treat and per-protocol)

Outcome	Conventional	Dual Mobility	p-value
Mean HHS (SD)			
Preoperative	45.1 (14.6)	42.6 (15.1)	0.35
6 weeks postoperative	69.6 (14.8)	67.3 (15.1)	0.34
1 year postoperative	75.3 (17.4)	75.7 (13.7)	0.15
2 years postoperative	79.9 (12.4)	79.8 (13.6)	0.96
Mean HOOS JR (SD)			
Preoperative	49.7 (14.1)	48.7 (13.3)	0.64
6 weeks postoperative	73.2 (15.5)	72.7 (16.8)	0.82
1 year postoperative	79.2 (20.4)	83.5 (16.2)	0.18
2 years postoperative	82.5 (17.4)	83.7 (14.4)	0.74
Mean SANE (SD)			
Preoperative	36.1 (26.9)	28.0 (24.5)	0.10
6 weeks postoperative	70.9 (23.7)	64.9 (25.4)	0.14
1 year postoperative	82.8 (21.8)	83.7 (17.7)	0.80
2 years postoperative	88.8 (17.0)	84.5 (23.6)	0.34
Mean Flexion (SD)			
Preoperative	88.4 (13.7)	88.6 (12.1)	0.91
6 weeks postoperative	93.9 (7.2)	94.8 (8.8)	0.62
1 year postoperative	95.7 (7.6)	96.0 (8.4)	0.87
2 years postoperative	98.3 (11.2)	97.3 (7.7)	0.74

Table 3: Overall complications by randomization (no difference between intention-to-treat and per-protocol)

Complication	Conventional	Dual Mobility	p-value
Dislocation, n (%)	1 (0.8)	0 (0.0)	1.00
Infection, n (%)	5 (3.9)	0 (0.0)	0.06
Fracture, n (%)	0 (0.0)	2 (1.7)	0.23
Revision, n (%)	5 (3.9)	1 (0.8)	0.22
Readmission, n (%)	4 (3.1)	6 (5.0)	0.53

Table 4: Complications in those with a history of spinopelvic fusion by randomization (no difference between intention-to-treat and per-protocol)

Complication	Conventional (n=41)	Dual Mobility (n=40)	p-value
Dislocation, n (%)	0 (0.0)	0 (0.0)	
Infection, n (%)	1 (2.8)	0 (0.0)	1.00
Fracture, n (%)	0 (0.0)	2 (5.9)	0.23
Revision, n (%)	1 (2.8)	1 (2.9)	1.00
Readmission, n (%)	1 (2.8)	4 (11.8)	0.19

Table 5: Complications in patients meeting inclusion criteria for Reasons other than spinopelvic fusion by randomization (no difference between intention-to-treat and per-protocol)

Complication	Conventional (n=99)	Dual Mobility (n=95)	p-value
Dislocation, n (%)	1 (1.1)	0 (0.0)	1.00
Infection, n (%)	4 (4.3)	0 (0.0)	0.12
Fracture, n (%)	0 (0.0)	0 (0.0)	
Revision, n (%)	4 (4.3)	0 (0.0)	0.12
Readmission, n (%)	3 (3.3)	2 (2.3)	1.00