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Large Femoral Heads Decrease the Incidence of Dislocation After Total Hip Arthroplasty

A Randomized Controlled Trial

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Investigation initiated and undertaken by the Discipline of Orthopaedics and Trauma, University of Adelaide, Adelaide, South Australia, Australia and performed at Royal Adelaide, St Andrew's, Glenelg, and Modbury Hospitals, Adelaide, South Australia, Australia; Whyalla Hospital, Whyalla, South Australia, Australia; Royal North Shore Hospital, Sydney, New South Wales, Australia; St. John of God and Ballarat Base Hospitals, Ballarat, Victoria, Australia; Geelong Hospital, Geelong, Victoria, Australia; Maroondah and St. Vincent's Hospitals, Melbourne, Victoria, Australia; Royal Bournemouth Hospital, Bournemouth, England; Southampton General Hospital, Southampton, England; and Ninewells Hospital, Dundee, Scotland

Background: The use of larger femoral heads has been proposed to reduce the risk of dislocation after total hip arthroplasty, but there is a lack of evidence to support this proposal. The aim of this multicenter randomized controlled trial was to determine whether the incidence of dislocation one year after total hip arthroplasty is significantly lower in association with the use of a 36-mm femoral head articulation as compared with a 28-mm articulation.

Methods: Six hundred and forty-four middle-aged and elderly patients undergoing primary or revision arthroplasty were randomized intraoperatively to receive either a 36 or 28-mm metal femoral head on highly cross-linked polyethylene. Patients who were at high risk of dislocation (including those with dementia and neuromuscular disease) and those undergoing revision for the treatment of recurrent hip dislocation or infection were excluded. Patients were stratified according to other potential risk factors for dislocation, including diagnosis and age. Diagnosis of hip dislocation required confirmation by a physician and radiographic evidence of a dislocation.

Results: Overall, at one year of follow-up, hips with a 36-mm femoral head articulation had a significantly lower incidence of dislocation than did those with a 28-mm articulation (1.3% [four of 299] compared with 5.4% [seventeen of 316]; difference, 4.1% [95% confidence interval, 1.2% to 7.2%]) when controlling for the type of procedure (primary or revision) ($p = 0.012$). The incidence of dislocation following primary arthroplasty was also significantly lower for hips with a 36-mm femoral head articulation than for those with a 28-mm articulation (0.8% [two of 258] compared with 4.4% [twelve of 275]; difference, 3.6% [95% confidence interval, 0.9% to 6.8%]) ($p = 0.024$). The incidence of dislocation following revision arthroplasty was 4.9% (two of forty-one) for hips with a 36-mm articulation and 12.2% (five of forty-one) for hips with a 28-mm articulation; this difference was not significant with the relatively small sample size of the revision group (difference, 7.3% [95% confidence interval, −5.9% to 21.1%]) ($p = 0.273$).

Conclusions: Compared with a 28-mm femoral head articulation, a larger 36-mm articulation resulted in a significantly decreased incidence of dislocation in the first year following primary total hip arthroplasty. However, before a 36-mm metal-on-highly cross-linked polyethylene articulation is widely recommended, the incidence of late dislocation, wear, periprosthetic osteolysis, and liner fracture should be established.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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Dislocation is the most common early complication following total hip arthroplasty and is one of the most common causes of early to intermediate-term revision of primary total hip arthroplasty[1,2].

The use of larger femoral heads has been proposed as a means of reducing the risk of dislocation because larger-diameter articulations have a relatively larger femoral head-to-neck ratio, which increases hip motion before impingement between components occurs[3,4]. Larger femoral head implants require a greater amount of femoral head displacement before dislocation occurs within a well-oriented acetabular component[4]. However, concerns about polyethylene wear in larger-diameter articulations, such as those involving 36 or 40-mm femoral heads, have prevented their use with earlier generations of ultra-high molecular weight polyethylenes. The development of highly cross-linked polyethylenes has now made the use of larger articulations feasible in total hip arthroplasty, given that the articulations involving the newer polyethylenes have shown less wear than the previous generation of polyethylenes in hip-simulator studies[5,6] and randomized controlled trials[7-10].

Two nonrandomized cohort studies of primary arthroplasty in which larger (≥30-mm) articulations were compared with 28-mm articulations suggested that increased femoral head size may be associated with a decreased risk of dislocation[11,12], whereas other studies have not conclusively shown this finding[13,14].

There are two important issues that need to be addressed when determining the potential magnitude of the effect of articulation size on the incidence of dislocation following hip arthroplasty. First, the risk of dislocation may be influenced by a number of other factors, including patient-related factors (such as diagnosis[14-16], age[16,17], and sex[15]) and surgical technique. Dislocation is more common in association with the posterior approach[11,17-19] and with a highly abducted acetabular component orientation[4] and is less common following soft-tissue repair[20,21]. Second, the rate of hip dislocation is frequently under-reported, primarily because of inadequate follow-up[22]. As the number of data sources used to identify episodes of dislocation increases, the capture rate increases significantly[22].

The aim of the present study was to examine the hypothesis that the incidence of dislocation at one year after total hip arthroplasty is significantly lower in association with a 36-mm femoral head articulation than with a 28-mm articulation. We undertook a randomized controlled trial in which a number of factors that may influence the risk of hip dislocation were controlled for by the study design and dislocation was tracked with a number of different methods.

Materials and Methods

The results of this trial are reported in accordance with CONSORT (Consolidated Standards of Reporting Trials) 2010 guidelines[23]. The study was undertaken as a multicenter, stratified, parallel-group randomized controlled trial involving fourteen hospitals (see Appendix). Consultants, or fellows or residents under their supervision, performed all procedures. The trial involved patients undergoing primary or revision total hip arthroplasty who were intraoperatively randomized to receive either a 28 or 36-mm femoral head articulation. Ethics approval was received from the institutional review board of every participating hospital. The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12609000678291).

Every patient who was scheduled to be managed with total hip arthroplasty by one of the collaborating surgeons was screened for inclusion in the trial. The reasons for, and the numbers of, preoperative exclusions are shown in the Appendix.

Eligible patients provided written informed consent if they were willing to participate in the trial. Patients were then stratified according to a number of factors to increase the likelihood that possible risk factors for dislocation would be distributed equally between patients randomized to a 36 or 28-mm femoral head articulation. The stratification and randomization procedures are described in detail in the Appendix.

The reasons for, and the numbers of, intraoperative exclusions for patients undergoing primary and revision procedures are shown in the Appendix. The randomization envelope was opened in the operating room after all exclusion criteria had been considered and it had been determined the patient was to be included. The envelope was opened after the acetabular component had been inserted and fixed with at least one screw but prior to the insertion of the stem. The patient received either a 36 or 28-mm articulation, according to the number in the envelope.

All arthroplasties were performed with use of uncemented acetabular components, which comprised a cluster three-holed acetabular shell (Trilogy; Zimmer, Warsaw, Indiana) fixed with one or two screws and a 10° elevated 36 or 28-mm-inner-diameter highly cross-linked polyethylene liner (Longevity; Zimmer). A cemented femoral stem was used for all primary arthroplasties (CPT; Zimmer). Either a cemented femoral stem (CPT; Zimmer) or an uncemented stem (ZMR; Zimmer) was used for revision arthroplasties. During the trial, the taper of the CPT femoral stem was changed from a 6° taper to a 12/14 taper by the manufacturer. When possible, each surgeon completed his allocated randomization block before commencing with the use of the 12/14 taper.

All primary arthroplasties were performed through a posterior surgical approach. Revision arthroplasties were performed through a posterior, transfemoral, or transtrochanteric approach. Repair of the capsule and external rotators was performed routinely during primary arthroplasties and, when possible, during revisions. The operative technique for insertion of the acetabular component through a posterior approach included reliance mainly on the alignment guide and confirmation by the surgeon's judgment that the component was reasonably positioned.

Determination of the incidence of hip dislocation required the use of a number of different approaches to ensure that all dislocations were identified. Prior to discharge, each patient was provided with a Dislocation Card, to be given to any physician who subsequently treated the patient for dislocation, with instructions for that physician to notify the study coordinator of the dislocation. Case notes were reviewed to check for inpatient episodes of postoperative dislocation. The patient was then reviewed at six weeks to three months and at one year, and any complications were noted. In addition, at each visit, the patient completed a Hip Instability Questionnaire, which we had previously developed and validated, and a Hospital Visit Questionnaire. The former included the item "hip came out of joint and was put back in by a physician," whereas the latter asked about all visits to an emergency room as well as any admissions. Dislocation was defined as an event requiring reduction by a physician or surgeon for which there was radiographic confirmation of a dislocation.

Patients, surgeons, and local study coordinators were not blinded to the articulation size received.

Radiographs showing the initial hip dislocation in every patient were assessed by one of the authors (D.W.H.) to determine the direction of dislocation. The position of the femoral head relative to the acetabular cup on the anteroposterior and lateral radiographs was used to determine the definite direction of the dislocation. If the lateral radiograph was unavailable or inadequate, the anteroposterior pelvic radiograph was used. The prominence of the lesser trochanter was compared to that of the contralateral side to determine the rotation of the femur and thereby the probable direction of dislocation. If only an anteroposterior hip radiograph was available, the prominence of the lesser trochanter was used to determine the possible direction of dislocation.

TABLE I Incidence of Dislocation One Year Following Total Hip Arthroplasty According to Type of Total Hip Arthroplasty or Type of Stem and Articulation Size

	Incidence of Dislocation					
	36–mm Articulation		28-mm Articulation			
	Number of Hips That Dislocated per Number of Hips in Group	Percentage*	Number of Hips that Dislocated per Number of Hips in Group	Percentage*	Difference Between Groups* *(%)*	P Value
Type of total hip arthroplasty						
All	4 of 299	1.3 (0.0 to 2.6)	17 of 316	5.4 (2.9 to 7.9)	4.1 (1.2 to 7.2)	0.012
Primary	2 of 258	0.8 (0.0 to 1.9)	12 of 275	4.4 (2.0 to 6.8)	3.6 (0.9 to 6.8)	0.024
Revision	2 of 41	4.9 (0.0 to 11.5)	5 of 41	12.2 (2.2 to 22.2)	7.3 (−5.9 to 21.1)	0.273
Type of stem						
CPT 12/14	2 of 163	1.2 (0.0 to 2.9)	8 of 178	4.5 (1.5 to 7.5)	3.3 (−0.6 to 7.5)	0.101
CPT 6°	1 of 117	0.9 (0.0 to 2.5)	7 of 120	5.8 (1.6 to 10.0)	4.9 (0.1 to 10.7)	0.072
ZMR	1 of 19	5.3 (0.0 to 15.3)	2 of 18	11.1 (0.0 to 25.6)	5.8 (−15.1 to 28.0)	0.542

*The 95% confidence intervals are given in parentheses.

The position of the acetabular component was assessed on the most recent anteroposterior pelvic radiograph that had been made prior to the dislocation. Inclination and anteversion of the acetabular component were measured with use of EBRA (Ein-Bild-Roentgen-Analyse) (EBRA-CUP, University of Innsbruck, Innsbruck, Austria).

Statistical Analysis

With use of a power of 80% and a two-sided alpha of 0.05, initial sample size estimates indicated that a total sample size of 650 patients would be required to detect a significant and clinically important reduction in the incidence of dislocation at one year from 8% in the 28-mm articulation group to 3% in the 36-mm articulation group, if such a difference were to exist. A planned interim analysis by an independent data-monitoring committee indicated adequate power for our data, even allowing for a 5% rate of patient attrition, and therefore a decision was made to stop recruitment after 644 patients had been randomized.

Poisson regression with, first, main effects of type of procedure (primary or revision arthroplasty) and articulation size (36 or 28 mm) and, second, type of stem (CPT 12/14, CPT 6°, or ZMR) and articulation size, was used to examine whether the primary outcome measure, the incidence of dislocation one year following total hip arthroplasty, was affected by articulation size. Log of the total number of patients was used as offset. An analysis with use of a Cox model was also undertaken to take into account the observed experience of patients who were lost to follow-up within the first year, either through death, revision, reoperation, or other reasons. Differences between means were assessed with use of an independent-samples t test, and differences in proportions were assessed with use of chi-square tests.

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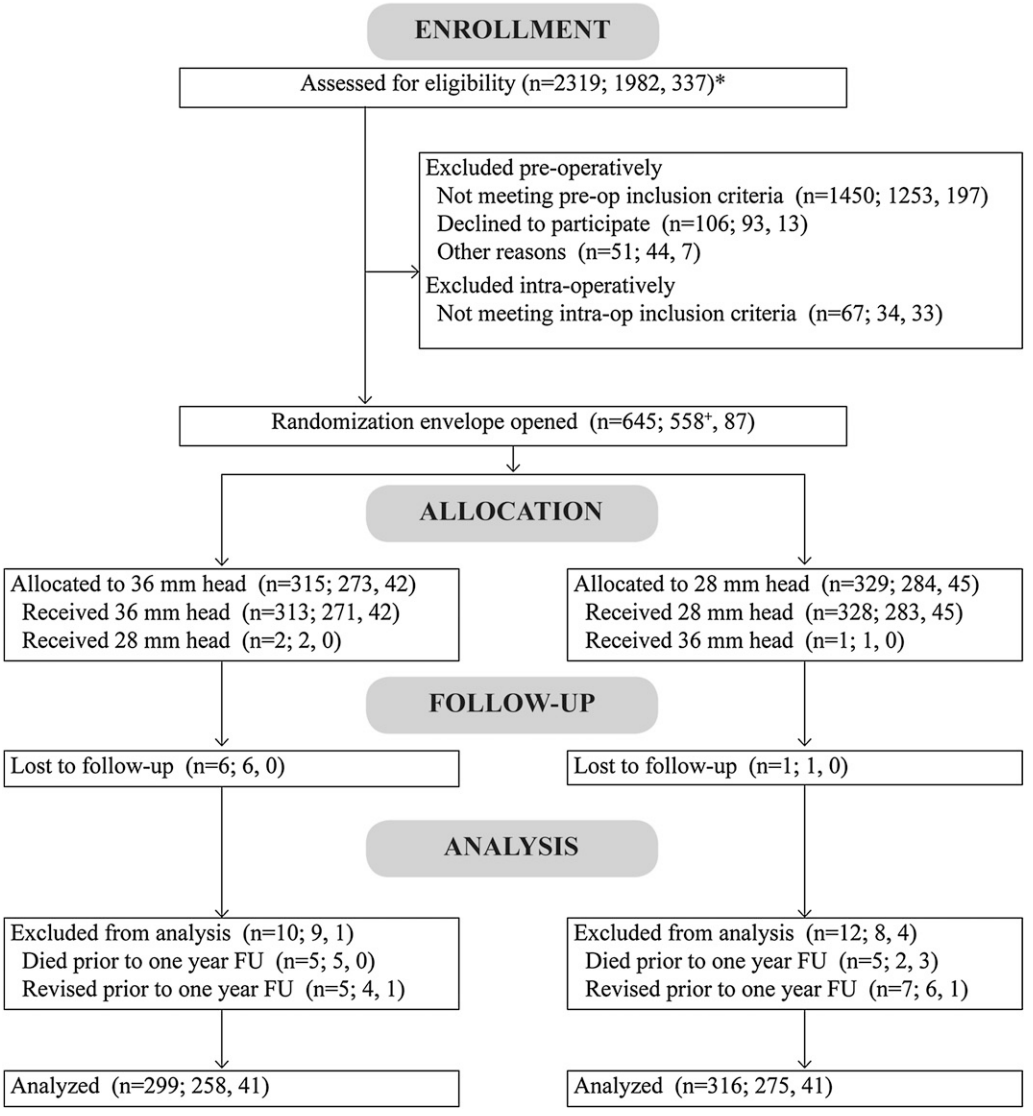
Results

Patients were recruited from September 2001 to June 2007. The numbers of patients who were assessed for eligibility, who were excluded preoperatively or intraoperatively, and who were randomized and included in the analyses are shown in Figure 1. Three patients received the wrong articulation size. These errors were due to breaches of protocol, with the envelope being opened prior to confirmation of the availability of all required components of the prosthesis and the required component in the allocated size subsequently being identified as not being available. These patients were included in the analysis according to their allocated articulation size; none of these patients had a dislocation. Seven (1.1%) of the 644 patients were lost to follow-up at one year and were excluded from the analysis. Another twenty-two patients were also excluded, ten because they died before the one-year follow-up without having a dislocation and twelve because they had undergone revision arthroplasty or reoperation, for reasons other than dislocation, that involved a change of implant or potential damage to the hip as a result of the surgery, which may have altered their risk of dislocation.

The incidence of dislocation at one year following hip arthroplasty was significantly lower in patients with a 36-mm femoral head articulation than in patients with a 28-mm articulation. One year following primary or revision arthroplasty, four (1.3%) of 299 hips with a 36-mm articulation and seventeen (5.4%) of 316 hips with a 28-mm articulation had dislocated (Table I). Controlling for the type of procedure (primary or revision), the articulation size was significantly related to dislocation ($\chi^2 = 6.4$, $p = 0.012$), with a significantly lower incidence of dislocation at one year in hips with a 36-mm articulation than in those with a 28-mm articulation. The incidence of dislocation at one year following primary hip arthroplasty was also significantly lower in hips with a 36-mm articulation than in those with a 28-mm articulation (0.8% [two of 258] compared with 4.4% [twelve of 275]) ($\chi^2 = 5.1$, $p = 0.024$). One year following revision arthroplasty, the



* (n=all THA pts; primary THA pts, revision THA pts)

+ One patient was withdrawn intra-operatively: the patient's randomization envelope was mistakenly opened at the onset of surgery, the patient then developed symptoms requiring surgery to be abandoned and the patient did not subsequently undergo surgery by a trial surgeon.

Fig. 1

CONSORT 2010 flow diagram. THA = total hip arthroplasty, FU = follow-up, pts = patients.

incidence of dislocation was not significantly different between hips with a 36-mm articulation and those with a 28-mm articulation (4.9% [two of forty-one] compared with 12.2% [five of forty-one]) ($\chi^2 = 1.2$, $p = 0.273$), most likely because of an insufficient number of revision procedures in the trial to achieve adequate power for this comparison. A Cox model stratified by the type of procedure (primary or revision) confirmed a lower risk of dislocation for hips with a 36-mm articulation during the first year following arthroplasty, taking into account the observed experience of patients who were subsequently lost to follow-up during the first year either through death, revision, reoperation, or another reason ($p = 0.005$). Controlling for the type of femoral stem, articulation size was significantly related to dislocation ($\chi^2 = 6.4$, $p = 0.012$). However, there was no significant difference in the incidence of dislocation between articulation sizes within any of the three stem types when

TABLE II Relationship Between Outer Diameter of Acetabular Cup, Articulation Size, and Dislocation Within One Year Following Primary and Revision Total Hip Arthroplasty

	Primary Total Hip Arthroplasty				Revision Total Hip Arthroplasty			
	36-mm Articulation (N = 255*)		28–mm Articulation (N = 275)		36-mm Articulation (N = 41)		28-mm Articulation (N = 41)	
Outer Diameter of Acetabular Cup *(mm)*	No. of Hips	No. of Hips That Dislocated	No. of Hips	No. of Hips That Dislocated	No. of Hips	No. of Hips That Dislocated	No. of Hips	No. of Hips That Dislocated
50	28		26		0		1	
52	58	1	68	3	4		1	
54	48		66	4	1		2	
56	58		54	5	5		2	1
58	34	1	27		8		6	1
60	15		22		8	1	7	
62	8		8		5	1	5	1
64	5		3		3		7	1
66	0		1		3		6	
68	1		0		1		1	
70					1		2	1
72					2		0	
74					0		1	

*The outer diameter of the acetabular cup was unknown for three patients.

considered individually, likely because of the smaller sample sizes in the individual analyses (Table I).

Given the relatively small number of patients with larger acetabular cup diameters, the relationship between femoral head size, cup diameter, and dislocation risk could not be determined in this study (Table II). However, three of the twenty-one patients with a dislocation had a 28-mm articulation in an acetabular cup with a diameter of at least 62 mm, representing a radius mismatch of at least 17 mm, which previously was identified as a risk factor for dislocation[24].

In both the primary and revision arthroplasty groups, the patients who were randomized to a 36-mm articulation were

TABLE III Characteristics of Patients at Time of Primary Total Hip Arthroplasty According to Allocation to Articulation Size

	36-mm Articulation (N = 273)	28-mm Articulation (N = 284)	P Value	Total (N = 557)
Female* *(%)*	56.0 (50.2 to 61.9)	61.3 (55.6 to 66.9)	0.212	58.7 (54.6 to 62.8)
Age *(yr)*				
Mean*	72.3 (71.5 to 73.0)	72.3 (71.6 to 73.1)	0.891	72.3 (71.8 to 72.8)
Range	59 to 93	60 to 92		59 to 93
BMI†				
Mean*	28.0 (27.4 to 28.7)	28.4 (27.8 to 29.0)	0.371	28.2 (27.8 to 28.7)
Range	16.7 to 44.0	18.8 to 51.5		16.7 to 51.5
Primary or secondary osteoarthritis*† *(%)*	96.3 (94.1 to 98.6)	95.4 (93.0 to 97.9)	0.588	95.9 (94.2 to 97.5)
Type of stem* *(%)*			0.704	
CPT 12/14	59.3 (53.5 to 65.2)	60.9 (55.2 to 66.6)		60.1 (56.1 to 64.2)
CPT 6°	40.7 (34.8 to 46.5)	39.1 (33.4 to 44.8)		39.9 (35.8 to 43.9)

*The 95% confidence intervals are given in parentheses. †Data on BMI (body mass index) were available for a total of 484 patients (237 with a 36-mm articulation and 247 with a 28-mm articulation). ‡Primary or secondary osteoarthritis without a previous fracture, traumatic dislocation, or surgery to the index hip.

TABLE IV Characteristics of Patients at Time of Revision Total Hip Arthroplasty According to Allocation to Articulation Size

	36-mm Articulation(N = 42)	28-mm Articulation(N = 45)	P Value	Total (N = 87)
Female* *(%)*	45.2 (30.2 to 60.3)	48.9 (34.3 to 63.5)	0.733	47.1 (36.6 to 57.6)
Age *(yr)*				
Mean*	75.2 (72.7 to 77.7)	73.8 (71.5 to 76.0)	0.384	74.4 (72.8 to 76.1)
Range	54 to 89	56 to 87		54 to 89
BMI†				
Mean*	28.9 (27.3 to 30.5)	27.8 (26.4 to 29.2)	0.304	28.3 (27.3 to 29.4)
Range	21.6 to 44.6	21.8 to 42.9		21.6 to 44.6
Type of revision* *(%)*			0.591	
Revision of hemiarthroplasty	11.9 (2.1 to 21.7)	17.8 (6.6 to 29.0)		14.9 (7.5 to 22.4)
1st revision of total hip arthroplasty	78.6 (66.2 to 91.0)	68.9 (55.4 to 82.4)		73.6 (64.3 to 82.8)
≥2nd revision of total hip arthroplasty	9.5 (0.7 to 18.4)	13.3 (3.4 to 23.3)		11.5 (4.8 to 18.2)
Type of stem* *(%)*			0.880	
CPT 12/14	26.2 (12.9 to 39.5)	31.1 (17.6 to 44.6)		28.7 (19.2 to 38.2)
CPT 6°	28.6 (14.9 to 42.2)	26.7 (13.8 to 39.6)		27.6 (18.2 to 37.0)
ZMR	45.2 (30.2 to 60.3)	42.2 (27.8 to 56.7)		43.7 (33.3 to 54.1)

*The 95% confidence intervals are given in parentheses. †Data on BMI (body mass index) were available for a total of eighty-one patients (thirty-nine with a 36-mm articulation and forty-two with a 28-mm articulation).

similar to those who were randomized to a 28-mm articulation (Tables III and IV).

Overall, seventeen (81%) of the twenty-one hips that dislocated within one year after primary or revision arthroplasty had a 28-mm articulation (Table V). The majority (nine) of the fourteen hips that dislocated after primary arthroplasty did so within thirty days after surgery, whereas hips that dislocated after revision arthroplasty showed a tendency to dislocate later. Approximately one-third of dislocating hips redislocated. Within the first year after hip arthroplasty, revision surgery for the

TABLE V Characteristics of Patients Who Had Hip Dislocation Within One Year After Primary or Revision Total Hip Arthroplasty

	Primary Arthroplasty (N = 14)	Revision Arthroplasty (N = 7)
36-mm:28-mm articulation *(no. of hips)*	2:12	2:5
Female:male ratio *(no. of hips)*	9*:5*	3*:4*
Age† *(yr)*	73 (62 to 84)	76 (61 to 83)
BMI†	29 (20 to 39)	26 (23 to 34)
Primary or secondary osteoarthritis‡	12*	NA§
Type of revision (revision of hemiarthroplasty:1st revision of total hip arthroplasty:≥2nd revision of total hip arthroplasty) *(no. of hips)*	NA§	1:4#:2
Stem type (CPT 6°:CPT 12/14:ZMR) *(no. of hips)*	5:9#:NA§	3*:1:3*
1st dislocation (≤10 days:11 to 30 days:31 to 100 days:>100 days postop.) *(no. of hips)*	4:5*:3*:2	1:1:4*:1*
>1 dislocation *(no. of hips)*	5*	3
Revised because of recurrent dislocation *(no. of hips)*	2*	3
Closed reduction of 1st dislocation *(no. of hips)*	13#	6#

*Includes one patient with a 36-mm articulation. †The values are given as the median, with the range in parentheses. ‡Primary or secondary osteoarthritis without a previous fracture, traumatic dislocation, or surgery on the index hip. §NA = not applicable. #Includes two patients with a 36-mm articulation.

treatment of recurrent dislocation was required in two of the fourteen hips that dislocated after primary arthroplasty and three of the seven that dislocated after revision arthroplasty; another hip that had dislocated after primary arthroplasty was revised because of failed closed reduction of the dislocation.

Of the fourteen first dislocations that occurred after primary arthroplasty, three were classified as definitely posterior, seven were classified as probably posterior, one was classified as possibly posterior, and three were classified as probably anterior. Of the seven first dislocations that occurred after revision arthroplasty, two were classified as definitely posterior, two were classified as probably posterior, two were classified as anterior, and one was classified as having an indeterminate direction.

The median inclinations of the acetabular components used for primary and revision total hip arthroplasties with a 28-mm articulation that subsequently dislocated were 44° (range, 34° to 52°) and 45° (range, 41° to 51°), respectively, and the median anteversions were 15° (range, 7° to 32°) and 16° (range, 10° to 22°), respectively. The two hips with a 36-mm articulation that dislocated after a primary procedure both had an inclination of 48° and anteversions of 5° and 7°. The two hips with a 36-mm articulation that dislocated after a revision procedure both had an inclination of 43° and an anteversion of 10°.

Discussion

The purpose of the present randomized controlled trial was to determine whether a larger (36-mm) femoral head articulation significantly reduced the incidence of dislocation within the first year following total hip arthroplasty in comparison with a 28-mm articulation. The results of this trial indicated that the incidence of dislocation within one year after primary arthroplasty was five times lower in patients with a 36-mm articulation (0.8%) than in those with a 28-mm articulation (4.4%); this difference was both clinically important and statistically significant.

The use of larger femoral head implants for total hip arthroplasty has been increasing during the last decade[25-27], largely on the basis of the premise that larger articulations are efficacious for preventing dislocations. Our trial showed that a larger articulation significantly reduced the risk of dislocation following primary arthroplasty. The number of patients undergoing revision arthroplasty as part of the trial was relatively small, and therefore the difference in the incidence of dislocation between the 36 and 28-mm articulations did not attain significance. It should be noted, however, that initial sample size calculations estimated the total number of patients required for an analysis of the effect of articulation size on the incidence of dislocation rather than the numbers required to examine the effects in the primary and revision arthroplasty groups independently.

Our conclusion that a larger articulation decreased the risk of dislocation following total hip arthroplasty supports the findings of two cohort studies[11,12] as well as those of two registry studies that showed a decreased risk of revision for dislocation after total hip arthroplasty with larger articulations[18,28].

Although we have been able to determine the short-term benefits of a larger, 36-mm metal-on-polyethylene articulation in total hip arthroplasty, specifically in terms of decreasing the incidence of dislocation up to one year following arthroplasty, what is best at one year may not be best at ten years. This needs to be emphasized because the use of a larger articulation in a metal-on-polyethylene bearing is not without potential risks. In an acetabular component of a given outer diameter, a 36-mm liner will of necessity be thinner than a 28-mm liner, particularly at the rim. The polyethylene thickness for a 36-mm liner in an acetabular component with an outer diameter of 50 mm is 6.7 mm at the pole and 5.8 mm at 45°. This may increase wear or even wear-through compared with the smaller-diameter liner, although the findings of simulator studies have been encouraging[29,30]. However, even if cross-linking improves wear resistance, the mechanical properties of highly cross-linked polyethylenes are reduced, leading to increased fracture potential of such liners, irrespective of the inner diameter[31,32].

Wear has been used as a surrogate measure of osteolysis with previous generations of polyethylene implants. Given the same rate of linear wear, volumetric wear will be greater in a larger articulation. However, the relationship between head penetration, volumetric wear of highly cross-linked polyethylene, and osteolysis is not yet well defined[33].

The major strength of our randomized trial was the ability to control for other variables that may affect the risk of dislocation. We chose to exclude patients who had certain characteristics that, although not common, could significantly increase the risk of dislocation and could affect the results if not equally distributed across the 36 and 28-mm articulation groups. Importantly, patients who were to undergo revision were excluded if revision was being undertaken because of recurrent dislocation or infection. Patients were stratified by other factors that were also considered possible risk factors for dislocation.

One limitation of our study is that seven (1.1%) of the 644 patients were lost to follow-up at one year and that six of these patients had received a 36-mm articulation. For patients who had been lost to follow-up, reviews of hospital records and, when available, local physician records suggested that no dislocations had occurred. However, as it could not be confirmed that no dislocations had occurred, the patients were treated as having been lost to follow-up and were excluded from the analysis.

In our randomized trial, the incidence of dislocation in the first year after primary total hip arthroplasty with a 28-mm articulation was 4.4%. Although this figure is at the upper end of the range of incidences reported in large cohort studies, two factors are likely to have influenced this finding. First, the incidence of dislocation is known to be higher in association with a posterior approach[11,17-19]. Second, the reported incidence is higher when patients are routinely followed and when the number of methods used to track dislocation increases[22].

In conclusion, the present randomized trial showed that a larger articulation significantly reduced the incidence of dislocation in the first year after total hip arthroplasty with a metal-on-highly cross-linked polyethylene articulation. It must be emphasized that before a 36-mm metal-on-highly cross-linked polyethylene articulation is widely recommended,

particularly in younger patients or those at lower risk of dislocation, the incidence of late dislocation, wear, periprosthetic osteolysis, and acetabular liner fracture needs to be established.

Appendix

eA Tables showing a description of the study centers and the reasons for the preoperative and intraoperative exclusion of patients from the study and additional paragraphs describing the stratification and radomization preocedures are available with the online version of this article as a data supplement at jbjs.org. ■

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TABLE E-1 Description of Study Centers

			No. of Patients (No. of Hips That Dislocated)	
Hospital	Type of Hospital	No. of Surgeons	Primary	Revision
Australia				
Royal Adelaide	Teaching, tertiary referral	12	135 (5)*	33 (3)
St. Andrew's, Adelaide	Metropolitan	1†	28	1
Glenelg, Adelaide	Metropolitan	1†	5	0
Modbury, Adelaide	Teaching, metropolitan	1†	10	0
Whyalla, Whyalla	Non-metropolitan	1†	5	0
Royal North Shore, Sydney	Teaching, tertiary referral	2	58 (1)	0
St. John of God, Ballarat	Non-metropolitan	1	45 (1)	1
Ballarat Base, Ballarat	Teaching, non-metropolitan	1†	8	0
Geelong, Geelong	Teaching, non-metropolitan	2	15 (1)	0
Maroondah, Melbourne	Metropolitan	2	11	0
St. Vincent's, Melbourne	Teaching, tertiary referral	2	8	3 (1)
England				
Royal Bournemouth	Teaching, tertiary referral	1	124 (2)	43 (3)
Southampton General	Teaching, tertiary referral	2	79 (3)	0
Scotland				
Ninewells, Dundee	Teaching, tertiary referral	2	26 (1)	6
All 14 hospitals		26	557 (14)	87 (7)

*A different surgeon operated on each of the five patients. †Surgeon also in trial at other listed hospital.

TABLE E-2 Numbers of Patients Excluded Preoperatively According to Exclusion Criteria, by Type of Total Hip Arthroplasty

	No. of Patients Excluded*	
Exclusion Criterion	Primary Total Hip Arthroplasty	Revision Total Hip Arthroplasty
Too young (<60 years old for primary procedures†; <50 years old for revision procedures)	559	20
Simultaneous bilateral total hip arthroplasty	2	0
Contralateral hip already in trial	50	6
Previous infection in hip	11	7
Diagnosis other than osteoarthritis, rheumatoid arthritis, inflammatory arthritis, or previous fracture/dislocation/surgery involving the hip	13	NA
Revision for hip instability	NA	34
Revision for infection	NA	17
Second stage of 2-stage revision or previous excision arthroplasty	NA	15
Not revision of hemiarthroplasty or conventional total hip arthroplasty	NA	5
Planned prosthesis		
Not Trilogy/CPT	455‡	NA
Not Trilogy/CPT or ZMR	NA	50
Planned approach		
Not posterior	4	NA
Not posterior, transtrochanteric, or transfemoral	NA	0
Intention to return to sports involving running or contact sports	0	0
Abnormal acetabulum	29	NA
Abnormal abductor mechanism	4	8
Likely postoperative leg-length inequality of >5 cm	1	1
Neuromuscular disease affecting hip	15	1
Primary or metastatic tumor involving index hip	10	1
Unable to provide informed consent (insufficient ability to communicate in English language/cognitive disorder/psychiatric illness)	73	15
Unable to complete follow-up (life expectancy <2 years/unable to complete English-language questionnaires/unable to return easily)	27	17
Total	1253	197

*Patients were excluded in a hierarchical manner, with only the first listed relevant exclusion criterion being recorded. NA = not applicable. †All Australian surgeons excluded patients less than sixty-five years old, one surgeon from the UK excluded patients less than seventy years old, and the other surgeons from the UK excluded patients less than sixty years old. ‡In one collaborating center, elderly, less-active patients received a cemented cup for cost reasons.

TABLE E-3 Numbers of Patients Excluded Intraoperatively According to Exclusion Criteria, by Type of Total Hip Arthroplasty

	No. of Patients Excluded*	
Exclusion Criterion	Primary Total Hip Arthroplasty	Revision Total Hip Arthroplasty
Surgical approach		
Not posterior	2	NA
Not posterior, transtrochanteric, or transfemoral	NA	0
Infection involving joint	0	0
Abnormal acetabulum	8	NA
Abnormal abductor mechanism	4	5
CPT or ZMR stem not inserted	2	11
Acetabular component not Trilogy with an outer diameter of ≥50 mm and fixed with at least one screw	8	14
Trial 28-mm liner not in place or trial stem not reduced	NA	2
Standard 28-mm or offset 36-mm liner not appropriate, or plan to use a long-neck skirted head	1	0
28 and 36-mm heads and liners for inserted shell not in operating room	9	1
Total	34	33

*Patients were excluded in a hierarchical manner, with only the first listed relevant exclusion criterion being recorded. NA = not applicable.

Appendix E-1

Prior to randomization, patients undergoing primary arthroplasty were stratified by surgeon, age (sixty to seventy-four years; seventy-five years or more), and diagnosis (previous fracture, traumatic dislocation, or surgery involving the index hip, irrespective of diagnosis; osteoarthritis without previous fracture, traumatic dislocation, or surgery; rheumatoid arthritis or inflammatory arthritis without previous fracture, traumatic dislocation, or surgery). If a patient had a diagnosis of osteoarthritis without previous fracture, traumatic dislocation, or surgery and was under seventy-five years old, he or she was also stratified by Charnley grade (A or B; C) and, if the patient was classified as Charnley A or B, he or she was further stratified by sex, resulting in eight strata per surgeon. Allocation of randomization sequences, with an allocation ratio of 1:1, was undertaken in block sizes of two, four, six, or eight on the basis of the anticipated prevalence of patients in each stratum, with larger block sizes being used for initial allocations. All ninety-eight possible allocation sequences were listed numerically, and each specific sequence was then chosen with random-number generation in Excel, without repetition, with use of the RANDBETWEEN command to choose from the required block size (block of two, sequences one to two; block of four, sequences three to eight, etc.). Each surgeon's unique randomization protocol initially allowed for forty-eight patients over the eight strata, with further allocations added subsequently if required. Sealed envelopes containing a folded piece of cardboard with either a "36" or "28" sticker were prepared in accordance with each consecutive allocation of a 36 or 28-mm articulation, over consecutive strata. Each envelope was then assigned a number with use of RANUNI, an SAS software random-number function (SAS Institute, Cary, North Carolina) programmed to generate forty-eight random numbers without replacement. The local study coordinator was notified of the next envelope number in the appropriate stratum, and that envelope was taken to the operating room.

Patients undergoing revision arthroplasty were stratified first according to the type of stem (cemented [CPT; Zimmer, Warsaw, Indiana] or uncemented [ZMR; Zimmer]) and then by whether they were undergoing revision of a hemi-arthroplasty or, if undergoing revision of a total hip arthroplasty, the number of previous revisions (first revision, second revision, or third revision [or greater]), resulting in four strata in each of the two randomization protocols, one being for revision with a CPT stem and the other for a ZMR stem. The randomization process for revision arthroplasty was the same as that described above for primary arthroplasty, except that each patient was allocated an envelope number from both the CPT and ZMR protocols, given that the decision to use a cemented or uncemented stem is occasionally made intra-operatively.

The Study Epidemiologist (O.T.H.) was responsible for every aspect of stratification and randomization. Participating surgeons and local study coordinators, who were responsible for enrolling patients, were not aware of the stratification and randomization

protocols. Local coordinators were advised by email of the allocated envelope number for each patient and ensured that this envelope was available in the operating room at the time of surgery. Envelopes allocated to patients who were excluded intraoperatively were returned unopened, to be reused when appropriate.