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Dislocation in Revision THA

Do Large Heads (36 and 40 mm) Result in Reduced Dislocation Rates in a Randomized Clinical Trial?

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Abstract

Background Dislocation after revision THA is a common complication. Large heads have the potential to decrease dislocation rate, but it is unclear whether they do so in revision THA.

Questions/purposes We therefore determined whether a large femoral head (36 and 40 mm) resulted in a decreased dislocation rate compared to a standard head (32 mm).

Methods We randomized 184 patients undergoing revision THA to receive either a 32-mm head (92 patients) or 36- and 40-mm head (92 patients) and stratified patients by surgeon. The two groups had similar baseline demographics. The primary end point was dislocation. Quality-of-life (QOL) measures were WOMAC and SF-36. The mean followup for dislocation was 5 years (range, 2–7 years); the mean followup for QOL was 2.2 years (range, 1.6–4 years).

Results In the 36- and 40-mm head group, the dislocation rate was 1.1% (one of 92) versus 8.7% (eight of 92) for the 32-mm head. There was no difference in QOL outcomes between the two groups.

Conclusions Our observations confirm a large femoral head (36 or 40 mm) reduces dislocation rates in patients undergoing revision THA at short-term followup. We now routinely use large heads with a highly crosslinked polyethylene acetabular liner in all revision THAs.

Level of Evidence Level I, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
This work was performed at the University of British Columbia; the University of Manitoba; Rush University Medical Center; and Mount Sinai Hospital.

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Introduction

In the United States, surgeons perform approximately 35,000 revision THAs each year [2], representing 17.5% of all annual THAs. It is estimated the number of revision THAs being performed annually will double between 2005 and 2030 [19].

One of the most common complications after revision THA is instability. Some estimate between 7% and 20% of revision THAs will dislocate [1, 21]. In many cases, this problem is recurrent, requiring further surgery. Springer et al. [24] found the most common cause of failure of revision THA is instability, accounting for 35% of all failed revision THAs.

With the advent of highly crosslinked polyethylene, larger heads of 36- and 40-mm-diameter have become available to surgeons. The mechanical advantage of the large head and increased head-to-neck ratio in preventing dislocation is demonstrated in cadaveric and mathematical models [4, 11, 22], as well as in vitro studies [8, 17].

There are several articles that look at the effect of head size in primary THA [3, 7, 10, 12–14, 20, 25], but very few address the issue in revision THA [9, 23]. Kung and Ries [18] observed no dislocations in 42 patients undergoing revision THA with 36-mm heads with intact abductors compared to a dislocation rate of 12.7% in groups with 28-mm heads. While this suggests femoral head size is associated with revision hip dislocation risk, the study is limited due to its design and sample size. Their study is also a noncontrolled comparative cohort study, which cannot fully address the potential for selection bias or multiple confounding factors. Given that the risk factors for dislocation are multifactorial, this type of study design can only suggest superiority. Only in a randomized controlled trial can multiple risk factors and biases be controlled and causation, rather than association, established.

Therefore, in this randomized trial, we determined whether a large femoral head (36 or 40 mm) resulted in a decreased dislocation rate compared to a standard head (32 mm) in revision THA.

Patients and Methods

For a prospective randomized clinical trial, we recruited 184 patients between March 2003 and August 2008 at seven centers in North America. Initial inclusion criteria were (1) patients undergoing revision THA, (2) revision of both acetabular and femoral components, (3) acetabular components with a minimum of 50-mm outer diameter, and (4) patients with the ability to reply to questionnaires in French or English. Exclusion criteria were (1) revision for recurrent dislocation, (2) revision of acetabulum requiring structural allograft or a reconstruction cage, (3) revision of the acetabulum with a cemented all-polyethylene cup, or (4) intraoperative decision to use a constrained liner. In the early part of the study, isolated acetabular revisions were not included, as stems often did not have large heads such as Porous-coated Anatomic (PCA®) (Howmedica, Rutherford, NJ, USA). In February 2007, 36-mm heads became available for most stems, and we included patients undergoing isolated acetabular at this point. We recruited patients and obtained consent in accordance with institutional ethics and IRB protocols at all participating sites.

Participating surgeons and their research staff recruited eligible patients at each center. Randomization took place in the operating room after surgeons were satisfied that they could implant either a standard head (32-mm diameter) or large head (36- or 40-mm diameter). Once randomized, patients in the large-head group received a 40-mm head if the stem and cup would accept this diameter. In cases where this was not possible, the patient received a 36-mm head and corresponding acetabular liner. For cup sizes 58 mm and greater, a 40-mm head was used when available [16]. We stratified patients first by surgeon and then by use of Trabecular Metal™ (Zimmer, Inc, Warsaw, IN, USA) shells. After stratification, the surgeons randomized the patients using sealed envelopes. Single blinding concealed the component design from patient, caregivers, and those related to the study, other than the surgeon and operating room staff. Allocation was a ratio of 1:1, with permuted blocks of four and six. Eleven surgeons at seven centers participated in recruitment and enrollment of patients.

We randomized 184 patients at the seven centers (Table 1). Included in these 184 patients were two patients in each group who died before 2 years postoperatively. In addition to the 184 randomized patients, there were six we excluded from the study: two needed a large head, one was removed because the original 32-mm head was used, one was deemed unfit due to possible laryngeal cancer, one was

Table 1. Recruitment by research center

Center	Number of patients	
	Recruited	Randomized
Vancouver	165	91
Winnipeg	48	28
Toronto	40	33
Chicago	25	16
Fort Worth	12	12
Ottawa	3	3
Halifax	1	1
Total	294	184

Table 2. Length of followup from index surgery

Statistic	Followed for dislocation (n = 179)*				Followed for quality of life (n = 133)†			
	Large head (n = 89)		Standard head (n = 90)		Large head (n = 67)		Standard head (n = 66)	
	Months	Years	Months	Years	Months	Years	Months	Years
Mean	64	5.2	62	5.1	26	2.2	27	2.2
Minimum	28	2.3	26	2.1	19	1.6	21	1.8
Maximum	92	7.6	91	7.5	42	3.5	46	3.8

* Four patients (two in each cohort) deceased before their 2-year followup for dislocation; one additional patient was randomized but excluded due to intraoperative fracture; †only a subset of patients chose to complete the quality-of-life scores at 2-year followup.

ineligible, and one was removed due to extensive loss of abductors. We followed patients for a minimum of 2 years for the primary outcome of dislocation and the secondary outcome of QOL. For dislocation as outcome, minimum followup was 2 years (mean, 5 years in both groups; range, 2–7 years) (Table 2).

We based the sample size calculation on the primary end point of this study: the first dislocation. We included patients in the analysis on an intention-to-treat basis and still followed patients who withdrew early for the primary outcome. We performed analysis using Fisher's exact test. We designed the study to evaluate for a reduction in dislocation rate from 10% in the control (32-mm ball) to 5% in the experimental group (36- and 40-mm ball). We were only interested in superiority of the large femoral head and employed a one-tailed test with α set at 0.05 and power of 80%. Using Fisher's exact test, we required 381 cases for a balanced design and anticipated a dropout rate of 10%, resulting in a target sample size of 419 patients in each surgical arm of the study. We carried out an interim analysis after enrollment of 175 patients, at which time the safety committee decided to stop further enrollment due to the marked difference in dislocation rates between the two groups.

Preoperatively, we recorded patient demographics, including age, sex, education level, BMI, and occupation (Table 3). Checking the randomization analysis with group comparisons at baseline revealed no unexpected results. At baseline, all patients completed a self-administered comorbidity score and completed quality-of-life (QOL) questionnaires. The QOL questionnaires at baseline were the WOMAC [5] and SF-36 [15].

The surgical approach for all cases was left to the discretion of the operating surgeon. The femoral component inserted was the VerSys® beaded full-coated (Zimmer) or ZMR™ (Zimmer) femoral stem or CPT™ (Zimmer) cemented stem, which can all accept the VerSys® 36- or 40-mm cobalt-chrome head (Zimmer). The acetabular component used was the Trilogy® cup (Zimmer) or the Trabecular Metal™ modular shell (Zimmer). Both cups were used in the study, but the decision to use one or the other was left to the operating surgeon. The Longevity® highly crosslinked acetabular liner (Zimmer) was used in both shells. The postoperative protocols were also left to the discretion of the operating surgeon (Table 4). We did not collect data regarding the postoperative use of abduction braces.

Table 3. Demographic data for study population (n = 184)

Variable	Large head	Standard head
Number of patients	92	92
Women	43	44
Men	49	48
Mean age (years)	68	70
Mean BMI (kg/m^2)	27.4	27.4
Mean comorbidity index	1.8	2.0
Education (number of patients)		
Less than high school	22	28
High school graduation	44	34
University undergraduate degree	15	18
Postgraduate degree	7	10
Did not answer question	4	2
Work Status (number of patients)		
Employed	12	11
Unemployed (homemaker, retired)	62	63
Unemployed because of disability	12	13
Other employment status	4	4
Did not answer question	2	1

We followed patients at 3, 12, 24, and 60 months postoperatively, asking patients to respond to a followup questionnaire at each interval. We contacted those who did not return questionnaires by telephone and encouraged them to complete the submission. At each followup, the questionnaires included the WOMAC and SF-36. Additionally, we questioned patients at each interval as to whether they had a dislocation. Annually, we contacted the family physician and local orthopaedic surgeon to check for any dislocation events. The mean followup for the QOL

Table 4. Surgical variables (n = 184)

Variable	Large head (n = 92)	Standard head (n = 92)
Arthroplasty (number of hips)		
First revision	56	54
Second revision	27	25
Third revision	5	9
More than 3 revisions	1	2
Did not answer question	3	2
Reason for revision (number of hips)		
Aseptic loosening	73	63
Infection (Stage 1)	0	0
Infection (Stage 2)	7	14
Polyethylene wear	4	3
Osteolysis	2	6
Instability	0	0
Implant fracture	1	1
Bone fracture	0	0
Other	2	4
Did not answer question	3	1
Surgical approach (number of hips)		
Smith/Peterson	1	0
Anterolateral	4	5
Posterolateral	62	68
Direct lateral	19	17
Did not answer question	6	2
Femoral stem (number of hips)		
VerSys®	36	42
ZMR™	42	37
CPT™	3	2
Stem not replaced	11	11

was 26 months (range, 19–42 months) for the large-head group and 27 months (range, 21–46 months) for the standard-head group (Table 2).

The WOMAC osteoarthritis index is the tool recommended for disease-specific outcome measures of hip and knee arthroplasty [6]. It is a self-administered multidimensional index containing dimensions for pain (five items), stiffness (two items), and function (17 items). Items contain five Likert responses, which may be reported singly and in aggregate. The WOMAC is valid [5] and reliable in patients with osteoarthritis of the hip and knee. Presently, it is the most frequently used measure of pain and functional disability among arthroplasty patients. WOMAC is scored using normalized data, with a score of 0 being the worst and 100 being the best.

The SF-36 is a self-administered generic measure of QOL with eight subscales: (1) physical functioning, (2) social functioning, (3) role limitations (physical), (4) role limitations (emotional), (5) pain, (6) mental health, (7) vitality, and (8) general health perception. The SF-36 is widely used and is reliable and valid across a broad spectrum of medical conditions [15].

We compared baseline values between cohorts regarding age, BMI, comorbidity index, outcome measures of the SF-36 physical and mental scales, and WOMAC function, stiffness, pain and aggregate scales, via two-sample t-tests. Only the SF-36 mental scale differed (at $\alpha = 0.05$) between cohorts, but the difference was less than ½ of a SD on the 50/10 scale (SD, 4.6). We compared baseline to followup within each cohort on the outcome measures listed above using a one-sample t-tests on differences.

Results

The rate of dislocation was lower ($p = 0.035$) for the large-head group than for the standard-head group: 1.1% (one of 92) versus 8.7% (eight of 92), respectively. In the standard-head group, there were eight patients with dislocations. The mean time from surgery to first dislocation was 131 days (range, 3–507 days; median, 25 days). Five of these patients required no further surgery; four of these five had only one dislocation, while the fifth had three, but all remained stable with no further surgery at final review. Three patients in the standard-head group had further surgery to stabilize their hips. In the large-head group, the one patient who dislocated required further surgery to stabilize the hip.

In both groups, we observed improvements in all QOL scores from preoperative values (Table 5). The SF-36 mental component was the only score that differed between the two groups at followup, with the large-head group scoring higher ($p = 0.043$) than the standard-head group.

Discussion

Dislocation after revision THA is a common complication. To date, the theoretical advantages of large heads have not been proven clinically. Therefore, we determined whether a large femoral head (36 and 40 mm) resulted in a decreased dislocation rate compared to a standard head (32 mm) in revision THA.

There are some limitations in our study. First, we stopped the study early because an interim analysis showed a statistical difference and we believed it unethical to continue the study. Nonetheless, we controlled both known and unknown confounders and balanced the two groups at baseline (Table 3). Also, we eliminated bias as an explanation for the results seen. Further, we believe the findings

Table 5. Quality-of-life outcomes

Quality-of-life measure	Mean preoperative scores		Mean 2-year postoperative scores		Intergroup p values*
	Large head	Standard head	Large head	Standard head	
WOMAC pain	55.1	53.4	85.8	85.4	0.896
WOMAC stiffness	51.0	49.4	76.0	73.7	0.530
WOMAC function	48.6	46.4	75.5	76.8	0.664
WOMAC global	51.5	48.1	77.7	78.3	0.815
SF-36 physical	27.8	29.7	41.6	41.7	0.940
SF-36 mental	53.2	48.6	55.7	51.6	0.043
Satisfaction overall			88.2	84.7	0.409

* Intergroup p value = difference in quality-of-life score between the large-head group and the standard-head group at a minimum of 2 years postoperatively using two-sample t tests.

are generalizable to other centers since we included high- and low-volume centers (Table 1). Second, most of the eligible patients had both sides of the joint revised. There is the possibility these results are not generalizable to all revisions, particularly single-component revision. However, there is no clinical reason to suspect this is the case. Third, we did not include patients with deficient abductors since this was an exclusion criterion in the protocol. Fourth, while we used a one-sided test to demonstrate superiority, we think this is reasonable since there is no evidence to support that large femoral heads result in an increased dislocation rate.

Over the last 5 to 7 years, heads larger than 32 mm in diameter have been introduced. In a study by Kung and Ries [18], 36-mm heads resulted in a dislocation rate of 0%, much lower than the 28-mm group. While this suggests a clinical advantage, the authors presented no data to show the two groups were equivalent for risk factors for dislocation. To answer the question of large heads versus standard heads, we performed this randomized clinical trial. This study definitively showed dislocation rates decreased when using larger 36-or 40-mm heads compared to standard 32-mm heads. Indeed, we noted a dislocation rate of 1.1% in the large-head group, which occurred in a patient with a 36-mm head. In the patients who received a 40-mm head, we observed no dislocations, suggesting benefits to using the largest femoral head possible.

While this study clearly showed an advantage to large heads in dislocation, we have not provided the exact mechanism for dislocation. Certainly the increased head-to-neck ratio and increased jump distance come into play. One other possible explanation is the mismatch between the head size and outer diameter of the acetabular component in the 32-mm head group. In a study by Kelley et al. [16], the authors believed mismatch between cup size and head size was an important factor for an increased dislocation rate in 28-mm heads versus 32-mm heads in primary THA. If one uses their criterion of 60 mm or less as the cutoff, the dislocation rate in our 32-mm group would be 6% (three of 50 hips) for cups with an outer diameter of 60 mm or less and 12.8% (five of 39 hips) for cups with an outer diameter of 62 mm or greater (Table 6). While this is not an objective of this study, mismatch may account for some of the differences seen here between 32- and 40-mm heads.

Table 6. Standard femoral head (32 mm) and corresponding acetabular shell size

Outer diameter of shell (mm)	Number of hips that dislocated	Number of hips that did not dislocate	Total number of hips
50	1	1	2
52		4	4
54		5	5
56		9	9
58		16	16
60	2	12	14
62	3	17	20
64		6	6
66	2	5	7
68		4	4
70		2	2
Blank (no data)		1	1
Total (received 32-mm head)	8	82	90
Required large head*		2	2
Total (randomized to 32-mm head)	8	84	92

* Two patients were randomized to the standard-head (32-mm) group but required a larger head; one patient received a 36-mm head and the other received a 40-mm head.

Our data demonstrate the superiority of large heads in preventing dislocation in revision THA. As a result, we now routinely select the largest-diameter head available to articulate against a highly crosslinked polyethylene acetabular liner in cases where we are performing revision

with intact abductors. One must be particularly careful to avoid excessive cup abduction angles when combining large heads with small-diameter cups, particularly those between 50- and 54-mm outer diameter. In these cases, the polyethylene is very thin at 45° and is at risk of fracture.

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