

# The Use of Porous Titanium Coating and the Largest Possible Head Do Not Affect Early Cup Fixation

## A 2-Year Report from a Randomized Controlled Trial

Georgios Tsikandylakis, MD, Kristian R.L. Mortensen, BSc, MSc, Kirill Gromov, MD, PhD, Anders Troelsen, MD, PhD, Henrik Malchau, MD, PhD, and Maziar Mohaddes, MD, PhD

*Investigation performed at Copenhagen University Hospital Hvidovre, Copenhagen, Denmark, and the Department of Orthopaedics, Sahlgrenska University Hospital, Mölndal, Sweden*

**Background:** Cups are more frequently revised than stems after uncemented total hip arthroplasty, which warrants the development of cup surfaces that provide long-lasting, stable fixation. Large heads have become popular with the aim of reducing dislocation rates, but they generate greater frictional torque that may compromise cup fixation. We aimed to investigate (1) if a novel porous titanium surface provides superior cup fixation when compared with a porous plasma spray (PPS) surface and (2) if the use of the largest possible head compromises cup fixation when compared with a 32-mm head.

**Methods:** Ninety-six patients were randomized to receive either a cup with a porous titanium coating (PTC) or a cup with PPS. A second randomization was performed to either the largest possible (36 to 44-mm) or a 32-mm head in metal-on-vitamin-E-infused polyethylene bearings. Roentgen stereophotogrammetric analysis (RSA) examinations were obtained postoperatively at 3, 12, and 24 months. The primary outcome was proximal cup migration when comparing the 2 cup surfaces and also when comparing the largest possible head with the 32-mm head. The patients were followed for 2 years.

**Results:** The median (and interquartile range) proximal cup migration was 0.15 mm (0.02 to 0.32 mm) for the PTC cup and 0.21 mm (0.11 to 0.34 mm) for the PPS cup. The largest possible head had a proximal cup migration of 0.15 mm (0.09 to 0.31 mm), and the 32-mm head had a proximal cup migration of 0.20 mm (0.04 to 0.35 mm). There were no significant differences between the cup surface ( $p = 0.378$ ) or the head size ( $p = 0.693$ ) groups.

**Conclusions:** Early cup fixation was not superior with the novel PTC cup; the use of the largest possible head (36 to 44 mm) did not compromise early cup fixation.

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

Porous plasma spray (PPS) is a well-established surface that is used in uncemented cups with very good long-term survival<sup>1,2</sup>. However, cups are still revised more frequently than stems in isolated component revision following aseptic loosening<sup>3,4</sup>. In order to enhance cup fixation, a porous titanium coating (PTC) with a rougher structure has been introduced for acetabular cups<sup>5,6</sup>. However, it remains uncertain whether this coating provides superior cup fixation.

Large heads have increased in popularity because they seem to provide greater stability in total hip arthroplasty (THA)<sup>7,8</sup>. However, the use of  $\geq 36$ -mm heads in metal-on-cross-linked polyethylene (XLPE) THA has demonstrated a lower survival rate when compared with 32-mm heads in long-term reports<sup>9,10</sup>. Besides increased volumetric polyethylene wear<sup>11</sup>, increased frictional torque, which is generated by large heads<sup>12</sup> (especially in metal-on-vitamin-E-infused polyethylene [MoVEPE] bearings)<sup>13</sup>, has been suggested as the mechanism of failure. The increased frictional torque could be

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TABLE I Eligibility Criteria for Enrollment\*

Inclusion Criteria	Exclusion Criteria
<p>Patients with primary OA scheduled to receive a unilateral uncemented THA</p> <p>Age 18-75 years</p> <p>No severe comorbidities (ASA <math>\leq</math>3)</p> <p>Able to speak and understand Danish or Swedish (depending on the country of enrollment)</p> <p>Cognitively intact and able to give informed consent</p> <p>Expected to be able to complete all postoperative follow-ups up to 10 years</p>	<p>Rheumatoid arthritis</p> <p>Previous hip fracture</p> <p>Osteonecrosis of the femoral head</p> <p>Previous history of hip infection</p> <p>Severe osseous deformity warranting nonstandard implants</p> <p>Metastasis around the hip</p> <p>Pregnant patients or planned pregnancy during the follow-up time</p> <p>Bone quality warranting cemented fixation</p> <p>Active medical treatment for documented osteoporosis</p> <p>Comorbidity with altered pain perception (e.g., diabetes with neuropathy)</p> <p>THA revision during follow-up</p> <p>Intraoperative periprosthetic fracture</p> <p>Intraoperative necessity for cemented cup fixation</p> <p>Intraoperative necessity for screw fixation of the cup</p> <p>Patient's anatomy not adequate to receive a 50 to 64-mm uncemented cup</p>

\*OA = osteoarthritis, THA = total hip arthroplasty, and ASA = American Society of Anesthesiologists.

transmitted to the cup-bone interface and compromise cup fixation<sup>14</sup>, but, to our knowledge, this hypothesis has not yet been tested clinically. Roentgen stereophotogrammetric analysis (RSA) is a method that can predict future implant failure as early as 2 years postoperatively<sup>15,16</sup>. Therefore, we designed a randomized controlled trial (RCT) that was aimed at answering the following 2 questions: (1) Does a PTC cup provide superior early cup fixation compared with a PPS cup in terms of decreased 2-year RSA cup migration? (2) Does the use of the largest possible head (36 to 44 mm) compromise early cup fixation with MoVEPE THA when compared with a 32-mm head in terms of increased 2-year RSA cup migration?

## Materials and Methods

### Study Design

We conducted a single-blinded RCT at 2 international centers. Following eligibility screening (Table I), 96 patients were enrolled and randomly allocated into 2 groups at a 1:1 ratio according to the cup surface and into 2 groups at a 1:1 ratio according to the head size that they would receive. Either PTC or PPS was used for the cup surface. The head size was either the largest possible size between 36 and 44 mm that could fit in the thinnest insert available for the specific cup size or a 32-mm head. Forty-eight patients received a PTC cup and 48 received a PPS cup (control group). Similarly, 48 patients received the largest possible head and 48 received a 32-mm head (control group) (Fig. 1). When comparing the PTC cups with the PPS cups, the primary

outcome was proximal cup migration along the y axis. Secondary outcomes were the presence of periacetabular radiolucencies and patient-reported outcome measures (PROMs). When comparing the largest possible head with the 32-mm head, primary outcomes were proximal cup migration along the y axis and cup rotation around the x axis (Fig. 2).

The study was conducted according to the Consolidated Standards of Reporting Trials (CONSORT)<sup>17</sup> and was approved by the ethical review board at each center. All of the patients provided informed consent prior to inclusion. The study was registered at ClinicalTrials.gov (NCT02316704).

### Sample Size Calculation

A difference in 2-year proximal cup migration of 0.2 mm between the PTC and PPS cups was considered clinically relevant<sup>16</sup>. The expected standard deviation [SD] was 0.3 mm<sup>18</sup>. At least 36 patients in each group were required to detect a significant difference with 80% power (2 independent-samples t tests). The enrollment of 48 patients in each group ensured sufficient power despite a 20% rate of dropout.

### Implants and Patient Care

At the time of surgery, the acetabulum and the proximal aspect of the femur were each marked with at least six 0.8-mm tantalum markers. All of the implants were provided by Zimmer Biomet. The G7 acetabular cup system<sup>19</sup>, with limited pre-plugged holes but without any screw fixation, was used in the

50 to 64-mm sizes. Its coating was either OsseoTi or PPS. OsseoTi is a novel PTC with a consistent porosity of 475  $\mu\text{m}$ ; it is made of Ti-6Al-4V alloy using additive manufacturing (3-dimensional [3D] printing) and is designed to provide a rougher 3D structure that mimics cancellous bone and therefore enhances osseointegration<sup>20</sup>. PPS is a blasted surface that is produced by high-speed projection of semimolten titanium powder that adheres to the cup and creates a meshed surface with variable pore distribution (100 to 1,000  $\mu\text{m}$ )<sup>21</sup>. All of the patients received the neutral E1 antioxidant-infused polyethylene insert, which has an apical thickness varying from 14.7 to 4.7 mm and can accommodate head sizes from 32 to 44 mm. The insert was marked with at least six 1.0-mm tantalum markers. The Echo Bi-Metric stem with a modular CoCrMo alloy head was used. Follow-up occurred at 3, 12, and 24 months.

### Randomization, Allocation, and Data Collection Process

Computer-generated randomization was utilized to create 2 blocks of envelopes (1 for each of the centers that was used in the RCT). Each block contained 48 envelopes allocating patients to PTC and the largest possible head (12), PTC and a 32-mm head (12), PPS and the largest possible head (12), and PPS and a 32-mm head (12). This ensured that the type of cup surface was balanced across the 2 head-size groups and vice versa. The envelopes were closed and shuffled. They were opened either during surgery, after the acetabulum was reamed (center 1), or 1 week before surgery during templating (center 2) to ensure that at least a 50-mm cup, which can accommodate a 36-mm head, could be used. Patients were blinded to their treatment. Unblinded research administrators and the attending orthopaedic surgeons collected all of the data prospectively.

### RSA and Radiolucency Analysis

Baseline plain and RSA radiographs were acquired on postoperative day 1. Follow-up RSA examinations were acquired at 3, 12, and 24 months postoperatively in a standardized way (Table II). All of the RSA radiographs were analyzed at center 1 with the model-based RSA software (RSACore version 4.2; Leiden University Medical Center). At least 3 markers with adequate scatter in the acetabulum, corresponding to a condition number (CN) of  $\leq 120$  and a mean error of rigid-body fitting of  $\leq 0.35$ , were required to establish a valid reference bone model. A 3D model of each cup, derived from reverse engineering, was fitted using contour detecting and 3 position-optimization algorithms. Translations were calculated as the movement of the model's center of mass (CoM) in relation to the reference bone model, and rotations were calculated as movement around the CoM point. Postoperative examinations provided the reference of bone and 3D models. The patients underwent radiography in duplicate at the 3-month follow-up. The RSA precision was calculated by multiplying the critical t value by the SD of the double measurements from zero.

Radiographs obtained at the 1 and 2-year follow-up appointments were reviewed by 2 successive observers for signs of radiolucency using mdesk software (version 3.6.7.0; RSA Biomedical). A radiolucency was present if the maximal vertical distance between the acetabulum and the cup was  $\geq 0.5$  mm, extending to  $>50\%$  of the Charnley-DeLee zone<sup>22</sup> (Fig. 2). Any radiolucencies that were present on the immediate postoperative radiographs were defined as gaps. A gap that was no longer present in a subsequent radiograph was defined as filled, and, if a gap was still present but had not increased by

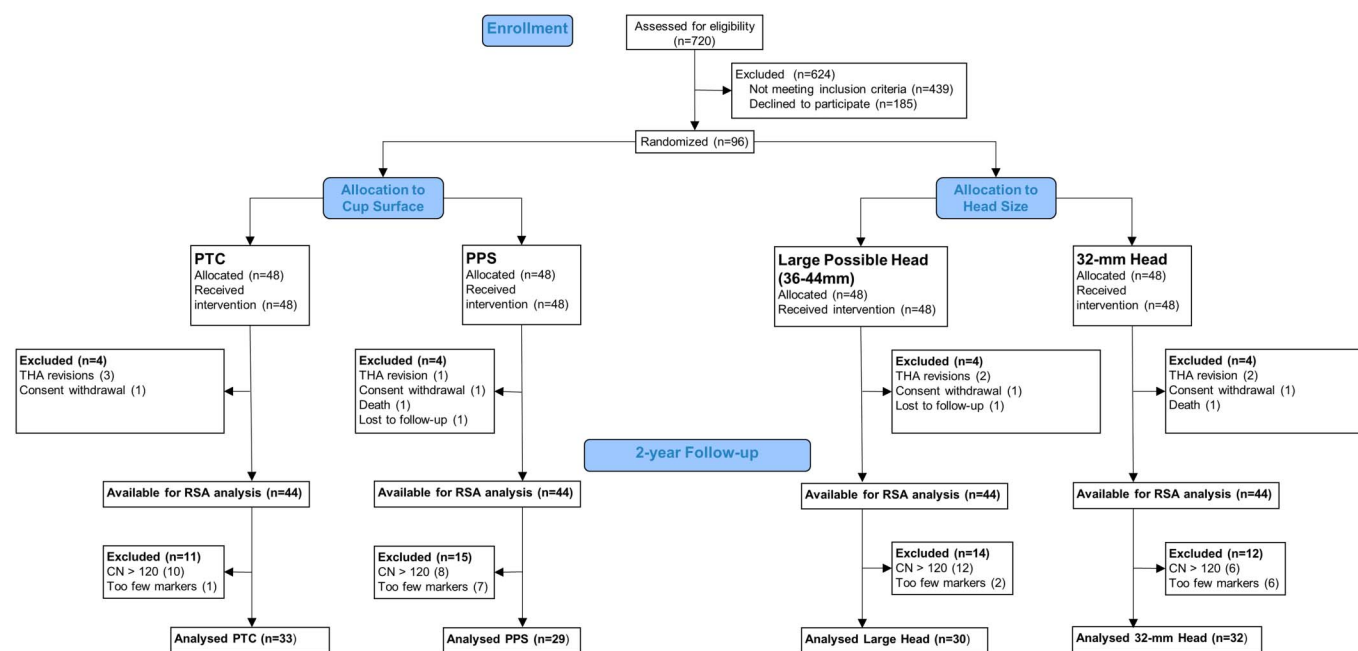
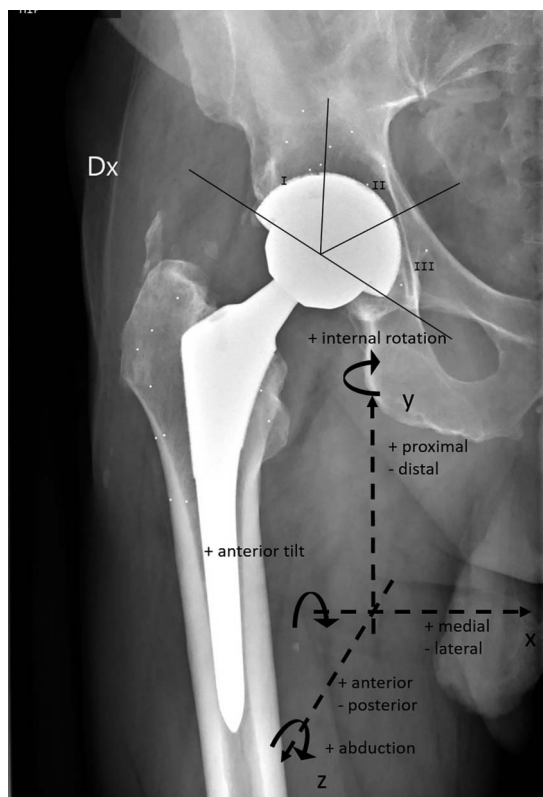


Fig. 1

Flowchart showing how the final number of patients available for RSA analysis at the 2-year follow-up was determined. PTC = porous titanium coating (OsseoTi), PPS = porous plasma spray, THA = total hip arthroplasty, RSA = roentgen stereophotogrammetric analysis, and CN = condition number.



**Fig. 2**  
Anteroposterior view of a postoperative radiograph of a right hip. The coordinate system of the RSA examination is presented with the definition of translations along and rotations around the x, y, and z axes. Proximal cup migration was defined as proximal translation along the y axis. Radiographs were examined for radiolucencies in each Charnley-DeLee zone (I-III).

>1 mm in thickness, it was defined as persistent. Progression of radiolucency was defined as an increase in thickness by  $\geq 1$  mm or extension to adjacent zones.

### PROMs

PROMs were used to measure hip function, activity level, and health-related quality of life (HRQoL) preoperatively and at the time of the follow-up appointments. Hip function was measured with the Oxford Hip Score (OHS: 0 to 48) and the Harris

hip score (HHS: 0 to 100). HRQoL was measured with the 3-level EuroQol-5 Dimensions (EQ-5D) score (0 to 1) and the EQ-5D-VAS (visual analog scale) score (0 to 100). Activity level was measured with the University of California Los Angeles (UCLA) Activity Scale (1 to 10).

### Statistics

Categorical data were described in absolute numbers and percentages. The z test or the Fisher exact test, where applicable, was used for comparison of categorical data. Numerical data were described with medians and interquartile ranges. The significance of cup migration within each group was assessed with the Wilcoxon signed-rank test. The Mann-Whitney U test was used to compare numerical data among the groups. The level of significance was set to 0.05. Statistical analyses were performed with SPSS software (version 26; IBM).

### Results

#### Participant Flow

Patients were enrolled between December 2014 and February 2017 and were followed for 2 years between January 2017 and March 2019. They had similar baseline demographics and surgery characteristics for cup surface and head size (Table III). By the 2-year follow-up, 8 patients had dropped out: 2 had withdrawn their consent (1 PTC cup with the largest head size and 1 PPS cup with a 32-mm head), 1 died of lung cancer (PPS cup with a 32-mm head), 1 did not come for radiographic examination (PPS cup with the largest head size), and 4 had been revised. Of those THAs that had been revised, 2 (both PTC cups with a 32-mm head) were due to dislocation, 1 was due to stem subsidence (PPS cup with the largest head size), and 1 was due to peri-prosthetic femoral fracture (PTC cup with the largest head size). There were no revisions due to cup loosening.

#### RSA Cup Migration: PTC Versus PPS

The RSA precision for proximal cup migration was 0.2 mm. Of the 88 patients who were available for follow-up at 2 years, 26 could not be analyzed due to a CN of  $>120$  or the presence of  $<3$  visible markers in the acetabulum. Thus, 33 patients with PTC cups and 29 with PPS cups were available for analysis. Both types of cups migrated significantly. The median 2-year

**TABLE II Standardization of RSA Examinations at Each Center**

Characteristic	Center 1	Center 2
Patient position	Supine (operated leg parallel to the y axis of the cage)	Supine (operated leg parallel to the y axis of the cage)
Angle between the ceiling-mounted radiographic RSA tubes	46°	42°
Source-to-image detector distance	150 cm	160 cm
Type of uniplanar calibration cage	CarbonBox 021 (MEDIS Medical Imaging Systems)	Cage 77(RSA Biomedical)
Image detector	Carestream DRX-1	Canon CXDI-50RF

**TABLE III Baseline Characteristics Stratified for Cup Surface and Head Size\***

Characteristic	Cup Surface		Head Size	
	PTC (N = 48)	PPS (N = 48)	Largest (N = 48)	32 mm (N = 48)
Women (no. [%])	20 (42)	23 (48)	21 (42)	22 (46)
Median age (IQR) (yr)	63 (55-69)	63 (58-69)	62 (55-67)	65 (59-71)
Median BMI (IQR) (kg/m <sup>2</sup> )	27 (24-29)	28 (25-30)	27 (26-29)	26 (24-30)
ASA group (no. [%])†				
1	21 (44)	21 (44)	23 (48)	19 (40)
2	23 (48)	24 (50)	21 (44)	26 (54)
3	4 (8)	2 (4)	3 (6)	3 (6)
Head size (no. [%])				
32 mm	24 (50)	24 (50)	0 (0)	48 (100)
36 mm	5 (10)	6 (13)	11 (23)	0 (0)
40 mm	18 (38)	16 (33)	34 (71)	0 (0)
44 mm	1 (2)	2 (4)	3 (6)	0 (0)
Cup surface (no. [%])				
PTC	48 (100)	0 (0)	24 (50)	24 (50)
PPS	0 (0)	48 (100)	24 (50)	24 (50)

\*PTC = porous titanium coating, PPS = porous plasma spray, IQR = interquartile range, BMI = body mass index, and ASA = American Society of Anesthesiologists. †Data about the ASA grade were missing in 1 patient who had received a PPS cup and the largest possible head.

proximal cup migration was 0.15 mm (interquartile range, 0.02 to 0.32 mm;  $p < 0.001$ ) for the PTC cups and 0.21 mm (0.11 to 0.34 mm;  $p < 0.001$ ) for the PPS cups (Fig. 3). The difference

between them was not significant ( $p = 0.378$ ); 45% (15 of 33) of the patients with PTC cups and 52% (15 of 29) with PPS cups had values of  $>0.2$  mm ( $p = 0.624$ ).

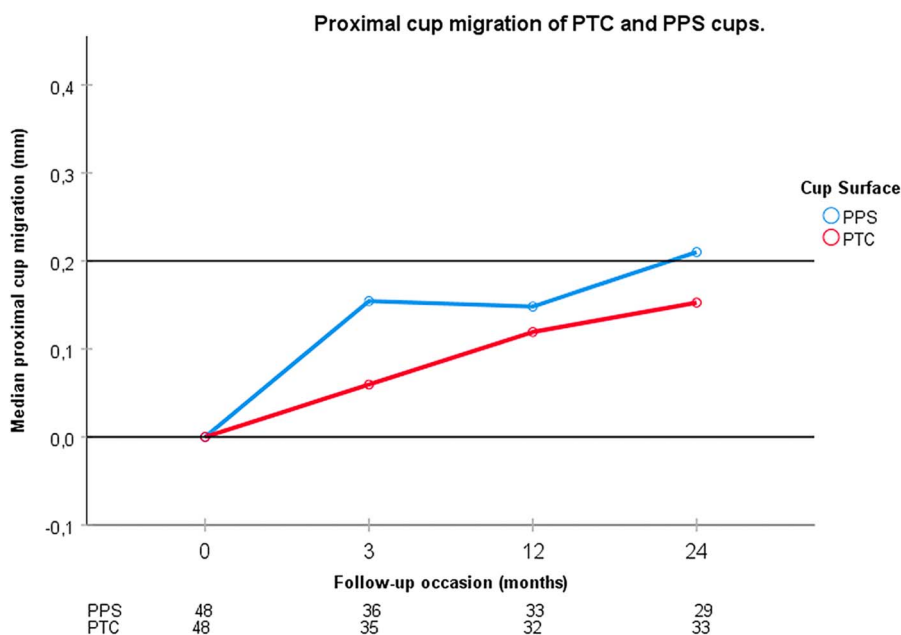


Fig. 3 Proximal cup migration for PTC (OsseotI) and PPS G7 acetabular cups is shown at the 3-month, 1-year, and 2-year follow-ups. The table below the graph shows the number of analyzed patients at each follow-up. The median PPS cup migration exceeded 0.2 mm at 2 years and was bigger than the median cup migration of PTC cups, but the difference between them did not reach significance at any follow-up.

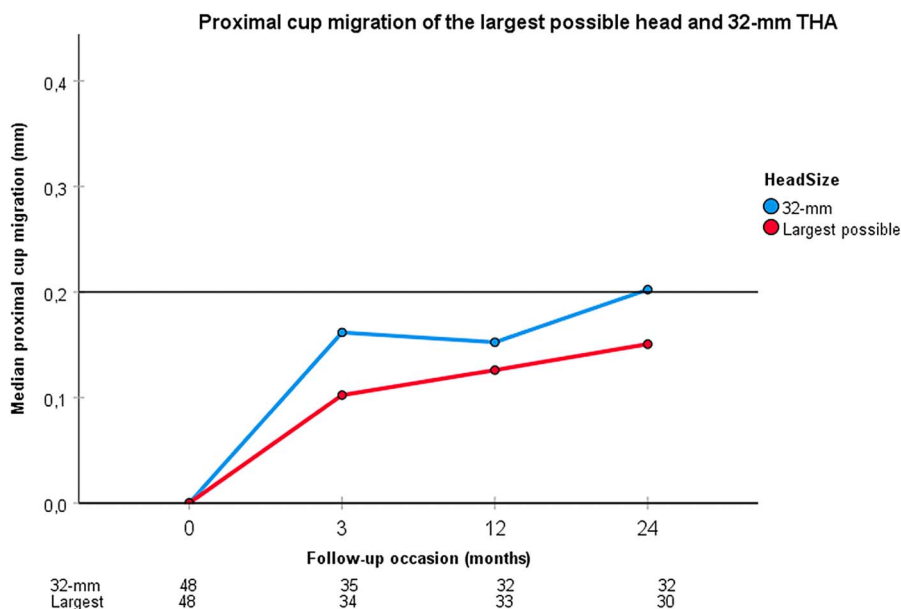


Fig. 4 Proximal cup migration for the largest possible head and a 32-mm head used during THA is shown at the 3-month, 1-year, and 2-year follow-ups. The table below the graph shows the number of analyzed patients at each follow-up. The 32-mm head tended toward greater values of proximal cup migration, but there were no significant differences between the 2 head size groups at any follow-up.

**RSA Cup Migration: Largest Head Versus 32-mm Head**

At the 2-year follow-up, 30 patients with the largest possible head could be compared with 32 patients with a 32-mm head. The median proximal cup migration was 0.15 mm (interquartile

range, 0.09 to 0.31 mm) for THA with the largest possible head, and 0.20 mm (0.04 to 0.35 mm) for THA with a 32-mm head (Fig. 4). The cups of both groups migrated significantly ( $p < 0.001$ ), but their difference was not significant ( $p = 0.693$ ).

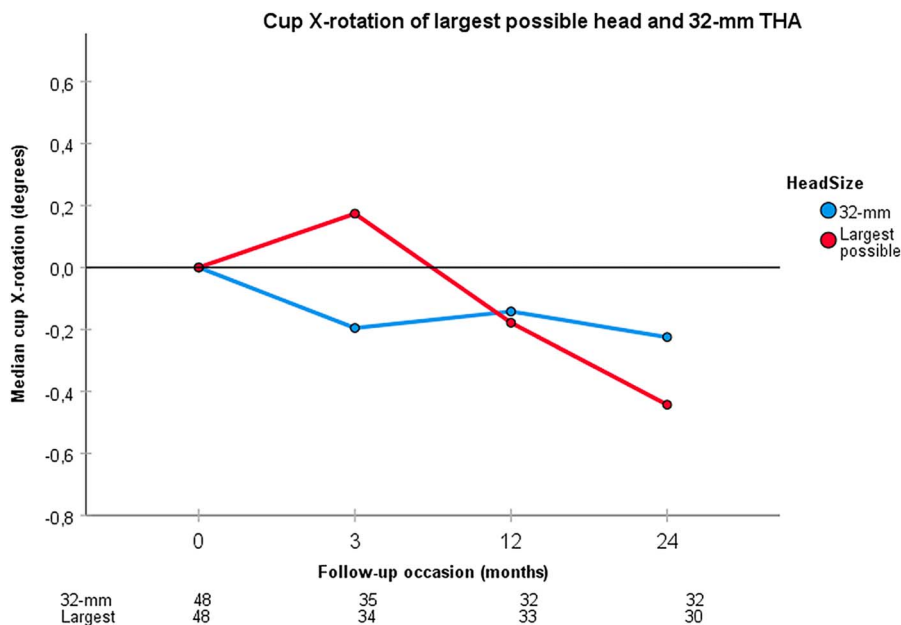


Fig. 5 Cup X-rotation for the largest possible head and a 32-mm head used during THA is shown at the 3-month, 1-year, and 2-year follow-ups. The table below the graph shows the number of analyzed patients at each follow-up. Both head sizes demonstrate a significant negative X-rotation (posterior tilt) at 2 years. There was a tendency for greater posterior tilt for the largest possible head used during THA at 2 years, but the difference was not significant compared with a 32-mm head used during THA.



TABLE IV Comparison of Gaps Between the 2 Cup Surfaces\*

	PTC (N = 48)			PPS (N = 48)			P Value†
	With Gaps	Without Gaps	Ratio	With Gaps	Without Gaps	Ratio	
Total	8	40	8:40	4	44	4:44	0.355
Zone 1	3	45	3:45	0	48	0:48	0.242
Zone 2	5	43	5:43	2	46	2:46	0.435
Zone 3	0	48	0:48	3	45	3:45	0.242

\*PTC = porous titanium coating, and PPS = porous plasma spray. The values are given as the number of patients. †Fisher exact test.

Of the THAs with the largest possible head, 43% (13 of 30) had values of  $>0.2$  mm compared with 53% (17 of 32) of THAs with a 32-mm head ( $p = 0.441$ ). The precision for cup X-rotation was  $1.11^\circ$ . THAs with the largest possible head demonstrated a posterior cup tilt of  $0.44^\circ$  ( $-0.20^\circ$  to  $0.84^\circ$ ;  $p = 0.023$ ) and THAs with a 32-mm head demonstrated a posterior cup tilt of  $0.23^\circ$  ( $-0.02^\circ$  to  $0.77^\circ$ ;  $p = 0.031$ ) (Fig. 5). Their difference was not significant ( $p = 0.622$ ).

#### Radiolucencies Around the Cup

Gaps were observed in 8 patients in the PTC group and in 4 patients in the PPS group (Table IV). By the 2-year follow-up appointments, 2 in the PTC group and 1 in the PPS group with gaps had dropped out. Of the remaining 10 gaps (9 patients), 5 had filled in and 1 had progressed in the PTC group, while all 4 in the PPS group had filled in (Table V). At the 1-year follow-up, new radiolucencies were observed in 2 patients in the PTC group and in 4 patients in the PPS group (Table VI). At the 2-year follow-up, all 7 of the radiolucencies that had been observed in these 6 patients at 1 year were absent (Table VII), while 6 new radiolucencies in the PTC group and 4 in the PPS group had appeared.

#### PROMs

At baseline, 94 patients had completed the OHS PROM, 95 had completed the HHS PROM, 94 had completed the EQ-5D PROM, 92 had completed the EQ-5D-VAS PROM, and 94 had completed the UCLA PROM. At 2 years, the numbers were 89, 87, 89, 87, and 88, respectively. No clinically relevant differences were found in any PROM between patients with PTC and PPS cups (Table VIII).

#### Discussion

We investigated whether a novel PTC surface provides more stable early cup fixation when compared with PPS. We found a lower proximal cup migration with the PTC, but the difference (0.06 mm) did not reach significance and could therefore not be generalized. We also investigated if using the largest possible head with MoVEPE THA could jeopardize early cup fixation because of the presumed increased frictional torque when compared with a 32-mm head. We found a lower proximal cup migration but a greater posterior tilt when the largest possible head was used in THA. However, the differences between the head size groups were small (0.05 mm and

TABLE V Gap Progression at the 1 and 2-Year Follow-ups\*

Comparison	PTC†			PPS‡		
	Filled	Persistent	Progressed	Filled	Persistent	Progressed
A. Between postop. and 1-year radiographs						
Zone 1	3	0	0	0	0	0
Zone 2	2	1	0	2	0	0
Zone 3	0	0	0	1	2	0
Total	5	1	0	3	2	0
B. Between postop. and 2-year radiographs						
Zone 1	3	0	0	0	0	0
Zone 2	2	0	1	2	0	0
Zone 3	0	0	0	2	0	0
Total	5	0	1	4	0	0

\*PTC = porous titanium coating, and PPS = porous plasma spray. The values are given as the number of gaps. †6 zones in 6 patients. ‡5 zones in 4 patients for A; 4 zones in 3 patients for B.

**TABLE VI Comparison of Radiolucencies Between the 2 Cup Surfaces at the 1 and 2-Year Follow-ups\***

Comparison	PTC			PPS			P Value†
	With Radiolucencies	Without Radiolucencies	Ratio	With Radiolucencies	Without Radiolucencies	Ratio	
1-year follow-up							
Total no. of patients	2	41	2:41	4	43	4:43	0.679
Zone 1	1	42	1:42	0	47	0:47	0.478
Zone 2	2	41	2:41	4	43	4:43	0.679
Zone 3	0	43	0:43	0	47	0:47	‡
2-year follow-up							
Total no. of patients	6	38	6:38	4	40	4:40	0.739
Zone 1	0	44	0:44	2	42	2:42	0.494
Zone 2	3	41	3:41	2	42	2:42	1
Zone 3	3	41	3:41	0	44	0:44	0.241

\*PTC = porous titanium coating, and PPS = porous plasma spray. The values are given as the number of patients; a patient may have radiolucencies in more than 1 zone. †Fisher exact test. ‡P value could not be calculated.

0.21°, respectively) and not significant. Whether these differences have any clinical relevance could not be assessed in this report because no complications related to cup loosening have yet been observed.

Our study has certain limitations. There were 15 more dropouts than we had accounted for, but our study maintained a reasonable statistical sensitivity for detecting differences in proximal cup migration (minimum of 0.22 mm) among the groups because the SD of our measurements was much lower (0.1 mm) than the 0.3 mm that was used in sample size calculation. Moreover, the suggested threshold of 0.2 mm refers to the 2-year cup migration within the same group, not the difference among the groups. Therefore, if a 2-year cup migration of 0.2 mm (SD, 0.3 mm) within a group is considered predictive for long-term cup survival<sup>16</sup>, 21 patients in each group are enough to detect it with 80% power (Wilcoxon signed-rank test). Despite having many dropouts, our study was still sufficiently powered to detect such a 2-year migration. The markers in the polyethylene, hidden by large heads in uncemented cups, were not visible in the majority of the RSA examinations. Thus,

only a model-based approach could be used. The precision of this markerless technique was initially reported as comparable with traditional marker-based RSA<sup>23</sup>; however, more recent studies have reported an inferior precision, especially regarding rotation<sup>24,25</sup>. Approximately half of the proximal cup migration values were below the precision of the RSA examinations. A subgroup analysis, including only patients with 2-year RSA measurements that were above the method's precision, still showed no difference in proximal cup migration between the cup surfaces or the head sizes (Table IX). Finally, the inclusion of only 2 different types of cups from the same manufacturer makes our results on cup migration related to head size less generalizable for other cup designs.

The 2-year proximal cup migration for PTC cups was below the 0.2-mm threshold that has been suggested as predictive for implant failure<sup>16</sup> in subsequent years. In other reports, the early migration of PTC cups has varied. Salemyr et al. compared 2 different PTC cups and reported 2-year proximal migration of 0.24 and 0.38 mm, respectively<sup>26</sup>.

**TABLE VII Progression of Radiolucencies Between the 1 and 2-Year Radiographs\***

Zone	PTC†			PPS‡		
	Filled	Persistent	Progressed	Filled	Persistent	Progressed
Zone 1	1	0	0	0	0	0
Zone 2	2	0	0	4	0	0
Zone 3	0	0	0	0	0	0
Total	3	0	0	4	0	0

\*PTC = porous titanium coating, and PPS = porous plasma spray. The values are given as the number of gaps. †3 zones in 2 patients. ‡4 zones in 4 patients.



TABLE VIII PROMs at Baseline and at 3, 12, and 24 Months Postoperatively\*

PROM	Baseline			3 Months			12 Months			24 Months		
	PTC†	PPS†	P Value	PTC†	PPS†	P Value	PTC†	PPS†	P Value	PTC†	PPS†	P Value
OHS	23 (16-28)	22 (17-26)	0.384	38 (35-45)	42 (32-45)	0.584	45 (40-48)	46 (44-48)	0.323	45 (40-48)	47 (42-48)	0.171
HHS	57 (48-65)	58 (43-67)	0.8	91 (79-100)	93 (81-100)	0.584	98 (90-100)	100 (95-100)	0.439	99 (94-100)	100 (100-100)	0.026
EQ-5D score	0.723 (0.648-0.772)	0.723 (0.660-0.768)	0.753	0.935 (0.824-0.985)	0.883 (0.794-1)	0.667	0.969 (0.834-1)	0.969 (0.824-1)	0.701	0.969 (0.846-1)	0.969 (0.851-1)	0.889
EQ-5D-VAS	51 (40-75)	60 (37-72)	0.644	85 (80-91)	84 (72-90)	0.852	86 (70-94)	87 (70-95)	0.674	86 (70-95)	90 (70-99)	0.172
UCLA	4 (3-7)	5 (3.5-7)	0.446	6 (4-7)	6 (4-7)	0.838	7 (4-8)	7 (5.5-8.5)	0.756	7 (5-8)	6.5 (6-8.5)	0.902

\*PROMs = patient-reported outcome measures, PTC = G7 cup with OsseoTi porous titanium coating, PPS = G7 cup with porous plasma spray surface, OHS = Oxford Hip Score, HHS = Harris hip score, EQ-5D = EuroQol-5 Dimensions score, VAS = visual analog scale, and UCLA = University of California Los Angeles Activity Scale. †The values are given as the median, with the interquartile range in parentheses.

Sillesen et al. reported a 3-year proximal migration of a PTC cup from 0.17 to 0.62 mm in 2 different centers<sup>27</sup>. The difference was attributed to diversity in the reaming technique and screw placement between the centers. In our study, the proximal cup migration did not differ between the 2 centers ( $p = 0.369$ ), which both applied 1 mm of underreaming and no screws. The 2-year proximal migration was even smaller for the novel PTC cup in our study compared with the above-mentioned cups and the PPS cups, but the difference was not large enough to reach significance. Thus, the PTC surface seems to provide early cup fixation that is as stable as the PPS surface.

To our knowledge, the association between large heads and cup fixation has not been previously studied in clinical trials. In an *in vitro* study, Meneghini et al. reported an increased frictional torque when larger metal heads were combined with XLPE, as well as when VEPE was used<sup>13</sup>. Scholl et al. also reported an increased frictional torque when larger metal and ceramic heads were combined with XLPE<sup>12</sup>. Jahnke et al. reported increased translational and rotational micro-motions of uncemented cups when increased frictional

torque was applied<sup>14</sup>. In our study, proximal cup migration was more likely with the largest possible head, but posterior tilt was more likely with a 32-mm head. Nevertheless, the differences could not be generalized. Our interpretation is that cup movement did not differ between the groups according to head size. Thus, our results do not support the hypothesis that the use of the largest possible metal head affects early cup fixation.

Our secondary outcomes comprised periacetabular radiolucencies and PROMs. There were twice as many patients with gaps in the group with the PTC cups as in the group with the PPS cups. This may be due to the rougher surface of the PTC cup, which requires a harder impaction in the underreamed acetabulum. However, gaps did not seem to compromise cup fixation because all except for 1 filled in. The presence of gaps with highly porous cups varies widely in the literature, with a reported prevalence of  $\geq 20\%$ , but the majority are usually filled in by the time of final follow-up<sup>28</sup>. Lindgren et al. compared a different PTC cup with another PPS cup and reported a higher risk for radiolucencies and patient-reported pain at the 5-year

TABLE IX Subgroup Analysis of RSA Proximal Cup Migration at 2 Years After Exclusion of Patients with Values Smaller than the Precision of the RSA Examination\*

	Subgroup Analysis				Whole Sample			
	Experimental Group	Control Group	$\Delta$ †	P Value‡	Experimental Group	Control Group	$\Delta$ †	P Value‡
Cup surface	PTC	PPS			PTC	PPS		
Proximal cup migration§ (mm)	0.34 (0.29 to 0.43)	0.34 (0.29 to 0.40)	0	0.967	0.15 (0.02 to 0.32)	0.21 (0.11 to 0.34)	-0.06	0.378
Sample size	15	15			33	29		
Head size	Largest	32 mm			Largest	32 mm		
Proximal cup migration§ (mm)	0.32 (0.28 to 0.35)	0.34 (0.29 to 0.41)	-0.02	0.563	0.15 (0.09 to 0.31)	0.20 (0.04 to 0.35)	-0.05	0.693
Sample size	13	17			30	32		
Posterior tilt§# (deg)	0.42 (-1.4 to 2.39)	1.37 (-0.06 to 1.55)	-0.95	0.755	0.44 (-0.20 to 0.84)	0.23 (-0.02 to 0.77)	0.21	0.622
Sample size	6	8			30	32		

\*PTC = porous titanium coating, and PPS = porous plasma spray. Results for the whole sample are also presented for comparison. †Difference between medians. ‡Mann-Whitney U test. §The values in the 2 groups are given as the median, with the interquartile range in parentheses. #Reverse X-rotation.

follow-up for the PTC cup<sup>29</sup>. In our study, neither the number of radiolucencies nor the PROMs differed between cup designs.

We conclude that the early cup fixation provided by the novel PTC surface was equal to rather than superior to the PPS surface. The use of the largest possible head (ranging from 36 to 44 mm) in MoVEPE bearings does not seem to compromise early cup fixation. The safety and potential superiority of the novel PTC surface need to be evaluated in longer-term reports regarding clinical outcome before its introduction in THA. Longer-term RCTs assessing polyethylene wear and dislocation rates, in addition to cup fixation, are needed to evaluate the safety of large heads. ■

Georgios Tsikandylakis, MD<sup>1,2</sup>  
 Kristian R.L. Mortensen, BSc, MSc<sup>3,4</sup>  
 Kirill Gromov, MD, PhD<sup>3,4</sup>  
 Anders Troelsen, MD, PhD<sup>3,4</sup>  
 Henrik Malchau, MD, PhD<sup>1,2,5,6</sup>  
 Maziar Mohaddes, MD, PhD<sup>1,2</sup>

<sup>1</sup>Department of Orthopaedics, Sahlgrenska University Hospital, Mölndal, Sweden

<sup>2</sup>Department of Orthopaedics, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

<sup>3</sup>Department of Orthopaedic Surgery, Copenhagen University Hospital Hvidovre, Copenhagen, Denmark

<sup>4</sup>Department of Clinical Medicine, Faculty of Health Sciences, University of Copenhagen, Copenhagen, Denmark

<sup>5</sup>Harris Orthopaedic Laboratory, Massachusetts General Hospital, Boston, Massachusetts

<sup>6</sup>Harvard Medical School, Harvard University, Boston, Massachusetts

Email address for G. Tsikandylakis: tsikandylakis@gmail.com

ORCID iD for G. Tsikandylakis: [0000-0002-9255-075X](https://orcid.org/0000-0002-9255-075X)

ORCID iD for K.R.L. Mortensen: [0000-0001-8174-4965](https://orcid.org/0000-0001-8174-4965)

ORCID iD for K. Gromov: [0000-0002-8114-5193](https://orcid.org/0000-0002-8114-5193)

ORCID iD for A. Troelsen: [0000-0003-0132-8182](https://orcid.org/0000-0003-0132-8182)

ORCID iD for H. Malchau: [0000-0002-4291-2441](https://orcid.org/0000-0002-4291-2441)

ORCID iD for M. Mohaddes: [0000-0003-1848-9054](https://orcid.org/0000-0003-1848-9054)

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