

# Midterm Results of Fourth-Generation Ceramic-On-Ceramic Total Hip Arthroplasty

## Abstract

**Purpose:** There are limited reports for the results of the fourth-generation ceramic-on-ceramic (CoC) articulation total hip arthroplasty (THA). And, throughout the surgical experience, we encountered some cases of liner pulling-out phenomenon after liner fixation and femoral preparation. The objective of this study was to evaluate the incidence, risk factors of delta ceramic liner or head fractures, and also the clinical and radiological results of using the fourth-generation CoC articulation in THA. **Patients and Methods:** We retrospectively reviewed 242 patients (263 hips) who underwent primary THA using the fourth-generation CoC articulation with a minimum followup of 2 years. Demographic data, Harris Hip Score (HHS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Patient's satisfactory level were recorded. The radiological evaluation was used to evaluate the implant fixation and complications. Mean followup duration was 5.2 years. **Results:** Mean HHS and WOMAC score were significantly ( $P < 0.05$ ) improved at the last followup. About 98.5% of the patients were satisfied with results of the surgery. All acetabular components were placed in adequate position and there was no osteolysis on acetabular or femoral components and subsidence of femoral stem. Four patients showed complications including one-liner fracture. **Conclusion:** Our midterm study demonstrated excellent clinical and radiological results with only one ceramic liner fracture. Moreover, the results of this study indicate that one possible cause of pulling-out phenomenon is the resonance effect during implantation in Dorr type A patients with the thick cortex. If the surgeon is aware of the liner malposition throughout the operation, the fourth-generation CoC articulation THA could be an outstanding treatment.

**Keywords:** Ceramic-on-ceramic, delta ceramic, liner fracture, midterm result, total hip arthroplasty

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## Introduction

Among various articulations of total hip arthroplasty (THA), ceramic-on-ceramic (CoC) articulation has been a preferable choice for surgeons to treat young patients who want to sustain their active life. CoC articulation is harder, more scratch resistant, and more hydrophilic compared to other articulations, consequentially reducing wear and osteolysis around the joint.<sup>1,2</sup> In spite of a long history of clinical success of CoC articulation with substantially low wear rates and osteolysis,<sup>3,4</sup> ceramic fracture remains the most serious complication of CoC articulation that can lead to catastrophic failure of THA.<sup>5-7</sup>

Regarding the ceramic femoral head fracture, a short 28 mm head is known to be the most important risk factor for the ceramic fractures due to its short bore

distance.<sup>8</sup> On the other hand, for the ceramic liner fracture, malpositioning of the liner or edge loading was known as the most important risk factor.<sup>9</sup> Moreover, the taper angle of the cup could also affect the incidence of liner malposition.

Since 2011, we have used cementless Continuum™ acetabular cup (Zimmer®, Warsaw, IN, USA) which is relatively new designed cup with Trabecular Metal™ technology and fourth-generation CoC articulation for all patients. Throughout the surgical experience, we encountered some cases of liner pulling-out phenomenon after liner fixation and femoral preparation. We assumed that this phenomenon could result in the malposition of the ceramic liner.

The objective of this study was to evaluate the incidence, risk factors of delta ceramic liner or head fractures, and also the clinical and radiological results of using the fourth-generation CoC articulation in THA.

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## Patients and Methods

### Patient inclusion and study design

From April 2011 to December 2017, we selected patients who underwent primary THA using the fourth-generation CoC articulation in our institute. Of these patients, we included patients who were followed up for a minimum of 2 years. To have a consistent evaluation, we included only patients who underwent THA using a specific acetabular cup system and Biolox<sup>®</sup> Delta liner and head. After exclusion, a total of 242 patients (263 hips) were finally included. Ethical approval was given by the institutional review board of our institute, and informed consent was obtained from all patients. We retrospectively reviewed clinical and radiological medical records of these patients.

There were 175 males and 67 females with a mean age of 53.6 years (range 23–84 years) at the time of surgery. Their mean body mass index (BMI) was 23.8 (range 16.6–32.2). The average followup duration was 5.2 years (range 2.0–6.5 years) with a minimum followup of 2 years. Regarding preoperative diagnosis, osteonecrosis of the femoral head was found for 166 hips, osteoarthritis for 59 hips, femoral neck fracture for 25 hips, septic hip sequelae for 7 hips, and Legg–Calvé–Perthes disease sequelae for 6 hips [Table 1]. All operations were performed by a senior author at a single institute. The surgery was performed when the patients suffer from severe enough symptoms to undergo THA, after a period of conservative treatment. Regarding the surgical approach, modified minimally invasive two-incision method,<sup>10</sup> minimally-invasive one incision method (posterolateral approach) and conventional method (posterolateral approach) were used for 184 (70.0%), 64 (24.3%), and 15 (5.7%) hips, respectively.

Regarding acetabular components, a cement-less Continuum<sup>™</sup> acetabular cup (Zimmer<sup>®</sup>, Warsaw, IN, USA) and fourth-generation ceramic head and liner (Biolox<sup>®</sup> Delta, CeramTec AG, Plochin-gen, Germany) were used in all patients. To minimize bias, two-matched cementless stem produced by Zimmer Company were used in all patients. M/L Taper<sup>®</sup> stem (Zimmer<sup>®</sup>, Warsaw, IN, USA) was used in 126 (47.9%) hips while, Fitmore<sup>®</sup> stem (Zimmer<sup>®</sup>, Winterthur, Switzerland) was used in 137 (52.1%) hips.

### Surgical technique and postoperative care

For implantation, after opening the joint capsule and cutting the neck of femur, meticulous soft-tissue removal and proper acetabular reaming were done. Acetabular cup was inserted into adequate position at the center of the hip. After cup implantation, we inserted the liner carefully with hand and a liner insertion instrument. We checked fluoroscopy intraoperatively with C-arm whether the liner was symmetrically seated in the cup not only visually, but also touching the rim of the liner radiologically. Secure impaction of the liner was then performed with adequate power through the axis of the liner. For femoral stem implantation, broaching and implant fixation were done in a fashion as described in the previous work of Yoon *et al.*<sup>10</sup> Head component was inserted into the stem along the axis of the neck on a clean taper with adequate impaction. Head reduction was made into the liner. After checking implant position, stability, and leg-length discrepancy through C-arm, the operation was finalized with or without Hemovac suction drainage insertion.

Patients were encouraged to start mobilization on the very next day of operation. Cautious full weight-bearing ambulation supported by crutches or walking frame was permitted unless the patients felt intolerable pain. These patients were followed up at postoperative 1 month, 3 months, 6 months, 1 year, and every year thereafter.

### Clinical and radiological analysis

For clinical analysis, we evaluated pre- and postoperative Harris hip pain and function scores (Harris Hip Score [HHS])<sup>11</sup> and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score.<sup>12</sup> Patient’s satisfactory level (fully satisfied, satisfied, dissatisfied, and fully dissatisfied) was also checked through followup interview. Any clicking or squeaking sound from the articulation was recorded.

For radiological evaluation, we checked postoperative anteroposterior and lateral view and lower extremity scanogram at 3 months, 6 months, 1 year, and annually thereafter. We evaluated the last followup radiograph for the orientation and stability of the acetabular and femoral component. We checked acetabular inclination angle on anteroposterior radiograph. Acetabular inclination angle was measured between a line connecting teardrop of both

**Table 1: Recent good reports of fourth generation ceramic-on-ceramic articulation total hip arthroplasty**

Publication	Number of hips	Followup duration (years)	Ceramic fractures	Total revisions	Survival rate (%)
Cai <i>et al.</i> , 2012 <sup>22</sup>	51	3.3	0	2	N/A
Hamilton <i>et al.</i> , 2015 <sup>24</sup>	345	5.3	2 (liner)	9	97.3
Aoude <i>et al.</i> , 2015 <sup>25</sup>	133	6	0	1	99.3
Kim <i>et al.</i> , 2017 <sup>23</sup>	334	7.8	0	1	99.7
Current study	263	5.2	1 (liner)	4	98.5

N/A=Not available

sides and a line along the lateral side of the acetabular component. For the appropriate orientation of the acetabular component, we measured the degree of vertical migration from the inferior aspect of the teardrop, and the degree of horizontal migration from the Köhler line. For acetabular osteolysis, we used DeLee and Charnley<sup>13</sup> classification. Engh *et al.*<sup>14</sup> and Gruen *et al.*<sup>15</sup> classifications were used to check femoral stem fixation and osteolysis while Callaghan *et al.*<sup>16</sup> classification was used to evaluate the subsidence of femoral component. We also categorized the femur preoperatively using Dorr *et al.*<sup>17</sup> classification to determine risk factors for alumina delta ceramic liner or head fractures.

**Statistical analysis**

For statistical analysis, Student’s *t*-test was used for continuous variables (HHS and WOMAC score) while Chi-square test was used for categorical variables. Pearson Chi-square test was used to evaluate the relationship between the pulling-out phenomenon of liner and different variables such as age, sex, BMI, diagnosis, surgical technique, cup size, liner size, stem type, and Dorr type. Survival rate was analyzed using Kaplan–Meier technique<sup>18</sup> (with 95% CI) with revision for any reason as an end point. *P* < 0.05 was considered statistically significant. All statistical analyses were performed using SPSS 24.0 (SPSS, Chicago, IL, USA).

**Results**

**Clinical results**

Mean HHS and WOMAC score were significantly (*P* < 0.05) improved at the last followup. Preoperative mean HHS was 56.3 points (range 39–72). It was improved to 93.6 points (range 82–100) postoperatively. WOMAC score was improved from 69.4 points (range 59–84) preoperatively to 11.8 points (range 5–20) postoperatively. Two hundred and fifty nine patients (98.5%) were satisfied with results of the surgery. Four patients felt dissatisfaction due to thigh pain, clicking sound, recurrent dislocation, and postoperative infection.

**Radiological results**

Using Dorr classification, patients were categorized into three groups preoperatively: 75 hips in type A, 159 hips in type B, and 28 hips in type C. Mean acetabular inclination angle was 37.3° (range 20.6–49.5), and mean acetabular anteversion was 20.7° (range 4.8–36.1). At the last followup plain radiograph, implants on both acetabular cup and femoral stem were stable in every patient. During the followup, one patient showed failed osteointegration of femoral stem component after 1-year postoperatively. However, there was no osteolysis on acetabular or femoral components and subsidence of femoral stem. The position of all acetabular components was adequate with the center of the hip showing 19.2 mm (range 15.2–25.9)

vertically from the teardrop and 38.7 mm (range 30.5–48.2) horizontally from the Köhler line [Table 2].

*Intraoperative risk factor analysis*

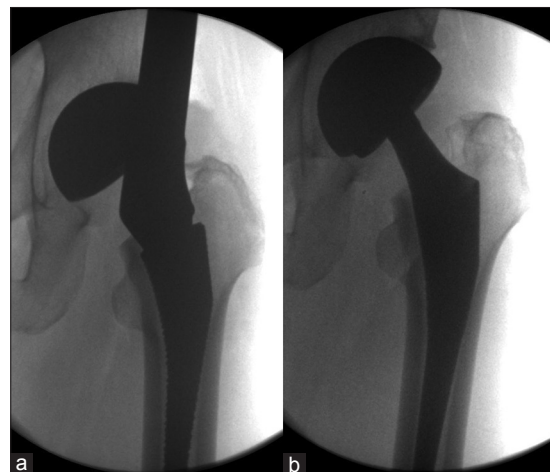
Liner pulling-out phenomenon due to the resonance effect.

Intraoperatively, we experienced five cases of liner pulling-out phenomenon during the implantation process. After completing the acetabular cup implantation and liner insertion with adequate power of hammer stroke, we double-checked correct positioning of the liner not only by manual palpation but also with the C-arm. After the broaching of the femur, five patients showed liner pulling-out phenomenon, and this could be a result of resonance effect during the femur broaching [Figure 1]. The first patient was overlooked during the surgery. At 8 months after the surgery, the patient showed alumina delta liner fracture due to impingement of malpositioned liner [Figure 2]. After the first liner fracture case, 4 liner pulling-out phenomenon were detected during the operation through C-arm and re-visualization of the liner after femoral implantation [Figure 3]. We were able to re-adjust

**Table 2: Demographic data of the patients**

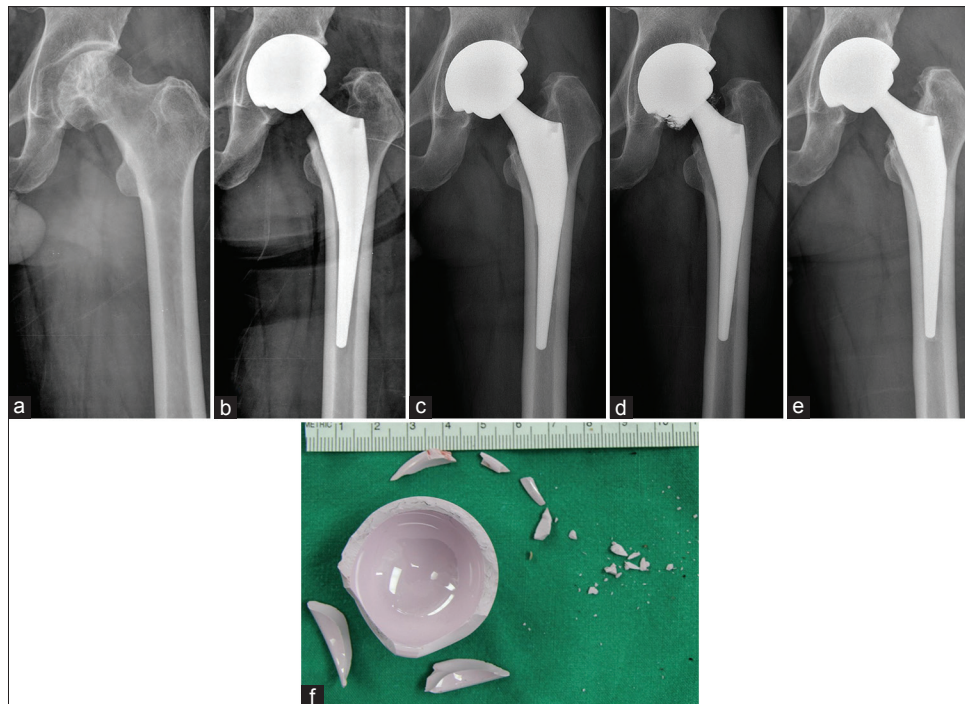
Number of patients (hips)	242 (263)
Male:female	175:67
Mean age at surgery, years (range)	53.6 (23-84)
Mean height, m (range)	1.7 (1.4-1.8)
Mean weight, kg (range)	66.3 (40-100)
Mean BMI, kg/m <sup>2</sup> (range)	23.8 (16.6-32.2)
Cause of surgery, <i>n</i> (%)	
Osteonecrosis	166 (63)
Osteoarthritis	59 (22)
Fracture	25 (10)
Septic hip sequelae	7 (3)
LCPD sequelae	6 (2)
Average followup duration, years (range)	5.2 (2.0-6.5)

BMI=Body mass index, LCPD=Legg-Calvé-Perthes disease



**Figure 1: (a) Well-positioned cup and liner after implantation. (b) Malpositioned liner due to liner pulling-out phenomenon after femur broaching and implantation**





**Figure 2:** A 47-year-old male BioloX<sup>®</sup> Delta liner fracture patient (a) Preoperative radiograph. (b) Immediate postoperative radiograph. (c) 6 months' postoperative radiograph. (d) Liner fracture on 8 months of followup. (e) Final followup at 6 years and 5 years after liner change. (f) The fractured BioloX<sup>®</sup> Delta liner

the liner to correct position and completed the surgery minimizing the risk of liner fracture.

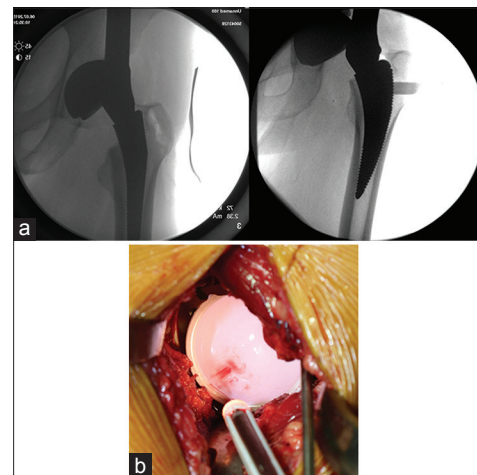
Through this study, we analyzed risk factors of the liner pulling-out phenomenon due to resonance effect considering gender, age, BMI, diagnosis, surgical technique, cup size, liner size, stem type, and Dorr type [Table 3]. Among various factors, Dorr type A was found to be a significant ( $P = 0.002$ ) risk factor for liner malposition due to the resonance effect.

### Complications

Four (1.5%) of 263 hips underwent revision surgery due to various complications. One patient showed recurrent dislocation and underwent stem revision. Another patient who showed anterior thigh pain due to failed osteointegration also underwent stem revision and became satisfied. One patient who had an infection after the surgery was treated with two-stage reconstruction. The patient, who showed liner fracture at 8-month postoperatively, underwent liner change. There were no intraoperative complications such as calcar fracture or periprosthetic femur fracture. There was no ceramic head fracture either. Considering revision for any reason as the end point, the mean survival rate was 98.5% (95% CI, 0.96–1.00) at 5.2 years [Figure 4].

### Discussion

For decades, alumina ceramics in THA has been improved since 1970s. In 2004, BioloX<sup>®</sup> Delta, the fourth generation of alumina ceramic, was introduced by CeramTec



**Figure 3:** Liner pulling-out phenomenon due to resonance effect. (a) C-arm and (b) Manual rechecking

AG (Plochin-gen, Germany). BioloX<sup>®</sup> Delta is consisted of aluminum oxide (81.6%), yttria-stabilized zirconia particles (17%), and traces of chromium dioxide and strontium crystals. This generation ceramic has shown increased material density and five times smaller grain size than the previous generation of CoC articulation.<sup>19,20</sup>

Through this study, we report good midterm results of THA with the fourth generation CoC articulation using BioloX<sup>®</sup> Delta ceramic liner and head. Excellent clinical and radiological outcomes could be accomplished with those Implants. The patients HHS and WOMAC score were improved significantly after the THA. There was

**Table 3: Radiological results**

Parameter	Number of hips
Dorr type, <i>n</i> (%)	
A	75 (28.5)
B	159 (60.5)
C	28 (11.0)
Acetabular component, degree (range)	
Inclination angle	37.39 (20.6-49.5)
Anteversión	20.7 (4.8-36.1)
Center of the hip, mm (range)	
Vertical	19.2 (15.2-25.9)
Horizontal	38.7 (30.5-48.2)
Acetabular cup osteolysis, <i>n</i> (%)	0
Femoral stem osteolysis, <i>n</i> (%)	0
Radiolucent line (>1 mm), <i>n</i> (%)	1 (0.4)

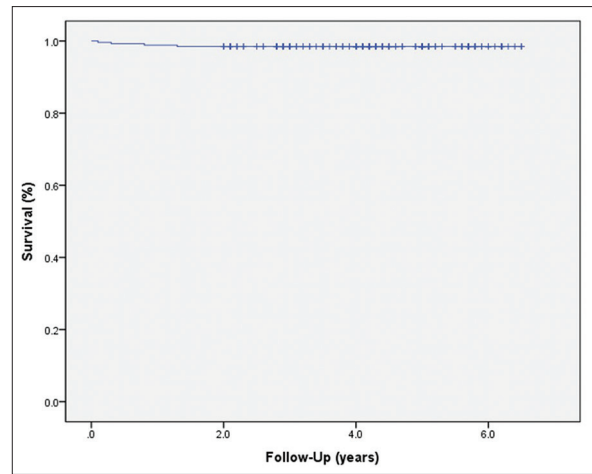
no evidence of wear or osteolysis. The survivorship was 98.5%, similar to those of current reports [Table 4]. There is no doubt that CoC articulation THA is a well-proven excellent articulation.

However, one major concern for surgeons to use CoC articulation is ceramic fracture. Until now, there is no unbreakable ceramic material. This proposition is also applies for BioloX<sup>®</sup> Delta ceramic. In our study, there was no ceramic head fracture but one liner fracture. The liner fracture occurred due to mal-position of the liner and impingement during the hip joint movement.

According to reports of the manufacturer (CeramTec GmbH, Plochin-gen, Germany) and Agency Nationale de Sécurité du Médicament et des Produits de santé, ceramic head fracture of BioloX<sup>®</sup> Delta has been 10–100 times lower than third-generation ceramic which was 0.0013%–0.002% and ceramic liner fracture was slightly lower which was 0.025%–0.028%.<sup>21</sup> And also, previous reports did not report any ceramic head fracture.<sup>22,23</sup> These results have made the fourth generation of CoC articulation as an attractive articulation of choice to treat young active patients who require long survival of THA. Actually, recent studies have reported very good results of the fourth CoC articulation of THA.<sup>22-25</sup> Kim *et al.*<sup>23</sup> have reported survival rate of 99.7% without any ceramic fracture in 334 cases during a 7.8-year followup. Hamilton *et al.*<sup>24</sup> have reported survival rate of 97.3%, with only two ceramic liner fractures in 345 cases during a 5.3-year followup.

However, the use of BioloX<sup>®</sup> Delta ceramic does not seem to have significantly reduce the incidence of liner fracture. Hamilton *et al.*<sup>24</sup> reported 2 cases of BioloX<sup>®</sup> Delta liner fractures and no head fracture of 345 hips at 5.3 years' followup study, Hwang *et al.*<sup>26</sup> reported one case of liner fracture, and our study also demonstrated one liner fracture.

The risk factor of liner fractures includes mal-positioning of components, design of the cup, taper angle of the stem, thickness of liner, edge loading, and other functional



**Figure 4: Kaplan–Meier survival curve at 5.2 years with revision for any reason as an end point**

problems. In our study, the liner fracture was caused by a combination of pulling-out phenomenon and impingement during the hip joint movement. It was not significantly associated with sex, age, BMI, cup size, or liner thickness. However, the correlation between the liner fracture and Dorr type appeared statistically significant. As for the reason of the liner pulling-out phenomenon, the liner might be pulled-out during femoral component implantation owing to the resonance effect.

Resonance is a phenomenon that a vibrating system or external force drives another system to oscillate with greater amplitude at specific frequencies. When resonance occurs, the oscillation with greater amplitude makes the liner become pulled-out from the acetabular cup.

First, according to our study, all five patients were classified as Dorr type A femur. In these cases, during femoral component implantation, the surgeon performed relatively more times and more forced broaching for femoral preparation due to the thick cortex and higher bone mineral density.

Second, natural frequency ( $\omega_n$ ) is proportional to the stiffness of the material ( $k$ ),

$$\omega_n = \sqrt{k / M}$$

BioloX<sup>®</sup> Delta liner's natural frequency is likely to be very high due to its stiffness. Although it does not frequently show resonance phenomenon,<sup>27</sup> in some cases as in our study (5 cases), when the external force matches the natural frequency of the liner, resonance effect could occur, consequently leading to liner pulling-out phenomenon.

In Dorr Type A patients, when there are increases in intensity (powerful femur broaching) and frequency (multiple femur broaching) of the external forces and vibration transmissibility due to elevated bone mineral density, resonance effect could occur during the operation.

**Table 4: Intraoperative liner pulling-out phenomenon risk factor analysis**

	<i>In situ</i>	Pulling-out	Total	<i>P</i>
Gender				
Male	186	5	191	0.166
Female	72	0	72	
Age				
20-29	9	0	9	0.891
30-39	40	1	41	
40-49	49	2	51	
50-59	70	1	71	
60-69	47	1	48	
70-79	36	0	36	
80-89	7	0	7	
Diagnosis				
Osteonecrosis	161	5	166	0.561
Osteoarthritis	59	0	59	
Fracture	25	0	25	
Septic hip sequelae	7	0	7	
LCPD sequelae	6	0	6	
BMI				
16-17	6	0	6	0.462
18-19	19	1	20	
20-21	49	0	49	
22-23	67	0	67	
24-25	51	3	54	
26-27	44	1	45	
28-29	15	0	15	
30-31	6	0	6	
32-	1	0	1	
Cup size (mm)				
44	1	0	1	0.859
46	10	0	10	
48	42	0	42	
50	33	0	33	
52	84	2	86	
54	45	2	47	
56	40	1	41	
58	3	0	3	
Liner size (mm)				
28	11	0	11	0.462
32	75	0	75	
36	129	4	133	
40	43	1	44	
Stem type				
M/L Taper®	107	2	109	0.822
Fitmore®	134	3	137	
Surgical technique				
MIS-2	179	5	184	0.335
MIS-1	64	0	64	
CONV	15	0	15	
Dorr type				
A	71	5	76	0.002
B	159	0	159	
C	28	0	28	

BMI=Body mass index, LCPD=Legg-Calvé-Perthes disease, MIS=Minimally invasive surgery

Based on previous studies, CoC articulation is a very attractive articulation of choice not only for patients but also for surgeons due to its very low rate of wear and osteolysis. As mentioned earlier, alumina delta ceramic is a very hard, hydrophilic, and stiff material. However, it also requires very delicate technical maneuvers, especially for the impaction of components and well positioning in the acetabular cup. Surgeons should always pay attention to the well-positioning of the liner in the cup and head on the taper until the operation is completed.

There are several limitations to this study. First, this is a retrospective study. We included patients with a single type of acetabular system to minimize variables. Second, all operations were performed by a single surgeon in a single institute. This may lead to bias interpreting the data. However, our study concluded similar results to other previous reports. Such similarity with other studies may reduce single-surgeon bias. Third, we did not measure femoral component anteversion which could be a risk factor of ceramic liner fracture.

**Conclusion**

Our midterm study of the fourth-generation CoC articulation in THA demonstrated excellent clinical and radiological results with only one ceramic liner fracture. There was no wear or osteolysis around the joint. The result of our study indicates that one possible cause of pulling-out phenomenon is resonance effect during implantation in Dorr type A patients with thick cortex. This can consequently lead to liner fracture. Therefore, if the surgeon is aware of the possibility of malpositioned liner with thorough inspection of liner positioning throughout the operation, the fourth-generation CoC articulation in THA could be an outstanding treatment of choice for young and active patients, showing a high rate of survivorship.

**Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patient understands that name and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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Nil.

**Conflicts of interest**

There are no conflicts of interest.

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