Original article

What factors predict ceramic liner malseating after ceramic-on-ceramic total hip arthroplasty?

Short title: The risk factors of ceramic liner malseating after total hip arthroplasty.

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Abstract

Background:

There is a lack of evidence about the risk factors associated with the malseating of the acetabular liner after ceramic-on-ceramic (CoC) total hip arthroplasty (THA). Therefore, we performed a complementary retrospective case-control study to determine the factors predicting the malseating of the acetabular liner after CoC THA and to evaluate the relationship between malseating and 1) osteoarthritis, 2) particularly in terms of the new radiographic parameter "bone sclerotic length" of the acetabular bone.

Hypothesis:

Osteoarthritis, particularly bone sclerotic length, was an independent risk factor for malseating of ceramic liners.

Patients and Methods:

In total, 219 CoC THAs (174 women and 45 men) were evaluated to determine the risk factors influencing the malseating of the acetabular ceramic liner. An average patient age at the time of surgery was 55.9 ± 9.5 years (range, 23 to 75 years). Data on patient background and preoperative radiographs, such as Tönnis grades; Crowe classification; and indices of acetabular osteoarthritis change; including bone cyst, osteophyte and bone sclerosis, were assessed. The sclerotic length in patients with osteoarthritis was measured as the length between the bilateral edges of sclerosis lesions. The bone sclerotic length was measured as the slant distance between the bilateral edges of the sclerosis lesion of the acetabulum on the anteroposterior view

Results:

Preoperative less flexion (hazard ratio [HR]: 0.98; 95% CI: 0.97-0.99), osteoarthritis (HR: 3.15; 95% CI: 1.02-9.70) and the bone sclerotic length (HR:1.83; 95% CI: 1.35-2.48) were independent risk factors determining the malseating of ceramic liners. Receiver operating characteristic curve analysis showed that a bone sclerotic length of 24.6 mm was defined as the cut-off point for the malseating of the ceramic liner.

Discussion:

Age, preoperative less flextion, osteoarthritis, and the bone sclerotic were independent risk factors determining malseating of ceramic liners. The acetabular shell can also deform upon insertion of the cup with sclerotic bone of the acetabulum and prevent correct seating of liners. Therefore, these factors must be taken into consideration when seating the ceramic liner.

Level of evidence: Case control study, level 3 case control retrospective design.

Keywords:

Ceramic on Ceramic bearings; Total hip arthroplasty; Liner malseating, Risk factor; Ceramic liner with a metal-back titanium sleeve

1. Introduction

In an attempt to avoid problems caused by wear debris, hard bearing surfaces such as ceramic-on-ceramic (CoC) have been developed [1]. However, early usage of CoC bearings was met with discouraging results secondary to ceramic component fracture [2,3]. The third generation of alumina (Biolox® forte) has addressed the problems of earlier ceramic.

Initially, third generation ceramic liners without a metal-backed titanium sleeve were fit directly to the acetabular component. However, ceramic liner fracture caused by impaction during implantation and impingement has been reported [4-6]. In an effort to decrease the risk of ceramic liner fracture during insertion, and to protect the ceramic liner from prosthetic impingement on the femoral neck, a ceramic liner with an elevated metal-backed titanium sleeve was then developed [5,7]. However, a ceramic liner with a metal-backed titanium sleeve is thought to prevent ceramic fracture, although metallosis caused by impingement of the femoral neck upon the ceramic liner with an elevated metal rim has been reported. [8].

On the other hand, malseating of the acetabular ceramic liner has been reported to be an important complication of CoC with a metal-back titanium sleeve [9-13]. Malseating might be associated with acetabular shell deformation and negative clinical consequences such as chipping of ceramic liner and ceramic liner fracture [14]. Malseating can occur with other material such as metal and polyethylene;

however it may not be a problem as polyethylene is more flexible compared to ceramic [14]. A fourth generation ceramic liner (Biolox® Delta) was developed to hopefully reduce the risk of ceramic fracture [15].

Previous studies using the Trident acetabular shell have estimated the incidence rate of ceramic liner malseating to range between 7.2% and 20% [9-13]. Previously, we reported that malseating of the acetabular liner was associated with a significantly higher prevalence of osteolysis likely due to fretting of the metal backing by relative motion between the interfaces [13]. However, no reports have proved statistically the risk factors associated with ceramic liner malseating.

Therefore we performed a complementary case control study to evaluate the relationship between malseating and 1) osteoarthritis, 2) particularly in terms of the new radiographic parameter "bone sclerotic length" of the acetabular liner in CoC total hip arthroplasty (THA). We hypothesized that osteoarthritis, particularly bone sclerotic length, was an independent risk factor for malseating of ceramic liners.

2. Materials and Methods

2.1 Patient selection

Between September 2001 and June 2011, we performed 549 consecutive primary THAs, which included CoC with or without metal-backed titanium sleeve, MoM, and metal-on highly cross-linked polyethylene (MoXPE) THAs. The type of THA was determined by the senior surgeon. We excluded 57 MoM THAs, 189 MoXPE THAs, 84 CoC THAs without metal-backed titanium sleeve. 219 primary CoC THAs (196 patients) with metal-backed ceramic liners at our institution. All 219 THA cases were eligible for the study (Fig. 1). Of the patients, 174 were women and 45 were men, with a mean age at the time of surgery of 55.9 ± 9.5 years (range, 23 to 75 years). Informed consent was obtained from all patients, and the study was approved by the ethics committee of our hospital.

2.2 Methods

All surgeries were performed by a single senior surgeon or a junior surgeon who had been coached by the senior surgeon. The posterolateral approach was used for surgery, with patients in the lateral decubitus position. We did not change the surgical technique during the 10-year study period.

We reamed the acetabulum at the planned cup position be planned with a cup center edge angle >0° [16]. The acetabulum was prepared and reamed by the same size of cup. Actually reaming size means underreaming by 1.8 mm, as previous described (52mm shell = 53.8mm periphery at the rim of the shell) [10]. The socket was fixed in the acetabulum using an acetabular alignment guide [17]. The guide was inserted into the acetabular component at an abduction angle of 45° and an anteversion angle of 20°. Moreover, the surgical technique for CoC THA requires the surgeon to verify the correct seating of liner along the circumference of acetabular fossa [12]. The senior surgeon (instructor) checked whether the ceramic liners were completely recessed within the cup or if they were flushing around the periphery of the cup when inserted, which reduces soft tissue interposition or bony impingement that could lead to malseating of the liners. After impaction, we checked whether the liner was correctly-seated circumferentially and attempted to gently lift the liner out with elevators to confirm properly seating and stability of liner seating.

Acetabular and femoral components for all THAs were manufactured by Stryker Orthopaedics (Mahwah, NJ, USA) (Fig. 2 and Table 1). Trident PSL and TriAD are similar designs with a hydroxyapatite arc-deposited titanium surface; the difference between these cups is only the number of screw holes. The number of screw holes were 3 to 5 and 5 to 9 in Trident PSL and TriAD, respectively. In the Trident PSL and TriAD systems, the ceramic liners are recessed within a metal-backed titanium sleeve to prevent ceramic chipping and fracture (Fig. 2). Anti-rotation tabs on the shell ensure correct seating of the liner, which is then impacted to engage with morse taper within the shell. Although the ceramic material in two implants was the same, the ceramic liner and head were BIOLOX®forte (Ceramtec, Plochingen, Germany).

2.3 Methods of assessment

The patients' clinical data including their range of motion (ROM) were prospectively recorded by a senior surgeon 1 month prior to THA. We measured ROM (flexion, abduction, and adduction) in the supine position by using a goniometer. Maximum

ROM was defined by the point of soft tissue resistance or pelvic movement on passive motion. These data were then retrospectively investigated from the patients' medical records.

Using the Neochart computer system (Fujitsu Co., Tokyo, Japan), radiographs of the hips in the standard anteroposterior (AP) view, with both hips in neutral rotation and 0° abduction, and in the Lauenstein view, with the patient in the supine position with the hips in 45° abduction (frog leg position), were obtained in the immediate post-operative period and, thereafter, at each time point of post-THA assessment [18,19]. The AP and Lauenstein radiographs were evaluated using a previously described technique [9-12]. Radiographic evaluations were performed by two independent surgeons. Malseating of the acetabular liner was defined by a gap between the metal-back of the liner and the rim of the acetabular shell at any point on the AP and Lauenstein views. The liner was judged to be correctly seated if there was no visible gap (Fig.2 and 3).

Preoperative radiographs were assessed for Tönnis grade [20], Crowe classification [21], and indices of acetabular osteoarthritis change, such as bone cyst, osteophyte, and bone sclerosis. We recorded the bone cyst, osteophyte, and bone sclerosis as radiographic features in reference to a previous report [22]. When bone sclerosis of the acetabulum was observed, the bone sclerotic length was measured as the slant distance between the bilateral edges of the sclerosis lesion of the acetabulum on the AP view (Fig. 4).

2.4 Statistical analysis

Statistical analyses included the Fisher exact test, Student's *t*-test and stepwise multivariate logistic regression analysis was performed to determine the independent factors of malseating of the acetabular liner. Receiver-operating characteristic (ROC) curve analysis was performed to identify volume thresholds at which statistically significant changes of risk probability of malseating occur. To determine an adequate sample size, we performed a power analysis using the hypothesis test with a power of 75% to detect a difference in the incidence rate of malseating among patients with osteoarthritis. This study has no missing data. All analyses were performed using SPSS version 21 (IBM Corp., Armonk, NY). A p value <0.05 was considered statistically significant. Kappa coefficients and intraclass correlation coefficients (ICCs) were calculated and used to determine the interobserver reliability for the diagnosis of malseating of the acetabular liner, bone cyst, osteophyte, and bone sclerosis of the acetabulum, and the measurement of bone sclerotic length.

3. Results

3.1 The risk factors of malseating

Among the 219 CoC THA cases included in our analysis, malseating of the acetabular liner was identified in 55 cases, indicating an incidence rate of 25.1%, with correct seating of the liner maintained in 164 cases (74.9%). All malseating cases were defined by radiograph 1 week after surgery. Despite confirming if malseating has not occurred, unfortunately we could not notice the malseating during surgery.

The incidence rates of malseating were 19.3% and 29.4% with respect to instructor and trainee surgeons, respectively (p=0.115). There was no liner breakage or squeaking in the malseating groups. Osteolysis was observed in 6 cases (10.9%) in the malseating group. Seven malseating liners (12.7%) disappeared during the study period (1 to 12 months after surgery) according to X-ray.

Patients with an identified liner malseating were classified into the malseating group, and those with maintained correct liner seating were classified into the correct group for analysis. The power analysis indicated that a sample of 54 cases was required in each group to detect a significant difference in the incidence rate of malseating among patients with osteoarthritis.

All instances of liner malseating were identified from radiographs obtained in the immediate postoperative period. The kappa coefficient for diagnosis of malseating, bone cyst, osteophyte, and bone sclerosis were 0.833, 0.875, 0.898, and 0.875, respectively ($p = 0.003$ for malseating and $p < 0.001$ for the other indices), with an ICC of 0.741 (95% confidence interval [CI], 0.48–0.95; $p = 0.023$) for measurement of bone sclerotic length.

The results of the univariate analysis revealed that the factors that influence the malseating of the acetabular ceramic liner were sex, height, cup design, preoperative ROM (flexion), and osteoarthritis (Table 2). The use of a screw with cup fixation was not influenced with malseating (Table 1).

Multivariate logistic regression analysis revealed that preoperative ROM (flexion; HR:

0.98; 95% CI: 0.97–0.99) and osteoarthritis (HR: 3.15; 95% CI: 1.02–9.70) were the independent risk factors of ceramic liner malseating (Table 3). The results of multivariate logistic regression analysis indicated that difference of cup designs was not a significant risk factor.

3.2 The risk factors of the malseating associated with osteoarthritic

In addition, we performed a subanalysis of the association between malseating and osteoarthritic changes such as bone cyst, osteophyte, and bone sclerotic length of the acetabulum for patients with osteoarthritis (n = 182). In accordance with the subanalysis for evaluating the risk factor of malseating, the univariate analysis revealed that osteophyte and bone sclerotic length influenced the ceramic liner malseating (Table 4). In addition, the multivariate logistic regression analysis revealed that bone sclerotic length (HR: 1.83; 95% CI: 1.35–2.48) was an independent risk factor of ceramic liner malseating (Table 5). The ROC curve analysis revealed that a bone sclerotic length of 24.6 mm was defined as the cutoff point for the occurrence of ceramic liner malseating (sensitivity, 0.969 and specificity, 0.960) (Figure 5).

4. Discussion

This study is the new report to define the significant risk factor of ceramic liner malseating. Several factors can contribute to malseating of the acetabular liner. Malseating of the acetabular ceramic liner has been reported to be an important complication of CoC systems associated with osteolysis and ceramic fracture after ceramic on ceramic THA [9-13]. However, no reports have proved statistically the risk factors associated with ceramic liner malseating. The acetabular shell can also deform upon insertion of the cup and liner, particularly with dense and sclerotic bone of the acetabulum with osteoarthritis [9,10,12]. With deformation, the angular taper geometry of the shell would be slightly altered, preventing full insertion of the liner [9]. Thus, when acetabular bone is considered sclerotic or hard by surgeon, underreaming by only 0.8 mm rather than the usual 1.8mm is recommend to reduce the risk of deformation of the acetabular shell [10].

Our present study suggests that patients with osteoarthritis and a bone sclerotic length of >24.6 mm must be aware of malseating. We used a median cup size of 48 mm, and 24.6 mm was nearly half of the cup size. When a bone sclerosis has a bone sclerotic length of more than half of the cup size to be used, attention should be given to the risk of malseating and prefer to ream the acetabulum by 1 mm under or line to line to reduce the risk of deformation of the acetabular shell, as previous reports have described [10].

Interposition of soft tissue or bone may be such a factor, resulting in poor visualization of the entire circumference of the acetabular shell [9,12]. Body mass index (BMI) and length of incision could also potentially influence alignment of the acetabular component and poor visualization of the acetabular shell, therefore, increasing the incidence of liner malseating [9,12]. A BMI >40 kg/m^2 led to increased postoperative complication including reoperation and infection [23]. However, BMI was not associated with malseating in this study as the mean BMI of malseating group was 23.7 kg/m^2, which was not particularly heavy compared to 40 kg/m^2. The independent predictor identified was a lower preoperative flexion angle. We could not clarify the relation between the lower flexion and malseating. Maybe because we could not check the liner seating circumferentially, resulting in poor visualization and inadequate position by less flexion.

The rate of malseating (25.1%) in this study was higher than those in previous reports (7.2%-20%) without a significant difference [8-12]. A possible explanation for malseating is the surgical learning curve and the surgeon's technique [8,9]. In this study, there was no significant difference of malseating rate between instructor and trainee surgeons, but it occurred more frequently with trainee surgeons. Thus, a low experienced surgeon should be careful of malseating whilst performing this procedure.

This study has some limitations: 1) our study is retrospective in nature, with a relatively small number of patients. As well, analysis was based on consecutive cases with no randomization. No power analysis was performed to determine if sufficient patients were included to detect clinically meaningful differences between groups. 2) it is possible that minimal malseating of the ceramic liner, which would not be diagnosable by radiography, could be present in group correct, that is patients in whom seating of the acetabular liner was deemed to be correct.

However, according to the power analysis, the number of patients in this study was enough to confirm that osteoarthritis was significantly associated with malseating. Thus the number of patients did not jeopardize the conclusions of the study. 3) we did not evaluate the test-retest reliability of manual goniometers to measure passive ROM. In the literature, intraobserver reliability of the goniometer proved to be excellent, and similar to that of an electromagnetic tracking system [24]. Thus the reliability of measure passive ROM did not jeopardize the conclusions of the study. 4) this study is based on a single brand design and other thick cups were not evaluated. We analyzed only Trident PSL and TriAD, composed of very thin and relatively soft metal. This could be the reason why the incidence of malseating for this cup design was high. Thus, we have no information regarding the malseating rate of the other cup designs. As a lot of malseating occurred, we could confirm that osteoarthritis was significantly associated with malseating. 5) we could not assess soft tissue. Interposition of soft tissue can contribute to malseating of the acetabular liner. However, we could not evaluate that by Magnetic Resonance Imaging due to artifact, making it a difficult problem to solve by modern technology. 6) we could not evaluate bone mineral density (BMD). BMD is useful for evaluating bone sclerosis. Thus, further studies are needed to determine if high BMD increases the risk for ceramic liner malseating. However, we could confirm that our hypothesis was correct. Thus the lack of BMD measurements did not jeopardize the conclusions of the study.

5. Conclusion

Age, preoperative range of motion (flexion), osteoarthritis, and bone sclerosis were the independent risk factors determining ceramic liner malseating. A bone sclerotic length of 24.6 mm was defined as the cutoff point for the occurrence of ceramic liner malseating. Therefore, these factors must be taken into consideration when seating the ceramic liner.

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Author's contribution:

Yoshitoshi Higuchi: the conception and design of the study, or acquisition of data, or analysis and interpretation of data, Statistics, experimentation or surgery performance

Taisuke Seki: drafting the article or revising it critically for important intellectual content, experimentation or surgery performance

Yasuhiko Takegami: Statistics

Yusuke Osawa: the conception and design of the study, or acquisition of data, or analysis and interpretation of data

Taiki Kusano: the conception and design of the study, or acquisition of data, or analysis and interpretation of data

Naoki Ishiguro: final approval of the version to be submitted

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Figure captions

Figure 1: Study flowchart

Figure 2: 2a) The figure shows the correct seating of ceramic liner. The acetabular shell and ceramic liner, with the peripheral self-locking titanium shell and recessed metal-backed alumina liner shown. 2b) The figure shows the malseating of ceramic liner, defined as the angulation between the rim of acetabular shell and the liner (white arrow).

Figure 3: 3a) Anteroposterior view 3b) Lauenstein view. The radiograph showing malseating of the liner in the 1 week postoperative period, an inferomedial gap (white arrow).

Figure 4: The radiograph shows the bone sclerotic length, defined as the slant distance between the bilateral edges of sclerosis lesion of the acetabulum on anteroposterior view.

Figure 5: Receiver operating characteristic (ROC) curve analysis shows a sensitivity and specificity of 0.969 and 0.960. A bone sclerotic length of 24.6 mm was defined as the cut-off point for the occurrence of ceramic liner malseating, with an area under the curve of 0.979 and a confidence interval of 95% between 0.949 and 1.

Table 1. Characteristics of implants

Parameters	Malseating (n=55)	Correct (n=164)	p values
Cementless Cup (n, %)			0.012
Trident PSL	39 (70.1%)	84 (51.2%)	
TriAD HA	16 (29.1%)	80 (48.7%)	
Cup size median (mm) (range)	48 (46 - 54)	48 (46 - 58)	0.481
Cup thickness (mm) (range)	3.28 ± 0.50	3.23 ± 0.45	0.560
	(2.79 – 3.81)	(2.79 – 3.81)	
Cup fixation with Screw (n, %)	34 (61.8%)	87 (53.0%)	0.165
Head diameter (n, %)			0.800
26mm	0	2 (1.2%)	
28mm	34 (61.8%)	88 (53.7%)	
32mm	21 (38.2%)	74 (45.1%)	
Cementless Stem (n, %)			0.080
Securfit	4 (7.3%)	29 (17.7%)	
Super Securfit HA	51 (92.7%)	135 (82.3%)	

All values given as mean and standard deviation (SD).

Table 2. Patient demographics

Parameters	Malseating (n=55)	Correct (n=164)	p values
Age (years) (range)	58.4 ± 7.3	55.0 ± 10.4 1	0.009
	(43-73)	(23-75)	
Sex (female /male)	49/6	125/39	0.028
Height (cm) (range)	153.8 ± 7.3	156.1 ± 8.3	0.048
	(136.5-176.0)	(139.0-180.0)	
BMI (kg/m²) (range)	23.7 ± 3.9	23.3 ± 3.5	0.477
	(16.6-39.4)	(15.1-34.9)	
Preoperative ROM (°) (range)			
Flexion	65.8 ± 23.0	74.5 ± 25.8	0.026
	(25-110)	(10-130)	
Abduction	13.5 ± 7.7	14.5 ± 8.4	0.427
	(-5-30)	(-15-35)	
Adduction	11.1 ± 4.6	12.0 ± 5.7	0.823
	(-5-20)	(-5-30)	
Diagnosis (n, %)			0.050
Osteoarthritis	50 (91.0%)	132 (80.5%)	
Avascular necrosis	5 (9.0%)	32 (19.5%)	
Operative side	25/30	77/87	0.486

Right/Left			
Surgical history of the hip	10/45	33/131	0.216
(Yes/No)			
Tönnis grades	0/6/49	2/21/129	0.612
Mild/Moderate/Severe			
Crowe classification	48/7	136/16	0.411
I and II / III and IV			
Surgeon	37/18	126/93	0.115
Trainee/ Instructor			

All values given as mean and standard deviation (SD). BMI: Body mass index. ROM: Range of motion

Table 3. Preoperative factors for the ceramic liner malseating (Multivariate analysis)

Parameters	Hazard Ratio	95% CI	p values
Preoperative ROM Flexion	0.98	0.97 – 0.99	0.036
Osteoarthritis	3.15	1.02 – 9.70	0.046

ROM: Range of motion. CI: Confidence interval

Table 4. Preoperative risk factor of osteoarthritis for the ceramic liner malseating (Univariate analysis)

Parameters	Malseating (n=50)	Correct (n=132)	p values
Bone cyst	18 (36.0%)	46 (34.8%)	0.085
Osteophyte	28 (56.0%)	50 (37.9%)	0.027
Bone sclerotic length (mm)	33.8 ± 7.8	7.1 ± 6.9	< 0.001
(range)	(136.5-176.0)	(0-180.0)	

All values given as mean and standard deviation (SD).

Table 5. Preoperative risk factor of osteoarthritis for the ceramic liner malseating (Multivariate analysis)

Parameters	Hazard Ratio	95% CI	p values
Bone sclerotic length	1.83	1.35 - 2.48	< 0.001

CI: Confidence interval

Figures

Fig.1

Total of 549 primary cementless total hip arthroplastys (THAs) between September 2001 and June 2011

↓

Exclusion criteria

1) Metal on Metal THA (n=57)
2) Metal on Highly cross-linked Polyethylene THA (n=189)
3) Ceramic on Ceramic THA without a metal-backed titanium sleeve (n=84)

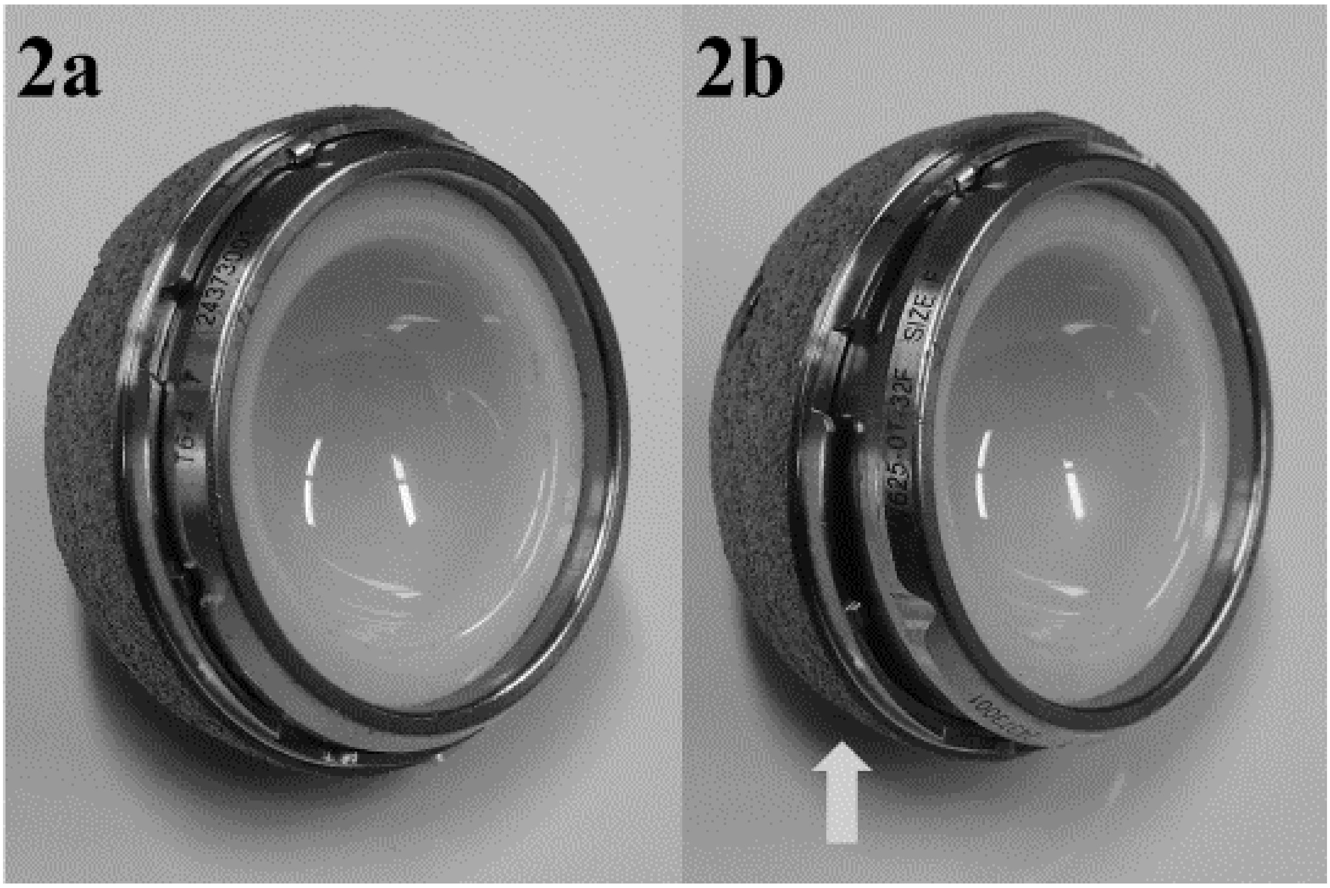
↓

Included in this study

Total of 219 Ceramic on Ceramic THAs with metal-backed ceramic liners

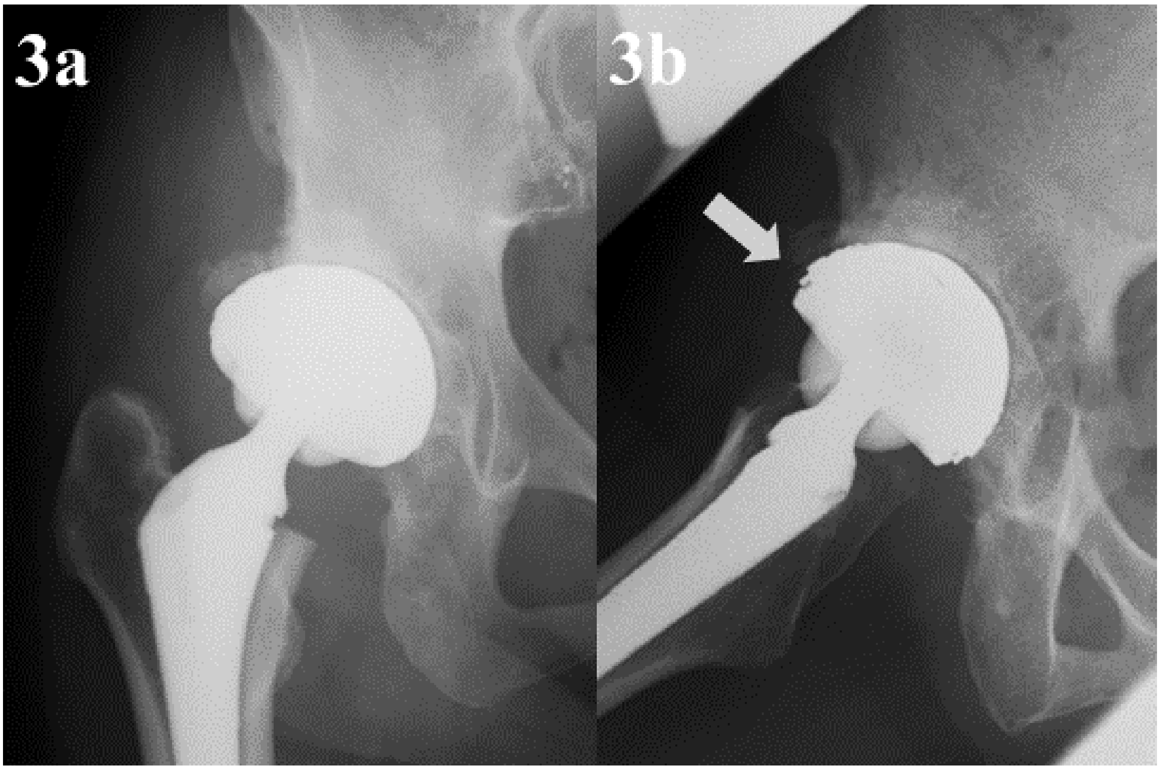
Figures

Fig.2



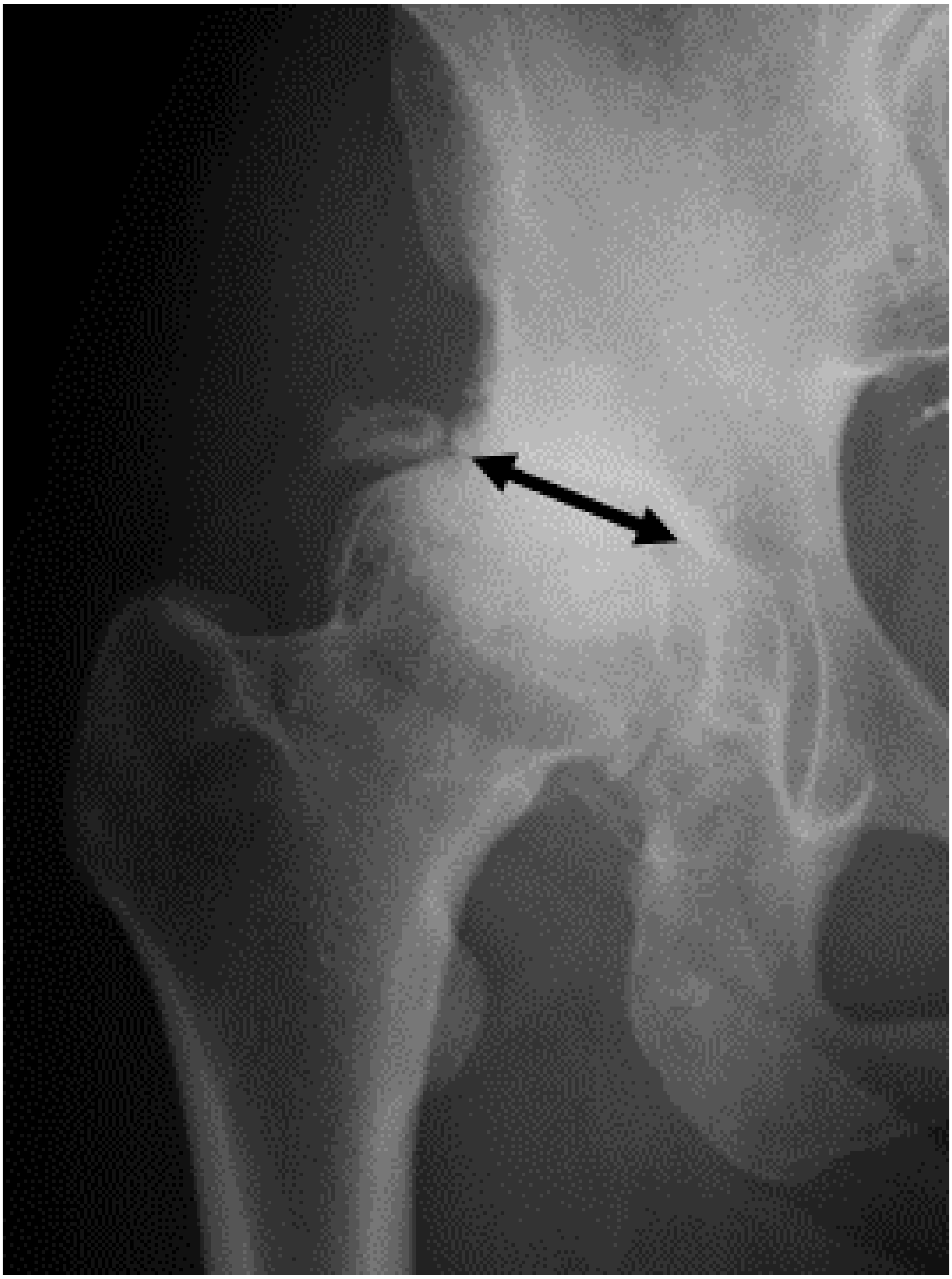
Figures

Fig.3



Figures

Fig.4



Figures

Fig.5