

# **32-mm ceramic-on-ceramic total hip arthroplasty versus 28-mm ceramic bearings: 5- to 15-year follow-up study**

**Short title:** 32-mm versus 28-mm ceramic-on-ceramic total hip arthroplasty

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## Abstract

**Introduction:** This study aimed to compare the clinical and radiographic results of 28-mm ceramic-on-ceramic (CoC) total hip arthroplasty (THA) to those of 32-mm CoC during a 5- to 15-year follow-up period.

**Methods:** 107 joints (95 women and 6 men) underwent 28-mm CoC, and 60 (49 women and 7 men) underwent 32-mm CoC. The average patient age at the time of surgery was 56.1 and 55.7 years in the 28- and 32-mm CoC groups, respectively. Clinical and radiologic measurements of all patients were analysed.

**Results:** The mean preoperative Harris hip score (HHS) was similar in the 2 groups (28-mm, 58.9; and 32-mm, 58.5). However, at final follow-up, the mean HHS of the 32-mm CoC (91.8) was significantly better than that of the 28-mm CoC (88.2) ( $p=0.003$ ), as were the ranges of motion (ROM) for flexion ( $98.3 \pm 13.5^\circ$  vs.  $87.3 \pm 19.3^\circ$ ,  $p<0.001$ ) and abduction ( $27.8 \pm 14.9^\circ$  vs.  $22.1 \pm 19.3^\circ$ ,  $p=0.007$ ). The mean wear rate was 0.0044 mm/year for the 28-mm CoC and 0.0044 mm/year for the 32-mm CoC. No ceramic fractures were found in the 2 groups. One joint in the 28-mm CoC (0.9%) required revision owing to progressive osteolysis. Kaplan-Meier survival at 10 years, with implant loosening or revision THA as the endpoint, was 98.3% for 28-mm CoC and 100% for 32-mm CoC ( $p=0.465$ ).

**Conclusion:** There was no significant difference in ceramic-related complications between the 2 groups. Our study demonstrated that the 32-mm and 28-mm CoC are safe and are associated with good clinical outcomes.

**Keywords:** Ceramic-on-ceramic bearing, 28-mm ceramic articular, 32-mm ceramic articular, total hip arthroplasty, wear

## Introduction

Total hip arthroplasty (THA) has become a common treatment for osteoarthritis of the hip.<sup>1</sup> Prior to the development of highly cross-linked polyethylene and hard bearing surfaces, surface wear and the resultant wear-induced osteolysis were major limitations to long-term prosthesis survival.<sup>2</sup>

To avoid the problems caused by wear debris, hard bearing surfaces such as ceramic-on-ceramic (CoC) have been developed.<sup>3</sup> However, the early results of CoC bearings were discouraging owing to ceramic component fractures.<sup>4</sup>

Femoral heads >32 mm provided a greater range of motion (ROM) and virtually complete elimination of component-to-component impingement, and large (32- and 36-mm) ceramic heads have become popular over recent years in an effort

to reduce the rate of dislocation.<sup>5,6</sup> However, an increase in head-size necessitates a commensurate reduction in the thickness of the ceramic liner, thus reducing its resistance to fracture.<sup>6</sup> In a hip simulator study, the wear rate of the 36-mm ceramic bearings was significantly higher than that of 28-mm bearings owing to their larger contact area and paucity of lubrication when subjected to edge loading conditions.<sup>7</sup> This suggests the possibility of increased volumetric wear with the use of large ceramic heads in certain circumstances. There are no reports on wear rate and ceramic fracture rate comparing 28-mm vs. 32-mm CoC with long-term follow-up.

The aim of the present study was to compare the clinical and radiographic results, especially wear rate, ceramic fracture, and dislocation, of 28-mm CoC to those of 32-mm CoC during a 5- to 15-year follow-up period.

## **Materials and methods**

### **Patient selection**

Between October 2001 and December 2011, we performed 350 primary THAs. Among them, 157 patients (167 THAs) who completed a minimum follow-up period of 5 years were eligible for the study. The excluded patients were: 183

who had metal-on-highly cross-linked polyethylene THAs, 1 who died from causes unrelated to surgery, 6 patients who moved abroad, and 3 patients with Crowe group III/IV hips).

We measured the acetabular diameter and selected appropriately sized acetabular components based on preoperative computed tomography (CT). We selected 32-mm ceramic articulations for patients using 50- or 52-mm acetabular components, and 28-mm ceramic articulations for patients with 46- or 48-mm acetabular components.

Demographic data are given in Table I. No significant differences were noted between the groups with regard to age, gender, body mass index, or diagnosis. However, patient height at surgery was significantly lower in the 28-mm CoC group than in the 32 mm CoC group. This is because there was a tendency to use larger acetabular components for taller patients.

**Table I.** Patient demographics and characteristics of implants.

<i>Parameters</i>	28 mm	32 mm	P values
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	(n=107)	(n=60)	
<i>Age (years) (range)</i>	56.1 (28-72)	55.7 (23-77)	0.701
<i>Gender (male / female)</i>	6/95	7/49	0.131
<i>Height, mean± SD (cm)</i>	150.6±5.2	158.6±6.0	< 0.001
<i>BMI, mean± SD (kg/m<sup>2</sup>)</i>	23.0±3.5	23.4±3.5	0.990
<i>Follow up mean (years)</i>	8.4 (5-15)	8.8 (5-15)	0.671
<i>(range)</i>			
<i>Diagnosis (n, %)</i>			0.157
Osteoarthritis	102 (95.3%)	54 (90.0%)	
Avascular necrosis	5 (4.7%)	6 (10.0%)	
<i>Implant</i>			
<i>Cementless cup</i>			0.077
Trident PSL	45 (42.1%)	34 (56.7%)	
TriAD HA	62 (57.9%)	26 (43.3%)	
<i>Cementless stem</i>			0.129
Securfit	14 (13.1%)	14 (23.3%)	
Super Securfit HA	93 (86.9%)	46 (76.7%)	
<i>Femoral head neck length</i>			0.324
-4.0 mm	NA	5 (8.3%)	

-2.7 mm	15 (14.0%)	NA
0 mm	69 (64.5%)	40 (66.7%)
+4.0 mm	23 (21.5%)	15 (25.0%)

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BMI: body mass index; SD: standard deviation.

Informed consent was obtained from all patients, and the study was approved by the ethics committee of our hospital (ethics committee approval number: 2014-0106-2).

All operations were performed by a single senior surgeon or a junior surgeon who was coached by the senior surgeon. The posterolateral approach was used for surgery, with the patients in a lateral decubitus position. The socket was fixed in the acetabulum using an acetabular alignment guide; the targets for acetabular positions were 20° of anteversion and 45° of inclination.<sup>3</sup>

### Acetabular and femoral components

2 titanium alloy acetabular components were used in this study, namely, Trident PSL, and TriAD with a hydroxyapatite arc-deposited titanium surface (Stryker Orthopaedics) (Figure 1) (Table I). Although the ceramic material in the 2 implants was the same, the ceramic liner and head were BIOLOX forte

(Ceramtec). The ceramic liners of Trident PSL and TriAD were recessed within a metal-backed titanium sleeve. 2 titanium alloy (Ti-6AL-4V) femoral components with the same metal constituents as the acetabular components were also used, namely, Securfit and Super Securfit HA (Stryker Orthopaedics) (Figure 1) (Table I). The neck of the Super Securfit HA stem is narrower than that of the Securfit stem.

**[Figure 1.** Cementless components used in this study. White arrows show the difference in the thickness between the Securfit femoral stem and the Super Securfit HA femoral stem. The neck of the Super Securfit HA stem is narrower than that of the Securfit stem. **(a)** TriAD acetabular shell, ceramic liner and femoral head, Securfit femoral stem. **(b)** Trident PSL acetabular shell, ceramic liner and femoral head, Super Secur fit HA femoral stem.]

In the 28-mm CoC, the liner was 4.1 mm thick at its thinnest part, compared with 4.3 mm in the 32-mm CoC.

## Data collection

The patients' clinical data including their Harris hip score (HHS) and ROM were prospectively recorded by a senior surgeon 1 month prior to THA, 6 months and

1 year following THA, and then annually till the final follow-up visit. We measured ROM (flexion and abduction) in the supine position 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.

Radiographs of the hips in the standard anteroposterior (AP) view and the Lauenstein view, with the patient in the supine position, were recorded 3 months postoperatively, and then annually. AP radiographs with both hips in neutral rotation and 0° abduction, and Lauenstein view (frog position) radiographs with the hips in 45° abduction were collected for each patient.<sup>3</sup> The following precautions were taken for standardising the radiographic images: for the AP view, the beam was incident on the median line just above the pubic symphysis, and the feet were rotated internally by 15° to 20°; for the Lauenstein view, the beam was incident on the median line just above the pubic symphysis, and was oriented vertically.<sup>8</sup>

Radiographic evaluations, with images magnified to 400%, were independently performed by 2 surgeons who were not involved in this study by using the Neochart computer system (Fujitsu Co.).

Definite loosening of the femoral component was defined as progressive axial subsidence of >3 mm or a varus or valgus shift of more than 3°.<sup>9</sup> Definite loosening of the acetabular component was diagnosed if the position of the component changed (>2 mm vertically and/or medially or laterally) or if a continuous radiolucent line wider than 2 mm was seen on both AP and Lauenstein views on radiography.<sup>10</sup> Osteolysis was defined as progressive, non-linear areas of endosteal, intracortical, or cancellous destruction of the bone that exceeded 2 mm in width.<sup>11</sup> Acetabular inclination was measured by using the transischial line as reference, and anteversion was investigated by using the method described by Lewinnek et al.<sup>12</sup>

Using the methods of Dorr et al<sup>13</sup>, 2 surgeons examined femoral head penetration into the liners from digitized AP- and Lauenstein-view radiographs by using the computer-digitiser facilities of the Roman V1.70 software (Institute of Orthopaedics).<sup>2,3,14</sup> The size of the implanted femoral head (28 or 32 mm) was used as an internal reference. Wear rate was calculated by dividing total femoral head penetration by total years elapsed at the time of the last follow-up (Figure 2).

[**Figure 2.** Methods of measuring femoral head penetration. **(a)** More than 8 points were chosen on the edge of the femoral head, which were averaged to generate the center of the femoral head. **(b)** The implanted size of the femoral head (28 and 32 mm) was used as an internal reference. **(c)** Using the methods of Dorr et al<sup>13</sup>, femoral head penetration into the liners was measured from digitized AP- and Lauenstein-view radiographs.]

Intraclass correlation coefficients (ICCs) were calculated and used to determine the inter-observer reliability of the femoral head penetration measurements. The ICC was 0.737 (95% CI, 0.16-0.982,  $p=0.0043$ ) for CoC.

## Statistical analysis

Statistical analyses included Fisher's exact test, Student's *t*-test, and Kaplan-Meier survivorship analysis. All analyses were performed using SPSS version 21 (IBM Corp.). A *p* value  $<0.05$  was considered statistically significant.

## Results

### Clinical and radiographic results

Mean preoperative HHS was not different between the 28-mm and 32-mm CoC ( $p=0.941$ ) groups; however, the mean latest HHS of the 32-mm CoC group was

significantly better than that of the 28-mm CoC (Table II) group. Latest flexion and abduction ROMs of the 32-mm CoC group were significantly higher than those of the 28-mm CoC group (Table II).

**Table II.** Clinical findings.

Parameters	28 mm (n=107)	32 mm (n=60)	P values
<i>HHS</i>			
Preoperative, mean± SD	58.9±10.2	58.5±9.8	0.941
Latest, mean± SD	88.2±7.3	91.8±6.8	0.003
<i>Latest ROM</i>			
Flexion, mean± SD (°)	87.3±19.3	98.3±13.5	< 0.001
Abduction, mean± SD (°)	22.1±19.3	27.8±14.9	0.007
<i>Revision THA</i>	1 (0.9%)	0	0.631
<i>Deep joint infection</i>	0	0	1
<i>Dislocation</i>	2 (1.9%)	0	0.409
<i>DVT, PE</i>	0/0	0/0	1
<i>Heterotopic bone</i>	0	1 (1.7%)	0.359

<i>Ceramic fracture</i>	0	0	1
<i>Audible squeaking</i>	0	1 (1.7%)	0.359

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HHS: Harris Hip Score; ROM: range of motion; SD: standard deviation; THA: total hip arthroplasty; DVT: deep vein thrombosis; PE: pulmonary embolism.

Dislocation occurred in 2 joints (1.9%) in the 28-mm CoC group, and in no joints in the 32-mm CoC group (Table II). There was no significant difference in the incidence of dislocation between the 2 groups. All dislocations were successfully treated using non-operative, single, closed reductions. No recurrences were noted.

There were no ceramic fractures in the 2 groups. Audible squeaking was noted in 0 joints in the 28-mm CoC group and in 1 joint (1.7%) in the 32-mm CoC group. Revision THA was not required for audible squeaking, which was painless.

In the 28-mm group, 1 joint (0.9%) required revision THA for progressive femoral osteolysis, which may have been caused by metallosis secondary to femoral neck impingement on the elevated acetabular metal liner. We have

previously reported a similar phenomenon.<sup>15</sup> There was no revision THA in the 32-mm CoC group.

Kaplan-Meier survival at 10 years with implant loosening or revision THA as the endpoint was 98.3% (95% confidence interval [CI], 88.8-99.8) for 28-mm CoC, 100% for 32-mm CoC ( $p=0.465$ ).

### Radiographic results

There was no significant difference in the rate of osteolysis between the 2 groups (Table III). The osteolysis was focal and stable in all cases except for 1 joint wherein progressive femoral osteolysis necessitated revision THA. None of the joints in the 2 groups developed aseptic loosening.

The mean wear rate for the patients in the 28-mm CoC group was found to be 0.0044 mm on AP view radiographs, and 0.0046 mm on Lauenstein view radiographs. The mean wear rate for the patients in the 32-mm group was found to be 0.0044 mm on AP view radiographs, and 0.0049 mm on Lauenstein view radiographs. There was no difference in the wear rate between the 28- and 32-mm CoC groups (Table III).

**Table III.** Radiographic findings.

Parameters	28 mm (n=107)	32 mm (n=60)	P values
<i>Anteversion, mean± SD (°)</i>	14.7±5.1	15.9±6.1	0.142
<i>Inclination, mean± SD (°)</i>	45.6±5.4	44.8±5.6	0.551
<i>Osteolysis</i>			
Over all	4 (3.8%)	2 (3.3%)	0.625
Acetabular	3 (2.8%)	1 (1.7%)	0.542
Femoral	2 (1.9%)	1 (1.7%)	0.704
<i>Aseptic loosening</i>	0	0	1
<i>Wear rate (mm/year)</i>			
AP view	0.0044±0.0020	0.0044±0.0037	0.686
Lauenstein view	0.0046±0.0030	0.0049±0.0040	0.415

AP: anteroposterior.

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

Femoral head penetration could not be measured for 8 joints in the 28-mm group and 2 joints in the 32-mm group, because the margin of femoral head could not be identified clearly in these joints. The wear rate was measured for 99 joints in the 28-mm group and 58 joints in the 32-mm group.

## Discussion

Bio-inert CoC THA with greater wear resistance have been developed with the promise of reduced wear debris and extended implant longevity.<sup>3,7</sup>

However, CoC THA have their own inherent limitations, such as ceramic fracture and squeaking.<sup>1,16</sup> To the best of our knowledge, only small studies have investigated whether the ceramic head size affects clinical and radiographic results, such as ceramic fracture, squeaking, and wear rate.<sup>6,17</sup>

In particular, the only study to evaluate the correlation between ceramic head size and wear rate was a simulation study.<sup>7,8</sup> Thus, to the best of our knowledge, the current investigation is the first to evaluate the association between ceramic head size and clinical results, especially ceramic wear, in an in vivo clinical investigation.

Although it remains to be clinically proven, one theoretical advantage of using larger femoral heads in hip arthroplasty is increased ROM because of greater head to neck diameter ratio.<sup>18</sup> These studies suggest that a large femoral head can lead to greater ROM in comparison to a 28-mm heads THA.<sup>18</sup> In contrast, significant differences in hip ROM at 2 years after

surgery were not found when 32-mm THA was compared to 28-mm THA.<sup>19</sup> Additionally, femoral head >32 mm provided greater ROM and virtually complete elimination of component-to-component impingement.<sup>5</sup> Thus, femoral head size  $\geq$ 32 mm led to a significant decrease in the rate of hip dislocation compared with the 28-mm head.<sup>20,21</sup> In our study, the ROM for the 32-mm CoC group was greater than that of the 28-mm CoC group, resulting in a significantly superior HHS for the 32-mm CoC group. However, there was no significant difference in the rate of hip dislocation between the 2 groups.

There are few reports on the wear rate of ceramic bearings.<sup>2,3,22</sup> Previous studies have found a mean linear wear rate of 0.00183-0.0067 mm/year for CoC THA and a mean linear wear rate of 0.01-0.037 mm/year for MoP THA as observed on AP-view radiographs.<sup>2,3,7,16</sup>

In this study, the wear rate was 0.0044 mm/year for the 28-mm CoC group and 0.0044 mm/year for the 32-mm CoC group. The wear rate of both groups was low, with no significant difference between groups. Regardless of ceramic head diameter, the wear rate of the ceramic bearings was low.

The main problems related to CoC THA are ceramic fracture and squeaking.

The previously reported incidence of ceramic fracture after CoC THA varies between 0% and 2.0%, while those of squeaking ranged from 0% to 10.7%.<sup>3,4,23</sup>

Femoral neck impingement on the ceramic liner is a risk factor for ceramic fracture and squeaking.<sup>17,24</sup> It has been suggested that small femoral heads may be associated with ceramic fractures and squeaking secondary to impingement. However, 1 study found that the incidence of squeaking and ceramic fractures was not significantly higher with the 28-mm CoC.<sup>6</sup> Similarly, in our study, there were no significant differences in the incidence of audible squeaking and ceramic fractures in the 2 groups.

In our study, there was no evidence of the difference in the ceramic head diameter; rate of complications, including aseptic loosening of components and ceramic fracture and audible squeaking; also, wear rate or in the 10-year survival of the prosthesis. However, THA with the 32-mm CoC resulted in a greater ROM than with the 28-mm CoC. The National Joint Registry for Australia has reported that head size 28-mm CoC have a higher rate of revision due to dislocation compared to 32-mm CoC at 15 years after THA.<sup>25</sup> Finally, apart from the ROM, we demonstrated that THA with both

the 32-mm and the 28-mm CoC is similar in terms of safety and clinical outcomes.

This study has some limitations. 1st, this was a retrospective study, with a relatively small number of patients. However, power analysis conducted to determine the sample size for detecting the difference in HHS between the 2 groups identified the need for 60 samples in each group.

2nd, we measured femoral head penetration using the technique described by Dorr et al<sup>13</sup> along with the computer-digitiser facilities of the Roman V1.70 software. The validity of this method for measuring femoral head penetration following CoC THA has been previously reported.<sup>2,3</sup> This method, which is typically used to examine femoral head penetration following metal-on-polyethylene THA, is not easily applicable to CoC THA.<sup>3</sup>

In our study, we were unable to obtain measurements of femoral head penetration in 10 cases. Thus, the Ein Bild Roentgen Analyse (EBRA) software (University of Innsbruck) would have provided us with more reliable measurements for comparison.<sup>26</sup> 3rd, we did not evaluate the test-retest reliability of manual goniometers to measure passive ROM. In the literature, intra-observer reliability of the goniometer has proved to be excellent and similar to that of an electromagnetic tracking system.<sup>27</sup> 4th,

we used 2 titanium alloy femoral components with different stem neck designs. This difference may have affected the clinical and radiographic results. 5th, the incidence of ceramic liner malseating with the motion at the liner/shell interface after CoC with a metal-back titanium sleeve such as Trident PSL and TriAD has been reported.<sup>28</sup> We were unable to identify any relationship between wear rate and movement at the liner/shell interface, since we did not perform revision THA. However, in our previous study, we did not find any significant difference between the wear rate of the malseating and the adequate-seating CoC.<sup>28</sup>

## **Acknowledgements**

Dr Daigo Komatsu for technical support.

## **Declaration of conflicting interests**

The authors declare that there is no conflict of interest.

## **Funding**

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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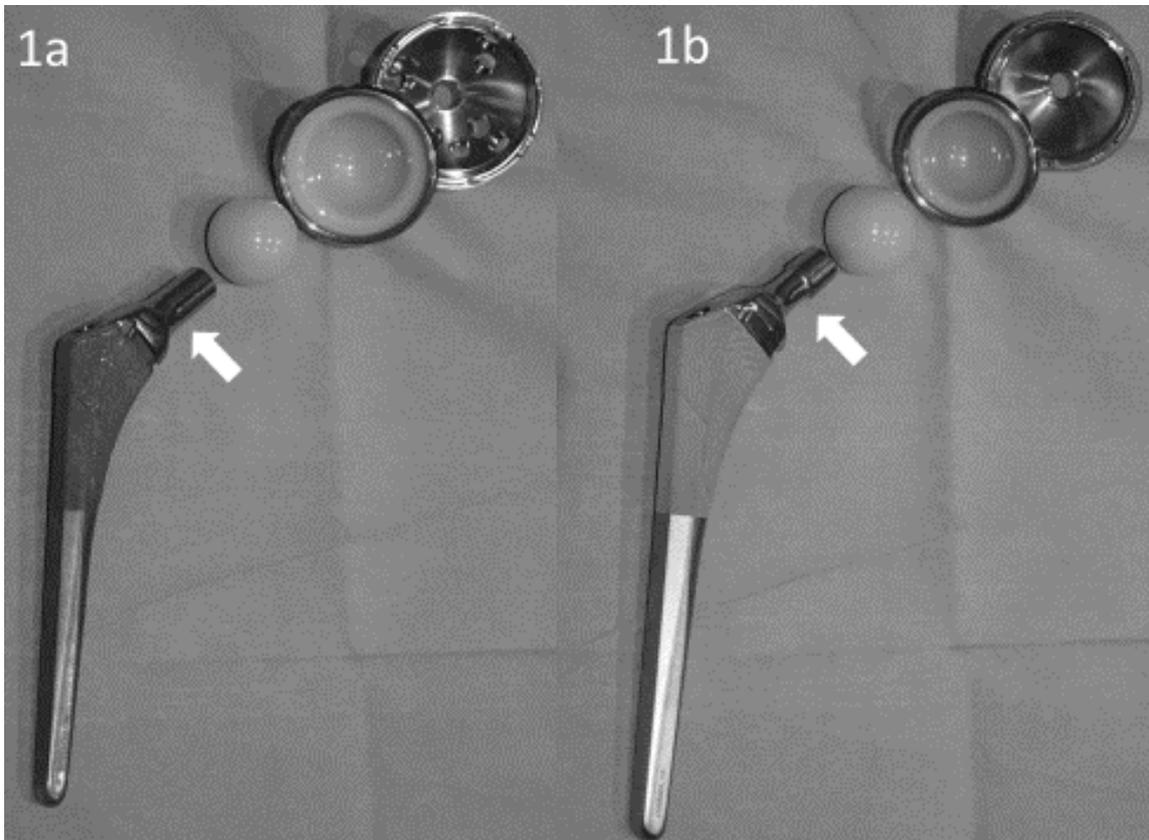
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1 Fig.1



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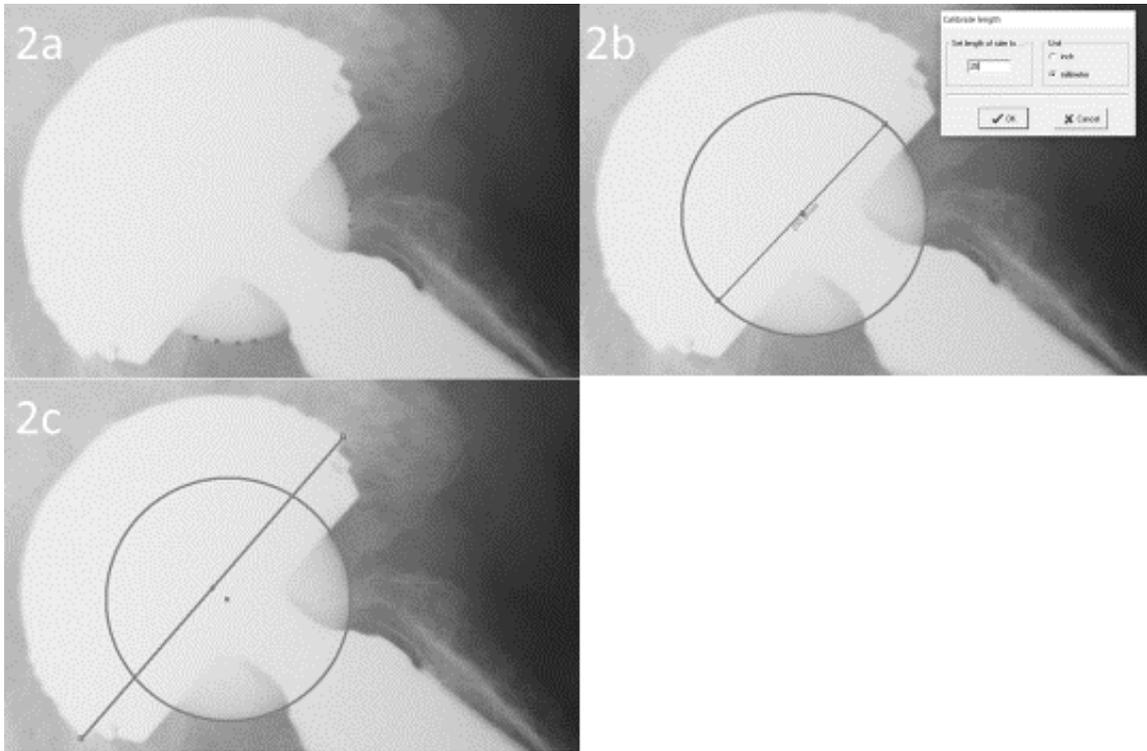
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12 **Fig.2**

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