Does increased diameter of metal femoral head associated with highly cross-linked polyethylene augment stress on the femoral stem and cortical hypertrophy?

Higher incidence of cortical hypertrophy with 36-mm than 32-mm femoral head in total hip arthroplasty with proximally coated cementless stem

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-Ethical Approval

This study was approved by the Inst. Ethical Review Board.

-Consent to Participate

All authors have participated in the research.

-Consent to Publish

All authors of this paper have read and approved the final version submitted.

-Authors Contributions

SI conceived the concept of this study. YH and SI designed the study. SI and YS obtained the data. SI wrote the initial draft. YH reviewed and edited the draft. SI and YH performed the statistical analysis. TB, KK, MI and YH ensured the accuracy of the data and analysis.

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-Competing Interests

We declare the authors have no conflict of interests.

-Availability of data and materials

Data available within the article or its supplementary materials.

Article title

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Abstract

Purpose

Cortical hypertrophy (CH) after total hip arthroplasty (THA) is thought as a process of femoral cortical functional adaptation against the stem. However, no study has been performed to investigate the association between CH and femoral head size. The purpose of this study is to investigate the factors related to femoral CH around the cementless stem after THA.

Methods

THAs in 31 patients using 36mm head and as a control, age matched 62 THAs with 32mm head has been analyzed. Radiographs were reviewed at 4 years to determine cortical thickness change from immediate postoperative one. Preoperative and immediate postoperative radiograph were used to calculate the femoral morphology, canal fill ratio, stem alignment, femoral and acetabular offset. Univariate and multivariate logistic regression analyses were performed to identify the risk factors for CH.

Results

Patients with a 36-mm head had a significantly higher rate of severe CH (P = 0.001) than those with a 32-mm head. The multivariate logistic regression analysis with dependent variables of CH showed that the use of a 36-mm femoral head had a significantly positive effect on CH. The odds ratio of a 36-mm femoral head in mild CH was 2.517 (95% confidence interval, 1.032–6.143; P = 0.043), and that in severe CH was 8.273 (95% confidence interval, 2.679–25.551; P = 0.000). Age and the Canal flare index were weakly and negatively influenced mild CH.

Conclusions

The use of a 36-mm head was the dominant risk factor for CH.

Key words: Total hip arthroplasty, cortical hypertrophy, cementless stem, large femoral head.

Introduction

Total hip arthroplasty (THA) using a cementless stem reduces pain and improves activities of daily living. The number of THA procedures increased by about six times from 2013 to 2018 in the United States [1,2]. Improvements in the materials and techniques used in THA have resulted in more THA procedures being performed in young and active patients, and the prevention of revision surgery has become an important issue. One of the major reasons for revision surgery is instability (17.4%), and aseptic loosening is a complication related to revision surgery (15.8%) [2].

Although dislocation is a major cause of revision surgery, a large-diameter femoral head is associated with a low dislocation rate because of its high jumping distance [3] and oscillation angle [4], and it is more commonly used in modern THA [2]. Wierd et al. [5] reported a low revision rate due to dislocation in cases with a large femoral head at 6 years (22–28 mm, 1.11%; 32 mm, 0.72%; 36 mm, 0.52%) using a Netherlands registry. However, the detrimental aspects of a large femoral head have not been clarified. In the above-mentioned study using the Netherlands registry, the authors also found higher revision rates for reasons other than dislocation in cases with a large than small femoral head (22–28 mm, 1.93%; 32 mm, 1.99%; 36 mm, 2.67%) [5]. Similarly, Georgios et al. reported no increase in the survival rate when using a 36-mm versus 32-mm head in their Nordic registry[6].

Aseptic loosening is also a major reason for revision surgery. Although longer survivorship due to the improved wear rate of polyethylene liners has been reported [7], further development is necessary to achieve better clinical results. In radiographic evaluations, various signs such as spot welds [8], reactive lines [9], and cortical hypertrophy (CH) [10] are used as surrogate markers to predict the longevity of cementless stems [11]. Although the influence of CH on clinical outcomes is still unclear, CH is a frequent radiographic phenomenon and is regarded as a detrimental sign. Several factors are associated with the occurrence of CH [12]. Distal femoral CH is reportedly more frequent in patients with distal filling of a uncemented proximally coated stem and could be a risk factor for aseptic loosening [12]. Another study indicated that patients with a higher canal flare index (CFI) and younger age had a higher incidence of CH [13].

Although the above-mentioned studies suggest that CH is related to a process of femoral cortical functional adaptation against the stem [14], no study has been performed to investigate the association between CH and femoral head size. This prompted us to question 1) whether the femoral head size influences the occurrence of CH and 2) which factors (patients' basic background factors, femoral morphology, canal fill rate, and femoral head size) have the greatest influence on CH. The present study was therefore performed to investigate the factors related to femoral CH around the cementless stem after THA.

Patients and Methods

Patients

After obtaining institutional review board approval, we retrospectively reviewed the medical records of all patients who had undergone THA at our university hospital from January 2010 to December 2015. In total, 597 THA procedures were performed in 522 patients during that period. Of the 597 hips, a titanium alloy (Ti-12Mo-6Zr-2Fe) femoral stem (Accolade TMZF, 127° neck angle; Stryker Corporation, Kalamazoo, MI, USA) and a cobalt/chromium femoral head (LFIT V40; Stryker Corporation) were used in 212 THAs in 183 patients. The exclusion criteria were THA for femoral neck fracture, early revision surgery, early death, ankylosing spondylitis, and no radiographic follow-up at 4 years ± 1 years after the surgery. After application of the exclusion criteria, 31 THAs in 31 patients using a 36-mm head (LFIT V40; Stryker Corporation) were included in this analysis, and 62 THAs in 62 patients using a 32-mm head were analyzed as age-matched controls (Fig. 1).

The implanted acetabular component was a Trident PSL (peripheral self-locking) Shell (Stryker Corporation). The bearing surface was highly cross-linked polyethylene in all patients.

Operative procedure

All surgeries were performed by a group of three to five orthopedists specializing in hip joint arthroplasty. The direct anterior approach or posterior approach was used in all cases.

Radiographic evaluation

Radiographic evaluation was performed using an anteroposterior radiograph in the supine position with both legs internally rotated 10°.

Femoral CH was assessed using an immediate postoperative radiograph and a radiograph at 4 ± 1 years after the surgery (mean, 4.1 years; range, 3.8–4.9 years).

The distance from the lateral corner of the stem to the tip was divided into three equal areas (Fig. 2). Each cortical area was defined as follows: the lateral cortex of the central one-third was defined as Zone A, the lateral cortex of the distal one-third was defined as

Zone B, the medial cortex of the distal one-third was defined as Zone C, and the medial cortex of the central one-third was defined as Zone D. In each of these areas, we measured the points at which the cortical thickness perpendicular to the femoral axis changed the most (Fig. 2). The CH value was calculated as follows: [(postoperative cortical thickness at 4 years postoperatively − immediate postoperative cortical thickness) / immediate postoperative cortical thickness] × 100. A CH value from 1.0 to 1.9 was defined as the 10% CH group (10% increase in cortical thickness), and a CH value of ≥2.0 was defined as the 20% CH group (20% increase in cortical thickness).

Preoperative radiographs were used to analyze the proximal femoral geometry using previously described radiographic parameters, including the morphologic cortical index, canal-calcar ratio, and CFI using the method described by Yeung et al. [15].

Immediate postoperative radiographs were used to assess stem alignment, acetabular offset, femoral offset, and the canal fill ratio of the stem (CFR). The CFR was defined as the width of the stem divided by the width of the canal at four points: at the lesser trochanter and 2 cm above, 2 cm below, and 7 cm below the lesser trochanter.

All measurements were conducted using a computerized picture archiving and communication system (SYNAPSE; Fujifilm, Tokyo, Japan). The measurements were performed by two authors (S.I. and Y.S.). The intraclass correlation coefficient (interobserver reliability) of CH was 0.86, which was interpreted as good [16]. The CH value was analyzed using the averaged data between the two observers.

Statistical analysis

The patients' baseline characteristics are expressed as mean ± standard deviation. The independent-samples Student's t test or the Mann–Whitney test was used for continuous variables, and the chi-squared test was used for dichotomous variables. A P value of <0.05 was considered statistically significant, and all tests were two-sided. Data were statistically analyzed using IBM SPSS Statistics for Macintosh, Version 22.0 (IBM Corp., Armonk, NY, USA).

Univariate and multivariate logistic regression analyses were performed to identify the risk factors for CH. Before conducting the multivariate analysis, we assessed the relationships between the variables by Spearman's rank correlation coefficient to prevent the effects of confounders. A P value of <0.05 was considered statistically significant, and all tests were two-sided.

Results

There were no significant differences in the patients' basic characteristic, femoral morphology, postoperative offset, stem alignment, CFR, or proximal–distal matching ratio between the 32-mm head group and the 36-mm head group (Table 1).

The area in which CH was most frequently observed was Zone A (Fig. 3). There was no significant difference in the frequency of CH in each area between the two groups.

The mean CH value was significantly higher with the 36-mm than 32-mm head (22.0 ± 22.5 vs. 12.0 ± 19.0, respectively; P = 0.027) (Table 2). Patients with a 36-mm head had a significantly higher rate of 10% CH (P = 0.04) and 20% CH (P = 0.001) than those with a 32-mm head (Table. 2).

The univariate analysis results are shown in Table 3. In patients with 10% CH, the use of a 36-mm femoral head was significantly more frequent than the use of a 32-mm head (P = 0.04); the other factors were not significantly different. In patients with 20% CH, age, the use of a 36-mm femoral head, the CFR at 2 cm below the lesser trochanter, and the proximal–distal matching ratio (P3/D1) were significantly different between the groups.

The multivariate logistic regression analysis with dependent variables of 10% and 20% CH and independent variables of age, height, weight, sex, head diameter (32 or 36 mm), CFI, CFR at 2 cm below the lesser trochanter (P3), and proximal–distal matching ratio (P3/D1) showed that the use of a 36-mm femoral head had a significantly positive effect on 10% and 20% CH. The odds ratio of a 36-mm femoral head in 10% CH was 2.517 (95% confidence interval, 1.032–6.143; P = 0.043), and that in 20% CH was 8.273 (95% confidence interval, 2.679–25.551; P = 0.000). Age and the CFI weakly and negatively influenced 10% CH.

Discussion

We retrospectively investigated the relationship between the femoral head size and CH around the cementless stem after THA. The use of a 36-mm head was a major risk factor for CH, and the present study is the first investigation to reveal this relationship. This distinctive bone remodeling pattern associated with a 36-mm head might be caused by the high frictional torque of a large femoral head, and this abnormal stress might be a potential risk factor for aseptic loosening of the cup and stem. A large-diameter head should be selected after considering both the benefits of dislocation resistance and the risks including the CH.

Although the exact mechanism underlying the higher incidence of CH when using the 36-mm than 32-mm head was not determined in this study, we presume the following explanations. First, high frictional torque of the 36-mm head on the sliding surface is transmitted to the distal end of the stem, generating higher mechanical stress at the inner surface of the medullary cavity. Scholl et al. [17] showed that torque increases as the diameter of the head increases. The authors reported a 1.5 times higher frictional torque with a 44-mm head than with a 28-mm metal and ceramic head. Second, the use of highly cross-linked polyethylene in this series contributed to the higher incidence of CH in the 36-mm group. Burroughs et al. [18] performed an in vitro study showing that highly cross-linked polyethylene has higher frictional torque than conventional polyethylene, and this difference increases with a larger head diameter.

Age and the CFI were also risk factors for CH, although they were weaker risk factors than the head diameter. The higher mechanical stress in young, active patients than in older patients can explain the higher CH in young patients. Bone morphologic parameters such as the CFI might also influence optimal or suboptimal load transmission in proximally coated cemented stems.

Past investigations have shown that CH is caused by distal load transmission of proximally coated stems. We observed a high incidence of CH in patients with a high CFR in the distal femur and a low CFR in the proximal femur [12] [13]. This proximal–distal mismatch of proximally coated stem can be considered suboptimal stem fixation, and patients who develop CH with proximally coated stems must be carefully followed up.

We believe that CH as a surrogate marker for stem implant survivorship should not be considered a good sign. CH is understood to be a result of "bone functional adaptation" in Wolff's law, reflecting the changes in the mechanical environment induced by THA. Abnormal load generation by the large head and suboptimal load transmission accelerated by higher activity levels in young patients, both of which produce an abnormal mechanical environment, contribute to the development of CH. Ritter and Fechtman [10] stated that CH was a result of an abnormal stress distribution in the stem, and this nonoptimal bone remodeling has also been observed in association with proximal bone atrophy [19]. Although some researchers have reported that CH is not related to pain [20], other reports have described CH due to pathways similar to those involved in stress fractures [21] [22].

In our opinion, a large-diameter head should be selected after considering the benefits of dislocation resistance and the risk of complications. Large femoral heads became more popular after highly cross-linked polyethylene became available [23 75]. An in vitro study showed that the friction wear rate of large heads was the same as that of small heads when highly cross-linked polyethylene was used [24]. Since then, the use of large heads has increased in the 21st century; in 2018, almost 70% of cementless THAs in the United States were performed with a ≥36-mm head (AAOS). One randomized controlled study revealed low dislocation rates of large heads (28-mm head, 0.8; 36-mm head, 4.4) [23], and a Nordic registry study showed a lower dislocation risk with 36-mm than 32-mm heads [6].

However, we suspect that the torque force generated by large heads, such as 36-mm heads, would increase the incidence of unexpected events after THA because our study revealed that the 36-mm femoral head was leading factor contributing to the development of CH. A Dutch arthroplasty registry study revealed that large heads were associated with higher revision rates (with the exception of dislocation) than were small heads [5]. Tsikandylakis et al. [6] reported a higher rate of cup loosening in associated with 36-mm than 32-mm heads (hazard ratio, 2.29; 95% confidence interval, 1.79–2.92; $P < 0.001$) using a Nordic registry. Moreover, historically, Sir Charnley originally used a 41.5-mm large-diameter head and reported a high rate of acetabular loosening with rapid wear. He changed his concept to “low-friction arthroplasty” using a 22.2-mm femoral head and reported an 89% survival rate of the acetabular component at 20 years [25].

This investigation has several limitations. First, the patients’ activity levels were not investigated in this study. However, because there were no differences in the preoperative age or diagnoses between the 32-mm and 36-mm groups, the difference in the patients’ activity levels was likely very small; therefore, this bias is expected to have a minimal impact on our results. Second, our series included a small number of 36-mm heads because this was a relatively small-sample comparative investigation. However, we found statistically significant differences in the factors associated with CH, and we stopped using the 36-mm heads because we experienced early complications such as cup loosening. Third, because multiple diseases were included in this study, the patients’ biological backgrounds might have influenced the development of postoperative CH. However, because there were no significant differences in the preoperative diseases between the two groups, the effect of this limitation is likely very small.

Conclusion

The use of a 36-mm head was the dominant risk factor for CH. This is the first in vivo study to suggest that the higher frictional torque of a large head might influence the distal end of the stem, leading to CH. Selection of the femoral head diameter should be performed only after sufficient consideration of the benefits and risks, including CH.

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Authors’ contributions: SI conceived the concept of this study. YH and SI designed the study. SI and YS obtained the data. SI wrote the initial draft. YH reviewed and edited the draft. SI and YH performed the statistical analysis. TB, KK, MI and YH ensured the accuracy of the data and analysis.

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Legends for figures and tables

Fig 1. Patients selection Study flow chart.

Fig 2. Evaluation for the cortical hypertrophy using four zones. The distance from the lateral corner of the stem to the tip was divided into three equal areas.

Fig 3. Results of cortical hypertrophy at four zone in 10% (mild) and 20% (severe) cortical hypertrophy.

Table 1. Patient characteristics in 32- and 36-mm femoral head.

Table 2. The cortical hypertrophy value and incidence of 10% (mild) and 20% (severe) cortical hypertrophy in 32- and 36-mm femoral head.

Table 3. The results of univariate analysis.

Table 4. The results of multivariate analysis.

Fig. 1

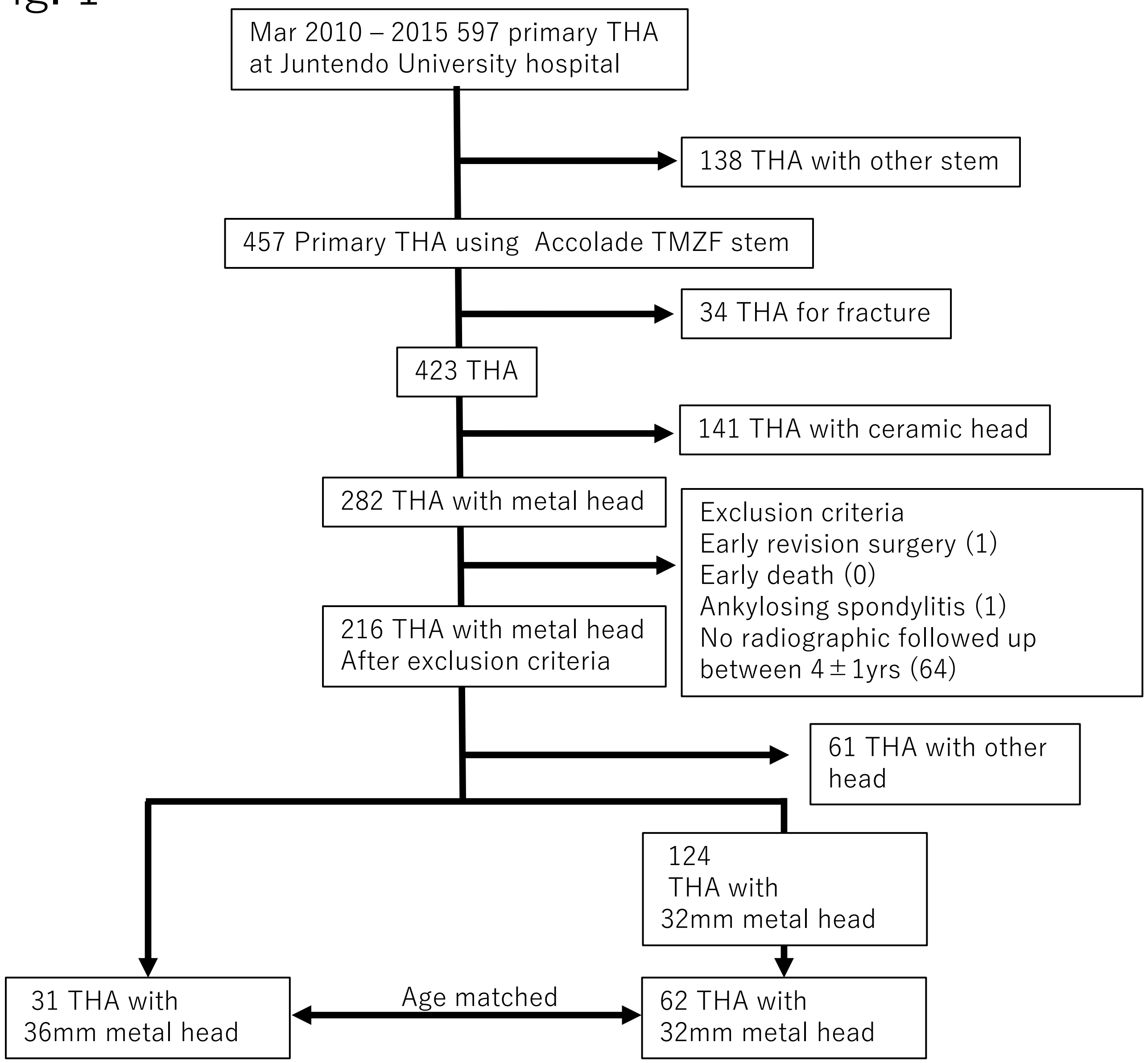
Mar 2010 – 2015 597 primary THA
at Juntendo University hospital
138 THA with other stem
457 Primary THA using Accolade TMZF stem
34 THA for fracture
423 THA
141 THA with ceramic head
282 THA with metal head
Exclusion criteria
Early revision surgery (1)
Early death (0)
Ankylosing spondylitis (1)
No radiographic followed up
between 4±1yrs (64)
216 THA with metal head
After exclusion criteria
61 THA with other head
124
THA with
32mm metal head
31 THA with
36mm metal head
Age matched
62 THA with
32mm metal head

Fig. 2

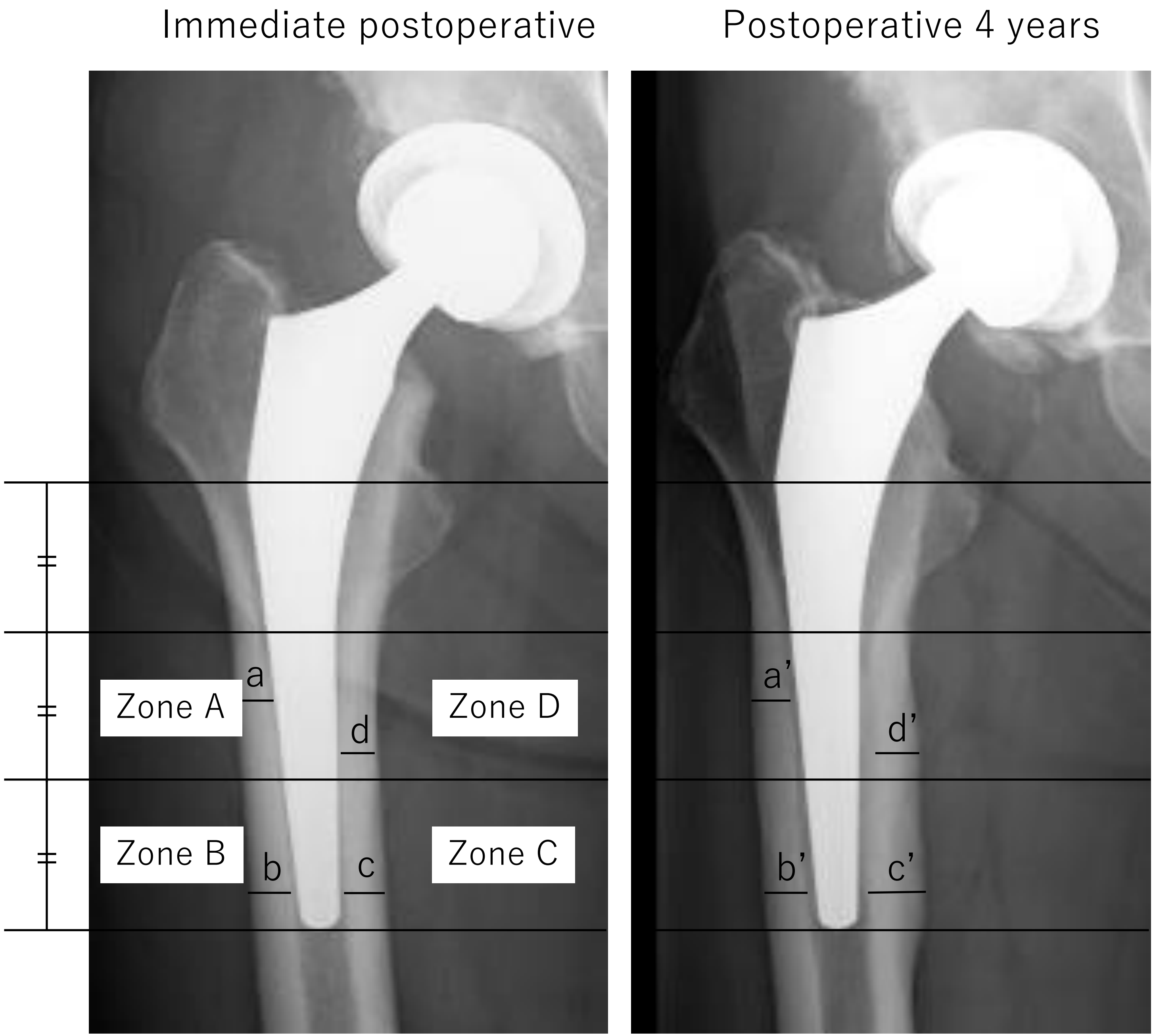
Immediate postoperative
Postoperative 4 years
Zone A
Zone B
Zone C
Zone D
a
b
c
d
a’
b’
c’
d’

Fig. 3

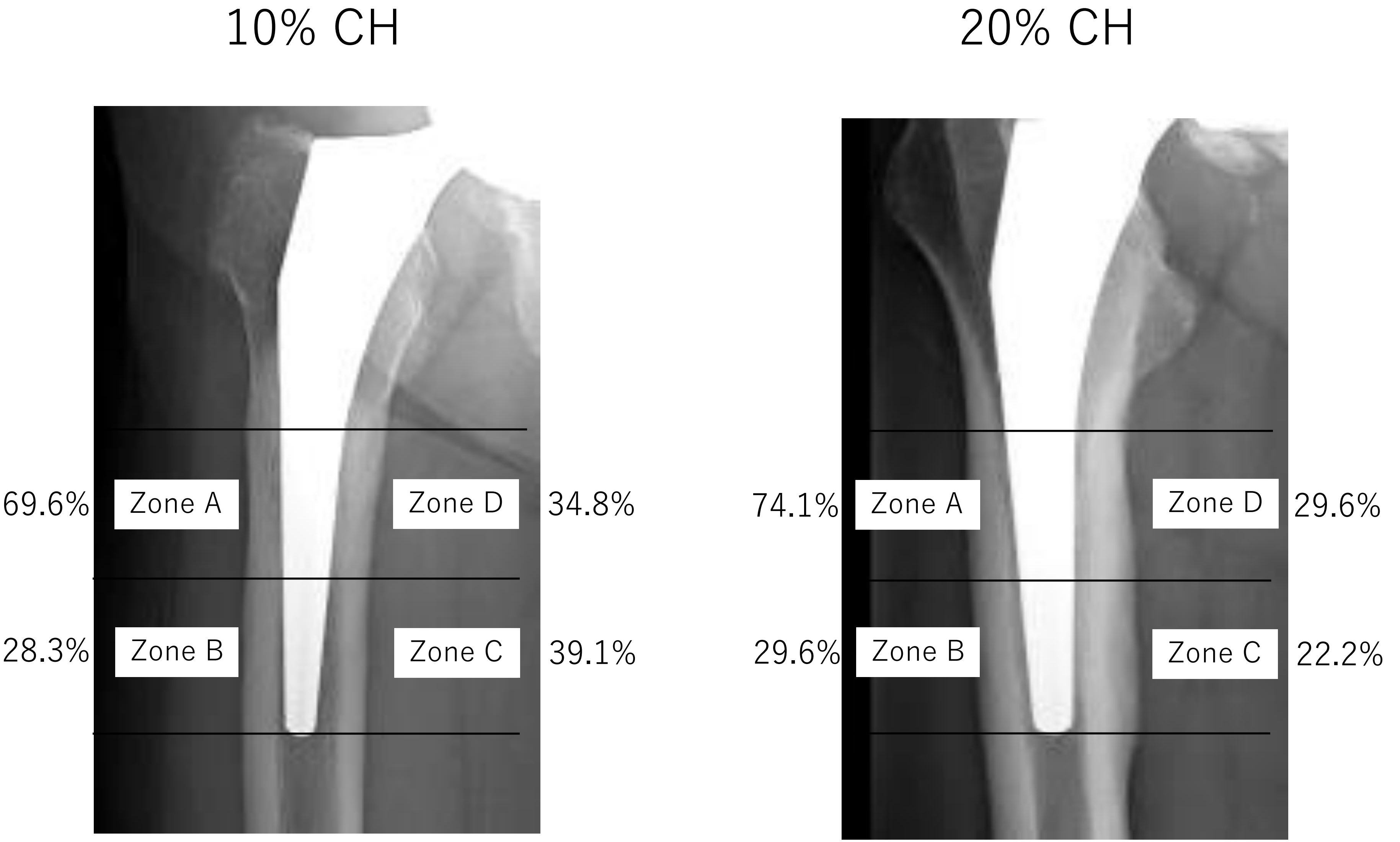
10% CH
Zone A
69.6%
Zone D
34.8%
Zone B
28.3%
Zone C
39.1%
20% CH
Zone A
74.1%
Zone D
29.6%
Zone B
29.6%
Zone C
22.2%

Table 1

	32mm	36mm	p value
	n=62	n=31	
Basic charactaristic			
Age (years)	66.1 ± 11.9	67.5 ± 11.8	0.609
Height (cm)	155.0 ± 8.6	154.7 ± 8.5	0.879
Weight (kg)	57.8 ± 12.3	58.2 ± 12.6	0.884
Sex (male / male + female) (%)	24.2	22.6	0.863
Etiology (OA / OA + ON) (%)	91.9	83.9	0.237
Approach (DAA / DAA + PA) (%)	62.9	51.6	0.296
Periods (Month)	49.5 ± 2.1	49.5 ± 2.1	0.978
Femur morphology (%)			
Morphologic cortical index	2.78 ± 0.39	2.9 ± 0.29	0.125
Canal-calcar ratio	0.48 ± 0.84	0.46 ± 0.79	0.291
Canal flare index	3.47 ± 0.69	3.63 ± 0.58	0.265
Postoperatie offset (mm)			
Femoral offset	40.8 ± 5.7	41.5 ± 5.09	0.52
Acetabular offset	32.7. ± 4.6	33.8 ± 4.8	0.27
Total offset	73.4 ± 7.7	75.4 ± 7.3	0.26
ΔFO	6.63 ± 7.28	8.8 ± 8.59	0.21
ΔAO	-7.23 ± 5.72	-8.28 ± 7.14	0.44
ΔTO	-0.6 ± 7.64	0.52 ± 7.5	0.50
Stem malalignment			
Varus>3 (%)	8.0	0	0.1
Valgus>3 (%)	4.8	3.2	0.72
Canal fill ratio (%)			
At 2cm above the LT (P1)	1.53 ± 0.22	1.53 ± 0.14	0.9
At the LT (P2)	1.18 ± 0.13	1.2 ± 0.14	0.44
AT 2cm below the LT (P3)	1.18 ± 0.12	1.21 ± 0.15	0.2
AT 7cm below the LT (D1)	1.17 ± 0.13	1.19 ± 0.16	0.68
Proximal-distal matching ratio (%)			
P1/D1	1.32 ± 0.24	1.31 ± 0.2	0.93
P2/D1	1.01 ± 0.15	1.03 ± 0.16	0.75
P3/D1	1.01 ± 0.11	1.03 ± 0.14	0.37

BMI, body mass index; OA, osteoarthritis; ON, osteonecrosis; LT, lesser trochanter; DAA, direct anterior approach; PA, posterior approach

Table 2

	32mm (n=62)	36mm (n=31)	p value
Mean ± SD	12.0 ± 19.1	22.0 ± 22.5	0.027
Incidence of CH (%)			
10% CH	41.9	64.5	0.040
20% CH	17.7	51.6	0.010

CH, cortical hypertrophy; SD, standard deviation.
CH value = [(postoperative cortical thickness at 4 years postoperatively − immediate postoperative cortical thickness) / immediate postoperative cortical thickness] × 100.

Table 3

	10% CH			20%CH		
	(+)	(-)		(+)	(-)	
	n=46	n=47	*P*	n=27	n=66	*P*
Basic charactaristic						
Age (years)	64.9 ± 11.0	68.2 ± 12.4	0.173	62.6 ± 11.0	68.2 ± 11.8	0.036
Height (cm)	155.7 ± 8.9	154.1 ± 8.0	0.356	157.0 ± 10.1	154.1 ± 7.7	0.138
Weight (kg)	58.4 ± 11.4	57.6 ± 13.3	0.760	60.2 ± 13.0	57.1 ± 12.0	0.274
Sex (male / male + female) (%)	21.7	25.5	0.667	29.6	21.2	0.386
Etiology (OA / OA + ON) (%)	87.0	91.5	0.480	92.6	87.9	0.505
Approach(DAA / DAA + PA) (%)	54.3	63.8	0.352	55.6	60.6	0.653
Head diameter (36mm / 32mm + 36mm) (%)	43.5	23.4	0.040	59.3	22.7	0.001
Femur morphology (%)						
Morphologic cortical index	2.85 ± 0.37	2.8 ± 0.36	0.505	2.82 ± 0.31	2.82 ± 0.38	0.995
Canal-calcar ratio	0.48 ± 0.08	0.47 ± 0.08	0.941	0.48 ± 0.09	0.47 ± 0.08	0.697
Canal flare index	3.46 ± 0.65	3.58 ± 0.65	0.389	3.40 ± 0.54	3.57 ± 0.69	0.260
Post-operative offset (mm)						
Femoral offset	40.7 ± 5.3	41.3 ± 5.7	0.576	41.3 ± 5.4	40.9 ± 5.5	0.694
Acetabular offset	33.5 ± 4.8	32.6 ± 4.6	0.383	33.2 ± 5	33 ± 4.6	0.876
Total offset	74.2 ± 7.3	74.0 ± 8.0	0.895	74.5 ± 7.4	73.9 ± 7.7	0.704
ΔFO	7.38 ± 9.84	7.32 ± 5.71	0.969	8.35 ± 10.3	6.94 ± 6.5	0.429
ΔAO	-7.47 ± 6.12	-7.69 ± 6.36	0.866	-8.43 ± 7.02	-7.23 ± 5.87	0.398
ΔTO	-0.09 ± 8.07	-0.37 ± 7.13	0.858	-0.85 ± 8.36	-0.29 ± 7.29	0.907
Stem malalignment						
Varus>3 (%)	4.35	6.38	0.664	3.70	6.06	0.647
Valgus>3 (%)	4.35	4.26	0.982	7.40	3.03	0.345
Canal fill ratio (%)						
At 2cm above the LT (P1)	1.51 ± 0.22	1.54 ± 0.16	0.330	1.51 ± 0.15	1.53 ± 0.21	0.483
At the LT (P2)	1.19 ± 0.13	1.18 ± 0.14	0.869	1.19 ± 0.14	1.18 ± 0.14	0.659
AT 2cm below the LT (P3)	1.21 ± 0.14	1.17 ± 0.12	0.108	1.24 ± 0.16	1.17 ± 0.13	0.014
0 AT 7cm below the LT (D1)	1.17 ± 0.15	1.18 ± 0.14	0.729	1.18 ± 0.17	1.18 ± 0.13	0.927
Proximal-distal matching ratio (%)						
P1/D1	1.31 ± 0.25	1.33 ± 0.21	0.659	1.30 ± 0.21	1.32 ± 0.23	0.688
P2/D1	1.03 ± 0.15	1.01 ± 0.16	0.664	1.03 ± 0.15	1.01 ± 0.16	0.739
P3/D1	1.04 ± 0.12	1.00 ± 0.12	0.076	1.06 ± 0.13	1.00 ± 0.12	0.031

BMI, body mass index; OA, osteoarthritis; ON, osteonecrosis; LT, lesser trochanter; DAA, direct anterior approach; PA, posterior approach

Table 4

	10% CH (+)		20% CH (+)	
	OR (95% CI)	*P*	OR (95% CI)	*P*
Age	——	——	0.937 (0.896 – 0.980)	0.005
Height	——	——	——	——
Weight	——	——	——	——
Sex (male : female)	——	——	——	——
Head diameter (36mm : 32mm)	2.517 (1.032 – 6.143)	0.043	8.273 (2.679 – 25.551)	0.000
Canal flare index	——	——	0.371 (0.157 – 0.877)	0.024
CFR at 2cm below the LT (P3)	——	——	——	——
P3/D1	——	——	——	——

CH, cortical hypertrophy; LT, lesser trochanter; CFR, canal fill ratio; OR, odds ratio; CI, confidence interval