

CLINICAL ARTICLE

Comparison of Femoral Bone Mineral Density Changes around 3 Common Designs of Cementless Stems after Total Hip Arthroplasty—A Retrospective Cohort Study

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Objective: The aim of this study was to compare the periprosthetic BMD changes around Tri-Lock “Bone Preserving Stem” with the other two common and longer stems (Corail and Summit) after THA.

Methods: It was a retrospective cohort study followed patients underwent the total hip arthroplasty from January 2013 to December 2015. They were selected and followed from January 2013 to January 2020. Patients without osteoporosis underwent hip replacements with three aimed stems were included. Among the 138 patients included, 49 patients received the Tri-Lock stem, 44 patients received the Corail stem, and 45 patients received the Summit stem. The periprosthetic BMD changes evaluated by the Dual energy X-ray absorptiometry (iDXA) measurement according to the seven Gruen zones was the primary outcome. The Radiographic changes including spot welds, pedestal sign and grade of stress shielding was evaluated by the consecutive hip images. Einzel-Bild-Roentgen-Analyse-femoral component analysis (EBRA-FCA) was used to measure the stem migration at 5 years postoperatively. Patient-reported outcomes (PROMs) and adverse events were assessed and compared in three groups. Finally, the subgroups for the periprosthetic BMD changes, radiological and clinical outcomes were made based on the age, gender and length of follow-up.

Results: A total of 138 patients were retrospectively followed for an average of 4.66 years. Excepting the different stems used in three groups, the age, gender and other characteristics of patients included were similar between groups. There was no significant difference between the three groups in periprosthetic BMD changes over postoperative 5 years. The Summit stem shown more BMD loss in Gruen zone 1 compared with the Tri-Lock and Corail stems without significant difference (7.49%, -1.89% and -2.62%, respectively, $P = 0.42$). And the most prominent BMD loss was found in Gruen zone 7 for all three stems (-12.60%, -11.84%, and -9.56%, respectively, $P = 0.91$). The spot weld was significantly more common around the Corail stem, while there was no difference in the stem migration between three groups. Patient reported outcomes (PROMs) were significantly improved compared with the preoperative values. Regarding the rate of postoperative complications, two patients underwent the dislocation and 25 patients sometimes felt mild to moderate thigh pain. Subgroup analysis showed that female patients older than 50 years lost more BMD and had lower clinical scores, while the stem stability was not good enough in male patients.

Conclusions: The Tri-Lock Bone Preserving Stem did not show significant difference in periprosthetic BMD changes compared with the other two conventional longer stems at 5 years after THA.

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Introduction

Periprosthetic bone mineral density loss secondary to the stress shielding was common after total hip arthroplasties and believed to be associated with thigh pain, prosthesis loosening, periprosthetic femur fracture, and revision¹. Stress shielding following the insertion of a cementless stem can be attributed to mechanical^{2,3} and biological factors^{4,5} in response to the new biomechanical situation. The characteristics of prosthesis including the geometry, length, material, coating and so on were key factors influence the degree of stress shielding. There are many types of hip prosthesis available in the market and each with different load-sharing philosophies⁶, but none of the prostheses could completely prevent stress shielding after total hip arthroplasty. Katozian *et al*⁷. analyzed the ideal prosthesis close to the physiological state from the pure mechanical point of view. The results showed that the shape of the prosthesis was irregular due to the individual differences and the complexity of the loading conditions *in vivo*, which could not be further applied in clinical practice. It is necessary to determine how the different factors of stems influenced the stress shielding and improve them. Proximal load transfer of the short stem was considered one major advantage compared to conventional stems, which typically produce clinically relevant stress shielding. Therefore, to decrease the periprosthetic bone loss after THA, several kinds of short, and even ultra-short stems were adopted, such as the Tri-Lock Bone Preserving Stem.

The shorter stemmed “Tri-Lock Bone Preserving Stem,” with the possible advantages of lower bone loss^{8–10}, suitability for smaller incision, and theoretically convenient for the revision, has become ever more popular. In theory, this short stem should be expected to improve proximal load transfer and decrease the degree of stress shielding for loading the proximal femur in a more physiological way^{11,12}. However, in a 2 years RCT, Slullitel *et al*¹³. reported that Tri-Lock stem (prostheses intended to preserve proximal femoral bone) does not necessarily perform better in this regard than conventional cementless designs (Corail stem) by the DXA-RFA analysis. To interpret this conclusion with caution, we found the length of stem was not the only difference between two stems, though both of them are tapered wedges made from the same titanium alloy. The type of surface coating and canal preparation technique of them were different. Therefore, we added a new group of Summit (Depuy Orthopedics, Inc., Warsaw, IN, USA) stem to compare with the Tri-Lock stem, which has similar coating and the same canal preparation technique with the Tri-Lock stem. Therefore, this was the first study comparing the periprosthetic bone mineral density changes between Tri-Lock Bone Preserving Stem with the other two cementless longer stems. This made the comparison more comprehensive and objective, that more key factors affected the periprosthetic BMD loss could be found and reducing the bias of comparison.

Investigations of load transfer after femoral stem implantation have generally been performed using dual-energy X-ray absorptiometry (DEXA) measurements. It was widely used and considered an effective way to evaluate the small changes in BMD around femoral implants over postoperative follow-up^{14–17}. And the evaluation of radiographical changes to determine the degree of stress shielding according to the Engh standard¹⁸ was also helpful.

Therefore, three groups of patients using different types of stems in the THA operation were retrospectively studied in this clinical research. The main aim of this study was to compare the periprosthetic bone mineral density changes between the three stems. The periprosthetic bone integration and stem migration based on imaging evaluation, postoperative functional recovery were the secondary aims of this study.

Methods

This retrospective cohort study has been reviewed and approved by the Institutional Review Board of the authors’ affiliated institutions (2012. Number (268)) and all subjects provided informed consent.

Patient Selection

The size of the sample was calculated by considering the average loss of BMD reported in previous studies in the seven zones of Gruen by power analysis^{4,7–10}. The results showed that detection of a 5% difference in BMD changes at the 5% significance level would require 40 patients in each group of this retrospective study.

Inclusion criteria: (i) patients underwent the total hip arthroplasty between January 2013 to January 2015; (ii) Tri-Lock, Corail and Summit stems were used during THA; (iii) periprosthetic BMD was measured by the DEXA after operation. Exclusion criteria: (i) patients diagnosed with osteoporosis; (ii) patients who took any medicines influencing bone metabolism; and (iii) other joint pathology of the lower extremities.

As shown in Fig. 1, 214 replacements with the Tri-Lock bone preserving stem (BPS) completed from January 2013 to December 2015 were reviewed. After excluding osteoporosis or metabolic bone diseases before the operation (110 cases), taking any bone-modulating drugs (42 cases), any other joint pathology of the lower extremities (including the contralateral hip; 12 cases), and one patient died from lung cancer, only 49 patients were included. The other two groups were matched 1:1:1 with the Tri-Lock group according to the similar age, BMI, preoperative BMD, diagnosis and femoral morphology. Nine patients were unable to go to the hospital for DEXA measurement and radiographical examination due to traffic inconvenience and lost follow-up. Therefore, these nine patients were followed through telephone inquiry, and no adverse event was found,

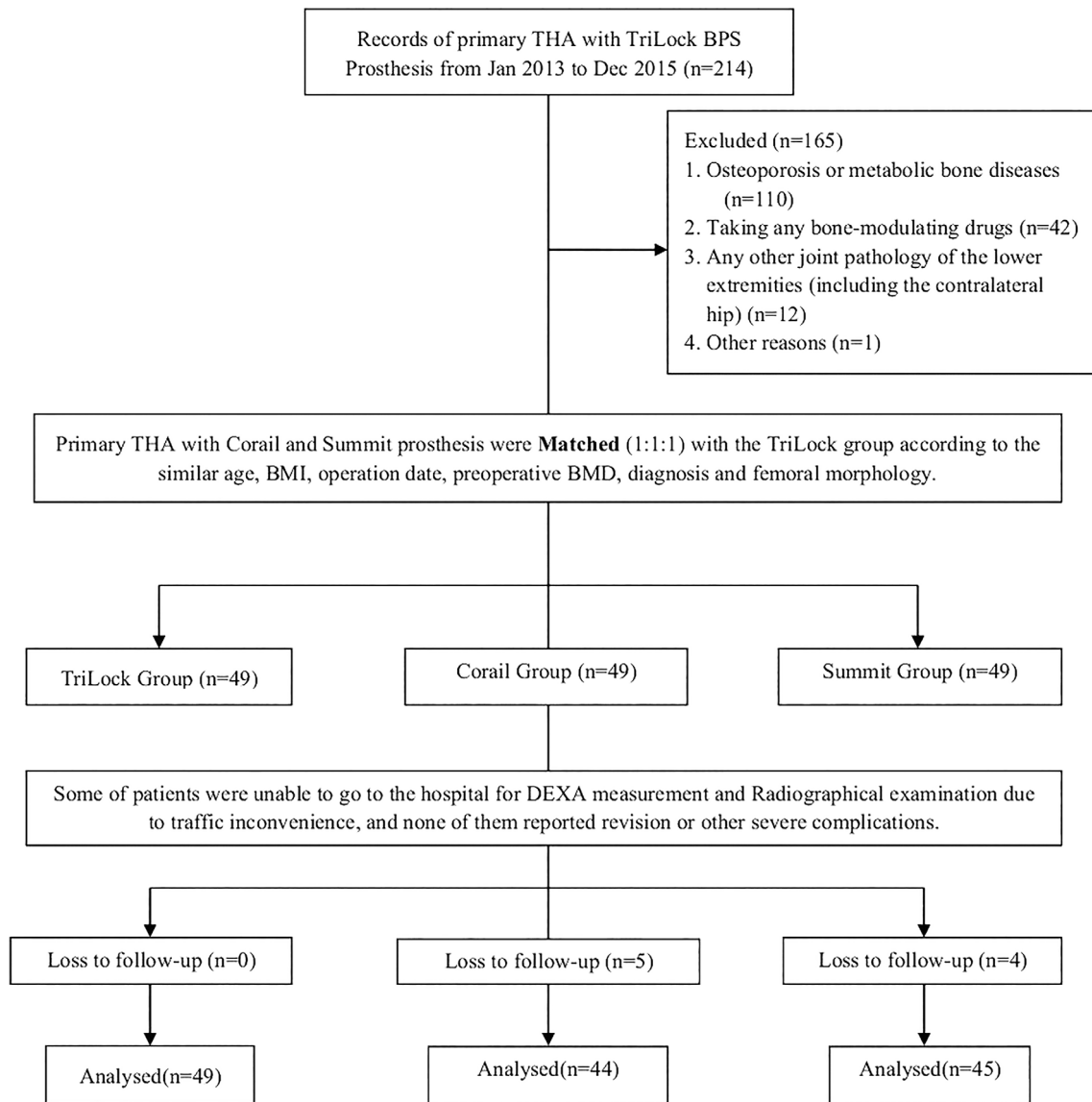


Fig. 1 Flow chart of patients included in this study

great functional recovery was reported. Finally, a total of 138 patients with 173 hips were included and followed up for an average of 4.66 years. As shown in Table 1, 49 patients with 63 hips received the Tri-Lock BPS stem, 44 patients with 52 hips received the Corail stem, and 45 patients with 58 hips received the Summit stem.

Prosthesis Design

The morphology and characters of three included stems were shown in Fig. 2 and Table 2.

All three stems were composed of the Ti 6Al-4V alloy. The length of Tri-Lock BPS was relatively shorter. The extent and material of coating was different. The Tri-Lock BPS (Depuy, Eagan, MN, USA) was a short tapered-wedge stem with GRIPTION microporous coating. Its

design features include a highly polished surface design at the distal end of the stem, distal flutes and a minimal lateral shoulder¹⁹. The collarless Corail[®] prosthesis (DePuy Synthes, Raynham, MA, USA) is wedge-shaped with a thin distal end, its textured surface is fully covered by a 150-micron hydroxyapatite (HA) coating. The proximal third of the Summit (Depuy Orthopedics, Inc., Warsaw, In, USA) stem coated with a POROCOAT[®] Porous Coating that favors bone ingrowth²⁰. Radial ZTT steps was designed to eliminate hoop stress by directing radial force into compression.

Surgery Technique

All replacements were performed by two senior surgeons (S.B. and Y.J.) under general anesthesia using the

TABLE 1 Baseline demographic information of patients followed in three groups

	Tri-Lock (n = 49)	Corail (n = 44)	Summit (n = 45)	One-way ANOVA	Post hoc test		
					Tri versus Cor	Tri versus Sum	Cor versus Sum
Number of hips	63	52	58				
Follow-up (years)	4.84 ± 0.68	4.95 ± 1.20	4.20 ± 1.00				
Age at surgery (years) ^a	50.30 ± 13.30	53.90 ± 11.20	52.10 ± 12.10	$P = 0.37, F = 1.00$	$P = 0.16$	$P = 0.49$	$P = 0.48$
BMI (kg/m ²) ^a	25.30 ± 4.30	24.10 ± 3.20	24.40 ± 3.30	$P = 0.28, F = 1.30$	$P = 0.15$	$P = 0.26$	$P = 0.70$
Female (%) ^b	24 (49.00)	18 (40.90)	20 (44.40)	$P = 0.74, \chi^2 = 0.62$	$P = 0.44$	$P = 0.66$	$P = 0.74$
Diagnosis (%) ^c				$P = 0.32^c$			
OA	23 (36.50)	13 (25.00)	19 (32.80)				
ONFH	30 (47.60)	29 (55.80)	32 (55.20)				
FNF	5 (7.90)	3 (5.80)	0 (0.00)				
RA	4 (6.30)	3 (5.80)	3 (5.20)				
AS	0 (0.00)	3 (5.80)	3 (5.20)				
Perthes' disease	1 (1.60)	1 (1.90)	1 (1.70)				

Note: Test function in stats package using R 4.0.3, multiple comparisons were not performed because the overall test did not show significant differences between three groups. The P value was derived from Fisher exact test, which is based on the probability mass function of hypergeometric distribution, a discrete probability distribution. That means we are able to directly calculate the p value.; Abbreviations: ANOVA, Analysis of Variance; AS, ankylosing spondylitis; FNF, femoral neck fracture; LOS, length of follow-up; OA, osteoarthritis; ONFH, osteonecrosis of the femoral head; RA, rheumatoid osteoarthritis.; ^aOne-Way ANOVA and post hoc test for quantitative data.; ^bChi-square test for multigroup categorical data.; ^cThe Fisher's exact test was performed by fisher.

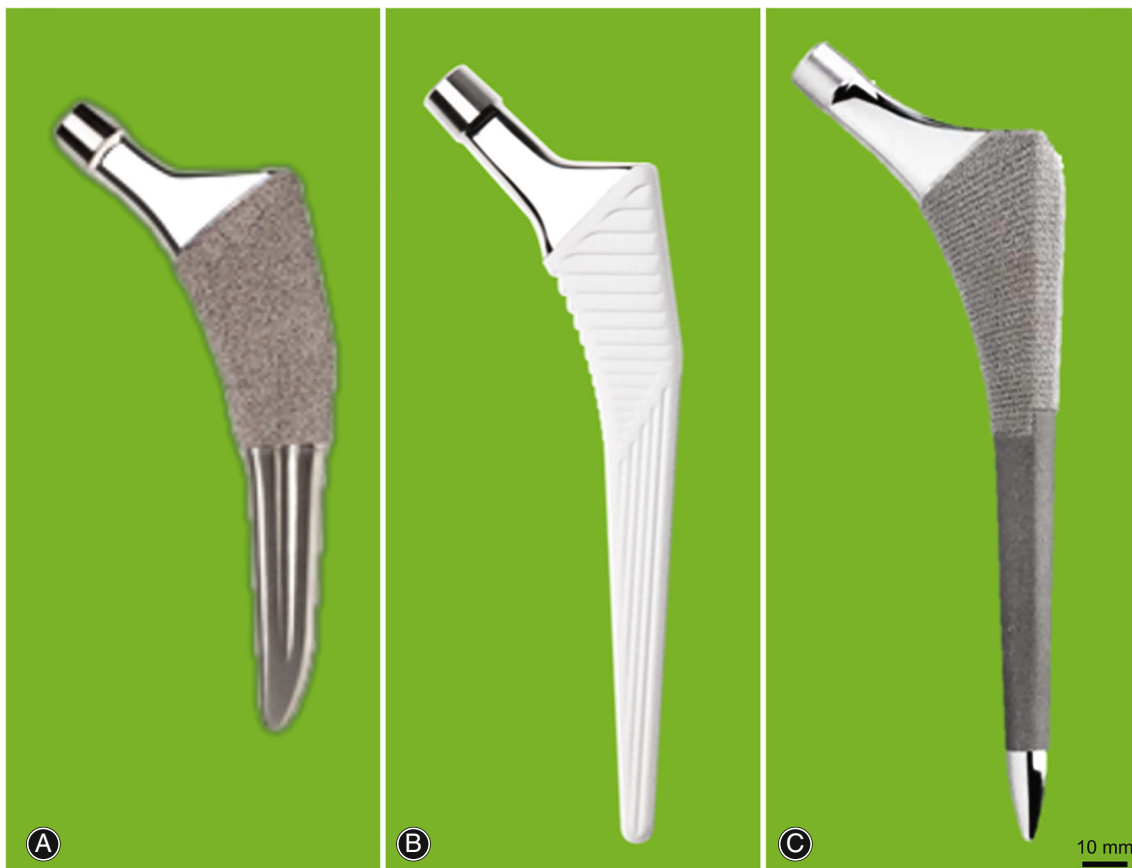


Fig. 2 The morphology and characters of three stems included in this study. (A) Tri-Lock stem; (B) Corail stem; (C) Summit stem

posterolateral approach. Three stems were separately implanted under the specific instruction. The Tri-Lock BPS and Summit stem were inserted with a bone-cutting broach,

while the Corail stem was inserted using a compaction broach. The PINNACLE[®] Acetabular Cup System was used for all participants.

TABLE 2 The characters of three stems

Femoral stem	TriLock BPS	Corail	Summit
Materials	Ti 6Al-4V alloy	Ti 6Al-4V alloy	Ti 6Al-4V alloy
Morphology	1. Reduced Neck Geometry 2. Intuitive Sizing 3. Short, Curved Distal Tip	1. Straight stem 2. Thin distal tip 3. 135° neck angle 4. 12/14 Morse taper 5. Progressive offset	1. Optimized Articuleze taper 2. 130° Neck Shaft Angle 3. Proportional neck length and offset 4. Polished distal bullet tip
Feature	1. Maximize bone preserving 2. Easy for revision	1. Reliable primary stability 2. Long-term biological fixation 3. Proximal load transfer	1. A proximally loading stem 2. Biomechanical Excellence 3. Direct lateralization
Coating	1. GRIPTION microporous coating 2. Optimal size of osseointegration aperture – 300 µm aperture 3. Step distribution forms the best mechanical loading interface – 80% porosity	1. Bioactive whole coating (HYDROXYAPATITE) 2. Horizontal proximal macrostructure 3. Distal longitudinal structure	1. POROCOAT® Porous Coating (Radial ZTT® steps) 2. Duofix™ hydroxyapatite coating 3. Distal grit-blasted surface
Insertion	Bone-cutting broach	Compaction broach	Bone-cutting broach

Outcome Measures

iDXA Measurement

Dual-energy X-ray absorptiometry in iDXA (Lunar iDXA, GE Healthcare, Madison, WI, USA) was an instrument designed to evaluate the small changes in BMD around femoral implants over postoperative follow-up. All participants underwent DEXA measurement in the operated hips at 1 day and 5 years after the operation. As shown in Fig. 3, bone mineral density (BMD) in the frontal plane of the femur was measured according to the seven Gruen zones²¹. In the horizontal plane, the tip of the lesser trochanter defines the distal border of zones 1 and 7. The midpoint between the lesser trochanter and the tip of the stem defines the border between zones 2 and 3, and 5 and 6. Zone 4 represents the total bone area 20 mm distally from the tip of the stem. Vertically, the center axis of the femur divides the medial and lateral zones. Postoperative values were taken as baseline for the periprosthetic BMD follow-up. The average percentage changes in the BMD at each Gruen's zone among the three types of stems were compared. The bone quality of the contralateral hip and the lumbar spine were also evaluated by the iDXA at the latest follow-up. The iDXA scan and the evaluation of BMD around implants were completed by a technician from the Department of Bone Mineral Density in the hospital.

Stress Shielding Grade

Stress shielding grade was a method to evaluate the bone mass changes around the less trochanter after operation based on the hip images from postoperative to the latest follow-up. Femoral bone loss resulting from stress shielding was graded 1st–4th according to the system described by Engh *et al*¹⁸. Atrophy of the femoral calcar was graded I, extended to the less trochanter was graded II, extended to the proximal isthmus of femur was graded III and isthmus atrophy was graded IV. The imaging data was evaluated by the senior radiologists and orthopedics doctors, and discrepancies were solved by the discussion with senior professors.

Spot Welds

Spot welds was the endosteal new bone formation on the prosthesis, meaning the ingrowth of bone into porosities of the surface coating²². It is a positive indication for the stability of cementless stems.

Pedestal Sign

The pedestal sign is an endosteal new bone formation below the distal end of the stem and it usually extends over 50% of the canal²³. Distal pedestal formation and calcar hypertrophy imply prosthesis-to-bone stress transfer away from the porous coating metaphyseal part of the implant and are associated with instability. The formation of this shelf of new bone is an apparent attempt to support the tip of the prosthesis. In addition, the combination of pedestal sign and radiolucent line might suggest the instability of the prosthesis.

Stem Subsidence

Stem subsidence is defined as the distal displacement of the prosthesis relative to the greater trochanter. The Einzel-Bild-Roentgen-Analyse-femoral component analysis (EBRA-FCA) was used to measure the migration between immediate post-operatively and at 5 years postoperatively^{24,25}. If the prosthesis migrates more than 2 mm to the distal femur, it can be judged as stem subsidence.

Harris Hip Score (HHS)

Harris hip score (HHS) is a widely used method to evaluate the function of hip joint, which is often used to evaluate the effect of total hip replacement²⁶. The HHS score system includes four sections: pain, function, disability and range of motion (ROM). The second section includes two aspects: gait and daily activities. Intervening statements are scored according to rank. The lighter the pain, the better the function, the greater the activity and the higher the score was. The full score is 100, 90 or above is excellent, 80–89 is good, 70–79 is fair, and less than 70 is poor. For the patients with two hip replacements, the right operated hip was evaluated for HHS and other clinical scores. Because some questions

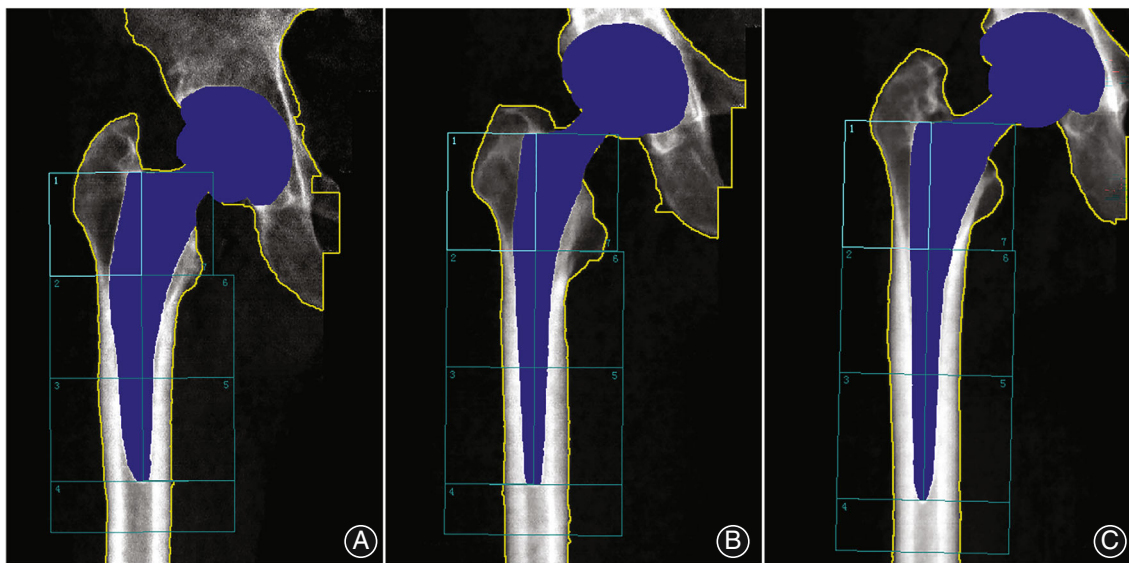


Fig. 3 The illustration of Gruen zones for DEXA measurement around three stems. (A) Tri-Lock stem; (B) Corail stem; (C) Summit stem

involved in the questionnaire are aimed at the whole body state and the completion of special movements of lower limbs. Therefore, only the right limb was evaluated in order to reduce the systematic deviation.

Short Form-12 Health Survey (SF-12)

The 12-item Short Form Survey (SF-12) is a general health questionnaire that was first published in 1995 as part of the Medical Outcomes Study (MOS)²⁷. The SF-12 measures eight concepts commonly represented in widely used surveys: physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality (energy/fatigue), social functioning, role limitations due to emotional problems, and mental health (psychological distress and psychological well-being). Thus, two summary scores are reported from the SF-12: a mental component score (MCS-12) and a physical component score (PCS-12). The score of every patient was measured by filling in the form online (<https://orthotoolkit.com/sf-12/>), and the data was scored automatically.

Forgotten Joint Score (FJS)

Forgotten joint score (FJS) scale has been used to evaluate the subjective feelings of patients after hip and knee arthroplasty in recent years²⁸. The scale includes 12 related questions based on patients' daily activities. Each question is composed of five options with a score of 0–4, with a full score of 100. The score is calculated according to Behrend *et al*²⁹. The higher the score, the better the subjective feeling in daily activities.

Statistical Analysis

Periprosthetic BMD changes during 5 years follow-up in seven Gruen zones were calculated as percentages. One-way ANOVA was first used to compare differences in mean clinical scores, distance of femoral stem migration and BMD percentage

changes between the three groups, and then a *post hoc* test was used to test for difference between multiple groups. The Kruskal–Wallis H test was used for the comparison of the grade of stress shielding. And a chi square test was used for the comparison of number of spot welds, and the pedestal sign was evaluated between the groups (when the minimum expected number was less than 5, the Fisher's exact test was adopted). *P* values of <0.05 were considered statistically significant.

Results

General Results

There are a total of 138 patients retrospectively followed for an average of 4.66 years. The operation time was 48.50 ± 4.80 , 47 ± 4.20 and 48 ± 3.70 min in Tri-Lock, Corail, Summit groups.

Periprosthetic BMD Changes

As shown in Table 3 and Fig. 4, different periprosthetic BMD changes were presented in the three groups. In the Tri-Lock group, it was slightly increased in the ROI 3 and 4 (1.27% and 0.19%, respectively), and decreased in the ROI 1,2,5,6, and 7 (–1.89%, –3.24%, –1.74%, –5.72% and –12.60%, respectively). The periprosthetic BMD decreased in all ROIs (–2.62%, –5.63%, –5.81%, –5.89%, –6.44%, –6.84% and –11.84%) in the Corail group. The Summit group was a little different, aside from the bone absorption in medial-proximal zones (–6.41%, –9.56% in ROI 6 and 7), the BMD in the lateral-proximal of the summit stem also decreased (–7.49%, –10.10% in ROI 1 and 2). However, the trend of bone remodeling around the proximal femoral prosthesis was similar in three groups, especially in the proximal medial and lateral Gruen zones. The BMD was decreased in proximal Gruen zones (1,2 and 6,7) in the three groups. It

TABLE 3 The periprosthetic BMD changes around three stems in 5 years after THA

Gruen zones	Time	Tri-Lock (n = 49)	Corail ^a (n = 44)	Summit (n = 45)	One-way ANOVA	Post hoc test		
						Tri versus Cor	Tri versus Sum	Cor versus Sum
ROI 1	post 1 day	0.70 ± 0.12	0.75 ± 0.12	0.92 ± 0.13	P = 0.42, F = 0.88	P = 0.52	P = 0.48	P = 0.19
	post 5 years changes	0.68 ± 0.12	0.72 ± 0.20	0.82 ± 0.18				
ROI 2	t-test	-1.89%	-2.62%	-7.49%				
	post 1 day	P = 0.53, t = -2.07	P = 0.90, t = 0.12	P = 0.13, t = -1.01				
ROI 3	post 5 years changes	1.71 ± 0.24	1.83 ± 0.25	2.01 ± 0.19	P = 0.46, F = 0.79	P = 0.62	P = 0.21	P = 0.40
	t-test	1.62 ± 0.26	1.71 ± 0.26	1.79 ± 0.20				
ROI 4	post 1 day	-3.24%	-5.63%	-10.10%	P = 0.04, F = 1.15	P = 0.24	P = 0.77	P = 0.18
	post 5 years changes	2.04 ± 0.15	2.02 ± 0.24	2.00 ± 0.22				
ROI 5	t-test	2.06 ± 0.18	1.89 ± 0.24	1.99 ± 0.25				
	post 1 day	P = 0.23, t = -0.74	P = 0.09, t = -0.42	P = 0.01, t = -0.59				
ROI 6	post 5 years changes	1.27%	-5.81%	0.03%	P = 0.18, F = 1.77	P = 0.08	P = 0.81	P = 0.19
	t-test	1.78 ± 0.21	1.84 ± 0.21	1.84 ± 0.21				
ROI 7	post 1 day	0.19%	-5.89%	-0.77%	P = 0.17, F = 1.81	P = 0.17	P = 0.62	P = 0.08
	post 5 years changes	2.03 ± 0.17	2.03 ± 0.2	2.05 ± 0.23				
ROI 8	t-test	1.97 ± 0.16	1.89 ± 0.2	2.04 ± 0.21				
	post 1 day	P = 0.29, t = 0.99	P = 0.01, t = -0.31	P = 0.87, t = 0.41				
ROI 9	post 5 years changes	-1.74%	-6.44%	0.16%	P = 0.94, F = 0.06	P = 0.72	P = 0.85	P = 0.90
	t-test	1.53 ± 0.21	1.84 ± 0.2	1.94 ± 0.2				
ROI 10	post 1 day	1.44 ± 0.24	1.70 ± 0.21	1.79 ± 0.26	P = 0.91, F = 0.09	P = 0.90	P = 0.68	P = 0.75
	post 5 years changes	-5.72%	-6.84%	-6.41%				
ROI 11	t-test	P = 0.18, t = -1.83	P = 0.02, t = -1.92	P = 0.12, t = -0.85				
	post 1 day	1.33 ± 0.24	1.31 ± 0.35	1.26 ± 0.33				
ROI 12	post 5 years changes	1.14 ± 0.27	1.11 ± 0.32	1.07 ± 0.28	P = 0.02, t = -2.01	P = 0.03, t = -2.54	P = 0.14, t = -1.59	
	t-test	-12.60%	-11.84%	-9.56%				

Note: Independent t test used for periprosthetic changes between post 1 day and post 5 years. One-Way ANOVA and post hoc test for periprosthetic BMD changes between three groups.; ^aThe decrease of BMD around the Corail stem should be partly attributed to the more systemic bone loss from the operation to the latest follow-up (Table 1).

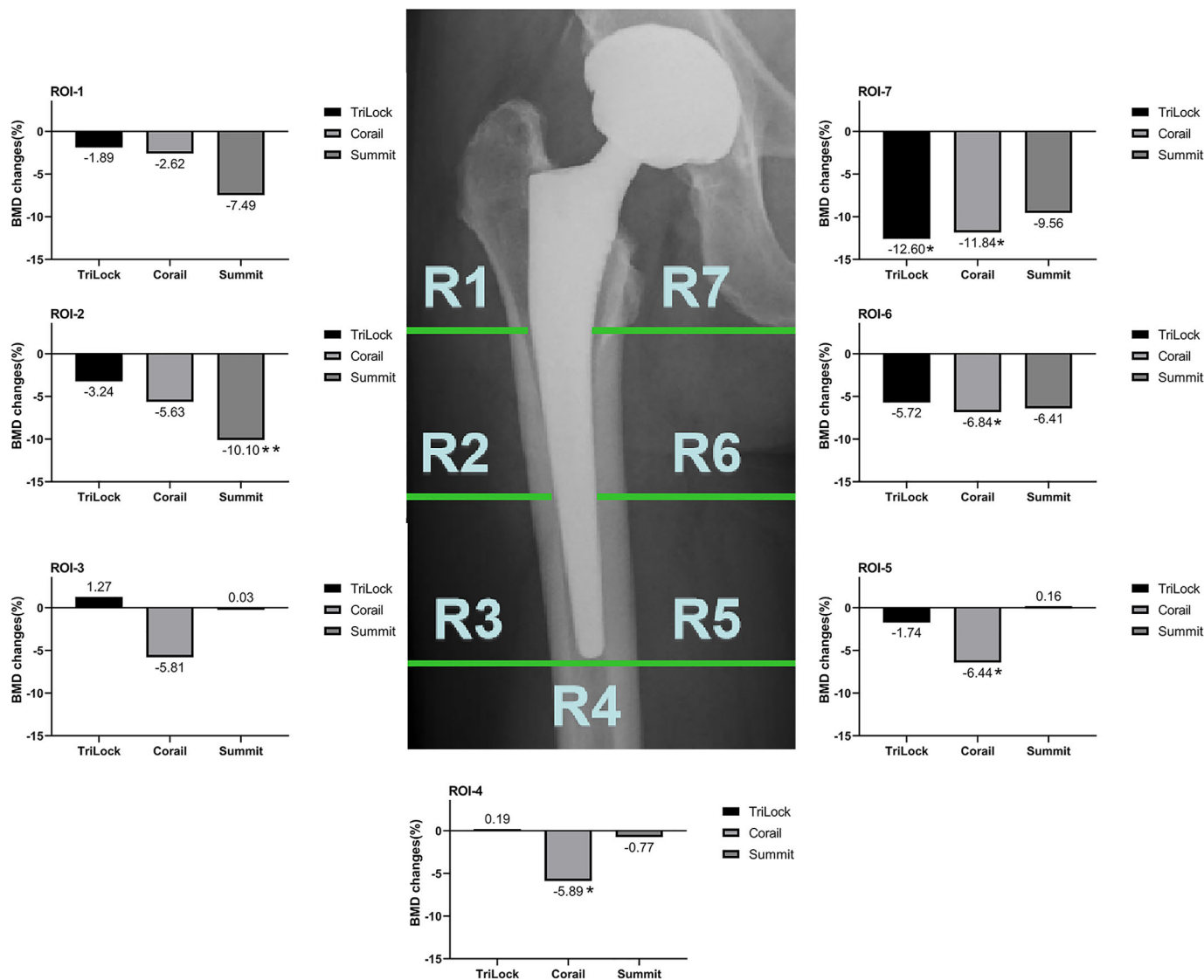


Fig. 4 Periprosthetic bone mineral density changes (%) in seven Gruen zones for three groups. * $P < 0.05$, ** $P < 0.01$

can be shown that the proximal femur was absorbed after three different prostheses were implanted.

Radiographical Changes

In the radiological grading of stress shielding, there were five cases (10.20%) in the Tri-Lock group, five cases (11.36%) in the Corail group and five cases (11.11%) in the Summit group graded III-IV without significant difference. The mean amount of stem migration was not significantly different in three groups and no case had progressive stem subsidence (1.89 ± 1.35 mm, 1.89 ± 1.31 mm, and 1.95 ± 1.19 mm, respectively, $p = 0.95$). In addition, spot weld occurred in 29 cases of 173 hips (16.76%) and most common in the Gruen zone 3 around the Corail stem (19 cases, 43.18%). The pedestal sign was mostly found under the tip of the Tri-Lock stem (5 cases [10.20%], 2

cases [4.55%], and 2 cases [4.44%] respectively), and no radiolucent lines was occurred in any cases. (Table 4, Fig. 5).

Clinical Outcomes

The Harris hip score and SF-12 score were all significantly improved at 5 years after THA compared with the preoperative values in the three groups, while there was no significant difference between them. In addition, the Forgotten Joint Sore (FJS) did not show significant difference between the groups at 5 years after THA (63.80 ± 35.00 , 63.40 ± 36.80 , and 63.80 ± 36.10 , respectively, $p = 1.00$). In view of radiographs, hip prosthesis achieved well biofixation at five years after THA (Fig. 6).

Complications

Regarding the occurrence of complications, two patients (4.50%) in the Corail group suffered a dislocation more than

TABLE 4 Radiographical changes in three groups in 5 years after THA

Radiographic Changes	TriLock (n = 49)	Corail (n = 44)	Summit (n = 45)	Three-group comparison	Post hoc test		
					Tri versus Cor	Tri versus Sum	Tri versus Cor
Spot welds (%) ^a	6 (12.24)	19 (43.18)	4 (8.89)	$P = 0.00, \chi^2 = 19.28$	$P = 0.00$	$P = 0.60$	$P = 0.00$
Pedestal sign (%) ^a	5 (10.20)	2 (4.55)	2 (4.44)	$P = 0.43, \chi^2 = 1.69$	$P = 0.47$	$P = 0.55$	$P = 0.72$
Stress shielding (%) ^b				$P = 0.90, H = 0.20$			
I	13 (26.53)	11 (25.00)	10 (22.22)				
II	19 (38.78)	15 (34.09)	18 (40.00)				
III	5 (10.20)	4 (9.09)	4 (8.89)				
IV	0 (0.00)	1 (2.27)	1 (2.22)				
Stem migration (mm) ^c	1.89 ± 1.35	1.89 ± 1.31	1.95 ± 1.19	$P = 0.95, F = 0.05$	$P = 0.99$	$P = 0.77$	$P = 0.80$

^a Chi-square test for multigroup categorical data.; ^b Kruskal-Wallis *H* test for grade data, multiple comparisons were not performed because the overall test did not show significant differences between three groups.; ^c One-Way ANOVA and post hoc test for quantitative data.

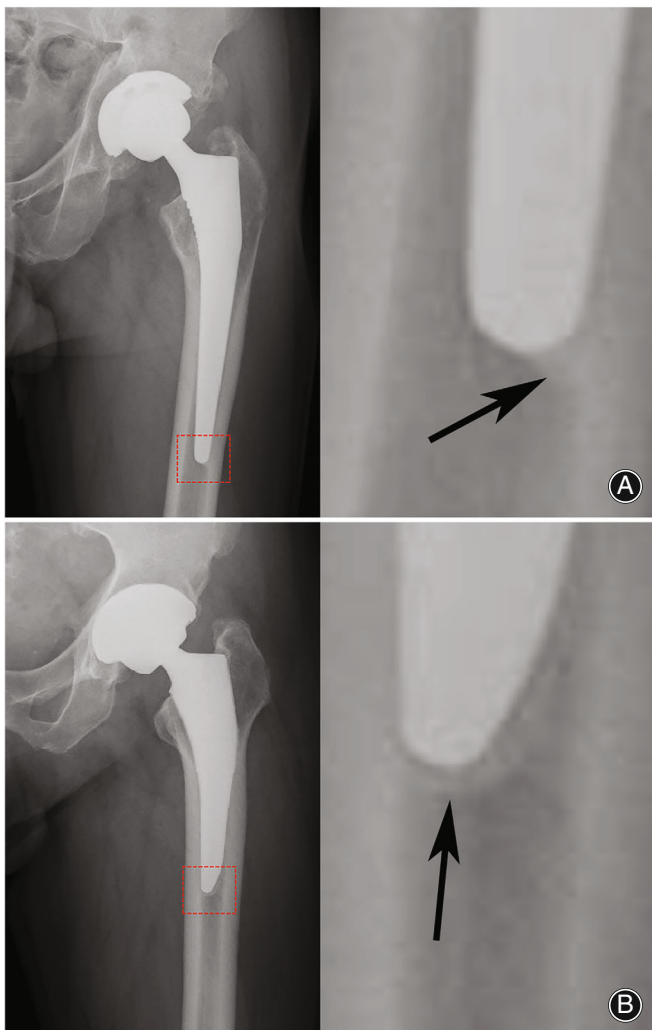


Fig. 5 The illustrations of spot weld and pedestal sign around stem on the hip radiograph. (A) Spot weld; (B) Pedestal sign

3 years after the operation and were treated with closed reduction. A total of 25 (14.50%) patients occasionally felt thigh pain. Two patients (3.80%) in the Corail group, one

patient (1.60%) in the Tri-Lock group and one patient (1.70%) in the Summit group felt moderate thigh pain (4–6 points) ($P > 0.05$). Remaining 21 cases of mild thigh pain (1–3 points) occurred in two conditions. Nine patients felt painful when it gets cold, three cases (4.80%) from the Tri-Lock group, three cases (5.80%) from the Corail group, and three cases (5.20%) from the Summit group ($P > 0.05$). Twelve patients felt painful when the implant was overloaded, four cases (6.30%) from the Tri-Lock group, four cases (7.70%) from the Corail group, and the last four cases (6.90%) was from the Summit group ($p > 0.05$). All cases of thigh pain could alleviate after having a rest without medicine or other treatment.

Results of Subgroup Analysis

Subgroup analysis for the periprosthetic BMD changes was made based on the age, gender and the length of follow-up. The results shown that the female patients older than 50 years lost significantly more bone mineral density than the male patients or patients younger than 50 years. In addition, female patients showed significantly more serious stress shielding than male patients ($p = 0.02$). The length of follow-up only made a difference on the BMD changes in Gruen 5, the BMD lost more in patients followed longer than 5 years.

Subgroup analysis for the radiological and clinical outcomes were made based on the age, gender and the length of follow-up. The grade of stress shielding was significantly higher in female patients older than 50 years. In addition, the incidence of pedestal sign and stem subsidence were significantly more in male patients older than 50 years. For the functional score system, all of them were significantly better in patients younger than 50 years, and the FJS was significantly greater in patients followed more than 5 years. And the two cases of dislocations were two male patients younger than 50 years and followed more than 5 years. Female patients older than 50 years were significantly easier falling the thigh pain.

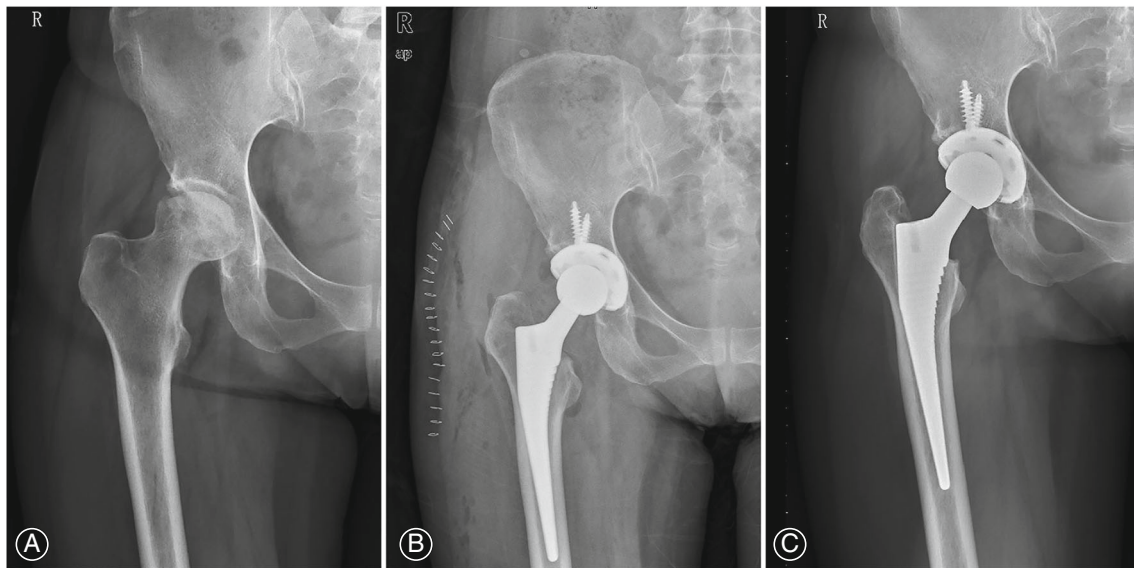


Fig. 6 Radiographs of a 57-year-old woman who underwent THA for the osteonecrosis of the femoral head. (A) Radiograph before THA, showing a necrotic and collapsed femoral head. (B) Postoperative radiograph with a Corail stem implanted. (C) Radiograph at 5 year postoperative

Discussion

Effect of Three Kinds of Stems on Periprosthetic BMD Changes

It is generally believed that the length of stem was a key factor affecting the strain distribution after the prosthesis implanted^{14,30,31}. The longer prosthesis transmits the stress to the more distal part of the femur results in a higher degree of stress shielding in the proximal femur. However, at the fifth year after THA, similar BMD loss was found in the proximal femur (Gruen zones 1, 2, 6 and 7) around all three kinds of cementless stems. The Tri-Lock bone preserving stem did not significantly reduce the proximal BMD loss compared with the other two conventional longer stems. Consistent with our finding, Slullitel *et al*¹³. found that the Tri-Lock BPS intended to preserve proximal femoral bone but do not necessarily perform better than conventional cementless designs (Corail stem) using the high sensitivity Dual-energy X-ray Absorptiometry Region Free Analysis (DXA-RFA). Hayashi *et al*. reported 7.85% loss of the periprosthetic BMD in Gruen zone 7 in the 24 months after the THA and concluded that the Tri-Lock BPS is not suitable for patients with poor bone mass³². But Meyer *et al*³³. reported a different result that the bone-preserving Fitmore stem exhibited less proximal femoral bone loss than the CLS Spotorno conventional stem. Therefore, how the prosthesis affected the periprosthetic bone remodeling was still in controversy. Apart from the length of the stem, other potential characters should be paid more attention.

Stiffness of stems was considered an important factor influencing the degree of stress shielding after THA^{34,35}. The closer the stiffness of prosthesis to femur, the lower degree of

stress shielding it produces². And the stiffness of stem was depended on the elastic modulus and Moment of Inertia (MOI). All three stems are made of Ti 6Al-4V alloy, that the elastic modulus was the same. While MOI is proportional to the fourth power of the cross-sectional area of the prosthesis. Therefore, the larger the diameter of the prosthesis made from the same material, the greater the cross-sectional area of the prosthesis, the greater the moment of inertia and finally the greater the stiffness³⁶. However, it was pretty difficult to design a prosthesis which could completely prevent a certain amount of stress shielding in the calcar and major trochanter regions, which was caused by the moderate underloading and distal load transfer, respectively. In addition, one must consider that research is still pending regarding the clinical value of the preservation of proximal bone mass in terms of long-term survival or improved options for revision surgery for these kinds of implants.

Relationship between BMD Changes and Clinical Outcomes

Postoperative pain was considered to be related to the stem design and stiffness of implants^{37,38}. The modulus of elasticity of normal cortical bone is less than 20 GPa³⁹, but most conventional metal stems occupying the diaphysis have a modulus of elasticity ranged 80 to 200 GPa⁴⁰. Therefore, the stress shielding from the different stiffness between implants and bone might cause the periprosthetic bone resorption and thigh pain.

However, this research found that neither the postoperative BMD changes around implants nor the clinical outcomes were significantly different between the three kinds of

stems. One possible explanation was that the final follow-up was too late to show a difference, because the periprosthetic BMD loss was most evident in the first postoperative year and the changes were minimal thereafter⁴¹. It was also proposed that the changes in the first year were more clinically relevant, as the initial periprosthetic bone remodeling process was mainly completed in the first 12 postoperative months^{42,43}. But it was still very necessary to perform a longer length of follow-up to evaluate whether different designs of stem and periprosthetic bone remodeling could make a difference on the rate of aseptic loosening and revision of implants.

Limitations

There were several limitations in our study. First, this study was performed retrospectively, the periprosthetic BMD were not measured in other time points, results of our study just indicated the periprosthetic BMD changes at a midterm follow-up. Second, it is important to note that the changes of

BMD do not represent the changes of bone strength, that the effect of the proximal BMD loss due to the stress shielding on the periprosthetic fracture and survival of implants still need further research in a longer follow-up period. Third, the risk factors affected the BMD changes like the smoking, drinking, and long-term bed rest were not reported in this study because the most of patients changed their lifestyle along with the aging.

Conclusion

The Tri-Lock Bone Preserving Stem did not show significant difference in periprosthetic BMD changes compared with the other two conventional longer stems at 5 years after THA.

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