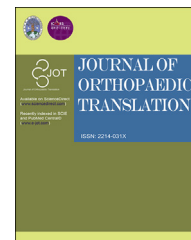




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ORIGINAL ARTICLE

Incidence of a stem sitting proud of a proximally coated cementless tapered wedge stem

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KEYWORDS

Hip replacement;
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Abstract *Background/objective:* A stem sitting proud (SP) or that above the final rasp position remains in some patients who undergo hip replacement using proximally coated tapered wedge stems. Surgeons may face challenges providing the best fit because of unpredictable SP of proximally coated tapered wedge stems. Zimmer Inc. introduced a new rasp to solve this issue but the clinical results of this rasp have not yet been published. Therefore, our aim was to address the following: (1) What is the stem SP incidence using a proximally coated cementless tapered wedge stem? (2) Does the new rasp system (0-mm rasp) improve seating height? and (3) What are the risk factors of stem SP?

Methods: We performed a retrospective study with 338 hips, in which Tri-Lock Bone Preservation Stem (BPS) was used in 181 hips and M/L Taper stem was used in 157 hips (82 hips before and 75 hips after 0-mm rasp use). A positive stem SP was defined as a stem proud height of >2 mm. We analysed and compared SP incidence in two stems and M/L Taper stems before and after the 0-mm rasp use.

Results: An incidence of stem SP was 13% in the Tri-Lock BPS and 15% in the M/L Taper stem before the 0-mm rasp use. Stem SP incidence in the M/L Taper stem substantially decreased after the 0-mm rasp use (4%). The significant risk factor for stem SP was use of the high offset option in Tri-Lock BPS.

Conclusion: The proximally coated tapered wedge stems present potential problems related to stem SP. The new rasp of the M/L Taper stem showed significant improvement in initial seating height.

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The translational potential of this article: This study was conducted to understand “stem sitting proud” in proximally coated tapered wedge stem as one of the most popular designs nowadays in adult hip joint arthroplasty field. In this study, we aimed to address the incidence of stem proud, investigated the risk factor and introduced the effect of new rasp system which improve stem seating height.

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Introduction

In the 1970s, cementless press fit stem design was developed for hip replacement, and since then, the use of cementless stems has increased [1,2]. Proximally coated tapered wedge stems are one of the most popular designs because of their excellent clinical results and simplicity of use [3–5]. Despite successful long-term clinical outcomes of these stems, we have consistently experienced a stem sitting proud (SP) or a stem above the final rasp position in some patients who undergo hip replacement using the Tri-Lock Bone Preservation Stem (BPS) (DePuy, Warsaw, IN, USA) or M/L Taper stem (Zimmer, Warsaw, IN, USA). Although this is a common clinical occurrence, the effect of a few millimetres of stem SP on clinical outcomes is unknown; however, surgeons may face challenges in providing their patients with the best fit because of unpredictable stem seating. To match the seating height of the real stem with that of the final rasp for equal leg length, we switched to smaller neck length in some cases.

As more than 80% of the bearing surface in total hip arthroplasty (THA) in Korea is ceramic-on-ceramic [6]; using short-neck ceramic heads may increase the incidence of ceramic head fracture [7]. In some patients with osteoporosis, additional hammer blows to seat the real stem to the final rasp position during surgeries have caused cracks in the proximal femur which may increase the risk of intraoperative periprosthetic fracture. In rare cases, surgeons may extract the stem and switch to a different stem size to restore equal leg length. In early 2013, Zimmer Inc. introduced a new rasp (0-mm rasp) to solve the issue associated with tapered wedge stems SP, but clinical results from use of this new rasp have not yet been published. Since December 2014, we have used this new rasp system for M/L Taper stems.

In this study, our aim was to address the following: (1) What is the stem SP incidence in proximally coated cementless tapered wedge stems? (2) Does the new rasp system improve seating height? and (3) What are the risk factors of a stem SP?

Materials and methods

Patient selection

This study was approved by the Institutional Review Board of Asan Medical Center. All data were analysed anonymously and the institutional review board waived the

requirement for informed consent (approval number: S2016-1008-0001). We performed a retrospective review of the medical records and simple radiographs of 415 hips from 372 patients who underwent THA or bipolar hemiarthroplasty using Tri-Lock BPS (DePuy) or M/L Taper stems (Zimmer) at our institution between March 2011 and May 2016. We excluded the following cases: (1) basicervical-type fractures in which the fracture line involves the neck base such that calcar reaming was not performed; (2) severely deformed femurs in which neck features were unidentifiable; (3) those with stem SP with an intraoperative final rasp and (4) intraoperative proximal femur fracture during rasping treated with a cerclage cable or wire. Finally, 338 hips were included in the study: the Tri-Lock BPS was used in 181 hips and the M/L Taper stem was used in 157 hips. As for cases that used the M/L Taper stem, the group was divided into two—82 hips before the adoption of 0-mm rasp system and 75 hips after the adoption of rasp system, which was routinely used for all M/L Taper arthroplasty cases.

Surgical technique

All procedures were performed by a single surgeon who had performed more than 400 cases of THA using the Tri-Lock BPS and more than 200 cases using M/L Taper stems. Surgery was performed in the lateral decubitus position using a posterior approach. Preoperative templating was performed with an anteroposterior (AP) hip radiograph to decide optimal femoral stem fit, the level of the femoral neck cut and the femoral component offset. In all cases, we used the box osteotome to open the lateral femur entry point and performed rasping by manual process subsequently. The calcar planer was used to plane the femoral neck after the final rasp had been inserted to the proper level in all cases. After performing trial reduction, an intraoperative radiograph film was obtained to check leg length, the femoral offset and component fit. The real stem was inserted by tapping the handle of the stem inserter with a mallet until the implant no longer moved forward. Biolox delta ceramic head (CeramTec, Plochingen, Germany) was used in all cases (32-mm heads for cup sizes 48–52 mm and 36-mm heads for cup sizes >54 mm). The postoperative rehabilitation was the same for all patients; patients were allowed flat foot partial weight-bearing with a walker or crutches on the postoperative Day 2 and allowed full weight-bearing as tolerated from 6 weeks postoperatively.

Data collection

To find a true AP hip view, the presence of the stem SP was evaluated using an AP hip radiograph taken within 6 weeks postoperatively which did not show medial calcar resorption. The height of the stem SP was determined by measuring the distance from the level of the femoral neck cut to the most proximal level of the stem's porous surface (Fig. 1). The measured distance was calibrated with a known outer diameter of the acetabular component. A positive stem SP was defined as a stem SP height of >2 mm. SP incidence of the M/L Taper stem was separately analysed before and after the 0-mm rasp use.

We reviewed the following variables as clinical parameters: age at the time of surgery, sex and preoperative diagnosis. We also evaluated the following radiologic parameters: morphology of the proximal femur, post-operative stem positioning, leg length discrepancy (LLD) and stem subsidence. The morphology of the proximal femur was categorized using preoperative radiographs according to the classification by Dorr et al. [8]. Stem position was evaluated as the angle between the femur's anatomical axis and the femoral stem's vertical axis. A measurement of $>2^\circ$ varus or valgus position was

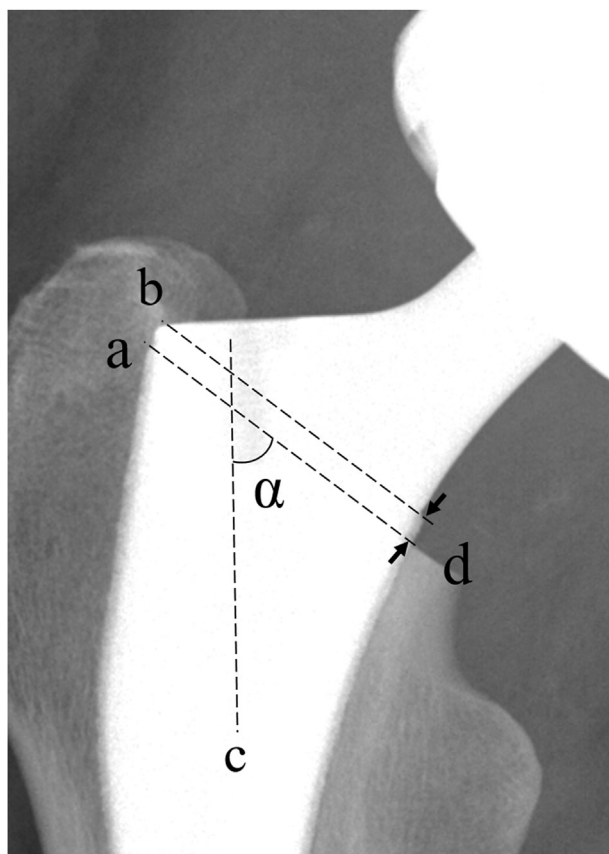


Figure 1 Definition of the stem sitting proud. The height of the stem proud (d) is the distance between the level of the femoral neck cut (line a) and the most proximal level of the porous surface of the stem (line b). (line c, the vertical axis of the femoral stem; α , the angle between lines a and c informed by the Zimmer inc.).

considered significant. To determine LLD, the first line was drawn between the lower margin of teardrop, and the second perpendicular lines were drawn from each tip of the lesser trochanters to the first line. LLD is defined as the difference in the two perpendicular lines. Stem subsidence was also measured using an AP hip plain radiograph at the 6-month follow-up. The following variables were also recorded: stem size, stem offset and femoral neck length. All radiographs were reviewed by two experienced orthopaedic surgeons.

Statistical analysis

To analyse patient demographics, independent t test, Mann–Whitney *U* test, Chi-square test and Fisher's exact test were performed. To evaluate the risk factor of stem SP on each variable, univariate analysis was performed using the categorical data from the Tri-Lock BPS and M/L Taper stem with Mann–Whitney *U* test, Chi-square test and Fisher's exact test. The variables in the univariate study included patient demographics, such as age, sex, preoperative diagnosis, Dorr type and operative details, such as the stem used, stem offset, stem size, stem angulation and stem position. For preoperative diagnosis, we hypothesised that the fragility fracture group has a lower risk of stem SP because of osteoporosis, among other factors. Therefore, we divided the patients into two groups: fragility fracture in patients older than 50 years and other diagnoses. For stem size, both Tri-Lock BPS and M/L Taper stem were divided into two groups: the first group included the smallest five sizes (0–4 for Tri-Lock BPS and 4–9 for M/L Taper stem) and the second group included all other higher sizes. To evaluate the independent effect of each variable on clinical outcomes and reduce bias because of confounding variables, multivariate subgroup analysis was performed using a logistics regression model. Using the order number of the cases, we compared the stem SP incidence in the case groups, each consisting of 30 cases, to evaluate the surgeon's learning effect. An intraclass correlation coefficient with 95% confidence interval was used to evaluate interobserver and intraobserver agreements for continuous variables, which were nearly perfect [9]. All statistical analyses were performed using SPSS v.21 software (IBM, Armonk, NY, USA). A *P* value of <0.05 was considered statistically significant.

Results

Statistical differences were found across mean age, sex, preoperative diagnosis and Dorr type between the Tri-Lock BPS and M/L Taper stem groups ($P < 0.05$); however, no significant difference was found within the M/L Taper groups before and after the 0-mm rasp use (Table 1). The SP incidence of the stem was 13% (23/181 hips) with a mean height of 3.0 mm (range: 2.1–4.3 mm) in Tri-Lock BPS and was 15% (12/82 hips) in M/L Taper stem with a mean height of 2.8 mm (range: 2.1–4.0 mm) before the 0-mm rasp use. After the 0-mm rasp use, only 4% (3/75 hips) showed stem SP with a mean height of 2.2 mm (range: 2.1–2.5 mm). There was no significant difference in the stem SP incidence between the Tri-Lock BPS and M/L Taper stem groups before 0-mm rasp use ($P = 0.670$); however, the stem SP

Table 1 Demographic and clinical characteristics.

Variables	Tri-lock (n = 181)	M/L taper (n = 157)	P value	M/L taper before the 0-mm rasp use (n = 82)	M/L taper after the 0-mm rasp use (n = 75)	P value
Age (yrs)	65.4 ± 13.1	60.8 ± 16.9	0.027	60.0 ± 16.1	61.6 ± 17.8	0.396
Female	104 (57%)	73 (46%)	0.044	34 (41%)	39 (52%)	0.186
Preoperative diagnosis			0.010			0.060
ONFH	69 (38%)	75 (48%)		48 (59%)	27 (36%)	
Fracture	58 (32%)	50 (32%)		22 (27%)	28 (37%)	
Secondary OA	40 (22%)	28 (18%)		11 (13%)	17 (23%)	
Primary OA	14 (8%)	4 (2%)		1 (1%)	3 (4%)	
Dorr type			0.036			0.883
Type A	29 (16%)	11 (7%)		5 (6%)	6 (8%)	
Type B	143 (79%)	136 (87%)		72 (88%)	64 (85%)	
Type C	9 (5%)	10 (6%)		5 (6%)	5 (7%)	

Values are presented as mean ± standard deviation or n (%). ONFH, osteonecrosis of the femoral head; OA, osteoarthritis.

incidence with the M/L Taper stem substantially decreased after the 0-mm rasp use ($P = 0.024$; Fig. 2).

According to the results of the univariate analysis, stem SP was significantly higher at high offset (19%) than at standard offset (8%) in the Tri-Lock BPS system ($P < 0.043$; Table 2). In the M/L Taper stem, however, there were no significant differences across all variables, including stem offset, between the stem SP and non-proud groups (Tables 3 and 4). With regard to preoperative diagnosis, the SP incidence was lower in fragility fractures in patients aged 50 years or older (0/18 hips) than in other diagnoses (12/64 hips) using the M/L Taper stem before the 0-mm rasp use, but this result was not statistically significant. When multiple logistic regression analysis was performed, the significant risk factor for stem SP was use of the high offset

option in the Tri-Lock BPS ($P = 0.048$; odds ratio = 2.474; 95% confidence interval, 1.009–6.063). There was no substantial difference in the stem SP incidence between the case groups, each consisting of 30 cases.

With regard to femoral neck length, short-neck femoral head was more frequently used in the stem proud group (13% in Tri-Lock BPS and 58% in M/L Taper stem) than in the non-proud group (4% in Tri-Lock BPS and 21% in M/L Taper stem), and there was a significant difference in the M/L Taper stem group ($P = 0.013$). The mean postoperative LLD was 3.0 ± 2.9 mm in the Tri-Lock BPS group, 3.6 ± 3.2 mm in the M/L Taper stem group before the 0-mm rasp use and 2.7 ± 2.3 mm in the M/L Taper stem group after the 0-mm rasp use. There was no significant difference in the mean postoperative LLD between the stem proud and non-proud groups regardless of the stem type. At a minimum 6-month follow-up, there was no measurable stem subsidence (more than 0.5 mm or less) across all cases.

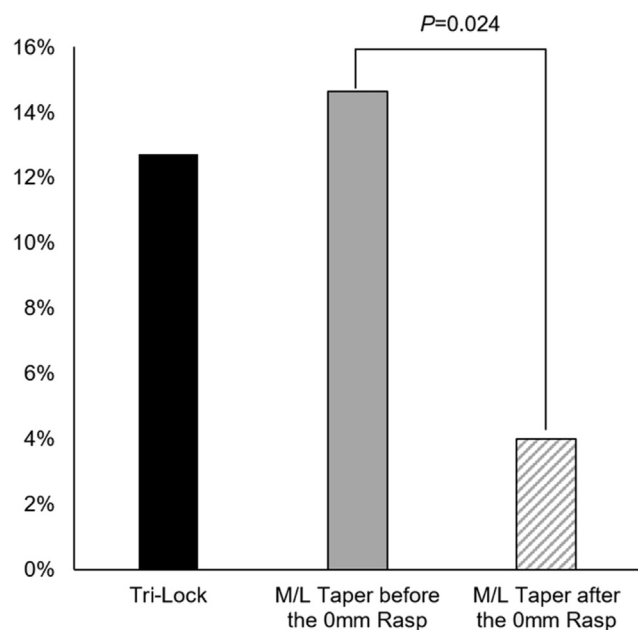


Figure 2 The incidence of sitting proud of the Tri-Lock BPS and M/L Taper stem before and after the use of the 0-mm rasp.

Discussion

According to a recent report by Zimmer Inc., more than 75% of surgeons experience at least one occurrence of a stem SP when using a proximally coated cementless tapered wedge stem system. The average stem SP incidence was 17% when using the Tri-Lock BPS, 14% when using the M/L Taper stem, 12% when using the Taperloc (Biomet, Warsaw, IN, USA) and 13% when using the Accolade I&II (Stryker, Mahwah, USA) [10]. Similarly, a stem SP incidence of 13% was found with the Tri-Lock BPS use and 15% with the M/L Taper stem use in the present study. The M/L Taper stem has a circumferential plasma spray porous coating on the proximal region, and the conventional M/L Taper rasp system has a 1 mm of total press fit in both AP and mediolateral (ML) dimensions of the proximal region. Therefore, Zimmer Inc. evaluated the performance of multiple rasp concepts with a modified press fit design in a stripped cadaveric femur and found that the 0-mm rasp was the most accurate rasp among all concepts tested, which has 0 mm of total press fit in the ML dimension and 1 mm of total press fit in the AP dimension of the proximal region.

Table 2 The results of the univariate analysis in Tri-Lock stem.

Variables	Proud group (n = 23)	Non-proud group (n = 158)	All (n = 181)	P value
Age (yrs)	63.6 ± 11.1	65.7 ± 13.3		0.324
Gender				0.723
Female	14 (13%)	90 (87%)	104 (100%)	
Male	9 (12%)	68 (88%)	77 (100%)	
Preoperative diagnosis				0.621
Fragility fractures in patients aged 50 years or older	5 (11%)	42 (89%)	47 (100%)	
Others	18 (13%)	116 (87%)	134 (100%)	
Dorr type				0.087
Type A	7 (24%)	22 (76%)	29 (100%)	
Type B	16 (11%)	127 (89%)	143 (100%)	
Type C	0 (0%)	9 (100%)	9 (100%)	
Stem offset				0.043
Standard (%)	9 (8%)	97 (92%)	106 (100%)	
High (%)	14 (19%)	61 (81%)	75 (100%)	
Stem size				0.789
0 to 4 (%)	19 (14%)	124 (86%)	133 (100%)	
More than 4 (%)	4 (11%)	34 (89%)	38 (100%)	
Stem position				0.164
Neutral (%)	11 (10%)	102 (90%)	113 (100%)	
Varus (%)	6 (21%)	22 (79%)	28 (100%)	
Valgus (%)	6 (15%)	34 (85%)	40 (100%)	

Values are presented as mean ± standard deviation or n (%).
BPS, Bone Preservation Stem.

In this study, the stem SP incidence significantly decreased from 15% to 4% after the 0-mm rasp use without risk of stem subsidence. To the best of our knowledge, this is the first clinical report to demonstrate the efficacy of the

0-mm rasp. The Tri-Lock BPS rasp system has the same 1 mm of press fit in the AP dimension as the M/L Taper stem, but only 0.5 mm of total press fit in the ML dimension. Similar to the M/L Taper stem, the Tri-Lock BPS was

Table 3 The results of the univariate analysis in M/L Taper stem before the 0-mm rasp use.

Variables	Proud group (n = 12)	Non-proud (n = 70)	All (n = 82)	P value
Age (yrs)	55.7 ± 16.4	60.8 ± 16.1		0.312
Gender				0.066
Male	4 (8%)	44 (92%)	48 (100%)	
Female	8 (18%)	36 (82%)	44 (100%)	
Preoperative diagnosis				0.060
Fragility fractures in patients aged 50 years or older	0 (0%)	18 (100%)	18 (100%)	
Others	12 (19%)	52 (81%)	64 (100%)	
Dorr type				0.815
Type A	1 (20%)	4 (80%)	5 (100%)	
Type B	11 (15%)	61 (85%)	72 (100%)	
Type C	0 (0%)	5 (100%)	5 (100%)	
Stem offset				0.173
Standard	11 (18%)	50 (82%)	61 (100%)	
Extended	1 (5%)	20 (95%)	21 (100%)	
Stem size				0.285
4 to 9	8 (19%)	35 (81%)	43 (100%)	
More than 9	4 (10%)	35 (90%)	39 (100%)	
Stem position				0.374
Neutral	12 (18%)	56 (82%)	68 (100%)	
Varus	0 (0%)	8 (100%)	8 (100%)	
Valgus	0 (0%)	6 (100%)	6 (100%)	

Values are presented as mean ± standard deviation or n (%).

Table 4 The results of the univariate analysis in M/L Taper Stem after the 0-mm rasp use.

Variables	Proud (n = 3)	Non-proud (n = 72)	All (n = 75)	P-value
Age (years)	62.0 ± 35.6	61.6 ± 17.1		0.635
Gender				0.241
Male	0 (0%)	48 (100%)	48 (100%)	
Female	3 (11%)	24 (89%)	27 (100%)	
Preoperative diagnosis				0.256
Fragility fractures in patients aged 50 years or older	2 (11%)	23 (89%)	25 (100%)	
Others	1 (2%)	49 (98%)	50 (100%)	
Dorr type				1.000
Type A	0 (0%)	6 (100%)	6 (100%)	
Type B	3 (5%)	61 (95%)	64 (100%)	
Type C	0 (0%)	5 (100%)	5 (100%)	
Stem offset				1.000
Standard	2 (5%)	39 (95%)	41 (100%)	
High	1 (3%)	33 (97%)	34 (100%)	
Stem size				1.000
4 to 9	2 (5%)	42 (95%)	44 (100%)	
Over 9	1 (3%)	30 (97%)	31 (100%)	
Stem position				1.000
Neutral	3 (5%)	60 (95%)	63 (100%)	
Varus	0 (0%)	5 (100%)	5 (100%)	
Valgus	0 (0%)	7 (100%)	7 (100%)	

Values are presented as mean ± standard deviation or n (%).

designed as a broach-only femoral stem. The new Gription porous coating (DePuy) on the Tri-Lock BPS covers up to 63% of the stem surface and offers an enhanced coefficient of friction compared with that of the Porocoat porous coating on the original Tri-Lock BPS [11,12]. The plasma spray porous coating on the M/L Taper stem also has a higher coefficient of friction than the Porocoat porous coating. This increased surface roughness may ensure initial stability of the femoral stem but may also be one of the reasons for the SP of these stems. Proximally coated cementless tapered wedge stems provide good axial fixation within the femoral canal because of contact at the lateral and medial endosteal cortices [12]. Therefore, the press fit of the conventional rasp system may be inappropriate to provide the best fit for the second-generation porous-coated stem in some cases within the resistant lateral and medial cortex.

In this study, the new rasp system of the M/L Taper stem was found to have a substantially decreased SP incidence by decreasing press fit in the ML dimension. We hypothesized that the bone quality of the lateral and medial femoral cortex affected the initial stem seating; however, we did not routinely check bone mineral density in all patients. Despite a lack of statistical significance, there was a lower stem SP incidence in fragility fractures in patients aged 50 years and older than that in patients with other diagnoses in the M/L Taper stem before the 0-mm rasp use. A large number of cases with bone mineral density result should be necessary to evaluate the influence of bone quality on the initial stem seating.

In this study, a positive stem SP was defined as a stem SP height of >2 mm. Zimmer Inc. showed that a new rasp achieved a 99% success rate in initially seating a stem to

within +/- 2 mm of the final rasp seating position [10]. The incidence of stem SP may be much higher if a smaller cut-off was used; however, it would be difficult to measure when considering radiological measurement errors.

Multiple logistic regression analysis revealed that using the high offset stem in the Tri-Lock BPS was the only significant risk factor for stem SP. The Tri-Lock BPS offers a standard and high offset stem. The high offset option lateralizes the stem by 6–8 mm depending on the size without affecting leg length by maintaining a constant 130° neck angle and is usually used for hips with coxa vara or the high-riding greater trochanter to restore tissue tension and avoid impingement of the greater trochanter against the ilium (Fig. 3) [13,14]. Uneven force to the stem from the curved inserter rather than the straight one in femoral morphologies may result in a higher occurrence of stem SP; however, use of the extended offset M/L Taper stem was not a significant risk factor for stem SP. This difference may be a result of the different indications of the two stems. The neck length and vertical height of the M/L Taper stem are longer than the Tri-Lock BPS; therefore, we tend to use the Tri-Lock BPS in patients with coxa vara and short femoral neck length to make conservative neck resections and restore proper leg length. Several studies have shown excellent clinical outcomes from the use of cementless tapered wedge stems with second-generation proximal porous coating surfaces [2–5,11,12]. At our institution, both Tri-Lock BPS and M/L Taper stem have been used in almost all patients with no complications directly associated with stem SP. However, the mismatch between rasps and real stems makes it challenging for surgeons to fine-tune the stem to the patient's anatomy [10].

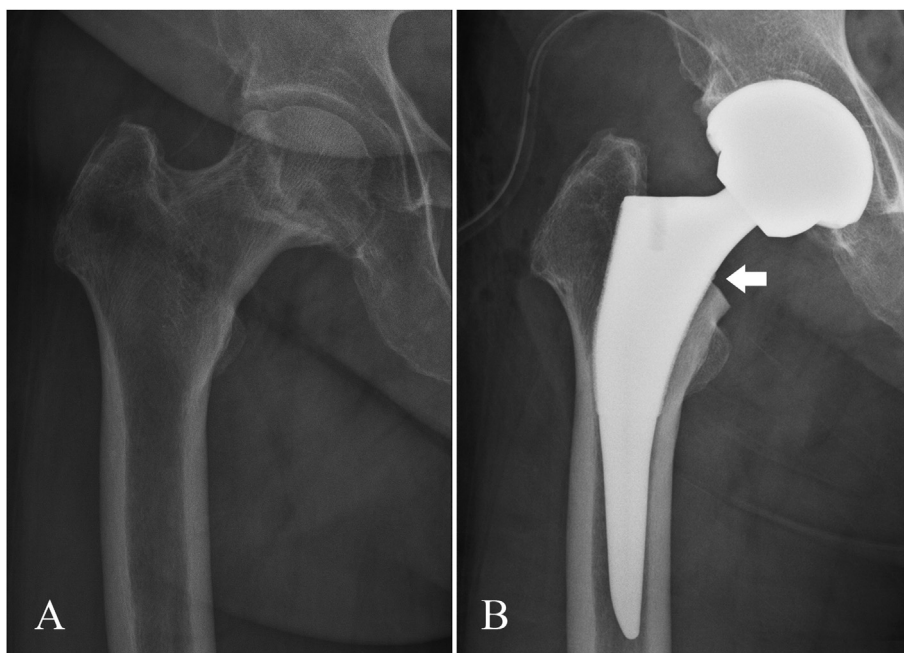


Figure 3 Preoperative and postoperative plain radiographs of the patient who underwent THA using the high offset stem. (A) Preoperative anteroposterior plain radiograph showing osteonecrosis of the femoral head in the right hip with relatively high-riding greater trochanter and short neck. (B) Postoperative plain radiograph showing 4.3-mm proud (arrow) of the high offset Tri-Lock BPS. The shorter offset of the femoral head was used to equalize the limb length in this case.

BPS, Bone Preservation Stem; THA, total hip arthroplasty.

The mismatch results in several potential risks, as prominent SP of the real stem can cause unexpected leg lengthening; in this case, the surgeon should use a short offset femoral head to equalize leg length. Using a short offset head in hip replacement can put the hip at risk of femoral bone impingement against the pelvis during extreme motion [14]. A finite element and retrieval analysis showed that the short neck offset with a 28-mm alumina ceramic head has a potential risk of ceramic failure because of the lowest distance at the inner corner between the roof and tapered bore of the head [7,15]. Although the femoral head fracture rate of BioloX delta ceramic is lower than that of a third-generation alumina ceramic [16], the risk of head fracture still exists and is a critical issue for surgeons who predominantly use the ceramic bearing surface. An additional hammer blow for stem seating can cause a proximal femoral fracture, especially in patients with osteoporosis. Although we cannot determine the direct reason for fracture occurrence based on a retrospective review, there were proximal femoral fractures in 11 (5.8%) of 189 Tri-Lock BPS cases and 6 (6.2%) of 97 M/L Taper stem cases using the conventional rasp system. Nearly all fractures occurred in early case series; therefore, surgeons unfamiliar with these types of stems should be aware of the possibility of stem SP. There was no intraoperative proximal femoral fracture after the 0-mm rasp use. In rare cases, improperly seated stems should be extracted and corrected to a different size to correct LLD; however, this may not guarantee the best press fit of the new stem and can lead to an unintended increase in medical costs. In this study, there was no case requiring stem exchange because of stem SP.

Our study has its limitations as it is a retrospective and single-surgeon study; however, the stem SP incidence was similar to the previous surveillance by Zimmer [10]. Although we categorized the femoral morphology using Dorr classification, the influence of other morphological variables, such as femoral anteversion and deformity of the trochanter, was not evaluated.

In summary, proximally coated cementless tapered wedge stems are associated with potential problems related to stem SP. The newly developed 0-mm rasp of the M/L Taper stem showed significant improvement in initial seating height compared with the conventional rasp system without postoperative stem subsidence. The use of the high offset Tri-Lock BPS was the only risk factor for stem SP, but its clinical significance remains unknown. Therefore, large-scale multicenter studies should be conducted to determine relevant risk factors for SP of these stems using a conventional rasp system, and a long-term follow-up study is needed to evaluate the influence of stem SP on the clinical outcome.

Conflict of Interest

The authors have no conflicts of interest to disclose in relation to this article.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jot.2019.02.002>.

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