MEDICAL SCIENCE MONITOR

CLINICAL RESEARCH

e-ISSN 1643-3750
© Med Sci Monit, 2016; 22: 670-677
DOI: 10.12659/MSM.895709

Received: 2015.08.19
Accepted: 2015.09.22
Published: 2016.02.29

Comparison of Clinical Efficacy Between Modular Cementless Stem Prostheses and Coated Cementless Long-Stem Prostheses on Bone Defect in Hip Revision Arthroplasty

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Data Interpretation D
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Source of support: Departmental sources

Background: The aim of this study was to investigate and compare the clinical efficacy of modular cementless stem and coated cementless long-stem prostheses in hip revision arthroplasty.

Material/Methods: Sixty-five patients with complete hip revision surgery data during January 2005 to March 2015 were selected from the People's Hospital of Linyi City and randomly divided into a S-ROM group (implanted with cementless modular stem prostheses, n=32) and a SLR-PLUS group (implanted with cementless coated long-stem prostheses, n=33). Harris score was used to evaluate the hip function of the patients in order to measure the clinical efficacy of the prostheses in total hip arthroplasty. Anteroposterior pelvic radiographs and lateral pelvic radiographs were taken and each patient's hip arthroplasty condition was recorded. Kaplan-Meier method was applied to compare the cumulative 5-year non-revision rate between the 2 prostheses and log-rank method was used to inspect the statistical data.

Results: The Harris scores of both the S-ROM group and the SLR-PLUS group were significantly higher at 12 months after the operation than those before the operation (both $P<0.05$). The Harris scores of the patients with type I/II bone defects in the S-ROM group were not significantly different from those of the same types in the SLR-PLUS group at all time points (all $P>0.05$), while the Harris scores of the patients with type IIIA/IIIB in the S-ROM group were both significantly higher than those of the same types in the SLR-PLUS group at 3 months, 6 months, and 12 months after the operation (all $P<0.05$). No significant difference was found in the cumulative 5-year non-revision rate between the type I/II patients in the S-ROM group (92.31%) and the patients of the same types in the SLR-PLUS group (85.71%) ($P>0.05$). However, the cumulative 5-year non-revision rate of the type IIIA/IIIB patients in the S-ROM group (89.47%) was significantly different from the patients of the same types in the SLR-PLUS group (42.11%) ($P<0.05$).

Conclusions: The modular stem prostheses in hip revision arthroplasty were clinically more effective in the treatment of type IIIA and IIIB bone defects than the coated long-stem prostheses according to the Harris score and the cumulative 5-year non-revision rate.

MeSH Keywords: **Arthroplasty • Arthroplasty, Replacement, Hip • Hip Prosthesis**

Full-text PDF: http://www.medscimonit.com/abstract/index/idArt/895709

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Background

Post-operative loosening, dislocation, collapse, infection, or other complications of the prostheses may occur after total hip arthroplasty (THA), resulting in great pain. Patients suffering from the pain have to undergo re-implantation of a new prosthesis to improve and restore joint function through hip arthroplasty [1]. The efficacy of hip arthroplasty revision is affected by many factors; the most important ones are bone defects [2], among which the femoral defects most dramatically affect the stability of new prostheses. Previous studies found that different types of new prostheses should be selected according to the type of femoral defects [3–5]. There are 2 categories of new prostheses: cemented ones and uncemented ones. Based on the results of long-term follow-up studies, the uncemented prostheses have been selected as the superior ones in the field of hip arthroplasty because of their advantages in biological fixation [6–9].

The modular stem prostheses and the all-coated long-stem prostheses are 2 types of commonly used clinical uncemented prostheses [10]. The modular stem prostheses are flexible in matching both the far-end and proximal-end of the prostheses and provide different eccentricity, neck length, and geometry shape, able to meet the physical demands of the femur [11]. The all-coated long-stem prostheses are characterized by the stem and the surface coating. The long stem across the proximal end of femoral bone defect region helps to keep the initial stability of the distal femur shaft, and the surface coating can promote the stability of anaphase bone ingrowth and at the same time inhibit bone cement leakage, which may cause multiple losses in bone mass and nonunion [12]. In severe cases of femoral defects, the modular stem prostheses can overcome all kinds of shortcomings that may occur in the cemented femoral prostheses or the uncemented femoral prostheses with modular stem, and can dramatically improve the survival rate of hip arthroplasty patients after the revision surgery [13,14]. At present, there are few studies about the comparison between the modular stem prostheses and the coated long-stem prostheses. Therefore, we conducted a randomized clinical study to compare the clinical efficacy of the 2 prostheses applied in the treatment of bone defects in hip revision arthroplasty.

Material and Methods

Research Subject

Sixty-five patients with complete artificial hip arthroplasty surgery done during January 2005 and March 2015 were selected from the Department of Orthopedics in People's Hospital of Linyi City and were randomly divided into 2 groups, the S-ROM group and the SLR-PLUS group. The S-ROM group consisted of 32 patients implanted with cementless modular stem prostheses (S-ROM, Depuy) (Johnson & Johnson, Warsaw, IN, USA), including 14 males and 18 females, aging from 56 to 77 years old with an average of 65.27±5.32. The SLR-PLUS group consisted of 33 patients implanted with cementless coated long-stem prostheses (SLR-PLUS uncemented stem plus) (produced by Preuss Company), including 16 males and 17 females, aging from 55 to 76 years old with an average of 66.20±4.52. The inclusion criteria were: (1) it was his/her first time to receive hip revision; (2) the time period from the first arthroplasty surgery to the hip revision should be 2~15 years; (3) the patient had completed the surgeries by the same surgeon; (4) the patients had femoral bone defects. The exclusion criteria were: (1) it was his/her second time to receive hip revision; (2) the revision surgery was required due to infection; (3) the patient had uncontrolled high blood pressure, coronary heart disease, cerebrovascular disease, diabetes or other internal diseases; (4) the patient had some disease in nerves and muscles that could affect the lower limb function; (5) the patient had some other conditions that may affect the assessment of the results, such as mental illness; (6) the evaluated score by American Society of Anesthesiologists (ASA) before the revision operation was higher than Level III. This study was approved by the hospital ethnics committee and conformed to the Declaration of Helsinki [15]. Informed consent was received from each patient enrolled in this study before randomization.

Bone defect assessment

The classification of preoperative femoral defects was based on the Paprosky classification [16]: type I was defined as small bone defects in femoral metaphysis with a complete diaphysis; type II was defined as extensive defects in metaphysis with a complete femoral diaphysis; type IIIA was defined as serious damage in femoral metaphysis which causes the loss of supporting, with a complete cortical bone (≥4 cm) detected in the femoral isthmus; type IIIB was defined as serious damage in the femoral metaphysis, with a complete cortical bone (<4 cm) detected from the tip to the isthmus of the femur.

Hip arthroplasty revision

Sufficient and detailed preparations before surgery were made to ensure the successful conduct of the surgeries, including detailed medical history inquiries, full physical examinations, precise Harris scoring, comprehensive assessment of the parenchyma condition of the muscles around the hip and the length of both legs of the patients, and a well-prepared corresponding post-operative rehabilitation program for each patient. Combined anesthesia or general anesthesia was applied to the patients before the first incision was made. After reaching the place of hip dislocation, we removed the granulation,

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scar and bone tissue at the medullary canal entrance and then removed the implant. The method of extended trochanteric osteotomy (ETO) was adopted to remove the bone cement in the medullary canal; the removal of the distal bone cement in the medullary canal was particularly difficult to conduct. The subsequent process of bone reaming and bone implanting was performed according to the design of the selected prostheses. Then, a modular stem prosthesis or an all-coated long-stem prosthesis was fixed after the confirmation of the conditions in the medullary cavity, and a drainage tube was implanted before the suture [17]. The post-operative trapezoid pad was fixed in between the thighs to prevent bone dislocation, and the postoperative antibiotics were administered for 3 consecutive days to prevent infection. Ten mg of rivaroxaban (produced by Bayer Schering Pharma AG) was administered orally 10 hours after the operation and also once daily for the following 35 days in order to prevent deep vein thrombosis. The drainage tube was removed 48 hours after the operation. The quadriceps flexion exercise should be done once daily after the operation, and the walking exercise should be done in the assistance of crutches from the third day after the operation. With the exercises practiced for 3 consecutive months, fully weight bearing of the prostheses would be achieved.

Follow-up

The post-operative planned clinic reviews, 1 month, 3 months, 6 months, and 1 year after the surgery, were conducted in the same hospital in order to assess the hip function using the Harris score and measure the clinical efficacy of the prostheses for bone defects in hip arthroplasty revision, based on pain, function, range of motion, and deformity. The hip function was categorized as excellent (Harris score ≥90), good (Harris score 80~89), medium (Harris score 70~79), or poor (Harris score ≤69) [18]. A 5~10-year long-term follow-up was carried out for all the patients implanted with prostheses and the hip revision was taken as the end point. The last follow-up date was April 30th, 2015; subjects with no hip arthroplasty revision by this date would then be considered as censored data. Among all the 65 patients who were followed up, there were 6 censored cases in the S-ROM group and 5 censored cases in the SLR-PLUS group, and all the follow-up data of the patients were collected through outpatient records, call visits analysis, or medical records reviewing. Anteroposterior pelvic radiographs and lateral pelvic radiographs were taken to record the incision healing status of the patients after hip arthroplasty revision. The Harris scoring and X-ray loose classification criteria were implemented to assess the implant position, bone absorption, and prosthetic loosening situation. If the prostheses shifted, the prosthetic bone cement fracture would be regarded as definite loosening; if a continuous translucent area (>2 mm) appeared around the prostheses, the prosthetic bone cement fracture would be regarded as possible loosening.

Statistical analysis

The SPSS20.0 statistical software package (SPSS Inc, Chicago, IL, USA) was applied for data analyses. The numerical data were presented as means ± standard deviation ($\overline{\chi}$±*s*) and compared by t test (conforming to normal distribution) or by ANOVA (conducting the homogeneity test of variance). The categorical data were presented as percentage or rate and compared by χ^2 test or Fisher's exact test. The Kaplan-Meier method was applied to compare the revision rates in a 5-year period of both prostheses, and the log-rank test was used to test the difference and to calculate 95% confidence interval. $P<0.05$ was considered statistically significant.

Results

Baseline characteristics of the patients

Among the 32 patients in the S-ROM group, who were implanted with cementless modular stem prostheses, there were 3 cases of type I bone defect, 10 cases of type II bone defect, 11 cases of type IIIA bone defect, and 8 cases of type IIIB bone defect. Among the 33 patients in the SLR-PLUS group, who were implanted with cementless coated long-stem prostheses, there were 2 cases of type I bone defect, 12 cases of type II bone defect, 10 cases of type IIIA bone defects, and 9 cases of type IIB bone defect. The differences between the 2 groups in sex, age, time of artificial joint replacement surgery, initial surgery reason, initial surgical procedure, revision reason, and bone defect classified by Paprosky classification were not significant (all $P>0.05$) (Table 1).

Clinical evaluation

The mean Harris score of the patients in S-ROM group was significantly higher 12 months after the operation than that before the operation (85.08±5.43 *vs.* 43.49±9.01, $P<0.05$). There were 8 cases of excellent (>90), 22 cases of good (80–89), 2 cases of medium (70–79), and no cases of poor (<70) hip function 12 months after the operation; the "good" and "excellent" accounted for 93.75%. Similarly, the mean Harris score of the patients in SLR-PLUS group was dramatically higher 12 months after the operation than before the operation (75.62±12.85 *vs.* 43.40±8.18, $P<0.05$). There were 7 cases of excellent (>90), 7 cases of good (80–89), 4 cases of medium (70–79) and 15 cases of poor (<70) hip function 12 months after the operation; the "good" and "excellent" accounted for 42.4%. The Harris score comparison of bone defects with different types in pre-operation and in post-operation for 3 months, 6 months, and 12 months between the S-ROM group and the SLR-PLUS group were statistically significant (all $P<0.05$), and the comparison within and between different types of bone defects at different

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Table 1. Baseline characteristics of the eligible patients.

	S-ROM (n=32)	SLR-PLUS (n=33)	χ^2/t	*P*
Gender (M/F)	14/18	16/17	0.147	0.702
Mean age	65.27±5.32	66.20±4.52	0.760	0.450
Mean time of artificial joint replacement surgery (month)	50.33±8.65	54.23±7.56	1.937	0.057
Initial surgery reason (n)				
Femoral neck fractures	13 (40.63%)	16 (48.48%)	0.527	0.768
Femoral head necrosis	16 (50.00%)	15 (45.45%)		
Ankylosing spondylitis	3 (9.37%)	2 (6.07%)		
Initial surgery procedure (n)				
Artificial femoral head replacement	9 (28.13%)	8 (24.24%)	0.127	0.722
Total hip arthroplasty	23 (71.87%)	25 (75.76%)		
Revision reason (n)				
Aseptic loosening	21 (65.63%)	20 (60.60%)	0.342	0.843
Femoral prostheses subsidence	6 (18.75%)	6 (18.18%)		
Periprosthetic femoral fractures	5 (15.62%)	7 (21.22%)		
Paprosky bone defect classification				
Type I	3 (9.37%)	2 (6.06%)	0.899	0.826
Type II	10 (31.25%)	12 (36.36%)		
Type IIIA	11 (34.38%)	10 (30.30%)		
Type IIIB	8 (25.00%)	9 (27.27%)		

M – male; F – female.

time points of pre-operation and post-operation were statistically significant (all $P<0.05$). The mean Harris scores of type I patients or type II patients were not significantly different at any time point between the S-ROM group and the SLR-PLUS group (all $P>0.05$). However, the Harris scores for type IIIA and type IIIB patients in S-ROM group were significantly higher than those patients in the SLR-PLUS group at 3 month, 6 month and 12 month after the operation (all $P<0.05$) (Table 2).

Survival analysis

The revision rate analysis was conducted with the identification of hip revision as the end point. The cumulative 5-year non-revision rate for the type I patients and type II patients in S-ROM group was 92.31%, and the cumulative 5-year non-revision rate for type I patients and type II patients in SLR-PLUS group was 85.71%; there was no significant difference between the 2 groups ($P=0.586$) (Figure 1A). However, the cumulative 5-year non-revision rate for the type IIIA/IIIB patients in S-ROM group was 89.47%, and the cumulative 5-year non-revision rate for type IIIA/IIIB patients in SLR-PLUS group was 42.11%; there was a significant difference between the 2 groups ($P=0.0271$) (Figure 1B).

Radiologic imaging findings

The associated radiologic findings between the 2 groups were as follows. The refurbishment program for the 8-year hybrid hip replacement (femoral biotypes + acetabular bone cemented type): impaction bone grafting of the femur + modular stem prostheses (Figure 2A, 2B). The refurbishment program for the 15-year total hip arthroplasty: structural bone grafting + particle bone grafting + all-coated long-stem prostheses + steel and titanium nails with internal fixation (Figure 3A, 3B). The femur stem conditions of all the patients were good with no varus or valgus, and there was no case of femoral stem displacement within 1 year after the operation (the angular variation of varus or valgus >30).

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Table 2. Preoperative and postoperative (1, 3, 6, 12 months) Harris score comparison between the S-ROM group and SLR-PLUS group.

	S-ROM	SLR-PLUS	t	*P*
Pre-operation				
I (3–2)	58.50±6.60	57.30±5.60	0.2092	0.8477
II (10–12)	48.20±5.44	49.45±4.54	0.588	0.5631
IIIA (11–10)	42.40±4.27	41.30±3.28	0.6568	0.5192
IIIB (8–9)	33.48±6.21	34.58±5.22	0.3969	0.697
One month after operation				
I	60.25±3.58	59.34±2.63	0.3026	0.7819
II	54.28±6.22	52.18±5.22	0.8617	0.3991
IIIA	48.26±4.26	47.38±3.44	0.5173	0.6109
IIIB	39.36±5.29	41.39±3.28	0.9636	0.3505
Three months after operation				
I	75.41±4.27	72.31±3.27	0.8565	0.4547
II	65.23±5.24	63.43±4.14	0.9007	0.3784
IIIA	56.52±3.34	50.68±5.22	3.084	0.0061
IIIB	51.25±4.56	42.56±3.23	4.577	0.0004
Six months after operation				
I	84.01±4.24	82.21±3.24	0.5011	0.6508
II	76.33±4.95	74.23±5.15	0.9691	0.3441
IIIA	65.09±4.09	58.24±3.24	4.224	0.0005
IIIB	62.00±2.65	54.42±5.34	3.628	0.0025
Twelve months after operation				
I	88.01±4.24	85.31±3.62	0.7314	0.5175
II	89.89±3.55	90.21±4.55	0.181	0.8582
IIIA	83.09±3.27	68.34±4.13	9.118	<0.001
IIIB	80.71±5.41	62.09±4.09	8.064	<0.001

Discussion

The lesions in soft tissue, bone, and many other parts around the prostheses and the treatment delay may cause complex bone defect issues, for which the hip arthroplasty has developed into a routine clinical surgery. However, orthopedic surgeons are always faced with great challenges due to the selection of bone defect treatment and the development of new prostheses implanting technology [19]. According to the current clinical research, patients implanted with either modular stem prostheses or all-coated long-stem prostheses could achieve good outcomes [20–22]. Our study aimed to analyze and compare the clinical efficacy of modular stem prostheses and all-coated long-stem prostheses applied for the treatment of bone defects in hip arthroplasty. The results showed that the Harris scores and the cumulative 5-year non-revision rates of both type IIIA and type IIIB patients implanted with modular stem prostheses were higher than those of the same types implanted with all-coated long-stem prostheses.

The results of this study indicated that the Harris scores of the S-ROM patients and the SLR-PLUS patients were both significantly higher at 12 months after the operation than those before the operation, and the radiographic analysis of the femoral stem condition was good, with no cases of displacement, which was consistent with the results of previous studies [20–22].

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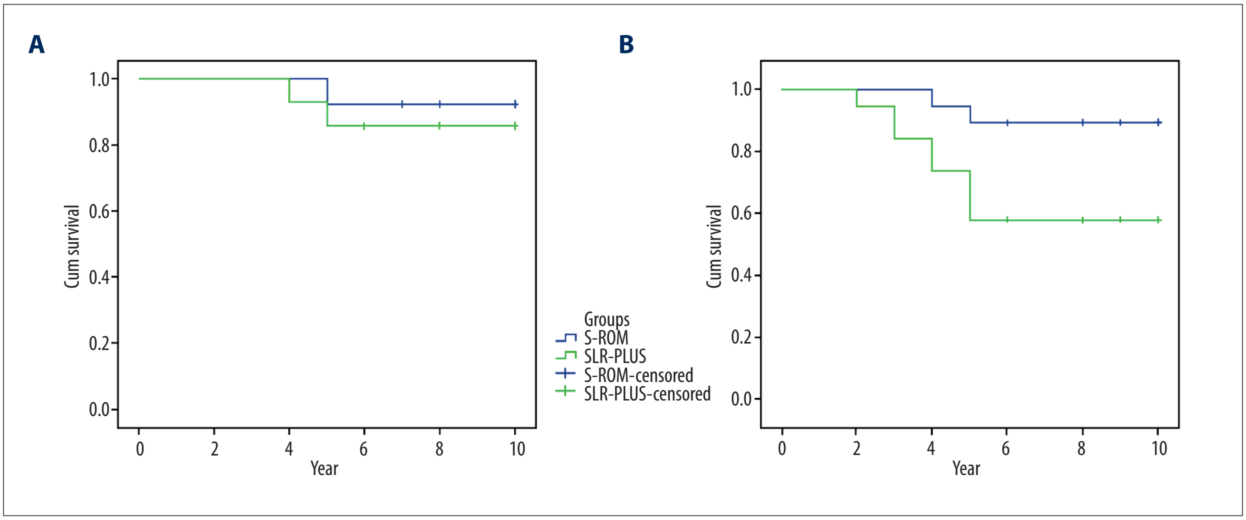

Figure 1. The cumulative 5-year non-revision rate curve of bone defects in S-ROM and SLR-PLUS groups (**A**: type I and type II; **B**: type IIIA and type IIIB).

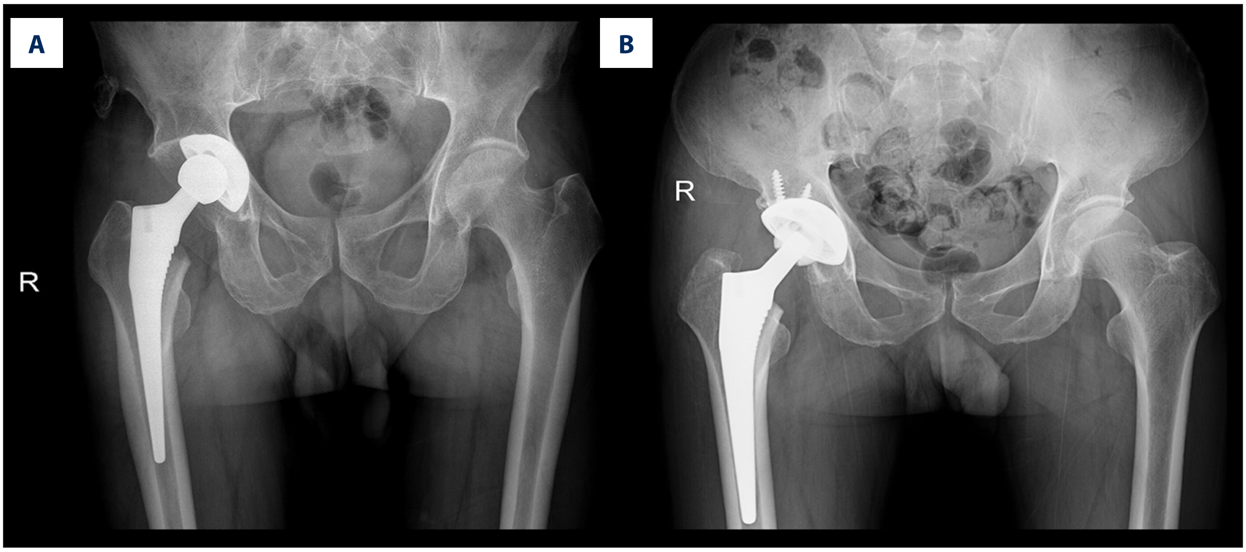

Figure 2. The X-ray diagram of the cementless modular stem prostheses (**A**: Pre-operation; **B**: 12 months after the operation).

The Harris scores for type I and type II patients in the S-ROM group at 3 months, 6 months, and 12 months after the operation showed no significant difference from those of patients in the SLR-PLUS group at the same time point, while the Harris scores of type IIIA and type IIIB patients in the S-ROM group were significantly higher than those of the same types in SLR-PLUS group. Revision of the hip arthroplasty within a 10-year post-operation period was taken as the end point. The cumulative 5-year non-revision rates of type I and type II patients in the S-ROM group were not significantly different from those of the same types in the SLR-PLUS group, but the cumulative 5-year non-revision rates of type IIIA and type IIIB patients in the S-ROM group was significantly higher than those of the same types in the SLR-PLUS group. Therefore, the modular stem prostheses achieved better therapeutic efficacy compared to the all-coated long-stem prostheses in serious cases of bone defects. Previous studies showed that patients with type I, type II, and type IIIA bone defects had in normal distal femur volume and the femur defect was only limited at its proximal end, so more reconstruction methods were potentially applicable, especially for type I and type II bone defects [23,24]. As for type IIIA bone defects, there were only partial bone defects in the femoral metaphysis and diaphysis, so 20 cm of fixed distal femoral stem prostheses were required [3]. However, the IIIB-type bone defects varied greatly in femoral metaphysis and diaphysis, and the length of the possible distal fixation of the femoral shaft was less than 4 cm, so even longer distal fixation prostheses or modular stem prostheses were required [25]. The results indicated that the use of modular stem prostheses for the type IIIA and type IIIB

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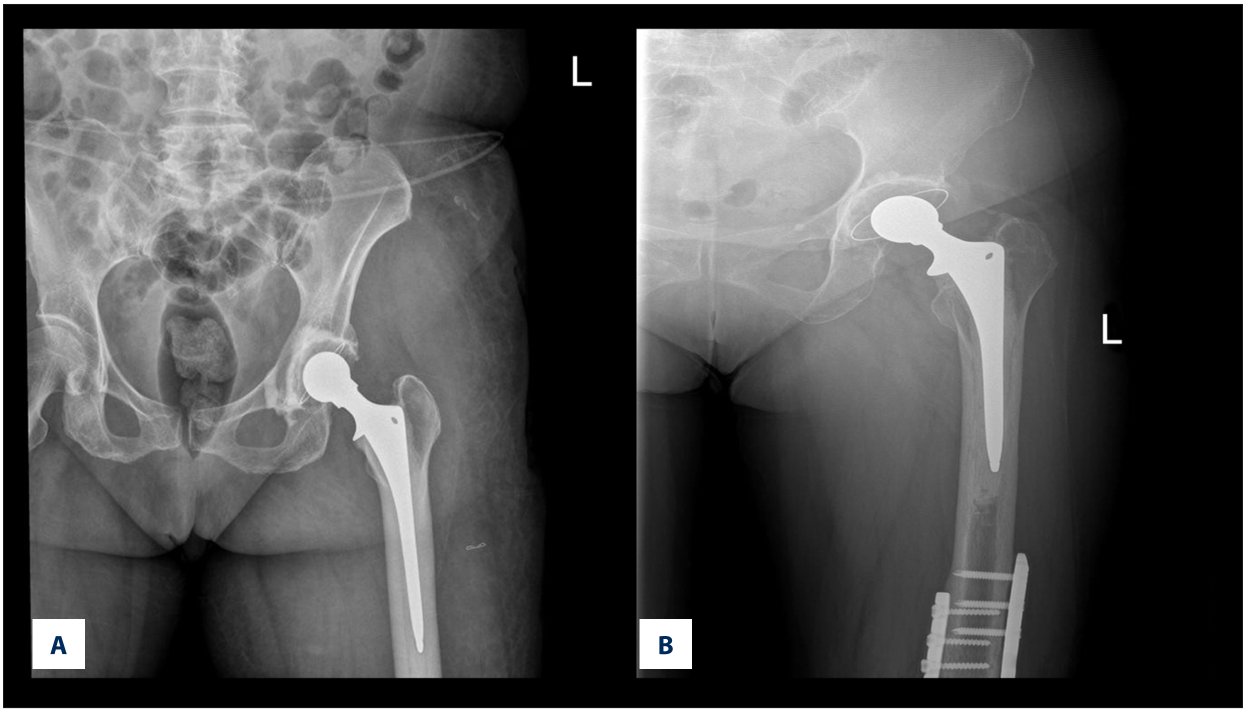

Figure 3. The X-ray diagram of the cementless coated long-stem prostheses (**A**: Pre-operation; **B**: 12 months after the operation).

patients had a unique advantage in the treatment of serious and irregular bone defects in femoral metaphysis and diaphysis, and better results could be achieved [8]. The major reason for this was that all-coated long-stem prostheses were single-stem prostheses, which can hardly solve the problems of femoral offset, neck length, shaft angle, and other factors involved in type IIIA and type IIIB bone defects. However, the modular stem prostheses were designed especially for complicated hip arthroplasty, such as the congenital hip dislocation and femur deformities, to meet the physical demands of the femur to the greatest extent possible by providing different eccentricities, neck lengths, and geometry shapes [26].

With the wide application of THA in hip arthroplasty disease and other clinical diseases, various prostheses complications occurred and more revision surgeries are needed, increasing the number of hip arthroplasty surgeries challenged by many technical limitations [19]. The development of uncemented prostheses has gradually developed into a major focus in the hip arthroplasty field.

Conclusions

Based on the analysis and comparison of the clinical efficacy between the modular stem prostheses and the coated long-stem prostheses implanted for patients with type IIIA and type IIIB femoral defects, our study provides more evidence and further insights into the selection of prostheses to achieve better therapeutic outcomes in hip arthroplasty.

Acknowledgments

We would like to give our sincere appreciation to the reviewers for their helpful comments on this article.

Competing interests

The authors have declared that no competing interests exist.

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