

Clinical Application and Evaluation of a New Combined Hip Prosthesis System: A Multicenter Randomized Controlled Non-inferiority Study

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Abstract

Background: To evaluate the efficacy and safety of a new hip prosthetic system compared with the control group.

Methods: A total of 140 patients (140 hips) who met the inclusion criteria in three clinical institutions were selected. The main outcome were to judge the excellent and good rate of Harris score in the experimental group and the control group 5 years after operation, and whether the lower limit of the 95% confidence interval of the difference between the two groups was greater than the non-inferior threshold (the non-inferior cutoff value was -10%). The secondary outcome were the comparison of Harris scores, the number of adverse events, safety test and evaluation, the results of X-ray films and the concise health status questionnaire (SF-36) between the two groups before operation and after operation.

Results: During the 5-year follow-up, the excellent and good rates of Harris scores in the experimental group and the control group were 96.8% and 96.7% respectively, and the rate difference was 0.1%. The lower limit of the 95% confidence interval was -8.9%, which was greater than the non-inferiority boundary value (the non-inferiority boundary value was -10%). There was no significant difference in Harris score, adverse events, safety test, imaging, and SF-36 analysis between the two groups before operation and after operation.

Conclusion: The new combined hip prosthesis system meets the requirements of clinical safety and effectiveness, and is worth popularizing in clinical application.

Trial registration: researchregistry, researchregistry5771. Registered 1 July 2020 - Retrospectively registered. <https://www.researchregistry.com/researchregistry5771>

Background

In 1938, Phillip wiles performed the first total hip arthroplasty [1]. The prosthesis was designed with stainless steel, but the design failed soon after operation because of loosening. Then, Charnley [2], known as the father of modern total hip arthroplasty, put forward the concept of "metal-plastic" total hip replacement for the first time, and found a low-wear material-ultra-high molecular polyethylene. He boldly applied this new material to the acetabular cup and achieved good results. Therefore, the compatibility of metal and ultra-high molecular weight polyethylene determines its clinical application status.

With the in-depth study of biomechanics of hip joint, the selection and design concept of prosthesis materials have been further optimized. Zirconia [3], alumina composite ceramics [4] and radiation crosslinked ultra-high molecular weight polyethylene (UHMWPE) have relatively prolonged the life of the prosthesis, and achieved good clinical results[5].

Now, hip arthroplasty has become the ultimate treatment for hip disease, and its materials are varied.

A company in Beijing has developed a new total hip prosthesis system: zirconia-based composite ceramic [6] is used in the design of the femoral head and forged titanium alloy coated with hydroxyapatite coating on the femoral handle, combined with radiation crosslinked ultra-high molecular weight polyethylene acetabular lining and forged titanium alloy acetabular cup to form a complete total hip prosthesis system- a new combined hip prosthesis system, as shown in Fig. 1. The product entered the clinical verification stage in 2013, and this study evaluated the postoperative efficacy and safety of the experimental group.

Methods

1.1 Object.

1.1.1 Inclusion criteria.

- (1) the inpatient who signed the informed consent form;
- (2) the age is 18 and 75 years old;
- (3) male or female who is not in pregnancy or lactation;
- (4) patients with surgical indications and planning to undergo artificial hip arthroplasty.

Only if all the above contents are "yes" can you be selected.

1.1.2 Exclusion criteria.

- (1) participated in other clinical trials within 3 months before the start of the study;
- (2) patients with local infection of hip joint;
- (3) complicated with serious diseases, such as heart disease, pulmonary valve insufficiency, diabetes and so on;
- (4) patients with special medical history;
- (5) patients with embolism of heart, brain and other important organs;
- (6) acute and chronic infection with local or systemic infection;
- (7) Bone defect;
- (8) The patient has severe osteoporosis;
- (9) Those with a history of allergic reactions to various substances, showing moderate allergic reactions, are not suitable for in vivo implants;

(10) In any case, the researcher considers the patient to be unsuitable for this treatment;

(11) There are other factors affecting the efficacy of this study.

Only if all the above items are "no".

1.1.3 Criteria and procedures for stopping the test

If a subject experiences a serious adverse reaction, or if the study physician feels that it is not in the best interest of the patient to continue participating in the study, the physician may decide to withdraw the subject from the study. If this happens, the physician will notify the patient in a timely manner and recommend appropriate alternatives. If the doctor believes that the abrupt interruption of the trial will affect the subject's health, the patient may be asked to come to the hospital for a check-up before stopping the trial.

1.2 Research method.

This clinical trial is conducted in strict accordance with the Helsinki Declaration, the current laws and regulations of China, and the requirements of this trial program, and the clinical trial program has been approved by the ethics committees of various institutions. Since the experiment was not registered with National Clinical Trial at the beginning, we registered on the researchregistry website with the registration number researchregistry5771.

During the period from November 2013 to March 2015, the test methods adopted the method of stratified section randomization, according to the central stratification, given the number of seeds and the length of the section, according to the experimental group (GS- N2 combined hip prosthesis system) and the control group (Corail femoral stem, Biolog Delta femoral head, and Duraloc acetabular) 1:1 proportion, 1:1 proportion in three centers, resulting in a random grouping arrangement of a total of 140 subjects, that is, the treatment assignment (random code table) with the running number of 001-140 is listed, and the running number is corresponding to the subject number. The random code table is kept by a person designated by each center. Before the study began, all subjects signed informed consent.

1.2.1 Treatment

Patients were disinfected routinely in supine position or contralateral position. According to the doctor's experience, take the hip incision to enter layer by layer, open the joint capsule, amputate the femoral neck at 1-1.5cm on the lesser trochanter of the femur, remove the femoral head, expose the acetabulum, and deal with the acetabular part first. To trim the acetabulum with different types of acetabular files, the doctor must first fix the acetabulum at the right angle and position. According to the doctor's preoperative measurement and intraoperative acetabular repair, the doctor should choose the suitable acetabular prosthesis implantation, and the doctor should judge whether to use bone cement according to the type of prosthesis. To deal with the femoral bone marrow cavity, put the box-type pulp opener close to the posterior bone cortex of the femur, and accurately open the pulp is a prerequisite for the correct insertion

of the femoral bone marrow cavity file. The measurement result of preoperative X-ray film is the basis to judge whether the type of prosthesis is appropriate or not during operation. Select a suitable femoral stem prosthesis to be implanted into the femoral bone marrow cavity (Co-Cr-Mo alloy femoral handle should be used with bone cement), install the femoral head, hit the femoral head lightly with a ball-head impactor, and then reduce it.

1.3 Statistical processing.

Because the medical device can not set blindness to the operating doctor, so it adopts single blind design and only sets blindness to patients.

Non-inferiority test and confidence interval method were used to determine the Harris score of the curative effect outcome 5 years after operation, the classified variables were expressed by quantity and percentage, and the continuous variables were expressed by mean \pm standard deviation.

After the normal distribution of continuous variables was tested by Shapiro-Wilk test, t-test or Mann-WhitneyU test was used to compare the two groups. The classification variables were compared by Pearsons χ^2 test or Fisher, exact test. According to the deviation of the scheme in the experiment, the safety set (SS), the full analysis set (FAS) and the Per Protocol Set (PPS), were established and statistically analyzed.

1.3.1 Description of validity parameters

In this clinical trial, Harris score was adopted as the main efficacy evaluation outcome, and the specific scoring criteria were as follows: the full mark of Harris score was 100, including 44 for pain, 47 for function, 5 for range of motion, 4 for deformity and 10 for flexion deformity. 90-100 is excellent, 80-90 is good, 70-80 is medium, and less than 70 is poor.

1.3.2 Safety evaluation method.

Blood routine test (hemoglobin, platelet, leukocyte and neutrophil percentage), urine routine (urine red blood cell, white blood cell, urinary protein and glucose), liver and kidney function (ALT,AST,BUN and Cr) and electrocardiogram were performed in the experimental group and control group within 7 days before operation and 7 days after operation. In addition to the above examination, the long-term safety of the product was observed by hip X-ray within 7 days before operation, 6 months and 5 years after operation, and the stability of the prosthesis was evaluated, and whether loosening, dislocation, deformation and osteolysis occurred after implantation. The number of adverse events in the test group and the control group within 6 months and 5 years after operation were statistically analyzed.

1.3.3 Procedures for replacing subjects.

If the subjects decide to withdraw from the test because of their own will, and on the premise that no adverse reactions occur during the trial, in order to ensure that the number of cases in the trial meets the

statistical needs, other patients who meet the requirements can be selected to replace the withdrawing subjects. If the doctor thinks that the sudden interruption of the test will affect the subject's health, he may be asked to come to the hospital for an examination before stopping the trial.

1.4 Outcome Indicators

1.4.1 Main Indicators:

It was calculated whether the lower limit of the 95% confidence interval between the experimental group and the control group was greater than the non-inferiority margin of -10%.

1.4.2 Secondary outcome indicators:

- (1). Comparison of Harris score before operation, 6 months and 5 years after operation between the two groups.
- (2). To compare the number of adverse events between the experimental group and the control group during the observation period of 6 months and 5 years after this trial. Adverse events include prosthesis loosening, prosthesis wear, prosthesis fracture and prosthesis upward / posterior dislocation.
- (3). Compare the safety test before and 7 days after operation between the experimental group and the control group.
- (4). To compare the X-ray results of the experimental group and the control group, and 5. To compare the scores of the concise health status questionnaire (SF-36) before operation, 6 months and 5 years after operation between the experimental group and the control group.

1.5 Data processing.

1.5.1 sample size estimation:

The excellent and good rate in the control group after operation $\pi=0.95$, Non-inferiority cutoff value $\delta=0.1$. Test the level of significance $\alpha=0.05$, Degree of control $(1-\beta) = 0.8$, According to the formula

$\tilde{N} = 2(Z_{1-\alpha} + Z_{1-\beta})^2 \pi(1-\pi) / \delta^2$, At least 59 subjects need to be selected in each group, and the test drop rate is conservatively estimated to be 15%. In this experiment, the sample size of each group is determined to be $59 / (1-0.15) \approx 70$ cases, and the total sample size is 140 cases.

1.5.2 Minimum and maximum number of subjects per clinical trial institution in multicenter clinical trials.

There were 140 cases in 3 clinical centers, and the distribution of the number was basically shared according to the proportion of 1:1:1. However, because the enrollment situation of each center is different, on the basis of not affecting the statistical significance and ensuring the total number of cases, each clinical institution undertakes 23 ± 5 cases in the experimental group and the control group. The

significance level of the test was $\alpha = 0.05$, and the degree of control ($1-\beta$) was 0.8. The test drop rate is conservatively estimated to be 15%.

1.5.3 Eligibility / disqualification criteria for clinical trial results.

The patients who met the enrollment criteria, completed the operation and followed up for 5 years \pm 1 month, and obtained the Harris score of the curative effect outcome were qualified cases.

The cases of program deviation were unqualified cases, and the unqualified criteria were as follows: discontinuation of adverse reactions, change of treatment plan after operation, poor compliance, visiting hyper window, loss of follow-up, not meeting the inclusion and exclusion criteria, randomization failure or blindness.

1.5.4 Statistical procedures for all data, together with processors for missing, unused or erroneous data (including midway exit and withdrawal) and unreasonable data.

All the patients in the clinical trial who met the enrollment criteria and underwent preoperative safety evaluation and surgery constituted the Intent to treat (ITT) population in the study (Figure 2). All patients who completed surgery (including operation failure) who met the inclusion criteria were enrolled in the SS. All patients who completed surgery (including patients who lost follow-up after operation) entered FAS. All patients who had been observed for 5 years \pm 1 month and completed the survey of Harris scale were enrolled in PPS.

Carry forward the missing data of SS and FAS respectively, in order to make the test results fully credible, do not carry forward the missing data of the standard control group, the missing data of the test group is the least conducive to the carry-over of the test results, that is, for the SS, the missing data are carried forward according to the adverse reactions, for the FAS, the Harris score of the curative effect outcome is carried forward according to the lowest score of the test group. At the same time, the carry-over and uncarried-over SS and FAS are analyzed.

1.5.5 Procedures for reporting deviations from the original statistical plan.

For the cases of program deviation, the composition of each deviation type was reported according to the deviation type, the percentage and total rate of each deviation type were calculated, and whether each deviation case was included in FAS and PPS was reported.

1.5.6 Selection criteria and reasons for subjects included in the analysis.

In order to ensure the full credibility of the test results, all the patients who completed the operation (including operation failure) entered the SS, all the successful patients entered the FAS, and those without program deviation entered the PPS.

Results

2.1 Baseline of the characteristics

A total of 140 patients were enrolled in this study, including 70 patients in the experimental group and 70 patients in the control group. As shown in Table 1, there was no significant difference in baseline data such as sex, age, BMI, major complications and Harris scores between the two groups (all $P > 0.05$), suggesting comparability.

Table 1
Basic data of patients in each group

Basic information	Experimental group	Control group	P value
Age (year)	64.1 ± 25.0	63.3 ± 26.8	> 0.05
Male/female	32/38	30/40	> 0.05*
BMI (kg/ m ²)	24.7 ± 4.6	23.4 ± 4.9	> 0.05
Preoperative complication (n)			
Copo	5	3	> 0.05*
Hypertension	15	13	> 0.05*
Preoperative hip Harris score	49.7 ± 10.3	52.4 ± 11.9	> 0.05
Note: * is the P value of chi-square test, and the remainder is the P value of T-test.			

2.2 Effectiveness Evaluation (FAS and PPS)

The experimental group was randomly enrolled in 70 patients, all of whom were successfully operated, among whom 6 patients were lost to follow-up in the 5th year, with a loss to follow-up rate of 8.5%.

The control group included 70 patients, all of whom were operated successfully, including 8 patients lost to follow-up in the 5th year, with a loss to follow-up rate of 11.4%. (Fig. 2)

As shown in Table 2, the excellent and good rates of the experimental group and the control group were 88.6% and 85.7% in FAS during 5-year postoperative follow-up, and the difference between the excellent and good rates of the experimental group and the control group was 2.9%. The lower limit of the 95% confidence interval was - 8.6%, which was larger than the non-inferiority margin (the non-inferiority margin was - 10%).

Table 2
Comparison of excellent and good rates between the two groups 5 years after surgery

	EG			CG			Rate Difference	95% CI
	N.	n	Rate	N	n	Rate		
FAS	70	62	88.6%	70	60	85.7%	2.9%	-8.6% – 14.3%
PPS	64	62	96.8%	62	60	96.7%	0.1%	-8.9% – 9.4%

Note: EG: Experimental Group, CG: Control Group, N: total number of patients, N: Number of patients with excellent and good Harris score, FAS: Full Analysis Set, PPS: Per Protocol Set

In PPS, the excellent and good rates of the experimental group and the control group were 96.8% and 96.7%, respectively, and the difference between the good and good rates of the experimental group and the control group was 0.1%. The lower limit of the 95% confidence interval was – 8.9%, which was larger than the non-inferiority margin (the non-inferiority margin was – 10%).

The above results suggest that the non-inferiority hypothesis of the main outcomes is valid.

2.3 Comparison of Harris score before operation, 6 months and 5 years after operation between the two groups.

The t-test of two independent samples showed that there was no significant difference in Harris score between the experimental group and the control group within 7 days before operation, 6 months after operation and 5 years after operation. As shown in Table 3.

Table 3
comparison of Harris scores before operation, 6 months and 5 years after operation between the experimental group and the control group

	EG	CG	t value	P value
Harris score(Mean ± SD)				
Preoperative	49.7 ± 10.3	52.4 ± 9.1	-1.6	0.10
Six months after surgery	84.7 ± 9.5	85.6 ± 10.2	-0.5	0.59
Five years after surgery	88.3 ± 10.6	87.5 ± 9.4	0.4	0.63

Note: EG: Experimental Group, CG: Control Group,

2.4 Imaging evaluation of two groups of patients before and after operation.

2.4.1 Comparison of imaging material between the two groups.

The patient was an elderly male who was diagnosed as right steroid-induced osteonecrosis of the femoral head (ARCO stage: IV) and underwent total hip arthroplasty (The new hip prosthesis). No special discomfort was reported during the follow-up 5 years after operation. As shown in Fig. 3.

The patient was an elderly male who was diagnosed as right femoral head necrosis (ARCO stage: stage IV) and underwent total hip arthroplasty (The prosthesis of the control group). No special discomfort was reported during the follow-up 5 years after operation. As shown in Fig. 4.

2.5 Comparison of the number of adverse events.

In PPS, one patient in the experimental group developed posterior dislocation of the prosthesis at 2 months and recovered well after manual reduction. The incidence of adverse events in the experimental group was 1.5%. In the control group, 2 patients developed posterior dislocation of the prosthesis at 2 and 3 months after operation, and manual reduction was performed under intraspinal anesthesia, and the recovery was good. The incidence of adverse events in the control group was 3.2%. No other adverse events were found. Chi-square test between the two groups showed that there was no significant relationship between the type of prosthesis and adverse events 5 years after operation ($P > 0.05$). As shown in Table 4.

Table 4
Comparison between groups and adverse events.

Group	Whether adverse events have occurred		Chi-square value	P value
	YES(n)	NO(n)		
Experimental group	1	63	0.0	1.0
Control group	2	60		

Note: n: the number of events. Chi-square value: continuity correction chi-square test.

2.6 SS: Safety test results

Within 7 days before operation and 7 days after operation, the blood routine, urine routine, blood biochemistry, blood coagulation function, liver and kidney function and ECG were compared between the test group and the control group, and judged according to the range of normal value and the test results of the subjects. it can be divided into three conditions: normal, abnormal has no clinical significance, abnormal has clinical significance.

According to the statistics of various outcomes, no abnormality is found in all the outcomes before and after operation. There was no difference in the results of safety test before and after operation.

2.7 Comparison of the scores of the Concise Health status questionnaire (SF-36).

The t-test results of two independent samples showed that there was no significant difference in all SF-36 outcomes between the experimental group and the control group before operation.

During the follow-up of 6 months and 5 years after operation, the SF-36 scores of the two groups were compared. The t-test results of the two independent samples showed that there was no significant difference in the outcomes between the two groups ($P > 0.05$), as shown in Table 5 and Fig. 5.

Table 5

comparison of SF-36 scores between the test group and the control group before operation and 6 months after operation and 5 years after operation.

Patients	EG (Mean ± SD)	CG (Mean ± SD)	T value	P value
Preoperative	(n = 70)	(n = 70)		
PF	70.25 ± 17.63	71.52 ± 15.74	-0.37	0.71
RP	34.56 ± 40.45	35.73 ± 45.23	-0.28	0.78
BP	58.53 ± 23.05	56.78 ± 21.34	0.54	0.59
GH	55.40 ± 20.47	58.64 ± 20.53	-0.88	0.37
VT	73.24 ± 17.35	70.56 ± 19.34	0.98	0.32
SF	60.82 ± 27.24	62.34 ± 25.35	-0.45	0.65
RE	33.45 ± 30.56	30.48 ± 27.87	0.62	0.53
MH	60.12 ± 16.39	57.18 ± 39.14	0.59	0.55
Six months after operation	(n = 65)	(n = 64)		
PF	84.23 ± 12.64	85.37 ± 11.10	-0.49	0.63
RP	75.59 ± 16.25	73.05 ± 15.36	0.73	0.46
BP	68.45 ± 19.38	70.47 ± 17.50	-0.66	0.50
GH	76.38 ± 11.30	79.26 ± 18.75	-1.13	0.25
VT	86.24 ± 10.47	85.46 ± 13.59	0.49	0.62
SF	75.58 ± 16.76	79.63 ± 18.57	-1.33	0.18
RE	69.91 ± 13.36	71.27 ± 14.21	-0.42	0.67
MH	72.37 ± 14.15	74.37 ± 10.65	-0.93	0.35
5 years after operation	(n = 64)	(n = 62)		
PF	86.51 ± 11.72	88.26 ± 10.47	0.88	0.37
RP	77.46 ± 13.74	76.81 ± 14.63	0.25	0.79
BP	69.85 ± 17.84	71.32 ± 16.92	-0.47	0.63
GH	79.81 ± 13.53	80.41 ± 14.19	-0.23	0.81

Note: n: the number of patients. EG: Experimental Group, CG: Control Group. PF: Physiological Function, RP: Role Physical, BP: Body Pain, GH: General Health, VT: Vitality, SF: Social Function, RE: Emotional Role MH: Mental Health

Patients	EG (Mean ± SD)	CG (Mean ± SD)	T value	P value
VT	88.35 ± 9.54	86.07 ± 12.32	1.1	0.24
SF	76.96 ± 15.08	80.57 ± 17.65	-1.2	0.21
RE	71.48 ± 12.53	72.16 ± 15.70	-0.2	0.78
MH	75.83 ± 13.32	77.58 ± 11.03	-0.8	0.42

Note: n: the number of patients. EG: Experimental Group, CG: Control Group. PF: Physiological Function, RP: Role Physical, BP: Body Pain, GH: General Health, VT: Vitality, SF: Social Function, RE: Emotional Role MH: Mental Health

Discussion

During the 5-year follow-up in this study, the excellent and good rates of the experimental group and the control group were 88.6% and 85.7% in FAS, respectively, and the difference between the experimental group and the control group was 2.9%. The lower limit of the 95% confidence interval was -8.6%, which was greater than the non-inferior boundary value (the non-inferior boundary value was -10%). During the 5-year follow-up, the excellent and good rates of the experimental group and the control group were 96.8% and 96.7% in PPS, respectively, and the difference between the experimental group and the control group was 0.1%. The lower limit of the 95% confidence interval was -8.9%, which was greater than the non-inferior boundary value (the non-inferior boundary value was -10%). There was no significant difference between the two groups in terms of postoperative safety and SF-36 at 6 months and 5 years after operation. Chi-square test between the two groups showed that there was no significant relationship between the type of prosthesis and adverse events 5 years after operation ($P > 0.05$). There was no difference in the results of safety test before and after operation. The above results suggest that compared with the prosthesis of the control group commonly used in clinic, the new hip prosthesis system has similar efficacy and safety.

Total hip arthroplasty is a common method for the treatment of old femoral neck fracture, osteonecrosis of the femoral head, degenerative osteoarthritis and so on. The advantage lies in better recovery of hip joint function, relief of pain and improvement of patients' quality of life. At first, it was mainly used in the elderly or other patients with limited motor ability, but now more and more patients with severe hip disease choose this procedure for better quality of life [10]. Improving the friction loss of the stress surface of the prosthesis is an effective means to increase the service life of the prosthesis. At present, there are three ways to achieve this goal: first, the use of highly crosslinked ultra-high molecular weight polyethylene (UHMWPE). The second is alumina ceramics, and the third is metal. A high degree of cross-linking state can significantly increase the wear resistance of UHMWPE without harming other important properties of the material. Wear and tear of acetabular components based on highly cross-linked UHMWPE is almost impossible to measure during the expected clinical life [11]. We found that osteolysis

occurred in 2 patients in the experimental group during the 5-year follow-up, which may be related to the release of wear particles by polyethylene wear, which leads to inflammatory reaction.

Alumina ceramic, as a bioceramic, can provide high mechanical strength and no rejection, is non-toxic to tissue, and has blood compatibility [4, 12, 13]. In addition, zirconia ceramics have been widely used in total hip arthroplasty[14]. Among all ceramics, zirconia has excellent wear resistance, which makes zirconia a substitute for alumina in THA [15]. Due to the high brittleness of ceramics, obesity, strenuous exercise and trauma may cause ceramic damage, but in these cases, the load on the friction surface of ceramic joints is still far lower than the failure limit of ceramic materials.

Zirconia ceramics are expensive and require a doctor to guide patients with postoperative exercise to prevent noise caused by friction during early exercise[16]. The main problem of polyethylene on metal prosthesis is the formation of polyethylene wear debris, which causes osteolysis around the prosthesis by releasing cytokines and proteolytic enzymes, resulting in the failure of prosthesis implantation[17]. Polyethylene wear is considered to be the ultimate cause of the failure of most joint replacements [18]. Aseptic loosening leads to an increase in the revision rate of the hip joint. Compared with metal-to-polyethylene, the advantage of ceramic over ceramic prosthesis lies in its high level of hardness and friction resistance, but it also has corresponding disadvantages, such as abnormal noise during movement[19–22]. In addition, the hydrophilic prosthesis can improve lubrication, reduce friction coefficient and have excellent wear resistance. Therefore, due to the reduction of wear, ceramics are an ideal choice for implants for young patients.

Although total hip arthroplasty is widely used in clinic, it also has related adverse reactions, such as prosthesis loosening, abnormal noise, prosthesis wear, prosthesis fracture and prosthesis upward / posterior dislocation, this is related to the surgeon's technique and the material of the prosthesis as well as the patient's physical condition[23].

There were 3 patients with posterior dislocation of the hip in this study. the factors affecting the rate of dislocation included: (1) patient factors, such as sex, hip muscle weakness, excessive drinking and age; (2) surgical factors, such as surgical methods, excision or repair of the joint capsule, and the location of the implant; (3) implantation factors, such as femoral neck length, offset and head diameter. Some studies have found that dislocation is more likely to occur in the first three months after operation, and the risk is reduced after that [24]. Prietzel et al.[25] clearly recommended that the hip joint capsule should be preserved and reconstructed in primary THA. Therefore, for patients and operators, better surgical methods and more suitable prosthesis materials are effective measures to prolong the service life of the prosthesis and reduce the revision rate.

Limitations: since it is impossible to blind physicians, only single blindness may adversely affect the results of the trial. In the course of follow-up, some patients are followed up by telephone, and the understanding deviation may occur in language communication, which leads to the score deviation of the questionnaire, which leads to bias in the test.

Conclusion

There is no significant difference in clinical efficacy and safety between the new combined hip prosthesis system and the prosthesis of the control group, the new combined hip prosthesis system meets the requirements of clinical safety and effectiveness. clinical trials provide a basis for its application and are worth popularizing.

Abbreviations

THA	Total Hip Arthroplasty
UHMWPE	ultra-high molecular weight polyethylene
SS	Safety Set
FAS	Full Analysis Set
PPS	Per Protocol Set
ITT	Intent To Treat

Declarations

Ethics approval and consent to participate:

This study has been approved, Ethics Committee terms: Ethics Committee of Clinical Trials of Drugs/Devices in China-Japan Friendship Hospital. Number:2013-58

Consent to publish:

All authors agree to the publication of this study

Availability of data and materials:

Due to the sensitive nature of the questions asked in this study, survey respondents were assured raw data would remain confidential and would not be shared.

Competing interests:

The authors declare no conflict of interest.

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Authors' Contributions:

All authors participated in the study design; in the collection, analysis and interpretation of data; in the writing of the report.

Acknowledgments:

All authors have contributed significantly to the work and have reviewed and approved the final version of the manuscript.

References

1. Wiles P. The surgery of the osteoarthritic hip. *Br J Surg*; 45(193)1958: 488.
<https://doi.org/10.1002/bjs.18004519315>
2. Charnley J. Total hip replacement. *JAMA*; 230(7)1974: 1025.
3. Cales B. Zirconia as a sliding material: histologic, laboratory, and clinical data. *Clin Orthop Relat Res*; (379)2000: 94.
4. Kurtz SM, Kocagoz S, Arnholt C, Huet R, Ueno M, Walter WL. Advances in zirconia toughened alumina biomaterials for total joint replacement. *J Mech Behav Biomed Mater*; 312014: 107.
<https://doi.org/10.1016/j.jmbbm.2013.03.022>
5. Learmonth ID, Young C, Rorabeck C. The operation of the century: total hip replacement. *Lancet*; 370(9597)2007: 1508. [https://doi.org/10.1016/S0140-6736\(07\)60457-7](https://doi.org/10.1016/S0140-6736(07)60457-7)
6. Hannouche D, Zingg M, Miozzari H, Nizard R, Lubbeke A. Third-generation pure alumina and alumina matrix composites in total hip arthroplasty: What is the evidence? *EFORT Open Rev*; 3(1)2018: 7.
<https://doi.org/10.1302/2058-5241.3.170034>
7. Louboutin L, Viste A, Desmarchelier R, Fessy MH. Long-term survivorship of the Corail standard stem. *Orthop Traumatol Surg Res*; 103(7)2017: 987. <https://doi.org/10.1016/j.otsr.2017.06.010>
8. Lee YK, Ha YC, Yoo JI, Jo WL, Kim KC, Koo KH. Mid-term results of the BIOLOX delta ceramic-on-ceramic total hip arthroplasty. *Bone Joint J*; 99-B(6)2017: 741. <https://doi.org/10.1302/0301-620X.99B6.BJJ-2016-0486.R3>
9. Bjorgul K, Novicoff WM, Andersen ST, Brevig K, Thu F, Wiig M, Ahlund O. No differences in outcomes between cemented and uncemented acetabular components after 12-14 years: results from a randomized controlled trial comparing Duraloc with Charnley cups. *J Orthop Traumatol*; 11(1): 2010 37. <https://doi.org/10.1007/s10195-010-0082-2>
10. Eingartner C. Current trends in total hip arthroplasty. *Ortop Traumatol Rehabil*; 9(1)2007: 8.
11. Santavirta S, Bohler M, Harris WH, Konttinen YT, Lappalainen R, Muratoglu O, Rieker C, Salzer M. Alternative materials to improve total hip replacement tribology. *Acta Orthop Scand*; 74(4)2003: 380. <https://doi.org/10.1080/00016470310017668>
12. Masson B. Emergence of the alumina matrix composite in total hip arthroplasty. *Int Orthop*; 33(2) 2009: 359. <https://doi.org/10.1007/s00264-007-0484-9>

13. Al-Hajjar M, Jennings LM, Begand S, Oberbach T, Delfosse D, Fisher J. Wear of novel ceramic-on-ceramic bearings under adverse and clinically relevant hip simulator conditions. *J Biomed Mater Res B Appl Biomater*; 101(8)2013: 1456. <https://doi.org/10.1002/jbm.b.32965>
14. Kelly JR, Denry I. Stabilized zirconia as a structural ceramic: an overview. *Dent Mater*; 24(3)2008: 289. <https://doi.org/10.1016/j.dental.2007.05.005>
15. De Aza AH, Chevalier J, Fantozzi G, Schehl M, Torrecillas R. Crack growth resistance of alumina, zirconia and zirconia toughened alumina ceramics for joint prostheses. *Biomaterials*; 23(3)2002: 937. [https://doi.org/10.1016/s0142-9612\(01\)00206-x](https://doi.org/10.1016/s0142-9612(01)00206-x)
16. Knight SR, Aujla R, Biswas SP. Total Hip Arthroplasty - over 100 years of operative history. *Orthop Rev (Pavia)*; 3(2)2011: e16. <https://doi.org/10.4081/or.2011.e16>
17. Bizot P, Nizard R, Hamadouche M, Hannouche D, Sedel L. Prevention of wear and osteolysis: alumina-on-alumina bearing. *Clin Orthop Relat Res*; (393)2001: 85. <https://doi.org/10.1097/00003086-200112000-00010>
18. Das DH, van der Weegen W, Wullems JA, Brakel K, Sijbesma T, Nelissen RG. Periprosthetic pathology in 'at risk' ceramic-on-polyethylene total hip arthroplasty: a clinical study using MARS-MRI in 50 patients. *Hip Int*; 26(3)2016: 244. <https://doi.org/10.5301/hipint.5000342>
19. Baruffaldi F, Mecca R, Stea S, Beraudi A, Bordini B, Amabile M, Sudanese A, Toni A. Squeaking and other noises in patients with ceramic-on-ceramic total hip arthroplasty. *Hip Int*; 30(4)2020: 438. <https://doi.org/10.1177/1120700019864233>
20. Barrow JA, Divecha HM, Panchani S, Boden R, Chitre A, Gambhir A, Porter ML, Board TN. Is patient satisfaction related to patient reported sounds from ceramic on ceramic total hip arthroplasty? A study of 265 hips. *Eur J Orthop Surg Traumatol*; 29(6)2019: 1243. <https://doi.org/10.1007/s00590-019-02426-2>
21. Lee YK, Kim KC, Kim JW, Ha JH, Yoon BH, Ha YC, Koo KH. Use of ceramic-on-ceramic bearing in total hip arthroplasty for posttraumatic arthritis of the hip. *J Orthop Surg (Hong Kong)*; 27(2)2019: 2309499019836378. <https://doi.org/10.1177/2309499019836378>
22. Yoon BH, Park JW, Cha YH, Won SH, Lee YK, Ha YC, Koo KH. Incidence of Ceramic Fracture in Contemporary Ceramic-on-Ceramic Total Hip Arthroplasty: A Meta-analysis of Proportions. *J Arthroplasty*; 35(5)2020: 1437. <https://doi.org/10.1016/j.arth.2019.12.013>
23. Varnum C. Outcomes of different bearings in total hip arthroplasty - implant survival, revision causes, and patient-reported outcome. *Dan Med J*; 64(3)2017.
24. Blom AW, Rogers M, Taylor AH, Pattison G, Whitehouse S, Bannister GC. Dislocation following total hip replacement: the Avon Orthopaedic Centre experience. *Ann R Coll Surg Engl*; 90(8)2008: 658. <https://doi.org/10.1308/003588408X318156>
25. Prietzel T, Hammer N, Schleifenbaum S, Adler D, Pretzsch M, Kohler L, Petermann M, Farag M, Panzert S, Bauer S, von Salis-Soglio G. [The impact of capsular repair on the dislocation rate after primary total hip arthroplasty: a retrospective analysis of 1972 cases]. *Z Orthop Unfall*; 152(2)2014: 130. <https://doi.org/10.1055/s-0034-1368209>

Figures



Figure 1

GS- N2 hip prosthesis system. Note: The total hip joint prosthesis is composed of femoral stem, femoral head and acetabular prosthesis.



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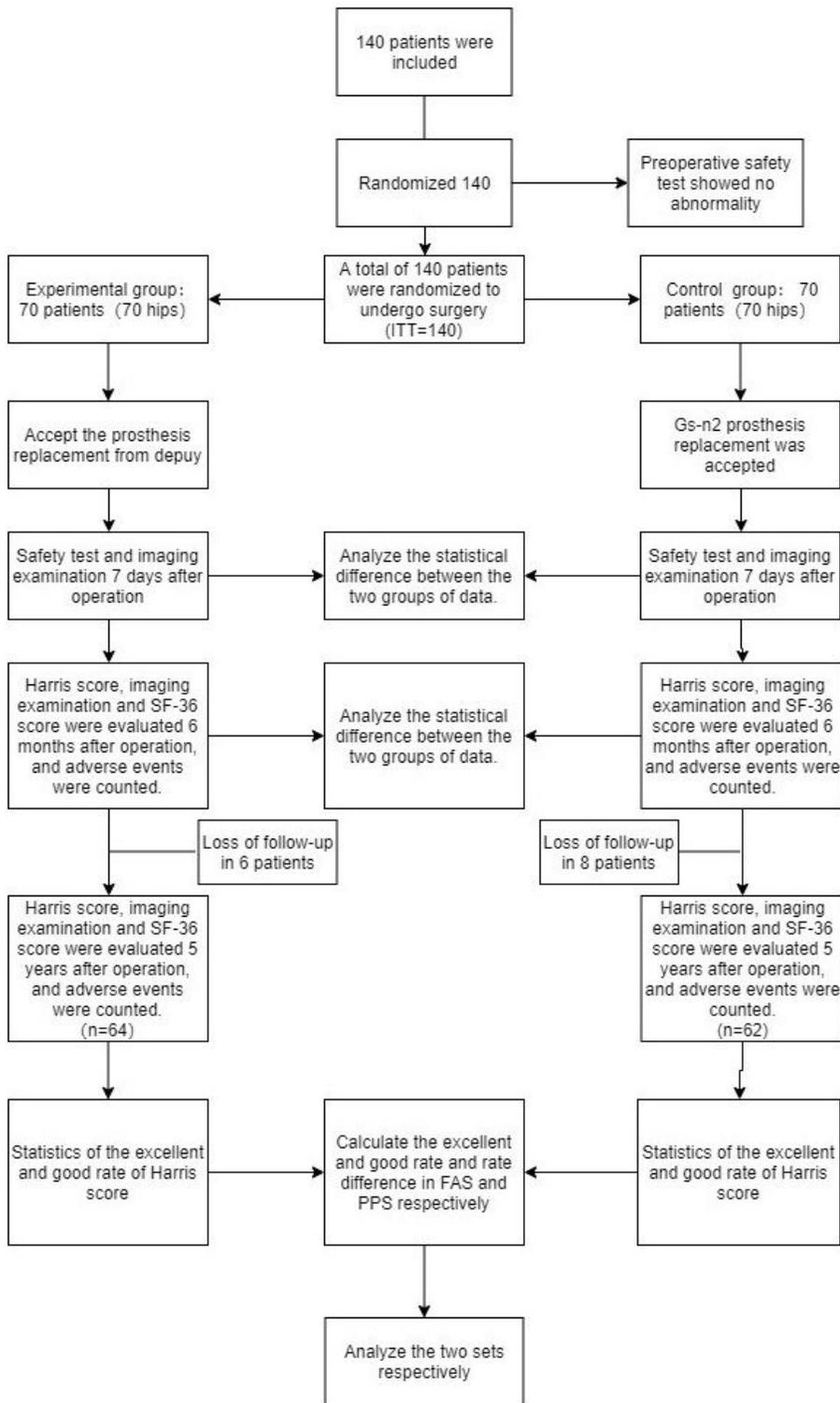


Figure 2

Test process

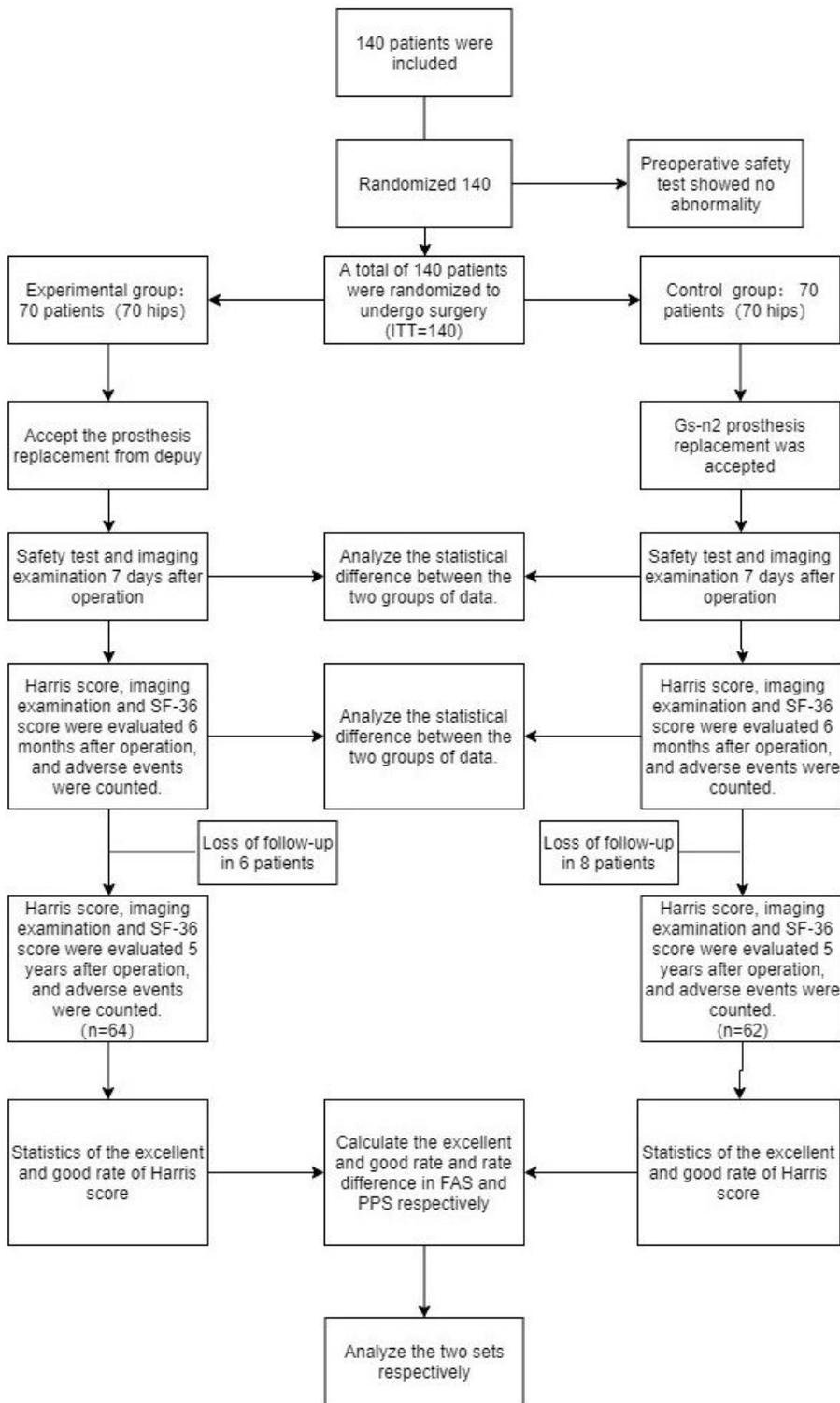


Figure 2

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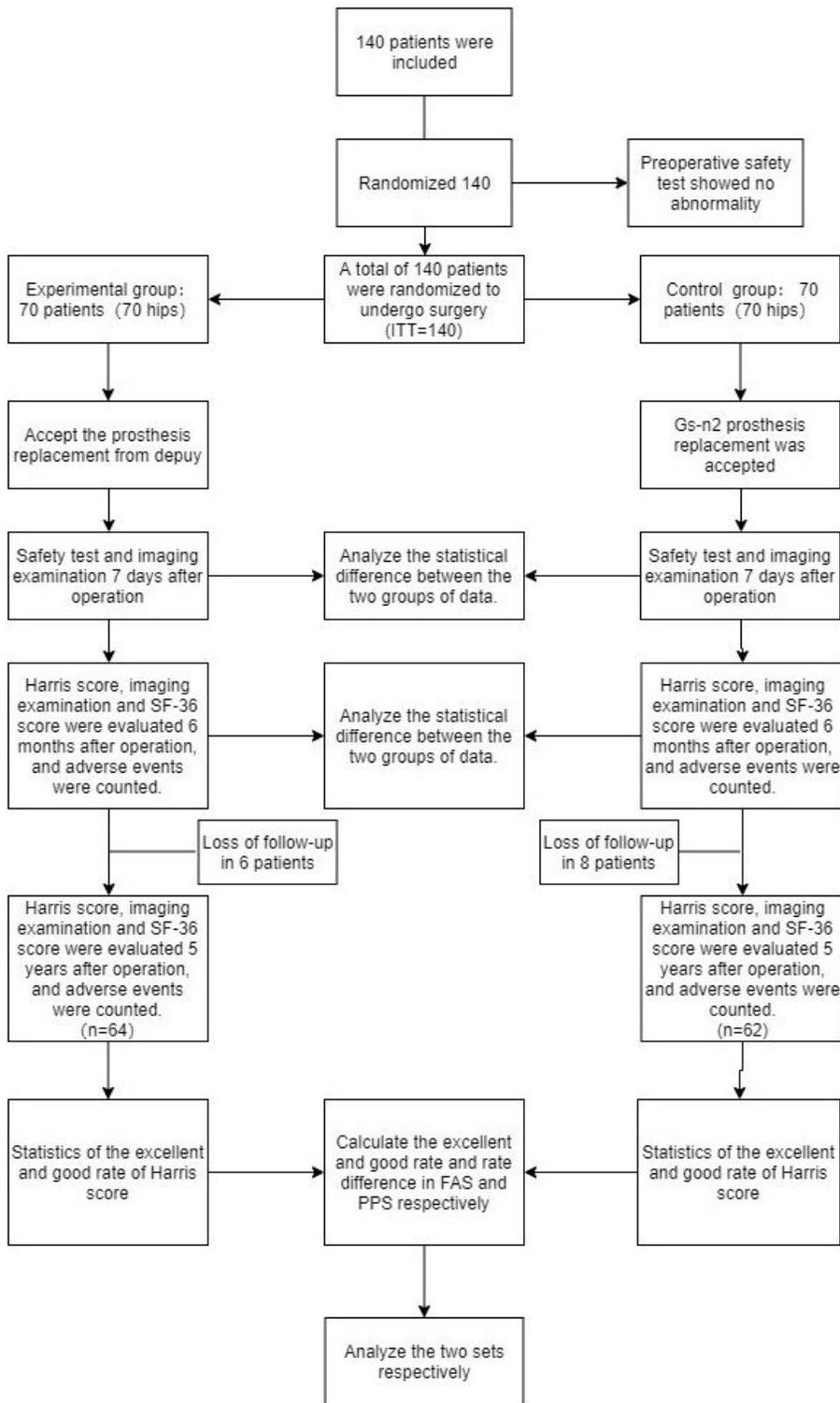


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Test process

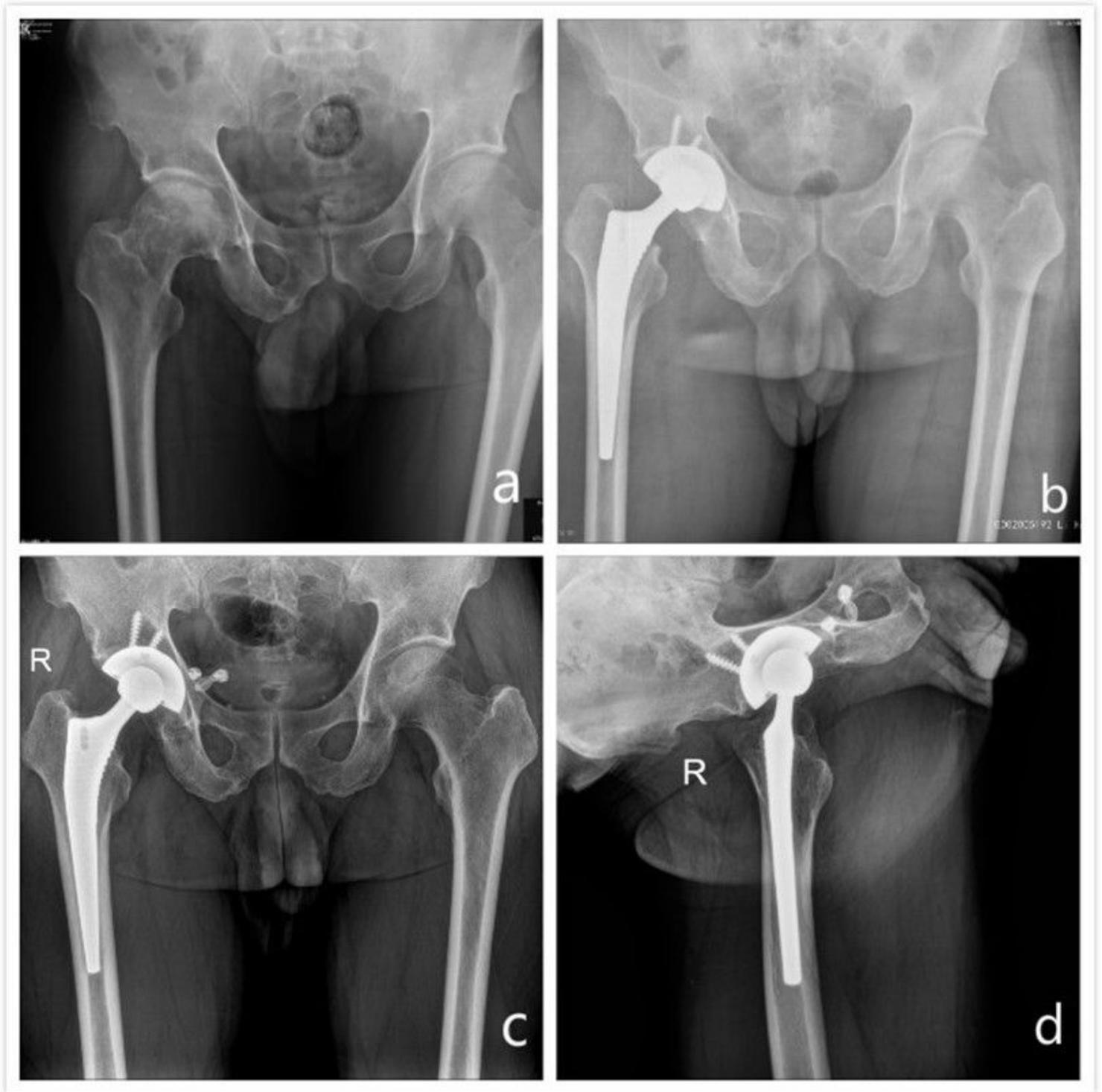


Figure 3

Imaging material of patients in the experimental group. Note: a: preoperative X-ray of hip joint b: X-ray of hip joint 6 months after operation c: X-ray of hip joint 5 years after operation d: lateral X-ray of hip joint 5 years after operation

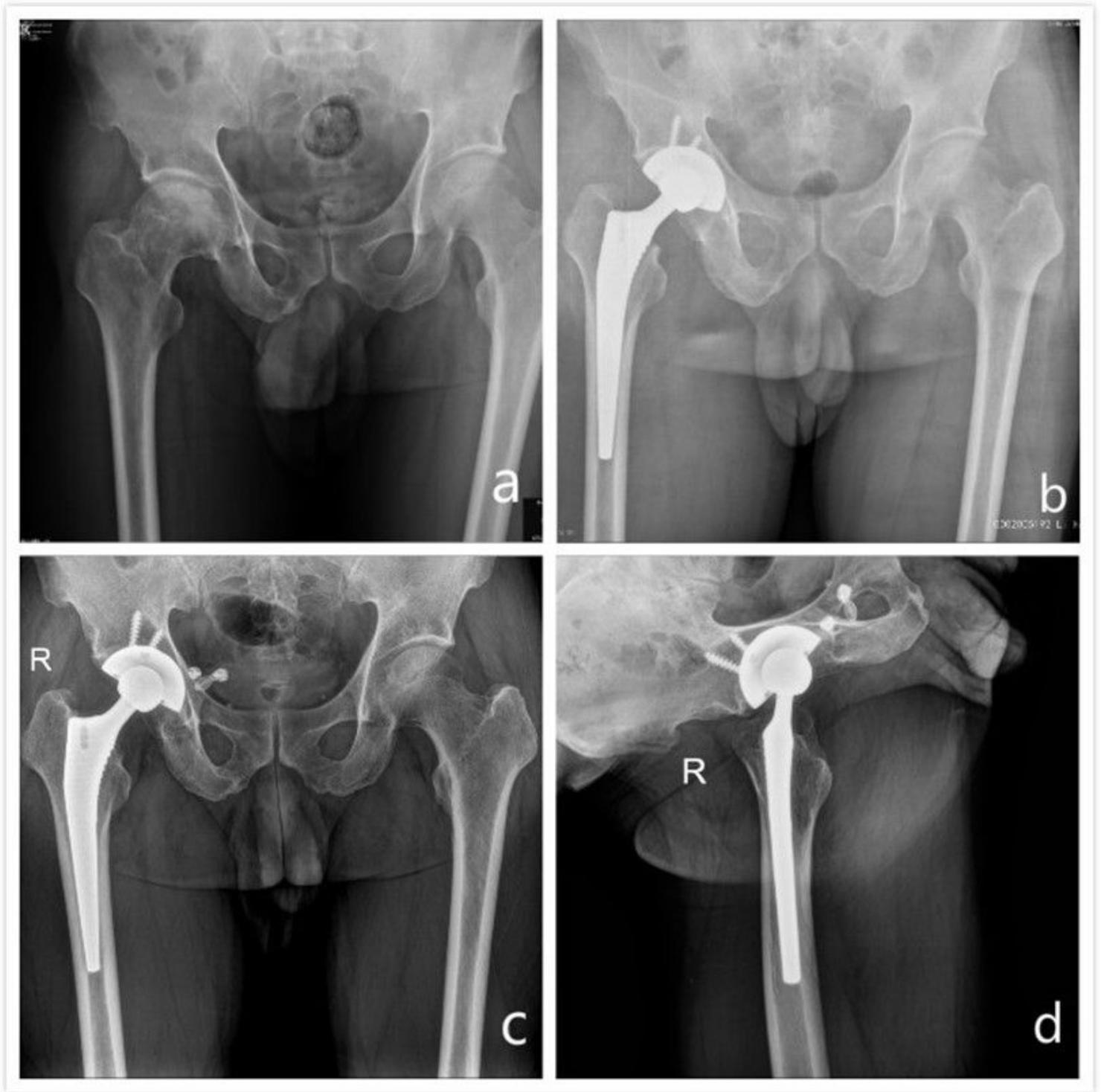


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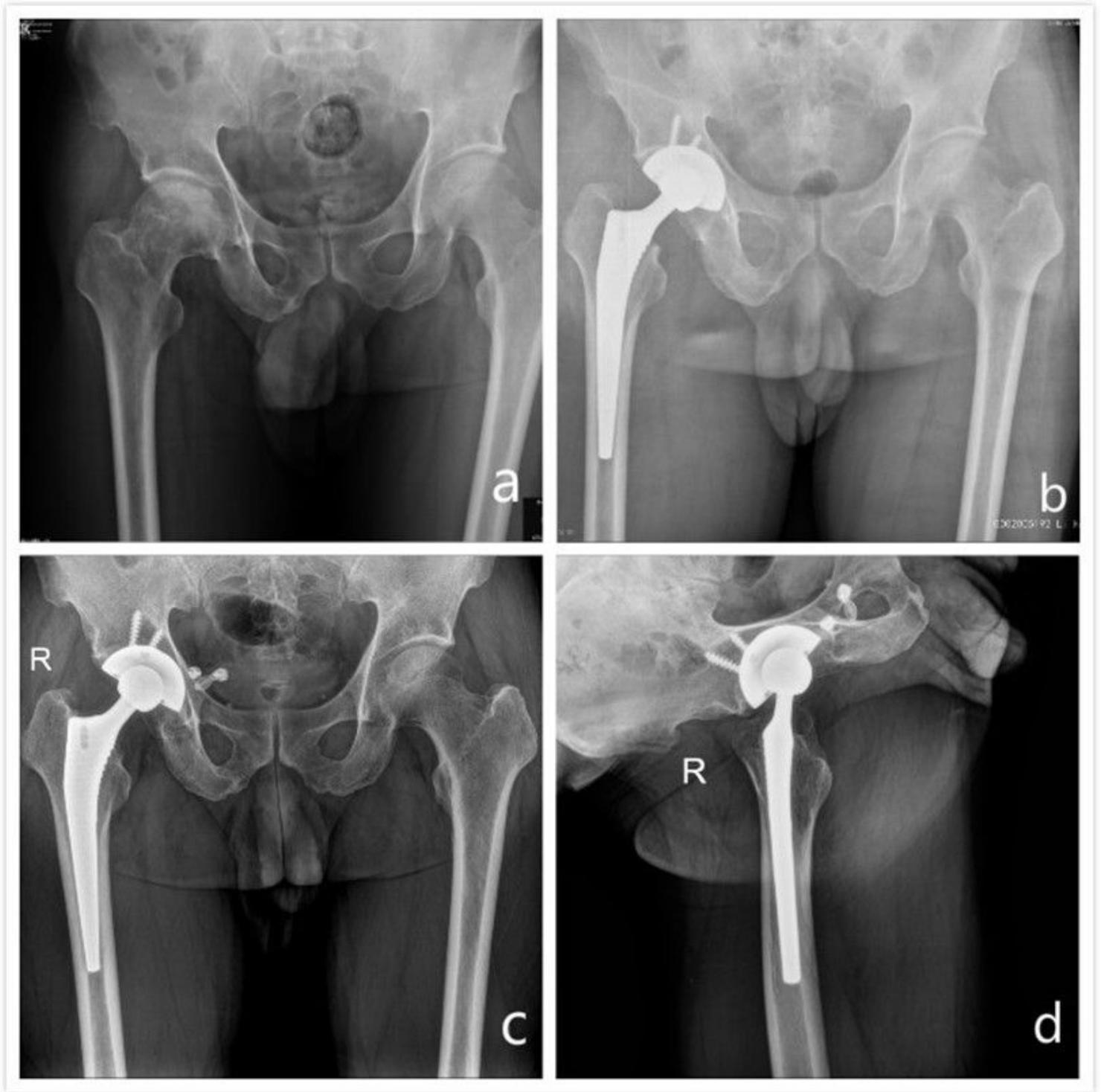


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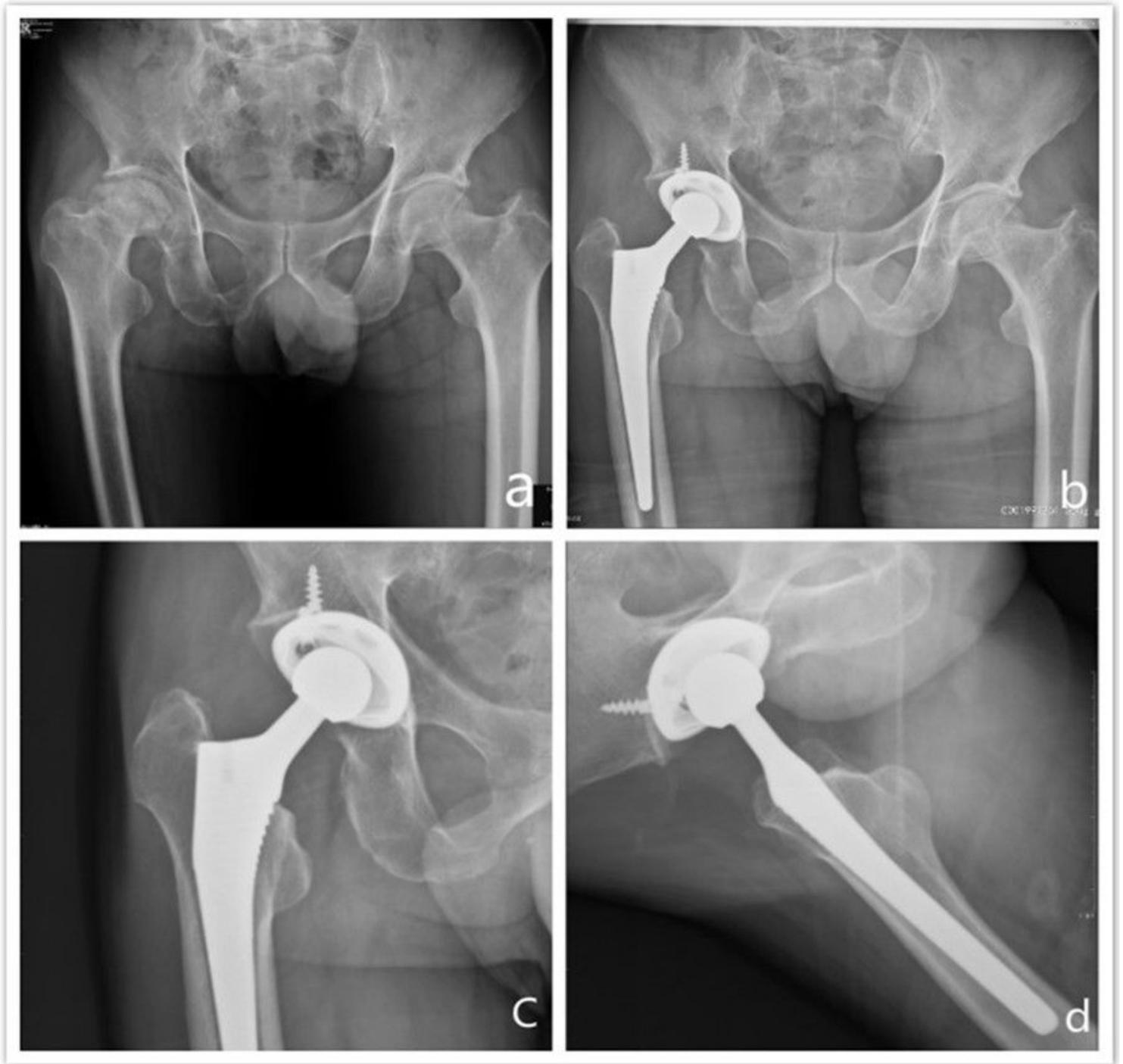


Figure 4

Imaging material of patients in the control group. Note: a: preoperative X-ray of hip joint b: X-ray of hip joint 6 months after operation c: X-ray of hip joint 5 years after operation d: lateral X-ray of hip joint 5 years after operation

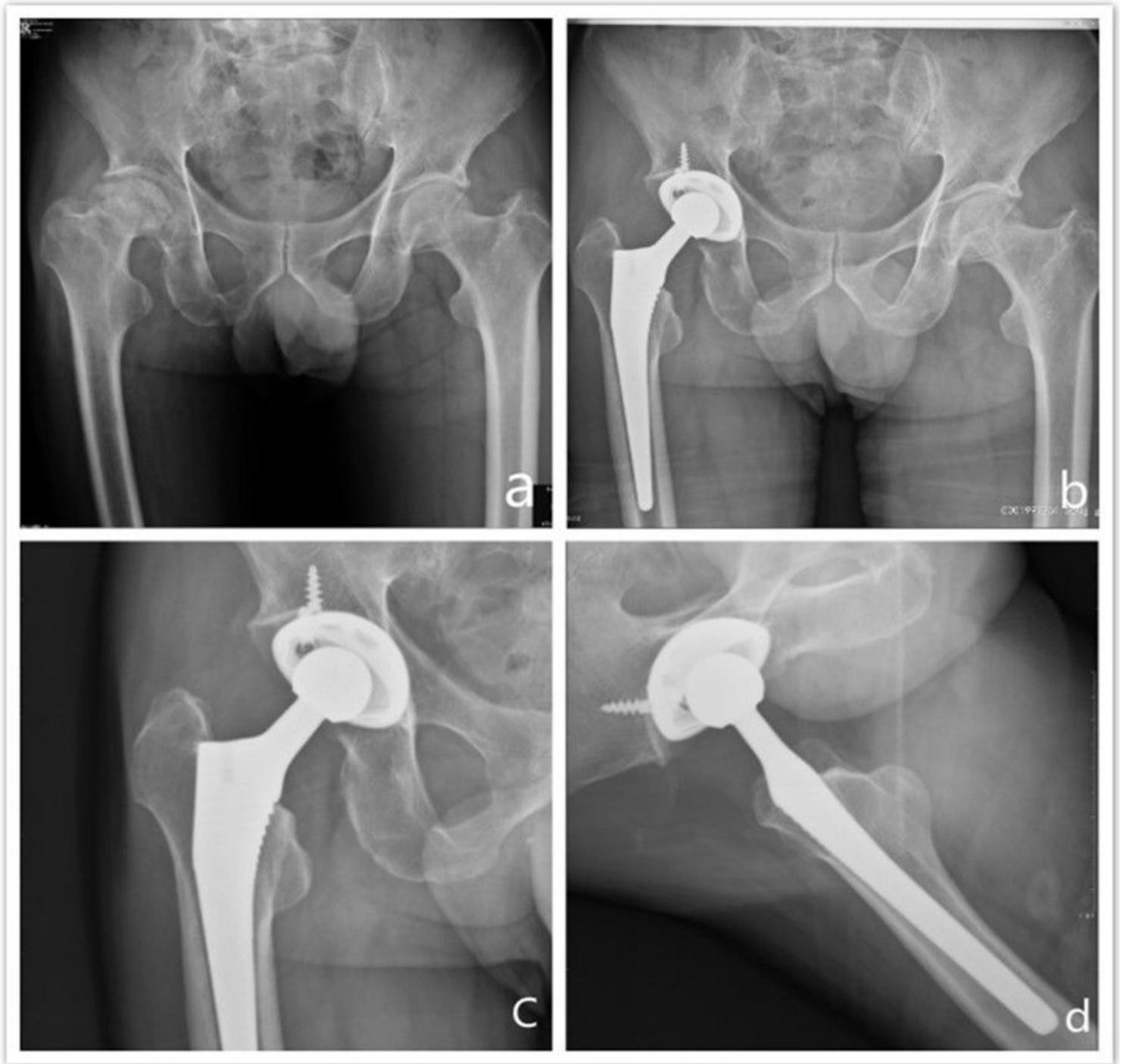


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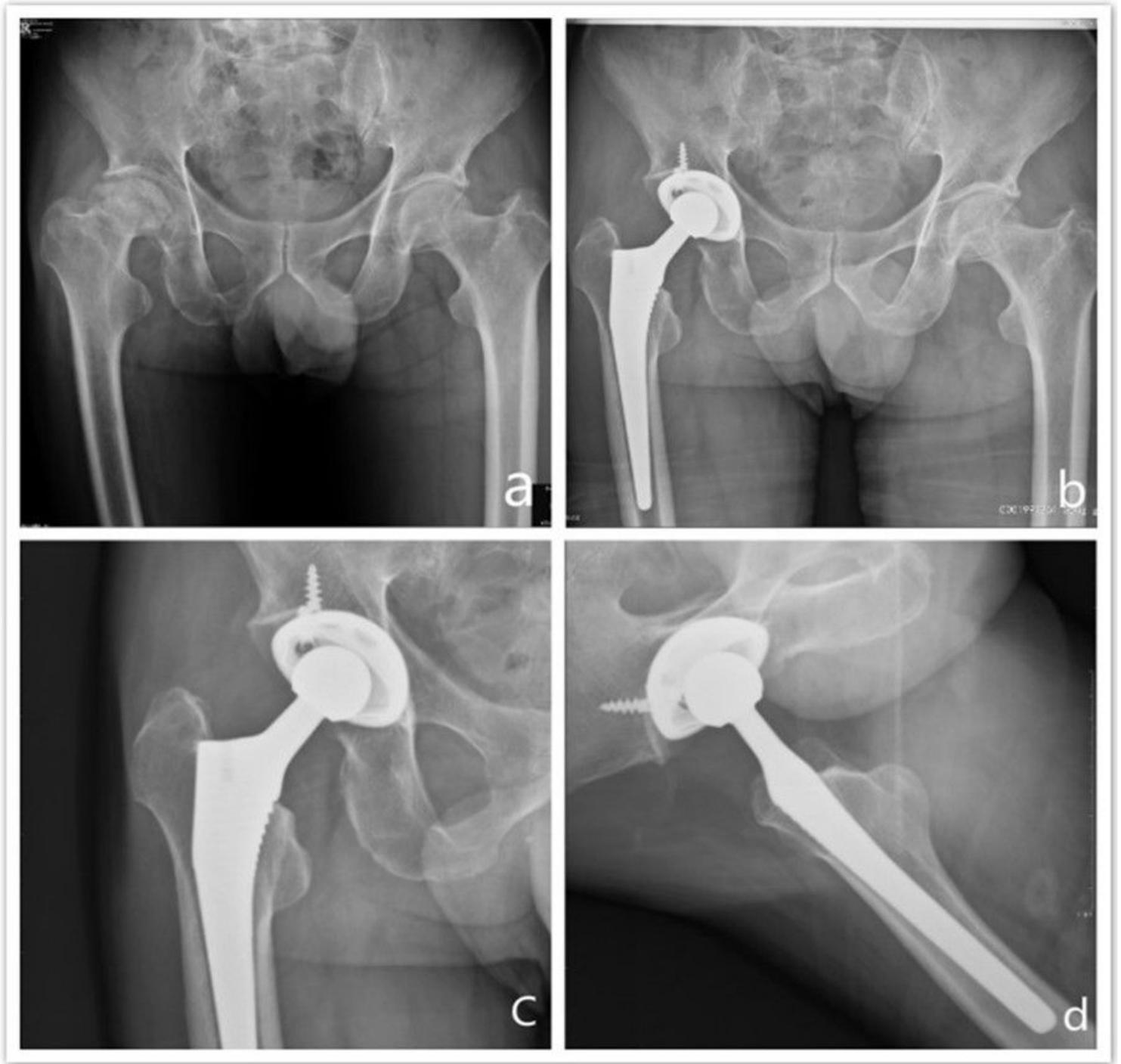


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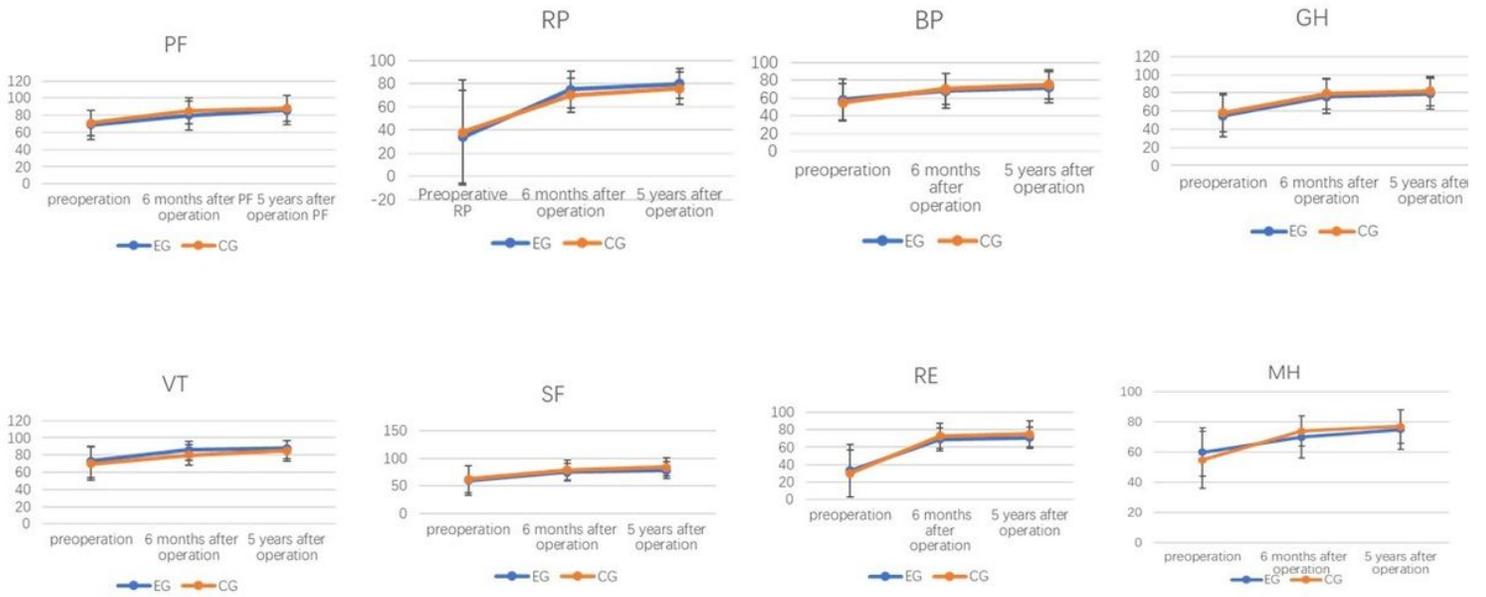


Figure 5

Comparison of two groups of sf-36 line charts. Note: EG: Experimental Group, CG: Control Group. PF: Physiological Function, RP: Role Physical, BP: Body Pain, GH: General Health, VT: Vitality, SF: Social Function, RE: Emotional Role MH: Mental Health

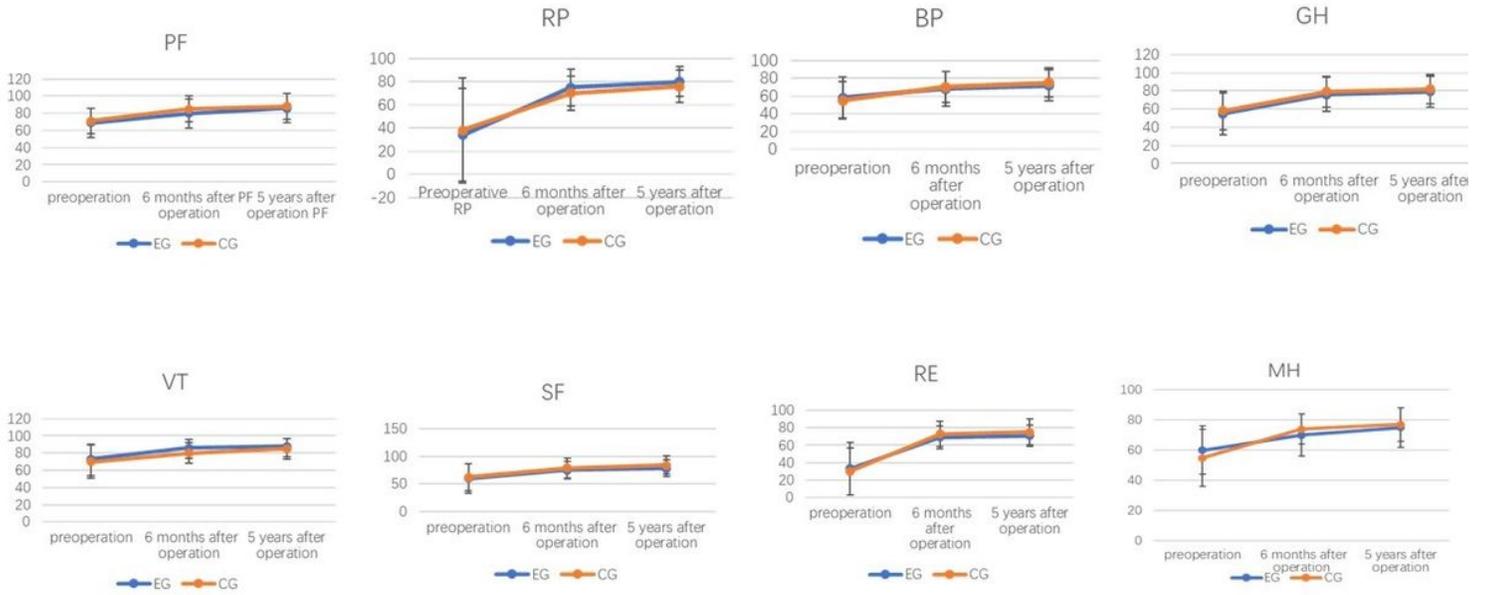


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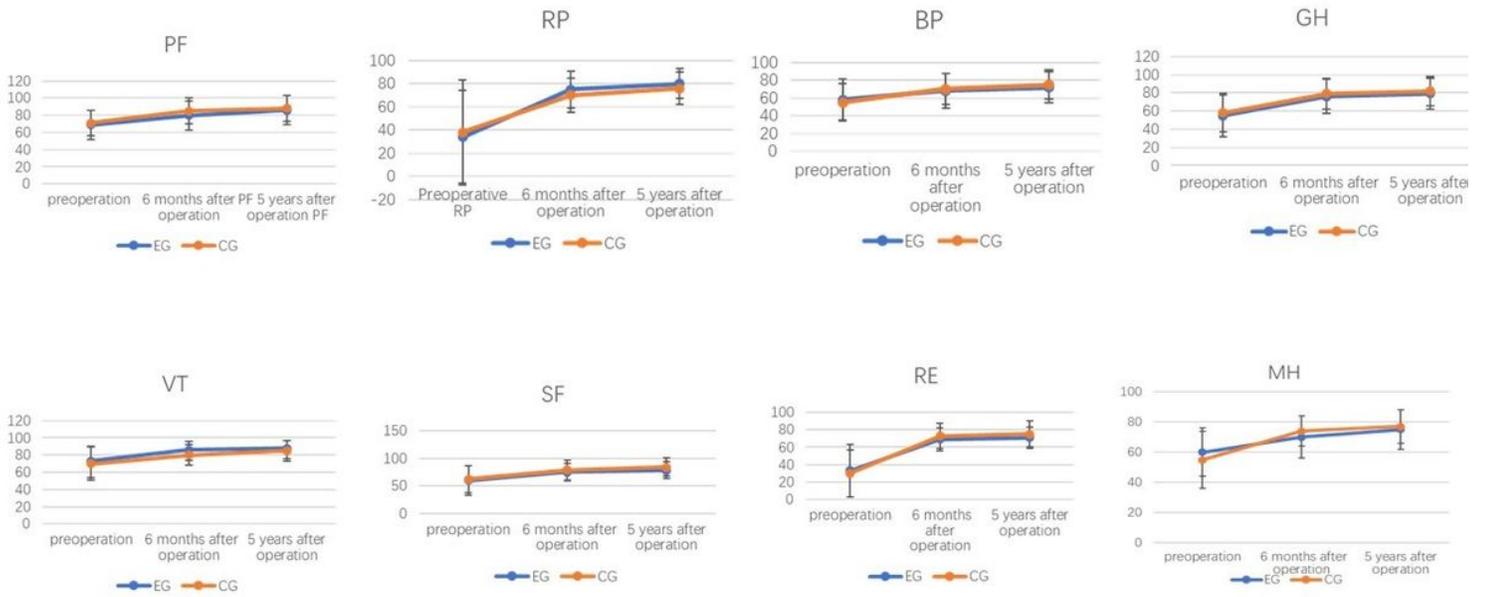


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