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Original Article

The LANCET robotic system can improve surgical efficiency in total hip arthroplasty: A prospective randomized, multicenter, parallel-controlled clinical trial

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ABSTRACT

Objective: To evaluate the accuracy and safety of the LANCET robotic system, a robot arm assisted operation system for total hip arthroplasty via a multicenter clinical randomized controlled trial.
Methods: A total of 116 patients were randomized into two groups: LANCET robotic arm assisted THA group (N = 58) and the conventional THA group (N = 58). General information about the patients was collected preoperatively. Operational time and bleeding were recorded during the surgery. The position of the acetabular prosthesis was evaluated by radiographs one week after surgery and compared with preoperative planning. Harris score, hip mobility, prosthesis position and angle and complications were compared between the two groups at three months postoperatively.
Results: None of the 111 patients who ultimately completed the 3-month follow-up experienced adverse events such as hip dislocation and infection during follow-up. In the RAA group, 52 (92.9 %) patients were located in the Lewinnek safe zone and 49 (87.5 %) patients were located in the Callanan safe zone. In the control group were 47 (85.5 %) and 44 (80.0 %) patients, respectively. In the RAA group, 53 (94.6 %) patients had a postoperative acetabular inclination angle and 51 (91.1 %) patients had an acetabular version angle within a deviation of 5° from the preoperative plan. These numbers were significantly higher than those of the control group, which consisted of 42 (76.4 %) and 34 (61.8 %) patients respectively. There were no significant differences between the two groups of subjects in terms of general condition, intraoperative bleeding, hip mobility, and adverse complications.
Conclusion: The results of this prospective randomized, multicenter, parallel-controlled clinical study demonstrated that the LANCET robotic system leads conventional THA surgery in accuracy of acetabular cup placement

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and does not differ from conventional THA surgery in terms of postoperative hip functional recovery and complications.

The translational potential of this article: In the past, the success rate of total hip arthroplasty (THA) relied heavily on the surgeon's experience. As a result, junior doctors needed extensive training to become proficient in this technique. However, the introduction of surgical robots has significantly improved this situation. By utilizing robotic assistance, both junior and senior doctors can perform THA quickly and efficiently. This advancement is crucial for the widespread adoption of THA, as patients can now receive surgical treatment in local facilities instead of overwhelming larger hospitals and straining medical resources. Moreover, the development of surgical robots with fully independent intellectual property rights holds immense value in overcoming the limitations of high-end medical equipment. This aligns with the objectives outlined in the 14th Five Year Plan for National Science and Technology Strategy.

Introduction

According to the 7th census of China in 2020, there are 264.02 million individuals (18.70 %) aged 60 and over, including 190.64 million people (13.50 %) aged 65 and over [1]. In 2050, there will be 2.02 billion elderly people (defined as 60 years and over) worldwide, of whom 480 million will live in China, accounting for nearly 25 % of the global elderly population [2]. According to the research with 20,110 participants, the frequency of hip fractures was 1.58 % for adults aged 60–69 years and 5.4 % for those aged 70 years and older [3]. By 2020, the cumulative number of patients with non-traumatic femoral head necrosis in China will reach 8.12 million, with a significantly higher prevalence in men (1.02 %) than in women (0.51 %) [4]. Total hip arthroplasty (THA) is the most effective technique to treat end-stage hip disease, reduce joint discomfort, correct joint deformity, and restore joint function [5]. The location and angle of the acetabular prosthesis during THA have a significant influence on the patient's prognosis. An incorrect acetabular prosthesis location and angle might cause it to impinge, dislocate, and loosen [6,7]. Although skilled surgeons may preoperatively arrange the exact location of the acetabular cup, including the angle of tilt and version, the learning curve for conventional total hip arthroplasty is around 40–50 cases or 6 months [8,9]. Surgical robot system provides possible solutions for preoperative planning, precise intraoperative placement of prosthetic locations, and shortening of the surgical learning curve [10–12].

Robotic assist systems used for orthopedic surgery include ROBODOC, MAKO, ROSA, NAVIO, CASPAR and Acrobat [13,14]. ROBODOC was first introduced into orthopedic surgery for preoperative planning and performance of THA, and MAKO was the most commonly used robotic assist system for orthopedic surgery [15,16]. ROSA and NAVIO don't require preoperative advanced imaging and can only be used for knee arthroplasty, while CASPAR and Acrobat were not available on the market [13,17]. MAKO robotic-arm assisted systems provided real-time sensory feedback, precision implant placement, protection of healthy bones and soft tissues, and other benefits to surgeons [18]. However, the MAKO system is still in its infancy in China. High price and maintenance costs, limited accessory supplies, and variances in prosthesis for East Asian limited its promotion [19]. To address the above limitations, National Medical Products Administration (NMPA) has approved the HURWA total knee arthroplasty (TKA) navigation system, the 'SkyWalker' orthopaedic robot, the LANCET robot system, the TiRobot-assisted system, the ARTHROBOT THA navigation system and the 'KUNWU' orthopaedic robot [20–22]. The 'SkyWalker' and 'HURWA' systems were solely employed in TKA surgery [21]. The TiRobot-assisted system was mainly used to assist in orthopedic trauma surgery [23]. The ARTHROBOT THA navigation system, the LANCET robotic system, and the 'KUNWU' orthopaedic robot were designed for THA, but fewer relevant clinical studies have been reported. Overall, there are still fewer surgical robots used to assist THA in China, and there is a lack of relevant clinical randomized controlled trials.

The LANCET robotic system consists of a robotic arm system cart, a control and operating system cart, an optical tracking system cart, operating software and accessories (Fig. 1). In the present study, we performed a randomized, multicenter, parallel-controlled trail of the LANCET robot arm assisted (RAA) THA versus conventional THA to study the effectiveness and safety of this system in humans.

Materials and methods

Study design

This study was a randomized, multicenter, parallel-controlled trial

Figure 1. The robot console and the surgical platform of the LANCET robotic system.

approved by the Institutional Review Board of Affiliated Drum Tower Hospital Medical School of Nanjing University, Zhongda Hospital Southeast University, the Second Affiliated Hospital Zhejiang University School of Medicine and the Second Affiliated Hospital of Anhui Medical University. The entire clinical trial process was carried out in compliance with the Helsinki Declaration and national clinical trial research standards. All individual signed informed consent.

Patient recruitment

From November 2021 to July 2022, patients underwent primary unilateral THA in four clinical centers were divided into two groups by a computer-generated sequence of random numbers: the LANCET RAA THA group and conventional THA group. The inclusion criteria were as follows: age between 18 and 85 years with mature bones, indications for first-time unilateral THA surgery, and voluntary participation in this clinical trial. The exclusion criteria were as follows: Patients with contraindications to hip surgery, simultaneous bilateral hip arthroplasty, hip dysplasia CROWE type III or IV, BMI >35 kg/m^2, neuromuscular insufficiency (e.g. paralysis, rhabdomyolysis or abductor muscle weakness), severe bleeding tendencies or clotting abnormalities, abnormal liver function (ALT, AST $\geq$1.5 times the upper limit of normal), abnormal renal function (Cr, urea or urea nitrogen $\geq$1.5 times the upper limit of normal), psychiatric abnormalities or unstable medical conditions, pregnant or lactating women, planning to become pregnant within 6 months, participated in other interventional clinical trials within 1 month prior to this trial, deemed by the investigator to be unsuitable for participation.

3.3. Surgical procedures

All surgeries were performed by the same experienced surgeon in both the conventional surgery group and the RAA THA group at each clinical research center. RAA THA was performed using the LANCET robotic system (Hangzhou Lancet Robo Co. Ltd). Preoperative CT scan of both hips (layer thickness 0.625 mm, 5 cm above the anterior superior iliac crest to 5 cm above the knee joint line) was taken and the CT data was imported into the LANCET robotic system to personalize the placement of the acetabular cup in the preoperative plan. Preoperative surgical planning included the acetabular cup size, femoral stem size, acetabular version and acetabular inclination. The type and position of the prosthesis can be simulated in the LANCET operating system (Fig. 2). In the conventional THA group, the type and position of the prosthesis were determined by the surgeon based on the results of the patient's physical examination, CT images and pelvic plain radiographs.

The patient was placed in a lateral position under general anesthesia with static suction and a posterolateral approach, with the pelvic reflex matrix placed percutaneously at 5 cm above the anterior superior iliac spine. After exposure of the hip capsule along the surgical approach and partial resection, the dislocated hip was prepared with conventional osteotomy followed by femoral marrow expansion. The acetabulum was fully exposed to 1 cm beyond the acetabular rim and the reflex matrix was held while the acetabulum is spotted for acetabular registration (Fig. 3). Following registration, verification was performed to ensure that the registration error is less than 0.5 mm. After registration was complete, the robotic arm was pushed in and the acetabular grinding file was performed in the fixed line, limited depth mode to the preoperative planning depth. The acetabular cup was fitted with the assistance of the robotic arm and the version and inclination angles shown on the operating table at this point are saved (Fig. 4). For both the conventional and robotic surgery groups, the technique for opening the skin, fascia, separating the muscles, and opening the joint capsule was the same. In contrast, there is no registered procedure in the conventional surgical group. The surgeon manually manipulated the abraded acetabulum to install the acetabular cup, and manually performed a femoral head osteotomy to install the femoral stem prosthesis. After installing the prosthesis, the stability, looseness and mobility of the hip joint were tested intraoperatively in all angles.

3.4. Clinical and radiologic outcome evaluation

Preoperatively, clinical data including age, sex, height, body weight, and other general information were gathered. Additional clinical information was collected and entered into the database by an independent researcher during the perioperative and follow-up periods. The patient's acetabular cup version and inclination angles displayed in the robotic system during surgery were recorded. Operation time, bleeding volume, and mechanical failures during surgery (if any) were recorded at the end of the procedure. Postoperative acetabular cup version and inclination angles were obtained by a clinically experienced surgeon on

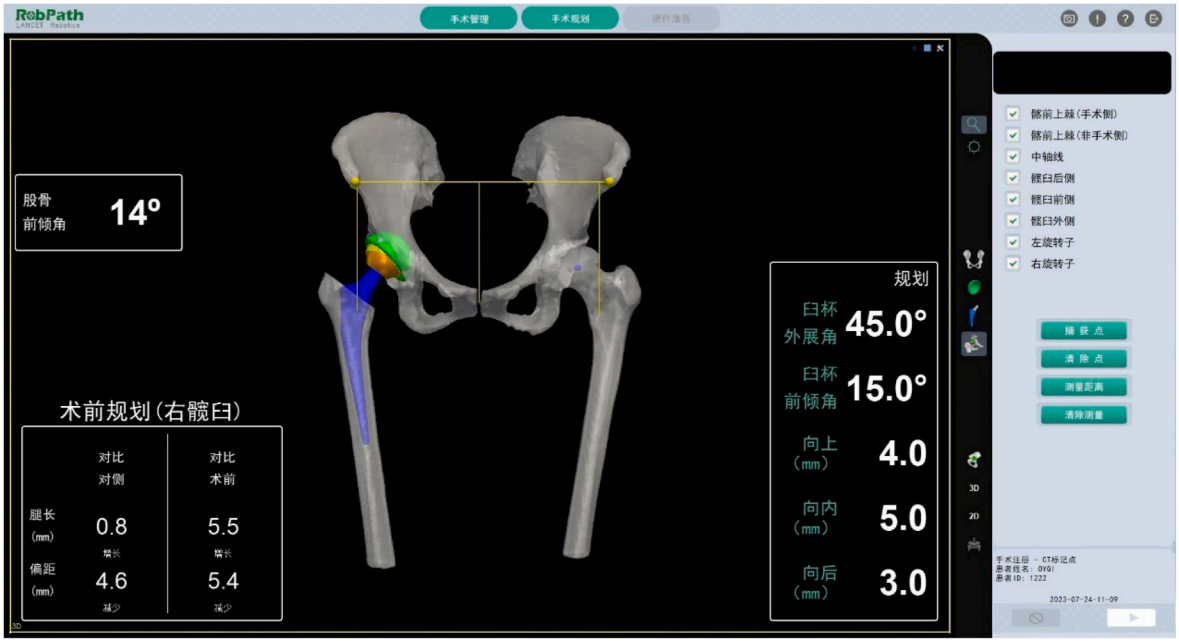

Figure 2. Preoperatively planned position and angles of hip prosthesis by the LANCET robotic system.

Figure 3. The registration procedure of LANCET robotic system.

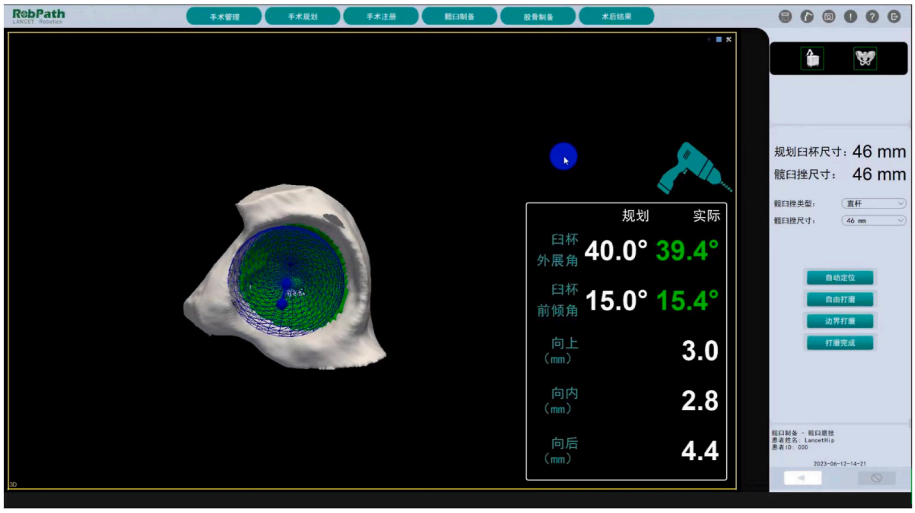

Figure 4. Intraoperative measurement of acetabular cup position in real time.

hip radiographs and CT scan a week after surgery. The primary evaluation indicator was the postoperative difference of no more than 5° from the planned acetabular cup version and inclination angles. The safety objectives of this study were based on device performance indicators and the incidence of THA complications. Harris score and hip mobility were recorded at the 3-month follow-up after surgery. All complications during the perioperative period and the 3-month follow-up period were recorded. The surgeons who measured the imaging parameters and performed the functional examination of the subjects were blinded to the grouping. The data analyst was blinded to the details of group, which were labeled A or B.

3.5. Statistical analysis

$P < 0.05$ was regarded as statistically significant during the Graphpad Prism. After checking data normality, descriptive statistics (means, standard deviations, and ranges) were computed. The proportions of angles within an absolute error of 5° were calculated. After checking the data for normality, descriptive statistics (mean, standard deviation, and 95 % CI) were performed. Measurements that conformed to a normal distribution were tested using t-tests. Chi-square and Fisher's exact test were performed to assess secondary evaluation index.

Results

The study collected prospective data from four centers for the period from December 2021 to May 2022. A total of 116 eligible patients were included, of whom 111 (95.7 %) received at least 3-month follow-up were enrolled. The graphical abstract of clinical trial was shown in Fig. 5. 56 patients were included in the RAA group with a mean age of 58.51 ± 13.68 years, and 55 patients were included in the control group with a mean age of 60.42 ± 11.79 years ($P = 0.4372$). A total of 67 (60.4

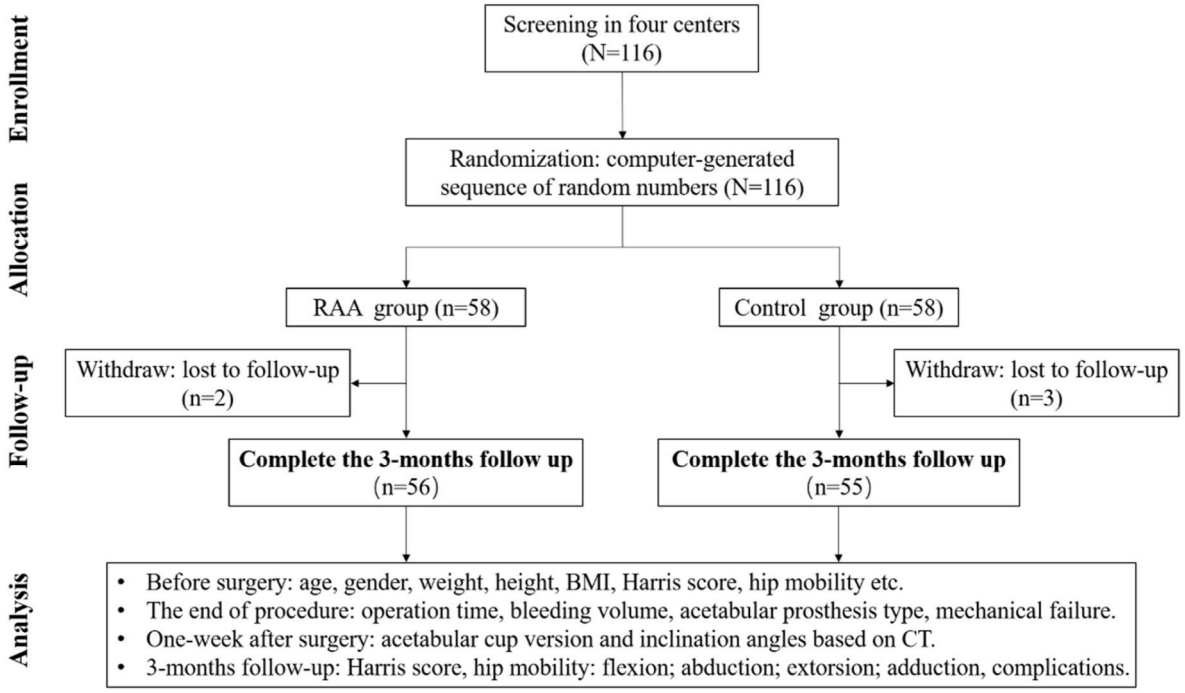

Figure 5. Graphical abstract of this clinical trial.

%) women were included, 29 (51.8 %) in the RAA group and 38 (69.1 %) in the control group (P = 0.3770). Mean body mass index (BMI) was 24.56 ± 3.15 in the RAA group and 23.93 ± 3.25 in the control group (P = 0.3128). In terms of age, sex, height, or weight, there was no significant difference between the control group and the RAA group. Patient demographics are presented in Table 1.

Acetabular cup sizes implanted in the RAA group were 44 in 5 cases, 46 in 5 cases, 48 in 13 cases, 50 in 7 cases, 52 in 10 cases, 54 in 14 cases, 56 in 1 case, and 58 in 1 case. Acetabular cup sizes implanted in the control group were 44 in 2 case, 46 in 5 cases, 48 in 16 cases, 50 in 10 cases, 52 in 13 cases, 54 in 6 cases, 56 in 2 cases, and 58 in 1 case. The operative time was 109.5 ± 28.63 min in the RAA group and 87.11 ± 30.73 min in the control group (P < 0.001). There was no significant difference in intraoperative bleeding between the two groups (P = 0.9384), 163.8 ± 118.5 ml in the RAA group and 165.5 ± 113.4 ml in the control group. The preoperative Harris score was (59.31 ± 19.24) in the RAA group and (58.84 ± 20.23) in the control group (P = 0.8993). The Harris score at three months postoperatively was (87.92 ± 10.76) for patients in the RAA group and (87.99 ± 11.06) for patients in the control group (P = 0.9786). The hip mobility on the operative side was assessed three months following surgery. In the RAA group, the average hip flexion angle was 101.49 ± 15.43°, the average abduction angle was 28.19 ± 8.66°, the average external rotation angle was 23.40 ± 10.36° and the average internal retraction angle was 18.66 ± 7.00°. In the control group, the average hip flexion angle was 105.11 ± 18.48°, the average abduction angle was 28.56 ± 10.68°, the average external rotation angle was 24.33 ± 13.02° and the average internal retraction angle was 18.67 ± 8.33°. Preoperative Harris scores in the RAA group was 59.31 ± 19.24, and three months postoperative Harris scores was 87.92 ± 10.88. Preoperative Harris scores in the control group was 58.84 ± 20.23, and three months postoperative Harris scores was 87.99 ± 11.19 (Table 2).

Table 1
Patient demographics.

Index statistics	Sum (N = 111)	RAA group (N = 56)	Control group (N = 55)	P value
Age (years)				
Mean ± SD	59.46 ± 12.82	58.51 ± 13.68	60.42 ± 11.79	0.4372
Miñ Max	22.15–82.89	24.06–79.30	22.15–82.92	
Median (P25~P75)	61.83 (53.69–69.26)	60.14 (51.10–68.28)	62.86 (54.35–69.69)	
Gender, N (%)				0.3770
Male	44 (39.6)	27 (48.2)	17 (30.9)	
Female	67 (60.4)	29 (51.8)	38 (69.1)	
Weight (kg)				
Mean ± SD	63.23 ± 10.18	64.55 ± 10.91	61.88 ± 9.18	0.1697
Miñ Max	35~94	40~94	35~85	
Median (P25~P75)	63 (58~69.55)	64.7 (57.25–71.20)	62 (58.4–67)	
Height (cm)				
Mean ± SD	161.19 ± 8.00	161.85 ± 8.02	160.51 ± 7.92	0.3801
Miñ Max	141~179	145~179	141~174.5	
Median (P25~P75)	160 (156~167.5)	160.5 (156~168.55)	160 (156~165.5)	
BMI (kg/m^2)				
Mean ± SD	24.25 ± 3.21	24.56 ± 3.15	23.93 ± 3.25	0.3128
Miñ Max	14.69–33.29	14.69–32.53	16.65–33.29	
Median (P25~P75)	24.24 (22.43–26.2)	25.00 (22.64–26.53)	23.63 (22.05–25.58)	

Abbreviations: BMI, body mass index; RAA, robotic-arm assisted;

Table 2
Statistic description of medical history, hip mobility and Harris scores.

Index statistics	RAA group (N = 56)	Control group (N = 55)	P value
Operation time (mins)			
Mean ± SD	109.5 ± 28.63	87.11 ± 30.73	0.0001
95 % CI	101.8, 117.2	78.8, 95.4	
Bleeding (ml)			0.9384
Mean ± SD	163.8 ± 118.5	165.5 ± 113.4	
95 % CI	132.0, 195.5	134.8, 196.1	
Preoperative hip mobility			
Flexion (°)			0.2250
Mean ± SD	74.17 ± 34.32	82.18 ± 35.46	
95 % CI	65.15, 83.20	72.60, 91.77	
Abduction (°)			0.1430
Mean ± SD	20.57 ± 10.77	23.76 ± 12.23	
95 % CI	17.74, 23.40	20.46, 27.07	
Extorsion (°)			0.1273
Mean ± SD	16.48 ± 10.53	19.58 ± 10.91	
95 % CI	13.71, 19.25	16.63, 22.53	
Adduction (°)			0.5370
Mean ± SD	12.76 ± 8.49	13.78 ± 9.08	
95 % CI	10.53, 14.99	11.33, 16.24	
Postoperative hip mobility			
Flexion (°)			0.3149
Mean ± SD	101.5 ± 15.6	105.1 ± 18.69	
95 % CI	96.91, 106.1	99.5, 110.7	
Abduction (°)			0.8591
Mean ± SD	28.19 ± 8.75	28.56 ± 10.8	
95 % CI	25.62, 30.76	25.31, 31.8	
Extorsion (°)			0.7082
Mean ± SD	23.4 ± 10.47	24.33 ± 13.17	
95 % CI	20.33, 26.48	20.38, 28.29	
Adduction (°)			0.9965
Mean ± SD	18.66 ± 7.08	18.67 ± 8.42	
95 % CI	16.58, 20.74	16.14, 21.2	
Preoperative Harris score			0.8993
Mean ± SD	59.31 ± 19.24	58.84 ± 20.23	
95 % CI	54.25, 64.37	53.42, 64.26	
Postoperative Harris score			0.9786
Mean ± SD	87.92 ± 10.88	87.99 ± 11.19	
95 % CI	84.61, 91.23	84.62, 91.35	

In the control group, the Lewinnek safe zone and Callanan safe zone were occupied by 47 (85.5 %) and 44 (80.0 %) patients. 52 (92.9 %) and 49 (87.5 %) of the patients in the RAA group were in the Lewinnek and Callanan safe zones (Fig. 6). The angles of acetabular inclination and acetabular version measured on postoperative X-rays one week after surgery were compared with the angles planned preoperatively to determine the percentage of difference within 5°. 53 (94.6 %) patients in the RAA group had the acetabular inclination angles within 5° of the preoperatively planned angles, compared with 42 (76.4 %) in the control group (P = 0.0061). In the RAA group, 51 (91.1 %) patients had the acetabular version angles within 5° of the preoperative planned angles compared to 34 (61.8 %) in the control group (P = 0.0003). This demonstrated that the patient's acetabular cup position with the assistance of the robotic arm was less different from the preoperative plan and more precisely positioned than with conventional surgery. Patients in the RAA group had a mean leg length difference of 2.27 ± 4.19 mm, while patients in the control group had a mean leg length difference of 1.29 ± 4.33 mm, with no statistically significant difference (P = 0.2538). Global offset was 2.67 ± 3.26 mm in the RAA group and 2.12 ± 3.0 mm in the control group (P = 0.3882) (Table 3).

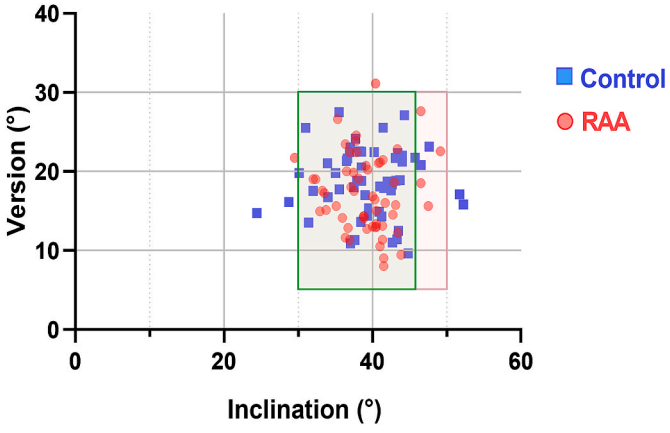

Figure 6. Postoperative radiographic assessment of acetabular cup position within the Lewinnek safe zone and Callanan safe zone.

There were no malfunctions such as system leaks, broken linked sections of the entire system, loose or dislodged parts, anomalous startup circumstances, automated interruptions or shutdowns, system crashes, etc. during the operation. Among the adverse events possibly related to the LANCET system, there was one case of prolonged hospitalization due to anemia resulting from intraoperative bleeding in the RAA group (1.8 %). In the control group, there were no procedure-related adverse events. None of the 111 patients had complications such as hip dislocation or joint prosthesis infection during the 3 months follow-up period.

Discussion

With the increasing use of surgical robots in orthopedic surgery, it has been found that robotic technology assistance can improve the accuracy and radiological alignment of implant placement [24,25]. Young surgeons can learn and perform complex, highly precise orthopedic procedures using robot-assisted surgery system which includes 3D models for preoperative planning and precise intraoperative positioning and calculations [26]. This study compared the clinical results of individuals who underwent RAA THA to those who underwent conventional THA after 3 months of follow-up. There were no statistical differences in age, gender or BMI between two groups. This study found that the LANCET robotic system performed well in terms of reaching precision in pre-operative planning. In the RAA group, over 90 % of patients' postoperative acetabular cup inclination angles and version angles within 5° of the preoperative plans, compared with only 60%–70 % in the control group. This was in line with previous studies where approximately 90 % of the acetabular cup positions in RAA THA deviated from the preoperative plan by less than 5°, much higher than in the conventional group [27,28]. This is due to the surgeon's ability to accurately file the acetabular fossa with the robotic arm, reducing the error in cup placement. The LANCET robotic system can achieve a filing error of less than 0.5 mm, allowing the maximum amount of bone to be preserved with precise placement of the acetabular cup.

Placing the cups outside the safe zone can lead to complications, including dislocation, instability, wear and tear of the implants and revision surgery, reducing the patient's prognosis and increasing the financial burden [29]. Acetabular cup positions within the Lewinnek

Table 3
Radiographic outcome one week after surgery.

Index statistics	RAA group	Control group	P value
Inclination and version (N)			
Lewinnek safe zone	52 (92.9 %)	47 (85.5 %)	0.2092
Callanan safe zone	49 (87.5 %)	44 (80.0 %)	0.2838
Acetabular inclination discrepancy			0.0061
Within 5°	53 (94.6 %)	42 (76.4 %)	
Outside 5°	3 (5.4 %)	13 (23.6 %)	
Acetabular version discrepancy			0.0003
Within 5°	51 (91.1 %)	34 (61.8 %)	
Outside 5°	5 (8.9 %)	21 (38.2 %)	
LLD (mm)	2.27 ± 4.19	1.29 ± 4.33	0.2538
Global offset (mm)	2.67 ± 3.26	2.12 ± 3.00	0.3882

safe zone (92.9 %) and the Callanan safe zone (87.5 %) were also greater in the RAA group of patients than in the control group, 85.5 % and 80.0 % respectively. This finding was comparable to Tian et al.'s percentage of acetabular cups in the Lewinnek safe zone using the JianJia robotic system (90.5 %) [30], and higher than Guo et al. using the Mako system (69.81 %) [31]. A retrospective study showed of Robotic THA, 87.1%–97.78 % were located within the Lewinnek safe zone and 77.42%–94.07 % within the Callanan safe zone [32]. We found that the patients in the RAA group who were outside the safe zone were due to preoperative planning angles close to or above the safe zone boundary, rather than due to surgical manipulation errors. This may be related to precise acetabular fossa filing with the assistance of a robotic arm, so that the surgeon can plan the acetabular cup angle more precisely for the patient preoperatively. This study also demonstrated no significance between the RAA group and the control group regarding hip mobility, leg length discrepancy (LLD), global offset, intraoperative bleeding, and Harris score. Therefore, we can conclude that robotic system is ahead of conventional THA surgery in terms of accuracy in placing the acetabular cup, and is consistent with conventional THA surgery in terms of postoperative recovery of hip function, and complications within 3 months postoperatively. Dislocation of the hip prosthesis occurs in approximately 2 % of patients within 1 year of surgery [33]. Longer follow-up is ongoing to observe the differences in hip functionality and postoperative complications between the two groups.

The reasons of above-mentioned advantages can be attributed to the following reasons. 1) The patient's CT was imported into the LANCET robotic system prior to surgery. Compared to conventional surgery, the LANCET robotic system takes the CT data and planning parameters to construct a three-dimensional template. The anatomical landmarks of the acetabular fossa are more easily identified in the 3D model, and based on these landmarks the size, position and depth of the acetabular cup can be determined more precisely [34]. 2) At the start of the RAA THA, the 32 marker points of the pelvis were sequentially recorded using the probe and the next step was unlocked only when the validation error was less than 0.5 mm. Before both acetabular filing and acetabular cup placement, it was necessary to verify that the error was within range before unlocking the next step. In conventional surgery, acetabular information acquisition and filing depth were based on the surgeon's experience and habits. With the aid of the LANCET robotic system, both steps have become visualized and standardized, greatly improving the accuracy of the acetabular prosthesis fitting, as verified by the post-operative imaging results. In addition, the LANCET robotic system was designed to automatically stop when the planning area was exceeded to avoid excessive acetabular injury. 3) It is now widely recognized that changes in body position cause changes in the angle of the spine to the pelvis, which in turn leads to changes in the angle of acetabular abduction and inclination [35]. The LANCET robotic system ultimately achieves individualized precision surgery for each patient by combining pelvic registration information with real-time intraoperative measurements of acetabular prosthesis position and angle, and by predicting parameters such as postoperative lower extremity force lines.

Although the MAKO robotic system has demonstrated its superiority, several obstacles are existed and affected its wide application in China [36]. Cost is an important factor in the implementation of RAA, with expensive equipment acquisition and maintenance costs, reliance on imported equipment components and long maintenance cycles. Expensive prices and complex maintenance have led to imported surgical robots being concentrated only in large hospitals in major cities, which will further exacerbate the imbalance in medical resources in China. Take a large tertiary hospital as an example, the MAKO robotic system costs about RMB 15,000 to use and RMB 10,000 to RMB 20,000 in consumables for one THA case. In comparison, the LANCET robotic system costs about RMB 5000 to use and RMB 5000 in consumables in one THA case. Compared to the MAKO robotic system, one THA case with the LANCET robotic system can save RMB 15,000 to RMB 20,000. The LANCET robotic system has its own property rights and can replace expensive imported products with affordable and same-quality domestic consumables and products. This will facilitate the promotion of domestic surgical robots in China's primary hospitals. In addition, the design parameters and adapted prosthesis models of imported surgical robots were generally based on the needs of Caucasians. During surgery we have found that the type of prosthesis is not perfectly adapted to all THA patients. Therefore, the development of a domestic joint replacement robot and a suitable prosthesis based on the anatomical characteristics and needs of the Chinese population is very promising.

Based on the above reasons, several policies have been issued by China's government to support the research and development of domestic surgical robots. The 14th Five-Year Plan emphasizes the development of independently developed high-tech medical devices, and the Ministry of Industry and Information Technology has incorporated biomedicine into the national special plan, accelerating the high-quality development of the medical equipment industry, solving the "neck" technology and increasing the share of localization of high-end technology products. With China's ageing population and socio-economic development, people's health awareness is gradually increasing and they are putting forward higher demands for quality of life. The number of hip joint replacement surgeries will increase significantly year by year. As one of the largest and most complex operations in orthopedics, THA relies heavily on the skill and experience of the surgeon in charge. Experienced surgeons tend to be concentrated in the tertiary hospitals in major cities, and it is difficult to meet the demand of the society with the number of surgeries performed each year. The surgical robot is characterized by standardization and reproducibility. With standardized training and clinical specifications, surgical robots can effectively shorten the learning curve for doctors, especially young doctors, to quickly master complex surgery and improve the overall level of medical services in hospitals and the region [26,37,38]. A large number of skilled surgeons, lower equipment prices and easy maintenance are conducive to the promotion and popularity of domestic robots in primary care institutions such as secondary hospitals, alleviating to some extent the problem of uneven distribution of medical resources and solving the problem of ""expensive and difficult access"" to primary care patients.

There are some limitations in this study. Mean operative time was significantly higher in the RAA group than in the control group because procedures such as acetabular registration took a lot of time. The surgeon's preoperative planning time in both conventional THA and LANCET robotic system-assisted THA was 5–10 min. Filing the acetabulum and placing the acetabular cup takes approximately 10–20 min. Because the required depth can be attained in a single filing with the LANCET robotic system, it is faster and more precise than the conventional method of filing numerous times. This is based on the surgeon's experience and more clinical cases are needed to analyze the time distribution of each step of robot-assisted THA. The learning curve of surgical robots for THA has been previously reported to be 13–19 cases, which is much lower than that of conventional THA [30,31,39,40]. A surgeon skilled in the use of the LANCET robotic system after performing 10 robotic-assisted THA operations. The results of the learning curve of the LANCET robotic system also need to be summarized with data from more clinical trials and surgeons.

Conclusion

The results of this prospective clinical study demonstrated that the LANCET robotic system is ahead of conventional THA surgery in terms of accuracy in placing the acetabular cup, and is consistent with conventional THA surgery in terms of postoperative recovery of hip function, and complications. The development and promotion of domestically produced surgical robots is a significant solution to alleviate China's existing medical resource imbalance through scientific and technical innovation, as well as to improve patients' medical satisfaction.

The translational potential of this article

In the past, the success rate of total hip arthroplasty (THA) relied heavily on the surgeon's experience. As a result, junior doctors needed extensive training to become proficient in this technique. However, the introduction of surgical robots has significantly improved this situation. By utilizing robotic assistance, both junior and senior doctors can perform THA quickly and efficiently. This advancement is crucial for the widespread adoption of THA, as patients can now receive surgical treatment in local facilities instead of overwhelming larger hospitals and straining medical resources. Moreover, the development of surgical robots with fully independent intellectual property rights holds immense value in overcoming the limitations of high-end medical equipment. This aligns with the objectives outlined in the 14th Five Year Plan for National Science and Technology Strategy.

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Declaration of generative AI in scientific writing

The AI technique was applied to improve the readability and language under the supervision of corresponding author.

Declaration of competing interest

None.

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