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HURWA robotic-assisted total knee arthroplasty improves component positioning and alignment – A prospective randomized and multicenter study



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ABSTRACT

Background: The objective of this study was to compare the radiologic and clinical outcomes of HURWA roboticassisted total knee arthroplasty (TKA) to those of conventional TKA. *Methods:* A total of 150 patients were randomized into two groups – 73 and 77 patients underwent robotic-assisted TKA and conventional TKA, respectively. Preoperative and postoperative Western Ontario McMaster University Osteoarthritis Index (WOMAC) score, Hospital for Special Surgery (HSS) score, 36-item Short Form Health Survey (SF-36) score, Knee Society Score (KSS) and range of motion (ROM) were obtained and compared between these two groups. The preoperative and postoperative hip-knee-ankle (HKA) angle and the rate of HKA \leq 3° in the two groups were also compared. *Results:* The postoperative mean HKA angle was 1.801° ± 1.608° of varus for the robotic-assisted TKA group and

 $3.017^{\circ} \pm 2.735^{\circ}$ of varus for the conventional TKA group; these values were significantly different. The alignment rate for mechanical axis lower than 3° in the robotic-assisted TKA group and the conventional TKA group were 81.2% and 63.5%, respectively. Patients undergone robotic-assisted TKA or conventional TKA had similarly improved knee flexion and functional recovery reflected by WOMAC score, HSS score, SF-36 score and KSS. *Conclusion:* HURWA robotic-assisted TKA is a safe and effective, resulting in better alignment for mechanical axis

than conventional TKA. The improvement in knee flexion and functional recovery after HURWA robotic-assisted TKA were similar to those after conventional TKA. However, longer follow-up is needed to determine whether the improved alignment of mechanical axis will produce better long-term clinical outcomes.

The translational potential of this article: Recently, the robotic-assisted TKA system has been introduced to clinical practice for TKA. Several robotic-assisted TKA systems, including CASPAR, Tsolution, ROSA, ROBODOC and Mako, have been implemented into clinical application.However, the clinical application of these robotic systems was limited due to their technical complexity, insufficient versatility and increased operative time. Until now, there are still no robotic-assisted TKA systems approved by the National Medical Products Administration of China. Therefore, more robotic-assisted TKA systems need to be designed and improved, particularly in China. Through our randomized, multicenter, single blind and parallel controlled trial, we showed that HURWA robot-assisted TKA system is a safe and effective system for TKA, which had improved knee flexion.

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Abbreviations: TKA, total knee arthroplasty; KOA, Knee osteoarthritis.

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1. Introduction

Knee osteoarthritis (KOA) is characterized by degradation of articular cartilage [1–4]. KOA is the most frequent type of arthritis, causing progressive pain and physical debilitation [5–7]. A previous study demonstrated that about half of individuals older than 65 years suffered from KOA [8]. The prevalence of KOA is expected to be on the rise due to the expanding aging population [3]. Total knee arthroplasty (TKA) is the best method for the treatment of late-stage KOA [9–12]. In China, over 370, 000 TKAs were performed each year with an annual growth rate of 15% [13]. Soft tissue balancing and mechanical alignment play important roles in implant survival rate, patient functionality, and TKA success [14–16]. Previous studies showed that the proportion of hip-knee-ankle (HKA) angle outliers greater than \pm 3° in the conventional TKA was 10–20% [17]. This may cause knee prosthesis failure and abnormal load and is strongly associated with limited range of motion and reduced satisfaction [18].

Despite the emergence of patient-specific instrumentation, standard cutting guides, navigation, and accelerometer-based navigation, these new operation approaches are costly [19-21]. Recently, the robotic-assisted TKA system has been introduced to clinical practice for TKA [22]. The robot-assisted system is a new technology which uses computed tomography (CT) data of patients' lower limb to make a preoperative plan and three -dimensional planning to orientate and size and uses the robotic arm to cut the bone and place for components [23,24]. Several robotic-assisted TKA systems, including CASPAR, Tsolution, ROSA, ROBODOC and Mako, have been implemented into clinical application [25-28]. Previous studies showed that robotic-assisted TKA can offer more accurate bone cuts, precise placement of implants and provide balanced extension and flexion gaps [29,30]. Moreover, robotic-assisted TKA can reduce the extent of bone resection and damage to the soft tissue, which are associated with postoperative pain [31]. However, the clinical application of these robotic systems was limited due to their technical complexity, insufficient versatility and increased operative time [31]. Until now, there are still no robotic-assisted TKA systems approved by the National Medical Products Administration of China. Therefore, more robotic-assisted TKA systems need to be designed and improved, particularly in China. Available types of robotic-assisted TKA include (1) robotic arm designed to provide a haptic interface; (2) handheld robotic burr manually controlled by the surgeon; (3) CT based autonomous system for implant fit and positioning; and (4) motor-powered robotic system that performs precise tibial and femoral cuts. Each type has distinct requirements for manual input from the surgeon and preoperative CT scan and has different compatibility with

knee prosthesis. Recently, a new robotic-assisted TKA system (HURWA, BELJING HURWA-ROBOT Technology Co. Ltd) has been designed (Fig. 1). Our system also uses the CT data of lower limb to perform the preoperative plan and three -dimensional planning to orientate and size and actively uses the robotic arm to cut the bone and place for components. We previously investigated the accuracy and safety of this system in a sheep model and found that it might be an accurate and safe tool for TKA [32]. Moreover, we found that the accuracy of all of the bone resection levels was below 0.6 mm and all of the bone resection angles were below 0.6° in the HURWA robotic-assisted TKA group [33].

In the present study, we performed a randomized, multicenter, singleblind, two-arm, parallel-group controlled trial of HURWA roboticassisted TKA versus conventional TKA to study the effectiveness and safety of this system in humans.

2. Materials and methods

2.1. Study design

Our study was a randomized, multicenter, single blind and parallel controlled trial that was approved by the Institutional Review Board of Peking Union Medical College Hospital (IRB # KS2020328), Affiliated Beijing Chaoyang Hospital of Capital Medical University 1 (IRB # 2020-10-28-2) and Tianjin Hospital (IRB # 2020-QX-004). All patients had provided written informed consent.

2.2. Patient recruitment

From January 2020 to March 2021, a total of 150 patients were randomized into two groups - 73 patients underwent robotic-assisted TKA and 77 underwent conventional TKA. Patients with primary KOA who underwent TKA using the Legion system (Smith & Nephew, London, UK) were included. The inclusion criteria were as follows: older than 18 years old with primary and unilateral TKA. The exclusion criteria were as follows: Patients with post-traumatic osteoarthritis, infection, severe systemic disease (severe diabetes, severe heart disease, severe liver and/ or kidney insufficiency, active tuberculosis infection, hemorrhagic disease), neuromuscular dysfunction of lower limbs (e.g. sequelae of poliomyelitis, myasthenia) and participated in clinical studies of other drugs, biological agents or devices in the last 3 months. All operations were performed by experienced surgeons for the conventional and robotic-assisted groups at three hospitals. All patients who underwent TKA with the robotic-assisted or conventional operations underwent the clinical and radiologic assessment.



Figure 1. The robot console and the surgical platform of HURWA robot-assisted TKA system.



Figure 2. Preoperatively planned position and posture of a femoral component by the HURWA robot-assisted TKA system.



Figure 3. Preoperatively planned position and posture of a tibial component by the HURWA robot-assisted TKA system.

2.3. Surgical procedures

Conventional TKA was performed using the Legion system (Smith & Nephew, London, UK) according to the manufacturer's instructions. In brief, 10 mm of tibial bone was resected with the 7° posterior tibial slope. Femoral rotation was followed to three axes: (1) the transepicondylar axis, (2) Whiteside line and (3) 3° of external rotation relative to the posterior aspect of the femoral condyles. Tibial component rotation was aligned with the medial one third of the tibial tubercle.

Robot-assisted TKA was also performed using the Legion system together with the HURWA robotic-assisted TKA system (HURWA, BEI-JING HURWA-ROBOT Technology Co. Ltd). Preoperative CT scan of lower limbs was taken for preoperative surgical planning. CT scan of lower limbs files included images of 3 regions (hip, knee, and ankle). These DICOM files were imported into the HURWA software system and segmented to build 3-D bone models. Preoperative surgical planning included varus/valgus angles, flexion/extension angles, internal/ external rotation angles, axes and implant alignment planning (Fig. 2 and Fig. 3). After intraoperative registration, bone resection was performed by surgeons with the robotic arm (Fig. 4).

2.4. Clinical outcome evaluation

Clinical information, including age, sex, height, body weight and other general information was collected preoperatively. Other clinical information were collected and entered into the database preoperatively and postoperatively by an independent investigator. The primary evaluation index was the rate of malalignment for mechanical axis greater than 3°. The safety objective of this study was based on the rate of intraoperative and postoperative TKA complications. The secondary evaluation indexes included: HSS score, KSS, WOMAC score and operation time. Preoperative clinical scores were collected on the day before surgery and



2.6. Statistical analysis

Statistical analysis was determined by SPSS (version 25, Inc, Chicago, IL) and P < 0.05 was considered to be statistically significant. Non inferiority one-sided Z-test and confidence interval were used to evaluate the main effectiveness evaluation indexes. Chi-square and Fisher's exact test were performed to assess safety evaluation indexes and secondary evaluation index.

3. Results

The mean follow-up period of all patients was 3 months. There was no significant difference in sex, age, height or weight between the control group and the robot-assisted TKA group (Table 1). All patients were diagnosed as severe osteoarthritis at the stage of middle and late stages. Table 2 summarized the preoperative radiological and clinical data in the two groups. There were no significant differences between these two groups about knee flexion, HSS score, KSS score, WOMAC score and SF-36 score. The preoperative mean hip-knee-ankle (HKA) angle was $8.65^{\circ} \pm 0.49^{\circ}$ of varus for the robot-assisted TKA group and $7.96^{\circ} \pm 0.65^{\circ}$ of varus for the conventional TKA group (Table 3); these values were not significantly different.

The postoperative mean hip-knee-ankle (HKA) angle was $1.801^\circ\pm1.608^\circ$ (range, 0.15° to 7.75°) of varus for the robot-assisted TKA group and $3.017^\circ\pm2.735^\circ$ (range, 0.20° to 15.15°) of varus for the conventional TKA group (Table 4); these values were significantly different. The primary effectiveness endpoint is alignment of coronal mechanical axis at 3 months defined as achieving varus-valgus alignment less than $\pm3^\circ$ in the frontal plane after TKA. The robot-assisted TKA group showed a 81.2% malalignment for mechanical axis lower than 3° and the conventional TKA group showed a 63.5% malalignment for mechanical axis lower than 3°.

In the robot-assisted TKA group, the range of knee flexion was from 60° to 135° and the average range was $114.5\pm18.41^\circ$ at 12 weeks after

surgeon can perform the osteotomy with a cutting saw once the cutting jig that move to the planned position. postoperative clinical scores were measured at minimally 3 months after surgery by an independent investigator.

2.5. Radiologic outcome evaluation

Preoperative (within 7 days before the surgery) and postoperative (3 months after the surgery) radiologic data were obtained by two independent investigators. The anteroposterior radiograph of the entire lower extremity during weight bearing and the anteroposterior and lateral radiographs of the knee were performed. Mechanical alignment was determined by measuring the mechanical femorotibial angle (mFTA). The rate of malalignment for mechanical axis greater than 3° was recorded.

Table 1

Demographic data.

Index statistics	Sum(N =	150)	Study grou	up(N = 73)	Control g	roup(N = 77)	Statisticvalue	P value
Age (years)							-0.84	0.4009
Number of cases (missing)	150	(0)	73	(0)	77	(0)		
Average value(Standard Deviation)	68.5	(7.02)	68.0	(7.97)	69.0	(6.00)		
Median (Q1, Q3)	69.0	(64.0, 73.0)	68.0	(63.0, 73.0)	70.0	(65.0, 72.0)		
Min, Max	30.0,	86.0	30.0,	86.0	54.0,	83.0		
Age group, n(%)							0.14	0.7040
<65 years old	39	(26.0)	20	(27.4)	19	(24.7)		
\geq 65 years old	111	(74.0)	53	(72.6)	58	(75.3)		
Gender, n(%)							0.07	0.7928
Male	28	(18.7)	13	(17.8)	15	(19.5)		
Female	122	(81.3)	60	(82.2)	62	(80.5)		
Weight (kg)							-2.05	0.0424
Number of cases (missing)	150	(0)	73	(0)	77	(0)		
Average value(Standard Deviation)	70.7	(10.49)	69.0	(9.87)	72.4	(10.84)		
Median (Q1, Q3)	70.0	(65.0, 76.0)	69.0	(63.0, 75.0)	71.0	(67.0, 78.0)		
Min, Max	43.5,	100.0	48.0,	95.0	43.5,	100.0		
Weight group, n(%)							4.52	0.1044
<65 kg	34	(22.7)	21	(28.8)	13	(16.9)		
\geq 65 kg and <90 kg	105	(70.0)	49	(67.1)	56	(72.7)		
≥90 kg	11	(7.3)	3	(4.1)	8	(10.4)		
Height (cm)							-2.11	0.0363
Number of cases (missing)	150	(0)	73	(0)	77	(0)		
Average value(standard deviation)	161.2	(7.51)	159.9	(7.20)	162.5	(7.63)		
Median (Q1, Q3)	160.0	(156.0, 165.0)	160.0	(155.0, 164.0)	160.0	(157.0, 165.0)		
Min, Max	145.0,	185.0	145.0,	178.0	150.0,	185.0		
BMI(kg/m ²)							-0.86	0.3891
Number of cases (Missing)	150	(0)	73	(0)	77	(0)		
Average value(standard deviation)	27.2	(3.32)	26.9	(3.26)	27.4	(3.38)		
Median (Q1, Q3)	27.3	(25.2, 29.1)	26.8	(24.6, 28.8)	27.3	(25.5, 29.2)		
Min, Max	16.2,	38.5	20.0,	38.5	16.2,	35.0		
BMI group, n(%)							0.31	0.5749
$<28 \text{ kg/m}^2$	89	(59.3)	45	(61.6)	44	(57.1)		
\geq 28 kg/m ²	61	(40.7)	28	(38.4)	33	(42.9)		



Statistical description of present medical history, knee function and life-quality scores.

Index Statistics	Sum(N = 150)	Study group(N = 73)	Control group(N = 77)	statistic value	P value
Present medical history SOC classification, n(%)				_	_
Various musculoskeletal and connective tissue diseases	150 (100.0%)	73 (100.0%)	77 (100.0%)		
Present medical history staging				0.13	0.7149
Initial stage, n(%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		
Early stage, n(%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		
Middle stage, n(%)	25 (16.7%)	13 (17.8%)	12 (15.6%)		
End stage, n(%)	125 (83.3%)	60 (82.2%)	65 (84.4%)	0.00	0 1 400
Affected knee	92 (EE 20/)	26 (40, 20%)	47 (61 004)	2.08	0.1489
Pight lower extremity, n(%)	63 (33.3%) 67 (44 7%)	30 (49.3%)	47 (01.0%)		
ROM of affected knee(°)	07 (44.790)	37 (30.7%)	30 (39.0%)	-0.07	0 9437
Number of cases (missing)	150 (0)	73 (0)	77 (0)	-0.07	0.9437
Average value(standard deviation)	99 9(20 10)	99 8(20 95)	100 0(19 40)		
Median number (O1, O3)	100.0 (90.0, 115.0)	100.0 (90.0, 115.0)	95.0 (90.0, 110.0)		
Min. Max	45.0. 140.0	45.0. 140.0	50.0. 140.0		
HSS Overall Score	,	,		1.52	0.1298
Number of cases (missing)	150 (0)	73 (0)	77 (0)		
Average value(standard deviation)	63.7(12.81)	65.3(11.34)	62.2(13.96)		
Median number (Q1, Q3)	64.5 (55.0, 73.0)	66.0 (58.0, 73.0)	63.0 (55.0, 71.0)		
Min, Max	31.0, 94.0	40.0, 89.0	31.0, 94.0		
HSS overall score group, n(%)				NA	0.4986
\geq 85 points	5 (3.3%)	2 (2.7%)	3 (3.9%)		
70–84 points	53 (35.3%)	29 (39.7%)	24 (31.2%)		
60–69 points	45 (30.0%)	23 (31.5%)	22 (28.6%)		
<60 points	47 (31.3%)	19 (26.0%)	28 (36.4%)		
KSS Objective score				1.71	0.0899
Number of cases (missing)	150 (0)	73 (0)	77 (0)		
Average value(standard deviation)	36.8(19.66)	39.6(18.27)	34.2(20.66)		
Median number (Q1, Q3)	34.0 (26.0, 43.0)	35.0 (29.0, 57.0)	33.0 (22.0, 39.0)		
Min, Max	-12, 76	-3, 76	-12, 76		
KSS symptom score	4 = 0 (0)		(0)	-0.39	0.6984
Number of cases (missing)	150 (0)	73 (0)	77 (0)		
Average value(standard deviation)	15.8(3./1)	15.7(3.53)	15.9(3.89)		
Min Mox	10.5 (13.0, 19.0)	10.0 (13.0, 18.0)	17.0 (13.0, 19.0)		
VSS patiente' satisfactory value	2, 23	0, 25	2, 23	0.38	0 7072
Number of cases (missing)	150 (0)	73 (0)	77 (0)	-0.50	0.7072
Average value(standard deviation)	17 1(6 00)	16 9(5 60)	17 2(6 39)		
Median number (O1, O3)	18.0 (14.0, 20.0)	18.0 (14.0, 20.0)	18.0 (14.0, 22.0)		
Min. Max	0. 34	0.30	4, 34		
KSS Score of surgical expectations	.,	- ,		0.08	0.9333
Number of cases (missing)	150 (0)	73 (0)	77 (0)		
Average value(standard deviation)	14.4(1.50)	14.4(1.54)	14.4(1.47)		
Median number (Q1, Q3)	15.0 (15.0, 15.0)	15.0 (15.0, 15.0)	15.0 (15.0, 15.0)		
Min, Max	6, 15	6, 15	8, 15		
KSS functional score				1.65	0.1002
Number of cases (missing)	148 (2)	71 (2)	77 (0)		
Average value(standard deviation)	34.8(17.70)	37.3(16.68)	32.5(18.40)		
Median number (Q1, Q3)	35.0 (22.5, 46.0)	38.0 (27.0, 48.0)	31.0 (21.0, 44.0)		
Min, Max	-10.0, 84.0	-10.0, 76.0	-10.0, 84.0		
WOMAC Score				-0.04	0.9715
Number of cases (missing)	150 (0)	73 (0)	77 (0)		
Average value(standard deviation)	119.0(40.63)	118.9(40.44)	119.2(41.07)		
Min Mar	117.5 (90.0, 144.0)	112.0 (88.0, 145.0)	122.0 (92.0, 141.0)		
Mill, Max	9.0, 238.0	28.0, 238.0	9.0, 235.0	1.01	0 21 42
Number of cases (miscing)	140 (1)	72 (1)	77 (0)	1.01	0.3142
Average value(standard deviation)	177 (1) 40 20(16 569)	7 4 (1) 50 71(17 120)	47 96(16 025)		
Median number (01 03)	47 40 (37 70 61 00)	47 45 (37 85 64 20)	46 60 (37 30 57 60)		
Min Max	18.8.89.5	18.8.89.5	197 874		
	10.0, 09.0	10.0, 09.0			

Table 3

Statistical description of preoperative lower limb alignment between the two groups.

Index Statistics	Study = 69)	group (N	Contro = 74)	ol group (N
Absolute value of lower limb alignment(°) Number of cases(Missing) Average Value(Standard Deivation) P Value	69 8.65 0.3917	(0) (0.49) 7	74 7.96	(0) (0.65)

operation. Compared with the baseline data, the range of motion at 12 weeks after operation was significantly increased by $14.4 \pm 22.24^{\circ}$ in the robot-assisted TKA group (95% CI: 9.0, 19.7). In the conventional TKA group, the range of knee flexion was ranged from 75° to 140° with an average of 111.6° \pm 18.75° at 12 weeks postoperatively. Compared with the baseline data, the range of range of motion at 12 weeks postoperatively significantly increased by 11.1° \pm 20.33°(95% CI: 6.4, 15.8). There was no significant difference in activity improvement between these two groups (P = 0.2877) (Table 5).

Statistical description of lower limb alignment correction between the two groups.

Index Statistics	Study g (N = 69	roup))	Control (N = 74	group ł)
Absolute value of lower limb alignment(°)				
Number of cases(Missing)	69	(0)	74	(0)
Average Value(Standard Deivation)	1.801	(1.6080)	3.017	(2.7352)
Median Number(Q1,Q3)	1.250	(0.60,	2.450	(1.10,
		2.55)		4.00)
Min,Max	0.15,	7.75	0.20,	15.15
Whether lower limb alignment is corrected successfully [1]				
Yes, n(%)	56	(81.2)	47	(63.5)
No, n(%)	13	(18.8)	27	(36.5)
Correction rate(%) and 95%CI [2]	81.2	(69.9,	63.5	(51.5,
		89.6)		74.4)
Lower limb alignment correction assesement Rate(%) and 95%CI [3]	17.5	(3.2, 31.9)		
P Value [3]	0.0207	,		

Table 5

Statistical description of ROM of subjects in follow-up when compared to baseline.

Follow up statistics	Study group $(N = 69)$	Control group $(N = 74)$
Baseline		
Number of cases (missing)	69 (0)	74 (0)
Average value(standard deviation)	100.1 (20.82)	100.5 (19.31)
Median number (Q1, Q3)	100.0 (90.0, 115.0)	97.5 (90.0, 115.0)
Min, Max	45, 140	50, 140
POD 12 weeks \pm 10 days		
Number of cases (missing)	69 (4)	74 (0)
Average value(standard deviation)	114.5 (18.41)	111.6 (18.75)
Median number (Q1, Q3)	120.0 (105.0,	115.0 (95.0,
	130.0)	130.0)
Min, Max	60, 135	75, 140
Relative Change of Baseline		
Number of cases (missing)	69 (0)	74 (0)
Average value(standard deviation)	14.4 (22.24)	11.1 (20.33)
Median number (Q1, Q3)	15.0 (0.0, 30.0)	7.5 (-5.0, 25.0)
Min, Max	-45, 75	-35, 70
Average value 95%CI	(9.0, 19.7)	(6.4, 15.8)
Adjusted average value(Standard	14.238(2.040)	11.211(1.970)
error) [1]		
Adjusted mean difference(95%CI)	3.027(-	
[1]	2.580,8.634)	
P Value [1]	0.2877	

The HSS score of the experimental group ranged from 40.0 to 99.0, with an average score of 80.10 ± 12.461 . Compared with the baseline data, the postoperative HSS score was significantly increased by 14.38 ± 14.958 (95% CI: 10.78, 17.97). The control group ranged from 39.0 to 98.0 points, with an average of 79.45 ± 11.520 points. Compared with the baseline data, the postoperative HSS score was significantly increased by 16.43 ± 15.113 points (95% CI: 12.92, 19.93). There was no significant difference in the improvement of HSS score between the two groups (P = 0.9862) (Table 6).

Based on the objective knee score, the average score of the experimental group was 70.0 \pm 7.31, ranging from 44 to 77. Compared with the baseline data, the average objective knee score of the experimental group was improved to 30.4 \pm 20.13; The control group ranged from 27 to 78 with an average of 67.8 \pm 10.06; Compared with the baseline data, the average objective score of the control group was improved to 32.5 \pm 23.75, and there was no significant difference between the two groups (P = 0.1107) (Table 7).

Based on the symptom score, the score range of the experimental group was 6–21, and the average score was 12.5 ± 3.89 . Compared with the baseline data, the average symptom score of the experimental group

Table 6

Statistical description of HSS overall score of subjects in follow-up when compared to baseline.

Follow up statistics	Study group $(N = 69)$	Control group $(N = 74)$
Baseline		
Number of cases (missing)	69 (0)	74 (0)
Average value(standard deviation)	65.7 (11.20)	63.0 (13.28)
Median number (Q1, Q3)	66.0 (60.0, 73.0)	64.0 (55.0, 72.0)
Min, Max	40, 89	32, 94
POD 12 weeks \pm 10 days		
Number of cases (missing)	69 (0)	74 (0)
Average value(standard deviation)	80.10 (12.461)	79.45 (11.520)
Median number (Q1, Q3)	83.00 (75.00,	81.00 (74.00,
	87.00)	86.00)
Min, Max	40.0, 99.0	39.0, 98.0
Relative Change of Baseline		
Number of cases (missing)	69 (0)	74 (0)
Average value(standard deviation)	14.38 (14.958)	16.43 (15.113)
Median number (Q1, Q3)	14.00 (5.00, 24.00)	14.00 (7.00, 25.00)
Min, Max	-36.0, 45.0	-17.0, 65.0
Average value 95%CI	(10.78, 17.97)	(12.92, 19.93)
Adjusted average value(Standard	15.454(1.397)	15.421(1.349)
error) [1]		
P Value [1]	0.9862	

improved to -3.2 ± 4.86 ; The control group ranged from 6 to 23, with an average of 11.5 \pm 3.75; Compared with the baseline data, the average symptom score of the control group was - 4.4 \pm 5.71, and there was no significant difference between the two groups (P = 0.1390) (Table 7).

Based on patient satisfaction, the score of the experimental group ranged from 10 to 40, with an average score of 25.2 ± 7.31 . Compared with the baseline data, the average satisfaction score of the experimental group was improved to 8.3 ± 8.46 ; The control group ranged from 14 to 40, with an average of 26.8 ± 6.26 ; Compared with the baseline data, the average satisfaction score of the control group was improved to 9.5 ± 8.18 , and there was no significant difference between the two groups (P = 0.1760) (Table 7).

Based on the expected score of surgery, the average score of the experimental group was 8.8 ± 2.91 , ranging from 3 to 15. Compared with the baseline data, the average score of the experimental group was improved to 5.6 ± 3.12 ; The control group ranged from 3 to 15, with an average of 8.7 ± 2.41 ; Compared with the baseline data, the average score of the control group was -5.8 ± 2.66 , and there was no significant difference between the two groups (P = 0.9019) (Table 7).

Based on the functional score, the score of the experimental group ranged from 5 to 90, and the average score was 58.2 ± 18.19 . Compared with the baseline data, the average functional score of the experimental group was improved to 21.2 ± 22.84 ; The control group ranged from 5 to 89, with an average of 54.7 ± 19.52 ; Compared with the baseline data, the average functional score of the control group was improved to 21.4 ± 21.91 , and there was no significant difference between the two groups (P = 0.3942) (Table 7).\

The WOMAC scores of the experimental group ranged from 0 to 193, with an average score of 80.6 \pm 46.52. Compared with the baseline data, WOMAC score decreased to - 37.8 \pm 58.65 (95% CI: - 51.9, - 23.7). The control group ranged from 7 to 206, with an average of 72.1 \pm 44.40; Compared with baseline data, WOMAC score decreased by - 45.7 \pm 49.38 (95% CI: - 57.2, - 34.3). There was no significant difference in WOMAC score between the two groups (P = 0.2559) (Table 8).

The score of the experimental group ranged from 14.4 to 97.1, with an average score of 61.19 \pm 19.906. Compared with the baseline data, the average SF-36 Health Scale score of the experimental group was improved to 10.74 ± 20.409 ; The control group ranged from 16.7 to 97.3 with an average of 63.05 \pm 19.021; Compared with the baseline data, the average SF-36 Health Scale score of the control group was improved to 14.27 \pm 21.204, and there was no significant difference between the two groups (P = 0.4511) (Table 9).

Statistical description of life quality assessments of subjects in follow-up when compared to baseline.

Index Follow up Statistics	Study group $(N = 69)$	Control group $(N = 74)$
Objective Velue	((
Baseline		
Number of cases (missing) Average value(standard deviation) Median number (Q1, Q3)	69 (0) 39.6 (18.40) 35.0 (29.0, 57.0)	74 (0) 35.2 (20.29) 33.0 (23.0, 41.0)
Min, Max	-3, 76	-12, 76
POD 12 weeks \pm 10 days	40 (D)	
Number of cases (missing) Average value(standard deviation) Median number (Q1, Q3) Min, Max	69 (0) 70.0 (7.31) 72.0 (66.0, 76.0) 44, 77	74 (0) 67.8 (10.06) 70.5 (64.0, 76.0) 27, 78
Relative Change of Baseline		
Number of cases (missing) Average value(standard deviation) Median number (O1, O3)	69 (0) 30.4 (20.13) 37.0 (16.0, 44.0)	74 (0) 32.5 (23.75) 36.0 (25.0, 46.0)
Min, Max	-11, 62	-49, 88
Average value 95%CI Adjusted average value(Standard error)	(25.6, 35.2) 32.732(1.055)	(27.0, 38.0) 30.371(1.019)
P Value ^{[1}	0.1107	
Symptom Score		
Baseline		
Number of cases (missing)	69 (0)	74 (0)
Average value(standard deviation)	15.7 (3.60)	15.9 (3.95)
Min. Max	6, 23	2, 23
POD 12 weeks \pm 10 days	-,	_,
Number of cases (missing)	69 (0)	74 (0)
Average value(standard deviation)	12.5 (3.89)	11.5 (3.57)
Median number (Q1, Q3)	12.0 (9.0, 16.0)	12.0 (9.0, 13.0)
Mill, Max Relative Change of Baseline	0, 21	0, 23
Number of cases (missing)	69 (0)	74 (0)
Average value(standard deviation) Median number (Q1, Q3)	-3.2 (4.86) -4.0 (-7.0, 0.0)	-4.4 (5.71) -4.0 (-8.0,
Min. Max	-12.7	-1.0)
Average value 95%CI	(-4.4, -2.1)	(-5.7, -3.1)
Adjusted average value(Standard error)	-3.355(0.446)	-4.277(0.431)
[1]		
P值[1]	0.1390	
Baseline		
Number of cases (missing)	69 (0)	74 (0)
Average value(standard deviation)	17.0 (5.46)	17.4 (6.49)
Median number (Q1, Q3)	18.0 (14.0, 20.0)	18.0 (12.0, 22.0)
Min, Max	0, 30	4, 34
POD 12 weeks \pm 10 days	69 (0)	74 (0)
Average value(standard deviation)	25.2 (7.31)	26.8 (6.26)
Median number (Q1, Q3)	26.0 (20.0, 30.0)	28.0 (22.0, 30.0)
Min, Max	10, 40	14, 40
Relative Change of Baseline		
Number of cases (missing)	69 (0) 8 2 (8 46)	74 (0)
Average value(standard deviation)	8.3 (8.46)	9.5 (8.18)
Min. Max	-14, 30	-10.30
Average value 95%CI	(6.3, 10.3)	(7.6, 11.4)
Adjusted average value(Standard error)	8.111(0.801)	9.626(0.774)
[1]		
P Value ¹¹	0.1760	
Baseline		
Number of cases (missing)	69 (0)	74 (0)
Average value(standard deviation)	14.4 (1.58)	14.5 (1.35)
Median number (Q1, Q3)	15.0 (15.0, 15.0)	15.0 (15.0, 15.0)
Min, Max	6, 15	8, 15
POD 12 weeks \pm 10 days	60 (0)	74 (0)
Average value(standard deviation)	8 8 (2 91)	74 (0) 8 7 (2 41)
Median number (O1. O3)	9.0 (6.0, 11.0)	9.0 (7.0, 9.0)
Min, Max	3, 15	3, 15

Table 7 (continued)

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Index	Study group	Control group
Follow up Statistics	(N = 69)	(N = 74)
Relative Change of Baseline		
Number of cases (missing)	69 (0)	74 (0)
Average value(standard deviation)	-5.6 (3.12)	-5.8 (2.66)
Median number (Q1, Q3)	-6.0 (-8.0,	-6.0 (-8.0,
	-4.0)	-5.0)
Min, Max	-12, 2	-12, 3
Average value 95%CI	(-6.4, -4.9)	(-6.4, -5.1)
Adjusted average value(Standard error)	-5.671(0.316)	-5.725(0.305)
[1]		
P Value ^{[1}	0.9019	
Functional Score		
Baseline		
Number of cases (missing)	67 (2)	74 (0)
Average value(standard deviation)	37.4 (17.15)	33.3 (18.31)
Median number (Q1, Q3)	39.0 (26.0, 49.0)	31.5 (22.0, 45.0)
Min, Max	-10, 76	-10, 84
POD 12 weeks \pm 10 days		
Number of cases (missing)	68 (1)	74 (0)
Average value(standard deviation)	58.2 (18.19)	54.7 (19.52)
Median number (Q1, Q3)	60.5 (46.5, 71.0)	56.5 (40.0, 71.0)
Min, Max	5, 90	5, 89
Relative Change of Baseline		
Number of cases (missing)	66 (3)	74 (0)
Average value(standard deviation)	21.2 (22.84)	21.4 (21.91)
Median number (Q1, Q3)	22.0 (5.0, 42.0)	21.0 (9.0, 33.0)
Min, Max	-45, 62	-38, 81
Average value 95%CI	(15.6, 26.8)	(16.3, 26.5)
Adjusted average value(Standard error)	22.708(2.247)	20.058(2.121)
[1]		
P Value ¹¹	0.3942	

Three typical cases which performed by HURWA robot-assisted TKA system were showed (Fig. 5).

4. Discussion

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KOA is one of the common joint diseases in the elderly and it is also the main cause of knee pain and functional limitation in the elderly [34,35]. TKA is a relative successful and effective method for relieving pain and

Table 8

Statistical description of WOMAC overall score of subjects in follow-up when compared to baseline.

Follow up Statistics	Study group $(N = 69)$	Control group (N = 74)
Baseline		
Number of cases (missing)	69 (0)	74 (0)
Average value(standard	118.4 (40.73)	117.8 (41.29)
deviation)		
Median number (Q1, Q3)	112.0 (86.0, 145.0)	119.0 (91.0, 140.0)
Min, Max	28, 238	9, 235
POD 12 weeks \pm 10 days		
Number of cases (missing)	69 (0)	74 (0)
Average value(standard	80.6 (46.52)	72.1 (44.40)
deviation)		
Median number (Q1, Q3)	80.0 (44.0, 111.0)	62.5 (38.0, 92.0)
Min, Max	0, 193	7, 206
Relative Change of Baseline		
Number of cases (missing)	69 (0)	74 (0)
Average value(standard	-37.8 (58.65)	-45.7 (49.38)
deviation)		
Median number (Q1, Q3)	-38.0 (-73.0,	-44.0 (-71.0,
	-11.0)	-13.0)
Min, Max	-196, 164	-181, 81
Average value 95%CI	(-51.9, -23.7)	(-57.2, -34.3)
Adjusted average value(Standard	-37.563(5.297)	-45.962(5.115)
error) [1]		
P Value ^{[1}	0.2559	

Statistical description of SF-36 health scale value of subjects in follow-up when compared to baseline.

Follow up statistics	Study group $(N = 69)$	Control group $(N = 74)$
Baseline		
Number of cases (missing)	68 (1)	74 (0)
Average value(standard deviation)	50.80 (17.431)	48.50 (16.086)
Median number (Q1, Q3)	48.05 (37.45,	47.65 (37.70,
	64.20)	58.20)
Min, Max	18.8, 89.5	19.7, 87.4
POD 12 weeks \pm 10 days		
Number of cases (missing)	69 (0)	72 (2)
Average value(standard deviation)	61.19 (19.906)	63.05 (19.021)
Median number (Q1, Q3)	63.60 (47.70,	61.80 (51.30,
	75.20)	77.35)
Min, Max	14.4, 97.1	16.7, 97.3
Relative Change of Baseline		
Number of cases (missing)	68 (1)	72 (2)
Average value(standard deviation)	10.74 (20.409)	14.27 (21.204)
Median number (Q1, Q3)	11.15 (-1.35,	14.20 (-1.15,
	24.50)	32.60)
Min, Max	-55.0, 54.6	-50.8, 53.7
Average value 95%CI	(5.80, 15.68)	(9.28, 19.25)
Adjusted average value(Standard	11.360(2.197)	13.677(2.135)
error) [1]		
P Value ¹¹	0.4511	

functional recovery of end-stage knee osteoarthritis, which has been widely carried out worldwide [9,36]. Reconstruction of good lower limb alignment is one of the main purposes of TKA, and it is also an important guarantee of patient satisfaction and prosthesis survival rate after TKA [37,38]. Traditional TKA depends on surgical instruments to complete knee joint parameter measurement, prosthesis model selection and surgical scheme implementation. Although new prosthesis and surgical instruments with more perfect design are constantly coming out, and the surgical technology of the operator is also improving year by year, TKA has not yet become a perfect operation, and its postoperative dissatisfaction rate is as high as 20% [39,40]. The main cause is that TKA has high requirements on the position of prosthesis placement, reconstruction of lower limb force line and maintenance of postoperative stability, while manual operation is difficult to ensure the accuracy and consistency of surgical operation [41-43]. Therefore, poor prosthesis position and poor alignment of lower limb occur from time to time, which seriously affects the stability of knee joint and recovery of motor function and the long-term survival rate and postoperative satisfaction of patients were reduced.

The lower limb force line is relative to the vertical line through the pubic symphysis [44]. It is a line starting from the rotation center of the femoral head and ending at the midpoint of the medial and lateral malleolus. It represents the mechanical transmission line of the lower limb in the load-bearing position. With the continuous improvement of science and technology, as well as the in-depth study of coronal force line, it is generally believed that controlling the lower limb force line after TKA in the coronal plane, genu varus within $\pm 3^{\circ}$ is the relative "safe area", and this standard is used to distinguish the good or bad force line [45].

Many developments in surgical technologies have been achieved in the field of operations. Although robotics has been applicated for about two decades in the other specialties, it has only recently been widely utilized in the field of abdominal surgery. Standard extramedullary and intramedullary guides procedures are the most common technologies for obtaining component alignments for TKA surgery [46,47]. Recently, robotic-assisted TKA surgery has been developed and applicated to ameliorate accuracies in component positioning and bone resection, as well as to improve patient satisfaction and functional outcomes of knee [48–51]. For instance, it has showed that MAKO robotic-assisted TKA ameliorated postoperative pain and perfected implant positioning with equally or slightly superior amelioration of the clinical outcomes, compared to control TKA, at postoperative one year [52]. Sires and their colleagues also found that MAKO robotic-assisted TKA can improve the accuracy of component positioning and the precision of bone resection [53]. Recently, Seidenstein and their colleagues demonstrated that ROSA robotic-assisted TKA improve the precision of bone resection compared to conventional TKA in the cadaveric study [54]. However, more robotic-assisted TKA systems still need to be designed and developed, especially in China.

Recently, one new HURWA robotic-assisted TKA system (Beijing, China) was utilized in TKA surgery. Our previous studies showed that this new robotic-assisted TKA system significantly improve the accuracy of bone resection levels and angles in the Sawbone model [33]. Moreover, we demonstrated that this new system is a safe and accurate tool for TKA surgery in the sheep model [32]. However, clinical experiments are required to confirm the safety and accuracy of this system. Herein, we performed a randomized, multi-centers, single blind and parallel control trial of HURWA robotic-assisted versus conventional TKA to study the effectiveness and safety of this system. We found that the postoperative mean HKA angle was $1.801^{\circ} \pm 1.608^{\circ}$ of varus for the robot-assisted TKA group and $3.017^{\circ} \pm 2.735^{\circ}$ of varus for the conventional TKA group; these values were significantly different. The robot-assisted TKA group showed a 81.2% malalignment for mechanical axis lower than 3° and the conventional TKA group showed 63.5%. In this study, we used for 4 scoring systems to analyze



Figure 5. Three typical cases which performed by HURWA robot-assisted TKA system. A. A case of severe varus deformity. B. A case of severe values deformity. C. A case of severe varus deformity that has been performed by THA of right side and TKA of left side.

patient outcomes The WOMAC score is widely used in the analysis of knee osteoarthritis. It has 3 major components, namely, pain, stiffness and physical function. The HSS score is used for evaluating the clinical results of knee arthroplasty and has six major components: pain, function, range of motion, muscle strength, knee flexion deformity, and stability. KSS score system is user-friendly and concise, providing assessment of the following key areas: pain, flexion contracture, extension lag, total range of motion, and stability in the anteroposterior and mediolateral planes. The SF-36 score system is more responsive measure of the overall quality of life of osteoarthritis patients and is frequently used for measuring knee arthroplasty outcomes [55]. Therefore, we chose these four scoring systems. Our study also found that these patients who underwent robot-assisted TKA had improved knee flexion and functional recovery following to HSS score, KSS score, WOMAC score and SF-36 score compared with preoperative, even though there was no significant difference between the conventional TKA group. The reasons may include two aspects: 1. The knee joint performance and function are affected by many factors, such as soft tissue balance, muscle relaxation, bone condition, postoperative rehabilitation exercise, patient complications, etc; 2. The correction of lower limb alignment may not lead to the incremental improvement of clinical efficacy in a short time, or it may be due to the small sample size, which is difficult to observe the difference between groups; Therefore, long-term follow-up or increasing the sample size are needed to further observe the improvement of clinical efficacy. Furthermore, this system did not increase the risk of TKA.

Our study has some major limitations. The sample size in our study is relatively small and more cases are needed to validate this new roboticassisted TKA system. Secondly, no other robotic-assisted TKA systems were used as the control group. Future studies should provide a head-tohead comparison of safety and efficacy of different robotic-assisted TKA systems. Third, the follow-up time is relative short and long-term follow-up is needed to observe the improvement of clinical efficacy. In summary, HURWA robot-assisted TKA system is a safe and effective system for TKA, which had improved knee flexion and functional recovery compared with preoperative, even though there was no significant difference between the conventional TKA group. Moreover, we found that HURWA robot-assisted TKA has a lot of advantages over conventional TKA including its ability to improve malalignment for mechanical axis. Thus, longer follow-up period is needed to study whether the improve malalignment for mechanical axis will lead to improve long-term survival and better clinical outcomes.

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Declaration of competing interest

The authors declare that they have no competing interests.

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