Superior component position during robotic-assisted Oxford unicompartmental knee arthroplasty (UKA) compared with conventional technique: A 5-year follow-up study

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Abstract

Background

The purpose of our present work was to compare robotic-assisted UKA and conventional UKA regarding the clinical and radiographic results at 5-year follow-up.

Methods

Forty-one medial UKAs were conducted with robotic assistance (group ROA) between January 2010 and January 2015, and these subjects were matched with 44 subjects undergoing medial UKAs using the same prosthesis, implanted by conventional technique (group CON). In a 5-year follow-up, subjects were clinically evaluated by using Knee Society functional (KSF), Knee Society clinical (KSC), and Knee Society pain (KSP) scores. Radiographic assessments with regards to coronal mechanical axis (CMA) and condylar twist angle (CTA) were compared between group ROA and group CON.

Results

In the evaluation, the mechanical limb alignment was significantly increased after operation in each group. The implantation accuracy of the coronal mechanical axis was similar in both groups. As for the evaluation of femoral rotation, the internal rotation in group ROA was remarkably less than that in group CON. The difference was not significant in KSP, KSF, KSC scores between group ROA and group CON.

Conclusion

Our results showed that robotic assistance improves component position without gaining superior CMA or increasing clinical results versus conventional UKA at 5-year follow-up. To conclude, using robotic assistance in UKA is recommended as compared to conventional UKA. Long-term follow-up will be needed to draw conclusion about the overall outcomes of robotic assistance as compared with conventional technique.

Trial registration

Current Controlled Trials ChiCTR2000033918. Registered 16 June 2020.

1. Background

Recently, there has been a significant increase in the number of UKA performed in comparison with total knee arthroplasty (TKA). There are a variety of advantages of UKA, for instance, less blood loss, faster recovery, as well as improved proprioception [1,2]. It has been proven that good to excellent outcomes are found in the mid-term and long-term follow-ups in properly selected patients who underwent UKA [1,3]. Nevertheless, the implant has a shorter longevity and the revision rate is higher in UKA as compared to TKA [2,4,5]. A variety of factors are responsible for the relatively high failure rate in UKA, for instance, limb
malalignment and poor component position after operation [6-8]. The accuracy and reproducibility of component position seem to be essential to the longevity of the implant in UKA [6,8,9]. Therefore, technique which improves component position might result in improvement in implant lifespan.

Robotically assisted UKA has been introduced, which provides accurate feedback of the relative position of the cutting jigs and the host bones during operation. A number of reports have demonstrated that implantation could be more accurate in robotically assisted UKA as compared with conventional technique on a consistent basis [10-12]. Apart from that, robotically assisted operation can be more reproducible, which is of great benefit because the technics of the procedure are challenging in UKA surgery. As a result, it can be expected that the use of robotic assistance is able to improve implant lifespan as well as patients’ satisfaction.

Although several reports have already illustrated the short-term outcomes of robotic-assisted UKA [10,12], there are few studies containing mid-term results [13,14]. Unfortunately, to our knowledge, no prospective randomized study comparing component position or clinical outcomes of the robotic-assisted UKA with conventional UKA at a mid-term follow-up is available. As a result, scientific evidence underlying mid-term outcomes of robotic-assisted UKA is very limited and controversial.

The purpose of our present work was to provide data from a prospective, randomized trial comparing the component position and clinical outcomes between conventional UKA and robotic-assisted UKA in a follow-up for five years. It was hypothesized that UKA with robotic assistance possessed improved radiological results as well as clinical outcomes as compared to conventional UKA.

2. Methods

Study Design

This prospective, randomized controlled trial was approved by the Regional Ethical Committee. From January 2010 to January 2015, all subjects who visited our hospital were assessed for participation in this study. All subjects were finally recruited and treated by the same senior surgeon, and were evaluated in the same department by two physiotherapists after operation in blinded follow-up.

The Criteria of Inclusion and Exclusion

Inclusion criteria were as follows: (1) 45-75 years old; (2) the evaluated ASA physical status between I-III; (3) with normal mobilization before operations; (4) the changes of arthritis below grade III in the femoral-patella compartment and below grade IV in the lateral compartment; (5) BMI \( \leq 30 \) and the varus degree less than 10°. The criteria of exclusion were as follows: insufficiency of ligament; inflammation-related arthritis; augmentation for the deformity; disorders in neurological movement; pathological status of the contralateral knee, hips, feet, or ankles resulting in obvious gait alteration or pain; those eventually requiring a TKA.

Randomization
Participants have been randomized according to a computer-generated procedure. The randomization codes have been kept by an independent researcher ensuring blindness. The subjects have been randomly assigned into robotic-assisted or conventional UKA groups following collection of informed consent and acquisition of baseline measurements. The stratified randomization was used according to the technique applied.

The Characteristics of the Robot

It has been well illustrated that the MAKO RIO system has satisfactory accuracy. By using this system, the accuracy of the mechanical alignment is less than 1.6° compared with the plan made before the surgery. The accuracy of the soft tissue balancing is less than 0.53 mm at all flexion angles compared with the original plan. Additionally, the accuracy of the femoral component positioning is less than 0.8 mm and 0.9° and tibial component positioning less than 0.9 mm and 1.7° compared with the original plan.

Assessment

Demographic characteristics were collected preoperatively and shown in Table I. Clinical outcomes (KSP, KSF and KSC scores) were scored preoperatively and at each follow-up visit. Non-digitized, weight-bearing and anteroposterior radiological images of the long leg were taken. The axial radiographs of the coronal axis of the long leg were taken during the 5-year follow-up. The coronal axis was defined as the line starting from the central point on the femoral head and ending at the central point on talocrural joint. On the radiological images, condylar twist angle (CTA) was defined as the angle between the posterior condylar axis (PCA) and the clinical epicondylar axis (CEA), which was the line connecting the lateral and medial epicondylar prominences (Fig 1).

Statistical Analysis

All the patients were included in the analysis. Data were presented as average value ± standard deviation or average value (95% confidence interval) as mentioned. When the continuous data between groups were analyzed, independent sample t-test was used for the data with normal distribution and Mann-Whitney U-test was applied to evaluate nonparametric results. When the continuous data within groups were analyzed, paired t-test was used for normal data and Wilcoxon signed-rank test was applied if the results did not conform with the parametric assumptions. The chi-square and the Fisher exact tests were applied in comparing categorical results. All the statistical analyses were conducted by using SPSS 16.0 for Windows (SPS Inc, Chicago, IL). The sample size was calculated to eliminate type II error. The calculation of power indicated that the difference of knee scores between two groups was 15% and there should be more than 31 patients included in every group \([\alpha=0.05, (1-\beta) = 0.80]\). Eighty five participants were finally included in case that some may dropout during the research.

3. Results
There were 123 patients in accord with the inclusion criteria and eligible for the study. Thirty-eight patients declined, leading to an inclusion of 85 patients. We randomly assigned the 85 patients into the 2 intervention groups, of whom 59 completed the follow-up lasting for 5 years (29 in group ROA and 30 in group CON). The total follow-up rate was 70% (Fig 2). In the 5-year follow-up, no significant difference was found between groups in BMI, age, education, gender, pain duration, diagnosis as well as morbidities (Table I).

During the 5-year follow-up, the mean KSP score increased from 7.4 (before the surgery) to 39.3 in group ROA and 7.5 to 38.5 in group CON (p=0.36). The mean KSF score increased from 51.6 to 68.1 in group ROA and 50.2 to 65.3 in group CON (p =0.58). The mean KSC score increased from 34.3 to 86.3 in group ROA and 35.1 to 85.1 in group CON (p=0.63). There was no difference in these three scores between group ROA and group CON in the 5-year evaluation (Table II).

Radiographic outcomes are displayed in Table II. The radiographic assessment demonstrated that the CMA in group ROA and group CON was almost the same before operation and in the follow-up at the fifth year. The angles were detected after the operation and in the follow-up at the fifth year. The differences between the two angles detected at different time points were 0.9°±0.03° and 0.8°±0.04° in group ROA and group CON, respectively. The difference between group ROA and group CON was not statistically significant. In group ROA, CTA was significantly reduced compared with Group CON in the follow-up at the fifth year. In the follow-up at the fifth year, the results of long leg mechanical axis presented that the outliers rate (valgus or varus from the axis and the degree>3°) was 19.3% and 16.1 % in group CON and group ROA, respectively (p=0.085).

4. Discussion

To our knowledge, the present investigation is the first randomized responder analysis comparing robotic-assisted UKA with conventional UKA in a mid-term follow-up. In our study, patients in both groups exhibited excellent radiographic and clinical outcomes. However, only robotic-assisted UKA showed advantages in CTA results. There was no significant difference in clinical outcomes. We therefore rejected the null hypothesis that robotic-assisted UKA improved both radiological and clinical outcomes as compared to conventional UKA.

UKA survivorship is considered to be determined by limb alignment [8,10,15,16]. Nevertheless, it still remains controversial in the standard of correct limb alignment following UKA. It has been suggested that the aim of conducting UKA is to replace damaged joint surface and ensure the coronal axes of the lower extremities staying in the physiological positions to prevent degenerative disorders [17-19]. It is remarkably different from the theory that the mechanical axis alignment can be 0° in TKA, which is usually accompanied by slight valgus in the lateral knee or slight varus in the medial knee. It has been advocated by some researchers that passing through the central line of the knee joint could restore the axis [6-8, 20-21]. Nonetheless, it has also been brought up that the degenerative disorders in lateral compartments can be promoted by overcorrecting the varus deformity [22,23]. According to some reports
of Oxford UKA, all the alignment of the knees via balancing the ligaments passed through the central line of the knees, which was usually similar to the contralateral part [8,24-25]. Additionally, it was demonstrated that the operations with robotic assistance remarkably improved the alignment of the limbs following medial UKA in comparison with the conventional technique [26,27]. Nonetheless, similar results were not found in our study.

It was widely recognized that maintaining the initial MCL tension was of great necessity when UKA was conducted, especially when mobile bearing prostheses were used [4,28]. Excessive release could result in instability or overcorrection in the follow-ups [6,29]. Soft tissues or ligamentous release should be avoided when Oxford UKA was performed. When navigation or conventional operations were performed, we carefully avoided changing the association between lower extremities alignment and the soft tissue balance. It has been proved by our study that no significant difference was found in CMA between group CON and group ROA, even if femoral component was more precisely implanted in group ROA. Hence, the alignment had the initial tension between ligaments and bony resection in both groups. According to the results above, robotic assistance during the surgery could not influence the overall alignment of the limbs, even if femoral component was more precisely implanted in group ROA.

There are some strengths in our current work. First, this was a randomized study, and thus the possibilities of undergoing surgeries with or without robotic assistance were the same. Thus, the selection bias could be avoided. Secondly, all participants followed the same protocols before or after the surgeries, which included rehabilitation intensity and type, analgesia management and anesthesia strategy, and the discharge standards. Furthermore, the whole procedures were conducted by one surgeon who was experienced in UKA and using robotic assistance. This surgeon carried out 58 robotic-assisted operations before randomization was conducted. Therefore, the results in this study were not affected by the surgeon's experience or learning curve problem.

Our current work also had limitations which must be considered in the context of the results, among which the most important one was the failure of follow-ups in 30% of the participants. We lost contact with most of them and this might brought in potential bias. Secondly, the participants were all Chinese people. Before using the results for reference in the study containing other populations, it is necessary to note the demographic features in this study, for example, the majority of the patients receiving UKA were females. However, the features of the lifestyle and daily activities in the Chinese people, such as kneeling or squatting more frequently, can be used to make comparisons with those who have high-flexion activities. In our study, motion range was not discussed. Moreover, the duration of the follow-up in this study was not long enough, and further follow-ups in a long-term study are required.

5. Conclusion

In conclusion, the authors demonstrated that at 5-year follow-up, the outcomes of the robotic-assisted UKA were at least equivalent to the widely used conventional technique. Moreover, the authors gained encouraging outcomes in a mid-term follow-up which suggested that the component position was better
in subjects receiving operations with robotic assistance. In the future, it is necessary to keep following up the trial participants to evaluate if superior component position will result in a lower revision rate in a long-term follow-up. The number of the participants was rather small and a multicenter trial including more participants should be conducted in the future.

6. List Of Abbreviations

1. unicompartmental knee arthroplasty (UKA)
2. total knee arthroplasty (TKA)
3. Knee Society functional (KSF)
4. Knee Society clinical (KSC)
5. and Knee Society pain (KSP)

Declarations

Ethics approval and consent to participate

This study has been registered in the ethical committee of our hospital (Taizhou people's hospital, Taizhou, Jiangsu), and all patients gave informed consent (the consent we obtained from study participants was written).

Consent for publication

All images have been consented for publication.

Availability of data and materials

The datasets are available from the corresponding author on reasonable request.

Competing interests

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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Authors' contributions

Tw Z, E C analyzed and interpreted the patient data. Hm D, Zx Z analyzed the Clinical and radiographic outcomes. All authors have read and approved the final manuscript.

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Tables

Table I - Preoperative characteristics of patients

| Variable                  | group ROA (N=41) | group CON (N=44) | P value |
|---------------------------|------------------|------------------|---------|
| Gender (%)                |                  |                  | 0.084   |
| Male (n)                  | 18               | 20               |         |
| Female (n)                | 23               | 24               |         |
| Age (mean±SD, year)       | 61.2±3.6         | 62.6±4.9         | 0.325   |
| Body mass index (mean±SD, kg/m²) | 25.6±1.2         | 24.3±2.4         | 0.063   |
| Education (%)             |                  |                  | 0.624   |
| Primary school            | 10 (24%)         | 11 (25%)         |         |
| Middle school             | 20 (49%)         | 21 (47%)         |         |
| High school               | 6 (15%)          | 6 (14%)          |         |
| University                | 5 (12%)          | 6 (14%)          |         |
| Pain duration (%)         |                  |                  | 0.716   |
| <3                        | 6 (15%)          | 7 (16%)          |         |
| 3-5                       | 29 (70%)         | 32 (73%)         |         |
| >5                        | 6 (15%)          | 5 (11%)          |         |
| Diagnosis (%)             |                  |                  | 0.751   |
| Anterior medial osteoarthritis (AMOA) | 37 (90%)         | 39 (89%)         |         |
| Osteonecrosis (DN)        | 3 (7%)           | 3 (6%)           |         |
| Post-traumatic osteoarthritis (PTOA) | 1 (3%)           | 2 (5%)           |         |
| Comorbidities (principal) |                  |                  | 0.267   |
| Cardiac diseases          | 9 (23%)          | 9 (20%)          |         |
| Respiratory diseases      | 12 (29%)         | 13 (30%)         |         |
| Endocrine diseases        | 8 (19%)          | 11 (25%)         |         |
| None                      | 12 (29%)         | 11 (25%)         |         |

Table II - Clinical and radiographic outcomes in two groups preoperatively and at the 5-year follow-up
|          | group ROA |          | group CON |          | Post-op |
|----------|-----------|----------|-----------|----------|---------|
|          | Pre-op    | Post-op  | P         | Pre-op   | Post-op | P       |
| KSP      | 7.4±0.5   | 39.3±1.4 | <0.01     | 7.5±0.7  | 38.5±3.3| <0.01   |
| KSF      | 51.6±4.3  | 68.1±8.3 | <0.01     | 50.2±2.1 | 65.3±6.9| <0.01   |
| KSC      | 34.3±2.8  | 86.3±9.0 | <0.01     | 35.1±3.5 | 85.1±7.4| <0.01   |
| CMA      | 5.8±0.3   | 2.2±0.4  | <0.01     | 5.3±0.6  | 2.6±0.4 | <0.01   |
| CTA      | ——        | 1.3±0.5  | ——        | ——       | 5.2±0.4 | ——      |

**KSP**: Knee Society Pain; **KSF**: Knee Society Functional; **KSC**: Knee Society Clinical

**CMA**: coronal mechanical axis; **CTA**: condylar twist angle

**Figures**

**Figure 1**

Radiographic evaluation of coronal mechanical axis (CMA)
Figure 2
Radiographic evaluation of condylar twist angle

Supplementary Files

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- CONSORT2010Checklist1.doc