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Reduction Osteotomy versus Extensive Release on Clinical Outcome Measures in Simultaneous Bilateral Total Knee Arthroplasty

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Background: During total knee arthroplasty (TKA) in varus knee deformities, reduction osteotomy (RO) and medial soft tissue release are alternative techniques to aid in achieving deformity correction. In this study, we investigated the effect of RO compared to extensive medial soft tissue release (ER) on clinical outcome measures in simultaneous bilateral TKA.

Material/Methods: We prospectively enrolled 24 patients (48 knees) with bilateral varus knee deformity from July 2014 to December 2015. For each patient, one knee was assigned to the RO group and the contralateral knee was assigned to ER group. One year postoperative, follow-up outcomes were collected and analyzed.

Results: Time to 90° flexion of the knee was significantly different in the RO group (1.6±0.3 days) compared to the ER group (2.0±0.4 days) ($p<0.001$). Using a 10-item patient reported outcome questionnaire, total scores were significantly different between the RO group (86.3±3.2) and the ER group (82.4±2.7) ($p<0.001$). Analysis of variance showed a significant difference on the visual analogue scale (VAS) score ($p<0.001$) but no significant difference in the range of motion (ROM) of the knee ($p>0.05$) during the follow-up year.

Conclusions: Knees treated with RO were associated with greater improvements in pain and function than knees treated with conventional ER technique. Additionally, RO technique did not confer an increased risk for adverse clinical outcomes. RO may therefore be a safe method to decrease postoperative pain, achieve earlier functional recovery, and increase patients' subjective satisfaction after TKA.

MeSH Keywords: **Arthroplasty, Replacement, Knee • Osteotomy • Therapy, Soft Tissue • Visual Analog Scale**

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Background

Total knee arthroplasty (TKA) can reduce pain and restore function in arthritic patients. Within this patient population, the medial compartment is the most commonly affected compartment and is often accompanied with varus knee deformity [1–3]. TKA can be challenging in these knees with varus deformity as it is typically followed by progressively contracted medial soft tissues and attenuated lateral soft tissues. Ligament balance is therefore been considered essential to the success of TKA [4,5].

Obtaining balanced mediolateral (ML) ligamentous structures during TKA requires release of contracted medial soft tissues and removal of medial peripheral osteophytes. A widely applied technique to correct varus knee deformity is a step-by-step release of contracted medial soft tissues from their attachment sites until appropriate medial-lateral soft tissue tension is achieved. In patients presenting with severe varus knee deformity, an extensive medial release is almost always required; including progressive release of the deep medial collateral ligament (MCL), superficial MCL, posteromedial capsule, semimembranosus tendon, and pes tendons [2,3,6,7]. This technique, however, has a risk of over-release leading to subsequent ML instability, which can in turn require a thicker polyethylene insert or even a constrained implant [8–10].

Recently, reduction osteotomy (RO) has been proposed as a soft tissue-sparing technique to achieve ML gap balance [11–16]. It is a technique capable of reducing the amount of medial release and preventing over-release of the medial soft tissue structures. Dixon et al. [14] and Mullaji et al. [15] reported the effectiveness of downsizing the tibial component for RO in cases with severe varus knee deformity. This technique is expected to be a safer option to correct varus deformity. However, removal of the medial tibia plateau bony margin may decrease the bone quality of the medial tibia, which probably leads to a premature loosening or subsidence of the tibia prosthesis. Yasuo et al. [16] reported nine cases of tibial component subsidence in a group of 39 knees treated with RO within the first postoperative year. In order to compare RO to traditional extensive medial soft tissue release (ER) for correction of varus deformity, we designed a prospective randomized controlled trial. To the best of our knowledge, this is the first study to assign, within the same patient, one knee to RO and the other knee to ER. We hypothesized that there would be no significant differences in clinical outcomes between knees treated with RO and knees treated with ER on intraoperative and postoperative clinical outcomes.

Material and Methods

Participants

From July 2014 to December 2015, we prospectively enrolled patients with knee osteoarthritis and bilateral varus knee deformities undergoing primary simultaneous bilateral TKA. Exclusion criteria were rheumatoid arthritis, neutral and valgus knees, traumatic osteoarthritis, and a history of previous knee surgery. This study was approved by the Human Research Ethics Committee of our hospital, and all patients completely informed and signed written consent.

Interventions

All study patients underwent the operative procedure with the same general anesthetic. Under tourniquet control, a standard TKA procedure was performed through a perpendicular midline incision and a medial parapatellar approach. With a minimal quadriceps tendon longitudinal split, the patella was laterally retracted instead of totally everted. The peripheral osteophytes of the proximal tibia and the distal femur were totally removed. The deep MCL was released in all patients. Following this release, each knee was treated with either RO or EE in accordance to randomization. All operations in this study were performed and supervised by a senior surgeon in our hospital, who is also the corresponding author of this article. All procedures were the same except the technique for varus knee deformity correction. All patients received a posterior cruciate-substituting cemented prosthesis (Genesis II Oxinium; Smith and Nephew, Memphis, TN, USA). Postoperatively, all patients were mobilized according to a standardized physical therapy protocol.

Reduction osteotomy (RO)

In the RO group of knees, the tibia component trial was positioned as laterally as possible to identify a suitable tibia component size first, and then a smaller sized tibia component trial was fixed on the tibia plateau for the modularized of the tibia and RO of the medial proximal tibia. A spacer block was used to determine the extension space and flexion space and the equality of the ML ligament tension, then progressive soft tissue release was carried out carefully until symmetrical. Finally, ML ligament balance was confirmed with trial prosthesis.

Extensive medial soft tissue release (ER)

In the ER group of knees, the tibia component trial was similarly positioned as laterally as possible to identify a suitable tibia component size, and then it was fixed on the tibia plateau for the modularized of the tibia, without RO performed. A spacer block was used to determine the extension space

and flexion space and the equality of the ML ligament tension, then progressive extensive soft tissue release was carried out carefully until symmetrical. Finally, ML ligament balance was confirmed with trial prosthesis.

Outcomes

The primary clinical outcome measures were time to achieving straight leg raise (SLR) and 90° knee flexion, the change in ROM after surgery, and the change in pain as measured by the VAS score. Knee ROM was measured with a leg goniometer; every knee was measured three times and the average value was recorded. VAS scores were calculated on a 0–10 scale with 0 being “no pain” and 10 being “unbearable pain.” Additionally, a standardized weight-bearing anteroposterior radiograph of the whole lower extremities was flushed to assess the preoperative and postoperative knee alignment angle of the joint. The hip center, notching center of the distal femur, and the ankle talus center were identified and connected with a line. The preoperative varus knee angle was assessed using the preoperative radiograph, and the corrected knee angle was assessed with the postoperative radiograph of the whole lower extremities before the second operation. Existing knee scoring systems, such as the HSS, WOMAC, and SF-36 scores, are not designed for simultaneous bilateral TKAs in the same patient; therefore, we constructed a questionnaire based upon previous clinical experience [17]. Based on a patient’s subjective satisfaction, with 10 the most satisfied and 1 the least satisfied, a total score of 10 items was identified as the degree of a patient’s subjective satisfaction.

Randomization and blinding

A computer-generated random sequence was used to randomize knee treatments. Using a sealed envelope, assignment was concealed until the patient was in the operation room. While the surgeon was not blinded to treatment assignment, he was not responsible for collecting clinical outcome measures. Two independent investigators who were blinded to treatment assignment obtained baseline data and subsequent intraoperative and postoperative clinical outcome measurements. They also performed radiographic evaluations. All patients were also blinded as to which knee had been assigned to which treatment.

Statistical methods

Categorical variables were presented as absolute numbers and relative frequencies, of which the chi-square test was used to test the differences. Continuous variables were presented as the mean and standard deviation. Analysis of variance (ANOVA) and Student’s *t*-test were used to investigate parametric data. ANOVA was performed using GraphPad Prism, and other data analyses were performed using standard statistical software

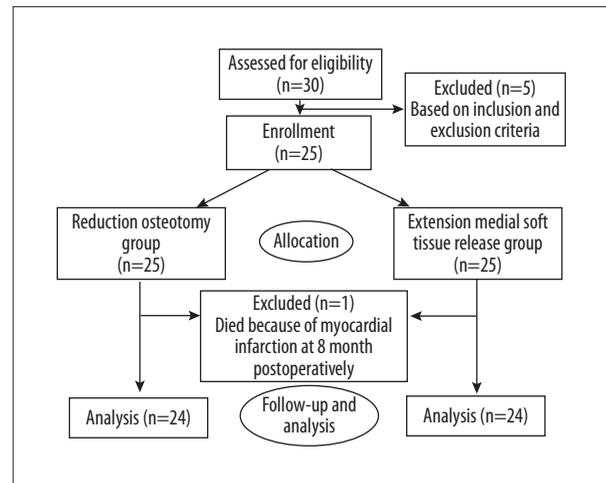


Figure 1. Patient flowchart.

(SPSS, Inc., USA). Tukey’s HSD post hoc analyses were conducted for each significant ANOVA. The results were considered as significant if the *p* value was <0.05.

Results

Participant flow

A total of thirty patients were enrolled and assessed initially, of which five patients were excluded preoperatively. During the follow-up period, one patient died because of myocardial infarction at eight months postoperatively. Beyond that, no patient was lost to follow-up and none of them died during the one year follow-up period, leaving 24 patients for inclusion in the trial (Figure 1).

An example of a standardized preoperative and postoperative weight-bearing anteroposterior radiograph of the whole lower extremities is presented in Figure 2.

Baseline data

The two groups were matched equally with regard to preoperative knee flexion contraction and maximum flexion, angles of knee varus deformity, and VAS score. Baseline patient demographic and clinical data are presented in Table 1.

Clinical outcomes

Clinical outcome data is presented in Table 2.

The time when the knee achieved SLR was 2.4 ± 0.5 days in the RO group and 2.3 ± 0.4 days in the ER group; no significant difference was found between the groups ($p=0.623$). However, with regard to achievement of 90° flexion of the knee, a significant

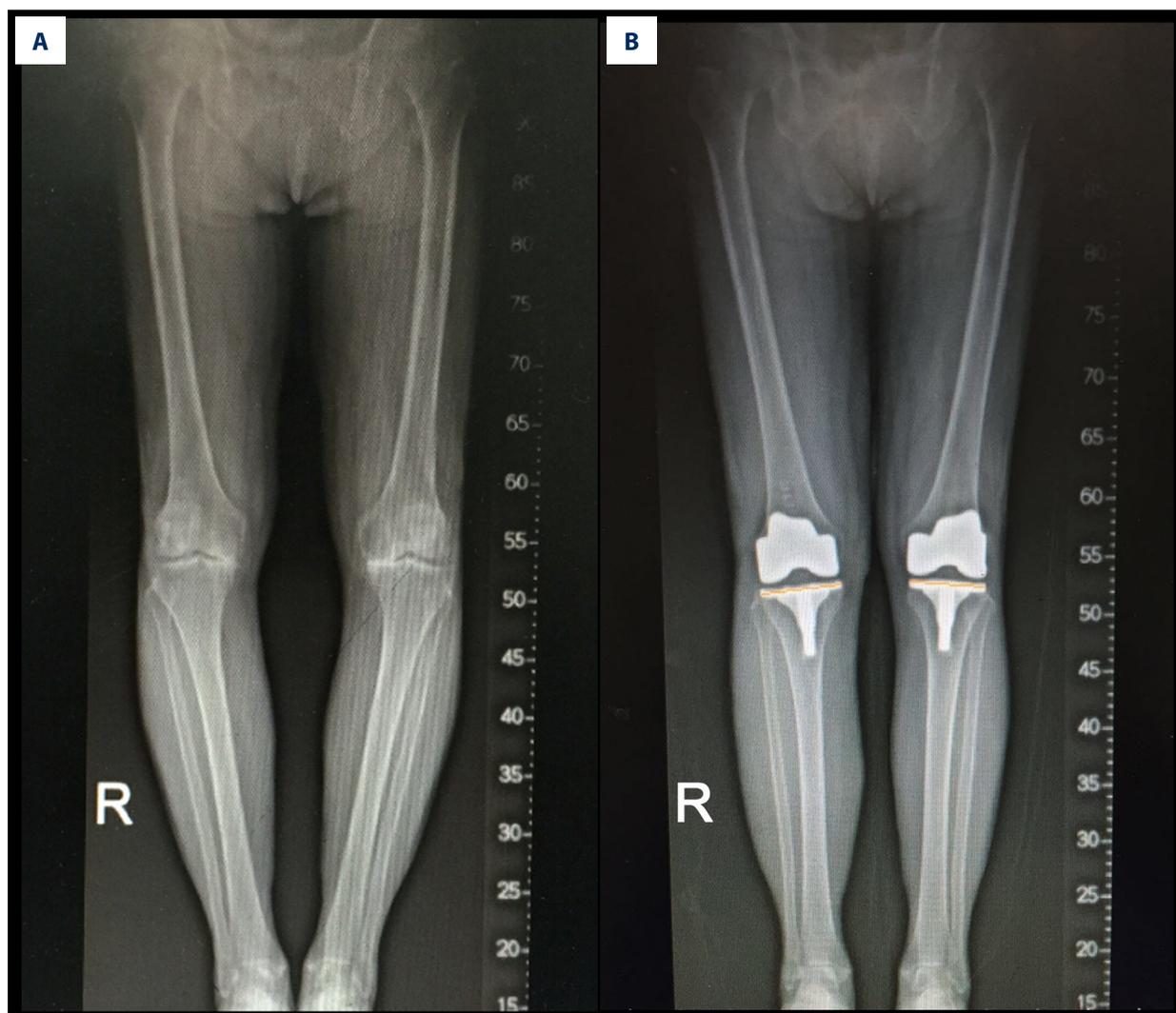


Figure 2. Standardized preoperative and postoperative weight-bearing anteroposterior radiograph of the whole lower extremities are presented respectively in a same patient. **(A)** Bilateral varus knees before arthroplasty. The patient's left knee was treated with reduction osteotomy and the right knee was treated with extensive medial soft tissue release. **(B)** The left tibial prosthesis is one size smaller than the right tibial prosthesis due to resection of tibial bone.

difference was found ($p < 0.001$); time to achieving 90° flexion was 1.6 ± 0.3 days in the RO group and 2.0 ± 0.4 days in the ER group. Total score on the 10-item questionnaire was significantly different: 86.3 ± 3.2 in the RO group and 82.4 ± 2.7 in the ER group ($p < 0.001$).

For ROM and VAS scores; both groups showed continuous improvement over time. The interaction between the analysis components was found to be non-significant for the ROM of the knees throughout the follow-up period ($p = 0.259$). However, the VAS score was found to be significantly different between the two treatment groups over the period of one year. Two-way ANOVA showed significant differences with a p value of 0.0007. Line graphs and detailed data are presented in Figures 3 and 4. We also performed post hoc ANOVA tests. Tukey's post hoc

test was conducted following the analysis for the ROM scores. We found that RO was significantly better ($p < 0.05$) than ER across all follow-up time points; except for preoperative ROM versus one month ROM, three month ROM versus six month ROM, three month ROM versus one year ROM, and six month ROM versus one year ROM. Tukey's post hoc test was conducted following the analysis for VAS scores. We found that RO was significantly better ($p < 0.05$) than ER across all follow-up time points; except for preoperative score versus score at one-day postoperative, one-day score versus two-day score, three-month score versus one-year score, six-month score versus one-year score, and three-month score versus six-month score postoperative.

Table 1. Baseline data (mean ±SD).

Parameters	RO	ER	P value
Sex (male/female)	9/15	9/15	–
Age (y)	71.5±6.1	71.5±6.1	–
BMI (kg/m ²)	26.0±1.3	26.0±1.3	–
Right/left knees	11/13	13/11	–
Knee varus angle	14.4±3.3	14.2±2.8	0.575
Knee flexion contraction angle	5.7±1.2	5.5±1.3	0.658
Knee maximum flexion degree	114.8±6.0	116.3±6.8	0.423
VAS score (score)	5.1±1.3	5.4±1.3	0.457

RO – reduction osteotomy; ER – extensive medial soft tissue release; BMI – body mass index.

Table 2. Postoperative clinical outcomes (mean ±SD).

Parameters	RO	ER	P value
Operation time (minutes)	88.8±4.2	89.7±3.5	0.463
Length of the incision (cm)	12.4±0.6	12.5±0.7	0.447
Complications	2 (10.2%)	3 (12.5%)	0.637
SLR (days)	2.4±0.5	2.3±0.4	0.623
90 degree knee flexion (days)	1.6±0.3	2.0±0.4	<0.001*
Subjective satisfaction (scores)	86.3±3.2	82.4±2.7	<0.001*
Postoperative alignment angle	0.46±2.1	0.75±1.3	0.564

RO – reduction osteotomy; ER – extensive medial soft tissue release; SLR – straight leg raise. * Indicate a significant difference

Discussion

For TKA patients, an essential consideration for future success is ML soft tissue balance. For those patients with varus knee deformities, surgeons have conventionally carried out a technique of extensive medial soft tissue release (ER) to achieve varus deformity correction. In the present study, we found that reduction osteotomy (RO) was better than conventional technique for correction of varus deformity. This technique of RO could decrease postoperative pain, achieve early knee functional recovery, and increase patients' subjective satisfaction after TKA; no additional risks were found regarding other clinical outcomes.

Varus knee deformity can be corrected by various methods during TKA surgery, including the step-by-step medial soft tissue release [1,2,18], pie-crusting of the superficial medial collateral ligament [19–24], RO of the uncapped tibia plateau surface with a one-size minimal tibia component [11-16] and medial epicondylar osteotomy of the distal femur [25]. Each technique has its own potential advantages and disadvantages. One retrospective study [25] proposed an alternative method of medial epicondylar osteotomy of the distal femur and

found medial epicondylar osteotomy for varus deformity in TKA could provide reliable medial stability. However, a review study [26] questioned the need for an epicondylar osteotomy in severely varus knees. With this technique, the knee can become more unstable in flexion and an implant with higher constraint may be necessary. A previous study [19] found the pie-crusting technique was safe, efficient, and reliable for the soft tissue balancing in varus TKA. However, a cadaver study [24] considered the success of the MCL pie-crusting technique is likely technique dependent since failure occurs within the ligament itself. A new-published article [23] also found that the pie-crusting technique has a higher rate of failure in the ML gap balance compared with RO.

The technique of ER was one of the major focuses in our present study. In the ER group, we performed a careful progressive soft tissue release until ML balance was achieved. Dixon et al. [14] described the technique of resecting the medial uncapped tibia plateau bone after downsizing and lateralizing the tibia tray for correction of the varus deformity. This technique can indirectly increase the length of the medial ligamentous structures by shortening the distance between the origin and insertion without an ER.

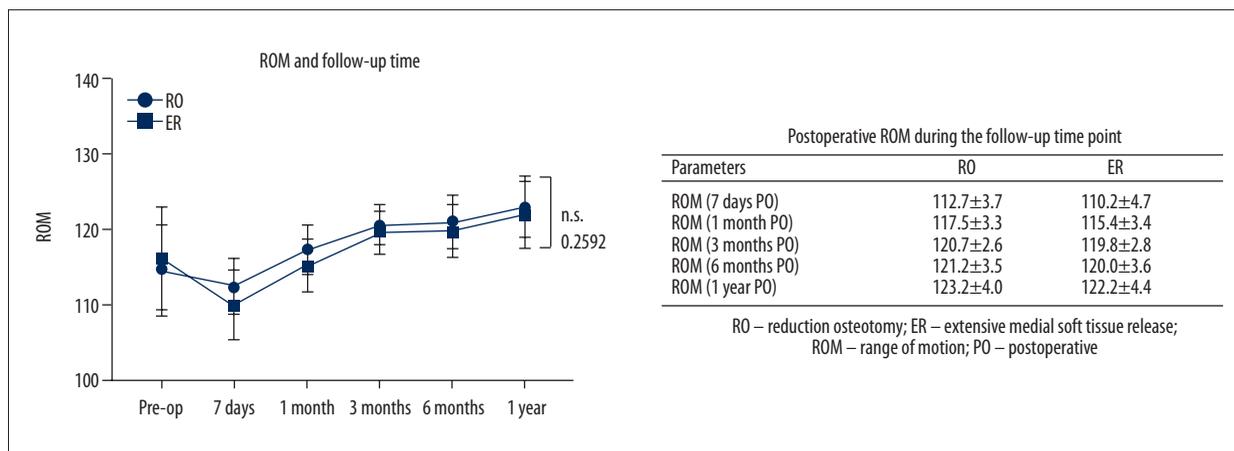


Figure 3. Postoperative ROM during the follow-up time point. The Analysis of variance (ANOVA) shows no significant difference between the groups ($p=0.2592$).

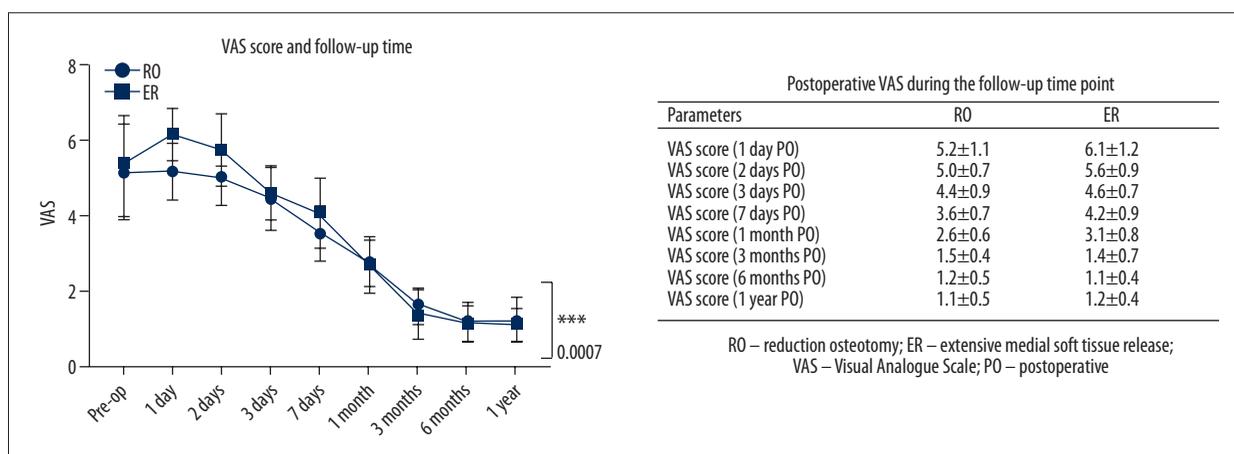


Figure 4. Postoperative VAS score during the follow-up time point. The Analysis of variance (ANOVA) shows a significant difference between the groups ($p=0.0007$).

In RO, the tense medial ligamentous structures are decompressed by downsizing of the medial uncapped tibia plateau. Furthermore, medial soft tissue stripping is only limited to the deep MCL and those structures attached to the resected bone fragments. The advantage of this technique of RO is achievement of ML soft tissue balance but with less bleeding and decreased risk of medial instability. The medial soft tissue structures also gradually lengthen after resection of the medial tibia bone. This lengthening with limited soft tissue release was enough to completely correct the varus deformities in our cohort. In our present study, knees treated with RO had lower pain scores than knees treated with ER at one-month follow-up. We attribute this preferable clinical outcome to greater preservation of the medial soft tissues. Due to better pain control at postoperative times, functional exercises in the less painful knee may have been easier for patients. Along with an alleviation of pain, we also observed that the knees achieved early 90° flexion at earlier time point. During one-year follow-up, we found no case of premature loosening or subsidence of the tibia prosthesis.

Given the aforementioned clinical outcomes, we suggest that RO can be used as a primary technique for correcting varus deformity during TKA, as it has the potential ability to completely correct the deformity without excessively disturbing the medial soft ligamentous structures. This in turn could decrease postoperative pain reaction, achieve early knee functional recovery, and promote patient's subjective satisfaction.

The strength of this study was that it was a prospective randomized controlled and blinded trial. We compared RO and ER using clinical outcome measures in simultaneous bilateral TKA. By using the same surgeon and assigning knees within the same patient to different conditions, we were able to reduce variability.

However, several limitations of this study should be noted. First, this study had a small sample size; we only enrolled 24 patients in the one-year study period. This was hard to avoid as bilateral asymmetric varus knee deformities are less

common than unilateral varus knee deformities. Second, the senior surgeon could not be blinded to the procedure, which may bring potential bias to the study. Last, we only evaluated the clinical outcomes between the groups in the early postoperative period. Some complications, such as loosening and tibial component subsidence, can occur years later. Therefore, further studies examining long-term follow-up outcomes beyond two years are necessary.

Conclusions

This prospective randomized controlled trial on simultaneous bilateral TKA indicated that RO was better than the conventional technique for correction of the varus deformity, it could

decrease postoperative pain reaction, achieve early knee functional recovery, and promote the patient's subjective satisfaction after TKA; no additional risks were found regarding other clinical outcomes. Additionally, more carefully and scientifically designed randomized controlled trials are still required to further support our conclusions.

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Conflict of interest

None.

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