Clinical efficacy and feasibility of simple navigation technology with an ordinary laser pen and surgical instrument box in open-wedge high tibial osteotomy

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Research Article

Keywords: Laser navigation, Leg alignment, Open-wedge high-tibial osteotomy (OWHTO), Femoral tibial angle

Posted Date: February 16th, 2022

DOI: https://doi.org/10.21203/rs.3.rs-1341575/v1

Abstract

Background: The clinical outcomes of open-wedge high-tibial osteotomy (OWHTO) for medial knee osteoarthritis depend mainly on the precision of correction. The present study aimed to determine the efficacy and feasibility of simple navigation technology with an ordinary laser pen and surgical instrument box.

Methods: Seventy-one patients were randomly divided into the navigation (n=36) and traditional groups (n=35). In the navigation group, the hip, knee (Fujisawa point), and ankle centers were located preoperatively using the lid of the surgical instrument box. The leg was aligned with an ordinary laser pen. Radiation exposure, operative time and cost, required labor and postoperative complications were evaluated. The visual analog scale (VAS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores were recorded. After 24 months, the femoral tibial angle (FTA), medial proximal tibial angle (MPTA), posterior slope angle (PSA), and rate of excellent correction were recorded. The Kaplan-Meier method was used to evaluate the survival time of affected knees.

Results: Radiation exposure, operative time and cost, required labor, rate of excellent correction, and postoperative complications were better in the navigation group than in the traditional group ($P < 0.05$). Six months postoperatively, the VAS and WOMAC scores were significantly improved in both groups ($P < 0.001$). At 24 months, the FTA, MPTA and PSA were corrected in both groups ($P < 0.001$), and no between-group differences were found ($P > 0.05$). There was no difference in the postoperative knee survival time between the traditional and laser navigation groups ($P = 0.533$).

Conclusions: Simple laser navigation technology can effectively increase the rate of excellent leg alignment correction and reduce radiation exposure, operative time and cost, required labor, and postoperative complications.

Background

Open-wedge high-tibial osteotomy (OWHTO) is a widely performed procedure for the treatment of medial knee osteoarthritis [1–5]. It is best indicated for young and active people with moderate arthritis (narrowing of the joint line by as much as 100% without any bone wear or instability). The goal of the surgery is to correct the lower limb mechanical axis by osteotomy of the proximal tibia to reduce the abnormal stress distribution in the knee joint and transfer the compressive loads from the medial compartment to the relatively normal lateral compartment. At present, the recommended range of lower limb alignment correction is 62–66% of the lateral knee platform [6–7]. The precision of correction is more stringent than that of total knee arthroplasty (TKA), and the error is generally required to be controlled within ± 1° [8]. Over- and undercorrection can affect long-term clinical outcomes [9, 10].

At present, intraoperative assessments of correction precision depend mainly on X-ray and repeated measurements of the metal pole or cable [11, 12]; however, repeated fluoroscopy results in a prolonged operation time, increased radiation exposure and fatigue among surgeons and imaging technicians.

Moreover, the precision of these measurements is limited, and there is a high risk of technical error. Therefore, overcorrection and undercorrection often occur after OWHTO [13–16]. In recent years, computer navigation technology has improved the precision of correction [11, 17–19], but due to the complexity of the technical operation, the long learning curve and the high cost of the equipment, the implementation of OWHTO in primary hospitals is limited [20, 21].

Inspired by common laser pens and surgical instrument boxes with grids, this study utilized a laser beam in a simple navigation system because it is monochromic, nondivergent, and advanced in a straight line [22, 23]. In addition, with the help of a grid-shaped instrument box, the hip, knee, and ankle joint centers and proximal tibial osteotomy channel can be located efficiently and accurately.

Only a few studies have used laser navigation technology to position the force lines in hip and knee arthroplasty and orthopedic percutaneous surgeries [24–26]. However, this technology has been widely used in urology, oral surgery and ophthalmology applications and has demonstrated satisfactory clinical effects [27–29]. This is the first time that laser navigation technology has been applied to OWHTO. The purpose of the study, therefore, was to investigate the feasibility and efficacy of simple navigation technology using an ordinary laser pen and surgical instrument box in the operating room. The hypothesis of the present study was that simple laser navigation technology can more accurately correct the mechanical force line of the lower limb, improve operation efficiency, help reduce the workload of medical staff, reduce radiation exposure, and improve the rate of excellent leg alignment correction.

Materials And Methods

All experimental protocols were approved by Ethics Committee of Affiliated Hospital of Guizhou Medical University and informed consent was obtained from all patients. All methods were carried out in accordance with relevant guidelines and the Helsinki Declaration. The patients included 22 males and 49 females aged 50–60 years; 39 operations were performed on the left, and 32 were performed on the right (Table 1).

The inclusion criteria were as follows: (1) age younger than 65 years (females < 60 years); (2) basically normal mobility of the knee joint; (3) flexion contracture deformity < 10°; (4) 5° < varus deformity < 20°; (5) proximal tibial angle < 85°; and (6) normal lateral meniscus and cartilage function. The exclusion criteria were as follows: (1) K/L grade of IV; (2) secondary osteoarthritis (infectious arthritis, rheumatoid arthritis, hemophilic arthritis, etc.); (3) meniscus and ligament injury; and (4) severe cardiovascular diseases, liver and kidney diseases, endocrine system diseases, blood system and mental diseases.

Table 1
Demographics

General case	Traditional group	Navigation group	*P*-value
Sex (male/female)	10/25	12/24	0.798
Age (years)	54.5 ± 0.3	55.5 ± 0.2	0.526
K/L grade ([illegible]/[illegible])	17/18	15/21	0.637
Affected side (left/right)	19/16	20/16	1.000
Basic diseases			1.000
Primary hypertension (cases)	2	2	
Type II diabetes (cases)	2	3	
Coronary heart disease (cases)	0	0	
Severe liver kidney diseases (cases)	0	0	
Radiological angle			
MPTA (°)	81.0 ± 2.4	81.3 ± 1.6	0.645
FTA (°)181.2 ± 3.2 180.3 ± 2.7			0.219
PSA (°)8.5 ± 0.68.5 ± 0.4			0.976

No significant differences in age, sex, BMI, K/L grade, or comorbidities were observed between the two groups ($P > 0.05$).

Surgical procedure and rehabilitation

A surgical instrument box (the edge distance of the square was 0.5 cm) and X-ray fluoroscopy (Fig. 1d ~ 1f) were used to locate the hip, knee (62–66% of the lateral platform of the knee), and ankle centers. The surgical instrument box needed to be properly placed horizontally, the body surface references were marked (Fig. 1a ~ 1c), and a protuberant device was placed in the hip joint center so that it could be identified during the operation.

A thigh tourniquet was applied with the patient in the supine position. An approximately 4- to 5-cm incision was made longitudinally at the 3- to 4-cm medial portion of the anterior ridge of the tibia. The medial collateral ligament was released from the tibia, and the semitendinosus and gracilis tendons were preserved. An oblique osteotomy was performed using osteotomes and a bone saw, leaving the lateral cortex intact to serve as a hinge. After the osteotomy channel was established, the distractor was used to correct the leg alignment. During the operation, to obtain an accurate correction in the alignment of the lower limb, the patella was kept in a neutral position when correcting the alignment of the lower limb [9]. When the laser beam from the laser pen (DL552001, Deli, Jiangsu, China) passed through the projection of the hip, knee, and ankle joint centers, the mechanical axis was considered corrected. The laser beam source had a wavelength of 650 ± 10 nm. The maximum output was 5 mW, and the laser grade was 3R. With the exception of the possibility of retinal damage when an individual stares directly at the beam, laser beams are harmless to humans (Fig. 2a ~ 2d). The prepared autogenous iliac bone block was inserted into the osteotomy channel, and the osteotomy was supported using a locking plate designed for open-wedge high-tibial osteotomy (HTO) (TomoFix, Synthes, Bettlach, Switzerland). Postoperatively, partial weight bearing was permitted from 1 day after surgery, and full weight bearing was permitted from 2 weeks after the operation. Active knee motion exercises were started postoperatively after the removal of the drainage tube.

Outcomes

The patients did not know the group assignments for the trial. All data were evaluated by independent physicians who remained blind to the study. The VAS and WOMAC scores were recorded for both groups before and at 24 months after the operation. The FTA, MPTA and PSA were measured preoperatively and postoperatively. The number of C-arm fluoroscopies, operation time and cost, required labor and postoperative complications were recorded. At 1 day and 24 months postoperatively, the rate of excellent mechanical axis correction was evaluated.

Statistical analysis

The data were analyzed by SPSS 25.0 (IBM company, Chicago, USA). All data were normally distributed. All measurement data were expressed as means ± standard deviations. Repeated-measures analysis of variance was used for comparisons between time points within the same group. The least significant difference (LSD) or Tamhani test was used to compare groups. Paired or independent-samples t tests were used for comparisons between the two groups. The Kaplan-Meier method was used for evaluating the survival time of the affected knees. The significance level was $P = 0.05$.

Results

Pain level

One month after the operation, the average pain score (Fig. 3a) of the traditional group changed from 4.8 ± 0.7 to 5.0 ± 0.6 ($P = 0.011$) and that of the laser navigation group changed from 4.8 ± 0.6 to 4.7 ± 0.9 ($P = 0.966$). The VAS scores of the two groups improved significantly at 6, 12, 18, and 24 months after the operation ($P < 0.001$), but no significant differences were found between the groups ($P > 0.05$).

Functional scores

One month after the operation, the average WOMAC index (Fig. 3b) in the traditional group changed from 107.0 ± 3.5 to 107.3 ± 5.4 ($P = 0.001$); in the laser navigation group, the index changed from 106.3 ± 3.7 to 106.3 ± 3.8 at 1 month postoperatively ($P = 1.000$). At 6, 12, 18 and 24 months after the operation, the WOMAC index significantly improved ($P < 0.001$), but there were no significant differences between the two groups ($P > 0.05$).

Radiological assessment

The MPTA, FTA and PSA (Table 2) were significantly corrected in both groups at 24 months ($P < 0.001$), and no significant differences in the MPTA, FTA and PSA were observed between the groups ($P > 0.05$).

Table 2
Anatomic angle

	Traditional group		Navigation group	
Anatomic angle	Preoperatively	24 months	Preoperatively	24 months
MPTA (°)	77.1 ± 2.3	88.4 ± 4.2	77.2 ± 2.1	88.1 ± 4.2
FTA (°)	181.2 ± 3.2	173.5 ± 2.6	180.3 ± 2.7	173.6 ± 2.8
PSA (°)	8.5 ± 0.6	10.1 ± 0.7	8.5 ± 0.4	10.6 ± 0.8

The MPTA, FTA, and PSA were significantly corrected after 24 months in both groups ($P < 0.001$), but no significant differences were observed between the groups ($P > 0.05$).

The rate of excellent leg alignment correction

At 1 day and 24 months postoperatively (Fig. 7a ~ 7c), varus malalignment in the traditional and navigation groups was significantly corrected ($P = 0.000$). The mechanical axis shifted to cross the lateral aspect of the tibial plateau at a point located at approximately 64.0 ± 3.1% and 63.0 ± 2.7% 1 day postoperatively and at approximately 64.1 ± 7.6% and 63.6 ± 1.7% at 24 months postoperatively in the two groups (Fig. 4). At 1 day and 24 months after the operation, no significant difference was found between the two groups in the accuracy of leg alignment correction ($P = 0.156$; $P = 0.350$), but the incidence of outliers was significantly lower in the laser navigation group ($P = 0.014$; $P = 0.014$, respectively).

Perioperative situation

Compared with the traditional group, the laser navigation group had better results (Fig. 5a ~ 5d) regarding the number of X-ray fluoroscopies, operation time and cost, and labor investment ($P < 0.05$), and this method effectively reduced the occurrence of postoperative complications (Table 3) ($P < 0.05$).

Table 3
Postoperative complications

Postoperative complications	Traditional group	Navigation group	*P*-value
Infection	0	0	
Incision exudation	0	0	
Delayed healing of incision	2	1	
Limb swelling	6	1	
Fracture of the lateral cortex or of the proximal fragment of the tibia	0	0	
Nonunion of bone	0	0	
Lower limb ischemia	0	0	
Sensory disturbance	0	0	
Deep vein thrombosis	0	0	
Incidence of complications	8/35	2/36	$P = 0.028$

More postoperative complications occurred in the traditional group than in the laser navigation group ($P = 0.028$).

Survival analysis

The survival time of the affected knee 24 months after the operation was analyzed by the Kaplan-Meier method. The results showed that two patients in the traditional group underwent knee arthroplasty, and one patient in the laser navigation group underwent knee arthroplasty (Fig. 6). There was no difference in the survival time of the knee between the two group ($P = 0.533$).

Discussion

The most important finding of this prospective randomized controlled study was that simple laser navigation technology can effectively improve the rate of excellent mechanical axis correction, reduce radiation exposure and operation time and cost, reduce the labor required, and reduce postoperative complications. Simple laser navigation technology is therefore advantageous compared with traditional positioning technology.

In our study, knee pain and function, as evaluated by the VAS and WOMAC scores, continued to improve for 12 months after the operation. The main reason for this improvement may be that OWHTO causes significant changes in the load distribution of the knee joint, which could cause early degenerative changes and dysfunction if left untreated. Because the time of bone remodeling of the TomoFix plate is appropriately 6–18 months, we chose to remove the implants at 18 months postoperatively. Therefore, the improvement in knee function from 12 to 24 months postoperatively can be explained by implant removal. Cartilage degeneration has been linked with knee osteoarthritis. It has been reported that varus malalignment is correlated with cartilage damage in the medial compartment on MRI, with a dose effect [30]. The results of this study agree with those of previous clinical studies in the sense that the correction of alignment protects the knee from additional cartilage damage, induces cartilage regeneration, and improves knee pain and function [31–33].

The traditional technology involves the use of a metal pole or cable to correct the lower limb mechanical axis, which inevitably negatively affects the operation. The pole or cable can be deformed by external forces, which ultimately affects the accuracy of the operation. It can also be deformed by other external forces during the disinfection and transportation processes, so it needs to be calibrated regularly, resulting in a high maintenance cost. Although computer navigation technology has basically solved the problem of correction accuracy [34–40], the equipment is expensive; in addition, this technology increases the complexity of the operation and thus is not suitable for implementation in areas with limited medical resources. Simple laser navigation combined with a mesh surgical instrument box can effectively improve the accuracy and stability of surgical correction. Laser navigation technology is easy to operate, and beginners can quickly master its use. Moreover, like other computer navigation technologies, it can effectively reduce the probability of outliers, since the laser has a strong anti-interference ability and will not interfere with the positioning accuracy of the operator. Moreover, an intuitive lower limb mechanical axis can be created when the operator uses the laser beam. The application and maintenance costs are very low, and the operation is simple and convenient to perform. It is suitable for use in hospitals at any level.

Radiation exposure contributes to iatrogenic injury. Iatrogenic radiation injury is becoming a problem of increasing concern in the international medical community [41–47]. The application of metal poles and cables in traditional medial high osteotomy is complicated and requires medical personnel to carry out repeated X-ray fluoroscopies to verify the precision of the mechanical axis correction, which inevitably exposes both medical workers and patients to radiation. Simple laser navigation technology solves the problem of insufficient anti-interference ability of the traditional force pole. The laser cannot deform due to interference from external forces [6]. It has higher precision and stability than traditional poles and cables and can effectively reduce the incidence of undercorrection and overcorrection.

Previous comparisons of computer navigation technology with traditional treatment in terms of operation time and radiation exposure have indicated that the former is advantageous. This study also focused on hospital costs and labor input and determined whether laser navigation can reduce the occurrence of postoperative complications. The findings revealed that the operation time of the laser navigation group was significantly shorter than that of the traditional group, primarily because the time required for positioning the surface references for the lower limb force line and proximal tibial plateau osteotomy decreased when the surgical grid-shaped instrument box was used. Since laser navigation will not affect the operation and its application is simple and convenient, it can reduce the operation time. In addition, the decreased operation time and reduced number of X-ray fluoroscopies indirectly decrease the cost of using a C-arm machine and anesthesia. Because navigation requires less intraoperative fluoroscopy, it can effectively reduce the labor input.

Due to the many X-ray fluoroscopies required in the traditional group, the operation time and the duration of tourniquet use were longer than in the navigation group, which led to an increase in the occurrence of body ischemia-reperfusion injury and the release of inflammatory factors [44–49], thereby increasing the probability of limb swelling after the operation. Moreover, adjusting the mechanical axis repeatedly during the operation increased traction and damage to the surrounding soft tissue, resulting in a higher incidence of postoperative complications in the traditional group.

This study showed that 2 patients in the traditional group underwent knee replacement at 18 and 24 months postoperatively, and 1 patient in the laser navigation group underwent knee arthroplasty at 18 months postoperatively. In the traditional group, the reason for knee replacement was severe tibial plateau compression fracture in 1 patient and no obvious improvement in knee pain in 1 patient. In the laser navigation group, the meniscus and cartilage of the affected knee sustained severe trauma in a traffic accident, and the resulting pain was not relieved by arthroscopic treatment. After consideration, we performed knee arthroplasty in these patients. This investigation suggests that the main reason for knee replacement was unexpected trauma. While the effect in one patient in the traditional group was unsatisfactory, the survival time of the affected knee after OWHTO was satisfactory in most patients, which is consistent with most clinical research results [18, 19].

However, this study has some limitations. First, the sample size was small, and more cases need to be studied to increase the quality of the evidence. Second, the status of the knee cartilage was not observed postoperatively, which requires attention in the next step of the research. Finally and most importantly, the observation period was short, and a longer follow-up period is needed to determine the clinical efficacy of simple navigation technology. A follow-up period of 2 years does not allow us to draw conclusions about the long-term clinical outcomes of our patients, including the need to undergo total knee replacement in the future.

Conclusions

Simple laser navigation technology can effectively improve the rate of excellent lower limb mechanical axis correction, reduce radiation exposure among medical staff members and patients, reduce operation time and cost, and reduce labor input.

Abbreviations

Femoral tibial angle, FTA; Posterior slope angle, PSA; Medial proximal tibial angle, MPTA; OWHTO, Open-wedge high-tibial osteotomy

Declarations

Ethics approval and consent to participate

All experimental protocols were approved by Ethics Committee of Affiliated Hospital of Guizhou Medical University and informed consent was obtained from all patients.

Consent for publication

Written informed consent was obtained from the patients' guardians for publication of clinical data.

Availability of date and material

The datasets of the current study are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This study was supported by Science and Technology Fund of Guizhou Provincial Health Commission [Program Number: gzwkj2021-248].

Author's contributions

C-Y, G-T, and RG-Z designed the study, and CY also assisted with revision of the paper. Z-X collected the date and was a major contributor in writing the manuscript. C-L and ZY-W analysed the date. All authors read and approved the final manuscript.

Acknowledgements

The authors thank Guang Tian, M.D., from Department of Orthopedics, Guihang Guiyang 300 Hospital, for their assistance with initial project planning and study design.

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Figures

Figure 1

(a~c) show the surface references of the hip, knee, and ankle centers, and (d~f) show the hip, knee, and ankle centers using X-ray fluoroscopy. A wire coil was used as a reference in fluoroscopy (arrow). The red line represents the distance from the reference point to the center of the joint.

Figure 2

(a, b) show the common laser pen and installation location in the operation room, (c, d) show the correction of the lower limb mechanical axis using the laser beam from the common laser pen.F

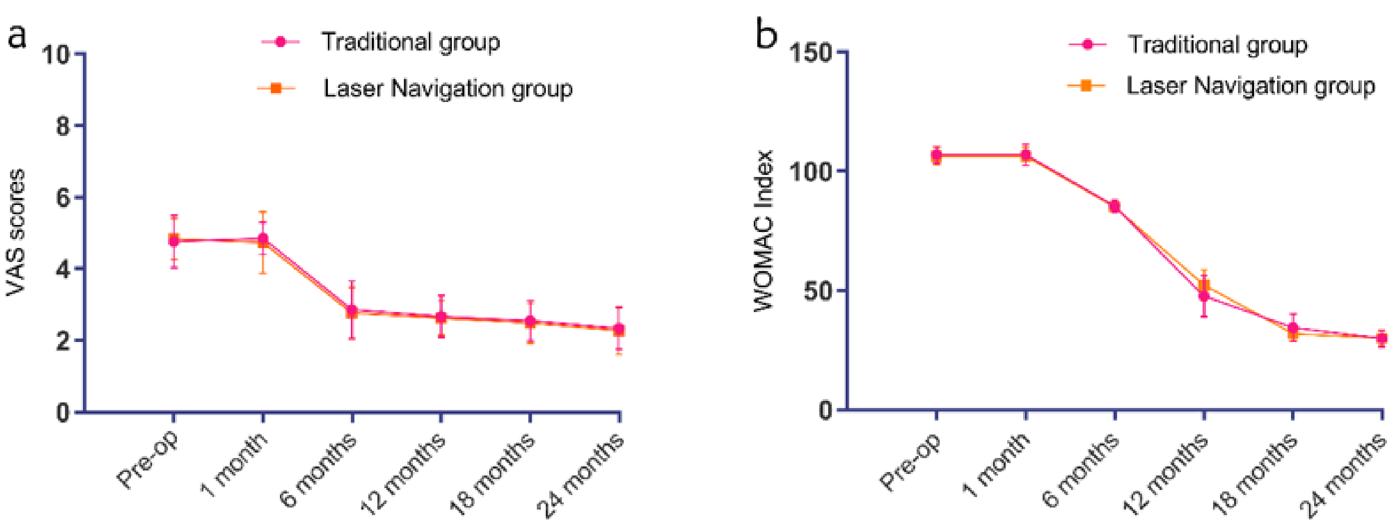

Figure 3

(a, b) The pain level and knee function in both groups significantly improved at 6, 12, 18 and 24 months ($P < 0.001$), but no significant differences were observed between the two groups ($P > 0.05$).

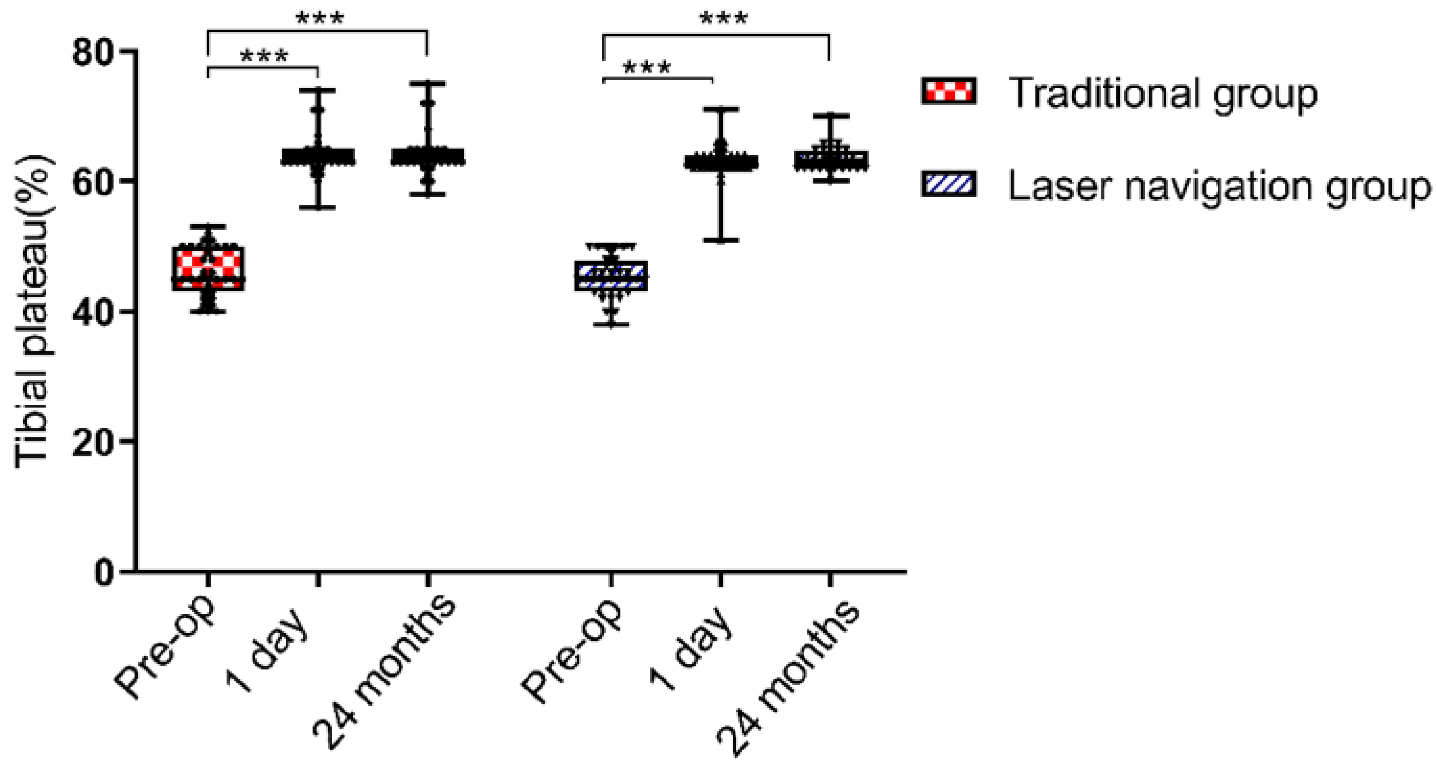

Figure 4

At 1 day and 24 months after the operation, the varus deformity was significantly corrected in both groups (P = 0.000), but the correction precision did not significantly differ between the groups (P = 0.156; P = 0.350, respectively). One day after the operation, there were 4 cases of overcorrection and 4 cases of undercorrection in the traditional group and only 1 case of overcorrection in the laser navigation group. The correction effectiveness did not change at 24 months postoperatively. The reliability of correction was significantly higher with the laser navigation system (P = 0.014; P = 0.014).

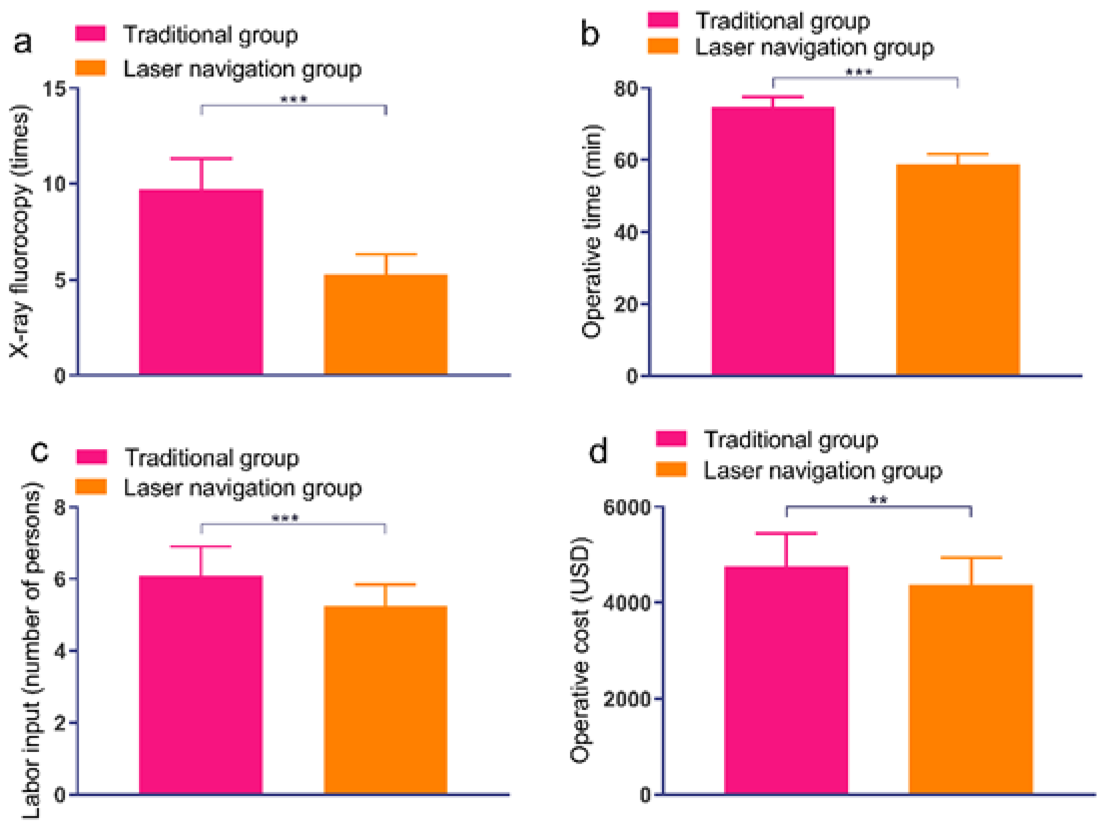

Figure 5

(a~d) The number of X-ray fluoroscopies, operation time and cost, and labor input were lower in the laser navigation group than in the traditional treatment group (*P* < 0.05).

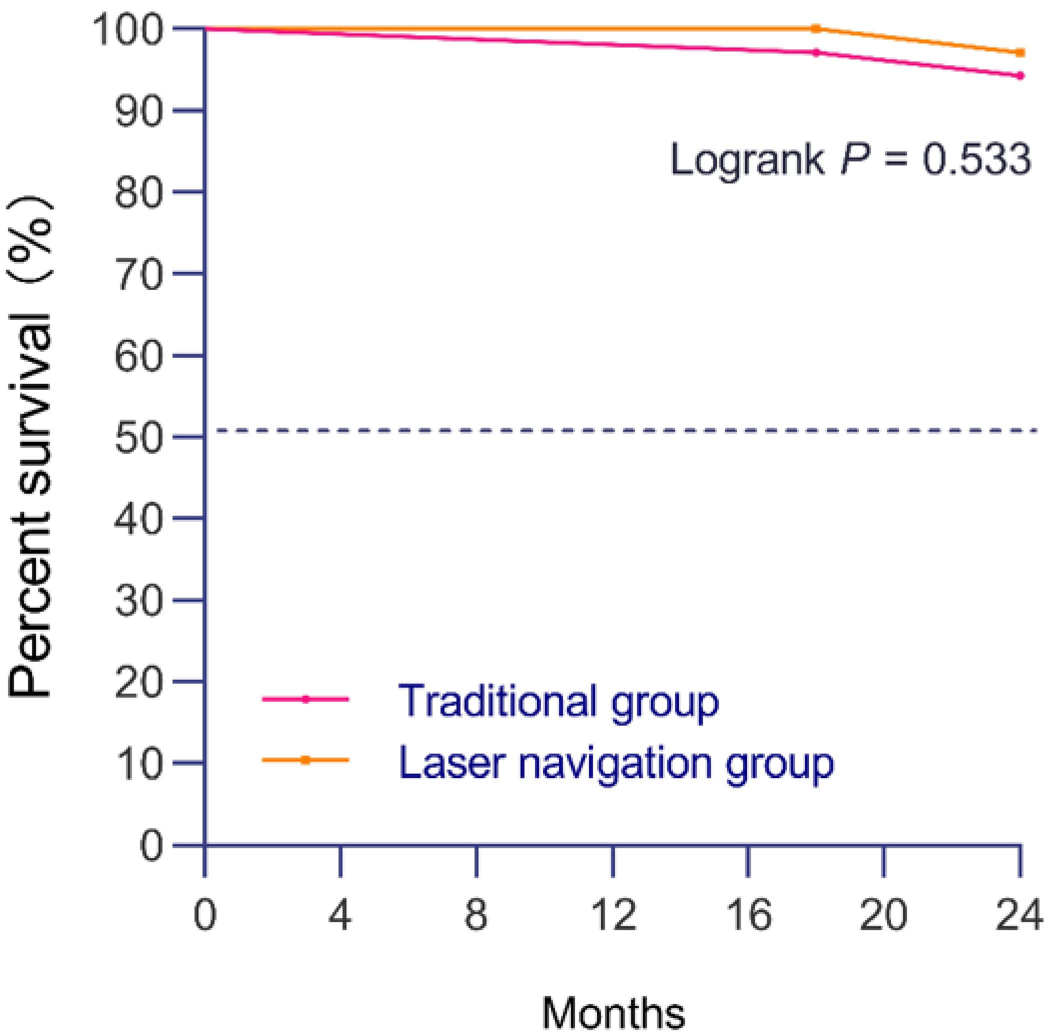

Figure 6

There was no difference in the postoperative knee survival time between the traditional and laser navigation groups (P = 0.533).

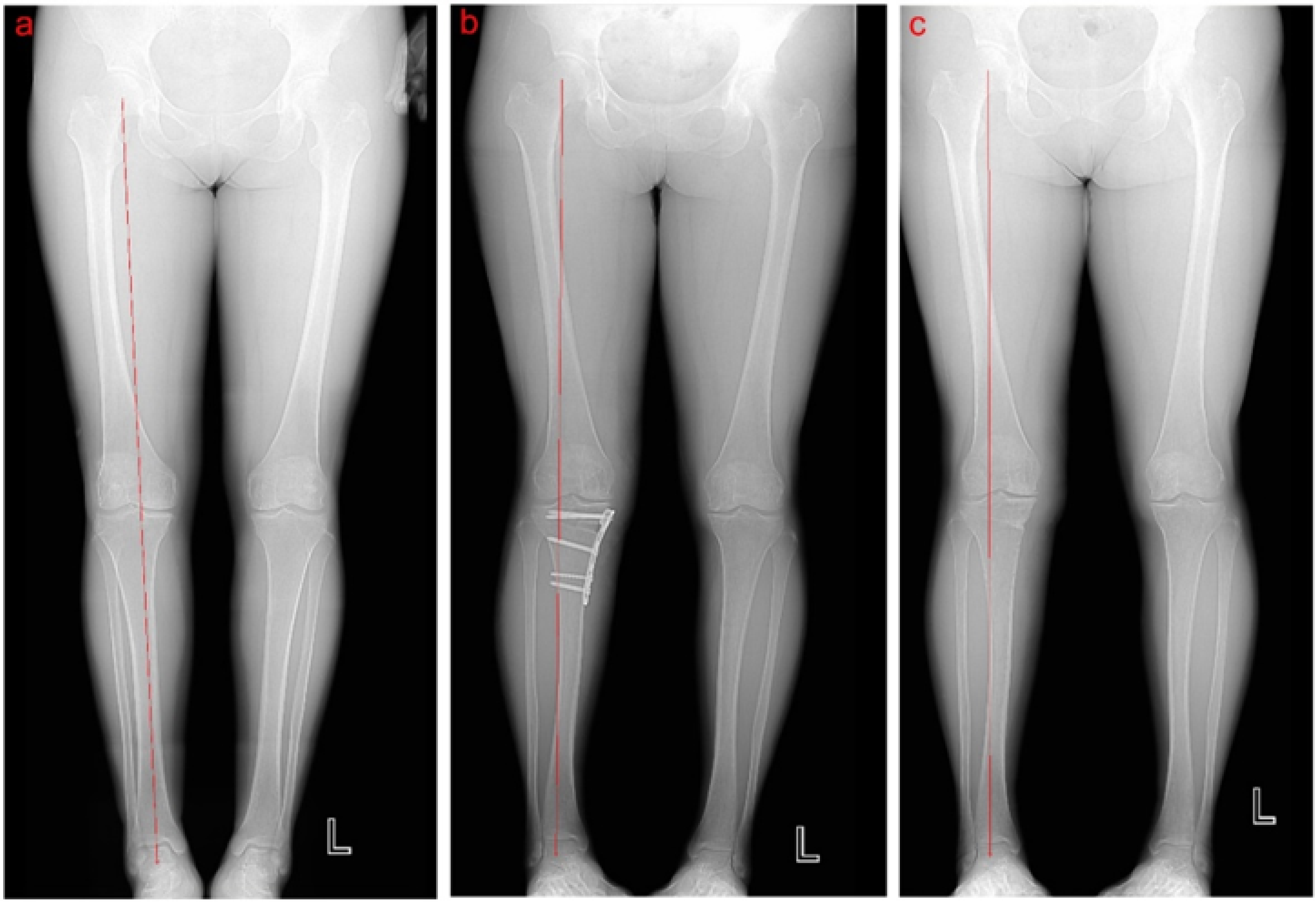

Figure 7

(a) X-ray in the weight-bearing position before the operation, (b, c) X-rays in the weight-bearing position at 1 day after the operation and two years after the implants were removed.