Knee Surg Sports Traumatol Arthrosc (2012) 20:1503–1510
DOI 10.1007/s00167-011-1726-3

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The accuracy of bone tunnel position using fluoroscopic-based navigation system in anterior cruciate ligament reconstruction

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Received: 1 June 2011 / Accepted: 11 October 2011 / Published online: 22 October 2011

Abstract
Purpose The first purpose of this study was to examine whether fluoroscopic-based navigation system contributes to the accuracy and reproducibility of the bone tunnel placements in single-bundle anterior cruciate ligament (ACL) reconstruction. The second purpose was to investigate the application of the navigation system for double-bundle ACL reconstruction.
Methods A hospital-based case–control study was conducted, including a consecutive series of 55 patients. In 37 patients who received single-bundle ACL reconstruction, surgeries were performed with this system for 19 knees (group 1) and without this system for 18 knees (group 2). The positioning of the femoral and tibial tunnels was evaluated by plain sagittal radiographs. In 18 patients who received double-bundle ACL reconstruction using the navigation system (group 3), the bone tunnel positions were assessed by three-dimensional computed tomography (3D-CT). Clinical assessment of all patients was followed with the use of Lysholm Knees Score and IKDC.
Results Taking 0% as the anterior and 100% as the posterior extent, the femoral tunnels were 74.9 ± 3.0% in group 1 and 71.5 ± 5.8% in group 2 along Blumensaat's line, and the tibial tunnels were 42.3 ± 1.4% in group 1 and 42.5 ± 4.6% in group 2 along the tibia plateau. The bone tunnel positions in group 1 were located significantly closer to the position planned preoperatively and varied less in both femur and tibial side, compared with those without navigation (group 2). (Femur: $P < 0.05$, Tibia: $P < 0.001$) 3D-CT evaluation of double-bundle ACL reconstruction (group 3) also demonstrated that the bone tunnel positions of both anteromedial (AM) and posterolateral (PL) were placed as we expected.
Conclusion The fluoroscopic-based navigation system contributed to the more reproducible placement of the bone tunnel during single-bundle ACL reconstruction compared with conventional technique. Additionally, this device was also useful for double-bundle ACL reconstruction.
Level of evidence Case–control study, Therapeutic study, Level III.

Keywords Anterior cruciate ligament (ACL) · Computer-assisted surgery · Navigation · Double-bundle · Tunnel position

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Introduction

One of the most critical factors for successful anterior cruciate ligament (ACL) reconstruction and long-term stability is the bone tunnel placements [15, 20, 22, 40]. However, to place the bone tunnels in reproducible and correct positions is technically challenging under only arthroscopic view in ACL reconstruction. Previous radiological and cadaveric studies indicate that approximately

Table 1 Patient demographic data

	Single-bundle		Double-bundle	*P* value
	Navigated reconstruction group 1	Conventional reconstruction group 2	Navigated reconstruction group 3	
Number of patients	19	18	18	NS
Gender (m/f)	9/10	8/10	9/9	NS
Age (year)	26.7 ± 9.1	27.5 ± 9.6	28.9 ± 11.1	NS
Height (cm)	164.2 ± 10.2	166.2 ± 9.2	164.9 ± 5.2	NS
Weight (kg)	66.1 ± 13.8	62.3 ± 13.5	63.8 ± 10.1	NS
Meniscus injury	Menisectomy: 2	Menisectomy: 2	Menisectomy: 3	NS
	Meniscus repair: 4	Meniscus repair: 3	Meniscus repair: 3	

Mean ± SD

NS no significant difference

10–40% of drill holes in primary ACL reconstructions have been incorrectly placed [4, 18, 38]. New strategies to acquire ideal graft placements as expected in ACL reconstructions are therefore emerging.

To this end, navigation systems have been developed to assist in the accuracy of tunnel placement [7, 23] and the restoration of the knee kinematics more closely to physiologic condition after ACL reconstruction [25, 34, 41]. However, there is little evidence examining the feasibility and usefulness for the bone tunnel creation of navigation system in the clinical setting [8, 14, 29].

Furthermore, precise placements of bone tunnels are more significant in double-bundle ACL reconstruction [13, 33], which has been popular recently due to good rotational stability [1, 31]. Therefore, the navigation system is sure to be useful in this technique.

The aim of this study was to prove the hypothesis that fluoroscopic-based navigation system contributes to the accuracy and reproducibility of bone tunnel placements in single-bundle ACL reconstruction than those of conventional method. The second object of this study was to examine the application of the navigation system to double-bundle ACL reconstruction from the aspects of radiographic outcomes.

Materials and methods

A hospital-based case–control study was conducted, including a consecutive series of 55 patients (26 men, 29 women) who underwent primary reconstruction of the ACL by a single surgeon (T.H.), between 2006 and 2008, using a hamstring tendon autograft. The study was performed with the approval of the institutional review board, and all patients signed the consent form drafted for the study. All patients in this study received surgery at one institution (Takatsuki General Hospital), and all patients involved in this study were followed up for at least 3 years. Patients with associated ligament injuries requiring surgical treatment, evidence of chondral damage, or degeneration were excluded from this study. Those who refused to participate in this study were also excluded.

Among them, 19 knees in 19 patients (9 men, 10 women) underwent single-bundle ACL reconstruction using the fluoroscopic-based navigation system (group 1). Another 18 knees in 18 patients (8 men, 10 women) were underwent single-bundle ACL reconstruction without this system and were served as the control group (group 2). Double-bundle ACL reconstruction was performed by the use of navigation in other 18 patients (9 men, 9 women; group 3). Demographic data of the patients are shown in Table 1. All patients were followed up for at least 36 months postoperation. The mean follow-up period was 47.6 months (range, 36–60 months). All patients had unilateral injures. Associated surgery at the time of reconstruction included partial menisectomy (7 knees) and meniscal repair (10 knees).

Navigation system

A computer-assisted fluoroscopic-based navigation system (Vectorvison® ACL system, BrainLAB, Heimstetten, Germany) was used in this study. This system comprises a C-arm fluoroscope and a navigation system. The navigation system has two devices consisting of a core machine with a digitizing camera, which localizes the C-arm calibration target and all of the trackable instruments, and the navigation display. The mean probe tip error of this system is reported to be 0.97 ± 0.49 mm [10, 21].

At the beginning of the surgery, a reference frame was rigidity attached to the midshaft of the distal femur and proximal tibia by two threaded pins to track the position of the patient's leg during the procedure. And anteroposterior (AP) and lateral view images of the knee joint were

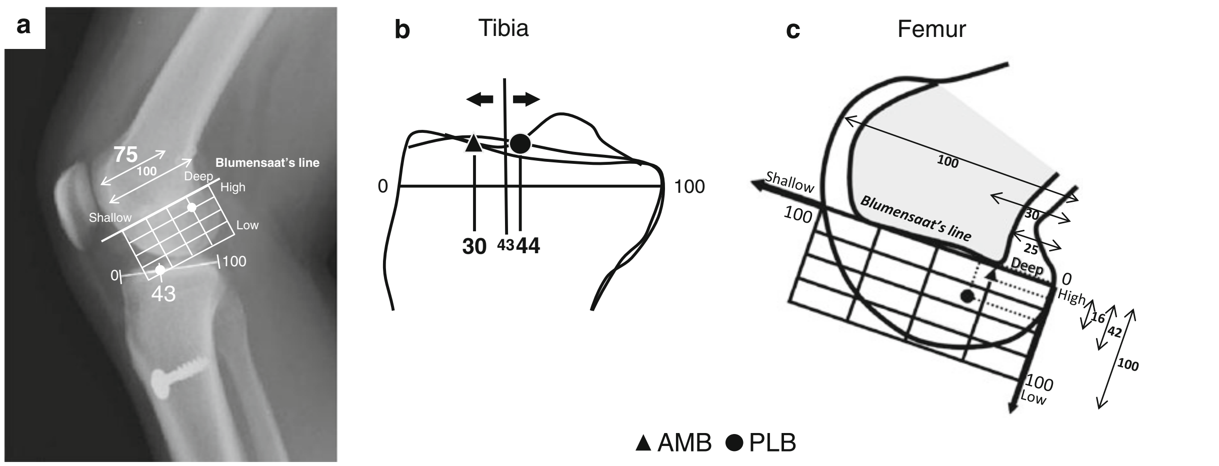

Fig. 1 **a** The ideal bone tunnel positions in single-bundle ACL reconstruction. *White closed circles* show ideal bone tunnel positions. **b** The ideal tibial bone tunnel positions in double-bundle ACL reconstruction. **c** The ideal femoral bone tunnel positions in double-bundle ACL reconstruction. *Black closed triangle* shows the AM bundle, and *black closed circle* shows the PL bundle

obtained by C-arm fluoroscopy to capture the calibration target and the reference frame simultaneously by the camera. Next, to provide detailed information on planned positions, the notch geometry and the insertion areas of the ACL on femoral and tibial side were roughly traced under arthroscopic control using navigation pointers. After registration was completed, operative instruments with reference markers were displayed on the fluoroscopic image of the navigation monitor in a real-time manner, regardless of the actual position of the knee during operation.

Surgical procedure

When we used the navigation system, the centers of bone tunnels in femur and tibia were planned on the lateral radiograph using the navigation system according to the Quadrant methods [5] for the femur and Staublis methods [35] for the tibia. In the single-bundle reconstruction, the center of the tibial tunnel was aimed 43% along the tibial plateau, with 0% as the anterior and 100% as the posterior extent. The center of the femoral insertion of the ACL was aimed at low and shallow corner of the deepest and highest quadrant (Fig. 1a). In the double-bundle ACL reconstruction, the center of the anteromedial (AM) tibial bone tunnel was placed 30% and posterolateral (PL) tibial bone tunnel was 44% along the tibial plateau as recommended by previous reports [42] (Fig. 1b). On the femoral side, as shown in the previous cadaveric studies [39, 42], the AM tunnel was aimed at 25% from the deep margin in a deep-shallow direction and at 16% from Blumensaat's line in a high-low direction, and the PL tunnel was aimed at 30% in a deep-shallow direction and at 42% in a high-low direction, according to the quadrant method described by Bernard et al. [5] (Fig. 1c).

The system was able to show the predicted position of bone tunnels and the ACL graft route on the navigation (Fig. 2). We created bone tunnels at the setup positions using a transtibial technique. If there is a possibility of the predicted bone tunnel communication or the notch impingement, it requires a minimum amount of adjustment. Finally, the graft was placed and then fixed with Endobutton CL (Smith & Nephew, Andover, MA) on the femur and a cancellous bone screw on the tibia at 20° of knee flexion.

When we did not use the navigation system, the center of the tibial tunnel was placed around where the ACL had been attached. And the femoral tunnel was aimed to place at the 10:30-o'clock position in a right knee and the 1:30-o'clock position in a left knee with reference to original footprint under arthroscopic view. The other surgical procedures did not differ from those in navigation groups.

Postoperative rehabilitation

Postoperatively, continuous passive motion (CPM) exercises were started immediately after surgery, and weight bearing was begun as soon as tolerable, usually on the third postoperative day. Patients were encouraged to resume a full range of joint motion by 12 weeks. Jogging started after 4 months, and return to full sports activity was permitted from 6 months at the earliest.

Radiological assessments

The location of the bone tunnels was evaluated on non-weight-bearing lateral-view radiograph 1, 6, and 12 months after surgery. The lateral view was obtained in an intermediary position, by carefully confirming the rotation of

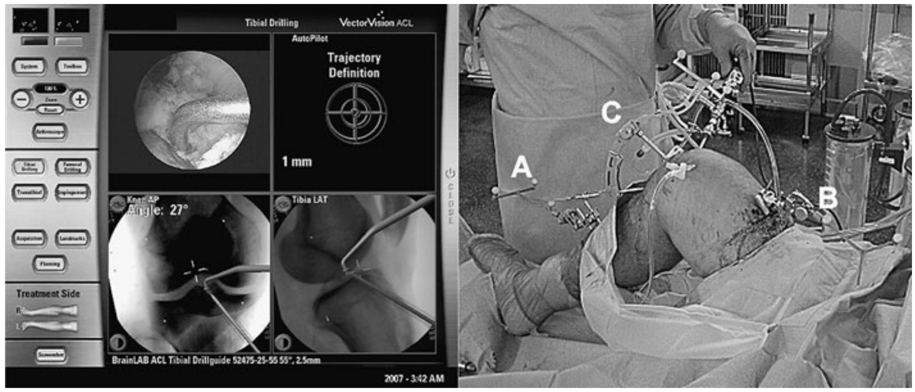

Fig. 2 Femoral and tibial arthroscopic navigated K-wire drilling in operation of the navigation surgery. The reference frames of the tibia (**a**) and femur (**b**) and a tibial drill guide (**c**) are seen. Display of the navigation images on the screen shows the expected bone tunnel placements in fluoroscopic image, in addition to the conventional arthroscopic view

the knee. In the double-bundle ACL reconstruction (group 3), 3D-CT was taken 3 months after surgery. All parameters on radiographs were independently assessed by two observers (Y.K. and Y.H.) using an image analyzer [Volume Graphics GmbH Studio MAX software (Heidelberg, Germany)] and calculated to one decimal place. The results reported represent those of observer 1 (Y.K.). The decision to use the results of one examiner was made once reliability was established. Intra-observer Spearman–Brown coefficient was 0.87, and the intra-class correlation was 0.84, which Landis and Koch [24] suggest may be substantial agreement.

In single-bundle reconstruction groups (group 1, 2), the center position of the tibial tunnel was calculated and expressed as a percentage of the total length of the tibia plateau on the lateral radiograph (a/t in Fig. 3a). Placement of the center of the femoral tunnel was also assessed as a percentage of the total length of the Blumensaat's line on the lateral radiograph (b/f in Fig. 3a).

In cases of the double-bundle reconstruction group (group 3), three-dimensional computed tomography (3D-CT) was used to assess the bone tunnel placement. Femoral tunnels were assessed on the sagittal plane, and tibial tunnels were assessed on the axial plane (Fig. 3b).

Clinical assessments

To compare the functional state among the three groups, all patients were assessed preoperatively and 24 months after surgery using the International Knee Documentation Committee forms (IKDC) evaluation and Lysholm knee score. Postoperative ligamentous stability was assessed using the Lachman test and Pivot-shift examinations and graded per IKDC criteria. Assessments were performed by a surgeon (T.H.) and a physiotherapist (not an author). The examiners were not informed about operative techniques (navigated or conventional, single-bundle or double-bundle) used in each patient. All patients had long pants during testing in order to hide the scars left by the trackers. Postoperative complications were also evaluated.

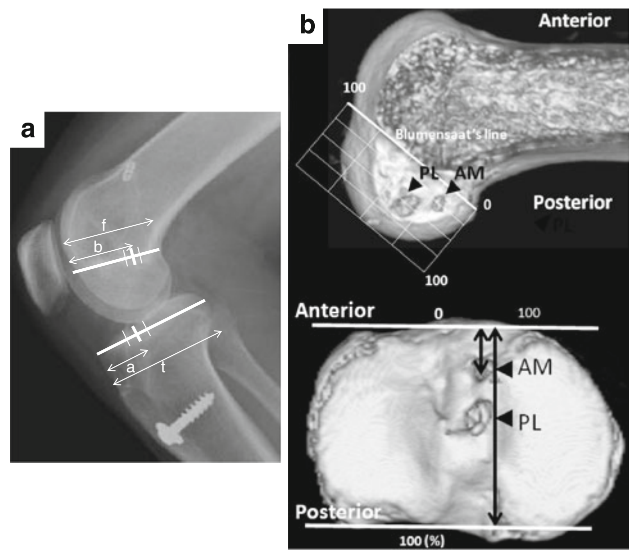

Fig. 3 **a** Radiographic parameters used to evaluate the positioning of the tibial and femoral tunnel in this study. The method of measuring the tunnel position in single-bundle ACL reconstruction is demonstrated in the sagittal radiograph. The center of the tibial tunnel was expressed as a percentage of the total length of the tibia plateau on the lateral radiograph (*a*/*t*). The center of the femoral tunnel was expressed as a percentage of the total length of the Blumensaat's line on the lateral radiograph (*b*/*f*). *a*, the distance of the center of tibia tunnel from the anterior edge of tibia plateau; *b*, the distance of the center of femur tunnel from the anterior femoral condyle; *t*, the total length of the tibia plateau; *f*, the total length of the Blumensaat's line. **b** The method of measuring the tunnel position in double-bundle ACL reconstruction is demonstrated in the 3D-CT

Statistical analysis

Based on the previous pilot study, we determined that we would need 17 samples to detect difference in bone tunnel placements as calculated using G*power 3.1 [9] when alpha was set at 0.05 and power was set at 0.9. Similarly, 15 patients in each group would be required to demonstrate a difference in clinical assessment when alpha was set at 0.05 and power was set at 0.9. The results were statistically analyzed using a software package (Graph Pad Prism^{TM}, MDF software, Inc). All values were expressed as mean ± standard deviation (SD). Statistical analysis was performed using the F test for analysis of variance of the two groups. The multiple comparisons among groups were made using a one-way analysis of variance (ANOVA). Post hoc analysis was performed by Fisher's protected least significant difference test. The comparison of clinical instability results was performed with Fisher's exact test and chi-square test. Statistical significance was defined as $P < 0.05$.

Results

Bone tunnel positions of single-bundle ACL reconstruction

In the navigation group (group 1), the midpoint of the tibial tunnel was located at a mean (and standard deviation) of 42.3 ± 1.4% posterior along the tibial plateau. The midpoint of the femoral tunnel was located at a mean of 74.9 ± 3.0% posterior along Blumensaat's line. In the control group (group 2), the midpoint of the tibial tunnel was located at a mean of 42.5 ± 4.6% posterior along the tibial plateau, and the midpoint of the femoral tunnel was located at a mean of 71.5 ± 5.8% posterior along Blumensaat's line. The distributions of the midpoint of placements of the tibial and femoral tunnels are shown in Fig. 4a. Measurement data at the tibial and femoral side in single-bundle ACL reconstruction are shown in Table 2.

When we compared the bone tunnel placements and dispersion of the single-bundle ACL reconstruction between both groups, the bone tunnels using navigation (group 1) were located more closely to the position which we had planned before the operation and varied less on both the femur and the tibial side ($P < 0.05$, $P < 0.001$, respectively).

Bone tunnel positions of double-bundle ACL reconstruction

In the 3D-CT evaluation of the double-bundle ACL reconstruction, the dispersions of the bone tunnel positions are demonstrated in Fig. 4b. Measurement data at the tibial and femoral side in double-bundle ACL reconstruction are shown in Table 3. 3D-CT images showed that the centers of the PL tunnels of the tibia side tended to be located posterior to our predicted positions in order to avoid connection with the AM tunnels. However, the other tunnel positions were placed as planned before the operation.

Physical examination

The mean Lysholm knee scale was 92.8 ± 5.5 (group 1), 90.2 ± 8.3 (group 2), and 93.3 ± 3.5 (group 3), and the mean subjective IKDC score was 91.1 ± 5.5 (group 1), 87.8 ± 5.1 (group 2), and 92.5 ± 4.0 (group 3). In this study, we found no statistical differences in Lysholm Knee scale and subjective IKDC score among the three groups.

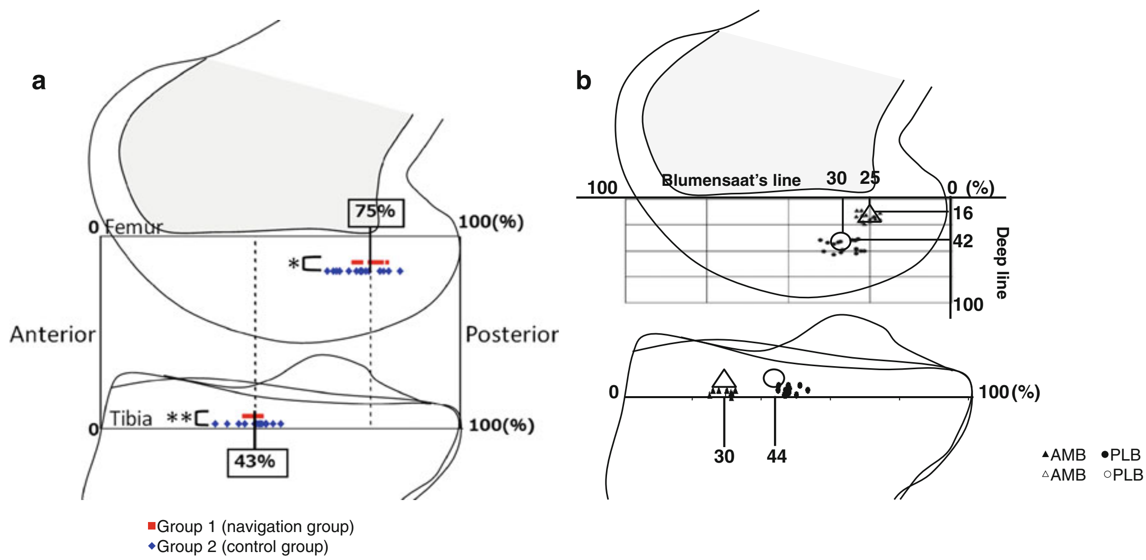

Fig. 4 **a** The distribution of the radiological femoral and tibial tunnel placements in single-bundle ACL reconstruction. *Closed box* shows group 1 (navigation group), and *closed diamond* shows group 2 (control group). **b** 3D-CT evaluation of double-bundle ACL reconstruction. *Closed triangles* demonstrate the distribution of the bone tunnel of the AM, and *closed circles* demonstrate the distribution of the bone tunnel of the PL. *Open triangle and circle* show the ideal bone tunnel placements as planned before the operation. *$P < 0.05$, **$P < 0.001$

Table 2 Measurement data at the tibial and femoral side in single-bundle ACL reconstruction

	Measurement data at the tibial side Anterior–posterior: from anterior (%) along tibia plateau	Measurement data at the femoral side Anterior–posterior: from anterior (%) along Blumensaat's plateau
Group 1 (navigation group)	42.3 ± 1.4	74.9 ± 3.0
Group 2 (control group)	42.5 ± 4.6	71.5 ± 5.8

Table 3 Measurement data at the tibial and femoral side in double-bundle ACL reconstruction

Measurement data at the tibial side	Anterior–posterior: from anterior (%) along tibia plateau	
AMB	29.2 ± 2.4	
PLB	48.3 ± 2.4	
Measurement data at the femoral side	Quadrant methods	
	From Blumensaat's line (%)	From deep (%)
AMB	17.6 ± 4.5	25.7 ± 2.8
PLB	45.9 ± 5.4	32.9 ± 4.4

The Lachman examination was positive in three cases postoperatively, described as IKDC criteria 1. Two patients were in group 2, and the other one was in group 1. The Pivot-shift examination was positive in five cases described as IKDC criteria 1 (glide) postoperatively. Three patients were in group 2, and the other two were in group 1. No postoperative instability was found in group 3. However, there was no statistical difference among three groups in Lachman test and Pivot-shift test in this short series.

Complications

One patient (group 1) suffered a local infection at the tibia insertion for the navigation antenna. Surgery and the postoperative courses were uneventful for all other patients in all groups.

Discussion

The major finding of the present study was that the fluoroscopic-based navigation system improves the accuracy and reproducibility of tunnel placement in single-bundle ACL reconstruction. Moreover, in the cases of double-bundle ACL reconstruction, we could place the bone tunnels as planned using this navigation system as illustrated in postoperative 3D-CT scanning.

Individual variation in joint geometry and the difficulty in intra-operative arthroscopic identification of correct insertions are supposed to be the main causes of bone tunnel misplacement [4, 6, 18]. For example, the intercondylar roof angle varies from 22° to 64° [2]. In chronic cases, original anatomical foot prints are indefinable, and anterior subluxation of the tibia is revealed [3]. Because it is difficult to evaluate such variation and identify the correct insertions by arthroscopy, the surgeon sometimes needs to confirm the location of the guide pin by intra-operative radiography or fluoroscopy [12, 19]. However, recognition of the exact pin position using regular radiography is difficult because the radiographs are often obtained in an improper orientation. The navigation system is helpful in tackling such problems. There are two advantages with the use of this navigation system for ACL reconstruction: (1) This device renders the reconstruction more reproducible, eliminating the problem of skeletal variation among patients, and (2) a surgeon can perform the ACL reconstruction under not only an arthroscopic but also a navigated view in real time and prevent the breakout of the posterior femur wall and the roof impingements by the prediction of tunnel positions before drilling. Therefore, accurate guide pin placement to the designed position can be easily accomplished during the first attempt. The results of this study showed that we could place the bone tunnels more reproducible placement to the designed position by using this navigation system than control group. This outcome is consistent with our hypothesis that navigation system is useful to improve the accuracy of the bone tunnel placement.

For ACL reconstruction surgery, there are two types of navigation system, image-free navigation [14, 17] and fluoroscopic-based navigation, which is based on an image monitor [23, 26]. Image-free ACL navigation systems determine the tunnel position based on intra-operative bone surfacing parameters. However, similar to conventional arthroscopic methods, they are restricted by arthroscopic problems of identifying the ACL insertions. Therefore, these navigation systems resulted in a considerable variation among operators. In contrast, fluoroscopic-based ACL navigation systems, as used in this study, require image acquisition at the beginning of the surgery. Once the images have been recorded, the procedure with this system is simple. The contribution of fluoroscopic images to the identification of ACL insertion and mapping of the bone surface can help achieve a reproducible drill hole planning for ACL reconstruction according to radiological parameters, thus facilitating precise drill-hole placement. Klos et al. [23] reported that the technique with the navigation system significantly reduced the variability of graft placement in their clinical trial. For the placement of the tibial portion of the graft, the SD of the anterior/posterior graft location decreased from 6% to less than 3%. Additionally, Nakagawa et al. [26] also referred that fluoroscopic-based navigation was useful for technically demanding revision ACL reconstructions.

In context with double-bundle ACL reconstruction, navigation systems are of special interest. Recently, some previous reports demonstrated the usefulness of navigation-assisted anatomical double-bundle ACL reconstruction [27, 36, 37]. In our study, we could place the bone tunnels as planned using this navigation system as illustrated in postoperative 3D-CT scanning. As far as we know, this is the first report that demonstrates the clinical application of the fluoroscopic-based navigation system for double-bundle ACL reconstruction. However, there are still some problems to solve before the navigation system can come into widespread clinical use for double-bundle reconstruction; namely, the most optimal places for double-bundle ACL reconstruction are still controversial [16, 28, 39, 42]. To perform anatomic AM and PL bone tunnel placements, topographical osseous anatomical landmarks such as resident's ridge [32] and lateral bifurcate ridge [11] on the femoral side, and the medial and lateral intercondylar tubercles on the tibial side [30] were reported to be important. Ishibashi et al. demonstrated that the osseous landmarks can be very useful during navigation-assisted ACL reconstruction in their cadaveric study [17]. We believe that this fluoroscopic-based navigation system also contributed to identify such osseous landmarks more clearly by combining intra-operative fluoroscopic images with actual arthroscopic images.

We did not compare navigation-based double-bundle ACL reconstruction with conventional methods, and this may be appear to be a limitation of this study warrants discussion. However, there was little previous clinical study reporting the effect of navigation on double-bundle ACL reconstruction, and our primary object was to demonstrate the therapeutic potential of navigation system as a new tool for double-bundle ACL reconstruction. Another point that requires discussion is no statistic difference between navigation groups and control group in clinical outcomes in our short-time follow-up study. The role of fluoroscopic navigation system on clinical performance and longevity need further investigation with larger sample sizes and longer-term randomized trials.

We believe that the fluoroscopic-based navigation system will be valuable as an assisting device for conventional arthroscopic ACL reconstruction because this system improves visibility of the surgical field and increases the geometric accuracy during surgical procedure. Moreover, we believe that we can do technically demanding double-bundle ACL reconstruction more safely by using this system.

Conclusion

This study demonstrated that computer-assisted fluoroscopic-based navigation system can improve the accuracy for designed ACL insertion site and decrease the dispersion of the femur and tibial bone tunnel placements in single-bundle ACL reconstruction. Additionally, the availability of the system for double-bundle ACL reconstruction was shown in this paper. It is necessary to consider the extra work involved in the navigation system; however, the use of fluoroscopic navigation system may be helpful in placing the bone tunnel in the predetermined position with accuracy and repeatability during ACL reconstruction.

Acknowledgments The authors would like to thank Ms. Janina Tubby and Mr. Daniel Gilpin for help in preparing the manuscript. 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, nor have any funds been received in support of this study.

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