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Authors' contributions:

All authors have made substantial contributions to (1) the conception and design of the study, or acquisition, analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; (3) final approval of the version to be submitted; and (4) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately resolved. The specific contributions of the authors are as follows:

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3. Drafting the article: KN
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Abstract

Purpose To evaluate the effect of tibial tunnel coalition on knee rotatory laxity and clinical outcomes after double-bundle (DB) anterior cruciate ligament (ACL) reconstruction.

Methods Forty-one patients who underwent anatomic DB ACL reconstruction were included prospectively. Three-dimensional computed tomography of the knee joint was obtained at approximately 1 year postoperatively to determine if tunnel coalition occurred. After excluding seven cases of femoral tunnel coalition, two groups were established based on the existence of tibial tunnel coalition. The pivot-shift test was quantitatively evaluated on the basis of tibial acceleration preoperatively and at 1 year postoperatively. Two subjective scores, the International Knee Documentation Committee (IKDC) subjective and Lysholm scores, were also collected. The pivot-shift measurement and subjective scores were compared between the ACL-reconstructed knees with and without tibial tunnel coalition. The independent t-test, Pearson chi-square test, and Student t-tests were used in data analysis.

Results Twenty-one knees had tibial tunnel coalition (group C), whereas 13 knees did not have tunnel coalition(group N). Pivot-shift was significantly diminished postoperatively in both groups on the basis of the clinical examination and quantitative evaluations ($p<0.05$). However, there was a small but significant difference in tibial acceleration demonstrating larger pivot-shift in group C (1.0±0.6 m/s^2) than in group N (0.5±0.3 m/s^2, $p<0.05$). No significant difference was observed in the IKDC subjective and Lysholm scores (both n.s.).

Conclusion When tibial tunnel coalition occurs after DB ACL reconstruction, knee rotatory laxity may not be restored in ACL-reconstructed knees, as expected in those without tunnel coalition. It is recommended that two tibial tunnels should be created separately when performing DB-ACL reconstruction in order to achieve better control of rotatory knee laxity.

Keywords: double-bundle anterior cruciate ligament reconstruction, tunnel coalition, electromagnetic measurement system, quantitative measurement, pivot-shift test

Level of Evidence: Level III

Introduction

Anatomic double-bundle (DB) anterior cruciate ligament (ACL) reconstructions have been developed over the past decades. Several clinical advantages of DB ACL reconstruction such as improved clinical outcome [15, 25, 32] and fewer graft failure [14] have been reported. Contrarily, some reports could not find such clinical benefits of the DB technique over the single-bundle (SB) technique [1, 4]. A systematic review of comparison studies between DB and SB techniques concluded that better restoration of knee rotatory laxity was observed after anatomic DB ACL reconstruction than after SB reconstruction [5].

DB ACL reconstructions are performed to replicate the original two-bundle structure of the ACL [6, 9, 22, 23] and thus, recent techniques mostly create two separate tunnels for the anteromedial (AM) and posterolateral (PL) bundles of the femur and the tibia in the anatomic locations [2]. However, bone tunnel coalition occurs as a surgical complication due to technical errors or as a result of tunnel enlargement during the patient's postoperative course [18, 31]. Although technical improvement resulted in relatively fewer cases of tunnel coalition on the femoral side (ranging from 2% to 19%), tibial tunnel coalition remains present in up to 77% of cases of DB ACL reconstructions [16, 18, 19, 31].

The effects of bone tunnel coalition on clinical outcomes and anterior knee laxity have been reported previously [16, 18, 19, 31]. However, rotatory knee laxity or pivot-shift was not fully examined in those previous studies mostly because of a lack of objective evaluation systems although, it is crucial to assess the efficacy of DB ACL reconstruction. Nowadays, there are some clinically usable and validated quantitative evaluation systems for assessing rotatory knee laxity [3, 13, 14, 23, 26, 28], and the electromagnetic system has been shown to have superior diagnostic reliability to the pivot-shift test [28].

In our study, the effects of tibial tunnel coalition after DB ACL reconstructions on knee rotatory laxity and clinical outcomes were evaluated. It was hypothesized that adverse effects of tibial tunnel coalition would be observed on knee rotatory laxity and clinical outcomes.

Materials and Methods

Ethics Statements

This study was approved by the Institutional Review Board of Kobe University (ID No. B190055). Written informed consent was obtained from all participants in this study.

Study Design and Population

Unilateral ACL-injured patients who underwent primary DB ACL reconstruction using hamstring tendon autografts at the Kobe University Hospital between January 2015 and March 2018 were prospectively enrolled. One-hundred-and-twenty-three patients of ACL reconstructions were performed, and double bundle technique was primarily used in almost all cases regardless of their footprint size. However, the number of ACL reconstruction cases with quantitative measurement of the pivot-shift was limited due to the availability of the electromagnetic measurement system, which was only one available at our hospital. The pivot-shift measurement by an electromagnetic system was conducted randomly in as many primary ACL reconstruction cases as possible. As a result, 51 patients in whom quantitative evaluation was obtained were included in this study.

Patients aged 15 to 50 years who were followed up for more than 1 year after ACL reconstruction with the quantitative evaluation of the pivot-shift, and those who underwent post-screw removal surgery and computed tomography (CT) evaluation as per the clinical routine were included. Exclusion criteria were previous knee surgeries, additional knee ligament injuries, skeletal immaturity, cartilage injuries, and early re-tear and knee ligament injuries to the contralateral knee. Eight patients who did not undergo CT imaging and two cases with early re-tear were excluded.

After diagnosing a torn ACL based on clinical examinations and confirmation by magnetic resonance imaging, anatomic DB ACL reconstruction was performed using a previously reported technique [2]. Before the ACL reconstructions, the pivot-shift test was performed with the patients under general anesthesia, and the result was evaluated quantitatively using an electromagnetic system as described later. At Approximately 1 year postoperatively, ACL-reconstructed patients underwent post-screw removal surgery as per our clinical routine. Quantitative evaluation of the pivot-shift test result was repeated for the post-screw removal surgery with the patient under general anesthesia.

In order to determine the existence of tunnel coalition, multidetector computed tomography (MDCT) images were obtained in 41 patients at 1 year postoperatively. Three-dimensional (3D) CT assessment of tibial tunnel coalition was performed as described later. Seven patients who were confirmed to have femoral tunnel coalition were excluded in order to focus on the tibial tunnel coalition in this particular study, and ultimately, 34 patients (15 men and 19 women) remained for further analysis. The group of patients who had tibial tunnel coalition was categorized as group C, and no coalition was categorized as group N. There were 21 cases in group C and 13 cases in group N.

Surgical Technique

As previously described [2], the original anatomic positions of the AM and PL bundle insertion sites were identified in reference to the ACL remnant arthroscopically, and bone tunnels were created at the center of each ACL bundle attachment. Two femoral bone tunnels were created by the outside-in or transportal technique, and two tibial bone tunnels were independently created using a tibial drill guide (Acufex Director, Smith & Nephew Inc., Boston, MA, USA). Meniscal repair or meniscectomy was performed as needed. An adjustable suspensory fixation device (UltraButton, Smith & Nephew Inc.) was used for fixation on the femoral side, and a post-screw with a washer (Low Profile Cancellous Screw and Washer, Arthrex Inc., Naples, FL, USA) was placed on the tibial side.

Rehabilitation

From the first postoperative day, all patients performed active quadriceps exercise and started intermittent passive motion exercise. Patients were allowed 50% weight bearing at 1 week and full weight bearing at 2 weeks postoperatively. A functional knee brace was worn for 8 weeks. At 3 months, patients resumed running and were permitted to return to sports activities after 9 months.

Quantitative Evaluation of the Pivot-shift Test

For a quantitative evaluation of tibial acceleration during the pivot-shift test, an electromagnetic measurement system (JIMI Kobe, Arthrex Japan, Tokyo, Japan) was used, as in previous studies [14, 28]. This system consists of a transmitter that produces an electromagnetic field, and three electromagnetic receivers. The two receivers are firmly attached to the thigh and shank with plastic braces, and represent the six-degrees-of-freedom motion of the femur and tibia, respectively, after setting the coordinate system, as follows: seven anatomic landmarks (the greater trochanter, medial and lateral epicondyles, crossing point between the medial joint line and the medial collateral ligament, fibular head, and medial and lateral malleoli) were identified by the third receiver, and their 3D positions were recorded relative to the positions of the two receivers on the body. The femoral coordinate system was configured on the basis of positional data of one to three anatomic landmarks in relation to the receiver on the thigh, whereas the tibial coordinate system was set using the data of four to seven landmarks relative to the receiver on the lower leg. Relative movement between the two receivers during knee motion can be converted to six-degrees-of-freedom knee kinematics in accordance with the Grood and Suntay coordinate system [10]. Tibial acceleration was one of the quantitative measurements for the pivot-shift test, and related to clinical grading of the pivot-shift test [14, 28].

Tibial acceleration (m/s^2) was calculated from the data of anteroposterior translation during the pivot-shift test, and the maximum value just before the pivot-shift phenomenon (sudden tibial posterior translation relative to the femur was used for further analysis) [14]. The accuracy of this measurement was reported as the average standard deviation of three measurements, was 0.2 ± 0.1 m/sec^2[14].

Computed Tomography Protocol and Processing Software

CT scans were obtained at about 1 year after ACL reconstruction. One slice of the post-operative MDCT image consisted of 512×512 ($X \times Y$) voxels. Knees were scanned from 5 cm proximal to the femoral epicondyle to 5 cm distal to the tibial tubercle using 64-slice MDCT (Aquilion 64; Toshiba Medical Systems, Tokyo, Japan), and the images were evaluated using Mimics software version 21.0 (Materialise, Leuven, Belgium) and 3-matic (Materialise). Three-dimensional recognition and digital image analysis of MDCT was conducted as per Miyaji et al.'s study [24].

The following steps were used to evaluate the position of the bone tunnels. First, the bone tunnels of the femur and tibia were identified semi-automatically by using Mimics. If a range was selected three-dimensionally along each bone tunnel, the bone tunnel was automatically extracted as a cylinder (Fig 1A). Second, 3D models of the femur and tibia were automatically created based on MDCT (Fig 1B). Third, the intersection of the center of the bone tunnels and the intra-articular bone surface of the tibia were defined as the position of the bone tunnel.

The existence of tunnel coalition was determined if the AM and PL tunnel outlets overlapped the intra-articular bone surface of the femur or the tibia (Fig 1C). Additionally, the positions of the tibial tunnels were explored using 3D CT to determine if the tunnel placements were different between the groups. Medial and lateral intra-articular bone surfaces of the tibia were approximated and defined as the intra-articular surfaces of the tibia. The medial and lateral edges of the tibial plateau were identified by using the method reported by Uozumi et al. [35], and the line connecting these two points was set as the medial-lateral axis. Next, the anterior-posterior axis was defined as the line orthogonal to the proximal-distal and medial-lateral axes. Finally, the position of the tibial bone tunnel was evaluated by the ratio of the distance from the anterior axis and the distance from the medial axis (Fig 1D).

The width of the tibia from anterior to posterior was determined as the length of the anterior-posterior axis, and the width from medial to lateral was determined as the length of the medial-lateral axis.

Tunnel enlargement was determined based on CT in the axial view at the intra-articular surface at 2 weeks and 1 year, and was assessed by measuring the axial width of the tibial bone tunnel, perpendicular to the long axis of the tunnel. In the case of tunnel coalition, each bone tunnel diameter was measured with an elliptical approximation. The percentage change in the diameter was defined as the degree of tunnel enlargement, as Kawaguchi et al described[18].

Clinical Evaluation

Clinical evaluation was also performed prior to ACL reconstruction and at a mean of 1 year postoperatively. The clinical grading of the pivot-shift test result was determined according to the International Knee Documentation Committee (IKDC) form, as follows: none (–), glide (+), clunk (++), or gross (+++). Subjective scores including the Lysholm knee score and IKDC subjective score were also collected.

Statistical Analysis

Tibial acceleration during the pivot-shift test and the two subjective knee functional scores were compared between groups C and N using the independent t-test. The Pearson chi-square test was used to evaluate between-group differences in the clinical grading of the pivot-shift test results. Statistical significance was set at $p<0.05$ for two-sided tests.

A priori sample size calculation was performed on the basis of the measurement accuracy reported in previous studies, that utilized an electromagnetic system to quantify the pivot-shift test results [12, 14, 28]. Twenty-eight subjects were required to detect a 0.5-m/s^2 difference in tibial acceleration, assuming a power of 0.80, significance level of 0.05, and common variance of 0.5 m/s^2 using a two-sided Student t-test.

All statistical analyses were performed using SPSS software, version 22 (SPSS Inc., Chicago, IL, USA). Statistical power was calculated for the not statistically significant differences using G*power 3.1 (Christian Albrecht University, Kiel, Germany).

Results

Patient demographics are shown in Table 1. There were no statistically significant differences in sex, age, height, weight, total graft diameter on the tibial side (AM+PL bundles), concomitant meniscus injury, time from injury to surgery, and the width of the tibia between the groups. Preoperative clinical grading of the pivot-shift test results and subjective scores were not significantly different between the groups. There was also no significant difference in preoperative evaluation of the pivot-shift test result between the groups (Table 2).

Tibial acceleration and clinical grading of the pivot-shift test result were significantly reduced by the ACL reconstruction at the follow-up evaluation (both, $p<0.01$). Tibial acceleration at 1-year follow-up was significantly higher in group C (1.0±0.6 m/s^2) than in group N (0.5±0.3 m/s^2, p<0.01) (Fig. 2).

Clinical grading of the pivot-shift test results and subjective scores were similar between the groups (all not significant; statistical powers for clinical grading, IKDC score, and Lysholm score: 0.21, 0.44, and 0.82, respectively; Table 3). There was no significant difference in the tibial tunnel position at 1 year postoperatively between the groups(Table 4).

The tunnel diameter at 2 weeks and 1 year, and the degree of tunnel enlargement were similar between the groups (Table 5).

Discussion

The most important finding of this study was that higher tibial acceleration during the pivot-shift test was detected in the ACL-reconstructed knees with tibial tunnel coalition than in those without tibial tunnel coalition. Thus, knee rotatory laxity may be affected by tibial tunnel coalition. However, the short-term clinical outcome was not worsened by tibial tunnel coalition, mainly because of the small sample size. The current study is the first to determine the relationship between rotatory knee laxity and tunnel coalition after DB ACL reconstruction using quantitative evaluation of the pivot-shift test results, as previous studies evaluated rotatory knee laxity only by manual examination [18, 31].

Manual examination of rotatory knee laxity is notorious for subjectivity and variability [21, 26, 29]. Thus, it could have been difficult to detect the effect of tunnel coalition on rotatory knee laxity by manual tests in previous studies.

Several devices can quantify knee laxity during the pivot-shift test, such as the KiRA accelerometer system [3], iPad [13, 26], navigation system [23], and electromagnetic measurement system [14, 28], and such measurement devices have been clinically validated [27]. These systems can also evaluate pivot-shift movements, such as tibial acceleration and/or tibial translation. Tanaka et al. [28] reported that the electromagnetic measurement system was more sensitive and specific for detecting pivot-shift movements than the iPad and accelerometer [34]. Thus, in our study, the electromagnetic measurement system was selected for evaluating the pivot-shift test results.

Tibial tunnel coalition is not a rare complication after DB ACL reconstruction. In the current study, tibial tunnel coalition occurred in 62% of cases at 1 year after DB ACL reconstruction. Hantes et al. [11] reported a case of tibial tunnel coalition caused by an intraoperative error (bone tunnel drilling using an anatomic aimer) at the level of the joint line [11]. When creating the tibial bone tunnels one by one independently, tibial tunnel coalition occurred in 27-77% of cases [18, 19, 31], so, the frequency of tibial tunnel coalition in the present study was not very different from frequencies reported in the previous studies. There was no difference in tibial bone size or tunnel enlargement between the two groups. Therefore, surgical technique seems to be an important factor in tunnel coalition.

The pivot-shift phenomenon is described as forward subluxation of the lateral tibial plateau on the femoral condyle in extension, and the spontaneous and sudden reduction in flexion [7, 8]. AM and PL bundles have different functions for knee stability. The main function of the AM bundle was considered to prevent anterior tibial translation, and that of the PL bundle was considered to maintain rotational stability [30, 37]. Because of the presence of tibial tunnel coalition in the ACL-reconstructed knees, the posterior wall of the AM bone tunnel disappeared, resulting in an increase of tibial anterior subluxation, and the anterior wall of the PL bone tunnel collapsed and affected rotational instability. The biomechanical pathology of tunnel coalition is still unknown, so further investigation is warranted.

The current study did not determine the effect of tunnel coalition on clinical outcomes, similar to previous studies [16, 18, 19, 31]. The main reason for this was this study’s small sample size. However, the remaining pivot shift could affect clinical outcomes later on. Kocher et al. [18] reported that patients with a higher pivot-shift grade had lower overall knee function and lower Lysholm scores [20], and Jonsson et al. [15] reported that positive pivot shift may contribute to long-term degenerative changes of the knee [17]. In the long-term, increased rotatory knee laxity caused by tibial tunnel coalition, if any, may induce degenerative changes of the knee and worsen the clinical outcomes.

The present study has some limitations. First, this study did not include cases of SB ACL reconstruction. Previously, better rotational stability during the pivot-shift test was demonstrated after DB ACL reconstruction than after anatomic SB reconstruction [2, 36]. Previous studies of DB ACL reconstruction were highly likely to have cases of tibial tunnel coalition, but rotational stability was still better after DB ACL reconstruction than after SB reconstruction. DB ACL reconstruction with a separate tibial tunnel could be even more effective than SB reconstruction, and the knees with tunnel coalition after ACL reconstruction may be similar to those after SB reconstruction. Second, the number of cases in this study was too small to obtain definitive results in the subjective evaluations. The sample size was calculated mainly to detect the difference in pivot-shift test results, and it was achieved successfully. Nevertheless, it is necessary to increase the number of cases in the future. Third, the post-operative evaluation was performed at only 1 year after reconstructive surgery. However, the primary aim of this study was not to test the clinical outcomes, but to evaluate the biomechanical influence of tibial tunnel coalition. Moreover, most athletes who have ACL reconstruction resume their normal activities at approximately one year after the operation, and in our hospital, the second-look arthroscopy was performed at the time of tibial screw removal, around one year after surgery. The objective evaluation of the pivot-shift test under general anesthesia could only be performed at that time. So, one year might be sufficient to address the biomechanical function of the knee after ACL reconstruction. However, the short-term clinical effect of tibial tunnel coalition was not observed in this study. So, the longer term follow-up study is required to obtain a thorough understanding between tunnel coalition and clinical outcomes.

On the basis of this study's results, bone tunnels should not be created to make tunnel coalitions. Independent bone tunnel drilling can carry the risk of bone tunnel coalition, so establishing a procedure and/or a useful surgical device to create separate tibial tunnels reliably and consistently is desirable for further clinical improvement of DB ACL reconstruction.

Conclusions

Tibial acceleration during the pivot-shift test was higher in the ACL-reconstructed knees with tibial tunnel coalition than in those without tibial tunnel coalition. In order to avoid future concerns regarding remaining rotatory knee laxity, it is clinically preferable to create two completely separate tibial tunnels when performing DB ACL reconstruction.

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Tables

Table 1. Patients' demographic data

	All cases	Group C	Group N	*p* value
Sex (male/female)	15/19	13/10	7/6	n.s.
Age (years)	25.2±10.1	24.0±8.5	27.5±12.2	n.s.
Height (cm)	164.0±7.5	163.1±7.9	165.4±6.6	n.s.
Weight (kg)	63.1±9.6	61.7±9.5	65.4±9.2	n.s.
Total bone tunnel diameter (mm)	11.9±2.2	11.8±0.7	12.1±0.4	n.s.
Meniscal tear (medial/lateral)	12/10	8/6	4/4	n.s.
Delay from injury to surgery (days)	253±406	274±322	310±600	n.s.
The width of the tibia (anterior to posterior) (mm)	50.1±4.3	50.9±4.3	49.3±4.1	n.s.

The width of the tibia (medial to lateral) (mm)	73.5±5.7	74.5±5.7	72.7±5.6	n.s.

Group C, knees with tibial tunnel coalition; Group N, knees without tibial tunnel coalition; n.s., not significant

Table 2. Preoperative data of the clinical grading of the pivot-shift test results, subjective scores, and tibial acceleration of the pivot-shift test

	Group C	Grpup N	*p* value
Clinical grading (-/+/++/+++)	0/9/10/2	0/7/6/0	n.s.
IKDC score (points)	63.4±12.2	67.3±7.9	n.s.
Lysholm score (points)	77.5±13.1	79.4±10.3	n.s.
Tibial acceleration (m/s^2)	1.2±0.8	1.0±0.5	n.s.

Group C, knees with tibial tunnel coalition; Group N, knees without tibial tunnel coalition; IKDC, International Knee Documentation Committee

Table 3. Postoperative data of the clinical grading of the pivot-shift test results and subjective scores

	Group C	Grpup N	*p* value
Clinical grading (-/+/++/+++)	15/6/0/0	11/2/0/0	n.s.
IKDC score (points)	88.3±9.9	89.8±9.2	n.s.

Lysholm score(points)	87.1±6.4	91.1±2.6	n.s.

Group C, knees with tibial tunnel coalition; Group N, knees without tibial tunnel coalition; IKDC, International Knee Documentation Committee

Table 4. Tibial tunnel position at 1-year follow-up

		Group C	Group N	*p* value
AMB	A-P (%)	37.5±7.1	35.3±7.7	n.s.
	M-L (%)	44.6±2.5	44.7±1.8	n.s.
PLB	A-P (%)	48.9±6.9	51.5±7.5	n.s.
	M-L (%)	45.4±1.4	44.6±1.6	n.s.

Group C, knees with tibial tunnel coalition; Group N, knees without tibial tunnel coalition; AMB, anteromedial bundle; PLB, posterolateral bundle; n.s., not significant

Table 5. Tibial tunnel diameter at 2 weeks and 1 year and tunnel enlargement at 1year

		Group C	Group N	*p* value
AMB	2 weeks (mm)	6.56±0.63	6.47±0.48	n.s.
	1 year (mm)	7.72±1.48	7.39±1.16	n.s.
	the degree of the tunnel enlargement (%)	18.8±26.8	14.9±22.1	n.s.
PLB	2 weeks (mm)	6.10±0.60	5.98±0.69	n.s.
	1 year (mm)	6.94±0.84	6.78±1.26	n.s.
	the degree of the tunnel enlargement (%)	15.1±19.1	14.8±26.0	n.s.

Group C, knees with tibial tunnel coalition Group N, knees without tibial tunnel coalition

Figure legends

Fig. 1 Three-dimensional (3D) evaluations of the bone tunnel position and tunnel coalition

A: The bone tunnels of the femur and tibia are identified semi-automatically using Mimics. By selecting a 3D range along each bone tunnel, the tunnel is automatically extracted as a cylinder.

B: The 3D models of the femur and tibia are automatically created based on multidetector computed tomography.

C: Tibial tunnel coalition is determined by observing the anteromedial and posterolateral tunnel outlets on the intra-articular bone surface. The upper figure is an example of tibial tunnel coalition, and the lower one is an example of no tibial tunnel coalition.

D: Evaluation of the tibial tunnel position.

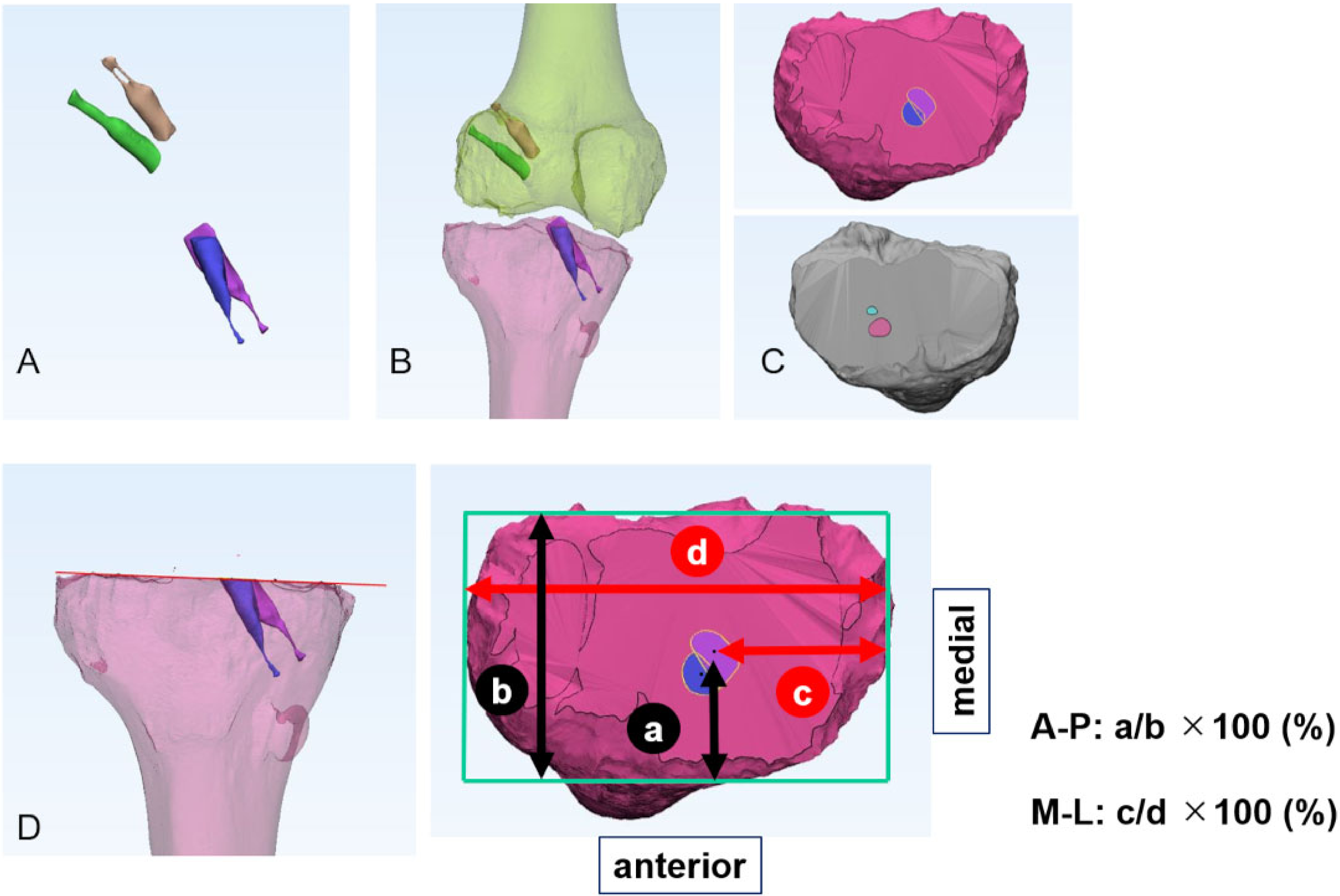
Medial and lateral intra-articular bone surfaces of the tibia are approximated and defined as the intra-articular surfaces of the tibia. The medial and lateral edges of the tibial plateau are identified, and the line connecting these two points is set as the medial-lateral axis. The anterior-posterior axis is then defined as the line orthogonal to the proximal-distal and medial-lateral axes. Finally, the position of the tibial bone tunnel is evaluated by calculating the centroid position of the tunnel apertures on the surface plane, as the percentage of total anteroposterior width from the anterior end (a/b×100%) and the percentage of total width from the medial end (c/d×100%). In this figure, the tibial tunnel position of the posterolateral bundle is measured. A-P, anterior-posterior; M-L, medial-lateral

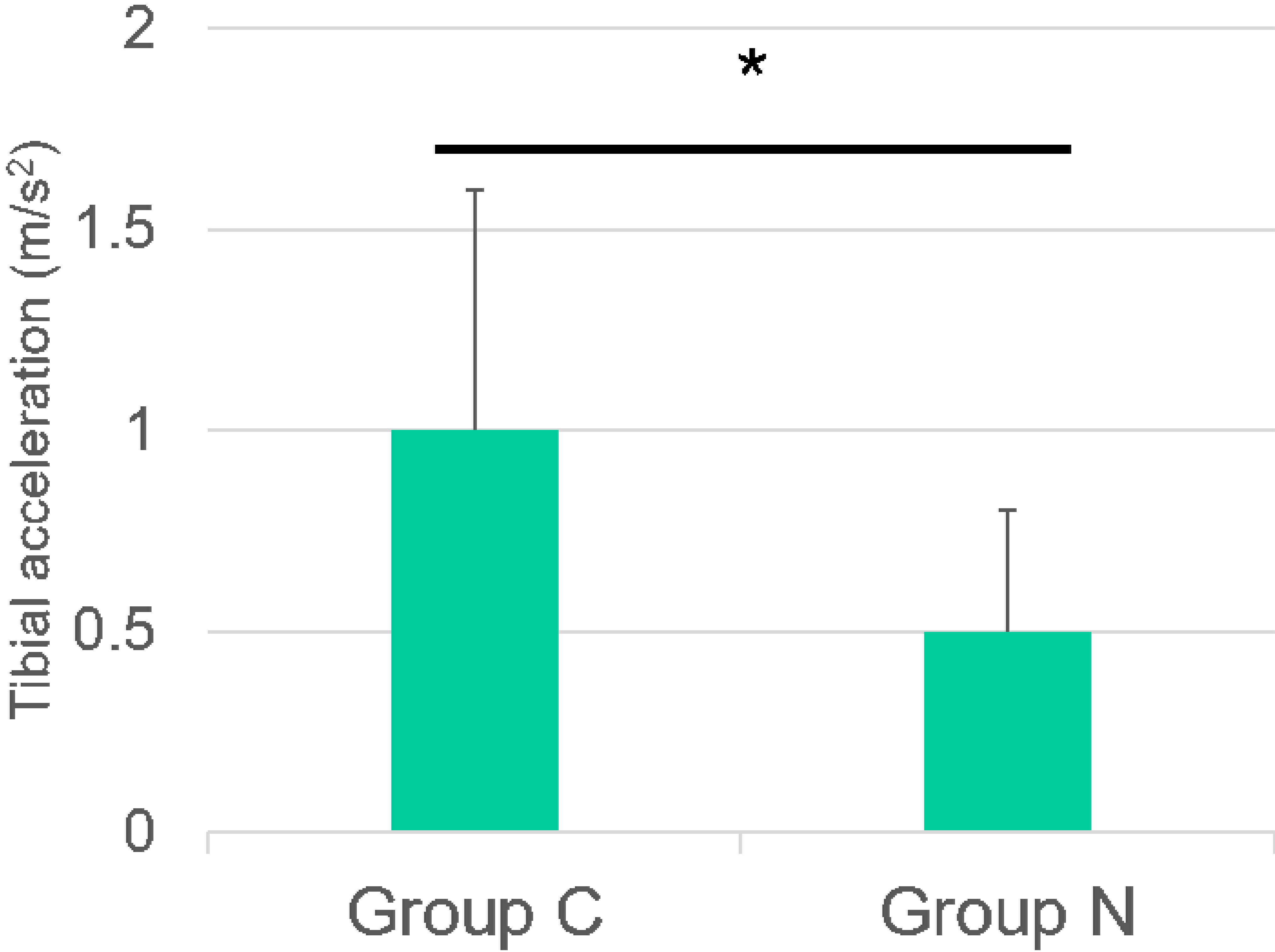
Fig. 2 Tibial acceleration during the pivot-shift test at 1-year follow-up

Tibial acceleration during the pivot-shift test is significantly higher in group C than in group N.

*p<0.05

Group C, knees with tibial tunnel coalition; group N, knees without tibial tunnel coalition


A
B
C
D
a
b
c
d
medial
anterior
A-P: a/b ×100 (%)
M-L: c/d ×100 (%)



2
1.5
1
0.5
0
Tibial acceleration (m/s2)
*
Group C
Group N