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**Risk factors of residual pivot-shift after anatomic double bundle anterior cruciate ligament reconstruction**

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24    The study was performed in accordance with the ethical standards of the institutional review board of our

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27    Informed consent was obtained from all the participants.

**Risk factors of residual pivot-shift after anatomic double bundle anterior cruciate ligament reconstruction**

## Abstract

Introduction: Although anterior cruciate ligament reconstruction (ACLR) is considered a successful procedure, residual pivot-shift after surgery remains to be solved. The purpose of this study was to comprehensively evaluate the risk factors of residual pivot-shift after anatomic double-bundle (DB)-ACLR.

Materials and Methods: A total of 164 patients who underwent primary anatomic DB-ACLR between January 2014 and December 2019 and screw removal after the index ACLR in our hospital were included in this retrospective case-control study. The manual pivot-shift test was performed under general anesthesia during screw removal surgery, and patients with grade 1 or higher pivot-shift were classified as the positive pivot-shift group, and those with grade 0 were defined as the negative pivot-shift group. Univariate and logistic regression analyses were performed to identify the factors associated with postoperative residual pivot-shift. Assessment included sex, age, time to surgery, preoperative Tegner activity scale, preoperative pivot-shift grade, preoperative anterior tibial translation by the KT-2000 arthrometer measurement, meniscus injury and its surgical procedure, knee hyperextension, cartilage damage, Second fracture, medial and lateral posterior tibial slope, lateral – medial slope asymmetry, participation in pivoting sport/activity at the time of injury, and return to sports at postoperative one year. Line

Results: Postoperative positive pivot-shift was observed in 14 (8.5%) of 164 patients. The KT-2000 measurement at 1-year postoperatively was significantly higher in the residual pivot-shift positive group than in the negative group ( $P < 0.05$ ). Logistic regression analysis revealed that patients  $< 20$  years of age

19 [P < 0.05, odds ratio (OR): 6.1)], preoperative pivot-shift grade (P < 0.05, OR: 4.4), and hyperextended  
20 knee (P < 0.05, OR: 11.8) were risk factors of postoperative pivot-shift. There were no statistically  
21 significant differences between other variables.

22 Conclusions: Patients < 20 years of age, with high-grade preoperative pivot-shift, or hyperextended knees  
23 had a higher risk of residual postoperative pivot-shift.

24 **Keywords:** anterior cruciate ligament reconstruction; double bundle; **residual pivot-shift**; risk factor;  
25 hyperextension of the knee

26

## 27    **Introduction**

28    Anterior cruciate ligament reconstruction (ACLR) is considered a successful surgical procedure in the  
29    treatment of patients with anterior cruciate ligament (ACL) injuries. However, residual anterolateral  
30    rotatory instability after ACLR persists. The pivot-shift test is one of the most specific clinical assessments  
31    of pathologic anterolateral rotatory knee instability after ACL injury when performed in patients under  
32    anesthesia [1]. It has been reported that postoperative residual pivot-shift was associated with poor  
33    subjective symptoms and clinical outcomes, and it was suggested as a cause of the early progression of  
34    osteoarthritis (OA) of the knee [2–4]. Therefore, it is important to manage postoperative residual pivot-shift  
35    to improve outcomes after ACLR.

36    In terms of surgical procedures, previous biomechanical and clinical studies have reported that double-  
37    bundle (DB)-ACLR provided better knee stability and pivot-shift control compared with single-bundle  
38    (SB)-ACLR [5–11], while other studies reported that clinical outcomes were not significantly different  
39    between SB-ACLR and DB-ACLR [5, 12, 13]. Despite the biomechanical advantages of DB-ACLR in  
40    controlling the pivot-shift phenomenon, residual pivot-shift was still observed in approximately 10%–20%  
41    of the knees after DB-ACLR in previous reports [6, 9, 14].

42    Previous studies have reported various factors associated with residual pivot-shift after ACLR, such as  
43    younger age [15, 16], medial and lateral meniscus tears [15, 17, 18], concomitant grade 2 medial collateral  
44    (MCL) injury [19], hyperextension of the knee [20], preoperative large pivot-shift phenomenon [18, 20–

22], and period from injury to surgery [18, 19, 23]. However, surgical procedures were not consistent in the previous literature, and few studies have comprehensively examined the risk factors of postoperative residual pivot-shift after anatomic DB-ACLR.

Therefore, the purpose of this study was to investigate the risk factors of residual pivot-shift after anatomic DB-ACLR in a single center. It was hypothesized that risk factors of residual pivot-shift after DB-ACLR could be identified.

## **Materials and methods**

### **Patient selection**

The study was performed in accordance with the ethical standards of the institutional review board of our hospital (ID No. B190055). Informed consent was obtained from all the participants. Patients who underwent DB-ACLR between January 2014 and December 2019, and underwent screw removal after the index ACLR in our hospital were retrospectively examined.

Patients were excluded if they had prior ACL injury, posterior cruciate injury, or meniscus injury in the ipsilateral or contralateral knee, concomitant collateral ligament injuries (grade 2 or 3) [24], reinjuries or contralateral injuries before screw removal, no screw removal, or incomplete data.

A total of 318 patients underwent DB-ACLR during the study period. After the exclusion process, 164 patients (75 males and 89 females,  $24.6 \pm 10.3$  years old) were selected and included in this study (Figure



63 1).

#### 64 **Surgical procedure**

65 Patients were treated according to the clinical standard of care in the institution. After ACL injury was  
66 diagnosed clinically, with confirmation by MRI, ACL reconstruction was scheduled and then performed  
67 using an anatomic reconstruction technique. DB-ACLR was performed using hamstring tendon autografts.  
68 Briefly, the semitendinosus alone or both semitendinosus and gracilis tendons were harvested for the ACL  
69 graft. The femoral and tibial bone tunnels were created within the original attachments of the anteromedial  
70 bundle (AMB) and posterolateral bundle (PLB). Femoral tunnels were created in an inside-out fashion  
71 through far anteromedial portal or outside-in fashion using a drill guide system (ACUFEX PINPOINT  
72 Anatomic ACL drill guide system, Smith & Nephew Inc., Andover, MA). The suspensory buttons and a  
73 6.5-mm cancellous screw with a washer were used for the femoral fixation and the tibial fixation,  
74 respectively. The PLB graft was fixed first at knee extension with manual maximum force and then the  
75 AMB was fixed at 20° - 30° of knee flexion.

#### 76 **Postoperative rehabilitation**

77 An identical postoperative protocol was applied to all the patients. A progressive range of motion exercises  
78 and one-third of weight bearing on the operated side of the limb was started three days after surgery and  
79 full weight bearing was allowed two weeks after surgery. An ACL brace (DONJOY FULLFORCE,  
80 DJO, Carlsbad, CA, USA) was worn for postoperatively 2 months. Jogging was permitted at three months

postoperatively followed by gradual progression of endurance and agility exercises. Full return-to-sport activity, including competitive sports was permitted approximately nine months after surgery.

### **Pivot-shift test**

The pivot-shift test was performed under general anesthesia before ACLR and screw removal surgery. One of the two experienced orthopedic surgeons who were not in charge of the patient was assigned to perform the pivot-shift test after blinding for the preoperative data of the patient. Both examiners were instructed to perform the pivot-shift test as similarly as possible before using the standardized technique [25]. The standard clinical grading was determined by the examiner on the International Knee Documentation Committee (IKDC) guidelines: none (grade 0), glide (grade 1), clink (grade 2), or gross (grade 3) [26]. Patients with grade 1 or higher pivot-shift test under anesthesia at the time of screw removal surgery were defined as the residual pivot-shift group. The patients in which pivot-shift test of injured knee was positive and there was no side-to-side difference between injured and uninjured knee were categorized into negative residual pivot-shift group.

### **Data collection**

Patient databases were searched for demographic, preoperative, intraoperative, and postoperative information. Demographics included age at the time of surgery and sex. Preoperative data included time from injury to surgery, Tegner activity scale, and Second fracture, which were confirmed by preoperative radiographs. Intraoperative data were obtained from surgical records, such as medial and lateral meniscal

tears, and cartilage damage. Information about surgical procedures for meniscal injuries (repair, partial meniscectomy, or rasping) was also collected. Knee hyperextension was also evaluated preoperatively under anesthesia. Hyperextension was defined as an extension angle of  $> 10^\circ$ . The posterior tibial slope (PTS) of the medial and lateral plateau were measured on preoperative MRI as previously reported [27]. PTS was expressed as degree and the lateral–medial slope asymmetry was calculated by subtracting the medial PTS from the lateral PTS (lateral PTS - medial PTS). Anterior knee laxity was evaluated by side-to-side difference in anterior tibial translation using the KT-2000 arthrometer (MEDmetric, San Diego, CA, USA) at manual maximum load preoperatively in each surgery. Clinical outcomes were evaluated using the IKDC subjective score. Type of sports and activities at the time of injury were investigated on medical records and divided into two types, pivoting sport/activity and non-pivoting sport/activity according to whether the sport frequently involves rotation, cutting, or jumping (e.g., soccer, basketball, volleyball, and skiing). (Figure 2). Further, whether the patient had returned to sports at one year postoperatively was also examined.

## **Statistical analysis**

All statistical analyses were performed using GraphPad Prism 9 software (GraphPad Software, San Diego, CA, USA). Statistical significance was defined as  $p < 0.05$ . Univariate analysis, chi-squared test, and Mann–Whitney U test were used to compare clinical outcomes and demographic, preoperative, and intraoperative variables between the two groups. The variables showing significant differences in univariate

analysis were used as independent variables, and the status of the postoperative positive pivot-shift test was set as a dependent variable. Logistic regression analysis was performed, and the odds ratios (ORs) with 95% confidence intervals (CIs) were calculated for all independent variables to identify risk factors of postoperative residual pivot-shift. Post-hoc power analysis in logistic regression showed that the power of teenagers, preoperative pivot-shift, and hyperextension knee were 1.00, 1.00, and 0.85, respectively, with an alpha of 0.05, using G-power 3.1 software (Kiel University, Kiel, Germany).

## Results

In the evaluation of the pivot-shift test under anesthesia, 14 out of the 164 patients (8.5%) were graded as grade I positive and included in the residual pivot-shift group, while 150 patients were graded as negative and included in the negative pivot-shift group. No significant difference was detected in the IKDC subjective scores between the two groups (Table 1). The percentage of the patients who had returned to sports at one year postoperatively was 54.3% (89/164 patients). No significant difference was observed in the percentage of patients who had returned to sports at one year postoperatively between the two groups ( $P = 0.87$ ).

In the univariate analysis, age < 20 years, hyperextended knee, preoperative pivot-shift grade, and postoperative KT-2000 side-to-side differences were found to be significantly different between the two groups (Table 2). The proportion of patients who were < 20 years of age and with hyperextended knee were

significantly higher in the residual pivot-shift group than in the negative group ( $P = 0.01$ ,  $P < 0.01$ , respectively). Preoperative pivot-shift grade and postoperative KT-2000 side-to-side differences were significantly higher in the residual pivot-shift group than in the negative pivot-shift group ( $P < 0.01$ ,  $P = 0.02$ , respectively).

In logistic regression analysis, age  $< 20$  years, hyperextended knee, and preoperative pivot-shift grade were used as independent variables. Since postoperative KT-2000 side-to-side difference was not considered a risk factor of residual pivot-shift, it was excluded from the variables. Logistic regression analysis revealed that patients of  $< 20$  years of age ( $P = 0.04$ , OR: 6.13), preoperative pivot-shift grade ( $P = 0.02$ , OR: 4.35), and hyperextended knee ( $P = 0.01$ , OR: 11.77) were factors associated with postoperative residual pivot-shift (Table 3).

Regarding involvement of pivoting sports at the time of injury and return to sport at postoperative one year, significantly higher proportion of the patients who were  $< 20$  years old participated pivoting sports at the time of injury than those who were  $> 20$  years old ( $P = 0.01$ ), while return to sport ratio was lower in the patients  $< 20$  years old ( $P < 0.01$ ). Therefore, to exclude the potential confounding effect, statistical analyses were performed only in the patients who were  $< 20$  years of age. In the univariate analysis, the proportion of patients with hyperextended knee was significantly higher ( $P < 0.01$ ), and preoperative pivot-shift grade was significantly higher in the residual pivot-shift group than in the negative pivot-shift group ( $P < 0.01$ ). The logistic regression analysis revealed that preoperative pivot-shift grade ( $P = 0.02$ , OR: 5.30),

and hyperextended knee ( $P < 0.01$ , OR: 22.60) were also factors associated with postoperative residual pivot-shift in the age group (Table 4).

## Discussion

The most important finding of the present study was that young age of  $< 20$  years, hyperextended knees, and preoperative high-grade pivot-shift were risk factors of postoperative pivot-shift after anatomic DB-ACLR.

Previous studies reported that more than 20% of patients who underwent SB-ACLR showed postoperative anterolateral rotatory instability detected by the pivot-shift test [3, 4]. An increasing number of studies have investigated the risk factors of residual knee instability after ACLR using hamstring tendon grafts, and several associated factors were suggested.

Ahn et al. reported that concomitant grade 2 MCL injury and time from injury to surgery  $\geq 12$  weeks were risk factors for postoperative knee instability of anterior translation ( $> 5$  mm on the stress radiograph) or manual pivot-shift test  $\geq$  grade 2 after SB- or DB-ACLR [19]. Yamamoto et al. reported that a large preoperative posterior tibial reduction during the pivot-shift test quantified by the navigation system was a risk factor of positive pivot-shift in the manual grading of the pivot-shift test in 100 patients who underwent SB- or DB-ACLR [21]. Similarly, Ueki et al. investigated the residual pivot-shift in 368 patients who received SB- or DB-ACLR, and reported that hyperextension of the knee and greater preoperative pivot-shift grade under anesthesia were risk factors for postoperative positive pivot-shift [20]. Furthermore,

Katakura et al. also examined the risk factors of residual anterolateral rotational instability after DB-ACLR in 42 cases using a kinematic rapid assessment (KiRA) triaxial accelerometer (OrthoKey, Lewes, DE, USA). They reported that patients with larger preoperative side-to-side differences in tibial acceleration during the pivot-shift test have a higher risk of residual anterolateral rotational instability [22]. Recently, Kawanishi et al. reported that greater preoperative acceleration and external rotation angular velocity of the pivot-shift measured by an inertial sensor were risk factors of residual pivot-shift [28]. Yamasaki et al. also reported that young age ( $< 18$  years) and knee hyperextension were risk factors of postoperative anterior tibial translation with KT-2000  $> 3$  mm and pivot-shift  $\geq$  grade 2 in non-athletic patients who received DB-ACLR [29]. Based on these previous reports, preoperative pivot-shift grade, knee hyperextension, and age were frequently reported as risk factors regardless of the surgical technique and evaluation methods (Table 5). Therefore, these reports together with our results strongly suggest that surgeons should exercise caution while performing ACLR in young patients with a large pivot-shift and knee hyperextension.

One of the possible reasons for the residual instability after ACLR is the larger stress on the reconstructed graft due to damage of the secondary restraint or inherent knee laxity, which eventually leads to the extension of the graft despite the anatomical reconstruction. Although a high magnitude of pivot-shift and anterior knee instability, defined as increased translation of the tibia, do not represent the same abnormal condition of the knee, both conditions can generate a large stress on the reconstructed graft. Another reason could be that current ACLR techniques cannot fully control the pivot-shift in conditions with abnormally

increased laxity or dynamic instability. Yasuma et al. reported that there was a significant difference in the parameters of the quantified pivot-shift measurement by inertial sensors between intact knees and ACL-reconstructed knees in the ACL/anterolateral structure (ALS)-deficient condition, while no statistically significant difference was found between ACL/anterolateral ligament (ALL)-reconstructed knees [30]. Therefore, to reduce the residual anterolateral rotatory instability, surgical procedures for augmentation of the anterolateral complex (ALC), such as lateral extra-articular tenodesis (LET) [31–35] and ALL reconstruction [36, 37] have recently been a topic of debate [38]. Getgood et al. conducted a multicenter prospective randomized controlled trial comparing the outcomes of ACLR combined with LET and SB-ACLR alone in patients younger than 25 years of age and those who met at least two of the following three criteria: grade 2 pivot-shift or greater, a desire to return to high-risk/pivoting sports, and generalized ligamentous laxity [39]. They reported that the SB-ACLR with LET group showed a lower rate of clinical failure, which consisted of graft rupture and residual positive pivot-shift rotatory laxity at 2 years after surgery compared with the ACLR group. Additionally, a recent systematic review reported that clinical outcomes after ACL combined with ALL reconstruction were more favourable than those after ACLR alone in terms of residual pivot shift and re-rupture rate [40]. Therefore, the addition of LET or ALL can be a treatment choice in patients with multiple high risks of residual pivot-shift. Meanwhile, there are several contradictory reports regarding the major contribution of ALC to rotational knee laxity in ACL-deficient knees and ACL-reconstructed knees [41–43]. Therefore, whether augmentation of the ALC is the optimal



207 solution or not in DB-ACLR needs to be determined in future studies.

208 The strength of this study is the homogeneity of the surgical procedure and postoperative follow-up, which  
209 includes physical therapy and clinical examination, since all surgeries were performed by experienced  
210 surgeons performing DB-ACLR in a single institution.

211  
212 **Limitation**

213 This study has several limitations. First, manual pivot-shift grading was used in the evaluation, which is  
214 not an objective measurement, as compared to electromagnetic sensors [44], triaxial accelerometers [45],  
215 or other devices [46]. There has also been discussion questioning the reproducibility of the manual pivot-  
216 shift test since it may be dependent on the physician performing the test. However, the test was performed  
217 by experienced surgeons, and the pivot-shift test technique was standardized before starting the present  
218 research to minimize the variation in the technique. Second, this study did not state detailed categorization  
219 based on different locations (anterior, medial, and/or posterior) of meniscal tears and different types of tears  
220 (horizontal, radial, and longitudinal) were not addressed. **Third, tunnel positions were not evaluated in this**  
221 **study, since postoperative CT images were not taken in all the patients. Therefore, it is possible that tunnel**  
222 **malposition was a factor contributing to residual pivot shift. Fourth,** the time to follow-up was only  
223 approximately one year until the screw removal surgery. Therefore, the follow-up may be too short to  
224 evaluate the clinical outcomes, and reinjury was not considered in this study. **Fifth,** although the post-hoc

225 analysis demonstrated an acceptable large power to detect the significant differences between the two  
226 groups, the sample size was small since only 14 patients were included in the residual pivot-shift group.  
227 Future studies with larger patient's population and including patients with reinjury are expected.

228 Despite the limitations, the results of this study provide information of which patients require more  
229 attention during DB-ACLR.

## 230 **Conclusions**

231 Patients younger than 20 years of age, with high-grade preoperative pivot-shift, or with hyperextended  
232 knees have a higher risk of residual postoperative pivot-shift after DB-ACLR.

## 233 **Declarations**

### 234 Funding

235 There is no funding source.

### 236 Conflicts of interest/competing interests

237 The authors declare that they have no conflict of interest.

### 238 Ethics approval

239 The study was performed in accordance with the ethical standards of the institutional review board of our  
240 hospital (ID No. B190055).

### 241 Consent

242 Informed consent was obtained from all the participants.

243 Authors' contribution statements

244 KK designed the study and wrote the initial draft of the manuscript. TaM contributed to analysis and  
245 interpretation of data and assisted in the preparation of the manuscript. KN, DA, NK, YH, ToM, TN and  
246 RK contributed to data collection and interpretation and critically reviewed the manuscript. All authors  
247 approved the final version of the manuscript and agree to be accountable for all aspects of the work in  
248 ensuring that questions related to the accuracy or integrity of any part of the work are appropriately  
249 investigated and resolved.

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**Figure legend**

Figure 1: Flowchart of the patient selection process

Figure 2: The data of the involvement of the sports or activity at the time of injury

**Table legends**

Table 1: Clinical data of patients at screw removal surgery (1 year after anterior cruciate ligament reconstruction)

Table 2: Univariate analysis of the patient characteristic data between residual pivot-shift negative and positive groups

Table 3: Results of logistic regression analysis of variables that showed significant difference in univariate analysis

Table 4: Results of logistic regression analysis in patients of < 20 years of age.

Table 5: Risk factors of postoperative residual pivot-shift reported in previous studies