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

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

Abstract

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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, Segond 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
- significant differences between other variables.
- 22 Conclusions: Patients < 20 years of age, with high-grade preoperative pivot-shift, or hyperextended knees
- had a higher risk of residual postoperative pivot-shift.
- Keywords: anterior cruciate ligament reconstruction; double bundle; residual pivot-shift; risk factor;
- 25 hyperextension of the knee

Introduction

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Anterior cruciate ligament reconstruction (ACLR) is considered a successful surgical procedure in the treatment of patients with anterior cruciate ligament (ACL) injuries. However, residual anterolateral rotatory instability after ACLR persists. The pivot-shift test is one of the most specific clinical assessments of pathologic anterolateral rotatory knee instability after ACL injury when performed in patients under anesthesia [1]. It has been reported that postoperative residual pivot-shift was associated with poor subjective symptoms and clinical outcomes, and it was suggested as a cause of the early progression of osteoarthritis (OA) of the knee [2-4]. Therefore, it is important to manage postoperative residual pivot-shift to improve outcomes after ACLR. In terms of surgical procedures, previous biomechanical and clinical studies have reported that doublebundle (DB)-ACLR provided better knee stability and pivot-shift control compared with single-bundle (SB)-ACLR [5-11], while other studies reported that clinical outcomes were not significantly different between SB-ACLR and DB-ACLR [5, 12, 13]. Despite the biomechanical advantages of DB-ACLR in controlling the pivot-shift phenomenon, residual pivot-shift was still observed in approximately 10%-20% of the knees after DB-ACLR in previous reports [6, 9, 14]. Previous studies have reported various factors associated with residual pivot-shift after ACLR, such as younger age [15, 16], medial and lateral meniscus tears [15, 17, 18], concomitant grade 2 medial collateral (MCL) injury [19], hyperextension of the knee [20], preoperative large pivot-shift phenomenon [18, 20–

45 22], and period from injury to surgery [18, 19, 23]. However, surgical procedures were not consistent in the 46

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.

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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

62 patients (75 males and 89 females, 24.6 ± 10.3 years old) were selected and included in this study (Figure 63 1).

Surgical procedure

Patients were treated according to the clinical standard of care in the institution. After ACL injury was diagnosed clinically, with confirmation by MRI, ACL reconstruction was scheduled and then performed using an anatomic reconstruction technique. DB-ACLR was performed using hamstring tendon autografts.

Briefly, the semitendinosus alone or both semitendinosus and gracilis tendons were harvested for the ACL graft. The femoral and tibial bone tunnels were created within the original attachments of the anteromedial bundle (AMB) and posterolateral bundle (PLB). Femoral tunnels were created in an inside-out fashion through far anteromedial portal or outside-in fashion using a drill guide system (ACUFEX PINPOINT Anatomic ACL drill guide system, Smith & Nephew Inc., Andover, MA). The suspensory buttons and a 6.5-mm cancellous screw with a washer were used for the femoral fixation and the tibial fixation, respectively. The PLB graft was fixed first at knee extension with manual maximum force and then the AMB was fixed at 20° - 30° of knee flexion.

Postoperative rehabilitation

An identical postoperative protocol was applied to all the patients. A progressive range of motion exercises and one-third of weight bearing on the operated side of the limb was started three days after surgery and full weight bearing was allowed two weeks after surgery. An ACL brace (DONJOY FULLFORCE, 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 Segond 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°. 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 sideto-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

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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, 136 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). 139 In logistic regression analysis, age < 20 years, hyperextended knee, and preoperative pivot-shift grade 140 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 142 analysis revealed that patients of < 20 years of age (P = 0.04, OR: 6.13), preoperative pivot-shift grade (P 143 = 0.02, OR: 4.35), and hyperextended knee (P = 0.01, OR: 11.77) were factors associated with postoperative residual pivot-shift (Table 3). 145 Regarding involvement of pivoting sports at the time of injury and return to sport at postoperative one 146 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 148 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 149 150 proportion of patients with hyperextended knee was significantly higher (P < 0.01), and preoperative pivotshift grade was significantly higher in the residual pivot-shift group than in the negative pivot-shift group 152 (P < 0.01). The logistic regression analysis revealed that preoperative pivot-shift grade (P = 0.02, OR: 5.30),

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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

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156 The most important finding of the present study was that young age of < 20 years, hyperextended knees, 157 and preoperative high-grade pivot-shift were risk factors of postoperative pivot-shift after anatomic DB-158 ACLR. 159 Previous studies reported that more than 20% of patients who underwent SB-ACLR showed postoperative 160 anterolateral rotatory instability detected by the pivot-shift test [3, 4]. An increasing number of studies have 161 investigated the risk factors of residual knee instability after ACLR using hamstring tendon grafts, and several associated factors were suggested. 162 163 Ahn et al. reported that concomitant grade 2 MCL injury and time from injury to surgery ≥ 12 weeks were 164 risk factors for postoperative knee instability of anterior translation (> 5 mm on the stress radiograph) or 165 manual pivot-shift test ≥ grade 2 after SB- or DB-ACLR [19]. Yamamoto et al. reported that a large 166 preoperative posterior tibial reduction during the pivot-shift test quantified by the navigation system was a 167 risk factor of positive pivot-shift in the manual grading of the pivot-shift test in 100 patients who underwent 168 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 ≥ 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

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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 ACLreconstructed 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

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

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

Limitation

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

KK designed the study and wrote the initial draft of the manuscript. TaM contributed to analysis and interpretation of data and assisted in the preparation of the manuscript. KN, DA, NK, YH, ToM, TN and RK contributed to data collection and interpretation and critically reviewed the manuscript. All authors approved the final version of the manuscript and agree 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 investigated and resolved.

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