Original Article

Graft Type and Diameter Are Predictors of Reinjury After Transphyseal Anterior Cruciate Ligament Reconstruction in Pediatric and Adolescent Patients

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Purpose: To report the rate of anterior cruciate ligament (ACL) graft failure by physis status (open, closing, closed) and to analyze which factors were associated with higher risk of ACL graft failure. **Methods:** Patients younger than 18 years who underwent transphyseal ACL reconstruction (ACLR) between 2000 and 2018 at a single institution were reviewed at minimum 2 years after ACLR. Patient records were reviewed for anthropometrics, surgical techniques, and ACL graft failure. Patients were subsequently stratified based on physis status (open, closing, closed) and analyzed. **Results:** A total of 272 patients (mean age of 15.4 ± 1.3 years) were assessed. The transtibial technique was used in 63.6% of cases. A hamstring autograft was used exclusively in the open physis group. A patellar tendon autograft was used in 65.9% of patients with a closing physis and 80.9% of patients with a closed physis. The overall graft failure rate was 13.2%, with a contralateral ACL injury rate of 11.0%. Kaplan-Maier analysis by physis status showed different injury free from ACL reinjury ($P < .001$). An open physis was associated with increased risk of ACL reinjury (hazard ratio, 5.2; $P < .001$) when compared to a closed physis. A closing physis presented a higher hazard ratio but was not statistically significant (hazard ratio, 2.6; $P = .08$). Hamstring graft type ($P = .03$) and lower graft diameter ($P = .04$) were significantly related to higher ACL reinjury after adjusting for physis status. **Conclusions:** Transphyseal ACLR is a safe procedure in pediatric patients. The rate of reinjury was 13.2%. This rate decreases with skeletal maturity, use of patellar tendon autograft, and a larger graft diameter. **Level of Evidence:** Level III, retrospective cohort study.

The rate of anterior cruciate ligament reconstruction (ACLR) among the pediatric patient population has increased over recent years.[1] The clinical standard of care for these young patients is to undergo ACLR to restore knee stability to protect the intra-articular structures from further damage and to return to activity in a timely manner.[2-4] The current evidence indicates that these patients should not delay ACLR because delayed surgical intervention is strongly correlated with increased risk of secondary meniscus and cartilage injuries.[5-10] Importantly, when performing ACLR in the pediatric patient population, it is critical to avoid damage to the growth plate, which is why specific ACLR techniques were developed for this patient cohort. Different surgical techniques are available for pediatric and adolescent patients. The surgical choice is mostly impacted by the surgeon's previous training, their surgical preference, and the amount of remaining bone growth for the patient.[11] Knee radiograph evaluation offers a simple and reliable approach to classify remaining growth in these patients by grading the femoral physis as open, closing, or closed.[12] The transphyseal ACLR technique is the most popular surgical technique used in pediatric patients.[11,13,14]

Despite undergoing ACLR and addressing residual impairments through postoperative rehabilitation, the rate of graft failure or injury to the contralateral anterior cruciate ligament (ACL) among pediatric and adolescent ACLR patients remains high. A review that

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evaluated the risk of second ACL injury (ipsilateral or contralateral) in young patients (<25 years old) found that up to 23% of ACLR patients who return to sports sustain a second ACL injury (ipsilateral or contralateral).[15] Younger age at the time of ACLR surgery has been consistently reported as a risk factor for second ACL reinjury.[16-18] Moreover, the evidence has indicated that patients who receive a hamstring (HS) tendon autograft, an overall smaller graft in diameter, and return to competitive sports participation are at greater risk for ACLR revision.[19-21] It has also been hypothesized that the rapidly growing and developing bones of the pediatric and adolescent patients who receive an ACLR can change the length, tension, and orientation of the ACL graft, which would expose patients to a higher risk of graft failure.[22] Furthermore, these patients demonstrate functional and strength deficits for at least 12 months after ACLR, which is directly associated with a higher incidence of second ACL injuries.[23-25] However, in comparison, the clinical outcomes after ACLR for the pediatric patient cohort have been little studied. Despite the current evidence, the rate of ACL reinjury across the degree of skeletal maturity remains unclear among the pediatric patient population.[26] A better understanding of the risk factors can also guide surgeons in treatment decision-making.

The purpose of this study was to report the rate of ACL graft failure by physis status (open, closing, closed) and to analyze which factors were associated with higher risk of ACL graft failure. We hypothesized that the risk of ACL reinjury would be directly related to the physis status and that pediatric patients with closed physis at the time of transphyseal ACLR would have significantly lower ipsilateral ACL graft failures.

Methods

Patient Selection

This was a single-center, retrospective cohort of patients younger than 18 years who underwent primary transphyseal ACLR (multisurgeon) between January 2001 and June 2018 at the same institution. Surgical technique is described in a previous article, and the rehabilitation protocol is available as a supplementary file.[27] A minimum follow-up time of 2 years was required. To obtain a more uniform population, we included patients who underwent ACLR with bone-patellar-bone (BTB) or HS autograft; other types of ACL grafts were excluded. Patients with previous knee infection or systematic joint inflammatory disease, malalignments, multiligament injuries (posterior cruciate ligament or posterolateral corner injury), and periarticular fractures were excluded from the study. The study was approved by our institution's review board (ID #13-005931).

Data Collection

Patient records were reviewed to collect demographics (age at surgery, sex, weight, body mass index [BMI]), ACL injury characteristics, surgical information (ACLR surgical technique, graft type and size, injury to surgery time), and clinical follow-up data, including ACL graft failure, new surgical interventions due to revision ACLR, and meniscal or chondral lesions. Follow-up time was calculated for all the patients relative to the last visit date effectuated in the hospital network for any kind of healthy issue. Preoperative Tegner score was extracted from the orthopaedic preoperative visit, and the postoperative Tegner score and the return-to-sport time were extracted from postoperative follow-up visits. Skeletal maturity was evaluated using frontal and lateral x-rays of the knee, and the grade of closure of the femoral growth plate was classified in 3 groups: open (entire physis is visible with radiolucent gap between diaphysis and epiphysis), closing (a radio-opaque line is visible with partial ossification spots usually in the central plate portion), and closed (radio-opaque line no longer visible).[12,28] Using the available preoperative magnetic resonance imaging, bone age was assessed using an atlas of skeletal development of the knee.[29]

Statistical Analysis

Patient characteristics were described as mean and standard deviation for continuous variables, whereas frequencies and percentage were used for categorical variables. Independent predictor variables included patient demographics (age at surgery, sex, physeal status, weight, BMI, Tegner score), ACL injury and surgical characteristics (contact/noncontact, surgical technique, graft type and dimension), postoperative information (time to return to sport and postoperative Tegner score). Comparisons of independent variables between patients grouped by physis status were made with analysis of variance for continuous variables or a χ^2 test for categorical and binary variables. Mean differences between patients who went on to have ACL graft failure and those who did not sustain another injury were calculated using t tests for continuous variables or χ^2 tests for proportions. The primary outcome for our study was the reinjury of the ipsilateral ACL by the physis status. The cumulative injury free from ipsilateral ACL reinjury was evaluated with the Kaplan-Meier analysis, and differences between the curves were calculated with the Wilcoxon test. Because length of the follow-up was not standardized, Cox proportional hazards regression was performed to determine the risk factors for ACL reinjury at the time of reinjury. A single variable evaluation nonadjusted and adjusted for physis status evaluated the significant variables associated with ACL reinjury. Significance was set at α less than .05 and a 95% confidence interval

Table 1. Patient Demographics by Femoral Physis Status

Characteristic	Overall (N = 272)	Open (n = 56)	Closing (n = 132)	Closed (n = 84)	*P* Value
Age at surgery,[a] y					
Mean ± SD	15.4 ± 1.3	14.2 ± 1.3	15.3 ± 0.9	16.4 ± 1.1	**<.001**
Median (min-max)	15.6 (10.2-17.9)	14.1 (10.2-16.4)	15.5 (11.5-17.4)	16.7 (12.3-17.9)	
Bone age at surgery,[a] y	15.8 ± 1.1	14.4 ± 1.0	16.0 ± 0.7	16.6 ± 0.7	**<.001**
Female patients[b]	171 (62.9)	24 (42.9)	91 (68.9)	56 (66.7)	**.002**
Right side[b]	133 (49.0)	29 (51.8)	65 (49.2)	39 (46.4)	.82
Weight,[a] kg	68.3 ± 15.0	63.4 ± 15.5	67.3 ± 14.3	72.3 ± 14.9	**.01**
BMI[a]	23.3 ± 3.9	22.2 ± 4.5	23.2 ± 3.6	24.0 ± 3.8	.09
Tegner preoperatively[a]	7.4 ± 0.7	7.6 ± 0.6	7.6 ± 0.6	7.0 ± 0.6	**<.001**
Trauma to surgery time,[a] mo	2.1 ± 2.8	2.1 ± 1.9	2.0 ± 2.8	2.2 ± 3.2	.84
Contact trauma[b]	46 (17.0)	13 (23.2)	25 (18.9)	8 (9.6)	.08
Tegner postoperatively[a]	7.3 ± 0.7	7.6 ± 0.6	7.4 ± 0.7	6.9 ± 0.7	**<.001**
Preinjury sport level	216 (83.7)	45 (86.5)	104 (81.2)	67 (85.9)	.56
RTS time,[a] mo	8.9 ± 1.6	8.5 ± 1.6	8.8 ± 1.7	9.4 ± 1.4	**.01**

NOTE. Values are presented as number (%) or mean ± standard deviation unless otherwise indicated. Bold indicates statistical significance. ACLR, anterior cruciate ligament reconstruction; BMI, body mass index; RTS, return to sport.
[a]Analysis of variance.
[b]χ^2 test.

(CI) for risk estimates not including 1.00. The analyses were performed using the JMP software package (version 14 Pro; SAS Institute) and GraphPad Prism 9.0 (GraphPad Software).

Results

Patient Characteristics

A total of 286 patients matched the inclusion criteria of being younger than 18 years when undergoing a transphyseal ACLR during the study period at our institution. Of these patients, 12 patients had incomplete data (lack of preoperative magnetic resonance imaging or x-ray images in 2 patients, 10 patients due to follow-up less than 2 years) and were excluded. From the remaining 274 patients, 2 had an alternative graft used during ACLR other than BTB or HS tendon autograft and were excluded to ensure homogeneity among our subject population. This left 272 eligible patients who were included in the study (101 boys and 171 girls, average age 15.4 ± 1.3 years, range from 10.2 to 17.9 years) and followed for an average time of 6.5 ± 4.5 years after ACLR. Patient characteristics by physis status (open, closing, closed) are presented in Table 1. Because the groups were based on advancing maturity, growth variables (age, bone age at surgery, weight, and BMI) increased from the open to the closed group, as expected. Surgical details are exposed in Table 2. During the study period, the preferred surgical technique for transphyseal ACLR evolved from the transtibial to independent tunnel drilling, which included anteromedial portal femoral socket drilling and retrograde tibial socket drilling. All the patients in the open physis group received an HS autograft. A BTB graft was used in 65.9% of the closing physis group and 80.9% of the closed physis group. Graft size significantly increased with physis maturation from 8.2 ± 0.8 in the open group to 9.2 ± 1.0 in the closing group and 9.6 ± 0.6 in the closed group ($P < .001$).

ACL Reinjury Rate

The overall rate of ipsilateral ACL reinjury was 13.2%. Differences between the patients who had an ACL reinjury and the patients who did not sustain a reinjury are reported in Table 3. The patients who had an ACL reinjury were younger at the time of surgery ($P < .001$) and had a lower bone age at surgery ($P < .001$), open growth plates ($P < .001$), a higher percentage of HS graft type ($P < .001$), a smaller graft diameter ($P < .001$), and a shorter time to return to sport ($P = .01$).

The Kaplan-Meier analysis by the physis status showed a statistically significant difference in injury free from ipsilateral ACL reinjury ($P = .01$), with open physis patients at a higher reinjury rate (26.8%), followed by closing physis (12.9%) and the closed physis group (4.8%) (Fig 1). The open physis group presented a higher risk of ACL reinjury compared to the closed physis group (hazard ratio [HR], 5.2; 95% CI, 1.7-15.9; $P = .003$). Even if the hazard estimate for the closing physis versus closed physis group was above 1.00, it was not statistically significant (HR, 2.6; 95% CI, 0.9-7.7; $P = .08$). The reinjury-free rate was 83.2%, 88.1%, and 97.5% at 2 years and 76.3%, 86.9%, and 93.1% at 5 years in the open, closing, and closed physis groups, respectively.

Risk Factors for Ipsilateral ACL Reinjury

The impact of the patients' demographics and surgical variables on the rate of ipsilateral ACL reinjury was estimated by the univariate Cox proportional hazard

Table 2. Surgical Variables by Femoral Physis Status

Characteristic	Overall (N = 272)	Open (n = 56)	Closing (n = 132)	Closed (n = 84)	*P* Value
Meniscal lesion at ACLR[a]	181 (66.5)	37 (66.1)	84 (63.6)	59 (70.2)	.61
Surgical technique[a]					.07
Independent	99 (36.4)	25 (44.6)	39 (29.5)	35 (41.7)	
Transtibial	173 (63.6)	31 (55.4)	93 (70.5)	49 (58.3)	
Graft type[a]					**<.001**
Hamstring	117 (43.0)	56 (100.0)	45 (34.1)	16 (19.1)	
Patellar tendon	155 (57.0)	0 (0.0)	87 (65.9)	68 (80.9)	
Graft diameter,[b] mm	9.1 ± 1.0	8.2 ± 0.8	9.2 ± 1.0	9.6 ± 0.6	**<.001**

NOTE. Values are presented as number (%) or mean ± standard deviation unless otherwise indicated. Bold indicates statistical significance.
ACLR, anterior cruciate ligament reconstruction.
[a]χ^2 test.
[b]Analysis of variance.

regression, and adjustment for the physis status (open, closing, closed) was also reported (Table 4). An increased risk of ACL reinjury was observed in patients treated with the HS graft compared to those treated with the BTB graft (HR, 2.6; 95% CI, 1.1-6.1; $P = .03$). Larger graft dimension was protective against ipsilateral ACL reinjury (HR per millimeter of increase, 0.7; 95% CI, 0.5-0.9; $P = .04$).

Table 3. Patient Characteristics by Ipsilateral ACL Reinjury

Characteristic	Reinjury (n = 36)	No Reinjury (n = 236)	*P* Value
Age at surgery,[a] y	14.7 ± 1.6	15.5 ± 1.2	**<.001**
Bone age at surgery,[a] y	15.1 ± 1.3	15.9 ± 1.1	**<.001**
Female patients[b]	20 (55.6)	151 (64.0)	.33
Right side[b]	19 (52.8)	114 (48.3)	.62
BMI[a]	22.8 ± 2.5	23.4 ± 4.0	.51
Trauma to surgery time,[a] mo	2.6 ± 4.4	2.0 ± 2.4	.25
Contact trauma[b]	8 (22.2)	38 (16.2)	.37
Physis status by x-ray[b]			**<.001**
Open	15 (41.7)	41 (17.4)	
Closing	17 (47.2)	115 (48.7)	
Closed	4 (11.1)	80 (33.9)	
Meniscal lesion at ACLR[b]	24 (66.7)	156 (66.1)	.95
Surgical technique[b]			.48
Independent	15 (41.7)	84 (35.6)	
Transtibial	21 (58.3)	152 (64.4)	
Graft type[b]			**<.001**
Hamstring	26 (72.2)	91 (38.6)	
Patellar tendon	10 (27.8)	145 (61.4)	
Graft nature[b]			.16
Autograft	34 (94.4)	233 (97.5)	
Contralateral autograft	2 (5.6)	3 (1.3)	
Graft diameter,[a] mm	8.2 ± 1.5	9.0 ± 1.6	**<.001**
Tegner postoperatively[a]	7.3 ± 0.7	7.3 ± 0.7	.64
Preinjury sport level	25 (73.5)	191 (85.3)	.08
RTS time,[a] mo	8.2 ± 1.5	9.0 ± 1.6	**.01**

NOTE. Values are presented as number (%) or mean ± standard deviation unless otherwise indicated. Bold indicates statistical significance.
ACLR, anterior cruciate ligament reconstruction; BMI, body mass index; RTS, return to sport.
[a]*t* Test.
[b]χ^2 test.

Discussion

We found that the overall graft failure rate was 13.2%. Our hypothesis was supported, and the status of the physis was related to ACL reinjury risk. Notably, patients with an open physis had a higher rate of ipsilateral ACL reinjury (26.8%) when compared with pediatric patients with a closing physis (12.9%) and a closed physis (4.8%). In addition, we found that graft type and graft size were significant risk factors for ACL graft failure after adjustment for physis status, with HS tendon autograft and smaller graft diameter associated with a higher risk of reinjury. In this study, the overall ipsilateral ACL reinjury rate was 13.2%, while the percentage of contralateral ACL lesion was 11.0%.

A wide range of ACL reinjury rates among the pediatric patient population is reported in the literature.[30,31] Younger age is a consistent risk factor for ipsilateral ACL reinjury despite studies that have indicated that the pediatric joint environment may have a higher healing potential or is protective to injury.[20,28,32] Our follow-up study on pediatric patients receiving a transphyseal ACLR found an overall ipsilateral ACL reinjury rate of 13.2%, which is higher than some studies that have focused on this same group of patients and other adult populations.[33,34] A recent systematic that analyzed the reinjury rate among skeletally immature patients reported a pooled ACL graft failure rate of 6.2% in the transphyseal cohort.[35] A long-term follow-up study of this same transphyseal cohort observed an ACL reinjury rate as high as 25% of their patients. This data further support that younger patients are exposed to a higher risk of a secondary injury. Moreover, our study provides evidence that the level of skeletal immaturity is important in the risk stratification for ACL reinjury. The rate of graft failure was higher in the open physis group with 26.8% and a mean age of 14.2 years (range, 10.2-16.4 years). The Kaplan-Meier analysis showed that there is a significant difference in injury free from ACL rerupture by the grade of maturity of the femoral physis, which confirmed the protective effect of the skeletal maturation. These findings demonstrate the

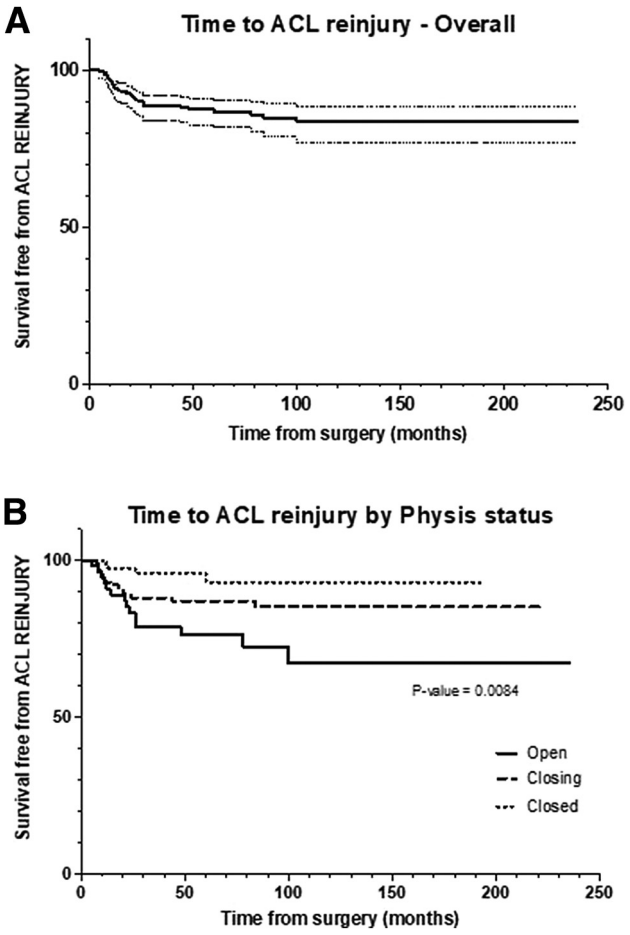

Fig 1. Kaplan-Meier analysis for cumulative injury free from ipsilateral anterior cruciate ligament reinjury. Overall curve with 95% confidence interval (A) and by physis status (B).

importance of including skeletal maturity as a confounding factor in future studies that examine reinjury rates to better differentiate patient groups or type of ACL injury treatments.[2,36]

Our analysis of identifying risk factors that are associated with higher ACL injury risk is consistent with what was previously found in the literature. After adjusting for femoral physis status, we found that HS tendon autograft and the graft diameter were associated with a significantly higher risk of ACL reinjury in our study cohort. Recent studies reported a higher reinjury rate with HS tendon autografts in both pediatric and adult populations.[37-40] However, the evidence in the literature is still controversial, with some studies finding no significant differences between the BTB and HS autografts used in this patient population. In addition, it has been widely reported in the literature that using a 10-mm diameter graft offers a protective role in adult patients and that decreasing the graft diameters below this mark may increase the risk of ACL reinjury in patients.[20,41-44] The Multi-center Orthopedic Outcomes Network group of investigators described a significantly higher ACL reinjury rate in patients with a graft diameter smaller than 8 mm in their cohort of patients, proposing this as a cutoff to perform a safe ACLR.[45] Furthermore, a systematic review and metanalysis reported a cutoff of a 7-mm graft diameter to lower the ACL reinjury rate.[46] At the same time, since the selection of graft dimension is usually related to a patient's skeletal maturity, it is difficult to distinguish between selection of graft type and skeletal maturity to determine the factor that contributes most significantly to increased risk of failure.

The open physis group of patients had the highest ACL reinjury rate in our study, and it may be worth comparing our results to the injury rates of the most used physeal-sparing surgical techniques in the literature. A study that had used an all-epiphyseal ACLR technique in pediatric patients had a graft failure rate of 11% at a 21-month follow-up.[47] However, the need to use fluoroscopy and the bone tunnel location close to the growth plates increased the difficulty of this ACLR technique and diminished its popularity. Additionally, limb length discrepancies were reported in up to 26% of the pediatric patients.[48] Alternatively, the extraphyseal iliotibial (IT) band ACLR was proved to be safe without any clinical growth disturbance and a rate of graft failure of 6.6%, which is lower than our study.[49] However, it should be noted that the postoperative outcomes were obtained only from 57% of the knees studied.[49] However, the postoperative care of patients undergoing this ACL technique differed from other surgical techniques. Importantly, the significant differences were that patients had partial weightbearing for the first 6 weeks, had limited range-of-motion rehabilitation, and used a knee brace up to 2 years after surgery.[50] Both the extra-articular reconstruction and the use of the brace postoperatively may have had a protective role, giving higher rotational stability and limitation of high-risk movements. A prospective comparison of transphyseal and IT band ACLR could help to clarify which option better fits the population of skeletally immature patients. Meanwhile, the physeal-sparing IT reconstruction can be considered a valid alternative for our open physis patients, especially due to the bone and growth plate preservation.

Limitations

This study is not without any limitations. First, a clinical knee examination was the only assessment of the pediatric patients approximately 2 years from surgery. Some patients may have been treated for new knee problems in other hospitals outside our clinical network and, therefore, would not have been accounted for in the present records. Accordingly, our study may have underestimated the recurrence rate. Second, the data were collected retrospectively from the patient

Table 4. Univariate Cox Proportional Regression for Injury Free From Ipsilateral ACL Reinjury

Nonadjusted and Adjusted for Physis Status				
	Unadjusted Injury Free of ACL Reinjury		Adjusted Injury Free of ACL Reinjury	
Characteristic	HR (95% CI)	*P* Value	HR (95% CI)	*P* Value
Age at surgery, per year increase	0.7 (0.6-0.8)	**<.001**	0.8 (0.6-1.0)	.07
Bone age MRI, per year increase	0.6 (0.5-0.8)	**<.001**	0.7 (0.5-1.0)	.08
BMI, per unit increase	1.0 (0.9-1.1)	.64	1.0 (0.9-1.1)	.97
Sex, female vs male	0.7 (0.3-1.3)	.22	0.8 (0.4-1.6)	.54
Meniscal lesion vs no lesion	1.0 (0.5-2.0)	.98	1.0 (0.5-2.0)	.95
Graft type, HS vs BTB	3.4 (1.6-7.1)	**<.001**	2.6 (1.1-6.1)	**.03**
Graft size, per mm increase	0.6 (0.4-0.8)	**<.001**	0.7 (0.5-0.9)	**.04**
RTS, per month increase	0.8 (0.6-0.9)	**.02**	0.8 (0.6-1.0)	.09
Surgical technique				
Transtibial vs independent	1.5 (0.8-3.0)	.23	1.5 (0.7-3.0)	.25

NOTE. Bold indicates statistical significance.

ACL, anterior cruciate ligament; BTB, bone-patellar-bone; CI, confidence interval; HR, hazard ratio; HS, hamstring; MRI, magnetic resonance imaging; RTS, return to sport.

records, and variables like graft choice or diameter were not randomized but instead subjected to surgeon and patient preferences. However, this methodology is a more accurate representation of standard clinical practice among our patient population as opposed to a prospectively forced randomization of surgical technique. Third, we only included patients who underwent transphyseal ACLR using BTB or HS grafts, which limits our comparison to other graft types in this patient population. Finally, some statistical limitations are worth pointing out. The Kaplan-Meier analysis presented some instability factors: all the patients with open physis received an HS graft for clinical reasons, and only 3 patients in the closed physis group reported an ipsilateral ACL reinjury. Moreover, the 2 most important graft variables, HS and smaller graft diameter, were both more frequently used in skeletally immature patients, demonstrating a grade of collinearity. For all these reasons, our predictive models were more unstable, with larger hazard ratio confidence intervals and *P* values. In addition, we did not report patient-reported outcomes because this is outside the scope of this current study, but another group has reported on establishing clinically significant outcomes after ACLR in pediatric patients.[51]

Conclusions

Transphyseal ACLR is a safe procedure in pediatric patients. The rate of reinjury was 13.2%. This rate decreases with skeletal maturity, use of patellar tendon autograft, and a larger graft diameter.

Disclosures

The authors report the following potential conflicts of interest or sources of funding: B.L. has received royalties and/or consulting fees from Arthrex and Smith & Nephew, has stock or stock options from COVR Medical LLC, and is on the editorial or governing board of *Journal of Knee Surgery*, *Knee Surgery, Sports Traumatology, Arthroscopy*, and *Orthopedics Today*. M.B. is a consultant for Stryker, Meda Pharma, and Angelini Farmaceutici. M.S. has received royalties and consulting fees from Arthrex and research support from Stryker and USA Hockey Foundation. A.J.K. has received royalties and consulting fees from Arthrex. All other authors (L.R., N.B., N.S., B.L., T.M., M.B., M.S., A.J.K.) declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. Full ICMJE author disclosure forms are available for this article online, as supplementary material.

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