Influence of Graft Diameter on Functional Outcomes After Anterior Cruciate Ligament Reconstruction: A Prospective Study with a 1-Year Follow-Up

Authors' Contribution:
Study Design **A**
Data Collection **B**
Statistical Analysis **C**
Data Interpretation **D**
Manuscript Preparation **E**
Literature Search **F**
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Background:
The aim of this study was to determine whether graft size is associated with recurrent instability and insufficient functional outcomes after ACL reconstruction.

Material/Methods:
We analyzed 214 consecutive patients with a completed follow-up of 12 months: 55 (25.7%) women and 159 (74.3%) men. Patients were divided into 3 groups according to the diameter of the middle of the hamstring graft. Follow-up examinations were performed pre-surgery and 3, 6, and 12-months postoperatively, and laxity assessments were performed using GNRB®. Differential laxity measured at 134N (Δ134=heathy *vs.* operated side). A "residual laxity" of the ACLR was defined as Δ134N>3 mm.

Results:
The results of the General Linear Model (Repeated Measures) showed that there was a significant main effect of time factor (F=379.759, p<0.001, η^2_p=0.681) on differential laxity. We found statistically significant differences (p<0.001) in assessments of differential laxity pre-surgery and at 3, 6, and 12 months postoperatively (time factor). Tegner activity score at 12 months after reconstruction significantly differed when comparing patients with "residual laxity" (4.23±0.83) and others (4.85±1.17) (p=0.038). The study revealed a positive correlation between Tegner activity score at 12 months after surgery and pre-injury Tegner activity score (r=0.728, p<0.001) and negative correlation between age (r=–0.43, p<0.001) or BMI (r=–0.33, p<0.001).

Conclusions:
Our study revealed that graft diameter is not associated with recurrent instability and does not affect laximetry results. The multiple regression model we developed made it possible to predict the Tegner activity score at 12 months after reconstruction based on pre-injury Tegner activity score, age (years), and BMI (kg/m²) of the patient.

MeSH Keywords:
Anterior Cruciate Ligament • Anterior Cruciate Ligament Reconstruction • Arthroscopy

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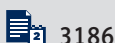
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Background

The active way of life and growing trend toward playing sports, together with greater complexity of sports movements, induce knee ligament injuries. The anterior cruciate ligament (ACL) is among the most commonly affected ligaments, and surgical treatment is chosen for most patients who present pain and knee instability [1]. Conservative treatment of ACL rupture is one of the possibilities and sometimes is successful, but patients wanting to return to sports and high-level activities are not satisfied with conservative treatment outcomes [2]. To achieve the best results, ACLR is needed. The selection of graft type depends on many factors, including surgeon preference, patient age, activity level, and patellofemoral pain, with the final decision discussed on an individual basis. Hamstring tendon (HT) autografts provide post-operative outcomes similar to patellar tendon autografts [3,4], but are less likely to be associated with anterior knee pain due to graft harvest morbidity, and enable smoother and less painful rehabilitation. Also, the recent literature indicates that hamstring autografts can have an inferior outcome in younger, more active patients and in female patients [5–8]. There is also much interest in graft size. Harvesting an autograft involves large variability in graft diameter, but biomechanical studies have shown inferior biomechanical properties of smaller grafts [9]. The literature also lacks information about graft size correlation with functional instability. So, clinically, grafts with a diameter less than 7 mm have been associated with an increased rate of failure and lead to early revision [7,10,11]. Investigators concluded that a small graft diameter did not necessarily increase instability or the chance of failure, but that a diameter of ≥8 mm would likely lead to better results [12]. The possibility of obtaining grafts with large variability of size, and its possible significant influence on the outcome of surgery, led to the search for characteristics that would help to anticipate the size of HT autografts as well as outcomes of ACLR.

Purpose

The purpose of this study was to determine whether graft size is associated with recurrent instability and insufficient functional outcomes after ACL reconstruction.

Material and Methods

The baseline data collection for this study was carried out at the Lithuanian University of Health Sciences (LUHS), Kaunas Clinics, Orthopedics and Traumatology Department, between January 2015 to January 2017. From the total pool of 360 ACLR patients, 214 consecutive patients with a completed follow-up of 12 months were enrolled in this study. We excluded 132 patients who did not meet inclusion criteria or did not finish the 12-month follow-up and 14 patients were lost during follow-up. Patients were divided into 3 groups according to the diameter of the middle of the graft (Ø ≤8 mm, 8 mm < Ø ≤9 mm, and Ø >9 mm).

Before surgery, we recorded patient age, sex, activity level by Tegner score [13], height, and weight. The Tegner activity score is a widely used score to numerically grade sports and work activities on a scale from 0 to 10 and was presented by Tegner and Lysholm in early 1985. The level from 7 to 10 corresponds to competitive sports, 4 to 6 to recreational sports, and 0 to 3 to activities of daily life. The graft diameter was recorded at the time of surgery. Standard radiographs and MRI were obtained for most of patients to rule out any additional bony injuries and to evaluate ligamentous, cartilaginous, and meniscal injuries. Follow-up examinations were performed pre-surgery and at 3, 6, and 12 months postoperatively by a physician who was not involved in the surgery. At all follow-up visits, laxity assessments were performed using GNRB® (GeNouRoB, France) [14]. GNRB® is the arthrometer designed to apply a reproducible force across the knee and mechanically measure the resulting displacement. The GNRB is an automated dynamic laximeter used in pre-surgery for diagnosis and postoperatively for follow-up of the knee joint to make sure knee stability is regained. The results are given as the difference of laxity in the injured and the un-injured knees in the patient. The measurement accuracy of the GNRB® is 0.1 mm [14]. A "residual laxity" of the ACLR was defined as differential laxity greater than 3 mm at 134N (Δ134N >3 mm) (Table 1).

This scientific study was approved by our institution's Research Ethics Committee (No. BE-2-30).

Surgical technique

An anatomical single-bundle ACLR with autologous hamstring (semitendinosus-gracilis) tendon grafts (minimum graft diameter in this study was 7.0 mm) was performed for every patient. Graft diameter was measured by the calibrator (accuracy: 0.5 mm) at the middle of the graft. Remnants of the native ACL was left, expecting better biological healing of the implanted ACL graft. After performing notchplasty, the femoral bone tunnel was made through a very low anteromedial portal in maximum knee flexion and was placed in the center of the native ACL footprint (between the anteromedial and posterior-lateral entries). For tibial bone tunnel placement, the arthroscopic aimer was inserted into the knee through the anteromedial portal and was adjusted to 45° when drilling, and was positioned approximately 5 mm behind the anterior meniscal ligament in a middle distance between the anterior horn of lateral meniscus and medial eminence of tibia. After the guide pin is drilled, the drill guide is removed and the knee is passively extended to exclude an impingement on the anterior

Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Complete ACL tear	Partial ACL tear
Reconstruction using HT graft	Bilateral ACL ruptures
Age 18 to 55 years	Combined ligament injuries
Tegner sports activity level recorded	Injury of the posterior cruciate ligament
	Inflammation process in knee joint
	Concomitant fractures
	Graft size <7 mm

intercondylar notch and medial wall of the lateral condyle. Once a check is performed, the tibia tunnel is established with a cannulated reamer to the graft diameters. The reaming debris is evacuated with a synovial shaver to minimize the fat pad inflammatory response. After creation of a tunnel on the femoral and tibial side, grafts were inserted and then fixed with bio-absorbable interference screws proximally and distally in 20–30° of knee flexion. The knee was cycled several times through the range of motion and the graft was examined arthroscopically to check tension and fixation quality and to exclude graft instability and impingement.

Rehabilitation

All patients underwent a standardized rehabilitation protocol. An extension knee brace was used for 2 weeks and protected weight-bearing was allowed for 2 weeks as tolerated. On the second postoperative week, the brace was fixed to allow motion between 0° and 60° of flexion, and quadriceps activity against gravity and hamstring contractions were permitted. Four weeks after surgery, patients were allowed knee motions between 0° and 90° of flexion, and quadriceps exercises were allowed between 45° and 90° of flexion. At 6–8 weeks, full isotonic hamstring contraction, hip abductor-adductor exercises, and swimming were permitted. At 8 weeks, patients were encouraged to achieve a full range of motion, to extend the knee against unlimited resistance between 45° and 90° of flexion, and to ride a stationary bicycle with resistance. At 12 weeks, unrestricted isotonic quadriceps-strengthening was allowed between 0° and 90° of flexion. Return to sports activity was allowed gradually 8 to 12 months postoperatively, and after 1 year without any restrictions.

Statistical analysis

For statistical analysis, IBM SPSS® 24.0 was used. The normal distribution was tested and confirmed with the Kolmogorov-Smirnov or Shapiro-Wilk tests for the metrical data. Descriptive characteristics are presented as mean ± standard deviation and range. ANOVA was used to compare the diameter of the graft, BMI, and age of patients between the 3 groups ($\varnothing \leq 8$ mm, 8 mm < $\varnothing \leq 9$ mm, and $\varnothing >9$ mm). Adjustment for multiple comparisons was made using the Bonferroni comparison test. The general linear model (repeated measures) was used to evaluate follow-up examinations, which were performed pre-surgery and at 3, 6, and 12 months postoperatively. The assessments at 4 different time points (before surgery and at 3, 6, and 12 months postoperatively) for outcome variables were used as the time factor (within-subject factor) and analyzed by investigation groups (between-subject factor). The Bonferroni pairwise multiple comparisons test was used for post hoc pair-wise comparisons. We used nonparametric ordinal analysis to compare the quantitative data that were not normally distributed. The differences between 2 independent variables were analyzed using the Mann-Whitney U test. To evaluate differences between categorical factors, the Pearson chi-squared (χ^2) test and Fisher's exact test were used. The relationship between investigated variables was estimated by using the Pearson correlation coefficient and multiple regression analysis. The suitability of the multiple regression model was evaluated with the coefficient of determination R^2. We calculated the coefficients of regression equation and their significance levels p. The level of significance was set at 5% for all the tests.

Results

A total of 214 patient were evaluated. There were 55 (25.7%) women and 159 (74.3%) men with the mean age 33.21±9.78 years (range 18–55), and the median age was 33 years. The mean time from injury to surgery was 17.66 (35.66) months, with a median of 4.5 months, and did not differ between the men (4.55) and the women (4.01) (p=0.347). Patients were divided into 3 groups according to the diameter of the graft ($\varnothing \leq 8$ mm, 8 mm < $\varnothing \leq 9$ mm, and $\varnothing >9$ mm) and the means of the graft diameter were significantly different in all 3 groups ($p<0.001$). There were 44 (20.6%), 90 (42.0%), and 80 (37.4%) patients in groups $\varnothing \leq 8$ mm, 8 mm < $\varnothing \leq 9$ mm, and $\varnothing >9$ mm, respectively. The demographic data of the study across the groups are presented in Table 2.

Table 2. Patient, graft, laxity, and Tegner activity score characteristics.

	Ø ≤8 (mm) (A)	8< Ø ≤9 (mm) (B)	Ø >9 (mm) (C)
Age at the time of surgery (years)	34.6±12.4	33.1±9.8	32.6±8.1
Sex (women)	25*BC	20	10
Sex (men)	19	70*A	70*A
Height (cm)	174±11.1	178±8.1	184±8.6#AB
Weight (kg)	75.6±14.6	81.3±14.2	89.4±13.7#AB
BMI (kg/m^2)	24.8±4.1	25.6±3.7	26.5±3.5
Graft diameter (mm)	7.8±0.3	8.8±0.2#A	10.1±0.8#AB
Δ134N pre-op (mm)	3.85±1.39	3.95±1.40	4.32±1.36
Δ134N after 3 months (mm)	1.02±0.80	1.13±0.83	1.38±1.13
Δ134N after 6 months (mm)	1.29±1.13	0.98±0.76	1.31±0.94
Δ134N after 12 months (mm)	1.01±1.03	1.20±1.12	1.37±1.13
No. with residual laxity (%) >3 mm	2 (5.7%)	6 (7.9%)	5 (7.0%)
Tegner activity score at 12 months	4.76±1.42	4.84±1.20	4.79±0.97

Values are expressed as mean ± standard deviation. For each significant pair, the key of the category with the smaller value appears under the category with the larger value. * $p<0.05$; # $p<0.001$.

Our study revealed that the graft diameter was significantly larger among men 9.27±0.96 than in women 8.47±0.84 ($p<0.001$). We calculated body mass index (BMI) as an attempt to quantify the amount of tissue mass in patients, and then categorized them as underweight, normal weight, overweight. The minimal value of BMI in our study was 19 kg/m^2, max – 39 kg/m^2, indicating that there were no underweight patients in our study. We allocated patients into the normal BMI group (<25 kg/m^2) and the overweight group (≥25 kg/m^2).

The means of the diameters of the grafts were significantly different between BMI groups (8.94±0.95 in normal BMI group vs. 9.23±1.06 in overweight group; $p=0.028$) and postoperative (12 months after surgery) differential laxity between BMI groups (1.04±1.099 in normal group vs. 1.38±1.097 in overweight group; $p=0.01$).

There were 149 (69.6%) meniscal repairs performed: 31 (70.5%), 61 (67.5%), and 57 (71.3%) respectively in 3 groups according to the diameter of the graft (Ø ≤8 mm, 8 mm < Ø ≤9 mm, and Ø >9 mm). We found no difference in the prevalence of meniscal tears between all groups ($p>0.05$). Thus, menisci injuries in all groups were equal and equally could bias the results, either repaired or removed, so statistically they had the same influence on the difference of the final ACLR results in all groups.

Laximetry GNRB® data according to the graft diameter

Values of the graft diameter and differential laxity measurements in the 3 groups are shown in Table 2 and Figure 1. The 3 groups with measured differential laxity at 134N were compared. The results of the general linear model (repeated measures) showed that there was a significant main effect of time factor ($F=379.759$, $p<0.001$, $\eta^2_p=0.681$) on differential laxity. We found statistically significant differences ($p<0.001$) in assessments of differential laxity before surgery and at 3, 6, and 12 months postoperatively, but assessments performed postoperatively did not differ significantly. There was no significant interaction between time factor and graft diameter groups ($F=0.859$, $p=0.525$). These findings suggest that differential laxity assessed postoperatively was similar among all graft diameter groups. Differential laxity before surgery was highest in the large-diameter (Ø >9 mm) group and lowest in the Ø ≤8 mm group, 12 month postoperatively the situation was similar for both groups (the difference was not statistically significant).

Residual laxity

There were 13 (6%) patients with "residual laxity" in our study. Distributions in graft diameter groups are shown in Table 2. The highest incidence was registered in the 8–9 mm graft group, but difference between groups was not statistically significant.
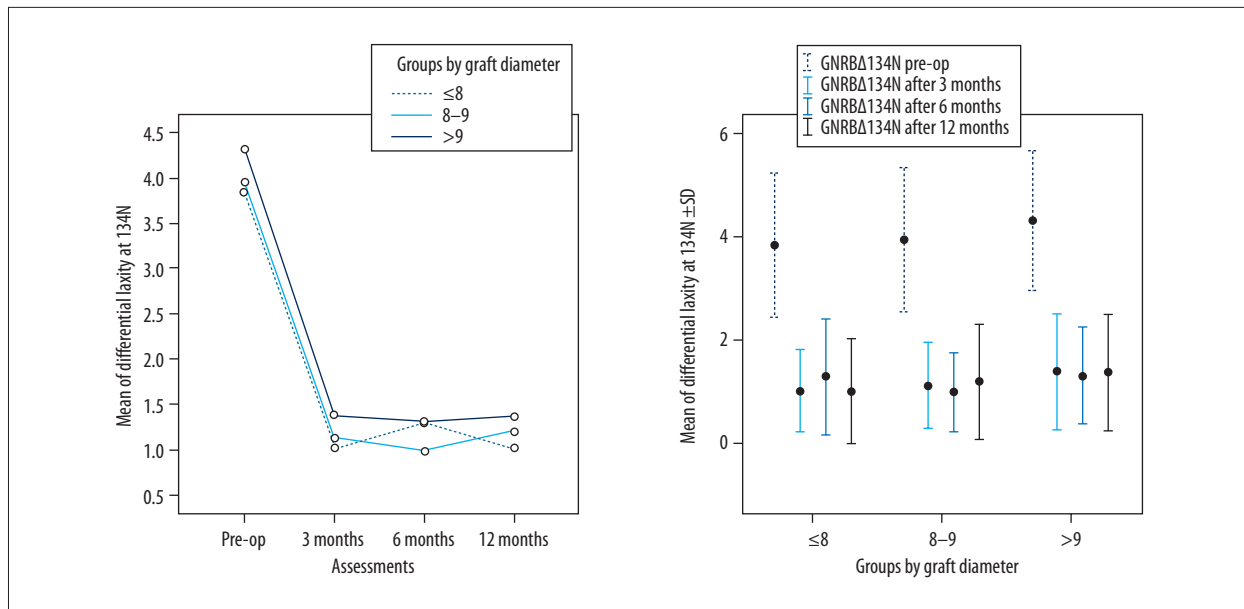
Figure 1. Laximetry GNRB® data according to the graft diameter in 4 assessments.

Table 3. Tegner activity score according to the BMI groups.

	<25 kg/m²	≥25 kg/m²	*p* Value
Pre-injury	5.81±1.36	5.41±1.12	0.008
12 months after surgery	5.07±1.28	4.63±1.07	0.019

Values are expressed as mean ± standard deviation.

There were 120 (56%) overweight patients in our study (BMI ≥25 kg/m²) and 25 (11.7%) of those patients had BMI higher than 30 kg/m². There were no patients with less than 18 kg/m² BMI (defined as underweight). There were 4 (5.3%) cases of "residual laxity" in the BMI <25 kg/m² group and 9 (8.4%) in the BMI ≥25 kg/m² group. Interestingly, looking deeper into GNRB® laximetry results at 12 months after surgery, we found statistically significant differences between normal BMI patients with good laxity difference (Δ134N ≤1.4) *vs.* overweight patients (BMI ≥25 kg/m²) with laxity difference 1.5–3 mm at 134N (*p*=0.032).

Tegner activity score

Pre-injury Tegner activity score scores were significantly different between men and women (5.67±1.13 (range 3–9) for men *vs.* 5.3±1.49 (range 3–9) for women; *p*=0.026). Tegner activity score 12 months after surgery was 4.85±1.07 (range 3–8) and 4.68±1.37 (range 3–9) for men and women, respectively, but the difference was not significant (*p*=0.173).

We found that Tegner activity score scores at 12 months after reconstruction differed significantly when comparing patients with "residual laxity" (4.23±0.83, range 3–5) and the other patients (4.85±1.17, range 3–9), (*p*=0.038). Table 3 shows Tegner activity score pre-injury and at 12 months after ACLR in BMI groups, with statistically significant differences between Tegner activity scores in BMI groups.

We found a positive correlation between pre-injury Tegner activity score and Tegner activity score 12 months after surgery (r=0.728, *p*<0.001) and a negative correlation between Tegner activity score 12 months after reconstruction and age (r=−0.43, *p*<0.001) or BMI (r=−0.33, *p*<0.001). We used multiple regression analysis to investigate whether age, sex, BMI, and pre-injury Tegner activity score could significantly predict patient Tegner activity scores (12 months after reconstruction). The results of the regression analysis indicated that the model explained 56% of the variance and that the model was a significant predictor of patient Tegner activity score (12 months after reconstruction), *F*=68.8, *p*<0.001. While pre-injury Tegner activity score (b_1=0.610, *p*<0.001), BMI (b_2=−0.042, *p*=0.008) and age (b_3=−0.015, *p*=0.028) contributed significantly to the model, sex was eliminated as a statistically insignificant predictor (Table 4). The final predictive model was:

Tegner score (12 months after reconstruction) = 3.002 + 0.610 × pre-injury Tegner score + (−0.042 × BMI) + (−0.015 × Age).

Table 4. Multiple regression model results.

Model	Unstandardized coefficients		Standardized coefficients	t	p Value
	B	Std. Error	Beta		
(Constant)	3.002	0.614		4.892	0.000
Tegner score (pre-injury)	0.610	0.053	0.640	11.436	0.000
BMI	−0.042	0.016	−0.139	−2.672	0.008
Age	−0.015	0.007	−0.123	−2.213	0.028

Discussion

Use of hamstring tendon grafts has become an increasingly popular among orthopedic surgeons for ACLR. Anatomical studies revealed that the mean diameter of the normal ACL is approximately 11 mm, with a range from 6 to 12 mm [7,15]. The parameters for graft size necessary to achieve a satisfactory result after ACLR have not been clearly defined, but at least 7 mm of graft diameter has traditionally been recommended for use in ACLR [16,17]. Magnussen et al. [7] reported that grafts smaller than 8 mm had greater incidence of ACLR failure. Another scientific study, based on animal models, evaluated the influence of graft diameter on graft strength and resistance, demonstrating that grafts smaller than 8 mm had failure due to tearing of the tendon, while in grafts larger than 10 mm failure occurs at the fixation screws due to traction [18]. The ability to predict which patients present greater risk of having hamstring tendons of insufficient diameter may be beneficial for surgical planning before the operation, thereby avoiding problems during the operation [7,16,17] Hamner et al. [9] demonstrated that the resistance, stiffness, and biomechanical properties of the graft tendon are affected by its diameter. However, the results from the few studies in the literature correlating patient anthropometric data with the length and diameter of flexor grafts continue to be contradictory. Therefore, we hypothesized that laxity 12 months postoperatively decreased when ACLR is performed with larger-diameter grafts. In the present study the minimal graft diameter was 7 mm and the largest diameter was 12 mm, but the mean graft diameter was 9.08 mm; therefore, we were able to analyze several different graft diameter groups. We found no statistically significant difference between graft diameter groups and differential laxity, especially "residual laxity", which is indicator of the failure [14]. The highest incidence of "residual laxity" was registered in the 8–9 mm graft group, but the difference was not statistically significant. This is in contrast to results reported by Magnussen et al. [7], who found the revision rate was significantly higher in patients with grafts sized 7 mm or smaller. In the present study, we also had small-sized grafts and both patients with 7-mm grafts in our study failed as well. Bedi et al. [19], in their biomechanical study, showed that increasing graft size did not increase knee stability at the time of reconstruction and doing this did

not compensate for the poor knee stability produced by malposition of the tunnels. Bedi et al. concluded that anatomic reconstruction is more important than graft size, at least for the time-zero stability. All ACLRs in our study were performed using the same surgical technique, so we did not analyze the influence of the tunnel position.

Our study shows that graft diameter was significantly larger among men than in women. It is clearly evident that women have a greater incidence of ACL tears compared with their male counterparts and female sex has also been reported to be a possible cause of increased failure of ACLR [6,20,21]. Similarly, Ma et al. [22] showed that hamstring grafts smaller than 8 mm in diameter are obtained in 42% of female patients but in only 18% of male patients. This sex-based difference in graft size may have affected revision rates of hamstring grafts in numerous comparative studies in which hamstring graft size is variable or not reported [7]. Several studies with a longer follow-up period also found no sex differences in return to sports activities [23,24]. McCullough et al. [25] found that 43% of patients returned to the same level of sports activities as before, while 30% did not return to any sports activity at all. In a study of 187 athletes at recreational and professional level, Ardern et al. [26] found that 31% returned to pre-injury sports activity levels within 1 year after ACLR, and Gobbi et al. [23] showed that 65% returned to same activity level. Our study found that 43.1% returned to their previous activity level within 1 year of ACLR. This indicates quite good results. Tegner activity score was significantly correlated with "residual laxity" in our study. We expected to find an association, because younger patients demonstrate higher activity levels as well higher Tegner scores [13]. The mean Tegner activity score was higher in the younger patients compared with older patients (6.04 vs. 5.15), but the difference did not reach statistical significance (P=0.066). In comparison, Treme et al. [27] reported no correlation between the diameter of the flexor grafts and patient sports and activity levels.

The strengths of this scientific study are that all patients were operated on using the same surgical technique and the laxity revision was performed with a precise and reproducible modern laximeter GNRB® [14].

Conclusions

Based on our study results, we conclude that graft diameter is not associated with recurrent instability and does not affect laximetry results. A multiple regression model could be useful to predict the Tegner activity score 12 months after reconstruction based on pre-injury Tegner activity score, age (years), and BMI (kg/m^2) of the patient.

Conflict of interests

None.

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