Anterior Cruciate Ligament Patellar Tendon Autograft Fixation at 0° Versus 30° Results in Improved Activity Scores and a Greater Proportion of Patients Achieving the Minimal Clinical Important Difference For Knee Injury and Osteoarthritis Outcome Score Pain: A Randomized Controlled Trial

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Purpose: The aim of the current study was to determine the effect of the knee flexion angle (KFA) during tibial anterior cruciate ligament (ACL) graft fixation on patient-reported outcomes, graft stability, extension loss, and reoperation after anatomic single-bundle ACL reconstruction. **Methods:** All 169 included patients (mean age 28.5 years, 65% male) were treated with anatomic single-bundle ACL reconstruction using patellar tendon autograft and were randomized to tibial fixation of the ACL graft at either 0° (n = 85) or 30° (n = 84). The primary outcome was the Knee Injury and Osteoarthritis Outcome Score (KOOS) 2 years after surgery. Secondary outcomes were the Marx Activity Scale (MAS), the rate of reoperation, and physical examination findings at 1 year, including KT-1000 and side-to-side differences in knee extension. **Results:** The follow-up rate was 82% (n = 139) for the primary outcome. Graft failure rate at 2 years was 1% (n = 2, 1 per group). ACL tibial graft fixation at 0° or 30° did not have a significant effect on KOOS scores at 2 years after ACLR. Patients whose graft was fixed at a knee flexion angle of 0° had greater scores on the MAS (mean 9.6 95% confidence interval [CI] 8.5 to 10.6, versus 8.0, 95% CI 6.9 to 9.1; $P = .04$), and a greater proportion achieved the minimal clinical important difference (MCID) for the KOOS pain subdomain (94% versus 81%; $P = .04$). There was no significant difference in knee extension loss, KT-1000 measurements, or reoperation between the 2 groups. **Conclusion:** In the setting of anatomic single-bundle ACLR using patellar tendon autograft and anteromedial portal femoral drilling, there was no difference in KOOS scores between patients fixed at 0° and 30°. Patient fixed in full extension did demonstrate higher activity scores at 2 years after surgery and a greater likelihood of achieving the MCID for KOOS pain. **Level of Evidence:** II, prospective randomized trial

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Over the last 2 decades, there has been a transition from a conventional transtibial (TT) anterior cruciate ligament reconstruction (ACLR) to anatomic ACL reconstruction to better recreate ACL graft dimension, collagen orientation, insertion, and isometry.[1-10] The native ACL is anisometric, with greatest tension and length in full extension.[11] Several studies have demonstrated that unlike transtibial ACLR, anatomic ACLR mimics this anisometric behavior, with graft tension and length varying significantly throughout knee range of motion (ROM).[2,4] Accordingly, the position in which the ACL graft is fixed and tensioned in anatomic ACLR

may have significantly more clinical implications with respect to stability, ROM, and joint contact pressures in comparison to conventional TT techniques.[12,13]

Previous biomechanical studies examining the effect of graft fixation angle during anatomic ACLR have demonstrated conflicting results.[14] Fixation at 30° has been associated with better stability but also loss of knee extension.[7,15] These findings would suggest a potential trade-off between knee stability and ROM in the context of trying to determine the optimal knee flexion angle for tibial fixation of an ACL graft. If graft fixation is performed in full extension (the position of maximal length/tension of the ACL), this may result in an increase in anteroposterior (AP) laxity in knee flexion, particularly if there is a significant degree of graft anisometry.[16] If graft fixation is performed at some degree of flexion (e.g., 30°), there is increased tension on the graft as the knee moves toward full extension, which could in turn result in extension loss, irreversible graft stretch (potential laxity), or graft injury.[2,16]

At the present time, consensus is lacking regarding the optimal knee flexion angle for ACL graft fixation, although it can be assumed to be an important factor for successful ACLR.[9,14,17] A survey of Canadian Orthopaedic Surgeons demonstrated that 40% of surgeons fix the ACL at 30°, and 30% perform fixation in full extension.[17] The aim of the current study was to determine the effect of the knee flexion angle (0° versus 30°) during tibial ACL graft fixation on patient-reported outcomes, graft stability, extension loss, and reoperation after anatomic single-bundle ACL reconstruction. We hypothesized that tibial fixation at 30° of knee flexion would result in improved patient-reported outcomes and AP knee stability and a higher rate of extension loss after ACLR.

Materials and methods

A patient- and assessor-blinded 2-arm parallel (1:1) group superiority randomized controlled trial was conducted at an academic sports medicine institution. Institutional review board -approval (2014-0006-B) was obtained from Women's College Hospital, Toronto, Canada, before the start of the trial. The manuscript was prepared in accordance with the CONSORT reporting guidelines.[18]

Patients were recruited from the clinical practice of 4 fellowship trained sports medicine surgeons. The inclusion criteria for this study were (1) patients >16 years old with an isolated ACL injury as diagnosed by clinical examination and magnetic resonance imaging (MRI); (2) no pre-existing arthritis as defined by the Kellgren-Lawrence radiographic rating system[19]; (3) treated with an initial period of rehabilitation to eliminate swelling, optimize quadriceps strength, and restore ROM; and (4) surgical management with anteromedial portal single-bundle ACLR with a patellar tendon autograft performed by 1 of 5 participating fellowship-trained orthopaedic sports surgeons. We excluded patients that had (1) acute ACL injuries that had not undergone an initial period of physical therapy to restore the above parameters; (2) associated grade III injury to the medial collateral ligament (MCL) (medial opening >10 mm at 30° of knee flexion or any medial opening in extension); (3) presence of a posterior cruciate ligament (PCL) or posterolateral corner injury; or (4) lack of informed consent.

We screened 220 individuals from June 2014 to October 2016. A total 183 patients were randomized intraoperatively to undergo fixation of the ACL graft on the tibial side at a knee flexion angle (KFA) of either 0° or 30°,[9] as measured by a sterile metal goniometer. The need for adjunct meniscal or cartilage procedures at the time of surgery was determined by the treating surgeon and documented. Patients underwent a minimal notchplasty to optimize visualization of the femoral footprint. The tibial guidewire for tunnel placement was inserted using a Acuflex guide (Smith & Nephew, Hanover, MA) with the angle set between 55° and 60° depending on surgeon preference. The tibial tunnel was drilled using a 10-mm cylindrical reamer. The center of the ACL footprint was marked by making an initial pilot hole with a 7-mm over-the-top guide from the anteromedial portal with the knee at 90° of flexion. Adequate placement of the pilot hole was confirmed by arthroscopic visualization from the medial portal. Drilling was completed with the knee in hyperflexion using a 10-mm half-fluted acorn reamer (Smith & Nephew) from the anteromedial portal to a depth of 25 mm.

Grafts were tensioned according to the maximum surgeon-applied tension in line with the bone–patellar tendon–bone autograft with a concomitant posterior tibial force (i.e., reverse Lachman). The amount of force applied to the graft or tibia was not formally measured. All surgeons used metal interference screws (Softsilk; Smith & Nephew) for graft fixation.

After surgery, patients were treated with a standardized accelerated physical therapy protocol.[20] Patients started therapy 1 to 3 days after surgery with an early focus on obtaining full extension, quadriceps activation, and swelling control. Walking aids and braces were discontinued once adequate quadriceps control was demonstrated. Whereas obtaining range of motion was emphasized in the first 6 weeks, increased focus on strengthening and introduction of incremental activity and loading was encouraged after this time frame. Return to sport and full activity was permitted after 6 months, once patients had full resolution of swelling, absence of pain, a stable knee, and single-leg hop >80% compared with the contralateral side.

The primary outcome was Knee Injury and Osteoarthritis Outcome Score (KOOS)[21] at 24 months postoperatively. The KOOS includes 42 items in 5

separately scored subscales: pain; symptoms; activities of daily living (ADL); function in sports and recreation (sports/rec); and knee-related quality of life (QOL).[22] Each subscale is scored from 0 to 100 (worst to best).

Secondary outcomes included (1) Marx Activity Score[23] at 24 months; (2) knee extension loss at 12 months; (3) side-to-side differences in AP stability as measured by the KT-1000 at 12 months[24]; and (4) the rate of reoperation after index ACLR. The Marx Activity Score was designed to assess the activity levels of patients with knee disorders and consists of 4 questions assessing running, cutting, decelerating, and pivoting.[23] Items are scored 0 to 4, depending on frequency. The overall score ranges from 0 to 16 (worst to best). Extension loss was measured using a goniometer in the outpatient clinic setting and recorded as (1) the difference in knee extension compared to the contralateral side and (1) the difference in heel heights in the prone position.[25]

Randomize.net was used to generate randomization tables using permutated blocks of 4 to produce 1:1 allocation. With regard to allocation concealment, randomization by a trained research coordinator was used to assign treatment after verification of the inclusion criteria. Patients, assessors, and data analysts were blinded to treatment status at all times. Objective physical assessment outcomes were performed by a trained research assistant who was blinded to the KFA randomization. Surgeons could not be blinded at the time of the intervention but were not reminded of treatment allocation at subsequent follow-up. Need for reoperation was determined by the treating surgeon in conjunction with the patient's symptoms.

At the time of enrollment, demographic and clinical data was collected for all participants including age, sex, concomitant knee injuries, mechanism of injury, time from injury to surgery, duration of symptoms, body mass index, and preoperative activity level. The KOOS and Marx Activity Score were administered by the research assistant at baseline and 24 months after ACLR. A trained research assistant conducted baseline and follow-up clinical measurements including maximum knee flexion and maximum knee extension with a goniometer using established techniques.[26] The instrumented KT-1000 arthrometer (MEDmetric Corp., San Diego, CA) was used to measure the anterior displacement of the tibia in relation to the femur and was recorded at 134 N and as the maximum manual test (side-to-side differences were calculated). Postoperative complications (e.g., infection, stiffness, graft rupture, reoperation, revision ACLR) were recorded by the clinical research assistant.

Statistical Analysis

The planned sample size was 168 patients, based on assuming a standard deviation of 15 points for the primary outcome (change from baseline in the KOOS score) and a 10-point difference between the fixation groups,[27] giving a standardized effect size of 0.67. We designed the trial to have 80% power at a 2-sided significance of $P < .05$ and allow for ≤20% loss to follow-up at the primary outcome time point, requiring 134 patients with completed outcomes for adequate power.

All statistical analyses were performed with 2-sided significance of .05 and conducted using SAS version 9.4 (Cary, NC). Means, medians, standard deviations, and interquartile ranges were calculated for continuous variables as appropriate, including baseline outcome scores. Categorical variables were presented as counts and proportions. Two-tailed unpaired *t* tests were used to assess differences in the primary outcome (KOOS subscale scores at 24 months) between treatment groups. Between-group differences in continuous secondary outcomes at 24 months were assessed with 2-tailed unpaired *t* tests, and categorical secondary outcomes were assessed with chi-squared tests.

In addition to examining differences in KOOS subscale scores between the 2 treatment groups, we also conducted a post hoc analysis to assess changes within individual patients and compared those between groups in the form the proportions of patients who achieved a patient-acceptable symptomatic state (PASS)[28] or minimal clinically important difference (MCID)[29] during the 24-month study period. These results were compared with chi-squared tests. A post hoc analysis of primary and secondary outcomes was performed after removal of patients who underwent reoperation for failed meniscal repair.

Results

Of the 183 patients randomized, 169 were eligible for inclusion in our analysis (Fig. 1). Of eligible participants, 139 (82%) completed the KOOS at 24 months. For secondary outcomes, 139 participants (82%; n = 65 0°, n = 74 30°) completed the Marx Activity Scale at 24 months, and 142 patients (84%, n = 68 0°, n = 73 30°) had ROM and KT-1000 measurements 12 months postoperatively.

Overall, the mean age was 28.5 years (95% confidence interval [CI] 27.2 to 29.8), and 65% (n = 110) were male. No differences in demographic, injury, or surgery related variables among patients in the 2 treatment groups were identified, including the presence of concomitant meniscal or cartilage lesions (Table 1). For our primary outcome, there was no difference between treatment groups in in KOOS pain, symptoms, ADL, sports/rec, or QOL subdomain scores 24 months postoperatively (Table 2).

Patients who had their ACL graft fixed in full extension had a higher Marx Activity Score 2 years

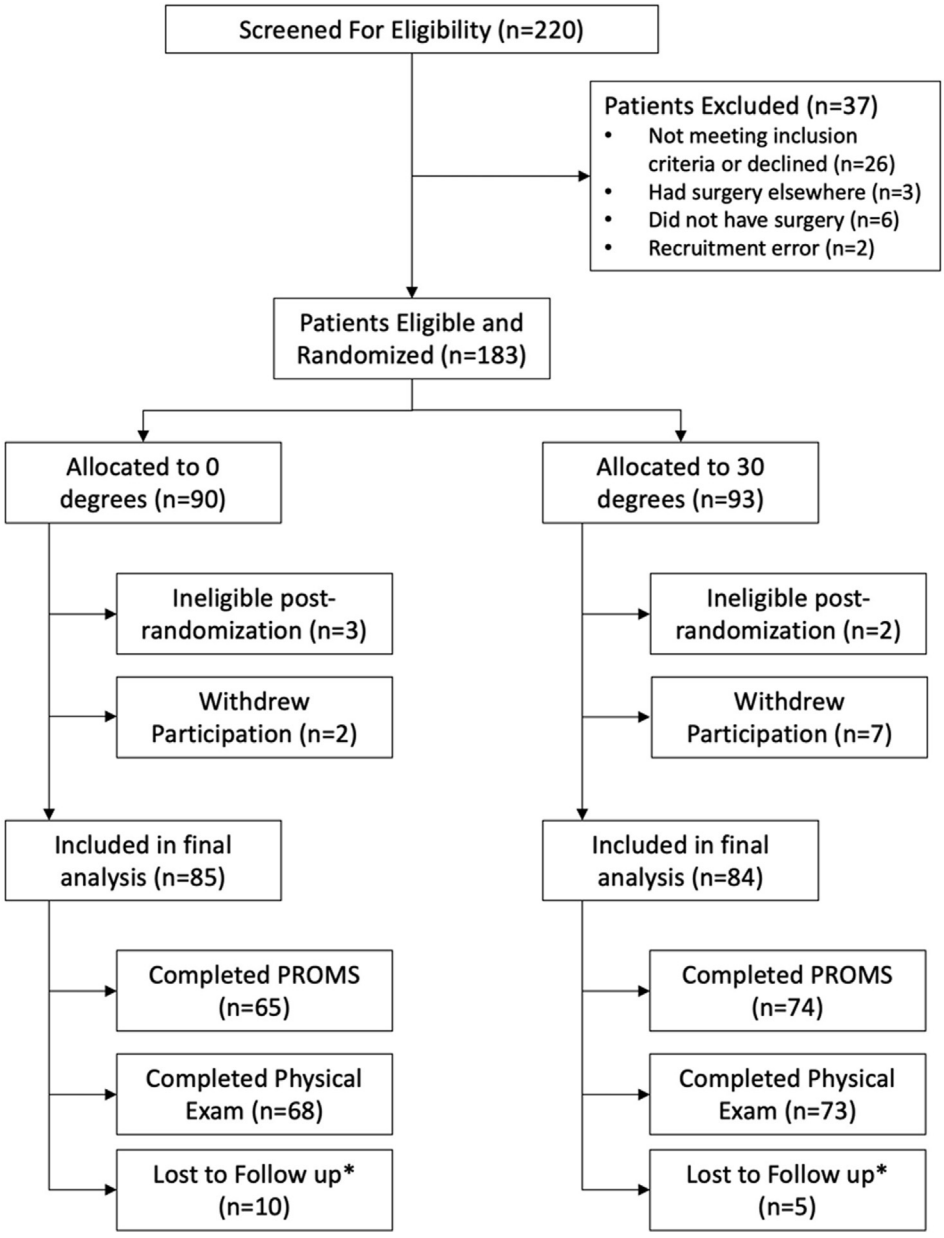

Figure 1. Participant flow diagram. *Lost to follow-up indicates patients that completed neither their patient-reported outcome measures nor their physical examination outcomes.

after surgery compared with patients who had fixation at 30° (9.6, 95% CI 8.5 to 10.6, versus 8.0, 95% CI 6.9 to 9.1, respectively; $P = .04$) (Table 3). Furthermore, 94% of patients fixed in full extension achieved the MCID for the KOOS pain subscale compared with 81% of patients who were fixed at 30° ($P = .04$). In terms of physical examination findings 1 year after surgery, we did not observe any significant differences in extension loss, prone heel heights, or KT-1000 findings among patients treated at 0° and 30° of graft fixation (Table 3).

Nine patients (5.9%) had a reoperation within the defined 2-year follow-up period for this study. The reoperation rate for patients treated at 0° and 30° was 2.4% (2/85) and 8.3% (7/84), respectively ($P = .10$). Among patients treated at 0°, the indications for reoperation were (1) new meniscus tear (n = 1) and (2) graft rupture (n = 1). For patients whose graft was fixed at 30°, indications for reoperation were (1) graft rupture (n = 1); (2) failed meniscus repair (n = 5); and (3) refractory arthrofibrosis (n = 1).

A post hoc analysis was performed after removing the 5 patients who underwent reoperation for failed meniscal repair, since this was improbably related to tensioning angle. This analysis demonstrated no change in significance of any outcomes (Table 4).

Table 1. Baseline patient characteristics

Characteristic	0°, n = 85	30°, n = 84	*P* Value
Patient factors			
Age (y)	27.7 (26.1 to 29.3)	29.3 (27.3 to 31.3)	.20
Male sex	61 (71.8)	49 (58.3)	.07
BMI (kg/m^2)	25.3 (24.4 to 26.1)	25.2 (24.3 to 26.0)	.88
Injury features			
Chondral lesion			
Total	37 (43.5)	35 (41.7)	.81
High grade	7 (8.2)	7 (8.3)	.98
Meniscal tear			
Medial	34 (40.0)	39 (46.4)	.40
Lateral	31 (36.5)	26 (31.0)	.45
Surgical details			
Meniscal repair	24 (28.2)	19 (22.6)	.40
Meniscectomy	27 (31.8)	33 (39.3)	.31
Microfracture	7 (8.2)	7 (8.2)	.98
Baseline outcome scores			
KOOS			
Pain	74.5 (71.4 to 77.6)	75.8 (72.2 to 79.3)	.60
Symptoms	55.2 (52.3 to 58.2)	57.2 (54.5 to 59.9)	.33
ADL	82.6 (79.3 to 85.9)	84.9 (81.7 to 88.1)	.33
Sport/play	48.6 (43.8 to 53.3)	49.0 (43.7 to 54.2)	.90
Quality of life	32.5 (28.7 to 36.4)	33.7 (29.7 to 37.7)	.67
Marx activity score	10.9 (9.9 to 12.1)	10.4 (9.2 to 11.6)	.53

Data are mean (95% confidence interval) or n (%). Age, BMI, and KOOS and Marx scores were analyzed using 2-tailed unpaired *t* tests. All categorical variables were analyzed using chi-square test of proportions. Abbreviations: ADL, activities of daily living; BMI, body mass index; KOOS, Knee Osteoarthritis Outcome Score.

Discussion

The most important findings in this study are that tibial fixation of the ACL graft at 0° versus 30° did not have an effect on KOOS scores, extension loss, AP stability, or reoperation after ACLR, whereas patients who were fixed in full extension were more likely to achieve the MCID for KOOS pain and demonstrated higher activity scores as measured by the Marx Activity Scale.

To our knowledge, this is the first randomized trial assessing the effect of KFA in patients undergoing anatomic ACLR.[14] We did not replicate the findings of a prior biomechanical studies that demonstrated benefit or harms of KFA at 30°.[15,30] Debandi et al.[15] showed increased rotational stability with graft fixation at 30° with anatomic ACLR, while Hoher et al.[30] found improved in situ contact forces at 30°, although while using a TT technique. Austin et al.[7] reported that in the setting of anatomic ACLR, the tensioning of the graft at 30° of knee flexion was associated with loss of knee extension. Our study did not evaluate contact pressures, pivot shift, or other rotational tests in follow-up, which presents an outcome of focus for future studies on this topic.

The current study assessed 2 KFAs specifically: 0° and 30°, consistent with comparator KFAs used in several biomechanical studies conducted previously.[14] It is possible that fixation at angles other than 30° could have had a different effect on the observed results. Kim et al.[5] recently performed an in vivo study to evaluate intraoperative graft isometry in anatomic single-bundle ACLR. Although the authors demonstrated that intra-articular length increased ≤3.5 mm from 120° to full extension, most of that change was observed between 120° and 30°. In fact, the average change in graft length between full extension and 30° was 0.4 to 0.6 mm,

Table 2. KOOS scores at 24 months

KOOS Test	0°, n = 65	30°, n = 74	Mean Difference (95% CI)	*P* Value
Pain	90.5 (88.1 to 92.8)	89.7 (87.1 to 92.4)	0.8 (−2.8 to 4.3)	.68
Symptoms	60.2 (57.8 to 62.7)	58.7 (56.6 to 60.8)	1.5 (−1.7 to 4.6)	.43
ADL	95.5 (93.8 to 97.3)	94.5 (92.4 to 96.6)	1.0 (−1.7 to 3.8)	.45
Sport/play	78.6 (74.7 to 82.5)	78.7 (74.3 to 83.1)	−0.1 (−6.0 to 5.8)	.97
Quality of life	68.8 (64.3 to 73.4)	68.7 (64.1 to 73.3)	0.2 (−6.3 to 6.6)	.54

Data are mean (95% CI). *P* values were produced using 2-tailed unpaired *t* tests. Abbreviations: ADL, activities of daily living; CI, confidence interval; KOOS, Knee Osteoarthritis Outcome Score.

Table 3. Summary of secondary outcomes

Patient-reported Outcome	0°, n = 65	30°, n = 74	*P* Value
Marx activity score	9.6 (8.5 to 10.6)	8.0 (6.9 to 9.1)	.04[a]
Achievement KOOS PASS			
Pain	41 (63.1)	43 (58.1)	.55[b]
Symptoms	44 (67.7)	50 (67.6)	.99[b]
ADL	25 (38.4)	22 (29.7)	.28[b]
Sport/play	48 (87.3)	53 (71.6)	.77[b]
Quality of life	46 (70.8)	53 (71.6)	.91[b]
Achievement KOOS MCID			
Pain	61 (93.8)	60 (81.1)	.04[c]
Symptoms	46 (70.8)	46 (62.2)	.28[b]
ADL	51 (78.5)	51 (68.9)	.20[b]
Sport/play	53 (81.5)	57 (77.0)	.42[b]
Quality of life	56 (86.2)	62 (83.8)	.70[b]
Physical examination	[d]	[e]	
Extension loss (°)	0.9 (0.6 to 1.2)	1.0 (0.5 to 1.4)	.86[a]
KT-1000 at 25° (mm difference)	0.4 (0.0 to 0.7)	0.4 (−0.1 to 0.9)	.82[a]
KT-1000 at 0° (mm difference)	−0.2 (−0.7 to 0.2)	0.2 (−0.2 to 0.6)	.12[a]
Prone heel height (mm difference)	1.0 (0.6 to 1.4)	0.7 (0.3 to 1.1)	.32[a]

Data are mean (95% confidence interval) or n (%). Abbreviations: ADL, activities of daily living; KOOS, Knee Osteoarthritis Outcome Score; MCID, minimal clinically important difference; PASS, patient-acceptable symptomatic state.

[a]Unpaired *t* test

[b]Chi-squared test.

[c]Fisher exact test.

[d]n = 68.

[e]n = 73.

depending on the amount of tension that was applied. Furthermore, graft tension (20 versus 30 lb) had a nonsignificant effect on changes in graft length from 0° to 30°. In the current study, the lack of an observed significant difference in knee extension and KT-1000 measurements between treatment groups may be explained by the small amount of graft excursion observed in anatomic reconstructions between 0° and 30°. There is also evidence that an anteromedial bundle tibial tunnel (consistent with our technique) is more isometric then a tunnel that is placed more posteriorly.[4] Finally, it is also possible that any constraint in ROM was overcome by a clinically imperceptible graft stretch/injury in patients fixed at 30°.[7,8]

Despite the lack of between-group differences in knee extension loss observed in this clinical trial, there was 1 patient in the 30° fixation group that had a captured knee with significant (15°) extension loss. This patient underwent a subsequent arthroscopy with lysis of adhesions and posterior capsulotomy, which restored extension partially. Ultimately, this patient had revision ACLR, which resulted in full extension and improved function. Based on this case, we suggest that if a surgeon decides to perform tibial fixation at 30°, an intraoperative examination should be performed to ensure that full extension can be achieved after fixation. If not, fixation should be revised in full extension or at a knee flexion angle beyond which there is minimal (<1 mm) graft excursion between the chosen angle and full extension.

Of note, secondary outcomes did demonstrate clinically and statistically differences in pain and activity states between the 2 treatment groups 2 years after ACLR. First, there was an increased likelihood of achieving MCID for KOOS pain in patients fixed in full extension. Although no differences in extension loss were observed, higher graft tension of a graft fixed at 30° does increase the quadriceps force required to achieve full knee extension after ACLR.[7] It is possible that this can be experienced as increased anterior knee discomfort in some patients owingto increased forces on extensor mechanism and hence the donor site for graft harvest. Second, patients fixed in full extension also had greater Marx Activity Scores yet statistically equivalent KOOS sports/recreation scores compared with those fixed at 30°. The former patient-reported outcome measure inquires about how often (i.e., frequency) patients engage in running, cutting, decelerating, and pivoting, whereas the latter asks about the degree of difficulty with squatting, running, jumping, pivoting, and kneeling. The 2 scales have overlapping items yet clear distinctions in how items are experienced that makes the 2 disparate outcomes plausible. Although it is not clear why patients who were fixed in full extension had better Marx Activity Scores at 2 years, this finding was replicated after removing the 5

Table 4. Post hoc analysis of outcomes after exclusion of those who had a failed meniscus repair

Patient-reported Outcome	0°, n = 65	30°, n = 69	*P* Value
KOOS scores at 24 mo			
Pain	90.5 (88.1 to 92.8)	89.7 (87.1 to 92.4)	.68[a]
Symptoms	60.2 (57.8 to 62.7)	58.7 (56.6 to 60.8)	.43[a]
ADL	95.5 (93.8 to 97.3)	94.5 (92.4 to 96.6)	.45[a]
Sport/play	78.6 (74.7 to 82.5)	78.7 (74.3 to 83.1)	.97[a]
Quality of life	68.8 (64.3 to 73.4)	68.7 (64.1 to 73.3)	.54[a]
Marx activity score	9.4 (8.3 to 10.5)	7.7 (6.5 to 8.9)	.04[a]
Achievement KOOS PASS			
Pain	41 (63.1)	41 (59.4)	.66[b]
Symptoms	44 (67.7)	48 (69.6)	.81[b]
ADL	25 (38.4)	22 (31.9)	.43[b]
Sport/play	48 (87.3)	50 (72.5)	.86[b]
Quality of life	46 (70.8)	50 (72.5)	.83[b]
Achievement KOOS MCID, n (%)			
Pain	61 (93.8)	55 (79.1)	.02[c]
Symptoms	46 (70.8)	43 (62.3)	.30[b]
ADL	51 (78.5)	46 (66.7)	.13[b]
Sport/play	53 (81.5)	53 (76.8)	.50[b]
Quality of life	56 (86.2)	58 (84.1)	.73[b]
Physical examination	[d]	[e]	
Extension loss (°)	0.9 (0.6 to 1.2)	0.9 (0.5 to 1.3)	.96[a]
KT-1000 at 25° (mm difference)	0.4 (0.0 to 0.7)	0.3 (−0.2 to 0.9)	.92[a]
KT-1000 at 0° (mm difference)	−0.3 (−0.6 to 0.1)	−0.1 (−0.4 to 0.3)	.39[a]
Prone heel height (mm difference)	1.0 (0.6 to 1.4)	0.7 (0.3 to 1.1)	.33[a]

Abbreviations: ADL, activities of daily living; KOOS, Knee Osteoarthritis Outcome Score; MCID, minimal clinically important difference; PASS, patient-acceptable symptomatic state.

[a]Unpaired *t* test

[b]Chi-squared test.

[c]Fisher exact test.

[d]n = 68.

[e]n = 73.

patients with failed meniscal repair in those fixed at 30°. It is possible that there is an association of higher scores on the Marx Activity Scale with a greater proportion of patients achieving the MCID for KOOS pain in the full extension group. In a recent study performed by our group, KOOS pain at 1 year was an independent predictor of single-leg hop performance and psychological readiness to return to sport in patients who underwent ACLR.[31] Hence the implications of a relatively pain free state as they relate to activity are significant.

To summarize, graft fixation in full extension created a state in which patients had less pain and were able to participate in running, cutting, decelerating, and pivoting activities more frequently compared with tibial graft fixation at 30° of knee flexion. This is certainly a favorable clinical outcome that has real implications for how patellar tendon grafts should be fixed on the tibial side during ACLR. Based on the findings in this study as they relate to the above secondary outcomes, the authors currently prefer to fix the ACL graft in full extension or at a knee flexion angle beyond which there is minimal (<1 mm) graft anisometry between the selected angle and full extension.

The strengths of this study include its level I design, concealed randomization, blinding of assessors and patients, follow-up rate (>80% for the primary outcome), and inclusion of patient-reported outcomes, as well as physical examination parameters that are pertinent to the specific aims of this study.

Limitations

This study has several limitations. First, our study may be underpowered to detect between-group differences. We achieved our recruitment target and a follow-up rate (82%) greater than our accounted-for loss to follow-up from our power calculation (80%). However, because of asymmetric loss to follow-up, the number of patients in the 0° group with completed outcomes (n = 65) was lower than our proposed per-group sample after accounting attrition (n = 67). This leaves the potential of type II error due to a lack of power. Second, some specific surgical variables such as graft tensioning and tunnel placement were not standardized across surgeons. Although some trials comparing different tensioning protocols have failed to demonstrate differences in outcomes with bone-to-bone (BTB) grafts,[32-34] others have suggested an important effect of graft tensioning on ACL outcomes.[35,36] This indicates the

potential for confounding with the unstandardized tensioning force in our pragmatic design. Third, physical examination outcomes were captured at 1 year after surgery versus the 2-year assessment of patient-reported outcomes, which may limit the long-term validity of our results. However, it has previously been demonstrated that the stability of BTB grafts is unlikely to attenuate beyond 6 weeks post-operatively.[37] Future studies examining graft fixation angles could incorporate a factorial trial design,[38] in which the effects of discrepant in-line graft tensioning and reverse Lachman forces are also examined with longer follow-up for all outcomes. Additional outcomes of interest could also be considered, including graft healing using quantitative MRI techniques, rotational stability, and functional performance data.

Conclusions

In the setting of anatomic single-bundle ACLR using patellar tendon autograft and anteromedial portal femoral drilling, there was no difference in KOOS scores among patients fixed at 0° and 30°. Patients fixed in full extension did demonstrate higher activity scores at 2 years after surgery and a greater likelihood of achieving the MCID for KOOS pain.

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