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## Double-bundle PCL reconstruction using autogenous quadriceps tendon and semitendinous graft: Surgical technique with 2-year follow-up clinical results

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#### ABSTRACT

*Objective:* The objective of this study was to evaluate the results obtained from posterior cruciate ligament (PCL) reconstruction with the double femoral tunnel technique, using quadriceps tendon and semitendinous autograft, in patients with isolated PCL tears or PCL tears associated with other ligament lesions, 2 years after surgery. *Methods:* The study included 14 patients with isolated PCL lesions and 20 with combined ligament lesions, who underwent PCL reconstruction using the double femoral tunnel technique and were evaluated 24 months after surgery using the International Knee Documentation Committee (IKDC) and Lysholm scores, a KT-1000 arthrometer, and the graduation of the posterior drawer test.

*Results:* Knees were considered normal ("A") or nearly normal ("B") in 92.9% of patients with isolated lesions and in 95.0% of patients with combined tears, according to the IKDC score. Good or excellent results were obtained in 100% of patients in both groups according to the Lysholm score. Absence or outstanding reduction of posterior tibial translation was seen in 92.9% of patients with isolated lesions and in 100% of patients with combined ligament tears, in the posterior drawer evaluation.

*Conclusion:* The PCL double femoral tunnel reconstruction technique using autografts was effective in restoring posterior knee stability, in isolated and/or combined PCL tears, showing remarkable clinical improvement in all patients.

Level of evidence: 2C.

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### 1. Introduction

The posterior cruciate ligament (PCL) provides restraining force against the posterior tibial translation, resisting between 85% and 100% of the forces directed posteriorly during knee flexion [1]. The PCL can be functionally divided in two parts: a higher anterolateral (AL) bundle and another, smaller, bundle, posteromedial (PM) [2–5], although some authors consider this division as somewhat arbitrary and simplified for such a complex structure [6,7].

Despite advances in techniques for PCL reconstruction, the results of surgical treatment of this ligament are not comparable to those of the reconstruction of the anterior cruciate ligament (ACL), probably due to several factors that affect the outcome and that are still a matter of controversy [5,8], including the number of bundles to be reconstructed, better positioning of the tunnels, the best method for graft fixation, inlay

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http://dx.doi.org/10.1016/j.knee.2014.02.021 0968-0160/© 2014 Elsevier B.V. All rights reserved. reconstruction versus transtibial tunnel, and the degree of graft tension during surgery.

Many authors have observed that reconstruction with single bundle provides good stability and restores the biomechanics of the knee immediately after surgery, but in some cases, with time, again the patient presents with abnormal posterior translation [9], secondary to a possible stretching of the graft caused by unequal distribution of tension forces [10]. Moreover, reconstruction with single bundle is not effective to correct the posterior laxity with the knee near extension, and with rotational instability in flexion angles >90° [11,12]. In an attempt to address these limitations, the double-bundle reconstruction was introduced.

Reconstruction with two femoral tunnels has been shown to be biomechanically superior compared with single bundle, providing better distribution of forces between the grafts and better stability throughout the range of motion [12–14]. Reconstruction with double bundle has also proved to be superior in a prospective randomized clinical trial [15]. The inlay reconstruction, although leading to lower subsequent degeneration of the graft in the posterior tibia, does not present clinical superiority in the published results [16–18].

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The use of homologous grafts in the reconstruction of the PCL is generally preferred in the literature due to lower morbidity and shorter surgical time, especially in combined lesions [19–21]. The use of autologous grafts, however, is a viable option in situations where a tissue bank is not available, besides having the theoretical advantage of a faster integration and eliminating the risk of transmitting diseases.

Despite many articles describing various techniques for PCL reconstruction and associated structures, few studies with long-term followup are available. The authors consider that the double-bundle reconstruction is effective and reproducible, and the objective of this study is to demonstrate the results obtained with this technique after 2 years of postoperative follow-up.

### 2. Patients and methods

### 2.1. Patients

This prospective study included all patients who underwent PCL reconstruction and associated lesions, when present, from September 2002 to March 2008 in the same service (a public university hospital) by the same surgeon. The study was approved by the ethics committee of the institution and the patients signed an informed consent form.

We considered the following as inclusion criteria: skeletally mature patients, regardless of age, who had intra-substantial, isolated ligament injuries (grade 2 or 3) or combined PCL lesions, regardless of the time of injury, with a normal contralateral knee. Patients with radiological signs of osteoarthritis, previous knee surgeries, fractures or major soft-tissue injuries around the knee were excluded from the study. Furthermore, those patients who were not willing to follow the protocol of postoperative rehabilitation or who were not able to attend physical therapy in our service were also excluded.

During the study period, 34 patients were included, 14 with single lesions and 20 with combined lesions, mostly men (82.4%). Half of the patients had the right knee affected. The mean age was 31.45 years (21–44 years).

The same surgeon evaluated the 34 patients preoperatively and postoperatively. Physical examination included assessment of the alignment of the lower limbs, abnormalities during gait, and range of motion of the affected knee, compared with the contralateral knee. The clinical test used to evaluate the PCL was the posterior drawer test with the knee at 90° in neutral position. The result was considered normal when there was no difference in posterior translation of the tibia compared with the contralateral side; grade 1, when the tibial anteromedial (AM) margin had a small posterior translation, but remained anterior to the medial femoral condyle; grade 2, when the tibial anterior margin was in line with the medial femoral condyle; and finally grade 3, when the tibial anterior margin was posterior to the medial femoral condyle [22].

The associated ligament injuries were evaluated through the opening maneuvers in varus and valgus with the knee in extension and in flexion of 30° to access the integrity of the capsule and collateral ligaments, posterior drawer maneuvers in internal and external rotation, external tibial rotation maneuver to 30° of flexion, and the reverse pivot-shift test for the posterolateral corner injuries. Lachman and pivot-shift tests were also performed to assess the sufficiency of the ACL.

A magnetic resonance imaging (MRI) study was performed preoperatively in all patients to confirm the diagnosis of rupture of the PCL and associated ligament injuries.

The evaluation with a KT-1000 arthrometer (MEDmetric Corp., San Diego, CA, USA) was considered as follows: when the posterior laxity, compared with the normal contralateral side, was between 0 and 2 mm, the patient was considered "normal"; when between 3 and 5 mm, as "grade 1"; when between 6 and 10 mm, as "grade 2"; and when above 10 mm, as "grade 3."

In patients with isolated lesions, PCL reconstruction was indicated in those with instability grade 3 at physical examination and in those with grade 2 after 6 months of physical therapy, still with pain or instability. In the cases of PCL lesions associated with other ligament injuries, surgical reconstruction was always indicated, due to the great instability, and evaluated both objectively and subjectively in these patients.

All patients were evaluated preoperatively and postoperatively with 6, 12, and 24 months by the International Knee Documentation Committee (IKDC) form [23], the Lysholm scale [24], by the KT-1000, and by the graduation of the posterior drawer, as already described, with all tests performed by the same author (RLPC). Reassessments were performed at 24 months after the initial surgery. The radiographic evaluation performed preoperatively consisted of an orthostatic panoramic radiograph of the lower limbs, to evaluate the alignment, and profile radiographs of the knees. The examinations were repeated postoperatively, except for the panoramic radiograph, which was replaced by the anteroposterior radiograph of the operated knee.

The same surgeon (RPLC) performed all surgical procedures in this study.

#### 2.2. Surgical technique

The procedure begins with a clinical examination under anesthesia to check the instability grade and the presence of associated lesions. The patient is then positioned in supine with a pneumatic tourniquet on the distal thigh. A metal bar is attached to the operating table, beside the patient, next to the distal thigh, to work as a bulkhead, facilitating arthroscopic inspection of the medial compartment.

With the knee flexed in 90°, the quadriceps tendon graft is harvested from the muscle central third, through a longitudinal incision of 50 mm, from the patellar superior pole proximally. The graft obtained is 10-mm wide and measures 130–150 mm in length at maximum. The bone fragment from the patella is trapezoidal, measuring  $20 \times 10 \times 5$  mm. The semitendinosus tendon is isolated and harvested with the aid of a closed tenotomy scissor, through a second longitudinal incision, 40-mm long, in the anterior medial aspect of the ipsilateral leg at the midpoint between the posterior margin of the tibia and the anterior tuberosity.

After closing the donor areas, we open the AM and AL portals. A 15-mm-long PM portal is routinely used to drill the tibial tunnel in order to pass the grafts.

The next step is to prepare the graft by removing residual muscle tissue with the aid of a curette and by preparing the tendon ends with polyester nonabsorbable suture (Ethibond) number 5, one at each end of the semitendinosus tendon and two for the quadriceps tendon. We carefully separate the three layers of the quadriceps, joining the superficial and intermediate layers (rectus femoris, vastus medialis, and lateralis tendons) with one suture and the deep layer (vastus



Fig. 1. Prepared quadriceps and semitendinous tendons grafts.

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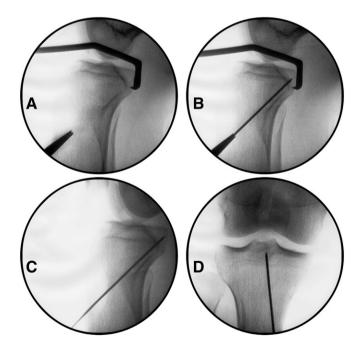
intermedius tendon) with the second suture (Fig. 1). The tendinous portion of the two grafts is prepared for a tibial tunnel of 12 mm, which was drilled in all patients.

Arthroscopy is initiated with an oblique scope (30°), introduced by the AL portal. The surgical procedure begins with the removal of PCL residues in the femur, through the AM portal, and in the tibia, through the PM portal. We then prepare the tibial tunnel with a guide 45° in the posterior region, in the lower half of the PCL facet. We check for the correct positioning by fluoroscopy. Then we drill the 12-mm tunnel. To reduce the risk of injury to the neurovascular bundle during drilling of the tibial tunnel, the knee is bent at an angle of about 100°, and the end of the tunnel is made by manual rotation of the drill (Fig. 2).

Femoral tunnels are also drilled from the outside-in of the knee joint through a longitudinal incision in the medial femoral condyle, in the median point between the joint cartilage and the femoral epicondyle. The guide, with an angle of 45°, is introduced through the AM portal up to the side of the medial femoral condyle, corresponding to the AL tunnel. A 10-mm tunnel (for the AL bundle) is drilled, guided by the remaining residues of the PCL, in a position of 1 h (right knee), with its center at a distance of 7 mm from the articular cartilage. The second tunnel, 7-mm wide (for the PM bundle), is placed proximally and posteriorly to the first, maintaining a bone bridge of 2–3 mm distance between them with its center located 9 mm from the articular cartilage (Fig. 3).

The grafts are inserted through the AM portal, toward the tibia, and passed through their respective tunnels. Thus, the semitendinosus tendon, folded over itself (Fig. 1), enters first and reproduces the PM bundle, and the quadriceps tendon, the AL bundle. The femoral fixation is made with interference screws introduced from outside to inside and tibial fixation is made with 4.5-mm cortical screws, with washers for soft tissues, independently for each graft. The quadriceps tendon graft is fixed with the knee at 90° of flexion, after reducing the posterior deviation, and the semitendinosus tendon is fixed with the knee extended, both after a pre-tensioning maneuver (Fig. 4). The tension of each graft is done manually during 20 cycles of flexion–extension of the knee.

When there is an ACL-associated injury, ACL reconstruction is performed in the same surgery, using the central third of the patellar



**Fig. 2.** A) Positioning of the tibial guide. B) Guide-wire passing through the tibia. C) Positioning of the guide-wire in the median point of the lower half of the posterior cruciate ligament (PCL) facet (profile). D) Positioning of the guide-wire in the central region of the PCL in the tibia.

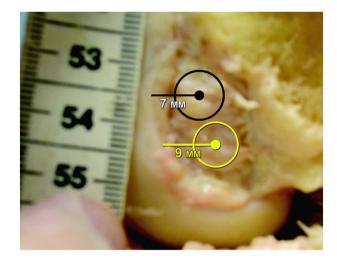


Fig. 3. Positioning of the femoral tunnels, anterolateral at 7 mm and the posteromedial at 9 mm from the articular cartilage.

ligament from the contralateral limb (bone-tendon-bone); the tibial tunnel is made with an external guide, with an angle of 55°, and the femoral tunnel is made by the transtibial route. The fixation of the ACL graft is performed with titanium interference screws, with the knee in full extension.

In cases of injury to the posterolateral compartment, the technique described by Fanelli-Larson [25] is used for reconstruction, taking the semitendinosus muscle tendon graft from the contralateral knee. The graft is obtained the same way as in the case of PCL reconstruction, but it is not folded over itself.

In combined lesions, we fix the PCL initially (femoral and tibial tunnels) and then proceed to the posterolateral reconstruction. The ACL reconstruction is then performed with the knee in total extension.

In cases where there are associated meniscal injuries, patients undergo arthroscopic partial meniscectomy. Cases with chondral lesions, with exposure of subchondral bone (Outerbridge grade 4) [26], are treated with microfractures. The other articular cartilage lesions, such as fissures and fibrillations, are regularized with the aid of motorized instruments. Meniscal and chondral lesions are treated in the same surgery.

### 2.3. Postoperative care

In the rehabilitation protocol used, previously published [27,28], for isolated lesions, the load was allowed early, in the first 2 weeks, and partially, with the use of crutches and a locked immobilizer in extension until the sixth week. In cases of combined injury (ACL, posterolateral corner), the load was released only in the sixth postoperative week. The objective was to obtain full range of motion of the knee until the second month, avoiding the contractures resulting from the tissuehealing process. Strengthening exercises and sensorineural training were oriented, avoiding overload on the graft and respecting the periods of scarring.

### 2.4. Statistical analysis

The software used for the statistical analysis was SPSS (Statistical Package for Social Sciences) for Windows, version 13.0.

For quantitative variables, the averages were calculated. For the qualitative variables, we calculated absolute and relative frequencies. The examination of the association between qualitative variables was performed using the chi-square or Fisher's exact test. The evaluation of patient outcomes between the preoperative and postoperative periods should have been done by the McNemar test, but due to the small sample size, this test could not be employed. Comparison of quantitative variables

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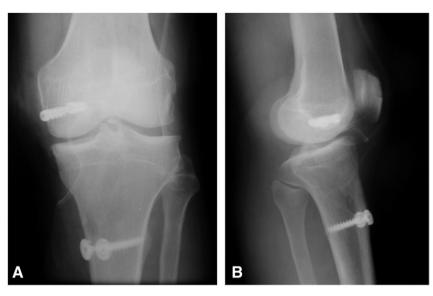


Fig. 4. Radiograph showing the graft fixation. A) Anteroposterior and B) profile incidences.

between the preoperative and postoperative periods was performed using the Wilcoxon test. The significance level was set at 5%.

#### 3. Results

Initially, the groups were compared, using the appropriate tests, regarding demographic and clinical variables (age, gender, side, chronicity, and interval between trauma and surgery). No difference was found between the groups. Time between trauma and surgery was greater in the group with isolated PCL lesion, but the difference was not statistically significant (Table 1).

Two patients of the group with isolated lesions had complications (14.3%), one having pain due to a meniscal lesion in the posterior horn of the medial meniscus, 1 year after the surgery, and the other due to loss of the operated knee flexion. Both required a second surgery (arthroscopic partial meniscectomy in the first and the second with arthroscopy and manipulation). In the group of patients with combined lesions, only one patient (5.0%) did not achieve the expected range of motion, requiring a second surgery to release adhesions and manipulation.

Tables 2–5 show the results in the functional scales (IKDC and Lysholm), the evaluation by the KT-1000, and the posterior drawer test. The group with combined lesions had a tendency to exhibit worse results, but the difference was not significant in the preoperative period. Statistical comparison of the Lysholm scores preoperatively was not possible due to sample size. The IKDC score and posterior drawer test showed no statistically significant differences between groups. In three patients, all belonging to the group with combined lesions, the evaluation by KT-1000 was not possible due to lesions in the contralateral knee.

In the postoperative period, it was not possible to statistically analyze the IKDC score, the KT-1000 evaluation, and the posterior drawer test results due to the sample size. The Lysholm score showed no difference between the groups, although the absolute number of cases considered "excellent" or "normal" was higher in the group with isolated lesions in both the Lysholm and IKDC scores.

The comparison between preoperative and the 24-month postoperative periods in both groups showed evident improvement in the Lysholm, IKDC, KT-1000, and the posterior drawer evaluations.

#### 4. Discussion

The results obtained in our series, employing PCL reconstruction with autologous grafts using double tunnel in the femur, show a clear improvement in all operated cases, with isolated or combined lesions, regardless of the evaluation criteria used (IKDC, Lysholm, or posterior drawer). Overall, we obtained 94.1% of normal and near-normal results in IKDC, 100% good and excellent results in the Lysholm score, and 97% negative rotation or obvious improvement in the evaluation by KT-1000 and by the posterior drawer test.

Several studies have demonstrated the biomechanical superiority of the reconstruction with double bundle in restoring the translational and rotational stability of the knee throughout the range of motion [9–14], but clinical outcomes have varied. In a study with 2 years of followup, Nyland et al. [29] showed normal or nearly normal results in 87% of cases in the subjective IKDC, and 90% of patients had good or excellent results in the Lysholm score. Yoon et al. [15] found good and excellent results in the Lysholm score in 93% of patients. Chen and Gao [30], in a series with 22 patients who underwent PCL reconstruction with double bundle in isolated lesions, reported 78.9% of normal and 15.8% almost normal results in the IKDC score, with a minimum follow-up of 2 years. Garofalo et al. [31], in turn, showed abnormal results in 40% of their patients undergoing PCL reconstruction with double bundle. Zhao et al. [32], using eight strips of flexor tendon in the reconstruction with double tunnel, had 100% results classified as normal or nearly normal in the IKDC. These findings, except for the results of Garofalo et al. [31], are superior to those achieved in the systematic review by Kim et al. [33], about reconstructions with single bundle (75% satisfactory results) in the treatment of isolated PCL injuries. The results of our series demonstrate a large percentage of satisfactory results (100% good and excellent according to the Lysholm scale and 94.1% of normal and almost normal according to IKDC) confirming the effectiveness of the technique of PCL reconstruction with double tunnel.

Another important point in our study was the attempt to compare the results obtained in each group (isolated lesions vs. combined lesions). Unfortunately, the statistical comparison between groups was not possible due to the limited sample size. However, we detected

#### Table 1

Baseline data comparison between groups with isolated lesions of the posterior cruciate ligament (PCL) or lesions combined with other ligament tears.

	Isolated PCL lesion ( $n = 14$ )	Combined ligament lesions $(n = 20)$	р
Age (years, mean)	32.5	30.4	0.345
Male gender (n)	11	17	0.672
Affected side (right, n)	7	10	>0.99
Chronicity	0A/14C	2A/18C	0.501
$\Delta t$ (from trauma to surgery, weeks, mean)	47.571	25.640	0.123

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#### Table 2

KT-1000 data comparison between groups with isolated lesions of the posterior cruciate ligament (PCL) or lesions combined with other ligament tears, before and after surgery.

		Normal (0 to 2 mm)	Grade 1 (3 to 5 mm)	Grade 2 (6 to 10 mm)	Grade 3 (>10 mm)	Not evaluated	Total
Before	Isolated PCL lesion	0	0	5 (35.7%)	9 (64.3%)	0	14 (100%)
	Combined ligament lesions	0	0	4 (20.0%)	13 (65.0%)	3 (15.0%)	20 (100%)
After	Isolated PCL lesion	8 (57.1%)	5 (35.7%)	1 (7.1%)	0	0	14 (100%)
	Combined ligament lesions	11 (55.0%)	6 (30.0%)	0	0	3 (15.0%)	20 (100%)

### Table 3

Posterior drawer results comparison between groups with isolated lesions of the posterior cruciate ligament (PCL) or lesions combined with other ligament tears, before and after surgery.

		Normal	Grade 1	Grade 2	Grade 3	Total
Before	Isolated PCL lesion	0	0	5 (35.7%)	9 (64.3%)	14 (100%)
	Combined ligament lesions	0	0	4 (20.0%)	16 (80.0%)	20 (100%)
After	Isolated PCL lesion	8 (57.1%)	5 (35.7%)	1 (7.1%)	0	14 (100%)
	Combined ligament lesions	12 (60.0%)	8 (40.0%)	0	0	20 (100%)

a slight tendency to better postoperative outcomes in patients with isolated injuries: considering the IKDC score, 21.4% of patients with isolated PCL lesions were classified as normal ("A"), 71.4% as near normal ("B"), and 7.1% as abnormal ("C"). On the other hand, in the group with lesions combined, no patient was considered normal, 95% were nearly normal, and the remaining had abnormal results. In the Lysholm score, 57.1% of the patients with isolated lesions were classified as excellent and 42.9% as good, compared with 35% in the group with combined lesions who were classified as excellent and 65% as good. In the posterior drawer test, on the other hand, interestingly, the group with combined lesions showed slightly better results: 60% of patients in this group had negative results (0-2 mm) and 40% with positive results (3-5 mm), with no cases of posterior instability of more than 5 mm postoperatively. In the isolated lesions group, 57.1% of the patients with isolated lesions showed a negative posterior drawer (0–2 mm), 35.7% + (3-5 mm) and 7.1% + + (6-10 mm). This, in our opinion, raises the question: is there the possibility that some patients with lesions considered "isolated" PCL lesions actually also have an asymptomatic injury of posterolateral corner structures that were not detected by the clinical and radiological evaluations initially performed? Considering that often the mechanisms of trauma were of high energy, a PCL injury alone becomes even less likely. When comparing the clinical scores preoperatively and postoperatively, it was noted that there was a much more pronounced improvement in patients with combined injuries, who had a more traumatized knee preoperatively due to multiple ligament injuries. The literature is scarce in the comparison of results between isolated and combined PCL lesions. In their review article, Hammoud et al. [34] found no differences in the IKDC and Lysholm scores in the comparison of isolated and combined PCL lesions. Patients with isolated lesions, however, showed a higher rate of return to the pre-injury level of activity [34].

We used autografts in all our cases, as we did not have availability of grafts in our tissue bank at the time when patients were treated in this series. Current literature indicates the use of homologous grafts, especially in cases of multiple ligament injuries, due to its greater thickness and no donor site harm [19–21]. In a recent systematic review, Hudgens et al. [35] evaluated the results of PCL reconstruction with autologous grafts versus allografts, concluding that both confer similar clinical and functional results in 2 years of follow-up, despite the low availability of data for a more precise analysis. Wang et al. [36], in a prospective study comparing autografts and allografts for PCL reconstruction, found no significant differences in functional and clinical scores and in radiographic changes between the two groups, with a higher rate of complications in reconstructions using autografts. In fact, we have observed some disadvantages with the use of autografts, such as long surgical time, which would increase the complication risk, and the postoperative morbidity, especially in cases with combined ACL reconstruction (in these cases, besides the flexor tendons, the contralateral patellar tendon was also grafted; therefore, an invasive procedure has to be performed in a healthy knee joint, with increased risk for complications and important functional abnormalities). Nevertheless, the high percentage of good and excellent results observed in our series showed that autologous grafts are a viable and effective option, especially where there is no access to a tissue bank, always having in mind the potential complications, especially when the contralateral knee is used for graft harvesting.

Finally, we noted a low complication rate (8.8% in total, 14.3% in the group with isolated lesions and 5% in the group with combined lesions), with only one case of persistent pain due to a new meniscal injury (in the group with isolated lesions), and two cases of range of motion loss due to arthrofibrosis (one in each group). Furthermore, when present, such complications were of relatively simple resolution (arthroscopic partial meniscectomy; manipulation and arthroscopic release of adhesions), allowing patients to achieve good results and good functional level. To our surprise, we have not observed major complications related to multiple graft harvesting. The only problem was pain, which was treated with analgesics.

As limitations, our study did not show a control group, both regarding the type of graft (autografts vs. allografts) and regarding surgical technique (single vs. double bundle), with which the results of this

#### Table 4

International Knee Documentation Committee (IKDC) results comparison between groups with isolated lesions of the posterior cruciate ligament (PCL) or lesions combined with other ligament tears, before and after surgery.

		А	В	С	D	Total
Before	Isolated PCL lesion	0	0	4 (28.6%)	10 (71.4%)	14 (100%)
	Combined ligament lesions	0	0	2 (10.0%)	18 (90.0%)	20 (100%)
After	Isolated PCL lesion	3 (21.4%)	10 (71.4%)	1 (7.1%)	0	14 (100%)
	Combined ligament lesions	0	19 (95.0%)	1 (5.0%)	0	20 (100%)

(A: normal; B: almost normal; C: abnormal; D: severely abnormal).

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### Table 5

Lysholm score results comparison between groups with isolated lesions of the posterior cruciate ligament (PCL) or lesions combined with other ligament tears, before and after surgery (In parenthesis, the range of score for each assignment).

		Excellent (95–100)	Good (84–94)	Fair (65–83)	Poor (<65)	Total
Before	Isolated PCL lesion	0	1 (7.1%)	9 (64.3%)	4 (28.6%)	14 (100%)
	Combined ligament lesions	0	1 (7.1%)	3 (15.0%)	16 (80.0%)	20 (100%)
After	Isolated PCL lesion	8 (57.1%)	6 (42.9%)	0	0	14 (100%)
	Combined ligament lesions	7 (35.0%)	13 (65.0%)	0	0	20 (100%)

study could have been compared. The posterior drawer test, although widely used in clinical practice, is a subjective measurement, which can significantly alter the results. The values of the KT-1000 were considered at intervals, and not by their absolute values in each case, making it difficult to compare statistically and being a possible cause of bias. Finally, the sample available for this study was small, mainly due to the relative rarity of PCL injuries, which hampered a more concrete statistical analysis.

### 5. Conclusion

Surgical treatment of injuries of PCL with double-bundle reconstruction, in isolated or combined lesions, using autologous grafts provided good or excellent results after 2 years of follow-up, both in clinical and in validated scores, with a low complication rate.

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