Original article

ACL reconstruction using a bone patellar tendon bone (BPTB) allograft or a hamstring tendon autograft (GST): a single-center comparative study

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Summary. *Background and aim of the work:* There is still debate on which graft is better indicated for anterior cruciate ligament (ACL) surgical reconstruction. The objective of this study was to evaluate the medium-term clinical outcomes of ACL reconstruction comparing patients managed with bone patellar tendon bone allograft (BPTB) versus patients treated with hamstring autograft (GST). *Methods:* Patients enrolled during the period 2013-2016 underwent a personal interview with the use of specific evaluation questionnaires (Tegner e Lyshom, Knee Injury and Osteoarthritis Outcome Score, International Knee Documentation Committee), a clinical evaluation with the use of objective functional tests (Lachman test, pivot-shift) and a physical examination of the knee. *Results:* In this study 43 patients were enrolled: 21 patients were treated by autograft and 22 patients by allograft. Patients who received allograft ACL reconstruction returned to normal sport activity earlier than patients operated on using autograft (11.7±10.3 vs 17.9±14.6 weeks, $p<0.05$). Data obtained with subjective tests, clinical and physical examination were positive overall, with no differences observed between the two groups. Finally, 15 allograft patients and 12 autograft patients accepted to perform the proprioceptive tests: no difference was found between the two groups. *Conclusions:* At follow-up evaluation after ACL reconstruction, both BPTB allograft and GST autograft patient groups showed similar results at subjective, objective clinical evaluation and proprioceptive properties of the limb. In particular, the use of allogenic BPTB allowed the patients to return earlier to normal activities of daily-living and sport activity. (www.actabiomedica.it)

Key words: ACL reconstruction, BPTB allograft, GST autograft, limb proprioceptive properties

Introduction

The Anterior Cruciate Ligament (ACL) is a key structure in the knee, acting as the primary restraint to anterior tibia displacement (1). Although ACL tears are common in orthopedic clinical practice (1), the optimal treatment for ACL tears remains controversial (1-3). Nowadays, there is still a debate on which type of graft is the most ideal ACL reconstruction. Three types of graft have been described: biological autograft, allograft and synthetic grafts (4). At the present time, synthetic grafts are less utilized, because most of orthopedic surgeons prefer hamstring autograft tendons or the patellar allograft tendon for anterior cruciate ligament reconstruction (ACLR) (4). In fact, the recent literature has suggested the use of biological autografts, especially in young patients, due to their potential for remodeling, tendon to bone healing and the advances they present when compared with allografts (5). Among the available graft options, hamstring tendon autografts with doubled semitendinosus tendon and gracilis tendon have become the most commonly used type for ACL reconstruction (6).

The comparison of clinical outcomes reported by allograft tissue vs autograft have led to contradictory results, with some case series reporting no differences in outcomes and others reporting an increased risk of failure (7-10). A systematic review showed no significant differences in graft failure rate, postoperative laxity or patient-reported outcome scores when comparing ACLR with autografts and non-irradiated allografts (11). Some authors reviewing the literature have underlined that bone patellar tendon bone (BPTB) allograft tissue used for ACLR presents a higher risk compared with surgery performed with a BPTB autograft (8). The differences between outcomes of allograft ACLR may be dependent on the fact that there are numerous protocols of processing and preparation (12, 13). The influence of these protocols on the allograft tissue is still to be defined. While some authors found that non-processed allografts and those irradiated with <1.8 Mrad, with or without chemical processing, did not have a different risk of revision compared with hamstring autografts after 2.5 years; others argued that these processes led to a different risk of revision (1).

In addition, anatomical and age factors may influence the outcome of ACLR. Lansdown et al. demonstrated that load to failure and graft stiffness varied across different tissue types. Regional differences were noted in patellar tendon grafts, with the central third showing the highest load to failure and stiffness. Graft diameter and donor age (older than 40 years, and especially older than 65 years), negatively impacted biomechanical properties, whereas gender had only a minimal effect (14).

Several studies that compared the outcome of autografts and allografts have failed to reach a conclusion as to which is the better, possibly because of different fixation materials and non-prospective study designs (15-21). In this contradictory context, the aim of the present study was to evaluate and compare the clinical outcomes and the results of subjective and proprioceptive tests of a series of patients who underwent ACLR with fresh-frozen bone patellar tendon bone allograft (BPTB) and ACLR with hamstring autograft (GST).

Material and Methods

Patients

From January 2013 to January 2016, a consecutive series of patients diagnosed with acute ACL ruptures underwent ACLR at our Level I healthcare trauma centre. All subjects participating in this study received a thorough explanation of the risks and benefits of inclusion and gave their oral and written informed consent to publish the data. The study was performed in accordance with the ethical standards of the 1964 Declaration of Helsinki as revised in 2000 and those of Good Clinical Practice (22).

Patient Selection

The inclusion criteria were instability due to ACL deficiency, with or without meniscal injury, treated by primary unilateral reconstructions of the ACL. All patients considered in this study had to be between 18 and 43 years of age and give their informed consent to participate. Exclusion criteria were as follows: patients with posterior cruciate ligament (PCL) injury or collateral ligament injury at the time of surgery, acute or chronic injuries in the same or contralateral leg, chondral injury of grade 2 or higher evaluated according to the Outerbridge classification system (23), degenerative joint disease of grade 2 or higher according to Kellgren-Lawrence score (24), and metabolic bone disease. All patients had a preoperative magnetic resonance imaging scan to exclude combined, complicated ligament injuries to their knees.

Surgical Technique

All patients underwent an intraoperative clinical examination under anaesthesia, followed by a diagnostic arthroscopy to confirm the preoperative diagnosis and to evaluate other intra-articular injuries (Figure 1). All ACLR procedures were performed by the same senior arthroscopic surgeon using a trans-tibial approach. In all operations, plexus anaesthesia was performed consisting in a regional block, which involved both sciatic and femoral nerves (bi-block), while sedation was used when necessary. Prophylactic cefazolin

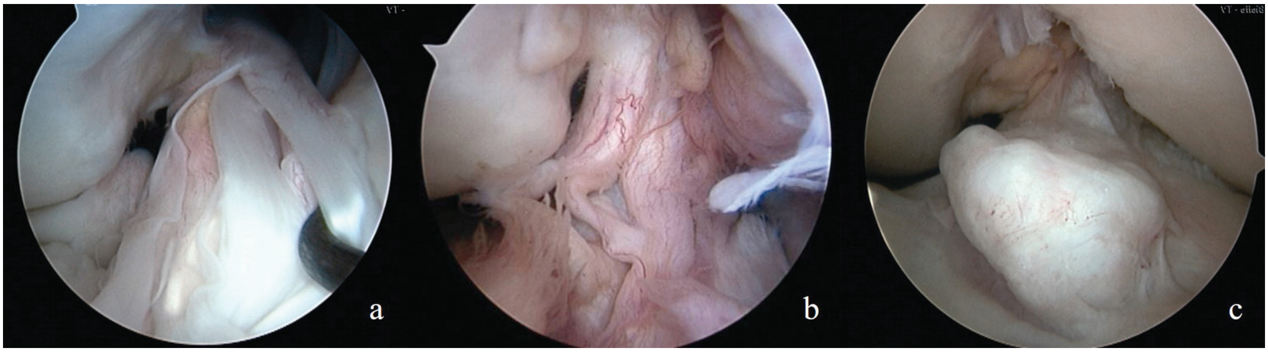

Figure 1. a-b-c. Different arthroscopic evaluations of ACL injuries

(2 g) was administered and continued 24 hours after surgery. Postoperative antithrombotic therapy (Natrium Enoxaparin) was given until full weight bearing was achieved. The patient was placed supine on an operating table; a thigh tourniquet was always applied.

At our I-level trauma centre the allografts are isolated from a whole BPTB received from the Musculoskeletal Tissue Bank (Treviso Tissue Bank Foundation). On the day of the operation, the graft was thawed in sterile physiologic solution at room temperature before preparation and then preconditioned using the graftmaster board at 20 lb of tension for 20 minutes (Figure 2). The autografts were prepared following the same protocol used for allografts. The autologous gracilis and semitendinosus tendons were harvested through an oblique 3 cm incision over the pes anserinus (Figure 3) using a tendon stripper (Arthrex, Naples, FL) with the patient positioned on the operat-

Figure 2. Three stages of allograft tendon preparation. a) BPTP at the initial stage, after thawing and preconditioning on the graft master; b) the part of BPTP choose for ACL substitution is measured and the bone part is shaped with an oscillating saw; c) allograft ready for implantation

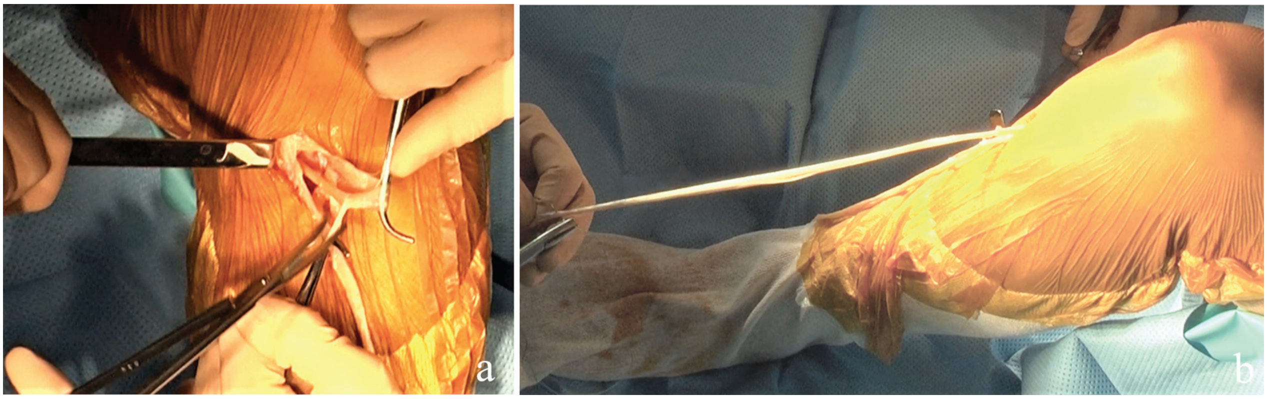

Figure 3. a-b. Gracilis-semitendinous autograft harvesting

ing table with his knee maintained at 90° flexion using a knee post that allowed complete flexion if needed. On a Graftmaster board (Arthrex), the tendons were cleaned from soft tissues and their taper parts were cut off. Both tendons were sutured together to form a 4-strand graft and looped over 1 single EndoButton (Smith & Nephew Endoscopy, Andover, MA). The distal free ends of the tendons were armed with No. 6 Ethibond sutures by a whipstitch technique, and the grafts were pre-tensioned under 20 lb for 20 minutes and made ready for the passage through the bone tunnels. The graft has been always shaped to obtain a 9mm diameter. For both graft types, tibial and femoral tunnels were drilled according to the precise diameter of the graft with the same technique; the tibial tunnel was first prepared in standard fashion. The tibial attachments of the remnants of the native ACL were preserved as much as possible to serve as a landmark for tibial guide pin placement. A 9 mm tunnel was then drilled at 55° from the tibial axis. The femoral tunnel was performed through the tibial tunnel following the classic technique reaching 3 cm depth. The graft was passed following the sutures through the tibial tunnel, along the joint, in the femur and through its lateral cortical bone. When correctly positioned, the graft was fixed using the De Puy-Mitek Rigid Fix system with polylactic 2.7 mm resorbable pins. After proximal fixation, 10 flection-extension join cycles were performed in all patients in order to pre-stretch the graft that was then fixed in the tibial tunnel with the knee flexed at 20° with a reverse anterior drawer manoeuvre under maximal manual tension. In both groups the fixation was performed using an interference screw (Smith and Nephew Endoscopy, Andover, MA, USA) with the same diameter of the tunnel.

Rehabilitation protocol

After ACLR, all patients followed a standardized postoperative rehabilitation protocol, which emphasized early restoration of full extension and strengthening exercises for the quadriceps; a brace allowing full range of motion and was used.

Full weight bearing using crutches and mobilization of the knee using a brace were allowed from the first day after surgery and during the first 15 postoperative days with flexion exercises beginning from 45° with a daily increase of 10°, not going beyond 120° during the first 4 weeks. Exercises to regain proprioceptive abilities were suggested starting 8 weeks after surgery. Swimming, cycling and running were allowed from the 12th week. Full return to the sport activity performed before the injury was planned 6 months after surgery.

Patient assessment

All patients underwent evaluation by history, physical examination, questionnaires and proprioceptive assessment at a minimum follow-up of 24 months. Data collection was retrospectively performed at our institution by two external and independent investigators, not involved in the patients' treatment and blinded to the graft being used for each patient.

The objective clinical examination included: testing knee laxity, the Lachman test, pivot-shift test, varus/valgus stress test, presence of effusion and range of motion (ROM) of the knee. Subjective clinical outcome was evaluated at the follow-up by the Knee Injury and Osteoarthritis Outcome Score (KOOS) (25), International Knee Documentation Committee (IKDC) (26), Tegner activity score and modified Lysholm knee scoring scale (27, 28). The Lachman, pivot-shift and varus/valgus stress tests were used before surgery and at final follow-up. KOOS, IKDC and Tegner activity score and the modified Lysholm knee score were used to evaluate knee function.

Evaluation of proprioceptive and balance ability was performed by the Pro-Kin Type B line system (Techno-Body TM) that evaluate the postural stability in a static or dynamic double or single-leg situation. The platform stability is provided via an electro-hydraulic system driven by two stepper motors. Furthermore, it allows upper body and lower body movements to be differentiated by assessing the variation of the trunk position using an angle inclination measure fixed on the sternum of the individual. Finally, the patients were divided into two groups: group I (patients who underwent to ACLR using BPTB allograft) and group II (patients who underwent to ACLR using GST autograft) and outcomes were compared between the two groups.

Statistical analysis

Continuous data were checked for a normal distribution using the Shapiro-Wilk test. Continuous variables were reported as mean±standard deviation. The outcomes of the continuous variables (IKDC, KOOS, Lysholm and Tegner Score, Fisioterapy and timing of sport return) were compared between the 2 groups using the Mann-Whitney U test. Categorical variables (recurvate and extension) were compared with the χ^2 test. The Lachman test, Pivot-shift test, varus/valgus stress test and presence of effusion were evaluated by Fisher's exact test. Proprioceptive sensitivity was evaluated in both groups looking at the differences between the operated limbs or comparing in each subject the proprioceptive properties of the repaired limb versus the contralateral healthy one. The data obtained were analysed and statistical difference was evaluated using the non-parametric Wilcoxon signed rank test. Statistical significance was defined as $p \leq 0.05$. All statistical analyses were performed using SAS 9.3 (SAS Institute Inc., Cary, NC, USA) for Windows.

Results

During a 3-year period, 71 patients with an ACL rupture were treated at our institution. It was not possible to evaluate 28 patients because 11 refused to participate for lack of interest, 2 had PCL injuries, 1 had an external collateral ligament injury, 3 had a contralateral ACLR, and 4 patients presenting cartilage lesions higher than II grade of Outerbridge at the time of surgery and a follow-up address could not be retrieved for 9 people. Hence, 43 patients (41 men and 2 women) were retrospectively enrolled in the present study. All patients underwent clinical assessment at the final follow-up, while twenty-seven patients accepted the stabilometric and proprioceptive assessment. Twenty-two patients underwent ACLR with BPTB allograft (group I) and twenty-one underwent GST autograft (group II). The average follow-up period was 44.8±20.4 months. The mean age of the patient cohort at the time of injury was 31.5±11.9; it was similar for group I (31.9±12.5) and for group II (31.0±11.7) (p=0.84). There were 13 right knees and 9 left knees in group I, 14 right and 7 in group II. No differences were observed regarding body mass index (BMI), recurvatum or valgus deformity between the two groups. No statistical differences between the two groups were reported as regard the durations of physical therapy: 9.5±4.2 months for allograft and 10.5±10.4 months for autograft (p=0.40).

The mean IKDC score was normal or nearly normal in both groups, 94.5±5.8 for group I and 94.4±9.3 for group II (p=0.31) (Table 1). Analyzing KOOS scores, group I reported a mean score of 89.4, while the group II mean score was 90.1 (p=0.40). Similarly, there was no statistical difference in Lysholm scores between patients in group I (96.4±5.0) and patients in group II (96.0±7.2) (p=0.99). As regard the return to sports practice (running, cycling or swimming), there was a statistical difference (p=0.049) in favor of group I: mean 11.7±10.3 months vs 17.9±14.6 months for

Table 1. Clinical outcomes of the cohort

Variable	Overall Patients (N=43)	Group I (N=22)	Group II (N=21)	p-value
IKDC (Mean ± SD)	94.5 ± 7.6	94.5 ± 5.8	94.4 ± 9.3	0.31
KOOS (Mean ± SD)	94.4 ± 8.8	93.9 ± 8.5	94.89 ± 9.26	0.40
Lysholm Score (Mean ± SD)	96.2 ± 6.1	96.4 ± 5.0	96.0 ± 7.2	0.99
Tegner Score pre (Mean ± SD)	6.5 ± 1.3	6.6 ± 1.3	6.3 ± 1.2	0.21
Tegner Score post (Mean ± SD)	5.8 ± 1.3	5.9 ± 1.2	5.8 ± 1.4	0.71
Return to sport (months, Mean ± SD)	14.8 ± 12.5	11.7 ± 10.3	17.9 ± 14.6	0.049
Return to work (months, Mean ± SD)	3.65 ± 3	3 ± 2.5	4.3 ± 3.5	0.049

SD = standard deviation.

the group II. Group I return to work earlier (mean 3±2.5 months) compared to group II (mean 4.3±3.5 months) ($p=0.049$). A reduction of the activity level was recorded in both groups of patients using the Tegner score. The mean Tegner score (of all patients) was 6.5±1.3 before ACL injury and 5.8±1.3 at the follow-up. In particular, the mean Tegner score for patients who underwent ACLR with BPTB allograft was 6.6±1.3 before injury and 5.9±1.2 at the follow-up and for the patients with GST autograft was 6.3±1.2 and 5.8±1.4, respectively. No statistical differences were reported among the two groups before and post injury ($p=0.21$ and $p=0.71$, respectively).

Data collected by physical examination showed no significant difference in outcomes between the two groups. In fact, the Lachman test was negative in 90.9% of group I patients and in 81% of patients of group II; the pivot shift test was negative for 100% of patients in group I and 90.5% in group II ($p>0.05$). There were also no significant differences between BPTB allograft and GST autograft groups in the percentage of patients with a knee stiff or swollen, or in the percentage with positive tests for meniscal tear.

Post-operative ROM was almost complete for both the two groups, in particular 21 (95.5%) patients for group I and 18 (85.7%) patients for group II could reach the full flexion (135°) and all 43 patients gained full extension of the knee. As regards the stability and proprioceptive scores no statistical difference were observed in the results of stabilometric bipodalic (with eyes open or closed) and monopodalic tests between the two groups. Patients of all groups obtained similar scores in the measures of center of pressure excursion for the operated knee and the contralateral one. In the dynamic tests there were no differences between the scores of group I and group II and with the scores reported for the contralateral non injured knee. The score of all index were comparable with the score reported by Techno-BodyTM for athletic subjects.

In particular:

- the mean bipodalic stability index was 1.2±0.5, group I 1.1±0.4 and group II 1.3±0.6 ($p=0.49$)
- the mean monopodalic stability index was 1.6±0.7, group I 1.5±0.6 and group II 1.8±0.7. ($p=0.32$). The mean scores of contralateral one was 1.8±1.0
- for the average track error (ATE) index, which evaluate the proprioception, the mean results for all 43 patients were 33.3±12.7 for the operated knee and 38.2±13.6 for the contralateral one. No statistical difference was found between group I (35.4±15.6) and group II (30.7±7.9) ($p=0.51$).

No major complications occurred and there were no reoperations. No cases of infection, fibrosis or deep vein thrombosis were recorded.

Discussion

Although comparative studies on the uses of autografts and allografts for ACLR have shown similar clinical and radiological outcomes (17-21, 29-32), most were conducted using patellar or Achilles tendons (17-19, 21, 29). In this study, we compared ACLR using BPTP allograft and GST autograft with a minimum 2-year follow-up. Our data demonstrated that there are no statistical differences in clinical outcomes and in the results of patient-oriented tests between subjects who underwent ACLR with BPTB allograft or GST autograft. Further, the outcomes were satisfactory and no complications or re-ruptures were recorded. Moreover, we did not find statistical differences in clinical, proprioceptive and stabilometric outcomes between the two groups of patients.

Comparing the clinical outcomes between the two groups, we did not observe statistical differences in anterior laxity or rate of graft rupture, according to the anterior drawer test (ADT) and the Lachman test. Further, the rate of rotational instability was not increased according to the pivot-shift test. Analyzing ROM measurements, no loss of extension was found between two groups and 39 (90.7%) patients reach 135° of flexion. Overall, good and excellent results at the clinical assessments for BPTB allograft and GST autograft are in line with the results reported in the literature (33-35). According to these studies, autograft does not provide better clinical outcomes than allograft. Subjective tests evaluating the knee functionality (IKDC, KOOS, Tegner activity score and Lysholm knee scoring scale) returned mean scores nearly close to normality. No difference between the two groups was found.

Sun et al. found no significant difference between autograft and BPTB allograft in their IKDC scores (32). They reported that 93 % of autograft and 91 % of BPTB allograft groups showed normal or near normal activity at the final follow-up (32). This study results of IKDC score was comparable to their results.

Analyzing the return to sport, we found a reduced number of patients that return to a regular previous sport activity, although the difference in Tegner scores before injury and at final follow-up after surgery was not statistically significant for both groups. Similar results were reported in a recent study by Legnani et al. (36). We found a difference between two groups evaluating the timing to return to work. The members of group I returned to work earlier than those of group II. This finding may depend on the lower level of pain experienced in the first post-operative period by patients with BPTB allograft, which avoid donor site morbidity. Other possible confounding factors evidenced by the literature (37), such as work placing a high demand on the knees or the period suggested to patients for using crutches, were comparable between the two groups.

Young et al. evaluated the mechanoreceptor reinnervation of autografts and allografts after ACLR (38). Histological examination showed significantly less neurofilament P (NFP)+ neural analogs both in allograft and autograft patients compared to healthy control tissue, but no differences were highlighted between the two graft groups (38). It was hypothesized that the loss of proprioceptive function occurred after ACL rupture may be due to deficit of reinnervation (38).

In our study both grafts showed similar proprioceptive and stabilometric performances. Moreover, we did not find difference between the performance of the operated knee compared to the contralateral one. Ozenci et al. and Reider et al. reported no significant difference in proprioception when ACL-reconstructed limbs were compared to the uninjured contralateral ones (39, 40), in accordance with our data. It should be mentioned that these data have to be confirmed by studies with larger populations. However, it is interesting to observe that an ACLR with BTPB allograft enables a restoration of proprioceptive capacity and stability of the limb similar not only to a hamstring autograft, but also to a native ACL.

Although we examined a limited number of patients, no complications or re-rupture occurred in our cohort, nor were there cases of infection or acute synovitis. In contrast, Guo et al. reported 3 cases of acute synovitis between 25 patients who underwent an ACLR with fresh-frozen BPTB allograft (33). Fresh-frozen allogeneic grafts can cause cytokine-induced inflammation and latent immunologic rejection leading to tibial tunnel enlargement (3). Acute synovitis may be the most common symptom of immunologic rejection: it is a condition, like the early infections, in which patients could complain of local swelling, fever, and severe pain.

Primary ACLR with fresh-frozen BPTB allograft could lead to clinical and proprioceptive results comparable to the ones reached with hamstring autograft, but avoiding donor site morbidity. The morbidity associated with harvesting the graft, such as anterior knee pain or quadriceps weakness after the use of autologous BPTB or reduction in knee flexion strength after the use of autologous hamstring tendons, needs to be considered when surgeons plan on performing an arthroscopic ACLR (41). Furthermore, Haviv et al. evidenced that midline incisions for BPTB harvesting could injure the infrapatellar branch and medial incisions for hamstring harvesting could injure the sartorial branch of the saphenous nerve (42): the incidence of infrapatellar branch of saphenous nerve injury in literature has been reported to be as much as 50% with the BPTB autograft technique and 30 to 59% with the hamstrings technique (5, 6).

Healthcare systems all over the world put an increased emphasis on understanding the cost drivers and high-value procedures within orthopedics. Recently, an important cost-effectiveness meta-analysis showed that the use of allograft in ACLR normally leads to higher costs compared to hamstring autograft (43), but the probability of different post-operative complications may induce surgeons to choose either BPTB allografts or autografts (42). Moreover, cost-effectiveness analysis could not replace the judgment of the individual clinician in a multifactorial decision like that of graft choice for ACLR, which must be taken based on clinical case and patient characteristics.

Several potential limitations may have influenced the results of our study. Firstly, its retrospective nature and the absence of randomization; secondly, the groups of patients are small and the follow-up time is intermediate.

However, to the best of our knowledge, no previous study has compared both clinical and proprioceptive outcomes between groups of patients who underwent ACLR with BPTB allograft or GST autograft by the same surgeon, with the same surgical technique and in the same structure.

Conclusions

In conclusion, this study highlighted the good clinical and proprioceptive outcomes at medium-term follow-up of ACLR with BPTB allograft and GST autograft. Further, the data confirmed that BPTB allograft is comparable to GST autograft when comparing clinical outcomes, antero-posterior laxity, failure rates and the recovery of proprioceptive ability. However, the BPTB allograft seems to enable an earlier return to work and sport compared to GST autograft. Further research with larger cohorts of patients are needed to make a more extensive comparison.

Declarations: All authors listed meet the authorship criteria according to the latest guidelines of the International Committee of Medical Journal Editors, and all authors are in agreement with the manuscript.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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