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Double bundle anterior cruciate ligament reconstruction: Failure rate and patients-reported outcomes at 4–11 years of follow up

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ABSTRACT

Background: Biomechanical studies have demonstrated that single bundle (SB) anterior cruciate ligament (ACL) reconstruction (SB-ACLr), which represents the gold standard for the management of ACL lesions, is not sufficient to completely restore the rotational stability and resistance to valgus stress of the knee.
Purpose: To evaluate the failure rate and patients reported outcomes at a long-term follow-up of double bundle anterior cruciate ligament reconstruction (DB-ACLr).
Study design: Retrospective cohort study.
Materials and methods: The database of arthroscopic DB-ACLr procedures performed from 2006 to 2015 at our Institution was retrospectively reviewed. Patients were screened for eligibility according to the following inclusion criteria: magnetic resonance imaging (MRI) evidence of anterior cruciate ligament (ACL) lesion, positive anterior drawer test and/or Lachman test; age ≤ 45 years at the time of surgery; DB-ACLr with autologous hamstrings, minimum follow up of 24 months. Patients were excluded if they presented associated lesions of the knee preoperatively or at the time of surgery, expect for meniscal lesions, or in case of inability to complete clinical questionnaires. Clinical outcomes were assessed at a mean follow up of 95.4 ± 21.9 months (range 51–129 months; median 98 months) using the Tegner-Lysholm score and the IKDC subjective score. Failures were defined as Tegner-Lysholm score ≤65 points, and were confirmed with MRI.
Results: 58 (81.7%) male and 13 (18.3%) female patients (mean age 29.7 ± 7.8 years) were included in the study. 2 (2.8%, 95% CI 0.3–9.8%) patients had a failure of DB-ACLr both occurred after a sports trauma. The IKDC subjective score was statically better in patients younger than 30 years. Tegner-Lysholm and IKDC subjective score were statistically better in professional athletes and in patients with isolated medial or lateral meniscus lesion instead of combined medial and lateral meniscus lesion.
Conclusion: DB-ACLr technique provides excellent clinical results at a long term follow-up. Low failure rate and high percentage of return to sports participation at the same pre-injury level was found in our cohort of patients.

1. Introduction

The anterior cruciate ligament (ACL) is essential for the knee joint biomechanics and function.[2] It efforts resistance to anterior dislocation of the tibia,[6] providing proprioception and rotational stability of the knee.[5]

In several sports activities requiring rotational motions or jumping like soccer, rugby, basketball, volleyball or skiing, the knee sustains high mechanical loads and the ACL is more prone to injury.[3,12] Surgical reconstruction of ACL lesions is often necessary, especially in young and active patients.[25] The aim of surgery is to restore the stability of the knee, allowing the return to sports participation, and preventing the development of associated lesions[7] such as meniscal or collateral ligaments tears,[1] chondral injuries,[32] fractures and early osteoarthritis.[33]

Anatomical studies have shown that the ACL is made of two bundles, the antero-medial and postero-lateral.[9,19,35] The single bundle (SB) ACL reconstruction (SB-ACLr) technique represents the gold standard for the management of ACL lesions.[14] However, several studies have demonstrated that, despite its capacities to restore stability in the antero-posterior plane, SB-ACLr is not sufficient to completely

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restore the rotational stability and resistance to valgus stress[11,24] of the knee. Moreover, 15–25% of unsatisfactory results were recorded, with some patients reporting persistent pain or instability.[4]

Double bundle (DB) ACL reconstruction (DB-ACLr) technique was proposed to reproduce a more anatomic and functional ligament, reconstructing both the ACL bundles. Various studies have shown a superiority of DB-ACLr respect to SB technique to restore rotatory stability of the knee,[22,23,30] while other studies found no differences between the two procedures in term of outcomes, complications and failure rate.[17,18]

The primary purpose of our study was to evaluate the failure rate of DB-ACLr technique at a long term follow-up. In our hypothesis, DB-ACLr presents a failure rate not superior to 3%. Moreover, we have assessed the clinical outcomes and return to sports participation according to patients age, meniscal lesions and level of pre-injury sports activity at the time of surgery.

2. Materials and methods

2.1. Ethics

The ethics review board of our institution approved the study.

2.2. Patient enrolment

We retrospectively reviewed the database of arthroscopic DB-ACLr procedures performed at our Institution from January 2006 to December 2015. A total of 162 DB-ACLr procedures were performed in 161 patients. Inclusion and exclusion criteria are shown in Table 1.

22 patients were excluded because of short term follow up, while other 30 patients were not compliant with the inclusion/exclusion criteria. The remaining 109 patients were contacted telephonically. 71 of them accepted our invitation and were enrolled in the study.

2.3. Clinical evaluation

Clinical outcomes were assessed at the final follow up using the Tegner-Lysholm score and the IKDC subjective score. Two blinded surgeons administered both questionnaires. The mathematical average of the results obtained by each examiner was used for statistical purpose.

The Tegner-Lysholm score[29] is a knee rating scale made of 8 sections, evaluating post-operative limp, pain, locking, stair-climbing capacity, necessity of support, instability, swelling, and squatting capacity. The final score ranges from 0 to 100, and it can be classified as excellent (> 90 points), good (84–90 points), fair (65–83 points), or poor (< 65 points). We have assumed as a failure a Tegner-Lysholm score ≤ 65 points.

The IKDC subjective score[15] is a knee rating scale made of 10 sections, evaluating post-operative knee pain, stiffness and swallowing, locking, instability, sport ability, and influence of knee surgery on activities of daily living. The final score ranges from 0 to 100 points, with lower scores indicating the worst function of the knee.

2.4. Imaging

All patients underwent preoperative MRI scans to diagnose ACL injury and associated lesions. Furthermore, a standard pre-operative radiographic assessment of the knee was performed in all patients using antero-posterior, lateral and axillary view. In all patients with poor results according to Tegner-Lysholm score and IKDC score, a MRI evaluation of the operated knee was performed at the final follow up.

2.5. Surgical procedure

The arthroscopic DB-ACLr technique has been previously described.[31] All the surgical procedures were performed by the senior full-trained knee surgeon (P.V.).

The patient, under spinal anesthesia, is placed in supine position with the inferior limb on a leg holder permitting knee movement from 0° to 110°. A diagnostic arthroscopy is firstly performed to evaluate the ACL rupture and to treat any meniscal lesion. In all patients presenting a meniscal lesion (medial or lateral or combined), a partial meniscectomy was performed preserving the more healthy meniscal tissue as possible.

Then, both semitendinosus (ST) and gracilis (G) tendons are harvested using a small oblique anteromedial (AM) incision at the level of the pes anserinus. Both tendons were doubled, and their diameters should be minimum 5–6 mm for the G tendon, and 6–7 mm for the ST tendon.

Two tibial tunnels were created with a calibrated tibial guide (DePuy Mitek, Raynham, MA) specifically designed by the senior surgeon to perform this technique. Then, the correct position of the femoral tunnels is identified using a Kirschner wire introduced into the joint through the tibial tunnels.

The PL femoral socket is created at a depth of 30 mm by passing through the PL tibial tunnel, while the AM femoral half-tunnel is created at a depth of 35 mm by passing through the AM tibial tunnel. 2 sutures are used to pass the graft (Fig. 1).

The G was used for the PL, while the ST was used for the AM. After placement and pretensioning of the grafts proximally, both PL and AM bundles are fixed by inserting two different pins through a cannula, while PL and AM bundles are distally fixed separately with a bioscrew. The fixation of the PL and AM bundle was performed with the knee flexed at 10° and 45° respectively. The tension of the graft was finally tested with a probe (Fig. 2).

2.6. Postoperative management

Postoperative management and rehabilitation protocol was the same in all patients. Full weight bearing was allowed from the day after surgery using two crutches. Passive and active flexion/extension exercises of the knee from 0 to 90° and active isometric contractions of the quadriceps muscle were started the same day and continued for 2

Table 1
Inclusion and Exclusion criteria.

	Patients enrolment	
	Preoperative	Postoperative
Inclusion criteria	MRI evidence of ACL lesion; positive anterior drawer test and/or Lachman test; age ≤ 45 years; DB-ACLr with autologous hamstrings	minimum follow-up of 2 years after surgery
Exclusion criteria	Clinical and laboratory evidence of knee infection; radiographic evidence of knee fractures; MRI evidence of cartilage lesions; arthroscopic finding of cartilage lesions; MRI evidence of posterolateral corner injury; clinical evidence of posterolateral corner injury; MRI evidence of medial or lateral collateral ligament lesion; clinical evidence of medial or lateral collateral ligament lesion	follow-up $<$ 2 years; inability to complete clinical questionnaires due to language problems or cognitive disorders

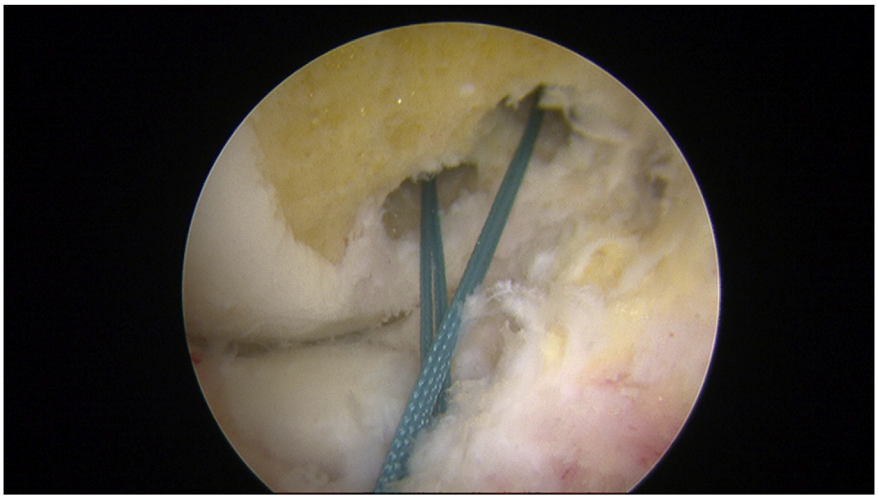

Fig. 1. Arthroscopic view through anterolateral portal of tibial and femoral tunnels.

weeks. Patients were encouraged to reach complete knee extension and at least 90° of knee flexion after two weeks from surgery. Then, the crutch contralateral to the operated leg was removed. One month after surgery, full weight bearing without crutches was allowed. The patients continued a supervised rehabilitation protocol in the pool to recover full range of motion of the knee, strengthening also the quadriceps and biceps femoris muscles. Two months after surgery, patients started swimming and cycling. Then, at three months from surgery, patients followed a supervised rehabilitation protocol into the gym, which was continued for other 3 months. At 6 months from the operation, return to sports participation was allowed.

2.7. Statistics

Statistical analyses were conducted using SPSS for Mac (IBM SPSS Statistics Desktop version 22.0; Chicago-Illinois). The following outcome scores were considered: Tegner-Lysholm score; IKDC subjective score. Outcome scores results were expressed as continuous variables ± standard deviation (range; median), while failure rate was expressed as number (%) and confidence interval (95%CI).

The independent variables analysed were: age, meniscal lesions and level of pre-injury sports activity. Comparison between the 2 groups for each independent variable was carried out with a two-tailed Mann-Whitney U test or with a three-tailed Kruscall-Wallis U test for continuous variables. Significance was set at $P < 0.05$.

3. Results

3.1. Demographic results

The study group included 71 patients who underwent DB-ACLr procedure. Of these, 58 (81.7%) were male and 13 (18.3%) were female. The male/female ration was 4.5.

The mean age of the patients at the time of surgery was 29.7 ± 7.8 years (range 18–45 years; median 29 years), and the follow up averaged 95.4 ± 21.9 months (range 51–129 months; median 98 months). The ACL injury occurred more commonly during sports activities: soccer in 37 (52.1%) patients, skiing in 14 (19.7%) patients, basketball in 4 (5.6%) patients, rugby and volleyball in 3 (4.3%) patients respectively, running tennis judo snowboard and dancing in 1 (1.4%) patient respectively. The remaining 5 (7.1%) patients had an ACL injury during a motor-vehicle accident.

63 (91.3%) patients were involved in regular sports activities prior to surgery. Of these, 14 (22.2%) were involved in professional sports activity: soccer in 6 patients (42.8%), basketball volleyball and rugby in 2 (14.2%) patients respectively, judo and karate in 1 (7.3%) patient respectively.

3.2. Complications

No patients expired infections or postoperative complications. No

Fig. 2. Arthroscopic view through anterolateral portal of DB-ACL graft.

neurovascular injuries occurred during surgery.

3.3. Failure rate

2 (2.8%, 95% CI 0.3–9.8%) patients reported a Tegner-Lysholm score lower or equal than 65 points and where considered as a failure. Both patients reported a re-rupture of the ACL, documented by MRI, 6 and 5 years after surgery during soccer and basketball respectively. As the reason of ACL rupture was a sports trauma in both patients, we have excluded these 2 patients from the final results and statistical evaluation.

3.4. Clinical outcomes

Overall, the mean Tegner-Lysholm score was 96.2 ± 5.7 points (range 65–100 points; median 99 points) at the final follow up. According to Tegner-Lysholm score, the results of surgery were excellent in 64 (90.2%) patients, good in 3 (4.2%) patients, fair in 2 (2.8%) patients and poor in 2 (2.8%) patients. Overall, the mean IKDC subjective score was 95.1 + 5.6 points (range 73.6–100 points; median 95.4 points) at the final follow up.

All the 14 (100%) professional athletes return to sports practice. 57 (90.5%) of 63 patients who were involved in sports participation return to practice sports.

3.5. Age

The patients were divided into two groups according to their age at the time of surgery (≤30 years; > 30 years). Demographic details of the two groups of patients are shown in Table 2.

The Tegner-Lysholm score was better in younger individuals: 97.3 ± 5.5 points in patients younger than 30 years vs 95.2 ± 5.6 points in patients older than 30 years (p = 0.064). The IKDC subjective score was statically better in patients younger than 30 years: 97.3 ± 4 vs 93.1 ± 6 points in patients older than 30 years (p = 0.001).

3.6. Meniscal lesions vs No meniscal lesions

Patients were divided into two groups according to the presence of a meniscal lesion at the time of surgery (present vs not present). Demographic details of the two groups of patients are shown in Table 3.

The mean Tegner-Lysholm score was 95.7 ± 4.8 points in patients with meniscal lesions vs 95.6 ± 6.2 points in patients without meniscal lesions (p = 0.138). The mean IKDC subjective score was 95 ± 5 points in patients with meniscal lesions, while it was 95.1 ± 6.3 points in patients without meniscal lesions (p = 0.632).

Patients with meniscal lesions were divided into three subgroups according to the presence of a medial meniscus injury (n.21), lateral meniscus injury (n. 11) or combined injury of both medial and lateral meniscus (n. 8).

The mean Tegner-Lysholm score was 95.8 ± 6.7 points, 98 ± 4.7 points and 96.2 ± 7.4 points in patients with medial, lateral or combined medial and lateral menisci injury respectively (p < 0.001). The mean IKDC subjective score was 95.5 ± 5.5 points, 95.8 ± 5.2 points and 92.7 ± 9.5 points in patients with medial, lateral or combined medial and lateral menisci injury respectively (p= < 0.001).

3.7. Professional athletes vs recreational sports patients

Patients were divided into two groups according to the level of preinjury sports participation (professional athletes vs recreational sports patients). Demographic details of the two groups of patients are shown in Table 3.

The mean Tegner-Lysholm score was statistically better in professional athletes: 99.3 ± 1.8 points vs 96 ± 4.8 points in recreational sports patients (p = 0.035). The mean IKDC subjective score was statistically better in professional athletes: 99.8 ± 0.2 points vs 95.5 ± 5.5 points in recreational sports patients (p < 0.001).

In our series there were 63 sports patients, and all of them return to sports practice after surgery. All professional athletes return to sports participation at the same preinjury level, while 43 (87.8%) of 49 patients who were involved in regular recreational sports activity return to sports participation at the same preinjury level.

Table 2
Clinical outcomes according to patients age.

	Age		P value
	< 30 years	> 30 years)	
N. patients	32	37	**NA**
Sex (M)	27	29	**NA**
Follow up (months)	91.5 (24–121)	110 (53–129)	**0.001**
Return to sport (%)	28/30 (93.4%)	35/36 (97.2%)	**NA**
Tegner-Lysholm score (points)	97.3 ± 5.5 (70–100)	95.2 ± 5.6 (80–100)	**0.064**
IKDC subjective score (points)	97.3 ± 4 (83.9–100)	93.1 ± 6 (73.6–95.4)	**0.001**

P value: result of Mann-Whitney *U* test (< 0.05 = statistically significant); M: male; Follow up: median (range); Tegner-Lysholm score: mean ± standard deviation (range); IKDC subjective score: mean ± standard deviation (range); NA: not applicable.

4. Discussion

In our study we have hypothesized that DB-ACLr technique presented a failure rate not superior to 3% at a long term follow up, and the analysis of our results confirmed this hypothesis. To our knowledge, no studies with such long term follow up are present in the literature about the topic. All the DB-ACLr failures reported in our series were caused by a DB-ACL re-rupture which occurred after a sports trauma. A recent study[28] including 22.460 patients of the Swedish National Ligament registry found that DB-ACLr presents a revision frequency of 2.0%, while the revision frequency of SB was 3.2%. However, the sample of patients who underwent DB-ACLr was significantly lower than the sample of patients who underwent SB-ACLr (21.846 patients in SB group vs 614 patients in DB group).[28]

An increased incidence of meniscal or chondral lesions in ACL deficient knees was reported.[7,21] No patients in our series reported associated injuries of the knee after DB-ACLr, and 90% of them returned to sports participation. Then, we believe that DB-ACLr is able to restore both antero-posterior and rotatory stability of the knee, preventing the development of associated injuries of the knee even in sports patients. Several biomechanical studies have confirmed our thoughts, showing the superiority of DB respect to SB to restore knee stability, especially regarding rotatory stability.[16,24] On the other hand, Karikis et al.[18] found no differences between patients who underwent SB or DB-ACLr in terms of clinical outcomes and pivot-shift test, KT-1000 laxity measurements, Lachman test, single-legged-hop test and square-hop test at 5 years of follow up. Moreover, they have found a major incidence of OA in patients who underwent DB-ACLr.[18]

The lesions of the ACL occur more commonly in young, active, high demands sports patients.[8,13,20] The analysis of our demographic results showed that the mean age of the patients at the time of surgery was 29 years, ranging from 18 to 45 years, and the male/female ratio was 4.5. At this age, patients often expect to return to practice sports, preferably at the same pre-injury level. Moreover, sports activities requiring rotational motions caused the ACL rupture in 93% of our patients.

The age of the patients at the time of surgery influences the outcomes of DB-ACLr. Wierer et al.[34] compared the outcomes of SB-ACLr procedure in patients younger than 40 years and patients older than 40 years at 24 months of follow up, detecting no statistically significant differences in Tegner-Lysholm score and IKDC subjective score between

Table 3
Clinical outcomes according to meniscal lesions and preoperative level of sports practice.

	Meniscal lesion			Sports level		
	Present	Not present	P value	Professional	Recreational	P value
N. patients	41	28	**NA**	14	49	**NA**
Age (years)	29.1 ± 8.4	31.2 ± 6.9	**0.193**	22.1 ± 3.7	32.4 ± 7.3	**< 0.001**
Sex (M)	34	22	**NA**	9	43	**NA**
Follow up (months)	98 (51–129)	101 (24–123)	**0.968**	91.5 (51–121)	108 (24–129)	**0.126**
Tegner-Lysholm score (points)	95.7 ± 4.8 (80–100)	95.6 ± 6.2 (70–100)	**0.138**	99.3 ± 1.8 (95–100)	96 ± 4.8 (80–100)	**0.035**
IKDC subjective score (points)	95 ± 5 points (82.8–100)	95.1 ± 6.3 (73.6–100)	**0.632**	99.8 ± 0.2 (98.9–100)	95.5 ± 5.5 (73.6–100)	**< 0.001**

P value: result of Mann-Whitney *U* test (< 0.05 = statistically significant); Age: median ± standard deviation; M: male; Follow up: median (range); Tegner Lysholm score: mean ± standard deviation (range); IKDC subjective score: mean ± standard deviation (range); NA: not applicable.

the two groups of patients. In our series, the patients younger than 30 years at the time of surgery reported better Tegner-Lysholm score and statistically better IKDC subjective score when compared with patients older than 30 years. Nevertheless, several studies reported no significant relationship between age and IKDC subjective or Tegner-Lysholm score.[26,27]

Another important factor that may affects the outcomes of ACLr surgery is the presence of meniscal or chondral lesions. In a multicentric cohort study on 1512 patients who underwent ACLr was shown that IKDC subjective score was lower in patients with grade 3 or 4 chondral lesion of the medial/lateral femoral condyle or of the medial tibial plateau at 6 years of follow up.[10] Then, to improve the quality of our results we have decided to exclude patients with chondral lesions, but we have enrolled patients with meniscal tears. No statistically significant differences of Tegner-Lysholm score and IKDC subjective score were present between patients with or without a partial meniscectomy who underwent DB-ACLr. However, patients who underwent partial meniscectomy of both medial and lateral menisci reported worst statistically significant outcomes when compared with patients who underwent isolated partial meniscectomy of the medial or lateral meniscus. Moreover, patients with lateral meniscus injury reported statistically better Tegner-Lysholm score and IKDC subjective score than patients with medial meniscus injury. Cox et al.[10] reported similar results, showing that patients who underwent ACLr and presenting a medial meniscus injury managed with partial meniscectomy reported worse IKDC and KOOS score at 6 years of follow up.

Professional sports patients presented statistically significant better outcome scores respect to patients involved in recreational sports activities. The rate of return to sports practice at the same pre-injury level was 100% for the professional athletes and 87.8% for the recreational sports patients. We believe that this discrepancy of results may be related with patient's motivations, expectations and intensity of postoperative rehabilitation. Furthermore, in our series, professional athletes were younger than recreational sports patients in a statistically significant fashion.

Major strength of our study is represented by the length of follow up period. With a mean follow-up of 7.8 years we can consider the results of surgery as well stabilized. Moreover, all the surgical procedures were performed by a full-trained senior arthroscopist (P.V.) who performs more than 350 arthroscopic ACLr procedures per year. Another important strength is that we have used two different clinical questionnaires for the evaluation of the knee function, and both of them were administered by two blinded orthopaedic surgeons who were not involved in surgery.

We are aware that the most important limitation of our study is represented by its retrospective design without a control group. Moreover, the number of patients enrolled in the study in not enough to consider our results as univocal. Other limitations are the non-homogeneous distribution of male and female patients, the lack of postoperative functional evaluation of the operated knee, especially including rotational stability assessment, and the lack of preoperative assessment of clinical condition of the patients.

In conclusion, DB-ACLr technique in safe and effective to manage ACL lesions in young and sports patients, providing excellent results at a long term follow-up. Low failure rate and high percentage of return to sports participation at the same pre-injury level was found in our cohort of patients. However, the surgical procedure requires high arthroscopic skills and should be performed only by expert arthroscopist. Moreover, it should be avoided in patients with ST tendon smaller than 6 mm and G tendon smaller than 5 mm, in order to guarantee an acceptable size of the graft.[30,31]

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jor.2019.02.021.

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