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Double-bundle non-anatomic ACL revision reconstruction with allograft resulted in a low revision rate at 10 years

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Abstract

Purpose This study aimed at reporting the long-term second revision rate and subjective clinical outcomes from a cohort of patients who underwent a double-bundle (DB) ACLR first revision with allograft at a single institution.

Methods The Institutional database was searched according to the following inclusion criteria: (1) patients that underwent DB-ACL first revision with Achilles tendon allograft, (2) surgery performed between January 2000 and December 2012, (3) age at revision ≥ 18 y/o. Patients' general information, history, surgical data, and personal contacts were extracted from charts. An online survey platform was implemented to collect responses via email. The survey questions included: date of surgeries, surgical data, date of graft failure and subsequent second ACL revision surgery, any other surgery of the index knee, contralateral ACLR, KOOS score, and Tegner scores.

Results Eighty-one patients were included in the survival analysis, mean age at revision 32 ± 9.2 y/o, 71 males, mean BMI 24.7 ± 2.7, mean time from ACL to revision 6.8 ± 5.4 years, mean follow-up time 10.7 ± 1.4 years. There were 12 (15%) second ACL revisions during the follow-up period, three females and nine males, at a mean of 4.5 ± 3 years after the index surgery. The overall survival rates were 85% from a second ACL revision and 68% from all reoperations of the index knee. Considering only the successful procedures (61 patients), at final follow-up, the mean values for the KOOS subscales were 84 ± 15.5 for Pain, 88.1 ± 13.6 for Symptoms, 93 ± 11.6 for ADL, 75 ± 24.5 for Sport, and 71 ± 19.6 for Qol. Twenty-nine (48%) patients performed sports activity at the same level as before ACLR failure.

Conclusions Double-bundle ACL revision with fresh-frozen Achilles allograft yields satisfactory results at long-term followup, with an 85% survival rate from a second ACL revision at mean 10 years' follow-up and good patient-reported clinical scores.

Level of evidence Level IV.

Keywords ACL · Revision · Allograft · ACL survival · ACL revision · Double bundle

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Introduction

According to the most recent literature, the long-term anterior cruciate ligament reconstruction (ACLR) outcomes are good, with a survival rate of over 90% and a high percentage of patients returning to sports activity at 10 years of follow-up [11]. Nevertheless, given that ACLR is a common surgical procedure [6, 17, 35, 42, 43, 45], it is most probable that the incidence of ACL graft failures and revision will also increase worldwide. In ACL revision, surgeons must address technical issues such as tunnel widening, timing, associated lesions, additional procedures, and graft selection [5, 18, 26, 40]. Recently, a survey was conducted among the members of the ACL study group [37]; it showed that surgeons perform more than 90% of ACL revisions with a single bundle (SB) technique and that allografts are used only in a minority of cases. Nearly all respondents (97%) agreed that non-irradiated, age-matched allografts do not perform comparably to autografts in young, high-level athletes and that allografts should be reserved for > 40 years or older recreational athletes. These beliefs are supported by the results of some large multicentric registries, such as the Multicenter ACL Revision Study (MARS) Group [24, 25, 44] and the Danish ACL registry [32]. They reported a significantly lower re-revision rate in patients undergoing ACLR revision with autograft, both at middle- to long-term follow-up. Some other studies also correlated the use of allograft with lower PROs and delayed return to sport rate [21, 24, 39, 44]. Nevertheless, allografts have been commonly used in the last decades [7, 8, 15, 33] and their safety and effectiveness have been extensively studied [1, 3, 4]. Irradiation is a processing method that has a deleterious effect on the graft. A meta-analysis that included 32 studies showed that after excluding irradiated allografts, outcomes were similar between autografts and allografts in terms of postoperative laxity and rates of complications and reoperations [13]. From a biological point of view, allograft incorporation proceeds with a similar but slower progression than autograft; fresh tendon allografts have been shown to stimulate a strong immunologic reaction while freezing the graft leads to cell death without altering its structural and mechanical properties [3, 4]. Currently, few studies in the literature report the mid- to long-term outcomes of allograft ACLR revision, mostly with non-homogeneous graft selections and different surgical techniques. Therefore, the purpose of this study was to report the long-term second revision rate and subjective clinical outcomes from a cohort of patients who underwent a double-bundle (DB) ACLR revision with allograft at a single institution. The hypothesis was that a survival rate comparable to what is reported in other studies and good clinical outcomes would be shown at long-term follow-up.

Materials and methods

Patients' selection

This study was designed as a retrospective cohort evaluation. Ethical approval was obtained from the local committee (Prot. n. 0,012,253 del 11/10/2019). The Institutional database (II Clinica Ortopedica, IRCCS Istituto Ortopedico Rizzoli) was searched according to the following inclusion criteria: (1) patients that underwent first DB-ACL revision with Achilles tendon allograft, (2) surgery performed between January 2000 and December 2012, (3) age at revision ≥ 18 y/o. The following exclusion criteria were applied: (1) second or more ACL revision, (2) primary ACL reconstruction with allografts, and (3) multi-ligament reconstructions with allografts.

Patients' general information, history, surgical data, and personal contacts were extracted from charts; all patients were contacted by phone to ask for their consent to participate in the study. The emails of those willing to participate were collected.

Patients' evaluation

An online survey platform (www.google.com/forms) was implemented to collect responses via email. The questions of the survey included: general medical and anthropometric data, date of primary ACL reconstruction and first ACL revision (index surgery), surgical data, date of graft failure and subsequent second ACL revision surgery, any other surgery of the index knee, and contralateral ACLR. Subjective clinical status was evaluated with the following patient-reported outcomes measures (PROMs): Tegner [41] activity score before native ACL rupture, maximum Tegner score before ACL graft failure, and ACLR revision, Tegner score at final follow-up, KOOS score [29, 34] at final follow-up. All responses were collected by email and automatically downloaded on an excel sheet (www.google.com/sheets). There is current evidence that electronic-based surveys provide equivalent results to paper-and-pencil surveys [30].

Surgical technique and rehabilitation

All surgeries (non-anatomic DB ACL first revisions) were performed between 2000 and 2012 by the two senior authors (M.M. and S.Z.) with a previously described technique [22]. For graft preparation, a non-irradiated fresh-frozen Achilles tendon allograft was split along the mid-line into two separate bundles, leaving a 2.5 cm long, uncut tendon attached to the calcaneal bone plug. The two bundles were then sutured independently (Fig. 1A). For the single tibial tunnel preparation, a small skin incision was made medial to the tubercle, a guide pin was drilled aiming at the posteromedial area of the native ACL footprint, and a 10 mm reamer was used to create the tibial tunnel. The femoral tunnel for the PL bundle was drilled over a guide inserted through the anteromedial portal with a 7-mm reamer. A 3 to 5-cm incision was then made immediately above the lateral femoral condyle to reach the "over the top" for the reconstruction of the AM bundle.

Once the graft passed through the joint, it was fixed at 60° of flexion. The bone plug was fixed distally on the tibial cortex at the entrance of the tibial tunnel with a Richards barbed staple (Smith & Nephews, Richards Inc., Memphis, USA) (Fig. 1B). Then, the proximal ends of the graft were fixed to the femur with two Richards barbed staples (Smith

Fig. 1 The drawings represent the surgical technique; A the Achilles tendon allograft was split along the mid-line into two separate bundles attached to the bone plug, the two bundles were then sutured independently. B Anterior view of the reconstructed ACL, the graft was fixed distally to the tibial cortex outside the tibial tunnel with a Richards barbed staple. C Posterior view of the reconstructed ACL; the posterolateral bundle was fixed to the lateral aspect of the femoral condyle and the anteromedial bundle to the overthe-top position with staples



& Nephews, Richards Inc., Memphis, USA). The PL bundle was fixed to the lateral aspect of the femoral condyle and the AM bundle to the over-the-top position (Fig. 1C).

All patients underwent the same postoperative rehabilitation protocol. No brace was used postoperatively. Range of motion, quadriceps muscle active exercises, straight-leg raises, and prone hamstring muscle-stretching exercises began the day after surgery. Patients were allowed partial weight bearing during the first 2 weeks. Stationary cycling, active knee extension with weights, and one-quarter squats were introduced four weeks after surgery. Running was started at 3 months and technical training in pivoting sports activities after 6 months. Return to competitive Sport was allowed from 8 to 10 months after surgery based on the completion of the rehabilitation protocol with sufficient quadriceps and hamstring muscular tone and strength.

Statistical analysis

All responses were automatically collected in an excel sheet; the information were integrated with the data from the institutional charts. Statistical analysis was performed with MedCalc software (Version 19.1.6, Acacialaan). Continuous variables were reported as the mean \pm standard deviation, while categorical variables were reported as the absolute number and proportion of the total sample. Only the Tegner activity level was reported as the median with interquartile range. The independent-samples t test was used to compare continuous variables. The Mann-Whitney test was used to compare Tegner activity levels, and the Fisher exact test to compare dichotomous categorical variables. Kaplan-Meier survival curves were constructed using the time to ACL second revision as the endpoint. The log-rank test was used to compare the survival curves according to sex, age at primary ACLR and ACL revision, preoperative sports activity level, and presence of at least one meniscal lesion during revision surgery.

For each KOOS subscale, patients were categorized as passing or not passing the threshold of the Patient Acceptable Symptom State (PASS) according to Muller et al. [31] (Pain, 88.9; Symptoms, 57.1; Activities of Daily Living, 100.0; Sport, 75.0; QoL, 62.5). Multiple regression analysis for each KOOS subscale was performed using sex, age at revision, and Tegner score \geq 7 as variables. Significant *p* was set at 0.05.

The sample size was calculated with the single mean method, based on the KOOS Pain subscale obtained from previous long-term ACLR studies [11]. The PASS value of the Pain subscale was considered for the null hypothesis value [31]. Eighteen patients were the minimum number required, with an alpha of 0.05 and a power of 80%.

Results

Ninety-one patients were extracted from the institutional database; 10 patients were excluded from the study since their index surgery was a second ACL revision. Eighty-one patients were included in the study; all gave consent to participate and responded to the online surveys. Patients' characteristics are reported in Table 1.

Surgical information

From surgical reports, at the time of ACL revision, medial meniscal (MM) lesions were reported in 32 (40%) patients, lateral meniscal (LM) lesions in 9 (11%) patients, and concomitant MM + LM lesions in 8 (10%) patients. Twenty-eight (35%) patients underwent an additional surgical procedure at the time of ACLR revision (34 in total, including

Table 1 Patient's demographic

information

	Total	Males	Females	p value
Number	81	71	10	
Age at primary ACLR	24 ± 15	24.1 ± 15.7	22.7 ± 9.8	ns
≤22 y/o	33	27	6	
>22 y/o	48	44	4	
Age at ACL revison	32 ± 9.2	32.3 ± 8.4	30.3 ± 14.1	ns
≤22 y/o	11	8	3	
>22 y/o	70	63	7	
BMI (kg/m ²)	24.7 ± 2.7	25.2 ± 2.3	21.7 ± 3.6	ns
Tegner activity score after ACLR	7 [1;7]	7 [1;7]	5 [1;7]	ns
<7	38	31	7	
≥7	43	40	3	
Time from ACLR to revision (years)	6.8 ± 5.4	6.7 ± 5.3	7.6 ± 6.6	ns
Final follow-up time (years)	10.7 ± 1.4	10.8 ± 1.5	10.5 ± 1.1	ns

BMI body mass index, ACLR anterior cruciate ligament reconstruction, ns non-significant

 Table 2
 Surgical data and additional surgical procedures

	n (%)
Meniscal lesions	
MM	32 (40%)
LM	9 (11%)
MM+LM	8 (10%)
Additional procedures	
MM repair	6 (7%)
LM repair	1 (1%)
MFC microfractures	9 (11%)
MAT	4 (5%)
Meniscal substitute	7 (9%)
HTO	4 (5%)
ACI	1 (1%)
OC scaffold	1 (1%)
MCL repair	1 (1%)

MM medial meniscus, *LM* lateral meniscus, *MFC* medial femoral condyle, *MAT* meniscal allograft transplant, *HTO* high tibial osteotomy, *ACI* autologous chondrocytes implantation, *OC* osteo-chondral scaffold, *MCL* medial collateral ligament

meniscal suture repairs). Additional surgical procedures are shown in Table 2.

ACL second revisions and reoperations

Overall, during the follow-up period, there were 12 (15%) second ACL revisions, 3 females and 9 males, at a mean 4.5 ± 3 years after the index surgery (Fig. 2A, B). Among this group, two patients also underwent a meniscectomy, and one underwent a medial meniscal allograft transplant (MAT). Additionally, 14 (17%) patients underwent 15 surgical procedures in total during the follow-up period. All reoperations are reported in Table 3. The overall survival

rates were 68% from all reoperations, 85% for a second revision. The log-rank test showed that having ≤ 22 years at primary ACLR led to a significantly increased risk of revision (HR 3.3 95%, CI 1.0–10.5; p = 0.0451) (Fig. 3A, B) (Table 4). Sex, age at ACL revision, preoperative sports activity level, and meniscal lesions did not influence survival according to the log-rank test. Finally, 24 (30%) patients had a contralateral ACL reconstruction at the final follow-up.

Clinical outcomes and return to sport

Patients who underwent ACL second revision were considered failed procedures and were excluded from PROMs analysis. To avoid confounding factors, patients who underwent HTO, MAT, or meniscal substitute during the followup period were excluded, leaving 61 patients for the PROMs analysis.

At final follow-up, the mean values for the KOOS subscales were 84 ± 15.5 for Pain, 88.1 ± 13.6 for Symptoms, 93 ± 11.6 for ADL, 75 ± 24.5 for Sport and 71 ± 19.6 for Qol (Fig. 4). PASS values were reached by 34 (56%), 58 (95%), 26 (43%), 41 (67%) and 43 (70%) patients, for the respective subscales (Fig. 5). No significant differences were shown based on sex or meniscal lesions. According to the multiple regression analysis, older age at the time of ACL revision was a significant predictor of lower values of Sport (-0.9) and Qol (-0.7) subscales (Table 5).

Median Tegner scores values were 7 [7;9] before primary ACLR, 7 [6;7] before ACL graft failure, and 5 [4;6] at the final follow-up. Twenty-nine (48%) patients performed sports activity at the same level as before ACLR failure, and 33 (54%) patients reported a Tegner score \geq 5 at the final follow-up (Fig. 6).



Fig. 2 Kaplan–Meier survival curves for all ACL revisions (A), and for male and female patients (B). The log-rank did not show significant differences in survival based on sex

 Table 3
 ACL second revisions and reoperations during the follow-up period

All reoperations	n (%)
ACL second revision	12 (15%)
MAT	5 (6%)
Partial meniscectomy	3 (4%)
Staple removal	2 (2%)
НТО	3 (4%)
Stem cell infiltration	1 (1%)
Arthroscopic debridement	2 (2%)
Meniscal substitute	1 (1%)
LET	1 (1%)
	Total
	30 procedures in 26 (32%) reoperated patients

MAT meniscal allograft transplant, HTO high tibial osteotomy, LET lateral extra-articular tenodesis

Discussion

The most important findings of the present study are that non-anatomic DB-ACL revision with fresh-frozen Achilles allograft yields satisfactory results at long-term follow-up, with an 85% overall survival rate at a mean of 10 years' follow-up. Patients younger than 22 years old at primary ACLR have a significantly increased risk of undergoing a second ACL revision. Regarding patients' reported outcomes, good mean values for all KOOS subscales were reported, and older age at the time of ACL revision is associated with lower Sports and Qol subscales. Only 56% and 43% of patients reached the PASS score in the Pain and ADL subscales, respectively, indicating that about half of these patients are experiencing discomforts linked to their operated knee. Finally, 48% of patients were still practicing Sports at the same level as the first ACL reconstruction.

Fresh frozen non-irradiated allografts have been used in ACL revision since the '90 s with satisfactory results in short to medium term [7, 33]. These grafts became popular due to their safety [3, 19] and some significant advantages over autografts, such as no donor site morbidity, good availability, shorter surgical time, and bigger size [3, 5, 8]. Moreover, the reports that attributed an increased failure rate to allografts in the ACL revision setting were somehow disproved by the fact that only gamma-ray irradiated grafts were linked to an increased failure rate and poorer clinical outcomes [1, 13, 16, 18, 28]. A systematic review, aimed at assessing rerupture rates between allografts and autografts [13], reported that the reoperation rate was 20% with all allografts, dropping to 2.2% if only non-irradiated grafts were considered, against the 6.6% reoperation rate with all autografts. Another recent review [28] that included higher quality Level II studies reported that autograft reconstruction had a failure rate of 4.1% compared to allograft reconstruction at 3.6%.

Grassi et al. [10] published a systematic review in 2017 reporting the mid to long-term failure rate of ACL revision; they included 16 studies and 716 patients. At a mean follow-up of 5 years (range 2–13 years), the re-rupture rate was reported to be broad, from 0 to 25%. Among the included studies, only three used allografts exclusively for ACL revision, reporting a re-rupture rate between 0 and 5% and midterm [2, 20, 27].

On the other hand, in 2018, data from the Danish ACL registry (DKRR) [32] showed that the re-revision rate was significantly higher for allograft (12.7%) compared with autograft (5.4%) at 10 years of follow-up. In 2021, data from the MARS study group [44] showed that at 6 years



Fig. 3 Kaplan–Meier survival curves for patients > 22 years old or \leq 22 years old at time of primary ACL reconstruction (**A**), and at time of ACL revision (**B**). The log-rank showed a significantly increased risk of failure for younger patients at time of primary ACLR (*HR 3.3; p = 0.0451)

	Survival (%)			
	2 y	5 у	10 y	
Total	95	91	85	
Males	95	93	85	
Females	90	80	70	
>22 at first ACLR	97	95	91	
\leq 22 at first ACLR [*]	91	85	72	

Table 4 Survival data for ACL revisions

p = 0.0451

*HR 3.3



Fig.4 KOOS scores at final follow-up, divided by subscales. The blue line represents male patients, the pink line represents female patients. No significant differences were shown

% of patients reaching PASS at final FU



Fig. 5 Percentages of patients reaching the Patient Acceptable Symptom State (PASS) at final follow-up, for each KOOS subscales

 Table 5
 Multivariate analysis and predictors of KOOS scores after

 ACL revision
 Prevision

	Pain	Symptoms	ADL	Sport	Qol
Sex (M)	11.5	1.9	2.1	14.1	1.7
Older age at ACL revision	4.5	-2.1	-0.2	-0.9	-0.7
Tegner≥7	0.4	1.6	-1.5	-3.8	-5.3

Bold indicates significant at p < 0.05

of follow-up, autograft ACL revision had a failure rate of 3.5% in comparison with 8.4% of non-irradiated allografts. Unfortunately, in this study, it was not possible to compare the survival rate of ACL revisions with different graft types; those results are, however, comparable to the re-rupture rates for allografts reported in this study, 9% at 5 years and 15% at 10 years.

Fig. 6 Tegner scores distribution at different time points. At final follow-up 48% of the patients performed sport activity at the same level than before ACLR failure, and 54% of the patients reported a Tegner score ≥ 5



TEGNER score distribution

Younger age at index surgery is a well-known risk factor for ACL graft and revision failure [12, 36]. This study shows that being < 22 years old at the time of primary ACLR also affects the survival of subsequent ACL revision, thus underlining how a knee injury early in life could affect an athlete's career even several years later.

Only a few recent studies report outcomes of DB ACL revision: Jiang et al. [19] retrospectively reviewed 34 patients (8 allografts, 20 mixed grafts, 6 autografts) at 2 years of follow-up; they reported excellent results, with no graft failures and improved IKDC and Tegner scores.

So et al. [38] reviewed 40 patients that underwent DB ACL revision with allograft at 45 months follow-up (range 11–88 months); they reported an 8.6% re-revision rate and improved clinical scores at final follow-up. They also reported that 65% of patients reached the IKDC PASS score at follow-up. These studies show that DB techniques are feasible in ACL revision surgery. They have, however, a short follow-up time with a broad range.

As regards return to Sport after ACL revision, Grassi et al. in a systematic review that included 23 studies, reported a pooled rate of return to the same pre-injury sport level of 52% and an overall return to sport activity of 84%, at a mean follow-up of 5.3 years (range 1.0–13.2 years) [14]. On the other hand, Golovac et al. [9], in a recent review that included 13 studies, underlined that the average rates of return to the previous level of play were variable, ranging from 13 to 69%; while the average rate of return to any level of play ranged from 56 to 100%. None of these studies was aimed at comparing the RTS rate between autograft and allograft. More recently, Mardani-Kivi et al. [23] reported the RTS of a cohort of patients undergoing ACL revision with Achilles allograft at 49 months follow-up (range of 2–6 years). Their 40.3% RTS rate at the same level before the injury is consistent with the results of this study, where 48% of the patients were able to RTS.

The major strengths of this study are the long-term follow-up with a narrow standard deviation, an unequivocal endpoint (defined as the second ACL revision), and the fact that only homogeneous patients with the same ACLR technique and graft type were included.

This study also presents several limitations. First, the retrospective design did not allow the evaluation of the patients at different time points. Unfortunately, apart from the ongoing registry studies [24, 25, 32, 44], retrospective designs are common among observational studies as the present one. Second, the lack of objective and radiographic knee examination did not allow to assess if an increased laxity was present at long-term follow-up; some patients might not have undergone a second ACL revision despite insufficient knee stability. On the other hand, the longterm rate of secondary surgeries for meniscal or cartilage lesions was low, thus indicating a good protective effect from other intra-articular lesions. Furthermore, using a clear endpoint, such as a second ACL revision, has the advantage of leaving no room for misinterpretation of outcomes. Lastly, the lack of a control group did not permit the evaluation of the outcomes between different graft types.

From a clinical point of view, the present study shows good long-term outcomes in patients who underwent non-anatomic Double Bundle ACL revision reconstruction using Achilles tendon fresh-frozen allograft.

Conclusions

Double-bundle ACL revision with fresh-frozen Achilles allograft yields satisfactory results at long-term follow-up, with 85% survival rate from a second ACL revision at mean 10 years follow-up. Patients younger than 22 years old at primary ACLR have a significantly increased risk of undergoing a second ACL revision. Regarding patients reported outcomes, good mean values for all KOOS subscales were reported, and older age at the time of ACL revision is associated with lower Sports and Qol subscales. As much as 48% of patients were still practicing Sport at the same level of the first ACL reconstruction at the time of final follow-up.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval Ethical approval was obtained from the local committee (Prot. n. 0012253 del 11/10/2019).

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