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ADVERSE EVENTS AND COMPLICATIONS REPORTED IN PROSPECTIVE *VS.* RETROSPECTIVE INVESTIGATIONS OF ACLR WITH BTB AUTOGRAFT: A SYSTEMATIC REVIEW

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ABSTRACT – *Objective:* The aim of this study was to evaluate differences in the incidence of reported postoperative complications and adverse events following primary anterior cruciate ligament reconstruction (ACLR) using ipsilateral bone-patellar tendon-bone (BTB) autograft reported in retrospective vs. prospective investigations.

Materials and Methods: A literature search was performed using PubMed, Embase, MEDLINE, and Cochrane library databases using the following terms combined with Boolean operators: 'Bone Tendon Bone'; 'Autograft'; 'Patellar Tendon'; 'Anterior Cruciate Ligament'; and 'Reconstruction'. The inclusion criteria consisted of level I to III human clinical investigations reporting complications following primary ACLR using ipsilateral BTB autograft with a minimum mean follow-up of 24 months. Exclusion criteria consisted of: studies including revision ACLR or using alternative grafts, cadaveric studies, animal studies, review articles, expert opinions, case reports, non-English language studies without English translation, studies that did not report a mean follow-up or had a mean follow-up of less than 24 months, and studies in which the presence or absence of complications were not reported.

Results: Forty studies consisting of 7,376 patients with a mean age of 28.8 years (mean range, 18-42.2 years) were identified. The overall incidence of reported complications in prospective studies (13.1%; n = 796/6,069) was 4.6 times greater when compared to retrospective studies (2.8%; n = 164/5,813 patients) ($p < .001$). The reported incidence of total graft failures ($p < 0.001$), reoperations ($p < .001$), infection ($p = .048$), residual laxity ($p < .001$), post-operative arthrofibrosis ($p < .001$), persistent anterior knee pain ($p < .001$), and development of degenerative changes ($p < .001$) were significantly higher in prospective studies.

Conclusions: Retrospective studies underreport complications following ACLR with an ipsilateral BTB autograft. The incidence of postoperative complications is 4.6 times higher in prospective studies, which report an overall complication rate of 13.1%, with a 7.4% rate of graft failure, 2.5% reoperation, and 1.0% infection rate.

KEYWORDS: Anterior cruciate ligament, ACL, BTB, Bone-tendon-bone, Patellar tendon.

INTRODUCTION

Anterior cruciate ligament reconstruction (ACLR) is one of the most performed procedures for sports-related knee injuries. Annually, over 200,000 ACLR procedures are performed in the United States alone[1,2]. As a result, reconstruction techniques and instrumentations have been the subject of countless research articles, focusing on minimizing surgical failures while improving graft healing and return to sport[1,3,4]. Multiple graft types are available during ACLR, with bone-patellar tendon-bone (BTB) autografts being among the most commonly utilized[1,3,5]. In the existing literature, the BTB autograft has been shown to be associated with low rates of graft failures, low infection rates, and comparable rates of return to sport relative to other graft options[1,6]. Despite the well-documented advantages in outcomes and reliability of the BTB autograft, various complications have been reported which are unique to a BTB autograft, with respect to hamstring tendon autografts. In particular, BTB autografts have unique risks of post-operative anterior knee pain[7-9].

Currently, most reported outcomes of ACLR are based on retrospective studies, inherently confounding results through potential recall or confirmation bias. In contrast, prospective investigations, while not without flaws, may provide more accurate data pertaining to the recording of specific variables, namely complications, during a patient's postoperative course. As such, we aimed to evaluate differences in the incidence of reported postoperative complications and adverse events following primary ACLR using ipsilateral BTB autograft reported in retrospective *vs.* prospective investigations. In our systematic review, we chose to focus on BTB grafts due to their widespread clinical popularity, biomechanical advantages, and documented low rates of graft failure, aiming to address an essential research gap in ACL reconstruction literature[3,7,8]. The authors hypothesized that the incidence of postoperative complications was significantly lower in retrospective *vs.* prospective investigations.

MATERIALS AND METHODS

Search Strategy and Data Extraction

A systematic review was conducted using the 2020 Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines (Figure 1)[10]. A comprehensive literature search was performed by two independent reviewers (G.J., T.H.) of manuscripts published between January 2002 and June 2022 using PubMed, Embase, MEDLINE, and Cochrane Library. The level of evidence of included studies was I to III. Studies must have reported the presence or absence of complications following primary ACLRs using an ipsilateral BTB autograft. The following Boolean search strategy was utilized: (((Bone Tendon Bone Autograft) OR (Patellar Tendon)) AND ((Anterior Cruciate Ligament reconstruction) OR (ACLR)).

Eligibility Criteria

The inclusion criteria consisted of Level I-III human clinical studies, those published in English or with English-language translation, studies reporting outcomes in patients undergoing primary ACLR with ipsilateral BTB autograft, studies with a minimum mean follow-up of 24 months, and those reporting the

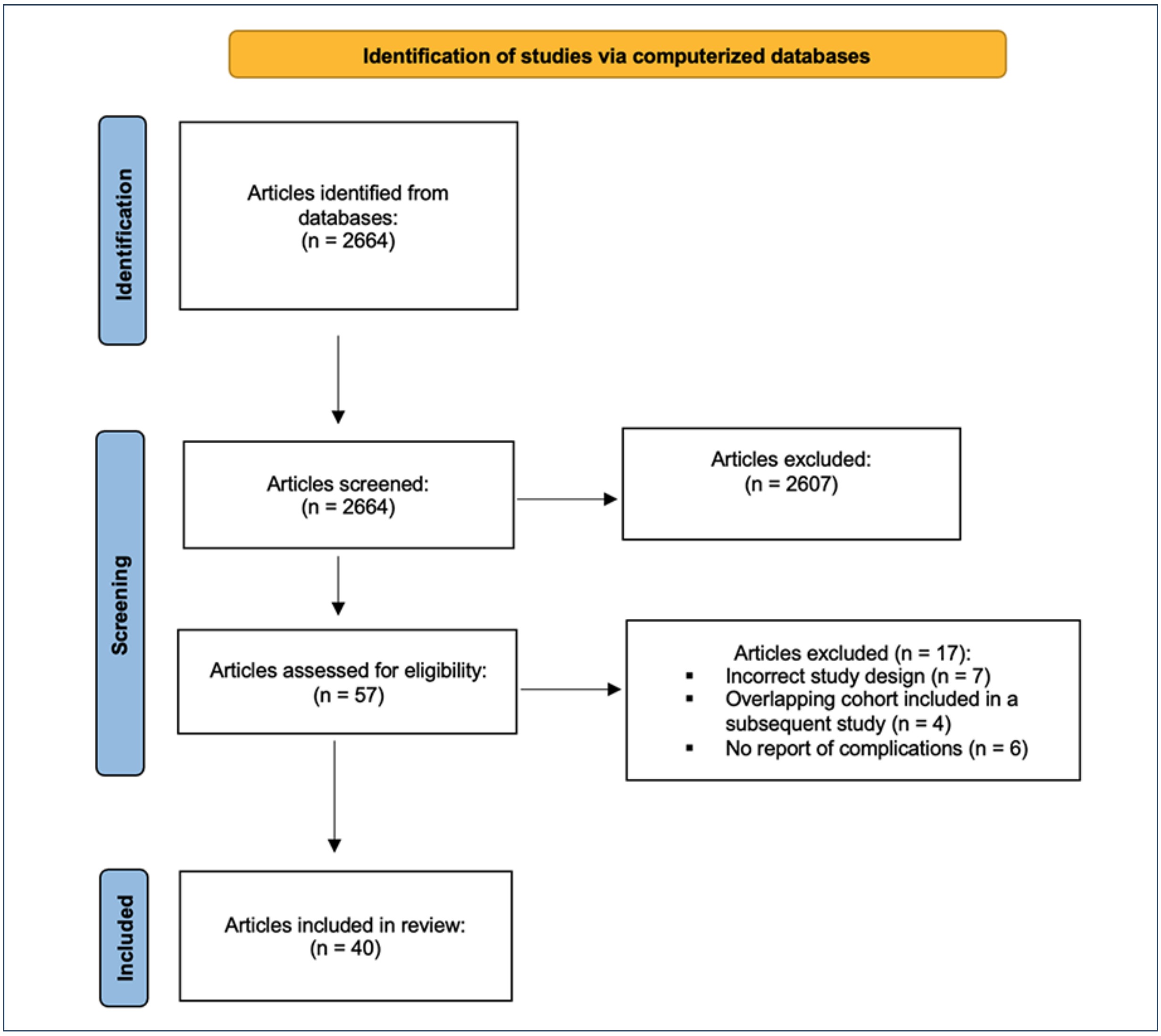

Figure 1. Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) flow diagram.

presence or absence of postoperative complications. Exclusion criteria consisted of animal, cadaveric or biomechanical studies, review articles, expert opinions, case reports, studies published prior to 2002, studies that did not report a mean follow-up or had a mean follow-up of less than 24 months, and studies without any mention of complications following primary ACLR. Studies reporting on patients undergoing revision ACLR, primary ACL repair, ACLR using alternative grafts (quadriceps tendon, hamstring tendon, allograft, contralateral BTB autograft) and studies with concomitant ligamentous procedures (posterior cruciate ligament, posterolateral corner, lateral collateral ligament, medial collateral ligament) were excluded. Studies in which meniscal debridement or repair was performed in conjunction with ACLR were not excluded.

Data Extraction

Two independent authors (G.J., E.M.) assessed article eligibility following the completion of the literature search, which included the title and abstract screening. If any disagreements occurred during the screening process, a third independent author (E.M.) resolved the conflict. To ensure that all available studies were identified, all references from the included studies were reviewed and reconciled to verify that no relevant articles were missed from the systematic review.

Studies were separated by design and classified as either prospective (Level I or II) or retrospective (Level III) by the two authors (J.G., D.D.). In the event of any disagreement, a third author (E.M.)

was consulted. Microsoft Excel version 16.63 (Redmond, WA, USA) was used for data extraction. Collected variables included article title, authors, publication year, level of evidence (per Wright et al[11]), patient demographics, mean follow-up, surgical technique, complications, graft failure rate, and re-operation rates. Graft failure incidences were accepted as reported by each study, despite heterogeneous definitions of failure. Recorded complications included postoperative pain (defined as general discomfort or pain experienced after surgery, which may include various factors such as incision pain, surgical site pain, or discomfort related to the overall recovery process), infection, readmissions, mortality, persistent postoperative laxity, arthrofibrosis, loss of knee extension, persistent anterior knee pain (defined as localized pain in the anterior part of the knee, often associated with activities like kneeling or climbing stairs), and tibial screw-related symptoms. Any complication/adverse event present that did not fit these categories was recorded as "other" during the data extraction phase before being incorporated into the statistical analyses.

Statistical Analysis

The total number of reported complications in prospective and retrospective studies was compiled, and the mean number of complications in prospective and retrospective studies was calculated. Graft failures were separated based on traumatic *vs.* atraumatic mechanisms. A 2-proportion Z-test was performed to evaluate any difference in the incidence of postoperative complications between retrospective and prospective studies. Statistical significance was set to $\alpha = .05$. All statistical analyses were conducted using IBM SPSS Statistics Software (Version 28.0, IBM Corp., Armonk, NY, USA).

RESULTS

Forty studies with a total pooled sample of 7,376 patients were identified. The mean patient age was 28.8 years (mean range, 18-42 years). Eleven retrospective studies[12-22], (Table 1) consisting of 5,818 patients, with an estimated mean age of 29.6 years (mean range, 18-42 years) and 29 prospective studies[23-51], (Table 2) consisting of 1,558 patients with an estimated mean age of 26.8 years (mean range 18-32 years) were analyzed. Mean patient follow-up time in prospective studies was 69.6 months (mean range, 24-360 months) *vs.* 68.7 months (mean range, 24-144 months) in retrospective studies.

The overall incidence of reported complications was 4.6 times greater in prospective investigations (13.1%; n = 796/6,069 patients) when compared to retrospective studies (2.8%; n = 164/5,813) ($p <$ .001). Reported graft failures were significantly higher in prospective studies (7.4%, n = 88/1,193; n =

Table 1. Patients' characteristics of retrospective studies.

Study	Study design	Level of evidence	Patient No.	Mean age (y)	Mean follow up (range), m	Sex (M/F)
Milankov et al[12]	Retrospective Cohort	III	2,215	NR	60 (24-96)	NR
Lecoq et al[14]	Retrospective Cohort	III	541	28.6	144	NR
Gudas et al[13]	Retrospective Cohort	II	88	23.3 (18-32)	48	61/27
Murgier et al[15]	Retrospective Cohort	III	261	18.1	37.2 (24-60.6)	157/104
Brophy et al[17]	Retrospective Cohort	II	945	27 (16-38)	72	NR
Hertel et al[19]	Retrospective Cohort	III	95	42.2 (22-66)	128.4 (110.4-144)	56/39
Kane et al[20]	Retrospective Cohort	III	100	19.8	24	52/48
Halder et al[18]	Retrospective Cohort	III	40	30 (16-54)	28.7 (24-40)	22/18
Barker et al[16]	Retrospective Cohort	III	1,430	34.1	60	NR
Järvelä et al[22]	Retrospective Cohort	III	31	32	120 (42-144)	18/13
Han et al[21]	Retrospective Cohort	III	72	27.8	24	68/4

NR=Not Reported; BTB=Bone-Tendon-Bone; m=months; y=years; M=Males; F=Females.

Table 2. Patients' characteristics of prospective studies.

Study	Study design	Level of evidence	Patient No.	Mean age (y)	Mean follow up (range), m	Sex (M/F)
Beynnon et al[24]	Prospective Cohort	II	28	28.5 (18-46)	36	18/10
Drogset and Grøntvedt[26]	Prospective Cohort	II	100	26 (16-48)	96	45/55
Dejour et al[25]	Prospective Cohort	II	25	27.5	25.4 (18-30)	17/8
Sun et al[30]	Prospective Cohort	II	76	31.7 (20-54)	67.2 (48-94.8)	61/15
Sonnery-Cottet et al[35]	Prospective Cohort	II	105	22.1	39.2 (24-54)	96/9
Holm et al[27]	RCT	I	28	25	120	18/10
Aglietti et al[31]	RCT	I	60	25 (16-39)	24	46/14
Sajovic et al[34]	RCT	I	26	27 (16-46)	60	14/12
Roe et al[33]	Prospective Cohort	II	90	25 (15-42)	84	48/42
Matsumoto et al[32]	RCT	I	37	23.7	87 (60-102)	21/16
Mohtadi et al[38]	RCT	I	103	28.7 (14-50)	59.8 (59.4-60.2)	60/43
Sun et al[29]	RCT	I	33	29.7 (16-59)	24.2 (13-45)	24/9
Feller and Webster[37]	RCT	I	31	25.8	36	23/8
Barrett et al[23]	Prospective Case Series	II	37	25.2 (13-52)	52 (24-58)	0/37
Mohtadi and Chan[36]	RCT	I	110	28.7 (14-50)	24	63/47
Sporsheim et al[39]	RCT	I	35	NR	360 (348-372)	NR
Keays et al[28]	Prospective Cohort	II	29	NR	72	NR
Holm et al[45]	RCT	II	53	27.9 (25-50)	144	NR
Marimuthu et al[47]	Prospective Cohort	II	79	28 (20-52)	36	79/0
Castoldi et al[43]	RCT	II	42	26.2 (15-40)	232.8 (228-242.2)	NR
Lund et al[46]	RCT	II	25	31	24	21/4
Arifeen et al[42]	Prospective Cohort	II	66	28.8 (21-40)	42 (24-60)	66/0
Al-Husseiny and Batterjee[41]	Prospective Cohort	II	42	26 (21-46)	29 (22-41)	42/0
Akgün et al[40]	Prospective Cohort	II	56	30.2 (17-44)	50 (24-87)	44/12
Harilainen et al[44]	RCT	I	40	NR	60 (47-67)	NR
Smith et a[51]	RCT	I	32	17.8	24	15/17
Heijne et al[48]	Prospective Cohort	II	34	29	24	22/12
Maletis et al[54]	Prospective Cohort	II	4,557	24.8 (11.5-84.1)	NR	3,150/1,407
Pinczewski et al[50]	Prospective Cohort	II	90	25 (15-42)	120	NR

NR=Not Reported; RCT=Randomized Control Trial; BTB=Bone-Tendon-Bone; m=months; y=years; M=Males; F=Females.

22 studies[23-27,29,31-40,42,43,46,48,50,51]) *vs.* retrospective studies (0.60%, n = 12/1,993; n = 5 studies[15,16,18,20,21]) ($p < 0.001$) (Table 3, Table 4). Specifically, atraumatic graft failures were more commonly reported in prospective studies (2.4%, n = 13/545 patients; n = 10 studies[24-27,29,31,32,34,35,38]) compared to retrospective studies (0.06%, n = 1/1,542 patients; n = 3 studies[16,18,21]) ($p < 0.001$). However, no significant difference was appreciated in the incidence of traumatic graft failures between prospective (5.8%, n = 42/723 patients; n = 14 studies[24-27,29,31,32,34,35,37,38,40,42,46]) and retrospective studies (4.2%, n = 2/48 patients; n = 3 studies[16,18,21]) ($p = 0.635$).

The reported incidence of reoperations was significantly higher in prospective (2.5%, n = 132/5,371 patients, n = 19 studies[23-27,29,31,32,34,36,39,40,42-44,46,48,51,54]) compared to retrospective (0.5%, n = 8/1,725 patients, n = 5 studies) studies[13,16,18,20,21] ($p < .001$). Postoperative pain was only reported in prospective studies (7.9%, n = 14/177 patients; n = 3 studies[40,41,47]). Anterior knee pain was significantly more commonly reported in prospective (21.8%, n = 165/758 patients, n = 14 studies[24,25,31-34,37,38,40-42,46,47,50,51]) when

Table 3. Postoperative complications reported in retrospective studies.

Study	No. patients	No. complications	Total graft failures	Atraumatic graft failures	Traumatic graft failures	Re-operations	Postoperative pain instances	Infections	Persistent postoperative laxity	Loss of Knee extension	Persistent anterior knee pain	Tibial screw-related symptoms/ complicationsx	Patella Fx	Osteoarthritis	Patella tendon rupture
Milankov et al[12]	2,215	15	NR	NR	NR	NR	NR	NR	NR	0	1	NR	10	NR	4
Lecoq et al[14]	541	57	NR	NR	NR	NR	NR	NR	0	NR	NR	NR	NR	57	NR
Gudas et al[13]	83	5	NR	NR	NR	2	NR	NR	5	NR	NR	NR	NR	NR	NR
Murgier et al[15]	261	8	8	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Brophy et al[17]	945	3	NR	NR	NR	NR	NR	3	NR	NR	NR	NR	NR	NR	NR
Hertel et al[19]	95	8	NR	NR	NR	NR	NR	0	NR	6	NR	NR	1	1	NR
Kane et al[20]	100	1	1	NR	NR	1	NR	NR	NR	NR	NR	NR	NR	NR	NR
Halder et al[18]	40	5	1	0	1	2	0	1	1	1	0	0	1	NR	NR
Barker et al[16]	1,430	7	1	1	0	1	NR	7	NR	NR	NR	NR	NR	NR	NR
Järvelä et al[22]	31	19	NR	NR	NR	NR	NR	NR	NR	NR	16	NR	NR	3	NR
Han et al[21]	72	36	1	0	1	2	NR	1	3	2	28	0	1	NR	NR
Total:	**5,813**	**164**	**12**	**1**	**2**	**8**	**0**	**12**	**9**	**9**	**45**	**0**	**13**	**61**	**4**
Incidence		**2.82%**	**0.60%**	**0.06%**	**4.17%**	**0.46%**	**0.00%**	**0.46%**	**1.22%**	**0.37%**	**1.91%**	**0.00%**	**0.54%**	**9.15%**	**0.18%**

No., number; NR, not reported.

Table 4. Postoperative complications reported in prospective studies.

Study	No. patients	No. complications	Total graft failures	Atraumatic graft failures	Traumatic graft failures	Re-operations	Postoperative pain instances	Infections	Persistent postoperative laxity	Loss of Knee extension	Persistent anterior knee pain	Tibial screw-related symptoms/ complicationsx	Patella Fx	Osteoarthritis	Patella tendon rupture	Other
Beynnon et al[24]	28	10	0	0	0	0	NR	0	3	NR	7	0	0	NR	NR	
Drogset and Grøntvedt[26]	100	69	11	1	10	11	NR	1	10	10	NR	NR	NR	30	NR	Flexion deficit (8)
Dejour et al[25]	25	27	0	0	0	2	NR	NR	NR	NR	9	NR	NR	NR	NR	Hypoaesthesia (17), Cyclops lesion (1)
Sun et al[30]	76	17	NR	NR	NR	NR	NR	0	5	4	NR	NR	NR	7	NR	DVT (1)
Sonnery-Cottet et al[35]	105	20	18	0	18	NR	NR	1	NR	NR	NR	1	NR	NR	NR	
Holm et al[27]	28	24	6	3	3	3	NR	0	NR	NR	NR	0	0	18	NR	
Aglietti et al[31]	60	50	0	0	0	0	NR	0	10	3	37	0	0	NR	NR	
Sajovic et al[34]	26	21	2	0	2	1	NR	0	1	0	5	0	0	13	NR	
Roe et al[33]	90	70	4	NR	NR	NR	NR	0	15	0	24	1	0	24	NR	Cyclops lesion (1), Patellar tendonitis (1)
Matsumoto et al[32]	37	14	0	0	0	12	NR	0	4	4	6	0	NR	NR	NR	
Mohtadi et al[38]	103	21	11	7	4	NR	NR	0	NR	0	10	NR	NR	NR	NR	
Sun et al[29]	33	5	2	2	0	0	NR	0	2	3	NR	NR	0	NR	NR	
Feller and Webster[37]	31	18	2	NR	1	NR	NR	1	1	1	11	NR	NR	0	NR	Notch impingement (2)
Barrett et al[23]	37	3	3	NR	NR	1	NR	NR	NR	NR	NR	NR	NR	NR	NR	

Continued

Table 4 *(Continued)*. Postoperative complications reported in prospective studies.

Study	No. patients	No. complications	Total graft failures	Atraumatic graft failures	Traumatic graft failures	Re-operations	Postoperative pain instances	Infections	Persistent postoperative laxity	Loss of Knee extension	Persistent anterior knee pain	Tibial screw-related symptoms/ complicationsx	Patella Fx	Osteoarthritis	Patella tendon rupture	Other
Mohtadi and Chan[36]	110	17	2	NR	NR	2	NR	3	NR	NR	NR	0	NR	NR	NR	Persistent Effusion (1), Periostitis (1), Nerve injury related to graft harvest (4), Wound dehiscence (1), Patellar Tendinopathy (1), Knee stiffness (4)
Sporsheim et al[39]	35	28	1	NR	NR	1	NR	NR	15	9	NR	NR	NR	NR	NR	Flexion deficit (2)
Keays et al[28]	29	18	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	18	NR	
Holm et al[45]	53	42	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	42	NR	
Marimuthu et al[47]	79	46	NR	NR	NR	NR	11	NR	7	3	16	NR	0	3	NR	Flexion deficit (6)
Castoldi et al[43]	42	48	12	NR	NR	4	NR	NR	7	NR	NR	NR	NR	36	NR	
Lund et al[46]	25	10	1	NR	1	1	NR	NR	12	NR	8	1	NR	NR	NR	
Arifeen et al[42]	66	38	1	NR	1	1	NR	3	NR	14	13	6	1	NR	NR	
Al-Husseiny and Batterjee[41]	42	12	NR	NR	NR	NR	1	1	2	2	1	NR	1	NR	NR	Flexion deficit (4)
Akgün et al[40]	56	14	2	NR	2	2	2	0	2	2	7	1	NR	NR	NR	
Harilainen et al[44]	40	12	NR	NR	NR	3	NR	1	8	NR	NR	2	NR	NR	NR	Femoral screw removal (1)
Smith et al[51]	32	1	0	NR	NR	0	NR	0	0	NR	NR	1	NR	NR	NR	
Heijne et al[48]	34	3	3	NR	NR	3	NR	NR	NR	0	NR	NR	NR	NR	NR	
Maletis et al[54]	4,557	85	NR	NR	NR	85	NR	NR	NR	NR	NR	NR	NR	NR	NR	
Pinczewski et al[50]	90	52	7	NR	NR	NR	NR	NR	13	19	11	2	NR	NR	NR	
Total:	**6,069**	**795**	**88**	**13**	**42**	**132**	**14**	**11**	**117**	**74**	**165**	**15**	**2**	**191**	**NR**	
Incidence		**13.10%**	**7.38%**	**2.39%**	**5.81%**	**2.46%**	**7.91%**	**1.03%**	**12.69%**	**7.72%**	**21.77%**	**1.89%**	**0.44%**	**34.48%**	**NR**	

No., number; NR, not reported; DVT, deep venous thrombosis.

compared to retrospective investigations (1.9%, n = 45/2,358 patients, n = 4 studies[12,18,21,22]) ($p < .001$). Reported post-operative infections were significantly more commonly reported in prospective (1.0%, n = 11/1,063 patients, n = 18 studies[24,26,27,29-38,40-42,44,51]) compared to retrospective studies (0.5%, n = 12/2,582 patients, n = 5 studies[16-19,21]) ($p < .048$).

Persistent postoperative laxity was significantly higher in patients reported in prospective (12.7%, n = 117/922 patients; n = 18 studies[24,26,29-34,37,39-41,43,44,46,47,50,51]) *vs.* retrospective studies (1.2%, n = 9/736; n = 4 studies[13,14,18,21]) ($p < 0.001$). The incidence of loss of knee extension following index surgery was more commonly reported in prospective (7.7%, n = 74/958 patients; n = 16 studies studies[26,29,30-34,37,38-42,47,48,50]) *vs.* retrospective investigations (0.4%, n = 9/2,422 patients; n = 4 studies[12,18,19,21]) ($p < .001$). The development of degenerative changes in the knee was reported in a higher number of patients in prospective (34.5%, n = 191/554 patients; n = 10 studies[26-28,30,33,34,37,43,45,47]) when compared to retrospective investigations (9.2%, n = 61/667 patients; n = 3 studies[14,19,22]) ($p < .001$).

The incidence of reported hardware-related complications was not significantly different in prospective (1.9%, n = 15/793 patients, n = 14 studies[24,27,30-36,40,42,44,46,51]) *vs.* retrospective studies (0.0%, n = 0/112 patients; n = 2 studies[18,21]) ($p = .142$). There was similarly no difference in the reported incidence of patellar fractures in prospective (0.4%, n = 2/452 patients, n = 9 studies[24,27,29,31,33,34,41,42,47]) compared to retrospective studies (0.5%, n = 13/2,422 patients, n = 4 studies[12,18,19,21]) ($p = 0.798$). Lastly, 4 cases of patellar tendon rupture were reported in one large-scale retrospective study[12], occurring in 0.18% (n = 4/2,215 patients), while no prospective studies reported the presence or absence of patellar tendon ruptures.

DISCUSSION

The main findings from this investigation were that the total incidence of postoperative complications in patients undergoing ipsilateral BTB autograft ACLR was 4.6 times greater in prospective studies when compared to retrospective studies, supporting our initial hypothesis. The reported incidence of factors included overall graft failures, atraumatic graft failures, reoperations, infections, anterior knee pain, post-operative laxity, loss of knee extension, persistent anterior knee pain, and the development of degenerative changes, which were more commonly observed in prospective studies. No significant differences were observed in the reported incidences of traumatic graft failures, postoperative pain, hardware-related complications, patellar fractures, or patellar tendon ruptures between study types.

Given the differences in study design, the higher reported rate of graft failures in prospective studies (7.4%) compared to retrospective studies (0.60%) is not surprising. Graft failures are often underreported as a result of ACLR in retrospective studies for several reasons, primarily due to patients lost to follow-up[52]. Prospective investigations, especially those with follow-up greater than 2 years, would be expected to capture more graft failures, providing more reliable data on the true incidence of graft failures. As such, while BTB autografts have a lower incidence of graft failures compared to other available graft sources[53], the difference in reported failure rates between prospective and retrospective studies should prompt further investigation and caution among surgeons when interpreting data from retrospective studies. The reported number of postoperative infections was also found to be higher in patients reported in prospective studies (1.0%) when compared to retrospective studies (0.5%). Postoperative infections after ACLR, though rare, can significantly impact graft integrity and chondral health, necessitating reoperations and extended antibiotic treatments[54-56]. While postoperative infections after ACLR are considered multifactorial, one potential cause of infection onset is thought to be the graft itself[54,55,57-59]. When compared to other commonly utilized grafts for primary ACLR, BTB autografts have been shown to possess a lower incidence of infections[54,55]. In a study of 10,626 cases, Maletis et al[54] found a significantly decreased incidence of infections using BTB autografts for ACLR (0.07%, n = 2/2,965) compared to hamstring tendon autografts (0.61%, n = 20/3,257; $p < .001$) at a mean follow-up time of 12 months. Furthermore, Murphy et al[55] found that when comparing various graft types, patients undergoing reconstruction using a BTB autograft were less likely to develop a postoperative infection (0.6%, n = 29/4,492) in comparison to the hamstring graft group (2.5%, n = 67/2670; $p < .001$), at a mean follow-up time of 12 months.

Reports of persistent laxity and loss of knee extension were also more commonly reported in patients from prospective studies compared to retrospective studies. A comparison of preoperative and postoperative laxity is commonly performed to assess graft integrity and the overall success of the ACLR procedure[60,61]. Several methods are used to evaluate knee stability, such as the Lachman and pivot-shift tests and objective tests, including anterior translation measurements (GNRB arthrometer, Laval, France)[61]. Meanwhile, postoperative extension loss can have a variety of causes, with poignant examples being inadequate tibial tunnel placement, cyclops lesions, and arthrofibrosis[62-64]. In a study performed by Rousseau et al[65] the authors reported a loss of extension, defined as a passive flexion deformity ≥ 5%, in 8.8% of patients at a follow-up time ranging from 8 to 12 weeks. These complications are likely more common in prospective studies due to longer follow-up and more rigorous follow-up procedures. Additionally, prospective studies yield a closer post-operative assessment and evaluation timeline when compared to retrospective studies. Retrospective studies, alternatively, are less likely to have as much control over data collection protocol, which could yield decreased reporting and analysis of postoperative complications and adverse events[66].

In our study, the prospective group also had increased rates of complications, such as persistent anterior knee pain (21.8% *vs.* 1.9%). The increased presence of complications such as persistent anterior knee pain and extension deficits in prospective studies is likely due to the nature of prospective *vs.* retrospective study design (prospective studies granting a more thorough postoperative follow-up period). The pervasiveness of these specific complications may also be related to the time from surgery, during which they were reported during the post-surgical follow-up period.

The most likely explanation behind our findings that prospective studies report higher rates of complications than retrospective studies lies in the inherent limitations of retrospective study designs, potentially resulting in the under-reporting of post-operative complications[66]. Specifically, retrospective studies rely on data previously documented in a chart or entered into a clinical database, as opposed to the collection of data in a predesigned protocol unique to a specific prospective study. Moreover, when study details are collected at later time points when compared to their occurrence, patients may be relied upon to recall specific events or findings, resulting in a recall bias. As a result, it is possible that certain data, such as subtle physical examination or clinic findings, including degrees of extension loss or objective measures of laxity, may not be recorded or reported inaccurately. Furthermore, the interpretation of data from retrospective studies must be performed cautiously due to the potential selection bias as a result of patient loss to follow-up. While the reason(s) for patients being lost to follow-up is often multifactorial, the presence of a complication or unsatisfactory outcome may lead patients to seek second opinions or a new treatment team. This may effectively result in widely inaccurate reporting of complication rate and incidence.

Significantly higher rates of degenerative changes in the knee were observed in the prospective group (34.5%) relative to the retrospective group (9.2%). Approximately one-third of patients sustaining ACL injury, regardless of surgical management, have been reported to develop degenerative changes within one decade injury[67,68]. This finding may be influenced by the increased follow-up time compared to the retrospective group found within this review [69.6 months (mean range, 24-360 months) *vs.* 68.7 months (mean range, 24-144 months)]. Furthermore, the prospective group had a great number of studies with at least a 5-year follow-up (12 studies[26-28,30,32-34,39,43-45,50]) compared to the retrospective group (5 studies[14,17,19,16,22]). In addition, the fact that patients enrolled in a prospective investigation may be more likely to undergo post-operative knee radiographs at specific time points following ACLR, which does not represent common practice unless clinical indications (increasing pain, swelling, trauma, graft laxity concerning hardware loosening/failure) dictate.

Limitations

This study is not without limitations. The defining criteria for each complication were heterogeneous across studies, limiting the conclusions that can be drawn from the sample meeting the inclusion criteria. For example, Drogset and Grøntvedt[26] defined a graft failure as a "Lachman and pivot shift test scores of at least 2+ and more than 3 mm of laxity on the tested side than on the contralateral side" *via* a KT-1,000 arthrometer device. Whereas Castoldi et al[43] included ACL revision surgery, a 3+ pivot shift, and "recurrent instability (> 1 episode), a difference in anterior knee laxity > 10 mm, a soft endpoint in the Lachman test" as part of their definitions of graft failure. Sonnery-Cottet et al[35] utilized MRI imaging studies, and side-to-side laxity greater than 4 mm to define their failures. These studies represent the majority of the prospective study graft failures found in this review. The lack of a standardized definition of graft failure presents a limitation to all attempts to review graft failure rates across multiple studies, and is also presented as a limitation of this review's analysis of retrospective studies.

While our inclusion criteria excluded studies reporting on patients undergoing concomitant ligamentous procedures, it is not possible to determine if all patients included within our analysis truly meet the inclusion criteria. Moreover, by not excluding patients undergoing meniscal procedures, the specific contribution of ACLR on outcomes in the presence or absence of any specific meniscal pathology cannot be inferred. Furthermore, the RCT conducted by Castoldi et al[43] included 43 patients with concomitant lateral extra-articular tenodesis, which has been reported to decrease revision rates. However, this may have a limited effect on the overall complication rate within our review, as 6,069 patients were included in the prospective group. Lastly, as in any systematic review, the search strategy and eligibility criteria may have excluded eligible subgroups of patients or related investigations.

CONCLUSIONS

Retrospective studies underreport complications following ACLR with an ipsilateral BTB autograft. The incidence of postoperative complications is 4.6 times higher in prospective studies, which report an overall complication rate of 13.1%, with a 7.4% rate of graft failure, 2.5% reoperation, and 1.0% infection rate.

Conflict of Interest:

The authors declare that they have no conflict of interest.

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Authors' Contributions:

Garrett Jackson and Luc Fortier: substantial conception/design of work, performed measurements, data collection, statistical analysis, interpretation of data, drafting the work, critically revising the work, manuscript preparation, approving final version for publication, and agreement for accountability of all aspects of work.
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