Original Research

Revision Rates After Primary Allograft ACL Reconstruction by Allograft Tissue Type in Older Patients

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Background: While there is extensive literature on the use of allograft versus autograft in anterior cruciate ligament (ACL) reconstruction, there is limited clinical evidence to guide the surgeon in choice of allograft tissue type.

Purpose: To assess the revision rate after primary ACL reconstruction with allograft and to compare revision rates based on allograft tissue type and characteristics.

Study Design: Cohort study; Level of evidence, 3.

Methods: Patients who underwent primary allograft ACL reconstructions at a single academic institution between 2015 and 2019 and who had minimum 2-year follow-up were included. Exclusion criteria were missing surgical or allograft tissue type data. Demographics, operative details, and subsequent surgical procedures were collected. Allograft details included graft tissue type (Achilles, bone–patellar tendon–bone [BTB], tibialis anterior or posterior, semitendinosus, unspecified soft tissue), allograft category (all–soft tissue vs bone block), donor age, irradiation duration and intensity, and chemical cleansing process. Revision rates were calculated and compared by allograft characteristics.

Results: Included were 418 patients (age, 39 ± 12 years; body mass index, 30 ± 9 kg/m^2). The revision rate was 3% (11/418) at a mean follow-up of 4.9 ± 1.4 years. There were no differences in revision rate according to allograft tissue type across Achilles tendon (3%; 3/95), BTB (5%; 3/58), tibialis anterior or posterior (3%; 5/162), semitendinosus (0%; 0/46), or unspecified soft tissue (0%; 0/57) (P = .35). There was no difference in revision rate between all–soft tissue versus bone block allograft (6/283 [2%] vs 5/135 [4%], respectively; P = .34). Of the 51% of grafts with irradiation data, all grafts were irradiated, with levels varying from 1.5 to 2.7 Mrad and 82% of grafts having levels of <2.0 Mrad. There was no difference in revision rate between the low-dose and medium-to high-dose irradiation cohorts (4% vs 6%, respectively; P = .64).

Conclusion: Similarly low (0%-6%) revision rates after primary ACL reconstruction were seen regardless of allograft tissue type, bone block versus all-soft tissue allograft, and sterilization technique in 418 patients with mean age of 39 years. Surgeons may consider appropriately processed allograft tissue with or without bone block when indicating ACL reconstruction in older patients.

Keywords: anterior cruciate ligament; ACL reconstruction; allograft; revision; failure; knee; arthroscopy

Graft choice in anterior cruciate ligament (ACL) reconstruction has been a topic of extensive study. There is ample literature on comparisons of autograft versus allograft ACL reconstruction, with overall higher failure rates in allograft cohorts,[14-16,36] specifically in younger patients.[7] These studies almost universally pool all allograft tissue types together or examine a single allograft type. There is also considerable literature guiding surgeons on autograft type, with 26 meta-analyses of bone–patellar tendon–bone (BTB) versus hamstring tendon,[2] over 28,000 patients in quadriceps tendon versus hamstring tendon comparisons,[34] and over 27 studies comparing BTB versus quadriceps tendon.[23]

On the contrary, there is a paucity of literature guiding surgeons on choice of allograft tissue type in ACL reconstruction. Reviews of graft choice in ACL reconstruction generally mention the allograft options but do not detail the differences between them,[6] or they discuss the biomechanical differences without clinical outcomes.[13,36] A prior

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report comparing clinical outcomes by allograft tissue type came from a multicenter registry and showed a 2.6% aseptic revision rate at mean follow-up of 2.1 years in patients with mean age of 34 years, with higher revision rate in BTB allografts compared with soft tissue allografts (hazard ratio [HR], 1.8).[35] Literature guiding allograft type in ACL reconstruction is valuable given that allograft is used in up to 42% of primary and 80% of revision ACL reconstructions performed in the community.[21] Additionally, an updated failure rate for allograft ACL reconstruction with modern indications is warranted. Much of the past allograft literature has shown relatively high failure rates, but in the past decade, a better understanding of anatomic ACL reconstruction and proper patient selection—namely, patients older than 35 to 40 years—has developed.[14]

The purposes of this study were to (1) assess the revision rate of allograft primary ACL reconstruction reconstruction would be lower than that seen in historical studies, and (2) there would be no difference in revision rate based on the type of allograft used or graft characteristics.

METHODS

This institutional review board–approved retrospective cohort study included patients who underwent allograft ACL reconstructions at a single academic institution between 2015 and 2019 and who had ≥2 years of follow-up. Exclusion criteria included absent surgical or allograft tissue type data, age <14 due to institutional review board regulations, and revision ACL reconstruction as the index procedure. We included patients who underwent surgery no earlier than 2015 to ensure that the procedures had occurred after broad awareness among surgeons of the literature showing that allograft ACL reconstruction was most strongly indicated in older patients[14,39] Similarly, the included surgeons were from an academic institution as opposed to the broader health care system to ensure the use of modern indications and surgical techniques, such as anatomic tunnel positioning.[12] Each of the included surgeons uses or used a tibial-independent drilling technique. Informed consent was waived given the retrospective nature of the study.

Allograft tissue type was selected in each case based on surgeon preference. The hospital system had partnerships with certified tissue banks Xtant Medical and RTI Surgical that provided the grafts and the company's corresponding standards of irradiation and chemical cleansing. Although a single academic institution was used to capture the study population, revision procedures could be seen in the electronic medical record if they were performed at any institution within the health care system, which is the largest such network in the state of Pennsylvania. Due to the health care system's additional role as an insurance provider, patients commonly stay within the network for the duration of their medical care.

Data regarding patient characteristics (age, sex, body mass index [BMI], race and ethnicity), operative details (procedure, prior surgical procedures), and subsequent revision ACL reconstruction were collected from the electronic medical record. Data on allograft characteristics were collected, including graft tissue type (Achilles tendon, BTB, tibialis anterior or posterior, semitendinosus, or unspecified soft tissue [e.g., unlabeled presutured allograft]) and allograft category (all–soft tissue vs bone block) from the electronic medical record, and donor age, irradiation duration and intensity, and chemical cleansing process from the allograft company. Bone block allografts consisted of all-BTB grafts and any Achilles tendon graft in which the calcaneal bone block was retained. Irradiation intensity was classified into low-dose (<2.0 Mrad or <20 kGy) or medium-to high-dose (2.0-3.0 Mrad or 20-30 kGy), with ≥2.5 Mrad representing high-dose.[18,28]

Statistical Analysis

The primary outcome was revision ACL reconstruction. Revision rates were calculated and compared according to allograft characteristics. Dichotomous variables were reported using counts and proportions (%), and continuous and ordinal data were reported as means ± standard deviations and proportions, respectively. Categorical variables were compared between groups with the chi-square or Fisher exact test. Two-group comparisons of continuous variables were analyzed with independent-samples *t* tests or Wilcoxon signed-rank tests. Multigroup comparisons of

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Ethical approval for this study was obtained from the University of Pittsburgh (No. 19030196).

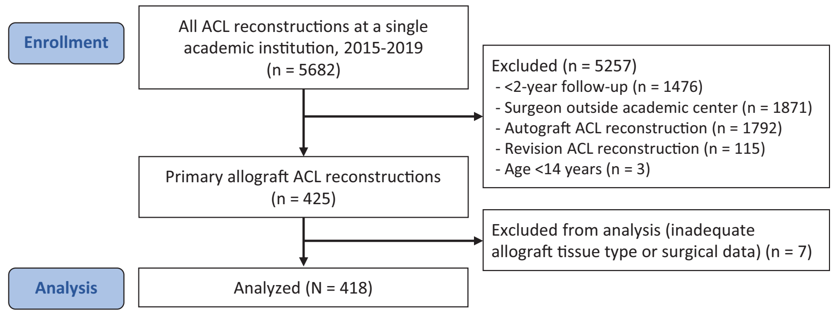

Figure 1. Flow diagram of patient selection. ACL, anterior cruciate ligament.

continuous variables were analyzed with 1-way analysis of variance or Kruskal-Wallis tests. Post hoc comparisons were adjusted with the Benjamini-Hochberg procedure. Statistical significance was set at .05. All tests were performed in SAS Version 9.4 (SAS Institute, Inc).

RESULTS

Of 5682 ACL reconstructions performed during the study period, 418 patients were included in the final study population (Figure 1). The mean patient age was 39 ± 12 years (range, 14-69 years), 46% were female, and the mean BMI was 30 ± 9 kg/m^2 (Table 1). The mean graft diameter was 9.4 mm. The revision rate was 3% (11/418) at a mean follow-up of 4.9 ± 1.4 years (range, 2.3-7.3 years). Racial and ethnic composition of the patient population was 83% White, 11% Black, and 6% other; there was no difference in the revision rate between White (3%) and racial and ethnic minority patients (3%) ($P > .99$). Among the 215 patients with graft donor data available, the revision rate was similar in patients with graft donor age <50 years (4%) versus ≥50 years (3%) ($P > .99$..

When analyzed by allograft tissue type, there were 23% Achilles (n = 95), 14% BTB (n = 58), 39% tibialis anterior or posterior (n = 162), 11% semitendinosus (n = 46), and 14% unspecified soft tissue (n = 57) allografts (Table 2). Among the 215 patients with data available on graft donor and irradiation, donor age was significantly different across allograft tissue types ($P < .001$) (Table 2). Mean graft donor age was younger in the BTB group than in the semitendinosus ($P < .001$), tibialis anterior or posterior ($P < .001$), and unspecified soft tissue groups ($P = .016$). Graft irradiation time (means ranging from 88 to 99 minutes; $P = .20$) and intensity (percentage low intensity ranging from 33% to 48%; $P = .10$) were not significantly different across allograft tissue types.

Regarding allograft tissue type, there were significantly more men ($P = .01$) and the graft donor age was significantly younger ($P < .001$) in patients with bone block versus all–soft tissue allograft. There were no other differences in characteristics or revision rate according to allograft category (Table 3), and there were no differences between bone block versus all–soft tissue allograft in graft irradiation time (93 ± 33 vs 95 ± 43 minutes, respectively; $P = .72$) or intensity (34% vs 40% low intensity, respectively; $P = .10$).

TABLE 1
Characteristics of the Study Cohort (N = 418)[a]

Variable	Value
Sex, female	193 (46)
Age, y	39 ± 12 (14-69)
BMI, kg/m^2	30 ± 9
Racial and ethnic composition	
White	347 (83)
Black	46 (11)
Other	25 (6)
Follow-up time, y	4.9 ± 1.4 (2.3-7.3)

[a]Data are reported as mean ± SD, mean ± SD (range), or n (%). BMI, body mass index.

Among the 215 patients with data available on graft donor and irradiation, the mean graft donor age was 45 ± 17 years. Regarding graft processing, all grafts were irradiated, and all underwent Bacterinse chemical processing. Bacterinse chemical processing is a proprietary process from Xtant Medical and involves the processing reagents gentamicin, polymyxin B sulfate, amphotericin B, cefazolin, povidone-iodine, alcohol, and surfactants. Radiation intensity levels varied from 1.5 to 2.7 Mrad. Of grafts with available data, 82% were exposed to low-dose radiation levels of <2.0 Mrad, and only 4% were exposed to high-dose radiation levels of ≥2.5 Mrad. Mean irradiation time was 94 ± 41 minutes (range, 68-317 minutes).

When comparing revision rates according to irradiation dose, there was no significant difference detected (4% revision for low-dose vs 6% revision for medium- to high-dose; $P = .64$). Similarly, there was no significant difference in mean irradiation time between the nonrevision patients (94 ± 41 minutes) and revision patients (88 ± 9 minutes) ($P = .75$). Among BTB allograft reconstructions with allograft data, no difference was detected in mean graft donor age (33 years in nonrevision vs 22 years in revision; $P = .23$), mean irradiation time (92 minutes in nonrevision vs 96 minutes in revision; $P < .99$), or irradiation intensity (35% low in nonrevision vs 33% in revision; $P < .99$). Similar nonsignificant differences according to revision rates

TABLE 2
Comparison of Characteristics and Revision Rate by Allograft Tissue Type[a]

Variable	Achilles Tendon (n = 95)	BTB (n = 58)	Tibialis Anterior or Posterior (n = 162)	Semitendinosus (n = 46)	Unspecified Soft Tissue (n = 57)	*P*
Sex, female	40 (42)	20 (34)	80 (49)	23 (50)	30 (53)	.22
Age, y	38 ± 13	40 ± 11	38 ± 11	42 ± 10	39 ±12	.22
Body mass index, kg/m^2	30 ± 8	29 ± 5	30 ± 6	29 ± 5	33 ± 17	.20
Graft donor age, y[b]	42 ± 19 (n = 39)	33 ± 14 (n = 31)	47 ± 16 (n = 96)	55 ± 11 (n = 38)	45 ± 11 (n = 11)	**<.001**
Revision	3 (3)	3 (5)	5 (3)	0 (0)	0 (0)	.35

[a]Data are reported as mean ± SD or n (%). Boldface *P* value indicates statistically significant difference between allograft tissue groups ($P < .05$; 1-way analysis of variance for multigroup comparisons; results of 2-group comparisons are detailed in the text). BTB, bone–patellar tendon–bone.
[b]Data available for 215 patients.

TABLE 3
Comparison of Characteristics and Revision Rate by Allograft Category[a]

Variable	Bone Block (n = 135)	All–Soft Tissue (n = 283)	*P*
Sex, female	49 (36)	144 (51)	**.01**
Age, y	39 ± 12	39 ± 11	.74
Body mass index, kg/m^2	30 ± 7	30 ± 9	.44
Graft donor age, y[b]	38 ± 17 (n = 64)	48 ± 15 (n = 151)	**<.001**
Revision	5 (4)	6 (2)	.34

[a]Data are reported as mean ± SD or n (%). Boldface *P* values indicate statistically significant difference between groups ($P < .05$).
[b]Data available for 215 patients.

were seen in graft donor age and irradiation time and intensity among all–soft tissue allograft reconstructions.

DISCUSSION

The primary findings of this study were that, with indications primarily being older patients and with appropriately processed tissue, low revision rates (0%-6%) were seen after allograft ACL reconstruction regardless of allograft tissue type, all–soft tissue versus bone block allograft, and sterilization technique. This is one of few studies that examined clinical outcomes across allograft tissue type and did so with a modern understanding of the indications for allograft ACL reconstruction given the included years. The low revision rates are encouraging for the use of allograft with modern indications, tissue processing, and surgical techniques and suggest that specific graft tissue type is not a critical factor in graft failure.

Literature indicating higher failure rates in ACL reconstruction with allograft versus autograft became strongest in the early 2010s, notably with the Multicenter Orthopaedic Outcomes Network (MOON) cohort.[5,33] Around that time, allograft failure rates were shown to be 10% to 25%, particularly among young and highly active populations.[14,16,39] This dampened enthusiasm for allograft, particularly by high-volume ACL reconstruction surgeons,[3,31] though allograft use remains high in the United States.[21] Further studies have shown allograft failure rates ranging from 0% to 35%.[9,13,25]

The explanation for such a wide range of failure rates with allograft use is likely multifactorial, including patient selection stemming from indications for allograft, allograft processing, slower maturation than autograft, and surgical technique. Each of these may help explain why the failure rate in the present study is appreciably lower than in many prior studies on allograft ACL reconstruction.

Regarding patient selection, literature is convincing that allografts have a high failure rate in young patients, particularly those aged <25 years.[24,39] This evidence led to a decrease in allograft use in patients aged ≤21 years from a peak of 28% in 2009 down to 9% in 2015 in one large registry.[20] In 2014, the American Academy of Orthopedic Surgeons published a clinical practice guideline that stated surgeons could use "autograft or appropriately processed allograft…because the measured outcomes are similar, although these results may not be generalizable to all allografts or all patients, such as young patients or highly active patients."[1] This literature suggests that around 2015 is when more narrowed indications for allograft use became widespread. This aligns with the beginning of the time interval for patient collection used in the present study to ensure that most allograft use was applied with a modern understanding of indications for allograft use in ACL reconstruction. This is represented in the relatively older mean patient age (39 years) in this study. The low revision rate found in the study patients may be attributed in part to the fact that older athletes typically participate in less intense sports and have overall lower activity level compared to high school or collegiate-aged patients.[40,41] Furthermore, older patients may not return to sports as early as their younger counterparts.[4]

The processing of allograft tissue with the goal of reducing the risk of disease transmission and increasing the availability of allograft tissue has been extensively studied, and irradiation has been shown to have an important effect on graft failure. Medium- to high-dose irradiation (≥2.0 Mrad) leads to decreased biomechanical load to failure[18] and increased ACL reconstruction failure rates.[28] On the contrary, low-dose irradiation (<2.0 Mrad) shows variable effects on biomechanical properties,[18] with mixed results on whether it leads to higher[26] or equivalent[10] failure rates in comparison with nonirradiated allograft tissue. More recently, multiple studies have shown no difference in failure rates of nonirradiated allografts versus autografts.[17,19,22,38] Chemical processing techniques are much less studied in part because they are proprietary and poorly reported,[30] though some processes such as BioCleanse have been shown to be associated with significantly higher rates of allograft failure. Allografts in the present study were predominantly (82%) treated with low-dose radiation as well as a chemical processing technique (Bacterinse) that has minimal prior published literature. These modern sterilization techniques—namely, avoiding high-dose radiation and chemical processing that has been shown to lead to higher graft failure—likely contribute to the low revision rate in the present study. Limited detailed graft data in the present study, with such data collected from 51% of the study population, should temper conclusions about irradiation levels.

Regarding surgical technique, the myriad technical variables in an ACL reconstruction across studies certainly play a role in variable failure rates but are challenging to measure and often not reported.[11] The academic center used in the present study highly values anatomic ACL reconstruction and appropriate tunnel placement, which leads to lower failure rates.[37] While tunnel placement was not assessed in this study, each of the included surgeons uses a tibial-independent drilling technique, which better recreates the anatomic femoral ACL footprint[8] but has not been conclusively shown to affect failure rates.[29]

The prior clinical outcomes study of allograft ACL reconstruction based on allograft tissue type was a large registry study with mean age of 34 years and mean follow-up of 2.1 years, in comparison with our mean age of 39 years and mean follow-up of 4.9 years.[35] Their revision rate of 2.6% was similar to that in our study. They found that BTB allografts had a significantly higher revision rate than soft tissue allografts (3.6% vs 2.2%; HR = 1.8), implying that our study too could have found a statistically significant difference with greater power, even if the clinical difference is more debatable. Alternatively, the older patient age in our study could contribute to our opposing finding of no difference in revision across graft types. Irradiation >1.8 Mrad (HR = 1.6) and use of BioCleanse processing (HR = 2.5) were associated with higher rate of revision in the prior study, whereas graft donor age was not. Given the nature of the multicenter registry used in that study, there was a wider variety of graft-processing techniques that could be analyzed than in the present study.

Limitations

Two possible sources of bias regarding graft use in this study are the higher proportion of female patients among the all–soft tissue cohort and the younger graft donor age in the BTB cohort. The first may reflect surgeon bias toward BTB use in the male population, while the second is due to a hospital system policy that has a younger maximum donor age for BTB grafts than for all–soft tissue grafts. Females across all ages have been shown not to have a higher revision rate after ACL reconstruction on meta-analysis,[27] and there are conflicting data on whether graft donor age is associated with graft failure.[32,35] Therefore, it is unclear if or how the study results would be changed by these findings.

There are additional limitations to this study. The primary limitation is the sample size, particularly given the subdivision of the population by allograft tissue type and the low revision rate, making the incidence of the primary outcome infrequent. Significant differences in revision rates among allograft types may have been found with a very large sample, as has been seen in the 1 prior study on this topic.[35] Nevertheless, such a difference may not be clinically relevant given that all graft types and variables in the present study showed revision rates of 6% or less. In comparing the overall revision rate in the present study with historical allograft ACL reconstruction studies, the more important factors in revision rate appear to be patient selection and appropriate graft processing rather than tissue type. Graft data on donor age and irradiation, which were collected from the allograft company, were unable to be collected for all patients. Therefore, conclusions drawn regarding donor age and irradiation—a secondary component of this study—are not as strong as they would be with complete data. Another limitation is the lack of randomization, with surgeon preference largely dictating choice of allograft type. Surgeons have inherent variability in their individual revision rates, likely due to a combination of patient population, surgical technique, rehabilitation program, and return-to-sport protocol. This combined with surgeon preferences in allograft type could have influenced the revision rates seen with each graft type. Furthermore, revisions could only be tallied if they were performed at any institution within the health care system; therefore, some revision reconstructions and nonoperatively treated revision cases could have been missed. However, given that the health care system is the largest network in the state of Pennsylvania and also serves as an insurance provider, patients are generally kept within the network, resulting in a high proportion of revisions that were likely counted. Patient-reported outcomes were not collected, missing some forms of “failure” that did not undergo revision ACL reconstruction. The primary concern with ACL reconstruction historically has been re-rupture and revision rate, less so subjective outcomes, so using revision as the definition of failure is of great utility in evaluation of allograft ACL reconstruction.[13] However, this definition may be limited in older patients who prefer to not undergo revision ACL reconstruction.

CONCLUSION

Allograft tissue type, bone block versus all–soft tissue allograft, and sterilization technique had similar low (0%-6%) revision rates for primary ACL reconstruction in 418 patients with mean age of 39 years. Surgeons may consider appropriately processed allograft tissue with or without bone block when indicating ACL reconstruction in older patients.

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