

# Allograft for Revision ACL Reconstruction

## *The RUSH Experience*

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**Abstract:** The technical aspects of anterior cruciate ligament (ACL) revision surgery are similar whether using allograft or autograft in terms of tunnel position and graft placement. Certain aspects such as saved donor harvest time and site morbidity, decreased tissue handling for exposure, and ability to customize bone blocks are easier with allograft than autograft. All patients who had a revision ACL reconstruction with non-irradiated patellar tendon allograft over a 10-year period were selected from our computerized database. For our series of ACL revisions, failure was defined as either the presence of a pivot shift, and/or greater than 5 mm side-to-side difference on KT-1000 testing. Nine out of 32 of our revision ACL reconstructions (28%) failed using our clinical criteria. There were no postoperative infections. No additional surgeries were performed. There was no clinical evidence of graft rejection. There were no cases of disease transmission. Even though very good results can be achieved in revision ACL reconstruction, outcomes are not as predictable as with primary ACL reconstruction. Long term follow-up is available which shows comparable results between allograft and autograft for ACL revision surgery. The experience at our institution supports findings from other studies that non-irradiated patellar tendon allograft is an acceptable choice for revision ACL reconstruction.

**Key Words:** anterior cruciate ligament, revision, reconstruction, allograft, patellar, tendon, outcomes

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Once it has been established that an ACL reconstruction needs to be revised, there are several graft options available to the surgeon. Iliotibial band, hamstring tendon, quadriceps tendon, patellar tendon—from the ipsilateral or contralateral knee—can be harvested or reharvested as a graft source. Those grafts obtained directly from a donor site on the individual undergoing surgery are categorized as autograft tissue.

Alternatively, allograft tissue can be used for the ACL graft. Allograft tissue is defined as tissue derived from a different individual of the same species. In humans, ligament allograft is universally obtained from cadaveric donors.

There are several theoretical advantages of using allograft tissue instead of autograft tissue. Advantages of use of allograft tissue include lack of donor site morbidity, decreased postoperative pain, and decreased operative time. Additional advantages of allograft in the revision setting include the ability to customize bone blocks, and the ability to make up for tissue lost from the standard donor site used during the index procedure.

Synthetic grafts such as Gore Tex or Dacron are not currently used for revision ACL surgery. Synthetic grafts used in primary ACL reconstruction have shown a higher incidence of early failure when compared with allograft or autograft.<sup>1–4</sup> Fact, the failure of synthetic graft may be an indication for revision ACL surgery.

This article reviews the advantages and disadvantages of using allograft tissue for revision ACL reconstruction and focuses on the results of using non-irradiated patellar tendon allograft for ACL revision surgery at our institution.

### Graft Selection: Non-irradiated Patellar Tendon Allograft

Allograft ACL reconstruction and allograft revision ACL reconstruction were first performed in the early 1980s.<sup>5,6</sup> The use of allograft has evolved over the ensuing decades to the present. It should be noted that all allografts are not the same. The modes of sterilization and preservation influence graft strength, which can have an impact on the outcome of ACL revision surgery.<sup>7–12</sup>

The different types of allograft are categorized by their preservation technique and mode of sterilization. Each different type of sterilization and preservation alters the graft in some way. Hopefully these techniques impart desirable properties onto the graft while minimizing undesirable side-effects caused by graft processing. This article focuses on the results of non-irradiated patellar tendon autograft for revision ACL reconstruction. Our rationale for choosing non-irradiated fresh-frozen patellar tendon allograft as our allograft of choice comes from the belief that this mode of sterilization and preservation maximizes beneficial graft properties without affecting graft quality.

To be safe for use in surgery the allograft tissue must be sterile. A major concern in the use of allograft tissue is disease transmission; viral, fungal, or bacterial. There are several ways to insure graft sterility. The first step begins even before graft harvest. The donor is screened for suitability prior to any procurement, and if the donor does not meet screening parameters, the tissue is not used for harvest. Next, the grafts

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can be harvested in an aseptic manner and transferred into packaging for preservation until implantation.

### Secondary Sterilization

Secondary sterilization is performed on grafts to insure lack of bacterial, fungal, or viral contamination. Chemical sterilization is commonly used on allograft tissue. Ethylene oxide is a common mode of sterilizing surgical instruments that cannot be autoclaved. Of historical interest, ethylene oxide was also used to sterilize allografts. Ethylene oxide is an extremely effective mode of killing pathogens. The drawback of ethylene oxide is that it can cause a persistent synovitis if the levels of ethylene oxide are high in the graft. Another mode of chemical sterilization widely in use is immersion in antibiotic solution. Grafts are soaked in antibiotic solution for 1 to 24 hours prior to preservation. Antibiotic solutions are a very effective way of limiting bacterial contamination, although they do not decontaminate viral pathogens.

Radiation can be used to insure graft sterility. Gamma irradiation has been applied to decontaminate allograft tissue since allografts were first used. The higher dose of radiation that is used, the more definite the killing of any bacteria and viruses. One drawback of gamma irradiation is that current literature suggests that the dose of gamma irradiation required to kill HIV, >3.5 MegaRads, is associated with changes in the collagen microstructure which ultimately cause weakening of the graft tissue, and potentially cause an unacceptable rate of graft failure. Additional alterations in the physical environment of the graft, such as boiling, heat, and ultraviolet light are used for secondary graft sterilization. Their effect on graft integrity is variable.

Alterations in the physical environment can be combined with chemical and/or radiation sterilization. For example, newer processes have been devised which combine chemical sterilization with vacuum/pressure sterilization. The vacuum/pressure process first removes blood, lipids, and marrow from the graft. The graft is subsequently exposed to chemical sterilants to eliminate pathogenic organisms. The last step involves washing the graft free of the chemical sterilants so that residual chemicals do not cause irritation once implanted.<sup>13</sup>

### Preservation Techniques

Multiple different preservation techniques exist to prolong allograft storage. Just as modes of secondary sterilization have their inherent benefits and drawbacks, different preservation techniques also have an effect on graft properties. Freeze drying, cryopreservation, and deep freezing all have unique characteristics, some of which are beneficial and others of which have a deleterious effect on allograft ligament tissue.

Freeze drying involves alcohol dehydration of graft tissue. The advantage is that grafts can be stored at room temperature. The disadvantage is graft brittleness and required rehydration. In both experimental and clinical studies, fresh-frozen grafts have performed superiorly to freeze dried grafts.<sup>14</sup> One proposed advantage of freeze dried grafts is a potential, although unproven, decreased risk of viral transmission because the freeze drying process may kill HIV. However, recent studies have shown that retroviral antigen and proviral DNA

can survive the freeze drying process. Therefore experimental evidence suggests that freeze drying should not be relied upon to inactivate HIV.<sup>15</sup>

Cryopreservation involves placing the graft in a hyperosmotic medium and controlled freezing of the graft at much colder temperatures than fresh freezing will allow. Cryopreserved grafts can last as long as 10 years in storage. Cryopreservation is the most expensive of graft preservation techniques.

According to a survey of the American Association of Tissue Banks, deep freezing (also known as fresh-frozen) is the most common method of allograft preservation.<sup>16</sup> Fresh-frozen grafts can be stored for 3 to 5 years. An added benefit of fresh freezing is that there is decreased cellular antigenicity due to the freezing process.

The ultimate goal of tissue processing and preservation is to make sure the graft is sterile, and that during the process of sterilizing the graft, the strength of the graft has not been compromised. In the United States, the American Association of Tissue Banks (AATB) and the Food and Drug Administration (FDA) regulate the use of allograft tissue.<sup>17</sup>

In summary, graft selection must take into account the positive and negative aspects of both the secondary sterilization technique and the mode of preservation, because both of these factors influence ultimate graft performance. In the authors' opinion, the current ligament allograft of choice is fresh-frozen, non-irradiated ligament graft due to its characteristics. At our institution, the preferred method is to use non-irradiated fresh-frozen BPB allograft. This is because fresh-frozen allograft maximizes the beneficial performance profile of allograft, while minimizing negative graft characteristics.

### Biomechanics

Allograft incorporation occurs via host tissue ingrowth. The allograft ligament tissue acts as a biologic scaffold for host cellular repopulation. Cellular infiltration into allograft ligament takes approximately 4 to 6 weeks. When compared with autograft, allograft bone-patellar tendon-bone remodeling occurs more slowly, taking 1 1/2 to 2 times longer than autograft.<sup>18,19</sup> There are unusual cases of failure of graft incorporation. Usually host cellular elements incorporate into the allograft in a fashion that is undetectable from autograft appearance both grossly and histologically.<sup>20,21</sup>

Allografts do undergo a period of relative weakness during their maturation phase. At 6 months, allografts have approximately 25% to 50% maximum load to failure when compared with intact anterior cruciate ligaments. Alternatively autograft has 61% maximum load to failure at 6 months when compared with intact ACL.<sup>22,23</sup>

Immunologic reaction of the host to donor tissue has been described.<sup>24,25</sup> With modern preservation techniques, reactions may occasionally be detected using biologic markers, but the reaction is subclinical and has not been associated with symptoms or graft failure.

### Disease Transmission

One cannot address the potential benefits of revision allograft reconstruction without taking potential risks into consideration. There are complications particular to the use of

allograft, which do not occur with the use of native tissue. Disease transmission is always a concern. Viral contamination due to unrecognized donor disease is an extremely rare occurrence. In 1985, the only case of HIV transmission due to viral graft contamination occurred.<sup>26,27</sup> Polymerase chain reaction (PCR) is the most stringent method used to detect viral antigens. It was not used universally in 1985. Among tissue banks that use PCR for HIV screening there are no documented cases of viral disease transmission.<sup>28-30</sup> The chance of contracting HIV from a contaminated graft has been calculated to be one in 1.6 million.<sup>31</sup> In addition to HIV, Hepatitis C virus HCV is also a concern. There is an 8 to 10 week period between infection with HCV and serum antibody response. If the tissue is donated in this window, there is a potential for HCV transmission, and several cases presumed to be transmitted in this manner have been reported.<sup>32,33</sup>

In addition to viral transmission, bacterial and/or fungal contamination can also occur. Fortunately, bacterial contamination of the graft due to harvest, storage, or processing loss of sterility, is also rare.<sup>34-36</sup> Including bone grafting, between 350,000 and 650,000 allografts for musculoskeletal surgery are used in the United States every year. To date, there have only been 26 reported bacterial infections. According to the Center for Disease Control, there are a total of 18 reported allograft infections associated with cadaveric ligament transplantation for ACL reconstruction. Isolated bacteria include clostridium species, gram negative bacilli, and polymicrobial infection.<sup>37,38</sup> A final comment on disease transmission from allograft tissue pertains to the method of recording the incidence of transmission. Disease transmission is tracked by the Centers for Disease Control based on reported cases. Disease transmission is likely under-reported, so the actual rates of disease transmission, while still exceedingly low, may be higher than the rates noted above.

## METHODS

For this study we used the same methods as several prior studies from our institution.<sup>39-41</sup> All patients who had a revision anterior cruciate ligament reconstruction with non-irradiated patellar tendon allograft were selected from our computerized database. The collection period was over a 10-year time interval from 1990 to 1999.

The study group comprised a retrospective, non-randomized cohort with a minimum 2-year follow-up. All of the surgery was performed by two experienced surgeons (BRB and CABJ). Those patients who were excluded from the study had the following: associated multi-ligament injury, concomitant extra-articular reconstruction, high tibial osteotomy, contralateral knee ACL deficiency, or contralateral ACL reconstruction.

The patients were evaluated with a subjective questionnaire, physical examination, arthrometric evaluation, functional testing, and validated knee scoring scales. Multiple knee scoring scales were used: KOOS, IKDC, Noyes, Tegner, Lysholm, and SF-12.<sup>42-47</sup>

All revisions were performed via a single or double incision arthroscopically assisted technique. During the diagnostic portion of the arthroscopy, articular cartilage

degeneration was documented. The surgical technique adhered to parameters necessitated by revision surgery. Correct tunnel placement was paramount. If existing hardware could be bypassed it was left in place. If hardware for prior surgeries blocked appropriate tunnel position, it was removed. The allograft bone blocks were crafted to appropriately fill tunnel voids. The allografts were fixed under tension with the knee in extension. The preferred mode of graft fixation was with interference screws. In the few cases where interference screws were not suitable, a staple or a screw and post configuration was used for fixation. Prevention of graft impingement was prevented by revision notchplasty if required.

Post-operatively, the patients followed the same protocol as with primary ACL reconstruction. A staged protocol starting with gait training and range of motion exercises was instituted. Full weight bearing was permitted immediately. A hinged knee brace was used until active quadriceps control was regained. Physical activity was increased in an incremental fashion. At 2 weeks stationary bicycling was started, jogging began at 12 to 16 weeks, and return to full sports activity was allowed at 4 to 6 months post-operatively.

## Data Collection

All patients underwent ligament testing at the time of follow-up. Lachman, anterior drawer, posterior drawer, varus and valgus stress at 0° and 30°, pivot-shift, and KT-1000 tests were performed. Lachman grading was as follows: grade 0 (0 mm displacement), grade 1+ (1 to 5 mm), grade 2+ (6 to 10 mm), grade 3+ (>10 mm). Pivot shift was graded: 0 (normal), 1+ (glide), 2+ (jump), 3+ (transient lock). Range of motion, prone heel height differences, and thigh circumference were recorded in addition to functional testing. Functional testing consisted of a timed single-legged 6-m hop, measured single legged hop, and single legged vertical jump. The functional testing was performed on both the operative and nonoperative legs, each test was completed three times and the result of each trial was averaged. Radiographs were also obtained so that degenerative changes could be documented.

A comprehensive knee questionnaire was completed by each patient. The answers from the questionnaire were used to determine IKDC, KOOS, Tegner, Lysholm, Noyes, and SF-12 results. The questionnaire also included a visual analog pain scale and a subjective patient satisfaction score.

## RESULTS

After screening for exclusionary criteria, 39 patients were eligible for the study. Of the 39 patients, 32 were able to return for follow-up examination and testing. Of the seven patients who did not return for re-evaluation, 3 were lost to follow-up, 3 resided internationally, and 1 died due to an unrelated medical condition. The time interval from initial ACL reconstruction to revision ranged from 9 to 101 months, with a mean interval to revision of 50 months. The follow-up after revision surgery ranged from 2.1 to 12.1 years, with average follow-up of 4.8 years. The patients' age at the time of revision ranged from 16 to 57 years, with an average age of 28 at the time of revision. The division of patients based

on gender was 14 males and 18 females. Twenty of the knees were right knees, and 12 were left knees. The patients had a range of 2 to 5 prior knee surgeries, with a mean of 2.8 surgeries prior to revision. Five patients studied had a previous revision ACL reconstruction. At time of surgery the arthroscopic grading of the status of the articular cartilage in each compartment showed that 73% (23 patients) had some degree of abnormal cartilage wear. Prior meniscal surgery had been performed in 50% (16 patients). There was no statistical significance between the status of the articular cartilage or prior meniscal surgery with consequent revision failure.

Ligament testing showed a statistically significant reduction in post-revision Lachman and pivot shift tests. Preoperative Lachman testing displayed 3 patients with a 1+ test, 16 patients with a 2+ test, and 13 patients with a 3+ test. Post-revision, the Lachman showed 18 patients at grade 0, 10 patients with a 1+ test, and 4 patients with a 2+ test. On pivot shift examination, pre-operatively 8 patients had a grade 1 pivot, 16 had a grade 2 pivot, and 8 had a grade 3 pivot. Post-revision the pivot shift tests were as follows: 23 patients were grade 0, 8 patients had a grade 1 pivot, and 1 patient had a grade 2 pivot. There were no patients with a grade 3 pivot shift test at the time of follow-up; Figures 1 and 2 depict the significant postoperative reductions in the Lachman and Pivot shift examinations.

Preoperative KT-1000 testing was performed on all patients. The maximum manual translation on the affected knee averaged 14 mm, with a range of 8 mm to 21 mm. The unaffected knee had an average of 6.5 mm of maximal manual translation, with a range of 2.5 mm to 13 mm. There was a statistically significant ( $P = 0.001$ ) difference in the arthrometric testing when the preoperative knee was compared with the normal knee. Postoperative KT-1000 testing was also performed. The maximal manual translation on the postoperative knee averaged 9.4 mm, with a range of 6 mm to 18 mm. The maximal manual translation for the unaffected knee at the time of follow-up was 7.8 mm, with a range of 5 mm to 10 mm. There was a statistically significant reduction ( $P = 0.001$ ) in the revised knees compared with their preoperative values.

Functional testing involved a timed single legged hop, a measured single legged hop, and a single legged vertical jump. The timed hop on the operative knee was 102% compared with the nonoperative knee, with a range of 81% to

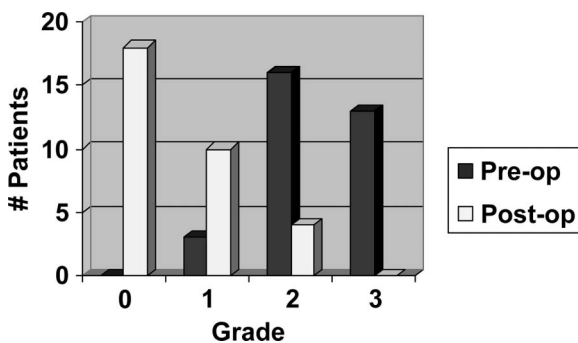


FIGURE 1. Lachman examination.

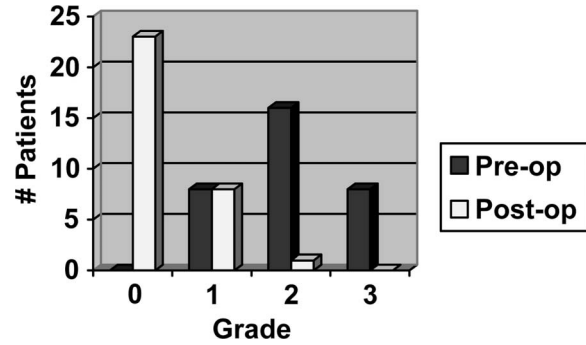


FIGURE 2. Pivot shift examination.

138%. The single legged hop for the operative knee was 96% of the nonoperative knee value, with a range of 78% to 107%. The vertical jump was 98% of the nonoperative knee value, with a range of 35% to 232%.

Multiple knee scores were used to gauge postoperative function as well as subjective patient satisfaction. The mean IKDC score was 71, with a range of 23 to 97. KOOS pain score averaged 84, KOOS symptom score averaged 77, and KOOS activities of daily living averaged 91. The mean Tegner score at most recent follow-up was 6.3, with a range of 0 to 10. The Lysholm score averaged 75, with a range from 30 to 100. The mean Noyes Sports Function score was 72, with a range from 0 to 100. The mean modified Cincinnati score was 7.2 with a range from 2 to 10. The SF-12 mental component averaged 55, with a range of 27 to 66. The mean SF-12 physical component was 48, with a range from 20 to 59. The visual analog pain scale mean was 2.9 with a range from 0 to 9. In terms of subjective satisfaction, 87% were completely or mostly satisfied (Table 1, Figure 3).

For our series of ACL revisions, failure was defined as either the presence of a pivot shift, and/or >5 mm side to side difference on KT-1000 testing. All patients who had >5 mm side to side difference on KT-1000 testing also had a pivot shift. Of patients who had a positive pivot shift, 8 patients had

TABLE 1. Knee Scoring Scales

Scale	Mean	Range	SD*
IKDC	71	23–97	22
KOOS pain	84	36–100	18
KOOS Symptom	77	25–100	21
KOOS ADL	91	50–100	14
Tegner (before any surgery)	8.4	2–10	2.1
Tegner (prior to revision)	5.0	0–10	3.3
Tegner (at most recent follow-up)	6.3	0–10	2.6
Lysholm	75	30–100	22
Noyes Sports Function	72	0–100	26
Modified Cincinnati	7.2	2–10	2.2
SF-12 Mental	55	27–66	8
SF-12 Physical	48	20–59	11
Visual Analog Scale	2.9	0–9	2.5

\*Standard deviation.

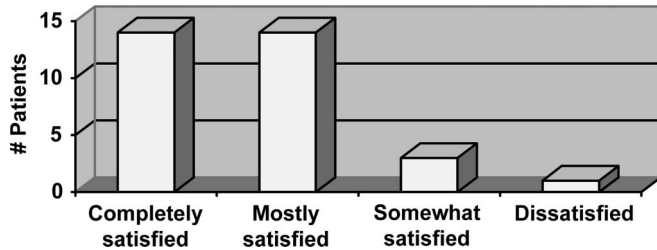


FIGURE 3. Subjective patient satisfaction.

a grade 1 pivot, and 1 patient had a grade 2 pivot. Therefore 9 out of 32 of our revision ACL reconstructions (28%) failed using our clinical criteria. However, it should be noted that some studies collectively report their negative and 1+ pivot scores. Our results would have considerably improved had we chosen to combine our negative and 1+ pivot scores.

When evaluating our complication rate, we looked at several parameters. There were no postoperative infections. No additional surgeries were performed. There was no clinical evidence of graft rejection. There were no cases of disease transmission (no serology was performed).

## DISCUSSION

There are a limited number of studies regarding allograft ACL revision surgery. The results that are reported are generally retrospective studies, using one or two graft sources, in a non-controlled non-randomized manner. The follow-up is also relatively short, from 2 to 4 years.<sup>48-55</sup> As highlighted previously, one has to be clear when analyzing allograft performance. In almost all studies the modes of graft sterilization and preservation are different. Consequently, the biomechanical properties of the graft, and ultimately graft performance are affected. Thus, allograft characteristics must be taken into consideration when reviewing results of series of allograft ACL revisions. For example, the dose of gamma irradiation required to kill HIV is above the minimum dose, which causes graft tissue degeneration and weakening. There are no studies that directly compare allograft to autograft in the revision situation in a prospective fashion. No study to date has shown a difference between allograft and autograft for revision. There are also no studies that directly address the comparison of irradiated versus non-irradiated allograft in the revision situation.

One of the earlier series reporting results of allograft for ACL revision was from Noyes reporting on patients from 1985 to 1990. A total of 66 patients were evaluated at a mean 42 months post-op. Bone-patellar tendon- bone allografts were used. The Cincinnati knee rating system was used for assessment. Significant improvement in symptoms, functional limitations, anteroposterior displacements, pivot shift, and overall rating scores were noted. Fifty-three percent had <3 mm increased displacement. The failure rate was 33%. Forty of the grafts were sterilized with 2.5 MegaRads of gamma irradiation. Thirty-two grafts had a ligament augmentation device (LAD) implanted in addition to the autograft. No significant benefit was found using the LAD in terms of

reduced anteroposterior displacement, symptoms, functional limitations, or improved overall rating scores. Patients reported a satisfaction rate of 70% who were completely satisfied and would have surgery again.<sup>56</sup>

Uribe reported on 54 patients who had revision ACL reconstruction, 19 of which were reconstructed with allograft. Results were followed at a mean of 32 months post-operatively. Lysholm knee score, Tegner activity scale, and subjective questionnaires were used for evaluation. Stability objectively improved in all patients. Allograft was compared with ipsilateral and contralateral BPB autograft. Revision improved stability in all patients, when either autograft or allograft was used. Functionally there was no significant difference between the autograft and allograft groups. Subjective results were worse depending on degree of articular cartilage degeneration. Only 54% returned pre-injury activity level.<sup>57</sup>

In general, the reported results for revision ACL surgery are not as favorable as for primary ACL reconstruction. But, all studies show an improvement after revision compared with pre-revision status. There are only a relatively small number of studies that focus on the outcome and results after ACL allograft revision. Our study supports these findings.<sup>58</sup> Our patients' subjective satisfaction scores were 88% mostly or completely satisfied. Our clinical instability tests, in particular the pivot shift examination showed a 28% failure rate.

## CONCLUSION

Allografts have been used in ACL reconstruction and ACL revision surgery. Long term follow-up is available, which shows comparable results to autograft tissue for ACL revision. Failure rates differ in each study, but in most studies targeting revision ACL surgery, autografts and allografts show similar performance.

Rehabilitation protocols have changed significantly since the beginning of ACL revision surgery. Rehabilitation in the revision setting should be more conservative than the standard, accelerated ACL postoperative protocol used in primary reconstruction. Concurrent procedures, such as meniscal surgery, may also occasionally necessitate alteration in rehabilitation protocols.

Disease transmission is always a concern when using allograft tissue. Fortunately, it is a rare occurrence. Allograft tissue is safe, but the surgeon must be knowledgeable regarding the processing of the graft obtained. The surgeon should also monitor the tissue bank that he or she chooses to use to insure that they follow the safety protocols recommended by the American Association of Tissue Banks and mandated by the Food and Drug Administration.

The technical aspects of revision surgery are similar whether using allograft or autograft in terms of tunnel position and graft placement. Certain aspects such as saved donor harvest time and site morbidity, decreased tissue handling for exposure, and ability to customize bone blocks are easier with allograft than autograft.

Even though very good results are achievable in revision ACL reconstruction, outcomes are not as predictable as with primary ACL reconstruction. It is extremely important to

convey to the patient that revision ACL should be considered salvage surgery. Regardless of graft choice, avoiding unrealistic patient expectations is critical prior to proceeding with revision surgery.

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