Nonirradiated Versus Irradiated Achilles Allograft: In Vivo Failure Comparison

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Nonirradiated Versus Irradiated Achilles Allograft

In Vivo Failure Comparison

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Background: Many studies suggest that gamma irradiation decreases allograft strength in a dose-dependent manner. No study has demonstrated that this decrease in strength translates into higher clinical failures.

Hypothesis: Irradiation of allograft tissue will lead to higher early clinical failure in anterior cruciate ligament (ACL) reconstruction.

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

Methods: Medical records were reviewed for 90 consecutive patients who had received Achilles allograft reconstruction for unilateral primary ACL injuries at one institution between July 2001 and June 2002. One half of patients received nonirradiated Achilles allograft and the other half received irradiated Achilles allograft at a dose range of 2.0 to 2.5 Mrad. The ACL allograft reconstructions were performed using the same surgical technique. The rehabilitation program was identical for both groups. All clinical failures were recorded.

Results: At least 6 months' follow-up was available on 42 subjects in the nonirradiated group and 33 subjects in the irradiated group. A significant difference was noted in early failure rates between the groups ($P < .01$). The nonirradiated group had 1 in 42 (2.4%) catastrophic failure. In the irradiated group, 11 of 33 (33%) Achilles tendon grafts failed.

Conclusions: Less than satisfactory results led the senior authors to discontinue the use of irradiated allografts in ACL surgery. Continued research into alternatives to gamma irradiation is needed.

Keywords: anterior cruciate ligament (ACL); allograft; irradiation; ACL reconstruction

The use of allograft tissue in orthopaedic surgery has increased over the past 2 decades. Multiple studies support the use of nonirradiated allograft tendon in orthopaedic surgery.[1,18-20,24,27,28,33,39] In anterior cruciate ligament (ACL) reconstruction, allografts create no donor-site morbidity and allow decreased surgical time and smaller surgical incisions. A disadvantage in the use of allograft tissue is the potential risk of disease transmission. Today, the incidence of human immunodeficiency virus (HIV) being transmitted via allograft tissue is estimated to be between 1:1 million and 1:1.5 million, primarily due to a stringent screening process of the donors.[2,5,6] Bacterial transmission in allograft surgery was highlighted in 2001, with the death of a recipient of an allograft contaminated with Clostridium species.[8] Soon after that case, other cases of allograft-associated infections surfaced, leading the Centers for Disease Control to recommend secondary sterilization of all allograft tissues.[8,9,10] As ethylene oxide sterilization led to poor clinical outcomes secondary to higher early clinical failures and persistent synovitis,[23,29] sterilization with gamma irradiation has become more commonplace.[37] Because most bacteria and spores are eliminated at 2.0 Mrad[12] of irradiation, many bone banks, including the one from which we receive the majority of our allografts, have adopted policies to irradiate and wholly sterilize soft tissue allografts. Unfortunately, virucidal efficacy at this level of irradiation is lacking.[13,36] Many studies have been done in vitro comparing the effects of irradiation on allograft integrity, strength, and other biomechanical parameters.[3,15-17,32] These studies suggest that gamma irradiation decreases allograft strength in a dose-dependent manner. The goal of this study was to determine whether the use of

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irradiated tissue in allograft Achilles tendon ACL reconstruction would lead to higher clinical failure rates.

MATERIALS AND METHODS

Using the database of 2 senior surgeons (P.A.I. and K.M.), patients were selected and medical records were reviewed for all patients who received primary unilateral ACL reconstruction with allograft Achilles tendon between July 2001 and June 2002. None of the patients in the series had other ligament injuries. In January 2002, our tissue bank changed the sterilization process for all allografts to include secondary sterilization with batch gamma irradiation at a dose range of 2.0 to 2.5 Mrad. Counting back from this date, the last 45 patients whose Achilles tendon allografts had not undergone gamma irradiation were selected. Beginning again at January 2002, the next 45 patients to receive irradiated Achilles tendon allografts for ACL reconstruction were chosen for the study. In this way, 90 consecutive patients were identified. The mean ages of the patients were 27 years (range, 14-57 years) in the nonirradiated group and 26 years (range, 14-59 years) in the irradiated group.

The 2 senior authors (P.A.I. and K.M.) performed the ACL allograft reconstructions using the same surgical technique. The rehabilitation program was identical for both groups. The patients were asked to return for clinic visits at 1, 3, 6, 12, and 24 weeks and at 1 year after surgery, or to call for an appointment at any time if a problem developed. At return visits, the Lachman test was used, along with the KT-1000 arthrometer (Medmetric, San Diego, Calif) to check anterior translation. The KT-1000 arthrometer test was performed by a trained physical therapist with the knee in 20° to 30° of flexion using maximum manual pull performed 3 times. Other physical tests, such as range of motion, were used to assess function. The knee was examined for abnormal swelling and/or evidence of infection. In addition, a set of 4 radiographs was used to check for graft placement failure—anteroposterior, lateral, Merchant, and tunnel views. Lateral projections were evaluated for improper anterior tunnel placement using the criteria that the tibial tunnel should remain posterior to Blumensaat's line.

All clinical failures found through regular clinic follow-up were recorded. Failures were designated by KT-1000 arthrometer by a difference of 5 mm or greater anterior translation on the affected side than on the nonaffected side, a positive Lachman test on physical examination, or MRI evidence of a failed graft.

Graft Preparation

All tissue used in this study was harvested under strictly sterile conditions by the same tissue bank. The tissue was processed under industry-accepted aseptic processing guidelines. The sterility of the tissue was checked with cultures throughout the preparation process. All tissues were deep frozen using controlled-rate freezing of 1° to 3°C per minute and maintained at a temperature of –80°C. At time of implantation, the allograft was warmed as per protocol in a warm saline bath before implantation.

Surgical Procedure and Rehabilitation

All ACL allograft reconstructions were performed by 1 of the 2 senior authors using the same surgical technique. An arthroscopic procedure immediately preceded the allograft ACL reconstruction in all of the cases, to identify and correct coexisting meniscal injury. Each Achilles allograft was pretensioned on a tensioning board at 15 lb of tension for at least 20 minutes before implantation.

The ACL reconstructive procedure was performed by a standard endoscopic technique. A transtibial tunnel approach was used in creating an appropriately placed femoral tunnel. The bone plug of the graft was placed close to the femoral tunnel aperture in the intercondylar notch. Because of the design of the graft, length mismatching was never a problem.

Femoral fixation of the graft was performed with an Endobutton (Smith & Nephew, Andover, Mass). Tibial fixation was achieved using a WasherLoc washer (Arthrotek, Warsaw, Ind). At the close of each case, once firm fixation was achieved, Lachman and pivot-shift tests were negative. The rehabilitation program was identical for both groups. This consisted of early mobilization with gradual strengthening once full range of motion was obtained as per standard protocol. Postoperative bracing was eliminated once the patient had obtained a normal gait pattern. Patients were trained in the use of crutches before the ACL reconstruction. Afterward, the patient's walking technique with crutches was evaluated and corrected, if necessary, by a physical therapist. The patient was urged to use crutches until they were able, in the opinion of the physical therapist, to maintain a safe, normal gait pattern without them. The athletes were allowed to return to sport when the quadriceps muscle and hamstrings had regained at least 80% of the strength of the opposite (control) leg.

RESULTS

Of the 90 patients who underwent ACL reconstruction using Achilles allograft, complete follow-up data were available on 75 patients. Nonirradiated Achilles tendon grafts had been used for 45 subjects, and 42 of these subjects completed 6 months of scheduled visits. The next 45 patients in the series had ACL reconstructions using irradiated Achilles tendon allografts. Of these, only 33 returned for the full series of clinic visits. Among the 75 patients returning, 12 failures were identified. Of 42 patients who completed follow-up in the nonirradiated group, only 1 (2.4%) had a clinical failure, whereas 11 of 33 (33.3%) patients in the irradiated group who completed follow-up had a clinical failure. A significant difference was noted in failure rates between the groups ($\chi^2 = 9.61$, $P < .01$) (Figure 1). The surgeons' failure rates were 15.6% and 7.6% overall.

Lateral projections were evaluated for improper anterior tunnel placement. None of the cases in this study demonstrated any tibial or femoral malposition. Clinically, none of the failures in our series were found to have coexistent untreated ligamentous injuries.

The probability of a successful ACL reconstruction using nonirradiated Achilles tendon allograft was 97.6%, whereas

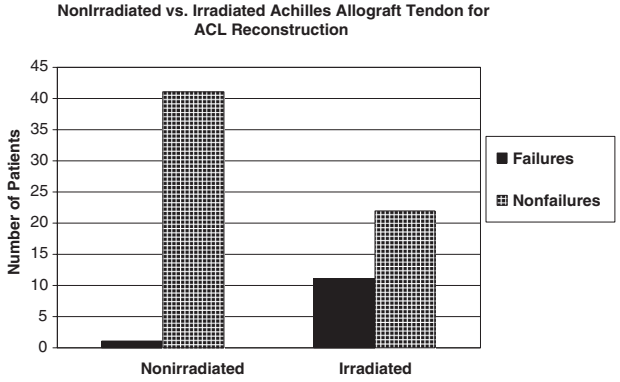

Figure 1. Outcome of patients who completed follow-up after receiving an Achilles tendon allograft for ACL reconstruction. In the group receiving the nonirradiated tendons, 1 of 42 ACL reconstructions failed. In the group receiving irradiated allografts, 11 of 33 ACL reconstructions failed. The difference in failure rates was significant ($P < .01$).

the probability of success using irradiated tendon allograft was only 66.7%. The relative risk of failure using an irradiated tendon compared with a nonirradiated tendon was 14:1 (11/33 divided by 1/42). Follow-up on all patients included in the study was at least 6 months. However, some patients had longer follow-up secondary to returning to the clinic with problems. The time to failure for the 1 failure in the nonirradiated tendon allograft group was at 22 months, whereas the average time to failure for the 11 failures in the irradiated group was 13.4 months (range, 5-27 months) (Table 1).

DISCUSSION

Failure of ACL reconstruction occurs for various reasons. Surgical technical errors, such as nonanatomic graft placement and failure to address associated ligamentous injuries at the time of the original procedure, are responsible for graft failures in most reported series.[4] Other reasons for ACL reconstruction revision include traumatic reinjuries and lack of graft incorporation.[7] A standard set of 4 radiographs were used to determine graft placement failure. One failure in the irradiated group was due to patient noncompliance with early return to activity before proper quadriceps function. Seven (6 irradiated, 1 nonirradiated) of 12 failures occurred at 1 year or more after the initial ACL reconstruction. Three of 11 of the irradiated failures were found by KT-1000 arthrometer testing within the first 6 months of surgery. The ultimate cause of the increased failure rate in our irradiated group is not fully understood.

After the protocol was changed so that Achilles tendon allografts were irradiated, we observed that our ACL reconstructions were failing more often. Anterior cruciate ligament reconstructions for 11 of the first 45 patients who received irradiated Achilles tendon allografts failed—some quite early. At this point, the possibility of instituting a prospective, randomized study was considered briefly; but we did not believe such a study would be in the best interest of

TABLE 1
Data for Patients with Failed Anterior Cruciate Ligament Reconstruction using Achilles Allograft[a]

Age (y)	Gender	Irradiated	3-mo KT (mm)	6-mo KT (mm)	Diagnostic	Time to Confirmation of Failure (mo)	Revision
23	M	No	0.5	none	Positive Lachman, MRI	22	Nonirradiated patellar tendon allograft
16	M	Yes	0.5	0.5	Positive Lachman, MRI	27	Nonirradiated Achilles tendon allograft
14	F	Yes	1.5	2	Positive Lachman, MRI	20	Patellar tendon autograft
17	F	Yes	None	4	Positive Lachman, MRI, 5.5-mm side-to-side difference on KT	10.5	Nonirradiated Achilles tendon allograft
19	F	Yes	2	0	Positive Lachman, 9.5-mm side-to-side difference on KT	19	Nonirradiated Achilles tendon allograft
18	F	Yes	0	1	Positive Lachman, MRI	12	Patellar tendon autograft
24	F	Yes	4.5	5	Positive Lachman, MRI	9	Patellar tendon autograft
17	M	Yes	2.5	2.5	Positive Lachman, MRI	16	Patellar tendon autograft
21	M	Yes	1.5	5	Positive Lachman, 5-mm side-to-side difference on KT	5	No revision
23	M	Yes	6	6	Positive Lachman, 6-mm side-to-side difference on KT	6	No revision
34	F	Yes	1	6.5	Positive Lachman, 6.5-mm side-to-side difference on KT	6	Revision at another institution
21	F	Yes	0.5	2	Positive Lachman, MRI	16.5	Revision at another institution

[a]KT, KT-1000 arthrometer (measuring anterior translation of the tibia).

our patients, some of whom would have received what we considered a suboptimal treatment. However, the differences between irradiated and nonirradiated Achilles tendon allografts was striking enough that we wanted to make this information available to other orthopaedic surgeons. Reporting a comparison of the failure rates between patients receiving irradiated allografts and those receiving nonirradiated allografts seemed the best option. The drawback to this type of study was that we were limited to the information available in the patients' charts.

The percentage of follow-up was 93% for the nonirradiated group and 73% for the irradiated group. At first glance, this difference appears problematic. However, it actually strengthens our findings. Follow-up was much better for the group receiving nonirradiated Achilles tendon allografts. If irradiated and nonirradiated Achilles tendons had worked equally well for the ACL reconstructions, we would have expected to see more failures in the nonirradiated group because we had follow-up on more patients. Instead, only 1 in 42 ACL reconstructions failed in this group.

In our experience, the use of nonirradiated Achilles allograft tendon for ACL reconstruction has been an excellent graft choice, allowing our patients a quick return to activity and providing very few failures. Others, including Harner et al,[18] Shelton et al,[33] Noyes and Barber-Westin,[27] and Bach et al,[1] have demonstrated good results with nonirradiated allograft tissue used in primary ACL reconstruction. Harner et al[18] compared a series of 64 patients reconstructed with nonirradiated allograft tissue with 26 patients reconstructed with autograft tissue. When patients were followed up (3 to 5 years after their operation), 92% of autograft patients and 94% of allograft patients had a side-to-side difference of <5 mm. Shelton et al[33] found no statistically significant difference at 2 years between 30 patients treated with nonirradiated bone-tendon-bone allografts and 30 patients treated with autograft bone-tendon-bone. Noyes and Barber-Westin[27] compared nonirradiated bone-tendon-bone allografts and nonirradiated fascia lata allografts with long-term follow-up. Based on KT-1000 arthrometer evaluation and pivot-shift testing, they reported 74% of 68 allografts as functional, 19% as partially functional, and 7% as having failed. Most recently, Bach et al[1] demonstrated excellent results with fresh-frozen nonirradiated patellar tendons used for ACL reconstruction. In 59 patients with long-term follow-up, 95% of patients had KT-1000 arthrometer side-to-side differences that were ≤3 mm and none >5 mm.

In the European literature, Victor et al[38] demonstrated good overall results with allograft, yet they demonstrated a 12% (3/25) rerupture rate at 2 years of follow-up in nonirradiated allograft bone-tendon-bone. The authors hypothesized that this higher rerupture rate may be due to failure of the tendon to complete ligamentization.[38] Contrary to Victor et al,[38] Siebold et al[35] showed higher clinical failure rates in fresh-frozen patellar tendon versus Achilles tendon allografts when combining laxity failures and reruptures—14.8% versus 7.3%, respectively.[35]

Shino et al[34] demonstrated that full graft maturity in allograft Achilles and patellar tendon does not occur until 18 months from implantation. On a microstructural level, once implanted both allograft and autograft tissue undergo a sequence of graft necrosis, cellular repopulation, revascularization, and collagen remodeling.[22] This ligamentization process has been shown to proceed at a slower pace in allograft tissue.[21,22,26] Recently, in an autopsy specimen, Malinin et al[25] showed lack of central vascularization and central acellularity in an allograft 2 years after implantation. Slower maturation when compared with autograft has led authors to hypothesize that this may lead to increased late failures in allografts.[21,38] In all of these studies, to the best of our knowledge, all allografts studied were nonirradiated. The effects of irradiation and the speed to ligamentization in vivo on a microstructural basis are not well understood currently.

It is well established that irradiation of allograft tendon decreases biomechanical properties in a dose-dependent manner.[15-17,31] Fideler et al[16] demonstrated that the initial biomechanical strength of allografts was reduced 15% when compared with controls after 2 Mrad of irradiation. He showed a dose-dependent effect of irradiation at 3 and 4 Mrad with significant decrease in biomechanical integrity of grafts. Furthermore, De Deyne and Haut[15] showed that at 2 Mrad of irradiation, the tensile strength and modulus of tendon allograft was decreased significantly. They also showed that with increasing doses of irradiation, the deleterious effects were expressed in the tendon on a microscopic level. Gibbons et al,[17] studying irradiated goat patellar tendons, showed that irradiation doses greater than 2 Mrad significantly reduced stress and strain values. These findings have been confirmed by the work of Schwartz et al.[32] In their study using a caprine model, they reported that high gamma irradiation (4 Mrad) adversely affected the viscoelectric and structural properties of ACL allografts at 6 months. Because of the altered biomechanics, they concluded that irradiation of allografts is not a feasible clinical option.[32] At the time we submitted this paper, no series had been published comparing outcomes in irradiated allografts versus nonirradiated allografts in similarly age-matched humans.

Curran et al[14] demonstrated an average load at failure of 1965 ± 512 N for irradiated patellar tendon grafts and 2457 ± 647 N for nonirradiated patellar tendon grafts—an average 20% decrease in strength for irradiated grafts. Curran et al[14] showed that after 1000 tensile cycles to 250 N, grafts elongated 27% more ($P = .03$) when irradiated than when not. The increase in elongation occurred primarily during the first several cycles in Curran's study, but we suspect that irradiated allografts may continue to elongate under increased cycles and loads. This could be one of the factors contributing to our increased failure rate with irradiated Achilles tendon allografts.

The parameters for irradiation are adopted based on risk assessment between sterilization and the potential damage to the graft. There are significant concerns of bacterial infection risk versus compromise of graft integrity. This study is the first to suggest an increase in early failures when irradiated allografts are used for ACL reconstruction. Irradiation for bacterial sterilization is plausible because low doses of irradiation do in fact eliminate these organisms. However, with regard to HIV infection, research suggests

that current gamma radiation doses of 1.5 to 2.5 Mrad do not constitute a virucidal dose for HIV.[35] Doses as high as 5 Mrad on allograft tissue still showed active viral replication of HIV in the exposed tissue.[13,35] At 5 Mrad, tissue is significantly compromised and not usable as a structural graft. Lastly, some tissue banks (including ours at the time of this series) batch-dose their irradiation. Therefore, depending on the distance of the graft from the irradiation, there can be a wide disparity between the amount of radiation received in each graft within a single batch.[11,30]

Limitations include those often found in retrospective studies, where information is limited to what has been recorded in medical records. The results of pivot-shift testing at the final clinic visit were recorded in many of the charts, but not all of them. A validated functional scoring system (International Knee Documentation Committee) was used to assess outcome, but scores were not in all patient charts. Preinjury activity level had not been recorded in medical records. Because the patients were from the same general population, were selected consecutively, and the groups were similar in age, we assumed that their activity levels were roughly the same. Likewise, information on length of time until the subject returned to his or her preinjury activity level was not available for enough subjects for analysis to be meaningful. The standard of care for Achilles tendon allograft ACL reconstruction is to follow patients for 6 months; thus, this was the longest time we could cover in a retrospective study. A prospective study with longer follow-up and a standardized functional outcome measure would be valuable. We hope such a study will be conducted in the future.

In conclusion, this study makes us aware of the potential adverse effects of irradiation of allograft tissue in vivo. Whether our increased failures were due to slowed ligamentization, increased creep, or an overall weakness of the graft is not well understood. The 33% failure rate in our patients receiving irradiated allograft reflects only patients who returned for regular clinical follow-up. More failures may have occurred in this group. Nevertheless, the 33% failure rate using irradiated allografts in ACL surgery was significant enough that the senior authors decided to discontinue the use of irradiated allografts in ACL surgery. We also considered our findings to be important and wanted to share them with the orthopaedic/sports medicine community. Continued research into the efficacy of gamma irradiation and into the cause of the higher early failure rate in the irradiated allografts is needed.

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