Failure of Primary Anterior Cruciate Ligament Surgery Using Anterior Tibialis Allograft

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Purpose: The purpose of this study was to evaluate the outcome of anterior cruciate ligament (ACL) reconstruction via anterior tibialis tendon allograft. **Methods:** We performed a retrospective review of 125 consecutive patients who underwent ACL reconstruction via an anterior tibialis tendon allograft. Of these patients, 69 were available for follow-up at a mean of 55 months (range, 42 to 74 months); their mean age was 31.7 years (range, 19 to 69 years). Clinical evaluation consisted of the Lysholm knee score, activity level assessment, and International Knee Documentation Committee assessment. **Results:** Of the 69 patients, 16 (23.1%) required revision ACL reconstruction for graft failure. In addition, 26 patients (37.7%) required repeat surgery, including 16 revision ACL reconstructions, 9 arthroscopic meniscal surgeries, and 1 total knee arthroplasty. The mean age of those patients in whom failure occurred was 22.8 years compared with 34 years in those in whom failure did not occur ($P = .0039$). The failure/reoperation rate of those aged 25 years or under was 55% (17/31), as compared with 24% (9/38) in those aged over 25 years. The mean Lysholm knee score was 85.6 (range, 15 to 100), and the mean activity score was 4.36 (range, 0 to 9). Of the 52 patients who did not require revision ACL surgery, 86.2% rated their knee as normal or nearly normal. **Conclusions:** A reoperation rate of 38% after primary ACL surgery is high. We do not recommend the use of anterior tibialis allograft in young patients (aged ≤25 years) or those who participate frequently in level I ACL-dependent sports. **Level of Evidence:** Level IV, therapeutic case series. **Key Words:** Anterior cruciate ligament—Allograft—Revision.

Arthroscopic reconstruction of the anterior cruciate ligament (ACL) continues to be one of the most commonly performed orthopaedic procedures. Published results of primary ACL reconstruction have generally been favorable.[1-3] Despite this success, graft choice continues to be controversial. The most commonly used grafts for reconstruction are currently either the bone–patellar tendon–bone (BPTB) or 4-strand semitendinosus-gracilis autograft.[4]

However, there continues to be increasing interest in the use of allografts for primary ACL reconstruction. The use of allograft tissue offers many potential benefits including no donor site morbidity, shorter operating time, no violation of the knee extensor or flexor mechanism, availability of larger grafts, improved cosmesis, improved postoperative knee range of motion, and easier rehabilitation.[5-11] Potential disadvantages include disease transmission, increased cost, immune reaction, delayed graft incorporation, and increased failure with time.[5-9]

Most previous reports of ACL reconstruction with allograft tissue have shown results similar to those of ACL reconstruction with autograft tissue.[5-10] However, most of these reports are of allograft with bony attachment, such as BPTB, not of an entire soft-tissue allograft, such as tibialis anterior. The purpose of this retrospective study was to evaluate the clinical results of primary ACL reconstruction with tibialis anterior allograft by a single surgeon.

METHODS

Approval for this retrospective study was obtained from our university's institutional review board. Pa-

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tients were identified via operating room logbooks and the allograft tissue list provided by corporate industry. To be included in this study, patients had to have undergone endoscopic primary ACL reconstruction with cryopreserved anterior tibialis allograft by a single surgeon using the same technique and rehabilitation protocol.[12] Patients with multiligamentous knee injuries, revision surgeries, osteotomies, or other graft sources were excluded. The study population was not restricted based on age or activity level. Patients with both acute and chronic ACL-deficient knees were evaluated. All patients underwent routine preoperative rehabilitation to obtain full range of motion before surgery. Thereafter, postoperatively, patients underwent an accelerated rehabilitation protocol previously described for autogenous BPTB surgery.[13]

We identified patients who underwent primary ACL reconstruction with tibialis anterior allograft between January 1999 and July 2001. ACL reconstructions with autograft BPTB and hamstring tendons were also done during this time period in select patients, but a tibialis anterior allograft was used in most reconstructions performed by the surgeon. All patients were offered a tibialis anterior allograft regardless of age and activity level if they agreed to undergo allograft placement. We identified 125 patients who underwent ACL reconstruction with tibialis anterior allograft, 69 of whom were available for follow-up by telephone. There were 38 male and 31 female patients with a mean age of 31 years (range, 15 to 65 years). The left knee was involved in 29 patients, and the right knee in 40. The mean time of follow-up was 55 months (range, 42 to 74 months). In addition to the ACL deficiency, 11 patients (16%) had lateral meniscal tears, 15 (22%) had medial meniscal tears, and 12 (17%) had bilateral meniscal tears.

Patients were assessed via telephone interview by use of the Lysholm knee score, Tegner activity score, subjective International Knee Documentation Committee rating, and return to previous sports as objective measures. In addition, they were asked via telephone if they had failure of the ACL requiring revision or any other procedures such as repeat arthroscopy for meniscal surgery/articular cartilage.

Operative Procedure

The operative technique has previously been described in detail.[12,14] All patients received a tibialis anterior allograft that had been harvested aseptically, deep-frozen in glycerol to $-70°$, and stored at $-135°$ (CryoLife, Marietta, GA). The graft was thawed 30 minutes before surgery was begun. Diagnostic arthroscopy was performed through anteromedial and anterolateral portals with tourniquet control and the leg in an arthroscopic leg holder. Partial meniscectomy, meniscal repair, or chondroplasty was performed as indicated. Limited notchplasty of the lateral wall and roof was performed to allow adequate visualization in the over-the-top position and to prevent graft impingement.

The graft was prepared by folding the graft over a No. 5 braided polyester suture once to achieve an approximate graft length of 100 mm. The graft was then sized to the nearest 0.5 mm. The graft was placed on a workstation and tensioned to 10 lb. A No. 5 braided polyester suture was placed in an interdigitating baseball stitch to a length of 30 mm on each end. The femoral side was reinforced with an EndoPearl device (Linvatec, Largo, FL).

The tibial guide pin was placed in the posteromedial footprint of the ACL with the ACL guide set at 50°. The tunnel was then reamed to match the appropriate graft size. The femoral guide pin was placed through the tibial tunnel and positioned at the 10:30 or 1:30 position. The tunnel was reamed to match the graft diameter and allow for a 2-mm posterior wall. The femoral side was secured with an 8×30–mm bioabsorbable interference screw placed anterior to the graft. The tibial side was fixed with a bioabsorbable interference screw, 1 mm larger than the tunnel diameter, posterior to the graft, with the knee in full extension. No backup fixation was used on the tibial side.

Rehabilitation

Patients performed an accelerated rehabilitation protocol with early motion and physiotherapy.[12,13] This protocol was designed for those patients having a BPTB autogenous graft, not a soft-tissue allograft. Postoperatively, the knee was placed in a hinged brace, and patients allowed immediate full weight-bearing in extension. Progressive unrestricted range-of-motion exercises and closed-chain strengthening were begun under the guidance of a physiotherapist after the first week. Brace use was discontinued when the patient exhibited good quadriceps control and was able to ambulate without a limp. The rehabilitation goals included normal terminal knee extension by postoperative week 1 via sitting hamstring stretching, normal knee flexion by postoperative week 3 via resisted seated heel glides and prone quadriceps stretching, and normal functional strength by 6 to 12 weeks via progressive resistive exercises. Functional assessment was performed at 3 months, and return to full competition was allowed after 4 months depending on functional ability, including run-to-sprint intervals, sidestep cutting, and timed recreation drills.[12]

RESULTS

Sixty-nine patients were available for follow-up. Of these, 16 (23.1%) required revision ACL surgery at a mean of 22 months (range, 5 to 47 months) after the initial surgery. The mean age of the patients in whom failure occurred was 22.8 years (range, 15 to 47 years) compared with 34 years (range, 16 to 65 years) in those in whom failure did not occur ($P = .0039$). Along with revision ACL surgery, 9 patients required repeat arthroscopy for symptomatic meniscal tears and 1 patient had a total knee arthroplasty. Overall, 26 patients (38%) required repeat surgery.

Functional assessment scores were obtained in patients who did not require revision surgery. The mean Lysholm score was 85.6 (range, 15 to 100), and the mean Tegner activity score was 4.36 (range, 0 to 9). The knee was rated as normal in 50.9% of patients, as nearly normal in 35.3%, as abnormal in 7.8%, and as severely abnormal in 5.9%. Of the patients, 30 (58%) were able to return to their previous activity level. Five patients complained of instability with activities of daily living.

To assess the effect of age on the outcome of ACL reconstruction with anterior tibialis allograft, patients were divided into 2 groups: those aged 25 years or under and those aged over 25 years. Of the patients in the younger group, 11 (35%) required revision ACL surgery, as compared with 5 patients (13%) in the older group. Overall, the failure/reoperation rate was 55% (17/31) in the younger group compared with 24% (9/38) in the older group. To assess age as a factor for failure rate, we used the Dunn multiple comparisons test for nonparametric variables and found a P value of less than .003.

DISCUSSION

The two most common grafts selected continue to be the BPTB and hamstring tendon autografts.[4] Results after ACL reconstruction with these grafts continue to be good and relatively equal, with failure rates of less than 10%, as reported in multiple peer-reviewed articles.[15-20] However, both of these grafts are associated with the potential for unique graft site morbidity and complications. Potential morbidity associated with the BPTB harvest includes anterior knee pain, pain when kneeling, patellar fracture, decreased quadriceps strength, extension loss, and arthrofibrosis.[4,16,20] Hamstring tendon use may be associated with a loss of knee flexion strength and higher rates of graft failure, particularly in female patients.[4,16,20]

There continues to be increased interest in the use of allograft tendons for primary ACL reconstruction. The use of allograft source allows for the avoidance of potential graft site morbidity. Other advantages may include shorter operating time, no violation of the knee extensor or flexor mechanism, availability of larger grafts, improved cosmesis, improved early postoperative knee range of motion, and easier rehabilitation.[5-11]

Potential disadvantages of allograft use include disease transmission, immune response, increased cost, delayed graft incorporation, and increased laxity over time. Allograft-associated bacterial infection remains a potential risk despite aseptic storage and handling. Despite the low rates, patients may still exhibit concern because of attention given in the lay press. As of 2002, there have been 26 cases of allograft-associated infections identified by the Centers for Disease Control and Prevention.[21] The risk of human immunodeficiency virus or hepatitis virus transmission has been estimated at 1 in 1.6 million.[22] Potential immune response is inherent to the use of allograft tissue. Both humoral and cell-mediated immune responses after use of fresh musculoskeletal allografts have been reported.[23,24] Freezing allograft tissue decreases immunogenicity.[23] However, the host immune response to musculoskeletal allograft has not been shown to have a clinical impact to date.[21]

Commonly used allografts include BPTB and Achilles tendon–bone allografts. Many reports have shown outcomes similar to that of ACL reconstruction with autograft sources.[5-10,25] Soft-tissue allograft sources include the anterior or posterior tibialis tendon. The tibialis anterior tendon has been shown in vitro to have structural properties similar to or greater than hamstring tendons, with mean failure loads of greater than 3,400 N.[26,27]

A number of studies have compared the results of BPTB allograft versus autograft ACL reconstruction. Kustos et al.,[9] Peterson et al.,[10] Shelton et al.,[28] Chang et al.,[5] Harner et al.,[6] Rihn and Harner,[21] and Kleipool et al.[8] have all reported comparative studies that showed no statistical difference in subjective clinical and objective laxity measurements between allograft and autograft reconstructions.

However, we believe that care must be used in extrapolating these results to those of soft-tissue allografts, until level I prospective studies can be completed. A successful ACL reconstruction is dependent on complete graft-to-tunnel healing at a pace that allows for appropriate knee rehabilitation. Careful matching of loads to biologic healing must occur. It has been well studied and published that graft-to-tunnel healing is slower for a tendon graft than for a bone plug graft. Estimates of the increased time required may be up to 4 to 8 weeks. Papageorgiou et al.[29] showed via histologic examination that at 6 weeks the bone block graft revealed progressive and complete incorporation but that the tendinous graft had only partial incorporation. Several other reports have confirmed this finding.[30-33]

There have been several studies evaluating the use of soft-tissue allografts in ACL reconstruction. Shino et al.[34] retrospectively evaluated 84 patients at a mean follow-up of 57 months. The patients received either soft-tissue Achilles tendon, anterior tibialis, or posterior tibialis allograft. Satisfactory anterior stability was obtained in 88% of patients, and good or excellent subjective results were obtained in 94% of patients. The reported graft failure rate was 3%. These results of Shino et al. are remarkably different than those of our study, where the failure rate was 23%. The patients' ages and activity level were similar in both studies. However, the rehabilitation protocols were vastly different. We used an accelerated rehabilitation protocol where patients had returned to sports at 4 months; on the other hand, Shino et al. waited 11 to 12 months before patients were allowed to resume athletic activity. This verifies the importance of matching rehabilitation to the graft source/biologic response and not to the operative procedure, ACL reconstruction.

Two studies have reported significant rates of graft failure using allograft material for ACL reconstruction. Stringham et al.[11] reported on 78 patients who received either patellar tendon autograft or allograft at a mean of 34 months. There was no difference in Lysholm or Tegner activity scores between the groups. However, the allograft group had a significantly higher rate of traumatic rupture (13% *v* 0%). Sterling et al.[35] reported on 18 patients who received a freeze-dried, ethylene oxide–sterilized BPTB allograft for ACL reconstruction. They reported a graft failure rate of 33% (6/18), which was attributed to using grafts that had an excessive shelf life. On the other hand, Poehling et al.[36] compared ACL reconstruction with Achilles tendon allograft versus BPTB autograft and found similar objective and subjective outcomes at 5 years.

The method of sterilization also plays an important role in the properties of allograft tissue. Freeze-drying involves freezing the tissue and then dehydrating it in a vacuum. This produces tissue with reduced antigenicity with no viable cells and deleterious effects on the material properties of the graft.[37] On the other hand, cryopreservation involves maintaining viable tissue and cells with increased antigenicity compared with freeze-dried grafts. However, cryopreserved grafts have been shown to maintain better biomechanical properties. Nikolaou et al.[38] reported that cryopreserved allograft strength was 80% of that in controls without surgery at 36 weeks.

We showed a high graft failure rate, particularly in those aged 25 years or under, who frequently perform sports in which there is a high risk for ACL injury; this has been unreported previously for ACL reconstructions with soft-tissue allograft. Of the 69 patients available for follow-up at a mean of 55 months, 16 (23.1%) had graft failure. The mean age of those with failure was 22.8 years compared with 34 years in those who did not have failure, a finding that achieved statistical significance ($P = .0039$). In addition, 55% of patients (17/31) aged 25 years or under either had failure or required further arthroscopic meniscal surgery at a mean of 22 months after primary ACL surgery (range, 5 to 47 months). Of the 52 patients who did not require revision ACL surgery, 86% rated the knee as normal or nearly normal, and they had a mean Lysholm score of 85.6.

We believe that the high failure rate in young active patients seen in our study was not solely a result of graft choice but resulted from the combination of graft choice, method of fixation, accelerated rehabilitation protocol, and early return to sports. Although there have been numerous reports of the successful use of allograft tissue in ACL reconstruction, studies have raised the concern of delayed graft incorporation with allografts.

Jackson et al.[39] showed a delayed rate of remodeling of allograft tissue after ACL reconstruction in a goat model. Histologically, the allografts showed a greater persistence of large-diameter collagen fibrils and decreased cross-sectional area. In addition, at 6 months, the allograft tissue exhibited a lower maximum load to failure. Other studies have confirmed this finding in animal models and with human histologic analysis.[30,40,41]

Because tendon-to-bone healing within the tunnel may require more than 4 to 8 weeks longer than bone-to-bone healing, as well as up to 12 weeks after surgery, graft fixation must provide enough initial strength and stiffness to withstand early rehabilitation.[32,42] The ideal fixation methods for soft-tissue grafts, particularly on the tibial side, remain controversial and problematic. Multiple factors may influence fixation strength including bone mineral density, length of fixation, insertion torque, and tunnel-screw geometry.[43-45] Recent studies by Kousa et al.[46] and Magen et al.[47] have shown inferior fixation of soft-tissue grafts using interference screws alone on the tibial side compared with other methods of fixation. Klein et al.[48] showed that the in vitro time-zero load to failure for a tibialis anterior graft fixed with an interference screw alone was only 223 N. This is well below the 450-N threshold required for safe postoperative rehabilitation.[49]

Of additional concern is the effect of cyclic loading during the rehabilitation period. It has been estimated that 6 weeks of activities of daily living corresponds to approximately 220,000 cycles to the ACL.[50] However, most biomechanical studies evaluating fixation strength are performed in vitro at time zero. There is evidence that the normal cyclic loading of the knee that occurs during rehabilitation and daily activities may lead to further graft slippage over time.[44,50] In our study patients with a soft-tissue allograft fixed with only interference screws on both the tibia and femur began immediate weight-bearing and range of motion, which may have contributed to early graft failure.

The patients in this series followed an accelerated rehabilitation protocol that has previously been described for both BPTB and quadrupled hamstring grafts with good results.[13,51] There are no studies comparing an accelerated and a traditional rehabilitation protocol for allograft ACL reconstructions, particularly with only soft tissue in a bone tunnel. However, given the evidence that allografts appear to undergo delayed remodeling and incorporation compared with autografts and that soft-tissue grafts undergo slower graft-to-tunnel healing, accelerated protocols may not be applicable to patients receiving soft-tissue allografts.

There was a significant difference in the graft failure rate in those patients aged 25 years or under. We assume that this failure rate was a result of the increased activity level in those patients. Given the retrospective nature of this study, we were unable to evaluate and compare the time spent performing ACL-dependent activities between the age groups.

This study has some weaknesses. It was retrospective and nonrandomized and used only historical controls for comparison. Our follow-up rate was only 55% (69/125 patients). Many of the patients who were not available were young patients who were frequently enrolled at our university or attending high school at the time of surgery. At 5 years' follow-up, these patients had graduated and moved away. Because many of our patients were only contacted via phone for follow-up, we were unable to include objective data regarding knee laxity via either manual examination or knee instruments. An additional weakness is the lack of preoperative outcome/function measurements with which postoperative results could have been compared. We did not report the status of the articular cartilage at the time of ACL reconstruction. Finally, although all of the patients who underwent revision surgery had sustained graft failure, a systematic evaluation for potential contributing factors, such as tunnel placement, was not performed. However, all surgeries were performed by a single sports medicine fellowship–trained orthopaedic surgeon who performed ACL surgery on other patients using autogenous tissue with outstanding outcomes during the study period.

CONCLUSIONS

Both allografts and autografts are used in ACL reconstruction. Many authors have reported results of allograft ACL reconstruction, such as Achilles tendon and BPTB grafts, similar to those of autogenous grafts. However, given the failure and reoperation rate that we observed, caution is warranted in using this combination of anterior tibialis allograft with interference screw fixation and an accelerated rehabilitation protocol in younger patients (aged ≤25 years) and older patients who are active.

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