Anatomic Double-Bundle Anterior Cruciate Ligament Reconstruction With a Hamstring Tendon Autograft and Fresh-Frozen Allograft: A Prospective, Randomized, and Controlled Study

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Purpose: To compare the clinical outcome of anatomic double-bundle (DB) anterior cruciate ligament (ACL) reconstruction with a hamstring tendon autograft versus fresh-frozen allograft. **Methods:** Between January 2010 and December 2011, in a prospective randomized study, we included 157 patients who were planned to receive anatomic DB ACL reconstruction with a hamstring tendon autograft or fresh-frozen allograft. All surgeries were performed by the same senior surgeon with the DB reconstruction technique. The fixation of femoral side grafts was by means of an EndoButton, and the tibial side grafts were fixed with a bioabsorble interference screw augmented with a staple. The same rehabilitation protocol was applied to all the patients. Patients were evaluated preoperatively and at the follow-up points. Evaluations included detailed history, physical examination, radiograph, functional knee ligament testing, KT-2000 arthrometer testing, Harner's vertical jump and Daniel's one-leg hop tests, Lysholm score, Tegner score, the International Knee Documentation Committee (IKDC) standard evaluation form, and Cincinnati knee score. **Results:** One hundred and twenty-one patients (Auto, 62; Allo, 59) fulfilled complete follow-up and got full clinical evaluations. The mean follow-up was 4.6 years (4.0 to 5.5 years) for both groups. No significant differences were found between the 2 groups according to the evaluations aforementioned except that patients in the Allo group had shorter operation time compared with the Auto group ($P = .001$). Fifty-three (85.5%) patients in the Auto group and 50 (84.7%) patients in the Allo group had a side-to-side difference of less than 3 mm. Four (6.5%) patients in the Auto group and 4 (6.8%) patients in the Allo group had a side-to-side difference of more than 5 mm. Fifty-nine (95.8%) patients in the Auto group and 55 (93.2%) patients in the Allo group were normal or nearly normal according to the overall IKDC. According to the subjective IKDC, the average scores were 90 and 89 points, respectively, for the Auto and Allo groups. The mean Lysholm and Tegner scores were 90 points and 7.9 points for the Auto group, respectively, and 89 points and 7.8 points for the Allo group, respectively. For the Cincinnati knee score, the average scores were 91 and 90 points, respectively, for the Auto and Allo groups. A total of 11.3% (7 of 62) of patients in the Auto group and 11.9% (7 of 59) of patients in the Allo group had an arthritic progression. There was no statistical difference between the 2 groups at the final follow-up. **Conclusions:** With the anatomic DB ACL reconstruction technique, comparable objective and subjective clinical results can be achieved with the use of a fresh-frozen hamstring tendon allograft compared with an autograft. **Level of Evidence:** Level II, prospective randomized clinical trial.

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Anterior cruciate ligament (ACL) rupture is one of the most frequent orthopaedic sports-related injuries, which is potentially devastating for the patient and can result in both acute and long-term clinical problems. Surgical reconstruction of the ACL has become the standard of care for ACL injuries in the active patient and is widely recommended to prevent knee instability, recurrent injury, and further intra-articular disease.[1,2] In the past decade, major advancement in ACL surgery has been made. Arthroscopic ACL reconstruction has shifted from traditional single-bundle (SB) reconstruction to anatomic

reconstruction. Several studies suggest that anatomic double-bundle (DB) ACL reconstruction could improve pivot-shift resistance, increase rotational knee control, help preserve menisci, and limit progression toward arthritis.[3-7] In a meta-analysis,[8] the authors analyzed the clinical outcomes of nonanatomic SB ACL reconstructions versus DB ACL reconstructions and they concluded better objective results of the DB technique, but subjective results showed no difference between the 2 groups. There was also extensive evidence supporting the SB ACL reconstruction with good clinical outcomes reported. Up to date, there is still a controversy about which technique being better.[9,10]

The optimal choice of graft material for ACL reconstruction also remains controversial. For many years the bone–patellar tendon–bone (BPTB) was regarded as the gold standard for ACL reconstruction. During the past decade, ACL reconstruction using autogenous hamstring tendons has increased dramatically with lots of benefits in using a hamstring tendon autograft.[11] The improvements in the tendon fixation materials recently also contribute to the success of reconstruction procedures using hamstring techniques.[10,12-14] Lots of studies reported that the ACL reconstruction with a hamstring tendon autograft produced satisfactory clinical results.[15-20] However, a desire to avoid the sacrifice of autogenous tissue and to minimize surgical trauma and postoperative morbidity has promoted the consideration of allograft sources.[21] Because there are many obvious advantages of an allograft including smaller incision, a shorter operation time, a lack of donor-site morbidity, no size limitation and more appropriate for multiple ligamentous injury, and so on, several studies have shown that allograft is a reasonable alternative to autograft for ACL reconstruction.[22] However, allograft also has its own problems such as rare risk of disease transmission, higher rates of graft laxity and failure, and delay in graft incorporation.[9,10,23] Gamma irradiation, which has known bactericidal and virucidal properties, is currently the most popular option for sterilization of allograft. However, some studies[24-26] have shown the deleterious effects that irradiation has on the biomechanical properties in a dose-dependent manner. Some studies also reported that irradiated allografts had an abnormal stability rate.[20,27] Surgeons are therefore faced with a dilemma when deciding which type of graft to use. In a previous study,[28] the authors compared the clinical outcome of arthroscopic SB ACL reconstruction with a hamstring tendon autograft versus fresh frozen allograft, and concluded that both groups of patients compared achieved almost the same satisfactory outcome in the average of 7.8 years of follow-up. The authors suggested the fresh-frozen hamstring tendon allograft as a reasonable alternative choice to the autograft for ACL reconstruction. Sun et al.[29] also reported their clinical outcomes of DB ACL reconstruction with an autograft and allograft. However, the DB reconstruction technique they adopted was not anatomic reconstruction. The grafts used in the study were also not identical. This may affect the clinical outcomes.

In the current study, we used the anatomic DB technique to reconstruct ACL with a hamstring tendon autograft versus fresh-frozen allograft. The allograft is nonirradiated and without deleterious effects of irradiation on biomechanical properties. The purpose of this study was to compare the clinical outcome of anatomic DB ACL reconstruction with a hamstring tendon autograft versus fresh-frozen allograft. We hypothesized that there would be no significant difference in the clinical outcome of anatomic DB ACL reconstruction with a hamstring tendon autograft versus allograft.

Methods

Patients and Inclusion Criteria

Patients scheduled for primary unilateral reconstruction of the ACL in the author's (S.T.) clinic were considered for enrollment. Inclusion criteria were no open physes being present, no severe arthritic changes in the knee, no previous injury or surgery on the affected knee, no multiple ligamentous injuries, no malalignment, not a revision reconstruction, or lacked the ability to complete the study protocol. Patients with associated injuries of the posterolateral corner, with deficiency or a reconstruction of the ACL in the contralateral knee, were excluded from the study. Patients with a tibial footprint site less than 14 mm, or a notch width less than 12 mm, measured during operation were also excluded. But the patients with minor medial collateral ligament sprains (<grade II), meniscal tears, or previous diagnostic arthroscopy were not excluded from the study. To meet all inclusion criteria, all patients were examined carefully in clinics and also preoperatively under anesthesia. All patients had a preoperative magnetic resonance imaging (MRI) scan to exclude combined complicated ligament injuries to their knees. MRI was also used to measure the size of the native ACL insertion to help in preoperative planning.

Between January 2010 and December 2011, ACL reconstruction with a hamstring tendon graft was performed on 178 patients, 162 of whom met the inclusion and exclusion criteria mentioned above. One hundred and fifty-seven patients who gave written informed consent participated in this study. They were randomized on the day of surgery using a computer to either the hamstring tendon autograft group (Auto, n = 78) or the allograft group (Allo, n = 79). The study was approved by the institutional review board of our hospital.