Journal of Zhejiang University SCIENCE B
ISSN 1673-1581 (Print); ISSN 1862-1783 (Online)
www.zju.edu.cn/jzus; www.springerlink.com
E-mail: jzus@zju.edu.cn

ACL reconstruction with BPTB autograft and irradiated fresh frozen allograft*

Kang SUN[†1], Shao-qi TIAN[†‡1], Ji-hua ZHANG[2], Chang-suo XIA[1], Cai-long ZHANG[1], Teng-bo YU[1]

([1]*Department of Orthopaedics;* [2]*Healthy Physical Examination Center, Affiliated Hospital of Medical College, Qingdao University, Qingdao 266003, China*)

[†]E-mail: sunkang_qy@yahoo.com.cn; shaoqi99@yahoo.com.cn

Received Oct. 23, 2008; Revision accepted Jan. 12, 2009; Crosschecked Feb. 24, 2009

Abstract: Objective: To analyze the clinical outcomes of arthroscopic anterior cruciate ligament (ACL) reconstruction with irradiated bone-patellar tendon-bone (BPTB) allograft compared with non-irradiated allograft and autograft. Methods: All BPTB allografts were obtained from a single tissue bank and the irradiated allografts were sterilized with 2.5 mrad of irradiation prior to distribution. A total of 68 patients undergoing arthroscopic ACL reconstruction were prospectively randomized consecutively into one of the two groups (autograft and irradiated allograft groups). The same surgical technique was used in all operations done by the same senior surgeon. Before surgery and at the average of 31 months of follow-up (ranging from 24 to 47 months), patients were evaluated by the same observer according to objective and subjective clinical evaluations. Results: Of these patients, 65 (autograft 33, irradiated allograft 32) were available for full evaluation. When the irradiated allograft group was compared to the autograft group at the 31-month follow-up by the Lachman test, the anterior drawer test (ADT), the pivot shift test, and KT-2000 arthrometer test, statistically significant differences were found. Most importantly, 87.8% of patients in the autograft group and just only 31.3% in the irradiated allograft group had a side-to-side difference of less than 3 mm according to KT-2000. The failure rate of the ACL reconstruction with irradiated allograft (34.4%) was higher than that with autograft (6.1%). The anterior and rotational stabilities decreased significantly in the irradiated allograft group. According to the overall International Knee Documentation Committee (IKDC), functional and subjective evaluations, and activity level testing, no statistically significant differences were found between the two groups. Besides, patients in the irradiated allograft group had a shorter operation time and a longer duration of postoperative fever. When the patients had a fever, the laboratory examinations of all patients were almost normal. Blood routine was normal, the values of erythrocyte sedimentation rate (ESR) were 5~16 mm/h and the contents of C reactive protein (CRP) were 3~10 mg/L. Conclusion: We conclude that the short term clinical outcomes of the ACL reconstruction with irradiated BPTB allograft were adversely affected. The less than satisfactory results led the senior authors to discontinue the use of irradiated BPTB allograft in ACL surgery and not to advocate using the gamma irradiation as a secondary sterilizing method.

Key words: Anterior cruciate ligament (ACL) reconstruction, Patellar tendon, Autograft, Allograft, Irradiation, Prospective randomized study
doi:10.1631/jzus.B0820335 **Document code:** A **CLC number:** R68

INTRODUCTION

Anterior cruciate ligament (ACL) reconstruction with a bone-patellar tendon-bone (BPTB) autograft has become a gold standard and well-documented procedure over the last several decades. Many studies reported that the ACL reconstruction with BPTB autograft produced good clinical results (Harner *et al*., 1996; Fu *et al*., 2000; Deehan *et al*., 2000; Gorschewsky *et al*., 2007; Han *et al*., 2008). However, a desire to avoid the sacrifice of autologous tissue and to minimize surgical trauma and postoperative donor site morbidity has promoted the consideration of alternative graft sources (Stringham *et al*., 1996; Siebold *et al*., 2003; Barrett *et al*., 2005).

‡ Corresponding author
* Project (No. 2004GG2202034) supported by the Natural Science Foundation of Shandong Province, China

One such alternative is allogenic tissue.

The use of allograft for ACL reconstruction has risen tremendously over the past decade. There are many potential advantages to the use of allograft, including elimination of donor site morbidity, no weakening of the extensor or flexor apparatus, shorter operating time, smaller incisions, less pain, better cosmetic result, easier rehabilitation, lower incidence of postoperative arthrofibrosis, availability of larger grafts, etc., thereby more appropriate for revision surgery, for multiple ligamentous injury or in the presence of patellar baja. Several studies (Siebold *et al*., 2003; Nyland *et al*., 2003; Lawhorn and Howell, 2003; Kustos *et al*., 2004) have shown that allograft is a reasonable alternative to BPTB autograft for ACL reconstruction.

There are, however, risks associated with the use of allograft, most notably being disease transmission, both bacterial and viral, such as human immunodeficiency virus (HIV) and hepatitis B. To minimize the risk of disease transmission by allograft tissue, the American Association of Tissue Banks (AATB) and the Food and Drug Administration (FDA) set forth guidelines of allograft tissue processing. In accordance with this, tissue banks adopted various methods of tissue processing, including donor screening, aseptic harvesting techniques, further sterilization techniques, etc., to ensure graft sterility.

Gamma irradiation, which has known bactericidal and virucidal properties, is currently the most popular option for sterilization of allografts. Many published studies (Fideler *et al*., 1995; Curran *et al*., 2004; Schwartz *et al*., 2006; Grieb *et al*., 2006; Balsly *et al*., 2008) have shown that gamma irradiation significantly alters the initial biomechanical properties of allografts in a dose-dependent manner. A dose as low as 2.5 mrad commonly used by tissue banks has been shown to reduce the initial stiffness and strength of tendon allografts. But up to now, there are only a few clinical investigations studying the clinical outcomes of irradiated allograft for ligament reconstruction (Noyes and Barber-Westin, 1997; Gorschewsky *et al*., 2005; Rihn *et al*., 2006), and whether or not the alteration in biomechanical property affects the clinical outcomes of ACL reconstruction with irradiated allograft remains controversial.

Besides the disease transmission, allograft has other problems, such as the possibility of a host immune response against the donor tissue, delayed incorporation, bone tunnel enlargement, increased postoperative traumatic rupture rate, and graft cost. Because of this, some studies (Olson *et al*., 1992; Prodromos *et al*., 2006) reported that the results of using allograft for ACL reconstruction were not satisfactory and did not advocate the use of allogenic tissue.

Surgeons are therefore faced with a dilemma when making a choice to do the reconstruction. Which type of graft should be used, allograft or autograft? If the allograft can be used as alternative to the autograft, does the irradiated allograft have the similar clinical outcomes with the autograft?

In this prospective randomized clinical study, we used irradiated BPTB allograft and autograft to reconstruct the ACL. The purpose of the study was to analyze the clinical outcomes of arthroscopic ACL reconstruction with irradiated BPTB allograft compared with autograft. We hypothesized that the clinical outcomes of ACL reconstruction with irradiated BPTB allograft would have significant differences compared with those with BPTB autograft by the objective and subjective evaluations.

MATERIALS AND METHODS

Patients and inclusion criterion

From July 2004 to October 2005, 102 patients with acute or chronic ACL ruptures underwent ACL reconstruction; 85 of these patients were eligible to participate in the study according to the preoperative examination. The study obtained the permission of the Medical Ethical Committee.

Patients were excluded from the study if they had a previous injury or surgery on the affected knee, multiple ligamentous injuries, or malalignment, or if they lacked the ability to complete the study protocol. Patients with revision reconstruction, associated injuries of the posterior cruciate ligament or the posterolateral corner, and deficiency or a reconstruction of the anterior cruciate ligament in the contralateral knee were also excluded. Only primary unilateral reconstructions of the ACL were included in the study. Patients with minor medial collateral ligament sprains (lower than Grade II), previous diagnostic arthroscopy, or meniscal tears were not excluded from the study.

To meet the inclusion criterion, all patients were examined carefully in clinic and were also preoperative under anesthesia. All patients had a preoperative magnetic resonance imaging (MRI) scan to exclude combined complicated ligament injuries to their knees.

Sixty-eight patients provided written informed consent to participate in the study. They were randomized on the day of surgery using a computer to BPTB autograft group (Auto group, Nos. 1~34) and irradiated allograft group (Ir-Allo group, Nos. 35~68).

Harvest and preparation of grafts

The central third BPTB autograft was harvested through an 8 to 10 cm incision centered over the medial aspect of the patellar tendon. The paratendon was incised and preserved for closure. Patellar tendon graft, 10 mm wide, was obtained with a 10 mm×25 mm patellar bone plug and a 10 mm×30 mm tibial bone plug. BPTB allograft was obtained from a certified tissue bank, which was 12 mm wide and was prepared with a 10 mm×25 mm patellar bone plug and a 10 mm×30 mm tibial bone plug.

All the allografts were fresh-frozen and supplied by a certified tissue bank, which had policies for serologic and microbiologic testing in accordance with guidelines set forth by AATB and FDA. The irradiated allografts received an irradiation dose of 2.5 mrad prior to distribution. On the day of the operation the graft was thawed in sterile physiologic fluid at room temperature before preparation, and then preconditioned using the Graftmaster board (Arthrex, Naples, FL, USA) at 66.75 N of tension for 10 to 20 min. After that the allograft was soaked in 0.05% (w/v) polyvinylpyrrolidone (PVP) for 10 min.

Surgical technique

All patients underwent an examination under anesthesia and diagnostic arthroscopy to confirm the preoperative diagnosis. All the ACL reconstruction procedures were performed by the same experienced arthroscopic surgeon.

The same surgical technique was used in both the groups. This endoscopic technique consists of the standard arthroscopic ACL reconstruction with grafts. Before the reconstruction, meniscal pathology was addressed. Tears in the red-red or red-white zone were repaired using an inside-out technique. A partial meniscectomy was performed for irreparable tears. Debridement or hole-drilling was done to the chondral damages. No patients needed concomitant surgery for medial or lateral collateral ligament injuries. When performing the reconstruction, the remnants of the ACL were debrided first and its anatomic attachment points on the tibia and femur were identified. Then in order to allow for adequate graft placement and to avoid impingement, notchplasties were performed arthroscopically. After the tibial guide pin was placed through the footprint of the ACL adjacent to the anterior horn of the lateral meniscus, the tibial tunnel was reamed. All tunnels were reamed according to graft size determined by graft sizers. The femoral guide pin was placed 5 mm anterior to the posterior cortex to allow for a posterior cortical rim after reaming at the 10 o'clock (right leg) or 2 o'clock (left leg) position. Intraoperative radiographs were obtained to ensure proper placement of the femoral guide pin, and the femoral tunnel was reamed until the anterolateral femoral cortex was reached but no farther (approximately 30~40 mm). Grafts were fixed at 90° of flexion on the femoral side first, and then the isometric positions of grafts were tested by flexing and extending the knee before screwing the tibial side with the knee in 60° flexion. All the graft fixations were accomplished by using titanium or bioabsorbable interference screws (Arthrex) that were size-matched to the bone plugs. Note that during fixation on the tibial side the tibia was loaded with a maximal posterior force to minimize graft laxity present at the time of surgery. An intraoperative radiograph was obtained again to verify correct placement of graft and screw. Then, the knee was taken through a full range of motion (ROM) to observe any graft impingement. Routine closure of all wounds was performed. After surgery the knee was placed in a standard postoperative brace locked in extension, and the rehabilitation protocol was applied.

Rehabilitation

Our rehabilitation protocol began at the time of the initial diagnosis. In this period before surgery, patients participated in physical therapy to restore full knee ROM and a normal gait and to eliminate knee swelling. After ACL reconstruction, all patients of the two groups followed the same postoperative accelerated rehabilitation protocol, which emphasized early restoration of full extension and strengthening exercises. Active, non-weight-bearing straight leg raise was encouraged to strengthen the quadriceps immediately after surgery to prevent extension lag. Hamstring stretching exercises were also done at the same time and progressed to weight-bearing gastroc/soleus stretches. Continuous passive motion (CPM) began the day after surgery for 2 h twice a day. Patients would start between 0° and 45° and increased 10° per day as tolerated to a maximum of 120°. Progression of weight bearing with crutches or canes was on an as-tolerated basis, which was guided by the presence and degree of pain and swelling. Crutch or cane use could be discontinued when gait was normalized. Closed kinetic chain exercises initiated 6 weeks postoperatively. Proprioception activities, such as slide board, use of ball, and racquet with balance activities, as well as aquatic program including pool running and swimming were allowed to do 8 weeks postoperatively and extended through approximately 6 months. Functional activities including walking, jogging, and running were permitted at 6 months postoperatively. Usually 10 to 12 months were needed for patients to return to work or full sports activity. Appropriate modifications to the ROM limits and weight bearing status were made for concomitant meniscal repairs and chondral treatment. A functional brace was recommended for use during sports activities for the first 1~2 years after surgery.

Clinical evaluation

Assessments of the involved knees were performed pre- and postoperatively to obtain objective and subjective measures of the clinical outcomes of the ACL reconstruction.

Examination of knee laxity included the Lachman test, the anterior drawer test (ADT), the pivot shift test, varus/valgus stress test, and the KT-2000 arthrometer test. Laxity was graded relative to the noninvolved side according to the International Knee Documentation Committee (IKDC) guidelines. The following definition was used: (1) Lachman test and ADT: Grade 0, −1 to 2 mm; Grade I, 3 to 5 mm; Grade II, 6 to 10 mm; and Grade III, >10 mm. (2) Pivot shift test: Grade 0, equal; Grade I, glide; Grade II, clunk; and Grade III, gross. (3) The IKDC classifies knees that are within 5 mm of a contralateral normal knee by means of KT-2000 (MedMetric Inc., San Diego, CA, USA) as being of "normal" stability (normal, <3 mm; and nearly normal, 3 to 5 mm). Knees that have a greater than 5 mm difference are classified as having "abnormal" stability (abnormal, 6 to 10 mm; and severely abnormal, >10 mm). Manual-maximum KT-2000 tests were performed to assess anterior laxity with the knee positioned in the 15° flexion. Side-to-side differences in anterior laxity were determined. Varus/valgus stress tests were used to evaluate the conditions of collateral ligaments preoperatively.

Functional tests included ROM of knee, Harner's vertical jump, and Daniel's one-leg hop tests, as well as the standard knee ligament evaluation form of the IKDC.

In the IKDC knee examination form, extension was compared to the contralateral normal side and was graded as normal (<3° loss of extension (LOE)), nearly normal (3° to 5° LOE), abnormal (6° to 10° LOE), or severely abnormal (>10° LOE); flexion was compared to the contralateral normal side and was graded as normal (≤5° loss of flexion (LOF)), nearly normal (6° to 15° LOF), abnormal (16° to 25° LOF), or severely abnormal (>25° LOF).

The Harner's vertical jump and Daniel's one-leg hop tests were performed 3 times respectively and compared with the opposite leg. A mean quotient (%) between the injured and non-injured leg was calculated to determine the limb symmetry index (normal, ≥90%; nearly normal, 76%~89%; abnormal, 50%~75%; or severely abnormal, <50%).

Subjective evaluation included Cincinnati knee score and IKDC subjective knee form that consists of a questionnaire rating symptoms of pain, swelling, instability, and so on. According to the subjective IKDC, higher scores (maximum, 100) reflect fewer symptoms and better knee function.

The Tegner activity score (maximum, 10) and the Lysholm knee scoring scale (maximum, 100) were also used to assess patient's activity level and knee function preoperatively, postoperatively, and at the final follow-up.

Weight-bearing anteroposterior (AP), lateral, and femoral-patellar in 30° flexion radiographs were taken of both knees (ipsi- and contralateral) preoperatively and at the final follow-up. The radiographs were taken under standardized conditions to obtain reproducible images. The grade of osteoarthritis (OA) was evaluated by two independent blinded radiologists according to the classifications of Kellgren (I, doubtful: minute osteophytes, doubtful significance; II, minimal: definite osteophytes, unimpaired joint space; III, moderate: moderate diminution of joint space; and IV, severe: joint space greatly impaired with sclerosis of subchondral bone).

At the clinical follow-up, all patients were examined by an orthopedic surgeon who was not the operative surgeon. The clinical follow-up was similar to the preoperative examination.

Statistical analysis

We used SPSS for Windows (version 12.0; SPSS Inc., Chicago, IL, USA) for statistical analysis. The independent *t*-test was used for the comparison of continuous variables, and the chi-squared test was used for the categorical variables. The significance level was set at $P\leq 0.05$.

RESULTS

Patients

At the time of surgery, it was determined through arthroscopy that 2 of the 68 patients enrolled in the study were ineligible for participation (one did not sustain an ACL rupture, and the other had posterior ligament injuries). Of those remaining 66 patients, 65 (Auto 33, Ir-Allo 32) were available for the full evaluation, but 1 patient was lost to follow-up.

These 65 patients (46 men and 19 women) had a mean 31 months (ranging from 24 to 47 months) follow-up after ACL reconstruction. The average age of the 65 patients at the time of index operation was 30.6 years (ranging from 16 to 63 years). The median interval between the injury and the ACL reconstruction was 1.6 months (ranging from 2 weeks to 3 months). Sporting activities were the main cause of injury of the patients. Playing football and basketball were the most common injury-causing sports. Patients' demographics and characteristics are outlined in Table 1.

Table 1 Demographic data and characteristics of study sample (*n*=65) patients

	Auto (*n*=33)	Ir-Allo (*n*=32)	*P*
Age at surgery (year)*	29.7±7.2 (16~59)	30.1±6.1 (20~63)	0.40
Patient number			
Gender	F, 9; M, 24	F, 8; M, 24	0.62
Side	R, 19; L, 14	R, 19; L, 13	0.86
Type of injury			0.34
Auto	0	0	
Sports	27 (81.8%)	30 (93.8%)	
Work-related	2 (6.1%)	1 (3.1%)	
Traffic accident	3 (9.1%)	1 (3.1%)	
Other/missing	1 (3.0%)	0	
Time from injury to surgery (month)*	1.5±1.2 (0.5~2.8)	1.6±1.3 (0.5~3.0)	0.79
Follow-up interval (month)*	24.2±5.8 (13~45)	25.6±6.7 (12~47)	0.15

F: female; M: male; R: right; L: left. *Data are expressed as mean±*SD* (range). All data show no statistical significant difference between the two groups

General results

The average duration of the autograft procedure (mean, 95.6 min; range, 75 to 120 min) was 29.8 min longer than that of the allograft procedure (mean, 65.8 min; range, 55 to 90 min). The mean postoperative duration of fever (>37.2 °C) of the Ir-Allo group (mean, 5.6 d; range, 0 to 7.7 d) was 2.9 d longer than that of the Auto group (mean, 2.7 d; range, 0 to 6.1 d). Significant difference was found between the two groups according to the evaluation above ($P<0.001$). When the patients had fever, the laboratory examinations of all patients were almost normal (blood routine was normal, the values of erythrocyte sedimentation rate (ESR) were 5~16 mm/h, and the values of C reactive protein (CRP) were 3~10 mg/L). In the two groups there was no patient with early postoperative infection or wound problems. No late infection and other complications occurred in the two groups.

Intraoperative findings

Lesions to the meniscus, cartilage, and ligament, as well as their arthroscopic therapy to meniscus and cartilage were outlined in Table 2. No treatment was done to the medial ligament injuries.

Objective clinical results

Patients of the Auto group showed no significant better rating according to the χ^2 test for the

Table 2 Arthroscopic findings and treatments at the time of ACL reconstruction for both groups

	Patient number		*P*
	Auto (*n*=33)	Ir-Allo (*n*=32)	
Meniscus			
Medial meniscal tears			0.93
None	18 (54.5%)	17 (53.1%)	
Partial	12 (36.4%)	13 (40.6%)	
Complete	3 (9.1%)	2 (6.3%)	
Lateral meniscal tears			0.88
None	16 (48.5%)	15 (46.9%)	
Partial	15 (45.5%)	14 (43.8%)	
Complete	2 (6.1%)	3 (9.4%)	
Treatments of meniscal tears			0.97
NA	14 (42.4%)	15 (46.9%)	
Repair	12 (36.4%)	11 (34.4%)	
Partial meniscectomy	7 (21.2%)	6 (18.8%)	
Cartilage damage (outerbridge)			0.97
Normal	27 (81.8%)	26 (81.3%)	
I	3 (9.1%)	4 (12.5%)	
II	2 (6.1%)	1 (3.1%)	
III	1 (3.0%)	1 (3.1%)	
IV	0	0	
Treatments for cartilage damage			0.98
NA	27 (81.8%)	26 (81.3%)	
Debridement	5 (15.2%)	5 (15.6%)	
Hole-drilling	1 (3.0%)	1 (3.1%)	
Medial ligament injuries			0.95
Normal	29 (87.9%)	28 (87.5%)	
I	4 (12.1%)	4 (12.5%)	
II	0	0	
III	0	0	

NA: not applicable as the meniscus or cartilage was normal. No statistical difference between the two groups

overall IKDC compared to the Ir-Allo group (P>0.05), although there was a trend of decrease according to IKDC in the Ir-Allo group (Table 3).

The average manual-maximum KT-2000 side-to-side difference in anterior tibial displacement of 15° knee flexion was 2.4 mm in the Auto group, and 5.5 mm in the Ir-Allo group. Twenty-nine (87.9%) of patients in the Auto group and just only 10 (31.3%) in the Ir-Allo group had a side-to-side difference of less than 3 mm. Two (6.1%) patients in the Auto group had a side-to-side difference of more than 5 mm. The rate of laxity with the side-to-side difference more than 5 mm in the Ir-Allo group was as high as 34.4% (11/32). When comparing the Ir-Allo group to the Auto group according to KT-2000 test, significant difference was found (P<0.05). The average of anterior tibial displacement of patients in the Ir-Allo group was also significantly higher than that of the Auto group (P<0.001) (Table 4).

Table 3 Knee functional assessment at the final follow-up

	Patient number		*P*
	Auto (*n*=33)	Ir-Allo (*n*=32)	
Overall IKDC			0.37
Normal	11 (33.3%)	9 (28.1%)	
Nearly normal	20 (60.6%)	19 (59.4%)	
Abnormal	1 (3.0%)	3 (9.4%)	
Severely abnormal	1 (3.0%)	1 (3.1%)	
Range of motion (ROM)			0.67
Normal	15 (45.5%)	16 (50.0%)	
Nearly normal	15 (45.5%)	14 (43.8%)	
Abnormal	2 (6.0%)	1 (3.1%)	
Severely abnormal	1 (3.0%)	1 (3.1%)	
Harner's vertical jump test			0.15
Normal	12 (36.4%)	8 (25.0%)	
Nearly normal	20 (60.6%)	20 (62.5%)	
Abnormal	1 (3.0%)	4 (12.5%)	
Severely abnormal	0	0	
Daniel's one-leg hop test			0.29
Normal	13 (39.4%)	10 (31.3%)	
Nearly normal	19 (57.6%)	19 (59.4%)	
Abnormal	1 (3.0%)	3 (9.4%)	
Severely abnormal	0	0	

No statistical difference between the two groups

Table 4 Preoperative and follow-up results of knee stability according to KT-2000

	Preoperative		Follow-up		*P*
	Auto	Ir-Allo	Auto	Ir-Allo	
Anterior tibial displacement (mm)*	10.0±3.8 (7~16)	10.0±2.9 (6~16)	5.0±2.5 (2~10)	9.2±2.4 (4~16)	<0.001
Side-to-side difference (*SSD*)					
Value (mm)*	–	–	2.4±0.6 (1~6)	5.5±3.6 (3~12)	<0.05
Patient number					0.004
SSD<3 mm	–	–	29 (87.9%)	10 (31.3%)	
SSD>5 mm	–	–	2 (6.1%)	11 (34.4%)	

*Data are expressed as mean±*SD* (range). Preoperative data of side-to-side difference was not available. Significant differences were found when comparing the Ir-Allo group to the Auto group

According to the pivot shift test, ADT, and the Lachman test, the clinical outcomes of ACL reconstruction with irradiated allograft were not satisfactory. Significant differences were found when comparing the Ir-Allo group to the Auto group according to the tests mentioned above (Table 5).

Table 5 Comparison of rotational and anterior stability of operated knees at the final follow-up

	Patient number		*P*
	Auto (*n*=33)	Ir-Allo (*n*=32)	
Pivot shift test			0.0021
0	31 (93.9%)	20 (62.5%)	
I	2 (6.1%)	8 (25.0%)	
II	0	4 (12.5%)	
III	0	0	
ADT			<0.001
0	28 (84.8%)	11 (34.4%)	
I	4 (12.1%)	12 (37.5%)	
II	1 (3.0%)	9 (28.1%)	
III	0	0	
Lachman test			<0.001
0	28 (84.8%)	10 (31.3%)	
I	3 (9.1%)	11 (34.4%)	
II	2 (6.1%)	11 (34.4%)	
III	0	0	

Significant differences were found when comparing the Ir-Allo group to the Auto group

Concerning ROM, the vertical jump, and one-leg hop tests, all data were collected and compared between the two groups at the follow-up (Table 3). The normal rates (normal and nearly normal) of ROM, vertical jump test, and one-leg hop test were 91.0%, 97.0%, and 97.0%, respectively in the Auto group, and 93.8%, 87.5%, and 90.6%, respectively in the Ir-Allo group. No significant differences were found between the two groups when undergoing ACL reconstruction.

Subjective clinical results

As shown in Table 6, according to the subjective IKDC, there was no significant difference between the two groups (P>0.05); The average scores were 88 and 84 points for the Auto and Ir-Allo groups, respectively. The mean Lysholm and Tegner scores were 90 and 7.7 points for the Auto group, respectively, and 87 and 7.0 points for the Ir-Allo group, respectively; there was no significant difference between the two groups. Most patients were satisfied with their performance in sporting activity. For the Cincinnati knee score, no significant differences were found yet between the two groups. We found that there was a trend of decrease in activity levels and patients' subjective rating scores of the Ir-Allo group.

Table 6 Subjective evaluations and activity level at the final follow-up*

	Score value (point)		*P*
	Auto (*n*=33)	Ir-Allo (*n*=32)	
Subjective IKDC	88±11 (68~100)	84±12 (55~100)	0.17
Cincinnati knee score	89±10 (50~100)	85±14 (45~100)	0.19
Lysholm score	90±9 (70~100)	87±10 (47~100)	0.20
Tegner score	7.7±1.3 (4~9)	7.0±1.7 (2~9)	0.07

*Data are expressed as mean±*SD* (range). No statistical difference between the two groups

Radiographs

As to the osteoarthritis rate of the operated knee according to the standardized radiographs, there were no severe preoperative osteoarthritic changes, and at the follow-up we did not observe severe progression.

DISCUSSION

Rupture of the ACL is one of the most common sport injuries in active young people (Boni and Herriott, 2002). A great number of studies (Engebretsen *et al*., 1990; Daniel *et al*., 1994) have proved that a torn ACL cannot heal with conservative management and repair alone. Today, arthroscopic reconstruction of the injured ACL with autologous BPTB is considered the gold standard and the first choice of many surgeons for a variety of reasons (Fu *et al*., 2000). However, the ACL reconstruction with BPTB autograft is also associated with troublesome donor-site morbidity, including patellar fracture, patellar tendonitis or rupture, patellar infra syndrome, quadriceps weakness, arthrofibrosis, anterior knee pain, tenderness, disturbance in anterior knee sensitivity, the inability to kneel, etc. In addition, the overall costs of autograft ACL reconstruction can be greater than those of allograft because of increased surgical and anesthesia time according to a recent report (Cole *et al*., 2005). As a result, many surgeons have been using allografts in an attempt to avoid such problems.

In 1984, Shino *et al*.(1984) described the replacement of the ACL by an allogenic tendon graft. Since then there has been increasing interest in the use of allografts for primary ACL reconstruction, and its role is expanding. There are several published clinical studies (Olson *et al*., 1992; Pritchard *et al*., 1995; Siebold *et al*., 2003; Nyland *et al*., 2003; Lawhorn and Howell, 2003; Chang *et al*., 2003; Kustos *et al*., 2004; Prodromos *et al*., 2006) evaluating autograft and allograft used in ACL reconstruction, but the findings vary greatly. These discrepancies are due in a large part to the variety of tissues used, and the tremendous variation in surgical technique, fixation, and postoperative protocols.

Associated with the use of allograft tissue, one of the major concerns is the risk of disease transmission. Although the risks of transmitting bacterial and viral diseases are low, with the risk for HIV being assessed to be 1 in 1 667 000 (Buck *et al*., 1989), in order to provide sterile allograft, significant efforts are being made by tissue banks to further minimize this risk. Apart from donor screening and aseptic harvesting techniques, gamma irradiation, which has known bactericidal and virucidal properties, is currently the most popular option for sterilization of allograft.

However, many studies (Fideler *et al*., 1995; Curran *et al*., 2004) have shown that gamma irradiation has adverse effects on biomechanical properties of allograft in a dose-dependent manner. Fideler *et al*. (1995) demonstrated a dose-dependent effect of irradiation on both the structural and mechanical properties of human BPTB allograft. Doses as low as 2 mrad resulted in a statistically significant reduction in biomechanical properties. The effect became more significant with the increase of the dose. More recently, Curran *et al*.(2004) also studied the effect of irradiation on the cyclic and failure properties of human BPTB allograft, and showed that the low dose of 2 mrad of irradiation could reduce the initial stiffness and strength of tendon allograft. They thought that the alteration in biomechanical properties may be detrimental to graft function and affect the clinical outcomes when used to reconstruct the ACL. They suggested the use of non-irradiated rather than irradiated allograft to avoid weakening effects of radiation on the graft. However, in 2006, Rihn *et al*.(2006) reported that patients undergoing ACL reconstruction with irradiated BPTB allograft had similar clinical outcomes compared to those reconstructed with BPTB autograft.

In the present study, when comparing the clinical outcomes of ACL reconstruction with irradiated BPTB allograft to those of ALC reconstruction with autograft, we found an increase in anterior laxity or rate of graft rupture in patients who underwent reconstruction with irradiated BPTB allograft according to the ADT, Lachman test, and maximal-manual KT-2000 test. The rate of rotational instability also increased according to the pivot shift test. The difference was statistically significant. Similarly, a meta-analysis (Prodromos *et al*., 2007) of the stability showed that irradiated grafts had an abnormal stability rate of 31% versus 12% for non-irradiated grafts, which was not to advocate the use of the irradiated allograft either, another reason against the use of irradiated allograft.

Therefore in recent years most grafts have been used without any form of sterilization to avoid the known adverse effects of radiation on the graft. However, it has been shown that a time window exists after obtaining certain bacterial or viral infections (Busch *et al*., 2000), which cannot be detected with currently available techniques. It is felt by many surgeons that unsterilized grafts pose unacceptable levels of risk to patients. The use of radiation is increasing now.

The aim of the use of gamma irradiation was to sterilize the allograft. However, Fideler *et al*.(1995) found that the dose of 2.5 mrad, which is a dose commonly used by tissue banks for sterilization, was just bacteriocidal but ineffective in eliminating viruses such as HIV. Doses of 3~4 mrad were necessary to inactivate the virus. Grieb *et al*.(2006) also proved that lower levels of radiation may be inadequate to kill hepatitis and HIV viruses, with dose of 5 mrad being necessary. When dose is increased, its clinical implications increase correspondingly. We must ask that as there are adverse effects of gamma irradiation and its failure to sterilize as required, why we are using this method. To avoid the disease transmission thoroughly, new alternative sterilization techniques are needed, which not only provide a complete protection against bacterial and viral infections but also have no interference with the biomechanical properties of the grafts.

With regards to IKDC, and functional and active levels of the operated knee at the follow-up, the follow-up time might be not long enough. No significant differences were found between the two groups according to the overall IKDC rating, Harner's vertical jump test, Daniel's one-leg hop test, Tegner activity score, and Lysholm knee scoring scale. There was no significant difference either according to the subjective evaluations. But there was a trend toward decrease of the IKDC rating, and functional and active levels of the operated knee with the irradiated BPTB allograft for reconstruction. The patients in the Ir-Allo group also felt uncomfortable more often than those in the Auto group. We believe that, as the time goes on, the functional and active levels of the patients in the Ir-Allo group will decrease significantly, as the operated knee now has represented serious laxity.

As to the ROM, none of the patients in either of the two groups developed loss of extension or flexion postoperatively, which required manipulation or debridement. As several studies (Harner *et al*., 1996; Shelton *et al*., 1997; Peterson *et al*., 2001; Rihn *et al*., 2006) reported, we found that individuals who had an autograft reconstruction had more significant numbness and dysesthesia in the area of the incision than individuals who underwent allograft reconstruction, but there was no difference in patient-reported kneeling problems.

As to the radiograph, several studies have reported that, after ACL reconstruction, the progression rate of OA increased (Ferretti *et al*., 1991; van der Hart *et al*., 2008). The surgical procedure for the ACL reconstruction may be of importance regarding the risk of eventual developing knee OA. The major factor with the potential to diminish this risk is improvement and maintenance of joint stability, resulting in a lower frequency of repeat injuries, especially of the meniscus and cartilage. In the present study, we chose relatively young patients [(29.7±7.2) vs (30.1±6.1) years] with shorter median time from injury to surgery (1.5 vs 1.6 months), as well as the strict inclusion criteria of patients, to study the progression rate of OA after ACL reconstruction. At the time of the primary ACL reconstruction to restore the stability of the injured knee, appropriated treatments were given to meniscus injury and cartilage damage. At the follow-up we did not find severe degenerative changes in the medial, lateral and femorotibial compartments of all patients undergoing ACL reconstruction with BPTB tissue.

The current study has several limitations. The first is the observer bias. The data were collected by only one fellowship-trained surgeon at one institution and not collected in a blinded fashion. Patients were informed as to the type of surgery by the surgeon after surgery, so the data collector may also have been aware at the time of the follow-up. Additionally, the incisions could also tip off observer the type of surgery. Secondly, although a standardized therapy protocol was prescribed to all patients postoperatively, the quality and consistency of the physical therapy might have varied at outside institutions. This can be a factor that affects the clinical outcomes. Furthermore, the follow-up time of the study is relatively short, so long term follow-up should be done to further evaluate the clinical outcomes of irradiated allograft and non-irradiated grafts. Finally, this is a single-surgeon study, and the results may not be generalized.

CONCLUSION

The short term clinical outcomes of the ACL reconstruction with irradiated BPTB allograft were adversely affected. The less than satisfactory results led the senior authors to discontinue the use of irradiated BPTB allograft in ACL surgery and not to advocate the use of gamma irradiation as a secondary sterilized method. Further research into alternatives to gamma irradiation is needed.

References

Balsly, C.R., Cotter, A.T., Williams, L.A., Gaskins, B.D., Moore, M.A., Wolfinbarger, L.Jr., 2008. Effect of low dose and moderate dose gamma irradiation on the mechanical properties of bone and soft tissue allografts. *Cell and Tissue Banking*, **9**(4):289-298. [doi:10.1007/s10561-008-9069-0]

Barrett, G., Stokes, D., White, M., 2005. Anterior cruciate ligament reconstruction in patients older than 40 years:

allograft versus autograft patellar tendon. *Am. J. Sports Med.*, **33**(10):1505-1512. [doi:10.1177/0363546504274202]

Boni, D.M., Herriott, G.E., 2002. Hamstring tendon graft for anterior cruciate ligament reconstruction. *AORN J.*, **76**(4):610-628. [doi:10.1016/S0001-2092(06)60936-8]

Buck, B.E., Malinin, T.I., Brown, M.D., 1989. Bone transplantation and human immunodeficiency vieus. An estimate of risk of acquired immunodeficiency syndrome (AIDS). *Clin. Orthop. Relat. Res.*, **240**:129-136.

Busch, M.P., Kleinman, S.H., Jackson, B., Stramer, S.L., Hewlett, I., Preston, S., 2000. Committee report. Nucleic acid amplification testing of blood donors for transfusion-transmitted infectious diseases: report of the interorganizational task force on nucleic acid amplification testing of blood donors. *Transfusion*, **40**(2):143-159. [doi:10.1046/j.1537-2995.2000.40020143.x]

Chang, S.K., Egami, D.K., Shaib, M.D., Kan, D.M., Richardson, A.B., 2003. Anterior cruciate ligament reconstruction: allograft versus autograft. *Arthroscopy*, **19**(5):453-462.

Cole, D.W., Ginn, T.A., Chen, G.J., Smith, B.P., Curl, W.W., Martin, D.F., Poehling, G.G., 2005. Cost comparison of anterior cruciate ligament reconstruction: autograft versus allograft. *Arthroscopy*, **21**(7):786-790.

Curran, A.R., Adams, D.J., Gill, J.L., Steiner, M.E., Scheller, A.D., 2004. The biomechanical effects of low-dose irradiation on bone-patellar tendon-bone allografts. *Am. J. Sports Med.*, **32**(5):1131-1135. [doi:10.1177/0363546503260060]

Daniel, D.M., Stone, M.L., Dobson, B.E., Fithian, D.C., Rossman, D.J., Kaufman, K.R., 1994. Fate of the ACL-injured patient. A prospective outcome study. *Am. J. Sports Med.*, **22**(5):632-644. [doi:10.1177/036354659402200511]

Deehan, D.J., Salmon, L.J., Webb, V.J., Davies, A., Pinczewski, L.A., 2000. Endoscopic reconstruction of the anterior cruciate ligament with an ipsilateral patellar tendon autograft. A prospective longitudinal five-year study. *J. Bone Joint Surg. Br.*, **82**(7):984-991. [doi:10.1302/0301-620X.82B7.10573]

Engebretsen, L., Benum, P., Fasting, O., Mølster, A., Strand, T., 1990. A prospective, randomized study of three surgical techniques for treatment of acute ruptures of the anterior cruciate ligament. *Am. J. Sports Med.*, **18**(6):585-590. [doi:10.1177/036354659001800605]

Ferretti, A., Conteduca, F., de Carli, A., Fontana, M., Mariani, P.P., 1991. Osteoarthritis of the knee after ACL reconstruction. *Int. Orthop.*, **15**(4):367-371. [doi:10.1007/BF00186881]

Fideler, B.M., Vangsness, C.T.Jr., Lu, B., Orlando, C., Moore, T., 1995. Gamma irradiation: effects on biomechanical properties of human bone-patellar tendon-bone allografts. *Am. J. Sports Med.*, **23**(5):643-646. [doi:10.1177/036354659502300521]

Fu, F.H., Bennett, C.H., Ma, C.B., Menetrey, J., Lattermann, C., 2000. Current trends in anterior cruciate ligament reconstruction. Part II. Operative procedures and clinical correlations. *Am. J. Sports Med.*, **28**(1):124-130.

Gorschewsky, O., Klakow, A., Riechert, K., Pitzl, M., Becker, R., 2005. Clinical comparison of the Tutoplast allograft and autologous patellar tendon (bone-patellar tendon-bone) for the reconstruction of the anterior cruciate ligament: 2- and 6-year results. *Am. J. Sports Med.*, **33**(8):1202-1209. [doi:10.1177/0363546504271510]

Gorschewsky, O., Klakow, A., Pütz, A., Mahn, H., Neumann, W., 2007. Clinical comparison of the autologous quadriceps tendon (BQT) and the autologous patella tendon (BPTB) for the reconstruction of the anterior cruciate ligament. *Knee Surg. Sports Traumatol. Arthrosc.*, **15**(11):1284-1292. [doi:10.1007/s00167-007-0371-3]

Grieb, T.A., Forng, R.Y., Bogdansky, S., Ronholdt, C., Parks, B., Drohan, W.N., Burgess, W.H., Lin, J., 2006. High-dose gamma irradiation for soft tissue allografts: high margin of safety with biomechanical integrity. *J. Orthop. Res.*, **24**(5):1011-1018. [doi:10.1002/jor.20079]

Han, H.S., Seong, S.C., Lee, S., Lee, M.C., 2008. Anterior cruciate ligament reconstruction: quadriceps versus patellar autograft. *Clin. Orthop. Relat. Res.*, **466**(1):198-204. [doi:10.1007/s11999-007-0015-4]

Harner, C.D., Olson, E., Irrgang, J.J., Silverstein, S., Fu, F.H., Silbey, M., 1996. Allograft versus autograft anterior cruciate ligament reconstruction: 3- to 5-year outcome. *Clin. Orthop. Relat. Res.*, **324**:134-144. [doi:10.1097/00003086-199603000-00016]

Kustos, T., Balint, L., Than, P., Bardos, T., 2004. Comparative study of autograft or allograft in primary anterior cruciate ligament reconstruction. *Int. Orthop.*, **28**(5):290-293. [doi:10.1007/s00264-004-0568-8]

Lawhorn, K.W., Howell, S.M., 2003. Scientific justification and technique for anterior cruciate ligament reconstruction using autogenous and allogeneic soft-tissue grafts. *Orthop. Clin. North Am.*, **34**(1):19-30. [doi:10.1016/S0030-5898(02)00029-9]

Noyes, F.R., Barber-Westin, S.D., 1997. Arthroscopic-assisted allograft anterior cruciate ligament reconstruction in patients with symptomatic arthrosis. *Arthroscopy*, **13**(1):24-32.

Nyland, J., Caborn, D.N., Rothbauer, J., Kocabey, Y., Couch, J., 2003. Two-year outcomes following ACL reconstruction with allograft tibialis anterior tendons: a retrospective study. *Knee Surg. Sports Traumatol. Arthrosc.* **11**(4):212-218. [doi:10.1007/s00167-003-0371-x]

Olson, E.J., Harner, C.D., Fu, F.H., Silbey, M.B., 1992. Clinical use of fresh, frozen soft tissue allografts. *Othopedics*, **15**(10):1225-1232.

Peterson, R.K., Shelton, W.R., Bomboy, A.L., 2001. Allograft versus autograft patellar tendon anterior cruciate ligament reconstruction: a 5-year follow-up. *Arthroscopy*, **17**(1):9-13.

Pritchard, J.C., Drez, D.Jr., Moss, M., Heck, S., 1995. Long-term followup of anterior cruciate ligament reconstructions using freeze-dried fascia lata allografts.

Am. J. Sports Med., **23**(5):593-596. [doi:10.1177/036354659502300513]

Prodromos, C.C., Fu, F., Howell, S.M., Johnson, D., Lawhorn, K., 2006. Controversies in soft-tissue anterior cruciate ligament reconstruction: grafts, bundles, tuneels, fixation, and harvest. *J. Am. Acad. Orthop. Surg.*, **16**(7):376-384.

Prodromos, C., Joyce, B., Shi, K., 2007. A meta-analysis of stability of autografts compared to allografts after anterior cruciate ligament reconstruction. *Knee Surg. Sports Traumatol. Arthrosc.*, **15**(7):851-856. [doi:10.1007/s00167-007-0328-6]

Rihn, J.A., Irrgang, J.J., Chhabra, A., Fu, F.H., Harner, C.D., 2006. Does irradiation affect the clinical outcome of patellar tendon allograft ACL reconstruction? *Knee Surg. Sports Traumatol. Arthrosc.*, **14**(9):885-896. [doi:10.1007/s00167-006-0036-7]

Schwartz, H.E., Matava, M.J., Proch, F.S., Butler, C.A., Ratcliffe, A., Levy, M., Butler, D.L., 2006. The effect of gamma irradiation on anterior cruciate ligament allograft biomechanical and biochemical properties in the caprine model at time zero and at 6 months after surgery. *Am. J. Sports Med.*, **34**(11):1747-1755. [doi:10.1177/036354650628885 1]

Shelton, W.R., Papendick, L., Dukes, A.D., 1997. Autograft versus allograft anterior cruciate ligament reconstruction. *Arthroscopy*, **13**(4):446-449.

Shino, K., Kawasaki, T., Hirose, H., Gotoh, I., Inoue, M., Ono, K., 1984. Replacement of the anterior cruciate ligament by an allogeneic tendon graft. An experimental study in the dog. *J. Bone Joint Surg. Br.*, **66**(5):672-681.

Siebold, R., Buelow, J.U., Bös, L., Ellermann, A., 2003. Primary ACL reconstruction with fresh-frozen patellar versus Achilles tendon allografts. *Arch. Orthop. Trauma Surg.*, **123**(4):180-185.

Stringham, D.R., Pelmas, C.J., Burks, R.T., Newman, A.P., Marcus, R.L., 1996. Comparison of anterior cruciate ligament reconstructions using patellar tendon autograft or allograft. *Arthroscopy*, **12**(4):414-421.

van der Hart, C.P., van den Bekerom, M.P., Patt, T.W., 2008. The occurrence of osteoarthritis at a minimum of ten years after reconstruction of the anterior cruciate ligament. *J. Orthop. Surg.*, **3**(24):1749-1759.