FRESH-FROZEN ALLOGRAFT RECONSTRUCTION IN CHRONIC ANTERIOR CRUCIATE LIGAMENT INSUFFICIENCY: SHORT-TERM RESULTS IN 17 PATIENTS*

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SUMMARY

Introduction: Our purpose was to evaluate the efficiency of the anterior cruciate ligament reconstruction with fresh-frozen non-irradiated tendon allografts in chronic ACL (anterior cruciate ligament) insufficiency by using objective and subjective evaluation methods.

Patients and Method: A prospective study was performed on 17 patients that underwent an arthroscopic ACL reconstruction. Bone-patellar tendon-bone grafts were used as an ACL substitute. The average age and follow-up period was 28.3 years and 29.3 months respectively. At the final evaluation, Lysholm and IKDC (International Knee Documentation Committee) scoring systems and Tegner activity scale were used to assess the status of the patients in addition to instrumented laxity testing. Paired t test and Wilcoxon tests were used to compare the preoperative and postoperative KT-1000 measurements and Tegner activity scale and the significance was set at $p<0.05$.

Results: Preoperative and postoperative mean side-to-side difference in KT-1000 evaluation was 5.8 ± 2.0 mm and 2.9 ± 2.8 mm respectively ($p<0.05$). Postoperative mean Lysholm score was 92.7 (range, 71 to 100) and 94% of the patients were in normal or near normal group according to IKDC scoring system. The mean Tegner activity score was increased up to 6.4 ± 1.3 postoperatively (preoperatively was 3.9 ± 2.3, $p<0.05$).

Discussion: Allografts restored the knee stability and activity of the patients. We believe that ACL reconstructions with fresh-frozen non-irradiated tendon allografts are low-morbid graft options in chronic ACL ruptures and early full weight bearing has no harmful effect on knee stability in short term.

Key Words: *ACL reconstruction, allograft, fresh-frozen, arthroscopy.*

ÖZET

Giriş: Kronik Ö.Ç.B. (ön çapraz bağ) yetmezliğinin taze dondurulmuş (fresh-frozen) tendon allogreftleri ile rekonstrüksiyonunun objektif ve subjektif değerlendirme kriterleri kullanılarak kısa dönemde etkinliğinin araştırılması.

Hastalar ve Yöntem: Kronik Ö.Ç.B. yetmezliği nedeniyle artroskopik Ö.Ç.B. rekonstrüksiyonu yapılan 17 hastada prospektif bir çalışma yapıldı. Hastalara bone-patellar tendon-bone tendon grefti transplante edildi. Hastaların yaş ortalaması 28.3 yıl ve ortalama izlem süresi de 29.3 ay olarak hesaplandı. Sonuçlar, KT-1000, Lysholm, IKDC ve Tegner skorlamalarına göre değerlendirildi. Preoperatif ve postoperatif KT-1000 ölçümleri ve Tegner aktivite skorları eşleşmiş t testi ve Wilcoxon testleri kullanılarak karşılaştırıldı ve $p<0.05$ anlamlı olarak bulundu.

Bulgular: KT-1000 ile yapılan ortalama sağlam-yaralanmış diz farkı değerlendirmeleri preoperatif dönemde 5.8 ± 2.0 mm iken postoperatif dönemde 2.9 ± 2.8 mm olarak bulundu ($p<0.05$). Postoperatif ortalama Lysholm skoru 92.7 (71-100) idi ve IKDC skorlaması kullanılarak yapılan değerlendirmede hastaların %94'ü normal veya normale yakın grupta yer aldı. Ortalama Tegner aktivite skoru preoperatif dönemde 3.9 ± 2.3 iken postoperatif dönemde bu değer 6.4 ± 1.3 olarak bulundu ($p<0.05$).

Tartışma: Allogreftler diz stabilitesini ve hasta aktivitesini etkin bir şekilde sağladılar. Kullanılan bu

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yöntemin kronik Ö.Ç.B. rekonstrüksiyonunda düşük morbiditeli bir yöntem olduğuna inanmaktayız ayrıca erken yük vermenin kısa dönemde diz stabilitesine zarar vermediğini düşünüyoruz.

INTRODUCTION

Although the autologous tendon use in primary ACL reconstruction is accepted as "gold standard"[1], there are also number of studies in the literature that report successful ACL reconstructions with tendon allografts[2-5]. Decision of the allograft ACL reconstruction should be made according to the patient's preferences (i.e. cosmetic reasons, less disturbance in kneeling activities or fear to have a disease transmission), availability of the allograft tissue, surgeon's preferences and the condition of the autograft tendon sources (i.e. previous ACL reconstruction with autograft). There are number of advantages of allograft use over autografts in ACL reconstruction, such as no donor site morbidity, shortened operation time, a shorter surgical incision and rich and various graft options. Potentially most disturbing disadvantages of allograft use are the risk of disease transmission, a slower graft remodeling process and potential for the immune response. To lower the risk of disease transmission, a few methods of secondary sterilization such as ethylene oxide and high-dose gamma radiation had been applied. But none of the procedures gave a hundred percent safety while preserving the graft material properties and preventing an antigenic response[6,7]. Thus, harvesting and preserving the graft in a sterile environment until the operation is currently the safest method available. Biomechanical studies on animals provide conflicting results. Both equal[8] and inferior[9] results were reported regarding the strength of the transplanted graft in in-vivo studies comparing auto and allografts.

Although there are number of studies reporting outcomes with the tendon allografts in ACL reconstruction, to our knowledge there are very few prospective studies on the use of fresh-frozen non-irradiated allografts without using any augmentation for the reconstruction of a chronic rupture of ACL[10-13]. In any of these, an early full weight bearing which we applied in our study was not reported.

The purpose of this study was to evaluate the patients with chronic ACL rupture by using objective and subjective evaluation methods after primary ACL reconstruction with non-irradiated fresh-frozen tendon allografts that underwent an accelerated rehabilitation and early full weight bearing programme postoperatively. Thus, to better understand the effect of early weight bearing on allograft tissue in a homogenous group of chronically injured knees.

PATIENTS AND METHODS

Patients

23 patients who had had a chronic unilateral rupture of ACL were operated consecutively using tendon allografts by the same senior surgeon (SG) between February 1999 and May 2002. Criteria for inclusion in this study were, no previous history of knee operation other than an arthroscopic meniscus surgery, no bilateral ligament injury, no posterior cruciate or posterolateral corner injury for the injured knee, at least one-month interval between the injury and operation. Thus, 20 patients (87%) who met these criterias and returned for the follow-up evaluations were included in this study and followed postoperatively. We used fresh frozen bone-patellar tendon-bone (in 17 patients) and Achilles tendon (in 3 patients) allografts according to availability of the allograft type. The number of Achilles tendon grafts was insufficient to compare statistically with the other graft type thus in order to get a homogeneous results these three patients excluded from the overall evaluation, thus only the bone-patellar tendon-bone allografts were evaluated. The mean follow-up was 29.3 months (range, 7 to 50 months). There were 15 male and 2 female patients, and their mean age at the time of the operation was 28.3 years (range, 18 to 40 years). 16 patients (94%) had sustained ACL injury during sports activities. Among them 15 patients (94%) had a non-contact injury. The mean interval between the injury and ACL reconstruction was 35 months (range, 1 to 221 months). During the arthroscopic procedures it was observed that 12 of the knees (71%) had a meniscal tear and 5 of them (29%) had normal meniscus. Partial meniscectomy was performed in 10 and sub-total meniscectomy in 1 knee. There was an incomplete tear of the lateral meniscus in 1 knee, thus the tear was left in situ.

Operative Procedure

Tissue-Organ Transplantation Committee in our hospital screens all of the donors precisely for viral, bacterial and fungal infections before the grafts are

harvested so that we were able to harvest the grafts safely from donors who donated their tendons as well. Thus, there was no extra graft expense for the patients. Harvesting procedures were done by one of the experienced orthopaedic surgeons in our department. Tendons were harvested in a sterile environment and stored sterile at -80°C until the surgical procedure. Preoperatively, information about the operation and allograft tissue was given to each patient and the consent was obtained. Allografts were thawed completely and soaked in an antibiotic solution for 30 minutes before the transplantation procedure.

A standard arthroscopic technique was preferred for reconstruction; only a single vertical 2 cm incision was made on the medial side of the patellar tendon just above the pes anserinus. Tibial tunnel was drilled and the graft was placed using this incision. Bone blocks were generally 25 to 30 mm long, 10 mm wide, and 8 to 9 mm deep, and the ligamentous portion was at least 10 mm wide. Tunnels were in 10 mm diameter for both femoral and tibial sites. We prefer to use metallic interference screws in 8 mm diameter and 25 or 30 mm length for bone block fixation both at the tibial and femoral sites.

Rehabilitation

The same accelerated rehabilitation protocol that we apply for the autograft ACL reconstructions was instituted after operation[14]. All patients were allowed a range of motion of 0 to 90 degrees immediately and attempted to reach 110 to 120° of flexion without an extension lack by the end of second week. Partial weight bearing was begun on the second postoperative day and was gradually increased to full weight bearing at approximately the end of first postoperative week. Muscle strengthening exercises including isometrics and straight-leg-raising were described on the first postoperative day. Return to sports activity is usually achieved at around 7 months post-operatively when the quadriceps muscle regained at least 80% of the strength of the opposite leg. A protective brace was recommended to use during the strenuous activities until the end of first postoperative year.

Evaluation

The instrumented evaluation consisted of preoperative and postoperative injured-uninjured knee measurements with a KT-1000 arthrometer (MEDMetric Corp., San Diego, California) at maximum manual testing. In an earlier study, it was reported that side-to-side differences were more important than absolute translations[15]. Thus, the differences between injured-uninjured knees were recorded for analysis.

A comprehensive knee examination was performed to assess range of motion and ligament stability. Other assessments using Lysholm scoring system[16], IKDC (International Knee Documentation Committee) knee examination form[17] and the Tegner activity scale[18] were also performed at the final follow-up for overall rating. Comparisons of preoperative and postoperative Tegner activity scale were also done.

A graft failure or a non-functioning graft defined as a knee that demonstrated any of the following signs: a) a positive pivot shift test, b) any Lachman test with a soft end point, c) a Lachman test more than 1+, d) a side-to-side difference of more than 4 mm in the KT-1000 arthrometer testing.

Statistical analyses were used to determine significant differences between the preoperative and postoperative KT-1000 evaluations and the Tegner activity scale. Paired t test and the Wilcoxon tests were used respectively, and the level of significance was set at $p<0.05$.

RESULTS

Mean interval between the injury and the ACL reconstruction was 35 months (range, 1 to 221 months) and the mean follow-up was 29.3 months (range, 7 to 50 months), (Table I). 94% of the injuries (16 patients) were occurred during a sports activity, and the injuring events were soccer in 13 patients (76%), pentathlon, handball, volleyball and jump from a height in 1 patient in each (6% in each). 4 patients (24% of the patients) were competitive athletes and they injured during a competition.

At the final follow-up (Table II) the mean Lysholm score was 92.7 (range, 71 to 100) and 29% of the patients (5 patients) were in group A (normal), 65% of them (11 patients) were in group B (near normal), and 6% of them (1 patient) were in group C (abnormal) according to IKDC scoring system. IKDC evaluation showed, 94% of the knees (16 patients) were normal or near normal, and similarly according to Lysholm score 88% of the knees (15 patients) were normally functioning (Fig.). The mean Tegner activity scale was

Table I
Injury Profile of the Patients

Case	Age at surgery	Injury mechanism	Injury type	Sports level	Meniscal pathology[a]	Meniscus surgery[b]	Injury-operation interval (months)	Follow-up (months)
1	40	Soccer	Non-contact	Competitive	MML	PM	221	30
2	28	Soccer	Non-contact	Recreative	LML	PM	13	25
3	29	Soccer	Non-contact	Recreative	LML-incomplete	None	1	13
4	33	Soccer	Non-contact	Competitive	MML	PM	9	27
5	33	Soccer	Non-contact	Recreative	LML+MML	PM	104	24
6	21	Soccer	Contact	Recreative	MML	PM	4	37
7	21	Pentathlon	Non-contact	Recreative	MML	PM	4	45
8	18	Handball	Non-contact	Competitive	None	None	39	8
9	37	Soccer	Non-contact	Recreative	None	None	6	50
10	22	Soccer	Non-contact	Recreative	MML	PM	33	36
11	39	Soccer	Non-contact	Recreative	None	None	26	15
12	18	Soccer	Non-contact	Recreative	MML	PM	5	45
13	22	Jump	Non-contact	Recreative	MML	STM	8	49
14	21	Volleyball	Contact	Competitive	None	None	1	36
15	32	Soccer	Non-contact	Recreative	LML	PM	65	7
16	40	Soccer	Non-contact	Recreative	MML	PM	28	26
17	27	Soccer	Non-contact	Recreative	None	None	28	26

[a] MML: medial meniscal lesion, LML: lateral meniscal lesion.
[b] PM: partial meniscectomy, STM: subtotal meniscectomy.

Table II
Results of Follow-up Examination.

Case	Lachman	Anterior drawer	Pivot shift	Lysholm score	Tegner scale Preop[a]	Tegner scale Postop[a]	Anterior knee pain	Allograft type[b]	IKDC scale[c]	Postop knee injury
1	0	0	0	90	9	9	none	BPTB	NN	no
2	1+	1+	0	100	2	6	none	BPTB	NN	no
3	0	0	0	92	1	5	none	BPTB	NN	no
4	0	0	0	100	4	9	none	BPTB	N	no
5	1+	1+	0	89	3	5	mild	BPTB	NN	no
6	1+	1+	0	87	4	6	mild	BPTB	NN	no
7	0	0	0	95	3	5	mild	BPTB	NN	no
8	0	0	0	96	7	7	none	BPTB	N	no
9	0	0	0	100	7	7	none	BPTB	N	no
10	0	0	0	95	7	7	none	BPTB	N	no
11	0	0	0	99	2	5	mild	BPTB	NN	no
12	1+	1+	0	76	4	6	mild	BPTB	NN	no
13	2+	2+	1+	71	2	6	moderate	BPTB	A	yes
14	0	0	0	95	2	7	mild	BPTB	NN	no
15	0	0	0	91	2	5	mild	BPTB	NN	yes
16	1+	1+	0	100	3	6	none	BPTB	NN	no
17	0	0	0	100	4	7	none	BPTB	N	no

[a] $p < 0.05$
[b] BPTB: bone-patellar tendon-bone
[c] N: normal, NN: nearly normal, A: abnormal.

significantly increased up to 6.4 ± 1.3 (mean ± standard deviation) postoperatively (preoperatively was 3.9 ± 2.3). Knee laxity testing showed an improvement postoperatively; 65% of the patients (11 patients) had a negative Lachman test, 65% (11 patients) had a negative anterior drawer test, and 94% (16 patients) had a negative pivot shift test. Instrumented knee laxity evaluations with KT-1000 test revealed a significant improvement postoperatively; mean side-to-side difference was decreased to 2.9 ± 2.8 mm (preoperatively was 5.8 ± 2.0 mm). 47% of the patients (8 patients) reported an anterior knee pain during or after an activity. Two patients reported that they had a

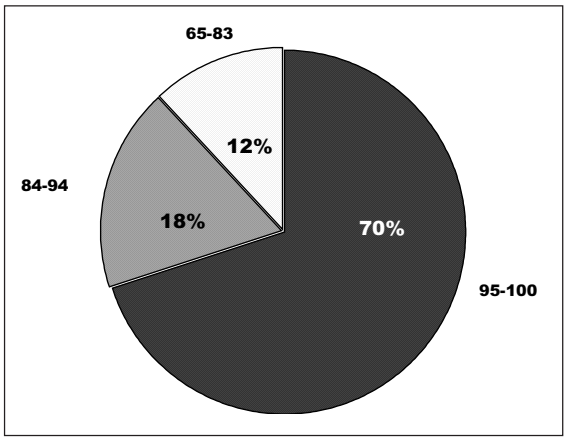

Fig: Postoperative Lysholm score distribution and percentage of knees.

postoperative knee injury so they had to decrease their activity level afterwards; one of them had the lowest score in entire group according to IKDC scale and Lysholm scoring system (case number 14).

DISCUSSION

In this prospective study our aim was to evaluate the allograft ACL reconstructions in average of 29.3 months postoperatively without applying any secondary sterilization procedures. Also, we did not change our postoperative rehabilitation protocol than we applied to autograft ACL reconstructions to see the effects of early weight bearing.

We obtained successfully functional grafts in 71% of the patients (12 patients) according to instrumented laxity testing. Assessments according to IKDC, Lysholm and Tegner scoring systems further supported this. Our findings were consistent with the few previous studies regarding ACL reconstruction with fresh-frozen tendon allografts in chronically injured knees[10-13]. In our study, five patients had a non-functional graft, among them two patients reported a postoperative knee injury that might have caused a stretch or a rupture of the ligament to decrease in their postoperative objective assessment levels. In a few previous studies that compared the auto and allografts in short term follow up, the only difference between the graft types detected was occurrence of ruptures in allograft group[19,20]. These reports support our two non-functional grafts in a way that allograft tissue maybe more at risk to rupture or stretching than autografts but this needs to be proven in long-term clinical studies. Other three patients with non-functional grafts could not recall any traumatic event but with the above mentioned reasons they might have a stretch with a minor trauma.

Although we believe that, preserving the meniscus should be attempted whenever possible, we did not perform any meniscal repair since the menisci were degenerated and in an unrepairable phase in most of the cases; the mean injury-operation interval for the meniscus-injured patients was 39 months (range, 4 to 221 months).

We preferred not to use any secondary sterilization procedures except soaking the graft in an antibiotic solution before transplantation since the secondary sterilization has harmful effects on ligament's mechanical properties and can cause toxic synovitis[6,7]. Despite these harmful effects on allograft tissue, secondary sterilization still does not provide a hundred percent safety, thus we believe that precise donor screening, sterile graft harvesting and the convenient storage are the key factors to prevent disease transmission.

Although animal studies showed that, revascularization and remodeling may takes longer for the allograft tissue[21], clinical studies demonstrated there is no difference in regard to knee laxity, functional status and the muscle forces in mid-term follow-up between allo and autograft ACL reconstructions[4,5,12].

We have not seen any deleterious effects of early full weight bearing on allograft tissue in this study. Barber-Westin and Noyes[10] reported that, early knee motion and weight bearing did not result an increased incidence of abnormal anteroposterior knee displacements, rather, the abnormal displacements occurred later, during the intensive strength training or return to sports.

In an in vivo study, Henning et al[22] was measured the strain in the partially torn ACLs of two patients by an elongation gauge inserted into the ACL. They reported that more strain was generated during leg extension (22° to 0°) and isometric contraction of quadriceps femoris muscles against resistance at 0°, 22° and 45° of flexion than walking. Recently, Beynnon et al[23,24] similarly measured the strain on the intact ACL in human subjects during rehabilitation exercises. They concluded that, there was no difference in ACL strain characteristics between squatting and isometric knee extension (15° and 30°), and between squatting and active flexion-extension of the knee, thus, these two exercise type (weight bearing and non-weight bearing) carry equal risk of permanently deforming or injuring the graft.

These in vivo measurements support our early weight bearing programme in such a way that, walking or weight bearing does not have potentially more harmful effect on ACL than an active flexion-extension exercise or an isometric quadriceps contraction in low degrees of flexion of the knee joint (latter two are the most commonly prescribed exercises in early postoperative period).

In conclusion, we consider that allograft ACL reconstruction is a reliable method to restore knee stability in chronic ACL insufficiency and early full weight bearing has no harmful effect on knee stability in short term.

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