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## Anterior cruciate ligament reconstruction with fresh-frozen patellar tendon allografts: sixty cases with 2 years' minimum follow-up

Received: 10 May 1996  
Accepted: 25 July 1996

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**Abstract** A prospective study was performed on 101 patients who underwent an arthroscopic anterior cruciate ligament (ACL) reconstruction with fresh-frozen patellar tendon allograft (bone-patellar tendon-bone). We present the results of the first 60 patients with a minimum follow-up of 2 years. Thirty-four were men and 26 women with a mean age of 23. In 45 patients, a postoperative arthroscopy was performed, and tissue biopsies of the reconstructed ACL were obtained. Patients were evaluated according to the International Knee Documentation Committee evaluation form. After a mean fol-

low-up of 47 months, the overall results were normal or nearly normal in 85%. Under postoperative arthroscopy, the macroscopic appearance of the implant was similar to that of a normal ligament. The ACL allograft was covered with a normal, well-vascularized synovium. There were no cases of infection, disease transmission or tissue rejection. We conclude that the use of fresh-frozen patellar tendon allografts is a good method of ACL reconstruction.

**Key words** Anterior cruciate ligament reconstruction · Allograft

### Introduction

Conservative treatment of anterior cruciate ligament (ACL) lesions often leads to recurrent episodes of giving way, meniscal damage, osteoporosis and osteoarthritis of the knee [23, 26, 27]. There is consensus that surgical treatment is convenient, but which surgical reconstructive procedure is the best is still controversial [26]. Although bone-patellar tendon-bone autograft has been considered the gold standard for ACL reconstruction, recent studies have shown no significant clinical differences in outcome in patients who received an autograft compared with those who received an allograft [15]. Besides, there are several disadvantages in the use of patellar tendon autograft, such as relative loss of flexion, limited extension, quadriceps weakness and anterior knee pain [13, 24, 38, 45]. The use of allografts eliminates donor tissue site morbidity, reduces surgical time, permits smaller incisions, is associated with a lower incidence of postoperative arthrofibrosis

[15, 18, 21, 32, 38, 44]; but it raises potential disadvantages including immunogenicity, the potential for disease transmission, possibly slower incorporation and cost effectiveness in ACL reconstruction [21]. This paper presents our experience with fresh-frozen patellar tendon allografts (bone-patellar tendon-bone) in patients who require either an ACL substitution or reinforcement.

### Materials and methods

Between 1988 and 1996, 101 patients underwent ACL reconstruction at the University Clinic of Navarra using fresh-frozen, nonirradiated allograft tissue. All had ACL-deficient knees that were unstable during sports and/or activities of daily living. All the ACL reconstructions were performed by one surgeon (J.V.N.). The first 60 patients with a minimum follow-up of 2 years (range 24–78 months) were included in this prospective study. All patients were told of the origin of the graft, and then informed consent was obtained. Laboratory tests were carried out as required by current Spanish legislation [2]. Thirty-four were men and 26 women with a mean age of 23 (range 16–32) at the time of ACL reconstruction.

We performed acute surgery in 4 patients and delayed surgery in 56. All patients followed a strict protocol with preoperative evaluation and monthly postoperative review during the first 6 months, at 6 and 12 months, and then yearly. Fifty-five patients sustained their injury during sports, 25 while playing soccer, 19 skiing, 5 playing basketball, 2 during gymnastics, 2 playing handball, 1 during athletics, and 1 while practising judo. Five were injured at work, at home or during leisure. Twenty patients (33.3%) had undergone a previous arthroscopy, and 12 (20%) a previous failed ACL reconstruction.

Anterior translation was assessed manually by the same physician with the Lachman's test at 25° and anterior posterior translation at 70° flexion. Rotatory instability was examined by pivot shift and reverse pivot shift tests. Instrumented measurement of anterior translation of the knee was not done because an arthrometer was not available at the time this study was conducted. The active and passive range of motion were assessed using standard goniometric technique.

Weight-bearing radiographs were taken, and a preoperative radiographic Lachman's test was carried out. In 30 patients a magnetic resonance imaging was also undertaken. In 45 patients arthroscopy was performed 10–36 months after surgery to obtain arthroscopic assessment and biopsies of the reconstructed ligament.

#### Operative technique

The patellar tendon allograft (bone-patellar tendon-bone) was stored in a freezer at -90°C, changing to -40°C the day before the operation. The tendinous part of the graft was 1 cm wide. Immediately before use, a stainless steel wire suture was inserted into both ends of the graft, and the two bone plugs were shaped with a small oscillating saw. Arthroscopy was performed in every case to evaluate the ACL and to treat any associated meniscal or cartilaginous lesions. The graft was implanted by arthroscopy alone in the last 40 patients, and in the remaining 20 a miniarthrotomy was performed. We used the two-incision 'rear entry' technique [10]. We tried to preserve the remaining fibers of the ACL to help revascularisation of the graft. Fixation was achieved by tying the wire suture over a screw and washer distally. The proximal bone plug was cut into a conical shape, allowing bone-to-bone wedge fixation so that the proximal screw was unnecessary.

#### Postoperative care and rehabilitation

Antibiotics were given routinely with cefazolin 1 g every 7 hours intravenously for the first 3 days and cefradoxyl every 8 hours orally for the next 4 days. A postoperative knee brace locked at 15° flexion was applied for 7 days, then active exercises were begun wearing the hinged functional brace to prevent hyperextension for 3 months. Rehabilitation was carried out for 2 months after the operation by a physiotherapist in a special centre and included active and passive exercises, electrical muscle stimulation and progressive weight-bearing as tolerated. Patients ambulated with crutches for the first 8 weeks. After 3–6 months depending on the strength of the quadriceps muscle, swimming, cycling, and jogging were permitted. After 1 year, any sport was allowed provided there was no pain or restriction of movement.

#### Criteria for evaluation

The follow-up evaluation was conducted according to the guidelines of the International Knee Documentation Committee [16]. The findings of the second-look arthroscopy were also assessed. The graft was considered normal when it was well oriented, with adequate thickness, tension, vascularization, and synovialization. It was considered nearly normal when there was adequate tension

and at least 75% of the fibers were well oriented, with normal vascularization and synovialization. When there was inadequate tension or more than 25% of the fibers were abnormal, the graft was considered abnormal, and in the case of absence of rupture of the graft, it was considered severely abnormal.

## Results

The final evaluation, following the IKDC guidelines, showed 30 normal knees (50%), 21 nearly normal (35%), 8 abnormal (13.3%), and 1 severely abnormal (1.7%) (Table 1). Subjective evaluation revealed normal knees in 36 patients (60%), nearly normal in 17 (28.3%), abnormal in 7 (11.7%), and poor in 0. The patients rated their symptoms by indicating the highest level of activity they could do before symptoms appeared (Table 2).

Thirty-three patients (55%) had undergone a meniscal repair prior to or during ACL reconstruction. The overall results of these patients are shown in Table 3.

At later follow-up evaluation, nine patients (15%) had moderate patellofemoral crepitus, and the only patient who had preoperative moderate patellofemoral crepitus developed mild patellofemoral pain.

One patient presented with 8° lack of extension, 5 patients with a lack of flexion between 6° and 15°, and one patient who developed arthrofibrosis presented with 35° lack of flexion. In three cases, manipulation of the knee under anesthesia was necessary due to lack of flexion. Two of those patients achieved a full range of motion, and one did not improve with manipulation, with a persisting lack of flexion of 35° and lack of extension of 8°. This patient underwent an open arthrolysis.

**Table 1** Rating according to International Knee Documentation Committee guidelines

	<i>n</i>
Rating	
Normal	30 (50%)
Nearly normal	21 (35%)
Abnormal	8 (13.3%)
Severely abnormal	1 (1.7%)
Frequency of abnormal rating	
Subjective	7
Symptoms	2
Range of motion	0
Laxity	7
One patient had a severely abnormal range of motion	
Number of abnormal categories per patient	
None	51
1	3
2	3
3	2
4	0
One patient had one severely abnormal category	

**Table 2** Symptoms

	<i>n</i>
Highest level of activity without pain	
Strenuous sports activities	41
Moderate sports activities	17
Light sports activities	2
Activities of daily living (ADLs)	0
Highest level of activity without swelling	
Strenuous sports activities	46
Moderate sports activities	12
Light sports activities	2
ADLs	0
Highest level of activity without partial giving-way	
Strenuous sports activities	45
Moderate sports activities	14
Light sports activities	1
ADLs	0
Highest level of activity without complete giving-way	
Strenuous sports activities	48
Moderate sports activities	11
Light sports activities	1
ADLs	0

**Table 3** Results with and without associated meniscal lesion

IKDC rating	Intact meniscus	1/3 partial meniscectomy
Normal	15 (55.6%)	15 (45.5%)
Nearly normal	10 (37%)	11 (33.3%)
Abnormal	1 (3.7%)	7 (21.2%)
Severely abnormal	1 (3.7%)	0

**Table 4** Manual ligament evaluation (– no translation, + less than 10 mm AP translation, firm endpoint, ++ less than 10 mm AP translation, soft endpoint, +++ more than 10 mm AP translation)

Preoperative	Postoperative			
	–	+	++	+++
Lachmann (25° flexion)				
+++	2	1	1	
++	24	14	5	5
+	34	28	6	
Total anteroposterior translation (70° flexion)				
+++	5	2	3	
++	36	17	15	4
+	19	13	6	
Pivot shift		Equal	Glide	Marked
Gross	2	1		1
Marked	24	14	5	5
Glide	34	28	6	

**Table 5** Sports activity level: preoperatively vs postoperatively

Intensity (level of activity)	0	LRS	VRS	CS
Light recreational sports (LRS)	26	1	24	1
Vigorous recreational sports (VRS)	22		21	1
Competitive sports (CS)	12		3	9
Occupational	–			

The results of manual ligament evaluation and sports activity level are shown in Tables 4 and 5, respectively. Between 10 months and 3 years after surgery, 45 patients had the distal screw removed, and at the same time an arthroscopy was performed. The ACL allograft appeared to be covered with normal, well-vascularised synovium which was hypervascularised at the ends compared with the middle part of the graft. Most of the graft's bundles were well oriented and under good tension. Histologically, there were viable fibroblasts and blood vessels interspersed between well-organised collagen bundles. The overlying synovium did not show any evidence of inflammation. On this second-look arthroscopy 20 grafts were normal (44.4%), 20 nearly normal (44.4%), 5 abnormal (11.2%), and none severely abnormal. The five patients with abnormal arthroscopic findings presented with an abnormal IKDC rating. Three patients with nearly normal grafts presented with an abnormal IKDC rating. The only patient who achieved a severely abnormal result had developed a severe postoperative arthrofibrosis that required arthrolysis. None of the patients had undergone a second reconstruction of the ACL during the follow-up period, and there were no cases of infection or rejection.

## Discussion

Soft-tissue allografts are an attractive alternative treatment for ligamentous lesions in the knee and other joints, provided they are available and their sterile preservation can be assured. Disease transmission must be avoided, and remodelling anticipated without loss of the ligament's mechanical properties. In our center we harvest our own bone and soft-tissue grafts from multiorgan donors under strict sterile conditions [3]. Unprotected allografting without any screening puts the risk of human immunodeficiency virus (HIV) transmission at 1:161 [5]. Use of the available screening tools lowers the estimated risk to 1:1 667 600 [5]. Nevertheless, it is important that both the donor and host be carefully selected.

The role of radiation for tissue sterilization and HIV eradication is controversial [37]. The American Association of Tissue Banks currently recommends a dose of 2.5 megarads for sterilization of soft-tissue allografts [1]. However, Fideler et al. [11] reported that 3.0 megarads are needed to completely inactivate HIV in bone-patellar ligament-bone allografts, and Conway et al. [7] postulates

the need for 3.6 megarads to kill free viruses and larger doses yet for intracellular viruses. On the other hand, gamma-irradiation alters collagen structural and tensile strength, decreasing the graft stiffness and maximum force [35] in a dose-dependent fashion [6, 12, 34]. The long-term mechanical properties of bone-patellar tendon-bone allografts after gamma-irradiation remain to be investigated [29].

Ethylene oxide sterilization produces acute and chronic synovial reaction with bone resorption, large cyst formation, and eventually complete dissolution of the graft [6, 8, 12, 19, 21, 35, 36].

Freezing and to a lesser extent freeze-drying of fresh sterile allografts do not alter the mechanical properties of the implant [8, 9, 17]. Clinical studies have shown better results with fresh-frozen allografts than freeze-dried allografts [17].

Studies reported by different authors confirm that the bone-patellar tendon-bone graft has good mechanical properties, and it is the preferred method of treating ACL lesions [50]. Its firm fixation in a bony tunnel allows as early rehabilitation as any type of synthetic implant [31]. There are very few experimental [44, 46, 47, 49] and clinical studies [15, 24, 28, 29, 44, 48] that could determine whether there is any difference in the mid- and long-term results between autografts and allografts. Harner et al. [15] found no significant differences in outcome.

Even though data obtained from animal models suggest that the phases of biologic remodelling may progress more rapidly in autografts than in allografts [21], we have found in an experimental study in lambs that 1 year after the operation there are no significant differences in mechanical properties, macroscopical and microscopical appearances, and final clinical outcome between the two groups [39].

The minimum follow-up of 2 years in our series seems adequate since graft maturity is attained 18 months after implantation [42]. Our results of fresh-frozen patellar tendon allografts are satisfactory when compared with data reported using other techniques and implants [15], particularly considering that 87% of our patients had chronic ACL lesions which have a worse outcome than acute injuries [18, 31, 38]. Our 85% normal and nearly normal results using allografts is similar to the 80% good results reported by Jackson et al. [19], the 88% reported by Shino et al. [43] and the 90% of Indelicato et al.'s series [17], even though they did not use the IKDC rating system. Our overall failure rate with the allograft was 15%, similar to the 14% reported by Noyes and Barber [30].

An instrumented arthrometer to measure anterior-posterior laxity was not available, and thus we could not perform an objective evaluation. There are inconsistencies in manual testing, but experienced clinicians have reported a high rate of accuracy in evaluation of the anterior-posterior laxity of the knee with the Lachman test [22].

In our series, only one patient had a lack of extension at follow-up. Harner et al. [13, 14] have found a statisti-

cally significant difference, with a higher incidence of loss of terminal extension in the autograft group over the allograft group. In his series, the mean loss of active extension in patients receiving an autograft was 3° compared with 1.2° for patients receiving an allograft.

Nine patients (15%) had moderate patellofemoral crepitus and one patient patellofemoral crepitation with mild pain at later follow-up evaluation. In Noyes and Barbers [30] series after a mean follow-up of 7 years, 24% of the patients had moderate crepitus and 1% severe crepitus. Patellofemoral crepitus after ACL reconstruction could be secondary to the effects of the initial injury, the operative procedure or the effects of disuse [30]. Although moderate crepitus was not associated with symptoms, it may eventually lead to pain and a reduction of the level of activity [30, 36]. Some authors have advocated the use of close-kinetic-chain exercises and avoidance of both stationary cycling and progressive resistance exercises with heavy weights to decrease patellofemoral pain [25, 30].

Even though there were more abnormal results in the group with partial meniscectomy, the statistical analysis of the percentages of abnormal knees in each group (chi-square) showed no statistically significant differences. The finding that the state of the menisci had no influence on the final outcome of our knees could be due to the fact that at least two-thirds of the meniscus were preserved in the patients who had undergone meniscectomy.

In our patients, there has been no clinical evidence of immunological reaction to the graft. Fresh-freezing at -90° C and at -180° C in liquid nitrogen markedly diminishes cellular immunogenicity [39, 40].

The results of the second-look arthroscopy should be interpreted with caution due to the different lengths of follow-up of the patients at the time it was performed (range 10 to 36 months). Nevertheless, there was a correlation between abnormal arthroscopic findings and abnormal IKDC score. Our arthroscopic findings of the allograft 18 months after implantation indicated that the appearance of the implant was similar to that of a normal ligament after 1 year. There was an initial slight decrease in vascularization in the middle part of the graft; this finding has also been reported by others [2, 21]. The vascular pattern becomes normal after 1 year [21]. The lack of inflammatory response found in histological specimens could be related to the freezing process, which denatures cell surface marker proteins and disrupts cell membranes, thereby reducing antigenicity [4].

The patients were assessed from a functional point of view, which is important since the aim of the procedure is to enable the patient to return to sport at the same level as before injury. Allografts are currently our graft of choice for ACL reconstruction procedure. Success is based on the principles which apply to all ACL reconstructions with autograft, namely the correct size and width of the implant, isometric placement and stable flexion with bone plugs, and early mobilization.

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