

# Poor results of bovine xenograft for knee cruciate ligament repair

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In 28 patients the anterior cruciate ligament of the knee was substituted with a bovine bioprosthesis (Xenograft®). Five patients underwent reoperations due to synovitis and graft rupture during the first postoperative year; and 2 patients, due to graft rupture after 3 years. After 3 years, 11/21 patients with a remaining graft had a rupture. Totally, 18/28 implanted grafts were considered to be ruptured. Our results indicate that the Xenograft® in its present form should not be used.

During the last 10 years, there has been a growing interest in developing a prosthesis to function as a substitute for the missing anterior cruciate ligament. Various materials, such as carbon fiber, polyethylene, proplast, and bovine tendons, had been subjected to experimental and clinical trials at the time of the start of this study (Jenkins 1978, Jenkins and McKibbin 1980, Scharling 1981, Tremblay and Laurin 1980, Abbink 1983).

A collagen prosthesis (Xenograft®) was developed by Xenotech Laboratories (Irvine, CA, USA). The prosthesis is manufactured from bovine tendons in which the collagenous material is stabilized by increasing the number of intermolecular cross-links by treatment with 0.2 percent glutaraldehyde (McMaster et al. 1976, 1986, McMaster 1985).

We report the results of substituting the missing anterior cruciate ligament with a Xenograft®, model CLR.

## Patients and methods

During the period April 1983 to May 1984, 28 patients (18 men and 10 women) with a median age of 25 (20-44) years underwent anterior cruciate ligament reconstruction with a Xenograft®. The median duration of symptoms before the operation was 3.5 (0.5-9) years.

The cause of the original injury was in all the cases rotatory knee trauma, mostly during sports. Five patients had an anterior cruciate ligament repair following the primary trauma, and 23 were treated without an

operation. As secondary procedures, but prior to the Xenograft® index operation, 6 patients had medial and 4 lateral meniscectomies. Seven patients had extra-articular stabilizing surgery, and 2 had an anterior cruciate ligament reconstruction (Table 1).

The indication for the Xenograft® reconstruction was instability with multiple giving-way episodes. A clearly positive pivot-shift sign (Galway et al. 1972) was present in 20 patients, and a further 8 patients had a clearly positive pivot-shift sign when examined under anesthesia. Arthroscopy confirmed the diagnosis in all the patients. The mean preoperative scores for the 28 patients were Lysholm score (max. 100):  $59 \pm 16$ , Lysholm stability score (max. 25):  $6 \pm 4$ , Lysholm pain score (max. 25):  $14 \pm 8$ , and Lachman score (max. 5):  $2.3 \pm 0.7$ .

## Operative technique

In all cases a comprehensive intercondylar notch plasty was made. Channels, 6-8-mm wide, were drilled depending on the thickness of the graft. The tibial tunnel was drilled 1 cm medial to the tibial tubercle and was directed towards the anatomic insertion of the anterior cruciate ligament on the intercondylar eminence. The femoral tunnel was drilled via a lateral incision posteriorly and as vertically as possible with the distal inner opening at the attachment of the anterior cruciate ligament.

Before implantation the Xenograft® was rinsed, as recommended, in 1.5 L of saline solution and continuously moved by hand under sterile conditions in three consecutive bowls for 5 min each. The rinsed graft was pulled through the femoral tunnel via the joint and passed through the tibial tunnel. The graft was then anchored proximally with double Richard's staples. A

Table 1. Data for 28 patients with anterior cruciate ligament reconstruction using Xenograft®

A	B	C	D	E	F	G	H <sub>0</sub>	I <sub>0</sub>	J <sub>0</sub>	K <sub>0</sub>	L <sub>0</sub>	M <sub>0</sub>	O	H <sub>1</sub>	I <sub>1</sub>	J <sub>1</sub>	K <sub>1</sub>	L <sub>1</sub>	M <sub>1</sub>	P <sub>1</sub>	Q <sub>1</sub>
1	M/20	1	R	Basket		2	58	5	10	+	3	29	S:8/11	59	15	25	-	4	35	0	45
2	M/25	4	L	Fall	MM	2	81	5	15	+	3	27		100	25	25	-	5	40	0	0
3	M/25	1	L	Soccer		2	45	5	10	+	2	28		95	25	25	-	5	38	0	0
4	M/20	1	R	Handball		2	42	5	10	+	2	29	GR/36	89	25	15	(+)	4	37	0	0
5	M/22	2	L	Orient.		2	71	10	15	+	2	26		95	20	25	-	4	38	0	5
6	M/28	4	L	Sailing	Ex.art.	2	64	5	15	(+)	2	27		89	25	20	-	4	37	0	15
7	F/33	9	R	Soccer	MM	2	52	5	20	(+)	2	25		99	25	25	-	4	38	0	0
8	F/21	2	L	Dancing		1	61	10	10	+	3	31		73	25	15	-	4	36	10	0
9	M/22	2	L	Soccer	Ex.art.	2	68	10	15	(+)	4	30		74	20	20	-	4	38	0	10
10	F/29	5	R	Squash		2	72	10	20	(+)	2	26	S:8/14	68	20	15	(+)	3	29	10	10
11	F/20	1	L	Handball		2	76	5	25	+	2	27		90	20	25	(+)	4	34	0	0
12	F/23	4	R	Soccer	1) ACL.sut. 2) ACL.rec.	1	44	5	0	+	3	26		74	25	10	-	5	40	10	15
13	F/20	2	L	Soccer	Ex.art.	2	80	10	25	+	2	26	S:5/6	90	20	20	(+)	4	31	0	0
14	M/23	2	R	Skating		2	80	10	25	(+)	3	30		87	25	5	-	5	40	5	50
15	F/24	9	L	Soccer	1) ACL.sut. 2) Ex.art.	1	40	0	5	+	2	24	GR/40	86	25	10	-	3	36	0	10
16	M/29	6	R	Soccer	1) ACL.sut. 2) Ex.art. 3) ACL.rec.	1	21	0	0	+	4	27		19	5	0	-	4	38	0	0
17	M/44	5	R	Traffic	LM	2	67	5	25	+	1	22		84	25	25	-	5	40	3	10
18	M/33	8	R	Soccer	1) MM, LM 2) Ex.art.	2	68	5	20	+	2	23		100	25	25	-	3	38	0	5
19	M/28	4	R	Soccer	LM	2	73	5	20	+	2	28		88	25	20	-	5	40	5	15
20	F/22	0,5	L	Soccer		2	59	10	5	+	3	29		82	25	10	-	5	39	5	20
21	F/21	2	L	Ind. bandy		2	68	5	10	+	2	25		78	25	10	-	5	40	10	20
22	M/29	2	R	Soccer	LM	2	51	10	5	(+)	2	28	S:4/10	61	10	15	-	4	36	0	0
23	M/23	7	R	Soccer	1) MM 2) Ex.art.	2	64	5	15	+	1	19		95	25	25	-	3	33	0	0
24	M/34	9	R	Squash	ACL.sut.	2	75	5	20	+	2	22	S:12/17	81	25	20	-	4	37	5	20
25	F/38	2	L	Fall	MM	2	22	0	5	(+)	3	27		95	25	25	-	4	39	0	0
26	M/27	4	R	Soccer		2	76	15	15	(+)	2	30		86	25	25	-	4	39	0	0
27	M/32	3	L	Skating	ACL.sut.	2	64	5	20	+	2	22		91	20	25	-	5	37	0	0
28	M/39	7	R	Skating	MM	2	53	5	5	+	2	22		83	25	15	-	5	39	0	10

A: Case number.

B: Sex and age at operation.

C: Years between primary trauma and Xenograft® reconstruction.

D: Side.

E: Cause of primary knee injury.

F: Surgery before Xenograft® reconstruction: ACL sut. = Ant. cruciate lig. suture, ACL rec. = Ant. cruciate lig., reconstruction, MM = Removal med. meniscus, LM = Removal lat. meniscus, Ex.art = Extraarticular procedure.

G: Subjective dominating symptom preop.: 1 = Pain, 2 = Giving way.

H<sub>0</sub>, H<sub>1</sub>, H<sub>2</sub>, H<sub>3</sub> = Lysholm score preop. (0) and at 1st, 2nd, and 3rd year postop.

I<sub>0</sub>, I<sub>1</sub>, I<sub>2</sub>, I<sub>3</sub> = Lysholm stability score preop. (0) and at 1st, 2nd, and 3rd year postop.

J<sub>0</sub>, J<sub>1</sub>, J<sub>2</sub>, J<sub>3</sub> = Lysholm pain score preop. (0) and at 1st, 2nd, and 3rd year postop.

careful check was made of any tension in the graft and eventual signs of impingement during full range of motion. The graft was then anchored without tension with double staples in the proximal tibia with the knee in 30° of flexion. The operation was supplemented by an Ellison procedure. The strip of fascia lata with its bone fragment from Gerdy's tubercle was passed below the lateral collateral ligament. The bone fragment was stapled distally and anteriorly to its original insertion. The defect in fascia lata was sutured. An intra-articular suction drainage was inserted for 24 h. Perioperatively, an antibiotic (cloxacillin natrium 2 g x 4) was administered and continued for 3 days after surgery. All the operations were performed in a bloodless field.

#### Aftercare

Postoperative rehabilitation was supervised by a physiotherapist. Continuous passive motion from 40°–80° of flexion was used for 3 days after the operation. A

custom-made hinged knee brace was then applied to the knee. During the first 6 postoperative weeks, no weight bearing was allowed, but movement exercises in the range of 40°–80° of flexion were permitted (Paulos et al. 1981). After 6 weeks, the brace was unlocked and active full-range motion exercises were initiated. Full weight bearing was permitted after 3 months, but the knee brace was used for 3–5 months. Jogging was allowed after 5 months. All the patients were recommended to refrain from strenuous sports for a year after surgery (Arms et al. 1984).

#### Postoperative evaluation

The patients were examined yearly by one of us (PN) who had not participated in the operation or the care of the patients. The Lysholm scores (Lysholm and Gillquist 1982) were used for subjective symptoms and a modified Marshall score (Marshall et al. 1977) for ob-

A	H <sub>2</sub>	I <sub>2</sub>	J <sub>2</sub>	K <sub>2</sub>	L <sub>2</sub>	M <sub>2</sub>	P <sub>2</sub>	Q <sub>2</sub>	H <sub>3</sub>	I <sub>3</sub>	J <sub>3</sub>	K <sub>3</sub>	L <sub>3</sub>	M <sub>3</sub>	P <sub>3</sub>	Q <sub>3</sub>	R	S	T	U	V	X
1	94	20	25	(+)	4	31	0	0	80	5	25	+	3	29	0	0	4.0	7.0	2.0	1.0	5	48
2	100	25	25	-	4	36	0	0	100	25	25	(+)	3	33	0	0	9.0	4.0	3.0	1.0	6	48
3	100	25	25	-	4	39	0	0	100	25	25	-	3	34	0	0	9.5	5.5	0.5	0.5	5	52
4	95	20	25	(+)	3	34	0	0	62	5	25	+	2	23	0	0						36
5	100	25	25	-	4	39	0	0	100	25	25	-	3	31	0	0	9.0	4.0	2.5	1.0	7	48
6	54	10	15	-	4	36	0	15	86	20	20	(+)	2	29	0	0	14.0	6.0	3.0	1.0	6	48
7	100	25	25	-	4	36	0	0	100	25	25	-	2	30	0	0	8.5	6.0	1.5	1.5	4	48
8	81	25	20	-	4	37	3	0	91	25	20	-	4	38	0	0	7.0	9.0	3.0	2.0	6	48
9	81	20	20	-	5	37	2	10	90	25	20	-	4	39	1	0	5.0	5.0	1.0	1.0	7	46
10	79	5	25	+	2	24	0	0	95	20	25	(+)	3	31	0	0	9.0	7.0	1.5	1.5	5	38
11	85	10	25	+	3	33	0	0	85	15	25	(+)	2	25	0	0	11.5	6.0	3.0	1.0	5	36
12	85	25	15	-	5	40	5	15	79	25	20	-	4	39	5	10	5.5	5.0	1.0	1.0	4	36
13	71	5	25	(+)	3	29	0	0	85	15	25	(+)	3	31	0	0	11.0	7.0	3.0	2.0	6	42
14	99	25	25	-	5	38	3	5	95	25	20	-	4	39	0	0	5.0	5.0	2.0	2.0	7	36
15	89	25	20	-	3	36	2	15	65	20	10	-	3	34	2	5	14.5	7.0	3.5	1.0	2	42
16	19	5	0	-	5	38	0	10	36	5	0	-	5	37	0	0	6.0	6.0	2.0	2.0	2	37
17	91	20	25	-	4	37	0	5	100	25	25	-	4	39	0	0	5.0	3.0	1.5	0.5	6	37
18	100	25	25	-	4	39	0	0	86	25	15	(+)	3	31	0	0	10.0	5.0	2.0	2.0	4	36
19	94	25	20	-	5	40	2	5	94	25	20	-	4	31	0	0	6.0	3.0	1.0	1.0	5	38
20	99	25	25	-	5	38	0	0	81	20	20	-	3	33	0	0	10.0	7.0	3.0	2.0	6	37
21	77	25	10	-	5	37	3	10	85	25	20	-	5	39	0	0	7.0	9.0	2.0	3.0	4	39
22									90	15	25	(+)	3	30	0	0	8.0	7.0	3.0	2.0	6	36
23	90	15	25	-	2	28	0	0	96	25	25	+	2	25	0	0	14.5	4.0	1.5	1.0	5	37
24									71	25	25	(+)	3	31	0	20	6.0	6.0	0.0	0.0	4	33
25	95	20	25	-	4	36	0	0	100	25	25	-	4	37	0	0	8.0	6.5	2.0	2.0	5	36
26	96	25	25	-	4	39	0	0	100	25	25	(+)	3	34	0	0	9.0	4.0	1.0	1.0	7	36
27	95	20	25	-	5	38	0	10	100	25	25	-	4	36	0	0	8.5	6.5	1.5	1.0	8	38
28	75	25	15	-	4	37	2	15	74	20	15	-	3	34	2	0	9.5	8.5	2.5	3.0	4	36

K<sub>0</sub>, K<sub>1</sub>, K<sub>2</sub>, K<sub>3</sub> = Pivot shift preop. (0) and at 1st, 2nd, and 3rd year postop. + = Clearly pos, (+) = Difficult to provoke, - = negative.

L<sub>0</sub>, L<sub>1</sub>, L<sub>2</sub>, L<sub>3</sub> = Lachman score preop. (0) and 1st, 2nd, and 3rd year postop. 5 = Normal; 4 = Slight < 1/2 cm; 3 = Moderate < 1 cm; 2 = Pronounced > 1 cm; = Extreme > 2 cm.

M<sub>0</sub>, M<sub>1</sub>, M<sub>2</sub>, M<sub>3</sub> = Total stability score (max 41 points) preop. (0) and at 1st, 2nd, and 3rd year postop.

O = Xenograft® explant; S = Synovitis: time of appearance (months) after index surgery/time of reoperation (months) after index surgery. GR = Graft rupture/time of reoperation after index surgery.

P<sub>1</sub>, P<sub>2</sub>, P<sub>3</sub> = Extension deficit (degrees) 1st, 2nd, and 3rd year postop.

Q<sub>1</sub>, Q<sub>2</sub>, Q<sub>3</sub> = Flexion deficit (degrees) 1st, 2nd, and 3rd year postop.

R = Arthrometric measurement at 3-year follow-up: Anterior drawer (mm) injured knee at 89 N pull.

S = Same as R for uninjured knee.

T = Compliance (mm) injured knee.

U = Compliance (mm) uninjured knee.

V = Activity score (Tegner) at the 3-year follow-up.

X = Follow-up time in months.

jective stability in which the Lachman test was graded on a five-point scale. The 3-5-year follow-up was completed by activity grading (Tegner and Lysholm 1985) and arthrometer (KT-1000) measurements (Daniel et al. 1985a); the anterior drawer motion was measured with the knee in 25° flexion and forward pull of 67 N and 89 N. Compliance was calculated as the difference between the 89 N and 67 N values in the same knee. The uninjured contralateral knee served as a control, and the injured-uninjured difference was calculated. According to Daniel et al. (1985b), we considered graft rupture to be present if this difference at 89 N pull was 3 mm or more.

As a reference group, 28 similar patients with a mean age of 27 years on a waiting list for an anterior cruciate ligament reconstruction were used (Lysholm score = 68 ± 10, Lysholm pain score = 19 ± 6, Lysholm stability score = 8 ± 4, Tegner score = 5.3 ± 0.5, Lachman score = 2.7 ± 0.5. Anterior drawer (mm) 89 N: In-

jured knee = 10.2 ± 2.4, uninjured knee = 5.8 ± 1.6, compliance: injured knee = 2.5 ± 0.9, uninjured knee = 1.3 ± 0.5).

The Student's *t*-test, Mann-Whitney's *U*-test, and Wilcoxon's rank test for paired observations were used, and *P* < 0.05 was considered significant.

## Results

There were no infections or wound complications, except that 1 patient had a synovial leakage through the tibial drill channel with a blister formation at the distal fixation of the graft. Seven Xenografts® have been removed.

### Graft removal

Five knees developed synovitis during the first postop-

erative year. At reoperation, there was an intense synovitis, and the graft was found to be ruptured in all 5 cases. The graft ends were lying totally unattached in the bony channels. Bacterial cultures were negative. The histologic studies showed synovitis with plasma cells and foreign-body giant cells. After the graft had been removed, the synovitis disappeared and the patients were rehabilitated within 6 weeks.

Two patients underwent reoperation for late graft rupture after 3 years, and a new anterior cruciate ligament reconstruction was performed. At reoperation the proximal and distal parts of the ruptured graft were found to be firmly adherent to the bone with connective tissue. There were no macroscopic or microscopic signs of synovitis or foreign-body reaction, and there was no definite histologic evidence of connective tissue or blood-vessel proliferation into the graft. The bone-graft connection in the drilled channels seemed to consist of connective tissue adherent to the graft surface.

#### Remaining grafts

There were 21 patients with a remaining Xenograft® at the 3-year follow-up. The mean Lysholm score was  $89 \pm 15$ , and 16 had never had any instability symptoms. Seventeen patients had a Lysholm score of 85 points or better, and 8 scored 100 points. During the follow-up period, there was an increase ( $P < 0.05$ ) in mean Lysholm score value between the first and third year.

Activity scoring (Tegner and Lysholm 1985) showed a mean score of  $5.4 \pm 1.4$  vs  $5.3 \pm 0.5$  for the reference group. Only 5 patients had an activity score of 7 or 8. These patients were active in slalom competition, orienteering, and strenuous recreational activities such as soccer and squash. All but 1 of the other 16 patients were physically active on a recreational level. Eighteen patients in this group had no pain or only moderate pain during heavy exercise.

At the 3-year follow-up, 19 patients had a full range of motion, and 2 patients had an extension deficit of  $2^\circ$  and  $5^\circ$ , respectively. The mean extension deficit in the total group of 21 patients successively decreased from  $2.3^\circ$  at 1 year to  $0.4^\circ$  at 3 years. There was no synovitis in the 21 patients with a remaining graft, but 1 male had had episodes of effusion.

Objective evaluation of knee stability showed a slight but definite decrease as a function of time ( $P < 0.001$ ). Only 1 patient had a clearly positive pivot-shift sign, while 15 were negative; in 5 patients the pivot-shift test was difficult to evaluate.

The 21 patients with remaining Xenografts® had an increased mean anterior drawer and compliance ( $P <$

Table 2. Arthrometric measurement values (mm), injured knees (I) uninjured knees (U) for 21 patients with a remaining Xenograft® (mean follow-up 40 months) compared with reference group consisting of 28 patients on waiting list for anterior cruciate ligament reconstruction. Mean values SD are given. Compliance is calculated as the difference between the 89 N and 67 N pull values in the same knee.

	Anterior displacement				Compliance			
	I		U		I		U	
Xenograft patients	8.5	2.7	5.6	1.8	1.8	0.8	1.5	0.7
Reference group	10.2	2.4	5.8	1.6	2.5	0.9	1.3	0.5

0.001; Table 2). Compared with the reference group, the grafted knees had better arthrometric values (Table 2). Eleven patients had an injured-uninjured difference of 3 mm or more at 89 N pull; the graft is presumed to be ruptured in these patients. There was no difference in Lysholm score between patients with or without a presumed graft rupture at the 3 year follow-up, but the former were less stable ( $P < 0.05$ ).

#### Discussion

A synthetic substitute for the anterior cruciate ligament might simplify surgery, spare normal tissues, and facilitate stronger repairs (Funk 1987). A prosthesis consisting of collagen is appealing. In animals the Xenograft® seemed compatible with ingrowth of blood vessels and host-tissue collagen (McMaster 1985), and mechanical tests suggested that it could carry the loads in the human knee joint (McMaster et al. 1986). Preliminary reports from the Netherlands and the United States — with clinical use of Xenograft® as an anterior cruciate ligament substitute in more than 100 patients — were encouraging (Abbink 1983).

Our results, however, must be considered unsatisfactory, although 17 out of 21 patients with a remaining Xenograft® had good or even excellent function. Comparing 1- and 3-year follow-up results, the objective stability scores decreased while the Lysholm score increased. The increase in Lysholm scores, however, is probably the result of adaptation with diminished demands of the knee in strenuous exercises.

Arthrometric measurement has increased the possibility of evaluating results after anterior cruciate ligament surgery (Daniel et al. 1985a). In the group of 21 patients with a remaining Xenograft®, 11 patients were considered to have a graft rupture according to the arthrometric measurements. Because 7 patients already had been reoperated on because of a ruptured graft, totally, at least 18 out of 28 implanted grafts must be con-

sidered to have ruptured. This accords with the results of Van Steensel et al. (1987), who found graft rupture in about half the cases after 3 years.

In 5 patients, synovitis occurred during the first postoperative year, and all of these patient had a ruptured graft. At the 3-year follow-up, all the knees with a remaining Xenograft® (with or without presumed rupture) lacked signs of effusion or synovitis. The combination of early rupture and synovitis suggests that small doses of glutaraldehyde remaining in the core of the graft could cause this reaction. This is in contradiction to the hypothesis that graft abrasion and

fragmentation with particular matter in the joint is the main cause of synovitis (McMaster et al. 1986). Van Steensel et al. (1987) reported 6 cases of synovitis, and none of those had a graft rupture; they attributed the synovitis to glutaraldehyde in the Xenograft®.

Good et al. (1985) reported poor results of 9 Xenograft® operations with graft rupture and severe synovitis, and Allen et al. (1987) had similar experience in 3 of 5 cases.

Despite the fact that some patients may benefit from the Xenograft® reconstruction, this prosthesis is unsatisfactory in its present form.

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