

# Goretex prosthetic ligament vs. Kennedy ligament augmentation device in anterior cruciate ligament reconstruction

A prospective randomized 3-year follow-up of 41 cases

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In a prospective randomized study on patients with functional instability due to old anterior cruciate ligament tears, 18 were randomized to a Goretex reconstruction and 23 to augmentation with the Kennedy Ligament Augmentation Device (LAD). All operations were performed with use of a modified over-the-top technique. At follow-up (median 36 months), improvements in Lysholm scores, activity scores, and arthrometry values were recorded in both groups as compared with preoperative levels. The LAD group had better Lysholm scores than the Goretex group. Among Goretex-reconstructed knees, effusion and pain occurred, and major effusions in two knees caused by the Goretex artificial ligament were indications for graft explant after 4 years. Our short-term results with the Goretex prosthetic ligament are not acceptable because of effusions and of pain. Our short-term results of the LAD polypropylene braid as an augmentation to an autologous graft seem promising.

The Goretex ligament prosthesis was developed to replace the anterior cruciate ligament. The graft material, polytetrafluoroethylene (PTFE), has for many years been used in vascular grafts. Ahlfeld et al. (1987) reported on 30 patients with an average follow-up of 24 months with satisfactory results in the majority.

The late John C. Kennedy (Kennedy et al. 1980, Kennedy 1983) developed the concept of augmentation where an intraarticular autograft is reinforced with a polypropylene braid (Ligament Augmentation Device, LAD). He pointed out that autogenous

structures normally used as anterior cruciate ligament substitutes undergo degradation and degeneration as long as 6 months postoperatively before they are reorganized, and there is new formation of collagen.

The purpose of the LAD is to provide internal protection for an autogenous graft during its phase of weakness. Experiments on goats with augmented and nonaugmented transplants showed that augmented anterior cruciate ligament reconstructions were stronger after 2 years (McPherson et al. 1985). In a retrospective study of Kennedy's LAD-augmented and nonaugmented reconstructions, Roth et al. (1985) concluded that augmented knees were better than nonaugmented ones, and no adverse reactions to the polypropylene braid were seen.

In this prospective randomized study, we compared anterior cruciate ligament reconstruction using the Goretex expanded PTFE ligament prosthesis with the Kennedy LAD technique with application of similar surgical approaches.

Table 1. Observations in 41 cases of reconstructed old anterior cruciate ligament tears

No	A	B	D	E	G	H	J			K			L			M			N			O			P			Q				
							0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	0	1	
1	1	24	10	45	0	12	1	67	89	100	20	25	25	4	4	5	2	0	0	0	0	2	5	5	25	39	39	•	6	6	•	3.5
2	2	36	16	45	0	180	1	50	89	91	15	25	25	3	4	4	2	0	0	0	0	2	5	5	25	40	38	•	6	5	•	4.5
3	1	25	10	48	0	46	1	84	100	100	25	25	25	4	5	6	1	0	0	0	0	3	5	5	31	40	40	•	5.5	5.5	•	4.5
4	1	28	10	38	0	42	1	85	88	95	25	20	20	5	3	6	1	0	0	0	•	2	5	5	26	39	40	•	4	5.5	•	3
5	1	28	10	47	0	45	1	66	99	99	25	25	25	3	3	7	2	0	0	0	0	3	5	5	28	40	40	•	1	5	•	3.5
6	2	20	5	47	0	32	1	80	81	90	25	15	20	4	3	4	2	0	2	0	2	2	5	3	25	40	28	•	8.5	9	•	3.5
7	1	42	10	46	0	51	1	61	90	82	20	25	25	4	4	5	1	0	0	0	1	2	5	4	26	37	36	•	6	5	•	7
8	1	24	10	46	0	37	1	67	100	100	20	25	25	4	6	5	2	0	0	0	0	2	5	4	24	38	37	•	5.5	7	•	5
9	1	23	10	46	3	30	1	75	100	95	20	25	20	3	4	5	1	0	0	1	0	3	3	3	29	29	33	•	8.5	8.5	•	5
10	1	24	10	46	0	18	1	54	99	100	25	25	25	4	4	9	2	0	0	0	0	2	4	4	25	37	34	•	10	7	•	3
11	1	32	10	36	0	40	1	73	92	96	25	25	25	4	4	5	2	0	0	0	•	2	5	5	30	38	40	13	8.5	9	7	6
12	2	24	10	34	1	23	1	61	88	90	10	20	25	4	4	7	2	0	0	0	•	3	5	4	28	40	37	9	7	8.5	4	5
13	1	29	10	36	0	47	1	72	69	90	15	15	25	4	3	6	2	1	0	1	•	2	4	3	25	37	37	9	6	9.5	7	8.5
14	1	19	10	34	1	30	1	56	81	100	15	15	25	3	3	6	2	0	0	0	•	2	4	5	24	36	40	10	9	7.5	6	6.5
15	2	28	9	33	0	132	1	76	100	100	25	25	25	3	4	6	2	0	0	0	•	2	5	5	24	39	39	15	7.5	8	9	7
16	2	23	10	33	0	18	1	71	76	92	20	20	25	4	4	5	2	0	0	0	•	3	4	4	28	36	37	7	7	9	4.5	5.5
17	1	23	6	33	4	30	1	74	78	100	15	25	25	4	8	8	1	0	0	0	•	3	5	5	31	37	40	7	5.5	6	4	5.5
18	2	29	9	24	1	74	1	70	100	94	15	25	20	4	4	4	2	0	0	•	•	2	5	5	23	40	38	14.5	7	10	9.5	7
19	1	37	17	24	0	6	1	75	100	100	25	25	25	4	6	6	2	0	1	•	•	2	4	4	24	38	36	9	8	8.5	5.5	7.5
20	2	22	9	24	3	52	1	66	100	95	15	25	20	5	6	6	2	0	0	•	•	3	5	30	40	40	13.5	9	10	8.5	8.5	
21	1	27	10	24	0	18	1	62	100	96	15	25	25	3	5	7	2	0	0	•	•	2	5	5	25	40	39	13	7	8	4	6
22	1	24	10	28	0	7	1	68	84	81	15	20	20	4	4	5	2	0	0	•	•	3	4	5	32	36	40	7.5	5.5	6	4	4.5
23	1	24	16	24	0	10	1	79	95	87	25	20	20	4	6	5	1	0	0	•	•	3	5	4	28	40	38	8.5	5	6	4	5
24	1	25	10	45	3	30	2	75	100	95	15	25	20	4	9	9	1	0	0	0	0	3	5	5	28	40	40	•	4.5	5	•	3.5
25	2	19	2	46	5	32	2	68	76	80	20	15	15	4	4	4	2	0	1	1	1	2	4	3	27	32	29	•	10	10.5	•	6
26	2	24	16	49	0	17	2	64	84	95	20	20	20	4	4	6	2	0	0	0	0	3	4	5	31	38	39	•	4	6	•	3
27	2	22	3	47	5	72	2	48	85	75	0	10	20	3	3	3	2	0	2	2	2	2	3	2	25	31	24	•	11.5	14	•	5
28	1	25	10	45	0	14	2	81	100	100	25	25	25	5	9	9	2	0	0	2	2	3	5	5	33	40	40	•	6.5	6	•	6
29	1	25	10	43	0	6	2	78	85	84	25	20	20	4	7	5	1	1	1	2	•	2	3	3	30	33	29	11	7	10	6	7
30	1	31	10	36	0	34	2	66	100	100	15	25	25	3	5	6	2	0	0	0	•	3	4	5	28	36	40	8	4.5	5.5	4	3
31	1	32	9	36	0	26	2	74	95	95	25	20	20	4	5	6	2	0	0	0	•	2	5	4	27	37	36	6	8	7	4	4.5
32	1	32	10	36	0	64	2	57	83	91	25	20	20	4	4	4	2	0	0	0	•	3	4	5	30	39	40	9	3	4.5	6.5	5
33	1	26	7	36	1	70	2	73	96	86	25	25	20	5	8	6	2	0	0	0	•	2	4	4	27	37	37	9.5	6	5.5	5	5
34	1	37	10	36	3	49	2	66	81	97	20	15	25	3	3	6	2	0	0	0	•	2	4	5	27	33	40	9	6	7.5	5	4
35	2	24	10	34	0	15	2	76	100	95	25	25	20	3	5	5	2	0	0	0	•	2	5	3	27	39	30	12	9	11	6	6
36	1	30	10	34	4	66	2	80	85	79	25	20	15	4	4	4	2	0	0	0	•	2	5	4	25	38	37	11	8	8	5	7
37	2	27	16	34	1	50	2	56	96	80	15	25	15	3	5	3	2	0	0	0	•	3	5	5	28	40	40	8.5	5	6	6	5
38	2	21	9	24	0	73	2	67	100	100	25	25	25	4	4	5	2	0	0	•	•	2	4	5	27	37	39	12	9	9	5.5	5.5
39	1	37	11	24	3	240	2	74	90	89	25	25	25	5	5	6	2	0	0	•	•	2	4	5	24	37	37	10	6.5	7	5	6
40	2	21	10	24	0	72	2	45	84	86	5	15	20	4	4	3	2	0	0	•	•	2	5	5	25	40	37	9.5	6	7	5.5	7.5
41	1	26	17	24	0	18	2	75	99	95	25	25	20	6	7	8	2	0	0	•	•	3	5	4	28	40	33	8	8	8	6	8.5

- A Sex: 1 male, 2 female
- B Age at index operation
- D Cause of injury
  - 1 racket sports
  - 2 indoor bandy
  - 3 basket
  - 4 unspc fall
  - 5 gymnastics
  - 6 handball
  - 7 motocross
  - 8 sailing
  - 9 skiing
  - 10 soccer
  - 11 icehockey
  - 13 traffic
  - 14 horseriding
  - 15 orienteering
  - 16 athletics
  - 17 other
- E Follow-up in months
- F Side: 1 right, 2 left

- G Surgery before index operation
  - 1 Reconstruction ant. cruc. ligament
  - 2 Lat. meniscectomy
  - 3 Med. meniscectomy
  - 4 Sutr med. coll. ligament
  - 5 Extra-articular reconstruction
- H Duration of symptoms preop. (months)
- I Type of surgery
  - 1 Kennedy LAD
  - 2 Goretex
- J0-2 Lysholm score, preop.-2nd follow-up
- K0-2 Lysholm pain score, preop.-2nd follow-up
- L0-2 Tegner activity score, preop.-2nd follow-up
- M0-4 Pivot shift, preop.-4th follow-up
  - 0 negative
    - 1 difficult to provoke
    - 2 clearly positive
- N0-2 Lachman score, preop.-2nd follow-up
  - 5 neg, ... , 1 > 2cm
- O0-2 Total stability score (max. 40p), preop.-2nd follow-up
- P0-2 Arthrometry injured knee, 89 N pull, preop.-2nd follow-up
- Q0-1 Arthrometry uninjured knee, 89 N pull, preop.-1st follow-up

No	Q2	R			S			T			V1	V2	W1	W2	X1	X2	Y								Z						
		0	1	2	0	1	2	0	1	2							A	B	C	D	E	F	A	B	C	D	E	F	G	H	
1	6	•	2.5	0	•	1.5	1	•	0.5	1.5	•	•	•	•	•	0	0	0	1	0	0	95	8	1	9.5	1	25	5	7		
2	6	•	1.5	-1	•	1	1	•	1.5	1	•	•	•	•	•	0	0	0	1	3	0	96	7.5	2.5	10	4	25	4	5		
3	5	•	1	0.5	•	1	0.5	•	0.5	0.5	•	•	•	•	•	0	0	0	1	0	0	96	5.5	0.5	7	1	25	6	5		
4	5	•	1	0	•	0.5	0.5	•	1	1	•	•	•	•	•	0	0	0	1	0	10	100	4.5	-1	6	-2	25	6	5.5		
5	6	•	-1.5	-0.5	•	0.5	0.5	•	0.5	1	•	•	•	•	•	0	0	0	1	0	0	100	7.5	0.5	10	0.5	25	7	7		
6	6	•	5	3	•	1.5	1	•	1	1	•	13	•	7	•	6	0	0	0	1	0	0	90	9	3	13	5	20	5	6	
7	4	•	1	1	•	1	0	•	1	1	•	7	•	5	•	2	0	0	0	2	0	0	75	10	2.5	12.5	3.5	20	3	7.5	
8	5.5	•	0.5	1.5	•	0.5	1	•	1	0.5	•	9.5	•	7	•	2.5	0	0	0	1	0	0	100	8	1	12	2.5	25	6	7	
9	6	•	3.5	2.5	•	1.5	1.5	•	1	1	•	11.5	•	7	•	4.5	0	0	0	1	0	0	100	7	1	9	1	25	6	6	
10	4.5	•	7	2.5	•	3	1	•	1	1	•	9.5	•	5	•	3.5	0	0	0	1	0	0	94	7.5	1.5	9.5	1.5	20	9	6	
11	8	6	1.5	1	3	1.5	2	1	1	1	•	11	•	9	•	2	0	0	0	1	0	15	100	8	2	10.5	2.5	25	6	6	
12	6	5	2	2.5	2	2	2	1	1	2	•	9.5	•	7	•	2.5	0	0	0	1	1	0	90	8	1	9	0.5	20	6	7	
13	8	2	-1.5	1.5	2	1	1.5	1	1	1	•	13	•	10	•	3	0	0	0	1	2	0	90	10	1.5	13	1	25	6	9.5	
14	7	4	2.5	0.5	2	2	1.5	1	1	1	11	10.5	7	9	4	1.5	0	0	0	1	0	0	100	8.5	1	11	0.5	25	6	7.5	
15	6.5	6	0.5	1.5	2.5	1.5	1	2	1	1	9	10.5	10	9	-1	1.5	0	0	0	1	0	0	100	8.5	1.5	10	1	25	6	7	
16	6	2.5	1.5	3	2	1	1	1	0.5	1	•	11	•	8	•	3	0	0	5	1	0	0	100	10	3	11	3	25	7	7	
17	6	3	0	0	2.5	1.5	1.5	2	1.5	1	6	8	6	7	0	1	0	0	0	1	0	0	100	6	1	8	1	25	7	5	
18	9	5	0	1	2.5	2	2	1.5	1.5	2	8	12	8	10	0	2	0	0	0	1	0	0	94	10	1	12	2	20	4	9	
19	7	3.5	0.5	1.5	2	2	1.5	0.5	1.5	1	9.5	10	9	8.5	0.5	1.5	0	0	0	1	0	0	100	8.5	1.5	10	1.5	25	6	7	
20	10	5	0.5	0	4	1.5	2	2	2.5	2	10	10.5	10	11.5	0	-1	0	0	0	1	0	0	95	10	0	10.5	-1	20	6	10	
21	5.5	9	1	2.5	4	1	1	1	1	1	9.5	10	8	7	1.5	3	0	0	0	1	0	0	96	8	2.5	10	3	25	7	5.5	
22	5.5	3.5	1	0.5	2	1.5	1	1	1.5	1	7	9	6	7.5	1	1.5	0	0	1	2	0	0	81	6	0.5	9	1.5	20	5	5.5	
23	4	4.5	0	2	2.5	1	1	0.5	1.5	1	7	7	6	5.5	1	1.5	0	0	1	5	0	0	97	6	2	7	1.5	20	5	4	
24	2	•	1	3	•	1	1	•	1	0.5	•	•	•	•	•	0	0	0	1	0	0	100	7	2	8	2	25	9	5		
25	6.5	•	4	4.5	•	2	1.5	•	1	0.5	•	•	•	•	•	2	0	4	2	0	0	71	10	2	11	1	15	3	8		
26	4	•	1	2	•	1	1	•	0.5	1	•	•	•	•	•	0	0	0	1	2	0	0	94	6.5	0	7	-0.5	20	6	6.5	
27	5	•	6.5	9	•	1.5	1	•	1	1	•	17	•	7	•	10	0	1	1	2	0	0	78	16	10	18	9.5	15	3	6	
28	6.5	•	0.5	-0.5	•	1.5	1.5	•	1	1	•	9	•	8	•	1	0	3	1	2	0	0	71	9	1.5	13	4	15	4	7.5	
29	7.5	5	0	2.5	2	1	1	1	2	1.5	•	12.5	•	8	•	4.5	0	3	1	2	0	0	74	11.5	4	15.5	5.5	15	3	7.5	
30	4.5	4	1.5	1	3	1	1	2	1	1	•	7.5	•	6	•	1.5	0	0	0	1	0	0	100	5	1	8	2	25	7	4	
31	5	4	3.5	2	2	1.5	2	1	1	1	•	10	•	6	•	4	0	0	0	1	0	0	95	7.5	3	10	4	20	6	4.5	
32	5.5	2.5	-2	-0.5	2	1	1	1.5	1	1	•	5	•	8	•	-3	0	0	0	1	0	0	86	8	0.5	10	0.5	20	4	7.5	
33	6	4.5	0.5	-0.5	1.5	0.5	0.5	1	1	1	•	7.5	•	8.5	•	-1	1	0	2	1	0	5	89	5.5	-0.5	7.5	-0.5	25	6	6	
34	6.5	4	2	1	2.5	1.5	1.5	1	1	1.5	•	10	•	8.5	•	1.5	1	0	2	1	0	0	94	7	1.5	9	2	20	5	5.5	
35	6	6	3	5	3	2	2	1	1	1	10	14	8	8.5	2	5.5	0	0	1	1	0	0	100	8.5	2.5	10.5	1.5	25	6	6	
36	7	6	1	1	3	1	1	1	1	1	9	10	7	10	2	0	2	0	1	2	0	15	81	8	-0.5	11	0.5	15	3	8.5	
37	6	2.5	0	0	2.5	1	1	2	2	1	7.5	8	9.5	8.5	-2	0	2	0	4	2	0	0	74	7	0	9	-2	15	4	7	
38	7.5	7.5	3.5	1.5	3	2	2	1.5	1.5	1.5	10.5	11	6	9	4.5	2	0	0	2	1	0	0	100	9	1.5	11	2	25	5	7.5	
39	5	5	0.5	0	2	1	1	1	1	1	8	8	8	7	0	1	0	0	1	1	0	15	89	7	0	8	1	25	6	5	
40	7	4	-1.5	0	1.5	1	0.5	0.5	1.5	1	7	8	8	8.5	-1	-0.5	1	0	0	1	0	0	86	7	0	8	-0.5	20	3	7	
41	8	2	-0.5	0	3	3	1	2	2.5	1	8.5	9	9	9.5	-0.5	-0.5	0	0	0	1	0	0	95	8	0	9	-0.5	20	8	8	

Q2 Arthrometry uninjured knee, 89 N pull, 2nd follow-up  
 R0-2 Arthrometric injured-uninjured difference, 89 N pull, preop.-2nd follow-up

S0-2 Compliance injured knee, preop.-2nd follow-up  
 T0-2 Compliance uninjured knee, preop.-2nd follow-up  
 V1-2 Maximum manual displacement injured knee preop.-2nd follow-up

W1-2 Maximum manual displacement uninjured knee, 1st and 2nd follow-up

X1-2 Maximum manual displacement difference injured-uninjured knee, 1st and 2nd follow-up

YA Effusion  
 0 no effusion  
 1 slight

YB Graft rupture  
 0 no rupture  
 1 suspected  
 2 spontaneous verified  
 3 traumatic rupture verified

YC Second operation after index surgery

1 arthroscopy  
 2 screw removal  
 3 operative mobilisation  
 4 Graft explant  
 5 medial meniscus

YD Patient satisfied  
 1 yes  
 2 no

YE Extension deficit (degrees) last follow-up

YF Flexion deficit (degrees) last follow-up

Last follow up

ZA Lysholm score

ZB Arthrometry injured knee, 89 N pull

ZC Arthrometric injured-uninjured difference 89 N pull

ZD Maximum manual displacement injured knee

ZE Maximum manual displacement difference injured-uninjured knee

ZF Lysholm pain score

ZG Tegner activity score

ZH Arthrometry uninjured knee, 89 N pull

## Patients and methods

During the period May 1985 until April 1987, 46 anterior cruciate ligament reconstructions were performed with use of the Goretex prosthesis or the Kennedy LAD because of functional knee instability due to old anterior cruciate ligament injuries.

All the patients were informed about the two different reconstruction methods and were asked whether or not they wanted to participate in a study where randomization was done between the two techniques by instructions in a sealed envelope. The study was approved by the Ethics Committee at Karolinska Hospital, Stockholm. Three patients were considered as salvage cases and unsuitable for randomization because of previous failed intraarticular reconstructions, and the Goretex-technique was chosen; and 2 patients actively preferred the Goretex method. These 5 patients were excluded from the study.

Forty-one patients were thus included in the randomized study, in which 18 Goretex and 23 LAD procedures were performed by 4 surgeons. The median follow-up time was 3 (2-4) years in both groups.

Most patients in both groups had been injured during sports, and 24 among the 41 randomized patients had sustained their injuries while playing soccer (Table 1).

The Goretex group comprised 11 men and 7 women with a median age at operation of 25 (19-37) years and a median preoperative duration of symptoms of 41 (6-240) months.

The LAD-group comprised 16 men and 7 women with a median age at operation of 24 (19-42) years. The median duration of symptoms prior to operation was 31 (6-180) months.

All the patients in the study had their anterior cruciate ligament rupture verified by arthroscopy preoperatively, and they all had marked functional subjective instability symptoms in the form of multiple giving-way episodes during sports, but also at work or during ordinary daily activities. The median preoperative Lysholm score was 70 (45-81) points and 70 (50-85) points in the Goretex and the LAD group, respectively. The median preoperative activity scores were similar in both groups (Tables 1 and 2). Before the index operation, all the knees in both groups had a positive Lachman test, and 16 in the Goretex group and 17 knees in the LAD group when examined without anesthesia had a clearly positive pivot shift sign preoperatively. Data for each patient are given in Table 1.

Table 2. Functional and activity scores, pivot shift and arthrometric values preoperatively and at last follow-up in patients who had an anterior cruciate ligament reconstruction with use of Goretex prosthetic ligament or Kennedy Ligament Augmentation Device (LAD). Median SD (range)

	Goretex (n 18)	<i>P</i> <sup>a</sup>	LAD (n 23)
Lysholm score			
preop.	70 (45-81)		70 (50-85)
last	89 (71-100)*	0.01	96 (75-100)*
Activity score			
preop.	4 (3-6)		4 (3-5)
last	5 (3-9)*	NS	6 (3-9)*
Pain score			
preop.	25 (0-25)		20 (10-25)
last	20 (15-25)	0.01	25 (20-25)*
Pivot shift clearly pos.			
preop.	16		17
last	3*		1*
Arthrometry (mm)			
Inj. knee, 89 N			
preop.	9.5 1.7		10.5 2.9
last	8.1 2.5*	NS	7.9 1.6*
Inj.-Uninj., 89 N			
preop.	4.4 1.6		4.5 1.8
last	1.6 2.5*	NS	1.3 0.9*
Compliance			
preop.	2.3 0.6		2.5 0.7
last	1.1 0.6*	NS	1.2 0.4*
Inj.-Uninj. MMD			
last	1.8 2.7	NS	1.7 1.5

<sup>a</sup> differences between groups are shown by *P*-values.

\* significant difference between preop. and last (*P* < 0.05).

## Operative techniques

The method originally intended for both the Goretex and the LAD method was the over-the-top technique. In order to make the two methods as similar as possible, we chose to use a modified over-the-top procedure in both groups with an extraarticular drill channel in the distal femur as described by Bolton and Bruchman (1985). The advantage of this technique compared with the original over-the-top method is that the graft becomes centrally located in the intercondylar notch without interference with the lateral femoral condyle. In both types of operations, similar incisions, one medial parapatellar and one lateral, were used. The patella was subluxated laterally and the intercondylar notch exposed. Notchplasty (Lambert 1983, Kieffer et al. 1984) was performed in every case, with careful widening of the intercondylar fossa by removing osteophytes and chiselling away 2-4 mm of the medial part of the lateral femoral condyle to expose the posterior part of the intercondylar fossa, and to make the anterior

opening of the intercondylar notch 21–22 mm wide. Via the lateral incision, the lateral and posterior face of the distal femur was exposed. A 7.9-mm bone tunnel was drilled from the lateral aspect of the femur to its posterior surface, with the inner opening of the channel located extraarticular just behind the intercondylar fossa. Sharp edges of the tunnel were smoothed with a reamer.

An over-the-top hook was introduced from the medial incision and the posterior capsule was perforated. A string of cotton was pulled through the femoral tunnel and the posterior capsule into the joint. When using the LAD technique, we harvested a 15–17-cm-long and 1-cm-broad half-thickness graft from the central one third of the quadriceps tendon, prepatellar tissue, and patellar tendon as described by Kennedy (1980) and Roth et al. (1985), with the distal insertion at the tibial tuberosity intact. A polypropylene braid was sutured to the graft with nonresorbable sutures at both ends and with resorbable sutures in the mid part. In both techniques the tibial tunnel was drilled 7.9-mm-wide through the proximal tibia to the medial part of the anatomic tibial insertion of the anterior cruciate ligament. Both types of graft materials were pulled in place via the tibial channel-joint-posterior capsule-femoral channel by connecting them to the string of cotton. Before graft fixation, a careful check of impingement signs during full range of motion was performed. When using LAD, the composite graft was tensioned to 5 kg with the knee in 30° flexion and then fixed at the distal femur with a screw and washer. The Goretex substitute was first secured to the distal femur with a screw, then manually hard-tensioned distally and screwed into the proximal tibia with the knee in 20° flexion.

All the patients received peroperative antibiotics for 24 hours (Cloxacillin natrium 2 g x 3). Intraarticular suction drainage was used for 24 h. Skin closure was performed with intracutaneous resorbable sutures. The knee was immobilized in plaster in 35° flexion.

### Rehabilitation

The postoperative treatment was mainly performed according to the recommendations for the two methods at the time of the start of the study, and it was supervised by a physiotherapist.

The Goretex method allowed early movement training; the knees were kept in a plaster cast for 2 weeks. After this period, a custom-made hinged brace allowing full range of motion was applied. Transcutaneous electrical stimulation was also used,

and early movement training took place in the warm-water pool at the physiotherapy department. Full weight bearing was permitted after 6 weeks. Light jogging and cycling were allowed after 4 months and sports activities after 8–12 months.

The recommendations by Paulos et al. (1981) were mainly followed for the LAD operated on patients. In this group the knee was immobilized in a plaster cast for 4 weeks in 35° flexion. From the 4th or 5th day, the program included general muscle training, ergometercycle exercises for the nonoperated on leg and transcutaneous electrical stimulation of the quadriceps on the operated on side. After cast removal a custom-made hinged brace allowing full range of motion was fitted on the operated on knee. Early movement training took place in a warm-water pool. Light weight bearing with use of two crutches was allowed after 6 weeks, and full weight bearing was permitted when knee movements were restored to nearly normal, usually 10–12 weeks after the operation. Light jogging and cycling were encouraged after 5 months, and return to full sport activities was permitted 1 year after the operation.

### Follow-up

All the patients were preoperatively evaluated with the Lysholm score (Lysholm and Gillquist 1982) and the Tegner activity score (Tegner and Lysholm 1985) for grading functional symptoms and activity level. A modified Marshall knee score (Marshall et al. 1977), in which the anterior drawer tested with the tibia in neutral, inward, and outward rotation plus the Lachman test graded in a five-point scale, was used for recording objective clinical findings. Pivot shift tests were performed as described by Galway et al. (1972), Losee et al. (1978), and Noyes et al. (1980). We have found it practical to grade the pivot shift as absent (0), difficult to provoke, or merely a slip or glide (1), and clearly positive (2). A clearly positive pivot shift in the present study corresponds to pivot shift Grades III and IV (subluxation, gross subluxation) presented by Noyes et al. (1983). In the analysis of results, a pivot shift sign that was difficult to provoke was recorded as negative because we hesitate about its clinical importance.

At the beginning of the study, an arthrometer was not available. From January 1986 preoperative arthrometry was made with the KT-1000 (Med-Metrics Corp. San Diego CA, USA) presented by Malcom et al. (1985) and Daniel et al. (1985a). All the measurements were made with the knee in 25° flexion with a forward pull of 67 N and 89 N, and with the uninjured knee serving as a control. Compliance

was calculated as the difference between the two loads. The use of the Maximum Manual Displacement test, in which a high manual force is applied to the proximal part of the calf as described by Daniel et al. (1985b), became a routine starting in January 1987.

All the patients were reexamined yearly by the authors.

### Statistics

For arthrometric measurements, the Student's *t*-test was used, and mean values are given. For the non-parametric scores, the Mann-Whitney *U*-test and the Wilcoxon rank sum test were used, and median values are given. For pivot shift, the chi-2 test was used.  $P < 0.05$  was considered significant.

## Results

### Complications

There were no infections or wound complications.

Six patients in the Goretex group had recurring effusions (Table 3). At the last follow-up, 4 of these patients declared that the effusions had diminished or disappeared. In 2 females (Cases 25 and 37) the effusions became severe, recurring as often as every month, and the grafts were removed after 44 and 48 months, respectively. The joint fluid was cloudy, with an increased leucocyte count. Bacterial cultures were negative. Arthroscopy showed in most cases that the Goretex prosthesis was covered with synovial tissue and was difficult to visualize, and often some filaments were seen to be broken. In both graft-explanted knees the Goretex graft had an adequate continuity, but with poor synovial covering. In one of these knees, many graft filaments in the intraarticular part were fragmented, but in the other knee no fragmentation of filaments could be seen. No ingrowth of bone into the grafts in the bony tunnels could be verified; the grafts seemed rather to adhere to the bone by fibrous tissue. The part of the graft that was located at the over-the-top position was intact with no fragmentation. Histologic studies of synovial tissue including polarized microscopy showed an inflammatory reaction with giant cells and microscopic foreign bodies incorporated in the synovium.

Two males in the Goretex group (Cases 28 and 29), with very high activity levels, continued to play

Table 3. Complications in patients who had an anterior cruciate ligament reconstruction with use of Goretex prosthetic ligament or Kennedy Ligament Augmentation Device (LAD)

	Goretex (n 18)	LAD (n 23)
Effusion		
Moderate	3	0
Severe	3	0
Traumatic graft rupture	2	0
Insufficient graft	1	0
Secondary operations		
Graft explant	2	0
Meniscectomy	0	1
Arthroscopy	10	1
Screw removal	3	0

competitive soccer after the index operation; they sustained reinjuries to their operated on knees after 30 months. Their reinjuries resulted in a traumatic hemarthrosis, and arthroscopy showed graft rupture. These 2 patients have had no signs of recurring effusions (Table 1).

None of the patients in the LAD group have had effusion problems. Altogether, there have been a greater number of secondary operations, such as arthroscopies, screw removals, and graft explants in the Goretex group (Table 3).

### General results

At the last follow-up, both Goretex- and LAD-reconstructed patients had improved in Lysholm scores, activity scores, occurrence of clearly positive pivot shift signs, and arthrometric measurement values (Table 2).

LAD patients had a better Lysholm score, 21 scoring 84 points or more, than the patients in the Goretex group, in which 12 patients had 84 points or more (Table 1). Among LAD operated on patients, 15 had no symptoms of pain compared with only 5 patients in the Goretex group.

An extension deficit of 5° or less was found in 5 patients with LAD knees, but in only 1 with a Goretex knee; and 2 patients in each group had a small flexion deficit.

At the last follow-up, 2 patients with LAD knees and 3 with Goretex knees had an injured-uninjured arthrometric difference of 3 mm or more.

## Discussion

Both methods in this series, with a short-term follow-up of a median of 3 years, produced patients who were pleased with the outcome. However, the Goretex patients obtained lower Lysholm functional scores than the LAD patients; otherwise, there was a maintained acceptable improvement in anterior-posterior stability in the Goretex group. Our results concerning improvement in stability for Goretex-reconstructed knees are in agreement with or even better than the studies of Ahlfeld et al. (1987), Indelicato et al. (1989), and Markolf et al. (1989). We believed that the Goretex prosthetic system with a screw fixation at both ends was a too stiff system and stiffer than the LAD technique. However, we did not find any difference in compliance between the two groups (Table 2).

The low functional score among Goretex patients was due to pain and moderate to severe effusions in 6 patients.

Effusion problems have not been reported in animal experiments with the Goretex prosthesis. In recently published reports presenting primary clinical results with use of the Goretex ligament prosthesis, sterile effusions have also been described as a major problem (Glousman et al. 1988, Indelicato et al. 1989). The etiology of these effusions is unclear. Histologic studies of synovial tissue from our explanted knees showed giant cells and microscopic foreign particles. Similar findings have been reported by Indelicato et al. (1989), who explained the effusions as being caused by a foreign-body reaction to PTFE particles liberated from the artificial graft. Synovial reactions to the polypropylene braid are uncommon. In the literature, 1 case of synovitis and foreign body reaction due to disruption of the LAD has been described by Roth et al (1988).

Although many patients are satisfied, our short-term results with the Goretex prosthetic ligament in its present form are unacceptable mainly because of effusions and increased occurrence of pain symptoms. Short-term results with the use of a polypropylene braid as an augmentation to an autologous graft seem promising.

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