

Cruciate ligament prosthesis vs. augmentation

A randomized, prospective 5-year follow-up of 41 cases

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In a prospective study, 18 patients were randomized to a prosthesis and 23 patients to the Kennedy Ligament Augmentation Device (LAD) because of functional instability due to old anterior cruciate ligament injuries. The operations were performed with use of a modified over-the-top technique. At the last follow-up (5 years), postoperative improvements in scores

were maintained for both groups, but LAD-reconstructed patients had better Lysholm and activity scores than the Goretex group. The achieved postoperative improvement in anterior stability (KT-1000) did not deteriorate for either of the groups during the 5-year follow-up. The Goretex patients had more effusion and pain and more secondary operations.

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In 1985 we started a prospective, randomized comparison of the Goretex and Kennedy LAD methods (Dahlstedt et al. 1990) for old, symptomatic anterior cruciate ligament injuries. We now report the 5-year results of this series.

Patients and methods

41 patients were included in the randomized study, and the operations were performed during the period May 1985 until April 1987. Patients and methods have been presented in a preliminary report (Dahlstedt et al. 1990).

The median time until last follow-up among all the Goretex patients was 59 (34-70) months. 1 patient was lost due to an aeroplane accident after the 3-year follow-up. The median time of follow-up among all LAD patients was 59 (56-78) months.

Results

At the last follow-up, both LAD- and Goretex-reconstructed patients had improved, compared to preoperative Lysholm and activity scores, occurrence of clearly positive pivot shift signs, and arthrometric measurement values (Table 1). We found no changes in scores and arthrometric values between the 2-year and 5-year evaluations. In the LAD group, 22/23 and in the Goretex group, 12/18 were satisfied with the outcome.

After 5 years, LAD patients had a better Lysholm score (Table 1), with all but one 84 points or more compared to 11/18 in the Goretex group. The Goretex patients had a higher incidence of pain problems both at the 2- and 5-year follow-ups. 15 LAD patients had no pain, compared to only 6 Goretex patients.

There were no differences between the groups in the occurrence of a clearly positive pivot shift sign, total stability scores and arthrometric measurements at the 2- and 5-year follow-ups. Arthrometry showed that none of the patients in the LAD group had at the last follow-up an injured-uninjured arthrometric difference of 3 mm or more, but a side-to-side difference of this magnitude could be shown in 3 patients operated on with the Goretex ligament.

3 patients in the Goretex group had severe recurring effusions. 2 were reoperated and a new reconstruction was performed. The third was considered for graft explant and a new reconstruction but he died in an aeroplane accident. 2 male patients in the Goretex group with very high activity levels sustained re-injuries with graft rupture. All 4 patients who have had their Goretex grafts removed in combination with a new ACL-reconstruction have recovered well after the reoperation. They have good function and stability and are without signs of effusion. None of the patients with a remaining Goretex graft had any sign of extension deficit, but in the LAD group 5 patients had a small extension deficit at the 5-year follow-up. In each group we found 4 patients with minor flexion deficits. Goretex patients had more secondary operations (4 graft explants, 11 arthroscopies, 3 screw removals; LAD 0, 4, 0, respectively).

Table 1. Goretex- versus LAD-operated patients. For scores median (range) values and for arthrometric measurements mean values *SD* are given.

	Goretex	LAD	P-value
Lysholm score (max 100 p)			
Preop	70 (45-81)	70 (50-85)	ns
2 y	93 (75-100)	95 (81-100)	ns
5 y	89 (71-100) *	98 (76-100) *	0.001
Lysholm pain score (25 no pain)			
Preop	25 (0-25)	20 (10-25)	ns
2y	20 (15-25)	25 (20-25)	0.01
5y	20 (15-25) *	25 (20-25) *	0.01
Tegner activity score (0-10)			
Preop	4 (3-6)	4 (3-5)	ns
2 y	6 (3-9)	6 (4-9)	ns
5 y	5 (3-8) *	6 (3-9) *	0.04
Total stability score (max 40 p)			
Preop	27 (24-33)	26 (23-32)	ns
2y	37 (24-40)	38 (28-40)	ns
5 y	37 (23-40) *	40 (30-40) *	ns
Pivot shift clearly positive (patient not anesthetized)			
Preop	16	17	ns
2 y	1	1	ns
5 y	2 *	1 *	ns
Arthrometry AD I (mm)			
Preop	9.5 1.7	10.5 2.9	ns
2 y	7.6 2.5	7.4 1.7	ns
5 y	8.1 2.3 *	7.3 1.4 *	ns
Arthrometry ADD I-U (mm)			
Preop	4.4 1.6	4.5 1.8	ns
2 y	1.7 2.5	1.2 1.2	ns
5 y	1.6 2.0 *	0.8 1.0 *	ns

* Difference ($P < 0.05$) between preoperative and 5-year assessments.

There was no difference between 2- and 5-year results.

AD I anterior displacement (mm) of injured knee at 89 N anterior pull.

ADD I-U anterior displacement difference (mm) between injured and uninjured knees at 89 N pull.

Discussion

There was an improvement for both groups 5-years postoperatively in subjective symptoms, in anterior knee stability, and a decrease in the frequency of clearly positive pivot shift signs. According to the Lysholm classification, two thirds of the Goretex patients and all but 1 of the LAD patients can be considered as excellent or good. In a recent review-study of different types of prosthetic ligaments (Johnson et al. 1992), it was pointed out that early success will be followed by disappointing long-term results. However, we could not find any serious deterioration between the 2- and 5-year follow-ups.

After 5 years, Goretex-substituted patients in the present study had lower median Lysholm functional scores compared to LAD-operated patients, but there was a maintained acceptable improvement in anterior stability in the Goretex group. Our results concerning improved stability for Goretex-reconstructed knees are in agreement with, or even better than, other reports

(Indelicato et al. 1989, Markolf et al. 1989). The lower functional and activity scores among Goretex patients were due to pain and effusion. In other reports the rate of effusions and mechanical failure continues to increase with extended follow-up, even if the majority of Goretex patients have been satisfied, and there has been an improvement in most categories (Indelicato et al. 1989, Sledge et al. 1991, Woods et al. 1991, Paulos et al. 1992). The etiology of the effusions is not clear, but might be explained by a foreign body reaction against PTFE particles liberated from the artificial graft (Indelicato et al. 1989).

Engebretsen et al. (1990) could not demonstrate that the LAD method was better than augmentation-reconstruction with use of an autogenous graft in the acutely injured knee. Increase in anterior-posterior laxity measured by roentgen stereophotogrammetry indicating graft lengthening after 2 years has also been reported (Jonsson et al. 1992). Noyes and Barber (1992) reported that the addition of a ligament augmentation device to an allograft was of no advantage for either

functional or arthrometric results after a mean follow-up of 3 years.

In our hands, the LAD-method has given acceptable results after 5 years, and we feel that the Goretex technique should not be recommended. It is still to be shown if methods using a synthetic augmentation device are better than present autogenous techniques.

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