EARLY RESULTS OF THE LEEDS–KEIO
ANTERIOR CRUCIATE LIGAMENT REPLACEMENT

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We report the two- to four-year results following the insertion of the Leeds–Keio prosthetic ligament for chronic anterior cruciate deficiency. Virtually all the 20 patients were less disabled by instability, but objective results were good or excellent in only two-thirds and under anaesthesia the pivot shift sign was still positive in half. Arthroscopic and histological assessment in 16 patients failed to show the development of a functional neoligament, and the common appearance of a synovitic reaction to polyester particles gave concern.

The Leeds–Keio open-weave polyester ligament (Howmedica, UK) provides the strength, relatively low stiffness and biological inertness which make it an attractive replacement for the anterior cruciate ligament (ACL). It is claimed that major ingrowth of longitudinally aligned collagen occurs, and that the bone plug fixation technique offers advantages in placement and anchorage (Fujikawa et al 1984). These claims have yet to be fully substantiated, although Fujikawa, Iseki and Seedhom (1989) have recently reported that a neoligament develops progressively within the meshwork of the prosthetic ligament during the first three to 24 months.

We have reviewed a series of patients both clinically and arthroscopically, at least two years after the insertion of Leeds–Keio ligaments for disabling knee symptoms secondary to chronic ACL rupture.

PATIENTS AND METHODS

From August 1985 to July 1987 20 Leeds–Keio ligaments were inserted into 20 patients suffering from chronic insufficiency of the ACL. During that period 97 patients had been referred with proven ACL tears, but most had been managed by intensive physiotherapy, with intermittent bracing in 12, and counselling to avoid certain sports.

Our criteria for operation were similar to those reported by Bray, Flanagan and Dandy (1988), namely, regular problems during everyday activities. Eight patients with chronic aching pain were excluded from the study since arthritic changes were already radiographically apparent.

All 20 patients were men, with a mean age of 30 years (range 21 to 41). The mean delay between the rupture and ACL replacement was 3.5 years (range 1 to 7). All showed gross anterolateral laxity by the Lachman test (Torg, Conrad and Kalen 1976) and the pivot shift test (Galway, Beaupré and MacIntosh 1972).

Technique. The operation followed the commercial instructions provided by the manufacturer of the prosthesis. Meniscal lesions were treated at the time of surgery, by repair or excision. Because of our concern about the adequacy of bone plug fixation, knees were splinted for four to six weeks postoperatively, then treated by physiotherapy with a removable splint. Supervision of each case was by an experienced physiotherapist, who ensured a graduated return of movement and weight-bearing over a period of 16 weeks.

Assessment. The knees were assessed at two to four years postoperatively, using the Tegner activity scale and the Lysholm knee score (Lysholm and Gillquist 1982; Tegner and Lysholm 1985). Examination was carried out independently by a physiotherapist and a surgeon who had not undertaken the operation. The initial examination was prior to two years, and the second later than two years after the date of surgery. A KT 1000 arthrometer (Stryker, UK) was used to augment the examination, and in 16 cases the prosthetic ligament was reviewed arthroscopically.

RESULTS

Every patient considered that the operation had improved the overall function of the knee, and had abolished episodes of giving way during daily activity. There were no surgical complications. The long period of conva-
escence was felt to be outweighed by the eventual gains, though in some, full extension and flexion were slow to return. In about half the knees a mild synovitis was apparent during the first nine months.

Of the 20 patients, seven achieved an excellent Lysholm score (above 90 points) but only one of these eventually considered that the knee was entirely normal. Six had good (over 77 points) and six had fair results. There was one poor result, which followed rupture of the prosthesis in an accident at work 18 months after operation. This patient requested a further replacement; this has now been done.

Eleven of the 20 patients scored 5 or more points on the Tegner activity scale (Fig. 1); two of them returned to their pre-injury level of sporting activity. The other nine patients did not return to active sport although the knee had acceptable function for everyday activities.

Four of the 16 patients so examined had negative pivot shift under anaesthesia and six had only a trace of subluxation (pivot slide). All but one of six patients with good or excellent Lysholm scores (over 77) had a negative pivot shift under anaesthesia, with no more than a grade I Lachman test; there was good correlation between this test and perceived instability (Bray et al. 1988). One of the most stable knees had previously been treated by an unsuccessful MacIntosh extra-articular repair.

Arthroscopic review. Informed consent was obtained for arthroscopic review of 16 ligaments. Of these, 11 prostheses were convincingly intact, but all were more lax than the natural ligament.

In five cases in which there had been apparent rupture of the prosthesis, fraying and synovitis made the ligament difficult to visualise. One of these patients had a good Lysholm score but a lax knee; despite this he returned to refereeing soccer without the giving-way he had experienced pre-operatively. Three patients achieved a fair Lysholm knee score and one had a poor result (< 68 points) since the ligament ruptured after a traumatic event.

Histological study. Specimens were obtained from 10 ligaments. In contrast to Fujikawa et al. (1989), we found that the collagen response to the prostheses was not always convincing. In some specimens, collagen was organised along intact polyester fibres (Fig. 2) but this varied from patient to patient, and did not correlate with the period since implantation. The fibroblastic response usually lacked axial orientation, but collagen bundles did appear to be arranged longitudinally (Fig. 3).

In the knee which showed greatest postoperative stability the prosthesis was covered by thin, hyperaemic synovium; but a biopsy from its deep layers showed a foreign-body fibroblastic response similar to that noted by McPherson et al. (1985) when they evaluated the Kennedy ligament augmentation device. Fragmentation of the artificial fibres was shown by birefringence (Fig. 4); giant cells were commonly seen in these regions of fibre debris. Synovitis was invariably seen, both microscopically and macroscopically, principally in close relationship to the ligament.

Bonding to bone was reviewed in the patient whose ligament needed replacement (Fig. 5), using trichrome staining. There was well-established collagen formation next to the bone plug, but the ruptured central portion of the ligament was covered with scanty connective issue.

**DISCUSSION**

We reviewed a small series of Leeds–Keio ligament replacements at up to four years, all of them in patients who had had disabling knee instability despite conservative treatment. Subjective improvement was generally satisfactory, but objective testing of laxity gave disappointing results when compared to those reported by Smith, McLaughlin and Seedhom (1987). They described 15 patients followed for up to three-and-a-half years, with 10 excellent and four satisfactory results.

Fujikawa et al. (1989) described progressive connective tissue induction within the prosthetic ligament in 27 of 42 knees examined arthroscopically at periods of up to 24 months after implantation. They found parallel collagenous fibres running along the length of the ligament although with "some hypercellularity". Despite this they did not mention significant synovitis, or fragments of the polyester in the biopsy specimens.

We consider that partial or complete rupture of a polyester ligament causes a foreign-body reaction, which is similar to that described in experimental studies using the Kennedy augmentation device by McPherson et al. (1985). Fraying of the ligament, which was more noticeable distally than in the intercondylar notch, seemed to release fibres and produce a mild localised synovitis. This could produce capsular fibrosis and increase articular cartilage degeneration in the longer term.
There is an orderly relationship between the strands of polymer and adjacent collagenous connective tissue, much of which resembles ligament. However, a minor phagocytic reaction can be seen to the left of the implant. (Haematoxylin and eosin; conventional illumination (a), polarised light (b), ×80).

Living and apparently thriving collagen-secreting fibroblasts lie alongside the implanted fibres (Haematoxylin and eosin; conventional illumination (a), polarised light (b), ×320).

Some broad strands of fibrous tissue can be seen, but in comparison with the organised fibres shown in Figures 2 and 3, the arrangement is disorderly. Multinucleate giant cells have formed in response to the particulate material shown in 4b by polarised light. The smaller particles are potentially more harmful because they produce a sustained low-grade inflammatory response. This could produce fibrosis in distant sites. (Haematoxylin and eosin; conventional illumination (a), polarised light (b), ×160).

Mature collagen has formed around the birefringent polymer although connective tissue is sparse between the polyester fibres themselves. Bone and connective tissue have bonded closely (Trichrome; polarised light, ×80 (a), ×160 (b)).
Markolf et al (1989) consider that some postoperative laxity may result from 'stretch out' of the ligament produced by the complex movements of the unstable knee (Kärholm et al 1988). Such a change in the structure of the prosthetic ligament, added to the effects of abrasion and partial rupture, probably account for the gradual deterioration in results. In the light of this process, doubt about the functional effect of tissue ingrowth is of serious concern. Prosthetic ligament replacement insertion alone may not be enough: it may be prudent to augment the repair with an autograft, especially as the longer term results of the use of a strip of patellar tendon or semitendinosus tendon are encouraging (Harter, Osternig and Singer 1989).

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REFERENCES


