Reconstruction of the anterior cruciate ligament using the polyester ABC ligament scaffold

A MINIMUM FOLLOW-UP OF FOUR YEARS


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We carried out a prospective study of 71 patients who had undergone reconstruction of the anterior cruciate ligament with the ABC scaffold. Their mean age was 28 years (18 to 50). All had either sub-acute or chronic traumatic deficiency of the ligament. The mean period of follow-up was five years (four to seven). Assessment included the use of the International Knee Documentation Committee score, the modified Lysholm score, the Tegner Activity score, the Knee Injury and Osteoarthritis Outcome score and measurement with the KT-1000 arthrometer. Two patients had mild recurrent synovitis. There were no infections and no failures of the ligament. During the period of study, two patients sustained a traumatic fracture of a femoral condyle. The implants retained their integrity in both cases. All patients returned to their previous or enhanced levels of daily activity by three months after operation and 56 (79%) achieved their pre-injury level of sporting activity by six months. The patients who were competing in National level sports returned to play at one level less after operation than before. The Lysholm score showed that 58% of the patients (41) were excellent, 34% (24) good, and 8% (6) fair, with a mean post-operative score of 93. According to the International Knee Documentation Committee score, 35% of knees (25) were ‘normal’, 52% (37) ‘nearly normal’ and 13% (9) ‘abnormal’. Complete satisfaction was noted in 90% of patients (64). The development of osteoarthritis and the management of anterior cruciate deficiency associated with laxity of the medial collateral ligament remains uncertain. Our results indicate that in the medium-term, the ABC ligament scaffold is suitable and effective when early and safe return to unrestricted activities is demanded. We acknowledge the current general hostility towards reconstruction of the anterior cruciate ligament with artificial materials following reports of early failure and chronic synovitis associated with the production of particulate debris. We did not encounter these problems.

The most common methods of reconstruction of the anterior cruciate ligament (ACL) use either a bone-patellar tendon-bone graft or one derived from the hamstring tendons. These autografts are compromised by initial weak bone-to-bone fixation with a decrease in graft strength during the long period of neoligamentisation. There are also complications associated with harvesting of the graft, such as fracture of the patella and rupture or contraction of the patellar tendon with bone-patellar tendon-bone grafts. Recently there has been a trend to using the tendons of semitendinous and gracilis as autografts in different combinations. However, there remain problems regarding graft fixation and stretching.

In order to avoid these complications, the option of artificial ligaments has been available since the 1980s. The early results were encouraging, but there was a high rate of late complications and failure of the implant. The scaffold types of artificial ligament promote biological tissue ingrowth and formation of a neoligament, leading to a better outcome. The ABC ligament (Surgicraft Ltd., Redditch, United Kingdom), available since 1985, is a scaffold suitable for reconstruction of the ACL.

We have used this implant since 1998 for patients with closed epiphyses with either sub-acute or chronic instability of the ACL following trauma, and who had received unsuccessful conservative treatment elsewhere. We have undertaken an objective evaluation of knee stability and the clinical outcome after surgery and assessed patient satisfaction.

Patients and Methods
There were 71 patients (64 men and 7 women) who were treated by operation between 1998 and 2001 using the ABC ligament. All the inju-
ties were unilateral (40 right, 31 left) and none of the knees had been treated surgically elsewhere. The mean age at operation was 28 years (18 to 50) and the mean follow-up was five years (4 to 7). A total of 13 patients were followed up for seven years, 17 for six, 19 for five and 22 for four. All the patients had subacute or chronic traumatic deficiency of the ACL. Of our patients, 53 (75%) had sustained a sports injury, 50 whilst playing football. There were three National level competitive athletes, with the remainder participating in less competitive recreational sporting activities. The majority wished to return to their former level of athletic activity.

The mean time from injury to attendance at our clinic was 13 months (2 months to 6 years). Following the initial injury, most patients had suffered repeated episodes of instability and 57 (80%) occasional locking of the knee, with frequent pain and effusion. On examination, all knees presented with anterolateral knee instability. Combined grade I to grade II injuries of the medial collateral ligament were seen in 29 patients (41%) who had already been treated conservatively elsewhere. Of these patients, four continued to have 5 mm of residual valgus laxity with a firm end-point. No other combined instabilities were noted. Prior to surgery, all patients were informed of the advantages and disadvantages of reconstruction with an artificial ligament; all gave informed consent.

The ABC artificial ligament (Fig. 1) is constructed from a partial polyester braid over a core of polyester. It has a tensile strength of 3.13 KN, which is greater than the strength of the natural ACL (2.50 KN). The implant has radial overbraiding at both ends, with integral bollard fixation, and has been designed to act as a scaffold, stimulating tissue cover and ingrowth into the implant. This ingrowth protects the ligament from friction at the exit to the tibial tunnel and from interfilament abrasion. Following an analysis of early failures of the ABC ligament, performed in the textiles department of Manchester University, England, new instrumentation was developed. A tibial drill jig with interchangeable right and left ‘rhino horn’ probes was introduced. This ensures the production of a tibial tunnel which avoids impinging on the intercondylar notch in the extended knee. A chamfering device for removal of sharp edges at the tibial tunnel exit was also developed.

A preliminary arthroscopy was performed by one of the authors (CC), whilst the open operation was carried out by the senior author (GP). Meniscal tears were found in 57 knees (80%) with a medial-to-lateral ratio of 2:1. In 11 knees both menisci were torn. Most meniscectomies were partial, but three were total. None of the meniscal tears were repairable. Chondral damage, as described by Outerbridge, was found in 30 knees (42%) with grade III changes in two knees, grade II changes in eight and grade I changes in 20.

Operative technique. The operation was performed under general anaesthesia and using a tourniquet. A medial parapatellar incision was made, followed by a generous notch-plasty, taking 7 mm of bone from the whole of the medial surface of the lateral femoral condyle, as well as from the lateral roof of the intercondylar notch. The bony ridge at the posterolateral end of the notch was removed completely. This procedure forms a groove in line with the ‘over the top route’ and any sharp edges were smoothed off.

A second incision was made over the lateral aspect of the distal femur, anterior to the intermuscular septum, locating the ‘over the top’ route. The groove was completed by external reaming through the lateral femoral incision. A guide wire was passed freehand through the proximal tibia emerging at the posterior part of the tibial foot-print of the ACL. The guide wire was then over-drilled with a 6 mm cannulated drill. The remnants of the ACL were not removed, but the margin of the exit of the tibial tunnel was chamfered with a back radius cutter (Surgicraft Ltd., Redditch, United Kingdom). The correct length of implant was determined using a graded measuring gauge. The implant was inserted according to the technique described by Mowbray and was guided via the ‘over the top’ groove to the distal outer femur. After distal fixation to the tibia with a bollard, the ligament was tensioned proximally and temporarily fixed to the femur by a K-wire passed through a special handle which holds the graft. The knee was tensioned at 30° of flexion. Anterior instability was checked before fixing the ligament to the femur with a second bollard. Finally, the knee was inspected for ligament impinge-
ment during a full range of movement. Additional removal of bone from the roof and the sides of the notch was undertaken if necessary. Impingement of the graft at the apex and roof of the intercondylar notch was avoided by positioning the exit of the tibial tunnel posteriorly as determined by surgical experience. We used bollards for fixation of the implant, although in the earlier operations a button was used for the tibia, and a screw with a washer for the femur, occasionally augmented by a staple. The tourniquet was released before wound closure and an autotransfusion drain was applied through the lateral incision. Drainage was continued for 48 hours. A second-generation cephalosporin was administered for 48 hours and low-molecular weight heparin was given for two weeks post-operatively on a prophylactic basis.

Reconstruction of the ligament was followed by a vigorous rehabilitation programme, with active and passive knee motion from the first day. Walking with full weight-bearing on the operated leg was permitted from the second day. Specific proprioceptive training was not undertaken. The patients remained in hospital for two weeks to allow us to supervise the physiotherapy sessions and to watch for any possible early complications such as infection or deep-vein thrombosis. At the end of the second week, the patients were discharged with instructions for self-administered rehabilitation. Crutches were used for a further two weeks.

The pre- and post-operative assessments included the Lachmann’s test, the anterior drawer test, KT-1000 arthrometer (MEDmetric Corporation, San Diego, California) readings, and the pivot shift test. We used the modified Lysholm knee score, the Tegner activity score, the International Knee Documentation Committee (IKDC) score and the Knee injury and osteoarthritis outcome (KOOS) score to assess outcome. Follow-up was undertaken at 3, 6 and 12 months, and at every two years thereafter. In five patients with intact implants and trouble-free knees more than five years after operation, the last assessment was conducted by telephone because of difficulties in attending. All five were without complaint.

**Results**

The Lachmann’s test and KT-1000 assessments were performed at 30° of knee flexion and the anterior drawer test at 70°. Pre-operatively the Lachmann’s test was grade 2 to 3 with a soft end-point, the anterior drawer test was grade 2 to 3 and the pivot shift test was also grade 2 to 3 in all knees. Post-operatively, the Lachmann and anterior drawer tests were graded 0 to 1 with a firm end-point. In 25 knees (35%), the estimated displacement was < 2 mm side-to-side difference on anterior drawer testing, in 43 knees (61%) 2 mm to 3 mm and in three knees (4%) 3 mm to 4 mm. The influence of subjectivity in arriving at these laxity measurements is a source of concern, but this was minimised by having the same two doctors (GP and CT) performing the tests throughout the series. The post-operative pivot shift test was absent initially, but gradually became positive grade 1 (glide and no jerk) in ten knees (14%) after one year. The remaining 61 knees (86%) had a negative pivot shift when last examined.

The pre-operative KT-1000 reading showed a mean maximum side-to-side difference of 12 mm (10 to 13). At the last follow-up, 14 knees (20%) showed a side-to-side anterior displacement difference of < 2 mm, 48 knees (67%) 2 mm to 3 mm and nine knees (13%) 3 mm to 4 mm. No patient complained of the knee ‘giving way’.

A total of five knees showed residual valgus laxity of 5 mm with a firm end-point. Of these, four had sustained a pre-operative medial collateral ligament injury and the fifth had slipped on a soapy floor after operation. Whilst these five patients did not trust their knees in competitive sporting activities, none complained of the knee ‘giving way’. Painless crepitus of the patellofemoral joint occurred in five knees (7%), and of the medial compartment in seven (10%). Some patients occasionally experienced slight difficulty on kneeling or squatting. Quadriceps wasting, measured at 10 cm above the superior pole of the patella, despite vigorous and early physiotherapy, persisted in 29 knees (41%), with a mean wasting of 1 cm (0.5 to 2). The mean wasting before operation was 3 cm (2 to 4). A full range of pain-free movement was present in all but two knees at the final examination, although at four weeks after operation all had a 10° lack of full extension and flexion, with a mild effusion. Thereafter, there were no signs of synovitis or restricted movement in the knee, except two which had recurrent mild synovitis, causing occasional dysfunction, associated with 10° lack of full flexion and extension.

The mean pre-operative Lysholm Knee score was 28 (11 to 64). At the last follow-up the mean score was 93 (75 to 100). There were 41 knees (58%) graded as excellent, 24 (34%) as good and six (8%) as fair. We had no poor results.

The mean Tegner activity score before injury was 7 (3 to 10). High scores were seen in the three National standard competitive athletes (basket-ball, karate, jumping) and athletes playing competitive sports (mostly football), with lower scores noted in less active individuals. During the first six months following surgery, there was a decrease in sporting activity by three levels, as measured by the Tegner activity score, or greater if the pre-operative level was > 7. The score gradually increased, particularly after the first year, to reach the same level of activity as before injury. There were 12 patients (17%) who were not keen athletes and who elected to reduce their hours of participation in sport (level 3 to 4). The three top athletes (4%) returned to one level less than their previous performance attainment (level 9). The Tegner score remained unchanged in 56 patients (79%) at the last examination and there was an increase in the hours of participation in sporting activity in some patients. Subjectively, 64 patients (90%) were completely satisfied with their knees, while seven (10%) were only partly satisfied because of a restriction in sports activities; five had residual valgus laxity and two mild recurrent
These seven knees were classified as ‘abnormal’ although all patients had returned to their previous jobs and some to heavier work.

The pre-operative IKDC evaluation score in all knees was D (severely abnormal). At the last examination, 25 knees (35%) qualified as ‘normal’ (A), 37 knees (52%) as ‘nearly normal’ (B) and nine knees (13%) as ‘abnormal’ (C). Details of the post-operative IKDC classification are presented in Table I according to the most significant problems, as defined by the IKDC evaluation.

The KOOS evaluation with the subscales of pain, symptoms, activities of daily living, function in sports recreation and knee-related quality of life are shown in Figure 2. The status before operation was influenced by meniscal, chondral, and medial collateral ligament lesions, in addition to the injured ACL. Before and after surgery, function in sports recreation and knee-related quality of life were the subscales most affected. These gradually improved following surgery, reaching an optimum level after one year and maintaining this state until the final review. The sports subscale showed the lowest final score in comparison to the other subscales, though the improvement was the most remarkable.

**Radiological assessment**. Post-operatively, mild to moderate osteoarthritic changes with minimal narrowing of the joint space were seen in 22 knees (31%) which were associated with concomitant co-morbidities including meniscal injuries, chondromalacia (grade II to grade III), two knees with post-operative fractures of a femoral condyle and three of the five with laxity of the medial collateral ligament. In one knee without concomitant lesions other than an injured ACL, a Fairbank positive sign was noticed without narrowing of the joint space. The total number of patients with radiological osteoarthritic changes was 23 (32%). Radiological osteoarthritis was first noted after the fifth post-operative year, although there were no associated clinical signs except for painless crepitus. At the last examination a radiograph taken with the knees in full extension showed that the anterior border of the majority of the tibial tunnels lay posterior to the apex and roof of the intercondylar notch, indicating that there was no impingement.

**Complications**. There were no peri-operative complications, although there were occasional post-operative haematomas. Only two knees had recurrent mild synovitis with an intact prosthetic ligament. There were effusions in all knees during the first month after operation which resolved spontaneously. There were no deep-vein thromboses or pulmonary emboli as judged by clinical criteria. A male patient sustained a fracture of the lateral condyle of the femur close to the femoral groove as the result of a road accident.

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**Table I. Post-operative classification of the knees according to the most significant problems as defined by the International Knee Documentation Committee evaluation**

<table>
<thead>
<tr>
<th>Problem area</th>
<th>Post-operative classification*</th>
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<tbody>
<tr>
<td>Patient subjective assessment</td>
<td>Nearly normal (37)</td>
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<tr>
<td>Symptoms</td>
<td>-</td>
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<tr>
<td>Range of movement</td>
<td>-</td>
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<tr>
<td>Instrumental anterior tibial displacement &gt; 3 mm</td>
<td>23</td>
</tr>
<tr>
<td>3 mm to 4 mm</td>
<td>4</td>
</tr>
<tr>
<td>Valgus knee laxity ≥ 5 mm</td>
<td>-</td>
</tr>
<tr>
<td>Patellofemoral painless crepitus</td>
<td>3</td>
</tr>
<tr>
<td>Medial compartment painless crepitus</td>
<td>4</td>
</tr>
<tr>
<td>Mild to moderate osteoarthritis</td>
<td>17</td>
</tr>
<tr>
<td>One leg hop (70% to 90% of opposite side)</td>
<td>8</td>
</tr>
<tr>
<td>Pivot shift test grade I (glide, no jerk)</td>
<td>4</td>
</tr>
</tbody>
</table>

* ‘normal’ knees were excluded, having no problems; ‘severely abnormal’ knees were not recorded as there were none. Some knees had two or three problems but are classified here only according to the most significant.
traffic accident four years after surgery. The fracture was fixed by percutaneous screws, and anterior stability was restored. A female patient slipped on a soapy floor two years after surgery, sustaining an undisplaced fracture of her medial femoral condyle and a grade II medial collateral ligament strain. The knee was treated conservatively, resulting in persistent valgus laxity of 5 mm with a firm end-point. The ACL implant was intact.

**Survivorship analysis.** This showed survival of 100%. Survival rates remained stable until the end of our seven-year follow-up period. Failure was defined as revision for any cause, including infection or rupture of the graft as evaluated by KT-1000, MRI or arthroscopy. If the five knees which did not attend the last examination, although successfully followed up (three patients for 6 years and two for 6.5 years), were assumed to be failures, the cumulative success rate at six years decreased to 89.2% (95% CI 78 to 100) and 69.4% at the seventh year (95% CI 47.9 to 94.1) (Table II).

**Discussion**

Our results with the ABC ligament are comparable to similar studies using bone-patellar tendon-bone grafts,\textsuperscript{30-34} artificial ACL ligaments\textsuperscript{11,35,36} or different combinations of hamstring grafts.\textsuperscript{37-39} In a review of the literature, Gillquist\textsuperscript{40} found the achievement of ‘good to excellent’ results after ACL reconstruction to be of the order of 66% to 90%. The clinical outcome of our patients, based on 100% follow-up at five years was at least as good as any reported and the majority of our patients were followed up for more than five years. No failure of the ligament occurred during the period of our study, whilst failure rates of 5% to 15% for autologous grafts have been reported at three to five years after surgery.\textsuperscript{41,42} On a subjective assessment, 90% of our patients were satisfied with the outcome.\textsuperscript{26,43,44} Most had returned to their previous occupation within three months. Three National standard athletes had returned to full sporting activities six months after operation and 56 patients (79%) returned to the same or an even higher level of athletic activity earlier than has been reported in comparative studies.\textsuperscript{35,45} Only 12 patients (17%) did not return to their previous level of sporting activity.

We noticed a gradual increase in anterior tibial displacement from < 2 mm to a maximum of 4 mm as measured by the KT-1000 arthrometer after one year. This did not increase further. There was no close correlation between the clinical outcome and the degree of laxity (Table III). A number of factors did have an adverse effect on outcome in this study including concomitant meniscal damage, residual valgus laxity of the medial collateral ligament of $\geq 5$ mm even with a firm end-point, a body weight $> 100$ kg, concomitant chondral lesions of grade II to grade III,\textsuperscript{18} post-operative fracture of femoral condyles with or without collateral ligament damage as a result of trauma, recurrent synovitis and increased time from injury to surgery associated with increased co-morbidity and development of osteoarthritis.\textsuperscript{46} The passage of time from injury to surgery is associated with an increased incidence of meniscal and chondral damage, and the IKDC score\textsuperscript{25} shows that this in turn leads to an increased incidence of mild to moderate osteoarthritis at five years after surgery, as judged on the radiographs. Associated medial collateral ligament laxity of any degree, even without frank episodes of giving way, reduced the level of patient satisfaction.

There may be a proprioceptive advantage in conserving the ACL remnants at the time of surgery, but proprioception may take many years to recover.\textsuperscript{47-49} Until this occurs, the stability of the knee will depend heavily on an intact anterior cruciate graft. We were able to confirm a good recovery of quadriceps and hamstrings following surgery.

<table>
<thead>
<tr>
<th>Time (yrs)</th>
<th>Number of patients at risk</th>
<th>Failures</th>
<th>Annual failure rate (%)</th>
<th>Annual success rate (%)</th>
<th>Cumulative success rate (%)</th>
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<tr>
<td>1</td>
<td>71</td>
<td>0</td>
<td>0</td>
<td>100</td>
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<tr>
<td>2</td>
<td>71</td>
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<td>3</td>
<td>71</td>
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<tr>
<td>7</td>
<td>9</td>
<td>2</td>
<td>22</td>
<td>78</td>
<td>69</td>
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| Instrumented anterior knee displacement (post-operative) | Post-operative classification
<table>
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<tbody>
<tr>
<td>Normal (25)</td>
<td>Nearly normal (37)</td>
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<tr>
<td>&lt; 2 mm</td>
<td>12</td>
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<tr>
<td>2 mm to 3 mm</td>
<td>13</td>
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<tr>
<td>3 mm to 4 mm</td>
<td>-</td>
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</table>

\textsuperscript{*} ‘severely abnormal’ knees were not recorded as there were none

Table II. Worst case scenario

Table III. Correlation between post-operative instrumented anterior knee displacement and clinical results according to International Knee Documentation Committee\textsuperscript{25} evaluation
We did encounter some complications. Recurrent synovitis and stiffness, perhaps due to particulate debris,\(^7\) was seen in two patients. We consider that the fibrous ingrowth into the ABC ligament discourages the release of artificial particulate debris\(^7\) and also our meticulous avoidance of impingement is important in this respect. The fracture of the lateral condyle of the femur was probably related to the aggressive preparation of the notch, but the primary cause was a road traffic accident.

We avoided any problems associated with the donor site, particularly the complications associated with the bone-patellar tendon-bone graft. Our incidence of patellofemoral crepitus was only 7%, compared with results as high as 45% in the literature.\(^6\) We did not observe tunnel expansion on follow-up radiographs, whilst others have recorded an incidence as high as 54%.\(^6\)

We found good and competitive short- to medium-term results using the ABC ligament for ACL reconstruction. The aim of this type of surgery is the restoration of function and the long-term maintenance of the health and integrity of the knee. At present it remains to be seen if this can be achieved with any of the techniques currently available.

Supplementary Material

A further opinion by Mr Robin Allum is available with the electronic version of this article on our website at www.jbjs.org.uk

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