Use of Carbon Fibers in the Reconstruction of Knee Ligaments

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Carbon fibers were used to reconstruct the anterior cruciate ligament and other knee ligaments in a consecutive series of 26 (mostly acute) patients who had suffered serious occupation-related injuries. After an average follow-up time of 52.4 months (one patient lost, one patient refused follow-up examination), the anterior drawer at 300 was less than 5 mm (side-to-side difference) in 14 patients, 5-10 mm in six patients, and greater than 10 mm in four patients. Of 24 evaluatable patients, 22 returned to work, including 20 patients who work underground. Chronic pain, recurrent effusion, infection, and tender nodes did not occur in the series. Arthroscopic examination of five patients revealed minimal intraarticular debris.

Jenkins and coworkers[5-8] used carbon fibers to reconstruct tendons and ligaments in animals and in man. They concluded that carbon fibers induced the growth of a neotendon and that carbon fibers were safe and effective for treating knee instabilities. Amis and coworkers[1-3] disputed those observations regarding formation of a neotendon. Rushton *et al.*[10] described persistent effusion and synovial thickening in patients who had been treated by carbon fiber reconstruction. Bray *et al.*[4] reported that a carbon fiber reconstruction provided no clinical benefit.

The purity of the carbon fibers and the surgical techniques employed may have been important factors leading to the apparently conflicting reports. The difficulty in preparing representative histologic specimens of tissue containing carbon fibers was probably a factor in the confusion regarding formation of a neoligament.

In 1982, when a suitable system involving carbon fibers became available,[11] the present authors began a clinical study to determine its safety and efficacy in a group of patients for which no satisfactory therapy previously existed. During the course of this study, histologic methods suitable for viewing the effects of carbon fibers on tissue were developed, and these methods were used to evaluate a tissue specimen obtained during the course of the study.

MATERIALS AND METHODS

The patients were employees of a mine in Orkney, Republic of South Africa, who suffered anterior cruciate ligament (ACL) injuries between June 1982 and May 1983 and consented to the treatment offered. The patients ranged in age from 19 to 37 years; none had previous significant knee injuries or previous intraarticular surgical procedures. Each of the patients in the study had an unstable or dislocated knee that required surgery. The group consisted of 26 unilaterally-injured patients; three had an isolated rupture of the ACL, 11 had additional injuries to one or both collateral ligaments, and 12 had injuries to the anterior and posterior cruciate ligaments. Carbon fibers were used to repair all injured ligaments. If surgery was performed within one month of injury, it was classified as acute; otherwise, the injury was regarded as chronic.

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The goal was to provide a treatment that would permit return to underground work (the most physically demanding work at the mine). Standard methods of reconstruction using autologous tissue have proved unsatisfactory because resulting instability frequently prevent-ed return to work underground. For this reason, concurrent controls were not included in the study design.

The implant (CFSTM, Plastafil Proprietary, Johannesburg, Republic of South Africa) consisted of a bundle of 40,000 carbon fibers (each 8 m in diameter with a carbon content greater than 95%); the carbon fibers had never been coated with epoxy or any other foreign substance. Carbon fiber debris (created during manufacturing and formation of the bundle) was removed by bathing the bundle in distilled water and wiping with a cellulose sponge; the bundle was coated with 10% gelatin dissolved in glycerin to improve handling characteristics of the implant during surgery (the coating had no other purpose.) All carbon fiber implants were fixed to bone using two specially - designed fixation devices:[11] the toggle was a bar of carbon fiber reinforced polysulfone and the bollard was a specially designed expanding rivet.

All patients were operated on by one of the authors; the surgical techniques are illustrated in Figure 1. For reconstruction of the ACL following a medial parapatellar arthrotomy, the synovium was incised and dissected off the ACL. A 4.8-mm hole was made from the anteromedial aspect of the tibia into the posterior part of the tibial attachment of the ligament. Through a separate lateral incision, the distal part of the iliotibial track was incised commencing at the lateral epicondyle of the femur and proceeding proximally for about 3 cm. This exposed a small triangle of femur bounded superiorly by the inferior edge of the vastus lateralis. A bollard hole was made in the middle of this triangle. The implant was passed through the hole in the tibia and through the remnants of the cruciate ligaments and then over the top of the lateral femoral condyle, where it was anchored using a bollard. The synovium was repaired to ensure that the total repair was retrosynovial.

For repair of the posterior cruciate ligament, a 4.8-mm drill hole was made through the medial femoral condyle into the middle of the femoral origin of the posterior cruciate ligament. The implant was threaded through the medial femoral condyle and through the anterior remnant of the posterior cruciate ligament and then brought through a hole in the tibia (anteromedial surface).

The carbon fibers were anchored using a toggle at the entrance of the hole in the medial femoral condyle and by a bollard on the anterior surface of the tibia. When the ligament had been avulsed from its femoral origin, the implant was threaded in the opposite direction.

For repair of the lateral collateral ligament, the implant was brought through a hole in the head of the fibula where it was anchored using the toggle. The implant was buried in the remnants of the ligament and anchored just proximal to the lateral epicondyle using a bollard.

For repair of the medial collateral ligament, the oblique and vertical parts were repaired primarily and reinforced by burying the implant in the ligament. Anchorage was achieved using three bollards on the anterior aspect of the tibia beneath the pes anserinus, on the medial epicondyle of the femur, and on the medial aspect of the tibia (Fig. 1). Frequently, when more than one ligament was re-

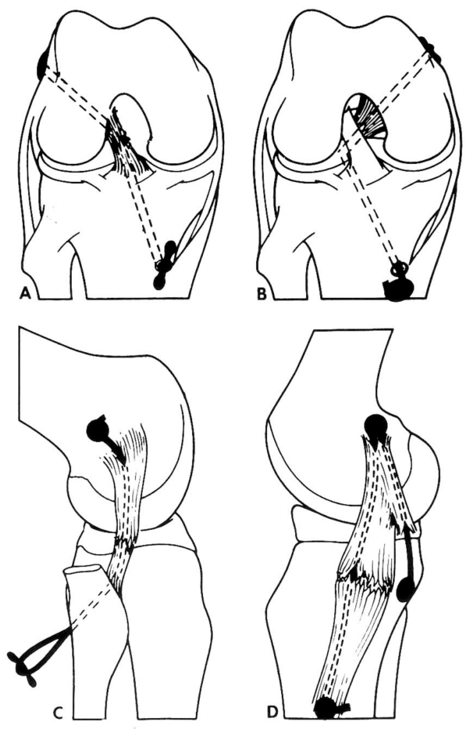


FIG. 1A-1D. Placement of carbon fibers in the repair of the cruciate and collateral ligaments in the knee. (A) anterior: (B) posterior: (C) lateral: and (D) medial ligaments.

paired, the portion of implant in different ligaments shared a common anchorage.

The entry and exit locations of all holes through bone were chamfered.

Most follow-up examinations were performed by one of the authors. In several instances, the patient had left employment at the mine and, in such cases, follow-up examination was performed by health officers at the patient's new location.

Effectiveness of the treatment was evaluated

TABLE 1. The Use of Carbon Fibers for the Repair and Reconstruction of the Anterior Cruciate Ligament

Case	*Category*	*Ligaments Repaired**	*Follow- Up Time (Months,)*	*ACL Stability (Class)***	*Pain*	*Work Status†*	*Comments*
1	Chronic	ACL, LCL	65	1	No	U	Arthroscopy performed at 65 months for removal of loose body revealed trace of carbon fibers in synovium. No inflammation.
2	Chronic	ACL, MCL	36	1	No	—	Died of unrelated cause.
3	Acute	ACL, PCL	71	1	No	U	
4	Chronic	ACL	71	2	No	U	Arthroscopy at 31 months. Showed trace presence of carbon fibers in the synovium, but no inflammatory reaction. Recurrent effusion due to instability.
5	Acute	ACL, PCL, LCL, MCL	70	3	No	S	Knee joint is stiff.
6	Acute	ACL, MCL	49	I	No	U	
7	Acute	ACL, PCL. MCL	64	2	No	U	Arthroscopy at 18 months. Revealed trace amounts of carbon fibers in the synovium, but no signs of infection or inflammation.
8	Acute	ACL, PCL	64	1	No	U	
9	Acute	ACL, MCL, PCL, LCL	64	3	No	S	
10	Acute	ACL, LCL	61	2	No	U	
11	Acute	ACL, PCL	61	1	No	U	
12	Acute	ACL. MCL	57	1	No	U	
13	Acute	ACL	56	1	No	U	
14	Acute	ACL. LCL	56	1	No	U	
15	Acute	ACL, PCL, MCL	54	I	No	U	
16	Acute	ACL. MCL. PCL	56	2	No	U	
17	Acute	ACL, LCL	53	I	No	U	
18	Acute	ACL, PCL	51	2	No	U	Arthroscopy at 21 months showed small pockets of carbon fiber proximal to the articular surface of the femur.
19	Chronic	ACL, LCL					Patient lost to follow-up examination seven months after surgery.

TABLE 1 *(Continued).*

Case	*Category*	*Ligaments Repaired**	*Follow-Up Time (Months)*	*ACL Stability (Class)***	*Pain*	*Work Status*	*Comments*
20	Chronic	ACL	45	3	No	U	When the patient returned to work underground as a driller, carbon fibers near the tibial plateau broke. The portion of the carbon fibers in the joint fibrosed to the synovium. Only trace presence of carbon fibers was seen during arthroscopy (at 45 months). The portion of the carbon fiber bundle in the tibia was recovered for histology.
21	Acute	ACL, MCL	19	3	No	U	
22	Acute	ACL, PCL, MCL	40	2	No	S	
23	Acute	ACL, LCL	41	1	No	S	
24	Acute	ACL, PCL				U	Refuses to be seen. Works in neighboring mine.
25	Acute	ACL	36	1	No	U	
26	Acute	ACL, PCL	18	1	No	U	

* ACL, anterior cruciate ligament LCL: lateral collateral ligament: MCL, medial collateral ligament: and PCL, posterior cruciate ligament.
** ACL stability: Class1, anterior drawer <5 mm: Class 2, 5-10 mm: Class 3. >10 mm.
† U. work underground: S. surface employment.

based on postoperative stability and the ability to return to previous level of employment. At each follow-up examination, the patient was grouped into one of three classes based on stability. Class 1 was defined as a case where the anterior drawer (30° of flexion) was less than 5 mm (side-to-side difference). An anterior drawer of 5-10 mm was regarded as a Class 2 result: a Class 3 result was one in which the anterior drawer was greater than 10 mm.

Inability to return to underground work was an indication that the course of treatment was not sufficiently successful to permit return to a previous functional level.

The implant failed to correct the instability in one case, necessitating revision surgery (after 45 months): at that time, the tihial (extraarticular) portion of the implant was removed. Because this was the worst case in the series and because of anecdotal reports that carbon fiber debris could be phagocytized and transported to regional lymph nodes, an inguinal lymph node was removed and examined to ascertain whether the patient was at risk for lymphatic system disease caused by carbon fiber debris. The tissues were fixed in 10% buffered formalin. For scanning electron microscopy (SEM). the carbon fiber specimen was dehydrated using a graded series of alcohols, frozen using liquid nitrogen. and cut traversely using a razor blade and hammer. The cleaved surface, which consisted of the implant and induced tissue in cross section. was subjected to critical-point drying (CPD 020 Balzers. Hudson, New Hampshire), coated with gold (Desk-2. Denton Vacuum. Cherry Hill. New Jersey), and examined in an AMR 1200 Scanning Electron Microscope (Amray. Bedford. Massachusetts) at an accelerating voltage of 25 kV. For light microscopy, 1.5mm cubes of the carbon fiber specimen were dehydrated, embedded in epoxy (SPI Chem, SPI Supplies. Westchester. Pennsylvania), and cut (0.2-0.3 micrometers) on an LKB model 5 ultramicrotome (LKB Instruments. Gaithersburg, Maryland) using a diamond knife. The tissue sections were stained using a modified Spurlock stain (E.T.S. 14980 Electron Microscopy Sciences, Fort Washington. Pennsylvania).

The lymph node was dehydrated, embedded in wax, cut into 10 micrometer sections, and every fourth section was recovered and stained with hematoxylin and eosin.

RESULTS

One patient could not be located and one patient refused follow-up examination; follow-up data were obtained on the remaining 24 patients at an average postoperative time of 52.4 months (standard deviation, ± 14.7 months). The results are listed in Table 1, and summarized in Figure 2.

Fourteen patients exhibited a Class 1 anterior drawer; Classes 2 and 3 were present in six and four patients, respectively. There was no apparent correlation between grade of stability and follow-up time (Fig. 2).

Nineteen patients recovered sufficiently to permit return underground work. In Cases 5, 9, 22, and 23, the extent of recovery permitted only surface employment. In Cases 5 and 9, the operated knee was unstable, and this directly contributed to the patient's inability to return to his previous functional level. In Cases 22 and 23, the injured knees were stable (either Class 1 or 2), but concomitant injuries suffered by the patient were the main factors contributing to functional limitation. In Cases 20 and 21, the patients were able to return to work underground despite the occurrence of a Class 3 anterior drawer.

Neither chronic pain nor recurrent effusions occurred in any of the patients, and infections related to the carbon fibers and its anchorages were not observed. Neither the popliteal nor inguinal lymph nodes of any patient were swollen or tender.

Arthroscopies were performed on Cases 1, 4, 7, 18, and 20 for various clinical indications. The arthroscopic appearance of the ACL depended on the nature of the reconstruction. In acute cases, where the carbon fiber tow was passed through the substance of the torn ligament, a normal-appearing ligament was seen as a white, taut structure. In acute cases where part of the ACL was removed or when the ligament had a narrow diameter or the carbon fiber tow was passed peripherally through the substance of the ligament, a black structure with a thin, sometimes transparent fibrous coat was seen. The carbon fiber bundle did not cause the growth of a neotendon on the outside of the bundle itself (which is the only location actually seen during arthroscopic examinations). Core biopsies of reconstructed ligaments were not taken, and consequently the existence of fibrous tissue inside intraarticular carbon fiber bundles cannot be confirmed. Trace presence of carbon fibers in the synovium were observed, but no inflammatory reactions were seen.

Surgical revision necessitated by implant failure occurred in Case 20. After surgery, the

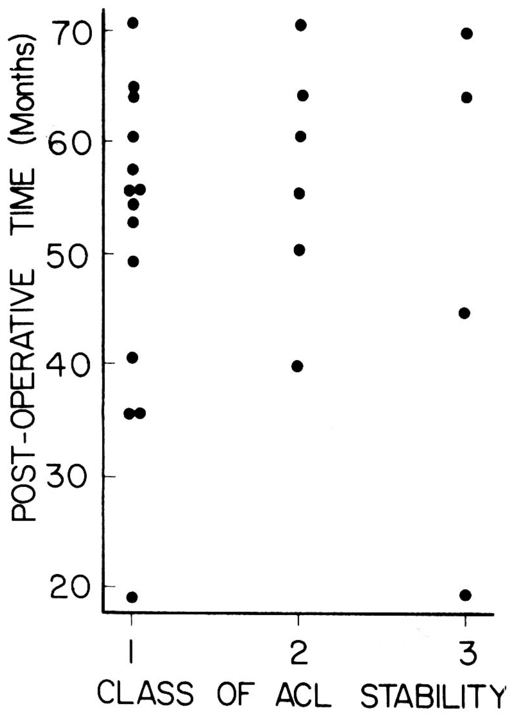
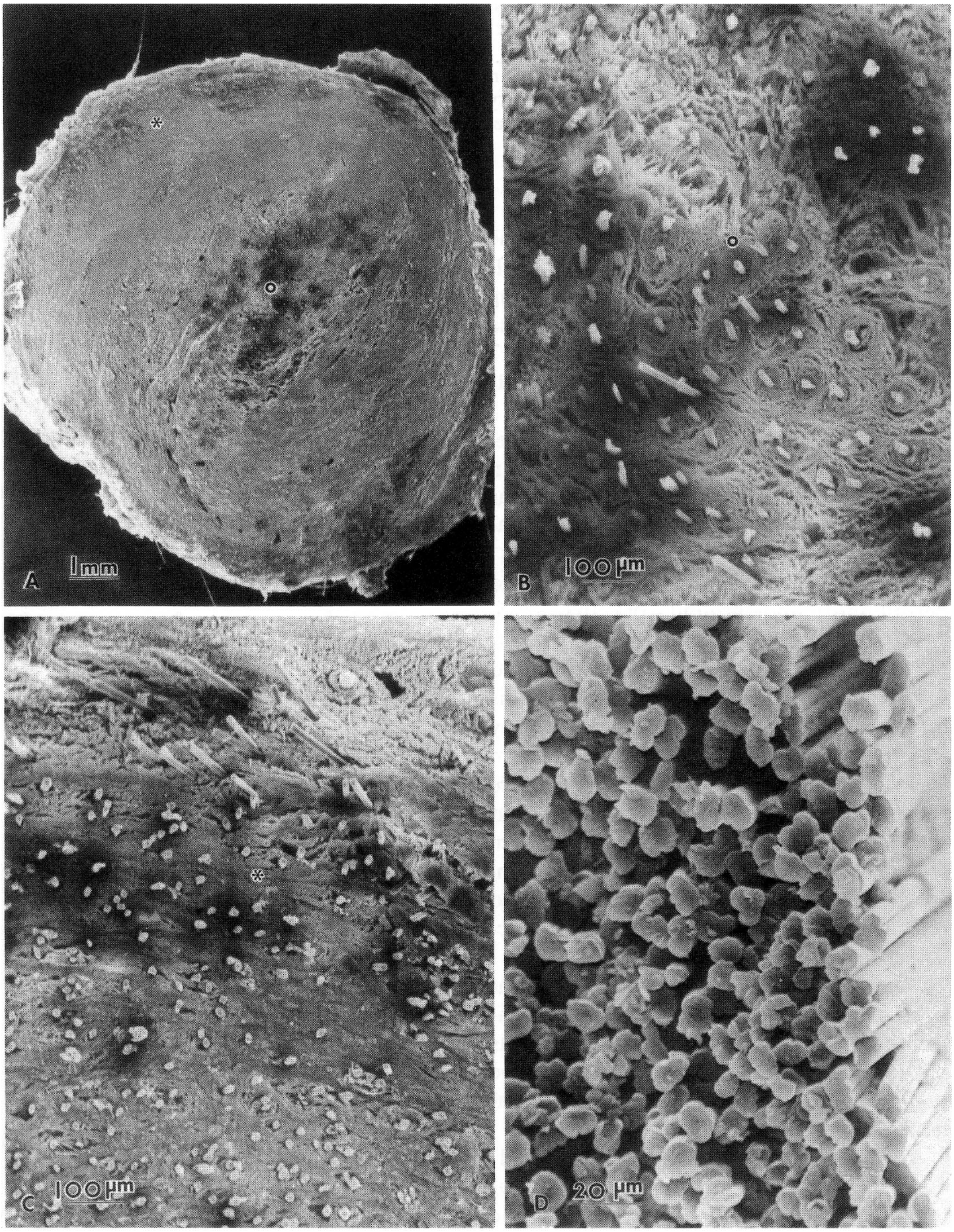


FIG. 2. ACL stability at longest follow-up time in a consecutive series of patients who received carbon fibers. Class 1, side-to-side difference during clinical exam less than 5 mm; Class 2, 5-10 mm; and Class 3, greater than 10 mm.



FIGS. 3A-3D. SEM views of tibial portion of failed carbon fiber implant, recovered after 45 months. (A) The individual fibers of the implant (40,000 fibers) have become surrounded with induced tissue. (B) Higher-power view of the region defined in A (circle). (C) Higher-power view of the region defined in A (asterisk). (D) Carbon fibers before implantation.

patient returned to work underground and the carbon fibers broke near the tibial plateau. The intraarticular portion of the implant fibrosed to the synovium, and the portion of the implant in the tibia was recovered and examined microscopically. The individual fibers throughout the implant were surrounded by induced tissue (Fig. 3A), which appeared to be more dense in the periphery (Fig. 3C) compared to the center (Fig. 3B). A mild foreign-body type granulomatous reaction to carbon fibers was observed in the epoxy-embedded sections. This reaction was characterized by occasional multinucleate giant cells and epithelioid cells or both, which frequently encased the carbon fibers. Scattered lymphocytes were seen in and around the giant cells. The carbon fibers remained sharply defined and showed no evidence of erosion or chemical attack. Macrophages containing particulate carbon were not seen. Moderate to large amounts of collagen separating the carbon fibers were observed, with occasional capillaries between the carbon fibers. The lymph node was normal and contained no carbon debris.

DISCUSSION

Carbon fibers used in many previous studies[5-9,12] were treated with methylethyl ketone or acetone to remove the epoxy coating that had been applied by the manufacturer. Neither the effectiveness of the organic solvents in removing the epoxy nor the residual amounts of the solvents were quantified. Moreover, commercially obtained fibers contain debris and fragments called dross. Normally, the dross is not removed because it is insignificant with regard to typical industrial uses of carbon fibers. Unless it is removed before the carbon fibers are placed in tissue, the dross becomes an implantation of debris. The carbon fibers used in this study were never coated with epoxy. In addition the dross was removed, resulting in the use of only intact carbon fibers at the implant site.

Since carbon fibers are brittle, any potential benefit they might confer cannot be manifest unless its known mechanical shortcomings are controlled. This necessitated two specific procedures during surgery: The edges of all bone holes were rounded to insure that the carbon fibers would not pass over a sharp bony edge, a situation known to result in fiber breakage. In addition, specialized fixation devices were employed because carbon fibers cannot be knotted or sutured to soft tissue and still be expected to maintain mechanical integrity.

With the incorporation of these changes, the authors found that the carbon fiber reconstruction in this series produced good results. Most patients returned to work, and there was an acceptable level of laxity in the group as a whole. Since there was no control group using another therapy, specific comparisons cannot be made except by the criteria of knee laxity (side-to-side difference) and return to functional level. In these respects the patients in this series fared better than those previously treated at this institution for similar injuries.

In one patient, the extraarticular portion of the implant was removed during revision surgery, and the presence of connective tissue throughout the implant was confirmed (Fig. 1). If such tissue induction actually occurred intraarticularly, it may constitute a mechanism behind the stability that was observed.

No chronic pain or effusions occurred in this series of cases. A previous report[10] of such symptoms may have resulted from the presence of epoxy and organic solvents in the knee. One inguinal lymph node was removed from a patient and was found to contain no carbon fiber debris. Moreover, carbon debris was not found in any cells inside the ligament specimen.

A controlled study will be required to unambiguously confirm the efficacy of carbon fibers in relation to other potential treatment in reconstructing the ACL.

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