PRE-MARKET APPLICATION

CFS™ FOR TREATMENT OF KNEE-LIGAMENT INJURIES

PLASTAFIL, INC.

VOLUME 5

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4E. OTHER CLINICAL INVESTIGATIONS

A. USE OF CARBON FIBERS IN SOUTH AFRICA

Purpose for Providing South African Clinical Data

Carbon fibers have been used clinically in South Africa since 1980. At the time of Plastafil's IDE application, more than 1,000 implants had been performed; these cases involved use of parts or prototypes of parts of the CFS™. We visited South Africa in November, 1982 and spoke with approximately ten surgeons who had done at least 10 such cases, and found no complications that could reasonably be attributed to the implant. This observation formed part of the justification for the IDE.

In December, 1986, we contacted FDA as a preliminary step toward preparation of our PMA, and learned that the 2-year follow-up originally proposed in the IDE was no longer viewed as adequate. We also learned that an issue of safety involving intra-articular carbon-fiber debris had been raised. FDA staff suggested that we obtain information regarding carbon-fiber cases that had been done in South Africa that had operative dates prior to those in the Plastafil study. Since the average follow-up would be longer than that in the Plastafil study, it was suggested that such information would be useful in evaluating the safety aspects of CFS™. Staff recognized that we would not be able to provide reliable information regarding efficacy from the South African data because each clinical series was uncontrolled, and lacked entry criteria and standardization among individual surgeons regarding criteria for evaluation. Nevertheless, the data would be important because of the safety considerations involved: Specifically, did the implants become infected? Were the knees symptomatic? Were the implants removed? Were regional lymph nodes painful or tender? Did intra-articular deris affect joint cartilage?

We contacted three surgeons who performed a significant number of ACL cases prior to initiation of the Plastafil IDE study, and whom we believed would be willing to call back each of his patients for follow-up examination. Each of the three surgeons whom we contacted agreed to provide the information we requested for a consecutive and inclusive series of their patients operated on between the dates that we specified.

Dr. Deodat Mare practices in Pretoria. Typically, his patients are soldiers or policemen; they are athletic individuals, mostly with chronic injuries. Dr. Mare provided data concerning a consecutive series of 57 patients who received carbon fibers for repair of isolated ACL injuries. The series includes all such patients who received carbon fibers in 1981-1984. Dr. Mare's follow-up was performed during the last several months of 1987; all patients in the series were seen at follow-up.

Dr. Paul Demmer practices in Orkney. His patients were miners, employed at the West Vaal Mines. Mostly, they were treated for acute injuries suffered in mine accidents. Dr. Demmer provided detailed information regarding a consecutive series of 26 patients that were implanted with carbon fibers in the ACL in 1982-1984; 24 patients in the series were seen at follow-up.

Dr. Cyril Botha practices in Johannesburg. His practice is typical of that of an orthopaedic surgeon in private practice in a large urban center. He agreed to provide data regarding a consecutive series of 37 patients that received carbon-fiber reconstruction of the anterior cruciate ligament in 1981-1984; 34 patients in the series were seen at follow-up.

Each physician agreed to examine each patient and provide an opinion regarding the stability of the operated limb. In addition we asked (1) whether there were any infections; (2) whether any implants had been removed; (3) whether chronic pain was present (if so, the basis for it); (4) any pain or tenderness in the popliteal or inguinal lymph nodes.

Dr. Mare provided the information requested on a standardized form which he designed, and the information has been tabulated and presented here in the form of a Table. Dr. Demmer provided detailed notes regarding his patients, and provided further information during several discussions. The data from this study is presented in the form of a manuscript. Dr. Botha presented his information using a form similar to that of Dr. Mare, and Dr. Botha's data is also presented here in the form of a Table.

PATIENTS OF DEODAT MARE, M.B., Ch.B.

A Consecutive Series of Cases Involving Repair and Reconstruction of the Anterior Cruciate Ligament. ACL stability: Excellent, anterior drawer of less than 5 mm; Good, anterior drawer o 5-10 mm; Fair, > 10 mm anterior drawer, but a functional joint; Poor, other. If the date o injury was within one month of the date of operation, the case was classified as acute (A); otherwise, it was classified as a chronic injury (C). Patient's evaluation (P's E): S, satisfied; NS not satisfied; I, indifferent.

							EVALUATION AT LAST FOLLOW-UP				
NO.	NAME	SEX	AGE	CATEGORY	LIGAMENT REPAIRED	FOLLOW-UP TIME (Months)	ACL STABILITY	CHRONIC PAIN	BACK TO WORK	SPORTS	P's
1	Claasen	?	?	?	ACL	78	Fair	No	Yes	Golf	S
2	Eloff	M	18	C	ACL	66	Excellent	No	Yes	Tennis	S
3	Smit	M	30	C	ACL	77	—	—	—	—	S
	COMMENT: Severe osteoarthritis which was present before surgery. Total knee, 1987.										
4	Pietersen	M	35	C	ACL	76	Good	Yes	Yes	Golf	S
	COMMENT: Osteoarthritis present before surgery.										
5	Cooper	M	36	C	ACL	77	Excellent	No	Yes	Tennis	S
6	Nel	M	28	C	ACL	77	Good	No	Yes	Golf	S
7	White	M	32	C	ACL	77	Excellent	No	Yes	Waterski	S
8	Steenkamp	M	28	C	ACL	76	Good	No	Yes	Golf	S
9	Van Rensburg	M	33	C	ACL	75	Good	No	Yes	Squash	S
10	Le Grance	F	26	A	ACL	74	Excellent	No	Yes	Squash	S
	COMMENT: Slight tattooing of skin over the surgical incision.										
11	Wolmarans	M	36	C	ACL	73	Good	No	Yes	Golf	S
12	Du Toit	M	34	C	ACL	73	Excellent	No	Yes	Squash	S
	COMMENT: Arthroscopy 1 yr. postoperative. Ligament appears to be of normal thickness, but dark.										
13	Ellis	M	26	C	ACL	73	Good	No	Yes	Tennis	S
	COMMENT: Mild osteoarthritis. Pain after sport.										

Mare cases (cont.)

NO.	NAME	SEX	AGE	CATEGORY	LIGAMENT REPAIRED	FOLLOW-UP TIME (Months)	EVALUATION AT LAST FOLLOW-UP: ACL STABILITY	CHRONIC PAIN	BACK TO WORK	SPORTS	P's
14	Pinto	M	24	C	ACL	73	Excellent	No	Yes	Rugby	S
15	Scheepers	M	40	C	ACL	71	Fair	Yes	Yes	None	S
	COMMENT: Mild pain occasionally due to osteoarthritis.										
16	Coetzee	M	25	A	ACL	71	Good	No	Yes	Squash	S
17	Lourens	F	25	C	ACL	70	Excellent	No	Yes	Waterski	S
18	Viljoen	F	30	C	ACL	67	Fair	No	No	None	S
19	Fourie	M	28	A	ACL	67	Good	No	Yes	Tennis	S
20	De Jager	M	45	C	ACL	67	Fair	No	No	No	S
	COMMENT: Occasional pain.										
21	Schoeman	F	27	C	ACL	67	Good	No	Yes	Squash	S
	COMMENT: Arthroscopy Oct., 1982. Knee appeared normal.										
22	Steenkamp	M	24	A	ACL	67	Excellent	No	Yes	Rugby	S
23	Radue	F	20	C	ACL	67	Fair	No	No	None	S
	COMMENT: Re-injured August 4, 1982.										
24	Bishoff	M	30	C	ACL	67	Good	No	Yes	Squash	S
25	Hanekom	M	22	A	ACL	66	Excellent	No	Yes	Rugby	S
26	Van Der Westhuizen	M	42	C	ACL	66	Fair	No	Yes	Golf	S
27	Stoffberg	M	24	A	ACL	65	Excellent	No	Yes	Rugby	S
28	Niemann	M	28	A	ACL	65	Good	No	Yes	Golf	S
	COMMENT: Arthroscopy 12/6/82. Ligament satisfactory; no inflammation.										
29	Botha	F	28	C	ACL	65	Excellent	No	Yes	Squash	S
30	Martitoli	M	32	C	ACL	65	Good	No	Yes	Squash	S
31	Cornetti	M	30	C	ACL	64	Excellent	No	Yes	Tennis	S

Mare cases (cont.)

NO.	NAME	SEX	AGE	CATEGORY	LIGAMENT REPAIRED	FOLLOW-UP TIME (Months)	EVALUATION AT LAST FOLLOW-UP: ACL STABILITY	CHRONIC PAIN	BACK TO WORK	SPORTS	P's I
32	Gustian	M	18	A	ACL	64	Good	No	Yes	Javelin	S
33	Engelbrecht	F	20	C	ACL	64	Excellent	No	Yes	Gym-nastics	S
34	Munroe	M	20	A	ACL	63	Good	No	Yes	Jogging	S
35	Gillmaster	M	25	C	ACL	64	Excellent	No	Yes	Sky-diving	S
	COMMENT: Arthrotomy and meniscal repair after re-injury 5/4/87. Ligament excellent; very few small black specks on lateral condyle. Early osteoarthritis.										
36	Van Huyssteen	M	36	C	ACL	63	Good	No	Yes	Rugby	S
37	De Wet	F	24	C	ACL	63	Good	No	Yes	Tennis	S
38	Van Schaick	M	32	C	ACL	62	Good	Yes	Yes	Golf	S
	COMMENT: Severe osteoarthritis due to previous meniscectomy. Due for total knee.										
39	De Kock	F	23	A	ACL	61	Excellent	No	Yes	Netball	S
40	Buys	M	38	C	ACL	61	Good	No	?	Jogging	S
41	Cronje	F	20	C	ACL	60	Good	Yes	Yes	None	NS
	COMMENT: Still severe pain. Over-protected by mother, therefore no post-operative physiotherapy. Second arthroscopy after surgery; ligament and joint surface normal.										
42	Myburgh	M	29	C	ACL	59	Fair	No	Yes	Golf	I
	COMMENT: Re-injured about 8 weeks post-operative. Pain during golf.										
43	Van Eeden	M	22	A	ACL	58	Good	No	Yes	Jogging	S
44	Van Vuuren	M	35	C	ACL	57	Excellent	Yes	Yes	None	S
	COMMENT: Pain due to osteoarthritis.										
45	Van Der Walt	M	30	A	ACL	54	Excellent	No	Yes	Rugby	S
	COMMENT: Re-injured during sport 12/6/83.										
46	Herbst	F	24	C	ACL	56	Good	No	Yes	Netball	S
47	Hill	M	29	A	ACL	53	Excellent	No	Yes	Squash	S

Mare cases (cont.)

NO.	NAME	SEX	AGE	CATEGORY	LIGAMENT REPAIRED	FOLLOW-UP TIME (Months)	EVALUATION AT LAST FOLLOW-UP: ACL STABILITY	CHRONIC PAIN	BACK TO WORK	SPORTS	P's
48	Breedt	M	33	C	ACL	52	Poor	No	Yes	None	NS
	COMMENT: Re-injury 4 weeks postoperative.										
49	Viljoen	M	25	C	ACL	52	Good	No	Yes	Tennis	?
50	Van der Merwe	M	30	C	ACL	51	Good	No	?	Tennis	S
51	Croft	F	26	A	ACL	49	Good	No	?	Swimming	S
52	Dreyer	M	20	A	ACL	49	Excellent	No	Yes	Javelin	S
53	O'Brien	M	33	A	ACL	49	Excellent	No	Yes	Body-building	S
54	Jonker	F	21	C	ACL	48	Excellent	No	Yes	Badminton	S
55	Steenkamp	M	?	C	ACL	42	Good	No	Yes	Jogging	S
	COMMENT: Slight pain when jogging.										
56	Oosthuizen	M	30	A	ACL	42	Good	No	Yes	Rugby	S
57	De Kock	M	26	A	ACL	38	Excellent	No	Yes	Rugby	S

FOLLOW-UP NOTES

About 20 arthroscopies were performed: Only minute traces of carbon in the joint were observed.

One case of chronic pain occurred (patient 41). The patient's knee was scoped three times, and no pathology was found.

There were no cases of tender lymph nodes in the popliteal or inguinal area. There were no cases in which the implant became infected necessitating its removal. There were no cases of chronic pain in the knee that could reasonably be attributed to the implant itself.

PATIENTS OF DR. PAUL DEMMER

Abstract

Carbon fibers of known purity 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 occupationally-related injuries. After an average follow-up time of 52.4 months (one patient lost to follow-up, one patient refused follow-up), we found that 14 patients exhibited anterior drawer at 30° of less than 5 mm (side-to-side difference), 6 patients at 5-10 mm, and 4 patients greater than 10 mm. Of 24 evaluatable patients, 22 returned to work, including 20 patients that returned to work underground. Chronic pain, recurrent effusion, infection and tender nodes did not occur in the series. Arthroscopic examination of 5 patients revealed minimal intra-articular debris.

Introduction

Jenkins and colleagues studied the use of carbon fibers in reconstructing tendons and ligaments in both animals and man (Jenkins et al. 1977; Jenkins 1978; Jenkins and McKibbin 1980). 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 colleagues (1984; 1985; 1988) disputed Jenkins' observations regarding formation of a neotendon. Rushton et al. (1983) described persistent effusion and synovial thickening in patients that had undergone carbon-fiber reconstruction. Bray et al. (1988) reported that a carbon-fiber augmentation of a MacIntosh procedure provided no clinical benefit.

It seemed to us that the purity of the carbon fibers and the surgical techniques employed were important factors in resolving the apparently conflicting reports. The difficulty in preparing representative histological specimens of tissue containing carbon fibers was also a fundamental factor in the confusion regarding formation of a neoligament.

In 1982, when a suitable system involving carbon fibers (Strover 1983) became available, we 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, histological methods suitable for viewing the effects of carbon fibers on tissue were developed, and these methods were used to evaluate tissue specimens obtained during the course of the study.

Methods

Patients

The patients were employees of the West Vaal Mines, Orkney, RSA, who suffered anterior-cruciate ligament (ACL) injuries between June, 1982 and May, 1983 and who consented to the treatment offered. The group consisted of 26 patients; 3 had an isolated rupture of the ACL, 11 had additional injuries to one or both collateral ligaments, and 12 had injuries to both 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.

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

Implants

The implant (Plastafil Pty., Johannesburg, RSA) consisted of a bundle of 40,000 carbon fibers (8 microns in diameter); the carbon fibers had never been coated with epoxy or any foreign substance. The carbon fibers were heated in an inert atmosphere to remove impurities (resulting carbon content, > 99%), cleaned of adhering broken carbon fibers that became associated with the carbon-fiber bundle during manufacturing, and coated with gelatin/glycerol (to improve handling characteristics of the implant during surgery). All carbon-fiber implants were fixed to bone using two specially-designed fixation devices (Strover 1983): The toggle was a bar of carbon-fiber reinforced polysulfone, and the bollard was a specially designed expanding rivet.

Surgical Procedures

All patients were operated on by one surgeon (PD) at the same hospital (West Vaal); the surgical techniques and methods of fixation described below were used (Figure 1).

For reconstruction of the anterior cruciate ligament, following a medial parapatellar arthrotomy, the synovium was incised and dissected off the anterior cruciate ligament. A 4.8-mm hole was made from the anteriomedial 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. 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 (Figure 1). Frequently, when more than one ligament was repaired, the portion of implant in different ligaments shared a common anchorage.

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

Follow-Up

Most follow-up examinations were performed at West Vaal. In several instances, the patient had left mine employment and in such cases follow-up was performed through the health officers at the patient's new location.

Effectiveness of the treatment was evaluated based on post-operative stability, and 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 (25-35° 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.

Microscopic Studies

The tibial (extra-articular) portion of an implant was removed from 1 patient (after 45 months); at the time of the revision, an inguinal lymph node was also recovered. 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, and frozen using liquid nitrogen and cut transversely 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 (Balzers CPD 020), coated with gold (Deton vacuum desk-2) and examined in an SEM (AMR 1200) at an accelerating voltage of 25 kV. For light microscopy, 1.5-mm cubes of the carbon-fiber specimen were dehydrated, embedded in Spurr, and cut (0.2-0.3 microns) on an ultramicrotome (LKB model 5) using a diamond knife. The tissue sections were stained using a modified Spurlock (Toludine O/Basic Fuchsin).

The lymph node was dehydrated, embedded in wax, sectioned at 10 microns, and every fourth section was recovered and stained with hematoxylin and eosin.

Results

One patient was lost and one patient refused follow-up; follow-up was obtained on the remaining 24 patients, at an average post-operative time of 52.4 (standard deviation, ± 14.7 months, N = 24) 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 exhibited by 6 and 4 patients, respectively. There was no apparent correlation between grade of stability and follow-up time (Figure 2).

Nineteen patients recovered sufficiently to permit return to work underground. In 4 cases the extent of recovery permitted only (less demanding) surface employment. In 2 of these cases (patients 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 the remaining 2 cases (patients 22 and 23), the injured knees were stable (either Class 1 or 2), but concommitant injuries suffered by the patient were the main function-limiting factors. In 2 cases (patients 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 patient, and infections related to the carbon fibers and its anchorages were not observed. Neither the popliteal nor inguinal lymph nodes of any patient was swollen or tender.

Arthroscopies were performed on 5 patients (patients 1, 4, 7, 18, and 20) for various clinical indications. Trace presence of carbon fibers in the synovium were observed, but no inflammatory reactions were seen.

Surgical revision necessitated by implant failure occurred in one case (patient 20). Following surgery, the patient returned to work underground, and the carbon fibers broke near the tibial plateau. The intra-articular portion of the implant fibrosed to the synovium, and the portion of the implant in the tibia was recovered (Figure 3). The individual fibers throughout the implant were surrounded by induced tissue, which appeared to be more dense in the periphery compared to the center (Figure 3). A mild foreign-body type granulomatous reaction to carbon fibers was observed. This reaction was characterized by occasional multinucleate giant cells and/or epithelioid cells 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 was observed (Figure 3), with occasional capillaries between the carbon fibers.

Discussion

Carbon fibers used in many previous studies were treated with methylethyl ketone or acetone to remove the epoxy coating that had been applied by the original 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 routinely contain debris and fragments (dross) which are normally not removed because they have no significant consequences with regard to typical industrial uses of carbon fibers. Unless it is removed before the carbon fibers are placed in tissue, the dross becomes simply an implantation of debris. The carbon fibers used in this study had never been 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 manifested unless its known mechanical shortcomings are controlled. This necessitated two specific procedures during surgery: All holes through bone (at both their entrance and exit) were radiused 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 expected to maintain mechanical integrity.

With the incorporation of these changes, we 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 the study group was not controlled using another therapy, we cannot make specific comparisons except to say that by the criteria of (1) knee laxity and (2) return to functional level, the patients in this series fared better than those previously treated at West Vaal for similar injuries.

The arthroscopic appearance of a carbon-fiber-reconstructed anterior cruciate ligament depends on the nature of the reconstruction. In acute cases, where the carbon-fiber tow is passed through the substance of the torn ligament, arthroscopic examination reveals a normal-appearing ligament consisting of a white, taut structure. In acute cases where part of the anterior cruciate ligament was removed (or when the ligament had a narrow diameter or the carbon-fiber tow was passed peripherally through the substance of the ligament) we observed a black structure with a thin, sometimes transparent fibrous coat. The carbon-fiber tow did not cause the growth of a neotendon outside the carbon-fiber tow itself (which is the only location actually seen during an arthroscopic examination). We did not take a core biopsy of any reconstructed ligament, and consequently cannot confirm the existence of fibrous tissue inside intra-articular carbon-fiber bundles. In one case, however, the extra-articular portion of the carbon-fiber tow was removed (the portion located in the tibia), and the presence of connective tissue throughout the implant was confirmed (Figure 3). The tissue would not have formed but for the presence of the carbon fibers. If such tissue induction actually occurred intra-articularly, it could constitute a putative mechanism for the provision of stability documented by our observations.

We observed no chronic pain or effusions: A previous report of these symptoms (Rushton et al. 1983) may have resulted from the presence of epoxy and organic solvents in the knee. One inguinal lymph node was removed from a patient, and found to contain no carbon-fiber debris.

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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FIGURE 1. Placement of carbon fibers in the repair of the cruciate and collateral ligaments in the knee. A-D, anterior, posterior, lateral, medial ligaments, respectively.

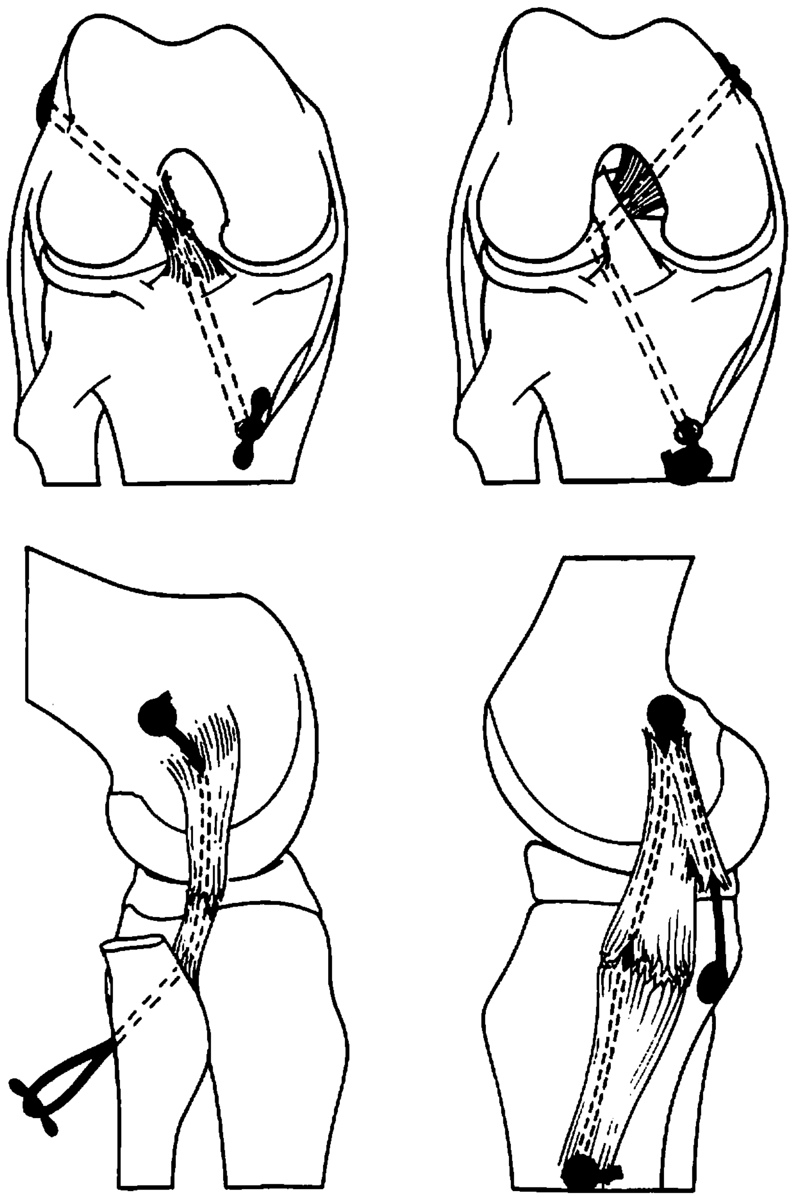


FIGURE 2. ACL stability at longest follow-up time in a consecutive series of patients who received carbon-fibers. Class 1, side-to-side difference during clinical exam less than 5 mm. Class 2, 5-10 mm. Class 3, greater than 10 mm.

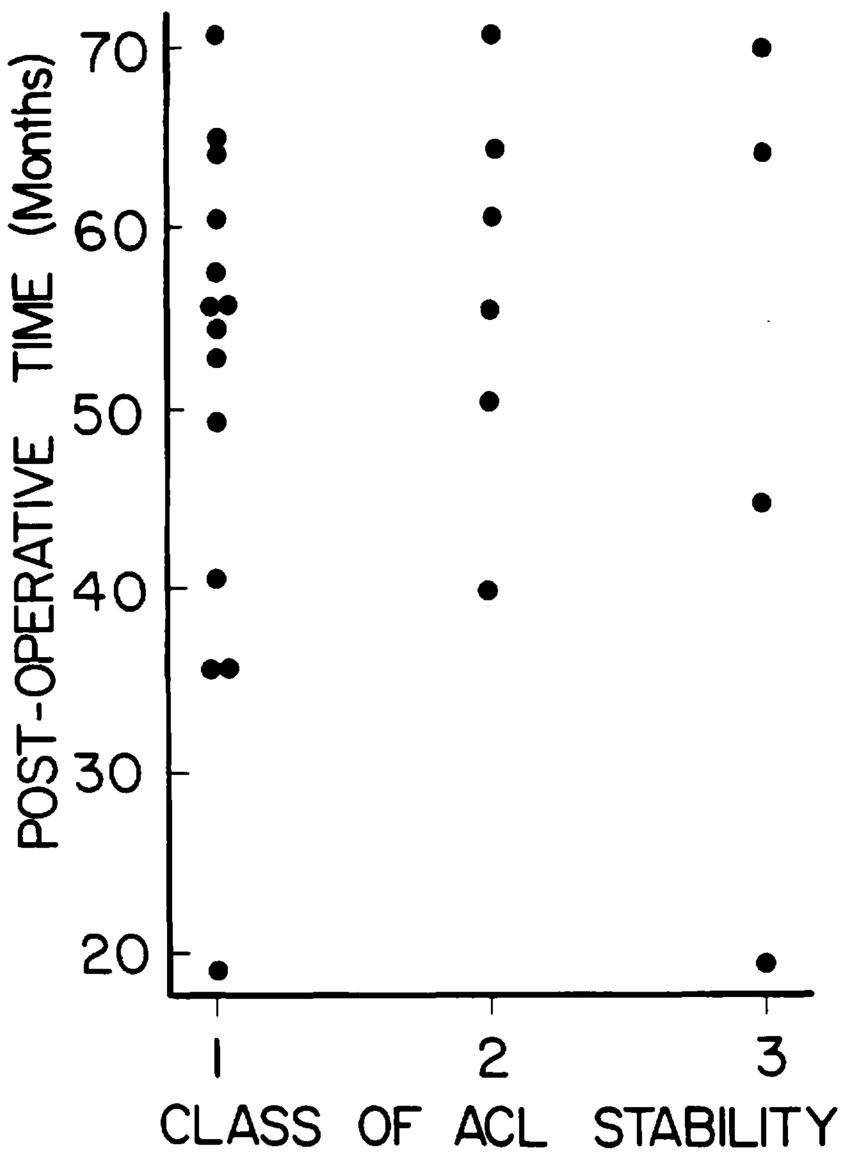


FIGURE 3. Scanning electron microscopic views of tibial portion of failed carbon-fiber implant, recovered after 45 months. A, the individual fibers of the implant (40,000 fibers) have become invaginated with induced tissue. B and C, higher-power views of the regions defined in A. D, carbon fibers prior to implantation.

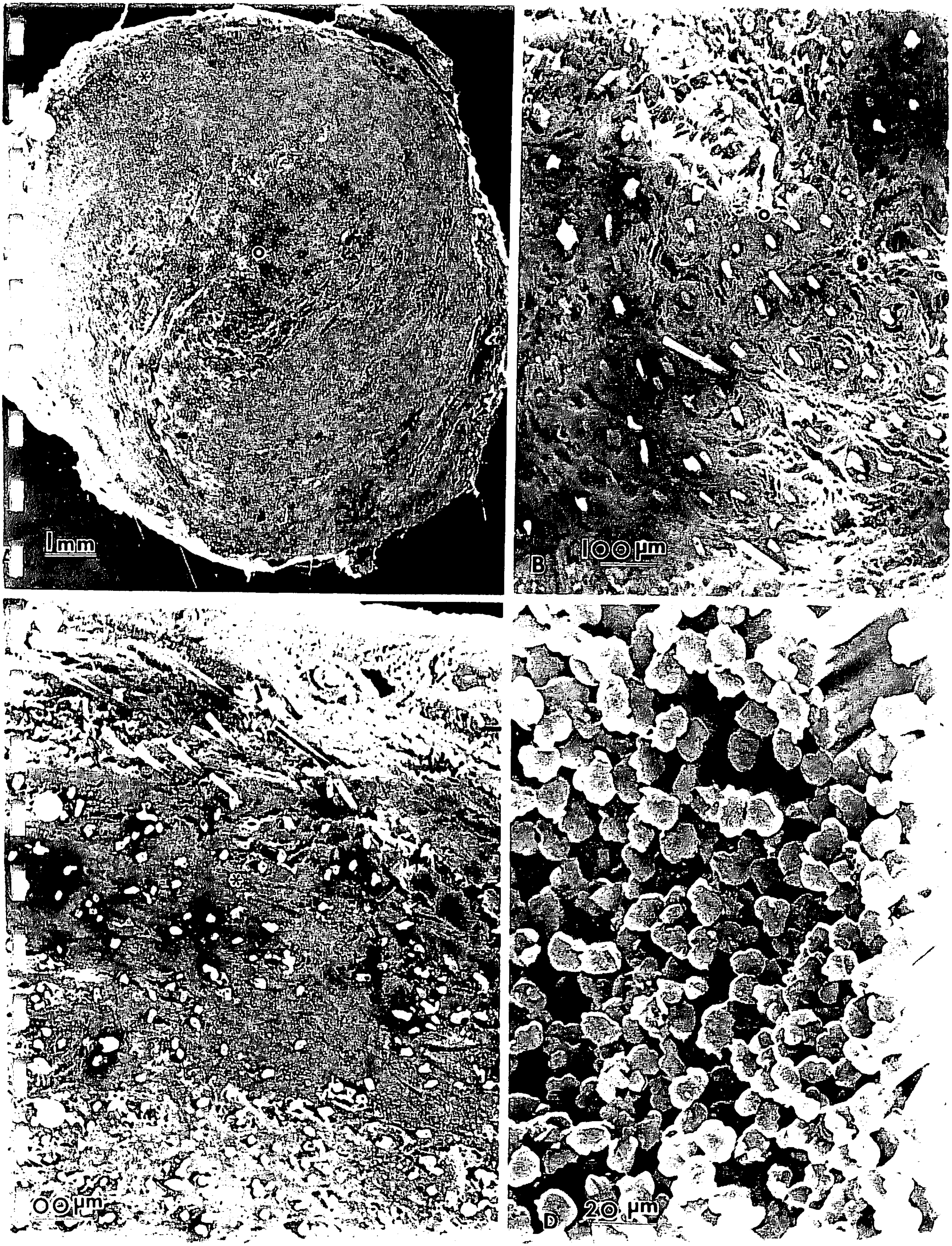

1mm
B
100 µm
D
20 µm

TABLE 1. THE USE OF CARBON FIBERS FOR THE REPAIR AND RECONSTRUCTION OF THE ANTERIOR CRUCIATE LIGAMENT. U, work under-ground. S, surface employment. ACL stability: Class 1, anterior drawer < 5 mm; Class 2, 5-10 mm; Class 3, > 10 mm.

PT. NO.	NAME	CATEGORY	LIGAMENTS REPAIRED	FOLLOW-UP TIME (Months)	ACL STABILITY (Class)	PAIN	WORK STATUS	COMMENT
1	Konoto	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	Thabang	Chronic	ACL, MCL	36	1	No	--	Died at 38 months (from a traffic accident).
3	Gakulugum	Acute	ACL, PCL	71	1	No	U	
4	Moshiae	Chronic	ACL	71	2	No	U	Arthroscopy (at 31 mos.) showed trace presence of carbon fibers in the synovium, but no inflammatory reaction. Recurrent effusion (due to instability).
5	Baksolele	Acute	ACL, PCL, LCL, MCL	70	3	No	S	Knee joint is stiff.
6	Ingwedani	Acute	ACL, MCL	49	1	No	U	
7	Esaia	Acute	ACL, PCL, MCL	64	2	No	U	Arthroscopy (at 18 mos.) revealed trace amounts of carbon fibers in the synovium, but no signs of infection or inflammation.
8	Thomas	Acute	ACL, PCL	64	1	No	U	
9	Biksi	Acute	ACL, MCL, PCL, LCL	64	3	No	S	
10	Mahlelihleli	Acute	ACL, LCL	61	2	No	U	
11	Thambeleli	Acute	ACL, PCL	61	1	No	U	
12	Chiwallo	Acute	ACL, MCL	57	1	No	U	

Table 1 (cont.)

PT. NO.	NAME	CATEGORY	LIGAMENTS REPAIRED	FOLLOW-UP TIME (Months)	ACL STABILITY (Class)	PAIN	WORK STATUS	COMMENT
13	Linoki	Acute	ACL	56	1	No	U	
14	Maolosi	Acute	ACL, LCL	56	1	No	U	
15	Welili	Acute	ACL, PCL MCL	54	1	No	U	
16	Simon	Acute	ACL, MCL PCL	56	2	No	U	
17	Kusanepi	Acute	ACL, LCL	53	1	No	U	
18	Thabo	Acute	ACL, PCL	51	2	No	U	Arthroscopy (at 21 mos.) showed small pockets of carbon fiber proximal to the articular surface of the femur.
19	Mogolabega	Chronic	ACL, LCL					Patient lost to follow-up 7 months after surgery.
20	Nkosinati	Chronic	ACL	45	3	No	U	When the patient returned to work underground (as a driller) the carbon fibers broke near the tibial plateau. 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	Patrick	Acute	ACL, MCL	19	3	No	U	
22	Timothy	Acute	ACL, PCL, MCL	40	2	No	S	
23	Cedric	Acute	ACL, LCL	41	1	No	S	
24	James	Acute	ACL, PCL				U	Refuses to be seen. Works in neighboring mine.
25	Kulube	Acute	ACL	36	1	No	U	
26	Alfred	Acute	ACL, PCL	18	1	No	U	

PATIENTS OF DR. CYRIL V. BOTHA

A Consecutive Series of Cases (5/22/81 to 12/11/84) Involving Repair and Reconstruction of the Anterior Cruciate Ligament. If the date of injury was within one month of the date of operation, the case was classified as acute (A); otherwise, it was classified as a chronic (C) injury. Patient's evaluation: S, satisfied; NS, not satisfied; I, indifferent.

							EVALUATION AT LAST FOLLOW-UP				
NO.	NAME	SEX	AGE	CATEGORY	LIGAMENT REPAIRED	FOLLOW-UP TIME (Months)	ACL STABILITY	CHRONIC PAIN	SPORTS	COMMENT	PATIENT'S EVAL.
1	Blumenthal	M	37	C	ACL	76	Excellent	No		Injured non-operated limb playing rugby at ___ mos. post-operatively.	S
2	Nel	M	40	C	ACL	75	Good	No	Golf		S
3	Brits	M	39	C	ACL	75	Good	No	Rugby ref.		S
4	Connelly	M	?	?	ACL	74	Excellent	No	Rugby		S
5	du Toit	M	28	C	ACL	72	Fair	Yes	Golf	Has pain, but no swelling. Previously had medial and lateral meniscectomies.	I
6	Newton	F	53	C	AC	46	Fair	No	Yes		S
7	Cloete	M	30	C	ACL	5	Good	No			S
8	Fulik	M	43	C	ACL	22	Good	No			S
9	Duncan	M	52	C	ACL	73	Fair	No	Limited		NS
10	Holzapfel	F	41	C	ACL	20	Good	No	Squash		S
11	Welsh	M	35	C	ACL	17	Good	No			S
12	Fourie	M	41	C	ACL,MCL	64	Fair	No	Golf,tenpin		NS
13	Bekker	M	38	C	ACL, LCL	52	Good	No	Tennis		S

NO.	NAME	SEX	AGE	CATEGORY	LIGAMENT REPAIRED	FOLLOW-UP TIME (Months)	EVALUATION AT LAST FOLLOW-UP: ACL STABILITY	CHRONIC PAIN	SPORTS	COMMENT	PATIENT'S EVAL.
14	Dixon	M	28	?	ACL,MCL	22	Good	No	Tennis		S
15	Marks (nee Hoogenbosem)	F	27	C	ACL	67	Good	No	Yes		S
16	van Wezel	M	34	C	ACL	66	Good	No			S
17	Botha	M	33	A	ACL,MCL	52	Good	No	Yes		S
18	Beukes	M	33	C	ACL	27	Good	No			S
19	Baigrie	M	30	C	ACL,MCL	43	Excellent	No			S
20	van Dalen	F	26	C	ACL	55	Good	No			S
21	Horn	M	?	?	ACL	?					
22	Misselhorn	M	33	C	ACL	23	Good	No	Squash		
23	Ward	M	30	C	ACL	8	Good	No	Yes		S
24	Kok	M	43	C	ACL	40	Good	No			S
25	Barnard	M	36	C	ACL	33	Excellent	No	Squash		S
26	van Niekerk	M	27	C	ACL	33	Good	No			S
27	Knox	M	37	C	ACL	9	Good	No			S
28	McLachlan	M	28	C	ACL	24	Good	No			S
29	Slabber	F	49	C	ACL	?					
30	Steyl (nee Kreigler)	F	24	C	ACL	36	Good	No			S
31	Bouwer	M	25	C	ACL,LCL	?	Good	No	Golf		S
32	Adkins	M	33	C	ACL	4	Excellent	No			S
33	Hopley	F	22	C	ACL	41	Good	No	Windsurfing, Cycling		S
34	Bekink	M	23	C	ACL,CL	19	Good	No	Squash		S
35	de Luca	F	57	C	ACL	40	Fair	No			NS
36	McCriskin	M	40	C	ACL	36	Excellent	No	Cricket, sailing		S
37	Schuster	M	36	C	ACL	36	Good	No			S

USE OF CARBON FIBERS IN CANADA

Introduction

J. Norgrove Penny, M.D., FRCS(C) is an orthopaedic surgeon in private practice in Victoria, British Columbia, Canada. Dr. Penny is a Fellow of the American Academy of Orthopaedic Surgeons.

Dr. Penny has no financial or commercial interest in Plastafil.

Beginning in 1983, Dr. Penny used carbon fibers in a clinical study involving the repair and reconstruction of knee ligaments. The carbon fibers and fixation devices were identical to those in the CFS™ used in the U.S. study; they were obtained directly from South Africa, pursuant to Canadian regulations governing importation of medical devices and implants. Dr. Penny's study was undertaken to examine his clinical hypotheses regarding the use of carbon fibers, and he was solely responsible for its design, conduct, and evaluation. Plastafil performed histological studies of some biopsy specimens provided by Dr. Penny.

Dr. Penny's study was not designed in contemplation of providing data to FDA, or in contemplation of supporting Plastafil's PMA for the CFS™. Even so, we believe that the data is pertinent for the same reasons that the South African data was pertinent. Consequently, we have provided all information regarding carbon fibers that was provided to us by Dr. Penny.

Purpose for Providing Canadian Clinical Data

The Canadian data is relevant to the issue of safety of carbon fibers for use in knee surgery. Dr. Penny performed clinical follow-up examinations and arthroscopic examinations of patients who received carbon fibers, and he documented the arthroscopic appearance of the reconstructions using videotape. In addition, Dr. Penny obtained synovial biopsies from patients who received carbon fibers; the biopsied tissue was examined by pathologists at his hospital. Dr. Penny removed part or all of several carbon-fiber-reconstructed anterior cruciate ligaments, and the specimens obtained provide useful information regarding the nature of the response of human tissue to intra-articular carbon fibers.

Patient Population

The patient population in this study consists of all patients who received carbon fibers from Dr. Penny for knee-ligament reconstruction prior to August, 1985.

A prospective, randomized, controlled study was performed involving a total of 64 patients. The essential criterion for admission to the study was anterior-cruciate-ligament instability requiring surgical correction. All patients that entered the study received combined intra- and extra-articular reconstructions, as appropriate for their particular injury. Iliotibial band and semitendinosis tendon were chiefly employed for the intra-articular portion of the reconstructions. In 36 of the patients the autologous-tissue reconstructions were augmented using carbon fibers. Cases in which the surgery was performed fewer than 30 days following injury were considered to be acute cases, and all other cases were regarded as chronic cases. The acute and chronic cases included in the study are listed in Tables 1 and 2, respectively.

In addition to the study described above involving anterior cruciate ligament insufficiency, 5 patients received carbon-fiber augmentation of a standard autologous tissue transfer technique for treatment of posterior cruciate ligament instability. The patients entered into this study are listed in Table 3.

Patient Evaluation Procedures

Clinical Examination

The patients were evaluated by clinical examination every three months until the end of the first post-operative year, and at the end of the second post-operative year. Thereafter the patients were not followed according to a pre-determined follow-up plan. Initially, the AOSSM Study Group ACL Follow-up Form was used to evaluate the patients during their 1-year follow-up visit. Subsequently, the data was recorded on a spread-sheet designed to display pertinent information. The Symptoms score is based on considerations of knee pain, giving way, swelling, and stiffness. The highest score (freedom from symptoms) is 5, and fractional scores are possible. The Function score is based on an assessment of activity level: 1, no sports; 2, sports activities significantly limited; 3, active but different sports; 4, same sports but lower performance level; 5, equal performance at same sports as before injury. The Stability score comes from an evaluation of the anterior drawer, Lachman's, and pivot shift tests: 1, if all tests are equal to or greater than 2+; 2, if two tests are 2+ and one test is 1+; 3, if two tests are 1+ and one test is 2+; 4, if none of the three tests is greater than 1+; 5, if none of the tests is greater than trace.

The nature of the follow-up in Dr. Penny's study is similar to that obtained in the Brooke, Iowa, and LSU series. Every patient could not be seen and evaluated at identical and fixed intervals post-operatively. Consequently, it was a random selection of patients -- and not the entire cohort -- that were examined within a given post-operative time inerval (say, 1-2 years). Put another way, some patients were not followed during 1-2 years post-operatively, but were seen and evaluated at 2-3 years.

Arthroscopy and Biopsy

Arthroscopy and synovial biopsy were performed in 21 carbon-fiber patients, and 5 control patients. The biopsied tissue was submitted to the Histopathology Section, Royal Jubilee Hospital laboratories, Victoria, B.C., Canada (Royal Jubilee) for pathological examination. Dr. Penny videotaped most of the follow-up arthroscopic procedures, and prepared a composite videotape consisting of 12 representative arthroscopies. A transcript of Dr. Penny's narration of the videotape is provided in Appendix 1.

Tissue Biopsies Analyzed by Plastafil

As of February, 1989, all or part of the carbon-fiber implant was removed in five of Dr. Penny's patients who received carbon fibers; they included 3 patients who are in this study group (received implant prior to August, 1985). The explanted tissue was provided to Plastafil for histological study. David Glowicki (patient 3, Table 1), a 19-year-old white male, received a carbon-fiber augmentation of an acute reconstruction on April 25, 1984. On follow-up performed December 5, 1985 the patient exhibited normal knee function. Shortly thereafter, he was injured playing basketball; during the next year he had four major instability episodes. On November 12, 1986 an arthroscopy was performed and the reconstructed ligament was found to be completely ruptured. The entire anterior cruciate ligament including the carbon fibers was debrided. The intra-articular portion of the reconstructed ligament was lost, but an extra-articular portion of the ligament (near the bollard) was saved.

Ruth Saunders (patient 16, Table 2), a white 21-year-old female, received a carbon-fiber reinforcement of an autologous tissue reconstruction of the ACL necessitated by gross rotatory instability, performed on September 7, 1984. At arthroscopy approximately one year later the knee looked excellent, but the repair had partially stretched. On April 8, 1986 the patient was seen in the emergency room following an automobile accident which resulted in an injury to the operated knee. Subsequently the patient complained of giving-way, and clear evidence of laxity in the knee was observed. An arthroscopy was performed on October 10, 1986, and a partial tear in the reconstructed ligament was observed. A non-functional portion of the reconstructed ligament was removed.

Kevin Watson (patient 8, Table 1), a 20-year-old white male, was operated on November 18, 1984. He received a carbon-fiber reinforcement of an acute autologous tissue reconstruction. He had a repeat injury and completely ruptured his ligament which was removed during an arthroscopy performed January 6, 1989. The remnants of the intra-articular anterior cruciate ligament were recovered.

Plastafil received two other tissue specimens of carbon-fiber reinforced ACL (patellar tendon was used in the surgery which was performed subsequent to the reporting period for this study). Terry Maxwell, a white male, had a reconstruction for chronic instability on February 27, 1986. He developed chronic instability and was arthroscoped on January 13, 1989. A portion of the reconstructed ACL which consisted of a small nodule at the base of the ligament was removed and sent to Plastafil for histological evaluation.

Scott Parker, a white male, received a carbon-fiber reconstruction of the ACL using patellar tendon (surgery performed subsequent to the reporting period for this study). He subsequently developed knee flexion contracture and was debrided 15 months after the reconstruction; a synovial biopsy was obtained during the biopsy.

In addition to these tissues, Plastafil also received a biopsy specimen taken from Sandra Drummond (patient 6, Table 2) (a patient whose biopsy was also processed and examined at Royal Jubilee).

Results

A summary of the clinical data obtained in this study is presented in Tables 4-8; they consist of pertinent data for chronic carbon-fiber cases, chronic control cases, acute carbon-fiber cases, acute control cases, and PCL cases, respectively. The cases described in Tables 4-8 are identical to those presented to the Canadian Orthopaedic Association, June 1-5, 1986, Edmonton, Alberta, Canada. The abstract of the presentation is contained in Appendix 2 (Carbon-Fiber Augmentation of Cruciate Ligament Reconstructions: Preliminary Results, J.M. Penny, JBJS 69B:511, 1987).

It was not possible to obtain quantitative data on each patient at a fixed time postoperatively. Consequently, for analysis, the data was grouped into the following (postoperative) time periods: 0-12 months, 13-24 months, 25-36 months, greater than 36 months. The patients actually examined were essentially a random selection from the existing population: this precondition for the use of Student's t test was therefore satisfied. The treatment (whether carbon or control) did not affect the scores for Symptoms, Function or Stability at any time interval considered in either chronic or acute cases (Tables 9-10, 12-13, 15-16, respectively), as determined using the unpaired t-test ($P > 0.05$). Because the comparable groups did not differ statistically, the data from the chronic and acute patients was pooled at each time interval for each parameter (Tables 11, 14, 17, respectively). Again, no significant differences were observed.

The results of the pathology reports from Royal Jubilee are summarized in Table 18 (the cases in which carbon fibers were not observed in the synovium) and Table 19 (cases in which carbon fibers were observed in the synovium).

<u>Histological Characterization of Furnished Biopsied Tissue</u>

A mild foreign-body reaction to carbon fibers was usually seen, characterized by occasional multinucleate giant cells and/or epithelioid cells which frequently encased the fibers (Table 20). Scattered lymphocytes were seen. There was usually an ingrowth of fibroblasts and occasionally capillaries between the fibers. There were moderate to large amounts of collagen. There appeared to be more collagen when the fibers were further apart. Hemosiderin-laden macrophages were occasionally seen. Several specimens had synovial-cell hyperplasia. Time did not correlate with specific findings. Carbon fibers remained sharply defined, and showed no evidence of erosion or chemical attack. Macrophages containing particulate carbon were not seen.

The scanning electron microscope (SEM) appearance of the reconstructed ligament removed from David Glowicki is shown in Figure 1.

Discussion

Clinical Observations

Apparent improved stability after carbon-fiber augmented grafts in chronic ACL insufficiency was reported in June, 1986 (Appendix 2); carbon-fiber augmentation in acute ACL and in PCL reconstructions produced no observable clinical benefit attributable to the carbon fibers. Function, as determined using the A.O.S.S.M. questionnaire revealed no significant differences between any clinical group and its corresponding control group. In a review of the cases presented at the Canadian Academy of Sports Medicine meeting (March, 1989), Dr. Penny concluded that there was no significant difference in function or stability in any of the groups studied (Tables 12-17).

In June, 1986, and March, 1989, at presentations before Canadian orthopaedic associations, Dr. Penny concluded that there was no difference between any carbon-fiber group and its corresponding control with respect to Symptoms (Tables 9-11). In none of the cases did there occur pain or other symptoms that could be attributed to the presence of the implant or implant debris. The popliteal lymph node did not become tender, painful, or enlarged in any patient. As of February, 1989, there has been no significant instance of infection associated with carbon fibers.

Royal Jubilee Pathology Reports

Only 7 of the 21 cases actually contained carbon fibers (Table 19). The reaction around the fibers varied from fibrosis (McCormick) to a relatively florid granulomatous or foreign body reaction (Saunders). Most cases apparently exhibited minor degrees of chronic inflammation with occasional giant cell or foreign body reaction. There was one mention of phagocytosis of carbon debris (Saunders), and one mention of eosinophils (Neubauer).

Fourteen of the 21 cases did not contain carbon fiber in the biopsy material (Table 18). The most common findings were chronic inflammation and/or fibrosis. No giant cells or epithelioid cells were specifically mentioned. (Giant cells and/or epithelioid cells including histiocytes were specifically mentioned in 5 of 7 cases where carbon fibers were seen.) Other findings included synovial hyperplasia and hemosiderin-laden macrophages, both of which are probably related to previous injury and disease.

Histological Characterization of Furnished Biopsied Tissue

Three synovial specimens and four ligament specimens contained carbon fibers, although only a few fibers were seen in two of the synovial specimens. Sections from the ligament and synovia that contained carbon usually revealed a mild foreign-body type granulomatous reaction to carbon fibers. This reaction was usually characterized by occasional multinucleate giant cells and/or epithelioid cells which frequently encased the carbon fibers. Scattered lymphocytes were seen in and around the giant cells. Time did not appear to correlate with specific findings. Carbon fibers remained sharply defined. Macrophages containing particulate carbon were not seen.

There was usually an ingrowth of fibroblasts and occasionally capillaries between the carbon fibers, with moderate to large amounts of collagen separating the carbon fibers. There appeared to be more collagen when the fibers were further apart.

Hemosiderin-laden macrophages were occasionally seen. These probably resulted from hemorrhage from previous surgery. Several specimens had synovial cell hyperplasia which may relate to previous disease and/or injury in the joint.

The observations made on pathology specimens examined in Canada at the Royal Jubilee essentially concurred with those seen in these specimens.

Conclusion

The synovial reaction to carbon fiber is similar to that seen with various types of suture material. The reaction is a mild foreign-body granulomatous reaction. The carbon fibers appear sharp and not scalloped or eroded, indicating no apparent breakdown of the carbon fiber. Carbon-containing macrophages were not seen in the synovial biopsies.

Particulate carbon material was not seen in the tissues surrounding the carbon fibers in the ligament; it was mentioned only once in the material that was examined at Royal Jubilee. These fibers apparently act as a framework for the ingrowth of fibroblasts which then lay down collagen fibers.

Neither the pathology reports from Royal Jubilee nor analysis of the furnished synovial biopsies provided evidence of any pathologic signs or conditions which would be viewed as a contra-indication to the intra-articular use of carbon fibers.

TABLE 1. Acute Cases Included in the Canadian Study. The listing includes all patients entered into the study during the study period (8/83 to 7/85).

CARBON-FIBER CASES

PATIENT NUMBER	NAME	DATE OF SURGERY
1	Hesselink, Ronald	1-25-84
2	Knudsen, Kelly	3- 9-84
3	Glowicki, David N.	4-25-84
4	Shillings, Cindy	6-19-84
5	Cameron, Vinzenza	7-10-84
6	Musfelt, Michael	7-14-84
7	Sandhu, Parvinder	10-7-84
8	Watson, Kevin	11-18-84
9	Russell, Darren	7- 7-84

CONTROL CASES

NUMBER	NAME	DATE OF SURGERY
10	Carbery, Brock	11-23-84
11	Bosenee, Tanya	2- 6-85
12	Hilberry, Meryle	4- 7-85
13	Brambell, Chris	4-10-85
14	Zubovic, Shirley	4-26-85
15	Copplestone, Alan	5-18-85

TABLE 2. Chronic Cases Included in the Canadian Study. The listing includes all patients entered into the study during the study period (8/83 to 7/85).

CARBON-FIBER CASES

PATIENT NUMBER	NAME	DATE OF SURGERY
1	Antonson, L.O.	11-14-83
2	McCormack, T.L.	12-7-83
3	Dyer (Matthews), I.	12-9-83
4	Mitchell, Michael	12-13-83
5	Tenning, Mark A.	1- 9-84
6	Drummond, Sandra	2- 8-84
7	Goldring, Paul S.	3- 7-84
8	Sykora, Edward	5- 7-84
9	Graham, Nelson P.	5- 9-84
10	Snowden, Marisa L.	5-25-84
11	Young, Richard R.	5-30-84
12	Willson, Garth E.	6-15-84
13	Gullickson, Karen	6-20-84
14	Stafford, Nigel	8- 1-84
15	Elliott, Richard D.	8- 8-84
16	Saunders, Ruth	9- 7-84
17	St. Hilaire, Bertrand	10-1-84
18	Cummings, Darryl	10-24-84
19	Neubauer, Carrie L.	11-5-84
20	Holmes, Stephen L.	11-13-84
21	Moore, Barbara D.	11-28-84
22	Smart, Vance	1-16-85
23	Sparks, Daryl W.	2- 4-85
24	Kaiser, Robert	2-11-85
25	Bowie, Susan	4-15-85
26	Johnson, Fred	4-29-85
27	Saddlemyer, Leslie	7-17-85

CONTROL CASES

NUMBER	NAME	DATE OF SURGERY
28	Staples, Kevin R.	8- 5-83
29	Laughlin, Andre H.	11-22-83
30	Lamb, Jim E.	1- 4-84
31	Caudle, Larry G.	2- 6-84
32	McCordic, Mark A.	3-19-84
33	Huber, David W.	5- 4-84
34	Manning, Benjamin	6-11-84
35	Drobott, Raymond A.	7-18-84
36	Thorne, Karen I.	9- 7-84
37	Denison, Brock G.	9-12-84
38	Johnny, Stephen W.	10-31-84
39	Brown, James G.	11-26-84
40	Haddon, Thomas	12-13-84
41	Murray, David	12-18-84
42	Hayton, Shelley	1-30-85
43	Hollings, Kim	1-31-85
44	Bryan, Joel E.	2-13-85
45	Callan, Martin	3-11-85
46	Gillingham, Milton	5- 6-85
47	MacDonald, Katherine	5-27-85
48	Toupin, Francois	5-31-85
49	DeCooman, Melody	7-22-85

TABLE 3. Chronic Cases Involving Carbon-Fiber Reconstruction of the PCL in the Canadian Study. The listing includes all patients entered into the study during the study period (5/83 to 7/85).

PATIENT NUMBER	NAME	DATE OF SURGERY
1	Winter, Suzanne	5- 9-83
2	Bridges, Mark	7-18-83
3	Cragg, Joan	12-28-83
4	Law, Gary	6-22-84
5	Hutchinson, Thomas	12-5-84

TABLE 4. Chronic Carbon-Fiber Cases Included in the Canadian Study. The listing includes all patients entered into the study during the study period 8/83 to 7/85. Numbers in parentheses indicate the number of postoperative months at which the corresponding clinical assessments were made. IT, iliotibial band. ST, semitendinosis. Unless otherwise indicated, a synovial biopsy was taken during each arthroscopy.

NAME	DATE OF SURGERY	AUTOLOGOUS TISSUE	FOLLOW-UP			COMMENTS
			Symp.	Func.	Stab.	
Antonson, L.O.	11-14-83	IT	(12) 3.25	4	4	Arthroscoped at 1 year. Knee feels stable. Central core of ACL is carbon fiber. Some CF exposed. No evidence of CF debris or staining.
			(35) 2.75	3	4	
McCormack, T.L.	12-7-83	IT	(12) 4.0	3	3	Arthroscoped at 1 year. Knee in general looks excellent. No significant synovitis or CF debris within joint. Some CF staining at base of ACL.
Dyer, I.S.	12-9-83	IT	(12) 5.0	3	5	Arthroscoped at 1 year. Considerable adhesion formation noted. CF stippling of synovium and CF debris in synovium. ACL looks good.
			(26) 3.25	3	5	
			(36) 3.25	1	5	
Mitchell, M.	12-13-83	IT	(13) 4.75	3	-	Arthroscoped at 1 year. No significant adhesion formation or synovial reaction. No CF debris seen.

Table 4 (cont.)

NAME	DATE OF SURGERY	AUTOLOGOUS TISSUE	FOLLOW-UP				COMMENTS
				Symp.	Func.	Stab.	
Tenning, M.A.	1-9-84	IT	(14)	3.5	1	2	Arthroscoped at 1 year. ACL is flimsy; no significant structural support. Few CF debris in deep layers of ACL posteromedially and in fat pad area.
Drummond, S.L.	2-8-84	IT	(12)	4.25	3	4	Arthroscoped at 1 year. Knee joint looks excellent. No CF seen in ligament. Vascular fibrous tissue filling the intercondylar notch.
			(32)	4.25	4	4	
Goldring, P.S.	3-7-84	IT					
Sykora, E.	5-7-84	IT	(12)	3.5	4	3	Arthroscoped at 1 year. Knee joint looks wonderful. CF well incorporated within fibrous substance of ligament. No significant CF deposits in joint. Minor fibrous adhesions in lateral compartment.
			(24)	4.0	4	3	
			(35)	3.75	4	3	
Graham, N.P.	5-9-84	IT	(24)	3.0	3	1	
Snowden, M.L.	5-25-84	IT	(12)	5.0	5	4	
			(27)	5.0	3	4	
Young, R.R.	5-30-84	IT	(18)	4.0	3	4	Arthroscoped at 1 year. Good fibrous tissue of new ACL. Few CF strands incorporated in fibrous tissue posterolaterally. No CF debris within joint. Excellent results.
			(33)	4.25	5	4	

Table 4 (cont).

NAME	DATE OF SURGERY	AUTOLOGOUS TISSUE	FOLLOW-UP	Symp.	Func.	Stab.	COMMENTS
Willson, G.E.	6-15-84	IT	(12)	4.75	5	3	
			(42)	4.5	5	3	
Gullickson, K.E.	6-20-84	IT	(13)	5.0	5	3	
Stafford, N.	8- 1-84	IT	(12)	5.0	5	5	Arthroscoped at 1 year. In general an excellent reconstruction. No exposed CF within the ligament or joint. No debris at all. Joint surfaces in excellent condition. Fibrous adhesions within the medial and lateral gutters. Biopsy taken but pathology report not available.
Elliott, R.D.	8-8-84	IT	(15)	5.0	5	5	
			(27)	4.5	5	5	
Saunders, R.	9-7-84	IT	(12)	2.75	3	3	Arthroscoped at 1 year. No CF debris within joint. Some flecks of CF noted in the superficial layer of the ACL. Repair stretched out to some extent. Arthroscoped again at 2 1/2 years. ACL stretched out. CF debris in the synovium, suprapatellar pouch and fat pad area. CF obviously disrupted within the ligament. Reoperated; CF removed.
			(24)	2.5	2	1	

Table 4 (cont.)

NAME	DATE OF SURGERY	AUTOLOGOUS TISSUE	FOLLOW-UP	Symp.	Func.	Stab.	COMMENTS
St. Hilaire, B.	10-1-84	IT	(12)	3.5	3	5	Arthroscoped at 1 year. ACL repair is in excellent condition and position. Good strength with probing, though ACL is not quite of normal diameter and CF is showing through the fibrous tissue.
			(30)	3.75	4	5	
Cummings, D.	10-29-84	IT	(12)	4.5	5	5	
Neubauer, C.-L.	11-5-84	IT	(12)	2.75	3	4	Arthroscoped at 18 months. CF disengaged from bollard; both removed. Lytic area in bone (shallow crater between tibial drill hole and bollard hole). No mucinous degeneration seen. No free CF except a few microscopic fragments in anterior synovium. No evidence of acute inflammatory reaction, no excessive synovial fluid.
			(27)	3.25	3	4	
Holmes, S.L.	11-13-84	IT	(20)	4.5	1	3	
Moore, B.D.	11-28-84	IT	(12)	3.5	3	4	
			(30)	4.5	3	4	
Smart, V.	1-16-85	IT					
Sparks, D.W.	2-4-85	IT					

Table 4 (cont.)

NAME	DATE OF SURGERY	AUTOLOGOUS TISSUE	FOLLOW-UP				COMMENTS
				Symp.	Func.	Stab.	
Kaiser, R.	2-11-85	IT	(12)	4.0	4	4	Arthroscoped at 1 year. Excellent structural integrity in ligament. A few tiny flecks of CF superficially at base of ligament, but no other CF to be seen. No intra-articular adhesions that could be released. The CF has incorporated very nicely into the neoligament. A biopsy was not taken.
			(24)	4.5	4	5	
Bowie, S.	4-15-85	IT					Arthroscoped at 16 months. CF staining of synovial tissues and anterior fat pad tissues. No overt inflammatory response. Moderate to severe CF debris. Fibrous tissue has delaminated from CF. Minor articular scuffing of the lateral femoral condyle. Joint surfaces look excellent. No significant adhesion formation or hypertrophy of synovial tissue. Biopsy taken but pathology report not available.

Table 4 (cont.)

NAME	DATE OF SURGERY	AUTOLOGOUS TISSUE	FOLLOW-UP	Symp.	Func.	Stab.	COMMENTS
Johnson, F.	4-29-85	IT	(14)	4.75	1	3	Arthroscoped at 1 year. Could find no CF within transfer. Fat pad very fibrous. Some degenerative change (grade 1-2 patchy areas of chondromalacia) in medial and lateral compartments. No CF seen in joint.
			(24)	2.75	1	3	
Saddlemyer, L.	7-17-85	IT	(12)	5.0	4	3	
			(24)	5.0	5	4	

TABLE 5. Chronic Control Cases Included in the Canadian Study. The listing includes all patients entered into the study during the study period 8/83 to 7/85. Numbers in parentheses indicate the number of postoperative months at which the corresponding clinical assessments were made. IT, iliotibial band. ST, semitendinosis. Unless otherwise indicated, a synovial biopsy was taken during each arthroscopy.

NAME	DATE OF SURGERY	AUTOLOGOUS TISSUE	FOLLOW-UP				COMMENTS
				Symp.	Func.	Stab.	
Staples, K.R.	8-5-83	IT	(24)	3.25	2	4	Arthroscoped at 2 years. Meniscal tear; cruciate reconstruction looks good.
Laughlin, A.H.	11-22-83	IT					
Lamb, J.E.	1-4-84	IT	(24)	4.75	3	4	
Caudle, L.G.	2-6-84	IT					
McCordic, M.A.	3-19-84	IT	(12)	5 0	4	5	
			(30)	5.0	4	4	
Huber, D.W.	5-4-84	IT	(24)	4.25	5	4	
Manning, B.	6-11-84	IT	(29)	4.25	3	4	
Drobott, R.A.	7-18-84	IT	(12)	4.75	4	3	Arthroscoped at 17 months. Cruciate transfer present and in anatomic position, but quite flimsy. Minor grade 1 to 2 fibrillation in intercondylar notch area, and early intercondylar osteophyte forming.
Thorne, K.I.	9-7-84	IT	(12)	4.5	3	4	Arthroscoped at one year. Knee generally stable. Reconstruction stretched out. Chronic synovitis.

Table 5 (cont.)

NAME	DATE OF SURGERY	AUTOLOGOUS TISSUE	FOLLOW-UP Symp.	Func.	Stab.	COMMENTS
Denison, B.G.	9-12-84	IT	(12) 4.55	4	3	
Johnny, S.W.H.	10-31-84	ST	(12) 4.25	5	3	
Brown, J.G.	11-26-84	ST	(27) 5.0	5	4	
Haddon, T.	12-13-84	ST	(12) 4.25	3	4	
Murray, D.	12-18-84	ST	(12) 4.5	5	5	Arthroscoped at 1 year. Synovium in fat pad area. Staple removed.
Hayton, S. (complex)	1-30-85	ST	(12) 3.75	4	2	
			(14) 3.75	4	2	
			(30) 3.75	3	4	
Hollings, K.M.	1-31-85	ST	(12) 4.75	4	4	
Bryan, J.E.	2-13-85	ST	(18) 4.5	3	3	
			(24) 4.5	3	3	
Callan, M.	3-11-85	ST	(12) 4.0	3	4	
			(24) 4.5	5	4	
Gillingham, M.G.	5-6-85	ST	(18) 4.25	2	4	Arthroscoped at 1 year. ACL graft intact and in good position. A fibro-fatty nodule found in the intercondylar notch caused by necrosis.
			(24) 5.0	4	4	
			(27) 5.0	1	4	
MacDonald, K. (complex)	5-27-85	ST	(12) 3.0	3	3	
			(24) 4.0	4	3	
Toupin, J.S.	5-31-85	ST	(12) 3.75	1	5	
DeCooman, M.	7-22-85	ST	(12) 4.0	4	3	
			(24) 5.0	4	3	

TABLE 6. Acute Carbon-Fiber Cases Included in the Canadian Study. The listing includes all patients entered into the study during the study period 8/83 to 7/85. Numbers in parentheses indicate the number of postoperative months at which the corresponding clinical assessments were made. IT, iliotibial band. ST, semitendinosis. Unless otherwise indicated, a synovial biopsy was taken during each arthroscopy.

NAME	DATE OF SURGERY	AUTOLOGOUS TISSUE	FOLLOW-UP				COMMENTS
				Symp.	Func.	Stab.	
Hesselink, R.	1-25-84	IT	(24)	4.5	5	4	
Knudsen, K.	3-9-84	IT	(12)	4.5	4	4	Arthroscoped at 1 year. Moderate synovial reaction. Considerable CF debris in anterior fat pad and medial and lateral compartments. Some Grade I and II articular chondromalacia involving medial femoral condyle.
			(24)	3.25	3	4	
Glowicki, D.	4-25-84	IT	(20)	4.5	5	5	Arthroscoped at 31 months after reinjury. Some CF debris in synovium throughout the joint, some concentrations in anterior fat pad. Patch of CF adhering to synovial surface of medial femoral condyle. ACL completely ruptured; frayed fibrous tissue with CF stippling within it. Reoperated.
			(30)	4.5	3	3	
Shillings, C.L.	6-19-84	IT	(12)	4.5	4	5	
Cameron, V.	7-10-84	IT	(17)	4.5	5	5	
			(27)	4.5	5	4	
Musfelt, M.	7-14-84	ACL remnants					

Table 6 (cont.)

NAME	DATE OF SURGERY	AUTOLOGOUS TISSUE	FOLLOW-UP				COMMENTS
				Symp.	Func.	Stab.	
Sandhu, P.	10-7-84	ST	(14)	4.75	5	5	
			(24)	4.5	5	4	
Watson, K.	11-18-84	IT	(12)	5.0	4	5	
			(24)	3.5	1	5	
Russell, D.R.	12-7-84	IT					

TABLE 7. Acute Control Cases Included in the Canadian Study. The listing includes all patients entered into the study during the study period 8/83 to 7/85. Numbers in parentheses indicate the number of postoperative months at which the corresponding clinical assessments were made. IT, iliotibial band. ST, semitendinosis. Unless otherwise indicated, a synovial biopsy was taken during each arthroscopy.

NAME	DATE OF SURGERY	AUTOLOGOUS TISSUE	FOLLOW-UP			COMMENTS
			Symp.	Func.	Stab.	
Carbery, B.A.	11-23-84	ST	(24) 4.25	5	5	Arthroscoped at 8 months. Adhesions found in several areas throughout the joint. Biopsy not taken.
Bosence, T.	2-6-85	ST	(12) 5.0	5	5	Staple removed at CF attachment to femur (4 months post-op).
Hilberry, M.	4-7-85	ST				
Brambell, C.	4-10-85	ST	(12) 4.75	4	5	
			(24) 5.0	3	5	
Zubovic, S.	4-26-85	ST				
Copplestone, A.	5-18-85	ST				

TABLE 8. Chronic PCL Carbon-Fiber Cases Included in the Canadian Study. The listing includes all patients entered into the study during the study period 5/83 to 7/85. Numbers in parentheses indicate the number of postoperative months at which the corresponding clinical assessments were made. IT, iliotibial band. ST, semitendinosis. Unless otherwise indicated, a synovial biopsy was taken during each arthroscopy.

NAME	DATE OF SURGERY	AUTOLOGOUS TISSUE	FOLLOW-UP				COMMENTS
				Symp.	Func.	Stab.	
Winter, S.	5-9-83	ST	(12)	3.5	1		
			(38)	3.0	2	2	
Bridges, M.	7-18-83	ST	(12)	4.75	2		
			(36)	4.75	3	2	
Cragg, J.	12-28-83	ST	(12)	2.5	1		
			(26)	1.75	1		
			(36)	1.5	1	1	
Law, G.	6-22-84	ST	(21)	4.25	5	2	
Hutchinson, T.	12-5-84	ST	(12)	5.0	4		
			(27)	4.75	5	4	

		TIME POST-OPERATIVELY (Months)			
		0-12 (N)	13-24 (N)	25-36 (N)	>36 (N)
TREATMENT GROUP	CARBON	4.0 ± 0.8 (12)	4.2 ± 0.9 (15)	3.7 ± 0.8 (14)	4.5 (1)
	CONTROL	4.2 ± 0.6 (8)	4.5 ± 0.4 (13)	4.3 ± 0.6 (8)	3.0 (1)

TABLE 9. SYMPTOMS Scores in Chronic Canadian Patients. N, number of patients.

		TIME POST-OPERATIVELY (Months)			
		0-12 (N)	13-24 (N)	25-36 (N)	>36 (N)
TREATMENT GROUP	CARBON	4.7 ± 0.2 (5)	4.2 ± 0.5 (4)	4.1 ± 0.7 (3)	--
	CONTROL	4.8 ± 0.2 (3)	4.6 ± 0.5 (2)	--	--

TABLE 10. SYMPTOMS Scores in Acute Canadian Patients. N, number of patients.

		TIME POST-OPERATIVELY (Months)			
		0-12 (N)	13-24 (N)	25-36 (N)	>36 (N)
TREATMENT GROUP	CARBON	4.2 ± 0.7 (17)	4.2 ± 0.8 (19)	3.8 ± 0.7 (17)	4.5 (1)
	CONTROL	4.3 ± 0.6 (11)	4.5 ± 0.4 (15)	4.3 ± 0.6 (8)	3.0 (1)

TABLE 11. SYMPTOMS Scores in All (Chronic plus Acute) Canadian Patients. N, number of patients.

		TIME POST-OPERATIVELY (Months)			
		0-12 (N)	13-24 (N)	25-36 (N)	>36 (N)
TREATMENT GROUP	CARBON	3.7 ± 0.8 (12)	3.1 ± 1.7 (15)	3.4 ± 1.2 (14)	5 (1)
	CONTROL	3.9 ± 0.8 (8)	3.4 ± 1.0 (13)	3.2 ± 1.4 (8)	3 (1)

TABLE 12. FUNCTION Scores in Chronic Canadian Patients. N, number of patients.

		TIME POST-OPERATIVELY (Months)			
		0-12 (N)	13-24 (N)	25-36 (N)	>36 (N)
TREATMENT GROUP	CARBON	4.4 ± 0.5 (5)	4.0 ± 2.0 (4)	3.7 ± 1.2 (3)	--
	CONTROL	4.3 ± 0.6 (3)	4.0 ± 1.4 (2)	--	--

TABLE 13. FUNCTION Scores in Acute Canadian Patients. N, number of patients.

		TIME POST-OPERATIVELY (Months)			
		0-12 (N)	13-24 (N)	25-36 (N)	>36 (N)
TREATMENT GROUP	CARBON	3.9 ± 0.8 (17)	3.3 ± 1.7 (19)	3.5 ± 1.1 (17)	5 (1)
	CONTROL	4.0 ± 0.8 (11)	3.5 ± 1.1 (15)	3.2 ± 1.4 (8)	3 (1)

TABLE 14. FUNCTION Scores in All (Chronic plus Acute) Canadian Patients. N, number of patients.

		TIME POST-OPERATIVELY (Months)			
		0-12 (N)	13-24 (N)	25-36 (N)	>36 (N)
TREATMENT GROUP	CARBON	3.8 ± 0.8 (11)	3.6 ± 1.2 (14)	3.9 ± 1.4 (14)	3 (1)
	CONTROL	3.6 ± 0.7 (8)	3.6 ± 0.9 (13)	3.9 ± 0.4 (8)	3 (1)

TABLE 15. STABILITY Scores in Chronic Canadian Patients. N, number of patients.

		TIME POST-OPERATIVELY (Months)			
		0-12 (N)	13-24 (N)	25-36 (N)	>36 (N)
TREATMENT GROUP	CARBON	4.6 ± 0.6 (5)	4.8 ± 0.5 (4)	3.7 ± 0.6 (3)	--
	CONTROL	5.0 ± 0.0 (3)	5.0 ± 0.0 (2)	--	--

TABLE 16. STABILITY Scores in Acute Canadian Patients. N, number of patients.

		TIME POST-OPERATIVFLY (Months)			
		0-12 (N)	13-24 (N)	25-36 (N)	>36 (N)
TREATMENT GROUP	CARBON	4.1 ± 0.8 (16)	3.8 ± 1.2 (18)	3.8 ± 1.2 (17)	3 (1)
	CONTROL	4.0 ± 0.9 (11)	3.8 ± 0.9 (15)	3.9 ± 0.4 (8)	3 (1)

TABLE 17. STABILITY Scores in All (Chronic plus Acute) Canadian Patients. N, number of patients.

TABLE 18. Carbon-Fiber Group without Fibers in the Biopsied Tissue.

PATIENT	MONTHS	LYMPHS	GIANT CELLS	EPITHELIOID	FIBERS	PLASMA CELLS	COMMENT
ANTONSEN, Lorne Synovium	12	Prob.	?	?	-	?	Mild chronic inflam. with hemosiderin
MITCHELL, Michael Synovial membrane	12	-	-	-	-	-	
Suprapat. pouch synovium		Prob.	-	-	-	?	Mild chronic inflam.
Anterior cruciate		Prob.	-	-	-	?	Mild chronic inflam.
DRUMMOND, Sandra Fat pad synovium	12	-	-	-	-	-	Fibrosis
Anterior cruciate		-	-	-	-	-	
TENNING, Mark Synovium	13	?	?	?	?	?	Fibrosis
SYKORA, Edward Fat pad synovium	12	+	-	-	-	?	Chronic synovitis
Suprapat. pouch synovium		-	-	-	-	-	
Anterior cruciate		-	-	-	-	-	
YOUNG, Richard Synovium (no tissue)	12						
Anterior cruciate		-	-	-	-	-	Fibrosis
STAFFORD, Nigel Synovium	13	?	-	-	-	?	Chronic synovitis, Hemosiderin
SAUNDERS, Ruth Fat pad synovium	12	?	-	-	-	?	
Anterior cruciate		?	-	-	-	?	
ST. HILAIRE, Bertrand Knee ligament	14	-	-	-	-	-	
Fat pad, suprapat. synov.		+	-	-	-	?	Pap. synov. hyper-plasia, chr. synov.
JOHNSON, Frederick Synovium	12	?	-	-	-	?	Fibrosis
THORNE, Karen Synovium	13	Prob.	-	-	-	?	Chronic synovitis
MURRAY, David Synovium	11	Mild	-	-	-	?	Mild chr. inflam.
DROBOTT, Raymond Synovium	17	?	-	-	-	?	Fibrosis
GILLINGHAM, Milton Synovium	13	Prob.	-	-	-	?	Fibrosis, mild chronic inflammation

TABLE 19. Carbon-Fiber Group with Fibers in the Biopsied Tissue.

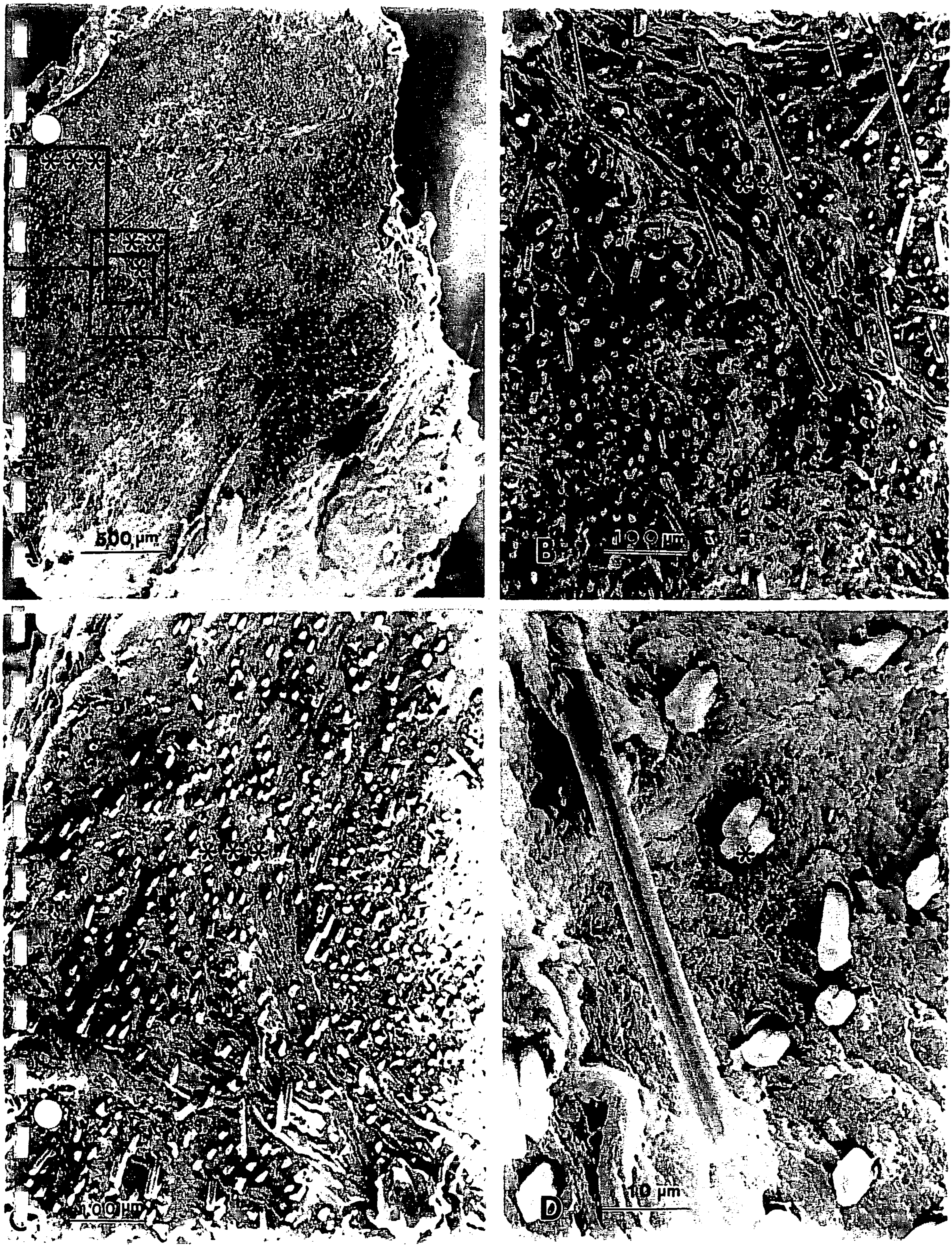
PATIENT	MONTHS	LYMPHS	GIANT CELLS	EPITHE-LIOID	FIBERS	PLASMA CELLS	COMMENT
TENNING, M. (wound infect.) Soft tissue outside knee	4	+	+	+	+	?	Chronic granulomat.
Synovial bx.		+	-	-	-	+	Chronic synovitis
DYER, Irene Fat pad synovium	12	Prob.	-	-	+	?	Mild chronic inflam.
Suprapat. pouch synovium		Prob.	-	-	+	?	Mild chronic inflam.
Anterior cruciate		-	-	-	-	-	Fibers embedded in fibrous tissue
McCORMICK, Terri Fat pad synovium	12	-	-	-	-	-	
Suprapat. pouch synovium		-	-	-	-	-	
Anterior cruciate		-	-	-	+	-	
NEUBAUER, Carrie Carbon fiber strand	14	+	?	Histio-cytes	+	?	Eosinophils
Bone biopsy, fixation site		-	-	-	-	-	
Anterior cruciate		-	-	-	+	-	Mucoid & fibrillar degeneration of lig. away from fibers
Synovium		?	-	-	-	?	Mild prolif. synov.; Fibrosis
SAUNDERS, Ruth Synovium	25	?	-	?	+	?	Mild proliferative synovitis with phagocytosis of carbon debris
Anterior cruciate		Prob.	+++	+++	+	Prob.	Granulomat. inflam., fibrosis
KNUDSEN, Kelly Fat pad synovium	12	Prob.	+	+	+	?	
Anterior cruciate		?	-	-	+	?	
Synovium	13	Prob.	-	-	-	?	Chronic synovitis
GLOWICKI, David Synovium	31	+	+	+	+	?	Chronic inflam.; Hemosiderin
Anterior cruciate		?	-	-	+	?	Fibrosis; Increased vascular.

TABLE 20. Plastafil Observations Regarding Canadian Biopsy Specimens.

PATIENT	MONTHS	GIANT/EPITHELIOID CELLS	FIBROBLASTS	DENSE COLLAGEN	FIBERS	HEMOSID.	COMMENT
GLOWICKI, David (C-1) ligament	30	rare-occ.	+++	++++	+	-	
GLOWICKI, David (C-2) synovium	30	-	+++	++++	Few	+	Occ. incr. capillaries; syn. hyperplasia
SAUNDERS, Ruth Intra-artic. (C-8)	32	Occ.	+++	++++	+	-	
Extra-artic. (C-9)		Occ.	+++	++++	+	-	Where fibers are close more fibroblasts & less collagen
WATSON, Kevin (C-12) ligament	50	Occ.	++++	++	+	-	
WATSON, Kevin (C-13) synovium	50	Occ.	++	++	+	+	Incr. cap., syn. hyperplasia; Focal mild chr. inflammation
MAXWELL, Terry (C-14) ligament	35	Occ.	++++	++	+	Few	Few chronic inflam. cells
DRUMMOND, Sandra (C-4) synovium	12	Occ.	++++	++	Few	Rare	Incr. cap., syn. hyperpl.; Polarizable brown pig. in synovial cells; Chronic inflammation
PARKER, Scott (C-10) synovium		-			-	+	Focal mild chr. inflam.; Incr. cap.

FIGURE 1

SEM cross-sectional view of the extra-articular portion of the reconstructed anterior cruciate ligament removed from David Glowicki 30 months postoperatively. A, cross-sectional view of the specimen. B-D, higher-power views taken from the regions indicated in A. Dotted line in A indicates the location of the epon-embedded sections that were prepared for pathological evaluation.



500 µm
B
100 µm
100 µm
D
10 µm

APPENDIX 1

Transcript of a composite video arthroscopy. Dr. Penny selected the videos of 7 arthroscopies in patients that received carbon fibers for ACL insufficiency, 3 ACL control patients, and 2 cases involving PCL reconstruction. A copy of the video is included in this volume. This Appendix contains a transcript of Dr. Penny's narration of the composite video.

This tape represents video arthroscopy follow-up on patients having undergone carbon-fiber augmentation of ligament reconstructions.

Case 1: R.K.

25 years old; right knee; 14 months post-reconstruction for anterior cruciate ligament reconstruction of the right knee. He is an excellent clinical follow-up. An anterior cruciate ligament which seems to be of excellent caliber. The fibrous tissue well-incorporated into the carbon fiber. No carbon fiber seen. Good tensile strength in the ligament. The original iliotibial band tissue is quite flimsy and is obviously hypertrophied considerably and formed a composite ligament with carbon fiber. A few tiny flecks of carbon fiber can be seen in the anterior fat pad area. Otherwise, no other carbon fiber is visible within the ligament or within the knee joint. Probing the ligament carefully, I could not lift off the fibrous tissue from around the ligament, so the new tissue has incorporated between the carbon fibers to form a composite neoligament. A few flecks of carbon fibers can be seen in this view staining the fat pad area and a few tiny fibers which have escaped. I am going into the medial compartment. The medial meniscus looks healthy, and the medial side wall. No evidence of carbon-fiber debris anywhere. Also on the lateral side, no evidence of carbon-fiber debris anywhere. Carbon fiber debris, when it occurs, seems to occur mainly in the anterior fat pad area and around the medial and lateral side walls of the suprapatellar pouch.

This gentleman also had repair of a peripheral tear in his medial meniscus. This is his medial meniscus, now 14 months post-repair, and it looks excellent. This repair was done by open means at the same time as his reconstruction. As will be seen in a moment, there is a very small area posteriorly that I can pass the probe through where the meniscus has not been healed through the synovial junction, but there is no instability of this meniscus. There is a small defect through which the probe can pass, a residual of the previous meniscus tear right at the meniscus-synovial junction. But the meniscus is otherwise (satisfactory). The articular surfaces look healthy. There are adhesion formations at certain parts of the reconstruction. The reconstruction consisted of extra-articular and intra-articular reconstruction using iliotibial band, tubulated to cover the carbon fibers. The iliotibial band is taken beneath the collateral ligament on the lateral side so as to act as a lateral restraint before it is passed over the top of the femoral condyle and into the knee joint. This is the standard procedure used for all anterior cruciate reconstructions demonstrated here. No evidence of carbon fiber in the medial compartment. This case is one of the better ones seen. The camera gave us good visibility despite the video arthroscopy later that gave us poor quality because of the poor camera system, and therefore I have taken more time than usual to demonstrate the entire evaluation. No evidence of carbon-fiber debris within the suprapatellar pouch. No evidence of hypertrophic synovitis along the lateral side wall here, some vascularity seen but no evidence of carbon-fiber vascularity in the synovium. Biopsies were taken in all of these cases of synovium in the suprapatellar pouch, anterior fat pad, and base of the anterior cruciate ligament. In this case there was no significant inflammatory response and no carbon fibers seen. This is the lateral compartment. This is a good-looking knee joint, the one you'd like to see after every knee reconstruction. Once again probing the anterior cruciate ligament, trying to demonstrate whether or not the fibrous tissue had ingrown into the carbon fibers or was simply attaching a covering. In this location there was a fibrous adhesion running up from the cruciate ligament to the condylar notch area. This demonstrates that one of the fibrous-tissue sources is the surrounding synovium, and not just the iliotibial band. The fat seems to come down into the bone hole.

Case 2: P.S.

27-year-old male, 12 months following reconstruction of left knee. Quality of picture a little poorer than the last. This was an old camera that gave us some trouble. The reconstruction here of his anterior cruciate ligament is excellent. Good caliber ligament; excellent tensile strength on probing. Good fibrous infiltration of the carbon fiber, but around the lateral side one can just see a few carbon fibers showing through the overlying fibrous tissue. The carbon fibers are well incorporated into the fibrous tissue, however. The fibrous tissue could not be separated from the carbon fiber, so a composite neoligament has been produced which is considerably thicker than the implanted iliotibial band/carbon-fiber ligament. No significant adhesion formation around the new ligament. He has a small osteophyte in the intercondylar notch. He has long-standing anterior cruciate insufficiency and has had a previous medial meniscectomy. Once again, a view of a few of the carbon fibers just showing through the fibrous tissue, but no loose carbon fiber within the joint. Looking into the fat pad area where often the carbon fiber is seen, it looks clear. Biopsies were taken which showed no carbon fiber microscopically. Medial compartment where the old medial meniscectomy has been done. The articular surfaces are smooth, and show no evidence of abrasion. The meniscus rim looks healthy. No carbon-fiber deposition along the meniscus-synovial junction or medial peripatellar/medial femoral gutter. Clinically, this man had an excellent result with a stable knee. No evidence of pivot shift. Looking into the suprapatellar pouch, the synovium is free of carbon-fiber debris. There is no significant evidence of adhesion formation. These patients are kept three weeks in a solid cast and then begun on range of motion, and a few of them do show fibrous adhesions begun on range of motion.

Case 3: R.Y.

27 years old, male; 12 months following reconstruction for anterior cruciate insufficiency right knee. He also had a medial meniscus repair done. This is a carbon-fiber augmentation. In this case the fat pad had adhesed down to the front of the graft and there was quite a bit of synovium in the intercondylar notch. A band of tissue much like the ligament and mucosum obscuring visualization to some extent. The ligament itself, however, looked healthy, strong, good fibrous tissue, no evidence of carbon fiber. This case also exemplifies a good result with excellent infiltration of the carbon fiber by the surrounding host fibrous tissue. Probing the posterior aspect of the ligament

at its entry point into the bone. Also trying to lift off the surface fibrous tissue to see whether or not there is any exposed carbon fiber. One can see the excellent tensile strength within this ligament. Pulling hard with the probe. Usually when I arthroscope these I'm not particularly gentle with the ligament. I pull hard on it to check its tensile strength, and also probe it thoroughly to see if the fibrous tissue is just a flimsy covering over the carbon fiber or whether it has actually infiltrated between the carbon fibrils. No significant synovitis in the intercondylar notch. Medial compartment looks good. This gentleman had a medial meniscus repair. It's not probed on this video, but it was excellent. It looks like a normal meniscus. Retropatellar surface shows no evidence of carbon fiber, no staining of the suprapatellar synovium, no significant adhesion formation, no inflammatory synovitis. A few wispy bits of synovium which are compatible with post-reconstruction changes. These are seen in knees who have not had carbon fiber as well. The lateral gutter; this area tends to collect carbon fiber when it is free within the joint.

Case 4: St.H.

Male, 33 years old, 14 months post-reconstruction for chronic anterior cruciate insufficiency of the right knee. He has had a previous medial meniscectomy. Initial evaluation showed this ligament and mucosum as a postoperative artifact and adhesion from the fat pad area coming down to the vicinity of the cruciate ligament. Working our way around this, the ligament itself would seem to be healthy and strong, very similar to the previous case. Good fibrous ligament, perhaps not quite to the normal diameter of the cruciate ligament. Slight laxity. Clinically, this man's knee felt stable with only a trace of Lachman test, and no pivot shift. There was a little bit of dark staining of the fibrous tissue as if we were looking at the carbon fiber through the fibrous tissue right in that central location. The quality of the fibrous tissue is excellent. No evidence of carbon-fiber debris within the joint. Synovial biopsies from multiple sites in this man showed no evidence of inflammatory change and no carbon-fiber debris. Just debriding now the tissue which is obscuring our visualization of the cruciate. This was flimsy tissue and was not adding anything to the repair. This gentleman had excellent objective findings but was complaining of chronic discomfort in the knee. He is a workmen's compensation case. In such cases where there are symptoms, I usually debride the fibrous adhesions and any areas of synovial hypertrophy. The ligament now can be seen a little better. Not quite normal caliber. A little bit of laxity within it, but still exhibiting excellent tensile strength on probing and excellent incorporation of fibrous tissue into the carbon fiber. The net result therefore is a biologic ligament which has been protected and strengthened by the carbon fiber in the early stages. He has had a partial medial meniscectomy which looks healthy, no carbon-fiber staining of joint surfaces or medial synovium, no evidence of inflammatory change within the joint. Looking at the cruciate ligament now from the other portal from the medial side. Sometimes, looking underneath the ligament, one can see some of the carbon fiber staining through. I just had the impression there that if we could just see some carbon fiber deep within the fibro-ligament but I could not strip the fibrous tissue away from the carbon fiber, and I feel it is therefore a well-incorporated neoligament. Suprapatellar pouch view, camera unfortunately a little blurred here, but there was no evidence of carbon fiber debris. A few synovial adhesions which were later debrided.

Case 5: M.M.

23-year-old male, right knee; arthroscopy 12 months from reconstruction. Unfortunately, using the old camera which is quite blurred. This gentleman has complex instability with anteromedial and anterolateral instability and marked A-P displacement, and has some residual post-operative instability: grade 2 Lachman test and negative pivot shift. The lateral rotatory instability seems well controlled. He functionally has a good result, but does have increased antero-posterior instability. The cruciate ligament itself is quite flimsy. There is definite fibrous tissue infiltration of the carbon fiber, but it is obviously stretched out and there is a lot of synovium covering the ligament. This seems to be a more flimsy response than the previous cases. No carbon fiber was seen, however. I could not find any carbon fibers within the neoligament, and there was no carbon-fiber debris within the joint despite the stretching out that has occurred. There is some stability afforded by this ligament, but very little. Plainly, his reconstruction has controlled his rotatory instability.

Case 6: T.Mc.

22-year-old female, 12 months post-reconstruction left knee. She has a complex instability with anteromedial and anterolateral instability and had a medial and lateral side reconstruction including pes anserinus transfer. This is a carbon-fiber augmentation of the anterior cruciate ligament. She had quite a bit of synovial tissue filling the intercondylar notch and anterior fat pad area, but this was not inflammatory, simply hypertrophic. There was one fibrous adhesion here stretching from the fat pad area to the base of the cruciate ligament. She has had a medial meniscectomy. Initially, a debridement was done removing this adhesion and also some of the fat pad tissue to gain better visualization of the knee. I could not see any carbon fiber in the ligament itself; it was well incorporated, but there was a small amount of carbon-fiber staining of the anterior fat pad tissues. Biopsy samples were sent to the laboratory which showed no inflammatory reaction. Poor quality picture. This is the anterior cruciate ligament with carbon fiber. Looking quite resilient on testing; some stretching out. She had residual instability with a grade 2 Lachman test and a grade 1 pivot slide. The actual pivot jerk has been obliterated. Hers was a markedly unstable knee preoperatively, and marginally improved postoperatively. Her functional result was fair but not excellent. The result of the carbon-fiber augmentation, however, indicates good incorporation into the neoligament. In general, I have found complex instabilities with large degrees of antero-posterior displacement tend to stretch out postoperatively despite using carbon fiber. Perhaps using patellar tendon or semitendinosis tendon would increase the tensile strength of this ligament. Showing a few carbon-fiber flecks there within the fat pad tissues. No inflammatory reaction around them, simply little tiny flecks of carbon fiber, less than 1 mm long, staining the anterior fat pad. Of 20 cases arthroscoped, I had 3 such patients.

Case 7: I.M.

24-year-old female, right knee; 20 months post-reconstruction for chronic anterior cruciate insufficiency. She has an excellent functional result. She was re-arthroscoped because she had sustained a medial meniscus tear. She exhibits the most florid case of carbon-fiber exposure and debris within the joint. Here is the carbon-fiber tow well seen within the ligament, just flimsy fibrous tissue covering over the carbon fiber. Obviously no significant fibrous-tissue infiltration of the carbon fiber itself, but rather just flimsy tissue covering over top of it. There was some resiliency to this ligament. The carbon fiber itself still seemed to have tensile strength and the surrounding fibrous tissue did to some extent, but the quality of the fibrous invasion of the carbon fiber was extremely poor. As a result of the exposed carbon fiber there was also a lot of debris within the joint. I was surprised to find this because her clinical result is excellent, with complete obliteration of the pivot shift and only a trace of Lachman test, and an excellent functional and symptomatic result -- so good, in fact, that she re-tore the meniscus participating in a recreational sport. Tensile strength seems reasonable despite the flimsy nature of the tissue. Now we can see the extent of carbon-fiber staining here of the fat pad tissues, blackening the tissues. Interestingly enough, no significant inflammatory hypertrophy. Here is a small area of chondromalacia of the medial femoral condyle, and one can see the carbon fiber adhering to the abnormal articular cartilage. There was no carbon fiber adhering to normal articular surfaces. Looking up along the medial side wall of the knee, extensive carbon-fiber staining of the synovium, very black in areas. Once again, no inflammatory villus formation. There are quite a few adhesions within the suprapatellar pouch; some of these were debrided. This case is the most florid example of carbon-fiber deposition that I have. I had three cases with extensive carbon-fiber deposits within the synovium, three other cases just mentioned with minute amounts of carbon fiber.

Case 8: K.S.

30-year-old male, left knee; 27 months post-reconstruction. This gentleman does not have carbon fiber in his knee. He is one of the iliotibial band controls utilizing iliotibial band passed retrograde over the femoral condyle -- an identical procedure to the carbon-fiber case, with no carbon fiber. So he's a good example of a control. Here is the iliotibial band tissue. It has thickened up in response to the surgery. This is thicker, healthier tissue than was implanted, but it is more flimsy than those cases where there has been carbon-fiber augmentation, and can definitely be deformed with probing. It's providing only a minimum of antero-posterior stability. He has a good functional result with a grade 1 Lachman test and no pivot shift. I think the lateral reconstruction is particularly important, the extra-articular reconstruction for obliterating the pivot shift which then obliterates the sign. In the distance you can see a bucket-handle tear of the medial meniscus which was the reason he was re-arthroscoped. He eventually had a trans-arthroscopic meniscectomy. No significant adhesion formation, no inflammatory synovitis. Synovial biopsy in this case and other controls indicated a similar synovial response to those who had carbon fiber.

Case 9: R.B.

23-year-old male, right knee; 18 months post-reconstruction using iliotibial band. Once again, no carbon fiber used; this is one of the control cases using iliotibial band as the intra-articular graft. The graft is in good position, but the quality of the tissue looks quite flimsy. This man has also had partial medial and lateral meniscectomies in the past. He has a good functional result. No pivot shift, moderate antero-posterior instability. The quality of this tissue is pretty flimsy. I did not think it was providing any substantial amount of support to antero-posterior movement. There is perhaps slight hypertrophy of the tissue since implantation, but definitely stretched out. I don't think there is any question but that the addition of carbon fiber in most cases augments this tissue, strengthens it, and causes it to hypertrophy. These cases did serve as controls for biopsy purposes as well, the synovial tissue looking very similar to the carbon-fiber group. Here, the anterior drawer being done to show the amount of instability. On biopsy, the synovium is a little thickened but does not show actual inflammatory change. In the carbon-fiber cases a similar situation exists, with phagocytosis of the carbon fibrils seen but no inflammatory reaction. In the carbon-fiber cases, multinucleate giant cells are also seen in the vicinity of the carbon fiber.

Case 10: D.M.

23-year-old male, right knee; arthroscoped 11 months post-reconstruction for chronic anterior cruciate insufficiency. This is a control with no carbon fiber, utilizing semitendinosis tendon as the intra-articular graft and iliotibial band as an extra-articular reconstruction on the lateral side. This is the semitendinosis graft which is in good position, offering some resistance to probing but obviously stretched out, providing not nearly as much resistance as a normal anterior cruciate ligament. The quality of the fibrous tissue is better than with an iliotibial graft, but not as good as those utilizing carbon fiber. No significant inflammatory response. A few synovial adhesions. Biopsy of the synovium, once again, helping us in terms of a control. This gentleman was re-arthroscoped and operated on because of a painful fixation staple on the lateral side of his knee which was removed at the time of this procedure. He has an excellent functional result, with obliteration of the pivot shift and a grade 1 antero-posterior instability. Good-looking joint surfaces.

The next two cases are examples of posterior cruciate reconstructions.

Case 11: G.L.

26-year-old male, left knee; 12 months following reconstruction for chronic posterior and postero-lateral rotatory instability. He had a combined reconstruction consisting of semitendinosis tendon and the medial head of gastrocnemius with carbon fiber for the posterior cruciate and an osseoligament as advancement on the lateral side for postero-lateral instability. This is the view through the intercondylar notch next to the anterior cruciate ligament. For orientation, here is the anterior cruciate ligament. A few fibrous adhesions around about it. We are going through the intercondylar notch and are able to see the posterior cruciate ligament through this exposure. It is apparent that the semitendinosis, medial head of gastrocnemius, and carbon fiber have all incorporated well into one ligament. There is no evidence of carbon fiber separate from the ligaments. This is of interest since in this procedure I do not wrap the carbon fiber, but simply lay it alongside the other reconstructions because I can't find any other technical way to do it. This man has residual grade 2 posterior instability. I have found posterior cruciate reconstructions particularly difficult insofar as restoring normal stability, and carbon fiber does not seem to help the matter very much. Here you can see there is some residual laxity in the ligament, although there is also tension within the ligament on posterior stressing. Here we're probing the medial head of gastrocnemius as it comes through the posterior capsule up to join the transfer just prior to entry into the femoral drill hole. There is one adhesion here in the foreground. Once again, here is the neoligament, the composite ligament consisting of carbon fiber, semitendinosis, and medial head of gastrocnemius. I felt that this had bunched up at the femoral drill hole and had not obtained good fixation into the femoral bone. But the quality of the fibrous tissue is excellent, and probing it, I could not find any carbon fiber within it; I could not expose the carbon fiber at all. There was no carbon-fiber debris in the joint. Biopsy of the adhesion surrounding the posterior cruciate ligament and synovium (both posteriorly and anteriorly) did not indicate any microscopic carbon fiber present and no evidence of inflammatory reaction in the knee. Three of five posterior cruciate reconstructions arthroscoped showed no evidence of carbon fiber, with a similar picture to this. Two of the five showed exposed carbon fiber and had extensive carbon-fiber debris within the joint. The retropatellar surface; he was complaining of chondromalacic symptoms. No evidence of carbon-fiber staining of the synovium. There were suprapatellar adhesions which were later debrided. His major symptom at this stage being patellofemoral dysfunction rather than any instability. This is the view through the postero-medial portal, looking at the medial head of gastrocnemius transfer coming through the posterior capsule. This dynamic transfer is probably what has given him his good result despite the residual instability. The quality of the picture poor in this location. I could not adequately visualize the carbon fiber and semitendinosis portions of the transfer, but the medial head of gastrocnemius was well seen.

Case 12: T.H.

29-year-old male, left knee; 12 months following reconstruction for chronic posterior cruciate ligament insufficiency using semitendinosis and medial head of gastrocnemius reinforced with carbon fiber. This is the view through the postero-medial corner. The old camera was very poor visualization, for which I apologize. The probe is coming through the intercondylar notch, and this is the medial head of gastrocnemius portion of the graft sitting with the capsular structures posteriorly. Quite stretched out. In this case I could not gain good visualization of the posterior cruciate ligament through the intercondylar notch, and the only view I could get was this one. It was apparent that there was no carbon-fiber debris within the joint whatsoever. No synovitis. Biopsies indicated no inflammatory response within the synovium. Like the last case, he had residual posterior cruciate insufficiency, grade 2. Here is the semitendinosis tendon coming up towards the femoral condyle, and it is sitting with the medial head of gastrocnemius. I presume that the carbon fiber is incorporated well within that.

APPENDIX 2

Carbon-Fiber Augmentation of Cruciate Ligament Reconstructions: Preliminary Results. J.N. Penny, J. Bone Joint Surg. 69B:511, 1987.

Carbon fibre augmentation of cruciate ligament reconstructions: preliminary results – *J. N. Penny* (Victoria, British Columbia) reported the results of a prospective clinical trial of carbon fibre augmentation of cruciate ligament reconstructions in 68 patients followed for one year after operation. Of these, 42 had carbon fibre augmentation of tissue graft and 26 controls had unaugmented grafts. No cases showed a significant clinical synovitis.

Improved stability was found after augmented grafts for chronic anterior cruciate ligament insufficiency, but acute reconstructions showed equivalent results with or without carbon fibre. In complex reconstructions and posterior cruciate replacement with marked displacement, carbon fibre failed to prevent stretching of the graft. Twenty patients with augmented grafts had arthroscopy one year or more after operation. Of these, 50% had excellent neoligament formation, while the other 50% showed limited fibrogenesis with two failures. Synovial biopsy revealed carbon fibre debris in six patients with a benign synovial response. There was no gross or histological evidence of significant inflammation, but a giant-cell response was seen with phagocytosis of carbon fibre particles. Carbon fibre within ligament tissue seemed inert. Complications included one case of deep infection and three patients requiring removal of fixation bollards because of local pain.

The author concluded that carbon fibre can safely be used to augment ligaments provided that the implant is adequately covered by soft tissue.