PRE-MARKET APPLICATION

CFS™ FOR TREATMENT OF KNEE-LIGAMENT INJURIES

PLASTAFIL, INC.

VOLUME 6

TABLE OF CONTENTS (THIS VOLUME)

INTRODUCTION

Carbon fibers entered orthopaedics in the 1970's when it was suggested that they had a propensity for inducing tissue growth, and that this property might be clinically useful. In South Africa in 1979, following animal and clinical studies by Jenkins and co-workers, a group of orthopaedic surgeons and bioengineers began an independent study of the use of carbon fibers for repairing ligaments. Plastafil was formed in the United States in 1982 to capitalize on the work of this group, and to conduct studies to permit objective evaluation of the usefulness of carbon fibers. Plastafil's investigators published little, and avoided public debates regarding carbon fibers because the data required to evaluate their usefulness did not exist. This is the first report from Plastafil containing an overall evaluation of the therapeutic use of carbon fibers: It sets forth, in detail, the basis for our conclusions.

The issues considered here are: (1) the usefulness of published animal and clinical studies involving carbon fibers; (2) the philosophy and rationale adopted by Plastafil regarding the design and conduct of the studies that it sponsored; (3) the consistency, coherence, and quality of the data obtained by Plastafil while performing the IDE study, and related studies; (4) the overall conclusions drawn by Plastafil regarding all reports and data involving carbon fibers, including the data presented in this PMA, and that contained in published studies.

ANIMAL STUDIES

In 1977 Jenkins et al. described studies involving Grafil HMS carbon fibers that had been treated with solvents to remove their epoxy coating, and then used to replace Achilles tendons in sheep and rabbits (1). Jenkins reported "a strong whitish cord of fibrous tissue around the implant", which he attributed to the presence of the carbon fibers ("it certainly appears that filamentous carbon can be used to induce the formation of new tendon or ligament..."). He also concluded that the carbon-fiber bundle itself contained connective tissue ("it appears that the filamentous implants have the power of attracting connective tissue ingrowth within their interstices with a laying-down of substantial deposits of strong collagenous fibers."). Jenkins interpreted his observations to indicate that the carbon fibers break down after they have induced the tissue response ("...it appears that the original carbon fiber may disintegrate having outlived its useful period and thus acted as a temporary scaffold...").

In 1978, Jenkins and co-workers described the use of Grafil AS carbon fibers to replace the Achilles tendons and anterior cruciate ligaments (ACL) in sheep (2). The Achilles-tendon animals were recovered up to 24 months after surgery and "naked eye examination ... showed development of an apparently normal tendon around the

carbon prosthesis." Again, Jenkins seems to suggest that new tissue grew inside the carbon-fiber bundle, not merely around its periphery. The ACL-treated sheep were sacrificed up to 8 months after surgery, and that naked-eye examination "showed the gradual development of a new cruciate ligament and a gradual envelopment of the carbon matrix." Jenkins' rationale for the use of carbon fibers involved their hypothesized capacity for tissue induction.

In the Achilles-tendon sheep (2), carbon debris was reported in macrophages and lymph nodes. In the ACL sheep however, no carbon was found in the regional nodes or anyplace else outside the joint.

In rabbits that received Grafil AS carbon fibers and were then sacrificed up to 16 weeks after implantation, Forster et al. (3) reported observing "black particles of carbon debris in the lymphatic vessels being transported away from the site of implantation." They reported that the carbon fibers exhibited a gradually diminishing diameter, and that they found the resulting carbon debris in macrophages, lymphatic capillaries, and regional lymph nodes. They concluded that "the mechanism of production of the new carbon-induced tendon obviously lies in the gradual mechanical weakening of the carbon implant due to its constant fragmentation. This puts more and more load on the young collagen in the newly built tendon, which responds by further growth, organization, and thickening."

In a study designed to evaluate possible long-term side effects of Grafil AS carbon fibers, bundles of 3,000 carbon fibers were inserted intramuscularly in the gluteal muscle of rats, tied around the midshaft of the femur in rats, or ground (in a mortar and pestle) and injected as a saline suspension into the gluteal muscle of rats (4). The animals in each group were killed 14-17 months after implantation: No carcinogenic changes in muscle or bone were observed in any animal. The basic histological reaction was that of a benign foreign-body response. In the rats that received carbon-fiber debris the authors reported "some of the smaller carbon fragments were present in lymphatic capillaries."

Amis and co-workers disputed each of the basic claims made by Jenkins and co-workers: Grafil HMS carbon fibers (washed in ketone to remove the epoxy) did not successfully replace the gastrocnemius tendons in sheep (5), or the ACL in rabbits (6). Grafil AS carbon fibers were not phagocytized by macrophages, and did not act as a scaffold for the ingrowth of connective tissue (7).

Alexander and co-workers used Hercules AS carbon fibers to replace the patellar tendon in dogs, and made various mechanical and histological observations on animals sacrificed up to 12 months after implantation (8-11). The carbon fibers were unsized (that is, they originally contained no epoxy), and were coated with poly-

lactic acid (PLA), a biodegradable polyester of lactic acid*; the PLA made the carbon fibers more convenient for the surgeon during implantation. The authors theorized that the PLA could prevent both what they termed premature fracturing, and the migration of carbon fibers.

In a study by Aragona et al., the gastrocnemius tendons of rabbits were removed and replaced with carbon fibers that were attached to the proximal and distal tendon stumps by weaving of the carbon fibers through the tendon (13). Based on histological and mechanical evaluations in specimens recovered 0-12 weeks following the procedure, the authors concluded that an effective anastomosis between the fibers and soft tissue had been obtained. We repeated this study, however, and found that a permanently secure anastomosis did not occur (14). We implanted one end of a bundle of carbon fibers in intact rabbit gastrocnemius tendons, and observed that the force required to pull the carbon fibers out of the tendon was low (about 14 newtons, on average), and was independent of time for 0-18 weeks after implantation. The same results were obtained with both Plastafil and PLA carbon fibers. We concluded, therefore, that carbon fibers do not form a secure soft-tissue anastomosis (14).

Aragona et al. employed PLA carbon fibers as a replacement for the medial collateral ligament in dogs, and recovered the animals 4-26 weeks after surgery (15). Microscopic examination of the regional lymph nodes revealed no spread of carbon fibers, which the authors attributed to the presence of the PLA ("the polymer in our hands appears to stop migration of carbon.").

The question of the effect of carbon-fiber debris on the knee joint was investigated by Parsons et al. (16). They injected 10 mg of carbon-fiber debris (10-80 micrometers, mean particle length, 51 micrometers) into the knee joints of rabbits, which were recovered up to 16 weeks after injection. Talc (magnesium tetrasilicate) was injected as a positive control for the carbon fibers. In both the carbon-fiber and talc joints, no debris became embedded in the cartilage surfaces. The debris was rapidly taken up in the synovium. By 8 weeks, the carbon debris was moved to deeper subsynovial fatty layers, and remained there benignly throughout the 16-week test period. No material was found embedded in the articular surface, and the articular surfaces were not abraded. No detectable histologic changes in the articular surface of the knee joint were observed.

In a similar study, Rushton and Rae injected Grafil AS carbon fibers (2-250 micrometers, 0.2 mg) into the knees of mice, which were recovered 2-52 weeks following implantation (17). A minimal tissue reaction was seen throughout the recovery period. Little

* The authors refer to the PLA-coated carbon fibers as a "composite." This is an unorthodox use of the term which is generally used to mean the use of carbon fibers as reinforcement for certain matrix materials (12). It is only in the latter sense that the term is used in this report.

difference was seen between the tissue reaction at 2 compared to 52 weeks after implantation. The regional lymph nodes were removed and apparently contained no carbon-fiber debris.

Gleason (18) used an unspecified form of carbon fibers to replace the medial collateral ligament in rabbits, 3 of which were used for ultrastructure studies. After 6 months, particles said to be carbon were identified in histiocytic cells. Following similar methods of histological preparation, however, Kramer was unable to identify carbon within cells in a knee ligament that had been recovered 3 years after implantation (19).

Mendes et al. (20) used carbon fibers (Plastafil and Lafil) to repair the transected quadriceps or triceps tendons in 10 dogs. They reported that fragmentation of carbon fibers was the exception, rather than the rule. Digestion of the connective-tissue component of the augmented tendon revealed a carbon tow that was largely intact. ("The appearance of fragmented carbon fibers in the histologic slides can therefore be assumed to be an artifact created by the microtome.") "Carbon-fiber debris may occasionally be seen in cells, but this is a relatively rare occurrence."

In a study by Bercovy et al. (21), an unspecified kind of carbon fibers was used to replace the ACL in sheep, and the animals were killed 18 months after the operation. There was no gross contamination of the knee joint with carbon fibers, and no carbon fibers were observed in regional lymph nodes using histologic techniques.

HUMAN STUDIES

Hexcel Integraft carbon fibers were used for the surgical repair of rotator cuff tears in 5 patients (22). The results were judged excellent in 2 cases, and good in 2 cases; there was one failure resulting in removal of the carbon fibers.

Weiss (23) reported early clinical results in a series of 82 (mostly chronic) patients who received carbon fibers for ACL injuries. A strip of iliotibial band was elevated, and carbon fibers were threaded along its length. The IT strip was tubed, passed over the lateral femoral condyle, through a hole in the tibia, and fixed using a bollard. After 24 months (8 patients) generally good results were observed.

In a study involving 30 patients with chronic injuries, carbon fibers were used to augment an ACL reconstruction (24). The central one-third of the patellar tendon was elevated and carbon fibers were woven thorugh the tendon strip. The preparation was tubed, passed into the joint through a hole in the tibial plateau, routed over-the-top of the lateral femoral condyle, passed underneath the lateral collateral ligament, and stapled to the tibia. Apparently some of the carbon-fiber patients were arthroscoped, and neither uncovered carbon fibers, nor carbon-fiber debris were found in the

joint. Generally good clinical results were reported, and no material-related complications, either locally or regionally, were observed.

In a controlled clinical study involving 20 patients, 10 patients received carbon fibers as a reinforcement of an autologous tissue transfer (patellar tendon or semitendinosis tendon). An additional 10 patients received one of the two control procedures, but without carbon fibers. After 1 year, there was no difference between the two groups. The inclusion of carbon fibers appeared to neither confer a clinical benefit nor result in adverse effects (25).

In a controlled study, carbon fibers were used as part of an extra-articular reconstruction for patients who had a positive pivot shift (26). Apparently there was no difference in functional status between the two groups after 1 year. The carbon-fiber patients were arthroscoped and despite "repeated biopsy" there was "no evidence of any form of synovial reaction other than the occasional suggestion of a giant cell."

Grafil AS carbon fibers that had been washed in acetone to remove the epoxy were implanted in 60 patients (beginning, apparently, about 1976) in knee ligaments and 6 other tendons and ligaments at various locations (27). Writing in 1980, the authors said they could "confirm the possible role of carbon fibers in the late reconstruction of ligamentous injuries." No biopsies of regional nodes were taken, but no evidence of lymph node enlargement was found even after the longest follow-up (3 years).

Some of Jenkins' cases from 1976-1981 were reviewed by Leyshon et al. (28) in 1984. Grafil AS carbon fibers were used to replace the ACL (7 cases), collateral ligaments (15 cases) and combined cruciate and collateral ligaments (41 cases). An apparently randomly selected group of 19 patients were arthroscoped to determine the tissue reaction to carbon fibers. The timing of the arthroscopies was not described. There was no evidence of macroscopic synovitis, but carbon-fiber debris was seen in the synovium. The investigators biopsied the carbon-fiber ligament, and they characterized the intra-articular tissue response as variable because it occurred in some patients, but not in others.

In 1985, in a brief report (29) Jenkins described good results in a series of 562 patients.

The most unsatisfactory clinical experience with carbon fibers is the series of studies reported by Dandy and co-workers (30-32). Carbon fibers were implanted arthroscopically in 20 patients, but no conclusions regarding efficacy were possible (30). Persistent synovitis was encountered in 4 patients; this was a higher incidence than expected on the basis of historical controls. The use of carbon fibers in 39 patients suffering from ACL insufficiency was described in 1983 (31). The patients may have included the previously reported group of 20 patients. Results were given for

10 patients who had a mean of 16.9 months after repair. These patients were arthroscoped, and the carbon-fiber bundle was biopsied: The carbon fibers had not induced a new ligament, and all 10 patients had synovitis macroscopically. In 1988, an analysis was given of 29 patients who received carbon fibers for treatment of knee instability (32) -- apparently, they included some of the same patients that had been included in the earlier reports (30, 31). The carbon fibers were inserted at arthrotomy in 15 patients and under arthroscopic control in 14 patients. The data suggested that the efficacy of an intra-articular repair using carbon fibers (at 6 years) was no better than that obtained using an extra-articular reconstruction (MacIntosh lateral substitution) (32). There were 0.94 complications per patient in the MacIntosh group, but 1.65 complications per patient in the carbon-fiber group. In each of the studies (30-32), Courtauld's Grafil AS carbon fibers were used. The authors appear to have been unaware that the carbon fibers were coated with epoxy, and they do not describe its removal prior to their implantation in patients.

Lemaire advocated the use of carbon fibers as an augmentation for extra-articular reconstructions and repairs (33,34), but no data was presented.

ANALYSIS OF PUBLISHED STUDIES

It is not clear from Jenkins' publications whether the formation of tissue that he described refers to the "whitish cord" of tissue that surrounded the carbon-fiber bundle, or to tissue that grew inside the carbon-fiber bundle. In the Achilles-tendon animal model, the tissue external to the carbon-fiber bundle may have been an injury response, and therefore not "induced" by the carbon fibers. On the other hand, in the ACL study, Jenkins reported that the ACL formed using 40,000 carbon fibers was significantly larger than that formed using 10,000 carbon fibers: Since true tissue induction is proportional to the amount of implanted material whereas no such proportion exists with regard to an injury response, this observation may indicate that Jenkins recognized that the tissue induced by carbon fibers actually occurred inside the carbon-fiber bundle.

To adequately characterize tissue (of any kind) it is necessary to obtain representative histological sections: Only in this circumstance can judgments validly be made regarding spatial relationships (whether induction occurred, or whether a particle is inside or outside a specific cell, for example). The histological methods used by Jenkins and co-workers (embedding specimens in wax followed by processing using routine histological techniques) do not yield representative tissue sections because the techniques are incapable of cutting carbon fibers, and hence cannot display the relationship between carbon fibers and any adjacent tissue.

Carbon fibers of unspecified size were reported by Jenkins in local and regional lymph nodes in sheep (1), by Forster (3) in

lymphatic vessels in rabbits, and by Tayton (4) in the lymphatic capillaries in rats. Since the investigators lacked the histological techniques needed to observe the claimed spatial relationships of carbon fiber in tissue, the reports are unreliable. None of the interpretations were quantified, or verified using appropriate techniques such as chemical analysis or ultramicroscopic analysis. Amis' studies were not an improvement over those of Jenkins and co-workers, and consequently the combined work of both groups leaves unresolved the issues of tissue ingrowth and phagocytization.

The animal studies of Alexander and co-workers employed a better grade of carbon fibers (no epoxy), and the carbon fibers were coated to facilitate implantation. These steps probably eliminated the debris-filled surgical field that occurs when uncoated carbon fibers are employed. On the basis of mechanical tests, Alexander and co-workers concluded that carbon fibers conferred a benefit when used in either tendons or ligaments, but the data is scanty. In at least one study (15) the regional lymph nodes were examined and found to be free of carbon debris.

The histological descriptions are more detailed than those given by Jenkins and co-workers, but they are similarly flawed because the requisite histologic preparative techniques were not employed: The studies do not adequately characterize the histological nature of the tissue induced in the carbon fibers.

Implantation of foreign body is expected to elicit a reaction in the host that is dependent upon the chemical nature of the implant. For a chemically inert material like carbon, we expect a walling-off reaction consisting of connective tissue and inflammatory cells. The important questions regarding the tissue induced by carbon fibers are: How much tissue is induced? How long does the process continue? What kind of tissue is induced? Does the response occur in the joint? These questions are not answered in the literature.

Phagocytization is an ordinary physiological response to the presence of foreign material. Macrophages can endocytose material via pinocytosis and phagocytosis. In pinocytosis, droplets of fluid are taken up together with dissolved solute, macromolecules, or small particles (less than 0.2 micrometers). In phagocytosis, larger particles are interiorized. In both processes, the plasma membrane invaginates in pits and pinches off; the resulting intracellular vesicle becomes exposed to powerful digestive enzymes, and the internalized plasma membrane is retrieved and recycled (35).

In phagocytosis, binding of the particle to a plasma membrane is normally required for interiorization (35). For example, phagocytosis of microorganisms involves recognition by macrophage receptors of manose and glucose residues on the microbial surface. Many pathogenic microorganisms or intact cells cannot be ingested without first being coated with opsonins (certain serum proteins) which facilitate phagocytosis. In essence, the phagocytes do not

recognize the particle surface itself, but rather the antibody bound to the particle.

It is clear that under certain experimental conditions, carbon can be endocytosed (36,37): In these studies the carbon was of colloidal dimension (about 25 nanometers), and was present at a sufficiently high concentration to overwhelm the reticuloendothelial system. Nopajaroonsri and Simon unilaterally injected colloidal carbon into the hamstring muscles of rats, and studied the fate of the injected material for up to 24 hours after injection (36). The para-aortic lymph nodes were embedded in epoxy and sectioned with a diamond knife (0.5-1 micrometer) and stained with Toluidine blue. Within a few minutes after injection, passage of the colloidal carbon into the lymphatic channels was observed. Phagocytosis of carbon particles by macrophages in the sinus of the lymph nodes was unambiguously confirmed by light and electron microscopy as early as 3-6 minutes after injection. The macrophages formed many finger-like micropseudopods, entrapping carbon fibers, which usually entered the cell at the base of the micropseudopods. Beginning at 30 minutes after injection, carbon particles could be identified in macrophages in the lymph node. Electron microscopic studies of lymph nodes other than the isolateral para-aortic node did not reveal any carbon.

Oghiso and Matsuoka used similar histological techniques and described the fate of colloidal carbon injected into mice via different routes (after 24 hours) (37). Following intraperitoneal injections, the carbon particles were mostly distributed in the mediastinal lymph nodes. Following subcutaneous injections, they were observed in the superficial lymph nodes. When injected in the footpad, the carbon was distributed to the mediastinal, mesenteric and pancreatic lymph nodes.

Colloidal carbon is used in tattoos where it is placed in the dermis and in subcutaneous tissue using a fine needle to pierce the skin. Some of the pigment is taken up by macrophages, but much of it remains extracellular in the dermis (38,39). When the tattoo is done professionally, the lines remain clear and do not fade (40), indicating that the deposition of the pigment is permanent.

It follows from these studies that phagocytization of colloidal carbon can occur, particularly when the reticuloendothelial system is overloaded with colloidal carbon, but that the more typical response (at least in the skin) is the permanent sequesterization of the colloidal carbon as an extracellular deposit.

Debris larger than colloidal dimensions might be endocytosed by phagocytization. Some inert materials are ingested in the absence of specific recognition factors from the serum (35). This non-immunological phagocytosis is particularly relevant to the function of the lung macrophages which must clear the airwaves of such materials as carbon, silica, berylium, asbestos, cellulose, cotton fibers, and other particulate pollutants. In most cases, however, particles phagocytosed by lung macrophages are small (less

than 5 micrometers) because it is not possible for larger particles to pass through the respiratory tree to the location of the lung macrophages. Phagocytosis of carbon fibers by macrophages may occur, but the process has not been clearly demonstrated.

Assuming that carbon-fiber debris was endocytosed, as reported in several studies (1,3,4,18), the question arises: What was the source of the debris? One possibility was that initially intact fibers begin to break after surgery, and that the broken fibers themselves broke into smaller and smaller fragments, until they became small enough to be taken up by tissue macrophages. If there exists some mechanism in the body that can break individual carbon fibers into progressively smaller segments, this hypothetical mechanism could produce carbon debris having any effective particle diameter.

It might be suggested that, after an individual carbon fiber is ruptured, host tissue somehow attaches to the free ends of the carbon fiber and reloads it in tension. But the evidence suggests that tissue does not adhere to carbon fiber because the carbon-fiber/tissue interface cannot transmit a mechanical force (14). Thus, it seems unlikely that macroscopic broken carbon fibers can be loaded in tension or shear. Perhaps carbon fibers can be ground between two tissue planes (or between two bones) thereby generating debris, via a mortar-and-pestle mechanism. However, this idea also seems improbable because such a mechanism produces debris when the substance being ground is softer (not harder) than the putative mortar and pestle. There is no tissue in the body that is remotely comparable in hardness to carbon fibers.

Two established mechanisms for the production of debris of a biomaterial in the body are chemical attack and fatigue. In principle, carbon fibers that remain intact between fixation points could produce debris via fatigue in which particles flake from intact carbon fibers. Such a hypothetical mechanism could produce debris of essentially any length, having a diameter less than the diameter of the individual carbon fibers. Such a fatigue-related mechanism seems highly improbable, given the relatively short duration of almost all studies in which carbon fibers have been reported to have been endocytosed. Furthermore, this hypothetical mechanism is unable to explain the claimed occurrence of carbon debris in macrophages in studies in which the carbon fibers were merely implanted, and never subjected to mechanical load (4).

A second possibility is that the carbon-fiber debris was produced during surgical implantation of the carbon fibers. Knotting of carbon fibers, use of uncoated carbon fibers, grasping carbon fibers with surgical instruments, passage of carbon fibers over sharp bony edges, are each certain to produce gross debris during surgery.

Another possibility is that the carbon-fiber debris was not produced in the animal after surgery, or during surgical implantation, but was actually part of the carbon-fiber implant itself.

Commercial-grade carbon fibers contain debris (dross) of size ranging from macroscopic to colloidal dimensions. Dross has no material effect on typical industrial applications of carbon fibers, but unless affirmative steps are taken to remove it, it remains present in the implant as a contaminant.

The question of the significance of debris in the joint was addressed in two studies in which simulated debris was implanted into the joint. Both studies failed to validate a concern regarding scoring and abrading of articular cartilage (16,17). In the rabbit study (16), the dose of carbon fibers injected into the knee was equivalent, on a weight basis, with grinding an entire human implant and injecting the debris into the joint.

The observations regarding the role of the synovium in removing injected debris from the joint (16,17) were consistent with previous studies regarding the reticuloendothelial (RES) function of synovium with regard to carbon (41-43). When carbon was injected intravenously, it was removed from the circulation by the synovium in a manner similar to that of RES tissue (41). The synovium performed the same role regarding carbon particles injected directly into the joint (42); macrophages removed the carbon from the synovial fluid and sequestered it subsynovially in a fibrous network. Sequesterization of carbon particles in the synovium of an individual who was occupationally exposed to carbon dust has been reported (43). These reports suggest that synovium has a greater affinity for carbon, compared to other non-RES tissues.

In summary, the animal studies suggest that carbon fibers elicit growth of a species of connective tissue within the bundle (1, 2,19). The overall histological response was benign and exhibited relatively few inflammatory and phagocytic cells (2,3); carbon fibers were not carcinogenic in a standard animal model (4). Moderately high amounts of carbon-fiber debris (created by grinding in a mortar and pestle) did not produce gross cartilage damage when injected into the knee joint (16,17). The questions whether carbon fibers confer a clinical benefit, how much, and in what cases, remain unresolved. Jenkins' rationale was that carbon fibers, standing alone, would confer a clinical benefit (27). Despite the use of carbon fibers for a variety of different pathologies, little actual data was presented. The sensitivity and specificity of the design of his studies was such that objectively supportable statements regarding efficacy could not have been made unless carbon fibers were dramatically successful in improving outcome, which was not the case. The rationale of the Hexcel studies involved the adjunctive use of carbon fibers in connection with a reconstruction using autologous tissue (22-26). The studies also involved a number of different pathologies, and this obviated any clear conclusions regarding efficacy. Two controlled studies based on the augmentation rationale could not demonstrate benefit when carbon fibers were used to augment standard reconstructions (25, 26). Clinical use of carbon fibers does not appear to have resulted in clinical complications such as infection, pain, joint effusion, or other complications. The exceptions are the reports by Dandy and

co-workers (30-32); their complications can reasonably be attributed to the use of epoxy-coated carbon fibers and arthroscopic instrumentation.

PLASTAFIL ANIMAL STUDIES

We performed animal studies to address specific issues involved in evaluating clinical use of carbon fibers. The carbon fibers used were the same as those used in the human studies: They had a mean diameter of 8 micrometers, greater than 95% purity, and had never been coated with epoxy or other foreign material. The carbon fibers were heated briefly in an inert atmosphere to volatilize any surface contaminants that may have contaminated the carbon fibers during shipment to Plastafil, and the fibers were washed to remove the dross. The carbon fibers were coated with gelatin/glycerol to facilitate handling during surgery.

Depending on the particular reconstruction, carbon fibers might be routed through fat or near nerves or muscles, and we therefore determined whether the fibers (either in the form of intact fibers, or debris) elicited any adverse reaction in these tissues. When fibers or debris were implanted in mice adjacent to the sciatic nerve, in axillary fat, or in quadriceps muscle, a thin encapsulating granulation tissue formed which had a generally benign histological appearance. The regional lymph nodes at both 1 and 5 weeks were examined grossly (for discoloration) and by polarizing microscopy (using squashed preparations to search for carbon fibers), but no evidence of lymphatic transport to the nodes was found in any of the animals.

The histological techniques used in this study (specimens embedded in wax) were insufficient to adequately characterize cells and tissue in the interstices of the carbon fibers. However, the study was appropriate for the study of the reaction of adjacent tissue (muscle, nerve, and fat). The tissues were unaffected by the presence of the carbon fibers, and exhibited no necrosis, fibrosis, inflammation, or demyelinization.

A long-term study involving rabbits was performed to determine the amount and histological nature of the tissue induced by carbon fibers. The gastrocnemius tendons in rabbits were removed and replaced with carbon fibers; the carbon fibers were passed through a drill-hole in the calcaneus, woven through the proximal tendon stumps, twisted together at that location and glued with methylmethacrylate. We compared the tissue reaction to that observed in control rabbits (which had been reconstructed using 2-0 nylon instead of carbon fibers).

We developed histological techniques that permitted preparation of representative histological sections (tissue embedded in epoxy, sectioned at 0.5 micrometers with a diamond knife). Using these techniques, the histological appearance at any predetermined

region of the carbon-fiber bundle could be studied and an unambiguous assessment could be made of the relationship between tissue and carbon fibers. Typical histological sections consisted of inter-fiber tissue and well-defined carbon-fiber channels that usually contained the microscopic carbon-fiber debris produced by the diamond knife.

Removal of the gastrocnemius tendons resulted in an injury-induced fibrosis that occurred in both the carbon-fiber and nylon reconstructed rabbits. This tissue was histologically distinguishable from that induced by the presence of the foreign-body material. The basic reaction to the carbon fibers was the formation of a fibrous membrane around the carbon-fiber bundle within about 1 month, followed by progressive encapsulation of individual fibers within the bundle by new connective tissue which was less dense and more cellular than the injury-induced fibrosis. The process originated at the periphery of the carbon-fiber bundle and moved centrally. After about 1 year, the individual fibers in the bundle were surrounded by an annular ring of tissue having an average thickness of about 6 micrometers. The same observations were made at 2 years and 3 years after implantation; thus the maximum amount of induced tissue occurred no later than 1 year following surgery.

The tissue induced inside the carbon-fiber bundle was histologically identical to the fibrotic reaction that occurred in the immediate vicinity of the nylon in the control animals. Induced tissue differed in the two cases only in amount (much more tissue in the case of carbon fibers) and perhaps in structural organization. Transport of carbon fibers to the iliac, inguinal, or popliteal nodes was not observed.

The rationale for the intra-articular use of carbon fibers is that they induce tissue that ultimately strengthens the implant site. It was therefore desirable to study the nature and extent of intra-articular tissue induction in an appropriate animal model. We chose the goat because its stifle joint was sufficiently large to permit a surgical procedure reasonably similar to that used in patients.

The treated joints were not immobilized, and the goats were pastured within a few days of surgery. Since the goat cranial cruciate ligament has an ultimate tensile strength of about 1500 newtons, and the mechanical strength of the CFS System is about 300 newtons, it is likely that the implants ruptured within a few days of surgery. The conditions of the study are therefore pertinent to an evaluation of the long-term results (the joints were examined up to 18 months after surgery) in which the implant failed shortly after surgery.

The failure site was extra-articular (mostly within a few centimeters of the bollard on the femur), and the joint cartilage was intact and unaffected by the carbon fibers. There was no grossly detectable carbon debris in the synovium. Fibrotic ingrowth into the carbon fibers was observed: After 18 months, the

average thickness of the fibrotic layer surrounding each carbon fiber was about 14 micrometers (twice as thick as that surrounding carbon fibers implanted in rabbit gastrocnemius tendons and recovered at 1-3 years post-operatively). The ultimate mechanical strength of the repaired ligament at 18 months (519 newtons) was significantly greater than the strength measured at 1.5-3 months post-operatively. This data is evidence that intra-articularly induced connective tissue can strengthen an implant site.

A safety-related concern regarding carbon fibers suggested in some studies (1,2) involved the possibility that carbon-fiber debris might be created and phagocytized, thereby leading to potential problems in the lymphatic system. To help evaluate this issue, we implanted carbon fibers in the abdominal wall in rats. The carbon fibers were woven into a fabric such that the amount of carbon fibers used (in 250-gram rats) was about 20% greater than that used for human implants (about 500 mg, compared to 400 mg for patients). The abdominal wall was removed, and replaced with the carbon-fiber fabric such that the carbon fibers were in direct contact with the abdominal organs. After 1 year, the carbon-fiber fabric was intact, tissue ingrowth had occurred in the interstices of the fabric, and no carbon-fiber debris was identified in the regional lymph nodes.

Bowed tendon is a common and debilitating form of tendinitis in horses. In racehorses, the most frequently affected tendon is the superficial digital flexor tendon. Both the nature of the injury and the anatomy of the tendon were particularly propitious with regard to testing a hypothesis regarding clinical efficacy of carbon fibers.

There is no accepted therapy for bowed tendon (other than a conservative treatment), and the prognosis is poor for returning to previous functional level. The lesion consists of distension or disruption of some fibers in the interior of the tendon; it is rarely manifested as a complete rupture. The tendon is 10-15 centimeters long, and the lesion typically occurs in the middle of the tendon. Carbon fibers were passed through such lesions in Thoroughbred racehorses to evaluate the possibility that the fibrotic response would anastomose with normal tissue proximally and distally to the lesion, thereby adding strength to the injury site. The effect of the treatment was assessed by observing the frequency with which a treated horse could return to its previous functional level -- that is, return to the racetrack. We found that 65% of horses that had suffered bowed tendon and had failed conventional therapy (conservative treatment) returned to the racetrack. In a second study involving acutely treated horses, 74% of the horses treated with carbon fibers returned to the racetrack, compared to 23% of horses that were treated conventionally.

In summary, our basic idea was that carbon fibers implanted in the body induced a form of connective tissue which itself anastomosed with other body tissues in such a way that the resulting structure conferred a clinical benefit. We showed that tissue

induction occurred both extra- and intra-articularly, and that the induced tissue could confer mechanical strength. We measured the amount of tissue induced, established the time constant for the process in a specific animal model, and characterized the histological nature of the induced tissue. Carbon fibers produced a clinical benefit in Thoroughbred racehorses. Carbon-fiber debris could not be detected in lymph nodes in mice, rats, rabbits, goats, or horses. It is unlikely that CFS carbon fibers were phagocytized and transported to lymph nodes.

PLASTAFIL HUMAN STUDIES

Introduction

Most clinical carbon-fiber studies did not include controls, and their absence largely precluded comparison of the results with those from studies in which other forms of therapy were used. There were also other important shortcomings in the published clinical studies.

No biomaterial can reasonably be expected to confer a clinical benefit irrespective of how it is used. Each method of routing carbon fibers through a joint, covering them (or not covering) with a specific autologous tissue, and attaching them to bone may constitute an important element in the overall result. When each element is chosen, the particular combination constitutes one particular form of therapy: It might be successful, and another form of therapy (another choice of combinations) might not be successful. Standard surgical techniques and methods of fixation of the carbon fibers were not followed, even within the studies of specific investigators. Thus, not only can results of various investigators not be compared, the results within each series do not provide a proper basis for comparison.

The material properties of carbon fibers place severe restrictions on how they are handled and used in the operating room. Carbon fibers are not remotely like other prosthetic-like devices with which the orthopaedic surgeon is familiar, and these material limitations must be strictly respected to provide a chance that the therapy will be effective. It is seriously wrong to use impure (epoxy-coated) carbon fibers because epoxy is toxic to tissue. Carbon fibers cannot be touched by any grasping surgical device whatever, except the fingers of the surgeon, because to do so results in broken fibers. Carbon fibers break easily when knotted, stapled, or passed over a sharp edge of bone (such as a drill hole). In most instances (the Hexcel studies are an exception) the implanted carbon fibers were not covered with a biologically compatible material capable of restricting the fibers to a tight bundle (essentially like a suture) to permit reasonably easy insertion during surgery. In the absence of such a coating, many individual fibers are inevitably broken, resulting in gross contamination of the surgical field. Most previous studies involved carbon fibers which were knotted or stapled to provide fixation, and which

were handled using ordinary surgical instruments during implantation. Each of these elements compromised the overall success of the therapy.

An appropriate follow-up is required for assessment of a clinical study: It consists in measuring or categorizing the status of all patients who entered into the study. In most reported clinical studies involving carbon fibers, follow-up consisted of subjective evaluation of only some of the patients entered into the study. Thus a valid statistical hypothesis could not be tested.

Clinical Studies

We conducted a randomized, prospective, controlled study. A total of 134 patients with injuries involving the anterior cruciate ligament (ACL) were entered, and randomized to either the carbon-fiber or control group. An additional group of 10 patients that were not randomized also received carbon fibers. Our rationale was that the tissue induced inside the carbon-fiber bundle would add mechanical strength at the anatomic location of the ACL. Thus, the carbon-fiber patients received carbon fibers but no intra-articular autologous tissue transfer, and the control patients received standard therapy (mostly, a patellar-tendon reconstruction).

The surgical procedure for implanting carbon fibers at the anatomic location of the ACL was standardized, and surgeons at each of the three Study Centers performed the same reconstruction. Surgical instruments required for handling the carbon fibers were designed and built, and were used by each study investigator. Specialized fixation devices required for attachment of carbon fibers to bone were designed, and incorporated in all carbon-fiber cases treated in the study. The follow-up instrument consisted of a standardized form that was completed at each follow-up visit. Predetermined weights were assigned to pertinent clinical observations regarding function, deformity, symptoms, laxity, and subjective evaluation. The statistical hypothesis involved comparison of total points achieved by patients in both groups at various postoperative times, using parametric statistics. Additionally, we considered various hypotheses involving the effect of type of treatment on distributions of patients among classes of clinical parameters.

Patients that had a surgically significant injury to the ACL but not the posterior cruciate ligament (PCL) were randomized into carbon-fiber or control groups according to a plan intended to produce approximately 60% carbon-fiber patients and 40% control patients. Ten additional patients with injuries to both cruciate ligaments were treated with carbon fibers, but not randomized. In the randomized study, 31 patients were treated acutely with carbon fibers (surgery performed within 14 days of injury), and 43 patients were treated for chronic injuries. In the control group, 24 and 36 patients, respectively, were treated using standard

therapy (mostly, patellar tendon transfer). In the non-randomized study, 7 patients were treated acutely with carbon fibers, and 3 patients were treated for chronic injuries.

In the carbon-fiber patients in the randomized study, the ACL was reconstructed using CFS™. If surgical treatment of the collateral ligaments or the PCL was needed, it was also performed using CFS™. This resulted in use of the CFS™ for repair of the collateral ligaments in 4 patients among the 43 chronic cases, and 12 patients among the 31 acute cases. In the non-randomized study, CFS™ was used to repair all injured ligaments in each of the 10 patients.

The plan in the Investigational Device Exemption required each patient to be examined at 3, 6, 9 and 12 months postoperatively; an overall evaluation of safety and efficacy was planned at 1 year postoperatively. The circumstances of the study, however, required a change in both the frequency and duration of the follow-up. It was not convenient for a significant majority of the patients in the study to be seen at follow-up 4 times in the year following surgery. The duration of the study was extended to 5 years postoperatively, and the procedure followed for obtaining follow-up was this. Each year following surgery, each patient was contacted and requested to appear for follow-up examination. If the patient refused (or if the examining physician could not see the patient at a time of the patient's choosing), the patient was not seen during the 12-month period. The process was repeated during the subsequent 12-month period, and if the patient had not been seen during the previous 12-month period, special efforts were made to encourage the patient to appear for follow-up examination. These efforts included repeated telephone calls, personal visits to the patient's home or place of employment, and offers to reimburse the patient. The effect of this procedure was to produce for follow-up exanimation a random sampling of the study patients. This procedure was carried out for 5 years. Of the 134 patients in the randomized study, and the 10 patients in the non-randomized study, we were unable to obtain follow-up beyond 24 months in 7 patients. One patient was killed in an automobile accident; the remaining 6 patients (2 carbon-fiber and 4 control patients) have consistently refused to consent to follow-up examination.

A standard follow-up form was used to record pertinent clinical indications for each patient at each follow-up visit. Points were assigned to the various classes for each clinical indication, and the points were combined according to a predetermined formula.

The overall results of the randomized study are listed in Table 4. In the chronic category, 4 patients were treatment failures in each group; consequently, 39 and 32 patients were available for follow-up examination in the carbon-fiber and control groups, respectively. During the first postoperative year, we obtained one (or more) follow-ups on 89.7% of the carbon-fiber patients and 87.5% of the control patients in the chronic category. The average Scores in the two groups were essentially identical (Table 4, 65.6

and 64.8 for the carbon-fiber and control groups, respectively). During the second postoperative year, the follow-up in the chronic category consisted of 20 patients in the carbon-fiber group and 19 patients in the control group. Several of the patients in each group had not been followed during the first postoperative year; consequently, the cumulative percentage of patients seen at follow-up rose to 94.9% and 96.9% in the carbon-fiber and control groups, respectively. The pattern for reporting data has been followed consistently throughout Table 4. For example, in the chronic category during 4-5 years postoperatively, follow-up examination was obtained on 27 (of 39) carbon-fiber patients and 17 (of 32) control patients; the cumulative percentage of patients followed was 100% in each group.

Comparable data for patients in the acute category is presented in Table 4B; Table 4C contains the combined data from Tables 4A and B.

Table 5 contains the overall results from the 10 patients in the non-randomized study (3 chronic and 7 acute patients).

We found that for the chronic cases, the acute cases, the acute plus chronic cases (with and without inclusion of the 10 non-randomized patients), patients treated with carbon fibers fared as well as patients treated with control procedures, regardless of postoperative time.

The effect of carbon-fiber and control treatment on patient classification regarding specific clinical items is shown in Tables 6-41 for the randomized study and Tables 42-53 for the 10 patients in the non-randomized study. Carbon fibers produced the same results as control treatment in chronic patients, acute patients, and chronic plus acute patients, with regard to the following items:

Anterior drawer (30°)
Anterior drawer (90°)
Pivot shift
Posterior drawer (90°)
Giving way (normal activities)
Giving way (sports activities)
Pain (normal activities)
Pain (sports activities)
Swelling (normal activities)
Swelling (sports activities)
Performance (sports)
Performance (normal activities)

Except as noted in the Tables, the respective pre-operative distributions were not different, both forms of treatment were associated with a beneficial effect, and at each post-operative time interval, the distributions were not different.

During their participation in the study, 8 patients required further surgery because of the failure of the initial surgery to

control instability. Four were carbon-fiber patients, and 4 were control patients; all were in the chronic group. A fixation device was removed in two patients because of an irritation in the soft tissue, or infection. Implant infection did not occur.

The data shows that the CFS™ is safe and effective for the treatment of ACL instability in patients who have not undergone previous surgical treatment. The CFS™ is as good as standard intra-articular reconstructions using autologous tissue in patients having either acute or chronic injuries.

South African Data

Carbon fibers have been used clinically in South Africa since 1980. At the time of Plastafil's IDE application, more than 1000 implants had been performed: These cases involved use of parts or prototypes of parts of the CFS™.

In December, 1986, we contacted FDA staff as a preliminary step toward preparation of our PMA. We learned that the 2-year follow-up which we had originally proposed in the IDE was no longer viewed as adequate, and that an issue of safety involving intra-articular carbon-fiber debris had been raised. 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. Staff recognized that we would not be able to provide reliable information regarding efficacy from the South African data because each clinical series was essentially uncontrolled, and lacked specific entry criteria and standardization among individual surgeons regarding criteria for evaluation. Nevertheless, the data would be pertinent to safety considerations: Specifically, did the implants become infected? Were the knees symptomatic? Were the implants removed? Were regional lymph nodes painful or tender? Did intra-articular debris affect joint cartilage?

We contacted three surgeons who had a significant number of ACL cases prior to initiation of the Plastafil IDE study, and whom we believed would call back each of his patients for follow-up examination. Each of the three surgeons 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 were soldiers or policemen; they were athletic individuals, mostly with chronic injuries. Dr. Mare provided data concerning a consecutive series of 57 patients that received Plastafil 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 ACL patients that were implanted with carbon fibers 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 provided an opinion regarding stability of the operated limb; the results are given in Tables 54-56. In addition we asked (1) whether there were any infections in the joint; (2) whether any implants had been removed; (3) whether chronic pain was present that was associated with the implant; (4) whether there was any pain or tenderness in the popliteal or inguinal lymph nodes. The answer to each question for each patient in each series was: No.

Canadian Data

Beginning in 1983, Dr. Norgrove Penny, Victoria, British Columbia, used Plastafil carbon fibers in a clinical study involving the repair and reconstruction of knee ligaments. The carbon fibers and fixation devices were identical to those used in the U.S. study; they were obtained directly from South Africa pursuant to Canadian regulations governing importation of medical devices and implants.

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 the particular injury. Iliotibial band and semitendinosis tendon were chiefly employed for the intra-articular portion of the reconstructions. In 36 patients, the autologous-tissue reconstructions were augmented using carbon fibers.

Arthroscopy and synovial biopsy were performed in 21 carbon-fiber patients. Carbon-fiber debris was either absent, or present only in trace amounts in the synovium. When biopsied, the affected synovium exhibited a mild foreign-body granulomatous reaction, similar to that seen with various types of suture material. The carbon fibers appeared sharp, not scalloped or eroded, indicating no apparent breakdown of the carbon fiber. Carbon-containing macrophages were not seen in the synovial biopsies.

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.

GUIDANCE DOCUMENT CONSIDERATIONS

In September, 1987, the FDA published "Guidance Document for the Preparation of Investigational Device Exemptions and Pre-Market Approval Applications for Intra-articular Prosthetic Knee Ligament Devices" (Guidance Document). The Guidance Document defined the clinical information needed for a proper PMA. The information specified was essentially identical to that collected in our study (our IDE was approved in April, 1983). The Guidance Document also provided that data from uncontrolled studies would no longer be considered appropriate, and in this regard also our study is in accord with the Guidance Document.

The Guidance Document mandated several other changes from pre-existing policy and procedure. Chief among them was a requirement that "the distribution of scores for each objective item from Appendix 6 and subjective assessment from Appendix 5 for the entire population, at each time point of data collection, (be presented) according to (the format of) Appendix 11." Essentially, this is a requirement that statistical analyses be performed using categorical data. But the Guidance Document does not indicate how the data should be used to make a decision regarding efficacy (or safety). To simply obtain data and decide later how it will be interpreted with regard to the experimental hypothesis violates basic principles of scientific design because the method of decision should be specified prior to adducing the data. Nevertheless, in conformity with the Guidance Document, we performed many hundreds of post hoc statistical tests of various hypotheses, and we could find no reasonable basis to reject the conclusion that carbon fibers were as safe and effective as standard therapy.

In the IDE, we characterize "giving way" using three classes (none, occasional, and frequent), whereas the Guidance Document employs 7 classes and 17 text lines to describe the classes. Such complicated schemes are probably not justified in the absence of prior validation because there is no reason to believe the data has value. Moreover, the disinterested cooperating clinician who performs the follow-up examination likely will perform the examination in the manner that constitutes standard procedure, regardless of the Sponsor's wishes.

The Guidance Document recommends the use of a device to quantify laxity. Initially, each investigator in our study was supplied with a mechanical arthrometer and asked to record anterior displacement (in millimeters) during each clinical follow-up visit. When two independent methods are mandated for the determination of a specific dependent variable, a choice must be made regarding how

conflicts between data obtained by the two methods will be resolved*. We ignored the arthrometer data because (1) it did not correlate with the results of the clinical examination; (2) we lacked the ability to insure that each arthrometer remained calibrated throughout the long study; (3) many follow-up examinations were made by physicians who were not investigators, and who had no access to an arthrometer.

CONCLUSION

The data shows that the CFS™ is safe and effective for the treatment of ACL instability in patients who have not undergone previous surgical treatment. The CFS™ is as good as standard intra-articular reconstructions using autologous tissue in patients having either acute or chronic injuries.

* Because bias would be produced if an individual physician was consulted about the data he recorded, the rule followed in this study was that no physician was asked any questions about any data entered.

REFERENCES

(1) Jenkins, D.H.R., Forster, I.W., McKibbin, B. and Ralis, Z.A.: Induction of tendon and ligament formation by carbon implants, J. Bone Joint Surg. 59B:53-57, 1977.

(2) Jenkins, D.H.R.: The repair of cruciate ligaments with flexible carbon fibre, J. Bone Joint Surg. 60B:520-522, 1978.

(3) Forster, I.W., Ralis, Z.A., McKibben, B. and Jenkins, D.H.R.: Biological reaction to carbon fiber implants, Clin. Orthop. 131:299-307, 1977.

(4) Tayton, K., Phillips, G. and Ralis, Z.: Long-term effects of carbon fiber on soft tissues, J. Bone Joint Surg. 64B:112-114, 1982.

(5) Amis, A.A., Campbell, J.R., Kempson, S.A. and Miller, J.H.: Comparison of the structure of neotendons induced by implantation of carbon or polyester fibres, J. Bone Joint Surg. 66-B:131-139, 1984.

(6) Amis, A.A., Campbell, J.R. and Miller, J.H.: Strength of carbon and polyester fibre tendon replacements, J. Bone Joint Surg. 67-B:829-834, 1985.

(7) Amis, A.A., Kempson, S.A., Campbell, J.R. and Miller, J.H.: Anterior cruciate ligament replacement: Biocompatibility and biomechanics of polyester and carbon fibre in rabbits, J. Bone Joint Surg. 70-B:628-634, 1988.

(8) Alexander, H., Weiss, A.B. and Parsons, J.R.: Absorbable polymer-filamentous carbon composites - A new class of tissue scaffolding materials, in Alloplastic Ligament Replacement, C. Burri and L. Claes, eds., Hans Huber Publ., Bern, 1983.

(9) Alexander, H., Parsons, J.R., Strauchler, I.D., Corcoran, S.F., Gona, O., Mayott, C. and Weiss, A.B.: Canine patellar tendon replacement with a polylactic acid polymer-filamentous carbon degrading scaffold to form new tissue, Orthop. Rev. 10:41-51, 1981.

(10) Alexander, H., Weiss, A.B., Parsons, J.R., Strauchler, I.D. and Gona, O.: Ligament and tendon replacement with absorbable polymer-filamentous carbon tissue scaffolds, Trans. 11th International Symposium for Biomaterials 3:72, 1979.

(11) Alexander, H., Weiss, A.B., Parson, J.R., Strauchler, I.D. and Gona, O.: Ligament and tendon replacement with absorbable polymer-filamentous carbon tissue scaffolds, 25th Annual ORS, San Francisco, February 20-22, p. 27, 1979.

(12) Donnet, J.B. and Bansal, R.C.: Carbon Fibers, Marcel Dekker, New York, 1984.

(13) Aragona, J., Parsons, J.R., Alexander, H. and Weiss, A.B.: Soft tissue attachment of filamentous carbon-absorbable polymer tendon and ligament replacement, Clin. Orthop. 160:268-278, 1981.

(14) Keating, E.M., Marino, A.A., Albright, J.A. and Specian, R.D.: Functional repair of rabbit gastrocnemius tendons using carbon fibers, Clin. Orthop. 209:292-297, 1986.

(15) Aragona, J., Parsons, J.R., Alexander, H. and Weiss, A.B.: Medial collateral ligament replacement with a partially absorbable tissue scaffold, Am. J. Sports Med. 11:228-233, 1983.

(16) Parsons, J.R., Bhayani, S., Alexander, H. and Weiss, A.B.: Carbon fiber debris within the synovial joint, Clin. Orthop. 196:69-76, 1985.

(17) Rushton, N. and Rae, T.: The intra-articular response to particulate carbon fiber reinforced high density polyethylene and its constituents: An experimental study in mice, Biomaterials 5:352-356, 1984.

(18) Gleason, T.F., Barmada, R. and Ghosh, L.: Can carbon fiber implants substitute for collateral ligament? Clin. Orthop. 191:274-280, 1984.

(19) Kramer, B.: Histological appearance of carbon fiber implants and neoligament in man, S. Afr Med. J. 63:113-115, 1983.

(20) Mendes, D.G., Iusim, M., Angel, D., Rotem, A., Roffman, M., Grishkan, A., Mordohohovich, D. and Boss, J.: Histologic pattern of biomechanic properties of the carbon-fiber augmented ligament tendon, Clin. Orthop. 196:51-60, 1985.

(21) Bercovy, M., Goutallier, D., Boisin, M.C., Geiger, D., Blanquaert, D., Gaudichet, A. and Patte, D.: Carbon-PGLA prostheses for ligament reconstruction, Clin. Orthop. 196:159-168, 1985.

(22) Post, M.: Rotator cuff repair with carbon filament, Clin. Orthop. 196:154-158, 1985.

(23) Weiss, A.B., Blazina, M.E., Goldstein, A.R. and Alexander, H.: Ligament replacement with an absorbable copolymer carbon fiber scaffold -- Early clinical experience, Clin. Orthop. 196:77-85, 1985.

(24) Witvoet, J. and Christel, P.: Treatment of chronic anterior knee instabilities with combined intra- and extra-articular transfer augmented with carbon-PLA fibers, Clin. Orthop. 196:143-153, 1985.

(25) Strum, G.M. and Larson, R.L.: Clinical experience and early results of carbon fiber augmentation of anterior cruciate reconstruction of the knee, Clin. Orthop. 196:124-138, 1985.

(26) King, J.B. and Bulstrode, C.: Polylactate-coated carbon fiber in extra-articular reconstruction of the unstable knee, Clin. Orthop. 196:139-142, 1985.

(27) Jenkins, D.H.R. and McKibbin, B.: The role of flexible carbon-fibre implants as tendon and ligament substitutes in clinical practice, J. Bone Joint Surg. 62B:497-499, 1980.

(28) Leyshon, R., Channon, G.M., Jenkins, D.H.R. and Ralis, Z.A.: Flexible carbon fiber in late ligamentous reconstruction for instability of the knee, J. Bone Joint Surg. 66-B:196-200, 1984.

(29) Jenkins, D.H.R.: Ligament induction by filamentous carbon fiber, Clin. Orthop. 196:86-87, 1985.

(30) Dandy, D.J., Flanagan, J.P. and Steenmeyer, V.: Arthroscopy and the management of the ruptured anterior cruciate ligament, Clin. Orthop. 167:43-49, 1982.

(31) Rushton, N., Dandy, D.J. and Naylor, C.P.E.: The clinical, arthroscopic and histological findings after replacement of the anterior cruciate ligament with carbon fiber, J. Bone Joint Surg. 65-B:308-309, 1983.

(32) Bray, R.C., Flanagan, J.P. and Dandy, D.J.: Reconstruction for chronic anterior cruciate instability, J. Bone Joint Surg. 70-B:100-105, 1988.

(33) Lemaire, M.: Reinforcement of tendons and ligaments with carbon fibers: Four years, 1300 cases, Clin. Orthop. 196:169-174, 1985.

(34) Lemaire, M.: Use of carbon fibers in surgery, in Alloplastic Ligament Replacement, C. Burri and L. Claes, eds., Hans Huber, Vienna, 148-149, 1983.

(35) Weiss, L.: Cell and Tissue Biology, 6th Edition, Urban and Schwarzenberg, Baltimore, 1988.

(36) Nopajaroonsri, Charn and Simon, G.T.: Phagocytosis of colloidal carbon in lymph nodes, Am. J. Pathol. 65:25-42, 1971.

(37) Oghiso, Y. and Matsuoka, O.: Distribution of colloidal carbon in lymph nodes of mice injected by different routes, Jap. J. Exp. Med. 49:223-234, 1979.

(38) Lever, W.F. and Schaumbert-Lever, G.: Histopathology of the Skin, J.B. Lippincott, Philadelphia, 19?.

(39) Roenigk, H.H.: Tattooing - history, technics, complication, removal, Cleveland Clin. Q. 38:179-186, 1971.

(40) Apfelberg, D.B., Laub, D.R., Maser, M.R. and Lash, H.: Pathophysiology and treatment of decorative tattoos with reference to argon laser treatment, Clin. Plast. Surg. 7:369-377, 1980.

(41) Schumacher, H.R.: Fate of particulate material arriving at the synovium via the circulation, Ann. Rheum. Dis. 32:212-218, 1973.

(42) Adam, W.S.: Fine structure of experimentally produced subsynovial carbon granuloma, Nature 505C:771-772, 1966.

(43) Bellamy, R. and Wood, T.P.: Graphite localization in the synovial membrane of the knee, J. Bone Joint Surg. 60-A:1149-1151, 1978.

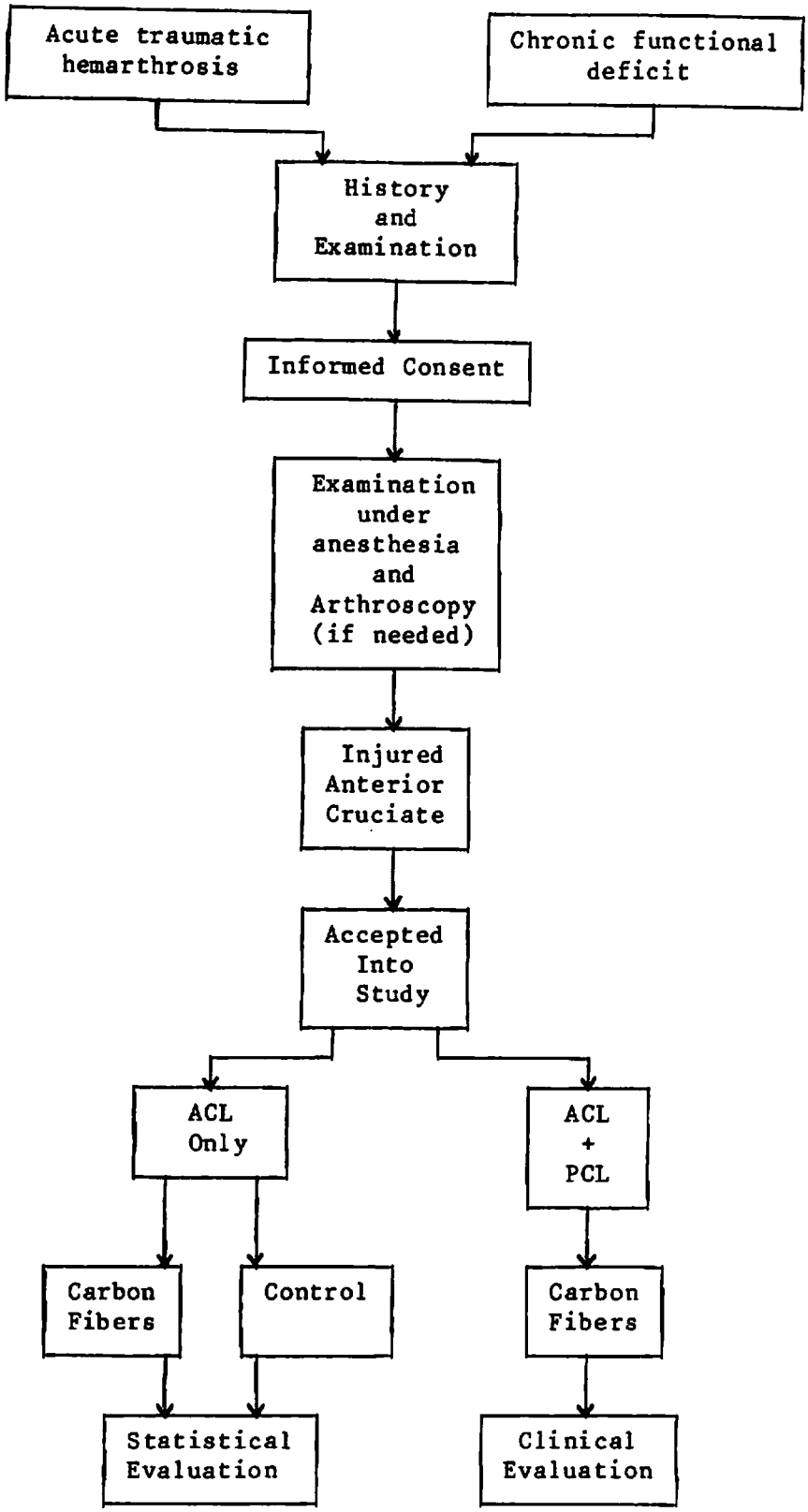

FIGURE 1. CLINICAL STUDY OF THE ACL.

TABLE 1. Patients Treated with Carbon Fibers. An injury for which surgery was performed within 14 days of injury was termed acute: All other injuries were termed chronic.

		NUMBER OF PATIENTS	
		Acute	Chronic
RANDOMIZED STUDY	Carbon Fibers	31	43
	Control	24	36
NON-RANDOMIZED STUDY	Carbon Fibers	7	3

TABLE 2. Follow-up Criteria (and Number of Classes) in Standardized Follow-up Form.

CRITERION	NO. OF CLASSES
SYMPTOMS	
Pain (sports)	5
(normal)	5
Swelling (sports)	5
(normal)	5
Giving Way (sports)	3
(normal)	3
FUNCTION	
Limp	4
Standing	4
Walking (function)	4
Stair climbing (function)	4
Running (function)	4
Sports	4
Support	4
Work tolerance	3
Control of instability	3
Type of control	3
Walking (activity)	4
Climbing stairs (activity)	4
Descending stairs	4
Kneeling	4
Jobbing	4
Running (activity)	4
Jumping	4
Stopping	4
Twisting	4

CRITERION	NO. OF CLASSES
DEFORMITY	
Patella alignment	2
ROM-active	6
ROM-passive	6
TP crepitation	4
PF crepitation	4
Varus or valgus stance	4
STABILITY	
Anterior drawer (30°)	4
Anterior drawer (90°)	4
Posterior drawer (30°)	4
Posterior drawer (90°)	4
Pivot shift	4
Varus stress (30°)	3
Valgus stress (30°)	3
PATIENT'S EVALUATION	
Performance level (normal)	6
Performance level (sports)	8
Standing	4
Walking (level)	4
Walking (uneven)	4
Climbing	4
Up stairs	4
Down stairs	4
Kneeling	4
Squatting	4
Running	4
Standing	4
Jumping	4
Twisting	4
Cutting	4

TABLE 3. Categories, Assigned Weight, and Scaling Used to Compute the Total Score (T) for a Clinical Examination (highest score, T = 100).

CATEGORY	MAXIMUM RAW POINTS	ASSIGNED WEIGHT	SCALE FACTOR
Symptoms	46	20%	0.437
Function	65	20%	0.311
Deformity	22	10%	0.458
Stability	48	30%	0.626
Patient's Evaluation	58	20%	0.349

TABLE 4. Total Scores and Standard Deviations Observed in the Chronic, Acute, and Chronic + Acute Categories (highest score, 100). The numbers in parentheses are patients followed in the indicated time interval. Each group was sampled annually: the cumulative percentage of patients who were followed is shown for each group.

A. Chronic

	TIME (Years)					
	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	50.0 ± 15.4 (39[a])[d]	65.6 ± 15.2 (35)	78.0 ± 14.4 (20)	80.1 ± 12.3 (24[a])	72.9 ± 15.2 (17[a])	73.8 ± 15.1 (27[b])
		89.7%	94.9%	100%	100%	100%
CONTROL	49.4 ± 13.2 (32[b])[d]	64.8 ± 13.0 (29[a])	80.1 ± 10.9 (19[c])	84.2 ± 10.4 (14)	83.4*± 12.4 (17)	77.8 ± 14.6 (17[b])
		87.5%	96.9%	96.9%	100%	100%

[a] The Total Score was incomplete for one patient.
[b] The Total Score was incomplete for four patients.
[c] The Total Score was incomplete for two patients.
[d] Four patients were treatment failures; their Scores are not included.
* P = 0.04

B. Acute

	TIME (Years)					
	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	32.4 ± 10.4 (31[a])	71.6 ± 16.5 (26)	85.0 ± 9.6 (12)	87.2 ± 8.9 (17)	88.1 ± 8.1 (21[b])	84.5 ± 10.2 (11[b])
		83.9%	100%	100%	100%	100%
CONTROL	33.6 ± 9.0 (24[c])	72.5 ± 14.2 (18)	84.5 ± 5.4 (14[d])	80.7 ± 12.2 (12[d])	83.2 ± 9.9 (12[d])	78.2 ± 11.8 (9[b])
		75%	87.5%	95.8%	95.8%	100%

[a] The Total Score was incomplete for three patients.
[b] The Total Score was incomplete for two patients.
[c] The Total Score was incomplete for five patients.
[d] The Total Score was incomplete for one patient.

Table 4 (continued)

C. Chronic + Acute

	TIME (Years)					
	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	42.6 ± 16.0 (70[a])	68.2 ± 16.0 (61)	80.5 ± 13.2 (32)	83.0 ± 11.5 (41[c])	81.2 ± 14.0 (38[d])	76.8 ± 14.6 (38[e])
		87.1%	97.1%	100%	100%	100%
CONTROL	43.0 ± 14.0 (56[b])	67.8 ± 13.9 (47[c])	81.9 ± 9.3 (33[d])	82.6 ± 11.1 (26[c])	83.3 ± 11.3 (29[c])	77.9 ± 13.3 (26[e])
		82.1%	92.8%	96.4%	98.2%	100%

[a] The Total Score was incomplete for four patients.
[b] The Total Score was incomplete for nine patients.
[c] The Total Score was incomplete for one patient.
[d] The Total Score was incomplete for three patients.
[e] The Total Score was incomplete for six patients.

TABLE 5. Total Scores and Standard Deviations Observed in the Chronic, Acute, and Chronic + Acute Categories of the Non-Randomized Group (highest score, 100). The numbers in parentheses are patients followed in the indicated time interval. Each group was sampled annually: the cumulative percentage of patients who were followed is shown for each group.

A. Chronic

	TIME (Years)					
	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	46.8 ± 2.7 (2)	64.6 ± 1.3 (1)	61.5 ± 16.8 (2)	--- (1)[a]	62.9 ± 5.4 (2)	63.6 ± 16.4 (1)
		50.0%	100%	100%	100%	100%

[a] The Total Score was incomplete for one patient.

B. Acute

	TIME (Years)					
	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	11.0 ± 8.1 (7)[a]	71.6 ± 9.6 (5)[a]	71.9 ± 15.5 (6)	64.8 ± 15.2 (4)[a]	71.8 ± 14.8 (5)	--- (0)
		71.4%	100%	100%	100%	100%

[a] The Total Score was incomplete for one patient.

C. Chronic + Acute

	TIME (Years)					
	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	19.9 ± 18.0 (9)[a]	70.3 ± 9.0 (6)[a]	69.8 ± 15.4 (8)	64.8 ± 15.2 (5)[b]	69.2 ± 13.0 (7)	63.6 ± 16.4 (1)
		66.7%	100%	100%	100%	100%

[a] The Total Score was incomplete for one patient.
[b] The Total Score was incomplete for two patients.

TABLE 6. Anterior Drawer - 30°. Chronic patients. FDA designation, App. 6, Item 1. IDE designation, ST-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	22 /22.9%	9 /37.5%	9 /36.0%	2 /11.1%	6 /22.2%
	CLASS 2	14 /32.6%	56 /58.3%	10 /41.7%	8 /32.0%	14 /77.8%	14 /51.8%
	CLASS 3	23 /53.5%	18 /18.8%	3 /12.5%	7 /28.0%	2 /11.1%	2 /7.4%
	CLASS 4	6 /14.0%	0	2 /8.3%	1 /4.0%	0	5 /18.5%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	2 /5.6%	35 /41.7%	10 /40.0%	9 /60.0%	5 /29.4%	4 /22.2%
	CLASS 2	13 /36.1%	36 /42.8%	13 /52.0%	2 /13.3%	12 /70.6%	11 /61.1%
	CLASS 3	17 /47.2%	13 /15.5%	1 /4.0%	3 /20.0%	0	2 /11.1%
	CLASS 4	4 /11.1%	0	1 /4.0%	1 /6.7%	0	1 /5.6%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 7. Anterior Drawer - 30°. Acute patients. FDA designation, App. 6, Item 1. IDE designation, ST-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	27 /39.7%	5 /38.5%	5 /29.4%	7 /33.3%	4 /36.4%
	CLASS 2	11 /35.5%	32 /47.0%	8 /61.5%	11 /64.7%	13 /61.9%	4 /36.4%
	CLASS 3	16 /51.6%	9 /13.2%	0	1 /5.9%	1 /4.8%	3 /27.3%
	CLASS 4	4 /12.9%	0	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	2 /8.3%	24 /51.1%	5 /31.2%	3 /25.0%	7 /58.3%	3 /33.3%
	CLASS 2	14 /58.3%	17 /36.2%	9 /56.2%	6 /50.0%	2 /16.7%	2 /22.2%
	CLASS 3	8 /33.3%	6 /12.8%	2 /12.5%	3 /25.0%	2 /16.7%	3 /33.3%
	CLASS 4	0	0	0	0	1 /8.3%	1 /11.1%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were different. In the carbon-fiber group, 36% of the patients had an anterior drawer of less than 5 mm. In the control group, 67% of the patients had an anterior drawer of less than 5 mm ($P < 0.05$).
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 8. Anterior Drawer - 30°. Chronic + acute patients. FDA designation, App. 6, Item 1. IDE designation, ST-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	49 /29.9%	14 /37.8%	14 /33.3%	9 /23.1%	10 /26.3%
	CLASS 2	25 /33.8%	88 /53.6%	18 /48.6%	19 /45.2%	27 /69.2%	18 /47.4%
	CLASS 3	39 /52 7%	27 /16.5%	3 /8.1%	8 /19.0%	3 /7.7%	5 /13.2%
	CLASS 4	10 /13.5%	0	2 /5.4%	1 /2.4%	0	5 /13.2%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	4 /6.7%	59 /45.0%	15 /36.6%	12 /44.4%	12 /41.4%	7 /25.9%
	CLASS 2	27 /45.0%	53 /40.4%	22 /53.6%	8 /29.6%	14 /48.3%	13 /48.1%
	CLASS 3	25 /41.7%	19 /14.5%	3 /7.3%	6 /22.2%	2 /6.9%	5 /18.5%
	CLASS 4	4 /6.7%	0	1 /2.4%	1 /3.7%	1 /3.4%	2 /7.4%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different ($P < 0.056$).
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 9. Anterior Drawer - 90°. Chronic patients. FDA designation, App. 6, Item 2. IDE designation, ST-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 /2.3%	31 /32.3%	10 /41.7%	9 /36.0%	4 /22.2%	8 /28.6%
	CLASS 2	15 /34.9%	49 /51.0%	9 /37.5%	12 /48.0%	11 /61.1%	15 /53.6%
	CLASS 3	21 /48.8%	16 /16.7%	3 /12.5%	3 /12.0%	3 /16.7%	3 /10.7%
	CLASS 4	6 /14.0%	0	2 /8.3%	1 /4.0%	0	2 /7.1%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	2 /5.7%	34 /40.5%	9 /36.0%	6 /40.0%	9 /52.9%	5 /27.8%
	CLASS 2	10 /28.6%	32 /38.1%	13 /52.0%	6 /40.0%	7 /41.2%	9 /50.0%
	CLASS 3	20 /57.1%	18 /21.4%	3 /12.0%	3 /20.0%	1 /5.9%	3 /16.7%
	CLASS 4	3 /8.6%	0	0	0	0	1 /5.5%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 10. Anterior Drawer - 90°. Acute patients. FDA designation, App. 6, Item 2. IDE designation, ST-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	5 /16.1%	28 /41.2%	3 /23.1%	6 /35.3%	7 /33.3%	3 /27.3%
	CLASS 2	9 /29.0%	29 /42.6%	8 /61.5%	10 /58.8%	11 /52.4%	4 /36.4%
	CLASS 3	15 /48.4%	11 /16.2%	1 /7.7%	1 /5.9%	3 /14.3%	4 /36.4%
	CLASS 4	2 /6.4%	0	1 /7.7%	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	8 /33.3%	22 /46.8%	6 /37.5%	3 /25.0%	7 /58.3%	2 /22.2%
	CLASS 2	9 /37.5%	21 /44.7%	8 /50.0%	9 /75.0%	3 /25.0%	3 /33.3%
	CLASS 3	7 /29.2%	4 /8.5%	2 /12.5%	0	1 /8.3%	3 /33.3%
	CLASS 4	0	0	0	0	1 /8.3%	1 /11.1%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 11. Anterior Drawer - 90°. Chronic + acute patients. FDA designation, App. 6, Item 2. IDE designation, ST-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	6 /8.1%	59 /36.0%	13 /35.1%	15 /35.7%	11 /28.2%	11 /28.2%
	CLASS 2	24 /32.4%	78 /47.6%	17 /45.9%	22 /52.4%	22 /56.4%	19 /48.7%
	CLASS 3	36 /48.6%	27 /16.5%	4 /10.8%	4 /9.5%	6 /15.4%	7 /17.9%
	CLASS 4	8 /10.8%	0	3 /8.1%	1 /2.4%	0	2 /5.1

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	10 /16.9%	56 /42.7%	15 /36.6%	9 /33.3%	16 /55.2%	7 /25.9%
	CLASS 2	19 /32.2%	53 /40.4%	21 /51.2%	15 /55.6%	10 /34.5%	12 /44.4%
	CLASS 3	27 /45.8%	22 /16.8%	5 /12.2%	3 /11.1%	2 /6.9%	6 /22.2%
	CLASS 4	3 /5.1%	0	0	0	1 /3.4%	2 /7.4%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 12. Pivot Shift. Chronic patients. FDA designation, App. 6, Item 3. IDE designation, ST-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years post-operatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	3 /7.0%	55 /57.3%	13 /54.2%	16 /64.0%	9 /50.0%	14 /50.0%
	CLASS 2	11 /25.6%	21 /21.9%	7 /29.2%	5 /20.0%	5 /27.8%	7 /25.0%
	CLASS 3	19 /44.2%	14 /14.6%	2 /8.3%	3 /12.0%	4 /22.2%	5 /17.9%
	CLASS 4	10 /23.2%	6 /6.2%	2 /8.3%	1 /4.0%	0	2 /7.1%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	1 /3.1%	63 /76.8%	15 /60.0%	8 /53.3%	15 /88.2%	10 /58.8%
	CLASS 2	7 /21.9%	14 /17.1%	9 /36.0%	5 /33.3%	2 /11.8%	6 /35.3%
	CLASS 3	20 /62.5%	5 /6.1%	1 /4.0%	2 /13.3%	0	1 /5.9%
	CLASS 4	4 /12.5%	0	0	0	0	0

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different, except at 3-4 years post-operatively.

TABLE 13. Pivot Shift. Acute patients. FDA designation, App. 6, Item 3. IDE designation, ST-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years post-operatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	5 /16.1%	49 /74.2%	9 /69.2%	12 /70.6%	16 /76.2%	6 /54.5%
	CLASS 2	2 /6.4%	12 /18.2%	4 /30.8%	4 /23.5%	4 /19.0%	4 /36.4%
	CLASS 3	17 /54.8%	3 /4.5%	0	1 /5.9%	1 /4.8%	1 /9.1%
	CLASS 4	7 /22.6%	2 /3.0%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	8 /33.3%	38 /80.8%	11 /68.8%	9 /81.8%	8 /66.7%	7 /77.8%
	CLASS 2	5 /20.8%	7 /14.9%	4 /25.0%	2 /18.2%	4 /33.3%	2 /22.2%
	CLASS 3	9 /37.5%	2 /4.2%	1 /6.2%	0	0	0
	CLASS 4	2 /8.3%	0	0	0	0	0

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 14. Pivot Shift. Chronic + acute patients. FDA designation, App. 6, Item 3. IDE designation, ST-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	8 /10.8%	104/ 64.2%	22 /59.4%	28 /66.7%	25 /64.1%	20 /51.3%
	CLASS 2	13 /17.6%	33 /20.4%	11 /29.7%	9 /21.4%	9 /23.1%	11 /28.2%
	CLASS 3	36 /48.6%	17 /10.5%	2 /5.4%	4 /9.5%	5 /12.8%	6 /15.4%
	CLASS 4	17 /23.0%	8 /4.9%	2 /5.4%	1 /2.4%	0	2 /5.1%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	9 /16.1%	101 /78.3%	26 /63.4%	17 /65.4%	23 /79.3%	17 /65.4%
	CLASS 2	12 /21.4%	21 /16.3%	13 /31.7%	7 /26.9%	6 /20.7%	8 /30.8%
	CLASS 3	29 /51.8%	7 /5.4%	2 /4.9%	2 /7.7%	0	1 /3.8%
	CLASS 4	6 /10.7%	0	0	0	0	0

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 15. Posterior Drawer - 90°. Chronic patients. FDA designation, App. 6, Item 8. IDE designation, ST-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	40 /93.0%	90 /93.8%	22 /91.7%	23 /92.0%	16 /88.9%	25 /92.6%
	CLASS 2	2 /4.6%	2 /2.1%	1 /4.2%	0	2 /11.1%	2 /7.4%
	CLASS 3	0	1 /1.0%	0	1 /4.0%	0	0
	CLASS 4	1 /2.3%	3 /3.1%	1 /4.2%	1 /4.0%	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	28 /80.0%	80 /95.2%	19 /76.0%	14 /93.3%	12 /70.6%	17 /94.4%
	CLASS 2	4 /11.4%	3 /3.6%	4 /16.0%	1 /6.7%	4 /23.5%	1 /5.6%
	CLASS 3	2 /5.7%	0	1 /4.0%	0	0	0
	CLASS 4	1 /2.8%	1 /1.2%	1 /4.0%	0	1 /5.9%	0

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was not associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 16. Posterior Drawer - 90°. Acute patients. FDA designation, App. 6, Item 8. IDE designation, ST-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	30 /96.8%	66 /97.0%	11 /84.6%	16 /94.1%	20 /95.2%	11 /100.0%
	CLASS 2	0	2 /2.9%	1 /7.7%	0	1 /4.8%	0
	CLASS 3	0	0	0	1 /5.9%	0	0
	CLASS 4	1 /3.2%	0	1 /7.7%	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	19 /79.2%	45 /95.7%	14 /87.5%	12 /100.0%	12 /100.0%	8 /88.9%
	CLASS 2	3 /12.5%	1 /2.1%	2 /12.5%	0	0	0
	CLASS 3	1 /4.2%	1 /2.1%	0	0	0	0
	CLASS 4	1 /4.2%	0	0	0	0	1 /11.1%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was not associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 17. Posterior Drawer - 90°. Chronic + acute patients. FDA designation, App. 6, Item 8. IDE designation, ST-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	70 /94.6%	156/95.1%	33 /89.2%	39 /92.8%	36 /92.3%	36 /94.7%
	CLASS 2	2 /2.7%	4 /2.4%	2 /5.4%	0	3 /7.7%	2 /5.3%
	CLASS 3	0	1 /0.6%	0	2 /4.8%	0	0
	CLASS 4	2 /2.7%	3 /1.8%	2 /5.4%	1 /2.4%	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	47 /79.7%	125/95.4%	33 /80.5%	26 /96.3%	24 /82.8%	25 /92.6%
	CLASS 2	7 /11.9%	4 /3.0%	6 /14.6%	1 /3.7%	4 /13.8%	1 /3.7%
	CLASS 3	3 /5.1%	1 /0.8%	1 /2.4%	0	0	0
	CLASS 4	2 /3.4%	1 /0.8%	1 /2.4%	0	1 /3.4%	1 /3.7%

CLASS 1: 0 mm
CLASS 2: < 5 mm
CLASS 3: 5-10 mm
CLASS 4: > 10 mm

1. The pre-operative distributions were not different.
2. In both groups, treatment was not associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 18. Giving way (normal activities). Chronic patients. FDA designation, App. 5, Item 4. IDE designation, S-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	12 /30.8%	65 /79.3%	17 /73.9%	22 /88.0%	10 /58.8%	17 /63.0%
	CLASS 2	14 /35.9%	14 /17.1%	5 /21.7%	3 /12.0%	7 /41.2%	8 /29.6%
	CLASS 3	13 /33.3%	3 /3.6%	1 /4.3%	0	0	2 /7.4%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	9 /28.1%	59 /85.5%	18 /75.0%	10 /71.4%	13 /76.5%	13 /76.5%
	CLASS 2	11 /34.4%	8 /11.6%	6 /25.0%	4 /28.6%	4 /23.5%	4 /23.5%
	CLASS 3	12 /37.5%	2 /2.9%	0	0	0	0

Class 1: None
Class 2: Occasional
Class 3: Chronic

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 19. Giving way (normal activities). Acute patients. FDA designation, App. 5, Item 4. IDE designation, S-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	3 /10.3%	57 /90.5%	13 /100.0%	15 /88.2%	19 /95.0%	8 /72.7%
	CLASS 2	2 /6.9%	3 /4.8%	0	2 /11.8%	1 /5.0%	3 /27.3%
	CLASS 3	24 /82.8%	3 /4.8%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	2 /9.5%	37 /84.1%	15 /93.8%	8 /66.7%	7 /58.3%	5 /55.6%
	CLASS 2	3 /14.3%	7 /15.9%	1 /6.2%	4 /33.3%	5 /41.7%	4 /44.4%
	CLASS 3	16 /76.2%	0	0	0	0	0

Class 1: None
Class 2: Occasional
Class 3: Chronic

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different except at 3-4 years post-operatively.

TABLE 20. Giving way (normal activities). Chronic + acute patients. FDA designation, App. 5, Item 4. IDE designation, S-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	15 /22.1%	122/84.1%	30 /83.3%	37 /88.1%	29 /78.4%	25 /65.8%
	CLASS 2	16 /23.5%	17 /11.7%	5 /13.9%	5 /11.9%	8 /21.6%	11 /28.9%
	CLASS 3	37 /54.4%	6 /4.1%	1 /2.8%	0	0	2 /5.3%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	11 /20.8%	96 /85.0%	33 /82.5%	18 /69.2%	20 /69.0%	18 /69.2%
	CLASS 2	14 /26.4%	15 /13.3%	7 /17.5%	8 /30.8%	9 /31.0%	8 /30.8%
	CLASS 3	28 /52.8%	2 /1.8%	0	0	0	0

Class 1: None
Class 2: Occasional
Class 3: Chronic

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 21. Giving way (sports activities). Chronic patients. FDA designation, App. 5, Item 4. IDE designation, S-6. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	25 /86.2%	14 /73.7%	17 /70.8%	4 /28.6%	12 /50.0%
	CLASS 2	11 /31.4%	3 /10.3%	5 /26.3%	7 /29.2%	9 /64.3%	10 /41.7%
	CLASS 3	24 /68.6%	1 /3.4%	0	0	1 /7.1%	2 /8.3%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	1 /4.2%	18 /75.0%	15 /75.0%	9 /64.3%	12 /75.0%	12 /75.0%
	CLASS 2	4 /16.7%	2 /8.3%	5 /25.0%	3 /21.4%	4 /25.0%	3 /18.8%
	CLASS 3	19 /79.2%	4 /16.7%	0	2 /14.3%	0	1 /6.2%

Class 1: None
Class 2: Occasional
Class 3: Chronic

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval the distributions were not different except at 3-4 years post-operatively.

TABLE 22. Giving way (sports activities). Acute patients. FDA designation, App. 5, Item 4. IDE designation, S-6. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	> 4
CARBON FIBER	CLASS 1	1 /3.6%	25 /78.1%	11 /100.0%	13 /76.5%	18 /90.0%	6 /60.0%
	CLASS 2	2 /7.1%	4 /12.5%	0	3 /17.6%	2 /10.0%	4 /40.0%
	CLASS 3	25 /89.3%	3 /9.4%	0	1 /5.9%	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	> 4
CONTROL	CLASS 1	0	12 /54.5%	11 /78.6%	7 /63.6%	6 /50.0%	5 /55.6%
	CLASS 2	1 /5.9%	7 /31.8%	3 /21.4%	2 /18.2%	6 /50.0%	4 /44.4%
	CLASS 3	16 /94.1%	3 /13.6%	0	2 /18.2%	0	0

Class 1: None
Class 2: Occasional
Class 3: Chronic

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval the distributions were not different.

TABLE 23. Giving way (sports activities). Chronic + acute patients. FDA designation, App. 5, Item 4. IDE designation, S-6. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 /1.6%	50 /82.0%	25 /83.3%	30 /73.2%	22 /64.7%	18 /52.9%
	CLASS 2	13 /20.6%	7 /11.5%	5 /16.7%	10 /24.4%	11 /32.4%	14 /41.2%
	CLASS 3	49 /77.8%	4 /6.6%	0	1 /2.4%	1 /2.9%	2 /5.9%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	1 /2.4%	30 /65.2%	26 /76.5%	16 /64.0%	18 /64.3%	17 /68.0%
	CLASS 2	5 /12.2%	9 /19.6%	8 /23.5%	5 /20.0%	10 /35.7%	7 /28.0%
	CLASS 3	35 /85.4%	7 /15.2%	0	4 /16.0%	0	1 /4.0%

Class 1: None
Class 2: Occasional
Class 3: Chronic

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 24. Pain (normal activities). Chronic patients. FDA designation, App. 5, Item 1. IDE designation, S-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	18 / 46%	74 / 87%	20 / 87%	25 / 100%	12 / 71%	23 / 85%
	CLASS 2	9 / 23%	4 / 5%	2 / 9%	0	2 / 12%	4 / 15%
	CLASS 3	12 / 31%	7 / 8%	1 / 4%	0	3 / 18%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	16 / 50%	61 / 87%	22 / 92%	14 / 100%	16 / 94%	16 / 94%
	CLASS 2	9 / 28%	6 / 9%	1 / 4%	0	1 / 6%	1 / 6%
	CLASS 3	7 / 22%	3 / 4%	1 / 4%	0	0	0

CLASS 1: No pain or mild occasional pain
CLASS 2: Mild chronic pain
CLASS 3: Severe pain

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 25. Pain (normal activities). Acute patients. FDA designation, App. 5, Item 1. IDE designation, S-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	5 / 17%	60 / 94%	13 / 100%	17 / 100%	19 / 95%	11 / 100%
	CLASS 2	0	2 / 3%	0	0	1 / 5%	0
	CLASS 3	25 / 83%	2 / 3%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	3 / 14%	43 / 98%	14 / 88%	7 / 58%	12 / 100%	9 / 100%
	CLASS 2	0	1 / 2%	1 / 6%	4 / 33%	0	0
	CLASS 3	18 / 86%	0	1 / 6%	1 / 8%	0	0

CLASS 1: No pain or mild occasional pain
CLASS 2: Mild chronic pain
CLASS 3: Severe pain

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different except at 2-3 years post-operatively.

TABLE 26. Pain (normal activities). Chronic + acute patients. FDA designation, App. 5, Item 1. IDE designation, S-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	23 / 33%	134/ 90%	33 / 92%	42 / 100%	31 / 84%	34 / 89%
	CLASS 2	9 / 13%	6 / 4%	2 / 6%	0	3 / 8%	4 / 10%
	CLASS 3	37 / 54%	9 / 6%	1 / 3%	0	3 / 8%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	19 / 36%	104/ 91%	36 / 90%	21 / 81%	28 / 96%	25 / 96%
	CLASS 2	9 / 17%	7 / 6%	2 / 5%	4 / 15%	1 / 4%	1 / 4%
	CLASS 3	25 / 47%	3 / 3%	2 / 5%	1 / 4%	0	0

CLASS 1: No pain or mild occasional pain
CLASS 2: Mild chronic pain
CLASS 3: Severe pain

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different except at 2-3 years post-operatively.

TABLE 27. Pain (sports activities). Chronic patients. FDA designation, App. 5, Item 1. IDE designation, S-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	5 / 15%	27 / 93%	16 / 84%	22 / 92%	10 / 71%	18 / 72%
	CLASS 2	4 / 12%	1 / 3%	1 / 5%	0	1 / 7%	2 / 8%
	CLASS 3	25 / 74%	1 / 3%	2 / 10%	2 / 8%	3 / 21%	5 / 20%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	5 / 21%	20 / 77%	18 / 90%	12 / 86%	14 / 88%	14 / 88%
	CLASS 2	2 / 8%	1 / 4%	1 / 5%	0	2 / 12%	0
	CLASS 3	17 / 71%	5 / 19%	1 / 5%	2 / 14%	0	2 / 12%

CLASS 1: No pain or mild occasional pain
CLASS 2: Mild chronic pain
CLASS 3: Severe pain

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 28. Pain (sports activities). Acute patients. FDA designation, App. 5, Item 1. IDE designation, S-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 / 4%	28 / 88%	10 / 91%	16 / 94%	19 / 95%	10 / 100%
	CLASS 2	0	0	0	1 / 6%	1 / 5%	0
	CLASS 3	26 / 96%	4 / 12%	1 / 9%	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	1 / 6%	18 / 82%	14 / 93%	7 / 64%	11 / 92%	8 / 89%
	CLASS 2	0	0	1 / 7%	2 / 18%	0	1 / 11%
	CLASS 3	15 / 94%	4 / 18%	0	2 / 18%	1 / 8%	0

CLASS 1: No pain or mild occasional pain
CLASS 2: Mild chronic pain
CLASS 3: Severe pain

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 29. Pain (sports activities). Chronic + acute patients. FDA designation, App. 5, Item 1. IDE designation, S-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	6 / 10%	55 / 90%	26 / 87%	38 / 93%	29 / 85%	28 / 80%
	CLASS 2	4 / 6%	1 / 2%	1 / 3%	1 / 2%	2 / 6%	2 / 6%
	CLASS 3	51 / 84%	5 / 8%	3 / 10%	2 / 5%	3 / 9%	5 / 14%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	6 / 15%	38 / 81%	32 / 91%	19 / 76%	25 / 89%	22 / 88%
	CLASS 2	2 / 5%	0	2 / 6%	2 / 8%	2 / 7%	1 / 4%
	CLASS 3	32 / 80%	9 / 19%	1 / 3%	4 / 16%	1 / 4%	2 / 8%

CLASS 1: No pain or mild occasional pain
CLASS 2: Mild chronic pain
CLASS 3: Severe pain

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 30. Swelling (normal activities). Chronic patients. FDA designation, App. 5, Item 5. IDE designation, S-3. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	22 /56.4%	71 /83.5%	21 /91.3%	25 /100.0%	15 /88.2%	23 /85.2%
	CLASS 2	4 /10.3%	7 /8.2%	1 /4.3%	0	0	3 /11.1%
	CLASS 3	13 /33.3%	7 /8.2%	1 /4.3%	0	2 /11.8%	1 /3.7%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	20 /62.5%	62 /88.6%	24 /100.0%	14 /100.0%	16 /94.1%	17 /100.0%
	CLASS 2	3 /9.4%	3 /4.3%	0	0	1 /5.9%	0
	CLASS 3	9 /28.1%	5 /7.1%	0	0	0	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 31. Swelling (normal activities). Acute patients. FDA designation, App. 5, Item 5. IDE designation, S-3. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 /3.3%	56 /88.9%	13 /100.0%	17 /100.0%	20 /100.0%	11 /100.0%
	CLASS 2	4 /13.3%	5 /7.9%	0	0	0	0
	CLASS 3	25 /83.3%	2 /3.2%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	2 /10.0%	39 /88.6%	16 /100.0%	12 /100.0%	12 /100.0%	9 /100.0%
	CLASS 2	0	3 /6.8%	0	0	0	0
	CLASS 3	18 /90.0%	2 /4.5%	0	0	0	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 32. Swelling (normal activities). Chronic + acute patients. FDA designation, App. 5, Item 5. IDE designation, S-3. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	23 /33.3%	127/85.8%	34 /94.4%	42 /100.0%	35 /94.6%	34 /89.5%
	CLASS 2	8 /11.6%	12 /8.1%	1 /2.8%	0	0	3 /7.9%
	CLASS 3	38 /55.1%	9 /6.1%	1 /2.8%	0	2 /5.4%	1 /2.6%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	22 /42.3%	101/88.6%	40 /100.0%	26 /100.0%	28 /96.6%	26 /100.0%
	CLASS 2	3 /5.8%	6 /5.3%	0	0	1 /3.4%	0
	CLASS 3	27 /51.9%	7 /6.1%	0	0	0	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 33. Swelling (sports activities). Chronic patients. FDA designation, App. 5, Item 5. IDE designation, S-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	13 /37.1%	26 /89.6%	17 /89.5%	22 /91.7%	12 /85.7%	18 /75.0%
	CLASS 2	3 /8.6%	0	1 /5.3%	0	1 /7.1%	1 /4.2%
	CLASS 3	19 /54.3%	3 /10.3%	1 /5.3%	2 /8.3%	1 /7.1%	5 /20.8%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	8 /33.3%	19 /79.2%	19 /95.0%	13 /92.8%	14 /87.5%	16 /100.0%
	CLASS 2	4 /16.7%	0	0	0	0	0
	CLASS 3	12 /50.0%	5 /20.8%	1 /5.0%	1 /7.1%	2 /12.5%	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 34. Swelling (sports activities). Acute patients. FDA designation, App. 5, Item 5. IDE designation, S-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	26 /81.2%	11 /100.0%	16 /94.1%	19 /95.0%	10 /100.0%
	CLASS 2	1 /3.7%	2 /6.2%	0	0	0	0
	CLASS 3	26 /96.3%	4 /12.5%	0	1 /5.9%	1 /5.0%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	21 /95.4%	14 /93.3%	7 /63.6%	10 /83.3%	8 /88.9%
	CLASS 2	0	0	1 /6.7%	2 /18.2%	1 /8.3%	1 /11.1%
	CLASS 3	15 /100.0%	1 /4.5%	0	2 /18.2%	1 /8.3%	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 35. Swelling (sports activities). Chronic + acute patients. FDA designation, App. 5, Item 5. IDE designation, S-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	13 /21.0%	52 /85.2%	28 /93.3%	38 /92.7%	31 /91.2%	28 /82.4%
	CLASS 2	4 /6.4%	2 /3.3%	1 /3.3%	0	1 /2.9%	1 /2.9%
	CLASS 3	45 /72.6%	7 /11.5%	1 /3.3%	3 /7.3%	2 /5.9%	5 /14.7%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	8 /20.5%	40 /87.0%	33 /94.3%	20 /80.0%	24 /85.7%	24 /96.0%
	CLASS 2	4 /10.2%	0	1 /2.8%	2 /8.0%	1 /3.6%	1 /4.0%
	CLASS 3	27 /69.2%	6 /13.0%	1 /2.8%	3 /12.0%	3 /10.7%	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 36. Performance Level (sports activities). Chronic patients. FDA designation, App. 5, Item 7. IDE designation, PE-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	6 /7.1%	4 /17.4%	5 /19.2%	3 /18.8%	3 /11.1%
	CLASS 2	1 /2.6%	3 /3.6%	5 /21.7%	3 /11.5%	5 /31.2%	4 /14.8%
	CLASS 3	4 /10.2%	11 /13.1%	1 /4.3%	8 /30.8%	2 /12.5%	4 /14.8%
	CLASS 4	3 /7.7%	3 /3.6%	3 /13.0%	2 /7.7%	0	2 /7.4%
	CLASS 5	31 /79.5%	61 /72.6%	10 /43.5%	8 /30.8%	6 /37.5%	14 /51.8%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	6 /8.4%	5 /20.8%	4 /28.6%	4 /23.5%	0
	CLASS 2	0	0	5 /20.8%	2 /14.3%	6 /35.3%	6 /40.0%
	CLASS 3	1 /3.1%	4 /5.6%	4 /16.7%	3 /21.4%	2 /11.8%	5 /33.3%
	CLASS 4	1 /3.1%	7 /9.8%	4 /16.7%	2 /14.3%	1 /5.9%	0
	CLASS 5	30 /93.8%	54 /76.1%	6 /25.0%	3 /21.4%	4 /23.5%	4 /26.7%

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 37. Performance Level (sports activities). Acute patients. FDA designation, App. 5, Item 7. IDE designation, PE-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	5 /7.7%	4 /30.8%	5 /29.4%	11 /52.4%	4 /36.4%
	CLASS 2	0	6 /9.2%	3 /23.1%	8 /47.0%	3 /14.3%	4 /36.4%
	CLASS 3	0	4 /6.2%	2 /15.4%	1 /5.9%	2 /9.5%	2 /18.2%
	CLASS 4	0	7 /10.8%	1 /7.7%	0	3 /14.3%	1 /9.1%
	CLASS 5	30 /100.0%	43 /66.2%	3 /23.1%	3 /17.6%	2 /9.5%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	0	5 /31.2%	3 /25.0%	2 /16.7%	0
	CLASS 2	0	8 /17.8%	3 /18.8%	2 /16.7%	3 /25.0%	4 /50.0%
	CLASS 3	0	3 /6.7%	2 /12.5%	4 /33.3%	4 /33.3%	1 /12.5%
	CLASS 4	0	7 /15.6%	2 /12.5%	0	3 /25.0%	0
	CLASS 5	24 /100.0%	27 /60.0%	4 /25.0%	3 /25.0%	0	3 /37.5%

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 38. Performance Level (sports activities). Chronic + acute patients. FDA designation, App. 5, Item 7. IDE designation, PE-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	11 /7.4%	8 /22.2%	10 /23.2%	14 /37.8%	7 /18.4%
	CLASS 2	1 /1.4%	9 /6.0%	8 /22.2%	11 /25.6%	8 /21.6%	8 /21.0%
	CLASS 3	4 /5.8%	15 /10.1%	3 /8.3%	9 /20.9%	4 /10.8%	6 /15.8%
	CLASS 4	3 /4.4%	10 /6.7%	4 /11.1%	2 /4.6%	3 /8.1%	3 /7.9%
	CLASS 5	61 /88.4%	104/69.8%	13 /36.1%	11 /25.6%	8 /21.6%	14 /36.8

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	6 /5.2%	10 /25.0%	7 /26.9%	6 /20.7%	0
	CLASS 2	0	8 /6.9%	8 /20.0%	4 /15.4%	9 /31.0%	10 /43.5%
	CLASS 3	1 /1.8%	7 /6.0%	6 /15.0%	7 /26.9%	6 /20.7%	6 /26.1%
	CLASS 4	1 /1.8%	14 /12.1%	6 /15.0%	2 /7.7%	4 /13.8%	0
	CLASS 5	54 /96.4%	81 /69.8%	10 /25.0%	6 /23.1%	4 /13.8%	7 /30.4%

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 39. Performance Level (normal activities). Chronic patients. FDA designation, App. 5, Item 7. IDE designation, PE-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	13 /15.5%	4 /17.4%	6 /23.1%	5 /31.2%	4 /14.8%
	CLASS 2	0	12 /14.3%	9 /39.1%	9 /34.6%	7 /43.8%	7 /25.9%
	CLASS 3	12 /30.8%	27 /32.1%	4 /17.4%	5 /19.2%	4 /25.0%	12 /44.4%
	CLASS 4	8 /20.5%	15 /17.9%	5 /21.7%	4 /15.4%	0	3 /11.1%
	CLASS 5	19 /48.7%	17 /20.2%	1 /4.3%	2 /7.7%	0	1 /3.7%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	10 /14.1%	6 /25.0%	6 /42.8%	6 /35.3%	3 /20.0%
	CLASS 2	0	4 /5.6%	8 /33.3%	4 /28.6%	7 /41.2%	4 /26.7%
	CLASS 3	3 /9.4%	20 /28.2%	9 /37.5%	4 /28.6%	2 /11.8%	7 /46.7%
	CLASS 4	12 /37.5%	14 /19.7%	1 /4.2%	0	1 /5.9%	0
	CLASS 5	17 /53.1%	23 /32.4%	0	0	1 /5.9%	1 /6.7%

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 40. Performance Level (normal activities). Acute patients. FDA designation, App. 5, Item 7. IDE designation, PE-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	6 /9.2%	5 /38.5%	7 /41.2%	10 /47.6%	3 /27.3%
	CLASS 2	0	19 /29.2%	5 /38.5%	8 /47.0%	4 /19.0%	5 /45.4%
	CLASS 3	0	14 /21.5%	3 /23.1%	2 /11.8%	7 /33.3%	3 /27.3%
	CLASS 4	3 /10.0%	12 /18.5%	0	0	0	0
	CLASS 5	27 /90.0%	14 /21.5%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	3 /6.7%	3 /18.8%	3 /25.0%	1 /8.3%	0
	CLASS 2	0	15 /33.3%	7 /43.8%	2 /16.7%	5 /41.7%	4 /50.0%
	CLASS 3	0	10 /22.2%	4 /25.0%	6 /50.0%	5 /41.7%	3 /37.5%
	CLASS 4	2 /8.3%	12 /26.7%	2 /12.5%	1 /8.3%	1 /8.3%	1 /12.5%
	CLASS 5	22 /91.7%	5 /11.1%	0	0	0	0

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 41. Performance Level (normal activities). Chronic + acute patients. FDA designation, App. 5, Item 7. IDE designation, PE-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	19 /12.8%	9 /25.0%	13 /30.2%	15 /40.5%	7 /18.4%
	CLASS 2	0	31 /20.8%	14 /38.9%	17 /39.5%	11 /29.7%	12 /31.6%
	CLASS 3	12 /17.4%	41 /27.5%	7 /19.4%	7 /16.3%	11 /29.7%	15 /39.5%
	CLASS 4	11 /15.9%	27 /18.1%	5 /13.9%	4 /9.3%	0	3 /7.9%
	CLASS 5	46 /66.7%	31 /20.8%	1 /2.8%	2 /4.6%	0	1 /2.6%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	13 /11.2%	9 /22.5%	9 /34.6%	7 /24.1%	3 /13.0%
	CLASS 2	0	19 /16.4%	15 /37.5%	6 /23.1%	12 /41.4%	8 /34.8%
	CLASS 3	3 /5.4%	30 /25.9%	13 /32.5%	10 /38.5%	7 /24.1%	10 /43.5%
	CLASS 4	14 /25.0%	26 /22.4%	3 /7.5%	1 /3.8%	2 /6.9%	1 /4.3%
	CLASS 5	39 /69.6%	28 /24.1%	0	0	1 /3.4%	1 /4.3%

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

1. The pre-operative distributions were not different.
2. In both groups, treatment was associated with a beneficial effect.
3. At each post-operative time interval, the distributions were not different.

TABLE 42. Anterior Drawer - 30° (Non-Randomized). Chronic + acute patients. FDA designation, App. 6, Item 1. IDE designation, ST-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 /12.5%	6 /46.2%	1 /10.0%	1 /25.0%	1 /14.3%	0
	CLASS 2	1 /12.5%	5 /38.5%	8 /80.0%	2 /50.0%	3 /42.9%	1 /33.3%
	CLASS 3	2 /25.0%	2 /15.4%	1 /10.0%	1 /25.0%	2 /28.6%	1 /33.3%
	CLASS 4	4 /50.0%	0	0	0	1 /14.3%	1 /33.3%

Class 1: 0 mm
Class 2: < 5 mm
Class 3: 5-10 mm
Class 4: > 10 mm

TABLE 43. Anterior Drawer - 90° (Non-Randomized). Chronic + acute patients. FDA designation, App. 6, Item 2. IDE designation, ST-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 /12.5%	4 /30.8%	3 /30.0%	1 /20.0%	1 /14.3%	0
	CLASS 2	1 /12.5%	7 /53.8%	6 /60.0%	3 /60.0%	3 /42.9%	2 /66.7%
	CLASS 3	2 /25.0%	2 /15.4%	1 /10.0%	1 /20.0%	2 /28.6%	1 /33.3%
	CLASS 4	4 /50.0%	0	0	0	1 /14.3%	0

Class 1: 0 mm
Class 2: < 5 mm
Class 3: 5-10 mm
Class 4: > 10 mm

TABLE 44. Pivot Shift (Non-Randomized). Chronic + acute patients. FDA designation, App. 6, Item 3. IDE designation, ST-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 /12.5%	12 /100.0%	9 /90.0%	4 /100.0%	4 /57.1%	2 /66.7%
	CLASS 2	0	0	1 /10.0%	0	1 /14.3%	0
	CLASS 3	2 /25.0%	0	0	0	1 /14.3%	1 /33.3%
	CLASS 4	5 /62.5%	0	0	0	1 /14.3%	0

Class 1: 0 mm
Class 2: < 5 mm
Class 3: 5-10 mm
Class 4: > 10 mm

TABLE 45. Posterior Drawer - 90° (Non-Randomized). Chronic + acute patients. FDA designation, App. 6, Item 8. IDE designation, ST-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	2 /25.0%	7 /53.8%	9 /90.0%	3 /60.0%	2 /28.6%	2 /66.7%
	CLASS 2	1 /12.5%	4 /30.8%	1 /10.0%	1 /20.0%	4 /57.1%	0
	CLASS 3	1 /12.5%	2 /15.4%	0	1 /20.0%	1 /14.3%	0
	CLASS 4	4 /50.0%	0	0	0	0	1 /33.3%

Class 1: 0 mm
Class 2: < 5 mm
Class 3: 5-10 mm
Class 4: > 10 mm

TABLE 46. Giving Way - Normal Activities (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 4. IDE designation, S-5. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	6 /46.2%	6 /60.0%	1 /20.0%	5 /71.4%	1 /33.3%
	CLASS 2	1 /12.5%	7 /53.8%	3 /30.0%	4 /80.0%	2 /28.6%	2 /66.7%
	CLASS 3	7 /87.5%	0	1 /10.0%	0	0	0

Class 1: None
Class 2: Occasional
Class 3: Chronic

TABLE 47. Giving Way - Sports Activities (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 4. IDE designation, S-6. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	3 /50.0%	2 /33.3%	1 /33.3%	4 /80.0%	2 /66.7%
	CLASS 2	0	2 /33.3%	2 /33.3%	2 /66.7%	0	1 /33.3%
	CLASS 3	7 /100.0%	1 /16.7%	2 /33.3%	0	1 /20.0%	0

Class 1: None
Class 2: Occasional
Class 3: Chronic

TABLE 48. Pain - Normal Activities (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 1. IDE designation, S-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	12 /92.3%	9 /90.0%	4 /80.0%	7 /100.0%	3 /100.0%
	CLASS 2	2 /22.2%	1 /7.7%	1 /10.0%	1 /20.0%	0	0
	CLASS 3	7 /77.8%	0	0	0	0	0

Class 1: No pain or mild occasional pain
Class 2: Mild chronic pain
Class 3: Severe pain

TABLE 49. Pain - Sports Activities (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 1. IDE designation, S-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	3 /50.0%	4 /66.7%	2 /66.7%	5 /100.0%	3 /100.0%
	CLASS 2	0	2 /33.3%	1 /16.7%	0	0	0
	CLASS 3	7 /100.0%	1 /16.7%	1 /16.7%	1 /33.3%	0	0

Class 1: No pain or mild occasional pain
Class 2: Mild chronic pain
Class 3: Severe pain

TABLE 50. Swelling - Normal Activities (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 5. IDE designation, S-3. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	1 /11.1%	11 /84.6%	10 /100.0%	4 /80.0%	7 /100.0%	3 /100.0%
	CLASS 2	1 /11.1%	2 /15.4%	0	1 /20.0%	0	0
	CLASS 3	7 /77.8%	0	0	0	0	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

TABLE 51. Swelling - Sports Activities (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 5. IDE designation, S-4. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	4 /66.7%	5 /83.3%	3 /100.0%	5 /100.0%	3 /100.0%
	CLASS 2	0	2 /33.3%	0	0	0	0
	CLASS 3	7 /100.0%	0	1 /16.7%	0	0	0

Class 1: None or slight occasional swelling
Class 2: Slight chronic swelling
Class 3: Moderate occasional or chronic swelling

TABLE 52. Performance Level - Sports (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 7. IDE designation, PE-2. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	0	0	0	2 /28.6%	1 /33.3%
	CLASS 2	0	3 /23.1%	3 /30.0%	2 /40.0%	2 /28.6%	1 /33.3%
	CLASS 3	0	2 /15.4%	2 /20.0%	0	0	0
	CLASS 4	0	0	0	0	0	1 /33.3%
	CLASS 5	9 /100.0%	8 /61.5%	5 /50.0%	3 /60.0%	3 /42.9%	0

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

TABLE 53. Performance Level - Normal (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 7. IDE designation, PE-1. The column numbers indicate patient distribution among the various classes in each group for the indicated time interval. During 0-1 years postoperatively, multiple follow-ups were obtained from many patients; the classification from each such examination was treated as an independent observation. The percentages indicate distribution within a column.

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	CLASS 1	0	0	1 /10.0%	0	1 /14.3%	1 /33.3%
	CLASS 2	0	6 /46.2%	2 /20.0%	2 /40.0%	2 /28.6%	0
	CLASS 3	0	4 /30.8%	4 /40.0%	3 /60.0%	1 /14.3%	2 /66.7%
	CLASS 4	1 /12.5%	2 /15.4%	3 /30.0%	0	3 /42.9%	0
	CLASS 5	7 /87.5%	1 /7.7%	0	0	0	0

Class 1: Pre-injury level
Class 2: 75-100% of pre-injury level
Class 3: 50-75% of pre-injury level
Class 4: 25-50% of pre-injury level
Class 5: Less than 25% of pre-injury level

TABLE 54. Results of Follow-up by Dr. Mare.

	NUMBER OF PATIENTS	AVERAGE FOLLOW-UP TIME	ACL STABILITY				CHRONIC PAIN
			EXCELLENT	GOOD	FAIR	POOR	
ACUTE	18	58.6±10.2	10	8	0	0	0
CHRONIC	38	65.3±8.8	12	18	6	1	5

TABLE 55. Results of Study by Dr. Demmer. ACL stability: Class 1, anterior drawer < 5 mm; Class 2, 5-10 mm; Class 3, > 10 mm.

	NUMBER OF PATIENTS	AVERAGE FOLLOW-UP TIME	ACL STABILITY			CHRONIC PAIN
			CLASS 1	CLASS 2	CLASS 3	
ACUTE	21	52.0±14.7	12	5	3	0
CHRONIC	5	54.2±16.5	2	1	1	0

TABLE 56. Results of Follow-up by Dr. Botha

	NUMBER OF PATIENTS	AVERAGE FOLLOW-UP TIME	ACL STABILITY				CHRONIC PAIN
			EXCELLENT	GOOD	FAIR	POOR	
ACUTE	1	52.0±0.0	0	1	0	0	0
CHRONIC	33	39.9±22.6	5	22	5	0	1

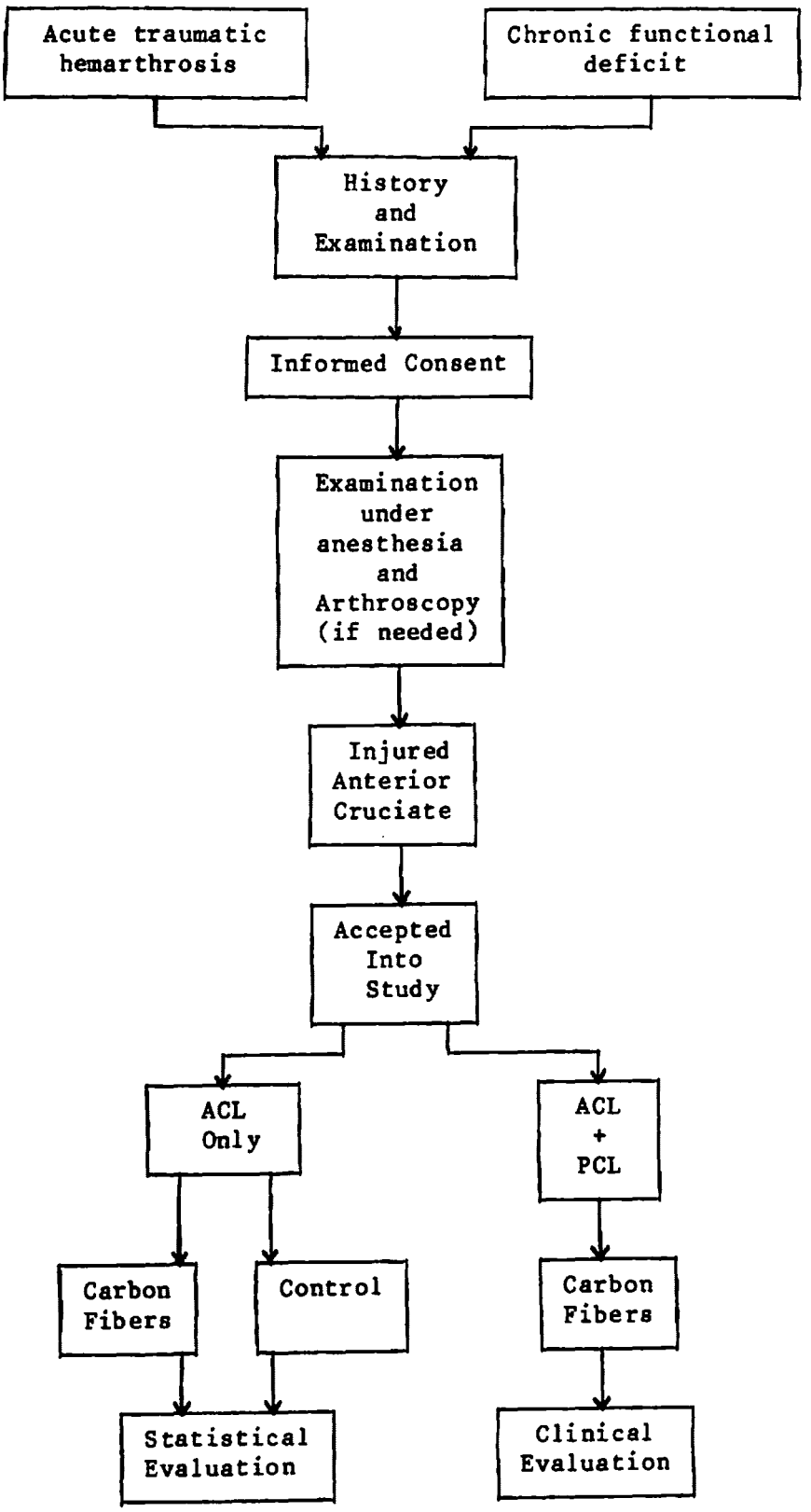

FIGURE 1. CLINICAL STUDY OF THE ACL.

6. PROPOSED LABELING

PLASTAFIL CFS™
LIGAMENT REPAIR SYSTEM

DESCRIPTION

CFS™ is a system consisting of an implant made of carbon fibers, two fixation devices used for attaching the implant to bone, a set of surgical instruments, and a specific surgical procedure for the cruciate and collateral ligaments of the knee. The implant is 48 cm long and 1.5 mm in diameter, and consists of a bundle of carbon fibers attached to a lead wire. The toggle is a rigid bar, 1 cm long, that accommodates one end of the carbon-fiber bundle, thereby permitting its attachment to bone. The bollard is an expanding rivet used for attaching carbon fibers to bone. The toggle and bollard are made of carbon-fiber-reinforced polysulfone. The implant and fixation devices are supplied sterile.

INDICATIONS

CFS™ is indicated for repair and reconstruction of the anterior cruciate ligament (ACL). If the ACL is repaired with the CFS™, the CFS™ may also be used to repair the posterior cruciate ligament, medial collateral ligament, and lateral collateral ligament, as needed. CFS™ should be used only in patients who have not had previous surgery involving the ACL, and it should be used in the absence of an intra-articular autologous tissue transfer.

THE PERFORMANCE OF THE CFS™ IS DEPENDENT UPON IMPLANT TECHNIQUE. ONLY QUALIFIED SURGEONS WHO HAVE RECEIVED IMPLANTATION TRAINING SHOULD USE THIS DEVICE.

OVERVIEW OF IMPLANT METHOD

For the ACL, the implant is passed through a drill-hole in the tibia and routed retrosynovially over the lateral femoral condyle: The implant is attached on the medial tibia and the lateral femur.

SPECIAL INSTRUMENTS

The instruments required for use of the CFS™ system are:

1. Anterior Cruciate Drill Guide
2. Posterior Cruciate Drill Guide
3. Drill (4.8 mm)
4. Implant Hook

5. Over-The-Top Hook
6. Railroading Wire
7. Bollard Drill
8. Back Radius Cutter
9. Hole Probe
10. Tubular Guide
11. Semitubular Guide - Straight
12. Semitubular Guide - Curved
13. Bollard Punch
14. Mallet

CONTRAINDICATIONS

Use of the CFS™ is contraindicated in patients who have an incomplete closure of the epiphyseal plate and in patients who have infection in the involved knee.

WARNINGS

The CFS™ is not designed, sold, or intended for use except as indicated. All other uses are investigational.

The CFS™ is not to be used for augmentation. It is to be used only as a total prosthesis; the efficacy of the CFS™ is dependent upon fibrous ingrowth into the implant. The portion of the implant within the joint capsule must be covered with synovial tissue.

Specialized instrumentation constitutes part of the CFS™, and failure to employ the instrumentation in the manner intended constitutes an experimental use of the CFS™.

Specialized fixation devices constitute part of the CFS™, and a failure to employ the fixation devices in the manner intended constitutes an experimental use of the CFS™.

A specific surgical procedure for the cruciate and collateral ligaments of the knee constitute part of the CFS™, and a failure to employ the specific surgical procedures described constitutes an experimental use of the CFS™.

POTENTIAL ADVERSE EFFECTS

There may be an increased risk of infection due to the surgical implantation of the synthetic material. Should a serious complication result, it may be necessary to do a second operation to remove either the implant or the fixation devices. There is a possibility that the device or the surgery may fail and that the instability present in the knee before surgery could return.

STERILITY

The CFS™ implant and fixation devices are provided sterile and should be removed from their protective packaging only at the time of use. Cleaning and resterilization of an opened device should not be attempted.

SURGICAL PROCEDURE

Surgical Procedure: Anterior Cruciate Ligament

1. Using the anterior-cruciate drill guide, a 4.8-mm drill hole is made from the anteromedial surface of the tibia beginning about 4 cm distal to the joint surface and emerging within the tibial attachment of the anterior cruciate ligament in the intercondylar area of the tibial plateau. The proximal and distal openings of the drill hole are radiused using the bollard drill and the back radius cutter. The hole is cleansed of bony debris using a saline rinse.

2. Through a separate incision on the lateral side of the knee beginning above the level of the lateral epicondyle of the femur and extending proximally, a small area of bone is exposed through a longitudinal incision in the iliotibial tract. The purpose of this dissection is to identify the supracondylar triangle, a bare area of bone bordered anteriorly by the vastus lateralis as it runs from the lateral intermuscular septum to the extensor mechanism, posteriorly by the lateral intermuscular septum to which the posterior portion of the iliotibial tract is attached, and distally by the lateral superior genicular vessels. The vessels emerge from the popliteal fossa through a hiatus in the lateral intermuscular septum. Elsewhere, the septum is attached to the lateral supracondylar ridge where it forms a fibrous arch over the vessels. The triangle contains a variable amount of fat which must be pushed aside to expose the underlying bone and the genicular vessels. If a fold of synovium from the suprapatellar pouch is encountered during this procedure the dissection should be taken further posteriorly or proximally to avoid entry into the synovial cavity.

3. The over-the-top hook is introduced through the hiatus in the lateral intermuscular septum. Trauma to the geniculate vessels should be avoided, if possible. If not, the vessels should be cauterized. At this level the hook will be proximal to the capsule of the knee joint. The end of the hook is kept close to bone and advanced to the intercondylar area where it can be palpated by a finger in the joint. Then the capsule is penetrated and the joint is entered. A little pressure in the direction of the long axis of the instrument and some additional flexion of the knee beyond 90° may be necessary to

deliver the end of the hook to view. It is important to avoid the posterior cruciate ligament on the medial side of the intercondylar notch. Sharp dissection through the remnants of the anterior cruciate ligament may be required to visualize the end of the hook.

4. The CF Implant is threaded through the hole in the tibia using the semitubular guide to protect the Implant from abrasion and to prevent it from snagging on cancellous bone spicules, as well as to create a soft-tissue tunnel in the remains of the anterior cruciate ligament.

5. After emerging in the intercondylar notch, the wire loop on the end of the CF Implant is linked to the trailing loop of the railroading wire and the leading end of the railroading wire is passed through the hole in the end of the over-the-top hook until it locks. The hook is then withdrawn around the femoral condyle pulling the railroading wire and the CF Implant behind it. A toggle placed through the terminal loop of the CF Implant anchors it at the tibial end.

6. A drill hole is made a short distance proximal to the geniculars vessels using the bollard drill, and a bollard, with the CF Implant wound around it and mounted on the bollard punch tube, is introduced gently into the hole and held in place loosely by hand. This procedure allows the bollard to rotate in the drilled hole as the tension on the CF Implant is adjusted. The knee should now be gently extended to 180°, avoiding hyperextension, to ensure that there is no restriction of movement which may indicate that the CF Implant has been secured in an excessively tight position. The correct residual laxity of the joint should be the same as that in the opposite, uninvolved knee joint (which for comparison must have been examined preoperatively). With the knee extended, the bollard is seated firmly with the punch tube and mallet, and then expanded and locked by driving home the central pin.

7. The CF Implant is cut off about 1.5 cm from the bollard and the free end is sutured to deep tissue using interrupted sutures.

8. From this point on, the knee is held in flexion while hemostasis is secured and the wound is closed in layers.

9. The intercondylar area should now be examined. The entire CF Implant should be retrosynovial within the remnants of the ligament. If any of the CF Implant remains uncovered it should be buried by closing synovial tissue over it using fine interrupted sutures. If insufficient tissue is present in the notch to cover the implant, soft-tissue covering for the carbon fiber can be fashioned from the retro-patellar fat pad. This flap, based on a broad pedicle distally, is raised and pulled into the intercondylar notch.

Surgical Procedure: Posterior Cruciate Ligament

1. The synovium over the anterior part of the ligament is incised, dissected off the ligament, and retracted laterally into the intercondylar notch. A posterior passage through the soft tissues is opened by blunt dissection until the posterior rim of the tibial plateau is reached in the midline.

2. Using the over-the-top hook, a soft-tissue track is dissected on the posterior aspect of the tibia until a position is reached 2-3 cm distal to the tibial plateau.

3. The posterior cruciate drill guide is then introduced through the intercondylar area to reach the posterior aspect of the tibia. When correctly positioned for the drill hole, the connecting limb of the drill guide should be parallel to the tibial plateau.

4. A 4.8-mm drill hole is made from front to back at about the middle of the tibial origin of the posterior cruciate ligament. If desired, placement of the drill hole may be confirmed by x-ray. The hole is radiused front and back.

5. The wire-threading tube is now fitted into the guide and placed through the hole in the tibia. A palpable click is felt as the end of the tube touches the drill guide posteriorly. The absence of a click indicates the presence of tissue between the guide and the tube; the soft tissue may be cleared by the use of the drill bit.

6. With the threading tube in position, the leading loop of the railroading wire is pushed down the tube through the hole in the drill guide. The loop locks automatically and the threading tube is removed leaving the wire in situ. After removal of the drill guide, the wire is drawn through the intercondylar region (from posterior to anterior) completing a full loop through the bone and over the top of the tibial plateau.

7. A 4.8-mm hole is drilled through the medial femoral condyle from a position just posterior to the synovium medially to the middle of the femoral attachment of the posterior cruciate ligament. The hole is radiused, both front and back.

8. If the ligament has been avulsed from its tibial attachment, the remnants of the ligament are pulled forward through the intercondylar notch and two or three stay sutures are attached to the ends. Threading of the CF Implant begins from the medial surface of the femoral condyle. The leading loop of the railroading wire is bent to insure that its free end trails through the soft tissue without snagging, and it is attached to the introducing loop on the CF Implant. The stay sutures on the remnants of the posterior cruciate ligament are threaded through the loop in the introducing probe, and the implant and stay sutures are pulled through the hole in the

tibia following the railroading wire. If the femoral attachment of the ligament has been avulsed or detached, the threading begins from the tibial side by linking the introducing probe onto the trailing end of the railroading wire. Once again, interrupted sutures are placed on the avulsed end of the ligament, but in this situation, they may be brought through separate holes in the medial femoral condyle, and will secure the remnants of the ligament in position over the CF Implant at the end of the threading procedure. In either event, the CF Implant will be pulled in the direction which best replaces the remnants of the ligament in an anatomical position. The CF Implant is anchored by a toggle in its looped end and by a bollard at its other end, following the adjustment of tension.

9. The CF Implant is cut off about 1.5 cm from the bollard and the free end is sutured to periosteum or deep fascia. The bollard and toggle are buried under deep fascia, and the synovial covering in the intercondylar notch is repaired with interrupted sutures.

Surgical Procedure: Medial Collateral Ligament

1. The total ligament is dissected and displayed, except that portion under the pes anserinus. The distal attachment of the ligament can be exposed distal to the pes anserinus. The deep part of the ligament is distinguished by its attachment to the medial meniscus (posterior oblique ligament).

2. The aim of the repair is to stabilize a torn ligament by burying the CF Implant into its substance and by attaching the CF Implant to the tibial and femoral origins of the ligament. Burying is achieved by the use of the semitubular introducer or by splitting the ligament longitudinally and suturing it over the CF Implant using a round-bodied needle.

3. Anchorage is achieved via three bollards placed at the three points of attachment of the ligament. The CF Implant is attached to the posterior tibial bollard, passed upwards to and once around the femoral bollard, and then down to the anterior tibial bollard which is placed distal to the pes anserinus. The stability of the ligament is tested in various degrees of flexion. After checking to ensure that none of the carbon fibers remain superficial to the ligament, the wound is then closed in layers.

Surgical Procedure: Lateral Collateral Ligament

1. A lateral approach is made beginning about 2 cm proximal to the origin of the ligament on the lateral epicondyle of the femur and extending 1-2 cm distal to the subcutaneous prominence of the fibular head. The iliotibial tract should be

incised along its posterior margin. The following structures should be defined and positively identified:

(a) The biceps tendon towards the posterior part of the incision inserting on the head of the fibula.
(b) The popliteus tendon passing from behind the knee to its insertion on the lateral femoral condyle deep to the lateral collateral ligament.
(c) The common peroneal nerve which lies deep and posterior to the biceps tendon. It is advisable to mark this important structure with a tape.
(d) The retinaculum of the vastus lateralis which may appear in the proximal corner of the wound deep to the iliotibial tract.
(e) The remnants of the ruptured lateral collateral ligament which, in the acute case can be identified by an area of contusion which indicates the traumatized area. In the chronic case the lateral structures may be extensively scarred and adherent to one another, and they may have gained abnormal attachments. These scarified and malunited elements must be isolated and repositioned into their correct places.

2. After exposing the origin of the lateral collateral ligament on the lateral epicondyle of the femur, a bollard hole is drilled in this position at 90° to the surface of the bone.

3. The head of the fibula is cleared of soft tissue on its anterior surface and a 4.8-mm hole is drilled from anterior to posterior using the bollard drill, taking care to avoid the common peroneal nerve. The hole should traverse the head of the fibula at its widest part.

4. The posterior edge of the hole is rounded off using the back radius cutter.

5. To facilitate complete coverage of the CF Implant, the remnants of the lateral collateral ligament are now either split, by cutting along the ligament axis or pierced along their length using the semitubular guide.

6. The CF Implant is introduced through the hole in the fibula and anchored by a toggle (a bollard can also be used at each end). It is then passed through the remnants of the ligament via the semitubular guide (or laid into the prepared bed of ligamentous remnants) and fixed with a bollard on the lateral femoral condyle, after adjustment of tension.

Surgical Procedure: Combined Ligamentous Injuries

When more than one ligament is involved in acute injuries to the knee, a single anchorage point may be placed in a convenient position to work for two or more ligaments. The following is a

brief description of some typical combined repairs:

1. Ruptured Anterior Cruciate and Lateral Collateral Ligaments. The lateral collateral CF Implant may be anchored with a toggle placed at the posterior entrance to the hole through the head of the fibula (or with a bollard on the anterior surface), and a bollard inserted just proximal to the lateral epicondyle of the femur. Instead of cutting the CF Implant at this stage, it can be continued to make an over-the-top repair of the anterior cruciate, ending on the tibia with a bollard. If, because of the position of the rupture in the anterior cruciate, it is decided to insert the carbon in the opposite direction, then a toggle anchorage on the tibia and bollards on the lateral femoral condyle and the proximal fibular head are recommended.

2. Combined Anterior Cruciate and Posterior Cruciate Repair. Once again the CF Implant can be introduced in either direction but only one bollard is required on the tibia. The other two points of anchorage may be secured by two bollards or one bollard and one toggle. In combined repairs each ligament, although sharing a common anchorage, must be independently stable.

3. Combined Posterior Cruciate and Medial Collateral Repair. In this situation both ligaments may be approached by a long medial parapatellar incision in which the distal end of the incision is extended more medially than would normally be done for a posterior cruciate repair alone. Drill holes through the tibia and medial femoral condyle are made and the railroading wire is positioned in preparation for threading the CF Implant, as described for the posterior cruciate repair. The three bollard sites are now positioned for the repair of the medial collateral ligament taking care to accurately place the site on the femoral epicondyle just proximal to the anatomical origin of the ligament.

   Threading begins by passing the CF Implant directly through the hole in the medial femoral condyle into the intercondylar notch. The railroading wire is attached to the wire loop on the CF Implant. Then, having insured that the barbed end is bent so that it trails without snagging, the wire is pulled through the tibial side, railroading the CF Implant behind it. The looped end is anchored by a toggle at the femoral condylar side, and after adjusting the tension and testing the joint laxity, it is anchored to the tibia by a bollard placed distal to the pes anserinus (or under the proximal part, which must be exposed by cutting the proximal 2-3 cm of the pes anserinus) at the site for the repair of the superficial part of the medial collateral ligament without cutting the CF Implant by passing it upwards to the anchorage point on the medial femoral condyle and ending on the tibia at the bollard for the deep leaf of the ligament.

CAUTION

Federal law restricts this device to sale, distribution, and use by or on the order of a physician.