PRE-MARKET APPLICATION

CFS™ FOR TREATMENT OF KNEE-LIGAMENT INJURIES

PLASTAFIL, INC.

VOLUME 4

VOLUME 4

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INTRODUCTION

Design of the Clinical Study

The overall design of the clinical study is illustrated in Figure 1. Patients with either acute or chronic ACL injuries requiring surgery were entered into the study. Patients with an ACL injury but no PCL injury were randomized into carbon-fiber (CF) and control groups ("the controlled study") according to a plan intended to produce approximately 60% carbon-fiber and 40% control patients. Ultimately, 74 patients received carbon fibers and 60 patients received control surgical procedures; our main purpose was obtaining statistically analyzable data from the patients in the controlled study.

The patients entered into the controlled study are listed in Table 1. Patients that received surgery within 14 days of injury were considered acute cases; any longer interval was considered to be a chronic case. Of the patients that received carbon fibers, there were 4 chronic cases in which one or both of the collateral ligaments was also repaired with carbon fibers. Among the acute cases, 10 patients had one or both collateral ligaments repaired using carbon fibers. Two patients received carbon fibers for repair of both cruciate ligaments (that is, they were randomized into the study). Among the chronic control patients there were 2 cases involving concurrent repair of one or both collateral ligaments. Among the acute control patients there were 4 cases of injuries involving the collateral ligaments, and there were 2 cases involving surgical repair of the posterior cruciate ligament (again, these patients were actually randomized into the study).

A further group of 10 patients who had injuries to both cruciates appeared during the study. Each of the patients received carbon fibers for the repair of both ligaments (Table 2); this group had no concurrent controls. This group (Table 2) consisted of all ACL-PCL patients that appeared during the course of the study and who gave informed consent for participation in the study (except for the 4 patients noted in the preceding paragraph).

Surgical Procedures

The procedures used for the carbon-fiber reconstruction of the anterior and posterior cruciate ligaments, and the medial and lateral collateral ligaments are described below.

The primary control surgical procedure was the Jones procedure (middle one-third of the patellar tendon), and most control patients received the Jones procedure. It was, however, ultimately the choice of the surgeon to use a different control procedure if it represented a better choice for a particular patient.

Additional Use of Carbon Fibers

Carbon fibers were implanted in 14 patients (Table 3) for either of two further indications. In 5 patients that exhibited gross instabilities and who had failed previous surgical procedures, carbon fibers were used as an alternative to fusion of the joint. In 9 additional cases, carbon fibers were used in repairing the PCL (in the absence of a significant injury to the ACL). Concurrent controls were not employed for either group. Since the series was too small to permit comparison with historical controls, the long-term follow-up was determined by the orthopaedic care required by each patient (not by the need to obtain study data)*.

METHODS AND MATERIALS

Surgical Instruments Used with Carbon-Fiber Implant

The surgical instruments used with the CF Implant are shown in Figure 2. The radius cutters are used for rounding off the edges of bone holes. The front radius cutter, a countersink, is used to round off the edges of holes that are accessible from the operative incision. (The front radius cutter also serves as the bollard drill.) The back radius cutter is used on the far edge of a hole that is inaccessible to the front radius cutter. It is used, for example, on the edge of any hole emerging in the intercondylar area of the knee.

The back radius cutter has a slot at one end through which a small retractable blade can be made to protrude. The instrument is introduced into a 4.8-mm hole with the blade in the retracted position. The lever-controlled blade is then extended, and the instrument is gently rotated, thereby permitting the blade to carve off the edge of the drilled hole. After the hole is radiused, the blade is retracted and the instrument is removed.

The tubular guides facilitate threading of the CF Implant through the substance of the ligament. They are pushed through the tissue to form a tunnel through which the CF Implant can be introduced.

The anterior-cruciate drill guide permits accurate placement of a hole in bone, for instance in the proximal tibia for the distal attachment of the anterior cruciate ligament. The pointed end of the jig is placed where the hole is intended to emerge, and the 4.8-mm drill sleeve is placed on the intended entrance of the hole. The bone is then drilled with a power drill while the guide and drill sleeve are held tightly together. The guide is also used to make the hole in the medial femoral condyle for the

* Plastafil has some data regarding these patients. The most complete information is in the patient records, University of Iowa.

proximal attachment of the posterior cruciate ligament.

The posterior cruciate drill guide permits placement of a hole through the proximal tibia below the tibial plateau. The hole enters on the anteriomedial aspect of the tibia, and exits on the posterior aspect of the tibia near the midline. The 4.8-mm drill and drill sleeve used with the anterior cruciate guide are also used with the posterior cruciate drill guide. After the hole is made and radiused, the posterior cruciate guide is used as a threading device to introduce the wire probe of the CF Implant through the bony hole.

The over-the-top hook is used to pass over-the-top of the lateral femoral condyle, and to appear in the intercondylar notch of the femur. It serves as both a dissector and threading device.

Railroading wire completes the linkage between the over-the-top hook (or the posterior cruciate threading device) and the CF Implant. The leading loop of the wire has a protruding barb which allows it to be pushed through the hole in the end of the over-the-top hook (or in the end of the posterior cruciate drill guide) and locked to prevent the hook from being pulled back through the hole. The trailing end of the railroading wire can be clipped on to the loop in the introducing probe of the CF Implant and pulled through soft tissue without snagging.

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 genicular 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 ligament 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.

Post-Operative Management

The carbon-fiber and control patients received identical post-operative rehabilitative programs consisting of progressive activities geared toward achieving a pre-injury or higher fitness level. The actual timing of each Phase of the rehabilitative program varied from patient to patient depending on the initial pathology, degree of post-operative stability, general physical condition, patient cooperation, and availability of equipment.

All patients were immobilized in 40-45° of flexion, except those in whom it was determined during examination at the time of repair that some other position was preferable. The patients were immobilized for one week, at which time motion was started in most patients. The presence of chondral or osteochondral fractures, significant chondromalacia, or meniscus repairs required up to six weeks of immobilization.

The general considerations, goals, and precautions that governed the individual rehabilitative programs are listed in Appendix 1.

Accounting for Implants Used in the Study

Each patient that received carbon fibers (for any indication) during the open time of the study (April, 1983 to November, 1985) is listed in Tables 1-3. Carbon fibers were not implanted by any investigator prior to or subsequent to the open time of the study. Plastafil carbon fibers have not been used in the United States in any surgical procedure involving patients except for those described in this PMA.

Compliance with FDA Requirements for Reporting the Data

The Guidance Document for the Preparation of Investigational Device Exemptions and Pre-Market Approval Application for Intra-articular Prosthetic Knee Ligament Devices (Guidance Document) requires (at page 22) 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, according to (the format of) Appendix 11." The items listed in Appendices 5 and 6 are shown in Table 4 (the items will be referred to as "FDA data").

The investigational protocol (IDE) for this study was approved by FDA in March, 1983. The approved format for the collection of data is shown in Table 5 (the items will be referred to as "IDE data"). The correspondence between the Guidance Document and the IDE is shown in Table 6. No data directly pertinent to item 14 in Appendix 5 or items 5, 7, 9-11, 15, 17, and 21 in Appendix 6 was collected.

Except where noted, the distribution of scores for each item in Appendices 5 and 6 (Table 4) for which there was a corresponding item (or items) in the IDE is presented here according to the format of Appendix 11. Appendix 5 items 2, 3, and 6, and Appendix 6 items 16, 18-20 (each of which (with the exception of Appendix 5, item 6) relate to pain) were noted during the clinical examination. Distributions of scores for these items are not provided because pain (of any kind at any location in the knee) occurred only rarely. Appendix 5 item 6 (Stiffness) was also noted during clinical examinations, and a distribution of scores is not provided for a similar reason.

We evaluated the difference in class distributions between the two treatment groups at various time intervals after surgery. The distributions were evaluated using the chi-square test which was performed at each time point for every item in Appendix 5 and Appendix 6. The number of classes into which the patients were grouped varied from item to item, and the efficiency of the classification scheme similarly differed from item to item. That is, the classes to which the patients were assigned frequently failed to produce a significant distribution, but rather resulted in most patients being grouped in only a few classes. In applying the chi-square test we used a 2x2 contingency table or a 2x3 contingency table if it did not result in fewer than five counts per cell. The Yates continuity correction was applied to all 2x2 contingency tables. A contingency table of 2x4 was employed only to test the preoperative distributions. For each item, the definition and population of each class is listed in the data.

Statistical Analysis of the FDA Data

The goal of this study was to compare the results obtained by treating patients with carbon fibers with those obtained using a

control treatment. The basic experimental hypothesis was that, in patients requiring surgical treatment, the results obtained with carbon fibers would be at least as good as those obtained using control treatment. There is, however, no single clinical parameter or combination of clinical parameters that can be measured and used to frame a unique statistical (null) hypothesis to test the experimental hypothesis. That is, prior to performing the study and obtaining the data, it is not possible to state what combinations or patterns of differences between the two groups with regard to the various measured parameters would require acceptance or rejection of the experimental hypothesis.*

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* In a typical experiment, the null hypothesis is derived directly from the experimental hypothesis, but it is the null hypothesis that is directly tested by the study. For example, suppose the question is asked whether drug A or B is more efficacious in treating infections. The drugs could be compared by administering them to separate (but comparable) groups of infected rats, and determining the percentage of healed animals in each group. If "healed" is defined as a microbial concentration below a specific value at a specified time (t_o), then the null hypothesis for the study could be stated prior to the study: The numbers of healed animals in the two groups at t_o are identical. The chi-square test could be used to determine whether the null hypothesis must be rejected; that is, to determine whether there is a difference in healing rates between the two groups. Or, put another way, whether the division of Group A rats into healed and not-healed classes is distinguishable (at $P < 0.05$) from the comparable division of Group B rats. Suppose, however, that the microbial concentration is measured at two time points (t_o, t_1, $t_1 > t_o$). Although the experimental hypothesis remains the same, the statistical hypothesis becomes more complex because the additional measurements provide the opportunity for consideration of different statistical hypotheses. For example, we might require that one drug be superior to the other at both time points for acceptance of the experimental hypothesis. Alternatively, it might be argued that intermediate measurements are not as significant as later measurements (because they correspond to a longer-term follow-up or evaluation of the animal), and consequently that only the data at t_1 is pertinent to a consideration of the experimental hypothesis. There are still other possibilities: It could be argued that the data evaluated at t_1 is significant only if the change in results between t_o and t_1 is also significant.

There is another important consideration. Microbial concentration below a specific value may not be a parameter sufficient to characterize the effect of the drug. A functional test, for example, might be performed on the animals in both groups to determine the existence of a possible functional deficit. For example, the length of time for a rat to negotiate a maze might be measured on the supposition that a healthier animal would negotiate the task more efficiently. What interpretation should be given to data that showed that the rats in Group A negotiated the maze more quickly at t_1, but had a higher microbial concentration?

Because there is no unique combination of results obtained with the items specified in Appendix 5 and Appendix 6 that will support the experimental hypothesis in this study, there is no unique statistical hypothesis. We performed appropriate statistical tests on comparable groups, and evaluated the pattern of results with regard to plausible clinical considerations, including:

1. Were the preoperative groups comparable with regard to the variable under consideration? If not, in which direction would the preoperative difference bias the results?

2. With regard to each parameter, is a pattern of difference observed between the two groups with time, or are only isolated differences seen? Do any variables that parallel the variable under consideration also show differences between the two groups at the time point under consideration? Is there a consistent pattern of differences pointing in one direction?

3. Is a difference seen in both acute and chronic patients?

The Problem of Repeated Tests

Under ordinary methods of statistical analysis, the predicate statistical test performed would involve comparison of carbon vs. control (regardless of time). Only if the groups differed, would justification exist for making comparisons at specific time points, because repeated statistical tests on any data base will yield some significant differences between groups even though their respective populations are identical. If the predicate statistical test showed that the groups differed (regardless of time), that would be evidence supporting the interpretation that the group exhibiting the desirable clinical characteristics fared better with the treatment that it received, compared to the treatment received by individuals in the other group. This, in turn, is evidence that the treatment itself is better than the comparison treatment. For example, if, with regard to pivot shift, the distribution of control patients exhibited a higher percentage of patients in the lower classes (Class 1 and 2), compared to the carbon-fiber patients, regardless of the postoperative time of evaluation, that would be evidence that the control patients did better with regard to pivot shift than did the carbon-fiber patients; this, in turn, would support the view that the control treatment was better than the carbon-fiber treatment. Suppose, however, that the two groups do not differ with regard to the classification by treatment during 1-5 years postoperatively: It is clinically pertinent (although not strictly justified statistically) to conduct further tests to inquire whether differences existed at specific time points. Even though these tests were not justified by statistical theory and consideration, they have been performed because of their clinical relevance, and each of the differences obtained under this procedure is explicitly discussed.

Compliance with IDE Requirements for Reporting the Data

Data was collected for each item in Table 5 by assigning the patient to a class having a pre-determined point value; the number of classes for each item and their corresponding point value is shown in Table 4. As proposed in the IDE, each patient received a total score (T) at each follow-up visit. T was obtained by combining the scores in each category after weighting (20% for each category, except 30% for Stability and 10% for Deformity) and scaling (0-100) (Table 8).

Statistical Analysis of the IDE Data

Comparisons between comparable groups were made using Student's unpaired t test at a chosen level of significance of 5%.

Follow-up Modeled as Random Sampling

The study population consisted of individuals from different social and economic strata who exhibited different degrees of motivation, interest, and cooperation. As a group, the patient population required extensive contact and motivation in order to obtain follow-up, and the difficulty became progressively worse with time. Contacts and follow-up examinations were, to a significant extent, performed through the offices of private physicians, and these factors mitigated against our ability to obtain follow-up on a specific individual within a specific time frame. For these reasons, and because of the mobility of the population, it was not possible to obtain follow-up on each patient within each time interval. Consequently, we obtained follow-up on representative samples of the patient population within each time interval.

Date of Last Follow-Up for this Report

This report includes follow-ups obtained before January 27, 1989. We were unable to obtain follow-up beyond 24 months in 7 patients. One patient (William Hall, LSU) was killed in an automobile accident. The specific efforts made to obtain follow-up in the remaining 6 patients are described in Appendix 3 (2 patients from the carbon-fiber group, and 4 patients from the control group).

RESULTS

FDA Data

Tables 9-86 were prepared as specified in the Guidance Document ("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, according to the format of Appendix 11"). The Guidance Document also requires (page 22, paragraph 7) "a patient-by-patient listing of the Lachman and pivot-shift laxity scores in a separate table, for the ACL patients should be presented according to Appendix 11." This data is listed in Table 115 (pivot shift) and Table 116 (Lachman). The data in Tables 9-86 was examined using the chi-square test to compare the

pre-operative distributions, and the annual post-operative distribution of carbon-fiber and control patients. More than 400 comparisons are made. The following comparisons were statistically significant ($P < 0.05$).

Item	Category	Year	Direction	Table
AD-30°	Acute	Pre-op	CF > Control	58
Pivot shift	Acute	Pre-op	CF > Control	64
Pain - normal	Acute	3	CF > Control	10
Pain - normal	Chronic + Acute	3	CF > Control	11
Giving way - normal	Acute	4	CF > Control	16
Giving way - sports	Chronic	4	Control > CF	18
AD-90°	Chronic + Acute	4	Control > CF	62
Pivot shift	Chronic	4	Control > CF	63

Tables 87-113 contain comparable data obtained from the non-randomized patients (Table 2). When the data from the non-randomized patients was grouped with that from the randomized study, the results of the statistical analysis were not altered.

IDE Data

The IDE data is summarized in Table 114.

Treatment Failures

During their participation in the study, 8 patients required further surgery. Four of these were carbon-fiber patients, and 4 were controls; all were in the chronic group. These patients and the time interval between entry in the study and re-surgery are listed below.

PATIENT NUMBER	NAME	SERIES	GROUP	SURGERY-TO-RE-OPERATION INTERVAL (months)
92	Grenon, George	Iowa	C-F	52
100	Northrup, Daniel	Iowa	C-F	48
112	Jons, Jennifer	Iowa	C-F	34
138	Bassett, Denton	Brooke	C-F	56
32	White, Ronald	LSU	Con.	46
35	Heckford, Terry	LSU	Con.	?
88	Burriola, Melinda	Iowa	Con.	13
109	Duncan, Donna	Iowa	Con.	18

Carbon-Fiber Patients

George Grenon (Iowa) was erroneously entered into the randomized study group. His medical history indicates he had previous ACL reconstruction. Two months after receiving the carbon-fiber implant, Mr. Grenon began reporting pain, occasional popping, and reduced range of motion. He was arthroscoped at 4, 13, and 33 months; in each case the ACL appeared intact and seemed to be progressing well. The symptoms continued, however, and he received a second operation to relieve the symptoms. At least some of the carbon fibers were removed (apparently to relieve tightness, but synovitis was also noted) at this time.

Daniel Northrup (Iowa) received a carbon-fiber implant because of chronic instability. No follow-up could be obtained for the first 24 months following surgery, but his hospital patient summary list indicates he presented with various injuries to his legs and knees (no specifications given) during this period. His second surgical procedure (at 48 months) was indicated by bilateral anterolateral rotatory instability. The patient was noncompliant with physical therapy and had been involved in a number of altercations in the past.

Jennifer Jons (Iowa) received a second surgical procedure at 34 months to correct posterolateral rotatory instability which first appeared 6 months after receiving the carbon-fiber implant. The operative report indicates that the carbon-fiber replacement was intact, and anterior to this was a replacement of tissue which appeared to look like an anterior cruciate ligament. The carbon fibers were removed from this area.

Denton Bassett (Brooke) slipped on some ice and twisted his knee 2 months following surgery, and subsequently developed instability. He was re-operated on at 56 months, following extensive unsuccessful conservative therapy.

Control Patients

Donna Duncan (Iowa) began experiencing frequent pain and giving way some time between 5 and 13 months post-operatively (no follow-ups during this interval), and received a second procedure 18 months post-operatively. No further indication for surgery was given.

Melinda Burriola (Iowa) was re-injured in an automobile accident 4 months post-operatively, and subsequently experienced pain and joint laxity. She was arthroscoped at 10 months post-operatively, at which time remnants of the ACL repair were visualized.

She received a second procedure at 13 months post-operatively.

Ronald White (LSU) was re-operated on (Maquet procedure) 46 months post-operatively to relieve pain.

The records for Terry Heckford (LSU) beyond the 24-month follow-up are unavailable to us. He (according to a doctor's clinic notes) apparently received a second surgical procedure some time between 24-46 months post-operatively. Also at some point during this interval, he was apparently involved in an automobile accident; however, we do not know if the accident was prior to or subsequent to the second procedure, or if it was a contributory cause of any problems he developed. Mr. Heckford has been incarcerated at three different institutions since his entry into the study, and we have had some difficulty in tracing his medical records.

There were no treatment failures among the acute patients.

Device-related complications occurred in two patients. Mark Boobar (Non-randomized study, LSU) experienced pain and tenderness in the area of the toggle, and it was removed in his physician's office under local anesthesia. Brian Cooper (LSU) underwent removal of both medial bollards after he developed an abcess two weeks postoperatively.

DISCUSSION

Comparability of Pre-Operative Groups

The pre-operative distributions of the carbon-fiber and control patients did not differ with regard to any of the Items considered except for the anterior drawer in the acute patients, and the pivot shift in the acute patients (Tables 58 and 64, respectively). In the case of the anterior drawer, approximately 36% of the patients exhibited pre-operative anterior drawers of fewer than 5 mm, but approximately 67% of the control patients exhibited anterior drawers in this range. The percentages of patients exhibiting pivot shifts in these ranges were 24 and 54% for the carbon-fiber and control patients, respectively. If the scores from patients in the non-randomized study (Table 103 for the anterior drawer, and 105 for the pivot shift) are included in Tables 58 and 64, then the pre-operative difference between the groups is accentuated. Thus, whether or not the non-randomized patients are included, any bias contributed by the pre-operative difference is in the direction of favoring control therapy.

Pattern of Differences

When a large number of statistical tests are performed, it is expected that a small number of statistical significances will be observed. In the post-operative data we found 7 comparisons that yielded statistically significant results (all at 3 and 4 years post-operatively). Three of the tests favor the carbon-fiber group over the control group, and the remaining 4 tests indicated that the control group fared better. The observations were not consistent in time (because results at one post-operative time point were not found in prior or subsequent years). The few statistically significant differences observed were likely a result of sampling errors, and not an indication of actual differences between the sampled populations.

Analysis

The data shows that the carbon-fiber and control groups were essentially identical at 2 years post-operatively. For both the acute and chronic patients, no differences were observed in the various measures of patient status that were used in this study. Since the measures used included essentially all acceptable orthopaedic characterizations of safety and efficacy, we conclude that the data shows that carbon fibers were safe and efficacious at 2 years post-operatively in both patient categories.

The results obtained at 2 years post-operatively were identical with those obtained at 3, 4, and 5 years post-operatively: In both patient categories the carbon-fiber and control patients were not different. In retrospect, it appears that there is no scientific justification for delaying a decision regarding assessment of group differences beyond 2 years post-operatively. The data observed here might be analyzed to support the hypothesis that scores

for some items decreased with time. This is a reasonable development because one expects a physiological decrement with advancing age, particularly in patients that have undergone major reconstructive surgery. The pertinent question for this PMA, however, is whether any age-related change is also group-related (that is, whether it depended on whether a patient received carbon-fiber or control therapy): The data clearly indicated that no such differences existed 2 years post-operatively, or thereafter.

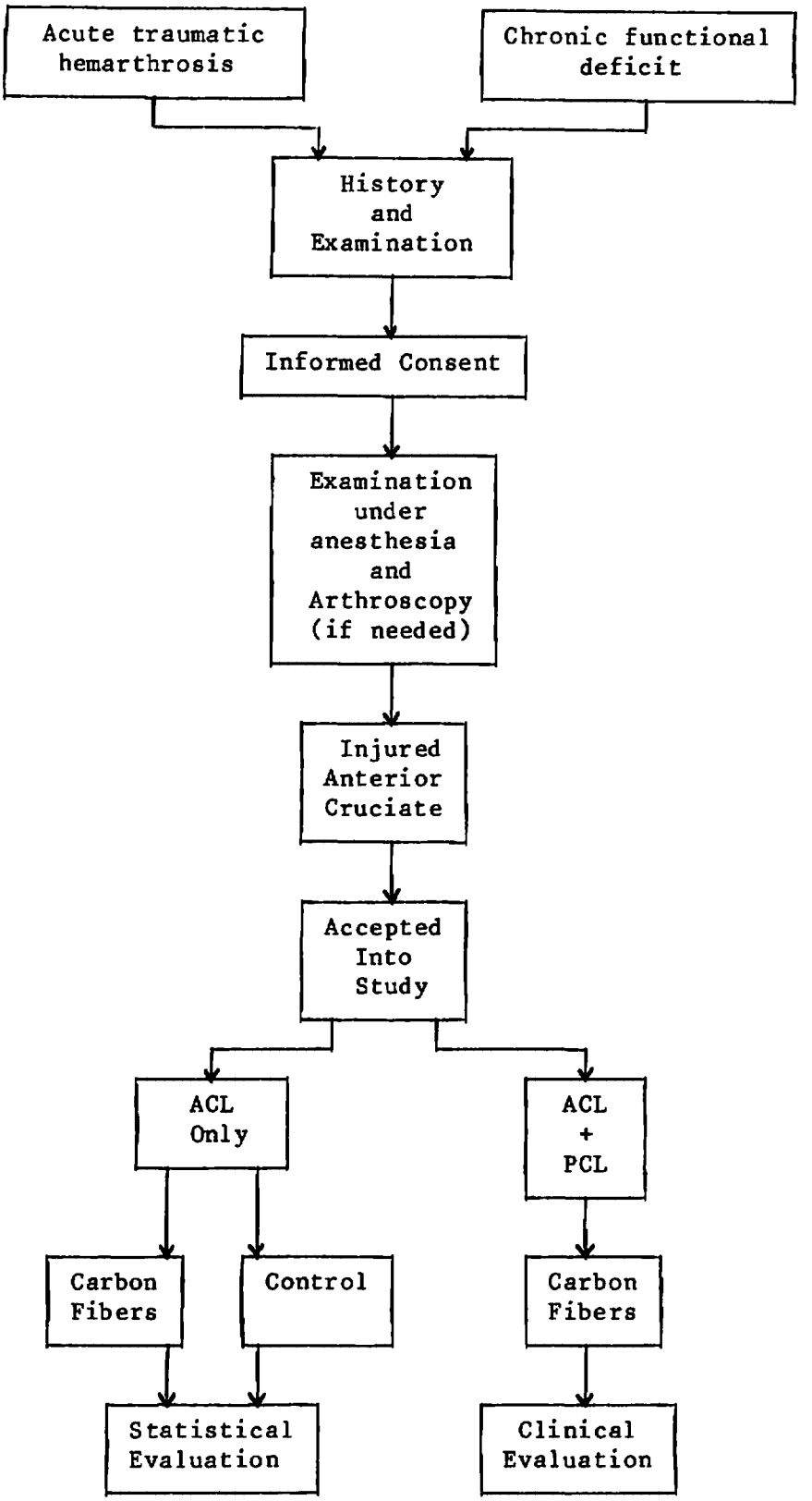
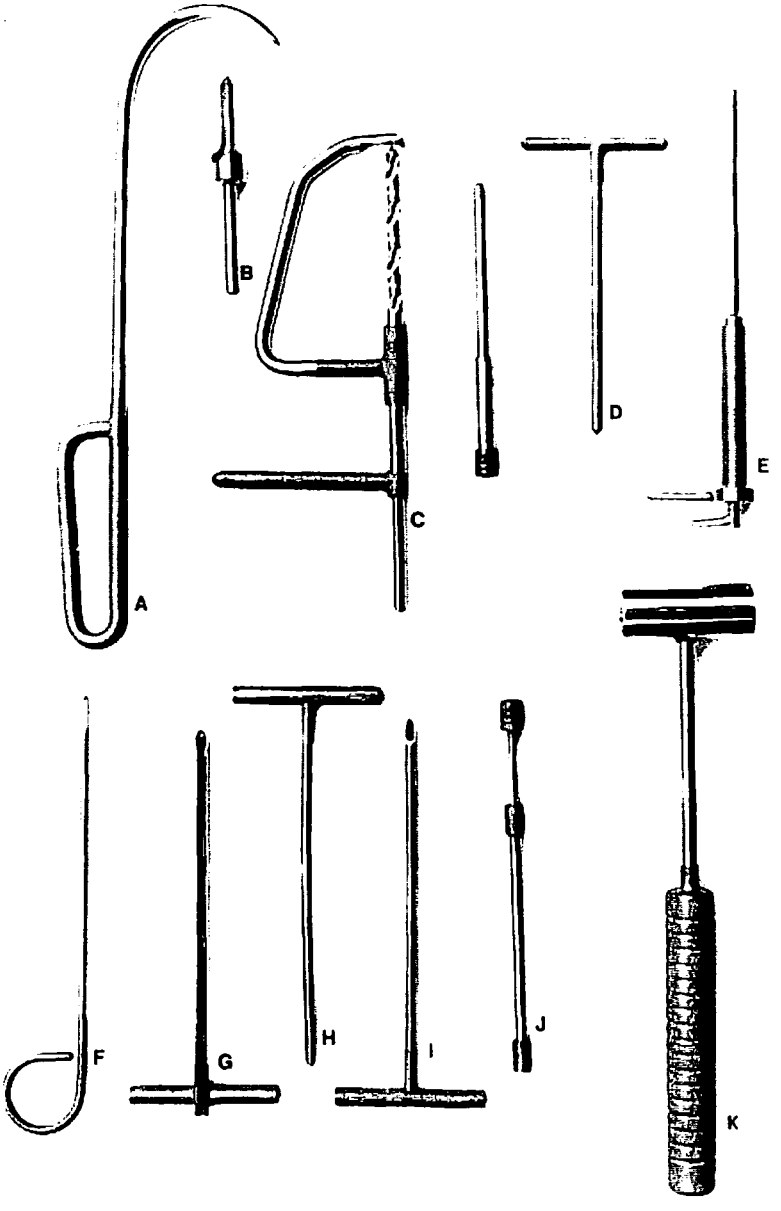


FIGURE 1. CLINICAL STUDY OF THE ACL.

FIGURE 2. Surgical instruments used with the CFS™. A, over-the-top hook; B, bollard drill/front radius cutter; C, anterior cruciate drill guide; D, hole probe; E, back radius cutter; F, implant hook; G-I, tubular guides; J, bollard punch; K, mallet.



CARBON-FIBER CASES
Chronic Cases

PT. NO.	SERIES	*EXTENT OF INJURY	PATIENT NAME
2	LSUMC	C-1	Gloer, Mark
4	LSUMC	C-1	Rasbury, Richard
12	LSUMC	C-1	Mondor, John
14	LSUMC	C-2	Cooper, Keith
15	LSUMC	C-1	Winkler (Allen), Sharon
16	LSUMC	C-1	Lux, Gregory
17	LSUMC	C-1	Larson, Larry
18	LSUMC	C-1	Darden, Lennie
22	LSUMC	C-1	Jenkins, Larry
25	LSUMC	C-1	Houston, Larry
36	LSUMC	C-2	Smith, Randy
37	LSUMC	C-1	Williams, Roberta
40	LSUMC	C-1	Perry, David
42	LSUMC	C-1	Halliburton, Lloyd
55	LSUMC	C-1	McKee, Billy
58	LSUMC	C-1	Riley, Mike
67	LSUMC	C-1	Peart, George
68	LSUMC	C-1	Love, Victor
73	LSUMC	C-1	Banks, Leonard
74	LSUMC	C-1	Daniel, Steven
76	LSUMC	C-1	Emanus, James
81	LSUMC /2Y	C-1	Harrison, Louis P.
86	Iowa	C-1	Hill, James
89	Iowa	C-1	Florey, Scott
92	Iowa	C-2	Grenon, George
95	Iowa	C-1	Malhotra, Kiran
98	Iowa	C-2	Kiener, Frank
100	Iowa	C-1	Northrup, Daniel
103	Iowa	C-1	Haldy, Glenn
110	Iowa a	C-1	Montgomery, Lesa
112	Iowa /	C-1	Jons, Jennifer
122	Brooke	C-1	Dreiling, Thomas
124	Brooke	C-1	Smetzer, John
126	Brooke	C-1	Toney, Randy
128	Brooke	C-1	Jordan, Darryl
130	Brooke	C-1	Tolley, Liza
132	Brooke	C-1	Landry, Andrew
138	Brooke	C-1	Bassett, Denton
139	Brooke	C-1	Mills, Caela
142	Brooke	C-1	Butts, William
144	Brooke	C-1	Corcoran, Robert
146	Brooke 1Y	C-1	Coad, Kelly
149	Brooke /	C-1	Walker, Fred

*C-1, ACL only
C-2, ACL + one or both collateral ligaments

TABLE 1. RANDOMIZED STUDY.

CONTROL CASES
Chronic Cases

PT. NO.	SERIES	EXTENT OF INJURY	PATIENT NAME	TREATMENT
20	LSUMC	C-1	Woodruff, Steve	PT
28	LSUMC	C-1	Bole, William	PT
29	LSUMC	C-1	West, Paul	PT
31	LSUMC	C-1	Beshea, Debra	PT
32	LSUMC	C-1	White, Ronald	PT
35	LSUMC	C-1	Heckford, Terry	Reoperation
41	LSUMC	C-1	Bass, James	Biceps
47	LSUMC	C-1	Sullivan, Jimmy	PT
57	LSUMC	C-1	Houghlan, Julie	PT
61	LSUMC	C-1	Thedford, Anthony	PT
62	LSUMC	C-1	Staggs, James	PT
66	LSUMC	C-1	Hall, William	PT
77	LSUMC	C-1	Jackson, Cedric	PT
79	LSUMC	C-1	Cooper, Roy	PT
80	LSUMC	C-1	Schumann, Raymond	PT
85	Iowa	C-1	Scheller, Arthur	PT
88	Iowa	C-2	Burriola, Melinda	PT
90	Iowa	C-1	Mullen, Christie	PT
97	Iowa	C-1	Sanderson, Joyce	PT
101	Iowa	C-1	Helle, Elizabeth	PT
105	Iowa	C-2	Edwards, David	Semitendinosis
109	Iowa	C-1	Duncan, Donna	Sutured
113	Iowa	C-1	Molander, Jeff	PT
119	Iowa	C-1	Singletary, Angela	Semitendinosis
120	Iowa	C-1	Waterman, Kyle	PT
123	Brooke	C-1	Clarke, Jeffrey	PT
125	Brooke	C-1	Lopez, Edgar Vega	PT
127	Brooke	C-1	Broyles, Keith	PT
129	Brooke	C-1	Barfield, Johnny	PT
131	Brooke	C-1	Duke, Carl	PT
133	Brooke	C-1	Minehart, Mark	PT
134	Brooke	C-1	Arrington, Robert	PT
141	Brooke	C-1	Jablonski, Catherine	PT
145	Brooke	C-1	Byrd, John	PT
148	Brooke	C-1	Robbins, Andrew	PT
150	Brooke	C-1	Jahn, Melanie	PT

TABLE 1 (continued)

CARBON-FIBER CASES
Acute Cases

PT. NO.	SERIES	EXTENT OF INJURY	PATIENT NAME
3	LSUMC	A-2	Hightower, Richard
5	LSUMC	A-2	Wittenburg, Steven
8	LSUMC	A-2	Garner, James
9	LSUMC	A-3	Jackson, Archie
13	LSUMC	A-1	Taylor, Dan
19	LSUMC	A-2	Toney, Lawrence
21	LSUMC	A-1	Pease, Randall
45	LSUMC	A-1	Collins, Jimmy
51	LSUMC	A-2	Bultynck, James
52	LSUMC	A-1	Brown, Gary
54	LSUMC	A-2	Bradberry, Wilson
63	LSUMC	A-1	Melton, Roderick
65	LSUMC	A-2	Wyatt, Mark
70	LSUMC	A-1	Mitchell, David
75	LSUMC	A-1	Williams, Christian
84	Iowa	A-2	Briggs, Cynthia
87	Iowa	A-1	Christison, Marlene
104	Iowa	A-1	Krueger, Holly
108	Iowa	A-1	Schlicher, Corey
111	Iowa	A-2	Sekafetz, Robin
114	Iowa	A-1	Ellis, Bill
115	Iowa	A-1	Wanckett, Anthony
116	Iowa	A-1	Ravenscroft, Robert
117	Iowa	A-1	Sennott, Timothy
118	Iowa	A-2	Murphy, David
121	Iowa	A-1	Green, Steve
136	Brooke	A-3	Clough, Som
137	Brooke	A-1	Robbins, Kenneth
140	Brooke	A-1	Leeper, Dale
147	Brooke	A-1	Hubbard, Rodney
151	Brooke	A-1	Edwards, Billy

*A-1, ACL only
A-2, ACL + one or both collateral ligaments
A-3, ACL + PCL

TABLE 1 (continued)

CONTROL CASES
Acute Cases

PT. NO.	SERIES	EXTENT OF INJURY	PATIENT NAME	TREATMENT
1	LSUMC	A-2	Warren, Monnie	PT
6	LSUMC	A-1	Kirkman, Greg	Conservative treatment
10	LSUMC	A-1	Williams, Marvin	PT
11	LSUMC	A-1	Jennings, Joe	Conservative treatment
23	LSUMC	A-2	Roberson, Ralph	PT
24	LSUMC	A-1	Perkins, Dave	Conservative treatment
26	LSUMC	A-3	Breakenridge, Robert	PT
34	LSUMC	A-1	St. Aubyn, Ron	PT
49	LSUMC	A-1	Sellers, Roderick	Sutured
50	LSUMC	A-1	Warren, Angela	PT
53	LSUMC	A-1	Sloan (Hurt), Betty	Conservative treatment
56	LSUMC	A-1	Koebke, Claus	PT
59	LSUMC	A-1	Tillman, Donald	PT
64	LSUMC	A-3	Messer, Gerren	Sutured
69	LSUMC	A-2	Bowermeister, Steve	PT
72	LSUMC	A-1	Crooks, Douglas	PT
94	Iowa	A-2	Davis, Brian	Sutured
96	Iowa	A-1	Oliver, Robert	Semitendinosis
99	Iowa	A-1	Booker, Scott	Sutured
102	Iowa	A-1	Kimber, Lloyd	Semitendinosis
106	Iowa	A-1	Dierks, Steven	Semitendinosis
107	Iowa	A-1	Troia, Tom	Semitendinosis
135	Brooke	A-1	Lewis (Horace), Glory	PT
143	Brooke	A-1	Thomas, Solomon	PT

TABLE 1 (continued)

CARBON-FIBER CASES

Acute Cases

PT. NO.	SERIES	EXTENT OF INJURY	PATIENT NAME
30	LSUMC	A-3	Herold, James
33	LSUMC	A-3	Burns, Jimmy
46	LSUMC	A-3	Harris, Flora
48	LSUMC	A-3	Pittman, Maurice
71	LSUMC	A-3	Jones, Emma
82	LSUMC	A-3	Jessie, William — ?
83	LSUMC	A-3	Walker, Maurice

Chronic Cases

27	LSUMC	C-3	Plemmons (Nall), Debra
38	LSUMC	C-3	Packard, James
60	LSUMC	C-3	Boobar, Mark

TABLE 2. NON-RANDOMIZED STUDY.

SERIES	PATIENT	INDICATION
Iowa	Ferguson, Debra	Salvage
Iowa	Neuzil, Paul	Salvage
Iowa	Burriola, Melinda	Salvage
Iowa	Rudnicky, John	Salvage
Iowa	Friedrich, Robert	Salvage
Iowa	Borneman, Julie	PCL
Iowa	Knight, Jeff	PCL
Iowa	Hefferman, John	PCL
Iowa	Emsick, Mark	PCL
Iowa	Clark, William	PCL
Iowa	Mackaman, Craig	PCL
Iowa	Renner, Curt	PCL
Iowa	Tracey, Edwin	PCL
LSUMC	Price, John	PCL

TABLE 3. ADDITIONAL PATIENTS WHO RECEIVED CARBON FIBERS

TABLE 4. Items Listed in Appendices 5 and 6 in the Guidance Document.

APPENDIX 5	APPENDIX 6
1. Intensity of pain	1. Lachman test
2. Location of pain	2. Anterior drawer
3. Type of pain	3. Pivot shift
4. Giving way	4. Valgus laxity at 25°
5. Swelling	5. Valgus laxity at 0°
6. Stiffness	6. Varus laxity at 25°
7. Functional activity	7. Varus laxity at 0°
8. Function-walking	8. Posterior drawer (90°)
9. Function-climbing stairs	9. Posterior sag
10. Function-descending stairs	10. Thigh circumference (5 cm above patella)
11. Function-running activity	11. Thigh circumference (15 cm above patella)
12. Function-jumping	12. Varus and valgus alignment
13. Support-daily living	13. Range of motion
14. Support-athletics	14. Patellofemoral crepitus
	15. Relative height of patella
	16. Apprehension to lateralward pressure
	17. Radiographic evaluation of patellofemoral joint
	18. Patellofemoral pain
	19. Effusion
	20. Meniscus test
	21. Neurovascular status

TABLE 5. Items Listed in the IDE.

SYMPTOMS (S)	FUNCTION (F)	DEFORMITY (D)
1. Pain-sports	1. Limp	1. Patella alignment
2. Pain-normal	2. Standing	2. ROM-active
3. Swelling-sports	3. Walking-Function	3. ROM-passive
4. Swelling-normal	4. Stair climbing-Function	4. TP crepitation
5. Giving way-sports	5. Running-Function	5. PF crepitation
6. Giving way-normal	6. Sports	6. Varus or valgus stance
	7. Support	
	8. Work tolerance	
	9. Control of instability	
	10. Type of control	
	11. Walking-Activity	
	12. Climbing stairs-Activity	
	13. Descending stairs	
	14. Kneeling	
	15. Jogging	
	16. Running-Activity	
	17. Jumping	
	18. Stopping	
	19. Twisting	

STABILITY (ST)	PATIENT'S EVALUATION (PE)
1. Anterior drawer (30°)	1. Performance level - normal
2. Anterior drawer (90°)	2. Performance level - sports
3. Posterior drawer (30°)	3. Standing
4. Posterior drawer (90°)	4. Walking - level
5. Pivot shift	5. Walking - uneven
6. Varus stress (30°)	6. Climbing
7. Valgus stress (30°)	7. Up stairs
	8. Down stairs
	9. Kneeling
	10. Squatting
	11. Running
	12. Standing
	13. Jumping
	14. Twisting
	15. Cutting

TABLE 6. Correspondence between Guidance Document and IDE. S, Symptoms; F, Function; ST, Stability; PE, Patient's Evaluation; D, Deformity.

APPENDIX 5	IDE
1. Intensity of pain	S-1, S-2
2. Location of pain	Clin. exam
3. Type of pain	Clin. exam
4. Giving way	S-5, S-6
5. Swelling	S-3, S-4
6. Stiffness	Clin. exam
7. Functional activity	PE-1,PE-2
8. Function-walking	F-3,F-11
9. Function-climbing stairs	F-4,F-12
10. Function-descending stairs	F-13
11. Function-running activity	F-5,F-16
12. Function-jumping	F-17
13. Support-daily living	F-7
14. Support-athletics	x

APPENDIX 6	IDE
1. Lachman test	ST-1
2. Anterior drawer	ST-2
3. Pivot shift	ST-5
4. Valgus laxity at 25°	ST-7
5. Valgus laxity at 0°	x
6. Varus laxity at 25°	ST-6
7. Varus laxity at 0°	x
8. Posterior drawer (90°)	ST-4
9. Posterior sag	x
10. Thigh circumference (5 cm above patella)	x
11. Thigh circumference (15 cm above patella)	x
12. Varus and valgus alignment	D-6
13. Range of motion	D-2,D-3
14. Patellofemoral crepitus	D-5
15. Relative height of patella	x
16. Apprehension to lateralward pressure	Clin. exam.
17. Radiographic evaluation of patellofemoral joint	x
18. Patellofemoral pain	Clin. exam.
19. Effusion	Clin. exam.
20. Meniscus test	Clin. exam.
21. Neurovascular status	x

x Data specifically related to this parameter was not recorded.

TABLE 7. Classes and Point Values for the Items Listed in the IDE.

SYMPTOMS	NUMBER OF CLASSES	CLASS DESIGNATION AND POINT VALUE
1. Pain/sports	5	None 8
2. Pain/normal	5	Mild/occasional 6
		Mild/chronic 4
		Severe/occasional 2
		Severe/chronic 0
3. Swelling/sports	5	None 5
4. Swelling/normal	5	Slight/occasional 4
		Slight/chronic 3
		Moderate/occasional 1
		Moderate/chronic 0
5. Giving way/sports	3	None 10
6. Giving way/normal	3	Occasional 5
		Frequent 0
		MAXIMUM SYMPTOMS SCORE 46

TABLE 7 (continued)

FUNCTION	NUMBER OF CLASSES	CLASS DESIGNATION AND POINT VALUE
1. Limp	4	None ..... 4 Mild ..... 2 Moderate ..... 1 Severe 0
2. Standing (comfortable, without support)	4	8 hours ..... 4 4 hours ..... 2 1 hour ..... 1 0 hours 0
3. Walking (without discomfort)	4	Unlimited ..... 4 1 mile ..... 2 1 block ..... 1 Unable to walk 0
4. Stair climbing	4	Alternate feet: no external support .. 4 Alternate feet: with external support. 2 Same foot first ..... 1 Unable to climb stairs . 0
5. Running	4	No limitation ..... 4 1 mile ..... 2 Short distances only ... 1 Unable to run 0
6. Sports	4	Unlimited ..... 4 Some sports: limited ... 2 Most sports: limited ... 1 All sports: limited 0
7. Support	4	None ..... 4 Cane or brace: Occasionally ..... 2 Cane or brace: Frequently ..... 1 Crutches or walker 0
8. Work tolerance	3	Full time ..... 4 Several days per week .. 2 Unable to work 0
9. Control of instability	3	Total ..... 4 Partial ..... 2 None 0
10. Type of control	3	Reflex ..... 2 Voluntary ..... 1 None 0

TABLE 7 (continued)

FUNCTION	NUMBER OF CLASSES	CLASS DESIGNATION AND POINT VALUE
11. Walking	4	No problem 3
12. Climbing stairs	4	Some difficulty 2
13. Descending stairs	4	Extreme difficulty 1
14. Kneeling	4	Unable to do 0
15. Jogging	4	
16. Running	4	
17. Jumping	4	
18. Stopping	4	
19. Twisting	4	
	MAXIMUM FUNCTION SCORE	65

TABLE 7 (continued)

DEFORMITY	NUMBER OF CLASSES	CLASS DESIGNATION AND POINT VALUE
1. Patella alignment	2	Normal ..... 2 Abnormal 0
2. ROM - active	6	121° or more 5
3. ROM - passive	6	91° to 120° ..... 4 61° to 90° ..... 3 31° to 60° ..... 2 10° to 30° ..... 1 Less than 10° 0
4. TP crepitation	4	None 3
5. PF crepitation	4	Mild ..... 2 Moderate ..... 1 Marked 0
6. Varus or valgus stance	4	None ..... 4 Less than 5° ..... 2 Between 5° and 15° ..... 1 Greater than 15° 0

MAXIMUM DEFORMITY SCORE 22

STABILITY	NUMBER OF CLASSES	CLASS DESIGNATION AND POINT VALUE
1. Anterior drawer (30°)	4	Negative (0 mm) 8
2. Anterior drawer (90°)	4	Mild (<5 mm) 6
3. Posterior drawer (30°)	4	Moderate (5-10 mm) 2
4. Posterior drawer (90°)	4	Severe (>10 mm) 0
5. Pivot shift	4	
6. Varus stress (30°)	3	Stability greater than uninjured limb 4
7. Valgus stress (30°)	3	Stability equal to uninjured limb ..... 2 Stability less than uninjured limb 0

MAXIMUM STABILITY SCORE 48

TABLE 7 (continued)

PATIENT'S EVALUATION	NUMBER OF CLASSES	CLASS DESIGNATION AND POINT VALUE
1. Performance level: normal	6	Better than pre-injury level . 6 Same as pre-injury level ..... 5 90% of pre-injury level ..... 4 75% of pre-injury level ..... 3 50% of pre-injury level ..... 2 25% of pre-injury level 1
2. Performance level: sports	8	At pre-injury level ..... 8 90% of pre-injury level ..... 7 75% of pre-injury level ..... 6 50% of pre-injury level ..... 5 25% of pre-injury level ..... 4 Severely affected but able to play ..... 3 Tried to compete but forced to quit ..... 2 Unable to compete 1
3. Standing	4	No problem 3
4. Walking - level	4	Some difficulty 2
5. Walking - uneven	4	Extreme difficulty 1
6. Climbing	4	Unable to do 0
7. Up stairs	4	
8. Down stairs	4	
9. Kneeling	4	
10. Squatting	4	
11. Running	4	
12. Standing	4	
13. Jumping	4	
14. Twisting	4	
15. Cutting	4	

MAXIMUM PATIENT'S EVALUATION SCORE 56

TABLE 8. Categories, Assigned Weight, and Scaling Used to Compare the Total Score (T) for the Follow-up Examination. See Table 3 in the IDE.

CATEGORY	MAXIMUM RAW POINTS	FACTOR TO CONVERT TO 0-100 SCALE	RAW POINTS 0-100 SCALE	ASSIGNED WEIGHT	FACTOR TO PRODUCE ASSIGNED WEIGHT	EFFECTIVE SCALE FACTOR
Symptoms	46	0.42	19.2	20%	1.04	0.437
Function	65	0.42	27.2	20%	0.74	0.311
Deformity	22	0.42	9.2	10%	1.09	0.458
Stability	48	0.42	20.1	30%	1.49	0.626
Patient's Evaluation	58	0.42	24.2	20%	0.83	0.349

TABLE 9. 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 10. 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 11. 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 12. 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 13. 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 14. 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 15. 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 16. 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 17. 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 18. 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 19. 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 20. 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 21. 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 22. 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 23. 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 24. 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 25. 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 26. 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 27. 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 28. 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 29. 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 30. 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 31. 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 32. 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 33. Function - Walking. Chronic patients. FDA designation, App. 5, Item 8. IDE designation, F-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	13 /33.3%	43 /50.6%	15 /65.2%	21 /80.8%	8 /50.0%	17 /63.0%
	CLASS 2	13 /33.3%	37 /43.5%	8 /34.8%	5 /19.2%	7 /43.8%	10 /37.0%
	CLASS 3	13 /33.3%	5 /5.9%	0	0	1 /6.2%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	13 /40.6%	32 /45.7%	19 /79.2%	11 /78.6%	15 /88.2%	14 /82.4%
	CLASS 2	15 /46.9%	34 /48.6%	5 /20.8%	3 /21.4%	1 /5.9%	3 /17.6%
	CLASS 3	4 /12.5%	4 /5.7%	0	0	1 /5.9%	0

Class 1: Unlimited without discomfort
Class 2: Limited by discomfort
Class 3: Unable to walk without discomfort

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. Function - Walking. Acute patients. FDA designation, App. 5, Item 8. IDE designation, F-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 /3.2%	40 /62.5%	12 /92.3%	13 /76.5%	18 /90.0%	9 /81.8%
	CLASS 2	5 /16.1%	21 /32.8%	1 /7.7%	4 /23.5%	2 /10.0%	2 /18.2%
	CLASS 3	25 /80.6%	3 /4.7%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	1 /4.5%	23 /52.3%	14 /93.3%	8 /66.6%	10 /83.3%	6 /75.0%
	CLASS 2	3 /13.6%	20 /45.4%	1 /6.7%	4 /33.3%	2 /16.7%	2 /25.0%
	CLASS 3	18 /81.8%	1 /2.3%	0	0	0	0

Class 1: Unlimited without discomfort
Class 2: Limited by discomfort
Class 3: Unable to walk without discomfort

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. Function - Walking. Chronic + acute patients. FDA designation, App. 5, Item 8. IDE designation, F-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	14 /20.0%	83 /55.7%	27 /75.0%	34 /79.1%	26 /72.2%	26 /68.4%
	CLASS 2	18 /25.7%	58 /38.9%	9 /25.0%	9 /20.9%	9 /25.0%	12 /31.6%
	CLASS 3	38 /54.3%	8 /5.4%	0	0	1 /2.8%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	14 /25.9%	55 /48.2%	33 /84.6%	19 /73.1%	25 /86.2%	20 /80.0%
	CLASS 2	18 /33.3%	54 /47.4%	6 /15.4%	7 /26.9%	3 /10.3%	5 /20.0%
	CLASS 3	22 /40.7%	5 /4.4%	0	0	1 /3.4%	0

Class 1: Unlimited without discomfort
Class 2: Limited by discomfort
Class 3: Unable to walk without discomfort

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. Function - Climbing Stairs. Chronic patients. FDA designation, App. 5, Item 9. IDE designation, F-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	24 /61.5%	71 /83.5%	20 /87.0%	23 /92.0%	12 /70.6%	24 /88.9%
	CLASS 2	8 /20.5%	9 /10.6%	3 /13.0%	2 /8.0%	5 /29.4%	3 /11.1%
	CLASS 3	7 /18.0%	5 /5.9%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	21 /65.6%	54 /78.3%	22 /91.7%	14 /100.0%	17 /100.0%	16 /94.1%
	CLASS 2	7 /21.9%	12 /17.4%	2 /8.3%	0	0	1 /5.9%
	CLASS 3	4 /12.5%	3 /4.3%	0	0	0	0

Class 1: Alternate feet
Class 2: Same foot first
Class 3: Unable to climb stairs

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. Function - Climbing Stairs. Acute patients. FDA designation, App. 5, Item 9. IDE designation, F-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	1 /3.2%	50 /78.1%	13 /100.0%	16 /94.1%	19 /95.0%	11 /100.0%
	CLASS 2	4 /12.9%	10 /15.6%	0	1 /5.9%	1 /5.0%	0
	CLASS 3	26 /83.9%	4 /6.2%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	34 /77.3%	15 /100.0%	11 /91.7%	12 /100.0%	9 /100.0%
	CLASS 2	4 /18.2%	8 /18.2%	0	1 /8.3%	0	0
	CLASS 3	18 /81.8%	2 /4.5%	0	0	0	0

Class 1: Alternate feet
Class 2: Same foot first
Class 3: Unable to climb stairs

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. Function - Climbing Stairs. Chronic + acute patients. FDA designation, App. 5, Item 9. IDE designation, F-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	25 /35.7%	121/81.2%	33 /91.7%	39 /92.8%	31 /83.8%	35 /92.1%
	CLASS 2	12 /17.1%	19 /12.8%	3 /8.3%	3 /7.1%	6 /16.2%	3 /7.9%
	CLASS 3	33 /47.1%	9 /6.0%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	21 /38.9%	88 /77.9%	37 /94.9%	25 /96.2%	29 /100.0%	25 /96.2%
	CLASS 2	11 /20.4%	20 /17.7%	2 /5.1%	1 /3.8%	0	1 /3.8%
	CLASS 3	22 /40.7%	5 /4.4%	0	0	0	0

Class 1: Alternate feet
Class 2: Same foot first
Class 3: Unable to climb stairs

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. Activity - Climbing Stairs. Chronic patients. FDA designation, App. 5, Item 9. IDE designation, F-12. 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%	75 /88.2%	22 /95.6%	25 /100.0%	14 /87.5%	23 /95.8%
	CLASS 2	11 /28.2%	5 /5.9%	1 /4.3%	0	2 /12.5%	1 /4.2%
	CLASS 3	6 /15.4%	5 /5.9%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	21 /65.6%	60 /85.7%	24 /100.0%	14 /100.0%	16 /100.0%	14 /100.0%
	CLASS 2	6 /18.8%	5 /7.1%	0	0	0	0
	CLASS 3	5 /15.6%	5 /7.1%	0	0	0	0

CLASS 1: Little or no difficulty
CLASS 2: Extreme difficulty
CLASS 3: Unable to climb stairs

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. Activity - Climbing Stairs. Acute patients. FDA designation, App. 5, Item 9. IDE designation, F-12. 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%	55 /85.9%	13 /100.0%	17 /100.0%	20 /100.0%	9 /90.0%
	CLASS 2	2 /6.4%	7 /10.9%	0	0	0	1 /10.0%
	CLASS 3	24 /77.4%	2 /3.1%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	2 /8.7%	39 /88.6%	16 /100.0%	12 /100.0%	12 /100.0%	8 /100.0%
	CLASS 2	3 /13.0%	4 /9.1%	0	0	0	0
	CLASS 3	18 /78.3%	1 /2.3%	0	0	0	0

CLASS 1: Little or no difficulty
CLASS 2: Extreme difficulty
CLASS 3: Unable to climb stairs

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. Activity - Climbing Stairs. Chronic + acute patients. FDA designation, App. 5, Item 9. IDE designation, F-12. 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	27 /38.6%	130/87.2%	35 /97.2%	42 /100.0%	34 /94.4%	32 /94.1%
	CLASS 2	13 /18.6%	12 /8.0%	1 /2.8%	0	2 /5.6%	2 /5.9%
	CLASS 3	30 /42.8%	7 /4.7%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	23 /41.8%	99 /86.8%	40 /100.0%	26 /100.0%	28 /100.0%	22 /100.0%
	CLASS 2	9 /16.4%	9 /7.9%	0	0	0	0
	CLASS 3	23 /41.8%	6 /5.3%	0	0	0	0

CLASS 1: Little or no difficulty
CLASS 2: Extreme difficulty
CLASS 3: Unable to climb stairs

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. Descending Stairs. Chronic patients. FDA designation, App. 5, Item 10. IDE designation, F-13. 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 /46.2%	73 /85.9%	23 /100.0%	25 /100.0%	14 /87.5%	21 /87.5%
	CLASS 2	15 /38.5%	5 /5.9%	0	0	2 /12.5%	3 /12.5%
	CLASS 3	6 /15.4%	7 /8.2%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	17 /53.1%	55 /78.6%	24 /100.0%	14 /100.0%	15 /93.8%	13 /92.8%
	CLASS 2	10 /31.2%	9 /12.8%	0	0	1 /6.2%	1 /7.1%
	CLASS 3	5 /15.6%	6 /8.6%	0	0	0	0

CLASS 1: Little or no difficulty
CLASS 2: Extreme difficulty
CLASS 3: Unable to descend stairs

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 43. Descending Stairs. Acute patients. FDA designation, App. 5, Item 10. IDE designation, F-13. 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	4 /12.9%	53 /82.8%	13 /100.0%	17 /100.0%	20 /100.0%	9 /90.0%
	CLASS 2	3 /9.7%	8 /12.5%	0	0	0	1 /10.0%
	CLASS 3	24 /77.4%	3 /4.7%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	3 /13.0%	38 /86.4%	16 /100.0%	12 /100.0%	12 /100.0%	8 /100.0%
	CLASS 2	3 /13.0%	5 /11.4%	0	0	0	0
	CLASS 3	17 /73.9%	1 /2.3%	0	0	0	0

CLASS 1: Little or no difficulty
CLASS 2: Extreme difficulty
CLASS 3: Unable to descend stairs

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 44. Descending Stairs. Chronic + acute patients. FDA designation, App. 5, Item 10. IDE designation, F-13. 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 /31.4%	126/84.6%	36 /100.0%	42 /100.0%	34 /94.4%	30 /88.2%
	CLASS 2	18 /25.7%	13 /8.7%	0	0	2 /5.6%	4 /11.8%
	CLASS 3	30 /42.8%	10 /6.7%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	20 /36.4%	93 /81.6%	40 /100.0%	26 /100.0%	27 /96.4%	21 /95.4%
	CLASS 2	13 /23.6%	14 /12.3%	0	0	1 /3.6%	1 /4.5%
	CLASS 3	22 /40.0%	7 /6.1%	0	0	0	0

CLASS 1: Little or no difficulty
CLASS 2: Extreme difficulty
CLASS 3: Unable to descend stairs

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 45. Activity - Running. Chronic patients. FDA designation, App. 5, Item 11. IDE designation, F-16. 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 /5.1%	13 /15.8%	7 /30.4%	13 /52.0%	3 /18.8%	7 /29.2%
	CLASS 2	4 /10.3%	16 /19.5%	9 /39.1%	5 /20.0%	8 /50.0%	9 /37.5%
	CLASS 3	13 /33.3%	5 /6.1%	5 /21.7%	3 /12.0%	1 /6.2%	4 /16.7%
	CLASS 4	20 /51.3%	48 /58.5%	2 /8.7%	4 /16.0%	4 /25.0%	4 /16.7%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	3 /9.4%	5 /7.1%	8 /33.3%	9 /64.3%	9 /56.2%	4 /28.6%
	CLASS 2	2 /6.2%	12 /17.1%	11 /45.8%	4 /28.6%	6 /37.5%	6 /42.9%
	CLASS 3	3 /9.4%	2 /2.9%	3 /12.5%	1 /7.1%	0	1 /7.1%
	CLASS 4	24 /75.0%	51 /72.9%	2 /8.3%	0	1 /6.2%	3 /21.4%

Class 1: No problem
Class 2: Some difficulty
Class 3: Extreme difficulty
Class 4: Unable to run

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 46. Activity - Running. Acute patients. FDA designation, App. 5, Item 11. IDE designation, F-16. 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 /3.2%	17 /27.0%	11 /84.6%	14 /82.4%	16 /80.0%	6 /60.0%
	CLASS 2	0	10 /15.9%	1 /7.7%	1 /5.9%	4 /20.0%	3 /30.0%
	CLASS 3	2 /6.4%	4 /6.4%	0	2 /11.8%	0	0
	CLASS 4	28 /90.3%	32 /50.8%	1 /7.7%	0	0	1 /10.0%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	7 /15.9%	6 /37.5%	7 /58.3%	6 /50.0%	5 /62.5%
	CLASS 2	0	12 /27.3%	7 /43.8%	3 /25.0%	5 /41.7%	3 /37.5%
	CLASS 3	0	4 /9.1%	1 /6.2%	2 /16.7%	1 /8.3%	0
	CLASS 4	23 /100.0%	21 /47.7%	2 /12.5%	0	0	0

Class 1: No problem
Class 2: Some difficulty
Class 3: Extreme difficulty
Class 4: Unable to run

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 47. Activity - Running. Chronic + acute patients. FDA designation, App. 5, Item 11. IDE designation, F-16. 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 /4.3%	30 /20.7%	18 /50.0%	27 /64.3%	19 /52.8%	13 /38.2%
	CLASS 2	4 /5.7%	26 /17.9%	10 /27.8%	6 /14.3%	12 /33.3%	12 /35.3%
	CLASS 3	15 /21.4%	9 /6.2%	5 /13.9%	5 /11.9%	1 /2.8%	4 /11.8%
	CLASS 4	48 /68.6%	80 /55.2%	3 /8.3%	4 /9.5%	4 /11.1%	5 /14.7%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	3 /5.4%	12 /10.5%	14 /35.0%	16 /61.5%	15 /53.6%	9 /40.9%
	CLASS 2	2 /3.6%	24 /21.0%	18 /45.0%	7 /26.9%	11 /39.3%	9 /40.9%
	CLASS 3	3 /5.4%	6 /5.3%	4 /10.0%	3 /11.5%	1 /3.6%	1 /4.6%
	CLASS 4	47 /85.4%	72 /63.2%	4 /10.0%	0	1 /3.6%	3 /13.6%

Class 1: No problem
Class 2: Some difficulty
Class 3: Extreme difficulty
Class 4: Unable to run

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 48. Function - Running. Chronic patients. FDA designation, App. 5, Item 11. IDE designation, F-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	4 /10.3%	14 /16.7%	13 /56.5%	14 /58.3%	4 /23.5%	10 /37.0%
	CLASS 2	3 /7.7%	8 /9.5%	4 /17.4%	5 /20.8%	4 /23.5%	4 /14.8%
	CLASS 3	13 /33.3%	21 /25.0%	4 /17.4%	4 /16.7%	6 /35.3%	11 /40.7%
	CLASS 4	19 /48.7%	41 /48.8%	2 /8.7%	1 /4.2%	3 /17.6%	2 /7.4%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	2 /6.2%	9 /13.2%	9 /37.5%	7 /50.0%	9 /52.9%	11 /64.7%
	CLASS 2	5 /15.6%	7 /10.3%	5 /20.8%	5 /35.7%	4 /23.5%	1 /5.9%
	CLASS 3	6 /18.8%	17 /25.0%	8 /33.3%	2 /14.3%	3 /17.6%	5 /29.4%
	CLASS 4	19 /59.4%	35 /51.5%	2 /8.3%	0	1 /5.9%	0

Class 1: No limitation
Class 2: 1 mile
Class 3: Short distances only
Class 4: Unable to run

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 49. Function - Running. Acute patients. FDA designation, App. 5, Item 11. IDE designation, F-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 /3.2%	16 /25.0%	11 /84.6%	12 /70.6%	14 /70.0%	8 /72.7%
	CLASS 2	0	6 /9.4%	0	3 /17.6%	3 /15.0%	2 /18.2%
	CLASS 3	0	16 /25.0%	1 /7.7%	2 /11.8%	3 /15.0%	1 /9.1%
	CLASS 4	30 /96.8%	26 /40.6%	1 /7.7%	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	9 /20.4%	7 /43.8%	6 /50.0%	6 /50.0%	7 /77.8%
	CLASS 2	0	7 /15.9%	5 /31.2%	2 /16.7%	2 /16.7%	1 /11.1%
	CLASS 3	0	10 /22.7%	3 /18.8%	4 /33.3%	4 /33.3%	1 /11.1%
	CLASS 4	22 /100.0%	18 /40.9%	1 /6.2%	0	0	0

Class 1: No limitation
Class 2: 1 mile
Class 3: Short distances only
Class 4: Unable to run

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 50. Function - Running. Chronic + acute patients. FDA designation, App. 5, Item 11. IDE designation, F-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	5 /7.1%	30 /20.3%	24 /66.7%	26 /63.4%	18 /48.6%	18 /47.4%
	CLASS 2	3 /4.3%	14 /9.5%	4 /11.1%	8 /19.5%	7 /18.9%	6 /15.8%
	CLASS 3	13 /18.6%	37 /25.0%	5 /13.9%	6 /14.6%	9 /24.3%	12 /31.6%
	CLASS 4	49 /70.0%	67 /45.3%	3 /8.3%	1 /2.4%	3 /8.1%	2 /5.3%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	2 /3.7%	18 /16.1%	16 /40.0%	13 /50.0%	15 /51.7%	18 /69.2%
	CLASS 2	5 /9.3%	14 /12.5%	10 /25.0%	7 /26.9%	6 /20.7%	2 /7.7%
	CLASS 3	6 /11.1%	27 /24.1%	11 /27.5%	6 /23.1%	7 /24.1%	6 /23.1%
	CLASS 4	41 /75.9%	53 /47.3%	3 /7.5%	0	1 /3.4%	0

Class 1: No limitation
Class 2: 1 mile
Class 3: Short distances only
Class 4: Unable to run

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 51. Activity - Jumping. Chronic patients. FDA designation, App. 5, Item 12. IDE designation, F-17. 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 /2.6%	12 /14.6%	6 /26.1%	11 /44.0%	3 /18.8%	7 /29.2%
	CLASS 2	4 /10.3%	17 /20.7%	13 /56.5%	8 /32.0%	7 /43.8%	12 /50.0%
	CLASS 3	13 /33.3%	9 /11.0%	2 /8.7%	1 /4.0%	3 /18.8%	3 /12.5%
	CLASS 4	21 /53.8%	44 /53.7%	2 /8.7%	5 /20.0%	3 /18.8%	2 /8.3%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	11 /15.7%	8 /33.3%	9 /64.3%	11 /68.8%	7 /50.0%
	CLASS 2	11 /34.4%	9 /12.9%	13 /54.2%	4 /28.6%	4 /25.0%	4 /28.6%
	CLASS 3	4 /12.5%	10 /14.3%	1 /4.2%	1 /7.1%	0	2 /14.3%
	CLASS 4	17 /53.1%	40 /57.1%	2 /8.3%	0	1 /6.2%	1 /7.1%

Class 1: No problem
Class 2: Some difficulty
Class 3: Extreme difficulty
Class 4: Unable to jump

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 52. Activity - Jumping. Acute patients. FDA designation, App. 5, Item 12. IDE designation, F-17. 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 /3.2%	19 /29.7%	11 /84.6%	12 /70.6%	18 /90.0%	7 /70.0%
	CLASS 2	0	10 /15.6%	0	4 /23.5%	1 /5.0%	2 /20.0%
	CLASS 3	2 /6.4%	3 /4.7%	0	1 /5.9%	1 /5.0%	0
	CLASS 4	28 /90.3%	32 /50.0%	2 /15.4%	0	0	1 /10.0%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	10 /22.7%	10 /62.5%	5 /41.7%	5 /41.7%	5 /62.5%
	CLASS 2	0	11 /25.0%	3 /18.8%	5 /41.7%	5 /41.7%	2 /25.0%
	CLASS 3	1 /4.4%	5 /11.4%	2 /12.5%	2 /16.7%	2 /16.7%	0
	CLASS 4	22 /95.6%	18 /40.9%	1 /6.2%	0	0	1 /12.5%

Class 1: No problem
Class 2: Some difficulty
Class 3: Extreme difficulty
Class 4: Unable to jump

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 53. Activity - Jumping. Chronic + acute patients. FDA designation, App. 5, Item 12. IDE designation, F-17. 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 /2.9%	31 /21.2%	17 /47.2%	23 /54.8%	21 /58.3%	14 /41.2%
	CLASS 2	4 /5.7%	27 /18.5%	13 /36.1%	12 /28.6%	8 /22.2%	14 /41.2%
	CLASS 3	15 /21.4%	12 /8.2%	2 /5.6%	2 /4.8%	4 /11.1%	3 /8.8%
	CLASS 4	49 /70.0%	76 /52.0%	4 /11.1%	5 /11.9%	3 /8.3%	3 /8.8%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	21 /18.4%	18 /45.0%	14 /53.8%	16 /57.1%	12 /54.6%
	CLASS 2	11 /20.0%	20 /17.5%	16 /40.0%	9 /34.6%	9 /32.1%	6 /27.3%
	CLASS 3	5 /9.1%	15 /13.2%	3 /7.5%	3 /11.5%	2 /7.1%	2 /9.1%
	CLASS 4	39 /70.9%	58 /50.9%	3 /7.5%	0	1 /3.6%	2 /9.1%

Class 1: No problem
Class 2: Some difficulty
Class 3: Extreme difficulty
Class 4: Unable to jump

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 54. Function - Support. Chronic patients. FDA designation, App. 5, Item 13. IDE designation, F-7. 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	20 /51.3%	36 /42.4%	18 /78.3%	18 /72.0%	13 /76.5%	25 /96.2%
	CLASS 2	8 /20.5%	18 /21.2%	5 /21.7%	5 /20.0%	2 /11.8%	0
	CLASS 3	3 /7.7%	26 /30.6%	0	2 /8.0%	2 /11.8%	1 /3.8%
	CLASS 4	8 /20.5%	5 /5.9%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	21 /65.6%	18 /25.7%	18 /78.3%	13 /92.9%	16 /94.1%	14 /82.4%
	CLASS 2	3 /9.4%	14 /20.0%	5 /21.7%	0	1 /5.9%	2 /11.8%
	CLASS 3	4 /12.5%	33 /47.1%	0	1 /7.1%	0	1 /5.9%
	CLASS 4	4 /12.5%	5 /7.1%	0	0	0	0

Class 1: None
Class 2: Cane or brace occasionally
Class 3: Cane or brace most of the time
Class 4: Crutches or walker

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 55. Function - Support. Acute patients. FDA designation, App. 5, Item 13. IDE designation, F-7. 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 /6.4%	29 /44.6%	13 /100.0%	17 /100.0%	20 /100.0%	10 /90.9%
	CLASS 2	1 /3.2%	7 /10.8%	0	0	0	1 /9.1%
	CLASS 3	2 /6.4%	23 /35.4%	0	0	0	0
	CLASS 4	26 /83.9%	6 /9.2%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	1 /4.6%	21 /47.7%	14 /87.5%	10 /83.3%	10 /83.3%	7 /77.8%
	CLASS 2	1 /4.6%	5 /11.4%	2 /12.5%	2 /16.7%	2 /16.7%	2 /22.2%
	CLASS 3	4 /18.2%	15 /34.1%	0	0	0	0
	CLASS 4	16 /72.7%	3 /6.8%	0	0	0	0

Class 1: None
Class 2: Cane or brace occasionally
Class 3: Cane or brace most of the time
Class 4: Crutches or walker

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 56. Function - Support. Chronic + acute patients. FDA designation, App. 5, Item 13. IDE designation, F-7. 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 /31.4%	65 /43.3%	31 /86.1%	35 /83.3%	33 /89.2%	35 /94.6%
	CLASS 2	9 /12.9%	25 /16.7%	5 /13.9%	5 /11.9%	2 /5.4%	1 /2.7%
	CLASS 3	5 /7.1%	49 /32.7%	0	2 /4.8%	2 /5.4%	1 /2.7%
	CLASS 4	34 /48.6%	11 /7.3%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	22 /40.7%	39 /34.2%	38 /82.0%	23 /88.5%	26 /89.7%	21 /80.8%
	CLASS 2	4 /7.4%	19 /16.7%	7 /18.0%	2 /7.7%	3 /10.3%	4 /15.4%
	CLASS 3	8 /14.8%	48 /42.1%	0	1 /3.8%	0	1 /3.8%
	CLASS 4	20 /37.0%	8 /7.0%	0	0	0	0

Class 1: None
Class 2: Cane or brace occasionally
Class 3: Cane or brace most of the time
Class 4: Crutches or walker

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 57. 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 58. 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 59. 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 60. 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 61. 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 62. 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 63. 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 64. 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 65. 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 66. 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 67. 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 68. 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 69. Valgus Stress - 30°. Chronic patients. FDA designation, App. 6, Item 4. IDE designation, ST-7. 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	1 /1.1%	0	0	0	0
	CLASS 2	31 /79.5%	84 /94.4%	22 /95.6%	22 /91.7%	15 /88.2%	24 /92.3%
	CLASS 3	8 /20.5%	4 /4.5%	1 /4.3%	2 /8.3%	2 /11.8%	2 /7.7%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	1 /3.1%	0	0	0	0	0
	CLASS 2	28 /87.5%	68 /94.4%	22 /91.7%	11 /78.6%	17 /100.0%	17 /100.0%
	CLASS 3	3 /9.4%	4 /5.6%	2 /8.3%	3 /21.4%	0	0

CLASS 1: Stability greater than uninjured limb
CLASS 2: Stability equal to uninjured limb
CLASS 3: Stability less than uninjured limb

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 70. Valgus Stress - 30°. Acute patients. FDA designation, App. 6, Item 4. IDE designation, ST-7. 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 /3.2%	0	0	0	0	0
	CLASS 2	18 /58.1%	63 /90.0%	11 /84.6%	15 /88.2%	20 /95.2%	9 /81.8%
	CLASS 3	12 /38.7%	7 /10.0%	2 /15.4%	2 /11.8%	1 /4.8%	2 /18.2%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	1 /2.1%	0	0	0	0
	CLASS 2	20 /83.3%	43 /91.5%	16 /100.0%	11 /91.7%	10 /83.3%	7 /77.8%
	CLASS 3	4 /16.7%	3 /6.4%	0	1 /8.3%	2 /16.7%	2 /22.2%

CLASS 1: Stability greater than uninjured limb
CLASS 2: Stability equal to uninjured limb
CLASS 3: Stability less than uninjured limb

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 71. Valgus Stress - 30°. Chronic + acute patients. FDA designation, App. 6, Item 4. IDE designation, ST-7. 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 /1.4%	1 /0.6%	0	0	0	0
	CLASS 2	49 /70.0%	147/92.4%	33 /91.7%	37 /90.2%	35 /92.1%	33 /89.2%
	CLASS 3	20 /28.6%	11 /6.9%	3 /8.3%	4 /9.8%	3 /7.9%	4 /10.8%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	1 /1.8%	1 /0.8%	0	0	0	0
	CLASS 2	48 /85.7%	111/93.3%	38 /95.0%	22 /84.6%	27 /93.1%	24 /92.3%
	CLASS 3	7 /12.5%	7 /5.9%	2 /5.0%	4 /15.4%	2 /6.9%	2 /7.7%

CLASS 1: Stability greater than uninjured limb
CLASS 2: Stability equal to uninjured limb
CLASS 3: Stability less than uninjured limb

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 72. Varus Stress - 30°. Chronic patients. FDA designation, App. 6, Item 6. IDE designation, ST-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	0	1 /4.3%	0	0	0
	CLASS 2	34 /87.2%	89 /100.0%	21 /91.3%	23 /95.8%	16 /94.1%	26 /100.0%
	CLASS 3	5 /12.8%	0	1 /4.3%	1 /4.2%	1 /5.9%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	1 /1.4%	0	0	0	0
	CLASS 2	29 /90.6%	68 /94.4%	21 /87.5%	13 /92.8%	14 /82.4%	13 /76.5%
	CLASS 3	3 /9.4%	3 /4.2%	3 /12.5%	1 /7.1%	3 /17.6%	4 /23.5%

CLASS 1: Stability greater than uninjured limb
CLASS 2: Stability equal to uninjured limb
CLASS 3: Stability less than uninjured limb

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 73. Varus Stress - 30°. Acute patients. FDA designation, App. 6, Item 6. IDE designation, ST-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	0	0	0	0	0
	CLASS 2	28 /90.3%	64 /91.4%	11 /84.6%	11 /64.7%	20 /95.2%	10 /90.9%
	CLASS 3	3 /9.7%	6 /8.6%	2 /15.4%	6 /35.3%	1 /4.8%	1 /9.1%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	0	0	0	1 /8.3%	0
	CLASS 2	21 /87.5%	46 /97.9%	16 /100.0%	12 /100.0%	11 /91.7%	9 /100.0%
	CLASS 3	3 /12.5%	1 /2.1%	0	0	0	0

CLASS 1: Stability greater than uninjured limb
CLASS 2: Stability equal to uninjured limb
CLASS 3: Stability less than uninjured limb

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 74. Varus Stress - 30°. Chronic + acute patients. FDA designation, App. 6, Item 6. IDE designation, ST-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	0	1 /2.8%	0	0	0
	CLASS 2	62 /88.6%	153/96.2%	32 /88.9%	34 /82.9%	36 /94.7%	36 /97.3%
	CLASS 3	8 /11.4%	6 /3.8%	3 /8.3%	7 /17.1%	2 /5.3%	1 /2.7%

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	0	1 /0.8%	0	0	1 /3.4%	0
	CLASS 2	50 /89.3%	114/95.8%	37 /92.5%	25 /96.2%	25 /86.2%	22 /84.6%
	CLASS 3	6 /10.7%	4 /3.4%	3 /7.5%	1 /3.8%	3 /10.3%	4 /15.4%

CLASS 1: Stability greater than uninjured limb
CLASS 2: Stability equal to uninjured limb
CLASS 3: Stability less than uninjured limb

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 75. Varus or Valgus Alignment. Chronic patients. FDA designation, App. 6, Item 12. IDE designation, D-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	33 /86.8%	85 /97.7%	21 /91.3%	23 /95.8%	13 /76.5%	18 /69.2%
	CLASS 2	5 /13.2%	2 /2.3%	2 /8.7%	1 /4.2%	4 /23.5%	6 /23.1%
	CLASS 3	0	0	0	0	0	2 /7.7%
	CLASS 4	0	0	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	26 /86.7%	66 /91.7%	22 /91.7%	9 /64.3%	11 /64.7%	11 /64.7%
	CLASS 2	4 /13.3%	5 /6.9%	2 /8.3%	4 /28.6%	3 /17.6%	4 /23.5%
	CLASS 3	0	0	0	1 /7.1%	3 /17.6%	2 /11.8%
	CLASS 4	0	1 /1.4%	0	0	0	0

CLASS 1: 0°
CLASS 2: < 5°
CLASS 3: 5-15°
CLASS 4: > 15°

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 76. Varus or Valgus Alignment. Acute patients. FDA designation, App. 6, Item 12. IDE designation, D-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	26 /92.8%	63 /96.9%	11 /84.6%	14 /82.4%	13 /65.0%	6 /60.0%
	CLASS 2	1 /3.6%	2 /3.1%	2 /15.4%	1 /5.9%	6 /30.0%	1 /10.0%
	CLASS 3	1 /3.6%	0	0	2 /11.8%	1 /5.0%	3 /30.0%
	CLASS 4	0	0	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	21 /95.4%	42 /93.3%	14 /87.5%	9 /75.0%	9 /81.8%	6 /66.7%
	CLASS 2	0	1 /2.2%	1 /6.2%	3 /25.0%	2 /18.2%	2 /22.2%
	CLASS 3	0	2 /4.4%	1 /6.2%	0	0	1 /11.1%
	CLASS 4	1 /4.5%	0	0	0	0	0

CLASS 1: 0°
CLASS 2: < 5°
CLASS 3: 5-15°
CLASS 4: > 15°

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 77. Varus or Valgus Alignment. Chronic + acute patients. FDA designation, App. 6, Item 12. IDE designation, D-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	59 /89.4%	148/97.4%	32 /88.9%	37 /90.2%	26 /70.3%	24 /66.7%
	CLASS 2	6 /9.1%	4 /2.6%	4 /11.1%	2 /4.9%	10 /27.0%	7 /19.4%
	CLASS 3	1 /1.5%	0	0	2 /4.9%	1 /2.7%	5 /13.9%
	CLASS 4	0	0	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	47 /90.4%	108/92.3%	36 /90.0%	18 /69.2%	20 /71.4%	17 /65.4%
	CLASS 2	4 /7.7%	6 /5.1%	3 /7.5%	7 /26.9%	5 /17.8%	6 /23.1%
	CLASS 3	0	2 /1.7%	1 /2.5%	1 /3.8%	3 /10.7%	3 /11.5%
	CLASS 4	1 /1.9%	1 /0.8%	0	0	0	0

CLASS 1: 0°
CLASS 2: < 5°
CLASS 3: 5-15°
CLASS 4: > 15°

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 78. Range of Motion - Active. Chronic patients. FDA designation, App. 6, Item 13. IDE designation, D-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	35 /89.7%	65 /74.7%	20 /87.0%	24 /100.0%	14 /82.4%	22 /84.6%
	CLASS 2	2 /5.1%	17 /19.5%	3 /13.0%	0	2 /11.8%	4 /15.4%
	CLASS 3	2 /5.1%	5 /5.7%	0	0	1 /5.9%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	23 /74.2%	40 /55.6%	19 /79.2%	14 /100.0%	14 /82.4%	15 /88.2%
	CLASS 2	3 /9.7%	19 /26.4%	5 /20.8%	0	3 /17.6%	2 /11.8%
	CLASS 3	5 /16.1%	13 /18.0%	0	0	0	0

CLASS 1: > 121°
CLASS 2: 90°-120°
CLASS 3: < 90°

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 79. Range of Motion - Active. Acute patients. FDA designation, App. 6, Item 13. IDE designation, D-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	10 /33.3%	45 /67.2%	10 /76.9%	13 /76.5%	17 /85.0%	10 /100.0%
	CLASS 2	8 /26.7%	15 /22.4%	2 /15.4%	4 /23.5%	3 /15.0%	0
	CLASS 3	12 /40.0%	7 /10.4%	1 /7.7%	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	10 /43.5%	33 /70.2%	13 /81.2%	10 /83.3%	9 /75.0%	7 /77.8%
	CLASS 2	1 /4.3%	11 /23.4%	2 /12.5%	2 /16.7%	3 /25.0%	2 /22.2%
	CLASS 3	12 /52.2%	3 /6.4%	1 /6.2%	0	0	0

CLASS 1: > 121°
CLASS 2: 90°-120°
CLASS 3: < 90°

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 80. Range of Motion - Active. Chronic + acute patients. FDA designation, App. 6, Item 13. IDE designation, D-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	45 /65.2%	110/71.4%	30 /83.3%	37 /90.2%	31 /83.8%	32 /88.9%
	CLASS 2	10 /14.5%	32 /20.8%	5 /13.9%	4 /9.8%	5 /13.5%	4 /11.1%
	CLASS 3	14 /20.3%	12 /7.8%	1 /2.8%	0	1 /2.7%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	33 /61.1%	73 /61.3%	32 /80.0%	24 /92.3%	23 /79.3%	22 /84.6%
	CLASS 2	4 /7.4%	30 /25.2%	7 /17.5%	2 /7.7%	6 /20.7%	4 /15.4%
	CLASS 3	17 /31.5%	16 /13.4%	1 /2.5%	0	0	0

CLASS 1: > 121°
CLASS 2: 90°-120°
CLASS 3: < 90°

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 81. Range of Motion - Passive. Chronic patients. FDA designation, App. 6, Item 13. IDE designation, D-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	36 /92.3%	67 /77.0%	20 /87.0%	24 /100.0%	14 /82.4%	23 /88.5%
	CLASS 2	2 /5.1%	16 /18.4%	3 /13.0%	0	2 /11.8%	3 /11.5%
	CLASS 3	1 /2.6%	4 /4.6%	0	0	1 /5.9%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	22 /71.0%	41 /56.9%	20 /83.3%	14 /100.0%	16 /94.1%	15 /88.2%
	CLASS 2	6 /19.4%	17 /23.6%	4 /16.7%	0	1 /5.9%	2 /11.8%
	CLASS 3	3 /9.7%	14 /19.4%	0	0	0	0

CLASS 1: > 121°
CLASS 2: 90°-120°
CLASS 3: < 90°

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 82. Range of Motion - Passive. Acute patients. FDA designation, App. 6, Item 13. IDE designation, D-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	13 /43.3%	46 /68.6%	10 /76.9%	16 /94.1%	16 /84.2%	10 /100.0%
	CLASS 2	9 /30.0%	15 /22.4%	2 /15.4%	1 /5.9%	3 /15.8%	0
	CLASS 3	8 /26.7%	6 /9.0%	1 /7.7%	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	11 /47.8%	34 /72.3%	13 /81.2%	11 /91.7%	9 /75.0%	7 /77.8%
	CLASS 2	3 /13.0%	9 /19.1%	2 /12.5%	1 /8.3%	3 /25.0%	2 /22.2%
	CLASS 3	9 /39.1%	4 /8.5%	1 /6.2%	0	0	0

CLASS 1: > 121°
CLASS 2: 90°-120°
CLASS 3: < 90°

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 83. Range of Motion - Passive. Chronic + acute patients. FDA designation, App. 6, Item 13. IDE designation, D-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	49 /71.0%	113/73.4%	30 /83.3%	40 /97.6%	30 /83.3%	33 /91.7%
	CLASS 2	11 /15.9%	31 /20.1%	5 /13.9%	1 /2.4%	5 /13.9%	3 /8.3%
	CLASS 3	9 /13.0%	10 /6.5%	1 /2.8%	0	1 /2.8%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	33 /61.1%	75 /63.0%	33 /82.5%	25 /96.2%	25 /86.2%	22 /84.6%
	CLASS 2	9 /16.7%	26 /21.8%	6 /15.0%	1 /3.8%	4 /13.8%	4 /15.4%
	CLASS 3	12 /22.2%	18 /15.1%	1 /2.5%	0	0	0

CLASS 1: > 121°
CLASS 2: 90°-120°
CLASS 3: < 90°

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 84. Patellofemoral Crepitation. Chronic patients. FDA designation, App. 6, Item 14. IDE designation, D-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	33 /86.8%	55 /63.2%	14 /60.9%	15 /62.5%	9 /52.9%	8 /30.8%
	CLASS 2	4 /10.5%	25 /28.7%	8 /34.8%	7 /29.2%	7 /41.2%	13 /50.0%
	CLASS 3	1 /2.6%	3 /3.4%	1 /4.3%	2 /8.3%	1 /5.9%	5 /19.2%
	CLASS 4	0	4 /4.6%	0	0	0	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	26 /83.9%	39 /54.2%	10 /41.7%	9 /64.3%	7 /41.2%	6 /35.3%
	CLASS 2	4 /12.9%	22 /30.6%	4 /16.7%	3 /21.4%	5 /29.4%	7 /41.2%
	CLASS 3	0	8 /11.1%	10 /41.7%	2 /14.3%	3 /17.6%	4 /23.5%
	CLASS 4	1 /3.2%	3 /4.2%	0	0	2 /11.8%	0

CLASS 1: None
CLASS 2: Mild
CLASS 3: Moderate
CLASS 4: Marked

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 85. Patellofemoral Crepitation. Acute patients. FDA designation, App. 6, Item 14. IDE designation, D-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	27 /93.1%	47 /70.1%	4 /30.8%	10 /58.8%	10 /50.0%	5 /50.0%
	CLASS 2	2 /6.9%	18 /26.9%	8 /61.5%	7 /41.2%	7 /35.0%	3 /30.0%
	CLASS 3	0	1 /1.5%	0	0	2 /10.0%	2 /20.0%
	CLASS 4	0	1 /1.5%	1 /7.7%	0	1 /5.0%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	22 /91.7%	38 /80.8%	8 /50.0%	5 /41.7%	5 /45.4%	2 /22.2%
	CLASS 2	1 /4.2%	9 /19.1%	7 /43.8%	5 /41.7%	4 /36.4%	4 /44.4%
	CLASS 3	0	0	1 /6.2%	1 /8.3%	2 /18.2%	3 /33.3%
	CLASS 4	1 /4.2%	0	0	1 /8.3%	0	0

CLASS 1: None
CLASS 2: Mild
CLASS 3: Moderate
CLASS 4: Marked

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 86. Patellofemoral Crepitation. Chronic + acute patients. FDA designation, App. 6, Item 14. IDE designation, D-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	60 /89.6%	102/66.2%	18 /50.0%	25 /61.0%	19 /51.4%	13 /36.1%
	CLASS 2	6 /9.0%	43 /27.9%	16 /44.4%	14 /34.1%	14 /37.8%	16 /44.4%
	CLASS 3	1 /1.5%	4 /2.6%	1 /2.8%	2 /4.9%	3 /8.1%	7 /19.4%
	CLASS 4	0	5 /3.2%	1 /2.8%	0	1 /2.7%	0

		TIME (Years)					
		Pre-Op	0-1	1-2	2-3	3-4	4-5
CONTROL	CLASS 1	48 /87.3%	77 /64.7%	18 /45.0%	14 /53.8%	12 /42.8%	8 /30.8%
	CLASS 2	5 /9.1%	31 /26.0%	11 /27.5%	8 /30.8%	9 /32.1%	11 /42.3%
	CLASS 3	0	8 /6.7%	11 /27.5%	3 /11.5%	5 /17.8%	7 /26.9%
	CLASS 4	2 /3.6%	3 /2.5%	0	1 /3.8%	2 /7.1%	0

CLASS 1: None
CLASS 2: Mild
CLASS 3: Moderate
CLASS 4: Marked

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 87. 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 88. 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 89. 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 90. 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 91. 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 92. 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 93. 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 94. 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 95. Function - Walking (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 8. IDE designation, F-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	0	5 /38.5%	4 /40.0%	2 /40.0%	4 /57.1%	1 /33.3%
	CLASS 2	1 /11.1%	7 /53.8%	6 /60.0%	3 /60.0%	3 /42.9%	2 /66.7%
	CLASS 3	8 /88.9%	1 /7.7%	0	0	0	0

Class 1: Unlimited without discomfort
Class 2: Limited by discomfort
Class 3: Unable to walk without discomfort

TABLE 96. Function - Climbing Stairs (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 9. IDE designation, F-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	1 /11.1%	9 /69.2%	8 /88.9%	3 /60.0%	7 /100.0%	3 /100.0%
	CLASS 2	1 /11.1%	4 /30.8%	1 /11.1%	2 /40.0%	0	0
	CLASS 3	7 /77.8%	0	0	0	0	0

Class 1: Alternate feet
Class 2: Same foot first
Class 3: Unable to climb stairs

TABLE 97. Activity - Climbing Stairs (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 9. IDE designation, F-12. 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%	5 /100.0%	7 /100.0%	1 /100.0%
	CLASS 2	1 /11.1%	2 /15.4%	0	0	0	0
	CLASS 3	7 /77.8%	0	0	0	0	0

Class 1: Little or no difficulty
Class 2: Extreme difficulty
Class 3: Unable to climb stairs

TABLE 98. Activity - Descending Stairs (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 10. IDE designation, F-13. 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%	1 /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: Little or no difficulty
Class 2: Extreme difficulty
Class 3: Unable to descend stairs

TABLE 99. Activity - Running (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 11. IDE designation, F-16. 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 /23.1%	1 /10.0%	1 /20.0%	2 /28.6%	0
	CLASS 2	0	2 /15.4%	4 /40.0%	1 /20.0%	2 /28.6%	0
	CLASS 3	1 /11.1%	0	1 /10.0%	0	2 /28.6%	0
	CLASS 4	8 /88.9%	8 /61.5%	4 /40.0%	3 /60.0%	1 /14.3%	1 /100.0%

Class 1: No problem
Class 2: Some difficulty
Class 3: Extreme difficulty
Class 4: Unable to run

TABLE 100. Function - Running (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 11. IDE designation, F-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	2 /15.4%	4 /40.0%	2 /40.0%	2 /28.6%	1 /33.3%
	CLASS 2	0	0	0	0	1 /14.3%	0
	CLASS 3	0	4 /30.8%	1 /10.0%	1 /20.0%	3 /42.9%	2 /66.7%
	CLASS 4	9 /100.0%	7 /53.8%	5 /50.0%	2 /40.0%	1 /14.3%	0

Class 1: No limitation
Class 2: 1 mile
Class 3: Short distances only
Class 4: Unable to run

TABLE 101. Activity - Jumping (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 12. IDE designation, F-17. 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	2 /15.4%	1 /10.0%	2 /40.0%	2 /28.6%	0
	CLASS 2	0	4 /30.8%	4 /40.0%	1 /20.0%	3 /42.9%	0
	CLASS 3	1 /11.1%	3 /23.1%	2 /20.0%	0	1 /14.3%	1 /100.0%
	CLASS 4	8 /88.9%	4 /30.8%	3 /30.0%	2 /40.0%	1 /14.3%	0

Class 1: No problem
Class 2: Some difficulty
Class 3: Extreme difficulty
Class 4: Unable to jump

TABLE 102. Function - Support (Non-Randomized). Chronic + acute patients. FDA designation, App. 5, Item 13. IDE designation, F-7. 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%	5 /71.4%	3 /100.0%
	CLASS 2	0	0	0	1 /20.0%	2 /28.6%	0
	CLASS 3	0	1 /7.7%	0	0	0	0
	CLASS 4	1 /88.9%	1 /7.7%	0	0	0	0

Class 1: None
Class 2: Cane or brace occasionally
Class 3: Cane or brace most of the time
Class 4: Crutches or walker

TABLE 103. 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 104. 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 105. 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 106. 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 107. Posterior Drawer - 30° (Non-Randomized). Chronic + acute patients. No FDA designation. IDE designation, ST-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	2 /25.0%	11 /84.6%	8 /80.0%	3 /75.0%	3 /42.9%	2 /66.7%
	CLASS 2	1 /12.5%	0	2 /20.0%	0	2 /28.6%	0
	CLASS 3	1 /12.5%	2 /15.4%	0	0	2 /28.6%	1 /33.3%
	CLASS 4	4 /50.0%	0	0	1 /25.0%	0	0

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

TABLE 108. Valgus Stress - 30° (Non-Randomized). Chronic + acute patients. FDA designation, App. 6, Item 4. IDE designation, ST-7. 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	0	0
	CLASS 2	3 /37.5%	12 /92.3%	8 /80.0%	5 /100.0%	5 /71.4%	3 /100.0%
	CLASS 3	5 /62.5%	1 /7.7%	2 /20.0%	0	2 /28.6%	0

Class 1: Stability greater than uninjured limb
Class 2: Stability equal to uninjured limb
Class 3: Stability less than uninjured limb

TABLE 109. Varus Stress - 30° (Non-Randomized). Chronic + acute patients. FDA designation, App. 6, Item 6. IDE designation, ST-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	0	1 /10.0%	0	0	0
	CLASS 2	4 /50.0%	13 /100.0%	9 /90.0%	4 /80.0%	5 /71.4%	3 /100.0%
	CLASS 3	4 /50.0%	0	0	1 /20.0%	2 /28.6%	0

Class 1: Stability greater than uninjured limb
Class 2: Stability equal to uninjured limb
Class 3: Stability less than uninjured limb

TABLE 110. Varus or Valgus Alignment (Non-Randomized). Chronic + acute patients. FDA designation, App. 6, Item 12. IDE designation, D-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	7 /87.5%	9 /81.8%	7 /87.5%	2 /50.0%	2 /40.0%	0
	CLASS 2	0	0	0	1 /25.0%	3 /60.0%	0
	CLASS 3	0	2 /18.2%	1 /12.5%	1 /25.0%	0	0
	CLASS 4	1 /16.7%	0	0	0	0	0

Class 1: 0°
Class 2: < 5°
Class 3: 5-15°
Class 4: > 15°

TABLE 111. Range of Motion - Active (Non-Randomized). Chronic + acute patients. FDA designation, App. 6, Item 13. IDE designation, D-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	2 /25.0%	9 /69.2%	5 /50.0%	0	4 /57.1%	0
	CLASS 2	0	2 /15.4%	5 /50.0%	5 /100.0%	3 /42.9%	2 /100.0%
	CLASS 3	6 /75.0%	2 /15.4%	0	0	0	0

Class 1: > 121°
Class 2: 90°-120°
Class 3: < 90°

TABLE 112. Range of Motion - Passive (Non-Randomized). Chronic + acute patients. FDA designation, App. 6, Item 13. IDE designation, D-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	3 /37.5%	9 /69.2%	5 /50.0%	0	4 /57.1%	0
	CLASS 2	0	2 /15.4%	5 /50.0%	5 /100.0%	3 /42.9%	2 /100.0%
	CLASS 3	5 /62.5%	2 /15.4%	0	0	0	0

Class 1: > 121°
Class 2: 90°-120°
Class 3: < 90°

TABLE 113. Patellofemoral Crepitation (Non-Randomized). Chronic + acute patients. FDA designation, App. 6, Item 14. IDE designation, D-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	7 /87.5%	11 /84.6%	7 /70.0%	1 /20.0%	1 /14.3%	0
	CLASS 2	0	2 /15.4%	2 /20.0%	3 /60.0%	3 /42.9%	1 /50.0%
	CLASS 3	0	0	1 /10.0%	1 /20.0%	3 /42.9%	1 /50.0%
	CLASS 4	1 /12.5%	0	0	0	0	0

Class 1: None
Class 2: Mild
Class 3: Moderate
Class 4: Marked

TABLE 114. 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 114 (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 114 (continued):

INCOMPLETE TOTAL SCORES

CHRONIC - CARBON-FIBER

PT. NO.	FOLLOW-UP	SCORE	COMMENT
18	9	14.3	Patient evaluation only
	12	67.4	No patient evaluation
36	9	51.6	No patient evaluation
	36	8.4	Patient evaluation only
	47	45.9	No patient evaluation
58	51	62.5	No patient evaluation
81	26	41.4	No deformity or stability
110	9	34.2	Deformity & stability only
126	57	43.3	No stability or deformity
132	62	60.6	No patient evaluation
139	Pre	17.7	No deformity score
144	3	33.9	Stability and deformity only
146	55	71.0	No patient evaluation

Table 114 (continued):

INCOMPLETE TOTAL SCORES

CHRONIC - CONTROL

PT. NO.	FOLLOW-UP	SCORE	COMMENT
29	3	37.6	Deformity & stability only
57	6	42.3	No symptoms or function score
79	Pre	29.8	No deformity score
80	21	67.2	No stability score
85	56	51.8	No function or patient evaluation score
101	58	69.4	No patient evaluation
119	Pre	31.0	No stability score
120	51	66.8	No patient evaluation
125	24	59.8	No patient evaluation
131	3	12.9	No stability score
141	Pre	1.0	No stability or deformity score
	3	24.4	No stability score
145	56	75.1	No patient evaluation
150	Pre	37.0	No stability score

Table 114 (continued):

INCOMPLETE TOTAL SCORES

ACUTE - CARBON-FIBER

PT. NO.	FOLLOW-UP	SCORE	COMMENT
13	3	27.5	Stability only
	42	83.9	No deformity score
45	3	35.8	Deformity & stability only
51	49	12.6	Patient evaluation only
	51	60.8	No patient evaluation
65	Pre	20.7	No deformity score
	42	51.5	No symptoms or function score
84	9	30.1	Deformity & stability only
104	52	58.2	No deformity or patient evaluation
116	Pre	25.4	No patient evaluation
121	9	49.9	No symptoms or function score
136	3	15.5	No deformity or stability score
137	3	24.5	No deformity or stability score
140	Pre	20.2	No deformity score

Table 114 (continued):

INCOMPLETE TOTAL SCORES

ACUTE - CONTROL

PT. NO.	FOLLOW-UP	SCORE	COMMENT
6	68	61.8	No patient evaluation
34	6	37.6	Stability & deformity only
53	Pre	53.1	No patient evaluation
	50	76.7	No patient evaluation
56	Pre	15.8	No symptoms score
59	Pre	38.6	No symptoms or function score
64	Pre	17.0	No deformity score
	25	54.2	No stability score
69	12	35.1	Stability & deformity only
96	46	72.2	No deformity score
102	20	62.2	No function score
106	6	36.2	No symptoms or function score
135	6	50.2	No deformity score
143	Pre	20.7	No deformity score

Table 114 (continued):

Non-Randomized - Chronic

	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	2/ 46.8 ± 2.7	2/ 64.6 ± 1.3	2/ 61.5 ± 16.8	0	2/ 62.9 ± 5.4	2/ 63.6 ± 16.4

Non-Randomized - Acute

	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	6/ 11.0 ± 8.1	9/ 71.6 ± 9.6	8/ 71.9 ± 15.5	3/ 64.8 ± 15.2	5/ 71.8 ± 14.8	0

Non-Randomized - Chronic + Acute

	Pre-Op	0-1	1-2	2-3	3-4	4-5
CARBON FIBER	8/ 19.9 ± 18.0	11/ 70.3 ± 9.0	10/ 69.8 ± 15.4	3/ 64.8 ± 15.2	7/ 69.2 ± 13.0	2/ 63.6 ± 16.4

Table 114 (continued):

NON-RANDOMIZED **INCOMPLETE TOTAL SCORES**

CHRONIC - CARBON-FIBER

PT. NO.	FOLLOW-UP	SCORE	COMMENT
60	26	59.4	No stability score

ACUTE - CARBON-FIBER

PT. NO.	FOLLOW-UP	SCORE	COMMENT
59	59	61.2	No deformity or patient evaluation score
46	3	21.5	No stability score
71	7	30.6	Stability and deformity only
	9	18.4	No stability or deformity score
	29	34.8	No stability score
82	Pre	0.0	Symptoms and function only

TABLE 115: A Patient-by-Patient Listing of the Pivot-Shift Laxity Scores for the ACL Patients

PIVOT SHIFT 1/27/89

CHRONIC - CARBON FIBER

PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
2	Pre	2	2					
	32	8				8		
	64	2						2
4	Pre	6	6					
	12	8		8				
	26	6				6		
	43	2					2	
	58	6						6
12	Pre	8	8					
	36	8				8		
14	Pre	8	8					
	6	8		8				
	9	8		8				
	19	8			8			
	25	8				8		
	41	6					6	
	63	8						8
15	Pre	2	2					
	6	8		8				
	23	2			2			
	40	2					2	
	55	0						0
16	Pre	0	0					
	3	8		8				
	6	8		8				
	9	8		8				
	12	8		8				
	35	8				8		
	56	8						8
17	Pre	0	0					
	3	8		8				
	6	2		2				
	9	8		8				
	37	8					8	
	55	8						8
18	Pre	2	2					
	6	8		8				
	12	8		8				
	29	8				8		
	53	8						8
22	Pre	2	2					
	6	8		8				
	20	8			8			
	28	6				6		
	53	8						8

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PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
25	Pre	6	6					
	3	6		6				
	6	8		8				
	25	8				8		
	51	2						2
36	Pre	2	2					
	3	8		8				
	6	8		8				
	9	6		6				
	23	8			8			
	26	8				8		
	47	8					8	
	58	2						2
37	Pre	2	2					
	3	8		8				
	6	8		8				
	12	6		6				
	24	6			6			
	36	8				8		
	49	8						8
40	Pre	2	2					
	3	8		8				
	22	8			8			
	53	6						6
42	Pre	2	2					
	3	8		8				
	15	8			8			
	22	8			8			
	37	8					8	
	49	8						8
55	Pre	6	6					
	15	6			6			
	24	6			6			
	38	8					8	
	52	6						6
58	Pre	2	2					
	6	8		8				
	9	8		8				
	14	8			8			
	25	8				8		
	51	8						8
67	Pre	6	6					
	9	8		8				
	21	8			8			
	45	8					8	
68	Pre	6	6					
	9	8		8				
	13	8			8			
	36	8				8		

PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
73	Pre	6	6					
	21	6			6			
	34	6				6		
74	Pre	8	8					
	6	6		6				
	14	8			8			
	27	8				8		
	40	8					8	
76	Pre	6	6					
	3	8		8				
	6	8		8				
	11	8		8				
	30	8				8		
81	Pre	2	2					
	12	2		2				
86	Pre	2	2					
	3	8		8				
	6	8		8				
	9	6		6				
	53	8						8
89	Pre	6	6					
	3	8		8				
	6	6		6				
	9	6		6				
	12	8		8				
	34	8				8		
	59	8						8
92	Pre	6	6					
	3	8		8				
	6	8		8				
	9	8		8				
	12	8		8				
	27	8				8		
95	Pre	2	2					
	3	6		6				
	6	8		8				
	9	6		6				
	12	8		8				
	24	6			6			
	61	6						6
98	Pre	0	0					
	3	8		8				
	6	2		2				
	9	6		6				
	12	6		6				
	24	6			6			
	37	6					6	
	51	8						8
100	Pre	2	2					
	24	0			0			

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PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
103	Pre	2	2					
	3	8		8				
	6	2		2				
	10	8		8				
	13	6			6			
	24	8			8			
	51	8						8
110	Pre	2	2					
	3	6		6				
	6	8		8				
	9	8		8				
	13	8			8			
	39	8					8	
112	Pre	0	0					
	3	8		8				
	9	6		6				
	12	2		2				
	44	8					8	
122	Pre	2	2					
	3	6		6				
	6	0		0				
	18	0			0			
	30	0				0		
	53	0						0
124	Pre	2	2					
	3	8		8				
	6	6		6				
	9	0		0				
	12	2		2				
	27	2				2		
	55	8						8
126	Pre	6	6					
	3	8		8				
	6	8		8				
	9	6		6				
	12	2		2				
	26	2				2		
	33	6				6		
128	Pre	6	6					
	3	6		6				
	6	0		0				
	12	6		6				
	37	6					6	
130	Pre	0	0					
	3	6		6				
	6	8		8				
	9	2		2				
	12	0		0				
	24	2			2			
	48	2					2	
	60	6						6

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PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
132	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	26	8				8		
	45	6					6	
	62	6						6
138	Pre	2	2					
	3	2		2				
	6	2		2				
	50	2						2
139	Pre	0	0					
	3	8		8				
	6	8		8				
	9	2		2				
	15	8			8			
	30	6				6		
	47	2					2	
142	Pre	0	0					
	3	2		2				
	6	0		0				
	36	8				8		
	50	2						2
144	Pre	0	0					
	3	6		6				
	6	2		2				
	12	2		2				
	47	8					8	
146	Pre	0	0					
	3	8		8				
	6	8		8				
	9	8		8				
	12	6		6				
	34	2				2		
	47	6					6	
	55	6						6
149	Pre	0	0					
	3	0		0				
	54	8						8

PIVOT SHIFT 1/27/89

CHRONIC - CONTROL

PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
20	Pre	6	6					
	22	8			8			
	40	8					8	
	55	8						8
28	Pre	6	6					
	3	8		8				
	6	8		8				
	32	8				8		
	60	8						8
29	Pre	2	2					
	3	8		8				
	6	8		8				
	15	8			8			
	30	8				8		
	48	8					8	
31	Pre	2	2					
	3	8		8				
	16	8			8			
	23	8			8			
	45	8					8	
32	Pre	6	6					
	3	8		8				
	6	6		6				
	9	8		8				
	12	8		8				
	26	6				6		
35	Pre	0	0					
	3	8		8				
	9	8		8				
	24	8			8			
41	Pre	8	8					
	9	8		8				
	17	8			8			
	36	2				2		
	47	8					8	
47	Pre	2	2					
	16	8			8			
	31	8				8		
	45	8					8	
57	Pre	6	6					
	6	8		8				
	14	8			8			
	26	6				6		
	42	6					6	

PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
61	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	12	8		8				
	27	6				6		
	39	8					8	
62	Pre	2	2					
	12	6		6				
	33	8				8		
	47	8					8	
66	Pre	2	2					
	7	6		6				
77	Pre	2	2					
	10	8		8				
	23	8			8			
	37	8					8	
79	Pre	2	2					
	9	6		6				
	12	2		2				
	27	2				2		
80	Pre	6	6					
	38	8					8	
85	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	12	8		8				
	24	6			6			
	56	6						6
88	Pre	2	2					
	3	8		8				
	6	6		6				
	9	8		8				
	12	2		2				
90	Pre	0	0					
	3	8		8				
	6	8		8				
	9	8		8				
	12	6		6				
	56	8						8
97	Pre	2	2					
	3	8		8				
	6	8		8				
	10	6		6				
	12	6		6				
	24	8			8			
	40	8					8	
	58	8						8

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PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
101	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	16	8			8			
	24	8			8			
	30	8				8		
	58	8						8
105	Pre	6	6					
	3	8		8				
	6	2		2				
	9	2		2				
	17	2			2			
	23	6			6			
	48	8					8	
109	3	8		8				
	6	6		6				
	13	6			6			
113	Pre	2	2					
	3	8		8				
	10	8		8				
	41	8					8	
119	3	6		6				
	12	8		8				
	18	8			8			
	39	8					8	
120	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	13	6			6			
	18	6			6			
	51	8						8
123	Pre	6	6					
	3	8		8				
	6	8		8				
	9	6		6				
	17	6			6			
	24	6			6			
	54	2						2
125	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	12	8		8				
	24	6			6			
	61	6						6

PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
127	Pre	2	2					
	3	8		8				
	6	8		8				
	9	6		6				
	34	6				6		
	57	6						6
129	Pre	2	2					
	3	2		2				
	6	8		8				
	9	6		6				
	12	8		8				
	61	8						8
131	Pre	2	2					
	6	8		8				
	40	6					6	
	54	6						6
133	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	20	6			6			
	56	6						6
134	Pre	2	2					
	3	8		8				
	6	6		6				
	32	8				8		
	44	8					8	
	57	8						8
141	6	8		8				
	9	8		8				
	14	8			8			
	32	8				8		
	50	8						8
145	Pre	0	0					
	6	8		8				
	9	8		8				
	12	8		8				
	27	8				8		
	41	8					8	
	56	8						8
148	Pre	0	0					
	3	8		8				
150	3	8		8				
	6	8		8				
	9	8		8				
	15	8			8			
	35	6				6		
	51	6						6

PIVOT SHIFT 1/27/89

ACUTE - CARBON FIBER

PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
3	Pre	8	8					
	9	8		8				
	12	8		8				
	33	8				8		
	46	8					8	
	60	6						6
5	Pre	0	0					
	9	8		8				
	12	8		8				
	26	8				8		
	42	8					8	
	58	8						8
8	Pre	8	8					
	9	8		8				
	12	8		8				
	31	6				6		
	42	6					6	
	55	8						8
9	Pre	0	0					
	24	8			8			
	43	6					6	
	60	8						8
13	Pre	2	2					
	3	8		8				
	9	8		8				
	12	8		8				
	33	8				8		
	42	8					8	
	66	8						8
19	Pre	2	2					
	6	8		8				
	29	8				8		
	42	8					8	
	62	8						8
21	Pre	8	8					
	3	8		8				
	6	8		8				
	12	8		8				
	24	8			8			
	45	8					8	
	60	8						8
45	Pre	8	8					
	3	8		8				
	12	8		8				
	25	8				8		
	41	8					8	

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PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
51	Pre	2	2					
	14	8			8			
	51	6						6
52	Pre	8	8					
	14	6			6			
	24	8			8			
	39	8					8	
54	Pre	2	2					
	18	8			8			
	32	8				8		
	44	8					8	
63	Pre	6	6					
	6	8		8				
	12	8		8				
	27	8				8		
	39	8					8	
65	Pre	0	0					
	7	6		6				
	18	8			8			
	31	8				8		
	42	8					8	
70	Pre	2	2					
	16	6			6			
	37	8					8	
75	Pre	2	2					
	3	8		8				
	6	8		8				
	12	8		8				
84	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	14	8			8			
	32	6				6		
	54	6						6
87	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	12	2		2				
	24	6			6			
	35	6				6		
104	Pre	6	6					
	3	8		8				
	6	8		8				
	9	8		8				
	12	6		6				
	24	6			6			
	52	6						6

PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
108	Pre	0	0					
	3	6		6				
	6	6		6				
	9	2		2				
	12	2		2				
	38	8					8	
111	Pre	2	2					
	3	8		8				
	12	8		8				
	30	8				8		
114	Pre	2	2					
	3	8		8				
	12	0		0				
	34	2				2		
115	Pre	0	0					
	3	8		8				
	6	8		8				
	12	8		8				
	26	8				8		
	45	6					6	
116	Pre	2	2					
	3	8		8				
117	Pre	2	2					
	3	8		8				
	6	8		8				
	8	8		8				
	12	8		8				
	24	8			8			
	46	8					8	
118	Pre	2	2					
	3	6		6				
	6	6		6				
	9	8		8				
	15	8			8			
	37	8				8		
121	Pre	2	2					
	3	8		8				
	6	8		8				
	9	6		6				
	11	6		6				
	36	8				8		
136	Pre	2	2					
	9	6		6				
	12	8		8				
	44	8					8	
137	Pre	0	0					
	6	8		8				
	9	6		6				
	45	8					8	

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PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
140	Pre	0	0					
	3	6		6				
	9	0		0				
	40	2					2	
	54	2						2
147	Pre	2	2					
	3	8		8				
	9	8		8				
	46	8					8	
151	Pre	2	2					
	3	8		8				
	6	6		6				
	9	8		8				
	30	6				6		
	46	6					6	

PIVOT SHIFT 1/27/89

ACUTE - CONTROL

PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
1	Pre	8	8					
	26	6				6		
	67	8						8
6	Pre	8	8					
	68	8						8
10	Pre	8	8					
	12	8		8				
	27	8				8		
	44	8					8	
11	Pre	8	8					
	12	8		8				
	24	8			8			
	42	8					8	
23	Pre	2	2					
	20	8			8			
	25	8				8		
	38	8					8	
	55	8						8
24	Pre	8	8					
	25	6				6		
	40	6					6	
26	Pre	6	6					
	3	6		6				
	9	8		8				
	19	8			8			
	37	8					8	
	57	8						8
34	Pre	8	8					
	3	8		8				
	6	8		8				
	9	8		8				
	12	8		8				
	28	8				8		
	43	8					8	
	54	8						8
49	Pre	6	6					
	24	8			8			
	41	8					8	
50	Pre	2	2					
	6	8		8				
	9	8		8				
	12	8		8				
	18	8			8			
	23	8			8			
	45	8					8	

PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
53	Pre	8	8					
	9	8		8				
	12	8		8				
	24	6			6			
	36	8				8		
	50	8						8
56	Pre	0	0					
	20	8			8			
	36	8				8		
	51	8						8
59	Pre	6	6					
	3	8		8				
	12	8		8				
	26	8				8		
	40	6					6	
64	Pre	8	8					
	12	8		8				
	37	8					8	
69	Pre	6	6					
	8	8		8				
	12	8		8				
	17	8			8			
	34	8				8		
72	Pre	6	6					
	10	8		8				
	20	6			6			
	34	8				8		
94	Pre	2	2					
	3	8		8				
	6	8		8				
	8	6		6				
	11	8		8				
96	Pre	2	2					
	4	8		8				
	6	6		6				
	9	8		8				
	12	8		8				
	46	6					6	
99	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	12	8		8				
102	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	12	8		8				
	20	8			8			

PATIENT NUMBER	FOLLOW-UP	PIVOT SHIFT	PRE-OP	0-12	13-24	25-36	37-48	>48
106	Pre	2	2					
	3	6		6				
	6	2		2				
	9	8		8				
	15	6			6			
	50	6						6
107	Pre	2	2					
	3	8		8				
	6	6		6				
	9	8		8				
	15	8			8			
	24	8			8			
135	Pre	2	2					
	3	8		8				
	6	2		2				
	9	8		8				
	16	2			2			
	46	6					6	
	58	6						6
143	Pre	0	0					
	3	8		8				
	6	6		6				
	9	6		6				
	13	6			6			
	33	8				8		

TABLE 116: A Patient-by-Patient Listing of the Lachman Laxity Scores for the ACL Patients

ANTERIOR DRAWER - 30 1/27/89

CHRONIC - CARBON FIBER

PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
2	Pre	2	2					
	32	2				2		
	64	2						2
4	Pre	2	2					
	12	6		6				
	26	6				6		
	43	2					2	
	58	6						6
12	Pre	2	2					
	36	2				2		
14	Pre	6	6					
	6	8		8				
	9	8		8				
	19	8			8			
	25	8				8		
	41	6					6	
	63	6						6
15	Pre	0	0					
	6	2		2				
	23	2			2			
	40	6					6	
	55	0						0
16	Pre	0	0					
	3	8		8				
	6	8		8				
	9	8		8				
	12	8		8				
	35	8				8		
	56	8						8
17	Pre	0	0					
	3	6		6				
	6	2		2				
	9	8		8				
	37	6					6	
	55	6						6
18	Pre	2	2					
	6	6		6				
	12	6		6				
	29	8				8		
	53	8						8
22	Pre	2	2					
	6	6		6				
	20	6			6			
	28	6				6		
	53	6						6

PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
25	Pre	2	2					
	3	6		6				
	6	6		6				
	25	2				2		
	51	6						6
36	Pre	2	2					
	3	6		6				
	6	6		6				
	9	2		2				
	23	6			6			
	26	6				6		
	47	6					6	
	58	0						0
37	Pre	0	0					
	3	8		8				
	6	8		8				
	12	6		6				
	24	8			8			
	36	8				8		
	49	8						8
40	Pre	2	2					
	3	6		6				
	22	8			8			
	53	6						6
42	Pre	6	6					
	3	6		6				
	15	8			8			
	22	8			8			
	37	6					6	
	49	6						6
55	Pre	2	2					
	15	6			6			
	24	6			6			
	38	6					6	
	52	6						6
58	Pre	6	6					
	6	8		8				
	9	6		6				
	14	8			8			
	25	6				6		
	51	6						6
67	Pre	6	6					
	9	8		8				
	21	6			6			
	45	6					6	
68	Pre	6	6					
	9	8		8				
	13	8			8			
	36	8				8		

PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
73	Pre	6	6					
	21	8			8			
	34	2				2		
74	Pre	2	2					
	6	2		2				
	14	2			2			
	27	6				6		
	40	6					6	
76	Pre	6	6					
	3	8		8				
	6	6		6				
	11	8		8				
	30	8				8		
81	Pre	6	6					
	12	6		6				
86	Pre	6	6					
	3	6		6				
	6	6		6				
	9	6		6				
	53	8						8
89	Pre	2	2					
	3	8		8				
	6	6		6				
	9	6		6				
	12	6		6				
	34	6				6		
	59	8						8
92	Pre	2	2					
	3	6		6				
	6	6		6				
	9	8		8				
	12	8		8				
	27	8				8		
95	Pre	6	6					
	3	6		6				
	6	6		6				
	9	6		6				
	12	6		6				
	24	6			6			
	61	2						2
98	Pre	2	2					
	3	6		6				
	6	2		2				
	9	6		6				
	12	6		6				
	24	6			6			
	37	6					6	
	51	6						6
100	Pre	2	2					
	24	0			0			

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PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
103	Pre	6	6					
	3	8		8				
	6	6		6				
	10	6		6				
	13	6			6			
	24	8			8			
	51	8						8
110	Pre	6	6					
	3	8		8				
	6	6		6				
	9	6		6				
	13	6			6			
	39	8					8	
112	Pre	0	0					
	3	6		6				
	9	6		6				
	12	2		2				
	44	6					6	
122	Pre	2	2					
	3	6		6				
	6	2		2				
	18	0			0			
	30	0				0		
	53	0						0
124	Pre	2	2					
	3	8		8				
	6	2		2				
	9	2		2				
	12	6		6				
	27	2				2		
	55	6						6
126	Pre	2	2					
	3	6		6				
	6	6		6				
	9	6		6				
	12	2		2				
	26	2				2		
	33	6				6		
128	Pre	2	2					
	3	2		2				
	6	2		2				
	12	6		6				
	37	6					6	
130	Pre	2	2					
	3	8		8				
	6	6		6				
	9	2		2				
	12	2		2				
	24	2			2			
	48	2					2	
	60	6						6

PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
132	Pre	2	2					
	3	6		6				
	6	6		6				
	9	6		6				
	26	6				6		
	45	6					6	
	62	6						6
138	Pre	6	6					
	3	6		6				
	6	2		2				
	50	0						0
139	Pre	0	0					
	3	6		6				
	6	8		8				
	9	6		6				
	15	6			6			
	30	8				8		
	47	6					6	
142	Pre	6	6					
	3	6		6				
	6	2		2				
	36	8				8		
	50	0						0
144	Pre	2	2					
	3	6		6				
	6	2		2				
	12	2		2				
	47	8					8	
146	Pre	2	2					
	3	6		6				
	6	6		6				
	9	6		6				
	12	6		6				
	34	2				2		
	47	6					6	
	55	6						6
149	Pre	2	2					
	3	6		6				

ANTERIOR DRAWER - 30 1/27/89

CHRONIC - CONTROL

PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
20	Pre	2	2					
	22	8			8			
	40	6					6	
	55	6						6
28	Pre	6	6					
	3	8		8				
	6	8		8				
	32	8				8		
	60	8						8
29	Pre	0	0					
	3	8		8				
	6	8		8				
	15	8			8			
	30	8				8		
	48	8					8	
31	Pre	0	0					
	3	8		8				
	16	8			8			
	23	6			6			
	45	6					6	
32	Pre	6	6					
	3	8		8				
	6	6		6				
	9	6		6				
	12	2		2				
	26	2				2		
35	Pre	0	0					
	3	2		2				
	9	2		2				
	24	0			0			
41	Pre	6	6					
	9	6		6				
	17	8			8			
	36	8				8		
	47	8					8	
47	Pre	6	6					
	16	6			6			
	31	8				8		
	45	6					6	
57	Pre	2	2					
	6	8		8				
	14	8			8			
	26	8				8		
	42	6					6	

PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
61	Pre	2	2					
	3	2		2				
	6	8		8				
	9	8		8				
	12	8		8				
	27	6				6		
	39	6					6	
62	Pre	2	2					
	12	2		2				
	33	2				2		
	47	6					6	
66	Pre	2	2					
	7	6		6				
77	Pre	2	2					
	10	8		8				
	23	8			8			
	37	6					6	
79	Pre	2	2					
	9	2		2				
	12	6		6				
	27	8				8		
80	Pre	6	6					
	38	8					8	
85	Pre	6	6					
	3	6		6				
	6	8		8				
	9	6		6				
	12	6		6				
	24	6			6			
	56	6						6
88	Pre	6	6					
	3	6		6				
	6	6		6				
	9	6		6				
	12	2		2				
	64	6						6
90	Pre	8	8					
	3	8		8				
	6	6		6				
	9	8		8				
	12	6		6				
	56	6						6
97	Pre	6	6					
	3	8		8				
	6	8		8				
	10	6		6				
	12	8		8				
	24	6			6			
	40	6					6	
	58	8						8

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PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
101	Pre	2	2					
	3	8		8				
	6	6		6				
	9	6		6				
	16	8			8			
	24	6			6			
	30	6				6		
	58	2						2
105	Pre	2	2					
	3	2		2				
	6	6		6				
	9	2		2				
	17	6			6			
	23	6			6			
	48	6					6	
109	Pre	2	2					
	3	6		6				
	6	6		6				
	13	6			6			
113	Pre	8	8					
	3	6		6				
	10	6		6				
	41	6					6	
119	Pre	6	6					
	3	6		6				
	12	6		6				
	18	6			6			
	39	6					6	
120	Pre	6	6					
	3	8		8				
	6	6		6				
	9	8		8				
	13	6			6			
	18	8			8			
	51	6						6
123	Pre	2	2					
	3	8		8				
	6	8		8				
	9	6		6				
	17	6			6			
	24	8			8			
	54	6						6
125	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	12	8		8				
	24	6			6			
	61	6						6

PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
127	Pre	2	2					
	3	2		2				
	6	2		2				
	9	2		2				
	34	0				0		
	57	0						0
129	Pre	6	6					
	3	6		6				
	6	6		6				
	9	6		6				
	12	6		6				
	61	6						6
131	Pre	2	2					
	3	8		8				
	6	8		8				
	40	6					6	
	54	2						2
133	Pre	0	0					
	3	6		6				
	6	6		6				
	9	2		2				
	20	2			2			
	56	6						6
134	Pre	6	6					
	3	6		6				
	6	6		6				
	32	8				8		
	44	8					8	
	57	8						8
141	Pre	2	2					
	3	6		6				
	6	8		8				
	9	8		8				
	14	8			8			
	32	8				8		
	50	8						8
145	Pre	6	6					
	6	8		8				
	9	8		8				
	12	8		8				
	27	8				8		
	41	8					8	
	56	6						6
148	Pre	2	2					
	3	6		6				
150	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	15	6			6			
	35	2				2		
	51	6						6

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ACUTE - CARBON FIBER

PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
3	Pre	2	2					
	9	6		6				
	12	8		8				
	33	8				8		
	46	8					8	
	60	6						6
5	Pre	2	2					
	9	6		6				
	12	8		8				
	26	6				6		
	42	6					6	
	58	8						8
8	Pre	2	2					
	9	6		6				
	12	8		8				
	31	6				6		
	42	6					6	
	55	2						2
9	Pre	0	0					
	24	6			6			
	43	6					6	
	60	8						8
13	Pre	2	2					
	3	8		8				
	9	8		8				
	12	8		8				
	33	8				8		
	42	6					6	
	66	6						6
19	Pre	2	2					
	6	8		8				
	29	6				6		
	42	6					6	
	62	8						8
21	Pre	6	6					
	3	8		8				
	6	8		8				
	12	6		6				
	24	6			6			
	45	6					6	
	60	8						8
45	Pre	6	6					
	3	8		8				
	12	8		8				
	25	6				6		
	41	8					8	

PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
51	Pre	0	0					
	14	6			6			
	51	6						6
52	Pre	2	2					
	14	6			6			
	24	8			8			
	39	6					6	
54	Pre	2	2					
	18	6			6			
	32	8				8		
	44	6					6	
63	Pre	6	6					
	6	8		8				
	12	8		8				
	27	8				8		
	39	8					8	
65	Pre	6	6					
	7	6		6				
	18	8			8			
	31	6				6		
	42	8					8	
70	Pre	6	6					
	16	6			6			
	37	2					2	
75	Pre	6	6					
	3	8		8				
	6	8		8				
	12	8		8				
84	Pre	6	6					
	3	8		8				
	6	8		8				
	9	2		2				
	14	6			6			
	32	6				6		
	54	6						6
87	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	12	6		6				
	24	8			8			
	35	6				6		
104	Pre	6	6					
	3	6		6				
	6	2		2				
	9	6		6				
	12	6		6				
	24	8			8			
	52	2						2

PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
108	Pre	2	2					
	3	6		6				
	6	6		6				
	9	2		2				
	12	2		2				
	38	8					8	
111	Pre	6	6					
	3	8		8				
	12	6		6				
	30	6				6		
114	Pre	6	6					
	3	6		6				
	12	8		8				
	34	2				2		
115	Pre	0	0					
	3	6		6				
	6	6		6				
	12	8		8				
	26	8				8		
	45	6					6	
116	Pre	2	2					
	3	6		6				
117	Pre	2	2					
	3	8		8				
	6	2		2				
	8	6		6				
	12	6		6				
	24	6			6			
	46	8					8	
118	Pre	6	6					
	3	2		2				
	6	2		2				
	9	8		8				
	15	8			8			
	37	6				6		
121	Pre	2	2					
	3	6		6				
	6	6		6				
	9	6		6				
	11	6		6				
	36	6				6		
136	Pre	2	2					
	3	6		6				
	9	6		6				
	12	6		6				
	44	8					8	
137	Pre	2	2					
	3	6		6				
	6	6		6				
	9	6		6				
	45	6					6	

PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
140	Pre	2	2					
	3	8		8				
	9	2		2				
	40	6					6	
	54	2						2
147	Pre	2	2					
	3	6		6				
	9	6		6				
	46	6					6	
151	Pre	0	0					
	3	2		2				
	6	6		6				
	9	6		6				
	30	6				6		
	46	6					6	

ANTERIOR DRAWER - 30 1/27/89

ACUTE - CONTROL

PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
1	Pre	6	6					
	26	2				2		
	67	0						0
6	Pre	6	6					
	68	8						8
10	Pre	6	6					
	12	8		8				
	27	6				6		
	44	8					8	
11	Pre	6	6					
	12	8		8				
	24	6			6			
	42	8					8	
23	Pre	2	2					
	20	8			8			
	25	8				8		
	38	8					8	
	55	2						2
24	Pre	8	8					
	25	6				6		
	40	6					6	
26	Pre	2	2					
	3	6		6				
	9	6		6				
	19	2			2			
	37	8					8	
	57	6						6
34	Pre	2	2					
	3	8		8				
	6	8		8				
	9	8		8				
	12	8		8				
	28	6				6		
	43	8					8	
	54	8						8
49	Pre	6	6					
	24	8			8			
	41	8					8	
50	Pre	2	2					
	6	8		8				
	9	8		8				
	12	8		8				
	18	8			8			
	23	8			8			
	45	8					8	

PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
53	Pre	8	8					
	9	6		6				
	12	6		6				
	24	6			6			
	36	8				8		
	50	6						6
56	Pre	2	2					
	20	6			6			
	36	6				6		
	51	8						8
59	Pre	6	6					
	3	8		8				
	12	2		2				
	26	6				6		
	40	2					2	
64	Pre	6	6					
	12	2		2				
	25	2				2		
	37	2					2	
69	Pre	6	6					
	8	2		2				
	12	6		6				
	17	6			6			
	34	6				6		
72	Pre	6	6					
	10	8		8				
	20	2			2			
	34	2				2		
94	Pre	2	2					
	3	6		6				
	6	6		6				
	8	6		6				
	11	2		2				
96	Pre	6	6					
	4	6		6				
	6	6		6				
	9	6		6				
	12	6		6				
	46	6					6	
99	Pre	6	6					
	3	8		8				
	6	8		8				
	9	8		8				
	12	8		8				
102	Pre	6	6					
	3	6		6				
	6	8		8				
	9	8		8				
	12	8		8				
	20	6			6			

PATIENT NUMBER	FOLLOW-UP	AD-30	PRE-OP	0-12	13-24	25-36	37-48	>48
106	Pre	2	2					
	3	6		6				
	6	6		6				
	9	6		6				
	15	6			6			
	50	2						2
107	Pre	2	2					
	3	8		8				
	6	8		8				
	9	6		6				
	15	6			6			
	24	6			6			
135	Pre	6	6					
	3	8		8				
	6	2		2				
	9	2		2				
	16	6			6			
	46	0					0	
	58	2						2
143	Pre	6	6					
	3	8		8				
	6	8		8				
	9	8		8				
	13	8			8			
	33	8				8		

APPENDIX 1: ABBREVIATIONS AND DEFINITIONS

A-1: A grade of acute patients exhibiting injuries to the ACL, but not to the PCL or the collateral ligaments.

A-2: A grade of acute patients exhibiting injuries to the ACL and one or both collateral ligaments (but not the PCL).

A-3: A grade of acute patients exhibiting injuries to both cruciate ligaments.

ACL: Anterior cruciate ligament

ACUTE INJURY: An injury for which surgery (or the appropriate definitive treatment) was administered within 14 days of injury.

C-1: A grade of chronic patients exhibiting injuries to the ACL, but not to the PCL or the collateral ligaments.

C-2: A grade of chronic patients exhibiting injuries to the ACL and one or both collateral ligaments (but not the PCL).

C-3: A grade of chronic patients exhibiting injuries to both cruciate ligaments.

CATEGORY: A patient classification based on duration of injury. A patient in the acute (chronic) category exhibited an acute (chronic) injury.

CHRONIC INJURY: An injury for which surgery was administered more than 14 days after injury.

CLASS: A designation of patient status regarding any Item in Appendix 5 or 6 (or the IDE).

GRADE: A designation of the extent of injury.

GROUP: A term that refers to kind of treatment received by the patients in the study. A patient was either a member of a carbon-fiber group, or a control group.

ITEM: The term is used in the same sense as in the Guidance Document. It refers to the Lachman test, anterior drawer, pivot shift, or any other clinical test or observation listed in Appendix 5 or 6 (or in the IDE).

OPEN TIME: The time during which patients were actually entered into the study (April, 1983 to November, 1985). It was during this time period that the patients received surgical treatment.

PCL: Posterior cruciate ligament

PT: Patellar tendon

APPENDIX 2: REHABILITATION PROGRAM FOR REPAIR OR RECONSTRUCTION OF THE ANTERIOR CRUCIATE LIGAMENT

Overview

The overall goal is to achieve maximum functional activity, including quadriceps function, without stretching the anterior cruciate repair. Therefore, care must be taken in monitoring the quadriceps exercise program. The dangers can best be appreciated by observing active extension in a patient with a torn anterior cruciate ligament who has significant anterior drawer laxity. With the patient lying supine and the knee moderately flexed, active extension is initiated. When the quadriceps muscle contracts, the tibia first moves forward on the femur and only then does active knee extension begin.

In view of the above, it is evident that active extension (ROM) should be avoided early in the program, and traditional progressive resistive quadriceps exercises should not be introduced until late. Modified straight leg raises (SLR) can be started initially. These require the quadriceps muscle to set, so the patient must be taught to simultaneously contract the hamstrings and quadriceps to minimize the anterior drawer force on the operated knee. Once the acute postoperative reaction has subsided, the patient can be instructed to generate greater quadriceps force during SLR. Active range of motion exercises, including active flexion and active assisted extension, should be initiated when the patient is placed in the knee brace, 5-10 days postoperatively. Active extension exercises will begin during the 6th postoperative week. Progressive resistance exercises are contraindicated during the early phases and should be avoided until 10 weeks postoperatively, at which time swimming and progressive cycling may also begin.

Initially, motion from 40°-80° will be allowed in the brace. Motion will be increased to 20°-80° at approximately the sixth week postoperatively and to 0°-120° on the 7th or 8th postoperative week.

It must be recognized that not all patients will progress to the highest level of rehabilitation, such as that needed for college or professional basketball competition. For those returning to competitive athletics full knee function is necessary. Few other patients will be motivated enough to achieve maximum function nor is it necessary for them to do so. In these patients, the program must be individualized, with the point of maximum benefit determined by the patient's needs and rate of progress. Many patients will never reach the stage where figure-of-8, running, cutting, or squats are instituted.

MINIMUM TIMES TO BEGIN THE FOLLOWING ACTIVITIES:
(From Date of Operation)

Motion:
1. 5-10 days: 40°-80°.
2. 6 weeks: 20°-90°.
3. 7-8 weeks: 0°-120°.

Exercises:
1. 5-10 days: SLR with co-contraction of quadriceps and hamstrings.
   Active flexion.
   Active assisted extension.
2. 6 weeks: Active extension.
3. 10 weeks: Progressive resistance, swimming, cycling.
4. 18 weeks: Step-ups.
5. 24 weeks: Jogging, squats, low-level sports skills.
6. 32 weeks: Running, figure-of-8, cutting.
7. 52 weeks: Athletic competition.

Weight Bearing:
1. 8 weeks: Partial-weight-bearing.
2. 12 weeks: Full-weight-bearing, wean from crutches (only if quad strength is adequate).

Wean from Brace:
1. 18 weeks: During specific exercises.
2. 24 weeks: For walking.
3. 32 weeks: For all but high-risk activities.

PRE-OPERATIVE:

1. Pre-operative instructions on SLR, hamstring sets and quadriceps/hamstring co-contraction along with crutch fitting and instructions on non-weight-bearing ambulation for acute anterior cruciate repairs.
2. Pre-operative Cybex testing (for surgical reconstruction cases only).

PHASE 1: MAXIMUM PROTECTION: DURATION: 0-6 WEEKS

A. Motion considerations:

1. Immobilized in cast or splint (40°-45° flexion) 5-10 days post-op.
2. 40°-80° flex within brace from 10 days to 6 weeks post-op.

B. Ambulation:

1. Crutches, non-weight-bearing.

C. Specific exercises

1. a) Modified straight leg raises with co-contracton of quadriceps and hamstrings within pain tolerance and without weights.
   b) Co-contraction isometrics of hamstrings and quadriceps.
   c) Abduction and adduction isometrics.
   d) Active flexion within brace.
   e) Active assisted extension within brace.
2. Muscle stimulation for quadriceps and/or hamstrings if indicated.

D. Functional activities:

1. Upper-body exercises as in weight training with Nautilus or Universal equipment, or other upper-body conditioning.
2. Contra-lateral exercise program.

E. Precautions:

1. Be aware of the possibility of infection. Monitor temperature, fatigueability, malaise, and increases in joint effusion and warmth.
2. Provide supervision initially regarding cast/brace positioning during weight-lifting and other activities. Appropriate action must be taken should softening of the cast or other complications arise.

F. Goals:

1. Proper cast maintenance.
2. Maintenance of muscle tone.
3. Maintenance of general body conditioning.
4. Education of the patient regarding the goals of the entire program.
5. Sufficient time for initial healing and satisfactory clinical assessment of repair.

PHASE 2: MODERATE PROTECTION: 6 WEEKS TO 4 MONTHS POST SURGERY

A. Motion considerations:

1. Brace settings.
   a) 6th week 20°-90° ROM
   b) 7th - 8th week 0°-120° ROM
2. Active range of motion (ROM) within brace limits, but probably will not reach full extention at 8th week.

B. Ambulation:

1. Non-weight bearing with crutches until 8th week.
2. Partial weight bearing with crutches at approximately the 8th week, but only when patient can actively extend to within 15° of full extension.
3. Wean from crutches at approximately 12th post operative week. Do not bear weight without brace.

C. Specific exercises

1. Continue exercises from Phase 1.
2. Active flexion and extension ROM exercises.
3. SLR with co-contraction in all planes without weights.
4. Begin progressive resistance exercises at approximately 10 weeks post surgical repair to patient tolerance. Resistance exercises can include SLR, isotonic knee extension and flexion.
5. Progressive cycling and swimming to begin the 10th post operative week.
6. Refer to rabbit protocol when indicated

D. Functional activities:

1. Upper-body conditioning.
2. Contra-lateral exercise program.

E. Precautions:

1. Do not force extension because of stress on knee.
2. Emphasize flexion for ROM.
3. Stay within the limits of tissue tolerance in order to avoid effusion and pain. Continually monitor known parameters and seek consultation and/or make adjustments as indicated. Specifically look for tibial displacement during exercises and avoid those that cause translation.

F. Goals:

1. Protect the healing repair.
2. Increase ROM, particularly flexion, to achieve a functional ROM without pain for normal daily activities.
3. Gain muscle control for walking.
4. Gradually increase strength.
5. Physician verification of tissue pathology and stability.

PHASE 3: MIMIMUM PROTECTION: 4 MONTHS TO 5 1/2 MONTHS POST SURGERY

A. Motion considerations:

1. Knee brace.
2. Brace initially worn at all times, while performing exercises, and even when sleeping.

B. Ambulation:

1. Continue to wean from crutches if needed.
2. Walking with brace, full weight bearing.

C. Specific exercises (APPENDIX C):

1. ROM exercises continued as indicated by dynamic function of knee.
2. PRE within pain-free range:
   a. SLR program continued.
   b. NK table hamstring isotonic program (flexion only).
3. Bicycle program continued.
4. Slow progression to more functional activities, e.g. step-ups. Criteria for initiation of Stage 1 step-up program is the performance of 3 sets of 10 repetitions of quadriceps SLR with 10-15% of body weight.
5. Using muscular control as the key or guide, gradually wean from brace during later stages of step-up program (when five minutes of step-ups can be performed without tissue reaction). Wear brace for other exercises, for walking, and possibly sleeping.
6. Acknowledging the relationship between type of exercise and the processes of healing, circulation, tissue repair, and learning, concentrate on endurance rather than strength during this phase.

D. Functional Activities:

1. Bicycle (progress to advanced) and swimming.
2. Upper-body conditioning.
3. Contra-lateral exercise program.

E. Precautions:

1. Avoid development of chondromalacia.
2. Evaluate joint stability carefully and regularly.
3. Continue to monitor tissue reaction to exercise.
4. Swelling.

F. Goals:

1. Full ROM without pain.
2. Specific exercise performance without brace and normal activity level with brace.
3. Maintain and monitor knee stability
4. Increase strength.
5. Obtain baseline fitness level for athletic competition.
6. Satisfactory clinical assessment of repair.

PHASE 4: ACCELERATED FUNCTIONAL ACTIVITY: 5 1/2 MONTHS TO 7 1/2 MONTHS POST SURGERY

A. Motion considerations:

1. Should have complete ROM without pain.

B. Ambulation:

1. In brace while performing low level sport skills, jogging, and other potentially risky activities.
2. Wean from brace while walking.

C. Specific exercises (APPENDIX C):

1. Quad setting in SLR program continued.
2. NK table hamstring isotonic program continued.
3. Orthotron or Universal program emphasizing flexion.
4. Begin leg press or squats to 90°.
5. Conscious-to-reflex hamstring control with repetitive practice.
6. Step-up program (progress to advanced).

D. Functional activities:

1. Bicycle.
2. Swimming.
3. Jogging (with brace) when 75% of normal strength recorded on Cybex.
4. Low-level sport skills or activities.

E. Precautions:

1. Pivot shift or other instabilities may develop with or without acute symptoms.
2. Rapid progression and/or instability complications may lead to tendonitis and/or synovitis.

F. Goals:

1. Perform normal activities and/or exercise activities without brace and without feeling of "giving way" or instability.
2. 70-80% strength in Cybex test.
3. Satisfactory clinical assessment of repair.

PHASE 5: CONDITIONING PROGRAM. 7 1/2 MONTHS TO 1 YEAR POST SURGERY.

A. Motion considerations:

1. Normal pain-free ROM.

B. Ambulation:

1. Out of brace except for designated high risk activities.

C. Specific exercises

1. Isolated hamstring exercise and control.
2. Advanced step-up program (optional).
3. Advanced leg press or squat program continued (optional).
4. Jogging or swimming.

D. Functional activities:

1. Initiate running with brace and progress from straight ahead, to figure-of-8, to cutting and full speed work with brace.
2. Progressive skill development from low level or simple to controlled intense or complex skills.

E. Precautions:

1. Progression beyond tolerance may cause tendonitis or synovitis.
2. Gradual development of instability may develop.

F. Goals:

1. Pre-injury or higher fitness level.
2. Pre-injury or higher strength level.
3. Skill level to perform competitively.
4. Satisfactory clinical assessment of stability and return status.

PHASE 6: RETURN TO ATHLETIC ACTIVITY.
12 MONTHS TO 16 MONTHS POST SURGERY.

Monitor stability, muscle strength and tissue tolerance. May return to competition when 90% (involved/uninvolved) of hamstring and quadriceps strength achieved on Cybex, and when patient can run through an obstacle course at full speed without feeling of instability.

APPENDIX 3: ACCOUNTING FOR PATIENTS FOR WHICH THE LONGEST FOLLOW-UP WAS FEWER THAN 24 MONTHS

WILLIAM HALL (LSU) was randomized to the control group for treatment of a chronic injury. Follow-up was obtained at 7 months after surgery on January 1, 1984. On February 1, 1984 Hall was killed in an automobile accident in Boca Raton, Florida.

CHRISTIAN WILLIAMS (LSU) was randomized into the carbon-fiber group for treatment of an acute injury. Follow-up was obtained 12 months following surgery. At the time of entry into the study, the patient lived in Grambling, Louisiana, and worked at the Ruston State School in Grambling. The telephone number and address that he had furnished were those of his place of employment. Williams was contacted repeatedly by letter through the office of Dr. George Belchic, Ruston, Louisiana, and asked to return for follow-up visits, but he failed to do so.

In late 1987 we contacted Williams at the Ruston State School by telephone and requested that he return for a follow-up orthopaedic examination. At that time, the patient provided the telephone number of some relatives with whom he was living. The patient agreed to be examined, but failed to keep his appointment.

Repeated efforts were made to encourage Williams to appear for examination. He was contacted by letter dated February 4, 1988 and by telephone on February 22 (two calls), February 24, February 26 (three phone calls), March 23, and March 30. In each case either the patient agreed to appear for examination, or a message was left with the individual who answered the telephone requesting that Williams make an appointment for an examination.

On April 6, 1988, Williams was arrested for cocaine possession, and for several months thereafter he was unavailable by telephone (although people at both the Ruston School and the home where he lived indicated that he was still living in Grambling). Letters to Williams requesting that he contact us or set up an appointment to be seen were sent on June 6, June 20, August 17, and August 30. The patient was repeatedly advised that any expenses incurred in traveling to the doctor's office for an examination would be reimbursed.

On September 15 we spoke directly with the patient for the first time in several months. During a long conversation, he related that earlier that day he had been kicked in the treated knee by a patient at the Ruston State School, and he was in considerable pain. On September 30 he returned to Dr. Belchic's office, and was diagnosed with tendinitis. The knee was too painful to perform the tests required for the standard follow-up, and an appointment was made for him for the following week; he did not keep the appointment.

We spoke with the patient again on October 25 and learned that he had taken a second job, and that, as a consequence, it was

failed to have his knee examined. The patient was called on October 2 and October 8, but there was no answer.

On October 14, 1987, we again spoke with the patient. He expressed anger and dissatisfaction with the condition of his knee and the results of his treatment. He said he had been forced to have his knee examined in California, but he refused to discuss the details of the treatment that he received, or to inform us whether it was necessary for him to have further surgery. The patient was very uncooperative, and we therefore relaxed our efforts at follow-up in the hope that his attitude might change.

On March 16, 1988 we again spoke with the patient. We renewed our offers to pay for the clinical examination, and to compensate him for any expenses incurred in having his knee examined. We offered $200.00 as an additional incentive. We reiterated our offer and request in letters dated June 6, July 1, August 26 and September 16, 1988, but cooperation was not forthcoming.

We attempted to telephone the patient on September 28, 1988 but learned that the telephone had been disconnected. We called the patient's father in Iowa requesting new information regarding the patient's whereabouts, but the patient's father became very uncooperative. He indicated that the family had essentially split up, and that he had not spoken or heard from his son in more than six months. The father requested that we no longer seek information regarding his son through him. At the close of the conversation, the father indicated that the last information he had regarding his son was that he was working for Safeway stores in California.

Through the personnel locator for Safeway stores in California, we determined that the patient was employed by Safeway. The Safeway representative, Mrs. Lee, informed us that it was company policy to not furnish information regarding the telephone number or address of their employees. Mrs. Lee agreed, however, to relay our messages to the patient.

Messages were relayed to the patient through Mrs. Lee on October 12, October 20, November 1, November 22, December 14, and February 16. The upshot of these efforts was that Mrs. Lee concluded that the patient was clearly aware of our efforts to obtain follow-up, but that, in Mrs. Lee's judgment, the patient simply would not cooperate, and that further efforts were futile.

SCOTT BOOKER was randomized into the control group and treated for an acute injury. Follow-up was obtained 12 months after surgery. The patient moved to Seattle, Washington, but frequently returns to Iowa to visit his parents. He has not agreed to be seen for follow-up in Iowa during one of his visits, despite repeated efforts through Dr. Albright's office. We spoke with the patient on July 7, 1989, and he agreed to be seen in Seattle in August, 1989.