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The Use of Carbon Fibers in Ligament Repair: Mechanical and Biological Properties

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Abstract

Carbon fibers are a potential, powerful tool that may become useful in ligament repairs, particularly after acute injuries. A clinical investigation underway at LSU Medical Center, Shreveport, uses carbon fibers coated with gelatin. Carbon fibers' attractive properties include their ability to direct, and possibly stimulate, oriented collagen formation; strength, which provides excellent initial stability; biocompatibility, which excites only a mild inflammatory and giant cell reaction; eventual fragmentation, allowing a new ligament to hypertrophy. Problems include brittleness and special anchorage techniques that must be used to gain adequate stability. A toggle and a bollard to secure fixation is the most satisfactory anchorage system designed to date.

Introduction

Interest in artificial materials that can be used to replace the function of injured ligaments has accelerated over the past 20 to 30 years. This paper discusses carbon fibers, one of the most recent materials used. Because the material is not yet available in the United States, this article focuses on the properties which make carbon fibers attractive for use in ligament repair.

Small changes in length severely affect the function of ligaments. Unlike tendons where an associated muscle can adapt readily to moderate changes in length, there is no effective way for a ligament to shorten once it has healed in a lengthened position. This limited tolerance poses a major challenge following an injury where simple repair of ligaments is destined to fail. Replacement with locally available structures presents additional problems leading to less than optimum results. The possiblility of using a preprocessed material to repair or replace injured ligaments offers an attractive alternative and numerous materials have been developed for this purpose.

Carbon fibers presently command the greatest attention and their worldwide use for the repair of selected tendons and ligaments, especially those about the knee, has grown dramatically since 1977 when Jenkins, et al, described their preliminary results in animals.[1] Carbon fibers are used clinically in at least 20 countries and implants are available commercially from at least four different companies. Carbon fibers from one company alone have been used in over 5000 cases. (Plastafil Corporation: Information from Company) Parisian surgeon Marcel LeMaire has used carbon fibers in 1300 cases over the last four years. (LeMaire M: Reinforcement of tendons and ligaments with carbon fibers - four years, 1300 cases. Second International Symposium on Synthetic Replacement of Ligaments and Tendons. New York. Nov. 30-Dec. 1, 1983.) South African veterinarians are using carbon fibers to repair the anterior cruciate ligament in dogs, until now an unsolved problem.[2] The unique property of carbon fibers to induce oriented collagen formation[3] explains in part the burgeoning interest.

The use of carbon fibers has not received much publicity in the United States since the material is not available for implantation due to FDA regulations. Two clinical studies are being conducted in this country. One study, under the direction of investigators in the Department of Orthopaedic Surgery at LSU Medical Center-Shreveport, uses carbon fibers coated with gelatin. The other medical centers participating in this study are Brooke Army Medical Center, San Antonio, Tex., and the University of Iowa. Investigators at the New Jersey Medical School in Newark, N.J. are directing the second study, which is using carbon fibers coated with polylactic acid, an absorbable polymer.[4] Multiple investigators throughout the country are participating in this study. If the results confirm the experience of investigators and practitioners in other countries, the techniques may become available in the United States.

Production

Pyrolysis of acrylic fibers in a controlled atmosphere creates carbon fibers. The process is similar to that used to make charcoal from wood. The acrylic fibers are heated, in stages, to 1200°C. During the process, the fiber diameter decreases from 15 to 7 microns as the noncarbon constituents are vaporized. The molecular structure of the original acrylic fiber is maintained during the conversion to carbon, and this endows the resulting fiber with its remarkable mechanical properties.

Mechanical Properties

For practical purposes, the suitability of a ligament replacement using carbon fibers depends upon the biomechanical properties of the entire ligament system. The determinants include the structure of the prosthesis, the anchorage system, and the behavior in vivo, in addition to the mechanical properties of the carbon fibers themselves.

A carbon fiber is pure carbon (greater than 98.5%) with a graphite structure, and trace amounts of nitrogen, oxygen and hydrogen. The fibers have a diameter of approximately 7 μ. A strand containing 40,000 fibers forms a surprisingly narrow structure, resembling twine.

The unique properties include (Table I): a high tensile strength (up to three or four times that of stainless steel); a high modulus of elasticity; little or no plastic deformation; and low shear strength, which makes them brittle and susceptible to breakage when bent over sharp edges or when tied.

Table 1. PROPERTIES OF CARBON FIBERS

Ultimate Tensile Strength	
Theoretical	2.5-3.0 x 10^9 N/M^2 (†)
40,000 fibers	4.9 x10^3 N (2)
Experimental	
10,000 fibers	4.25 x 10^2 N (1)
96,000 fibers	2.46 x 10^3 N (†)
Modulus of Elasticity	2.34 x 10^{11} N/M^2 (1)
	2.0-2.5 x 10^{11} N/M^2 (†)
Strain: 96,000 Fibers at 300 N Load	
Unidirectional	0.02% (†)
Braided	0.63% (†)
Braided with Collagen Coating	1.14% (†)
40,000 Fibers at Failure	
Theoretical	1.4% (2)
Fatigue Strength	80% (†)*

*% of Static Strength
† Plastifil Corporation: Information from Company

In practice, the tensile strength of a strand of carbon fibers is less than predicted by the material properties, due in part to the difficulty in mounting the fibers for testing so that the load is distributed equally. In actuality, some fibers bear load before the others and these fibers break first, leading to a series of failures and a lower ultimate tensile strength than predicted. Even so, a strand has good strength and will provide adequate postoperative support as long as it is protected against undue stress for a long enough period of time. For instance, a strand of 10,000 fibers can carry an ultimate load of 425 newtons (95.5 lbs) when tested in tension. Carbon fibers have a high modulus of elasticity and when loaded to the point of rupture show only elastic behavior with no plastic deformation. The high modulus (234 GN/M^2 for 10,000 fibers) results in a strain of only 0.47% at failure. Braiding a bundle of fibers considerably increases this strain. For example, a bundle of 96,000 fibers stretches only 0.02% with a 300 N load when the fibers are unidirectional. The strain increases to 0.63% by dividing the fibers into 32 rows of 3000 fibers and braiding them at an angle of 43°, 2-4p. Coating the fibers with a 2-4p thick layer of absorbable collagen produces an increase to 1.14%. Even then, the strain is strikingly less than natural ligaments which show strains of 10%-20% at the same load.'

From a practical standpoint, the brittleness of carbon fibers makes them hard to work with because they can break if not handled properly. When they pass over sharp edges they may break due to a low shear strength so all drill holes must be radiused (countersunk) to remove sharp edges which might serve as stress risers. This brittleness also can lead to fragmentation during insertion, causing dispersion of small carbon particles throughout the joint. Even though this does not appear to produce an adverse reaction, it seems unlikely that it would produce a beneficial effect. It therefore seems preferable to minimize the production of these particles and to coat fibers with material that decreases fragmentation.

Anchorage

Because of their brittleness, anchorage of carbon fibers is a major problem. It is calculated that the critical bend radius of a carbon fiber is about 100 times its radius, or about 0.4 mm. This precludes tying knots because the fibers will break as the knot is being tied, but before it can be cinched.

Difficulty in gaining stable, immediate fixation is the greatest challenge since the early period is by far the most crucial. The result for all subsequent periods hinges on that obtained initially. Numerous methods of fixation have been tried, but the most successful method in humans to date has been one that uses a bollard and/or a toggle made of carbon fibers and polysulfone to gain fixation. (Fig. 1) The most stable fixation requires anchorage to bone and fixation is best if the carbon fibers pass through bone before anchoring them. Anchorage in soft tissue is much more difficult to obtain. There is evidence that during healing the soft tissues do not always form a strong bond with the carbon fibers which then require surprisingly little force to pull them out of the tissue after two to three months.

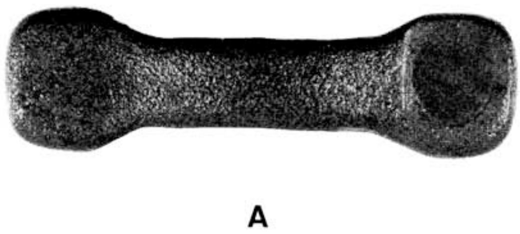
The toggle is used to secure the looped end of a carbon fiber implant and the bollard is used to secure the other end which is cut once anchorage is obtained. Actual fixation is produced by a compressive force on the carbon fibers by the shoulder of the bollard as it bears against the bone. The bollard is a rivet which a central pin expands. The carbon fibers are first wrapped around the bollard and it is driven into place. The central pin then is driven home to secure fixation.

A method using screws and washers has been used successfully in dogs, but this method is not as satisfactory as the use of bollards which are recommended in larger animals such as humans.

Biologic Response

The key property of carbon fibers that has caused such widespread interest is their ability to induce oriented collagen production. They also are flexible and very strong, which allows stable immediate fixation. Finally, they eventually fragment, allowing the new ligament to hypertrophy as required by normal joint forces. In effect, the carbon fibers act as a temporary scaffold while a new ligament- is forming. Ultimately, the newly induced tendon takes over the action. The implant itself then becomes progressively more irrelevant. The rationale behind the use of carbon fibers differs fundamentally from that of all other materials used to replace ligaments and tendons, except possibly the use of collagenous structures themselves.

Jenkins, et al, [1] were the first to recognize the ability of carbon fibers to induce oriented collagen production. The volume of newly formed tissue exceeded that of the originally implanted carbon fibers by 8-15 times. The carbon induced tissue reaction demonstrates three stages, represented by three different types of tissue.[6] Initially, macrophages from the host tissue coat the carbon fibers. Small numbers of young fibroblasts also are present. Granulation tissue containing capillaries, macrophages, mononuclear cells and fibroblasts then increases in quantity and separates the individual carbon fibers. Finally, mature collagenous fibrous tissue predominates. At the end of one year, histofibroblasts surround the carbon fibers, with fibrocytes and collagen fibers found in the adjacent tissue. (Fig. 2)



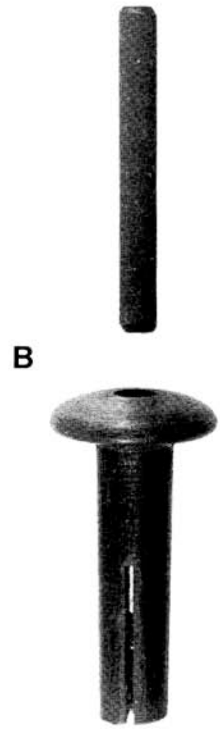
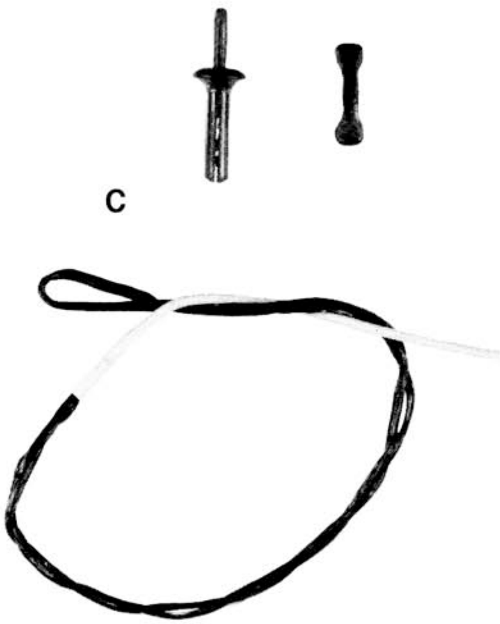


Figure 1. A. Toggle and Bollard
B. Strand of carbon fibers
C. The Toggle and Bollard are shown above a carbon fiber tow to illustrate their actual size.



Additional layers of histiofibroblasts and collagen also may be present. (Mendes D, Roffman M, Soudry M, et al: Laboratory experiments and clinical experience with carbon fiber ligament and tendon replacement. Second International Symposium on Synthetic Replacement of Ligaments and Tendons, N.Y., Nov. 30, Dec. 1, 1983).

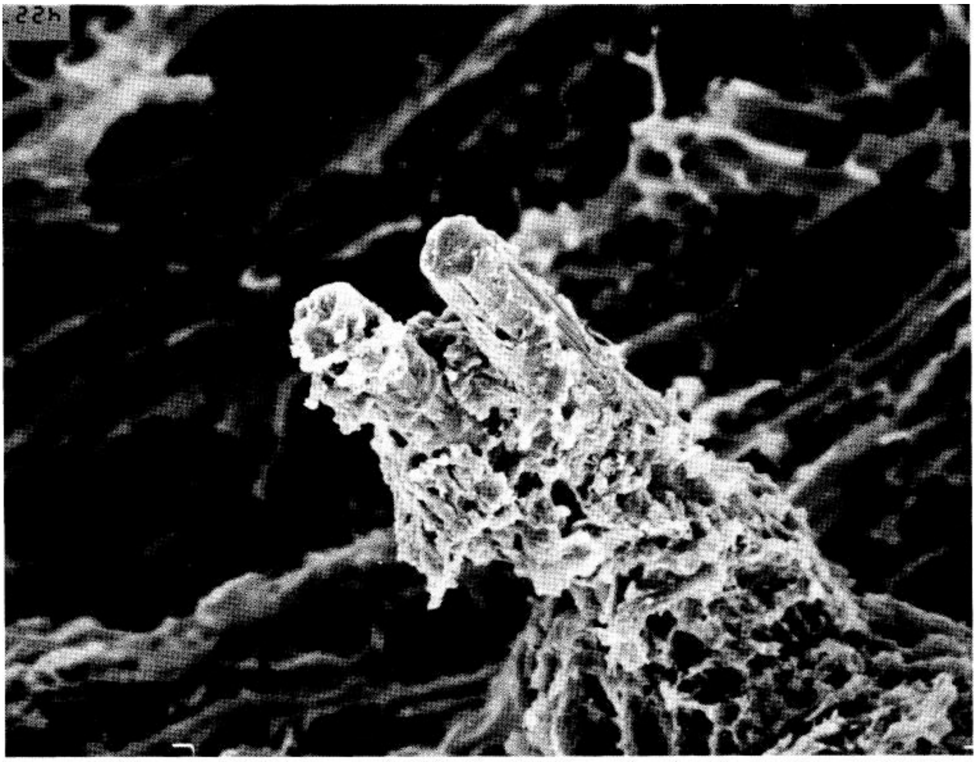


Figure 2. Carbon fibers closely associated with fibrocytes and collagen. S.E.M. (1700 x).

Even though the collagen which forms mimics normal, important differences are seen. The induced collagen does not have a normal "crimp" pattern which, although unproven, could affect the mechanical properties. "Crimp" represents the wavy pattern seen in ligamentous tissue and causes the initial nonelastic portion of the stress-strain curve that is characteristic of normal tendon. (Goodship AE: The development of tissue around various prosthetic implants used as replacements for ligaments and tendons. Second International Symposium on Synthetic Replacement of Ligaments and Tendons. N.Y. Nov. 30, Dec. 1, 1983.) There also is a prevalence of reticulin and an absence of elastic fibers and nerve fibers. The inflammatory response, although relatively mild, is similar to that evoked by foreign bodies in general. This response may persist for at least one and a half years and shows a small number of giant cells without neutrophil infiltration. The persistent reaction could be permanent. (Mendes D, Roffman M, Soudry M, et al: Laboratory experiments and clinical experience with carbon fiber ligament and tendon replacement. Second International Symposium on Synthetic Replacement of Ligaments and Tendons, N.Y., Nov. 30, Dec. 1, 1983.) If permanent, it would not be inconsistent with normal tendon and ligament function. Collagen typing studies show the type of collagen that forms may be normal.[7] Even if the tendon which forms in response to carbon fibers is not normal, it resembles a normal tendon more than scar tissue.[8]

Why carbon fibers induce the formation of collagenous tissue is not known. The material itself may stimulate this response or the small fiber diameter may be the critical factor, allowing fibroblasts to migrate along their length. We also do not know whether carbon fibers actually stimulate new collagenous tissue or whether they simply act as a scaffold along which the fibroblasts can migrate. What is known is that the new ligament is well oriented.

There are other interesting details. Regeneration of a new ligament will be more efficient if the carbon fibers run longitudinally in a loose bundle and are not tightly grouped together. This lets the new tissue separate the fibers. If the carbon fibers are grouped tightly, the tissue response is decreased and living tissue never may be able to penetrate the inner portion of the bundle. (Fig. 3)

In humans, the use of carbon fibers for acute ligament injuries appears to be more successful than for chronic repairs. This is consistent with the response in animals where a healing potential must be present or the response to carbon fibers is minimal. An acute injury excites intense cellular activity including infiltration of inflammatory cells and dedifferentiation of cells to more primitive forms, including fibroblasts. This response, in effect, establishes the conditions necessary for healing with rapid cellular and tissue growth. and redifferentiation into the type of cells required. When an injury "primes" the tissues for healing, the introduction of carbon fibers establishes a framework or scaffold to help orient growth that already has been programmed to occur. In contrast, when the tissues have matured and reached a state of relative equilibrium as in a chronic injury, the response to carbon fibers is much less vigorous and may be nil. The same lack of response is evident if carbon fibers are passed through a normal, intact tendon, or through a normal tendon sheath, parallel to the tendon. The successful use of carbon fibers in the repair of chronic ligament injuries may be directly dependent on surgically-induced trauma because this helps to reestablish the conditions necessary for healing.

Treatment of the anterior cruciate ligament poses special problems due to its intraarticular course. The anatomical position of the ligament increases the difficulty of obtaining revascularization and also exposes the ligament to synovial fluid if tissue is not mobilized enough to cover it before completing the operation. Synovial fluid appears to retard fibroblast activity and ligament growth. For both of these reasons, it is essential to cover the carbon fibers with tissue,[9] preferably vascularized tissue, if satisfactory results are to be obtained. Failure to do this invites problems, including the dispersal of carbon fragments throughout the joint, and an ineffective repair process with failure to grow an adequate ligament.[10]

Toxicity

The biocompatibility of carbon fibers has been judged excellent. [11] Historically, tissue tolerance has been demonstrated in tattoos using India ink, pencil graphite, lamp-black, and other carbonaceous material. L[2] Extensive experience also has been gained from the graphite industry where low levels of silica often are present in the carbon.[13] Silica produces known effects on the lung, masking the detection of a possible effect from carbon. Several studies, in humans and animals, in which silica-free carbon has been inhaled or ingested disagree whether carbon itself causes pneumoconiosis characterized by fibrotic lesions. [13]

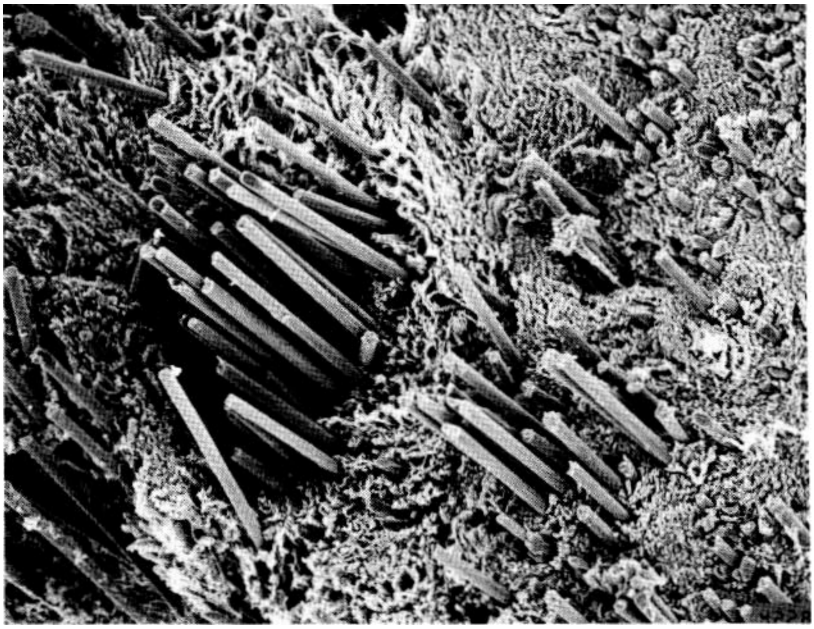


Figure 3. Carbon fibers surrounded by fibrocytes and dense collagen. The new tissue has not been able to penetrate the area of closely packed carbon fibers. S.E.M. (450 x).

Animal studies generally show little response to carbon fibers, other than that seen in ligaments and tendons following acute injury. Intravenous, intraperitoneal, intraarticular, and periarticular injections in rats of two types of carbon microparticles (one type had a particle size of 1 μ and the other less than 8 μ) found that the particles are absorbed by macrophages or by foreign body giant cells and are distributed via the lymphatic system. [11]

One of the major concerns for any material is its possible carcinogenic activity. Carbon particles have been found in the regional nodes of animals having had carbon-augmented anterior cruciate ligament repairs when the carbon fibers were left exposed in the joint without soft tissue coverage. Even though extra-articular dispersal has not been found when the fibers have been covered with soft tissue, the chance that this could occur over a long enough period of time raises the question of carcinogenicity. Studies in rats of carbon fibers implanted intramuscularly and extraperiostially,.and of carbon powder injected intramuscularly, found no evidence of malignant change up to 18 months later.[14] Silk, implanted in control animals, generated a greater tissue reaction. The fact that the rat is particularly prone to develop tumors, combined with the fact that commonly-used materials such as silastic, polymethylmethacrylate, high molecular weight polyethylene, and cobalt-chrome alloy stimulate the formation of tumors in rats after only a few months exposure, suggests that carbon fibers are unlikely to stimulate tumor formation.

Conclusion

Carbon fibers form a powerful tool that can be useful in ligament repairs, particularly after acute injuries. The property setting them apart from other artificial materials used for ligament repair is their ability to direct, and possibly stimulate, oriented collagen formation.

Other attractive aspects include their strength, which is sufficient to provide excellent initial stability; their biocompatibility, which excites only a mild inflammatory and giant cell reaction; and the fact that they eventually fragment (probably between three and 12 months postoperatively) which then allows the new ligament to hypertrophy and to carry a normal load.

There are still numerous details to be worked out if good results are to be obtained with carbon fibers. Because they are brittle, they must be handled as little as possible or they will shed multiple small fragments into the joint and the entire bundle may break. When used to repair the anterior cruciate ligament, they must be covered adequately with viable soft tissue. When used to repair other ligaments, they must be buried in the substance of the ligament, or in adjacent soft tissue. Special techniques of anchorage must be used to gain adequate stability due to their tendency to break if bent beyond an 0.4 mm radius. This obviates knot tying. The most satisfactory anchorage system designed to date uses a toggle and a bollard to secure fixation.

Because the material is not available in the United States, this article concentrates on the properties of carbon fibers and the biologic response to them. FDA approval of at least one of the two systems currently being studied may be obtained within the next two to three years. At that time, a thorough knowledge of the technical details necessary for clinical use will become increasingly important.

Acknowledgement

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