

A Healing Scaffold

A novel carbon fiber implant looks promising in the reconstruction of severely torn ligaments and tendons

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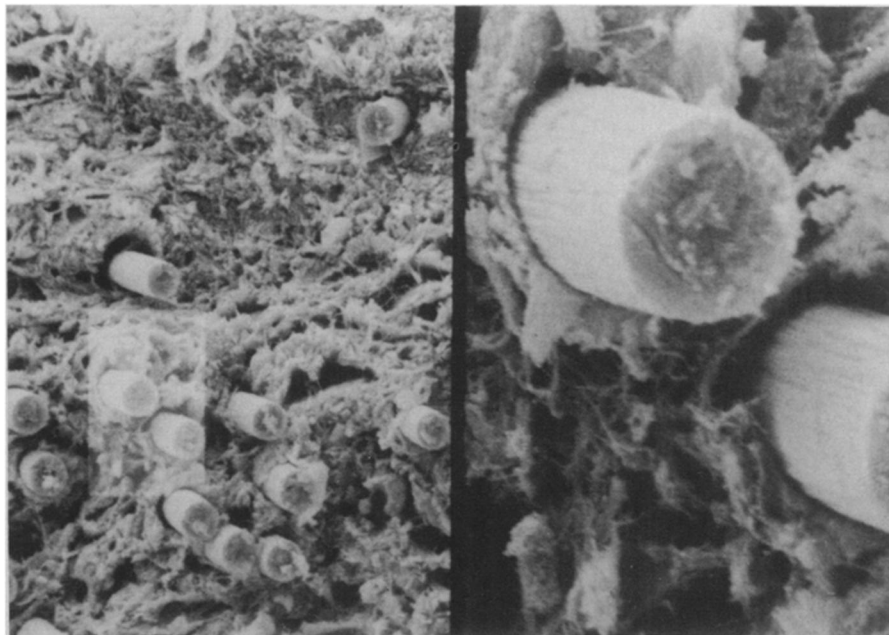
A new carbon fiber implant that helps reconstruct severely torn ligaments and tendons has been developed by a trio of scientists at the University of Medicine and Dentistry of New Jersey—orthopedic surgeon Andrew Weiss, mechanical engineer Harold Alexander and materials engineer John Parsons. Over the past 15 months the Newark researchers have used the implant to reconstitute torn ligaments and tendons in 50 patients. It has helped them all.

A ligament connects one bone to another. A tendon links muscle to bone. In many instances a torn ligament or tendon can be surgically repaired by simply sewing the torn ends back together. But in many other cases the cleavage is so severe that there isn't enough ligament or tendon left to sew back together. And while researchers have been trying to come up with a suitable prosthesis for severely torn ligaments or tendons, they haven't been very successful.

So Weiss and his colleagues thought that they might be able to design a product that would allow Mother Nature to be the ultimate engineer in ligament and tendon reconstruction—something that could be sewn in and around a ripped ligament or tendon to connect and reinforce it and to provide a lattice for scar-like connective tissue. The connective tissue would grow into the rift between the ligament or tendon, resulting in a reconstructed ligament or tendon almost identical to the original.

They attempted to find materials that would be suitable for such an implant. They knew from other researchers' efforts that carbon fibers are compatible with the human body. They also knew that other researchers had used carbon fibers in humans with limited success. However, they were also aware from past discoveries that carbon fibers are brittle and tough for a surgeon to handle. The aerospace industry had been combining carbon fibers with other materials for a number of years and had shown that such composites retain the strength of carbon fiber, yet are far more flexible than the fiber. They concluded that the supporting lattice for torn ligaments and tendons should be made of carbon fibers combined with some other material that would make it pliable. Their implant, Weiss points out, is "one of the first significant applications of aerospace composite material technology to orthopedic surgery."

The material they decided to combine carbon fibers with, or actually to coat them with, was polylactic acid—a plastic composed of long chains of lactic acid.



A human ligament reconstructed along carbon fibers (the cylindrical objects). Magnified at left 700 times and at right 3,500 times.

Polylactic acid does not just give carbon fibers a pliable ribbonlike structure that orthopedic surgeons can attach to needles and sew into torn ligaments and tendons, but since lactic acid is a natural metabolic byproduct of the human body it is also broken down by the body and eventually eliminated from it. The carbon fibers, they reasoned, would then be left as a scaffold for the healing ligaments and tendons.

They tested their polylactic acid-coated carbon fiber implant in animals. As they hoped, the innovative coating significantly improved carbon fibers' handling ability during implantation. The polylactic acid coating biodegraded after two weeks in the body, leaving carbon to form a support mesh for the torn ligament or tendon. At the same time, connective tissue grew around the carbon fibers. Nine months to a year later the connective tissue had filled in the gap in the ligament or tendon, and the connective tissue-reconstructed ligament or tendon was almost identical to the original. But most crucial, the reconstructed ligament or tendon greatly improved joint stability and function over what it had been before reconstitution.

With the permission of the Food and Drug Administration, they tried the implant on 50 patients with ligament or tendon tears in their knees or ankles that were so drastic that nothing else had helped. Some of the patients have been followed up to 15 months now. All of them have experienced improvement, some even dramatic improvement, in joint

strength and/or motion as measured by physical therapy machines and orthopedic evaluation. Meanwhile, the FDA has given the okay for the implant to be tested in a multicenter clinical trial. This trial has now been underway for 11 months, and some 100 patients so far have gotten the implant. Preliminary results look good, orthopedic surgeons participating in the trial agree. For instance, Michael Dillingham, clinical assistant professor of surgery at Stanford University Medical School in Palo Alto, Calif., has used the implant to rebuild knee ligaments in 20 patients and to restore an achilles tendon in one patient. Some of the implant's applications are very encouraging, he attests. Marvin Meyers, an orthopedic surgeon with the University of Texas Health Science Center in Dallas, has used the implant to re-establish badly torn knee ligaments in three patients. "My preliminary feeling," he says, is that "it is a good technique." Says Roy Rusch, a Portland, Ore., orthopedic surgeon who has tried the implant: "For many years we have struggled to repair torn ligaments in athletes and other individuals who rely on their ligaments for high-performance activities. [It now looks as if] we can induce the body to reconstruct a ligament that approximates the strength of the original."

Pending FDA marketing approval, the implant should be ready for general clinical use by late 1983. It could help at least 100,000 Americans annually, Weiss and co-workers estimate. □