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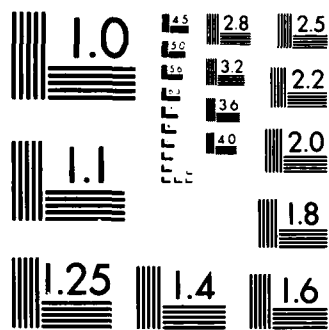
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The search continues to find an appropriate material for use as a replacement for injured ligaments, especially those in and around the shoulder, knee, and ankle. We have pursued a solution to define the optimum management of ligament injuries commonly observed in military personnel, especially the anterior cruciate ligament. The first study involved primary repairs of lacerated anterior cruciate ligaments, but the results were disappointing. When the lacerated ligaments were augmented with the medial one-third of the patellar

19. Prosthetic anterior cruciate ligament repairs: current status

H. Edward Cabaud
William G. Rodkey
John A. Feagin

Debate, research, and controversy continue over the management of the injured anterior cruciate ligament. Instability, pain, degenerative changes, disability, and even multiple surgeries may result in the patient with anterior cruciate ligament insufficiency. In an effort to resolve the problem of the acutely injured anterior cruciate ligament, we have conducted a series of experimental studies.^{4,6}

Our initial studies⁶ involved simple primary repairs of surgically transected anterior cruciate ligaments in dogs and monkeys. The anterior cruciate ligaments were repaired with a single size O-Dexon suture, and the limbs were immobilized for 6 weeks in long-leg casts. The animals were evaluated 4 months postoperatively, and the anterior cruciate ligaments were healed grossly in all of the monkeys and 7 of the 10 dogs. All animals, however, had degenerative joint changes, as well as functional and clinical instability. Maximum strength of the repaired anterior cruciate ligaments in the dogs was less than 10% of the normal anterior cruciate ligament.

In 1976 Feagin and Curl¹⁰ had published the results of their 5-year follow-up study of isolated anterior cruciate ligament repairs in West Point cadets. Follow-up in 32 of the 64 patients in the operated group revealed that 12 were functionally impaired, 24 felt they were athletically handicapped, and 8 were dissatisfied with the results.

Based on evidence from the experimental and clinical studies, we reasoned that simple primary repair was not an appropriate method, and that further studies testing procedures to augment or reconstruct the injured ligament should be conducted. When an injury occurs, the anterior cruciate ligament may stretch 30% to 40% by

□ The opinions or assertions contained in this chapter are the private view of the authors and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense. In conducting the research described in this chapter the authors adhered to the *Guide for Laboratory Animal Facilities and Care* as promulgated by the Committee on the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

the time it fails. There is a tenuous blood supply, which is markedly disrupted by an injury. Inadequate immobilization and stress following repair also may be contributing factors to an unsatisfactory result. In an effort to preclude the problems associated with primary repair, a surgical technique using the medial one third of the patellar tendon was developed to augment or reconstruct the repaired anterior cruciate ligament.⁴ The purpose of this approach was to provide an additional blood supply, have the transferred patellar tendon act as an internal splint for the healing anterior cruciate ligament, and perhaps provide additional strength to the repaired complex.

Eleven dogs were used in the augmentation study. All anterior cruciate ligaments were transected at the femoral origin of the anterior cruciate ligament, since this location most commonly is associated with clinical injuries. The anterior cruciate ligament was repaired with O-Dexon sutures, and the medial one third of the patellar tendon was then transferred and placed in the intercondylar notch in the manner of Eriksson.⁹ Thus the transferred patellar tendon lay adjacent to the repaired anterior cruciate ligament and supported it.

All repaired and augmented anterior cruciate ligaments healed.⁴ All dogs had clinical and functional stability in the extremity. There were minimal or no degenerate changes in the joints, and a thick synovial envelope surrounded the repaired complexes. Six of the dogs were sacrificed at 4 months, and five of the dogs were sacrificed at 8 months. The load deformation curves of the failure testing are shown in Fig. 19-1. By 8 months bony ingrowth had occurred at the repair site and during mechanical testing interstitial failure occurred. In fact, one of the repaired complexes was stronger than its control anterior cruciate ligament.

As a result of this augmentation study,⁴ we believe that primary repair with reconstruction or augmentation has become an accepted principle for acute ligament injuries. Although long-term studies are not yet available, augmentation has the potential to produce the best clinical result in acute anterior cruciate ligament injuries.

In the next phase of our studies, we sought to develop a biodegradable intraarticular ligament that would function as the intraarticular splint.⁵ By using a biodegradable ligament, autogenous tissue grafts, such as a portion of the patella tendon, would be avoided. Potentially the need for postoperative immobilization would be precluded, and the anterior cruciate ligament could be expected to heal while the joint was allowed some protected motion.

Braided polyglycolic acid (PGA) was selected as the material of choice from which to construct the ligament. This material is strong, easy to handle, readily absorbed over 4 to 6 weeks, well-tolerated intraarticularly, and produces little tissue reaction. Several hand-braided patterns were evaluated until a Y-shaped design was selected that had physical properties that approximately matched those of the normal canine anterior cruciate ligament. Fig. 19-2 shows the comparison between a normal anterior cruciate ligament and a polyglycolic acid ligament that was used in this study.⁵ The prosthetic ligament was approximately 80% as strong as a normal anterior cruciate

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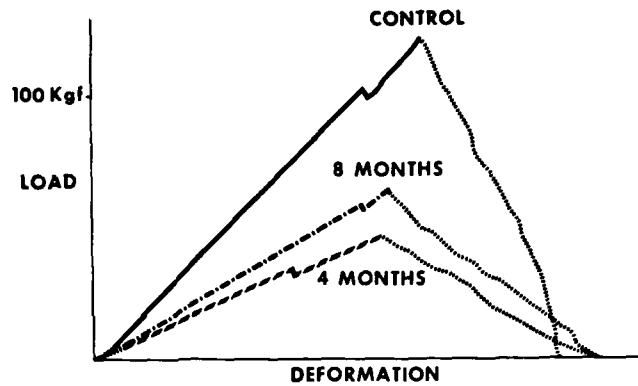


Fig. 19-1. Schematic load deformation curves of normal control dog anterior cruciate ligament compared to repaired anterior cruciate ligaments augmented with patellar tendon at 4 months and at 8 months postoperatively.

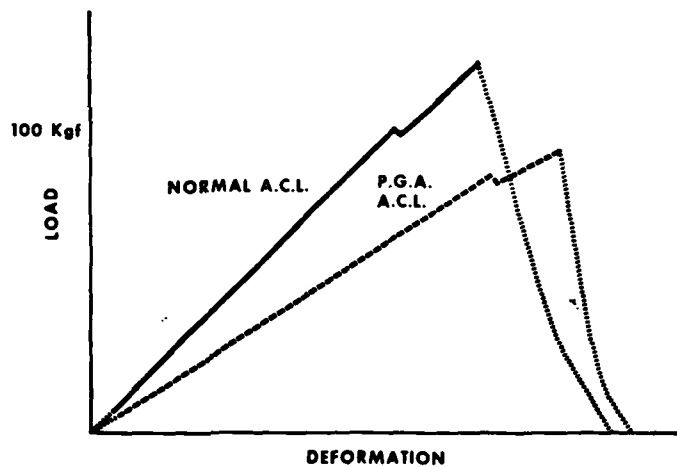


Fig. 19-2. Schematic load deformation curves of normal dog anterior cruciate ligament compared to polyglycolic acid prosthetic ligament. (From Cabaud, H. E., Feagin, J. A., and Rodkey, W. G.: *Am. J. Sports Med.* 10:295, 1982.)

ligament, but it was slightly more compliant. The strains and energy absorbed to failure were similar between the normal and the prosthetic ligaments, but the prosthetic ligament had higher ultimate stress and modulus of elasticity as a result of its smaller diameter.

We evaluated the biodegradable intraarticular ligament in canine stifle joints. Following transection of the anterior cruciate ligament at the femoral condyle and repair with an O-Dexon suture, we reinforced the repair with the polyglycolic acid ligament. The tails of the Y-shaped ligament were passed through parallel drill holes in the femoral condyle. Then the bulk of the ligament was passed through a vertical

hole in the tibia and two transverse holes in the tibial tubercle. The biodegradable prosthesis was placed with slightly greater tension than the O-Dexon sutures used to repair the anterior cruciate ligament.

The dogs were killed humanely, the legs were amputated, and the knee joints were evaluated. One dog was evaluated at 2 weeks postoperatively, one dog at 5 weeks, and the remaining ten dogs at 4 months, including one dog that had not been immobilized. In the dog evaluated at 2 weeks, the ligament constructed of PGA was intact with no evidence of degenerative changes, with no synovitis, and with mild residual hemorrhage from the arthrotomy. The repaired complex required over 40 kg of force (kg) to rupture. In the dog evaluated at 5 weeks, the majority of the prosthetic ligament had been resorbed. The remaining extraarticular portions of the ligament were still intact and showed little change from the time of their insertion. Intraarticularly there was no synovitis or degenerative changes, but a thick vascular synovial envelope had developed around the complex. Failure testing required 16 kg to disrupt the healing anterior cruciate ligament, which failed partially interstitially and partially from its repair site on the femoral condyle.

The remaining dogs were all evaluated 4 months postoperatively. All repaired and reinforced anterior cruciate ligaments had healed, including the one in the nonimmobilized knee. As in the augmentation study,¹ there were minimal or no degenerative changes, and a thick residual synovial envelope was present around the repaired anterior cruciate ligament. Clinical evaluation revealed that the length of the anterior cruciate ligament at 4 months was 20.4 mm, compared to a normal anterior cruciate ligament in the dog of 19.2 mm. Anterior drawer testing normally is 1 mm or less in the dog, and at 4 months five of the dogs had normal drawer tests and five measured between 2 and 3 mm. Fig. 19-3 shows load deformation tests comparing the normal canine anterior cruciate ligament with the augmented patellar tendon and the polyglycolic acid ligament-reinforced curves at 4 months. In addition, several of the repaired and control anterior cruciate ligaments were incubated in tissue culture with sulfur-35 to determine proteoglycan production. This technique is an evaluation of cellular viability, and the repaired anterior cruciate ligament showed 142% more activity than the control ligaments 4 months postoperatively.

We felt that, as a result of these studies with the biodegradable polyglycolic acid ligament, it was safe, strong, well-tolerated, and had satisfactorily provided the splinting function desired to provide clinical and functional stability in the dogs. However, the material had resorbed by 5 weeks, and a ligament intended for human clinical use must provide support over a longer period of time.

This brings us to the question of a permanent prosthesis for anterior cruciate ligament reconstruction and the current status of this problem. Any permanent prosthesis must meet the functional, physiologic, and biomechanical characteristics of a normal anterior cruciate ligament.^{21,26} Such a prosthesis must be biocompatible and durable, show comparable mechanical properties, and be surgically implanted with relative ease, yet allow for tissue incorporation or replacement over an appropriate period of time.

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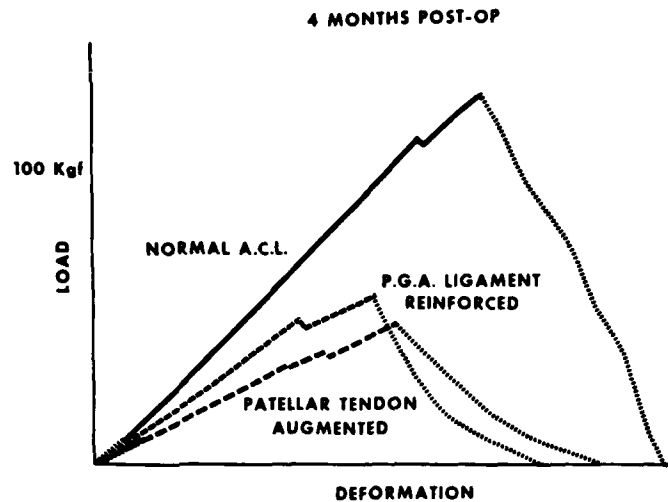


Fig. 19-3. Schematic load deformation curves of normal dog anterior cruciate ligament compared to repaired anterior cruciate ligaments either reinforced with polyglycolic acid ligament or augmented with patellar tendon at 4 months postoperatively. (From Cabaud, H. E., Feagin, J. A., and Rodkey, W. G.: *Am. J. Sports Med.* 10:295, 1982.)

The anterior cruciate ligament biomechanically provides stability to the knee joint, guides joint motion, and prevents excessive motion. As surgeons we find ourselves attempting to restore biomechanic stability of the knee joint with repairs (with or without reconstruction) following acute ligament injury or with autogenous tissue reconstruction for knees with chronic instability. Currently, surgeons are considering replacing the anterior cruciate ligament with a permanent prosthesis.

Biologically a prosthetic anterior cruciate ligament could be biodegradable, biodegradable and replaced, partially biodegradable, or permanent. A variety of materials* have been evaluated, but the only truly biodegradable substance evaluated is polyglycolic acid.⁵ Partially biodegradable or biodegradable and replaced materials include carbon-fiber ligaments and a PGA-Dacron material, which we are currently evaluating. Permanent materials that have been evaluated have included Dacron, Marlex, polyethylene, polypropylene, Proplast, Silastic, stainless steel, and Teflon (Table 19-1).

Our current approach is to develop a partially biodegradable ligament that undergoes controlled degradation and appropriate replacement by fibrous tissue. We have attempted to match the physical characteristics more exactly by varying weave patterns and composition, yet allow for a design in which fibrous tissue ingrowth can occur over a reasonable period of time. We believe that such a material can not only potentially be used for prosthetic repairs, either for acute injuries or chronic instability, but also for prosthetic reconstruction. The major problem in prosthetic

*References 2, 3, 5, 7, 8, 11-23, 25-28.

Table 19-1. Evaluation of permanent materials for prosthetic anterior cruciate ligament.

Material	Physical properties*		
	Stress	Strength	Elongation
Braided Dacron-silicon ¹¹	—	—	—
Braided wire ²³	—	123.75 kg, †	—
Carbon fibers			
PLA coated ¹	1.5-2.76 GP,	—	0.4%–3.0%
Plain ^{17, 18}	—	—	—
Dacron (polyethylene terephthalate)			
Heat set ¹⁴	40-50 psi	—	50%–80%
Knitted/Teflon coated ²⁵	—	29.25-40.50 kg, †	—
Velour ²¹	—	34.2 kg, †	—
Woven ²¹	—	34.2 kg, †	—
Ethilon ²⁷	—	36.0 kg, †	—
Nomex-Teflon-Proplast-carbon ¹⁶	—	68 kg, ‡	2.4% †
		158 kg, †	23.6% †
Polyethylene ¹² (ultrahigh molecular weight)	—	420 N †	10%
Polypropylene			
Braid ²²	—	1506 ± 12 N †	50 ± 1 mm §
Monofilament twisted ²¹	—	9.3 kg, †	—
Silastic-Dacron ²⁶	Variable, depending on construction		
Teflon ⁷	—	115 lb †	—
Tevdek ²⁶	—	56.25 kg, †	—

*Reported by authors or patents.

†Value at ultimate failure.

‡Value at yield point.

§Based on initial length of 250 mm.

management of anterior cruciate ligament injury or insufficiency is the intraarticular environment. There is rapid tissue breakdown, and the blood supply to the intercondylar notch structures is limited. There is rapid absorption of degradable materials and delayed fibrous ingrowth that remains disorganized over a prolonged period of time. There are also extreme torsional and tensile stresses in the knee joint. We are exploring the literature to find methods in which we can alter the synovial fluid environment to enhance its tissue nutrition and minimize the adverse effects of the degradative enzymes.

A variety of permanent prosthetic ligaments have been evaluated. One of the initial models was a Proplast stent, which consisted of a core containing Teflon and a textile fiber coated by Proplast that contained carbon fiber to stimulate fibrosis and attachment.¹⁶ The ligament had adequate strength and extensibility and was readily fixed with a metallic staple. The ligament was initially designed as an internal splint

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to ensure stability in a cast, maintain a normal path of motion in the joint, and allow sound healing of repaired and reconstructed ligaments and tendons. It was anticipated that eventual breakage would occur. The results of a clinical study using Proplast stents (19 patients) was published by Woods and others.²⁵ All patients had extensive extraarticular reconstruction, but at follow-up eight patients had broken stents and 50% had lost stability. Several patients required removal of the Proplast stents. They considered anterior cruciate ligament reconstruction with a Proplast stent a salvage procedure and expected this prosthetic ligament would fail.²⁵ The Proplast stents therefore showed more promise as ligament augmentation devices, and thus provided additional length or better fixation with patellar tendon-anterior cruciate ligament reconstructions.²⁵

Dacron has been evaluated for anterior cruciate ligament reconstruction.^{11,14} It is somewhat more compliant than the Proplast, shows good bony ingrowth through bony canals, and some fibrous ingrowth occurs into the interstices of the ligament. It is well-tolerated intraarticularly, but has been unsuccessful in dogs as an isolated replacement.

Arnoczky² has demonstrated excellent vascular ingrowth by microangiography techniques into Dacron velour grafts with associated fibrous tissue ingrowth. The fibrous tissue has remained disorganized. To date Arnoczky has not evaluated the strength of this Dacron velour reconstruction.

We are still searching for a prosthetic ligament with sufficient strength and appropriate compliance and adequate porosity to allow fibrous ingrowth. A ligament that has a scaffold principle is one possibility. Our preliminary studies with a woven PGA-Dacron combination *scaffold* has the potential of allowing fibrous tissue ingrowth as the PGA is resorbed and the Dacron fibers remain to provide the porous matrix for fibrous ingrowth. The weave pattern that we have evaluated is not satisfactory; as the PGA is resorbed the weave pattern becomes more open and allows a markedly increased compliance of the prosthetic ligament.

Studies of carbon fibers and carbon fibers coated with polylactic acid as ligament replacements have been conducted both in animals and in humans.^{1,3,17,18} Although the carbon fibers stimulate extensive fibrosis and collagen formation as they break up and degrade, as anterior cruciate ligament replacements these materials have not been successful. The carbon fiber is extremely brittle and has insufficient elasticity to meet the demands of the anterior cruciate ligament. To protect the carbon fibers in the intraarticular environment, it appears that an autogenous tissue graft, such as the semitendinosus or patellar tendon, is required.

The question remains: is a composite graft needed to meet both the mechanical demands and fibrous tissue ingrowth requirements? A composite permanent prosthesis developed in Canada constructed of a compressible Silastic core covered by high tensile Dacron fibers woven over the Silastic has appropriate mechanical properties, yet the complexity of this design would not withstand the test of time in the knee joint nor would it allow fibrous tissue ingrowth.²⁶

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ciate ligament is no exception. It has an elastic phase in its physical properties that allows 20% to 30% deformation before reaching the plastic phase.⁹ Loading of ligaments in this phase would allow collagenous tissues to remodel under mechanical demands, and we believe the loading would convert unorganized weak fibrous tissue into organized stronger tissue that can withstand the stresses of a normal cruciate ligament. Once satisfactory bony fixation is achieved with a prosthetic ligament, gradual transition of the loads from the prosthetic ligament to the regrown or ingrown fibrous tissue should allow a permanent prosthesis to function over a prolonged period of time. We believe that a synthetic substitute is needed. Limited success with ligament augmentation devices has already been apparent. Polypropylene stents as augmentation devices have been used in goats and in humans with encouraging results.²⁰

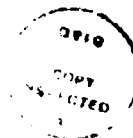
The clinical and investigational goals are momentous, but achievements in newly formulated materials, both biodegradable and permanent, as well as improvement in surgical technique with a better understanding of the anatomy and mechanics will facilitate development of prosthetic ligaments. The goals that we must strive for include the development of a prosthesis that is biologically compatible, has adequate strength and compliance, is easy to insert surgically or potentially arthroscopically, mechanically functions as a normal anterior cruciate ligament, and yet provides a satisfactory scaffold for fibrous tissue ingrowth.

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