Evaluation of a cross-linked acellular porcine dermal patch for rotator cuff repair augmentation in an ovine model

Gregory P. Nicholson, MD,[a] Gert J. Breur, DVM,[b] David Van Sickle, DVM,[b] Jian Q. Yao, PhD,[c] J. Kim,[b] and Cheryl R. Blanchard, PhD,[d] *Chicago, IL, West Lafayette and Warsaw, IN, and Austin, TX*

In this study we evaluated 2 commercially available rotator cuff repair augmentation patches in an in vivo sheep model using mechanical testing and histologic techniques. Bilateral infraspinatus tears were created and repaired in 2 groups of 8 adult ewes. Each group (killed at 9 or 24 weeks) included 5 repaired with suture alone, 6 repaired and augmented with a cross-linked acellular porcine dermal (PD) patch (Zimmer Collagen Repair Patch), and 5 repaired and augmented with a porcine small intestine submucosa (SIS) patch (Restore Orthobiologic Soft Tissue Implant; DePuy Orthopaedics). At 3 weeks, sheep with suture repair and an SIS patch had significant elevation of plasma fibrinogen levels ($P < .05$) whereas sheep with suture repair and a PD patch elicited no elevation in plasma fibrinogen levels. At 9 weeks, the mean failure load was 201 ± 60 lb for suture repairs, 182 ± 63 lb for PD repairs, and 137 ± 16 lb for SIS repairs. Within any individual sheep, the shoulder undergoing PD repair always had a higher failure load than the contralateral suture or shoulder undergoing SIS repair. At 9 weeks, macrophages were seen on all PD surfaces whereas most of the SIS materials were resorbed. At 24 weeks, failure loads were identical between groups. Macrophages had disappeared from the PD groups, and integration of the PD patch into the surrounding tissue with vascular and fibroblastic invasion was seen. For the SIS group, diverse tissue types (including ectopic bone) were seen. (J Shoulder Elbow Surg 2007;16:184S-190S.)

[a]From Rush University Medical Center, Chicago; [b]Purdue University, School of Veterinary Medicine, West Lafayette; [c]Zimmer, Austin; and [d]Zimmer, Warsaw.

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Reprint requests: Gregory P. Nicholson, MD, 1725 W Harrison St, Suite 1063, Chicago, IL 60612 (E-mail: *Orthonick@comcast.net*).

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Rotator cuff repair is a commonly performed surgical procedure. However, retear (nonhealing) rates of 30% in small to medium tears and up to 90% in large and massive tears have been documented.[1–5] The bone-tendon healing interface is the weak link. This can be a result of suture pullout from poor quality tendon or nonhealing of the bone-tendon junction. Consequently, efforts to mechanically support and biologically enhance the bone-tendon healing interface with reinforcement patches have been undertaken.

Desirable properties of a reinforcement patch would be that it has appropriate mechanical properties over a sufficiently long duration to decrease the load at the tendon-bone interface so as to minimize tendon-bone separation and to benefit healing of the tendon-bone junction. It should be conducive to integrating with surrounding tissues and enhance the healing process without inducing an overt undesirable inflammatory reaction.

Bioresorbable patches have been used in rotator cuff repair in large and massive tears without success.[3,5] Intense inflammatory reactions in the early postoperative period that have compromised repair have been reported.[3]

An acellular porcine dermal (PD), highly cross-linked, nonresorbable reinforcement patch (Zimmer Collagen Repair Patch; Zimmer, Warsaw, IN) was evaluated in this study via an acute rotator cuff tear repair ovine animal model. The purpose was to compare the efficacies of suture repair, repair reinforced with an absorbable patch (porcine small intestine submucosa [SIS]) (Restore Orthobiologic Soft Tissue Implant; DePuy Orthopaedics, Warsaw, IN), and repair reinforced with a PD patch. Analysis of histology and biomechanical testing was used to determine short- and long-term mechanical properties, tendon healing, and patch incorporation, as well as evidence of any adverse tissue reactions.

MATERIALS AND METHODS

Two commercially available rotator cuff repair augmentation patches were evaluated in 16 adult cross-bred ewes. Bilateral partial tenotomy of infraspinatus insertions was repaired surgically in 2 groups of 8 adult ewes (thus 16

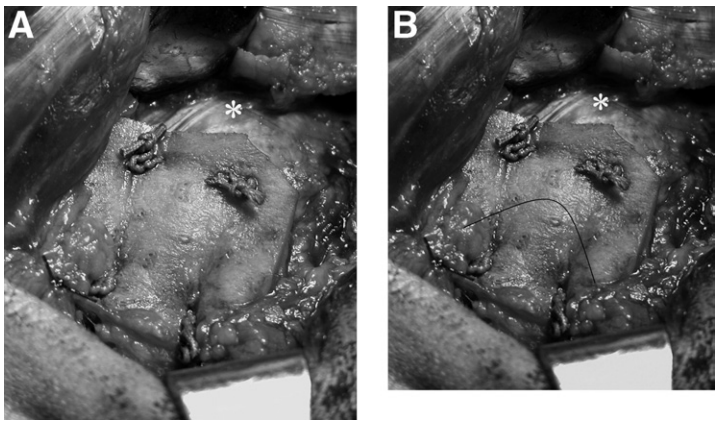

Figure 1 Intraoperative image of PD augmentation patch attached to infraspinatus tendon (*asterisk*) and humerus. **B**, The black crescent-shaped line represents the crescent-shaped tear created in the infraspinatus tendon. A superior and inferior "pillar" of infraspinatus tendon was always kept intact.

sites per group). Each group (killed at 9 or 24 weeks postoperatively) included 5 sites repaired with suture alone, 6 sutured and augmented with a cross-linked acellular PD patch, and 5 sutured and augmented with a porcine SIS patch. After death, the repair sites were evaluated via mechanical testing and histologic examination. The study was approved by the Purdue University Animal Care and Use Committee (West Lafayette, IN).

All sheep were adult female ewes weighing between 80 and 110 kg. During a 10-day conditioning period, a general and orthopaedic examination was performed, and blood and urine were collected for a complete blood count, serum chemistry, and urinalysis. Blood was also collected for measurement of serum fibrinogen concentrations preoperatively and at 3 and 6 weeks after surgery.

All sheep were premedicated with diazepam (0.1-0.5 mg/kg intravenously or 0.2-1.0 mg/kg intramuscularly). They were induced with thiopental sodium (12 mg/kg intravenously to effect) or a combination of ketamine (2-6 mg/kg) and xylazine (0.5-0.15 mg/kg intramuscularly or intravenously). Sheep were maintained via inhalation anesthesia with halothane (1%-3%) or isoflurane (1%-5%). Postoperative pain medication consisted of morphine (0.2-0.5 mg/kg intramuscularly or intravenously, 1 dose during the surgical approach and 1 dose at extubation) and buprenorphine (0.005-0.01 mg/kg every 8-12 hours for 24-48 hours after surgery). Ceftiofur sodium (Naxcel; Pfizer Animal Health, New York, NY) (0.5-1 mg/kg intramuscularly or 1 mL/22.7-45.4 kg intramuscularly) was administered at induction.

Aseptic bilateral surgeries were performed on each of the 16 ewes by the same board-certified veterinary surgeon. The infraspinatus tendon insertion was approached via a craniolateral approach to the shoulder with caudal retraction of the deltoid muscle. After measurement of the width of the infraspinatus tendon, a central inverted "T" defect was created, leaving the dorsal and ventral posts intact. The "hat" of the "T," the partial tenotomy perpendicular to the long axis of the tendon, was 1 cm, and each post was approximately 0.5 cm. This was a full-thickness defect. The defect was repaired via 1 of 3 randomly assigned techniques: sutures alone (5 repairs per group), sutures followed by augmentation with a cross-linked acellular PD patch (6 repairs per group), or sutures followed by augmentation with a porcine SIS patch (5 repairs per group) (Figure 1). The surgical treatment was alternated so that no pair of shoulders within a sheep had the same treatment. The sutures (2 braided nylon) of the primary repair and the augmentation devices were attached to the humerus via 2 bone tunnels created with a surgical drill in the insertion area of the infraspinatus tendon. With the primary repair, a simple interrupted suture pattern was used on each side of the defect (tendon-bone). The augmentation devices were attached to the tendon (device-tendon) and the bone (tendon-bone) with 3 and 2 simple interrupted sutures, respectively. The incision was closed by suturing the brachial fascia to the deltoid muscle (No. 2 polydioxanone, continuous suture pattern), followed by closure of subcutaneous and subcuticular tissue (both No. 2 polydioxanone, continuous suture pattern) and skin (skin staples).

Sheep were killed by intravenous injection with an overdose of barbiturate (Beuthanasia, 39 mg/kg intravenously; Schering-Plough Animal Health Corp., Branchburg, NJ). A necropsy was performed immediately after death. We collected and archived tissue samples from each ewe. Shoulders for histology were isolated, sparing the infraspinatus tendon area, and placed in fixative. Histologic examination was performed to determine the cellular and tissue response around the 3 materials used for tendon repair. Shoulders for biomechanical testing were prepared and placed in a cooler on ice packs. These were usually tested within 2 hours after necropsy, and after biomechanical testing, they were placed in fixative within 1 hour. Given the limited number of tendons available for histology only and because each mechanical specimen was refrigerated, tested within 2 hours of death, and then fixed, it was decided to perform histologic examination on the tested specimens where it was discovered that the cell and tissue morphology was very well preserved. Consequently, not only could the vascular penetration of the PD patch be seen, but the number and type of cells could be identified. In addition, the presence or absence of chronic inflammatory cells, as well as the type of tissue differentiation around the implant, could be identified.

Table I Mechanical testing

Type of repair	No. of specimens tested at 9 wk	No. of specimens tested at 24 wk
Suture	4	4
PD patch	5	6
SIS patch	4	4

Table II Histology tendon/treatment (primary use)

No. of weeks	Tendon No.	Treatment
9	1	Suture (histology only)
	1	PD (histology only)
	1	SIS (histology only)
	1	Suture (mechanically tested)
	1	PD (mechanically tested)
	1	SIS (mechanically tested)
24	1	Suture (histology only)
	1	PD (histology only)
	1	SIS (histology only)
	4	Suture (mechanically tested)
	5	PD (mechanically tested)
	4	SIS (mechanically tested)

Six tendons and their insertion from sheep killed after 9 weeks were studied microscopically from undecalcified, plastic-embedded sections (three intact and three after biomechanical testing). Fifteen tendons from sheep killed at 24 weeks (some with their insertions) were used for histologic evaluation (one intact and fourteen after mechanical testing) and studied from undecalcified, plastic-embedded sections or paraffin-embedded sections (three portions of three tendons) (Tables I and II). The histologic sections were studied microscopically, qualitatively and the results of the two time periods compared.

For mechanical testing, the test sample was mounted in a special fixture to tightly clamp the humeral bone on one end and tendon on the other end, resulting in a 2-cm-long gauge length. A line was drawn on the tendon where the tendon was clamped to detect any tendon slippage from the clamping plates. The humeral muscles and condyles, as well as the scapula and its muscular attachment to the humerus, were removed. Beginning at the caudal end of the infraspinatus, the muscle was dissected free from the scapula and the muscular tissue was carefully removed from the muscular portion of the tendon, leaving the cranial end of the infraspinatus tendon attached to the humerus. The tendon was carefully released from the infraspinatus bursa and the periosteum. The tendon was abducted, and two 16-gauge needles threaded with braided stainless steel wire were inserted on each side of the central 1 cm of tendon and the needles withdrawn, leaving the braided wire in place. By use of a surgical marker, a transverse line was marked 2 cm from the tendon/bone insertion to designate the level of the clamp. The isolated tendon was wrapped in a towel saturated with phosphate-buffered saline solution. The humerus was secured to the mounting fixture. Alignment was checked to ensure that the tendon could be secured in a vertical manner, and the 105° angle between the humeral shaft and infraspinatus tendon was checked several times to ensure anatomic correctness. The muscular portion of the tendon was secured in the clamping plates, leaving the 2-cm portion from the plates to the humerus to be tested.

The specimen was then placed in an MTS material tester (MTS Systems, Eden Prairie, MN) with a slight pretension of 2 to 5 lb applied to the tendon. Once proper alignment was achieved, the mechanical test was conducted with a linear ramp of 3 in at a rate of 0.01 in/s. The data were obtained at a rate of 100 samples per second with the LabVIEW program (National Instruments Corporation, Austin, TX). The ultimate tensile failure load was recorded for each test sample. No intact tendon specimens were tested, and no specimens were tested at time 0.

Table III Mean serum fibrinogen concentrations at different postoperative time intervals from sheep undergoing different treatment combinations

	Baseline	3 wk	6 wk
SIS-suture (n = 4)	176.3	236.3 ($P<.05$)	142.8
SIS-PD (n = 6)	168.2	195.5	219
PD-suture (n = 6)	146.5	157.2	181.3
Total (n = 16)	162.1	193.6	185.6

No statistical difference was observed between different time points and between different groups, except that the SIS-suture group showed elevated fibrinogen levels at 3 weeks postoperatively compared with baseline.

RESULTS

All sheep surgeries and recoveries were uneventful. Mild swelling developed over the incision side in all sheep, which subsided in 3 to 7 days. The swelling appeared to be independent of the repair technique that was used and was a consequence of the surgery.

Fibrinogen

The measured serum fibrinogen concentrations at different time points are summarized in Table III. Mean fibrinogen levels for all experimental sheep preoperatively and at 3 and 6 weeks were 162, 194, and 186 mg/dL, respectively. The mean baseline fibrinogen level for nonoperative sheep was 175.8 mg/dL (SD, 10.3). Because different treatments were applied to contralateral joints in the same animal (eg, some animals had PD-reinforced repair in one shoulder and SIS in the contralateral shoulder), fibrinogen subanalysis was performed on selected subgroups of animals without coimplantation of PD and SIS patches. At 3 weeks postoperatively, animals with suture repair and SIS coimplantation showed significantly elevated plasma fibrinogen levels ($P < .05$) whereas sheep with suture repair and PD coimplantation showed no significant elevation of fibrinogen levels.

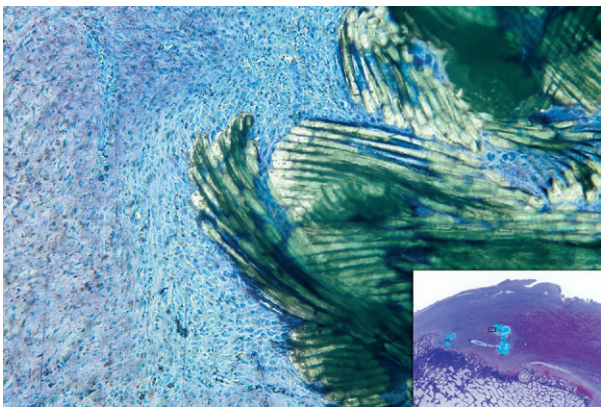

Figure 2 Suture-only repair specimen at 9 weeks. The sheath of macrophages and scattered giant cells around the suture is evident and separate from the fibroblastic connective tissue (new tendon on left). This sheath of cells could weaken the area around the suture, leading to tissue failure (specimen 2189 left, Magnification 20X, Toludine blue stain). (Inset is cross section of tendon with area of magnification marked by the lined box).

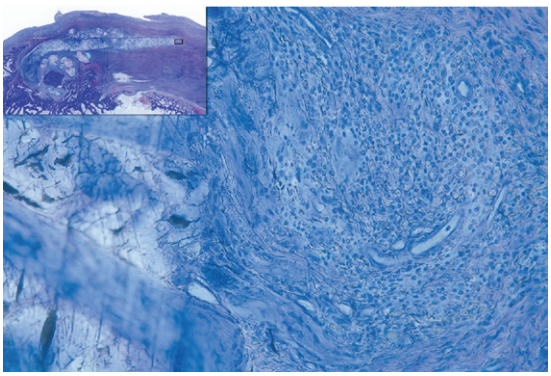

Figure 3 A PD graft at 9 weeks shows vascular layer of giant cells, macrophages, and fibroblasts on the PD graft, adjacent to the tendon on the left. Little interdigitation of connective tissue with the PD material is seen (specimen 2189, right, Magnification 40X, toludine blue stain). (Inset is cross section of tendon with area of magnification marked by the lined box).

Mechanical testing

Biomechanically, at 9 weeks, the mean failure load was 182 ± 63 lb for the PD-reinforced tendons, 137 ± 16 lb for SIS, and 201 ± 60 lb for suture. Furthermore, at 9 weeks, when within-subject comparisons were made, it was found that the PD reinforcement led to higher failure loads than either suture repair alone or SIS reinforcement (n = 4).

By 24 weeks, the mean peak load was 331 ± 55 lb for the suture-only tendon repair, 340 ± 33 lb for the SIS group, and 316 ± 97 lb for the PD group. However, the differences were not statistically significant.

Histology

At any time interval, with any repair technique, either grossly or histologically, there was no repair failure.

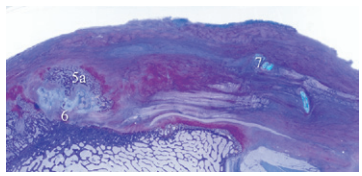

Figure 4 A 9-week SIS specimen. Panoramic view of tendon reinforced with SIS, with bone-tendon junction on left and infraspinatus tendon on right. The bone formation is at the site of the SIS material (specimen 152 left, Magnification 2:1, toludine blue stain).

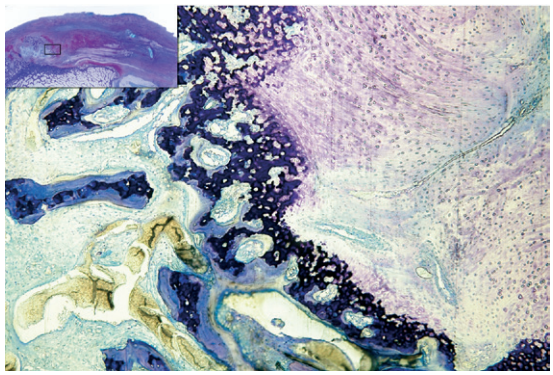

Figure 5 Pieces of the SIS are in the lower left quadrant of the image surrounded by loose connective tissue. Above it is a spicule of bone with a layer of osteoid. The bone has formed on calcified fibrocartilage. To the right of the spicule is bone and calcified fibrocartilage, and to the right of this area is a layer of vascularized fibrocartilage (specimen 152 left, magnification 10X, toludine blue stain). (Inset: lined box marks area of magnification form cross section of tendon).

Thus, all specimens were available for histologic analysis. At 9 weeks, the suture-only repair exhibited normal connective tissue formation (Figure 2). The PD patches were intact but were not fully integrated with surrounding tendon tissues at this time point. A large number of giant cells on the PD surface plus fibroblasts, macrophages, and lymphocytes were seen. There was no connective tissue interdigitation at 9 weeks (Figure 3). The majority of SIS patches appeared to be completely resorbed. The area of the resorbed SIS patches was surrounded by primitive connective tissue containing macrophages, fibroblasts, woven bone, and new cartilage (Figures 4–6).

At 24 weeks, PD patches were integrated into adjacent tendon tissues. Cellular and vascular invasion into the PD patch had occurred. The macrophages and giant cells seen at 9 weeks were no longer present. A mature tendon-bone insertion had formed (Figures 7 and 8).

A much more diverse tissue response was seen at 24 weeks with the SIS repair. Areas of calcification and fibrocartilage were associated with sutures and remains of SIS patches. Osteoid could be seen deposited on calcified tissue matrix (Figure 9). Even ectopic bone

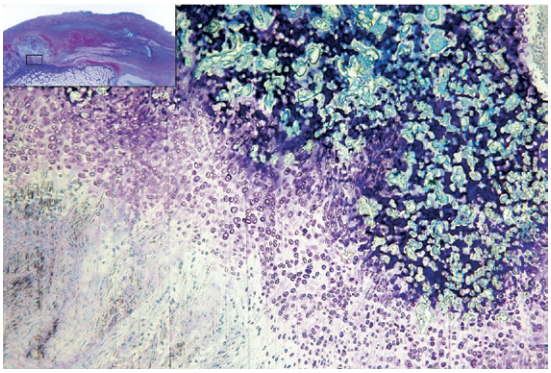

Figure 6 Formation of tendon reinsertion into bone. Tendon (collagen) is on the left. A layer of fibrocartilage is shown, with bone being formed in the cavities in the mineralized fibrocartilage (specimen 152 left, magnification 10X, toludine blue stain). (Inset: lined box shows area of magnification in tendon cross section).

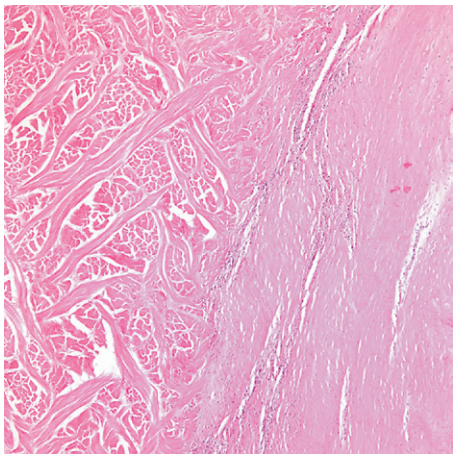

Figure 7 A 24-week PD specimen, with a similar area and results as in Figure 3 but in a different animal and with a different stain. This specimen had been mechanically tested, yet PD and the surrounding connective tissue did not separate (specimen 6136 right, magnification 10X, hematoxylin and eosin stain).

formation was observed in some tendons repaired with SIS patches. At 24 weeks in the group undergoing suture repair alone, surprisingly, necrosis and rarefaction of surrounding tissue matrix were observed around the nonresorbable suture (Figure 10). This may be a result of the ischemia of the tissue resulting from the tension caused by the suture alone, which is not shared by a patch.

DISCUSSION

Fibrinogen is an acute-phase reactant whose concentration increases during inflammation. Serum hyperfibrinogenemia commonly occurs with inflammatory processes and is considered an indicator of early inflammation in stages that even may precede leukogram changes. Determination of fibrinogen concentrations was included in the study to detect differences in inflammatory response between the different treat-

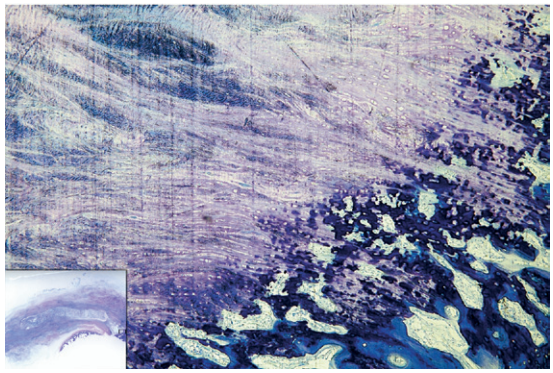

Figure 8 Reformation of bone-tendon junction (enthesis) in 24-week PD-reinforced tendon (specimen 8076 left, magnification 10X, toludine blue stain). (Inset shows cross section of tendon).

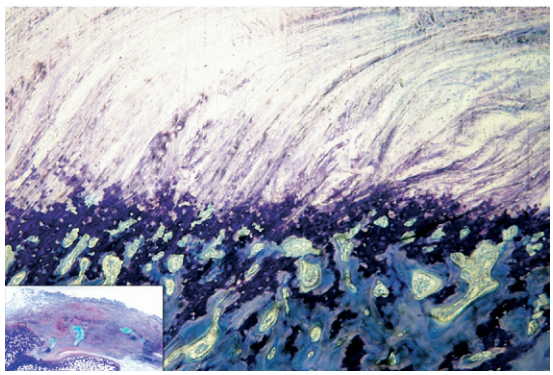

Figure 9 Restoration of tendon-bone junction adjacent to SIS implant at 24 weeks (specimen 122 left, magnification 10X, toludine blue stain). (Inset shows cross section of this tendon).

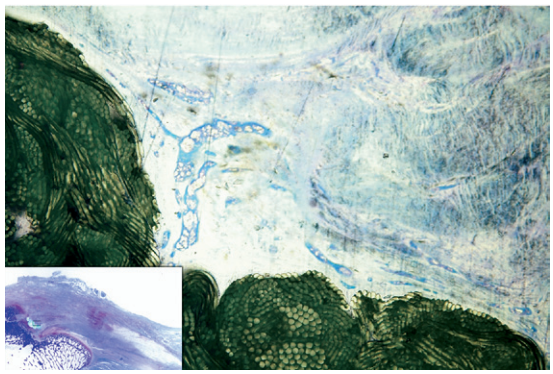

Figure 10 A 24-week suture-only repair showing areas of collagenous necrosis adjacent to the braided suture in an area of thinning connective tissue (specimen 122 right, magnification 10X, toludine blue stain). (Inset: cross section of this suture repair only tendon).

ment groups at different times postoperatively. The reported serum fibrinogen reference range in sheep is 100 to 500 mg/dL. The results of the fibrinogen study suggest that fibrinogen may be most useful for longitudinal monitoring but less suitable for cross-sectional comparisons. Indeed, longitudinal monitoring of fibrinogen levels revealed that, at 3 weeks postoperatively, animals implanted with SIS patches (with contralateral suture-alone repair) had significantly elevated plasma fibrinogen levels whereas those implanted with PD patches (with contralateral suture-alone repair) did not. However, the fibrinogen levels were not statistically significantly different from the preoperative baseline levels for any groups of animals at 6 weeks postoperatively.

This study allowed concurrent evaluation of 3 repair constructs: transosseous suture repair, an absorbable patch (SIS), and a nonresorbable patch (PD). The acute ovine tear model does not replicate the typical clinical scenario in human beings, which is a chronic tendon tear. The complete disinsertion of the infraspinatus tendon can lead to repair failure in an animal model. This acute tear model created a crescent-shaped central defect, leaving a dorsal and ventral "pillar" of tendon intact. The tendon was repaired and then the appropriate patch placed. This prevented early repair failure in the active animals and allowed histologic and mechanical evaluation at 9 and 24 weeks after repair.

The PD patch provided mechanical strength at 9 weeks that was superior to suture repair alone or SIS patch reinforcement. At 24 weeks, there was not a significant mechanical strength difference between the 3 groups. However, histologically, the tendon-bone junction was seen to be more organized with the PD patch. Integration of the PD patch by native tendon tissue was seen at 24 weeks, which was substantially different from the 9-week appearance.

At 9 weeks postoperatively, several histologic features were apparent. First, the surface of the PD patch was covered by a substantial cellular layer consisting of macrophages, lymphocytes, giant cells, and fibroblasts. Although the inflammatory cells could be indicative of chronic inflammation resulting from a foreign body, they usually follow a surgical event. No evidence of acute inflammatory cells (polymorphonuclear leukocytes), and few plasma cells were seen. The large giant cells were principally located in foci and were more prevalent around and in the nonresorbable braided sutures. This suture reaction was present regardless of the type of reinforcement material used. Although there were giant cells associated with the remaining fibers of SIS, the majority of the material appeared to have been resorbed by this time. By comparing the histology of the unimplanted PD with the implanted PD for 9 weeks, none of the material appeared to be resorbed.

On the basis of the comparison of the tissue response of all 3 materials, SIS produced the most diverse tissue reaction. A loose connective tissue was present around the fibers, whereas fibrocartilage/calcified fibrocartilage with associated osteogenesis occurred in the tissue around the material. In other words, within the vicinity of the SIS fibroblasts/fibrocytes, chondrocytes, osteoblasts, osteocytes, and undifferentiated cells were morphologically apparent and producing their respective types of tissue. This was indicative of a disorganized tissue healing response. Immature tendon-bone reinsertions were developing. However, the rate and degree of formation was more irregular in the SIS-treated animals than in the suture-only repair group.

At 24 weeks, the tissue reaction around the PD patch had changed completely. The surrounding layer of chronic inflammatory cells had decreased dramatically and in several instances was only focal in nature. It was largely replaced by a normal vascularized connective tissue. The connective tissue appeared to be not only interdigitating with the matrix of the PD material but penetrating deep into it, accompanied by blood vessels and fibroblasts.

The PD matrix and cells that have migrated from surrounding tissues into the matrix (fibroblasts) appeared to respond to the biomechanical forces that they experienced. For instance, at the bone end of the PD material, its fibers were more widely separated, possibly as a result of the adjacent restored bone-tendon junction transferring most of the force. There was a mature tendon insertion with Sharpey's fibers extending down into the bone. This formation of the bone-tendon reinsertion associated with the PD material appeared to be proceeding in a controlled manner and was more advanced than that in the specimens undergoing the other repair techniques.

SIS produced a diversity of tissues, as seen at 9 weeks, except there appeared to be more of an endochondral ossification response, which could result in a bony nidus in the matrix of the tendon. The restoration of the bone-tendon junction adjacent to the SIS material appeared to be proceeding in a more controlled manner at 24 weeks than at 9 weeks.

Areas of necrosis and rarefaction of the surrounding tendon matrix were observed around the suture and in the suture-only repair. We cannot, at this time, completely explain this finding. However, it may indicate either that fibrous remodeling was occurring around the suture as a result of the tendon-bone junction being mature enough to take more of the load or that, if the degree of soft-tissue remodeling became too great, the suture might be released from the tendon matrix. In the suture-only repair, this may be an indirect indication that a benefit of a patch would be load-sharing at the tendon-suture-bone junc-

tion, as well as that the necrosis around the sutures was not seen in the patch specimens.

In summary, by 24 weeks, the chronic inflammatory response around the PD material had been largely replaced by a normal interdigitating connective tissue incorporation. The material was becoming vascularized and populated throughout its matrix by fibrocytes. It appeared to have the capability of allowing the ingrown cells and tissue to respond to different degrees of mechanical force. Finally, the PD patch performed in its reinforcement role as well as the other material, persisted longer, did not produce a disorganized diversity of tissue (eg, ectopic bone), and did not appear to rarify or weaken with time.

This study is based on an acute injury model. Suture-alone repair led to satisfactory healing in this model, as has been seen clinically. However, when chronic injuries to the rotator cuff tendon occur, suture repair alone produces satisfactory clinical results but has also shown a high percentage of retears or nonhealing. This is more prevalent in large and massive rotator cuff tears.[1,2,4] A healed rotator cuff repair has a better outcome than a repair that did not completely heal. Thus, the beneficial effects of reinforcement patches over sutures alone in the larger, chronic tears may be desirable clinically.

In conclusion, in this acute injury model, we made the following observations:

- At 3 weeks postoperatively, fibrinogen levels were elevated in animals implanted with SIS patches but not in animals implanted with PD patches.
- At 9 weeks, the majority of SIS patches appeared to have resorbed. PD patches were intact but not fully integrated with surrounding tendon tissues.
- At 24 weeks, PD patches were integrated into adjacent tendon tissues. Ectopic bone formation was observed in some tendons repaired with SIS patches. Surprisingly, necrosis and rarefaction of surrounding tissue matrix were observed around the nonresorbable suture in the shoulders repaired with suture alone (without any patch reinforcement). This may result from ischemia of the tissue resulting from the tension caused by the suture alone, which is not shared by a patch, and further illustrates the benefit of the patch.

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