Biomechanical Evaluation of the Relation Between Number of Suture Anchors and Strength of the Bone–Tendon Interface in a Goat Rotator Cuff Model

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Purpose: The effect of contact area between tendon and bone on ultimate pullout strength of a repaired tendon is not known. The purpose of this study was to test whether the strength of a healed bone–tendon interface is related to the amount of tendon that is in contact with bone at the time of repair. **Methods:** A total of 20 mature goats underwent bilateral open rotator cuff repair of the infraspinatus tendon. The tendon edge was repaired to bleeding cancellous bone in each case with the use of suture anchors. The tendon was repaired with 2 anchors (contact area A; n=20) on 1 shoulder and 4 anchors (contact area B; n=20) on the contralateral shoulder. Ten goats were euthanized at 4 weeks (group 1) and 10 goats at 8 weeks (group 2) postoperatively. Twelve specimens were evaluated with ultrasound in the sagittal and coronal planes in a saline bath before mechanical testing was conducted. Ultimate load to failure was reported for each shoulder. Data were analyzed by means of a paired t test and Wilcoxon signed-rank test. **Results:** Ultrasound evaluation revealed several instances in groups 1/2 and contact areas A/B in which clear gap formation occurred without scar (collagen) interdigitation at the bone–tendon interface. Failures occurred at the bone–tendon repair site in all specimens during biomechanical testing. The mean load to failure for all specimens in group 1 was 350.7 N; it was 619.4 N for specimens in group 2 (P = .0002). In group 1, specimens with contact area A had a mean load to failure of 317.3 N; specimens with contact area B had a mean load to failure of 375.5 N (P = .15). In group 2, specimens repaired with contact area A had a mean ultimate load to failure of 635.8 N, whereas contact area B specimens had an ultimate failure strength of 688.5 N (P = .45; Wilcoxon signed-rank). **Conclusions:** Increasing the number of suture anchors and the surface area of the tendon that is in contact with bone at the repair site increased the ultimate load to failure of the repaired tendon at both 4 and 8 weeks postoperatively by less than 10% at both intervals. This was not a statistically significant increase in failure strength in this model. **Clinical Relevance:** This animal model shows no statistically significant differences in strength at the repair site between a 2-anchor and a 4-anchor rotator cuff repair. This information may have direct clinical applications for the surgical technique employed in the repair of rotator cuffs. **Key Words:** Rotator cuff—Shoulder—Goat—Repair site—Tendon.

The healing potential of the bone–tendon interface is a significant area of research in orthopaedics that has direct clinical applications. The attachment site between tendon and bone is the weak link during the early healing period, and objective evaluation of rotator cuff repairs demonstrates an approximately 30% rate of failure of secure healing between tendon and bone at 3 to 5 years postoperatively.[1-5] These high

rates of failure have been noted in patients who have undergone both open and arthroscopically assisted rotator cuff repair.[2,3]

It has been assumed that tendons heal more effectively to a bleeding cancellous bony surface than they do to cortical bone directly. Current surgical practice employs this philosophy, and soft tissue repairs are routinely placed onto bleeding cancellous bone. Recent studies have shown that medialization beyond 17 mm in a cadaveric shoulder model results in a significantly reduced moment arm in the shoulder and subsequent biomechanical disadvantage.[5] Numerous studies have examined methods for repair of tendons to bone, but very little is known about the basic biology of healing and the biomechanical characteristics of a healed tendon–bone construct.[6-12] Additional studies are needed to identify the factors that influence the strength of the tendon-to-bone repair. We hypothesize that the tendon–bone *contact area* is an important component in the strength of the bone–tendon interface. Such information may be important for determining optimal repair techniques or for directing postoperative rehabilitation, or it may suggest the need to augment tendon-to-bone reconstructions with autologous, allograft, or possibly biosynthetic tissue.

The purpose of this study was to test the hypothesis that increased contact area between tendon and bone at the repair site with the use of a greater number of suture anchors will produce a stronger tendon attachment. We sought to evaluate this in a goat model.

METHODS

Animal Model

The goat, *Capra hircus*, has a deep head and a superficial head of the infraspinatus muscle. The muscle's tendinous insertion is easily approached with minimal morbidity to the animal. Because the goat has both a deep and a superficial body of the infraspinatus muscle with corresponding separate tendons, the superficial muscle and tendon can be manipulated surgically with no effect on the goat's ability to ambulate. A pilot study conducted by St. Pierre et al. (personal communication) showed that although concurrent bilateral surgical tenotomy and repair of the superficial head of the infraspinatus allowed for immediate postoperative mobilization, they did not yield repair site failures. This model calls for performance of a paired study undertaken to evaluate a single independent variable. On the basis of the numbers in St. Pierre's study, we conducted a power analysis to determine the

number of animals needed to show a difference of 10% in attachment strengths between groups. We believed that a difference of this magnitude would be clinically significant. Use of data from the study described here, in which the total group of standard deviations fell between 188 N and 280 N for 20 goats (40 shoulders) in a paired study yields a power of 0.8, with $\alpha = 0.05$. Assuming a standard deviation of ±200 N, the smallest detectable difference would be 125 N. These data allowed us to detect a difference of less than 20%.

Surgery

All animals were nonpregnant females weighing between 80 and 100 lb. Animals were on average 1.5 years of age. Bilateral procedures on forelimbs were performed during a single surgical session. Institutional Animal Care and Use Committee approval was obtained from both institutions before the study commenced. Postoperatively, all animals were housed according to Association for Assessment of Laboratory Animal Care standards in the same enclosed pen. All animals were fed the same diet and were exposed to the same environment.

A vertical incision along the posterolateral aspect of the proximal upper limb was used to expose the superficial head of the infraspinatus tendon and its insertion into the proximal humerus. The superficial head of the tendon was sharply taken off of its insertion on the humeral head with no tendon left laterally. The tendon edge was then repaired to bleeding cancellous bone in each case with the use of conventional suture anchors (ROC-Z PLA Suture Anchor; Innovasive Devices, Marlboro, MA) that were loaded with No. 2 Ethibond (Ethicon, Johnson & Johnson, Somverville, NJ) sutures (Fig 1).

The tendon was repaired with the use of 2 anchors (contact area A; n=20) on 1 shoulder and 4 anchors (contact area B; n=20) on the contralateral shoulder. The cross-sectional area of the distal tendon that was in contact with bone was measured by hand for each animal by noting width, thickness, and length. All measurements were taken with the tendon flat with sharply demarcated ends. For contact area A repairs, anchors were placed 1 cm apart at the lateral margin of the free tendon edge; the tendon was repaired to bone with a nonabsorbable braided polyester suture according to a modified Mason-Allen suture technique. Contact area B repairs received the same 2 lateral tendon sutures as those used in A, but in addition, 2 anchors were
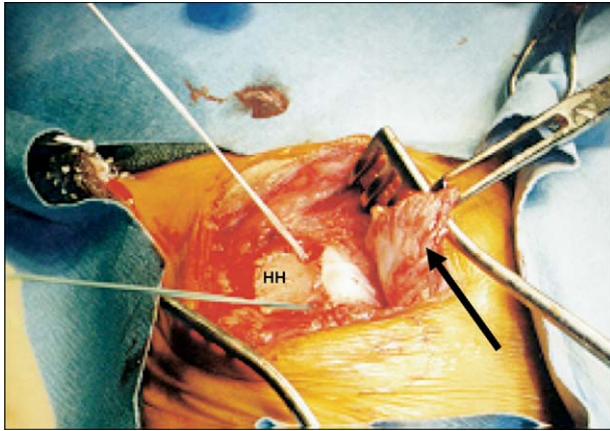
FIGURE 1. The tendon edge (arrow) was repaired to bleeding cancellous bone in each case with the use of conventional suture anchors.

placed 1 cm medially to the lateral anchors. Contact area B repairs consisted of 4 points of tendon-to-bone fixation 1 cm apart, which formed a 1×1 cm^2 repair site at the bone–tendon interface. Contact area A repairs had 2 points of fixation that were 1 cm apart.

Postoperatively, all goats were allowed to ambulate ad libitum. A total of 10 goats were euthanized at 4 weeks (group 1), and 10 were euthanized at 8 weeks (group 2) postoperatively. Specimens were frozen immediately after harvesting at $-4°$C after they had been placed in a protease inhibitor. Specimens were frozen and went through a single freeze–thaw cycle. Specimens were tested in uniaxial tension with the use of an Instron MTS (Admet, Norwood, MA). The deep head of the infraspinatus muscle–tendon unit was cut before mechanical testing was conducted in all specimens. Ultimate load to failure and site of failure were recorded for each shoulder. All specimens were mounted on the MTS platform with a special grip to allow the infraspinatus tendon to be pulled along its line of pull. Data were analyzed by means of a paired *t* test and Wilcoxon signed-rank test. All 20 specimens were subjected to biomechanical analysis after harvesting was completed. The humeral head and shaft were stripped of all soft tissues except for the infraspinatus tendon and muscle belly. Specimens, once mounted on the MTS platform, were preloaded with 15 N. The specimens underwent uniaxial tensile loading to failure at a rate of 50 mm/sec. Ultimate load to failure was calculated for each specimen.

Ultrasound Evaluation

A total of 12 specimens (group 1, n=6; group 2, n=6) were evaluated by means of ultrasound before mechanical loading took place. Specimens were thawed, and ultrasound evaluation took place in a saline bath. Each specimen was evaluated in the coronal and sagittal planes at the bone–tendon interface in an effort to determine the integrity of the tendon at the repair site. All ultrasounds were performed by one radiologist (R.S.A.) who used a linear phased array 13-Megahertz transducer (GE Medical Systems, Milwaukee, WI).

Biomechanical Evaluation

All specimens underwent a single freeze–thaw cycle before mechanical testing began. The muscle belly of the superficial head of the infraspinatus muscle was stripped of all muscle before testing. A pilot study that used sheep infraspinatus tendons found no slippage of the tendon in the grip during mechanical loading to failure. The humeral shaft was placed into an established bone-holding clamp and mounted onto a platform that allowed for 3 planes of manipulation. Each specimen was placed into the system so that the tendon would be loaded to failure in the proper mechanical vector of the tendon (Fig 2). Ultimate load to failure was calculated for each specimen. No instances of slippage of the tendon in the grip or rotation of the humeral shaft on the platform were noted during mechanical testing.
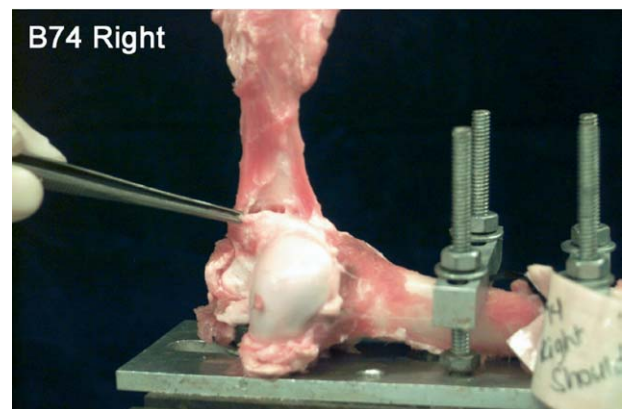
FIGURE 2. The humeral shaft was placed into an established bone-holding clamp and mounted onto a platform that allowed for 3 planes of manipulation. Each specimen was placed into the system so that the tendon would be loaded to failure in the proper mechanical vector of the tendon. The deep head of the infraspinatus muscle (in forceps) was cut before mechanical testing was conducted in each specimen.

RESULTS

All animals began to ambulate within 1 hour from the time of their surgery. Several animals were unable to be constrained while in the recovery pens despite concerted efforts to keep them grounded and protect the repair site. One specimen developed an infected seroma during its third postoperative week. This goat was transferred from group 2 to group 1 and was given an oral cephalosporin for 3 days before necropsy was performed. No deep infection was noted at necropsy. In all, 11 shoulders were found to have a moderately sized seroma deep to the deltoid muscle belly that communicated directly with the repair site. One animal had gross failure of the repair site bilaterally, which was noted at necropsy. Group 1 specimens exhibited robust, fibrous reparative scar formation at the repair site. Group 2 specimens had a more organized fibrous scar at the repair site with less inflammatory tissue noted. One suture anchor pulled out of the humeral head in a single specimen (group 1, contact area A); the repair site interface was intact, and the specimen was included in the mechanical testing.

Failure of all specimens occurred at the junction of the bone–tendon repair site. Of 20 specimens, 13 (65%) in group 2 were found to have bony fragments from the humerus that were in contact with the free tendon edge after they had been loaded to failure. The mean load to failure for all specimens in group 1 was 350.7 ± 91 N; for specimens in group 2, mean load to failure was 619.4 ± 112 N ($P = .0002$). In group 1, specimens with contact area A had a mean load to failure of 317.3 ± 99 N, and those with contact area B had a mean load to failure of 375.5 ± 127 N ($P = .15$). In group 2, specimens repaired with contact area A had a mean ultimate load to failure of 635.8 ± 120 N, whereas contact area B specimens had an ultimate failure strength of 688.5 ± 141 N ($P = .45$; Wilcoxon signed-rank) (Table 1).

Gross Evaluation

Specimens were grossly evaluated after mechanical testing was completed. Group 1 specimens were found

TABLE 1. *Load to Failure Results*

	Load to Failure (N)	Contact Area A (N)	Contact Area B (N)	A v B
Group 1	350.7 ± 91	317.2 ± 99	375.5 ± 127	$P = .15$
Group 2	619.4 ± 112	635.8 ± 120	688.5 ± 141	$P = .45$

to have a significant amount of degeneration and necrosis of the tendon edge with reparative scar tissue on the undersurface of the tendon where it was repaired to the humeral head. In some specimens, it appeared as if the repaired tendon had partially pulled away from its repair site onto the humeral head. Intact suture knots were found on top of the failed tendon, and the strands of suture passing vertically from the anchor through the tendon broke. No failure or pullout of the anchor from the bone was observed.

The area of scar formation on the tendon undersurface correlated with what appeared to be an area of gap formation between the suture anchors that was noted with ultrasound in the sagittal plane before loading. We did not study this histologically, however. Reparative tissue was consistently found between the lateral edge of the infraspinatus tendon and the humeral head. Whether or not there was direct tendon-to-bone healing or attachment on either side of this scar was unclear. Group 2 specimens had less reparative scar at the extreme lateral edge of the tendon, but reparative tissues could be seen on the undersurface of the tendon. Although the tendon-to-bone interface was measured before the tendon was repaired to bone, we were unable to measure direct tendon-to-bone apposition at the time of harvesting and during later testing. Direct surface area was not measured because the tendon could not be lifted off of the bone without destruction of the repair, which would compromise biomechanical testing. Furthermore, a uniformly exuberant scar had been created, which also made clear demarcation of the tendon edges impossible. Because no specimens were allocated for histologic analysis, 12 specimens were evaluated on ultrasound to determine whether the actual tendon edge that was placed at the repair stayed at the repair point.

Ultrasound Evaluation

A total of 12 specimens were evaluated by means of ultrasound in the sagittal and coronal planes in a saline bath before mechanical testing was conducted. Serial sagittal sections moving from lateral to medial on the humeral head clearly defined the location of the suture anchor and the surgical knot that was tied above it. Between the anterior and posterior anchors in specimens from contact areas A and B, loss of the normal fibrillar tendon architecture was noted, along with replacement by heterogeneous echogenic soft tissue consistent with scar formation (Fig 3). Furthermore, actual gap formations between tendon and bone were noted in specimens with contact areas A and B and
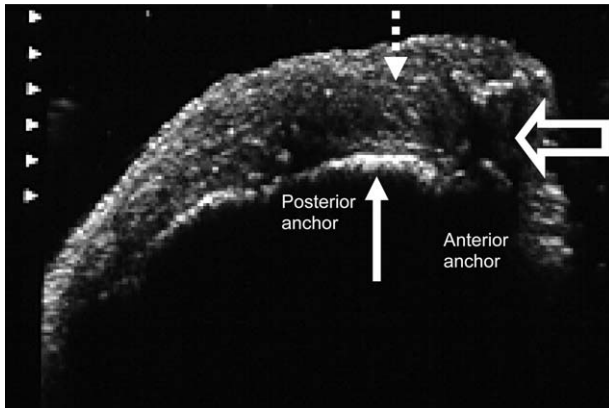
FIGURE 3. Between the anterior and posterior anchors in specimens from contact areas A and B, loss of the normal fibrillar tendon architecture was seen, along with replacement by heterogeneous echogenic soft tissue, which was consistent with scar formation. Scar formation (dashed arrow) can be clearly seen interposed between the tendon edge and the humeral head (solid arrow). The suture is visualized (hollow arrow) above the repair site.

from groups 1 and 2. Ultrasound in the coronal plane showed medialization or pulling away of the repaired infraspinatus tendon from the humeral head in each specimen. A relatively well-organized scar was interposed between the extreme lateral edge of the tendon and its originally repaired site on the humeral head (Fig 4). Gap formation was noted between the medial and lateral anchors in all specimens from groups 1 and 2. Ultrasound evaluation revealed repeated instances in both groups 1 and 2 and in contact areas A and B in which clear gap formation was noted between tendon and bone.

DISCUSSION

A sound rotator cuff repair requires healing of tendon to bone.[13-16] Tendons and ligaments attach to bone by 1 of 2 methods: fibrocartilaginous interface (direct insertion) or Sharpey's fibers (indirect insertion).[17] Basic science studies have demonstrated that tendon-to-bone healing can occur through formation of a direct or an indirect insertion.[18-21] Healing occurs by means of bone and tissue ingrowth into the interface zone that forms between the tendon and the bone. Studies undertaken to evaluate the relationship between attachment and biomechanical strength of the repair have not been performed.

Orthopaedists have devised many surgical techniques to maximize the ability of soft tissue to heal to its bony insertion.[6-8,10,11] Many different suture mate-

rials, varieties of tendon-grasping knots, and types of suture anchors have been developed to improve on the strength of a repair. Gerber et al.[8] evaluated the biomechanical properties of different suture materials, grasping sutures, and anchoring techniques. They found that nonabsorbable braided polyester and absorbable polyglactin and polyglycolic acid sutures had the best tensile strength and stiffness. A modified Mason-Allen suture technique yielded the strongest ultimate tensile strength (359 N) of the grasping sutures evaluated. Gerber and colleagues[8] recognized that little experimental information regarding the technique of repairing soft tissues to bone has been documented. They appropriately noted, "The ideal repair should have high initial fixation strength, allow minimal gap formation, and maintain mechanical stability until solid healing . . . it is clear that weak initial fixation leads to gap formation under load, poor healing, and possibly complete failure."[8]

Harryman et al.[2] retrospectively reviewed the results of 105 open rotator cuff repairs at an average of 5 years postoperatively. Clinical results were correlated with integrity of the repaired cuff through the use of ultrasonography. A total of 20% of patients who initially had tears of only the supraspinatus tendon had recurrent tears at follow-up, whereas more than 50% of patients whose tears involved more than the supraspinatus tendon had a recurrent defect. Recurrent defects were most commonly seen in older patients or
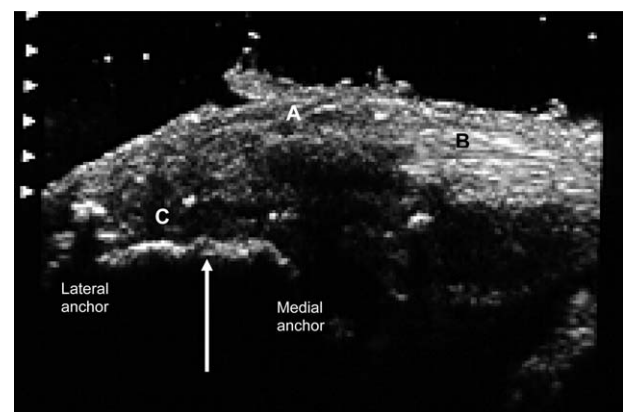
FIGURE 4. Ultrasound in the coronal plane demonstrated medialization or pulling away of the repaired infraspinatus tendon from the humeral head. A relatively well-organized scar (A) was interposed between the extreme lateral edge of the tendon (B) and its originally repaired site on the humeral head (solid arrow). Note the fibrillar echogenic (bright) appearance of the tendon, which corresponds to the co-parallel arrangement of minor tendon fascicles. Gap formation (C) was noted between the medial and lateral anchors in this specimen from group 2.

in those who had large defects at the time of surgery. Most patients were happy with their results, even when they experienced a recurrent cuff defect. However, patients who had an intact cuff showed a significantly greater range of active flexion, external and internal rotation, and strength of flexion, abduction, and internal rotation. Harryman et al.[2] reported that the size of the recurrent rotator cuff defect tended to correlate with the degree of functional loss. Lundberg[4] evaluated integrity of the cuff through single-contrast arthrography after open repairs and noted leakage of dye from the joint in 33% of patients. A direct correlation was noted between function of the shoulder and the rotator cuff defect as demonstrated by arthrography.

Liu and Baker[3] retrospectively evaluated shoulder function and rotator cuff integrity in 35 patients who had undergone arthroscopically assisted (mini-open) rotator cuff repair at an average of 3.7 years postoperatively. All patients were evaluated by means of shoulder arthrography and the University of California Los Angeles (UCLA) Shoulder Rating Scale at follow-up. They noted 92% patient satisfaction, with 86% of patients reporting good/excellent results. However, 34% of shoulders had a full-thickness defect, and 20% of patients experienced recurrent partial tears at follow-up. The size of these recurrent tears correlated with the size of the tear at the time of surgery. Patients who postoperatively had a full-thickness defect reported 80% good/excellent results, whereas those who described no defect postoperatively had 88% good/excellent results. Liu and Baker concluded that the size of a tear intraoperatively correlates with the size of a defect postoperatively, but that recurrent tears do not correlate with or determine functional outcomes. Blevins et al.[18] found no correlation between intraoperative rotator cuff tear size and postoperative satisfaction/function when patients were evaluated with the Hospital for Special Surgery Shoulder Score. These authors documented that 85% of patients with large and massive tears of the cuff and 79% of those with small and medium-sized tears had good/excellent results at a minimum of 2 years postoperatively; however, the healed repairs were not objectively evaluated.

Few studies have examined the mechanism of tendon healing to a bone surface. Healing appears to take place through bone ingrowth into the fibrovascular interface tissue that forms between the tendon and the bone.[6,19-27] Mechanical load has been found to be important for connective tissue healing and probably plays a critical role in re-establishment of a tendon-to-bone attachment site.[11,16] The amount, duration, and type of load (tensile v compressive) that can enhance healing are largely unknown at this time.

St. Pierre et al.[28] used a goat infraspinatus tendon-to-bone repair model to compare tendon healing to cortical bone with healing to a cancellous trough. Biomechanical testing demonstrated no significant differences between the 2 groups in load to failure, energy to failure, or stiffness at 6 and 12 weeks after operation. These authors reported formation of a cellular, fibrovascular tissue at the interface between tendon and bone, followed by progressive bone ingrowth into the interface tissue. Failure of the tendon–bone interface at 6 weeks occurred at a zone proximal to the reparative tendinous site. This zone was characterized by edema and vascular proliferation. St. Pierre et al. concluded that the tendon-healing process is equivalent whether the tendon is attached to cortical or to cancellous bone, as long as close apposition (minimal gap formation) is maintained until collagen interdigitation occurs.

Our study found an approximately 10% gain in load to failure of a repaired rotator cuff tendon at 4 and 8 weeks postoperatively when the surface area of tendon in contact with bone was increased. In our model, surface area was artificially increased in that we used twice as many suture anchors. These increases were not statistically significant. It is unclear whether this increase in mechanical failure strength is a function of a broader reparative surface area, or whether it is due to the simple fact that more suture is being used to provisionally fix the tendon. We believed that cutting our suture knots at the time of mechanical testing would necessarily cause damage to the integrity of the tendon, as the tendon was often encased in a thick, fibrovascular scar.

Our study had some clear limitations. We were unable to requantify the tendon-to-bone surface area obtained at the time of the index procedure. As mentioned earlier, we believed that we would have to destroy the repaired cuff repair if we were to measure the amount of tendon in contact with bone. Although we did not look at this histologically, we did evaluate 12 specimens ultrasonographically. However, we were not able to obtain detailed measurements of the length and width of the tendon in contact with bone as we had done at the time of surgery.

Another obvious shortcoming of this study, along with the chosen animal model, is that we were performing these procedures in a completely healthy environment, where no element of chronic muscle or tendon degeneration was found. The goat model is
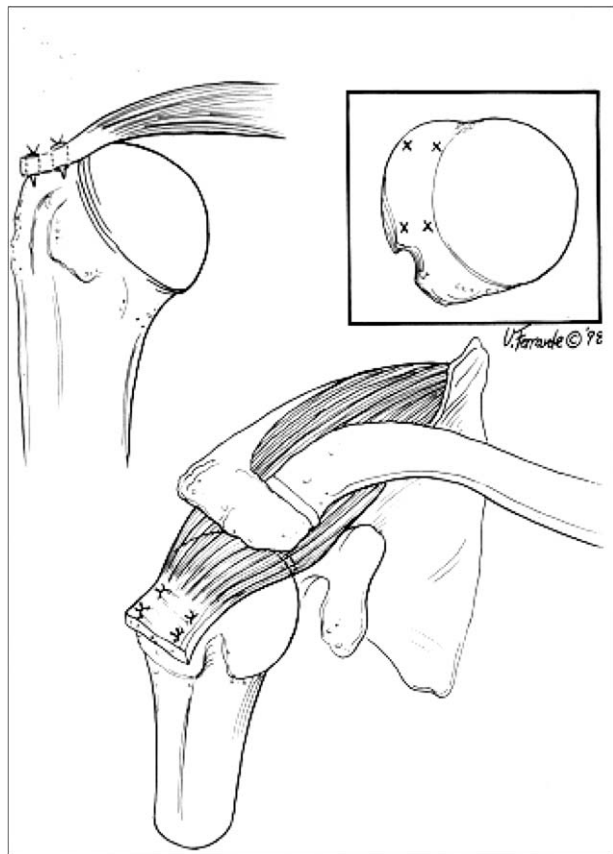
FIGURE 5. We attempt to recreate the normal tendon–bone interface with use of a 2-row fixation method and medial and lateral suture anchors. This is done to distribute the fixation stress over a greater surface area, to create a maximal surface area for biologic healing, and to appropriately recreate normal tendon anatomy.

clearly not analogous to that of an elderly degenerative cuff tear model. Whether a degenerative tendon model is analogous to a healthy animal model has recently been evaluated.[29] The chronic rotator cuff tear is characterized by tendinous degeneration and fatty infiltration of a previously normal muscle belly. Our model evaluated an acute cuff tear model wherein the effects of chronicity did not take place.

Last, we later realized that the anchors used in the 2-anchor construct were not placed immediately adjacent to the articular cartilage of the humeral head. Therefore, we cannot absolutely rule out the possibility of some tendon–to–cancellous bone healing medial to the 2 laterally placed suture anchors. This would have obviously given us a somewhat falsely elevated load to failure result at the time of testing.

We are currently in the process of examining this question in a cadaveric sheep model comparing con-

tact area A with contact area B at time zero. We have used this rotator cuff repair in the clinical setting at our institution for some time (Fig 5).

CONCLUSIONS

Increasing the surface area of tendon in contact with bone at the repair site by increasing the number of suture anchors increased the ultimate load to failure of the repaired tendon at 4 and 8 weeks postoperatively by less than 10% at both intervals. This was not a statistically significant increase in failure strength in this model.

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