Rotator Cuff Repair Healing Influenced by Platelet-Rich Plasma Construct Augmentation

F. Alan Barber, M.D., Scott A. Hrnack, M.D., Stephen J. Snyder, M.D., and Onur Hapa, M.D.

Purpose: To assess the effect of platelet-rich plasma fibrin matrix (PRPFM) construct augmentation on postoperative tendon healing as determined by magnetic resonance imaging (MRI) and clinical outcome of arthroscopic rotator cuff repair. **Methods:** A comparative series of patients undergoing arthroscopic rotator cuff repair was studied. Two matched groups of patients (20 each) were included: rotator cuff repairs without PRPFM augmentation (group 1) and rotator cuff repairs augmented with 2 sutured platelet-rich plasma (PRP) constructs (group 2). A single-row cuff repair to the normal footprint without tension or marrow vents was performed by a single surgeon. Postoperative rehabilitation was held constant. Postoperative MRI scans were used to evaluate rotator cuff healing. Outcome measures included American Shoulder and Elbow Surgeons, Rowe, Single Assessment Numeric Evaluation, Simple Shoulder Test, and Constant scores. **Results:** We followed up 40 patients (2 matched groups with 20 patients each) with a mean age of 57 years (range, 44 to 69 years) for a mean of 31 months (range, 24 to 44 months). Postoperative MRI studies showed persistent full-thickness tendon defects in 60% of controls (12 of 20) and 30% of PRPFM-augmented repairs (6 of 20) ($P = .03$). Of the control group tears measuring less than 3 cm in anteroposterior length, 50% (7 of 14) healed fully, whereas 86% of the PRPFM group tears measuring less than 3 cm in anteroposterior length (12 of 14) healed fully ($P < .05$). There was no significant difference between groups 1 and 2 in terms of American Shoulder and Elbow Surgeons (94.7 and 95.7, respectively; $P = .35$), Single Assessment Numeric Evaluation (93.7 and 94.5, respectively; $P = .37$), Simple Shoulder Test (11.4 and 11.3, respectively; $P = .41$), and Constant (84.7 and 88.1, respectively; $P = .19$) scores. The Rowe scores (84.8 and 94.9, respectively; $P = .03$) were statistically different. **Conclusions:** The addition of 2 PRPFM constructs sutured into a primary rotator cuff tendon repair resulted in lower retear rates identified on MRI than repairs without the constructs. Other than the Rowe scores, there was no postoperative clinical difference by use of standard outcome measures. **Level of Evidence:** Level III, case-control study.

Rotator cuff tears are a common source of shoulder pain and combine both traumatic and degenerative elements. Surgical repair of symptomatic full-thickness tears is a treatment option for patients with continuing symptoms despite nonoperative treatment. Even after surgical intervention, the incidence of persistent tendon defects, or "retears," is significant. The incidence of tendon retear after rotator cuff repair varies depending on the patient's age, number of tendons involved, and tear size. Reported retear rates of 80% to 90% exist in the radiology literature and are as high as 57% in the orthopaedic literature.[1-3] Because this may represent the biologic nature of the aging tendon, biologic factors offer promise in the treatment of these tendons. Platelet-rich plasma (PRP) has emerged as a new technology believed to stimulate revascularization of soft tissue and increase the concentration of growth factors to improve and accelerate tendon healing.

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PRP, defined as a supra-physiologic concentration of platelets, is increasingly used in orthopaedic surgery. PRP is theorized to play an important role in normal healing by stimulating growth factors and inflammatory cells to the area of repair. Several investigators have shown evidence for stimulating tendon healing after an injection of PRP.[4,5] Animal studies have shown increased short-term (<1 month) tendon healing in both patellar and Achilles tendon repair.[6,7] PRP is being used to augment various soft-tissue reconstructions including arthroscopic rotator cuff repairs.[8,9] It must be emphasized that the various commercial products called PRP differ significantly and a distinction must be made in considering what is being reported as PRP.[10] This study used the Cascade PRP fibrin matrix construct (Musculoskeletal Transplant Foundation, Edison, NJ) because it does not have thrombin activation or contain leukocytes and it releases growth factors over a period of several days. The purpose of this study was to assess the effect of PRP fibrin matrix construct augmentation on postoperative tendon healing as determined by magnetic resonance imaging (MRI) and clinical outcome of arthroscopic rotator cuff repair. Our hypothesis was that suturing a PRP construct into a primary rotator cuff repair would result in improved tendon healing and better clinical outcomes.

METHODS

A comparative series of patients undergoing arthroscopic rotator cuff repair was studied. During the study interval (from June 2006 through January 2009), 2 matched groups of patients were identified and followed up prospectively: rotator cuff repairs augmented with 2 sutured PRP constructs (Fig 1) (Cascade autologous platelet system) and rotator cuff repairs without PRP construct augmentation (control). All were diagnosed with full-thickness rotator cuff tears based on both physical examination and preoperative MRI. An arthroscopic single-row rotator cuff repair was performed in all cases by the same surgeon. At the end of the surgical repair, 1 group of patients had 2 PRP constructs sutured into the repair site. The PRP construct was created by a double-spin technique without thrombin activation. The control group patients had no PRP construct augmentation.

Inclusion criteria were patients with clinically significant, symptomatic, full-thickness 1- or 2-tendon tears measuring between 10 and 50 mm in width. Tendon retraction was allowed, as was mild (up to stage 2) fatty infiltration into the muscle, based on MRI.[11] Exclusion criteria were patients aged 70 years or older; patients with anemia (hemoglobin level <11.0 g/dL); smokers; diabetic patients; patients with a history of steroid use, thrombocytopenia, or blood dyscrasia; patients with previous rotator cuff surgery; patients with episodes of shoulder instability; patients with fractures in the glenohumeral area; patients with other forms of biologic augmentation; patients reporting falls onto the involved arm during the first 6 weeks after surgery; or patients who were noncompliant with the rehabilitation protocol and did not wear their abduction sling or were too aggressive in returning to full function.

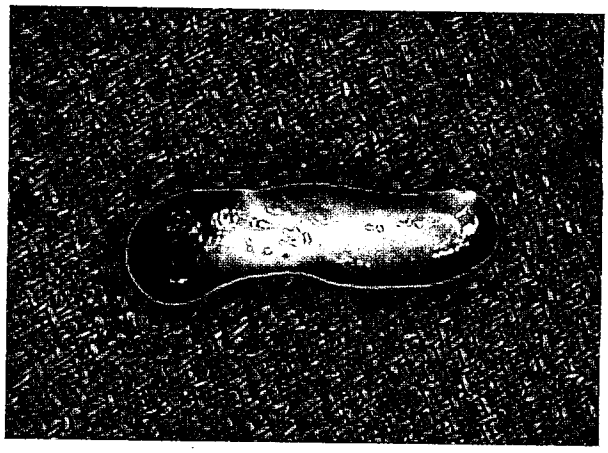

FIGURE 1. Platelet-rich construct before being sutured into cuff repair. © F. Alan Barber.

The primary endpoint was the determination of the presence or absence of a retear by postoperative MRI. Postoperative MRI studies were obtained to evaluate repair healing looking for full-thickness rotator cuff defects (retears) (Fig 2). These MRI studies were read by radiologists unrelated to the study and blinded as to which study group the patient belonged. The additional cost and invasive nature of gadolinium enhancement were not considered justified because of the accuracy of an unaugmented MRI study.[3,12,13] The secondary endpoint was the clinical response determined by outcome measures. Clinical outcome measures were obtained preoperatively and postoperatively at intervals starting at 4 months and annually thereafter. These measures included American Shoulder and Elbow Surgeons (ASES), Rowe, Single Assessment Numeric Evaluation (SANE), Simple Shoulder Test (SST), and Constant scores.

The PRP construct augmentation used in this study was the Cascade autologous platelet system. By use of the kit provided by the manufacturer, all patients had

FIGURE 2. Retear on postoperative MRI scan (arrow). An anchor is visible in the humeral head. © F. Alan Barber.

approximately 18 mL of blood drawn directly into 2 tubes preloaded with an inert polyester separator gel and an anticoagulant before lateral decubitus positioning. The tube was inverted 7 times to mix the components and then centrifuged for 6 minutes at 1,100 relative centrifugal force. Then, the material was transferred into a glass tube preloaded with calcium chloride, inverted 7 times, and centrifuged for 15 more minutes at 1,450 relative centrifugal force. At that point, each PRP construct was removed from the tube and was ready for use. This process produced a construct (Fig 1) that was used to deliver the PRP into the rotator cuff repair.

All patients underwent arthroscopic single-row rotator cuff surgery with bioabsorbable suture anchors and ultrahigh–molecular weight polyethylene–containing sutures. The repair consisted of 1 or 2 biodegradable anchors double loaded with high-strength sutures. The number of anchors was dependent on the size of the tear, with an anchor placed for every 1.5 cm of tearing. When appropriate (e.g., L- or V-shaped tears), margin convergence sutures were used. The anchors were positioned medially enough to avoid high repair tension and, depending on the available cuff material, were positioned about 5 to 10 mm from the articular cartilage edge. The dual-suture configurations used were either a mattress stitch combined with a central simple stitch as described by Scheibel and Habermeyer ("T-stop")[14] or 2 simple side-by-side stitches. The repair attempted to return the cuff tendon to the normal footprint area if enough tendon remained. The bone at the attachment site was prepared by removing the soft tissue and then abrading the exposed surface to create a bleeding bed without removing an extensive amount of the cortical bone. Microfracture of the bed to create bone marrow vents was not performed in this study. No capsular releases or interval slides were performed.

In the PRP group 1 of the repair sutures from an anchor was first passed twice through each PRP construct. To accomplish this, the free suture that was to be subsequently passed through the cuff tendon was retrieved out the clear instrumentation cannula in the lateral portal. A steel cannula was inserted over the free suture and past the rubber dam into the clear cannula. This bypassed the rubber obstruction and allowed easy passage of the PRP construct into the joint. A free needle was then placed on the free suture, and the suture was then passed twice through the PRP construct (much like placing a worm on a fish hook) to secure the material to the suture. Each PRP construct was then delivered into the bursal space by a combination of pulling the other end of the suture and pushing using a single lumen knot pusher through the steel cannula and then through the clear cannula (Fig 3). After the steel cannula was removed, re-establishing the effectiveness of the rubber dam, the suture end containing the PRP construct was loaded on an antegrade suture-passing device and passed through the cuff tendon. A sliding locking knot was tied routinely

FIGURE 3. A PRP globule threaded onto the suture anchor suture was delivered to the repair site. © F. Alan Barber.

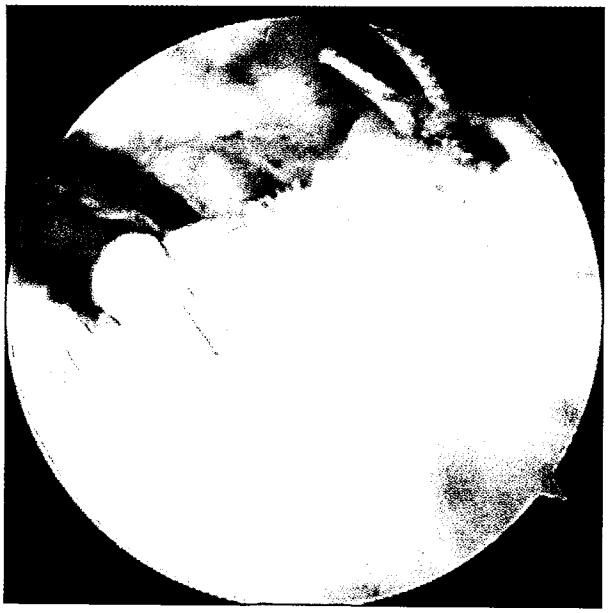

FIGURE 4. The suture was passed through the tendon and the knot tied, compressing the PRP construct into the interval between the tendon and the greater tuberosity. © F. Alan Barber.

and as the knot was advanced into position. The PRP construct was consequently compressed into the interval between the tendon and the reattachment site on the greater tuberosity (Fig 4). Two PRP constructs were inserted in this manner.

All patients participated in identical postoperative rehabilitation programs. An abduction sling was used to immobilize the patients for the first 3 weeks postoperatively and converted to a traditional sling for an additional 3 weeks to take the arm out of abduction and provide more mobility. At 6 weeks, passive range of motion under the guidance of a physical therapist began as well as a home exercise program.[15,16] After 10 weeks, strengthening began, and progressive strengthening above shoulder level started at 4 months. An MRI study to assess tendon healing was obtained at this point. Patients were allowed unrestricted activities at 6 months. The MRI studies were obtained at 4 months based on data that indicate that rotator cuff tears up to 3 cm in length show complete footprint restoration on ultrasound at 4 months after surgery (D. Buford, M.D., personal communication, April 2011).[17]

Statistical Analysis

An a priori power analysis was performed for the primary outcome measure (presence of retears after surgery). A decrease in the anticipated retear rate of approximately 40% associated with single-row cuff repairs by half (20%) would achieve a clinically meaningful effect. Two groups of 20 patients each, allowing for a 15% SD within groups, would provide a statistical power of 0.80. Statistical significance was established at $P < .05$. Unpaired t tests were used to compare the various postoperative clinical outcome measures between groups.

RESULTS

We followed up 40 patients (13 women and 27 men) with a mean age of 57 years (range, 44 to 69 years) for a mean of 31 months (range, 24 to 44 months). The right shoulder was involved in 29 and the left in 11. There were 28 cuff tears measuring 1 to 3 cm in width and 12 measuring at least 3 cm in width. Both groups of patients were matched, with no significant differences between them regarding demographics, size, number of tendons involved, anchors used, or the use of margin convergence stitches (Table 1).

Group 1 (control group) included 20 patients with no PRP sutured into the repair site. Postoperative MRI studies showed retears in 12 of 20 (60%) (Fig 2). Of the 14 tears in the control group that were initially less than 3 cm in anteroposterior (AP) length, 7 healed (50%). Of the 6 tears in the control group that were initially at least 3 cm in AP length, 1 healed.

Group 2 included 20 patients who had a PRP construct sutured into the tendon repair site. Postoperative MRI studies showed retears in 6 of 20 (30%). This was statistically different from group 1 ($P = .03$). Of the 14 tears in the PRP construct group that were initially less than 3 cm in AP length, 12 healed (86%).

TABLE 1. *Demographic Data for 2 Matched Study Groups*

	Group 1 (No PRP)	Group 2 (With PRP)
No. of patients	20	20
Sex	13 M and 7 F	14 M and 6 F
Mean age (yr)	57.8	57.6
Age range (yr)	44-69	44-69
Side	14 R and 6 L	15 R and 5 L
Follow-up (range) (mo)	33 (24-44)	28.3 (24-44)
Retears	12 of 20 (60%)	6 of 20 (30%)*
Cuff tear size (no. healed)		
<3 cm	7 of 14 (50%)	12 of 14 (86%)
≥3 cm	1 of 6 (17%)	2 of 6 (33%)
Anchors used	28	28
Margin convergence	7	8

*$P = .03$.

This was statistically different from group 1 ($P < .05$). Of the 6 tears in the PRP construct group that were initially at least 3 cm in AP length, 2 healed (33%). This difference did not achieve statistical significance ($P = .07$).

Clinical outcome measures for both groups were compared. A significant difference was observed in the Rowe score (84.8 in group 1 and 94.9 in group 2, $P = .03$). However, the differences in the ASES (94.7 and 95.7, respectively; $P = .35$), SANE (93.7 and 94.5, respectively; $P = .37$), SST (11.4 and 11.3, respectively; $P = .41$), and Constant (84.7 and 88.1, respectively; $P = .19$) scores were not statistically significant.

DISCUSSION

The purpose of this study was to assess the effect of adding a sutured construct of PRP fibrin matrix on the clinical outcomes and postoperative healing of a prospective group of arthroscopic rotator cuff repairs. Our hypothesis that enhanced tendon healing would occur with the addition of this version of PRP construct to a primary rotator cuff repair was supported by the MRI studies. The benefit for clinical outcomes was not established.

PRP contains high concentrations of platelets that release growth factors with healing properties as they undergo degranulation. It must be emphasized that considerable differences exist among the various commercial systems currently available for use in the United States including how they are prepared, the number of platelets available, the presence of anticoagulants, the use of leukocyte infusion, and most importantly, the presence of activators that can precipitate the expression of these factors over a short time measured in hours rather than days.[18] The number of platelets required for a clinically significant effect has not been determined, and a system that provides a higher number of platelets is not necessarily better, especially if all those platelets are activated and completely gone in a matter of hours after activation. In addition, the presence of leukocytes in the PRP may be disadvantageous because of the deleterious effects associated with neutrophils containing matrix metalloproteinases.[19] This study used 2 implanted constructs of the Cascade form of PRP that did not have thrombin activation and did not contain leukocytes. This globular fibrin matrix product is clearly more technically demanding to use because instead of simply injecting the product into the area of the cuff repair with a syringe, it must be sutured into the repair. On the other hand, its release of growth factors into the healing milieu lasts for several days rather than a matter of hours.

Our primary endpoint was to determine the presence or absence of full-thickness tendon defects (referred to as retears [Fig 2]) in the repaired rotator cuff tendons after surgery by use of MRI. An MRI study (without gadolinium) was used to make this determination for all patients in both groups. A statistically significant reduction in retear rates (from 60% to 30%) was shown by the addition of 2 PRP fibrin matrix constructs to the rotator cuff tendon repair ($P = .03$).

The incidence of retears in arthroscopic rotator cuff repair varies considerably in the literature, from as low as 10% to 90%.[2,3,12,20-23] Preoperative factors predictive of higher retear rates include a larger tear size, number of tendons involved, preoperative stage of fatty muscle degeneration, preoperative duration of symptoms, and increased age (>65 years).[3,20,24]

Most of the clinical outcome scores used in this study did not establish a difference between these groups. The ASES, SST, SANE, and Constant clinical outcome measures failed to show any statistical difference between the PRP and non-PRP groups. The Rowe score is heavily weighted for instability, and the statistical difference shown in our study ($P = .03$) could be explained by it being an inappropriate study measure for this condition. It is anticipated that differences in clinical outcomes exist between patients with healed and unhealed rotator cuff repairs.[25] However, these clinical differences may require a longer follow-up to manifest themselves because many patients with incompletely healed cuff tendons do well for some time before their symptoms significantly deteriorate.[26]

This study showed that suturing 2 constructs of PRP fibrin matrix into a rotator cuff repair decreased the incidence of MRI-observed retears and supports the use of this form of PRP to augment and enhance the healing of arthroscopic rotator cuff tears. The outcome reported in this study differs from that of Castricini et al.,[27] which may be explained by the use of 2 PRP fibrin matrix constructs instead of 1. Several issues differentiate the liquid forms of PRP from this solid construct, including the time during which the factors are eluted into the environment. Another factor that may be of critical significance is the amount of material available. Using twice as much PRP fibrin matrix construct seems a plausible rationale to explain the lower retear rate in our study group than that observed by Castricini et al.

However, as Arnoczky[28] points out when using the Castricini data to compare their patients with normal to abnormal values, their MRI data found that the use of PRFM actually resulted in a statistically greater return to a normal footprint area ($P = .02$) and MRI signal intensity ($P < .001$) when compared with non-PRFM–treated individuals.

Strengths of this study include all operations being performed by a single surgeon using a standard single-row technique with high-strength sutures and the presence of a control group. These data were prospectively collected and a standard protocol followed. Limitations of this study include the lack of blinded randomization, the lack of gadolinium enhancement in the MRI studies, the time interval at which the MRI examinations were obtained, and the limited number of patients. In addition, for ethical reasons, it was not possible to perform second-look arthroscopies to assess the healing in these patients.

CONCLUSIONS

The addition of 2 PRP fibrin matrix constructs sutured into a primary rotator cuff tendon repair resulted in lower retear rates identified on MRI than repairs without the constructs. Other than the Rowe scores, there was no postoperative clinical difference by use of standard outcome measures.

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Biomechanical Comparison of Arthroscopically Performable Techniques for Suprapectoral Biceps Tenodesis

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Purpose: The aim of this study was to biomechanically compare the cyclic and ultimate failure load (UFL) of 4 widely used techniques for arthroscopically performable suprapectoral tenodesis of the long head of the biceps tendon (LHB). **Methods:** We used 28 fresh-frozen human cadaveric specimens (mean age, 65 years [range, 43 to 78 years; SD, 6.7 years]; 43% male specimens) to investigate 4 different techniques for LHB tenodesis. All techniques were performed in an open manner, with localization at the entrance of the bicipital groove. Two suture anchor techniques (Healix [DePuy Mitek, Raynham, MA], 5.5 mm, with modified lasso-loop stitch; BioSwiveLock [Arthrex, Naples, FL], 5.5 mm, with interlocking Krackow stitch) and two techniques using tenodesis screws (Bio-Tenodesis screw [Arthrex], 8 × 23 mm; Biceptor [Smith & Nephew, Andover, MA], 8 × 25 mm) were investigated. Under a 10-N preload, an axial cyclic load with 100 cycles, 1-Hz frequency, and 50-N maximum load was applied. UFL was evaluated with an axial traction of 0.2 mm/s. LHB displacement during testing was measured by 3-dimensional photogrammetry. **Results:** All techniques had a mean displacement of less than 3 mm after cyclic loading. The highest UFL was measured with the Bio-Tenodesis screw (mean, 218.3 N; range, 134.0 to 313.0 N; SD, 59.7 N) and the lowest with the BioSwiveLock (mean, 111.2 N; range, 60.0 to 156.8 N; SD, 32.3 N). The Healix had the second highest UFL (mean, 187.1 N; range, 144.7 to 245.0 N; SD, 35.5 N), followed by the Biceptor (mean, 173.9 N; range, 147.0 to 209.3 N; SD, 27.2 N). There was no significant difference between the Healix, Bio-Tenodesis screw, and Biceptor ($P > .05$), but the Healix and Bio-Tenodesis screw had a significantly higher UFL than the BioSwiveLock ($P < .01$). The failure mode was either suture cutout or failure at the anchor-suture-bone interface or of the tendon itself and was generally dependent on technique. **Conclusions:** All techniques resisted cyclic testing without a higher grade of displacement, and all devices except the BioSwiveLock had a satisfactory UFL whereas different failure mechanisms were present. The modified lasso-loop stitch provides sufficient tendon fixation and is equivalent to interference screws. **Clinical Relevance:** The lasso-loop suture anchor technique is an appropriate alternative for suprapectoral LHB tenodesis compared with tenodesis screw techniques.

Lesions of the long head of the biceps tendon (LHB) are often associated with and cause pain of the shoulder.[1-11] LHB tenodesis has been shown to be an appropriate therapy for LHB partial tears, massive rotator cuff tears with biceps damage, and biceps pulley lesions, as well as SLAP lesions.[12-15] Several studies have described and evaluated different techniques for LHB tenodesis.[12,15-33] LHB tenodesis can be performed open,[17] mini-open,[20,22,24,29] or arthroscopically.[14-16,18,21,27,28] Two options regarding the position of the tenodesis have been described: the suprapectoral position,[14-16,18,21,25-28,32,33] at the entrance of the bicipital groove, and the subpectoral position,[19,20,29,31] under the tendon of the pectoralis major muscle. Kusma et al.[30] have biomechanically tested arthroscopically perform-

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