Effects of Platelet-Rich Fibrin Matrix on Repair Integrity of At-Risk Rotator Cuff Tears

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Background: Increased age, larger tear size, and more advanced fatty degeneration of the rotator cuff musculature have been correlated with poorer healing rates after rotator cuff repair. Platelets are an endogenous source of growth factors present during rotator cuff healing.

Hypothesis: Augmentation of rotator cuff repairs with platelet-rich fibrin matrix (PRFM) may improve the biology of rotator cuff healing and thus improve functional outcome scores and retear rates after repair.

Study Design: Cohort study; Level of evidence, 3.

Methods: Rotator cuff tears at risk for retear were prospectively identified using an algorithm; points were assigned for age (50-59 years = 1; 60-69 years = 2; >70 years = 3), anterior-to-posterior tear size (2-2.9 cm = 0; 3-3.9 cm = 1; >4 cm = 2), and fatty atrophy (Goutallier score 0-2 = 0; Goutallier score 3-4 = 1). Three points were required for enrollment. Arthroscopic rotator cuff repair was performed with the addition of PRFM. Preoperative and 1-year postoperative magnetic resonance imaging (MRI) and functional outcome scores were obtained. Imaging and functional outcomes were compared with historical controls meeting the same enrollment criteria.

Results: Sixteen and 21 patients were enrolled in the PRFM and control groups, respectively. Mean age (65 ± 7 and 65 ± 9 years; P = .89), tear size (3.8 ± 1.1 and 3.9 ± 1.1 cm; P = .79), and median Goutallier scores (2 and 3; P = .18) were similar between the PRFM and control groups, respectively. Retear rates (56.2% vs 38.1%) were statistically significantly higher (P = .024) in the PRFM group compared with controls. Functional outcome scores postoperatively were not significantly improved compared with controls. Complications included 2 infections in the PRFM group.

Conclusion: The augmentation of at-risk rotator cuff tears with PRFM did not result in improved retear rates or functional outcome scores compared with controls.

Keywords: rotator cuff; arthroscopic; platelet-rich plasma; platelet-rich fibrin matrix (PRFM); outcomes; tendon healing; magnetic resonance imaging

Rotator cuff tears after arthroscopic repair in certain populations, including those with large and massive rotator cuff tears, continue to occur at rates as high as 94%. Although pain, range of motion, strength, and function may still be improved from baseline if the rotator cuff retears, open and arthroscopic rotator cuff repair outcomes data suggest that range of motion, strength, and functional results are inferior if retear occurs. Increasing age, larger tear size, and advanced fatty degeneration of the rotator cuff musculature have been implicated as risk factors for poor healing after rotator cuff repair and characterize the population at higher risk for retear. Up to this point in time, most advances in improving healing after rotator cuff repair have focused on improved initial biomechanical fixation or changes in postoperative rehabilitation. Limited data exist on biologic adjuvants to improve healing after rotator cuff repair (S. Weber and J. Kaufman, unpublished data, 2010). Cytokines and growth factors known to have a positive role in connective tissue formation have been shown to be present in rotator cuff healing and...
represent a potentially augmentable component of the healing process.\(^\text{17}\) Platelets are a readily available, endogenous source of several of these growth factors.\(^\text{1}\)

Platelet-rich plasma (PRP) preparations have been studied in vitro as well as applied clinically to aid in connective tissue healing. In vitro studies have demonstrated increased demineralized bone matrix osteoconductivity,\(^\text{14}\) increased cellular proliferation,\(^\text{19}\) as well as upregulation of markers, indicative of increased tendon stem cell differentiation into active tenocytes after application of PRP.\(^\text{41}\) Platelet-rich plasma was first popularized clinically in maxillofacial surgery applications in the 1990s\(^\text{22}\) and has since been applied in orthopaedic surgery with clinical benefit to relieve chronic epicondylar tendinosis; to augment Achilles tendon repair; to improve pain, motion, and activity scores after open subacromial decompression; and to relieve pain in patients with knee osteoarthritis.\(^\text{5,12,23,39,31}\)

Until 2010, the only report in the literature of PRP application in rotator cuff repair was an uncontrolled case series of 13 patients in which visual analog scale (VAS), University of California, Los Angeles (UCLA), and Constant scores were significantly improved at 24 months compared with preoperative scores.\(^\text{24}\) Data from randomized controlled trials have recently been reported with variable clinical outcomes, but none of the studies have demonstrated improved rotator cuff healing rates after arthroscopic rotator cuff repair (S. Weber and J. Kauffman, unpublished data, 2010).\(^\text{4,25}\) To date, these level I studies have focused on isolated supraspinatus tears or a highly variable range of tear sizes. A possible explanation for the limited effect of PRP on healing may be because of the fact that the small tears are likely to heal independent of repair construct or possible healing adjuvant. No studies have evaluated the effect of PRP on rotator cuff healing in tears at risk for limited healing.

The purpose of this study was to determine the effect of platelet-rich fibrin matrix (PRFM) augmentation to at-risk arthroscopic rotator cuff repairs on healing rates and functional outcome scores. We performed an observational cohort study in which a consecutive series of patients with rotator cuff tears at risk for retear was prospectively evaluated after arthroscopic repair augmented with PRFM. Clinical and magnetic resonance imaging (MRI) outcomes of the PRFM-augmented repairs were compared with historical controls with similar at-risk tears without PRFM augmentation.

**MATERIALS AND METHODS**

The study was approved by the institutional review board before the initiation of enrollment. Patients were enrolled in the study by 3 attending surgeons. Patients presenting or referred to these surgeons with complaints of shoulder pain or loss of function underwent routine evaluation and treatment. No standardized nonoperative treatment regimen was performed. Formal physical therapy, injections, and expectant management were recommended as indicated. Those with a diagnosis of rotator cuff tear having failed nonoperative management were considered for the study.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td></td>
</tr>
<tr>
<td>50-60</td>
<td>1</td>
</tr>
<tr>
<td>61-70</td>
<td>2</td>
</tr>
<tr>
<td>&gt;70</td>
<td>3</td>
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<td>Tear size, cm</td>
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<tr>
<td>2-3</td>
<td>0</td>
</tr>
<tr>
<td>3-4</td>
<td>1</td>
</tr>
<tr>
<td>&gt;4</td>
<td>2</td>
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<tr>
<td>Fatty atrophy (Goutallier score)</td>
<td></td>
</tr>
<tr>
<td>0-2</td>
<td>0</td>
</tr>
<tr>
<td>3-4</td>
<td>1</td>
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</tbody>
</table>

**TABLE 1. At-Risk Rotator Cuff Algorithm**

**Treatment Group.** Enrollment for the study began in September 2008 and continued until March 2010. Patients were selected prospectively for the study based on a 3-part algorithm used to identify rotator cuff tears at risk for retear (Table 1). A total algorithm score of 3 or greater was required for enrollment in the study. Additional eligibility criteria are reported in Table 2. Enrollment continued until a total of 20 patients received PRP. Four patients were excluded retrospectively from the final data analysis. Two were excluded after preoperative MRI scans were read by a blinded musculoskeletal radiologist and tear size was determined to be less than 2 cm. The third patient was excluded based on a total algorithm score of 2 instead of 3 after a blinded musculoskeletal radiologist determined preoperative tear size. The fourth patient would not return for a follow-up clinical evaluation and MRI scan. Six patients prospectively consented to the study but were excluded based on intraoperative assessment that the rotator cuff tear was not repairable (n = 5) and because the PRFM was determined to be of insufficient quality to suture in place per study protocol (n = 1). A total of 16 patients were included in the final PRFM group.

**Control Group.** Patients for the control group were selected retrospectively. All patients undergoing arthroscopic rotator cuff repair by the same 3 attending surgeons from March 2007 through August 2008 were identified by CPT (Current Procedural Terminology) code through our billing office. A letter inviting participation in the study was sent to those who met the same inclusion and exclusion criteria as the PRFM group. Those not responding to the letter were contacted by telephone and invited to participate. Thirty-eight eligible patients were identified and contacted initially by mail. Twenty-one patients completed enrollment and follow-up requirements. This included the only 2 patients in the group who had a retear before study initiation. They were not able to return for follow-up but were interviewed over the telephone. Their postoperative MRI scans were obtained before the study during routine follow-up for a persistently painful and dysfunctional shoulder status after rotator cuff repair.
TABLE 2
Eligibility Criteria

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>Algorithm score ≥3</td>
<td>Inflammatory joint disease</td>
</tr>
<tr>
<td>Full-thickness rotator cuff tear at least 2 cm in size</td>
<td>Active use of oral steroids</td>
</tr>
<tr>
<td>Age ≥60 y</td>
<td>Irreparable rotator cuff tear</td>
</tr>
<tr>
<td>Tear repairable by arthroscopic-only techniques</td>
<td>Subscapularis tear requiring open repair</td>
</tr>
<tr>
<td></td>
<td>Claustrophobia</td>
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<tr>
<td></td>
<td>Prior rotator cuff surgery on the affected shoulder</td>
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<tr>
<td></td>
<td>Failure to return for follow-up magnetic resonance imaging scan</td>
</tr>
</tbody>
</table>

Clinical Evaluation

All preoperative and postoperative clinical evaluations were performed by a physical therapist blinded to patient treatment group or by an orthopaedic surgery resident. Evaluations were performed on all PRFM patients preoperatively and at least 1 year postoperatively. Control patients were evaluated at least 1 year postoperatively. Data were collected to allow a determination of the treatment group or by an orthopaedic surgery resident. Available sequences and specific protocols have previously been reported.

MRI Evaluation

Noncontrast MRI studies were performed preoperatively and at 1 year after repair in all patients except 3, who remained asymptomatic postoperatively and in whom existed a clinical suspicion of retear. This included one patient in the PRFM group who had an infection, remained asymptomatic, and underwent MRI 3 months postoperatively. Data were collected to allow a determination of the treatment group or by an orthopaedic surgery resident. Two control patients had postoperative shoulder MRI at 7.5 and 10 months because of persistent symptoms. All postoperative MRI studies were done on a Siemens 1.5-T Avanto scanner (Berlin, Germany) with a dedicated shoulder coil with a 256 × 192 matrix. The following sequences were performed: coronal and sagittal T1-weighted views with repetition time (TR) of 500 ms and echo time (TE) of 15 ms, coronal and sagittal fast spin echo (FSE) T2-weighted images with fat saturation with TR of 4500 ms and TE of 80 ms, and axial FSE proton density with fat saturation with TR of 2500 ms and TE of 12 ms. Preoperative MRI scans were obtained at multiple locations, often before referral to one of the enrolling surgeons. Therefore, available sequences and specific protocols varied in these scans, but quality was nearly equivalent to those obtained at our institution. All measurements were performed retrospectively on a picture archiving and communication system (PACS) monitor. The preoperative scans were evaluated for the sagittal oblique tear length and Goutallier score. The tear length was measured on the T2-weighted images by a blinded musculoskeletal radiologist as described by Davidson et al, and was recorded as a continuous variable. Subscapularis tear size was not included in this measurement. The Goutallier score originally described for computed tomography was applied to MRI. Sagittal oblique T1-weighted sequences were used to assess the supraspinatus and infraspinatus muscle fatty degeneration as viewed on the most lateral oblique sagittal T1-weighted magnetic resonance images in which the scapular spine was seen in contact with the scapular body. This method has been previously reported and applied in this manner. A single score was determined based on the muscle (supraspinatus or infraspinatus) with more advanced degeneration (Figure 1). Goutallier scores represent a consensus of 2 orthopaedic surgeon evaluators.

Production of PRFM

Eighteen milliliters of venous blood were drawn from the antecubital vein by a standard technique using a sterile vacuum tube containing trisodium citrate. Nine milliliters of blood were drawn into each of 2 tubes, which were subjected to the same centrifugation stops. The red blood cells were separated by centrifugation at 1100 rounds per minute for 6 minutes. The supernatant of PRF was transferred into a second tube containing calcium chloride, which initiates the fibrin-clotting cascade. This tube was centrifuged at 1450 rounds per minute for 15 minutes. This yielded a sutureable fibrin clot. The Cascade Autologous Platelet System (Musculoskeletal Transplant Foundation, Edison, New Jersey) was used to prepare the PRFM. Resulting platelet, white blood cell, red blood cell, and growth factor concentrations resulting from this method of preparation have previously been reported.

Surgical Technique

All operations were performed with the patient in the seated beach-chair position under general anesthesia. A supplemental interscalene block was performed on all patients to help control postoperative pain. Prophylactic antibiotics were administered to all patients and consisted of 1 to 2 g (dose based on weight of the patient) of first-generation cephalosporin or a suitable alternative if an allergy existed. A standard arthroscopic pump was used in all cases, and standard posterior and anterior portals were established to perform a thorough diagnostic examination and address any intra-articular injury. After the standard intra-articular examination, the scope was placed in the subacromial space via the posterior portal, and a lateral portal was developed. Subacromial bursal tissue was removed to gain a clear view of the rotator cuff and to evaluate the tear. After the tear had been debrided and evaluated for its configuration, it was assessed for reparable. If the tear was amenable to repair, accessory portals for
gaining visibility or placing instruments or suture-passing instruments were used as needed. The standard operating portals included the lateral portal for instrumentation, an accessory superior portal for anchor placement, and the previously established anterior and posterior portals. Frequently, the scope was placed in an accessory posterolateral portal for better visualization of the rotator cuff tear, leaving the direct lateral portal free for instrumentation.

The footprint area of the greater tuberosity was thoroughly cleaned of soft tissue, and then, a full radius resector was used on high speed to lightly buff the outer cortex; bleeding was induced, but the surface was not removed down to cancellous bone. Single- or double-row techniques, subacromial decompression, biceps tenotomy or tenodesis, and repair of the subscapularis tendon were performed at the discretion of the surgeon in both the PRFM and control groups. Two PRFM clots were inserted at the site of repair over one limb of 2 separate suture anchors (Figure 2). Knots were tied using either a sliding locking knot or multiple half-hitch throws, thus pulling the cuff down to the greater tuberosity with the PRFM at the bone-tendon interface.

Postoperatively, all patients used an abduction sling (Ultrasling, DonJoy Inc, Vista, California) and started on a rehabilitation program. Under supervision, passive range of motion (ROM) was started at 4 to 6 weeks. Active assisted ROM was typically started at 6 to 8 weeks postoperatively, and full active ROM was commenced at 8 to 12 weeks with the longer time periods for very large tears. Strengthening exercises were typically delayed for 12 or more weeks. Return to all activity including sports was allowed at around 20 weeks.

Statistical Analysis

Statistical analyses were performed using STATA version 11.0 (StataCorp, College Station, Texas). For comparisons of unordered categorical patient demographic variables, the 2 groups were compared using the \( \chi^2 \) test if no expected cell frequency was less than 5 or with the Fisher exact test otherwise. For ordered categorical variables, the 2 groups were compared using the Wilcoxon-Mann-Whitney test. For continuous variables, the independent group \( t \) test was used. Significance for all tests was determined at the \( P < 0.05 \) level.

Given that the follow-up time differed between the PRFM and control groups and that the time to retear was not accurately known, a Poisson regression approach was taken. Poisson regression was used for both the retear and infection outcomes. For the infection outcome, all cases were in one group, so ordinary Poisson regression could not converge on a solution. Exact Poisson regression was therefore used.
TABLE 3
Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Control Group (n = 21)</th>
<th>PRFM Group (n = 16)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ± SD (range), y</td>
<td>64 ± 9 (51-84)</td>
<td>65 ± 7 (54-77)</td>
<td>.59</td>
</tr>
<tr>
<td>Left side, n (%)</td>
<td>8 (38)</td>
<td>5 (31)</td>
<td>.57</td>
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<tr>
<td>Preoperative tear size, mean ± SD, cm</td>
<td>3.9 ± 1.10</td>
<td>3.8 ± 1.1</td>
<td>.79</td>
</tr>
<tr>
<td>Goutallier score, median (interquartile range)</td>
<td>3 (2-3)</td>
<td>2 (1-3)</td>
<td>.18</td>
</tr>
<tr>
<td>Operative time, mean ± SD, min</td>
<td>101 ± 40</td>
<td>152 ± 51</td>
<td>.49</td>
</tr>
<tr>
<td>Double row, n (%)</td>
<td>1 (5)</td>
<td>3 (19)</td>
<td>.30</td>
</tr>
<tr>
<td>Full-thickness subscapularis tear, n (%)</td>
<td>6 (29)</td>
<td>3 (19)</td>
<td>.70</td>
</tr>
<tr>
<td>Subscapularis tear repaired, n (%)</td>
<td>6 (29)</td>
<td>3 (19)</td>
<td>.70</td>
</tr>
<tr>
<td>Biceps tenotomy or tenodesis, n (%)</td>
<td>15 (71)</td>
<td>13 (61)</td>
<td>.49</td>
</tr>
<tr>
<td>No. of suture anchors, mean ± SD</td>
<td>2.9 ± 0.6</td>
<td>2.9 ± 0.7</td>
<td>.59</td>
</tr>
<tr>
<td>Follow-up time, mean ± SD (range), mo</td>
<td>27 ± 8 (18-46)</td>
<td>13 ± 4 (3-13)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

aPRFM, platelet-rich fibrin matrix; SD, standard deviation.

TABLE 4
Functional Outcome Scores

<table>
<thead>
<tr>
<th></th>
<th>PRFM Groupb (n = 16)</th>
<th>Control Groupc (n = 21)</th>
<th>Postoperative</th>
<th>Postoperative Group Difference, PRFM</th>
<th>Minus Control (95% CI)d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome</td>
<td>Preoperative Mean (Range)</td>
<td>Postoperative Mean (Range)</td>
<td>P Value</td>
<td>Postoperative Mean (Range)</td>
<td>Postoperative Group Difference, PRFM</td>
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<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>Constant</td>
<td>46 (20-72)</td>
<td>78 (51-88)</td>
<td>&lt;.001</td>
<td>76 (52-95)</td>
<td>3 (–8 to 14), P = .53</td>
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<tr>
<td>WORC</td>
<td>36 (6-69)</td>
<td>80 (22-100)</td>
<td>&lt;.001</td>
<td>82 (42-100)</td>
<td>–4 (–25 to 16), P = .66</td>
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<tr>
<td>SANE</td>
<td>27 (0-60)</td>
<td>89 (60-100)</td>
<td>&lt;.001</td>
<td>87 (60-100)</td>
<td>1 (–13 to 14), P = .92</td>
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<tr>
<td>ASSES</td>
<td>38 (15-67)</td>
<td>87 (60-100)</td>
<td>&lt;.001</td>
<td>84 (32-100)</td>
<td>–4 (–19 to 12), P = .65</td>
</tr>
<tr>
<td>UCLA</td>
<td>12 (6-20)</td>
<td>29 (19-34)</td>
<td>&lt;.001</td>
<td>29 (22-85)</td>
<td>2 (–4 to 7), P = .55</td>
</tr>
</tbody>
</table>

aPRFM, platelet-rich fibrin matrix; CI, confidence interval; WORC, Western Ontario Rotator Cuff Index; SANE, Single Assessment Numeric Evaluation; ASSES, American Shoulder and Elbow Surgeons; UCLA, University of California, Los Angeles.
bPaired sample t tests compare preoperative to postoperative scores for PRFM group only.
cPreoperative scores were not available for the control group.
dMultivariable linear regression on the postoperative value, with group as the primary predictor, controlling for follow-up time.

For the PRFM group, the preoperative values were compared with the postoperative values using a paired sample t test. The postoperative values were compared between PRFM and control groups using a multivariate linear regression, with the group as the primary predictor, and controlling for follow-up time.

RESULTS

A total of 16 and 21 patients were included in the PRFM and control groups, respectively. Patient, rotator cuff tear, and operative procedure characteristics for both groups are reported in Table 3. Age (64.6 ± 7.0 years and 65.0 ± 8.7 years; P = .89), rotator cuff tear size (3.9 ± 1.1 cm and 3.9 ± 1.1 cm; P = .79), and Goutallier scores (median, 2; interquartile range [IQR], 1-3; and median, 3; IQR, 2-3; P = .13) were statistically similar between groups. The incidence of full-thickness subscapularis tendon tears requiring repair (19% and 29%; P = .70), number of suture anchors used (2.9 and 2.9; P = .99), rate of biceps tenotomy or tenodesis (81% and 71%; P = .49), frequency of double-row repair (19% and 5%; P = .30), and operative times (152 and 161 minutes; P = .49) were similar between PRFM and control groups, respectively. Mean time to follow-up was significantly longer (P < .001) in the control group (27 ± 8 months) when compared with the PRFM group (13 ± 4 months). This was an expected finding given the study methodology.

Functional Outcome Scores

Mean preoperative and postoperative functional outcome scores as well as score ranges are reported for the PRFM group in Table 4. Control group postoperative scores are also reported in Table 4. Postoperative Constant, WORC, SANE, ASSES, and UCLA scores all significantly improved (P < .001) when compared with preoperative values. When compared with the control group postoperative functional outcome scores, the PRFM postoperative scores were not statistically significantly improved (P > .55). Controlling for follow-up time and using group as the primary predictor, there was no difference between PRP and control groups for any of the functional outcomes (P ≥ .55) (Table 4).
Rotator cuff retear rates are reported in Table 5. The rate in the control group (0%) was significantly higher than in the PRFM group (38%) \((P = .024)\). This significant difference remained when double-row repairs (3 from the PRFM group and 1 from the control group) were removed from the study \((P = .022)\) (Table 5). We observed no association between follow-up time and retear \((control\ group, r = .04, P = .86; PRFM\ group, r = -.06, P = .92)\).

**Complications**

Rate of infection was higher in the PRFM group (12%) than in the control group (0%). This difference did not reach statistical significance \((P = .16)\). The 2 patients who received PRFM and became infected underwent their index procedures within 1 week of each other. Both presented on a delayed basis postoperatively with vague symptoms of ongoing discomfort and persistent swelling without fevers. The aspirate finding was positive in both cases for *Propionibacterium acnes*. One patient underwent irrigation and debridement arthroscopically on 2 occasions, initially 5.5 weeks postoperatively and then again 1 week later. Suture anchors were removed at the time of the second irrigation and debridement. This patient was followed by the infectious disease service and treated with intravenous and oral antibiotics and was followed by the infectious disease service at our institution. His symptoms improved with treatment, and follow-up MRI demonstrated an intact rotator cuff. Both infections were reported to the institutional review board. Adverse event reports were filed per protocol. The second infection was confirmed after the final patient had been enrolled.

**DISCUSSION**

This historically controlled, observational cohort study failed to demonstrate that rotator cuff retear rates and functional outcome scores at 1 year postoperatively are improved in this at-risk population with PRFM augmentation. Not only do these results suggest a lack of improvement, but there is also concern for worse healing rates as well as an increased infection risk with PRFM augmentation.

An algorithm was developed to identify patients with rotator cuff tears at risk for a retear. Increasing age, larger rotator cuff tear size, and increased fatty degeneration of rotator cuff musculature have all been implicated as risk factors for poor healing after rotator cuff repair.\(^2,6,28,38\) This at-risk population includes those with large or massive rotator cuff tears but also included those with medium-sized tears coupled with other risk factors such as fatty degeneration or advanced age. The aim in isolating this population was to identify a population in which a retear after repair occurs at a high enough frequency that differences in retear rates with augmentation of PRFM might be detected with a relatively small number of patients. With a combined group retear rate of 46%, it was thought that the algorithm identified the targeted at-risk population, although the retear rate was lower than that reported for large massive arthroscopically repaired rotator cuff tears.\(^1,25\)

The PRP formulations are certainly of theoretical interest in this scenario and have basic science to support their use clinically.\(^14,41\) Applications in a variety of settings have also demonstrated promise.\(^9,18,28,30,32\) Rotator cuff animal models have demonstrated improved histological outcomes after biologic augmentation.\(^18,30\) However, randomized controlled studies applying PRP, including PRFM, to rotator cuff tears have not proven consistently beneficial when outcomes such as postoperative narcotic use, ASES score, Constant score, UCLA score, VAS, and postoperative MRI are evaluated (S. Weber and J. Kauffman, unpublished data, 2010).\(^4,28\) Castori et al.\(^4\) reported a trend toward improved MRI outcome with PRFM, but the study was not powered for the imaging outcome. The only positive clinical outcomes were reported by Randelli et al.\(^20\) and amounted to improved pain scores in the first postoperative month compared with controls and improved UCLA and Constant scores and external rotation strength at 3 months. Other level I studies failed to show significant improvements in clinical outcomes postoperatively compared with controls (S. Weber and J. Kauffman, unpublished data, 2010).\(^4\) Our clinical outcomes are consistent with this majority of data (unpublished data).

This is the first report of a statistically significant negative imaging outcome result following PRFM- and/or PRP-augmented rotator cuff repair. The concept, however, of delayed healing secondary to fibrin clot presence is not new. It was reported in a rat supraspinatus tear model in

### TABLE 5

<table>
<thead>
<tr>
<th>Outcome</th>
<th>PRFM Group ((n = 16))</th>
<th>Control Group ((n = 21))</th>
<th>Rate Ratio</th>
<th>95% Confidence Interval</th>
<th>(P) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of retears</td>
<td>9 (56%)</td>
<td>8 (38%)</td>
<td>8.30</td>
<td>1.16-7.77</td>
<td>.024</td>
</tr>
<tr>
<td>No. of retears in subgroup of single-row repairs</td>
<td>8/13 (62%)</td>
<td>8/26 (46%)</td>
<td>8.14</td>
<td>1.18-8.37</td>
<td>.022</td>
</tr>
</tbody>
</table>

*PRFM, platelet-rich fibrin matrix.*

Magnetic Resonance Imaging

Rotator cuff retear rates are reported in Table 5. The rate of retear in the PRFM group (56%) was significantly higher than in the control group (38%) \((P = .024)\). This significant difference remained when double-row repairs (3 from the PRFM group and 1 from the control group) were removed from the study \((P = .022)\) (Table 5). We observed no association between follow-up time and retear \((control\ group, r = .04, P = .86; PRFM\ group, r = -.06, P = .92)\).*
which fibrin clot was implanted at the defect site and led to a decrease in material properties at 3 weeks compared with controls. The authors suggested that an exogenous clot may have served as a barrier to tissue remodeling, thus the detrimental effect.

This study has several weaknesses and therefore may not definitively address the use of PRFM in this population. Although patients were prospectively identified and enrolled in our study, there was no randomization to a control group. There is inherent selection bias in using historical controls. Attempts to minimize this bias included subjecting control patients to the same selection algorithm and enrollment criteria as well as making a special effort to recruit patients to the control group who we knew had not done well postoperatively and had MRI-confirmed rotator cuff retears before initiation of the study. This included telephone interviews to complete questionnaires for those patients who were unable to travel to our institution. Despite the possibility of selection bias, the patient, rotator cuff tear, and operative procedure characteristics were similar between groups and suggest that an adequate comparison group was recruited.

The relatively small number of patients is also a weakness but would be of greater concern if results had not reached statistical significance. The heterogeneity of rotator cuff repair techniques may also be cited as a weakness. One control group patient and 3 PRFM group patients received at least a partial suture-bridge repair technique. There is some evidence to suggest that healing rates are improved with a double-row technique. This potential confounding variable would be of increased significance if the PRFM group had improved healing rates compared with controls. The mean clinical follow-up time of 13 months in the PRFM group is also a weakness. Thus, the PRFM group functional outcomes in this report should be considered preliminary, although it is unlikely with the higher retear rate that PRFM group scores would significantly improve with increased follow-up time relative to the historical control group with a mean clinical follow-up of 27 months.

The rate of infection in the PRFM group is concerning. A total of 20 patients at our institution received PRFM, although for reasons mentioned above, 4 were excluded. Two became infected; thus, we had a 10% infection rate including all patients who received PRP. This is markedly higher than the reported 0.006% to 3.4% infection rates for shoulder arthroscopy. No infections have occurred in other studies in which PRFM has been applied to rotator cuff tears (S. Weber and J. Kauffman, unpublished data, 2010). The root cause of the infection cannot be stated with any certainty, but the possible role of PRFM must be considered. The multiple steps necessary to prepare PRFM require additional interactions between sterile and nonsterile fields and introduce variables that may increase infection risk. Alternatively, Castillo et al proposed that leukocyte-poor PRP preparations may lack a component of immunomodulatory capacity that could aid in preventing infection at the site of tissue injury. The Cascade system used in this study is one such system, with reported leukocyte counts significantly lower than at least 2 other PRP preparations. More studies are needed to better delineate the role of leukocytes in PRP as well as the risk of infection associated with PRP use.

The failure of multiple studies to demonstrate consistent benefit of PRP is likely multifactorial but may be related to suboptimal platelet concentrations, delivery mechanisms, methods for retaining the platelets in vivo at the site of desired effect, and patient selection. Recent reports have emphasized that not all PRP separation systems yield a similar product. Platelet concentrations and therefore platelet-derived growth factor concentrations may differ between systems. The ideal concentration for optimized in vivo effect is not known, but PRP clot releasate has been shown to enhance tendon stem/progenitor cell proliferation in a dose-dependent manner in vitro, suggesting that platelet concentration does matter. Additionally, the nature of the PRP delivery is variable among systems and helps determine the efficacy and timing of growth factor activity. Han et al demonstrated that the use of bovine thrombin with PRP preparations induced immediate platelet degranulation and eliminated the stimulatory effects. Furthermore, the ability of a PRFM to retain elevated levels of TGF-β for 1 to 3 days and to stimulate cell proliferation in vitro was shown to be inferior to platelet-rich fibrin membrane. These studies highlight the necessity of an optimal PRP delivery medium. To our knowledge, the duration of platelet and growth factor retention at the site of delivery following PRP application under the conditions of arthroscopy has not been studied. The population to most benefit from PRP has not yet been clearly identified. We identified a population that may be at high risk for rotator cuff retear no matter how the repair is augmented. Other studies have not been able to demonstrate consistent improvement in postoperative functional or imaging outcomes following PRP augmentation for small to medium-sized tear repair (S. Weber and J. Kauffman, unpublished data, 2010). More evidence is needed to more clearly define the population that will benefit from PRP.

In conclusion, this study does not support the use of PRFM as formulated for this study for the augmentation of rotator cuff repair in this at-risk population. Inferior rotator cuff healing rates as assessed by MRI were demonstrated. No functional outcome benefit was obtained with PRFM augmentation, although these results may be considered preliminary secondary to follow-up time. The findings do not justify the increased expense, increased technical difficulty, and possibly increased risk of infection. Further study is needed to determine the role of autologous platelet-derived growth factors for augmentation of rotator cuff repair. It is possible that optimization of patient selection, platelet and growth factor concentration, delivery, and retention may yield more demonstrable clinical benefit.

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Repair Integrity and Functional Outcome After Arthroscopic Rotator Cuff Repair

Double-Row Versus Suture-Bridge Technique

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Background: Only a few studies have examined repair integrity and functional outcome after arthroscopic suture-bridge rotator cuff repair procedure. In addition, no reported study has compared outcomes between the suture-bridge and double-row techniques.

Purpose: This study compared the functional outcome and repair integrity of arthroscopic double-row and conventional suture-bridge repair in full-thickness rotator cuff tears.

Study Design: Cohort study; Level of evidence, 2.

Methods: Fifty-two consecutive full-thickness rotator cuff tears with 1 to 4 cm of anterior to posterior dimension that underwent arthroscopic rotator cuff repair were included. A double-row technique was used in the first 26 consecutive shoulders, and a conventional suture-bridge technique was used in the next 26 consecutive shoulders. Fifty shoulders (92.5%) underwent magnetic resonance imaging or ultrasonography postoperatively. Clinical outcomes were evaluated a minimum of 2 years (mean, 37.2 months; range, 24-54) postoperatively using the University of California at Los Angeles (UCLA), American Shoulder and Elbow Surgeons (ASES), and Constant scores. The postoperative cuff integrity was evaluated a mean of 33.0 (range, 10-54) months postoperatively.

Results: At the final follow-up, the average UCLA, ASES, and Constant scores improved significantly, to 32.3, 90.5, and 80.7, respectively, in the double-row group and to 30.6, 88.5, and 74.0, respectively, in the suture-bridge group. The UCLA, ASES, and Constant scores improved in both groups postoperatively (all \( P < .001 \)); however, there was no significant difference between the 2 groups at final follow-up (\( P = .185, .585, \) and .053, respectively). The retear rate was 24% in the shoulders that underwent double-row repair and 20% in the shoulders that underwent suture-bridge repair; this difference was not statistically significant (\( P = .733 \)).

Conclusion: The arthroscopic conventional suture-bridge technique resulted in comparable patient satisfaction, functional outcome, and rates of retear compared with the arthroscopic double-row technique in full-thickness rotator cuff tears.

Keywords: rotator cuff; double-row; suture-bridge

Arthroscopic rotator cuff repair is a common surgical procedure. Although most studies have shown improved clinical outcomes after repair, high rates of healing failure and retears have been observed with ultrasound and magnetic resonance imaging (MRI) after surgery.8,16 Biomechanical studies have shown that the recently introduced arthroscopic suture-bridge technique improved the pressurized contact area and mean pressure between the tendon and footprint compared with conventional double-row techniques.15,19 The suture-bridge technique has advantages over double-row repair in that it uses the suture limbs from the medial suture knots to bridge and compress the repaired tendon and reduces the surgical steps.18-20 In addition, suture-bridge repair may allow quick arthroscopic cuff repair with reduced knot impingement compared with conventional double-row techniques.

We hypothesized that these biomechanical advantages of the suture-bridge repair would result in a higher healing rate than for conventional double-row repairs. However, only a few studies have examined repair integrity and functional outcome of this arthroscopic suture-bridge rotator cuff repair procedure.5,11,12,24 To our knowledge, no reported study has compared clinical and radiological outcomes between the suture-bridge and double-row techniques. Thus, in this prospective study, we compared the functional outcome and repair integrity of the arthroscopic double-row and conventional suture-bridge repair methods in full-thickness rotator cuff tears.