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SECEC Research Grant 2008 II: Use of platelet- and leucocyte-rich fibrin (L-PRF) does not affect late rotator cuff tendon healing: a prospective randomized controlled study

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Background: Because the retear rate after rotator cuff repairs remains high, methods to improve healing are very much needed. Platelet-rich concentrates have been shown to enhance tenocyte proliferation and promote extracellular matrix synthesis in vitro; however, their clinical benefit remains unclear. We hypothesized that arthroscopic rotator cuff repair with leucocyte- and platelet-rich fibrin (L-PRF) results in better clinical and radiographic outcome at 12 months of follow-up than without L-PRF.

Methods: Thirty-five patients were randomized to receive arthroscopic rotator cuff repair with L-PRF locally applied to the repair site (L-PRF+ group, n = 17) or without L-PRF (L-PRF− group, n = 18). Preoperative and postoperative clinical evaluation included the Subjective Shoulder Value, visual analog score for pain, Simple Shoulder Test, and Constant-Murley score. The anatomic watertight healing, tendon thickness, and tendon quality was evaluated using magnetic resonance arthrography at 12 months of follow-up.

Results: No complications were reported in either group. The mean Subjective Shoulder Value, Simple Shoulder Test, and Constant-Murley scores increased from preoperatively to postoperatively, showing no significant differences between the groups. Complete anatomic watertight healing was found in 11 of 17 in the L-PRF+ group and in 11 of 18 in the L-PRP− group ($P = .73$). The mean postoperative defect size (214 ± 130 mm^2 in the L-PRF+ group vs 161 ± 149 mm^2 in the L-PRF− group; $P = .391$) and the mean postoperative tendon quality according to Sugaya (L-PRF+ group: 3.0 ± 1.4, L-PRF− group: 3.0 ± 0.9) were similar in both groups at 12 months of follow-up.

Conclusion: Arthroscopic rotator cuff repair with application of L-PRF yields no beneficial effect in clinical outcome, anatomic healing rate, mean postoperative defect size, and tendon quality at 12 months of follow-up.

Level of evidence: Level I, Randomized Controlled Trial, Treatment Study.

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Keywords: Shoulder arthroscopy; rotator cuff; leucocyte and platelet-rich fibrin (L-PRF); platelet-rich concentrates

This study complied with local ethical approval guidelines.

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Despite developments in surgical techniques and suture materials, the failure rates of open,[26,58] arthroscopic single-row,[6,24] and double-row repairs[20,31] are still very high. The incidence of failure of the tendon to heal after rotator cuff repair is variable and is reported in up to 94%.[24] Age is one of the most significant predisposing factors, with significantly higher failure rates in patients older than 65 years.[6] A possible explanation for this is decreased vascularization at the critical zone near the insertion of the rotator cuff.[41,50,52] Compared with healthier rotator cuff tissue, degenerative rotator cuff tissue has a significantly less vascular microcirculation.[4] This decrease in the vascular supply may predispose to the development of rotator cuff tendinopathy[53] and to a decreased healing rate after attempted repair.[19]

Owing to the limited ability of the rotator cuff to heal, several new strategies have been proposed, including biologic augmentation of the ruptured rotator cuff with growth factors and cytokines, gene therapy, and stem cell application.[10,32-34,48]

Platelet-rich concentrates are classified according to the presence of leucocytes and to the polymerization technique of the fibrin.[18] To our knowledge, 5 clinical studies have been published using a leucocyte- and platelet-rich plasma (L-PRP)[36,48] and a leucocyte-poor or pure platelet-rich fibrin (P-PRF)[3,10,51] in rotator cuff repair.

Conversely, autologous leucocyte- and platelet-rich fibrin (L-PRF), as described by Dohan et al,[14-16] is a bioactive component of whole blood that includes platelet activation and fibrin polymerization. This simple and open-access matrix can be produced by a standard centrifugation procedure during the surgical operation in less than 20 minutes. Its production is cost-effective because it can be produced in a glass-coated tube without any additives. Unlike PRP, L-PRF does not dissolve quickly during the hours after application.[57] Furthermore, due to the primary fibrin polymerization, the stable matrix leads to an entrapment of growth factors that allows a continuous slow release of growth factors for up to 28 days.[57] In addition to the platelets, the leucocytes produce a significant amount of growth factors that are known to promote healing.[17] The fibrin matrix in the L-PRF also may have an effect on the healing of the surrounding tissue by increasing neovascularization.[11] Our previous prospective randomized pilot study demonstrated that the application of L-PRF was technically feasible during arthroscopic rotator cuff repair and yielded higher early vascularization at 6 weeks.

To date, however, there are no data from randomized trials assessing the radiographic outcome and clinical benefit of L-PRF augmentation in rotator cuff repair. This study evaluated the clinical and radiographic outcome, with and without application of L-PRF in rotator cuff repair, of posterosuperior tears at 12 months postoperatively. We hypothesized that biologic augmentation with L-PRF would result in an increased improvement in shoulder outcome, a better anatomic healing rate, and increased tendon thickness and quality.

Materials and methods

This prospective randomized blinded study assessed the clinical and radiographic influence of intraoperative biologic augmentation of L-PRF in repair of chronic rotator cuff tendon tears.

Patient data

Thirty-five consecutive patients with chronic posterosuperior full-thickness rotator cuff tears were treated between October 2008 and March 2009 with a primary arthroscopic repair by the senior surgeon (P.B.) or under his direction.

Inclusion and exclusion criteria

Patients were included (1) if they had a posterosuperior chronic full-thickness detachment limited to the supraspinatus and infraspinatus tendon with intact insertions of the subscapularis, (2) if an arthroscopic double-row cuff repair with complete coverage of the footprint could be performed, if necessary, after release of the coracohumeral ligament from the coracoid and a supraglenoid capsular release, and (3) if they were aged older than 55 years. Also included were individuals with additional biceps pathology, including delamination, tenosynovitis, inflammation, subluxation, and dislocation.

Patients were excluded when the tear or the repair was only partial thickness and when there had been a previous operation at the rotator cuff. Diagnoses such as extension of the tear to the subscapularis tendon, which requires surgical intervention, an isolated subscapularis tear, workers' compensation claims, or a labral pathology amenable to surgical repair also resulted in the exclusion of these patients.

Contraindications to arthroscopic cuff repair were upward humeral migration (an acromiohumeral distance of <6 mm on the anteroposterior radiographs with the shoulder in neutral rotation), associated glenohumeral osteoarthritis, or severe muscle atrophy or fatty infiltration (stage 3 or 4 according to the classification system of Goutallier et al[30]) on a computed tomography arthrogram or magnetic resonance imaging (MRI) study.[22] Patients were definitively included in the study protocol after confirming the diagnosis at the beginning of the surgery when the diagnostic arthroscopy was performed.

Randomization

A block randomization was performed with a block size of 18 vs 17 patients.[44] In the test group (L-PRF+), we used an arthroscopic transosseous equivalent double-row rotator cuff repair with additional application of 4-folded L-PRF matrices in between the bone and the tendon. In the control group (L-PRF−), we used the same rotator cuff repair, without the application of L-PRF. Patients were blinded to the treatment they had received. Clinical assessments, scores, and radiographic evaluation were performed by independent observers blinded to the treatment provided.

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