

Arthroscopic Rotator Cuff Repair with Biphasic Interpositional Allograft Augmentation



Navya Dandu, B.S., Derrick M. Knapik, M.D., Athan G. Zavras, B.A.,
Grant E. Garrigues, M.D., and Adam B. Yanke, M.D., Ph.D.

Abstract: Rotator cuff repair in the setting of a chronic tear or poor tissue quality presents a surgical challenge because of the high risk of structural failure. Patients with an increased risk of retear may be candidates for entheses augmentation with a novel, biphasic allograft, composed of a demineralized cancellous matrix with a layer of mineralized bone. This interpositional graft was designed with the intention to promote both soft-tissue and osseous integration into the matrix, thereby conferring greater stability and regeneration of the transitional zone of the rotator cuff entheses. Here, we describe a technique for a transosseous-equivalent supraspinatus repair with placement of a biphasic interpositional allograft.

Arthroscopic rotator cuff repair is frequently performed with overall positive clinical improvement and long-term outcomes.¹ Despite clinical success, poor tendon healing frequently results in retear, with rates cited up to 94%.² Structural healing failure may subsequently lead to persistent pain, loss of functional capacity, and osteoarthritis progression.³ Several risk factors have been identified and investigated in relation to structural failure, including increasing patient age, tear size, male sex, tear thickness, tissue quality, and muscle quality.⁴

Addressing healing of the entheses is a well-recognized issue and has led to biomechanical comparisons of

various repair techniques.⁵ Graft augmentation on the superior surface of the tendon, frequently with human dermal allograft, has been evaluated in a recent meta-analysis showing improvement when a graft is used to augment a rotator cuff repair versus the repair alone.^{6,7} Despite its proposed benefits, limitations of dermal allograft still include dependence on graft availability, increased cost, and increased operative time. Furthermore, onlay graft options do not reliably address the core issue of inability to recapitulate the architecture of the transition zone—uniquely adept at transitioning stress from the soft tissue of the rotator cuff to the hard tissue of the greater tuberosity bone.⁸

Other options include graft augmentation under the tendon repair in an attempt to augment the healing of this critical area. Platelet-rich plasma and bone marrow aspirate concentrate have been used with some success to augment the biology in this region.⁹⁻¹³ Anchor fenestrations, open architecture, and wicks have all been used to allow egress of marrow elements from the greater tuberosity into the footprint, but as of yet, no superior clinical improvement in the efficacy of healing has been demonstrated.¹⁴⁻¹⁷

In 2013, Dickerson et al.¹⁸ demonstrated the use of a biphasic cancellous bone-derived scaffold prototype in an ovine model, with histological evidence of a regenerated transitional zone with the use of the allograft. After adaptations of this prototype, the current biphasic allograft is now available for clinical use. The graft is composed of human cancellous bone, with a portion of the graft demineralized to mimic the Sharpey fibers that form the critical transition between the hard and soft tissues of the transition zone. This design seeks to

From the Rush University Medical Center, Department of Orthopaedics, Chicago, Illinois, U.S.A.

The authors report the following potential conflict of interest or source of funding: G.E.G. reports personal fees from Additive Orthopaedics, CultivateMD, DJ Orthopaedics, Genesys, Mitek, PatientIQ, ROM3, Tornier, Inc., Encore Medical, DePuy Synthes, Wright Medical, Medical Device Business Service, Inc, Bioventus LLC, and Smith & Nephew; and other from Arthrex, AANA, ASES, DJ Orthopaedics, JSES, South Tech, and Techniques in Orthopaedics. A.B.Y. reports personal fees from JRF Ortho and Olympus; grants from Organogenesis, Vericel, Arthrex, Inc.; and non-financial support from Patient IQ, Smith & Nephew, and Sparta Biomedical; and other from Patient IQ. Full ICMJE author disclosure forms are available for this article online, as [supplementary material](#).

Received August 26, 2021; accepted November 21, 2021.

Address correspondence to Adam B. Yanke, M.D., Ph.D., Rush University Medical Center, Department of Orthopaedics, 1611 W Harrison St, Suite 300, Chicago, IL 60612, U.S.A. E-mail: Adam.yanke@rushortho.com

© 2022 THE AUTHORS. Published by Elsevier Inc. on behalf of the Arthroscopy Association of North America. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

2212-6287/211245

<https://doi.org/10.1016/j.eats.2021.11.021>

promote both soft tissue and osseous ingrowth for enhanced integration. Because of recent Food and Drug Administration approval for commercial use, long-term clinical studies to date are limited.

This article outlines a technique for arthroscopic, transosseous-equivalent supraspinatus repair augmented with a novel rotator cuff enthesis allograft augment (BioEnthesis; Sparta Biopharma, Madison, NJ).

Surgical Technique

Preoperative Assessment

For patients who meet operative indications for rotator cuff repair, extensive preoperative counseling should include optimizing all modifiable risk factors including smoking/nicotine cessation, management of hypercholesterolemia, optimization of diabetes mellitus, and education on postoperative sling use and rehabilitation to provide the optimal mechanical environment for healing.

Preoperative Positioning and Set-Up

An interscalene block is performed in the preoperative holding area. The patient is initially positioned supine with all bony prominences well padded to allow for the induction of anesthesia. The patient is then placed into the beach-chair position, and an arm positioning holder is attached, followed by standard prepping and draping of the operative shoulder.

Diagnostic Arthroscopy

A diagnostic arthroscopy is performed using the standard posterior portal to evaluate for intra-articular injury to the chondral surfaces of the glenoid and humeral head, the glenoid labrum, biceps tendon, the presence of any loose bodies, as well as the extent of rotator cuff tearing intra-articularly (Video 1). A standard anterior portal is created using spinal needle localization through the rotator interval. The arthroscope is then placed into the subacromial space, and a lateral portal is created to allow for performance of an anterolateral and posterior subdeltoid bursectomy. Acromial morphology is visualized, and an acromioplasty is performed when indicated in the presence of an acromial spur or down-sloping acromion. The quality and mobility of the rotator cuff tear is then determined, and the reducibility of the tear to the native footprint on the greater tuberosity is evaluated.

Rotator Cuff Repair with Graft Augmentation

Repair augmentation using the biphasic interpositional graft is indicated in the presence of thin, poor quality rotator cuff tissue, massive tears, or in the revision setting. The native tendon footprint at the greater tuberosity is gently debrided using a combination of an electrocautery device and bone cutting

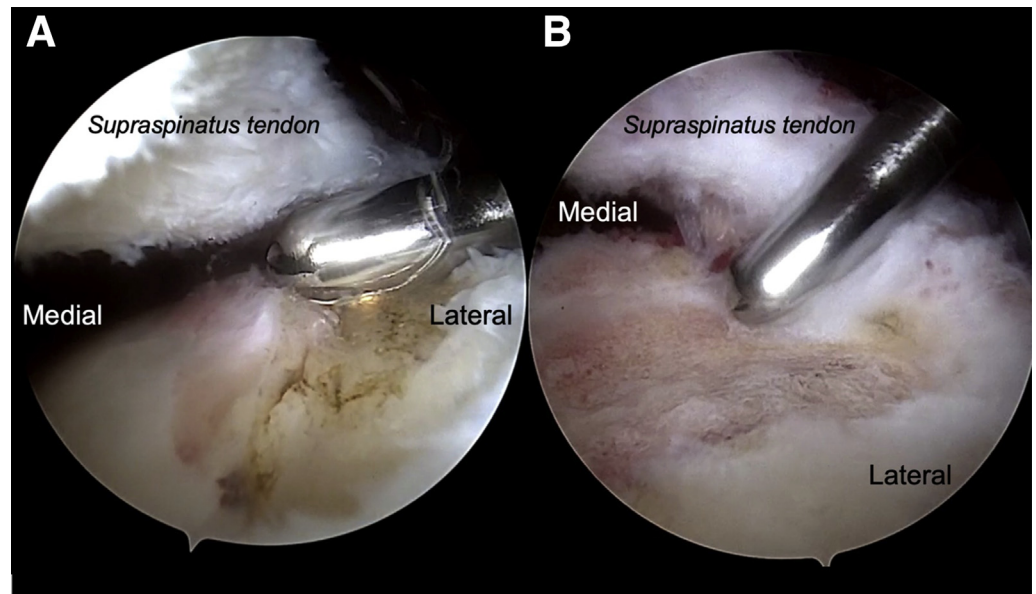
shaver to obtain a stable petechial bleeding bony surface (Fig 1). Two medial row anchors are then placed, spanning the exposed footprint, to set the anterior and posterior boundaries of the allograft along the medial edge. The anterior-to-posterior distance between the medial anchors is then measured, as well as the distance from the medial anchors to the lateral edge of the footprint to calculate the appropriate dimensions of the graft. Medial sutures are then passed using a suture passing device in a horizontal mattress configuration, while tapes are passed medial to the sutures in a rip-stop configuration. The greater tuberosity is then decorticated between the anchors using a bone cutting shaver to allow for the allograft to sit within the defect. Decortication can also be performed prior to anchor placement. The footprint can be further augmented with marrow stimulation, depending on the level of decortication performed.

The allograft is prepared on the back table by first hydrating the graft in saline solution and then cutting the graft using a scalpel to the appropriate size based on the measurements performed within the joint (Fig 2). The graft can then be introduced within the joint through the lateral portal using a grasper or hemostat. Care should be taken to not over compress the graft or fold it at acute angles. The graft is initially held in place with the cortical side of the graft on the footprint using 1 to 2 percutaneous spinal needles (Fig 3). The medial row sutures are tied down sequentially using standard knot-tying techniques, allowing for temporary reduction of the tendon with the allograft underneath. Suture tapes are then tensioned and secured to the anterolateral and posterolateral aspect of the footprint using knotless anchors, ensuring that the allograft remains interposed between the tendon and the footprint (Fig 4). Although typically not necessary because the medial row sutures provide a medial buttress, if desired, intra-articular placement of the arthroscope can confirm reduction of the rotator cuff as well as extra-articular placement of the graft. Bone marrow aspirate concentrate or platelet-rich plasma can be instilled into the spongy architecture of the graft, if desired. The arthroscope is then removed from the joint and standard arthroscopic portal closure is performed. Pearls and pitfalls of this technique are presented in Table 1.

Postoperative Rehabilitation

After surgery, patients follow a standard arthroscopic rotator cuff repair treatment algorithm. During the first-phase rehabilitation from weeks 0-6, patients remain in the sling at all times with the exception of pendulum and therapy activities. Early therapy can start at 2 weeks from surgery with exercises directed at beginning early passive range of motion, concentrating on closed-chain scapula and posterior capsule mobilization with avoidance to stretching the anterior capsule

Fig 1. With the patient in beach chair positioning, viewing from the posterior portal, preparation of the native footprint for placement of the allograft with (A) electrocautery device and (B) bone cutting shaver (Arthrex, Naples, FL) are performed through the anterior portal. This is determined to be satisfactory when a stable petechial bleeding bony surface is created.



with shoulder extension. Pendulums, as well as gentle elbow, wrist and hand range of motion exercises are encouraged. After 6 weeks, patients discontinue the sling and progress to working on aggressive range of motion and stretching of the posterior capsule with scapular strengthening, with no resistive rotator cuff strengthening until week 12. No resisted biceps flexion is advised until 8 weeks after biceps tenodesis. Beginning at 12 weeks, patients may perform full range of motion as tolerated with no motion or lifting restriction, along with the introduction of sport specific activities.

Restrictions are lifted, and full recovery with gradual return to play is generally achieved at 5 to 6 months after surgery.

Discussion

Massive and revision rotator cuff tears present a significant challenge to the treating surgeon, most commonly presenting as chronic injuries in an older patient population with significant medical comorbidities, all of which contribute to poor tissue quality.¹⁹⁻²¹ To increase the chance for a successful healing at the

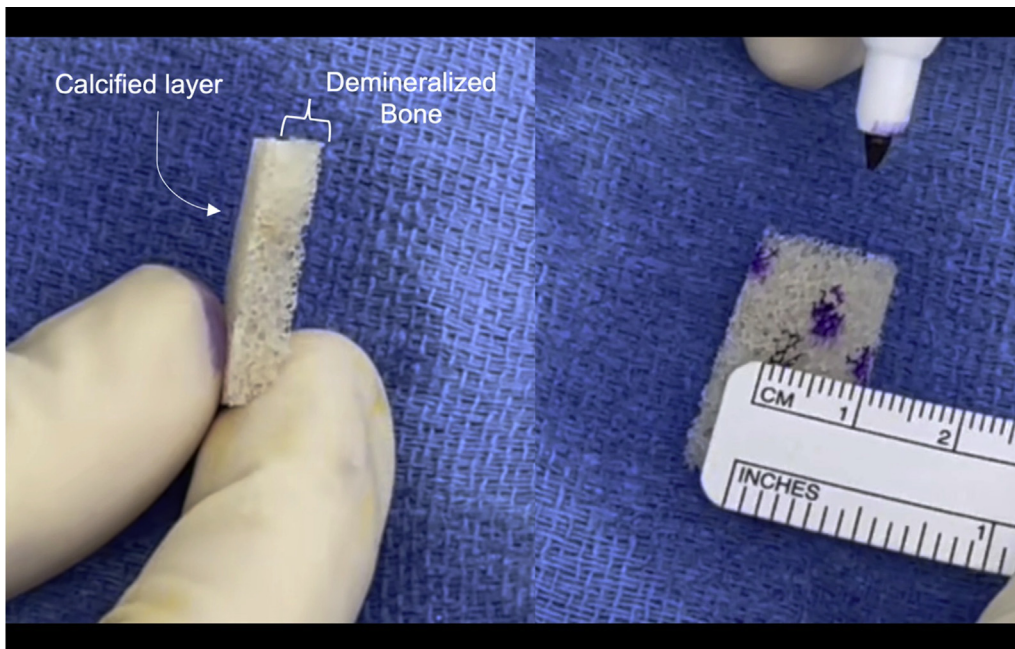


Fig 2. External view of the allograft profile demonstrating biphasic quality (cancellous and demineralized bone matrix). The graft should be hydrated while being marked for appropriate sizing with a surgical marker. The necessary sizing is determined after measurement of the prepared footprint.

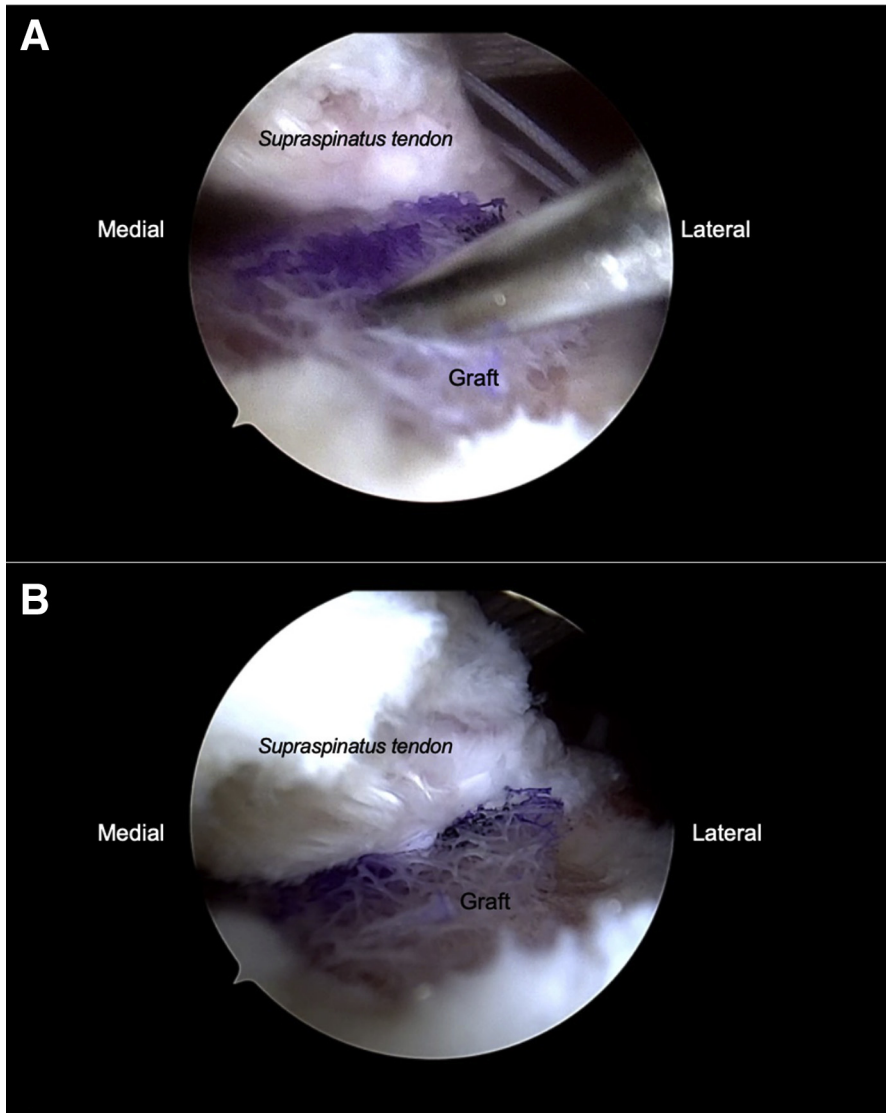


Fig 3. With the patient in a beach chair position, the graft is first shuttled in through a canula placed laterally, while viewing through the anterior portal, and directed to its final position by percutaneous spinal needle. (A) Placement of the graft can be aided by the use of a spinal needle until (B) final graft position is achieved.

entheses, mechanical scaffolds are often used to enhance the repair, either via augmentation or interposition techniques.^{22,23} Such scaffolds function also to promote ingrowth of native tissue, thus bridging the defect by facilitating collagen deposition and organized cellular growth, while providing the opportunity to incorporate exogenous or autologous stem cells or growth factors.²⁴ Current options include xenografts, allografts, autografts, and synthetic scaffolds.²⁵ However, these grafts have a limited capacity for proper osseous integration, particularly since most scaffolds are designed to mimic soft tissue.²⁶ To date, a meta-analysis by Bailey et al.⁶ demonstrated that graft augmentation or interposition resulted in significantly lower retear rates and improved American Shoulder and Elbow Surgeons scores.

Past studies have demonstrated that bone-to-bone healing is superior in preventing structural failure

than tendon-to-bone healing.^{27,28} The biphasic composition of the allograft leverages the advantages of both demineralized and mineralized bone matrices in promoting healing at the enthesis. Porous demineralized bone matrix (DBM) promotes full-thickness neovascularization and collagen deposition, while also remaining elastic and compressible.²⁹ On the other hand, the mineralized component has strong osteoconductive properties, thereby increasing the propensity for proper osseous ingrowth and integration to host bone.^{30,31} Advantages and disadvantages of the use of this product are detailed in [Table 2](#).

Marrying the collagenous tissues of the soft rotator cuff tendon to the hard bony surface of the greater tuberosity with a repair that is both strong and allows for stress transition mimicking the architecture of the native rotator cuff transition zone has been elusive. In several small and large animal models of rotator cuff repair,

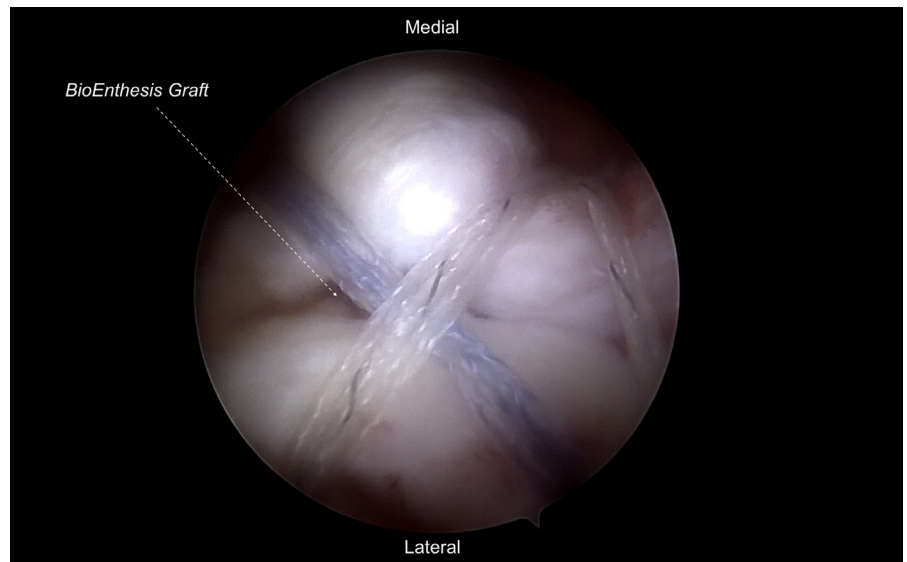


Fig 4. Arthroscopic view of the final double row suture-bridge construct from the direct lateral portal using a 30° arthroscope with the patient in beach-chair positioning.

fibrovascular scar tissue dominated the healing structure, without consistent reformation of both calcified and noncalcified fibrocartilaginous tissue.^{26,32-34} Biomechanically, this disorganized scar tissue remains inferior to native tissue, with the scar demonstrating

between 36% to 75% of native tendon strength.³² To address this issue, certain forms of augmentation were proposed to recapitulate the transitional zone. One such augmentation—an earlier iteration of this enthesis graft—demonstrated excellent integration into the host tissue and produced a near-normal four-zone fibrocartilaginous interface in a preliminary study by Dickerson et al.¹⁸

Table 1. Pearls and Pitfalls of Biphasic Allograft Augmentation During Rotator Cuff Repair

Pearls	
Ensure proper footprint preparation to a bleeding bone surface at the entheses to enhance healing	
Measure the distance between medial anchors and from the medial anchors to the lateral aspect of the footprint to appropriately size the dimensions of the BioEnthesis graft	
Decorticate the greater tuberosity between the medial anchors to create a trough for the BioEnthesis graft to sit	
Shuttle sutures through percutaneous portals to minimize risk of graft/suture entanglement	
Hydrate the BioEnthesis graft prior to cutting to the measured dimensions using a scalpel blade	
Can enlarge lateral incision or use a cannula to allow for easy BioEnthesis graft passage into the joint using an arthroscopic grasper	
Provisionally secure graft to footprint using spinal needle during medial row suture tying, ensuring the cortical side of the graft remains against bone	
Prior to securing lateral row, ensure BioEnthesis remains interposed between the tendon and footprint	
Pitfalls	
Failure to appropriately decorticate bone between the medial anchors to allow the BioEnthesis graft to sit	
Unintended graft breakage from cutting the graft without prior hydration	
Small incision making graft passage into the joint difficult or getting graft caught in soft tissue	
Failure to stabilize the graft during suture tying	
Avoid excessive graft manipulation in joint with grasper or spinal needle to minimize risk of graft degradation or breakage	
Failure to differentiate cortical from soft tissue surface with placement of cortical aspect of graft against overlying rotator cuff	

Currently, there are no clinical studies evaluating the outcomes of the BioEnthesis graft. To our knowledge, the only existing study in the literature to utilize a similar graft design is the proof-of-concept study by Dickerson et al.¹⁸ However, augmentation of the biology at the interface between the cuff tendon and the tuberosity has been an active area of research. Several implant designs have been proposed to promote the migration of bone marrow elements to the healing site, including fenestrated anchors, open coils, and wicks. Currently, the only high-level evidence (Level II) clinical study to our knowledge compared open-coil anchors with traditional screw-type anchors, found significantly greater bone mineral density surrounding

Table 2. Biphasic Allograft Augmentation Advantages and Disadvantages

Advantages	
Mimics the anatomic transition from soft tissue to bony tissue at the entheses through its biphasic structure	
Promotion of soft tissue and bony ingrowth for enhanced integration at tendon-bone interface	
Improved healing of the entheses and overall rotator cuff repair	
Can be used in rotator cuff repair with arthroscopic or open approaches	
Disadvantages	
Increased patient cost	
Increased operative time	
Not intended to provide structural support	

the anchor and mass within the anchor.¹⁴ However, there were similar clinical outcomes in terms of patient-reported outcomes and revision surgery between the 2 groups.¹⁴

In summary, we present here a technique for arthroscopic, transosseous-equivalent supraspinatus repair with a novel biphasic allograft composed of both demineralized and mineralized cancellous bone. Although longitudinal study of this graft is necessary to evaluate integration and graft resilience to structural failure in vivo, it presents a potential treatment option for concerning rotator cuff tears.

References

- Buyukdogan K, Aslan L, Koyuncu Ö, et al. Long term outcomes after arthroscopic transosseous equivalent repair: clinical and mri results of rotator cuff tears at a minimum follow-up of 10 years. *J Shoulder Elbow Surg* 2021;30:2767-2777.
- Galatz LM, Ball CM, Teefey SA, Middleton WD, Yamaguchi K. The outcome and repair integrity of completely arthroscopically repaired large and massive rotator cuff tears. *J Bone Joint Surg Am* 2004;86:219-224.
- Lee S, Park I, Lee HA, Shin S-J. Factors related to symptomatic failed rotator cuff repair leading to revision surgeries after primary arthroscopic surgery. *Arthroscopy* 2020;36:2080-2088.
- Ono Y, Dávalos Herrera DA, Woodmass JM, Boorman RS, Thornton GM, Lo IKY. Can grafts provide superior tendon healing and clinical outcomes after rotator cuff repairs? A meta-analysis. *Orthop J Sports Med* 2016;4:2325967116674191.
- Duquin TR, Buyea C, Bisson LJ. Which method of rotator cuff repair leads to the highest rate of structural healing? A systematic review. *A J Sports Med* 2010;38:835-841.
- Bailey JR, Kim C, Alentorn-Geli E, et al. Rotator cuff matrix augmentation and interposition: A systematic review and meta-analysis. *Am J Sports Med* 2019;47:1496-1506.
- Laskovski J, Abrams J, Bogdanovska A, Taliwal N, Taylor M, Fisher M. Arthroscopic rotator cuff repair with allograft augmentation: Making it simple. *Arthrosc Tech* 2019;8:e597-e603.
- Zumstein MA, Lädermann A, Raniga S, Schär MO. The biology of rotator cuff healing. *Orthop Traumatol* 2017;103:S1-S10.
- Liu XN, Yang C-J, Kim JE, et al. Enhanced tendon-to-bone healing of chronic rotator cuff tears by bone marrow aspirate concentrate in a rabbit model. *Clin Orthop Surg* 2018;10:99-110.
- Chen X, Jones IA, Togashi R, Park C, Vangsness CT Jr. Use of platelet-rich plasma for the improvement of pain and function in rotator cuff tears: A systematic review and meta-analysis with bias assessment. *Am J Sports Med* 2020;48:2028-2041.
- Neff P, Franklin DB III, Jones DL, et al. Transtendinous rotator cuff tear repair with bone marrow aspirate concentrate dermal allograft augmentation. *Arthrosc Tech* 2021;10:e975-e980.
- Muench LN, Uyeki CL, Mancini MR, Berthold DP, McCarthy MB, Mazzocca AD. Arthroscopic rotator cuff repair augmented with autologous subacromial bursa tissue, concentrated bone marrow aspirate, platelet-rich plasma, platelet-poor plasma, and bovine thrombin. *Arthrosc Tech* 2021;10:e2053-e2059.
- Garrigues GE. Editorial commentary: Biologically-enhanced patch augmentation: The perfect marriage of mechanical stability and biology for rotator cuff healing? Unfortunately, not yet. *Arthroscopy* 2020;36:1552-1554.
- Chahla J, Liu JN, Manderle B, et al. Bony ingrowth of coil-type open-architecture anchors compared with screw-type PEEK anchors for the medial row in rotator cuff repair: A randomized controlled trial. *Arthroscopy* 2020;36:952-961.
- Easley J, Puttlitz C, Hackett E, et al. A prospective study comparing tendon-to-bone interface healing using an interposition bioresorbable scaffold with a vented anchor for primary rotator cuff repair in sheep. *J Shoulder Elbow Surg* 2020;29:157-166.
- Pill SG, McCallum J, Tolan SJ, et al. Regenesorb and polylactic acid hydroxyapatite anchors are associated with similar osseous integration and rotator cuff healing at 2 years. *J Shoulder Elbow Surg* 2021;30:S27-S37.
- Denard PJ, Burkhart SS. The evolution of suture anchors in arthroscopic rotator cuff repair. *Arthroscopy* 2013;29:1589-1595.
- Dickerson DA, Misk TN, Van Sickle DC, Breur GJ, Nauman EA. In vitro and in vivo evaluation of orthopedic interface repair using a tissue scaffold with a continuous hard tissue-soft tissue transition. *J Orthop Surg Res* 2013;8:18.
- Papadopoulos P, Karataglis D, Boutsiadis A, Fotiadou A, Christoforidis J, Christodoulou A. Functional outcome and structural integrity following mini-open repair of large and massive rotator cuff tears: A 3-5 year follow-up study. *J Shoulder Elbow Surg* 2011;20:131-137.
- Boileau P, Brassart N, Watkinson DJ, Carles M, Hatzidakis AM, Krishnan SG. Arthroscopic repair of full-thickness tears of the supraspinatus: Does the tendon really heal? *JBJS* 2005;87:1229-1240.
- Steinhaus ME, Makhni EC, Cole BJ, Romeo AA, Verma NN. Outcomes after patch use in rotator cuff repair. *Arthroscopy* 2016;32:1676-1690.
- Lenart BA, Martens KA, Kearns KA, Gillespie RJ, Zoga AC, Williams GR. Treatment of massive and recurrent rotator cuff tears augmented with a poly-l-lactide graft, a preliminary study. *J Shoulder Elbow Surg* 2015;24:915-921.
- Modi A, Singh HP, Pandey R, Armstrong A. Management of irreparable rotator cuff tears with the GraftJacket allograft as an interpositional graft. *Shoulder Elbow* 2013;5:188-194.
- Adams JE, Zobitz ME, Reach JS Jr, An K-N, Steinmann SP. Rotator cuff repair using an acellular dermal matrix graft: An in vivo study in a canine model. *Arthroscopy* 2006;22:700-709.
- Thangarajah T, Pendegrass CJ, Shahbazi S, Lambert S, Alexander S, Blunn GW. Augmentation of rotator cuff repair with soft tissue scaffolds. *Orthop J Sports Med* 2015;3:2325967115587495.
- Rodeo SA, Arnoczky SP, Torzilli PA, Hidaka C, Warren RF. Tendon-healing in a bone tunnel. A biomechanical and histological study in the dog. *J Bone Joint Surg Am* 1993;75:1795-1803.

27. Smith MJ, Cook JL, Kuroki K, et al. Comparison of a novel bone-tendon allograft with a human dermis-derived patch for repair of chronic large rotator cuff tears using a canine model. *Arthroscopy* 2012;28:169-177.
28. Rodeo SA, Potter HG, Kawamura S, Turner AS, Kim HJ, Atkinson BL. Biologic augmentation of rotator cuff tendon-healing with use of a mixture of osteoinductive growth factors. *JBJS* 2007;89:2485-2497.
29. Smith MJ, Pfeiffer FM, Cook CR, Kuroki K, Cook JL. Rotator cuff healing using demineralized cancellous bone matrix sponge interposition compared to standard repair in a preclinical canine model. *J Orthop Res* 2018;36:906-912.
30. Sellaro TL, Ravindra AK, Stolz DB, Badylak SF. Maintenance of hepatic sinusoidal endothelial cell phenotype in vitro using organ-specific extracellular matrix scaffolds. *Tissue Eng* 2007;13:2301-2310.
31. Handley S, Lowther D. Extracellular matrix metabolism by chondrocytes III. Modulation of proteoglycan synthesis by extracellular levels of proteoglycan in cartilage cells in culture. *Biochim Biophys Acta* 1977;500:132-139.
32. Lebaschi AH, Deng X-H, Camp CL, et al. Biomechanical, histologic, and molecular evaluation of tendon healing in a new murine model of rotator cuff repair. *Arthroscopy* 2018;34:1173-1183.
33. Thomopoulos S, Williams G, Soslowky L. Tendon to bone healing: Differences in biomechanical, structural, and compositional properties due to a range of activity levels. *J Biomech Eng* 2003;125:106-113.
34. Galatz LM, Sandell LJ, Rothermich SY, et al. Characteristics of the rat supraspinatus tendon during tendon-to-bone healing after acute injury. *J Orthop Res* 2006;24:541-550.