Technical Note

Bioaugmentation of Rotator Cuff Repair With an Interpositional Nanofiber Scaffold

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Abstract: Rotator cuff repairs demonstrate variable success, with reported retear rates from 4% to 94%, and the highest retear rates are associated with large and massive tears. Scaffolds are an augmentation strategy for repairs aimed at fortifying healing of the bone-tendon junction by facilitating cellular repopulation and marrow elements at the tendon footprint. The Rotium nanofiber scaffold (Atreon Orthopedics, Columbus, OH) is an interpositional nanofiber scaffold that is compressed between the repaired rotator cuff and the footprint on the greater tuberosity. The bioabsorbable synthetic profile replicates the native tendinous attachment with minimal risk of immunogenicity and with resorption at 3 to 4 months. This article describes a preparation and implantation strategy to augment arthroscopic rotator cuff repair, adding minimal surgical time.

Up to an estimated 20.7% of the general population has full-thickness rotator cuff tears, a prevalence that increases with age.[1] When nonoperative treatment measures fail, operative management may offer pain relief and improved function but may also introduce potential complications such as stiffness, improper healing, and retear. Reported retear rates after repair range from 3.9% to 94%, with variability owing to several factors including patient age, tear size and chronicity, patient comorbidities, and surgical technique.[2-6] Worse clinical outcomes have been associated with recurrent tears, emphasizing the importance of patient selection and surgical techniques to improve both healing rates and clinical outcomes.[7]

In an effort to improve rotator cuff repair healing, several augmentation modalities have been introduced. Biological and synthetic scaffolds have quickly gained popularity owing to their ability to enhance healing success by decreasing the tension at the repair site, along with redirecting cellular healing in a way that optimizes the environment for an enhanced repair.[8] Scaffolds have been made from a variety of different materials, ranging from porcine dermis to synthetic nanofibers.[8,9]

Synthetic nanofiber scaffolds offer advantages such as lack of a host immune response to the scaffold, integrable biologics, and manufacturer reproducibility.[10] The Rotium Bioresorbable Wick (Atreon Orthopedics, Columbus, OH), one such nanofiber scaffold, was approved by the United States Food and Drug Administration in March 2019 for use in conjunction with suture anchors in rotator cuff repairs. It is completely synthetic and is resorbed in only 3 to 4 months.[11] The Rotium scaffold does not require the use of additional sutures or anchors and is compatible with most repair techniques. Moreover, the adjustable positioning of the scaffold allows for expansion of the footprint of the repaired rotator cuff tendon. Other techniques using an interpositional scaffold have been described, including preloading and threading suture anchors through the scaffold, which may create a larger hole in the graft than desired, prior to placement at the native rotator cuff footprint.[12,13] The purpose of this article is to describe our technique using a bioabsorbable interpositional nanofiber scaffold to augment an arthroscopic rotator cuff repair without requiring passage of sutures through the graft.

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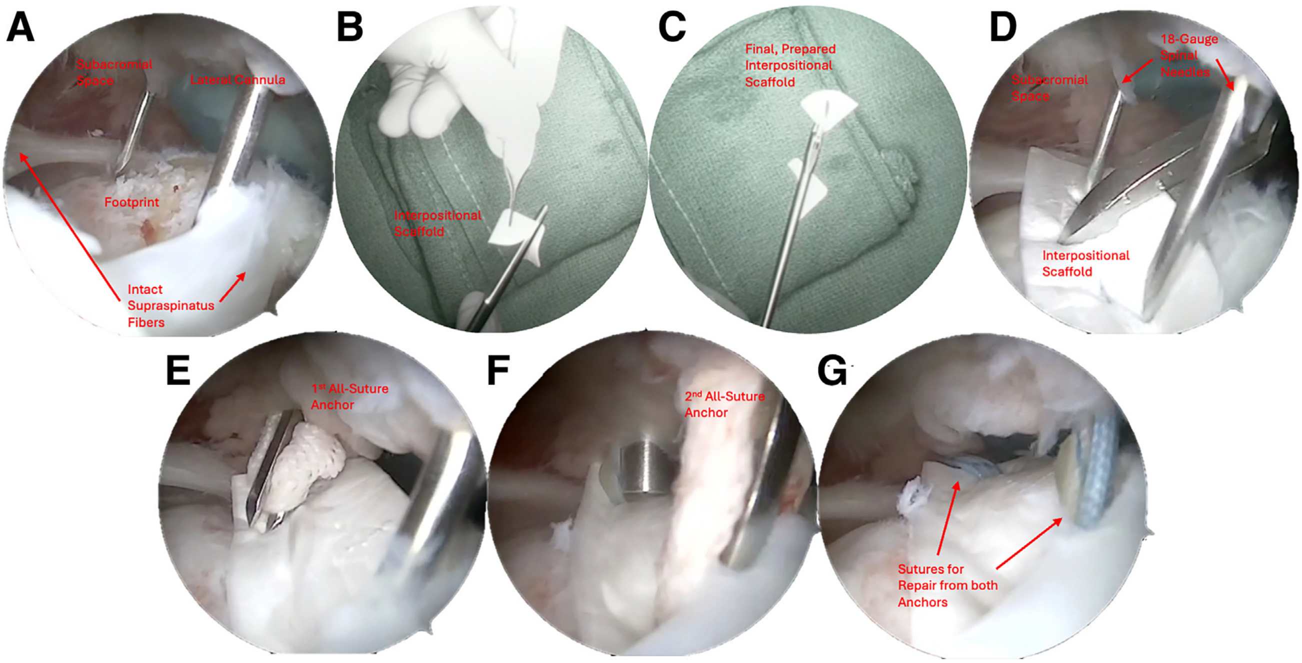

Fig 1. (A) A full-thickness segmental tear of the supraspinatus with retraction to the lateral third of the humeral head is shown, with the footprint of the rotator cuff debrided of soft tissue and 2 spinal needles placed along the footprint at the intended sites of anchor placement. (B) Scissors are used to round the medial edge of the scaffold to match the patient-specific rotator cuff footprint size and prevent protrusion of the scaffold into the intra-articular space. (C) The prepared scaffold is shown being held by a grasper, prior to insertion into the subacromial space via a lateral cannula. (D) The scaffold is placed flat on the surface of the tuberosity to cover the entirety of the footprint and is held in position by the previously inserted spinal needles. (E) The first spinal needle is replaced with an all-suture self-punching anchor along the medial edge of the footprint. (F) After the first anchor is advanced, the second spinal needle is replaced with the second all-suture self-punching anchor. (G) The second anchor is advanced, after which the anchor inserters are removed, and the sutures for the medial-row repair, already passed through the interpositional scaffold, are used to complete the rotator cuff repair. Intra-operative arthroscopic images of the patient's right shoulder were taken from the posterior viewing portal with the patient positioned in beach-chair.

Surgical Technique

Preparation

We prefer to perform rotator cuff repair with the patient in the beach-chair position, but this technique may be performed with lateral positioning as well. The procedure is performed with the patient under general anesthesia with an interscalene nerve block. Prior to rotator cuff repair, a standard diagnostic arthroscopy is performed. Once in the subacromial space, a lateral cannula is placed (8-mm × 4-cm Passport Button Cannula; Arthrex, Naples, FL). Mobilization of the rotator cuff to the footprint is confirmed prior to proceeding with repair. The greater tuberosity is then prepared via surgeon preference. We use a shaver to remove any residual soft tissue from the repair site and create bleeding bone lateral to the anticipated anchor site (Fig 1A). The wicking effect of the marrow growth factors released from the bleeding bone into the interpositional scaffold is theorized to enhance the healing process focused at the bone-tendon junction.

To ensure the nanofiber scaffold is not torn on anchor puncture in the subacromial space, an 18-gauge spinal needle may be used to create holes in the scaffold prior to placement; however, this is not necessary. One to two holes, to equal the number of medial anchors planned, are punctured near the medial edge of the scaffold. We choose to place these 3 mm from the medial edge to maximize the footprint coverage lateral to the medial-row anchors. The scaffold is cut with scissors to create a rounded medial edge, matching the medial aspect of the rotator cuff footprint, to prevent significant protrusion into the intra-articular space (Fig 1B).

Scaffold Insertion

After preparation, the scaffold is inserted using a grasper through the lateral cannula into the subacromial space and placed flat on the surface of the tuberosity to cover the entirety of the footprint (Fig 1C and D). A spinal needle is used to keep the scaffold fixated until the anchors are placed. In this case, 2 all-suture self-punching anchors (Iconix 2.3-mm all-suture anchors; Stryker, Kalamazoo, MI) are used as medial-row anchors and are placed just lateral to the articular surface. As one medial anchor is placed, the

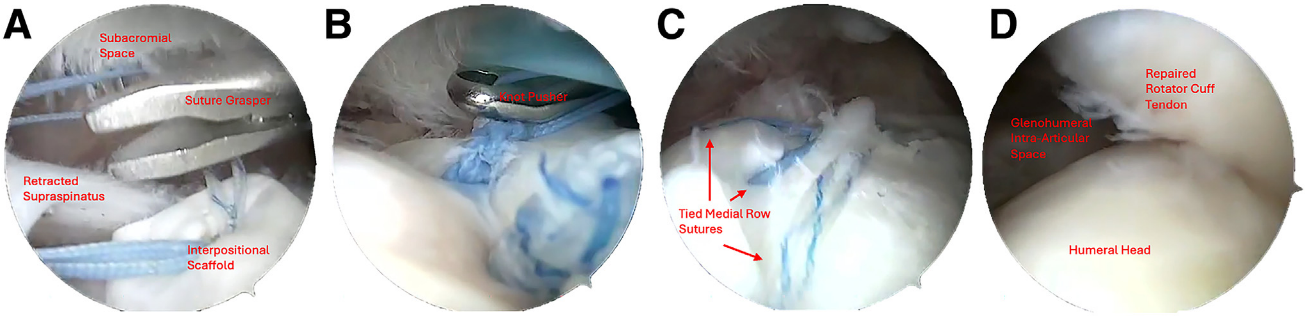

Fig 2. (A) The sutures of the medial-row anchors are sequentially placed in a retrograde manner through a series of horizontal mattress sutures through the retracted supraspinatus tendon. (B) The knots of the medial-row fixation are completed. (C) The secure, completed medial-row fixation is observed, and a lateral series of anchors is placed (not pictured) to complete the repair. (D) After completion of the repair, the arthroscopic camera is placed into the intra-articular space to confirm the reconstitution of a secure bone-tendon interface at the rotator cuff repair. Intra-operative arthroscopic images of the patient's right shoulder were taken from the posterior viewing portal with the patient positioned in beach-chair.

spinal needle remains set to keep the scaffold from moving (Fig 1E). Once the first medial anchor is placed, the second needle is removed and the second medial anchor is placed (Fig 1F). The placement of the nanofiber scaffold is strategic because the sandwiched position between the greater tuberosity and tendon after repair maximizes the absorption of the secreted growth factors from the bleeding bone created earlier (Fig 1G). The use of 2 anchors keeps the scaffold rotationally stable with less bunching at the medial edge during suture passage, although this technique may still be used in the setting of a single medial-row anchor.

Rotator Cuff Repair

After medial anchor placement through the scaffold is completed, the rotator cuff is repaired using standard repair techniques. In this case, a double-row rotator cuff repair is completed by passing 4 horizontal mattress sutures (Fig 2A). It is important to take care to avoid catching the lateral edge of the scaffold when using retrograde suture passers, which can damage the scaffold. We prefer a knotted medial-row repair passed to a lateral-row anchor (Fig 2 B and C) (5.5-mm SwiveLock anchor; Arthrex); however, this technique may be performed with a knotless double-row technique as well. After completion of the secure repair, the repair is re-evaluated and found to be stable through a full range of motion. The camera is placed back into the joint, with confirmation of restoration of the rotator cuff bone-tendon insertion and no protrusion of the scaffold into the intra-articular space (Fig 2D).

Discussion

Despite advancements in anchor and suture designs, retear rates after arthroscopic rotator cuff repair remain high.[3-6,14] With 40% of persons older than 60 years experiencing symptomatic rotator cuff tears, research into improving rotator cuff healing rates is increasingly important.[15] Healing is particularly challenging at the bone-tendon interface, where scar tissue formation can yield inferior clinical outcomes and compromise the integrity of the repair.[16] Augmentation with scaffolds, such as the nanofiber scaffold used in our technique, yields promising results with relative ease of use.[17,18] The biological efficacy of these scaffolds resides in their ability to immediately support the tension of the re-established enthesis, as well as redirect the bio-environment to promote a facilitated healing process. This allows collagen fibers to remodel into a more concentrated, stronger healed tendon that replicates the native tendon-bone connection and is theoretically more resistant to rupture than a traditional repair alone.[19]

Compared with biological scaffolds, synthetic scaffolds have the advantage of longer and more stable shelf-lives, decreased possibility of immunogenicity, and the ability to control the nanofiber contents.[20] Synthetic grafts' ability to negate a severe host migration response increases healing properties and diminishes the chance of graft rejection or an inflammatory response.[21] Compared with biological scaffolds, synthetic scaffolds have also been shown to have stronger mechanical properties, which are vital to resist a retear in the initial few months of recovery.[21]

The Rotium nanofiber scaffold's unique polymer profile of polyglycolic acid and poly-lactide co-caprolactone A mimics the characteristics of the native tendon extracellular matrix.[11] It focuses biological healing at the insertion with an "inlay" scaffold rather than an "onlay" scaffold construct placed on top of the tendon and away from the tendon-to-bone site of healing. Romeo et al.[11] observed a 75% restoration of native tendon strength in ultimate load to failure of the acutely repaired tendon using the Rotium nanofiber scaffold in a sheep model at 12 weeks, with the presence of Sharpey fibers replicating the native tendinous

Table 1. Advantages and Disadvantages

Advantages	
	Expands native rotator cuff footprint
	Scaffold is easy to apply (minimal learning curve)
	Expedited placement of graft with no preloading of anchors or passage of suture (adds minimal surgical time)
	Requires no additional staples or anchors
	Focused application of augmentation at site of enthesis to promote healing
	Early randomized trial showing lower radiographic retear rates with this augmentation[13]
	Complete resorption of scaffold in 3-4 mo
	Flexible capability with various repair techniques (i.e., knotted vs knotless and single vs double anchor)
	Flexible adjustment of anchor placement by placing scaffold at footprint first without anchors passed
Disadvantages	
	Additional cost
	No randomized trial showing difference in patient-reported outcomes or physical examination findings compared with standard repair

Table 2. Pearls and Pitfalls

Pearls	
	An 18-gauge spinal needle may be used to create holes in the scaffold, along the medial edge, prior to placement to ensure that the nanofiber scaffold is not torn on anchor puncture.
	Significant intra-articular protrusion can be avoided by cutting the scaffold to the appropriate patient-specific footprint size prior to placement.
	The use of 2 spinal needles is recommended to allow for positional adjustment of the scaffold as needed and to avoid bunching and ensure the scaffold lies flat against the greater tuberosity once placed at the footprint.
	The inserter for the first anchor can be left in place until the second anchor is fully advanced to avoid misplacement or bunching of the graft at the footprint.
Pitfalls	
	Special attention must be taken to avoid catching the lateral edge of the scaffold when using retrograde suture passers, which can damage the scaffold.
	Special care must be taken not to damage the scaffold while passing it through the cannula.

junction attaching to the humeral footprint. Beleckas et al.[13] used magnetic resonance imaging and ultrasound to assess for retear progression within a control cohort that underwent standard double-row repair without augmentation and a treatment cohort that received a repair augmented with the nanofiber scaffold. Cumulative results revealed a 7.1% failure rate in the scaffold-augmented cohort, whereas a 50% failure rate was found in the non-augmented cohort. Range of motion during the early recovery period was also superior in the scaffold-augmented cohort within the first year of follow-up; however, this difference dissipated by the end of the second year.[13]

The technique described in this article presents an efficient alternative technique for placement of the scaffold that does not require preloading of anchors or passage of sutures through the scaffold itself, thus decreasing the size of the hole in the center of the scaffold and allowing for an expedited placement of the graft (Video 1). Another benefit of this technique is that by placing the scaffold first at the footprint without the anchors passed, there is less guesswork in the creation of holes in the scaffold, which may lead to bunching. A summary of the advantages versus disadvantages of this technique is included in Table 1, and pearls and pitfalls are presented in Table 2. This technique allows for optimal placement of the scaffold to maximize its healing properties and full footprint coverage. Although the placement of the nanofiber scaffold creates an extra step when compared with a rotator cuff repair without augmentation, this process does not add significant time nor does it require any special equipment. The dual-anchor choice is used to ensure that the scaffold does not rotate or bunch up and maximizes its footprint, thus maximizing the healing potential of the graft.

Disclosures

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: J.C.L. reports a consulting or advisory relationship with DJO Orthopedics, Stryker, Globus Medical, Innomed, and Atreon Orthopedics and owns equity or stocks in Atreon Orthopedics. All other authors (A.D.M., G.F., C.M.B.) declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

1. Yamamoto A, Takagishi K, Osawa T, et al. Prevalence and risk factors of a rotator cuff tear in the general population. *J Shoulder Elbow Surg* 2010;19:116-120.
2. Inagaki K, Ochiai N, Hiraoka Y, et al. Effect of arthroscopic subacromial decompression during arthroscopic repair of small to medium-sized rotator cuff tears. *JSES Int* 2023;7:296-300.

3. Manop P, Apivatgaroon A, Puntu W, Chernchujit B. Risk factors for rotator cuff repair failure and reliability of the rotator cuff healing index (RoHI) in Thai patients: Comparison of the RoHI with a modified scoring system. *Orthop J Sports Med* 2023;11:23259671231179449.
4. Neri BR, Chan KW, Kwon YW. Management of massive and irreparable rotator cuff tears. *J Shoulder Elbow Surg* 2009;18:808-818.
5. Chalmers PN, Tashjian RZ. Patch augmentation in rotator cuff repair. *Curr Rev Musculoskelet Med* 2020;13:561-571.
6. Avanzi P, Giudici LD, Capone A, et al. Prospective randomized controlled trial for patch augmentation in rotator cuff repair: 24-Month outcomes. *J Shoulder Elbow Surg* 2019;28:1918-1927.
7. Kim HM, Caldwell JM, Buza JA, et al. Factors affecting satisfaction and shoulder function in patients with a recurrent rotator cuff tear. *J Bone Joint Surg Am* 2014;96:106-112.
8. Derwin KA, Badylak SF, Steinmann SP, Iannotti JP. Extracellular matrix scaffold devices for rotator cuff repair. *J Shoulder Elbow Surg* 2010;19:467-476.
9. Mandalia K, Mousad A, Welborn B, et al. Scaffold- and graft-based biological augmentation of rotator cuff repair: An updated systematic review and meta-analysis of preclinical and clinical studies for 2010-2022. *J Shoulder Elbow Surg* 2023;32:1784-1800.
10. Butler DL. Evolution of functional tissue engineering for tendon and ligament repair. *J Tissue Eng Regen Med* 2022;16:1091-1108.
11. Romeo A, Easley J, Regan D, et al. Rotator cuff repair using a bioresorbable nanofiber interposition scaffold: A biomechanical and histologic analysis in sheep. *J Shoulder Elbow Surg* 2022;31:402-412.
12. Seetharam A, Abad J, Baessler A, Badman BL. Use of a nanofiber resorbable scaffold during rotator cuff repair: Surgical technique and results after repair of small- to medium-sized tears. *Orthop J Sports Med* 2022;10:23259671221094848.
13. Beleckas CM, Minetos P, Badman BL. Short-term radiographic and clinical outcomes of arthroscopic rotator cuff repair with and without augmentation with an interpositional nanofiber scaffold [published online August 14, 2023]. J Orthop Exp Innov. doi:10.60118/001c.84269.
14. Trasolini NA, Waterman BR. Editorial commentary: Rotator cuff repairs fail at an alarmingly high rate during long-term follow-up: Graft augmentation and biologics may improve future outcomes. *Arthroscopy* 2022;38:2413-2416.
15. Lawrence RL, Moutzouros V, Bey MJ. Asymptomatic rotator cuff tears. *JBJS Rev* 2019;7:e9.
16. Ricchetti ET, Aurora A, Iannotti JP, Derwin KA. Scaffold devices for rotator cuff repair. *J Shoulder Elbow Surg* 2012;21:251-265.
17. Quigley R, Verma N, Evuarherhe A Jr, Cole BJ. Rotator cuff repair with graft augmentation improves function, decreases revisions, and is cost-effective. *Arthroscopy* 2022;38:2166-2174.
18. Saithna A. Editorial commentary: Bioinductive collagen implants reduce rotator cuff retear, yet cost-effectiveness and improvement in clinical outcomes are unclear. *Arthroscopy* 2024;40:1774-1776.
19. Aurora A, McCarron JA, van den Bogert AJ, Gatica JE, Iannotti JP, Derwin KA. The biomechanical role of scaffolds in augmented rotator cuff tendon repairs. *J Shoulder Elbow Surg* 2012;21:1064-1071.
20. Alaribe FN, Manoto SL, Motaung SCKM. Scaffolds from biomaterials: Advantages and limitations in bone and tissue engineering. *Biologia* 2016;71:353-366.
21. Vasiliadis AV, Katakalos K. The role of scaffolds in tendon tissue engineering. *J Funct Biomater* 2020;11:78.