

Use of a Nanofiber Resorbable Scaffold During Rotator Cuff Repair

Surgical Technique and Results After Repair of Small- to Medium-Sized Tears

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Background: The rate of retear after primary rotator cuff failure remains unacceptably high (up to 36% for small- to medium-sized tears). Augmentation of cuff repair with scaffold devices has been reported to improve healing after cuff repair.

Purpose/Hypothesis: To describe the surgical technique of using an interpositional nanofiber scaffold during rotator cuff repair and report on a retrospective series of patients regarding functional outcomes and postoperative healing on magnetic resonance imaging (MRI). We hypothesized that augmentation of cuff repair with an interpositional scaffold would result in a high rate of tendon healing and excellent functional outcomes.

Study Design: Case series; Level of evidence, 4.

Methods: A total of 33 patients underwent arthroscopic rotator cuff repair augmented with a nanofiber, bioresorbable polymer patch secured as an inlay between the tendon and underlying bone. Patients were evaluated preoperatively and postoperatively with the Simple Shoulder Test (SST), American Shoulder and Elbow Surgeons (ASES) shoulder score, and active range of motion (ROM) measurements. Postoperative MRI was used to evaluate repair status.

Results: At a minimum follow-up of 6 months, the patients showed significant improvement on SST and ASES scores ($P < .0001$ for both). ROM in forward flexion, abduction, internal rotation, and external rotation significantly improved at 6 months postoperatively ($P < .05$ for all). MRI at an average of 11 months postoperatively showed healing in 91% of patients; one patient had a recurrent tear with transtendon failure, and another patient had retear at the insertional site. The patch was not visible on postoperative imaging, suggesting complete resorption in all patients. No adverse events were associated with the patch.

Conclusion: Our results demonstrate the preliminary safety and efficacy of a novel, bioresorbable synthetic scaffold for rotator cuff repair. The use of the scaffold resulted in a 91% tendon healing rate and significant improvements in functional and patient-reported outcome measures. The results are promising for improving the current unacceptably high rate of rotator cuff repair failure.

Keywords: shoulder; rotator cuff; biological healing enhancement; tissue engineering

Rotator cuff injuries are among the most common musculoskeletal pathologies reported in the United States, second only to lower back pain. One study estimated that >17 million Americans may have shoulder impairment due to rotator cuff pathology.¹² Rotator cuff tears result in shoulder pain, stiffness, weakness, and loss of motion. Although some rotator cuff tears can be treated nonoperatively and with physical therapy, patients for whom nonoperative management fails may eventually require surgery. Operative treatment is still far from perfect, with repair failure rates of 20% to 94% reported in the literature.^{7,8,16,27} Repair failure is often related

to factors such as patient age, tear size and chronicity, muscle atrophy, tendon quality, repair technique, and postoperative rehabilitation.^{9,10,17,20,29,38} For more common tear patterns that typically involve small- to medium-sized tears, the failure rates range from 5% to 36%.^{9,26,31} Therefore, improved repair strategies are needed that provide both mechanical stability and augmentation of the intrinsic tendon healing process.

Natural and synthetic scaffolds for rotator cuff repair have been increasingly used over the past decade to address the high rate of repair failure. The use of a scaffold device for rotator cuff repair can provide mechanical augmentation by reducing tension on the repair during the immediate postoperative healing period and can provide biological augmentation to improve the rate or quality of healing.¹³

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Currently, scaffolds derived from mammalian extracellular matrix and synthetic polymers are cleared by the US Food and Drug Administration (FDA) for rotator cuff repair in humans.³⁴ Historically, scaffolds functioned as an onlay mechanism whereby they were sewn and incorporated onto the top of the tendon to augment the repair construct. Materials used in this fashion include human dermis, bovine and porcine dermis and intestinal submucosa, and, more recently, synthetic polymers. Incorporating these grafts into the repair itself is thought to provide both mechanical strength and structural support to improve healing.^{5,6,13,14,18} For example, a prospective, randomized controlled trial by Barber et al⁵ found significantly improved outcome scores and healing rates without an increase in complications among patients undergoing arthroscopic rotator cuff repair with acellular human dermal matrix augmentation. Several newer scaffolds have been released recently that function primarily to improve the biological parameters of the repair site rather than to improve the immediate mechanical strength of the repair. One such graft is a highly porous, bioinductive, bovine collagen implant. This graft is affixed to the top of the rotator cuff and has been shown to induce collagen formation and provide healing of partial-thickness rotator cuff tears.^{30,33}

A graft of particular interest is a synthetic nanofiber scaffold (Rotium; Atreon Orthopedics), which is the first implant to be cleared by the FDA as an interpositional device placed below the tendon and adjacent to the bone, helping to organize the cellular matrix during the tendon healing process. The scaffold has a microporous nature, which, combined with the structure of the nanofibers, is the likely mechanism through which the scaffold promotes a healing response similar to that of native tissue.^{1,22} In a recent sheep study, Romeo et al²⁸ demonstrated that the inclusion of the nanofiber scaffold significantly increased the strength of rotator cuff repair and produced more Sharpey fiber-like attachments at the enthesis at 3 months compared with repairs without scaffold augmentation. Specifically, incorporation of the scaffold into rotator cuff repair increased the ultimate failure force by 47% at 12 weeks compared with suture anchors alone. At present, no human studies are available for review.

The purpose of this study was to describe the surgical technique for appropriate insertion of the nanofiber scaffold in rotator cuff repair and to present postoperative imaging and patient-reported outcomes on a retrospective group of patients.

METHODS

Patient Selection

This study was a retrospective review of prospectively collected data; institutional review board approval and informed consent were obtained before data collection began. Between July 2019 and October 2020, a total of 85 consecutive patients with rotator cuff tears were included for initial participation in this study. Included were patients older than 18 years who had repairable primary rotator cuff tears of any size. Patients were excluded if they had irreparable rotator cuff tears ($\geq 50\%$ fatty infiltration diagnosed on magnetic resonance imaging [MRI], retraction of the tendon at or medial to the glenoid margin on coronal sequencing), failed primary repair requiring revision, inflammatory disease, or evidence of active infection.

The location and size of each tear were recorded for each patient. Rotator cuff tear size was further classified using the Cofield classification as small (<1 cm), medium (1-3 cm), large (>3 -5 cm), and massive (>5 cm).¹¹ Cuff tears were defined as acute if repair occurred within 3 months of the initial injury. Otherwise, the tears were defined as chronic. The electronic medical record was reviewed for each patient to collect relevant demographic information: age, sex, body mass index, tobacco use, and pertinent medical health history.

Operative Technique

Patients were positioned in the beach-chair position and underwent initial diagnostic arthroscopy of the shoulder. The rotator cuff tendons were examined, and the torn tendon and tear pattern were recorded. The biceps tendon was identified and underwent either tenodesis or tenotomy. Routine subacromial decompression was performed on each patient. All patients had a tear of the supraspinatus tendon, and some patients had concomitant tears of the infraspinatus or subscapularis tendon. The size and chronicity of tendon tear were recorded. The rotator cuff was repaired using a double-row repair technique, and the patients were treated with an average of 3 anchors (range, 2-6 anchors). The scaffold (Figure 1) was inserted over the sutures of one of the medial row anchors. Sutures from the anchor were retrieved through a lateral cannula and passed through the graft, and the graft was then folded in half and shuttled down the cannula with the use of a suture-grasping instrument (Figure 2). A free-eyed needle with a looped suture was used to facilitate the passage of multiple sutures through the graft at one time (Figure 2A). Within the

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Ethical approval for this study was obtained from Indiana University (ref No. 2002215493).

subacromial space, the graft was carefully unfolded and laid adjacent to the bone and below the tendon. The sutures through the graft were then individually passed through the rotator cuff tendon with a suture-passing instrument. Once all sutures had been passed, they were then incorporated into lateral row anchors in a crisscross fashion, compressing the tendon back to the bone. Postoperatively, all patients were immobilized in a sling for 4 weeks before the initiation of formal physical therapy and gradual advancement of motion and strength.

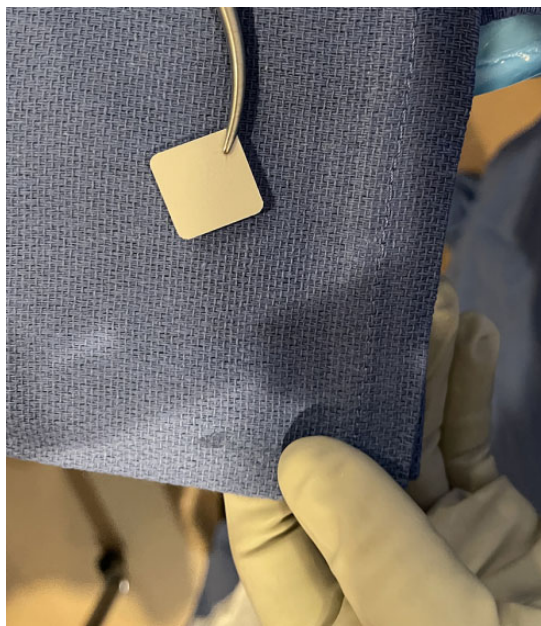


Figure 1. Nanofiber scaffold before insertion during rotator cuff repair.

Outcomes Measured

Preoperative and most recent follow-up outcomes were recorded. Active range of motion (ROM) of the repaired shoulder, including forward flexion, abduction, internal rotation with the shoulder abducted, and external rotation in neutral position and in shoulder abduction, was recorded using a standardized goniometer.²⁵ Patient-reported outcome measures were collected, including the Simple Shoulder Test (SST) and the American Shoulder and Elbow Surgeons (ASES) Standardized Shoulder Assessment Form.²

At a minimum of 6 months postoperatively, patients underwent rapid-sequence MRI of the surgically repaired shoulder in 1.5-T scanners. MRI was performed to radiologically assess for healing and any signs of repair failure. Healing was defined as a complete excursion of the repaired tendon to the greater or lesser tuberosity with attachment to bone. Images were independently evaluated by a board-certified musculoskeletal radiologist.

Complications were recorded. Failure of repair was defined as retear of the repaired tendon noted on follow-up MRI. Additional complications included postoperative infection, arthrofibrosis, and the need for additional surgeries.

Statistical Analysis

Preoperative and most recent follow-up clinical outcome data, including active ROM, ASES score, and SST score, were compared for statistically significant change using a paired *t* test. A chi-square test was used to compare categorical variables (sex, smoking, medical comorbidities, and complications) between total patients augmented with the graft and the final cohort included for analysis. This was done to determine whether there were statistically significant differences in potential confounding variables between the initial surgical group and those patients included for

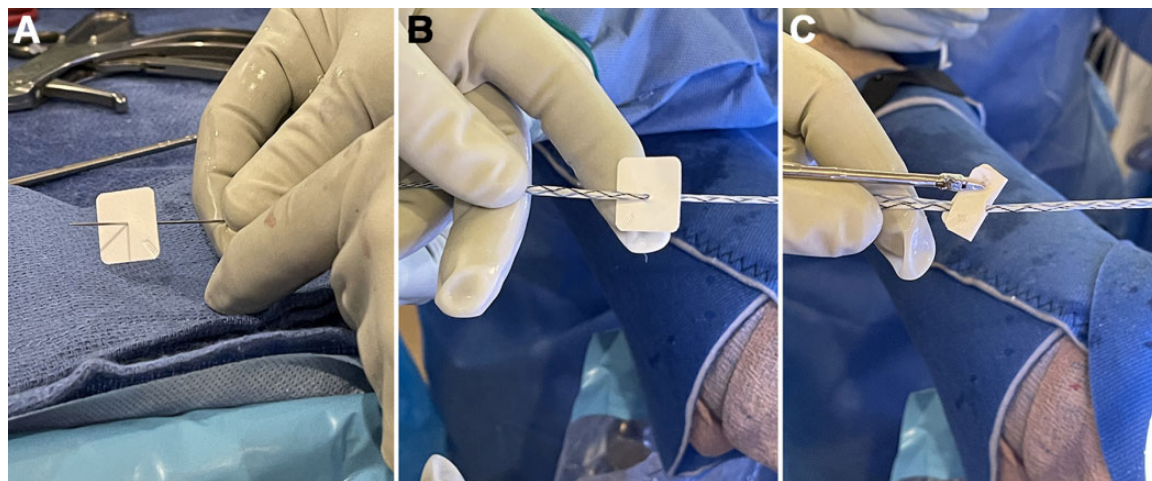


Figure 2. Intraoperative preparation and insertion of the scaffold. (A) The scaffold is inserted onto the suture of a medial row anchor. (B) The scaffold is advanced using the medial row anchor suture. (C) Before insertion through the cannula, the scaffold is folded in half before being unfolded and placed between the bone and tendon.

final analysis. A significance level of .05 was considered statistically significant.

RESULTS

Patient Demographic Characteristics

Of the 85 patients identified for this study, 55 patients met the inclusion criteria and underwent arthroscopic rotator cuff repair by the senior author (B.B.); all repairs entailed augmentation with the nanofiber scaffold. Of the 55 patients who underwent surgery, 33 patients had sufficient follow-up and imaging data for inclusion in the final analysis. A total of 10 patients did not undergo postoperative MRI; 5 patients refused inclusion; 5 patients were lost to follow-up; and 2 patients were noncompliant with early, aggressive, active ROM within 4 weeks of the repair (Figure 3).

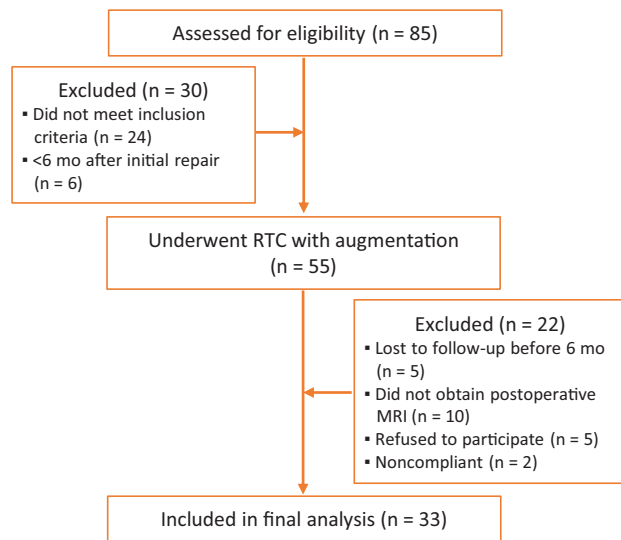


Figure 3. Flowchart of the patient selection process. RTC, rotator cuff repair.

For the 33 patients included in the final analysis, the mean age at the time of surgery was 62.6 ± 5.5 years, and mean body mass index was 31.5 ± 4.3 . Mean patient follow-up was 8.6 ± 2.4 months. No significant differences were noted between the 33 patients analyzed and the entire group regarding age, sex, or comorbidities (Table 1). Tear size and chronicity for the total patients and the analyzed patients are shown in Table 2.

Active ROM Outcomes

From the preoperative assessment to the most recent follow-up, significant improvements were seen in all planes of shoulder motion recorded (Figure 4). The mean forward flexion improved from $90^\circ \pm 41^\circ$ to $155^\circ \pm 16^\circ$ ($P < .001$). Mean shoulder abduction improved from $80^\circ \pm 35^\circ$ to $145^\circ \pm 19^\circ$ ($P < .001$). Mean external rotation with the arm in neutral position improved from $58^\circ \pm 13^\circ$ to $66^\circ \pm 11^\circ$ ($P < .01$). Mean external rotation with the shoulder at 90° of abduction improved from $69^\circ \pm 21^\circ$ to $83^\circ \pm 10^\circ$ ($P < .001$). Internal rotation with the shoulder at 90° of abduction improved from $50^\circ \pm 21^\circ$ to $63^\circ \pm 12^\circ$ ($P = .004$).

Patient-Reported Outcome Measures

Significant improvements were seen in ASES and SST scores from preoperative assessment to the most recent follow-up. The mean ASES score improved from 36.9 ± 13.1 to 86.8 ± 12.8 , whereas mean SST scores improved from 4.2 ± 2.6 to 11.7 ± 0.74 ($P < .00001$ for both) (Figure 5).

Magnetic Resonance Imaging

MRI of the repaired shoulder was performed at a mean of 10.5 ± 3.2 months after surgery (range, 6-16.7 months). Healing of the repaired tendon occurred in 91% of patients (30/33) (Figure 6A), whereas the repairs in the remaining 3 patients (9%) failed to heal. One patient with a chronic, large tear had a transtendon failure medial to the tendon-bone interface. The second failure occurred at the

TABLE 1
Characteristics of Patients in the Overall and Analyzed Cohorts

	Total Patients Augmented (n = 55)	Patients Analyzed (n = 33)	P
Age, y, mean \pm SD	61.8 ± 6.2	62.6 ± 5.5	.68
Sex, n (%)			
Male	23 (41.8)	13 (39.4)	.38
Female	32 (58.1)	20 (60.6)	.24
Body mass index, mean \pm SD	31.8 ± 3.9	31.5 ± 4.3	.82
Diabetes, n (%)	5 (9.1)	2 (6.1)	.63
Smoking status, n			
Never	33	22	.44
Former	20	9	
Current	2	2	
Hypertension, n	30	1	.23
Chronic obstructive pulmonary disease, n	2	1	
History of stroke or myocardial infarction, n	1	0	

TABLE 2
Rotator Cuff Injury Information for the Overall and Analyzed Cohorts

	Total Patients Augmented (n = 55)	Patients Analyzed (n = 33)
Tendon torn, n		
Supraspinatus	55	33
Infraspinatus	10	3
Subscapularis	1	1
Teres minor	0	0
Tear size, n		
Small (<1 cm)	11	5
Medium (1-3 cm)	40	26
Large (>3-5 cm)	2	1
Massive (>5 cm)	2	1
Chronicity, n		
Acute	24	14
Chronic	31	19

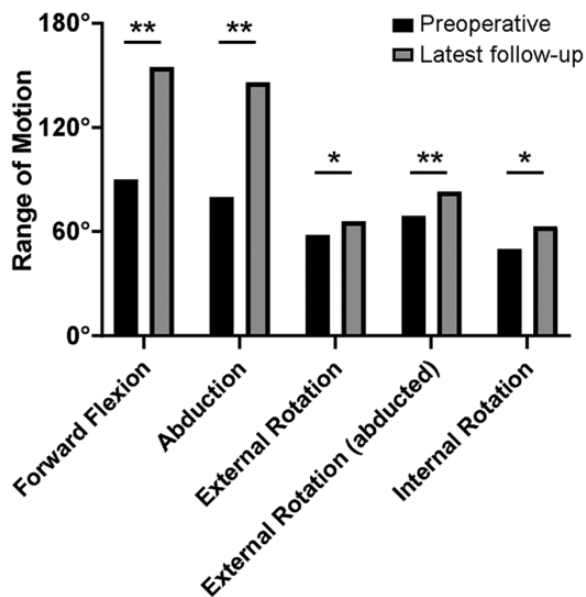


Figure 4. Comparison of preoperative and postoperative active shoulder range of motion. * $P < .01$. ** $P < .001$.

subscapularis insertion site in a patient with chronic, massive tear of the supraspinatus, infraspinatus, and subscapularis tendons. The third failure was due to anchor pullout in a patient with a chronic, medium-sized tear of the supraspinatus tendon. The nanofiber scaffold was not visible on any of the MRI scans, suggesting resorption of the graft postoperatively (Figure 6B).

Complications

Apart from the 3 patients with repair failures, no additional complications occurred in any patients.

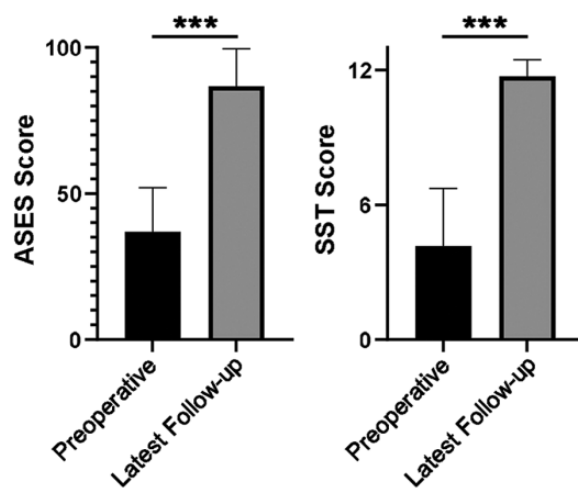


Figure 5. Comparison of preoperative and postoperative American Shoulder and Elbow Surgeons (ASES) and Simple Shoulder Test (SST) scores. Error bars represent standard deviations. *** $P < .00001$.

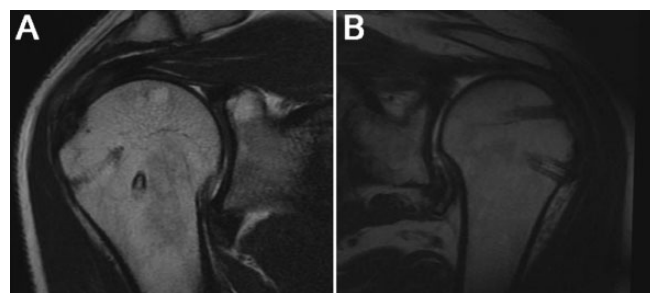


Figure 6. (A) Postoperative MRI demonstrating successful supraspinatus tendon repair without evidence of retear. (B) The nanofiber scaffold was not visible, suggesting complete resorption.

DISCUSSION

The current retrospective series of patients undergoing rotator cuff repair with nanoscaffold insertional site augmentation demonstrated a 91% (30/33) healing rate at average 10.5-month follow-up with significant improvements in ROM and functional outcome scores. Two failures of healing occurred in large and massive tear patterns, with one failure occurring as a transtendon failure medial to the tendon-bone junction and the other failure occurring at the tendon insertional site. The third failure occurred as a result of anchor pullout of a medium-sized tear. Most patients in this study had small- to medium-sized tears, and in this particular group, a 97% (32/33) healing rate was demonstrated, which is an improvement among healing rates reported in the literature.

Small- to medium-sized tears comprise the majority of tear patterns, and despite improvements in fixation technique, significant failure rates continue to be reported. In a multicenter study by Rashid et al,²⁶ small- and

medium-sized tears had 34% and 32% respective failure rates on MRI at 1 year. Bishop et al⁸ noted a 16% failure rate in arthroscopic repair of tears <3 cm. Methods to reduce failure rates by potentially improving the biological characteristics of the repair site can be of direct benefit to patients in terms of avoiding functional losses and revision surgeries caused by failure of tendon healing. Improving healing rates by augmenting the biological characteristics of the repair site may also be cost-effective when comparing additional upfront nanoscaffold costs versus the cost of continued surgeon office visits and subsequent revision or salvage surgeries in patients with failures. The cost of the graft at our institution is <\$1500, whereas estimated costs of revision rotator cuff surgery and even reverse total shoulder arthroplasty can exceed \$50,000.³⁶

The scaffold in the current study consists of 2 different polymers, poly(L-lactide-co-ε-caprolactone)¹⁵ and polyglycolide,⁴ both of which are biodegradable polymers that are used for several functions, such as implants for drug delivery or adjuncts for internal fixation of fractures.⁴ Synthetic scaffolds have the advantage of decreased inflammatory reaction when compared with biological scaffolds. Prior studies have shown that biological extracellular matrix scaffolds incite inflammatory reactions.^{23,35,37} In the current study, no issues with fibrosis or stiffness were noted. The benefits of synthetic polymers include less scarring at the bone-tendon interface due to diminished inflammatory response, which contributes to increased repair strength.²⁷ The graft used in our study is designed as an inlay device that is effectively sandwiched between the bone and rotator cuff tendon. Other scaffolds such as bovine collagen and acellular human dermal matrix have been used in the past to enhance cellular migration and the biological healing response, but these grafts are used as onlays and placed on top of the tendon. Much evidence suggests that rotator cuff failure occurs at the insertion point, so grafts affixed to the top of the tendon may not improve this mode of failure.^{3,19,24} The theoretical benefit of the inlay device, therefore, is that it may better facilitate cell migration and cell adhesion, which, in turn, may promote better tendon-bone healing in the zone where failure typically occurs. In a recently published sheep study, incorporation of the scaffold into rotator cuff repair increased the ultimate failure force by 47% at 12 weeks compared with control, which approached 75% of the nonsurgical tendon strength. Also, the tendon-bone attachment at 12 weeks histologically appeared more like native fibrocartilaginous insertion with prominent perforating collagen fibers.²⁸

Limitations

This study has several limitations. First, this series represents a small retrospective cohort. Although the data presented are encouraging, the lack of a control group makes it difficult to draw any concrete conclusions regarding the efficacy and long-term results of the use of the scaffold. A current, prospective comparative study is ongoing to further assess this. Second, we present a group of patients with small- to medium-sized tears, which may not carry failure rates as high as reported in other series. The use

of the graft in larger tears may have not yielded the same outcomes. Third, several patients were unable to complete follow-up, primarily because of the inability or refusal to obtain postoperative MRI scans. This was made additionally challenging because the majority of data collection occurred during the COVID-19 pandemic, and several patients were therefore hesitant or unable to complete the MRI scanning necessary to be included in our study. Fourth, the follow-up timepoint for imaging in the present study was 6 months. Other series have reported on timing of failures ranging from 3 to 15 months for medium-sized tears.³² We based the minimum 6-month imaging time frame on a study by Iannotti et al,²¹ which found that 95% of recurrent tears in patients with 1- to 4-cm tears occurred within the first 5 months postoperatively. We therefore believe that the inclusion of patients at 6 months would encompass most recurrent tears, but we submit that longer-term imaging follow-up may have yielded a higher failure rate than that reported.

CONCLUSION

We reported on the use of a novel, synthetic nanofiber scaffold for the interpositional augmentation of primary rotator cuff repair in a cohort of patients with a minimum 6-month follow-up. The use of the scaffold did not result in any major adverse events, and we noted a 97% tendon healing rate for small to medium-sized tears and a 91% healing rate for all tears. Patients in the cohort had significant improvement in active ROM, ASES score, and SST score. These early results are promising for the future of rotator cuff repair, and further randomized, prospective trials are currently underway.

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