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ORIGINAL ARTICLE

Radiologic and clinical evaluation of a bioabsorbable collagen implant to treat partial-thickness tears: a prospective multicenter study

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Background: Treatment of partial-thickness cuff tears remains controversial. Although conservative therapy may treat symptoms, these defects do not spontaneously heal and conversion to a full-thickness lesion with subsequent repair may alter the tendon footprint. The ability to induce new tissue formation and limit tear progression in intermediate- and high-grade partial-thickness tears without surgical repair may represent a significant advancement in the treatment paradigm for these lesions.

Methods: We prospectively enrolled 33 patients with chronic, degenerative, intermediate-grade (n = 12) or high-grade (n = 21) partial-thickness tears (11 articular, 10 bursal, 4 intrasubstance, and 8 hybrid) of the supraspinatus tendon in a multicenter study. Following arthroscopic subacromial decompression without repair, a bioinductive implant was attached over the bursal surface of the tendon. Clinical outcomes were assessed using American Shoulder and Elbow Surgeons and Constant-Murley scores preoperatively and at 3 and 12 months postoperatively. Magnetic resonance imaging was performed to assess postoperative tendon healing and thickness at the original tear site.

Results: At 1-year follow-up, clinical scores improved significantly ($P < .0001$) and the mean tendon thickness increased by 2.0 mm ($P < .0001$). Magnetic resonance imaging evidence of complete healing was found in 8 patients and a considerable reduction in defect size was shown in 23, whereas 1 lesion remained stable. In 1 noncompliant patient with a high-grade articular lesion, progression to a full-thickness tear occurred while shoveling snow 1 month after surgery. No serious adverse events related to the implant were reported.

This study was approved by Western Institutional Review Board (Puyallup, WA) (protocol No. 20141137). The common protocol of this study had institutional review board approval for each investigational site.

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Conclusions: Arthroscopic implantation of a bioinductive collagen scaffold is a safe and effective treatment for intermediate- to high-grade partial-thickness rotator cuff tears of the supraspinatus tendon.
Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Arthroscopy; rotator cuff tear; partial-thickness; shoulder; biological augmentation; tissue induction; collagen implant; magnetic resonance imaging

Partial-thickness rotator cuff tears (PTRCTs) represent a relatively common shoulder pathology with a prevalence approximately twice that of full-thickness tears.[8] However, treatment of PTRCTs remains controversial. Although a number of surgical techniques have been used to treat PTRCTs,[5,6,9,12,19-21,24,25,27,33,36,40,43,46] prospective randomized trials comparing outcomes have not identified one technique to be superior over another.[12,36] Treatment of PTRCTs involving less than 50% of the tendon thickness ranges from nonoperative activity modification and rehabilitation to tear débridement with or without subacromial decompression.[4,11] However, because PTRCTs do not heal spontaneously,[4,13-15] they have a propensity to increase in size and may develop into full-thickness lesions.[23,28,48] A recent prospective evaluation of asymptomatic degenerative tears reported that 44% of partial-thickness tears with a median length of 6 mm increased in size over a 5-year follow-up.[23] Although some surgeons have advocated conversion of PTRCTs to full-thickness lesions that are then repaired by conventional methods,[9,12,20,21,24,25,33,37,38] these techniques can have a reported failure rate of up to 18%.[29] The ability to limit tear progression or induce healing of PTRCTs without the need to convert these to full-thickness repairs is an attractive treatment option because it would not only preserve the native footprint of the intact tendon but also potentially reduce the attendant increase in recovery time associated with such repairs.

A preliminary study by Bokor et al[4] demonstrated magnetic resonance imaging (MRI) evidence of PTRCT healing following treatment with a highly porous collagen implant arthroscopically placed over the bursal surface of the supraspinatus tendon. Patients with intermediate- to high-grade bursal, articular, or intrasubstance partial-thickness tears of the supraspinatus tendon demonstrated no tear progression and showed progressive filling in of the defects coupled with improvement in tendon quality through 2-year follow-up. The mechanism of action for this healing response is thought to be related to the ability of the collagen implant to induce new host tissue formation and ingrowth over the bursal surface of the tendon.[4,45] This increase in tendon thickness is thought to improve the local biomechanical environment of the tear by reducing tendon strain, thus optimizing its healing potential.[4,45]

In an effort to validate initial findings, we conducted this study to further evaluate the safety and effectiveness of the same bioinductive implant in the arthroscopic treatment of intermediate- to high-grade PTRCTs in a larger patient population across multiple institutions. We hypothesized that when placed over the bursal surface of an injured tendon, the collagen implant would induce rapid host tissue ingrowth and create an environment that would either prevent tear enlargement or permit healing of the lesion as determined by MRI.

Materials and methods

A prospective, multicenter, open-label trial was conducted by 10 surgeons at 10 sites under a common protocol. All patients provided voluntary informed consent before enrollment.

Eligibility criteria

Patients were aged at least 21 years and had a diagnosis of a chronic, degenerative partial-thickness tear primarily of the supraspinatus tendon involving at least 25% of its thickness that was unresponsive to conservative treatment, such as pain medication, physical therapy, or injections, for a minimum of 3 months. A preoperative MRI scan was performed within 60 days prior to the procedure. Patients with full-thickness tears of the rotator cuff were excluded, as were those who presented with PTRCTs caused by acute injury or those who had undergone previous rotator cuff repair on the index shoulder. The exclusion criteria also included shoulder instability, chondromalacia of grade 3 or greater, cuff muscle fatty infiltration of grade 2 or greater, severe calcification within the index shoulder, and insulin-dependent diabetes. Patients with Workers' Compensation coverage; heavy smokers (>1 pack per day); those with a known hypersensitivity to bovine collagen; those with a genetic collagen disease; and those with a history of autoimmune, immunodeficiency, or chronic inflammatory disorders were excluded. To avoid potential inhibition of the healing process, oral steroid use within 2 months or a steroid injection within 1 month of enrollment was prohibited.

Patient evaluation

Prior to surgery, the medical history was recorded and each patient underwent a physical examination. In addition, the standardized American Shoulder and Elbow Surgeons (ASES) and Constant-Murley patient assessments were administered, and a noncontrast MRI scan of the affected shoulder was performed using a study-specific acquisition protocol. After eligibility was confirmed, the study procedure was performed within 60 days of this preoperative, or baseline, evaluation. At the time of surgery, intraoperative arthroscopic assessment of the rotator cuff pathology and visual confirmation of partial-thickness tear size were reviewed and recorded by the surgeon to confirm eligibility. Patients with a partial-thickness tear of less than 25% of the tendon thickness were not enrolled in the study.

Postoperative follow-up was performed 3 months and 1 year after the study procedure. At each follow-up, patients underwent a repeat