Porcine Small Intestine Submucosa Xenograft Augmentation in Repair of Massive Rotator Cuff Tears

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Abstract

In this prospective study, we evaluated the efficacy of using porcine small intestine submucosa (SIS) xenograft to augment the repair of massive rotator cuff tears. Our hypothesis was that SIS xenograft would help restore tendon tissue in the human model, as has been shown in several animal studies.

Eleven patients were followed clinically for a mean of 26 months (range, 14-38 months). Mean University of California Los Angeles end-result scores improved from 13.9 before surgery to 25.7 after surgery, American Shoulder and Elbow Surgeons scores improved from 36.3 to 71.8, and the visual analog scale pain score decreased from 6.6 to 2.0. All findings were statistically significant ($P<.01$). At a mean of 25 months after surgery, magnetic resonance arthrography (MRA) showed the repairs partially or completely intact in 44% of shoulders. Intact repairs were thin and wispy. There were 3 complications, which included 1 infection and 2 localized skin reactions that resolved spontaneously. SIS xenograft did not reconstitute rotator cuff tissue or add to the quality of the rotator cuff repair.

Given clinical concerns about localized reactions in this series and suboptimal MRA findings, use of SIS xenograft to augment rotator cuff repairs is not recommended.

The challenges of rotator cuff repair are magnified with massive-size tears. Despite multiple mobilization techniques, some tears are irreparable, or the repairs are very tenuous at best. An implant tissue (Restore Orthobiologic Implant; DePuy, Warsaw, Ind) made from porcine small intestine submucosa (SIS) was designed to reinforce soft-tissue repairs.[1] The concept is that this tissue construct will act as a resorbable biological scaffold and over time will be replaced by the patient's own soft tissue. Several animal studies have reported successful use of porcine SIS in restoring soft-tissue defects in orthopedic surgical applications.[1-3] Similar results were found in animal models using SIS as a bladder wall substitute,[4] in abdominal wall defects,[5] and in vascular settings.[6]

The purpose of this study was to evaluate the efficacy of using porcine SIS xenograft tissue to reinforce the repairs of massive rotator cuff tears. Our hypothesis was that SIS xenograft would help restore tendon tissue in the human model, as has been shown in several animal studies.

Materials and Methods

Institutional review board approval was obtained for this study. This prospective study was undertaken to evaluate shoulder function and rotator cuff integrity in patients undergoing porcine SIS xenograft augmentation of rotator cuff repairs. Indications for use of the SIS system in this study were either to augment rotator cuff repairs that could not be advanced to the native footprint or to reinforce repairs made tenuous by thin attritional tissues. In the case of a hemiparetic patient, SIS was used to bridge a defect between a retracted tendon and its insertion site involving the functional upper extremity (Figure 1).

Between November 1999 and March 2001, 11 patients, 9 men and 2 women (mean age, 48 years; range, 31-62 years), underwent SIS augmentation of a massive rotator cuff tear through an open superior approach. All surgeries were performed by the senior author (SAP). A massive tear was defined as being at least 5 cm at its largest diameter. The right side was affected in 9 cases, the left side in 2.

All 11 patients had a preoperative magnetic resonance imaging (MRI) study. They were followed clinically for a mean of 26 months (range, 14-38 months). Postoperative rotator cuff integrity was evaluated in 9 patients: 8 by magnetic resonance arthrography (MRA) a mean of 25 months (range, 14-38 months) after surgery and 1 by surgical exploration at 3 months. MRA results were evaluated by an attending shoulder surgeon (SAP) and a musculoskeletal radiologist. Rotator cuff repair was considered partially intact when the tear was smaller on postoperative MRA than on preoperative MRI. Functional outcome was assessed with University of California Los Angeles (UCLA) end-result score[7] and with the American Shoulder and Elbow Surgeons (ASES) standardized shoulder index

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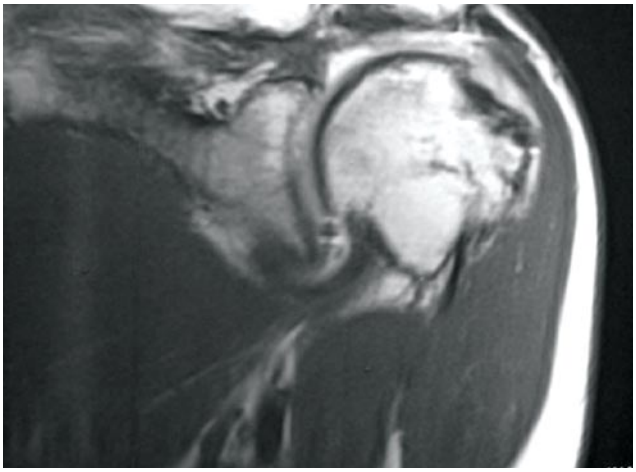

Figure 1. Two years after small intestine submucosa (SIS) was used to bridge defect, coronal magnetic resonance imaging (MRI) shows thin cuff-like tissue spanning defect. MRI also shows that SIS did not reconstitute into normal healthy rotator cuff tendon but covers humeral head.

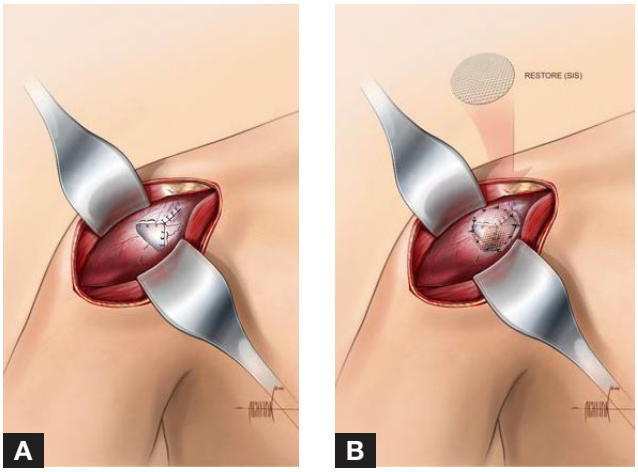

Figure 2. Drawings of (A) V–Y closure of rotator cuff tear and (B) small intestine submucosa augmentation of tenuous rotator cuff repair. Copyright 2009, Steve A. Petersen, MD.

score.[8] A visual analog scale was used to evaluate preoperative and postoperative pain. Statistical analysis was performed with SPSS software.

Operative Procedure

The shoulder is approached through an incision along the Langer skin lines. The deltoid origin is elevated off the anterior acromion and split along its fibers 2 to 3 cm. The rotator cuff is then mobilized using a series of 3 standard soft-tissue releases. First, the humeroscapular motion interface is freed between the rotator cuff and the overlying soft tissues. Second, releases are performed on the coracohumeral ligament, the rotator interval capsule, and, if necessary, the posterior interval between the supraspinatus and the infraspinatus along the scapular spine. Third, a posterior superior extralabral capsular release is performed. After these releases have been completed, the mobility of the rotator cuff is evaluated (Figure 2A). The SIS implant system was used when the attachment site was medialized[9] or when tendon quality was poor. The SIS graft was secured under tension to a bony attachment site by absorbable suture anchors approximating the footprint insertion site of the rotator cuff and sewn to the bursal surface of the rotator cuff, reinforcing the repaired rotator cuff tendon (Figure 2B).

Results

Three patients had a 1-tendon (supraspinatus) tear, 6 patients had a 2-tendon (supraspinatus, infraspinatus) tear, and 2 patients had a 3-tendon (supraspinatus, infraspinatus, subscapularis) tear. Seven patients had previously undergone rotator cuff surgery: 1 procedure (4 patients), 2 procedures (1 patient), 3 procedures (1 patient), or 4 procedures (1 patient) (Table). Mean UCLA end-result scores improved from 13.9 before surgery to 25.7 after surgery, and ASES scores improved from 36.3 to 71.8. Both findings were statistically significant ($P<.01$). The visual analog scale pain score decreased from 6.6 before surgery to 2.0 after surgery ($P<.01$). Ten (91%) of the 11 patients said they were satisfied with their outcome and would undergo the procedure again given the same circumstances. Active elevation improved from 109° (range, 30°-160°) to 126° (range, 40°-160°), but active external rotation with arm at side decreased from 37° (range, 10°-65°) to 28° (range, 10°-65°). Neither trend was statistically significant ($P>.05$). Active elevation improved in 6 patients, remained unchanged in 3, and decreased in 2. External rotation decreased in 7 patients, remained unchanged in 2, and improved in 2.

The rotator cuff integrity of 9 patients was evaluated with MRA (8 patients) or surgery (1 patient) (Table). Of the 8 MRI-evaluated repairs, 3 were intact, 1 partially intact, and 4 not intact; the 1 surgically evaluated repair was not intact. Overall, repairs were intact in 33% of the patients evaluated for rotator cuff integrity and in 44% when the partially intact repair was included. In general, the MRA appearance of the intact repairs was thin. There were 3 complications: 1 infection, which revealed dissolution of the graft during open surgical exploration and débridement, and 2 localized skin reactions, which resolved with nonoperative measures within a few weeks.

Discussion

The most pertinent evidence supporting use of SIS in rotator cuff repair was reported by Dejardin and colleagues[3] using a canine model. One group of dogs had their infraspinatus tendon surgically cut and repaired back to the greater tuberosity. The other group had the infraspinatus tendon excised, creating a 20-mm gap in length. This gap was filled with the SIS implant tissue. Mechanical and histologic evaluations were performed at 3 and 6 months. The appearance of the SIS-filled gap was grossly similar to that of the repaired tendon model and of the native infraspinatus tendon and spanned the entirety of the original defect when evaluated at both 3 and 6 months. Histologic evaluation at 3 months showed SIS-regenerated tissue well integrated into the infraspinatus, and

Table. Patient Data

Previous Surgery?	Surgeries (n)	Tendons Torn	Postoperative RC Evaluation	RC Intact?	RC Evaluation Period (mo)
Yes	1	2 (supraspinatus, infraspinatus)	MRA	Yes (partial)	13.5
Yes	4	1 (supraspinatus)	MRA	Yes	31
No	0	2 (supraspinatus, infraspinatus)	MRA	No	21
No	0	2 (supraspinatus, infraspinatus)	MRA	No	25
Yes	1	3 (supraspinatus, infraspinatus, subscapularis)	MRA	No	16.2
Yes	1	2 (supraspinatus, infraspinatus)	MRA	Yes	35.6
No	0	2 (supraspinatus, infraspinatus)	MRA	No	19.6
Yes	3	1 (supraspinatus)	MRA	Yes	37
Yes	1	3 (supraspinatus, infraspinatus, subscapularis)	Surgical	No	3
Yes	2	2 (supraspinatus, infraspinatus)	Not evaluated	Unknown	0
No	0	1 (supraspinatus)	Not evaluated	Unknown	0

Abbreviations: RC, rotator cuff; MRA, magnetic resonance arthrography.

no remnant of the original SIS implant could be seen. At 6 months, this regenerated tissue was similar to both repaired and normal native tendon. Mechanically, mean failure load of the repaired tendon was larger than the SIS construct at time 0 but was similar at 3 and 6 months. This animal model study found that use of this SIS xenograft tissue induced complete regeneration of a completely resected rotator cuff tendon and that the SIS-regenerated construct had mechanical strength properties similar to those of repaired tendon.

Investigating the use of SIS for Achilles tendon repair in a canine model, Badylak and colleagues[1] found that, 12 weeks after surgery, the implanted SIS material consisted of connective tissue similar to that of the normal, contralateral Achilles tendon. This similarity has also been found in anterior cruciate ligament surgery[2] and fascia lata defects[10] in dog models.

Postoperative function of patients undergoing rotator cuff repair correlates closely with preoperative tear size.[11,12] When more of the cuff is involved, it becomes more difficult to maintain the integrity of the rotator cuff repair. Harryman and colleagues,[13] using ultrasound at 6-year follow-up, found that only 57% of 2-tendon (supraspinatus, infraspinatus) repairs were intact, and only 32% of 3-tendon tears were intact. They also found that functional results were better when the repair remained intact. Similarly, Thomazeau and colleagues[14] used MRI to evaluate the integrity of rotator cuff repairs and found better flexion strength and Constant scores in intact repairs. Preoperative atrophy of the supraspinatus was the main predictive factor of a retear. Gerber and colleagues,[15] using MRI to evaluate 29 massive rotator cuff tears at a mean follow-up of 37 months, found 63% intact. Constant scores corresponded to a subjective value of 78% of a normal shoulder. Clinical results for patients with retears were clearly inferior to those with intact repairs.

For "irreparable" tears, subacromial decompression and débridement have been considered a treatment option.[16] However, results with débridement have been inferior to results with repair. Other options in treating irreparable massive rotator cuff tears involve muscle transfer using the latissimus dorsi[17,18] or the subscapularis,[19] hemiarthroplasty,[20] and reverse shoulder arthroplasty.[21,22]

There have been good results with repair of massive rotator cuff tears. Bigliani and colleagues[11] reported on 61 patients at a mean follow-up of 7 years. All patients had a massive tear of at least 2 entire tendons; 85% had satisfactory functional outcome, with 95% having good/excellent pain relief. Rokito and colleagues[23] reported on 30 patients who underwent repair of a massive rotator cuff tear. After a follow-up of more than 5 years, 77% of the patients had satisfactory results. Isokinetic strength testing showed mean peak torque in flexion, abduction, and external rotation ranging from 73% to 91% of the contralateral shoulder.

Two groups recently studied the use of SIS in rotator cuff repairs. In a retrospective review of 11 patients with large or massive rotator cuff repairs reinforced with SIS, Sclamberg and colleagues[24] found retear rates of 91% on MRI studies obtained 6 to 10 months after surgery. Clinical outcome scores were not improved. No adverse reactions were reported. Iannotti and colleagues[25] conducted a randomized controlled trial on 30 patients with chronic 2-tendon rotator cuff tears. Patients with prior shoulder surgery were excluded. Of the 15 patients who received SIS augmentation for repairs, only 4 (27%) had intact repairs evaluated with MRI imaging 1 year after repair. A sterile inflammatory-type reaction was found in 3 (20%) of the 15. Given the poor results, the investigators abandoned the clinical trial. Clearly, the results of using SIS in humans has not correlated with those reported in dog models.[1,3,10]

Our study is the third to investigate use of SIS for augmentation of massive rotator cuff tears, but it differs from the other 2 in several important ways. Our clinical and radiographic MRA follow-up was longer (mean, 2 years), our study was prospective, and the majority of our cases were revisions.

Use of SIS to augment massive rotator cuff repairs did not improve the structural integrity or healing of rotator cuff repairs in this study. Only 33% of the rotator cuff repairs remained intact, and reconstitution of tendon tissue was poor in most instances. Patient outcomes were less affected by tendon integrity; more than 90% of the patients were satisfied with their results. UCLA, ASES,

and pain scores all improved significantly. There was concern about a reaction to the SIS xenograft tissue. Two patients had atypical swelling with a superficial inflammatory reaction that resolved spontaneously with wound care and oral antibiotics. This swelling may have been a reaction to the graft tissue, as other studies have reported.[24,25] Symptoms appeared in both cases within the first few weeks after surgery.

A weakness of this study is its lack of comparison with conventional repair techniques for massive rotator cuff repair. However, the technique used in this study is the same one used by the senior author (SAP) for massive rotator cuff repair, except for the addition of SIS xenograft tissue. In addition, the percentage of intact repairs in this series was comparable to that reported by Harryman and colleagues[13] for 2-tendon repairs, and our clinical results seemed comparable to other investigators' results, discussed earlier. Jost and colleagues[26] also found that patients may have lasting improvement in symptoms after rotator cuff repair, whether or not it fails.

Conclusions

Despite reasonable patient satisfaction, use of SIS xenograft in this series did not show a clear superiority in restoration of rotator cuff integrity or in healing rate. The localized inflammatory reactions found in this series are of concern, as is their cause. The SIS implant system was designed to protect and reinforce soft-tissue repairs. Our MRA findings indicate that the SIS xenograft system did not reconstitute rotator cuff tissue. Given these findings, we do not recommend use of SIS xenograft tissue for augmentation of rotator cuff repairs.

Authors' Disclosure Statement

The authors report no actual or potential conflict of interest in relation to this article.

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