



Rotator cuff repair augmentation using a novel polycarbonate polyurethane patch: preliminary results at 12 months' follow-up

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Background: Preventing anatomic failure after rotator cuff repair (RCR) remains a challenge. Augmentation with a surgical mesh may permanently reinforce the repair and decrease failure rates. The purpose of this study is to assess the postoperative outcomes of open RCR augmented with a novel reticulated polycarbonate polyurethane patch.

Materials and methods: Ten patients with supraspinatus tendon tears underwent open RCR augmented with a polycarbonate polyurethane patch secured in a 6-point fixation construct placed over the repaired tendon. Patients were evaluated with preoperative and postoperative outcome measures, including the Simple Shoulder Test, visual analog pain scale, American Shoulder and Elbow Surgeons shoulder score, Cumulative Activities of Daily Living score, and University of California, Los Angeles shoulder scale, as well as range of motion. Postoperative magnetic resonance imaging was used to evaluate repair status.

Results: Patients showed significant improvements in visual analog pain scale, Simple Shoulder Test, and American Shoulder and Elbow Surgeons shoulder scores at both 6 and 12 months postoperatively ($P < .05$ and $P < .01$, respectively). The University of California, Los Angeles postoperative score was good to excellent in 7 patients at 6 months and in 8 patients at 12 months. Range of motion in forward flexion, abduction, internal rotation, and external rotation was significantly improved at both 6 and 12 months postoperatively ($P < .05$ and $P < .01$, respectively). Magnetic resonance imaging at 12 months showed healing in 90%; one patient had a definitive persistent tear. We found no adverse events associated with the patch, including the absence of fibrosis, mechanical symptoms, or visible subacromial adhesions.

Discussion: The polycarbonate polyurethane patch was designed to support tissue in growth and enhance healing as shown by preclinical animal studies. Clinically, the patch is well tolerated and shows promising efficacy, with a 10% retear rate at the 12-month time point.

Level of evidence: Level IV, Case Series, Treatment Study.

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Keywords: Rotator cuff; rotator cuff augmentation; surgical mesh; polyurethane scaffold; outcome

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Outcomes after rotator cuff repairs vary widely in the literature and are dependent on factors such as age,^{4,9,14,19} tear size,^{4,9,19,26} muscle atrophy,¹⁶ and chronicity.¹⁰ Despite improved understanding of rotator cuff pathology, surgical repair techniques, and instrumentation, a certain percentage of rotator cuff repairs still go on to failure.

Historically, studies have shown that despite repair failure, patients generally maintain a high level of satisfaction.^{16,19,24} However, critical examination of patient outcomes and recent long-term data has shown that healing and anatomic integrity of the rotator cuff repair site produce better outcomes.^{4,9,11,14,19,46} This knowledge has generated a trend among shoulder surgeons to place more emphasis on reducing anatomic failure rates in rotator cuff surgery.

Anatomic failure after rotator cuff repair is generally reported to occur in 20% to 40% of primary rotator cuff repairs,^{4,9,11,14,24,42} and the inability to attain high healing rates has fueled the investigation of a variety of biologic and bioengineered adjuncts to rotator cuff repair. Augmentation strategies including the use of Gore-Tex,²⁰ freeze-dried rotator cuff,^{32,33} periosteal patches,⁷ extracellular matrices,^{1,3,5,6,21,25,34,38,39,41} polyglycolide copolymers,^{2,13,30,35,47} polytetrafluoroethylene felt,²³ and chitosan-based hyaluronan polymers¹⁵ have all been investigated for augmentation scaffolding in rotator cuff tendon repair and regeneration; however, clinical data to support the use of these various devices are limited.

Reduced material properties of the rotator cuff muscle–tendon unit after a tear^{10,27,40,43} have significant effects on the repair and may ultimately be the driving force behind anatomic failure.⁴ Therefore, a possibility exists that the addition of a nonresorbable scaffold may provide permanent structural support to strengthen repairs and decrease anatomic failure rates.

The purpose of this study was to assess 6- and 12-month postoperative outcomes after mini-open rotator cuff repair augmented with a novel nonresorbable reticulated polycarbonate polyurethane patch (Biomerix, Fremont, CA).

Materials and methods

Study design

Before the initiation of this study, approval was given by the human subjects review board at the institution providing subject care (National Institute for Rehabilitation, Mexico City, Mexico) (09/08). Informed consent was obtained before enrollment into the study. A series of 10 female patients with full-thickness rotator cuff tears were identified by either ultrasound or magnetic resonance imaging (MRI). The criteria for inclusion were the presence of a full-thickness tear of either the supraspinatus or infraspinatus tendon and intact insertions of the subscapularis. All patients underwent preoperative assessment with the Simple Shoulder Test (SST), visual analog pain scale (VAS), American Shoulder and Elbow Surgeons (ASES) shoulder score, Cumulative Activities of Daily Living score, and University of California, Los Angeles

(UCLA) shoulder scale. Ten open repairs with augmentation were performed by the senior surgeon (I.E.-D.). Evaluation of tendon healing and cuff integrity was performed at 6 and 12 months after surgery with the use of MRI and ultrasound. Postoperative evaluation of patients was performed at 2 weeks, 4 weeks, 3 months, 6 months, and 12 months by use of validated scoring questionnaires and physical examination.

Patient population

Before surgery, all patients underwent a 6-month trial of conservative management consisting of physical therapy and anti-inflammatory medications. The mean patient age was 56.2 years (range, 44–65 years), and the mean duration of symptoms before surgery was 16.2 months. There were 9 right shoulders and 1 left shoulder, which corresponded to 8 dominant and 2 nondominant arms. Preoperative tear width was measured anterior to posterior and averaged 20 mm (range, 10–40 mm), and tear retraction averaged 21 mm (range, 10–35 mm).

Surgical technique

All patients were positioned in the beach-chair position under regional anesthesia. A 5-cm anterolateral approach was used. A small portion of the anterior and lateral fibers of the deltoid was detached from the acromion. The subacromial space was cleared of adhesions, and a subacromial decompression and partial bursectomy were performed exposing the underlying rotator cuff tear. The size of the tear was then measured with a ruler in the anterior-to-posterior and medial-to-lateral planes. Adhesions were then released to ensure adequate cuff mobility. The supraspinatus footprint was prepared with a rasp. Five-millimeter metallic anchors with double-loaded nonabsorbable sutures were then placed in the middle of the footprint without tension. Mason-Allen knot configurations were placed into the rotator cuff tendons approximately 10 mm from the free edge of the tendon. Once the repair was completed, the repair site was then reinforced with the augmentation patch. The patch was placed over the repair site on top of the tendon, and No. 2 polyester braided sutures were used to secure the patch with 6 points of fixation along the medial and lateral borders (Fig. 1). Concomitant biceps tenotomies were performed in all cases because of fraying and inflammation of the biceps tendon.

The postoperative regimen consisted of sling use for 4 weeks, after which patients commenced passive movement exercises under the supervision of a physiotherapist. Active movement exercises were commenced at 6 weeks. A cuff-strengthening exercise program was then followed, beginning at 8 weeks postoperatively.

Postoperative evaluation

Patients were evaluated postoperatively at 2 weeks, 4 weeks, 3 months, 6 months, and 12 months with validated scoring questionnaires, including the SST, VAS, ASES shoulder score, and Cumulative Activities of Daily Living score. The UCLA shoulder scale was used to evaluate patients at 6 and 12 months. Physical examination measured range of motion (ROM) for forward flexion, abduction, external rotation with the arm at the patient's

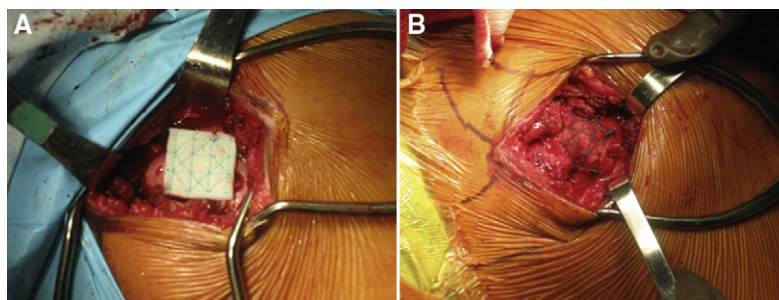


Figure 1 A and B, Intraoperative photographs showing 6-point suture repair configuration.

Table I Subjective shoulder surveys

	Preoperatively	6 mo postoperatively	<i>P</i> value: Preoperatively vs 6 mo postoperatively	12 mo postoperatively	<i>P</i> value: Preoperatively vs 12 mo postoperatively
VAS (maximum 10)	5.7	3.8	.009	2.6	<.001
SST (maximum 12)	3.6	6.5	.022	7.7	.004
ASES (maximum 100)	44.0	61.3	.008	73.3	<.001
CADL (maximum 20)	10.5	14.5	.054	16.6	.002
UCLA	N/A	27.8	N/A	29.2	N/A
SF-P	35.6	42.5	.027	40.4	.130
SF-M	45.5	53.1	.099	51.1	.318

CADL, Constant Activities of Daily Living; N/A, not applicable; SF-P, Short Form 12—Physical; SF-M, Short Form 12—Mental.

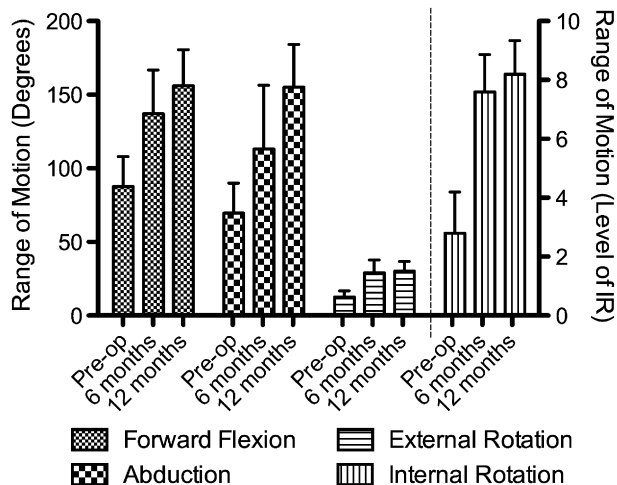


Figure 2 ROM. Forward flexion, abduction, and external rotation in degrees. Internal rotation values correspond to the level of internal rotation: dorsum of hand to interscapular region (T7) or higher (10), dorsum of hand to twelfth dorsal vertebrae (8), dorsum of hand to waist (L3) (6), dorsum of hand to lumbosacral junction (4), dorsum of hand to buttock (2), and dorsum of hand to lateral thigh or less (0). All 4 motions showed significant improvement from preoperatively to 6 months as well as preoperatively to 12 months ($P < .05$).

side, and internal rotation. All patients had MRI and ultrasound at 12 months postoperatively to evaluate repair site integrity.

Statistical analysis was performed with paired *t* tests to compare preoperative scores with 6-month and 12-month postoperative scores. The significance level was set at .05. Statistical

analysis was performed with GraphPad Prism 5.0 (GraphPad Software, San Diego, CA).

Results

Patients showed significant improvements in VAS, SST, and ASES scores at both 6 and 12 months postoperatively ($P < .05$ and $P < .01$, respectively). The UCLA postoperative score was good to excellent in 7 of 10 patients at 6 months and good to excellent in 8 of 10 patients at 12 months. The Cumulative Activities of Daily Living score was significantly improved ($P < .01$) at 12 months (Table I). ROM in forward flexion, abduction, internal rotation, and external rotation was significantly improved at both 6 and 12 months postoperatively ($P < .05$ and $P < .01$, respectively) (Fig. 2).

MRI and ultrasound at 12 months showed healing in 90% (9 of 10 patients) (Fig. 3); 1 patient showed a definitive re-tear (Fig. 4). No adverse events were found associated with the patch including the absence of fibrosis, mechanical symptoms, or visible subacromial adhesions. A summary of patient results is shown in Table II.

Discussion

High failure rates of rotator cuff repair result from a combination of reduced tissue quality^{10,27,29,36,43} after chronic injury and high stress seen at the tendon-bone



Figure 3 Postoperative MRI scan showing intact rotator cuff augmented with patch.

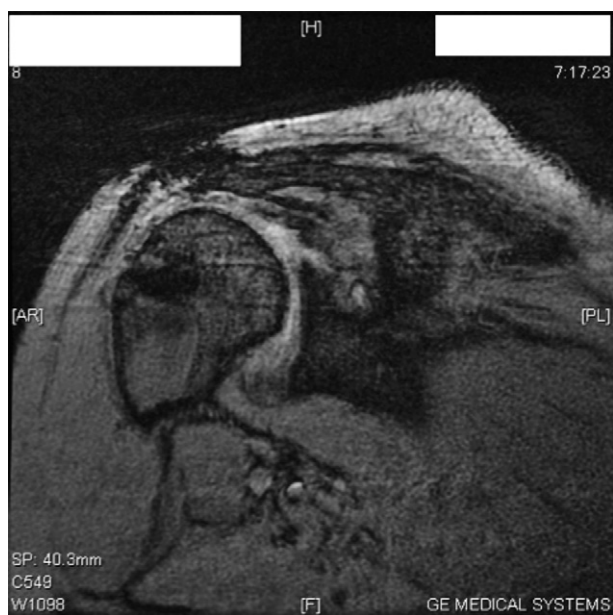


Figure 4 MRI scan at 12 months postoperatively showing retear of supraspinatus tendon.

interface.^{17,18} To address these problems, many researchers have investigated the use of augmentation devices secured over the repair site to buffer physiologic demands on the tendon and enhance mechanical properties of the repair. Many types of biologic devices have been described for augmentation. Our goal was to examine the efficacy of a new biocompatible nonresorbable synthetic device applied to provide long-term structural support to rotator cuff repairs.

Table II Summary of patient data, including demographic information; preoperative and 12-month postoperative data for VAS, SST, and ASES; and postoperative MRI

Patient No.	Sex	Age (y)	Tear size (cm ²)	VAS		SST		ASES		Postoperative MRI
				Preoperatively	Postoperatively	Preoperatively	Postoperatively	Preoperatively	Postoperatively	
1	F	65	20	2	0	5	7	73.3	83.3	Intact
2	F	51	62	7	4	7	12	36.7	75.0	Intact
3	F	59	20	5	4	4	2	36.7	53.3	Intact
4	F	52	40	5	1	1	9	40.0	81.7	Intact
5	F	51	70	8	3	3	7	26.7	73.3	Intact
6	F	44	40	4	1	6	7	56.7	86.7	Intact
7	F	64	80	4	3	3	6	53.3	61.7	Intact
8	F	53	50	8	3	6	10	41.7	71.7	Retear
9	F	61	30	7	4	1	8	51.7	68.3	Intact
10	F	62	15	7	3	0	9	23.3	78.3	Intact

Biologic extracellular matrix patches are composed of a collagenous matrix derived from xenogeneic or allogeneic tissue depending on the manufacturer. Human sources include processed human dermal tissue, whereas xenografts are generally derived from porcine dermis or small intestine submucosa. Although these patches are marketed as acellular, it has been shown that these grafts maintain DNA,¹² which may potentially incite inflammatory reactions after certain types of graft use.^{28,44,45,49} Malcarney et al²⁸ described an overt inflammatory reaction in 4 of 25 patients who underwent rotator cuff augmentation with porcine small intestine submucosal implants. In an animal model, Valentin et al⁴⁴ used histologic sampling to show inflammatory cellular responses in human dermal and porcine small intestine submucosal tissue grafts retrieved from Sprague-Dawley rats.

Our study used a synthetic device composed of biocompatible polycarbonate polyurethane-urea (Biomerix). Polyurethane has been found to be an innocuous polymer for soft-tissue applications in a variety of studies.^{8,22,31,37,48} The biologic response to supraspinatus tendon repairs augmented with a polycarbonate polyurethane patch in Sprague-Dawley rats has been examined previously, showing no inflammatory reaction on histologic sectioning and tissue in growth of 79.9%.⁸ Although histologic response was not examined in our study, we were unable to identify local inflammatory or adverse events associated with the polycarbonate polyurethane, consistent with previous investigations on the material.⁸

To shift the paradigm away from biologic resorbable augmentation, we used a synthetic nonresorbable reticulated polycarbonate polyurethane patch (Biomerix). It is difficult to compare the results of our study population with previous augmentation studies primarily because we performed augmentation on small and medium tears rather than large and massive rotator cuff tears, for which augmentation has typically been used. However, our premise was not to introduce a method of reconstructing larger cuff defects but was to address the more basic principle of anatomic failure after full-thickness tears, which is generally reported to occur in 20% to 40% of cases.^{4,9,11,14,24,42} In this study, we achieved a 90% healing rate at 12 months and significant improvements in postoperative clinical scoring and ROM by augmenting tears ranging from 1 to 4 cm with this device.

This study is not without limitations. The study population consisted of a small number of young female patients with only 12 months' follow-up. The mean tear width represents small- to medium-sized tears rather than large or massive tears, which would more often necessitate augmented repair. Furthermore, without a control group, it is difficult to assess all evaluation measures, including the healing rate. However, there is very little literature currently available on the clinical performance of synthetic nonabsorbable devices, and we have shown that a polycarbonate polyurethane patch can be safely implanted and

may enhance rotator cuff repair integrity and improve patient outcomes.

Conclusion

Despite improvements in rotator cuff repair techniques, anatomic failure rates after rotator cuff repair still remain high. Augmentation of the repair site with a nonresorbable scaffold may provide permanent structural support to strengthen repairs and decrease anatomic failure rates. The purpose of this study was to assess 6- and 12-month postoperative outcomes after rotator cuff repair augmented with a novel reticulated polycarbonate polyurethane patch (Biomerix) using subjective and objective outcome measurements including MRI. Clinically, the patch shows promising efficacy with a 10% retear rate at the 12-month time point. This augmentation device was well tolerated and did not show any adverse events at 12 months. This may provide a rationale for providing a permanent structural scaffold to enhance repairs and dissipate forces seen at the tendon-bone interface after rotator cuff repair.

Disclaimer

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