Early complications of biologic extracellular matrix patch after use for femoral artery repair

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ABSTRACT

Background: The CorMatrix (CorMatrix Cardiovascular, Roswell, Ga) biologic extracellular patch derived from porcine small intestinal mucosa provides a biologic scaffold for cellular ingrowth and eventual tissue regeneration. It has been used in a variety of applications, including cardiac and vascular repair procedures.

Methods: CorMatrix was used as a patch arterioplasty for femoral artery repair in conjunction with endarterectomy for seven separate procedures in six patients (one patient underwent staged, bilateral femoral procedures).

Results: Patients were a median age of 67 years (interquartile range, 3.6 years). Six of seven procedures (86%) were performed on male patients. There were no operative deaths. Three of seven procedures (43%) resulted in significant early complications. Two procedures (29%) resulted in catastrophic biologic extracellular matrix patch disruption (11 and 19 days after initial procedure), requiring emergency exploration, patch removal, and definitive repair with vein patch arterioplasty. Both patches demonstrated an absence of growth on culture. One procedure (14%) resulted in groin pseudoaneurysm formation. Use of the CorMatrix patch was suspended upon recognition of significant complications.

Conclusions: Use of CorMatrix patch in the femoral artery position demonstrates a high incidence of early postoperative complications, including catastrophic patch disruption and pseudoaneurysm formation. (J Vasc Surg 2016;■:1-6.)

CorMatrix (CorMatrix Cardiovascular, Roswell, Ga) is a biologic extracellular patch derived from porcine small intestinal submucosa (SIS). It is designed to provide a biologic scaffold for cellular ingrowth and eventual tissue regeneration. CorMatrix has been successfully used in a variety of applications, including cardiac and vascular repair procedures.[1,2] Some reports claim that the SIS material will become histologically indistinguishable from the tissue it is replacing.[3] Other reports document deficiencies in healing, resulting in significant complications.[3-7]

The initial impetus for this report was to examine the feasibility of implanting a CorMatrix patch as part of a femoral endarterectomy procedure. Outcomes are reported with an emphasis on complications.

METHODS

Institutional Review Board approved the protocol and informed consent, and all patients gave consent. A retrospective review was conducted to evaluate results of SIS implantation as an arterioplasty patch during femoral endarterectomy procedures. Patch implantation was suspended after the seventh implant upon recognition of a pattern of early complications. These seven procedures, performed in six patients (one patient underwent staged, bilateral femoral procedures) form the basis of this report.

Consecutive SIS patch implantation was conducted at Miriam Hospital (Brown University) beginning in November 2010. The last (seventh) implant was performed in November 2011, after which no new patients received SIS implants because of recognition of patch failure. Follow-up is reported through March 2016 for all patients in the study.

Each procedure was conducted as an otherwise standard, open-surgical common femoral/proximal superficial endarterectomy. Heparin (5000-6000 units) was administered before arterial clamping. A CorMatrix four-layer SIS patch was used for arterioplasty. SIS was prepared according to the manufacturer's specifications and secured into position with running 6-0 Proline (Ethicon, Somerville, NJ) suture. Graft patency was evaluated postoperatively in an outpatient setting using duplex ultrasound imaging and supplemented with angiography when available at the time of subsequent procedures.

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Table I. Patient characteristics, including operative details from each implant operation[a]

Patient			Risk factors				
Identifier	Age	Gender	DM	Smoker	HTN	HL	Chronic steroids
1	71	M	●		●	●	
2	66	M		●	●	●	●
3	66	M		●	●	●	
4	62	F		●	●		
5	67	M		●	●	●	
6	64	M		●	●	●	
7	79	M			●	●	

C, Claudication; *CFA,* common femoral artery; *DM,* diabetes mellitus; *F,* female; *HL,* hyperlipidemia; *HTN,* hypertension; *L,* left; *LOS,* length of stay; *M,* male; *R,* right; *SFA,* superficial femoral artery; *SVS,* Society for Vascular Surgery.
● Indicates that condition was present.
[a]Factors that were uniform across all cases included administration of perioperative cefazolin, minimal operative blood loss, and an absence of any additional/combined procedures or extended operative times.

Reporting and statistical methods are predominantly descriptive in nature. Given the relatively small number of patients, continuous data are represented as medians with interquartile ranges (IQRs).

RESULTS

Patients were a median age of 67 years (IQR, 3.6 years). Six of seven (86%) procedures were performed on male patients. The indication for surgery in each case was claudication, with severe peripheral arterial disease confirmed by angiography. There were no operative deaths. Three of seven procedures (43%) resulted in significant, early vascular complications. No complications were identified beyond the early postoperative period. All complications have been reported to the United States Food and Drug Administration (FDA). Additional details are provided in Table I.

Two of seven procedures (29%) resulted in biologic extracellular matrix patch rupture, identified 11 and 19 days postoperatively. In each case, the patients had a nearly identical clinical and operative course. Patients presented to the emergency room with a large (~25- × 15- × 15-cm) pulsatile groin mass. Both patients underwent immediate operative exploration. After evacuation of a large hematoma, active arterial hemorrhage was identified through a frank patch rupture. A full-thickness defect, measuring 0.5 cm in diameter, was observed in the exact center of the patch. All suture lines were intact. At the time, infection was presumed the cause. Intraoperative cultures were sent and empiric antibiotics (vancomycin/piperacillin-tazobactam) started.

The SIS material was removed in its entirety and replaced with a vein patch. Several days later, all intraoperative tissue cultures were negative for infection in both patients. At the time, infection remained the suspected cause, and a full course of antibiotics with oral levofloxacin (10 days) was completed. Additional perioperative details are provided in Table II for the two patients whose patch ruptured and required a second operation.

A gross specimen photograph (Fig 1) demonstrates the large, centrally located SIS patch defect. Histologic specimens (Figs 2 and 3) demonstrate that young fibroblasts have not yet produced adequate collagen.

One of seven procedures (14%) resulted in pseudoaneurysm formation. The patient presented for routine, outpatient follow-up 28 days postoperatively with no complaints. The physical examination identified a golf ball-sized pulsatile mass directly underlying his femoral endarterectomy incision. The patient was thin, and the anatomy was visualized clearly. He was offered treatment but refused. This pseudoaneurysm was chronologically the third complication encountered. Immediately upon its recognition, a pattern of noninfectious patch failure was recognized, and all further implantation of SIS was suspended.

Median patient follow-up was 56 months (IQR, 6.5 months), exclusive of one patient who was lost to follow-up. No late complications were identified. The remaining (four) femoral endarterectomy SIS patches were documented as patent by duplex ultrasound imaging and angiography.

The study design did not include a control cohort. For purposes of comparison, several observations can be made. One of the study patients in whom the CorMatrix patch ruptured had also undergone previous contralateral femoral endarterectomy using Dacron (DuPont, Wilmington, Del) for patch arterioplasty without complications. During the 4-year period immediately preceding this study, the same surgeon performed 44 consecutive femoral endarterectomy procedures using a Dacron patch for arterioplasty. No ruptures, pseudoaneurysms, or reoperations were identified on follow-up. During the same interval, 112 femoral endarterectomy procedures were performed at the same hospital by a number of