

Introduction

Atherosclerosis and thrombosis are the primary pathologies that affect ischemic stroke, coronary heart disease, and peripheral artery disease. Atherosclerosis affects approximately 3% to 10% of the U.S. population and is expected to increase to 20% in persons aged 70 years and older. Patients with symptomatic femoral artery (CFA) occlusive disease are typically treated with femoral endarterectomy with patch angioplasty, which is considered the gold standard approach. While these patch procedures are generally effective, there are limitations to current patch materials used in femoral reconstructive procedures. Aziyo's VasCure is a multi-laminate (6-ply) extracellular matrix (ECM) scaffold that is derived from porcine small intestinal submucosa (SIS) designed for surgical repair. The PERFORM Study (NCT02418156) is a prospective, multicenter, post-market observational study that evaluated the use of VasCure in patients that underwent femoral arterial reconstruction.

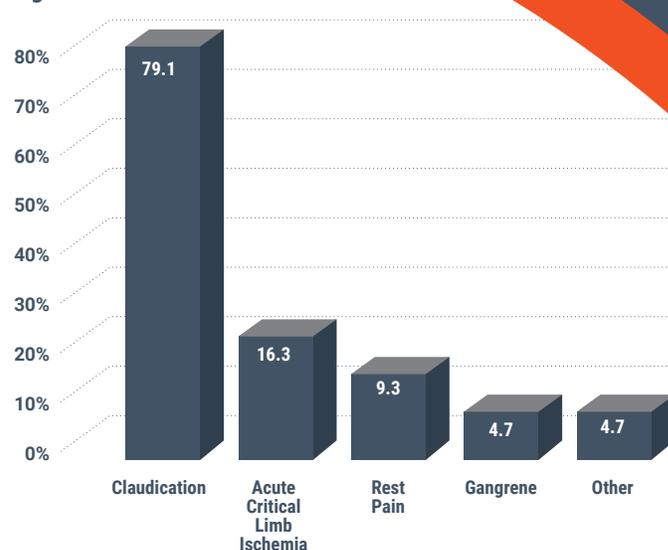
Methods

Patients eligible for the study were indicated for femoral arterial reconstruction with patch angioplasty using VasCure. The study endpoint was the proportion of patients with device-related events, defined as a clinical sign, symptom, or condition that was causally attributed to the device. Clinical follow-up included duplex imaging and evaluation of adverse events at: 4-6 weeks, 6 months, and 12 months following femoral arterial reconstruction.

Table 1. Patient Demographics & Medical History

Demographics	Patients n=38
Age	63.7 ± 11.0
Male Gender	27 (71.1%)
Medical History	Patients n=38
Hypertension	35 (92.1%)
Hyperlipidemia	26 (68.4%)
Diabetes	18 (47.4%)
Previous Peripheral Vascular Surgery	20 (52.6%)
Active Tobacco Use	15 (39.5%)
Chronic Renal Insufficiency	7 (18.4%)

Figure 1. Indications for Intervention



Results

A total of 38 patients were enrolled at 3 centers; 45 procedures were performed and included in the study analysis. The enrolled patients included 27 males (71.1%), and the mean patient age was 63.7 years ± 11.0. Patient demographics included hypertension (92.1%), hyperlipidemia (68.4%), diabetes (47.4%), previous peripheral vascular surgery (52.6%), chronic renal insufficiency (18.4%), and active tobacco use (39.5%) (Table 1). Patients in the study presented with the following indications for intervention: claudication (79.1%), acute critical limb ischemia (16.3%), rest pain (9.3%), gangrene (4.7%), and other (4.7%) (Figure 1).

Femoral revascularization procedures included ilio-femoral endarterectomy (66.7%), femoral endarterectomy (24.4%), ilio-femoral endarterectomy with profundaplasty (6.7%), and other (2.2%) (Table 2).

There were no device-related adverse events and no patch infections. Six patients (14.0%) experienced a total of seven procedure-related events including pseudoaneurysm due to suture break (VasCure remained intact) in one patient (2.3%), superficial wound infection (dermal) affecting one patient (2.3%), surgical site seroma in two patients (4.7%) and pain and/or numbness of the extremities in three patients (7.0%) (Table 3).

There was a 100% procedural success rate. Primary patency was maintained in 97.7% of procedures at an average of 252 days ± 166 as recorded with duplex imaging. There were no instances of patch explant reported.

PERFORM Study: Multicenter Study Using VasCure™ in Femoral Arterial Reconstruction

Table 2. Procedure Performed

Procedure Performed	Patients n=45
Ilio-femoral Endarterectomy	30 (66.7%)
Femoral Endarterectomy	11 (24.4%)
Ilio-femoral Endarterectomy with Profundaplasty	3 (6.7%)
Other	1 (2.2%)

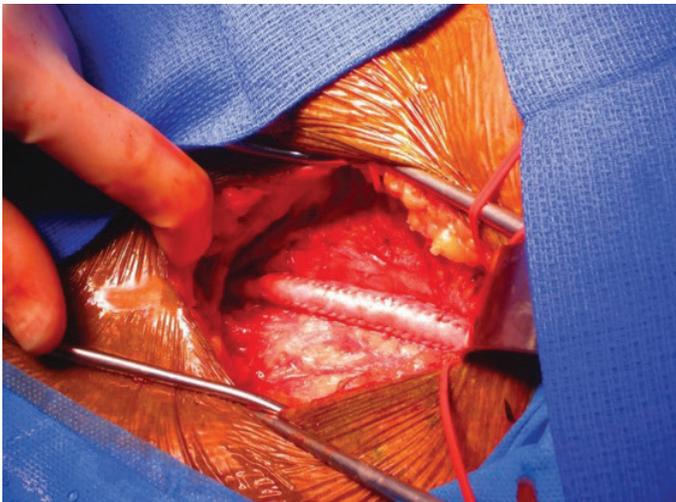
Table 3. Adverse Events

Device Related Events	# of Patients
Patch Infections	0 (0%)
Adverse Events	0 (0%)
Procedure Related Events	# of Patients
Pseudoaneurysm (Suture Break)	1 (2.2%)
Superficial Site Seroma	2 (4.4%)
Superficial Wound Infection	1 (2.2%)
Pain and/or Numbness of Extremity	3 (6.7%)

Conclusions

With no complications related to VasCure and a high primary patency rate at follow-up, the results of PERFORM demonstrated the safety and effectiveness of VasCure when used in arteriotomy closure during artery endarterectomy.

Figure 2. VasCure in femoral arterial reconstruction



Benefits of VasCure

- Remodels into site-specific tissue*
- Less susceptible to infection than synthetic graft material*
- Handles similar to vein and conforms to repair the defect*
- Hemostatic with minimal bleeding at suture lines*
- Unlike synthetic or cross-linked materials, the elastic modulus approximates normal tissue*
- Resists calcification*

* Data on file

CPT Codes used in PERFORM Study Thromboendarterectomy Procedures on Arteries and Veins:

- **CPT 35371** – Common femoral artery endarterectomy: thromboendarterectomy including patch graft, if performed.
- **CPT 35372** – Deep femoral artery endarterectomy: thromboendarterectomy including patch graft, if performed.
- **CPT 35355** – Thromboendarterectomy including patch graft, if performed.

VasCure is intended for use as a patch material for repair and reconstruction of peripheral vasculature including the carotid, renal, iliac, femoral, and tibial blood vessels. VasCure for Vascular Repair may be used for patch closure of vessels, as a pledget, or for suture line buttressing when repairing peripheral vessels.

Source: Adams JD, Robinson WP, Lumsden AB. Preliminary results of a prospective, multi-center study of extracellular matrix scaffold for femoral arterial reconstruction. Presented at the 44th VEITH Symposium 2017, New York, NY.



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