VasCure®
For Vascular Repair

PERFORM STUDY

MULTICENTER STUDY EVALUATING VASCURE® IN FEMORAL ARTERIAL RECONSTRUCTION

INTRODUCTION

Patch repair is the preferred method for arteriotomy closure following femoral or carotid endarterectomy. Choosing among available patch options remains a clinical challenge, as current evidence suggests roughly comparable outcomes between autologous grafts and synthetic and biologic materials. Biologic patches have potential advantages over other materials, including reduced risk for infection, mitigation of an excessive foreign body response, and the potential to remodel into healthy, vascularized tissue.[1]

VasCure is a multi-laminate (6-ply) extracellular matrix (ECM) scaffold that is derived from porcine small intestinal submucosa (SIS) designed for surgical repair.[2] Unlike synthetic and cross-linked biologic patches, VasCure, when implanted properly, can regulate the body's immune response, mitigating excessive calcification and inflammation, and can remodel into functional, site-specific tissue. The PERFORM Study is a prospective, multicenter, post-market observational study that evaluated the use of VasCure in patients that underwent femoral arterial reconstruction.

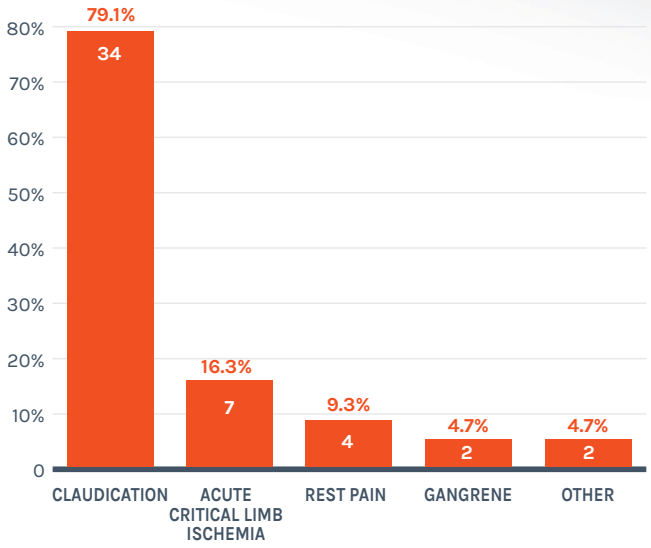
METHODS[1]

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	
Hypertension	35 (92.1%)
Hyperlipidemia	26 (68.4%)
Diabetes	18 (47.4%)
Previous Vascular Surgery	20 (52.6%)
Active Tobacco Use	15 (39.5%)
Chronic Renal Insufficiency	7 (18.4%)

FIGURE 1. INDICATIONS FOR INTERVENTION



RESULTS[1]

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%), previous vascular surgery (52.6%), diabetes (47.4%), active tobacco use (39.5%) , and chronic renal insufficiency (18.4%) (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).

TABLE 2. PROCEDURE PERFORMED

Procedure Performed	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%)

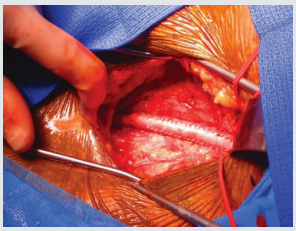
TABLE 3. ADVERSE EVENTS

Device Related Events	# of Patients
Patch Infections	0 (0.0%)
Adverse Events	0 (0.0%)
Procedure Related Events	**# of Patients**
Pseudoaneurysm (Suture Break)	1 (2.3%)
Superficial Site Seroma	2 (4.7%)
Superficial Wound Infection	1 (2.3%)
Pain and/or Numbness of Extremity	3 (7.0%)

There were no device-related adverse events and no patch infections. Five patients (13.2%) experienced a total of seven procedure-related events including pseudoaneurysm due to suture break (VasCure remained intact) in one patient, superficial wound infection (dermal) affecting one patient, surgical site seroma in two patients and pain and/or numbness of the extremities in three patients (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.

ECM FOR VASCULAR REPAIR IN FEMORAL ARTERIAL RECONSTRUCTION



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 VEITHsymposium 2017, New York, NY.

CONCLUSIONS[1]

This PERFORM Study demonstrated the safety and effectiveness of VasCure for Vascular Repair in femoral arterial reconstruction procedures through up to approximately 8 months with regular follow-up. There was 100% procedural success with good patency, and no device-related vascular complications.

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Extracellular Matrix Patches for Endarterectomy Repair[1]

References

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BENEFITS OF VASCURE FOR VASCULAR REPAIR:

- Preparation takes only 1-2 minutes in sterile saline.[2]
- Material can be custom shaped to fit needed anatomy.[2]
- Natural material, non-crosslinked bioscaffold[2]
- Remodels into site-specific tissue[1,3]
- More resistant to infection than synthetic material[4,5,6]
- Demonstrated similar compliance to native arteries compared to autologous grafts or synthetic material.[1,7]
- Hemostatic with minimal bleeding at suture lines[3]
- Modulates the biologic healing response and reduces inflammation[4,8]

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