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Vascu-Guard

PERIPHERAL VASCULAR PATCH

25+ YEARS

VASCU-GUARD IS ASSOCIATED WITH FAVORABLE OUTCOMES AND REDUCED SIGNIFICANT RESTENOSIS FOR CEA PATCH ANGIOPLASTY.

Carotid endarterectomy (CEA) is recognized as the best procedure for treatment of symptomatic and asymptomatic significant internal carotid stenosis.[1,2] When compared to primary closure, patch angioplasty may be associated with reduced long-term restenosis and reduced risk of stroke.[3] Furthermore bovine pericardium patch angioplasty may offer post-operative advantages over Dacron, autologous vein and Polytetrafluoroethylene (PTFE).[1]

VASCU-GUARD IS ASSOCIATED WITH A LOW INCIDENCE OF PERI-OPERATIVE AND LONG-TERM ADVERSE OUTCOMES.[4]

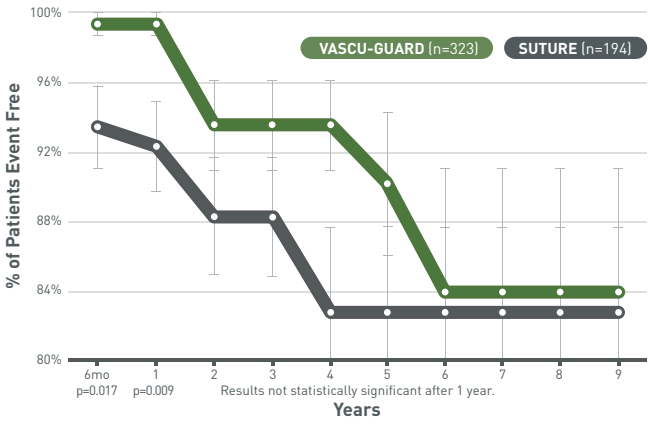
In a retrospective review of 129 CEA procedures with VASCU-GUARD patch angioplasty, Grimsley et al. (2001) observed the following peri-operative and long-term outcomes:

18 MONTHS FOLLOW UP
No peri-operative strokes
No peri-operative acute occlusions
No peri-operative bleeding episodes requiring reoperation
No peri-operative deaths
No significant restenosis (>70%)

41.7 ± 4.4 MONTH FOLLOW UP
No asymptomatic occlusions
No infections
No aneurysm
No rupture
2.6% significant restenosis (>70%)

VASCU-GUARD OFFERS COMPARABLE TO IMPROVED LONG-TERM RESULTS COMPARED TO PRIMARY CLOSURE AND DACRON PATCHES.[2,5]

VASCU-GUARD VS PRIMARY CLOSURE

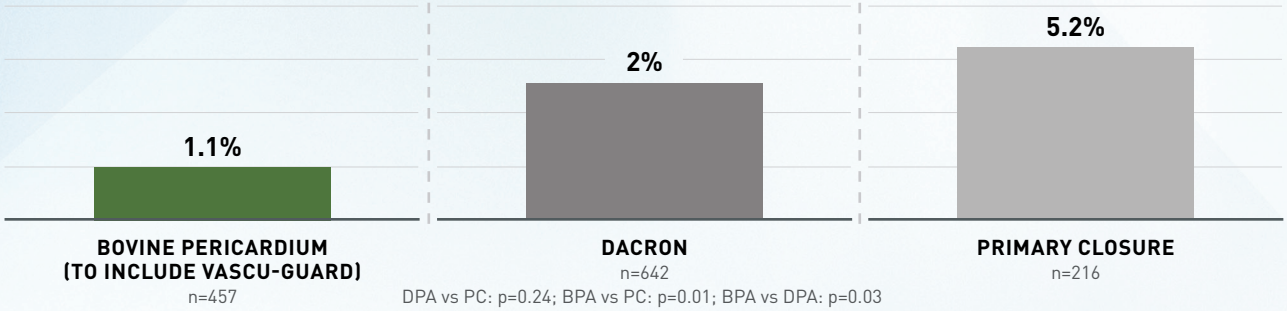


Biasi et al. (2002) followed 517 patients over a 9-year period from 1 to 108 months.

Patients were followed with duplex scan assessment at 1, 3, and 6 months and every year thereafter. Restenosis greater than 60% or carotid occlusion were considered adverse events. The adverse event rate was determined per year in each group of patients (VASCU-GUARD vs suture).[2] While not statistically significant after 1 year, patients receiving patch angioplasty with VASCU-GUARD had fewer adverse events over a 9-year period when compared to primary closure.

In a retrospective review of 1331 patients undergoing primary CEA procedures, Ho et al. (2012) compared results between primary closure and angioplasty with Dacron and bovine pericardium patches. Patients having received angioplasties with bovine pericardium patches (to include the use of VASCU-GUARD) had reduced restenosis at the 5-year mark when compared to both primary closure and angioplasty with Dacron patches.[5]

RESTENOSIS AT 5 YEARS: BOVINE PERICARDIUM VS DACRON AND PRIMARY CLOSURE



CAROTID ENDARTERECTOMY PROCEDURES WITH VASCU-GUARD OFFER COMPARABLE RESULTS TO EVERSION ENDARTERECTOMY.[6]

Dorweiler et al. (2015) evaluated outcomes of CEA with VASCU-GUARD compared to eversion endarterectomy (EEA) and concluded the two procedural types had comparable results for 30-day mortality, neurologic outcomes, and 5-year restenosis rates.[6]

DORWEILER ALSO NOTED LOWER INCIDENCE OF NECK HEMATOMAS DUE TO VASCU-GUARD'S:

- Decreased susceptibility for suture line bleeding
- Resistance to infection
- Enhanced biocompatibility

Clinical efficacy combined with its material properties make VASCU-GUARD an ideal choice for Vascular surgeons. Not only does the native collagen graft offer durability and excellent handling characteristics, VASCU-GUARD promotes high biocompatibility and low antigenicity.[2,7] Garcia-Aroz et al. (2018) noted that because VASCU-GUARD is associated with reduced infection, it is a suitable choice in immunosuppressed patients at greater risk for infection.[8] Overall VASCU-GUARD is associated with early, mid-term and long-term favorable outcomes.

For more information, contact your Baxter representative or visit www.advancedsurgery.baxter.com

VASCU-GUARD INDICATIONS FOR USE:
VASCU-GUARD Peripheral Vascular Patch is used for peripheral vascular reconstruction including the carotid, renal, iliac, femoral, profunda and tibial vessels.

CONTRAINDICATIONS & ADVERSE REACTIONS:
VASCU-GUARD is not designed, sold or intended for use except as indicated.

WARNINGS:
Failure to rinse the product may result in a sterile inflammatory reaction. Do Not freeze. The patch must remain moist at all times.

Rx only. For safe and proper use of this device refer to the complete Instructions for Use.

Advancing the art of healing

1. Edenfeld, L., et al. (2019). Outcomes of carotid endarterectomy in the Vascular Quality Initiative based on patch type. J Vasc Surg:1-8.
2. Biasi, G.M., et al. (2002). Nine-year experience of bovine pericardium patch angioplasty during carotid endarterectomy. J Vasc Surg, 36:271-277.
3. Hines, G.L., et al. (2007). Results of Carotid Endarterectomy with Pericardial Patch Angioplasty: Rate and Predictors of Restenosis. Ann Vasc Surg, 21: 767-771.
4. Grimsley, B.R., et al. (2001). Bovine pericardial patch angioplasty in carotid endarterectomy. The American Surgeon, 67: 890-895.
5. Ho, K.J., et al (2012). Intermediate-term outcome of carotid endarterectomy with bovine pericardial patch closure compared with Dacron patch and primary closure. J Vasc Surg, Mar;55(3):708-14.
6. Dorweiler, B. et al. (2015). Long-Term Performance of the Bovine Pericardium Patch in Conventional Carotid Endarterectomy. Thorac Cardiovasc Surg, Mar;63(2):168-74.
7. Matagas, M. I., et al. (2006). Carotid Endarterectomy with Bovine Pericardium Patch Angioplasty: Mid-Term Results. Ann Vasc Surg, 614-619.
8. Garcia-Aroz, S., et al. (2018). The use of bovine pericardial patch for vascular reconstruction in infected fields for transplant recipients. J Vasc Surg Cases Innov Tech, Mar6;3(1);47-49.

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