

CAROTID REGISTRY RESULTS

VasCure[®] was demonstrated to be a safe and effective option for vascular repair when used for carotid patch angioplasty.¹ Summarized below are outcomes after 2-year follow-up of 221 patients.

DESIGN

The Carotid Registry Study was a multi-center, prospective, single-arm, post-market, observational registry study. The objective of the study was to capture and assess patch performance data from subjects undergoing patch angioplasty of the carotid artery following carotid endarterectomy using VasCure. The endpoints were defined as carotid procedure and device-related adverse events. Carotid restenosis was evaluated with carotid duplex imaging.

METHODS

Patients undergoing carotid endarterectomy procedures and VasCure patch repair at participating centers were considered for enrollment and included if consent was obtained. There were 221 patients treated at six centers. Follow-up visits occurred at one to three months, six months, 12 months, and 24 months post-treatment.

CONCLUSION

The data from the Carotid Registry Study shows reductions in stenosis following carotid endarterectomy, with mean change from baseline in maximum carotid stenosis of at least 50% across all time points with patency maintained in 89% of patients through 24 months.¹ VasCure was demonstrated to be a safe and effective option when used for carotid patch angioplasty. Adverse events and restenosis rates were at or below those reported in the literature for other materials used for carotid patch angioplasty.

RESULTS

BASELINE DEMOGRAPHICS AND CHARACTERISTICS

- > 69.9 ± 10 Years of Age
- > 53.4% (118) Male
- > 82.4% (182) Hypertension
- > 38.0% (84) Diabetes
- > 33.9% (75) Smoking
- > 23.1% (51) Previous TIA
- > 10.0% (22) Previous TIA (symptomatic)
- > 19.5% (43) Previous Stroke
- > 9.0% (20) Previous Stroke (symptomatic)

SAFETY

- > There were 0% (0) device-related deaths
- > 13 Device-Related Adverse Events in 12 Patients:
- > Possibly related
 - 2.7% (6) Restenosis
 - 0.45% (1) Ulceration distal to VasCure patch
 - 0.45% (1) Occlusion
 - 0.45% (1) Thrombus opposite VasCure patch
 - 0.45% (1) Hematoma
- > Probably related
 - 0.5% (1) Herald bleed
- > Definitely related
 - 0.9% (2) Pseudoaneurysm/patch rupture*

**both events occurred in the same patient*

EFFECTIVENESS

MAXIMUM CAROTID STENOSIS

- > 85.5% Baseline mean carotid stenosis
- > 32.6% 6-month post-repair mean carotid stenosis
- > 33.6% 12-month post-repair mean carotid stenosis
- > 33.8% 24-month post-repair mean carotid stenosis

Comparison of Published Literature Carotid Repair Rates of Other Device Materials and VasCure

	CAROTID REPAIR WITH SYNTHETIC MATERIALS LITERATURE RATES					CAROTID REPAIR WITH VASCURE LITERATURE RATES	
	Synthetic Patch	Vein Patch	Dacron Patch	Bovine Pericardium	Acuseal (PTFE)	Carotid Registry ¹ n=221	Independent Study ¹³ n=275
Restenosis [*]	1-6% ²	2-10% ^{2,3,9}	2-19.7% ^{2,8}	1-3% ³⁻⁸	0-4% ^{5,7}	2.7%	4.5%
Patch Infection	0.1-1% ²	0-3% ^{2,9}	0.3% ⁸	0-0.6% ^{7,8}	3% ⁷	0%	0%
Stroke	0-5% ²	1-4% ^{2,3,8,10}	0-6% ^{2,8,11,12}	0.6-2% ^{3-8,10,12}	3% ⁷	0%	3.1%
Pseudoaneurysm	0.3% ²	3.6% ²	0.3% ⁸	0.2% ⁸	N/R	0.45%	0.3%
Hematoma	N/R	1.1% ⁹	2-3% ^{8,12}	0-6% ^{4-8,12}	1% ⁷	0.45%	N/R
Thrombosis Formation	N/R	2.2% ⁹	N/R	1% ⁷	1% ⁷	0.45%	0.3%
Aneurysm	N/R	2% ³	N/R	0% ³	N/R	0%	N/R
Artery/Patch Rupture	0.2% ²	0.4-1.7% ^{2,9}	N/R	N/R	N/R	0.45%	N/R
Occlusion	0% ²	N/R	5% ²	N/R	N/R	0.45%	N/R
Bleeding	N/R	N/R	1.7% ¹¹	N/R	N/R	0.45%	0.3%

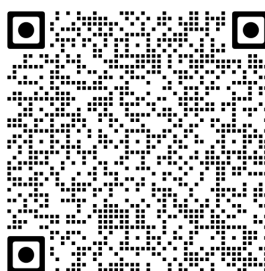
* Restenosis >50%

N/R: Not reported or collected in the study or publication

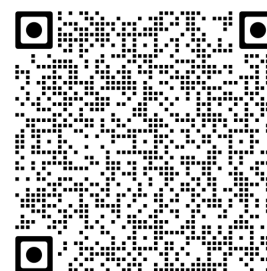
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Extracellular Matrix Patches for Endarterectomy Repair¹



Long-Term Results with CorMatrix ECM Patches After Carotid Endarterectomy¹³

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information. VasCure for Vascular Repair is indicated 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.

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