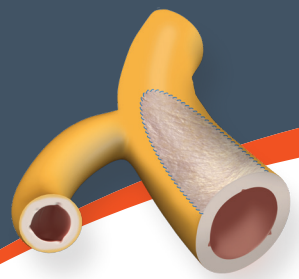

VasCure™ for Vascular Repair

Carotid Registry Results

VasCure™ was demonstrated to be a viable option for vascular repair when used for carotid patch angioplasty. 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 device performance data from subjects undergoing patch angioplasty of the carotid artery following carotid endarterectomy using the VasCure for Vascular Repair. 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 at participating centers were considered for enrollment and included if consent was obtained. There were 221 patients enrolled at six centers. Follow-up visits occurred at one to three months, six months, 12 months, and 24 months post-treatment with VasCure.

CONCLUSION

VasCure was demonstrated to be a viable option for vascular repair 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.

	n	Pseudoaneurysm	Thrombus	Restenosis
All Patients	221	0.5%	.5%	2.7%
Literature Rates	N/A	0.3 - 3.6%[1,2]	Up to 4%[3]	4.3 - 6.4%[2,4]

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RESULTS

BASELINE DEMOGRAPHICS AND CHARACTERISTICS

- 69 ± 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

- 12 Potentially Device-Related Events in 12 Patients
  - 2.7% (6) Restenosis
  - 0.5% (1) Pseudoaneurysm/Patch Rupture
  - 0.5% (1) Occlusion
  - 0.5% (1) Hematoma
  - 0.5% (1) Thrombus opposite VasCure patch
  - 0.5% (1) Ulceration distal to VasCure patch
  - 0.5% (1) Herald bleed
- 13 Deaths (None Device Related)

EFFICACY

MAXIMUM CAROTID STENOSIS

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

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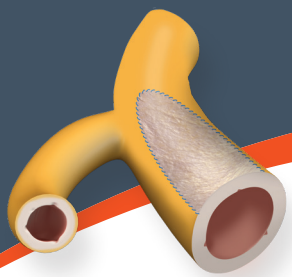

VasCure™ for Vascular Repair

VasCure is used for repair or reconstruction of peripheral vasculature including the carotid, renal, iliac, femoral and tibial blood vessels.

Comparison of Published Literature Rates of Other Device Materials and VasCure	LITERATURE RATES					VASCURE RATES (6-PLY)
	Synthetic Patch	Vein Patch	Dacron Patch	Bovine Pericardium	Acuseal (PTFE)	All Field-Reported Carotid/Vascular Events Including Registry Study* n = 37,820 [December 31, 2018]
Restenosis	1-6%[1]	2-10%[1,2,7]	2-19.7%[1,6]	1-3%[2-6]	0%[5]	0.037%
Infection	0.1-1%[1]	0-3%[1,7]	0.3%[6]	0-0.6%[5,6]	3%[5]	0.024%
Stroke	0-5%[1]	1-4%[1,2,7,8]	0-6%[1,6,9,10]	0.6-2%[2-6,8,10]	3%[5]	0.019%
Pseudoaneurysm	0.3%[1]	3.6%[1]	0.3%[6]	0.2%[6]	N/R	0.040%
Hematoma	N/R	1.1%[7]	2-3%[6,10]	0-6%[3-6,10]	1%[5]	0.034%
Thrombosis Formation	N/R	2.2%[7]	N/R	1%[5]	1%[5]	0.013%
Aneurysm	N/R	2%[2]	N/R	0%[2]	N/R	0.034%
Artery/Patch Rupture	0.2%[1]	0.4-1.7%[1,7]	N/R	N/R	N/R	0.045%
Occlusion	0%[1]	N/R	5%[1]	N/R	N/R	0.026%
Bleeding	N/R	N/R	1.7%[9]	N/R	N/R	0.011%

**Calculations include all post market registry adverse events classified as having a possible, probable, or definite relationship to the device. Some adverse events reported were used in an off-label indication.*

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

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