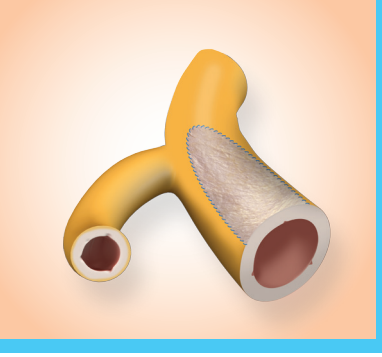

CorMatrix® for Vascular Repair

Carotid Registry One Year Report

CorMatrix® for Vascular Repair was demonstrated to be viable as a vascular repair material when used for carotid patch angioplasty. This data represents results after enrollment, treatment, and 1-year follow-up of 221 patients.

DESIGN

The Carotid Registry Study is a multi-center, prospective, single-arm, post-market, observational registry study. The objective of the study is to capture and assess device performance data from subjects undergoing patch angioplasty of the carotid artery following carotid endarterectomy using the CorMatrix ECM 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 treated at 6 centers. Patients were enrolled and followed at 1 to 3 months, 6 months, 12 months, and 24 months post-treatment with CorMatrix ECM. An additional 24 month follow-up is planned and will be presented in a later report.

CONCLUSION

Use of CorMatrix ECM for Vascular Repair was demonstrated to be viable as a vascular repair material when used for carotid patch angioplasty. Adverse events and restenosis were at or below the rates presented in the literature for other materials used for carotid patch angioplasty.

RESULTS

BASELINE DEMOGRAPHICS AND CHARACTERISTICS

- 69 ± 10 Years of Age
- 53.4% (n=118/221) Male
- 83.5% (n=182/218) Hypertension
- 38.5% (n=84/218) Diabetes
- 33.9% (n=75/221) Smoking
- 23.4% (n=51/218) Previous TIA
- 10.1% (n=22/218) Previous TIA (symptomatic)
- 19.7% (n=43/218) Previous Stroke
- 9.2% (n=20/218) Previous Stroke (symptomatic)

SAFETY RESULTS

- 10 Potentially Device-Related Events in 9 Patients
  - 0.9% (2/221) Pseudoaneurysms
  - 0.45% (1/221) Cerebrovascular accident
  - 0.45% (1/221) Patch dehiscence/patch rupture
  - 0.45% (1/221) Thrombus opposite ECM patch
  - 0.45% (1/221) Herald bleed
  - 1.81% (4/221) Restenosis
- 12 Deaths (None Device Related)
  - 2 Carotid/stroke related, but on carotid not treated with CorMatrix ECM (opposite side)

EFFECTIVENESS RESULTS

MAXIMUM CAROTID STENOSIS

- 85.5% Baseline mean carotid stenosis
- 32.2% Post-treatment mean carotid stenosis
- 33.8% 12-month mean carotid stenosis

	n	Pseudoaneurysm	Thrombus	Restenosis
All Patients	221	0.9%	.45%	1.81%
LIterature Rates	N/A	0.3 - 3.6%[1,2]	Up to 4%[3]	4.3 - 6.4%[2,4]

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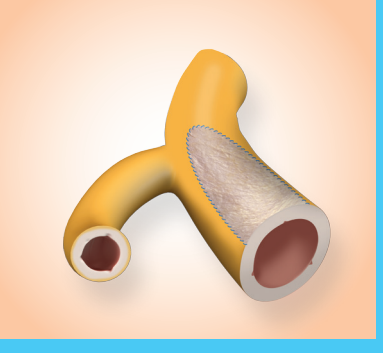

CorMatrix® for Vascular Repair

CorMatrix for Vascular Repair 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 CorMatrix® for Vascular Repair

	LITERATURE RATES					CORMATRIX RATES (6-PLY ECM)
	Synthetic Patch	Vein Patch	Dacron Patch	Bovine Pericardium	Acuseal (PTFE)	All Field Carotid/Vascular Events Including Registry Study n = 27,366 [March 31, 2017]
Restenosis	1-6%[1]	2-10%[1,2,7]	2-19.7%[1,6]	1-3%[2-6]	0%[5]	0.040%
Infection	0.1-1%[1]	0-3%[1,7]	0.3%[6]	0-0.6%[5,6]	3%[5]	0.029%
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]	0.026%
Pseudoaneurysm	0.3%[1]	3.6%[1]	0.3%[6]	0.2%[6]	N/R	0.048%
Hematoma	N/R	1.1%[7]	2-3%[6,10]	0-6%[3-6,10]	1%[5]	0.044%
Thrombosis Formation	N/R	2.2%[7]	N/R	1%[5]	1%[5]	0.018%
Aneurysm	N/R	2%[2]	N/R	0%[2]	N/R	0.033%
Artery/Patch Rupture	0.2%[1]	0.4-1.7%[1,7]	N/R	N/R	N/R	0.058%
Occlusion	0%[1]	N/R	5%[1]	N/R	N/R	0.037%
Bleeding	N/R	N/R	1.7%[9]	N/R	N/R	0.015%

**Calculations include all post market registry adverse events classified as having a possible, probable, or definite relationship to the device.*

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

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