Vascular Resistance in the Carotid Artery: An In Vitro Investigation of Embolic Protection Filters

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PURPOSE: To assess in vitro performance of four embolic protection filters (EPFs) with a varying mass of injected particles. Evaluation is based on capture efficiency, pressure gradient, flow rate, and vascular resistance.

MATERIALS AND METHODS: A bench-top flow apparatus was used for in vitro testing of four devices (Spider RX, FilterWire EZ, RX Accunet, and Emboshield). A silicone phantom with average human carotid artery dimensions and a 70% symmetric internal carotid artery (ICA) stenosis was used to model the carotid bifurcation. A blood-mimicking solution (glycerol/deionized water) was circulated at the time-averaged mean peak velocity for the common carotid artery. Five and 10 mg of 200- or 300-μm-diameter microspheres were injected into the ICA to evaluate the capture efficiency of the devices. The normalized pressure gradient, flow rate, and vascular resistance in the ICA were calculated from measured values of pressure and flow rate.

RESULTS: The Spider RX captured the most particles (99.9% for 5 mg, 98.4% for 10 mg) and was associated with the slightest increase in pressure gradient (+8%, +15%) for both masses of microspheres injected. The Spider RX and FilterWire EZ were associated with the slightest decreases in flow rate (Spider RX, −1.9% and −12.1%; FilterWire EZ, −3.5% and −8.2%) and the slightest increases in vascular resistance (Spider RX, +10.1% and +33.0%; FilterWire EZ, +20.5% and +32.7%). The device-specific porosity was calculated, and the Spider RX was found to have the greatest at 50.4%; the Emboshield had the lowest at 2.2%.

CONCLUSIONS: The Spider RX and FilterWire EZ had the best overall performances. Design features such as porosity and pore density are important parameters for improving the effectiveness of EPFs. Vascular resistance in the ICA is a flow-derived variable indicative of device performance and affected by the filter design features.

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Abbreviations: CAS = carotid artery stenting, CCA = common carotid artery, CEA = carotid endarterectomy, ECA = external carotid artery, EPF = embolic protection filter, ICA = internal carotid artery

A narrowing of the carotid artery resulting from atherosclerotic plaque accounts for 20%–30% of all cases of stroke, the third leading cause of death in the United States. Carotid artery stenting (CAS), a relatively new minimally invasive procedure, is quickly becoming a prominent alternative treatment for patients with a severely stenosed carotid artery. However, there is skepticism regarding the efficacy of CAS because of the possibility of periprocedural distal plaque embolization. The widespread acceptance of CAS is dependent on its comparable efficacy to the surgical approach of carotid endarterectomy (CEA). According to the North American Symptomatic Carotid Endarterectomy Trial (1), the 30-day death and stroke rate was 5.8% with CEA. The first major multicenter trial comparing CEA and CAS, the Carotid And Vertebral Artery Transluminal Angioplasty Study (2), reported no statistical difference in stroke and death rate between the two treatments in a randomized study of 504 patients (5.9% vs 6.4%). Concern for the risk of distal plaque embolization has led to the development of cerebral protection devices to improve the efficacy of CAS. The World Regis-

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try (3) has reported that, in 4,221 cases of protected CAS, the stroke and procedure-related death rate was 2.23%, compared with 5.29% for unprotected CAS.

There are three types of cerebral protection devices: distal balloon occlusion devices, proximal balloon occlusion devices, and embolic protection filters (EPFs). EPFs were selected for this investigation because of their advantage of allowing distal perfusion during CAS, which allows angiograms to be obtained during the procedure (4). EPFs usually consist of a 0.014-inch wire with a basket frame made of nitinol and a porous polyurethane membrane over the frame, a delivery sheath, and a retrieval sheath. Recently, new EPF designs have used a nitinol mesh or polymer fibers as the material of choice for the filter basket. Pore sizes for EPFs typically vary between 40 μm and 200 μm.

In the present investigation, we evaluated the effect of emboli mass on the performance of four EPFs (Spider RX [ev3, Plymouth, Minnesota], FilterWire EZ [Boston Scientific, Natick, Massachusetts], RX Accunet [Guidant, St. Paul, Minnesota], and Emboshield [Abbott Vascular, Santa Clara, California]) in an anatomic model of a human carotid artery with a stenosis in the internal carotid artery (ICA). The objectives of conducting this study were to (i) assess the performance of the devices based on the percentage of particles (a) missed after particle injection and (b) lost during device retrieval, and (ii) the effect device performance has on the change in normalized (a) pressure gradient, (b) flow rate, and (c) vascular resistance in the ICA. The clinical relevance of objective (i.a) is a measure of each device's ability to capture emboli larger than the pore size and a quantifiable measure of wall apposition; the smaller the percentage of particles missed, the greater the wall apposition, and thus the potential for more favorable clinical outcomes for the patient. Objective (i.b) is a measure of the ability of each device to retain emboli during removal of the filter from the patient's body; it also implies that the smaller the percentage of particles released, the more favorable the clinical outcome. Objective (ii) measures the blood flow blockage resulting from the use of an EPF; the lower the pressure gradient and vascular resistance and the greater the flow rate, the more favorable the clinical outcome. The authors' original contribution to this field of study is based on incorporating physiologically realistic features for testing EPFs, which include navigation of the device through a stenosis, pressure and flow measurements proximal and distal to the device, use of a blood-mimicking fluid in the flow model, indirect assessment of device wall apposition, and variability in the injected mass of embolized plaque particles.

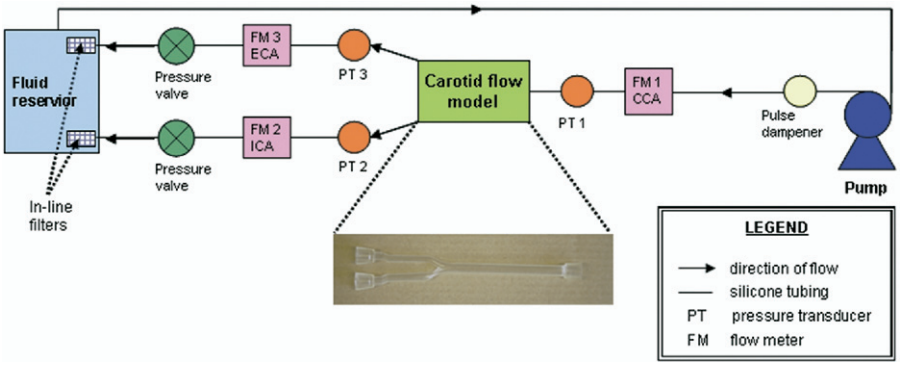


Figure 1. Schematic of flow loop system with inset of carotid artery model. (Available in color online at *www.jvir.org*.)

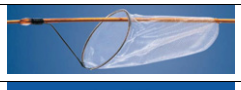
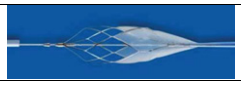
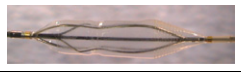
MATERIALS AND METHODS

Experimental Setup

The in vitro flow loop used in this investigation is illustrated in **Figure 1**. It consists of Tygon tubing (inner diameter, 0.25 inches) and a silicone carotid artery bifurcation model (Shelley Medical Imaging Technologies, London, Ontario, Canada). The carotid bifurcation model is an average representation of 62 human carotid arteries with a 70% symmetric stenosis in the ICA (5). Three low-flow magnetic flow meters (SeaMetrics, Kent, Washington) and three pressure transducers (Honeywell Sensotec, Columbus, Ohio) are placed adjacent to the common carotid artery (CCA), ICA, and external carotid artery (ECA). A blood-mimicking solution (viscosity, 3.5 cP) consisting of 36% glycerol and 64% deionized water was circulated at 737 mL/min by a peristaltic pump (Ismatec, Wertheim-Mondfeld, Germany) and using a pulse damper. This flow rate was calculated on the basis of the mean peak velocity averaged over one cardiac cycle for the human CCA (6). Pressure valves maintained physiologic CCA pressure (average, 97 mm Hg).

The EPFs tested have been described previously (4,7). The Spider

Table 1
Embolic Protection Filters Tested In Vitro: (A) Spider RX, (B) FilterWire EZ, (C) RX Accunet, (D) Emboshield

	DPD	Pore Size (microns)	Device Size (mm)
A		70-200	3, 4, 5, 6, 7
B		110	3.5-5.5 (one size fits all)
C		115	4.5, 5.5, 6.5, 7.5
D		140	3, 4, 5, 6