DIVERSION OF EMBOLI IN ARTERIAL BIFURACTIONS: IN VITRO EFFICACY OF A NEW PERMANENT ARTERIAL FILTRATION DEVICE

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ABSTRACT

The *Diverter* is a new permanent arterial diversion device designed to divert emboli away from the internal into the external carotid artery to prevent embolic stroke. The purpose of this study was to assess experimentally the hemodynamic performance and diverting capacity of the *Diverter* to be implanted at the carotid bifurcation.
Keywords: Emboli-Diversion, Embolic-Stroke Prevention, Carotid, Arterial-Blood-Filtration, Cardioembolism.

INTRODUCTION

The incidence of emboli bursts rate is very low, and typically measured as an event per years scale[1,2,3]. However, prevention of just one large embolus from circulating into the brain and resulting a major disabling stroke, would make the difference. The size of the brain infarct caused by an ascending embolus depends on multiple factors. As a general rule, however the smaller the embolus is and the more distal the small branch it occludes is located, the less likely it is to result an extensive stroke with significant disability. Indeed, several lines of research attest to a benign nature of micro emboli[4,5,6,7,8,9,10].

The pulsatile nature of the physiological flow regime in the carotid bifurcation can be momentarily frozen as depicted using streamlines in Fig. 1. The virtual streamline C-A borders between flow entering the internal carotid artery (ICA) and the external carotid artery (ECA), while B-A depicts the filtration portion of the *Diverter*. Small embolic particles will closely follow the appropriate streamline, and hit the filter B-A if located above C-A. The ECA:ICA flow ratio and spatial geometry dominates their number. Secondary factors are the CCA flow and pulse rates (Reynolds and Womersley numbers). Assuming that human emboli composition consists of a specific mass, which is closely within the specific mass range of blood, body forces may be significant only for the large Particle:Vessel ratio (>25% of CCA diameter).

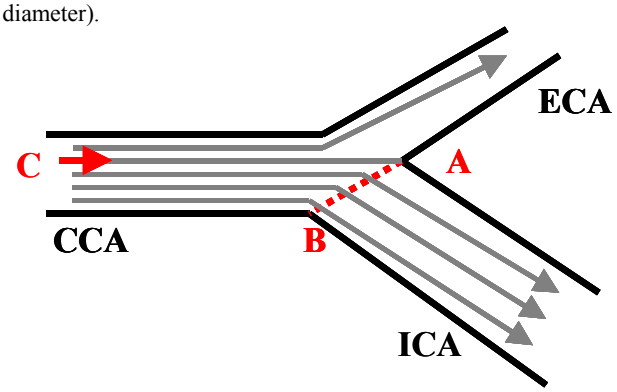

Fig. 1, Flow streamlines within the carotid bifurcation. A-B depicts the filtration portion of the Diverter. C-A depicts the virtual streamline bordering between flow entering the internal carotid artery (ICA) and the external carotid (ECA).

MATERIALS AND METHODS

The experimental system is schematically described in Fig. 2. A water-glycerin mixture, seeded with micro spheres, was pumped through a circuit of tubing into a compliant transparent "Y" shaped model of the carotid bifurcation. The Diverter was placed in the carotid bifurcation model. A computer controlled pulsating pump was used to simulate the physiological pulsating waveform. Rigid emboli-like particles and soft-sticky emboli made of clotted blood (predefined cutoff sizes ranging of 0.45-3mm) were driven towards the filter. An argon-ion laser light sheet was used to illuminate a thin layer of reflecting particles inside the fluid. The camera overlooking the interrogation window A-A-B-B at the filtered bifurcation captured the particles shift in the stream. The particles shift was digitally recorded to the

computer using a CCD video camera. A trap placed downstream to the ICA artery, was used to capture non-diverted particles.

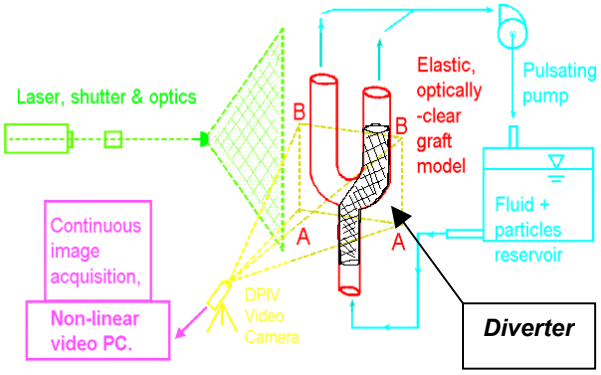

Fig. 2, the Diverter within the experimental setup

The ***Diverter*** was placed from the common into the external carotid (CCA - ECA), thus "jailing" the orifice of the internal carotid (ICA). The vascular models of the human carotid bifurcation were made of transparent elastic silicone. The Re (Reynolds) and α (Womersley) dimensionless numbers were maintained in physiological flow ranges and the pulse rate values replicated human physiological data (Average Re=400, 60-80 BPM). The flow division at the bifurcation was kept 3:1 (ICA: ECA). The *Diverter* used in these experiments was designed to divert particles larger than 400µm. The first set of emboli was simulated using rigid polystyrene 450-3000µm sized particles ("Polyscience" Polyball), within the specific fluid density (naturally buoyant). The second set used soft-sticky particles made of clotted human blood (500-2500µm) within the specific fluid density (naturally buoyant). These emboli were prepared using small quantities of fresh blood, which were deposited in glass tubing. The fresh clots were then removed from the glass and cut into smaller pieces.

RESULTS

The *Diverter* was tested under 4 different hemodynamic conditions. Pulsatile physiological flow conditions. Pulsatile physiological flow conditions with dynamically changing the CCA (common carotid artery) radius of curvature. Pulsatile physiological flow conditions using a modified non-favorable (ICA: ECA) flow ratio and constant flow at Re=414. However, the emboli driven toward the filter, both soft-sticky and rigid larger than the filtering pores, were diverted into the ECA and none passed into the filtered ICA ostium. The extreme ICA/ECA flow ratios, changes in bifurcation geometry, ICA/ECA angle or the radius of the CCA curvature did not result in any emboli trapping in the *Diverter* mesh. Emboli were only temporarily and rarely trapped under extreme non-physiological steady flow conditions.

DISCUSSION

The above experiment answer several fundamental questions regarding the *Diverter's* capability to divert clinically significant emboli.
We found that large particles, both soft-sticky and rigid emboli, were diverted into the ECA and that the *Diverter* performance is not emboli size dependent. It simply diverts any particle that is larger than its geometrical definition. Regarding the *Diverter's* pore size, the particles can be categorized into 3 parts. Particles smaller than the filtration pores may flow through the filter depending on the streamlines. Particles larger than the filtration pores are diverted into the ECA. Particles, which are equal to the pores size, have a theoretical chance to get stuck depending on their particular shape and specific spatial orientation when contacting the filtering portion of the *Diverter*.
Is the Diverter's performance hemodynamic-conditions dependent? We found that the increase of ICA:ECA flow ratio from 70:30% to 90:10%, and thus increasing the flow rate through the filter while worsening the filtration conditions, did not exhibit any problems with the filter. Nor did geometrical changes to the ICA:ECA angle or to the radius of the CCA curvature.
We also tested whether there are cases where emboli remain trapped inside the filtering portion of the diverter, thus obstructing the blood flow and discovered that under non-physiological, steady flow conditions, emboli are sometimes trapped when the emboli streamline is directed into the filtering portion.
Theoretically, there is nothing to prevent a thrombus from getting stuck into the filtering portion of the diverter and block it. However, we were unable to produce such events under pulsatile flow conditions. More precisely, nothing prevents a thrombus from touching the filtering portion. We suggest that the pulsatile nature of the flow is actually "shaking" such particles off the filter in the sequential cardiac cycle due to the local hemodynamic forces.

CONCLUSIONS

This permanent arterial filtration device was found to be efficacious in emboli diversion. These findings form the basis for a potential novel therapy for embolic disease by diversion to non-hazardous arterial beds.

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