Development of a new generation of neurovascular device for the treatment of cerebral bifurcation aneurysms

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I. Introduction

Cerebral (brain) aneurysm (CA), is an abnormal dilation of the cerebral arterial wall, which accounts for more than half a million deaths each year worldwide [1]. It is well recognized that hemodynamic factors play an important role in aneurysm development and propagation. Flow diverters (FDs) represent one method recently developed in treating CAs [2].

Evasc Medical System Inc., whose area of expertise is developing novel CA therapies, has recently introduced a novel FD (eCLIPs) for the percutaneous treatment of bifurcation cerebral aneurysms. Unlike other devices for such treatment, eCLIPs is implanted at the daughter arteries and does not impede the flow in the main or daughter arteries. Prior studies in the literature clearly indicate the advantages of eCLIPs over conventional FDs, such as Pipeline (Medtronic product), in disrupting the flow at the aneurysm neck [3]. In spite of its advantages over other FDs in the market, there are some shortcomings pertaining to eCLIPs design, including blood flow leakage through the gap between the device and parent artery where there is a fusiform-like pathology.

In partnership with Evasc, we have developed a new design for eCLIPs for particular aneurysms that have fusiform-like properties involving the confluence of the main and daughter branches.

II. Method

Geometry: The aneurysm geometry used to measure CFD consists of a symmetric model for the main and daughter arteries. For the modified design, shall be called eCLIPs New Design or ND-eCLIPs, the lateral edge of the implant has been extended to the main artery region to reflect the pathology of fusiform bifurcation aneurysms. This ND eCLIPs has been integrated into the aneurysm model at the neck, as shown in Fig. 1.

Numerical setup: ANSYS-CFX Commercial software was used for the CFD simulation of blood flow. The blood was assumed to be Newtonian and the inlet and outlet boundary conditions are mass flow at the peak systole and pressure, respectively. A fully developed laminar profile of velocity is applied at the inlet of the main artery.

III. Results

Results of this study indicate that by implanting eCLIPs at the neck of the aneurysm, there is ~40% and ~32% decrease in the aneurysm inflow and wall shear stress, respectively. Through a stepwise design modification process, and utilizing computational fluid dynamics (CFD) modeling, we improved the hemodynamics of eCLIPs. Such hemodynamic improvement is characterized by ~3.8%, ~3% and ~22% decrease in the aneurysm inflow, wall shear stress and area of aneurysm wall with WSS>2.0 Pa, respectively.

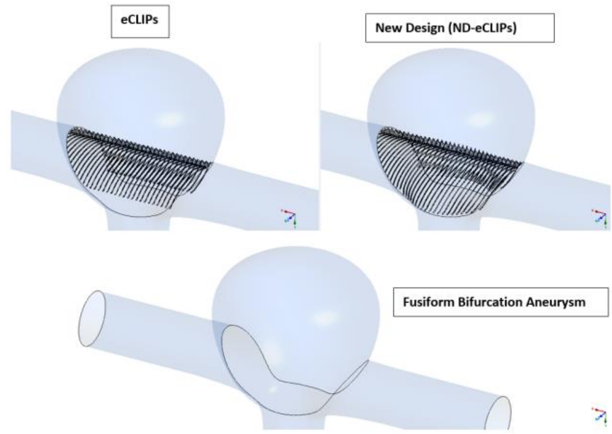

Fig. 1 Geometry of the fusiform bifurcation aneurysm with the eCLIPs and New Design implanted at the neck

Extending the lateral edges should not impact perforating vessels that are rare adjacent to the confluence of main and side branches. Thrombotic obstruction occurs by both reduced velocity and resulting stasis within the closed space of the aneurysm. Perforators have continued run-off, thus have no stasis, so thrombosis due exclusively to reduced velocity in these vessels should not occur.

Using this approach, further design optimization, using anatomic geometries, pulsatile non-Newtonian flow with compliant arterial wall and device structure, may allow for even further improvements in design for eCLIPs to achieve better device hemodynamics and further promote thrombosis inside the aneurysm sac, the ultimate goal of aneurysm treatment.

References

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