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DEVELOPMENT OF A NEW GENERATION OF NEUROVASCULAR DEVICES FOR THE TREATMENT OF CEREBRAL BIFURCATION ANEURYSMS WITH THE FUSIFORM OPATHOLOGY: A COMPUTATIONAL APPROACH

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ABSTRACT

Cerebral aneurysm (CA) is an abnormal dilation of the cerebral arterial wall, which accounts for more than half a million deaths each year worldwide. Flow diverters (FDs) represent one method recently developed in treating CAs. Typically, they do not need coiling (releasing micro-coils within the aneurysm) and act purely to prevent substantial blood inflow into the aneurysm.

In collaboration with Evasc Neurovascular Enterprises (Vancouver, Canada), whose area of expertise is developing novel CA therapies, we have developed a novel FD for the treatment of bifurcation CAs with fusiform-like properties involving the confluence of the main and daughter branches. To the best of authors' knowledge, currently there is no device for an effective treatment of such complex aneurysms.

Through a stepwise design modification process and utilizing CFD modeling, we have developed a new design for the Evasc FD (eCLIPs) with improved hemodynamics, which is characterized by more than 30% reduction in the aneurysm inflow and wall shear stress (WSS) for the new implant design over eCLIPs for this subset of aneurysms. The new device design, modified-design eCLIPs (MD-eCLIPs), can represent the only device available for the treatment of such CAs with fusiform pathology.

Keywords: Neurovascular device, flow diverter, cerebral aneurysms, computational fluid dynamics, hemodynamic analysis

1. INTRODUCTION

Cerebral (brain) aneurysm (CA), is an abnormal dilation of the cerebral arterial wall caused by the weakening of the tunica media (muscle layer) of the blood vessel [1]–[4]. CAs are usually asymptomatic before rupturing; however, if a CA ruptures, it promptly becomes life threatening since blood leaks into the brain and causes stroke (hemorrhagic stroke), death or permanent disability [5], [6].

The real cause of initiation, growth and rupture of CAs is yet to be understood. However, it is well recognized that genetics and hemodynamic factors play the key role in the aneurysm development and propagation.

Endovascular treatment of CAs has become prevalent due to its less invasive nature and faster recovery compared with surgical interventions [7]. Flow diverters (FDs) represent one method of endovascular techniques recently developed in treating CAs. Typically, they do not need coiling (releasing platinum micro-coils within the aneurysm) and act purely to prevent substantial blood inflow into the aneurysm, leaving

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behind stagnated blood within the aneurysm that then thromboses the aneurysm to occlude it [7]–[9].

Evasc Neurovascular Enterprises, Vancouver, Canada, has developed the first flow diverter (eCLIPs implant) indicated for a bifurcation. Unlike its earlier counterparts, eCLIPs is implanted at one of the daughter vessels to bridge the neck, and does not impede the flow in the main or daughter arteries. Some bifurcations, however, have fusiform dilatation of the confluence of the main and branch vessels (enlargement of both the width and the breadth of the neck region). In such a case, a 'gap' exists between the implanted FD and the wall of the adjacent vessels, Figure 1. Hence, a need exists to develop an implant to solve this challenging pathology.

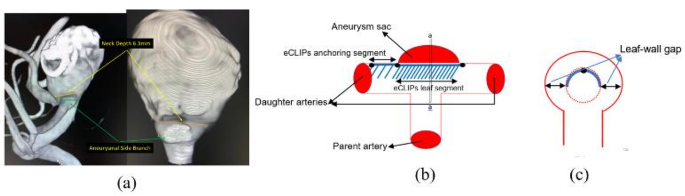

Figure 1: example of a bifurcation aneurysm with fusiform pathology (a), schematic view of such aneurysms with the implanted eCLIPs device (b), side view of section a-a (b) showing the gap between the device ribs and aneurysm wall, Courtesy of Evasc Neurovascular Enterprises

2. MATERIALS AND METHODS

To overcome the shortcoming of the eCLIPs implant for such CAs, a new design for the eCLIPs has been developed, which is characterized by an extension of the ribs on the device leaf segment to cover the aneurysm inflow gap. We also utilized CFD modeling, with ANSYS CFX V21, to optimize the hemodynamics of eCLIPs for these types of aneurysms. The goal of the hemodynamic optimization process is to achieve 20-30% reduction in the aneurysm inflow and WSS for the new device over the eCLIPs implant.

2.1 Geometry

A unique model for the basilar tip aneurysm was developed in which the aneurysm dome was recessed to the main artery region to reflect the fusiform characteristics of such aneurysms, as demonstrated in Figure 2. Based on clinical data, such aneurysms usually grow asymmetrically around the daughter vessels; therefore, upon implantation, eCLIPs is usually positioned eccentrically with respect to main artery flow. To mimic this particular condition in the CFD analysis, a few degree orientation was considered for the main artery with respect to the symmetric centerline of the aneurysm model. Subsequently, to model the MD-eCLIPs, the ribs of the eCLIPs implant at the leaf segment was extended to cover the gap between the device structure and the aneurysm wall, Figure 2.

2.2 Numerical setup

Due to the flow low Reynolds number in cerebral arteries, blood was considered to be incompressible and Newtonian with the density and dynamic viscosity of 1000 kg/m^3 and 0.004 Pa.s, respectively [10]. The non-compliant structure assumption was considered for the aneurysm/artery wall and device structure. A waveform flow rate for the basilar artery, with the mean and peak flow rate of 195 and 302 ml/min, respectively [11], [12], and a constant pressure with zero gradient condition were considered as the inlet and outlet boundary conditions (BC), respectively [10]–[12]. The inlet maximum Reynolds number is 337, which confirm the laminar flow behavior in our study. Due to low Womersley number (<3.0) at the inlet of the parent artery, the flow presents the Poiseuille condition with parabolic profile [10].

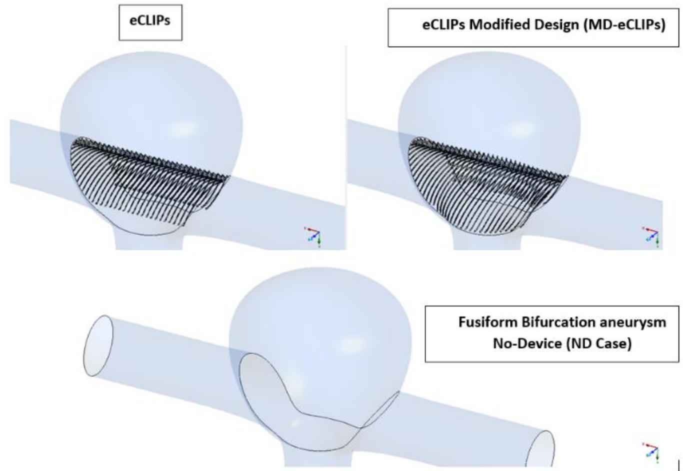

Figure 2: Geometry of the fusiform bifurcation aneurysm with the eCLIPs and eCLIPs-Modified Design implanted at the neck

2.3 Validation of the Numerical Model

The numerical model was validated with results of a study on the side wall aneurysm reported by Kim et al. [13], with respect to the velocity flow field and aneurysm inflow rate with less than 0.5% discrepancy. In addition, we are in the process of conducting some PIV tests, which will be also considered as an additional validation of our numerical model

3. RESULTS AND DISCUSSION

Results indicate that when there is no device present at the neck, more than 98% of the main artery flow enters into the aneurysm, while this ratio declines to 92% when eCLIPs is implanted at the aneurysm neck. Interestingly, only 67% of the incoming flow enters the aneurysm dome at the neck for the new device, which indicates more than 27% improvement in the aneurysm inflow reduction over the eCLIPs implant.

As noted in Figure 3, eCLIPs disturbs the aneurysm inflow at the neck which results in directing a portion of the main flow to the daughter vessels. This trend results in a significant decrease in the aneurysm inflow when the MD-eCLIPs is present at the aneurysm neck, as demonstrated in Figure 3, by reduced streamlines entering the dome at the neck.

Some studies suggest that aneurysm WSS higher than 2 Pa indicates the regions where inflow jet impinges on the aneurysm wall [10], [14]. Figure 4 shows the aneurysm WSS distribution with shear stress higher than 2 Pa. It clearly indicates a reduction in the aneurysm WSS when the eCLIPs is implanted at the neck. Further improvement is achieved when MD-eCLIPs is present at the neck, in which there is only a narrow region of high WSS adjacent to the Posterior Artery. Such a significant WSS reduction indicates the effectiveness of the new design in disrupting the aneurysm inflow jet and diffusing the flow at the neck.

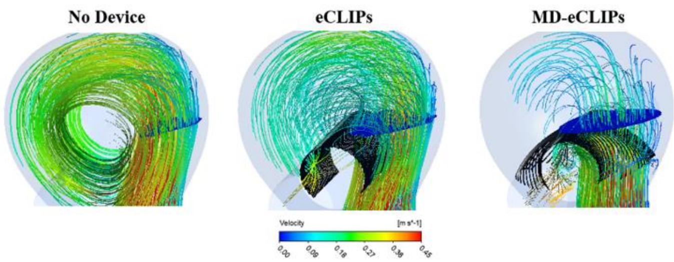

Figure 3: Side view of velocity vectors at the symmetry plane for eCLIPs, eCLIPs-MD and no device (ND) at peak systole

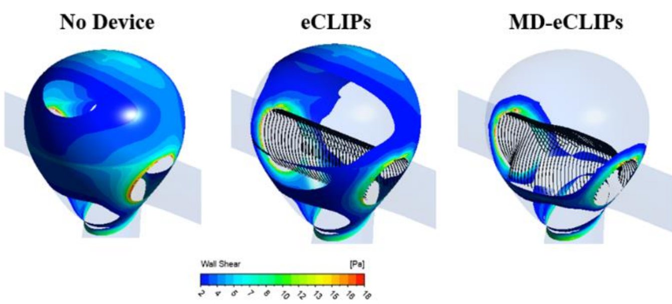

Figure 4: WSS contour on the aneurysm wall for the stress higher than 2 Pa for ND, eCLIPs and MD-eCLIPs cases, at the peak flow

Figure 5 presents a quantitative comparison of the eCLIPs and new design with respect to aneurysm inflow and time-averaged aneurysm WSS (TAWSS) reductions compared with the no implant case. Showing only 7 and 33% reduction in the aneurysm inflow and TAWSS, respectively, eCLIPs fails to provide a sufficient flow diversion effect at the neck. The MD-eCLIPs however, offers a significant hemodynamic improvement over eCLIPs, which is characterized by 33 and 53% reduction in the aneurysm inflow and TAWSS, respectively.

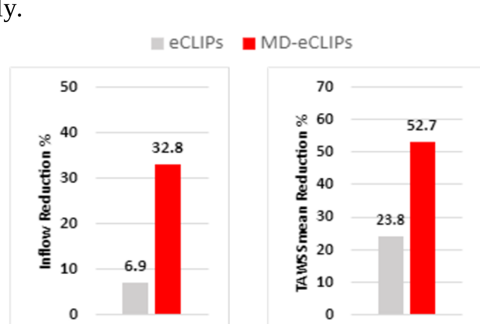

Figure 5: Aneurysm inflow and time-averaged aneurysm WSS reductions for the eCLIPs and MD-eCLIPs over no device case

4. CONCLUSION

Cerebral bifurcation aneurysm with fusiform pathology are extremely challenging for treatment due to their complex geometrical features. There is currently no device to offer an effective treatment for such CAs.

In this study, a new design for the eCLIPs implant for such aneurysms was developed, which is characterized by extended ribs on the device leaf segment to cover the inflow gap. CFD modeling was utilized for the hemodynamic optimization of the eCLIPs. Results indicate a clear hemodynamic improvement of the modified eCLIPs over its original design for this subset of CAs, which is characterized by 27 and 24% reduction in the aneurysm inflow and WSS, respectively, for the MD-eCLIPs compared with the eCLIPs implant. The new device can represent the only available device in the market for the treatment of such aneurysms.

It is worthwhile mentioning that extending the lateral edges of the eCLIPs implant 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.

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