Intracranial Aneurysms: Evaluation of Braid Pore Configurations on Flow Disruption with Flow Diverter Devices

Abstract

Flow diverters have recently been developed to treat intracranial aneurysms as an alternative to standard coiling. The Medtronic Pipeline™ flow diverter stent device had a positive impact on aneurysm repair in the past few years and is the leading braided Flow Diverter (FD) in the market. The main function of the flow diverter is to alter the hemodynamics within the aneurysm so that flow circulation is reduced to allow for gradual thrombosis within the aneurysm and subsequent healing. Thus, it is highly desirable to better understand the hemodynamic parameters and flow diverter efficacy. The objective of the study is to assess the hemodynamic impact of braided flow diverter, pore configuration parameters as related to flow circulation. Appropriate Computer Aided Design (CAD) and Computational Fluid Dynamic (CFD) models of an aneurysm, with and without presence of a Flow Diverter, were evaluated. Transient CFD analysis (Pulsatile flow) was performed with appropriate boundary conditions. Using CFD, the parameters that influence the flow into the aneurysm are evaluated and discussed.

Abbreviations

CAD - Computer Aided Design
CFD - Computational Fluid Dynamics
FD - Flow Diverter

Background and Purpose

A cerebral aneurysm is a balloon-like bulge (weak area) in an artery wall. World-wide, approximately 1 in every 50 people suffers a brain aneurysm, and which can potentially rupture. Current treatments include clipping, coils, and flow diverters. Research studies and experiments [1-4] have been previously conducted and observed the impact of flow diverters to alter the hemodynamic within the aneurysm. But these studies have focused primarily on the metal coverage ratio or pore size. It is evident from these studies that smaller pore size or increased metal coverage provides effective flow disruption, and thus can heal the aneurysm. This study is intended to assess more specific braided design parameters on the effectiveness of flow diversion without changing the pore size. The hypothesis of this study is that pore shape, area and pore orientation will play a role on flow diversion effectiveness. Thus, the objective of the current study is intended to identify the approximate pore size that effectively reduces the flow into aneurysm...
and to identify the impact of pore shape/orientation in reducing the aneurysm flow for the same pore size.

**Methods**

Computational Fluid Dynamic (CFD) modeling was utilized to assess how flow disruption dynamics can vary with pore area, width, shape/pore orientation. Hemodynamic parameters, such as flow rates, turnover time, wall shear stress, velocities and pressures were assessed. As for the case of the Pipeline™ flow diverter, some flow diverters are constructed of braided, helical metal wires, and the diverting power of these devices is determined partly by their porosity and pore density. The porosity of a diverter is calculated as the percentage of the overall open stent area and metal-free, while the quantity of pores per unit area presents the pore density.

Computational fluid dynamic simulations were conducted on an ideal straight-vessel aneurysm model with and without the presence of the flow diverter. The blood flow was approximated as an incompressible Newtonian fluid with a density of 1025 kg/mm3 and a viscosity of 3.5 centipoises. The literature shows that blood behaves as a Newtonian fluid with constant viscosity in vessel diameters greater than 0.005 mm [5]. The models were discretized with tetrahedral elements with 4 prism layers along the boundary. The total numbers of elements are around 1.5 to 2 million, depending on the size and shape of the aneurysm model. The host vessel diameter was 4 mm. The aneurysm models were developed with no stent, and with flow diverter pore sizes of 1000X1000, 500X500, 350X350, 250X250 and 150X150 microns embedded in the model across the aneurysm neck. The meshing and CFD simulations are carried out using commercial CFD software (Ansys Fluent V16.0, ANSYS, Inc., Canonsburg, PA, USA). The blood vessel and aneurysm models are considered as rigid walls. This assumption is valid considering the experimental observations by Tsang et al., [6] on diameters ranging from 5.6 to 1.6 mm in their study. Their experiments showed negligible expansion and constriction in the vessels.

**Numerical model and mesh independency study**

Typically, when analyzing small medical devices, predicting the results by means of experimental or analytical ways is extremely difficult. So, the best way is to create the most reliable numerical model for a defined problem. This would be helpful, ideally, when performance of the devices has to be analyzed. The numerical approach leads to less detailed solutions with less expense. To make the model more reliable, a grid independency study was performed, and an ideal mesh size was selected. Time step size and residuals were examined and maintained at a minimum to avoid any solver-based errors.

**Braid model with different pore sizes**

Aneurysm sizes can vary with a wide variety of aneurysm diameters and neck diameters. With reference to American Association of Neurological Surgeons (AANS), the aneurysm sizes in cerebral vessels are classified as below:

- **Small** = less than 7 millimeters in diameter
- **Medium** = 7-12 millimeters
- **Large** = 13-24 millimeters (size of a dime)
- **Giant** = more than 25 millimeters (quarter size)

An idealized sidewall-type saccular aneurysm geometric model with and without flow diverters were created as shown in figure 1 and 2 [7] with a host vessel inner diameter of 4 mm. As per statistics, approximately 90% aneurysms are saccular in cerebral vessels. The CAD model was created by means of the commercial computer modeling software package Solid works (Dassault Systems Solid Works Corporation, 175, Wyman Street, Waltham, MA 02451). A medium-size aneurysm with a diameter of 12.3 mm and with a 6.3 mm neck size was considered for this study.

![Figure 1: Dimensions of the vessel and aneurysm model.](image-url)
The braid models were developed with pore sizes of 1000X1000, 500X500, 350X350, 250X250 and 150X150 microns (Figure 3) and inserted in the aneurysm model. Flow direction was from corner to corner of each pore model. The braid wires were modeled as rigid wires.

**Braid pore orientation models**

The braid models were developed with different aspect ratios for various pore areas (Figure 4). Pore areas considered in the aspect ratio analysis were 0.02 mm$^2$, 0.0625 mm$^2$, 0.08 mm$^2$. In each configuration of the pore area, braid models were developed with the various pore aspect ratios or orientations. The stent wire diameter is 0.03 mm. A 10 mm length of flow diverter was considered for the analysis which would cover the total neck area of the aneurysm.
Boundary conditions

Pulsatile flow conditions were considered with a user defined inlet velocity profile (Figure 5) as input in the inlet and a fully developed outflow condition was applied at the outlet. The flow solutions were obtained for three cardiac cycles using 75 time-steps per cycle. Three cycles were used to stabilize overall blood flow in the model. Results are presented for the third cycle. The saccular aneurysm models were developed for measurement of flow parameters like velocities, wall shear stress and flow reversals.

Results

Turnover time vs FD pore size and volume flow rate

The simulation results show an increase in turn over time with decrease in the pore size. The 150X150-micron pore size results in good turn over time (slow flow within the aneurysm) which aids the clotting process inside the aneurysm. Figure 6 shows the relationship between turn over time and pore size of the flow diverter.
Figure 6: Turnover time inside the aneurysm increases as the pore size decreases, an indicator of stasis. The simulation results show a decrease in flow rate into the aneurysm as the pore size decreases. The amount of flow into the aneurysm is further reduced with pore sizes of 250X250 and 150X150 microns. Figure 7 shows this relationship between flow rate into the aneurysm and pore size.

Figure 7: Volume flow rate inside the aneurysm decreases as the pore size decreases, an indicator of stasis.
**Inflow into aneurysm vs pore size (Figure 8)**

![Flow path lines into the aneurysm without a Flow Diverter (left image) and flow path lines with the presence of a 1000X1000 micron pore size Flow Diverter (right image). It can be observed that such larger pore size has minimal effect on flow into aneurysm.](image1)

A flow reduction into the aneurysm is observed at a pore size of 500X500 microns (Figure 9) and begins to approach a threshold with further reduction in the pore size. This strongly suggests that a pore size of 500X500 microns and less would be expected to favorably reduce the amount of flow into aneurysm and initiate stasis. The Pipeline™ FD Device Dholakia et al., [8] has a pore size less than 500X500 microns, and thus results in effective flow diversion observed clinically.

![Flow path lines into the aneurysm for a 500X500 micron pore size FD (left image) and flow path lines with the presence of a 350X350 micron pore size FD (right image). Substantial reduction of inflow can be seen compared to the 1000X1000 micron pore size (Figure 10).](image2)
Turnover time vs pore width variation

Simulations were also conducted to observe the effect of pore width variation in the direction of flow. Pore area was maintained the same while the pore width was changed. This result in a different pore orientation in the direction of flow. Results are shown in figure 11 for three pore areas (0.02 mm², 0.04 mm² and 0.0625 mm²). It is evident that the turnover time decreases with increase in pore width for a given pore area from this study.

Figure 11: Turnover time vs pore width variation in the flow direction for different pore areas.

Figure 12 shows the pore width considered for different pore areas. This also gives insight into pore height-to-width ratio.
Discussion and Future Scope

The objective of this study is to better understand braided flow diverter effectiveness with different pore size and to identify the effect of pore orientation/pore shape on aneurysm flow for the same porosity models using CFD. Results show that a pore sizes of less than about 500X500 microns has a substantial beneficial effect in reducing the flow. A slight, additional benefit in flow disruption occurs for smaller pore sizes. A strong trend inflow reduction can be seen with increase in pore width (change in pore shape) in the flow direction without changing the pore area (Figure 11).

Flow is an inertia-driven in curved vessels Meng H et al., [9] and shear driven in side-wall aneurysms. The shear-driven (side-wall aneurysm) and inertia-driven (curved vessels) flow mechanisms will have a different result after stent placement across the aneurysm neck. However, is likely that the trends observed in this study will be similar.

In the present study, a straight vessel and side-wall aneurysm model was considered to perform hemodynamic modeling. In the research study conducted by Meng H et al., [9] straight vessels and curved vessels have variations in aneurysm flow after placement of stent, with metal coverage area critical in both cases. Modeling of the same pore density across the neck in a straight vessel model is possible (compared to curved vessels) because pore size is a constant and does not vary as per vessel curvature.

As our study focused on examining hemodynamic implications in aneurysms with variation in pore orientation without changing the pore area, we chose a side wall aneurysm along a straight vessel. Although this may be a limitation in the present study, this can be extended for curved vessels by modeling accurate and equal pore sizes even in curved vessels. Thus, future studies can be entertained in comparing the pore orientation effect even in the presence of inertia-driven flow.

As clearly discussed by Cebral et al., [10] while modeling of any kind is inherently an idealization of the full complex system, it provides a tool for exploring hypotheses and potentially reducing the number of variables and enabling the ranking of modeling limitations. CFD is one of the best methods for evaluating the influence of local hemodynamic trends for a Flow Diverter across an aneurysm.

Various assumptions such as rigid walls and outlet boundary conditions can be further enhanced to make such simulations more realistic. Shaik et al., [11] simulated the fluid flow considering both rigid and deformable arteries and showed that the wall shear stress was higher when rigid arteries were considered. They further showed that the wall shear was 30 to 40 % higher at the maximum shear stress location in their rigid artery computational model. Alishahi M et al., [12] also simulated and compared rigid vs deformable arteries and observed a 15% variation in pressure between deformable and rigid walls. Lee et al., [13] performed CFD Simulations and additionally observed that the distal vascular resistance and capacitance should be considered to further enhance predictions of hemodynamics.

Although the modeling assumptions in this study do not account for other vessel variables, the trends in flow modification for various pore areas and orientation can be expected to be useful and allow for a better understanding the effect of these variables in reducing aneurysm flow. Future scope is to enhance the models for consideration of these additional variables, such as curved vessels, flexible walls, vascular resistance/capacitance, and with much more sophisticated outlet pressure boundary conditions.

Conclusion

Based on the study, we conclude that a braided FD pore size less than about 500X500 microns would be beneficial in reducing the flow into an aneurysm. A pore orientation with smaller...
pore width (along the flow direction) for the same pore area is additionally beneficial in treating side wall aneurysms. Although an extremely small pore size improves flow diversion within the aneurysm, there exists a balance between pore size/area and the ability of the braid “footprint” to avoid potential blockage of occasional perforator vessels along the artery, and availability of sufficient pore area to allow for reendothelialization of the braided stent. Our results are consistent with Dholakia et al., [7] which shows pore size lower than about 500X500 microns would be an effective flow diverter for the treatment of cranial aneurysms.

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