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Investigation of metrics to assess vascular flow modifications for diverter device designs using hydrodynamics and angiographic studies

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Abstract

Intracranial aneurysm treatment with flow diverters (FD) is a new minimally invasive approach, recently approved for use in human patients. Attempts to correlate the flow reduction observed in angiograms with a parameter related to the FD structure have not been totally successful. To find the proper parameter, we investigated four porous-media flow models. The models describing the relation between the pressure drop and flow velocity that are investigated include the capillary theory linear model (CTLM), the drag force linear model (DFLM), the simple quadratic model (SQM) and the modified quadratic model (MQM). Proportionality parameters are referred to as permeability for the linear models and resistance for the quadratic ones. A two stage experiment was performed. First, we verified flow model validity by placing six different stainless-steel meshes, resembling FD structures, in known flow conditions. The best flow model was used for the second stage, where six different FD's were inserted in aneurysm phantoms and flow modification was estimated using angiographically derived time density curves (TDC). Finally, TDC peak variation was compared with the FD parameter. Model validity experiments indicated errors of: 70% for the linear models, 26% for the SQM and 7% for the MQM. The resistance calculated according to the MQM model correlated well with the contrast flow reduction. Results indicate that resistance calculated according to MQM is appropriate to characterize the FD and could explain the flow modification observed in angiograms.

Keywords

flow diverter; digital subtraction angiography; aneurysms; flow resistance; permeability

1. INTRODUCTION

Intracranial aneurysm treatment using flow diverters (FD) is a very active topic¹⁻¹⁴. The first FDs used in human patients, the Pipeline Endovascular Device, has passed clinical trials and is approved for large scale use in patients. One of the issues that needs to be studied is to relate the flow reduction observed in angiograms containing aneurysms or partially blocked vessels to a parameter describing the structural device geometry. There are no applicable analytical solutions due to the FD's complicated micro-structure. Fluid dynamics computational methods are also difficult to apply since the number of points needed to define the boundary conditions is currently too large to handle. In previous publications,^{12, 13} some authors quantified the effect that a stent has on flow in terms of the porosity of the stent. Lieber et al. in a particle image velocimetry (PIV) study¹³ found that

stents with a porosity of 76% but different wire diameter have different effects on flow. The results indicated that a more complex device parameter needs to be used in order to describe the effects that different geometric structures have on flow.

There are a few theories which describe the flow reduction through porous media based on the relation between the pressure across the mesh and the flow velocity. The simplest model given by Darcy's law provides a linear relation between the two quantities. The linear model uses a parameter called permeability, K , for the characterization of the medium, which has the same units as the surface. Depending on the analytical approach to calculate the permeability, there are two linear models: the capillary theory linear model (CTLM) and the drag force linear model (DFLM). In the CTLM the porous medium is treated as a collection of small tubes.¹⁵ The second linear theory, the DFLM, treats the porous medium as an ensemble array of cylinders at low Reynolds numbers.¹⁶

The linear model is further improved by adding a quadratic term yielding the modified Darcy's law, or simple quadratic model (SQM).¹⁷ Even the quadratic model is not fully applicable to a full range of flow conditions so a modified quadratic model was developed.¹⁸

The purpose of this paper is to find which model is adequate to describe the flow diverters and verify how it correlates with the angiographic data in aneurysms treated using such devices.

2. MATERIALS AND METHODS

The study was divided in two sections: first we evaluated applicability of four flow-through porous media models for FD characterization and second, we compared observed flow changes in angiograms with the four flow models.

2.1. Background of flow-through porous media models

Since flow-through porous media involve a very complex phenomenon, there is no exact solution for the problem; various models make approximations relevant to their field of applicability. Very often we see assumption such as: low or high Reynolds numbers, small or large pores etc. In general, the flow models give a relation between the flow velocity and the pressure difference across the porous medium; the two quantities are correlated using a porous media property such as permeability or flow resistance.

2.1.1. Linear flow model approximation—One of the simplest formulations is Darcy's law¹⁵ which assumes a linear relation between the pressure drop and the flow velocity:

$$U = \frac{K}{\mu} \frac{\partial P}{\partial l} \quad (1)$$

Darcy's law states that the flow through a porous medium is proportional to the pressure drop across the medium and inversely proportional to the viscosity of the fluid, μ . The proportionality constant K is called the permeability of the medium. K is measured in terms of the surface and intuitively can be described as the equivalent open area which can replace the permeable medium keeping the same flow velocity when the same pressure gradient is applied.

Variations of the linear models come from different ways to calculate the permeability. One approach treats the porous medium as a set of micro-channels (Figure 1(a)) and characterizes the flow reduction in terms of the flow changes that occur in the individual

micro-channel. The approach is called the capillary theory linear model (CTLTM), e.g. Kozeny-Caraman¹⁵, and the permeability formula calculated using this approximation is given by:

$$K = \frac{f\delta^2}{32} \quad (2)$$

where δ is the diameter of one channel and f is the medium porosity calculated by dividing the opened area by the total medium area.

The second linear model approximates the medium as a mesh of regular cylinders, Figure 1(b). Since the permeability is related to the drag force exerted by the array, we refer to this approach as the drag-force linear model (DFLM)¹⁶. The permeability according to the DFLM approximation is given by the following formula:

$$K = \frac{b^2}{4} \left[\ln\left(\frac{b}{a}\right) - \frac{1}{2} \left(\frac{b^4 - a^4}{b^4 + a^4} \right) \right] \quad (3)$$

where a and b are shown in Figure 2(b).

2.1.2. Quadratic flow model approximation—The second flow model we investigated assumes a quadratic relation between the pressure drop and the velocity. This model states

that the ratio between the pressure drop Δp and the dynamic pressure $\frac{\rho U^2}{2}$ is constant:

$$R = \frac{\Delta p}{\frac{\rho U^2}{2}} \quad (4)$$

where R is the flow resistance and ρ is the fluid density. There are many flow models used to calculate flow resistance, which are based on the material, geometry, and flow. For our device we selected two models: a simple quadratic model (SQM)^{17, 18}:

$$R = \begin{cases} 1.3(1-f) + \left(\frac{1}{f} - 1\right)^2 & \text{Re} \geq 10^3 \\ k'_{\text{Re}} \cdot 1.3(1-f) + \left(\frac{1}{f} - 1\right)^2 & 50 < \text{Re} < 10^3 \\ \frac{22}{\text{Re}} + 1.3(1-f) + \left(\frac{1}{f} - 1\right)^2 & \text{Re} < 50 \end{cases} \quad (5)$$

and a modified quadratic model (MQM)¹⁸

$$R = \frac{1-f}{f^2} \left(\frac{7}{\text{Re}} + \frac{0.9}{\log(\text{Re} + 1.25)} + 0.05 \log(\text{Re}) \right) \quad (6)$$

where k'_{Re} is a constant empirically derived¹⁷ and is shown in the Appendix, f is the porosity as defined above for equation (2) and Re is the Reynolds number calculated at wire of the porous structure:

$$\text{Re} = \frac{\rho d U_f}{\mu f} \quad (7)$$

where U_f is the modified velocity after placing the device, d is the wire diameter, f -porosity, and μ -viscosity and ρ is the fluid density.

A detailed derivation of the formulas for flow through porous media, presented in this section, is given by Ionita²².

2.2. Experimental evaluation of the Flow Models

2.2.1. Experimental evaluation of the linear flow models—We designed two flow experiments to verify the applicability of analytical or semi-empirical flow-through porous-media models to FD devices. We used six stainless steel wire meshes which are reviewed in Table 1. For the linear models we designed a flow experiment which is illustrated in Figure 2(a). In this experiment the screen is inserted inside a flange which is placed at a bottom of a cylindrical container. The flow can be stopped by connecting the exit of the flange to a silicon tube with a switch. The cylinder is filled with a liquid of known viscosity μ up to the height H_1 . Next, the bottom switch is turned on, and time, Δt , it takes the liquid column to fall between H_1 and H_2 is measured. We used a 50% glycerol-water mixture (per volume) with a viscosity of 0.0044 Kg/(m*s) (4.4 cP).

Permeability was found using the following formula:

$$K = \frac{\mu S_1 L_m}{\rho g S_0} \ln \left(\frac{H_1}{H_2} \right) \frac{1}{\Delta t} \quad (8)$$

where S_f is the area of the cylinder, S_0 is the flow cross section through the porous mesh, L_m the thickness of the mesh, μ -viscosity, ρ density, g gravitational constant. The measured permeability was compared with CTLM (eqn. 2) and DFLM (eqn. 3) models and reported as a percent difference. Percent difference was calculated as the absolute difference between the measured and calculated value, divided by the measured value.

2.2.2. Experimental evaluation of the quadratic flow models—For the quadratic model we used a constant pressure head Figure 2(b) and the same meshes as in the linear flow model setup. The fluid was pumped through the upper part; we maintained a certain level in the trough and had a set of lateral openings which were closed or connected to an additional pump which removed the surplus of water.

Using equation 4, flow resistance was calculated for eight heights, which corresponded to different static pressures and different velocities. The experimental resistance values were compared with the SQM, equation 5, and MQM equation 6 for each height. Percent differences between experiment and semi-empirical models were also calculated and reported as an average over all flow conditions for each mesh.

2.3. Angiographic measurements

The second part of the experiment was designed to verify the correlation between the contrast flow in aneurysms treated with various FD's and the flow through porous media models. The experimental setup is shown in Figures 3 and 4. The elastomer aneurysm phantom was build using a method previously described.¹⁹

The working fluid was a 50% per volume glycerol/water solution, which corresponded to a 47% per mass solution. The viscosity of the solution was 4.4 cP, and the density was 1063 kg/m³. The average flow rate was 3.8 ml/s which corresponds to a velocity of 30 cm/s and a Reynolds number in the vessel (prior to aneurysm location) of 308.

The fluid was pumped using a pulsatile blood pump (1400 Series, Harvard Apparatus, Holliston MA), which was operated at 40 pulses per minute, 35/65 systole/diastole ratio and 15cm³ volume per cycle. The pressure wave was measured using a research grade blood

pressure transducer (MA1 72-4496 Series, Harvard Apparatus, Holliston MA). The transducer was connected to a 6 Fr straight Envoy catheter (Boston Scientific, Natick, MA) and advanced to the vicinity of the bifurcation aneurysm phantom. The catheter tip did not protrude into the main flow.

A pulsed flow dampener was connected to the flow loop as shown in figures 3 and 4. The dampener was modified by adding a rubber pressure ball on top, to adjust the air cap pressure inside the dampener. The air pressure was adjusted only when the pump was active. The pressure in the reservoir was also adjusted using a second pressure rubber ball (Figure 3). The reservoir pressure controlled the lower limit of the pressure wave, while the pressure dampener adjusted the amplitude of the wave.

The pressures in the dampener and the reservoir were adjusted until we obtained a pulsed wave with a minimum of 70 mmHg and maximum of 120 mmHg. The flow conditions were in agreement with previously reported blood flow conditions in basal cerebral arteries.^{20, 21}

For the digital subtracted angiography, we used a 50% saline/iodine contrast solution (Omnipaque™, GE Healthcare Inc., Princeton NJ). The contrast was injected in the main stream at a distance from the aneurysm larger than ten vessel diameters, using a 6 Fr straight Envoy catheter (Boston Scientific, Natick, MA). The catheter tip was placed close to the main vessel but did not protrude into the main flow. We used an automatic injector (Figure 3) Mark V ProVis (Medrad, Warrendale, PA) and injected 5 ml of contrast at a rate of 5ml/s.

The contrast flow was imaged using a C-arm flat panel receptor at a rate of 30 frames per second, with an exposure of 2 ms per frame, and we calculated time-density curves from the high speed x-ray angiographic image sequences. The region-of-interest for the TDC calculation includes the entire aneurysm volume but excludes the vessel region. Since the phantoms, flow conditions and injections were identical, all the TDCs of the aneurysm region were then normalized to the peak density of the untreated aneurysms.

The final analysis was to verify the correlation between the proposed metrics and the contrast reduction in the aneurysm dome after the treatment with the FD. The observed contrast flow reduction was dependent only on the FD characteristics, since the flow conditions in the main loop were unchanged. In these conditions according to eqn. (1) the contrast reduction should be linear with the permeability of the FD or, according to the eqn. (4), inversely proportional with the square root of the resistance. As final proof, we plotted the TDC peak versus the permeability from each linear model and versus the inverse square root of resistance from the quadratic models and fitted them with a linear function. The R^2 statistic was calculated for each fit in order to estimate the appropriateness of each model.

3. RESULTS

Results of the new metric evaluations are shown in Figure 5 and Figure 6. Linear models are independent of flow velocity and they are reported for each mesh, while quadratic models need to be reported for every flow velocity setting.

For the linear flow models (Figure 5 left) the experimentally measured permeability was smaller than the CTLM and the DFLM values. The maximum value was $201 \pm 12 \mu\text{m}^2$ for the 70×70 mesh and $2.21 \pm 0.2 \mu\text{m}^2$ for the 500×500 mesh.

As seen in Figure 5 (right), there was a significant difference between the SQM and the measured resistance values especially at the low Re numbers.

Typical quadratic model curves are reported in Figure 5 (right) (dense meshes only). Such curves were measured for every mesh. On the x-axis and for all meshes, the Reynolds number refers to the values calculated according to eqn. (7). Calculations were done using eqn. (5) for SQM and eqn. (6) for MQM. For the both models the resistance of the denser meshes varies strongly with the Reynolds number. For the SQM models there is a significant difference between the measured values and those predicted by eqn. (5) at Re numbers smaller than 50.

We show the comparison between experiment and semi-empirical or analytical models in Figure 6. The results indicated percent differences of: 70% for the linear models, 26% for the SQM and 7% for the MQM. The large differences observed in the linear models were due to the flow velocity invariance assumption of the analytical models. This assumption is acceptable at very low velocities but not at magnitudes encountered in the arterial flow. The quadratic models work much better and the MQM gave acceptable results.

For the angiographic evaluation, snapshots of the angiographic acquisition are shown in Figure 7. The injector was set for a one second injection; however, at the location of the aneurysm, the bolus was spread over 2 seconds. The contrast in the untreated aneurysm clears very fast and after 3.33 seconds there is no contrast in the aneurysm dome. A vortex moving clockwise is visible in the untreated and treated aneurysms, except for the 400 and 500 wires/inch FD's. Slow contrast clearance was observed in all the treated aneurysms

Time Density Curves (TDC) are shown in Figure 8. Peak reduction was between 70 and 10%. There is an inverse relation between the number of wires per inch and the peak reduction except for the 150×150 FD. The FD's with more than 325 wires per inch had negligible contrast washout after 9 seconds from the bolus arrival, suggesting very slow flow in the aneurysm dome.

Plots of the TDC peak versus the permeability are shown in Figure 9, top row. The CTLM (left side) indicated that the contrast decreases with the permeability but it did not follow a linear behavior, the R^2 of the fit was 0.76. For the DFLM the same trend was observed and an R^2 was 0.71. The quadratic model plots are shown in Figure 9 (bottom); the peaks are plotted versus the inverse square root of the resistance. The linear fit yielded very good results for both models: 0.98 for SQM and 0.99 for MQM.

4. DISCUSSIONS

This work presented various approaches to parameterize the FD and correlate the observed contrast flow in high speed angiograms with the FD geometrical characteristics. The new metrics are not unique and they are used in other fields unrelated to the endovascular treatment of the aneurysms. Most of them were derived using approximations resulting from their engineering applications. The goal of this paper was to evaluate whether these metrics may be usable for FD characterization.

The results in the first part indicated that for the linear models there is a substantial difference (~70%) between the analytical models and the measured values for the permeability in the flow conditions relevant to arterial blood flow. Although an assumption of the permeability's independence of the fluid velocity may make the calculations much easier, it introduces errors.

Results with quadratic models indicated smaller percent differences between the semi-empirical models and the measured values; however, the SQM model could be cumbersome due to different formulations for various Re domains. As can be seen in figure 4 the largest differences appear for $Re < 50$.

For MQM, differences between the semi-empirical model and the measured values were under 10%. The model indicate larger resistance for small Re number. This might indicate a modulation of the blood flow velocity in the FD treated aneurysms. The low velocity during diastole could be significantly reduced while the higher velocities during systole are much less affected. This could result in flow dynamic changes in the aneurysm dome and their effects need to be further evaluated.

There is a limitation of the quadratic models. All the data presented assumes that the flow incidence angle on the porous media is larger 45° . According to E Brudett¹⁸, beyond this limit the models do not apply.

The angiographic analysis, showed large flow changes between untreated and treated aneurysms. Less contrast entered the aneurysms and it took a very long time to clear. Time density peaks correlated weakly with the permeability predicted by the linear models, strongly with the resistance predicted by SQM and most closely with the resistance predicted MQM. In particular the MQM, for these particular flow conditions, predicted that the 150 FD would have less of an effect then the 100 FD and this was also observed in the TDC peaks.

This study showed that the modified quadratic model for the flow diverters could be used to explain the contrast flow modifications observed in the FD treated aneurysms. In addition, we could use these formulations to design FD's which achieve the desired flow condition modifications. A comprehensive derivation and calculation for FD design is given by Ionita.²² In conclusion the new metrics could become a viable tool in designing the next FD's, given a range of flow settings; engineers could choose a design with a precise resistance to create conditions for clotting and healing of the aneurysm.

5. CONCLUSION

The work presented shows the initial results toward developing a flow reduction parameter for flow diverters used for treatment of intracranial aneurysms. Flow-through porous-media metrics to describe the FD performance were proposed and evaluated using two sets of experiments. The first part indicated that the modified quadratic model is adequate to describe the effects that structures with geometry similar to FD's have on flow. The second part indicated that the MQM model correlates strongly with the flow reductions observed in the aneurysms treated with various simulated FD's. Our findings could help prediction of the flow modifications and aid in device design.

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APPENDIX

Figure 1.
Approximate geometry used in capillary theory (a), and drag force theory (b)

Figure 2.
Experimental Setup: (a) Falling pressure head experiment setup, (b) Constant pressure head experimental setup

Figure 3.
Experimental setup

Figure 4.
Schematics of the flow experimental setup: the arrows indicate the direction of flow

Figure 5. Graphical display of the measured and analytical or semi-empirical values of linear or quadratic flow through porous media models

Figure 6. Percent difference between predicted values of the analytical or semi-empirical models and the experimental results.

Figure 7. Angiograms of untreated and treated bifurcation aneurysm, acquired at 30 frames per second. Numbers at the right of the figure indicate the numbers of wires per inch in the mesh. Frame timing is indicated on top. Initial frame was selected to contain the bolus arrival.

Figure 8.
Time Density Curves for FD-treated and untreated phantoms

Figure 9.
Correlation between the flow through porous media models and the observed maximum TDC

Table 1

Stainless Steel mesh properties: (Column 1 indicates the number of wires per inch in both directions; the porosity f in the last column was calculated by dividing the open area of the mesh to the total material area)

Mesh Type	Wire diameter (μm)	Pore Opening (μm)	Porosity (%)
70×70	165	198	30
100×100	114	140	30
150×150	66	104	37
325×325	36	43	30
400×400	28	36	31
500×500	25	25	25