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New Variable Porosity Flow Diverter (VPOD) Stent Design for Treatment of Cerebrovascular Aneurysms

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Abstract— **Using flow diverting Stents for intracranial aneurysm repair has been an area of recent active research. While current commercial flow diverting stents rely on a dense mesh of braided coils for flow diversion, our group has been developing a method to selectively occlude the aneurysm neck, without endangering nearby perforator vessels. In this paper, we present a new method of fabricating the low porosity patch, a key element of such asymmetric vascular stents (AVS).**

I. Introduction

THE self-expanding *V*ariable *Po*rosity flow-*d*iverter (VPOD) is a new flow diverting device which contains a low porosity patch-like region designed to cover the aneurysm neck (Fig.1) and occlude blood flow into the aneurysm, thus enabling embolization without endangering nearby perforator vessels [1]-[2].

A semi-porous patch, instead of a non-porous patch, is used so that blood flow would be diverted from entering the aneurysm, but not be excluded from supplying nutrients to enable vessel tissue to repair the main vessel channel as well as enable blood flow into important perforators that might be adjacent.

Over time, endothelial cell growth over the low porosity region may enhance the channel, bypassing the aneurysm, and restoring normal hemodynamics.

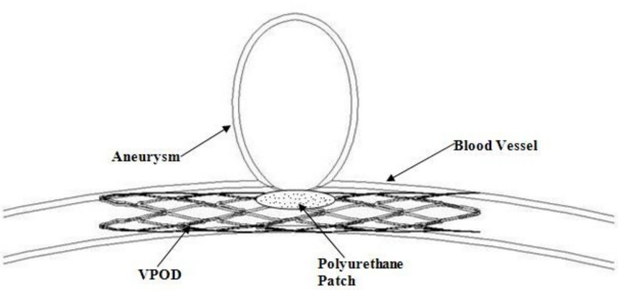

Fig.1. VPOD alignment in an aneurysm model

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II. Materials and Methods

The polymer used to fabricate the semi-porous patch was a biocompatible polyurethane solution, Chronoflex AR (Cardiotech International, Wilmington, MA), with a viscosity of 815 cP.

A. Procedure for fabricating the low porosity region

Three steps are required in creating the region with the desired low porosity.

First, a few (2-3) drops of polyurethane solution are placed onto a clean glass slide via a syringe. The film is then spread on the glass slide (while being observed under a standard microscope), with the aid of a thin tapered glass rod. Excess polymer is wiped off the glass rod, and a uniform spread is achieved.

Second, common table salt is ground with a mortar and pestle, and sieved through a stainless steel mesh with pore size of 200 micrometers. The refined salt crystals are then spread over the glass slide (with the liquid polyurethane film) in a random pattern, while still being observed under the microscope.

In the final step, the polyurethane film and salt crystals are sandwiched with another clean glass slide on top, and secured with a clip. This bundle is then immersed in a bowl of lukewarm water (@ 70 degrees centigrade), for about 1½ hours. After 1½ hours, the top slide is removed and the polyurethane membrane is gently removed and pinned on a silicone elastomer (made using SYLGARD ® 184) and left to air dry.

The semi-porous membrane is then ready for use, and is resistant to sterilization damage.

Fig.2. Microscopic image (X10) of the Semi-Porous Patch

Figure 2 shows a 10 times magnified image of the dry polyurethane membrane. The pores (voids) seen in the picture are created by the dissolution of salt crystals in the lukewarm water, and are up to the range of 200 micrometers. The overall porosity of the membrane can be controlled to be as low as 30%, or as high as 75%.

For this paper, all the test membranes had a porosity of 70%.

B. Testing of Membrane

In order to ensure that the membrane making process was effective in terms of flow modification and reproducible, an experiment was conducted to measure the flow vs. time for several different membranes. The principle of this experiment was based on Darcy's law:

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

which states that the flow, U, through a porous medium is directly proportional to the pressure gradient, (dp/dl), across the medium and inversely proportional to the viscosity of the fluid, μ. The proportionality constant, K, is known as the permeability of the medium, and 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 [3].

The result of this experiment ensured that the membrane making process was highly reproducible and could be varied for lower or higher porosity, as needed.

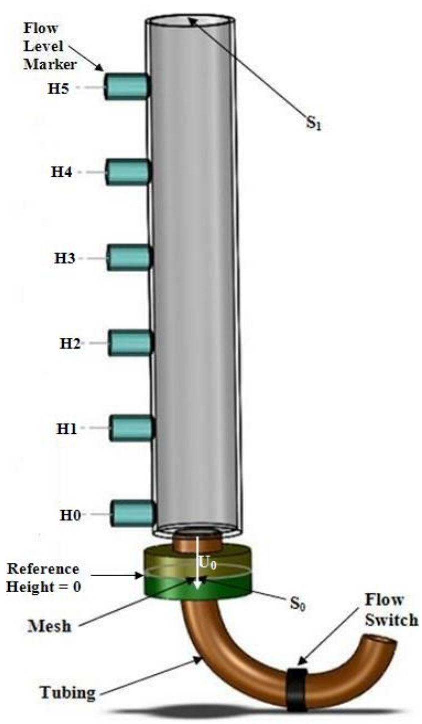

Fig.3. Experimental Setup for Flow Measurements

In the experimental setup shown above, a mesh is inserted between two flanges at the cylindrical tube which is filled with a liquid of a known viscosity (water, in our case) up to a known height H5. The flow switch is then opened and the liquid is allowed to drain to another height H4. The time taken for the liquid to drop to the new height is recorded as Δt and difference in heights is recorded as ΔH.

In order to find permeability in terms of height difference and time, we use the equation of continuity:

$$\mathbf{S_1U = S_0U_0} \quad (2)$$

which states that in a steady state process, the rate (volume) at which a mass enters a system is equal to the rate at which it leaves the system [3].

In equation (2), S_1 is the area of the cylinder, S_0 is the flow cross section area through the mesh, and U_0 is the velocity of water through the mesh. Re-arranging equation (2):

$$\frac{S_1}{S_0}\mathbf{U} = \mathbf{U_0} \quad (3)$$

Here, (U) is the velocity of the flow in the cylinder, and since velocity is defined as the rate of change of position of an object, (U) can be written as:

$$\mathbf{U} = \frac{dh}{dt} \quad (4)$$

Also, from (1):

$$\mathbf{U_0} = \frac{K}{\mu}\frac{\partial P}{\partial l} \quad (5)$$

Since the thickness of the mesh was very small (100 micrometers), we could consider the pressure gradient (dp/dl) across the mesh equal to the pressure of the fluid column (ρgh) divided by the thickness of the mesh, L_m.

Combining equations (3)-(5), we get:

$$\frac{S_1}{S_0}\mathbf{U} = \frac{S_1}{S_0}\frac{dh}{dt} = \frac{K}{\mu}\frac{\rho g h}{L_m} \quad (6)$$

Using separation of variables, and integrating between initial and final conditions, we get:

$$\int_{H_{i-1}}^{H_i}\frac{dh}{h} = \int_0^t \frac{S_0}{S_1}\frac{K\rho g}{\mu L_m}dt \quad (7)$$

Integrating equation (7), and solving for the permeability, K, we get the following expression [4]-[5]:

$$K = \frac{\mu S_1 L_m}{\rho g S_0} \ln\left(\frac{H_i}{H_{i-1}}\right) \frac{1}{\Delta t} \quad (8)$$

Re-arranging equation (8), for simplification:

$$K = \left(\frac{\mu}{\rho}\right) \left(\frac{S_1}{S_0}\right) \left(\frac{L_m}{g}\right) \ln\left(\frac{H_i}{H_{i-1}}\right) \frac{1}{\Delta t} \quad (9)$$

In equation (9), $\left(\frac{\mu}{\rho}\right)$ is the Kinematic Viscosity (v) of a fluid. Therefore, (K) becomes:

$$K = (v) \left(\frac{S_1}{S_0}\right) \left(\frac{L_m}{g}\right) \ln\left(\frac{H_i}{H_{i-1}}\right) \frac{1}{\Delta t} \quad (10)$$

Table I lists the meanings and values of the symbols used in the equations above.

TABLE I
SYMBOLS AND UNITS USED TO DEFINE PERMEABILITY

Symbol	Quantity	Value
μ	Dynamic Viscosity	0.001002 N.s/m^2
ρ	Density	1000 kg/m3
r_1	Radius of Cylinder	6 cm = 0.06 m
S_1	Area of Cylinder	Πr_1^2= 0.113 m^2
r_2	Radius of Exit	0. 35 cm = 0.0035 m
S_0	Area of Exit	Πr_1^2= 3.85E-05 m^2
L_m	Thickness of SS Mesh	100 micrometers = 1E-04 m
g	Gravitational Force	9.81 m/s^2
v	Kinematic Viscosity	10^{-6}m^2/s

Simplifying equation (10), we get the final expression for the permeability, K:

$$K = (2.94E\text{-}09\ m^2.s) \ln\left(\frac{H_i}{H_{i-1}}\right) \frac{1}{\Delta t} \quad (11)$$

III. Results and Discussion

The flow study was conducted for the following three pilot experiments:

First, there was no mesh used to collect the data. This was done to get the control for the experiment, to observe the natural dynamics of the system.

Second, a stainless steel (SS) mesh was used with no polyurethane coating. This mesh was taken from a balloon expandable Stent (Express[2], Boston Scientific) and helps in assessing the flow modification caused by the Stent itself; in absence of the semi-porous region.

Figure 4 shows the flattened out balloon expandable stent.

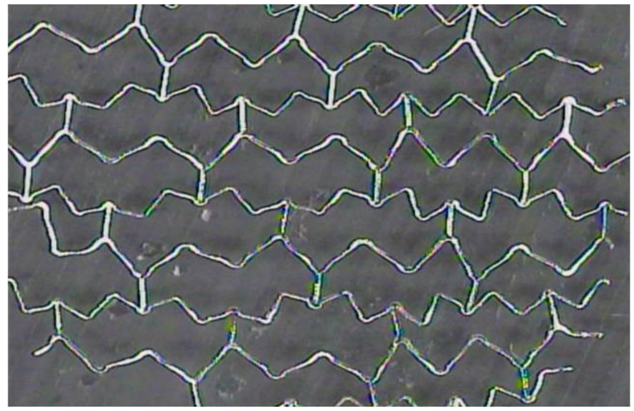

Fig.4. Flattened Stainless Steel mesh

Third, the flattened stainless steel mesh, taken from a balloon expandable Stent, was coated with semi-porous polyurethane membrane (Fig.5). The flow study was then conducted to observe the permeability of the membrane.

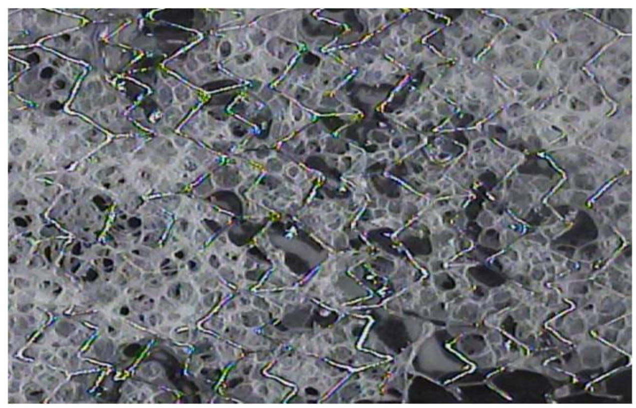

Fig.5. Flattened SS mesh with polyurethane membrane

Table II shows the height markers for the experimental setup shown in Fig.3. H_0 is 4cm from the reference point, and each subsequent height thereafter is separated by 10cm. Therefore, ΔH = 10 cm.

TABLE II
HEIGHT MARKERS CORRESPONDING TO FIG.3

Height Markers (cm)	$\frac{H_i}{H_{i-1}}$	$\ln\left(\frac{H_i}{H_{i-1}}\right)$
H_5 = 54	1.22	0.20
H_4 = 44	1.29	0.26
H_3 = 34	1.41	0.35
H_2 = 24	1.71	0.54
H_1 = 14	3.5	1.25
H_0 = 4		

Three sets of runs (time calculations) were recorded for each of the three pilot experiments described above. The time taken to drop each height was then averaged out and used to calculate the effective permeability for each experiment.

TABLE III

PERMEABILITY OF THE SYSTEM WITH NO MESH OR PATCH

Height Drops	Δ t (sec)	K (Darcy)
H5-H4	12	50
H4-H3	13	56.8
H3-H2	16	64
H2-H1	18	90
H1-H0	21	175

Table III shows the time taken, and the effective permeability value for each height drop for the case with no mesh. (1 Darcy ≈ 10^{-12} m^2)

TABLE IV

PERMEABILITY OF THE SYSTEM WITH ONLY MESH AND NO PATCH

Height Drops	Δ t (sec)	K (Darcy)
H5-H4	13	46.2
H4-H3	14	52.8
H3-H2	15	68.2
H2-H1	19	83.3
H1-H0	20	180

Table IV shows the time taken, and the effective permeability value for each height drop for the case with only mesh and no polyurethane membrane. It can be seen that the corresponding permeability values from Table III and IV are very similar; suggesting that using the mesh by itself does not offer much resistance against the flow.

TABLE V

PERMEABILITY OF THE SYSTEM WITH MESH AND PATCH

Height Drops	Δ t (sec)	K (Darcy)
H5-H4	44	13.7
H4-H3	47	16.2
H3-H2	56	18.3
H2-H1	71	22.4
H1-H0	88	42

Table V shows the time taken, and the effective permeability value for each height drop for the case with mesh and polyurethane membrane. A quick comparison with the previous tables indicates that the permeability values have significantly decreased.

The discrepancy in permeabilities for different heights is due to the fact that there is resistance against flow (hydraulic resistance) in the system, which is not accounted for in our calculations.

A flow model which includes resistivity influences is needed in order to accurately assess the permeability of the system. For the purpose of this paper, a comparison of the corresponding permeabilities, under the same flow conditions, gives an estimate of the effectiveness of using a patch.

Table VI shows the ratio of permeabilities for the system with no mesh vs. the system with mesh and polyurethane patch. It can be seen that under the same flow conditions, the permeability of mesh with patch (Table V) is approximately one-fourth of that of the system without any mesh or patch (Table III).

TABLE VI

PERMEABILITY RATIO OF (MESH WITH PATCH) AND (NO MESH OR PATCH)

K (patch/no patch)
0.27
0.28
0.28
0.25
0.24

IV. CONCLUSION

The flow studies conducted in this paper have suggested the feasibility of using a semi-porous polyurethane membrane on an asymmetric vascular stent for flow diversion.

Key point to note is that even though the semi-porous patches were 70% porous, it did not actually let 70% flow through it. This suggests that permeability, rather than porosity, is a better indicator of a flow through a porous object.

Preliminary laboratory testing has shown biocompatibility of the mesh material with attachment and overgrowth of bovine aortic endothelial cells.

This concept of aneurysm treatment can be used for treating different types of aneurysms, such as bifurcation aneurysms.

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