The pressure reduction coefficient: A new parameter to assess aneurysmal blood stasis induced by flow diverters/disruptors

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The pressure reduction coefficient: A new parameter to assess aneurysmal blood stasis induced by flow diverters/disruptors

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Abstract

Background and purpose: Pore density (PD), surface metal coverage (SMC) and the number of wires are all different parameters which can influence the efficacy of a flow disruptor/diverter. Nevertheless, the relative importance of a parameter to induce intra-aneurysmal blood stasis is still poorly evaluated. Therefore, comparison between devices based on a unique value is not reliable. The aim of this study was to propose a new bench top parameter (the pressure reduction coefficient (PRC; ξ)) in order to assess the global haemodynamic effect of each flow diverter/disruptor to slow flow.

Methods: Eight devices were tested in vitro during three different flow conditions. For the eight devices, the PRC was computed at different volumetric flow rates to characterise flow reduction. Comparison was made with SMC, PD and the number of wires.

Results: The PRC obtained for flow disruptors was on average 1.5 times more efficient in reducing flow compared to flow diverters. PD (mm^2) ranged from 24 to 38 for flow diverters and did not independently correlate with the PRC. The SMC of flow diverters ranged from 25% to 70%, and ranged from 20% to 100% for flow disruptors, without independent correlation to the PRC. The number of wires ranged from 48 to 96 for the flow diverters and did not correlate independently to the PRC.

Conclusion: There were no direct correlations between individual device characteristics and the PRC, suggesting a multi-faceted and interrelating association of the overall design of each implant. Hence, the PRC could be used as a simple, reliable parameter to assess the overall capacity of flow disruptors/diverters to induce intra-aneurysmal blood stasis.

Keywords

Flow disruptor, flow diverter, haemodynamic, pore density, surface metal coverage

Introduction

Flow diverter/disruptor devices have shown a higher degree of occlusion of difficult to treat intracranial aneurysms.[1,2] The aim of these implants is to disrupt the flow across the aneurysm neck in order to induce intra-aneurysmal blood stasis, thrombosis and definite aneurysm healing. Flow diverter devices are braided stents with fine meshes implanted within the artery across the aneurysm neck inducing intra-aneurysm blood stasis and allowing reverse reconstruction.[1,3,4] Flow disruptors also called 'intrasaccular flow diverters' are intrasaccular ellipsoid braided-wire embolization devices and present a single layer or dual layer allowing intra-aneurysmal flow disruption at the level of the neck.[5–9] The effect of these devices is due to their individual characteristics (lower porosity and pore size and higher number of wires and metal surface coverage), which lead to a permeability decrease compared to conventional stents.[10] The various devices currently used have different features and varying degrees of efficacy.[1] There is no consensus to date of the variable, between porosity and pore density (PD), that may best reflect the effectiveness of a flow diverter.[11–13] Furthermore, there is no standardised and reliable method to measure flow diverter porosity and PD.[14] However, measuring the capacity of this new generation device to induce blood stasis may help the clinician to understand better the predictive factors related to the effectiveness and safety of these devices. The aim

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of this study was to propose a new bench test parameter (the pressure reduction coefficient (PRC); ξ) in order to assess in one measure the global haemodynamic capacity of each flow diverter/disruptor to reduce flow.

Materials and methods

Experimental system

The experimental system is composed of a traction/compression machine in which a 60 ml syringe is disposed between the control of the volumetric flow rate and a plexiglass cube where an ‘artery’ has been drilled (Figures 1 and 2). A glycerin solution with a viscosity close to the blood at 25°C was used. The volumetric flow rate was controlled by the traction/compression machine and verified at the outlet by using a weighing scale. The volumetric flow rate tested (1.3, 1.7 and 2.1 mL/s) is within the physiological range.[15–18] The fluid pressure generated by the flow is measured by using a pressure sensor inserted in the plexiglass cube.

Definition of the bench test parameter

The Bernoulli equation for an incompressible flow, valid at any arbitrary point along a streamline is the sum of the internal energy, potential energy and kinetic energy of any fluid particle:

$$E = P + \rho \boldsymbol{g} z + \rho V^2/2$$

where V is the particle speed, P is the pressure, ρ is the liquid density, $\boldsymbol{g}$ is the acceleration due to gravity and z is the elevation of the point above the reference plane. The PRC (ξ) proposed in this paper as the bench test parameter is dimensionless and it characterises the loss of energy by the following equation:

$$\Delta P = \xi \, \rho V^2/2$$

In our experimental system the PRC can be determined measuring the difference of pressure caused by the device.

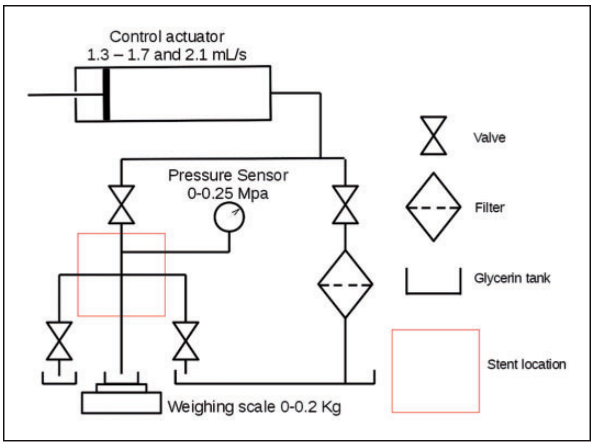

Figure 1. Diagram of the experimental set-up.

Experimental protocol

Firstly, the syringe was emptied at a given velocity to obtain the desired flow rate inside the system without the medical device (Figure 2(a)) and the pressure P_0 is registered (Figure 2(c)). Secondly, with the device deployed in the ‘artery’ the syringe was again emptied with the same velocity inside the system (Figure 2(b)). The pressure P_d is registered (Figure 2(c)).

To evaluate the pressure reduction of the device, the difference between P_0 and $P_\mathbf{d}$ (ΔP) was used as well as the imposed flow rate Q. To obtain a statistical value, these operations were repeated 10 times for each medical device. A 95% confidence interval of pressure drop was computed with a Student’s law and t-distribution.

Results

The error measurement of the PRC was low. Geometrical parameters and the PRC obtained for each device are summarised in Table 1. Comparison between inherit properties of the devices (surface metal coverage (SMC), PD, number of wires) and measured PRC are illustrated in Figure 3. The pressure reduction for each device is illustrated in Figures 4 and 5. Different flow diverters had different SMC,

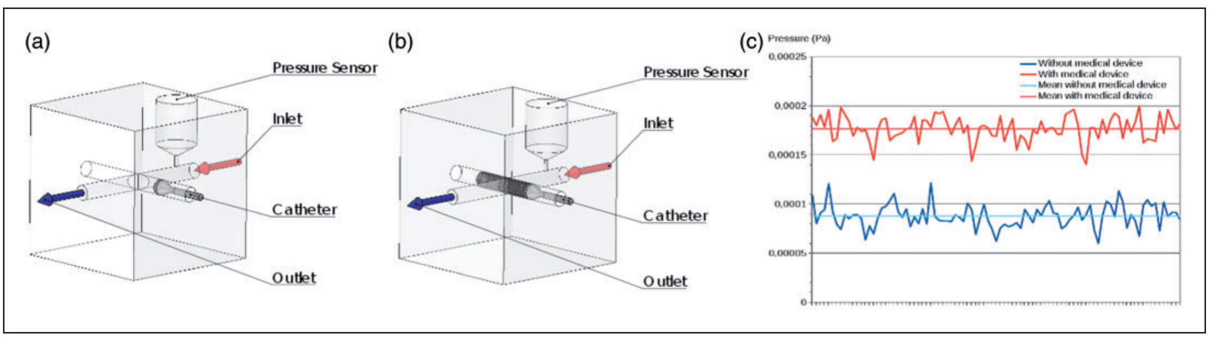

Figure 2. Representation of the plexiglass cube.

PDs, number of wires and different PRC (Table 1). There was no direct correlation between isolated characteristics of each device (SMC, PD, and number of wires) and the overall PRC (Figure 3). The flow diverter which had the more wires (Surpass) was not the one harbouring the highest PRC. Similarly, devices with the largest SMC (FRED) or lower PD (Pipeline) did not have the highest or lowest PRC (Figure 3).

Table 1. Geometrical parameters and pressure reduction coefficient obtained for each device.

Device	Surface metallic coverage (average)	Pore density (mm^2)	Number of wires	Pressure reduction coefficient/ξ
FRED 5 mm	33%	24	16+48	10
Surpass 5 mm	30%	21–32	48–96[a]	14
Pipeline 5 mm	30%	16	48	15
P64 5 mm	35%	24–38	64	17
Silk+ 5 mm	45%	30	48	18
WEB SL 5 mm	60%	NA	144	21
WEB SLS 5 mm	60%	NA	144	21
WEB DL 5 mm	60%	NA	216	25

NA: Not available.
[a]Depends on the flow diverter diameter.

Discussion

As expected, the flow disruptors with their very low PD, high SMC and very high number of wires were superior to flow diverters in inducing stasis with a PRC 1.5 times higher compared to the average flow diverter. This statement looks in accordance with clinical experience in which immediate complete or near complete flow cessation is observed in most of the flow disruptor procedures[4,6,8,9] compared to flow diverters in which complete stasis, according to the classification of Szikora et al.,[19] is commonly observed in only 6.6–15.7% of cases.[19,20]

Initially, we expected to find a direct correlation between PD and pressure reduction. Surprisingly, in our study, the PD was not the key parameter in predicting the flow reduction capacity between flow diverters. In our results, the less porous stent was not the less permeable and vice versa. In addition, the number of wires or the SMC do not appear to be a key factor proportional to flow reduction. However, PD and SMC are described as factors influencing flow dynamics.[21,22] Furthermore, in a previous study, Roszelle et al.[10] observed a greater reduction in fluid dynamic activity when a flow diverter, with low porosity, was implanted compared to an open cell design stent, even if three high porosity stents were telescopically

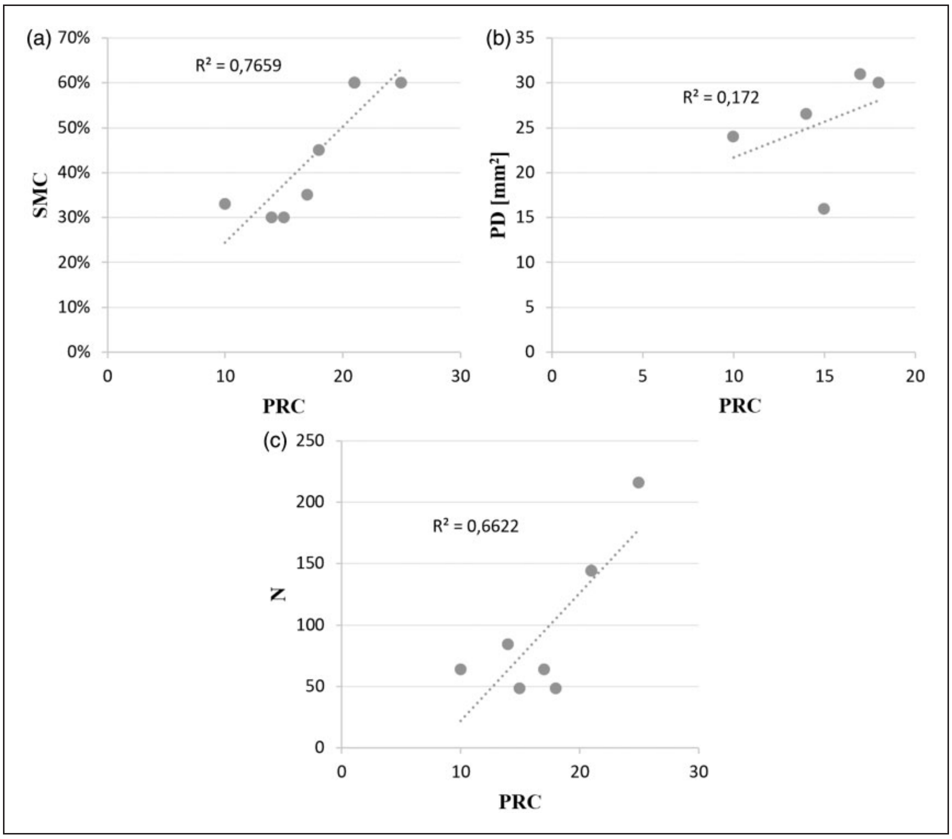

Figure 3. The correlation between the geometrical parameters and the pressure reduction coefficient (ξ). In order: (a) the surface metallic coverage (SMC); (b) the pore density (PD); and (c) the number of wires (N).

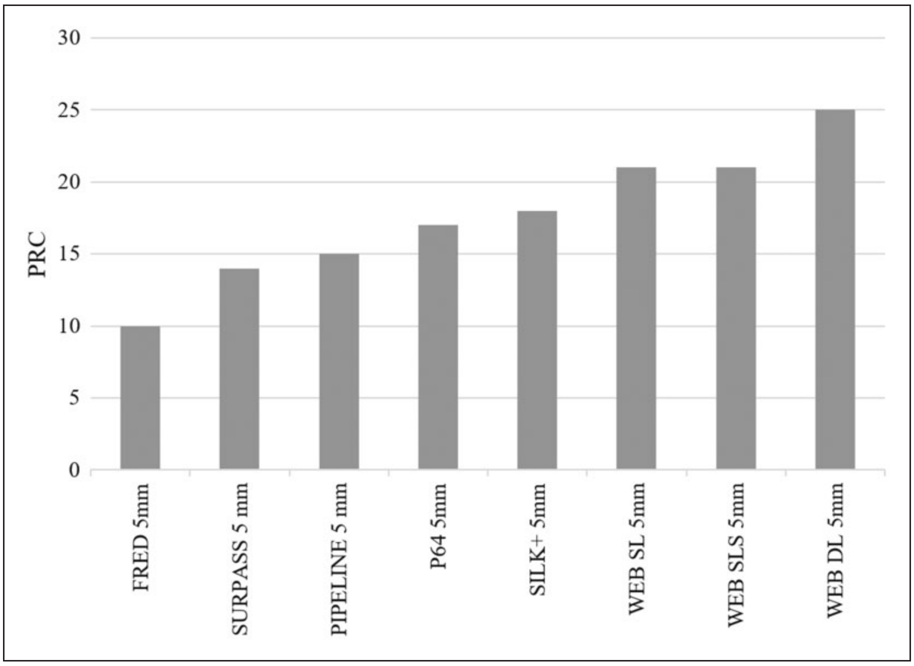

Figure 4. The pressure reduction coefficient (ξ) obtained for each device.

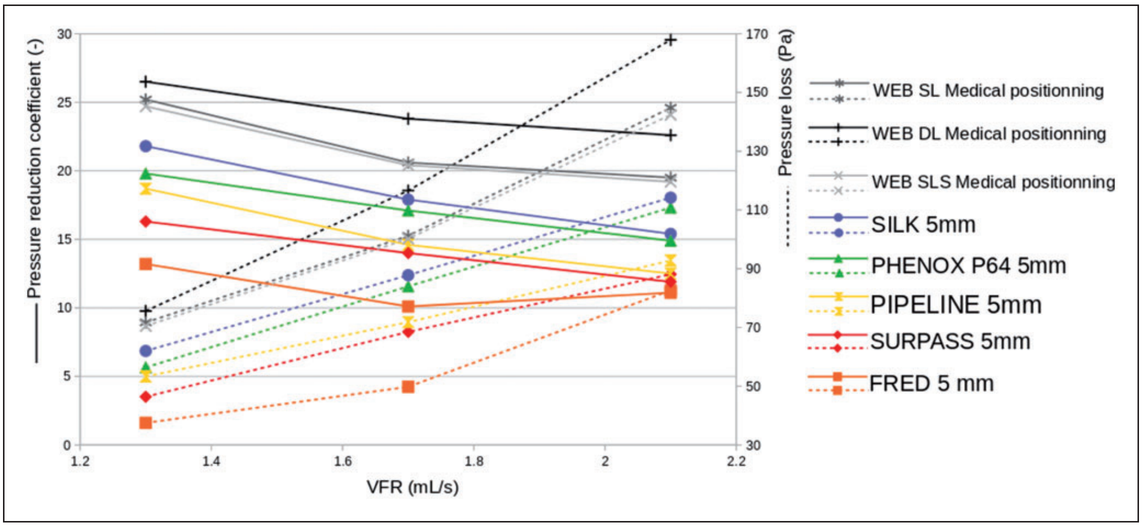

Figure 5. The pressure reduction coefficient (ξ) is shown by a continuous line and pressure loss (Pa) is shown by a dotted line obtained for all the devices for each volumetric flow rate (mL/s).

implanted. In contrast, Hodis et al.[23] observed that the factor influencing aneurysm thrombosis after flow diverter implantation in the rabbit model was not the PD or the SMC but was the diameter of the aneurysm ostium.

We hypothesise that each parameter (porosity, SMC, PD, number of wires) may influence the overall permeability that is not strictly related to a single mechanical parameter of the stent design. If we consider one single device design, the isolated modification of the PD will necessarily impact the permeability, but between two different stents with different wire numbers, the PD parameter itself is not sufficient to make a reliable comparison, as all the other parameters (SMC, wire diameter, wire angle) may greatly modify the pressure reduction capacity and can lead to different levels of efficacy in clinical studies.[1] Furthermore, automated or manual methods for measuring PD or porosity are not currently reliable.[14,24] Comparison between different devices using one isolated mechanical characteristic of the stent is therefore not appropriate.

The PRC appears to be a simple parameter to assess the overall capacity of a flow diverter to reduce the flow through its mesh whatever the manufacturer's parameter description. The overall design is tested in a simple and reproducible manner. It is important to underline that the measurement variability was very low between the 10 measures performed at each flow rate.

As low pressure is related to blood stasis, the PRC may be an ideal bench test to assess the clinical effectiveness of a flow diverter/disruptor according to fundamental haematological demonstration.[25–28] In this view, the permeability difference between devices may explain why certain types of flow diverter seem to induce a quicker per-angiographic thrombosis than others. When using a Silk or a P64 it is important to know that you are using the highest pressure reduction device, and that you may induce a more rapid aneurysm thrombosis compared to a Surpass or a Pipeline that may influence the postoperative pharmacological strategy to reduce the risk of acute thrombosis. This parameter may allow the physician to compare different devices regardless of the number of wires, the SMC, the PD or the design complexity, and could be used as a reliable evaluation parameter for future simulations and conception programmes.

This study presents some limitations. The pressure reduction related to intra-aneurysmal blood stasis is not synonymous with aneurysm healing taking into account the complexity of biological thrombosis, and the evolution of aneurysms treated by flow diverters is sometimes unpredictable.[29–32] This complex process is poorly understood and influenced by the patient and aneurysm characteristics and the pharmacological environment during the pre and postoperative phase. This simple parameter will stay a bench test indicator that could not guarantee the success of a given device for a given aneurysm. Furthermore, the tests are performed on a straight vessel of fixed diameter in order to simplify and reproduce easily the measurement and do not represent exactly what happens in vivo. In a realistic anatomical situation, the device is deployed against a curved vessel wall that necessarily induces a design modification of the stent on the inner and outer part of the curve resulting in an asymmetric design modification and consequently an asymmetric permeability modification. Nevertheless, the simplicity and the reproducibility of the bench test would have been altered by selecting a particular angle of the tube. We then assume that there should be proportionality between the behaviours observed in a straight vessel compared to a curved anatomical configuration between devices. Furthermore, in real cases of flow diverter implantations, blood flow only passes through one wall of the stent and not both, as is done in this experimental protocol, but the aim was to propose a single bench test manoeuvre that was highly reproducible in order to compare the mechanical characteristics of different devices and to assess a single parameter: the PRC; this last being the more accurate to represent the capacity of a given device to promote stasis in an aneurysm sac.

Conclusion

This study has demonstrated the lack of correlation between standard mechanical parameters and the flow stasis effect in a number of available flow diverters and flow disruptors. The PRC (ξ) could be utilised as a more general parameter to assess flow disruptor/diverter capacity to induce intra-aneurysmal blood stasis. The relation between the pressure reduction value and the healing process needs further investigation.

Author contributions

Conception and design of the study: GG, RF. DA, MS, FJ, VC; acquisition of data: GG, RF, DA, MS, FJ, VC; analysis and interpretation of data: GG, RF, MS, VC; drafting the article or revising it critically for important intellectual content: GG, KL, RF, DA, MS, FJ, VC.

Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

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