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Pattern Change of Flow Diverters Due to Bending

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Abstract **–**Flow diverters have a very short history, their research and clinical use for intracranial aneurysms spread in the last 10 years. Because of the novelty of these devices there are many fields to research, that correlate with the effect of flow diverters. Such research may improve the safety and efficacy of the technique. These devices are very flexible and can be slightly bent, but the surface muster changes frequency, so the metallic surface area in the surroundings of the aneurysm is not constant. The current manufacturers are working with several musters, there is not an ideal surface structure, and there is neither a standard index-number for the optimal MSA. The aim of this study is to test flow diverter devices from several producers in fixed bending angles, in variable points obtain the muster, and calculate the coverage. Based on the results an objective measurement for the local values can be defined. The ideal measurement for coverage can be decided by analyzing the microscopic images of the stents in the marked points and in the determined angles.

Keywords**:** flow diverter, pipeline embolization device, metallic surface area, bending, intracranial aneurysm

1. Introduction

Flow diversion has been recently introduced into the endovascular treatment of intracranial aneurysms. Long-term clinical tests prove that flow diverters (FD) can be safely and effectively used with a complication rate comparable to other methods (M.Y. Tse et al., Briganti et al.). FD-s are flexible, self-expanding, tubular devices that provide a high density wire mesh across the orifice of the aneurysm when implanted within the parent artery (Murthy et al.). The hydraulic resistance created by the FD will reduce the dynamic fluid exchange between the parent artery and aneurysm sac promoting aneurysm thrombosis. After successful aneurysm thrombosis, the construct becomes progressively incorporated into the parent artery, providing a homogeneous layer of tissue separating the aneurysm cavity from the parent artery's lumen (Pierot). The primary effect of the FD-s is related to the hydraulic resistance that is a function of the Metallic Surface Area (MSA), the percentage of surface covered by the metallic wires of the FD across the orifice. FDs are made of nickel titanium of cobalt-chromium alloys. In addition, platinum is used to provide radiopacity. The construct is packaged collapsed on a delivery wire and contained within a delivery sheath. When the construct is fully expanded it forshortens approximately 2.5 times to its nominal length. (P.K. Nelson et al.). Most manufacturers warrant 30-55% MSA with full expansion to their nominal diameter compared to 6-10% produced by non-flow diverting stents. FDs are available in different diameters from 2.5-5 mm having a nominal length of 10-50 mm. The pore size (the average area of the tetragon of the wire mesh) at nominal diameter is 0.02-0.05 mm2 (K.C. Wong et al.).

Shapiro et al. examined the variable porosity of a FD putting them in pipe sections of different diameters. The results confirmed that the compression of FD has a large impact on the pattern thereby to effectiveness factor: the MSA.

Due to specific characteristics of the intracranial vascular anatomy, instead of straight vessels, most aneurysms are located on curved sections of arteries. Subsequently, FD-s are bended to variable degrees once implanted. As bending of the FD may also impact its wire pattern it is important to analyse the resulting MSA in different bending angles and on different points along the circumference of the device.

2. Material and methods

2. 1. The flow diverters

During this study FD-s of different diameters were tested from two different manufacturers. Stereomicroscopic images (Olympus SZX16, Olympus, Tokyo, Japan, magnification: 20×, Figure 1-3) demonstrate the wire pattern when fully expanded and not bended.

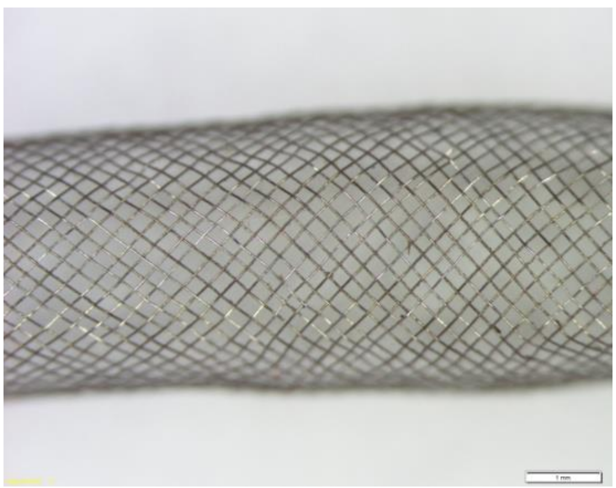

Fig. 1. Sample “A”

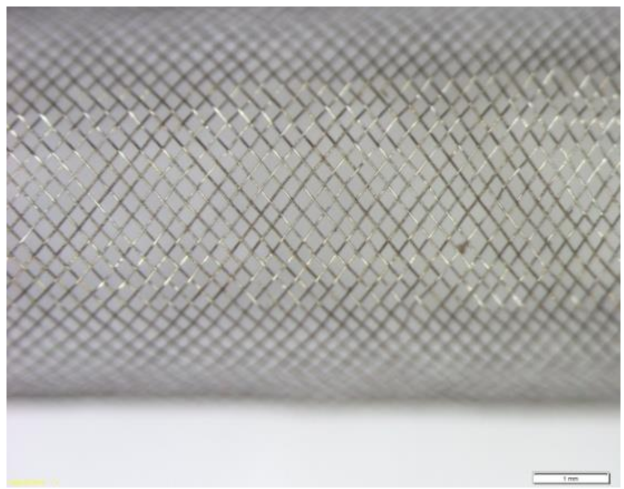

Fig. 2. Sample “B”

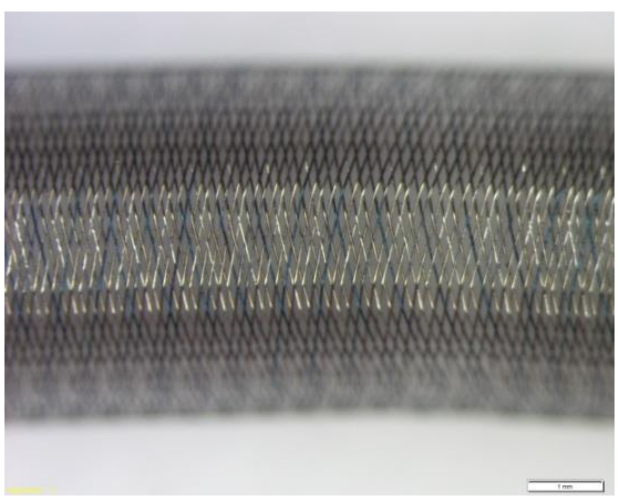

Fig. 3. Sample “C”

2. 2. Methodology

To observe the change of the muster, a holder was created to hold the sample in different angles without affecting the wire pattern. Both ends of a sample were placed in a silicone tube, as the silicone surface gives good adhesion, which promotes attachment of the sample at that position during bending. The angulation was stabilized by wires bent to the required angles. The angled section of the FD remained free from both the wires and the silicone tubes for unrestricted observation. Considering the nominal diameter of the samples, a 5 mm internal diameter silicone tube was chosen, making sure that compression has not changed the wire pattern during the investigation. Then the samples were put in the tube thus formed a bent position required for measurement. Figure 5 shows an illustration of the holder.

Fig. 5. The stent positioning holder

Images were taken using a stereo microscope of the samples in all chosen bending angles in three different positions: perpendicular to the internal, the external and the middle arc. Images are made under different magnifications to show through the bending angle and the position of the pattern as well. Using an open source image analysis software ImageJ (Version 1.49k 9 November 2014) two sides and the largest and smallest angles of the tetragons were measured. The wire tetragons demonstrated parallelogram character, the opposing side lengths and angles were roughly equal.

To determine MSA, crispy sections of the images were selected, representing the specific wire pattern. These pictures were analyzed with ImageJ, the area of the whole section was measured and on the principle of separation of lighter and darker areas the program could measure the percent of the metallic surface area corresponding to the MSA value in the observed position. This eliminates inconsistencies due to areas of out of focus and selection of the area analysed, as the MSA of each area was measured independently.

3. Results

Table 1 shows the average opening angle, side length and MSA at the three examined projections of the bending angles. The biggest opening angles were found at the internal projection in all but three measuring points. It was also observed that with increasing bending angle the opening angles increasingly differ and gradually converge to the non-bended value, as we might expect. The lowest opening angles were measured on sample “B”, the biggest ones on sample “C”.

Table. 1. Average side length (a, b), opening angle (φ), and MSA at the three examined projections of the bending angles

	Stent "A"				**Stent "B"**				**Stent "C"**			
	a (mm)	**b (mm)**	**φ (°)**	**MSA (%)**	**a (mm)**	**b (mm)**	**φ (°)**	**MSA (%)**	**a (mm)**	**b (mm)**	**φ (°)**	**MSA (%)**
0°	0.182	0.219	90.67	33	0.182	0.202	102.95	35.9	0.2155	0.2415	153.638	49.5
30°												
external	0.19	0.19	57.23	34.4	0.18	0.19	54.68	40.8	0.28	0.28	121.28	20.7
middle	0.16	0.23	106.61	29.2	0.19	0.20	99.99	29.3	0.23	0.26	131.98	27.3
internal	0.15	0.17	137.49	32.7	0.14	0.17	152.90	49.9	0.21	0.26	159.14	48.6
45°												
external	0.15	0.17	39.80	43.7	0.16	0.18	34.76	52.3	0.23	0.26	131.76	32.7
middle	0.19	0.20	118.07	30.0	0.19	0.20	118.37	26.2	0.24	0.25	150.90	31.5
internal	0.16	0.20	139.34	37.5	0.15	0.17	148.39	50.9	0.16	0.23	162.85	55.6
60°												
external	0.19	0.21	76.76	36.8	0.18	0.22	54.42	30.4	0.26	0.28	133.81	25.5
middle	0.19	0.21	100.75	30.9	0.19	0.22	98.92	21.4	0.23	0.26	142.38	30.1
internal	0.18	0.21	130.89	41.1	0.14	0.17	157.58	51.4	0.14	0.18	161.74	57.9
90°												
external	0.19	0.22	75.57	33.0	0.17	0.19	78.10	35.6	0.23	0.27	138.14	29.5
middle	0.20	0.22	92.50	17.0	0.18	0.20	114.78	33.7	0.23	0.27	150.29	35.2
internal	0.20	0.24	102.72	38.3	0.15	0.18	145.75	57.3	0.15	0.18	160.04	61.1
120°												
external	0.22	0.20	72.24	32.3	0.17	0.20	64.66	33.9	0.24	0.26	141.57	28.1
middle	0.19	0.23	76.39	30.3	0.20	0.22	97.04	31.5	0.22	0.26	152.10	31.4
internal	0.19	0.22	77.80	30.1	0.19	0.20	106.87	33.6	0.20	0.26	152.42	37.2
135°												
external	0.19	0.21	100.90	36.4	0.20	0.22	78.94	36.1	0.24	0.27	151.40	31.3
middle	0.20	0.20	111.27	37.0	0.20	0.21	95.87	35.1	0.25	0.29	141.67	26.1
internal	0.17	0.23	108.69	38.9	0.18	0.19	117.65	35.9	0.22	0.25	146.33	28.4

No similar trend was found for MSA. At the most bending angles the ratio of metal covered area in the external projections was higher than in the middle projection. In similar cases the MSA in the external projection was higher than in the internal projection. The difference between the calculated values in different positions becomes smaller by increasing the bending angle and converges also to the value of non-bended state like the opening angle. It can be seen that the MSA is higher for extremely high (over 140°) and extremely small (under 40°) opening angle values. The previous assumption that the pattern consists of parallelograms also confirms our results, because of the opposite angles in a parallelogram are the same and the summa of the internal angles is 360°. Consequently, the decrease of the observed angle had another angle pairs increase, so after a certain angle we got the same parallelogram but rotated 90° and the function of the MSA in the opening angle shows a parabolic nature.

4. Conclusion

The effect of flow diverters for treatment of intracranial aneurysms is thought to be related to the ratio of metallic surface area. Due to frequent tortuosity of cerebral vascular segments, flow diverters are often implanted in curved sections. In bended sections, none of the tested devices demonstrated the MSA value of 30-55%, as suggested by most manufacturers. The impact of vessel geometry may significantly influence the MSA and subsequently the efficacy of the device. The lowest measured value varied substantially in the three samples. Our studies demonstrated that with increasing bending angle, the opening angle also increased in all three cases. The opening angle of parallelograms of the pattern might be an ideal starting point for real coverage indicator. It would be worth to calculate a function between the opening angles in non-bended state and in each bending angles, so we could determine suitability of the flow diverter implantation in curved vessel.

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References

Briganti, F., Napoli, M., Leone, G., Marseglia, M., Mariniello, G., Caranci, F., Tortora, F., & Maiuri, F. (2014). Treatment of Intracranial Aneurysms by Flow Diverter Devices: Long-Term Results from a Single Center. *European Journal of Radiology, 83*, 1683–1690

Nelson, P.K., Lylyk, P., Szikora, I., Wetzel, S.G., Wanke, I., & Fiorella, D. (2011). The Pipeline Embolization Device for the Intracranial Treatment of Aneurysms Trial. *Am J Neuroradiol, 32*, 34–40.

Murthy, S.B., Shah, S., Rao, C.P.V., Bershad, E.M., Suarez, J.I. (2013). Treatment of Unruptured Intracranial Aneurysms with the Pipeline Embolization Device. *Journal of Clinical Neuroscience, 21*, 6–11

Pierot, L. (2011). Flow Diverter Stents in the Treatment of Intracranial Aneurysms: Where Are We? *Journal of Neuroradiology*, *38*, 40–46

Shapiro, M., Raz, E., Becske, T., & Nelson, P.K. (2014). Variable Porosity of the Pipeline Embolization Device in Straight and Curved Vessels: A Guide for Optimal Deployment Strategy. *AJNR Am J Neuroradiol*, *35*,727–33

Tse, M.M.Y., Yan, B., Dowling, R.J., & Mitchell, P. J. (2013). Current Status of Pipeline Embolization Device in the Treatment of Intracranial Aneurysms: A Review. *World Neurosurg. 80*(6), 829-835

Wong, G.K.C., Kwan, M.C.L., Ng, R.Y.T., Yu, S.C.H., & Poon, W.S. (2011). Flow Diverters for Treatment of Intracranial Aneurysms: Current Status and Ongoing Clinical Trials. *Journal of Clinical Neuroscience*, *18*, 737–740