Y-Crossing of Braided Stents with Stents and Flow Diverters Does not Cause Significant Stenosis in Bench-Top Studies

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Summary

Y-stent placement to treat bifurcation aneurysms requires the second device to cross the confines of the first stent, with concerns regarding the formation of stenosis of the second device at the site of crossing.

Various braided stents and flow diverters (FDs) were deployed to cross through a high porosity braided stent, in a Y configuration, with the ends of the devices inserted in plastic tubes of various diameters, leaving the mid-portion free to expand. The ensuing constructs were photographed, paying attention to the degree of stenosis, if any, created where the second device crosses the first stent. Experiments were repeated selecting different zones of the first stent as the site of crossing for the second device, different tube diameters, and changing the angle of the bifurcation.

Crossing the first stent did not cause the second stent to become significantly stenosed in any case. Crossing through the transition or expansion zone of the first device had no influence on results. Different bifurcation angles had no influence on the occurrence of stenosis.

Y-stent placement to treat arterial bifurcations using braided self-expanding stents and FDs does not lead to significant stenosis in bench-top studies.

Introduction

Stents and flow diverters (FDs) are increasingly used to treat intracranial aneurysms¹⁻⁶. Both devices are tubular structures appropriate

for lateral wall aneurysms, but more and more sophisticated stenting techniques are being described for difficult bifurcation aneurysms⁵⁻¹¹. The use of FDs in a bifurcation setting is becoming more common as well^{12,13}. The use of both types of devices has been the object of a recent review¹⁴.

Clinical attempts to reconstruct arterial bifurcations often involve deploying a second stent across the interstices of a first, porous stent (crossing Y-stent placement). Depending on the specific design of each device (open versus closed cells; laser-cut versus braided)¹⁵, radial expansion of the second stent may be constrained by the struts of the first stent, possibly causing stenoses, or potentially thrombogenic intraluminal flow disturbances from metal struts or filaments protruding in the lumen away from the vessel wall¹⁶.

Most stents are laser-cut from Nitinol hypotubes, but some recently introduced stents share the braided construction of the less porous FDs¹⁴. As they adapt to anatomical constraints, braided self-expanding devices share a number of characteristic deformations that can be studied using simple bench experiments¹⁷. When they are free to expand beyond the diameter of the parent vessel, as commonly occurs at the level of bifurcations, particularly a bifurcation bearing a wide-necked aneurysm, braided devices show heterogeneous porosities and diameters that can be reproduced in animal models and bench-top studies, with a more compact expansion zone and more porous transition zones^{17,18}.

We studied the configurations resulting from crossing Y-placement of various combinations

Figure 1 Experimental set-up. Three different FDs (A, B: Silk flow diverter; C, D: Pipeline flow diverter; E, F: SSFD48) are deployed across the transition (A, C, E) or the compaction zone (B, D, F) of a high porosity LVIS stent, without any resulting stenosis. Transition (TZ) and Compaction (CZ) zones are labeled in C, D.

of braided stents and FDs, looking for potentially significant stenotic deformations that could occur when these devices are crossed in an attempt to treat difficult bifurcation aneurysms.

Materials and Methods

Five different devices were studied: the LVIS, a 3.0×41 mm high porosity braided stent (Microvention, Tustin, USA), three low porosity

braided FDs: a 4.0×30 mm Silk Flow Diverter (Balt, Montmorency, France); a 3.75×32 mm prototype low porosity flow diverter (SSFD48; Microvention, Tustin, USA), a 3.5×21 mm Pipeline device (Covidien, Irvine, CA, USA), and a 3×20 mm Neuroform high-porosity open-cell laser-cut stent (Stryker, Kalamazoo, USA), for comparison with braided devices.

A high-porosity braided device (LVIS) was first deployed in a linear orientation, keeping the proximal and distal ends constrained into silicone tubes of various diameters (2.5, 3, 3.5, 4 mm), but leaving the mid-portion free to expand to simulate the space available at the site of an arterial bifurcation bearing an aneurysm neck in vivo (Figure 1). From within the lumen of this first stent, a guidewire was placed through either the transition or compaction zone (Figure 1)¹⁷, and a second device deployed to cross the first one at an angle of 45 degrees. The distal end of the second device was also constrained within a silicone tube, leaving the mid-portion of the device free to expand. For the Neuroform device, the site of stent crossing was selected at random, as this device does not exhibit the same characteristic deformation as braided stents. Scaled photographs were obtained with a stereoscopic microscope and the diameter of the second stent measured at the point where it crossed the first stent. A stenosis was defined as any decrease in diameter compared to the device diameter inside the tubes mimicking the parent artery (1- (diameter at crossing/diameter of stent in proximal tube)). A 'significant stenosis' was defined as $\geq 30\%$. Experiments were repeated three times, using various tube diameters (mimicking parent vessels of various sizes) for the proximal stent construction, keeping the distal tube (or branch) constant at 2.5 mm. Experiments were also repeated by varying the angle of the bifurcation (45, 65 and 90 degrees).

Results

Deploying a second device through the first braided low porosity LVIS in a Y-configuration, whether through the compaction or the transition zone, did not cause any stenosis at the point of crossing (Figure 1). The diameter of the second device as it crossed the first, more porous stent, was smaller by approximately 10% (but always larger than the proximal tube diameter) when the devices were deployed

Figure 2 The relationship between parent vessel diameter and diameter of the second crossing device in the only combination that resulted in stenosis. The relationship between the diameter of the proximal tube and the diameter ($\pm$ SD) of a second crossing LVIS device when crossing another LVIS is shown. The dashed line is the reference for no stenosis (compared to the parent artery; there was no stenosis compared to branch diameter in any case).

through the compaction zone compared to the transition zone (Figure 1). The only exceptions were the small amount of stenosis created when a high porosity LVIS device was deployed through the compaction zone of another LVIS, using tubes of 3.5 or 4.0 mm diameter (7% and 12% stenosis, respectively) (Figure 2).

Varying the parent vessel diameter while keeping the distal branch diameter constant at 2.5 mm demonstrated a proportional relationship between parent artery diameter and the diameter of the second device at the point of crossing. As the parent vessel diameter increased, so did the diameter of the second stent at the point of crossing (Figure 2).

Varying the angle of bifurcation had no effect on device diameter at the point of crossing, when the second device was deployed through either the compaction or the transition zone of the LVIS device (Figure 3).

Deploying a laser-cut Neuroform device through another Neuroform did not result in stenosis at the point of crossing in any configuration.

Discussion

The main finding of this work is that crossing Y-stent placement of various braided stents and FDs through a porous braided stent (LVIS) did not cause any significant stenosis of the second device. The particular segment of the first

Figure 3 The Y-construction with various angles between the LVIS stents. LVIS stent crossing the compaction zone of a second LVIS device at A) 45 degrees, B) 65 degrees, C) 90 degrees. Note that changing the angle between the 2 devices did not influence the crossing stent diameter.

braided stent that the second device crossed (transition or compaction zone) did not significantly influence the resulting diameter. In addition, varying the angle of the bifurcation did not impact results. Finally, if the diameter of the second device at the point of crossing is dependent on the diameter of the parent vessel in which both devices were inserted, crossing did not cause any stenosis with respect to the smaller branch vessel diameter. When the second device crossed the compaction zone of the first high porosity device, the stent filaments simply spread and then reorganized on each side of the second device.

Once reassured regarding the luminal diameter of the second device, one may be concerned regarding the flow-limiting effects of the second device on the blood flow through the first device, deployed in the first branch of the bifurcation, especially when this second device is a FD. Blood flow to the first branch must then pass through the mesh of the FD. It is somewhat reassuring to note that in all cases, the segment of the FD that flow has to traverse to reach the first branch was the most porous transition zone, on its convex side, when the stent is straight and the FD is inserted in the branch with the angulation, ensuring maximal possible porosity¹⁷. In all cases, the devices adopted conformations which preserved a metallic tubular structure, without a substantial degree of device stenosis. This suggests that this strategy can maintain an adequate metal conduit for blood to flow to normal branches; of course, the biological consequences in terms of thrombus, neointima formation, and aneurysm occlusion remain to be closely examined *in vivo*^{19,20}.

Early reports on Y-stenting used stents with high porosity, open-cell designs, such as the Neuroform stent²¹⁻²⁴, which do not restrict ex-

pansion of the crossing, second stent. However, various types of deformations, such as protruding struts within the bifurcation region, can have various effects on aneurysmal blood flow¹⁶. Open-cell laser cut stents are also subject to various deformations as they are deployed and adapt to local anatomical factors, and these deformations could explain some clinical failures and complications^{25,26}. Closed cell laser-cut stents have also been successfully used in assisting coiling of bifurcation aneurysms. Although they should maintain their cylindrical shape despite various anatomical constraints, the size of the cell can limit expansion of the second crossing device⁶.

Clinically available braided stents include the Leo (Balt) or LVIS (Microvention) stents; all FDs currently available are braided. Braided stents are retrievable in the event that the device fails to deploy in the intended manner. They can also be compacted to decrease porosity^{17,20}. However, due to poor visualization, deploying stents can be challenging. Pre-clinical visual confirmation that these devices do not become significantly distorted upon deployment is reassuring.

We previously described a characteristic deformation of braided stents and FDs that inevitably occurs when the device is oversized compared to the parent artery, as commonly prescribed to prevent device migration¹⁷. This deformation impacts on local porosities, *in vitro* and *in vivo*¹⁸. The various segments that can be described when the device adopts a fusiform shape include a transition zone (the more porous segment on each side of the compaction zone) and a compaction zone (the less porous middle segment). It is tempting to speculate that crossing the first stent with a guidewire would naturally occur more easily through the

transition zone, which offers pores of a larger size, and intuitively at least, would present fewer constraints to expansion of the second device. The present work shows that in most cases this does not matter, as crossing through the compaction zone did not cause any significant stenosis of the second device.

Limitations

The present work explores ways to reconstruct bifurcation aneurysms using devices that were not designed to be used in such aneurysms. We studied the LVIS device as the first braided stent, and a selection of second crossing braided devices; results may not apply to all braided stents and FDs. Bench-top experiments were done in artificial conditions, and while some of the described deformations have been documented in experimental animals¹⁸ and some clinical cases²⁷⁻²⁸, it is unclear how often

these results will be reproduced in clinical conditions using currently available devices. *In vivo* conditions may differ significantly from the artificial conditions we describe here, and any inference with human applications must be cautious.

Conclusion

Y-stent placement to treat arterial bifurcations using braided self-expanding stents and FDs does not lead to a substantial degree of metallic stenosis at the site of stent crossing, at least in our model.

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