ORIGINAL ARTICLE

Endovascular Treatment of Arterial Aneurysms With Side-Branches - A Simple Method. Myth or Reality?

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KEY WORDS: *aneurysm, multilayer stent*

Abbreviations
CTA = computed tomography angiography
EVAR = endovascular aneurysm repair
PIV = particle image velocimetry

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ABSTRACT

AIM: The aim of this study is to present performance data on the use of the multilayer stent, which is a three-dimensional (3D) braided mesh made of interconnected layers, particularly in patients with side branches within the aneurysm.

METHODS: A study protocol was designed to examine the safety and efficacy of the multilayer stent in patients with aneurysms in different target vessels. Between December 2006 and November 2009, 19 patients were enrolled in the study. Four patients had a renal artery aneurysm (1 male/3 females) (mean diameter: 18 mm), while the other 15 patients (all males) had iliac artery (n=12, mean diameter: 25 mm), popliteal artery (n=1, diameter: 55 mm), thoracic aorta (n=1, diameter: 57 mm) and abdominal aorta (n=1, diameter: 97.3 mm) aneurysms.

RESULTS: The multilayer stent was successfully deployed in all patients (100% technical success). The mean follow-up for the peripheral aneurysms was 28 months (range 12 to 36) and for the aortic aneurysms was 3 months. The occlusion rate of the aneurysm at the peripheral arteries was 100% and all the side branches remained patent. For the thoracic and the abdominal aneurysms, computed tomography angiography (CTA), performed at 3 months, showed patent artery side branches and reduced blood flow inside the aneurysmal sac.

CONCLUSION: The multilayer stent seems to be efficient in peripheral artery aneurysms with regard to the side branches which remain patent and the aneurysm is successfully excluded. The question remains about the time needed to achieve exclusion of the aneurysm in large arteries such as the thoracic and abdominal aorta; we believe this is related to the number and size of the branches within the aneurysm as well as the size of the target vessel itself. A larger multicenter study is needed to confirm the suitability of the multilayer stent for the large thoracic, abdominal and thoraco-abdominal aneurysms.

INTRODUCTION

Endovascular aneurysm repair has evolved into a routine procedure for the treatment of abdominal and thoracic aortic and peripheral aneurysms.[1-3] However, the use of endograft devices is limited to patients with aneurysms of suitable anatomy. Numerous devices are on the market, with some first- and second-generation stent-grafts having already been withdrawn due to improvements in the newer generation devices.[4] Among others, single-layer bare stents have been used clinically to treat aneurysms, but the porosity must be so low that the device becomes too rigid and inflexible to conform well to the vessel wall.[5] If an aneurysm is adjacent to or involving a major arterial branch, a stent-graft would occlude the branch as well.[6] If an aneurysm is particularly large, embolization becomes more problematic and expensive if coils are used. How then could one treat a large, wide-necked aneurysm in proximity to or involving a major arterial branch? A new type of multilayer self-expanding stent technology has been developed that may offer an endovascular alternative to surgery in such cases.[7] We report herein our initial experience with this novel technology in patients with aneurysms, particularly those involving side-branches.

METHODS

DEVICE USED

The 3-dimensional (3D) multilayer fluid-modulating stent (Cardiatis, Isnes, Belgium), employed in the present study, is made of a biocompatible cobalt alloy wire that is braided into a tube. Compared to monolayer braided or laser cut stents, the new stent is multilayer, self-expandable, and consists of a 3D-braided-wire tube structured in several interlocked layers (Fig. 1). This stent design superimposes two or more of these tubes to achieve an effective porosity that is low, while retaining flexibility from the high-porosity outer tube (layer). The 3-dimensional structure of this fluid modulating stent can be adapted to the hemodynamics of any artery by adjusting the number of layers. In vitro and in vivo testing in aneurysm models has been encouraging.[8,9] The stent is available in diameters from 2 to 50 mm, allowing treatment in small arteries but also of large aneurysms in other locations. The stent is very flexible and can be loaded in small (6F delivery system for a renal artery application, up to 18F for aortic application). Positioning is easy along stiff guide-wires.

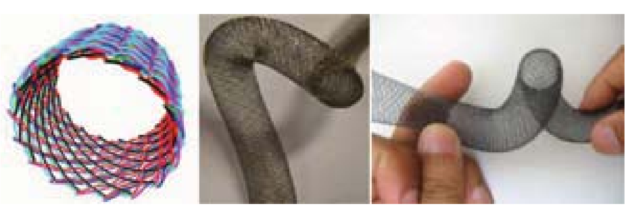

FIGURE 1. Left panel: synthetic picture of the multilayer stent. The middle panel, depicting the peripheral stent, and the right panel, depicting the aortic stent, show that whatever the tortuosity, the diameter of the stent remains unchanged, for the interlocked/ braided layers resist to distortion.

PATIENTS

Between December 2006 and November 2009, 19 patients (mean age 74.3±6.8 years, range 63–87) were treated with the multilayer stent for arterial aneurysm, after obtaining Ethics Committee approval. Four patients had a renal artery aneurysm (1 male & 3 females) (mean diameter: 18 mm), while the other 15 patients (all males) had iliac artery (n=12, mean diameter: 25 mm), popliteal artery (n=1, diameter: 55 mm), thoracic aorta (n=1, diameter: 57 mm) and abdominal aorta (n=1, diameter: 97.3 mm) aneurysms.

FOLLOW-UP

Computed tomography angiography (CTA) scans were obtained at 1, 6, and 12 months after endovascular aneurysm repair (EVAR) and yearly thereafter. During each follow-up visit, presence of aneurysm expansion or shrinkage, stent framework abnormalities or stent kinking, were carefully noted.

RESULTS

The 3D multilayer fluid modulating stent was successfully implanted in all (100%) patients (Fig. 2-5). Mean follow-up for the peripheral aneurysms was 28 months (range 12 to 36) and for the aortic aneurysms was 1 month. The occlusion rate of the aneurysm at the peripheral arteries was 100% and all side branches remained patent. For the thoracic and the abdominal aneurysms, CTA performed at 3 months showed

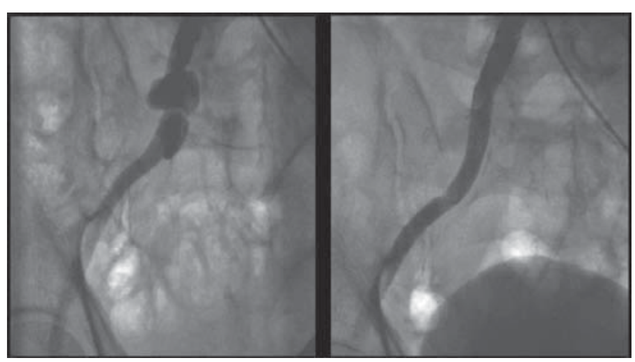

FIGURE 2. A right iliac artery aneurysm is shown before (left panel) and 24 hours post multilayer stent implantation (right panel).

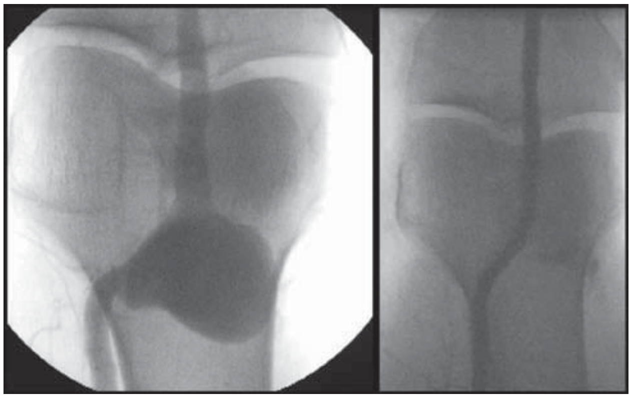

FIGURE 3. A large (55 mm) popliteal artery aneurysm is shown before stent implantation (left panel) and at follow-up angiography 2 years after stent implantation (right panel).

patent artery side branches and reduced blood flow inside the sac. No loss of patency or stent fractures occurred during the follow up.

DISCUSSION

The present study represents the very first clinical experience with this new stent. The multilayer stent is a new device for the treatment of all anatomical aneurysms (Fig. 2-5). For the peripheral vessel aneurysms (renal, splachnic, iliac, popliteal), the device is already CE marked and available for use. To understand the mechanism by which a multilayer stent can cause aneurysm absorption, one must study the hemodynamics within the sac of the aneurysm.

SACCULAR/FUSIFORM ANEURYSMS WITHOUT SIDE-BRANCHES

Figure 6 shows that in an aneurysm without side branches, a vortex is formed when the flow enters the aneurysmal sac. As it progresses along the wall, its strength increases and its residence time gets longer. The mathematical analysis of the path followed by the vortices show that they follow each other but do not follow the same route (figure showing vortices in different colors). This continued phenomenon is permanent; creating tension at the neck of the aneurysm, resulting in an expanded wall that gets thinner and thinner, until it ruptures.

The presence of a multilayer stent reduces the speed and the strength of the vortices, while increasing its residence time. The analyses of the routes followed show that the stent favours the alignment of the paths followed by the vortices. The slowed-down vortices and their alignment (Fig. 7) create a kind of 'traffic jam', which induces an organized thrombus. The in vitro tests, using the particle image velocimetry (PIV) method, confirm that when a multilayer stent is placed in front of the neck of an aneurysm, the velocity of the vortices entering the aneurysmal sac is reduced (Fig. 8). From the clinical point of view, the reduced velocity of the vortices that follow each other stimulates the formation of an organized clot.

SACCULAR /FUSIFORM ANEURYSMS WITH SIDE-BRANCHES

Arterial branching is characterized by a change in flow direction, which induces disturbances at the inlet and results in turbulence. This increases resistance in the blood path along the first few centimeters of the branch's course. With a monolayer stent in place, the vortex persists; a multilayer stent, however, laminates the flow and eliminates the vortex (Fig. 9). This modulation of flow is afforded by the spatial 3D geometry of the stent. When blood flows through the first

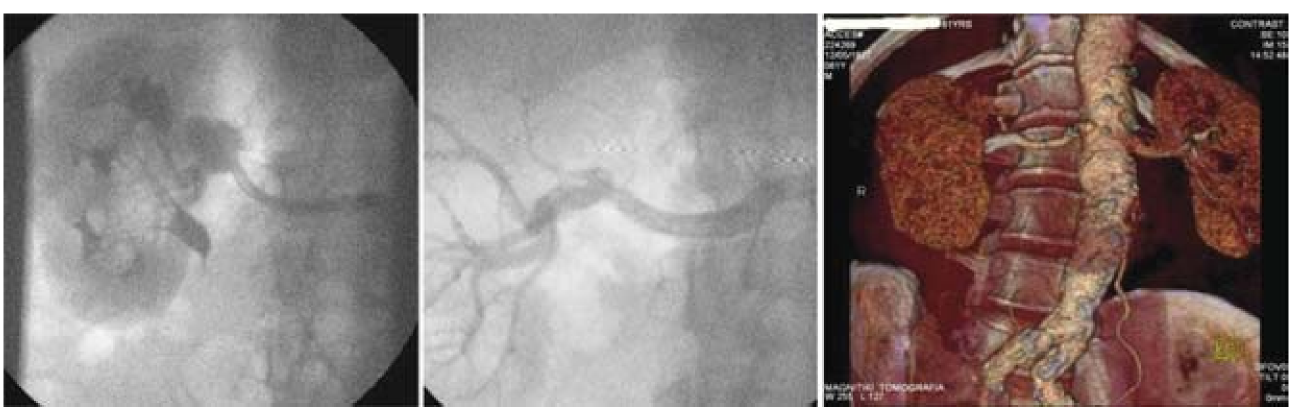

FIGURE 4. Left panel shows a right renal artery aneurysm, with a side branch arising from the aneurysm sac, feeding the upper pole of the kidney. Middle panel: 1-year follow-up angiography shows exclusion of the aneurysm with patent side branch. Right panel: follow-up CT-angiography at 30 months shows exclusion of the aneurysm with patent side branch.

FIGURE 5. Left panel: a 97.3 mm abdominal aortic aneurysm on CTA. Right panel: 3 months post treatment with a multilayer stent. CTA = computed tomography angiography.

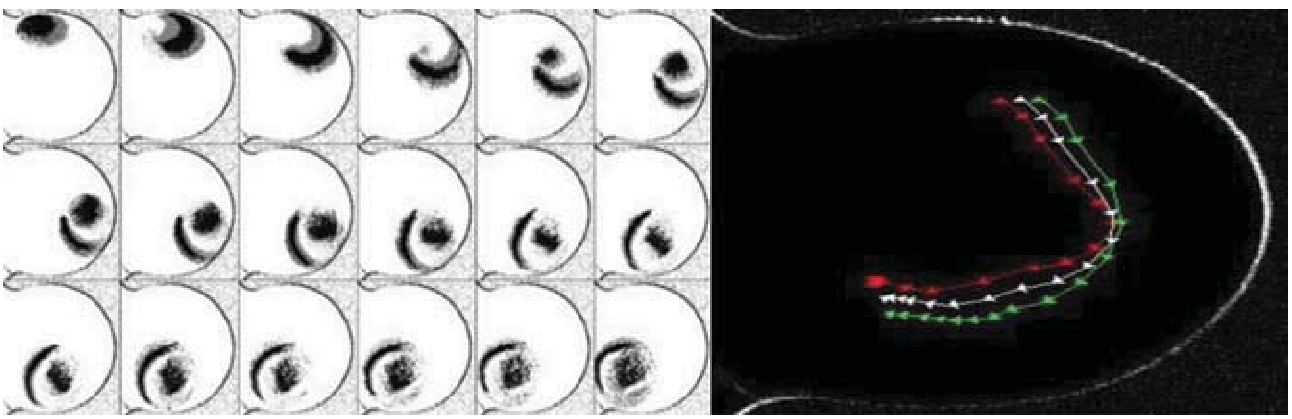

FIGURE 6. Chronological route of the vortex: all created vortices do not follow turbulence, without stent the same route.

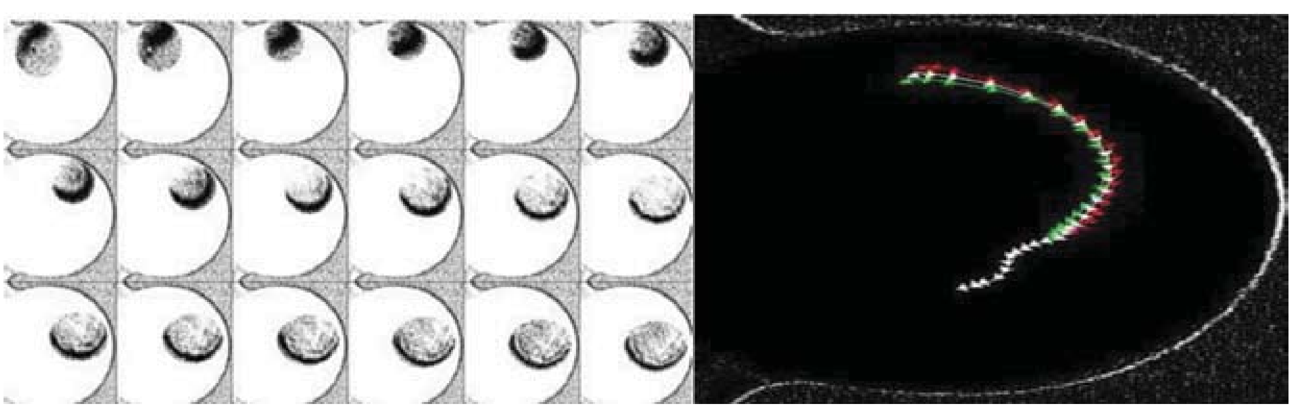

FIGURE 7. Chronological route of the vortex turbulence, with a stent the same route.

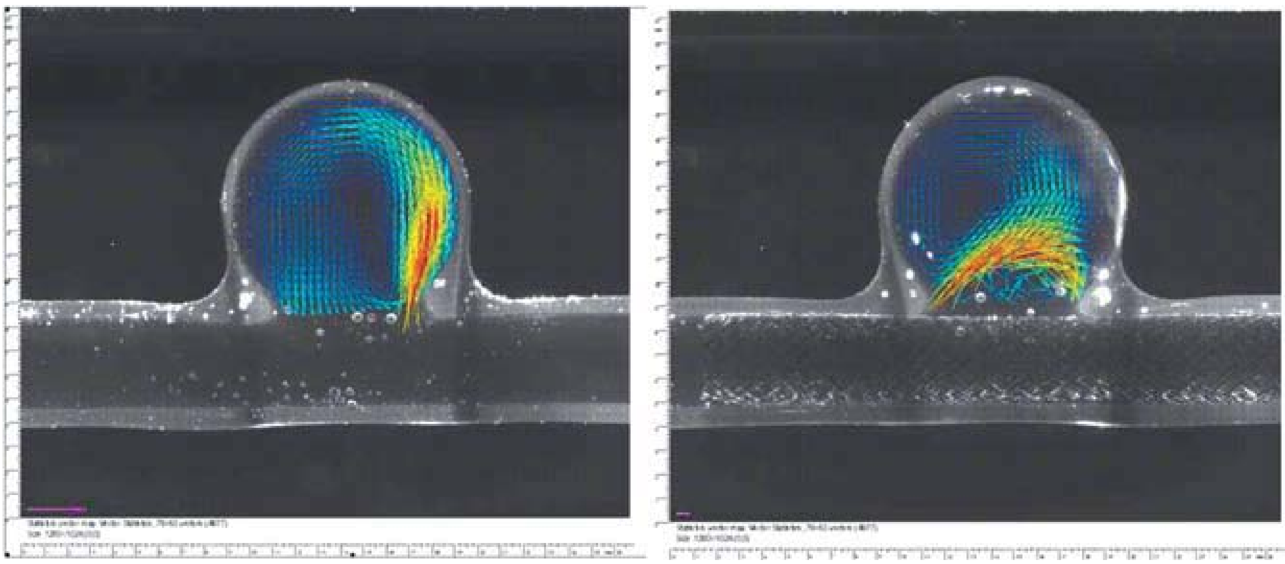

FIGURE 8. Left panel: without a stent the turbulence shears the wall of the aneurysm. Right panel: in the presence of a multilayer stent the speed of the shearing vortex is reduced.

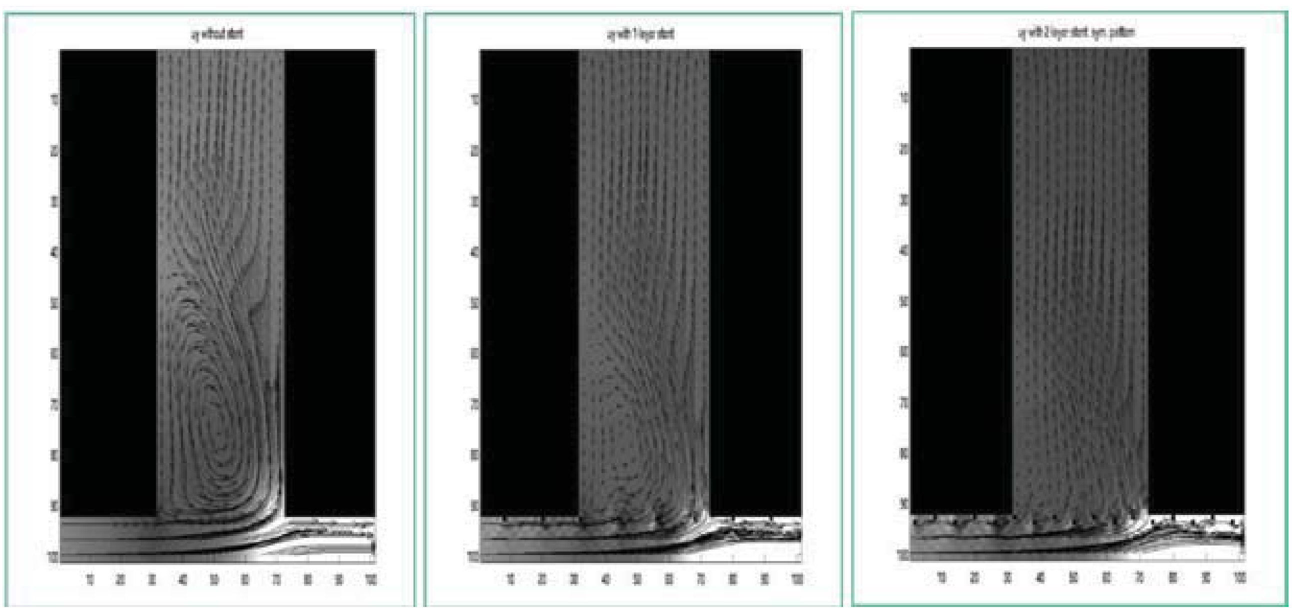

FIGURE 9. Left panel: systematic turbulence at branch. Middle panel: persistence of turbulence with 1-layer stent. Right panel: flow alignment with multilayer stent – vortex disappears.

layer, its pressure decreases to ΔP1; when reaching the second stent layer, the pressure decreases to ΔP2, then to ΔP3 and so forth through the layers. The drop in pressure corresponds to an increase in velocity through the stent, which prevents a vortex from generating.

Tests on animals have shown a significant flow difference within branches before and after implanting a multilayer stent.[10] Better flow circulation in the branches was observed after a multilayer stent had been placed. Interestingly, this sustained permeability is linked to the fact that the multilayer stent, unlike classical stents, becomes lined with endothelium except in the area of branches (Fig. 10).[10]

In an aneurysm with a branch the stent redirects the flow toward the ostium of the collateral by creating a kind of suc-

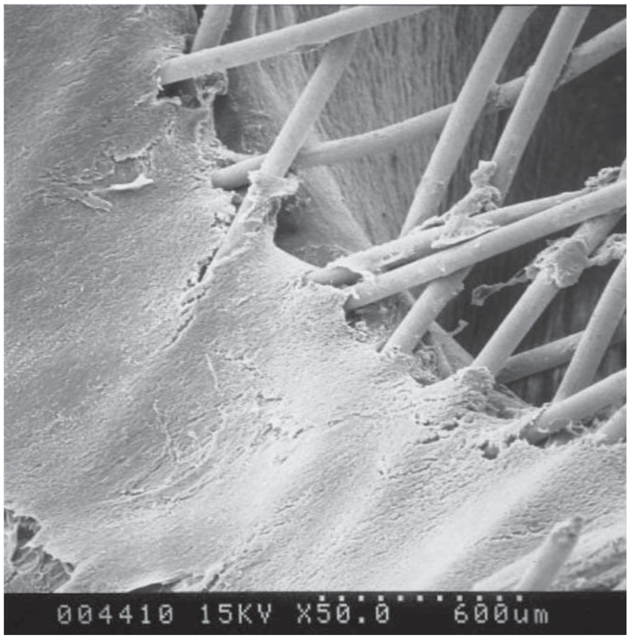

FIGURE 10. The multilayer stent, unlike classical stents, becomes lined with endothelium except in the area of branches.

tion effect; the aneurysm collapses (shrinks) while keeping the collateral patent (Fig. 11).

EFFECTS ON ANEURYSMS

The multilayer stent behaves different in saccular or fusiform aneurysms. In a saccular aneurysm the stent slows flow within the aneurysmal sac, causing an organized thrombus to form and physiologically excludes the aneurysm from circulation. In fusiform aneurysms the flow is laminated along the wall. The collaterals sprouting from the aneurysm remain patent (Fig. 12).

CONCLUSION

The multilayer stent seems to be efficient with regard to

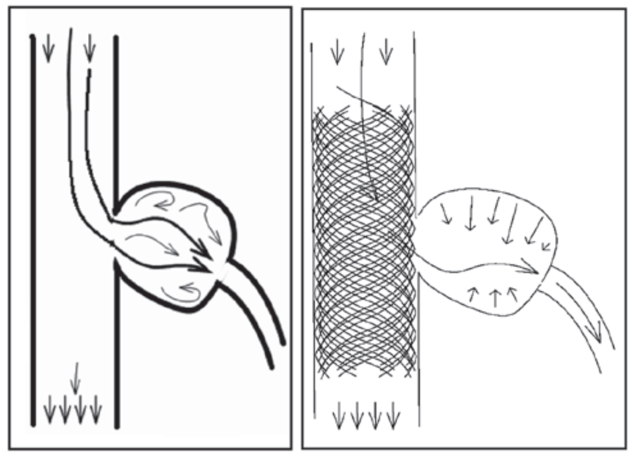

FIGURE 12. In fusiform aneurysms the flow is laminated along the wall. The collaterals sprouting from the aneurysm remain patent.

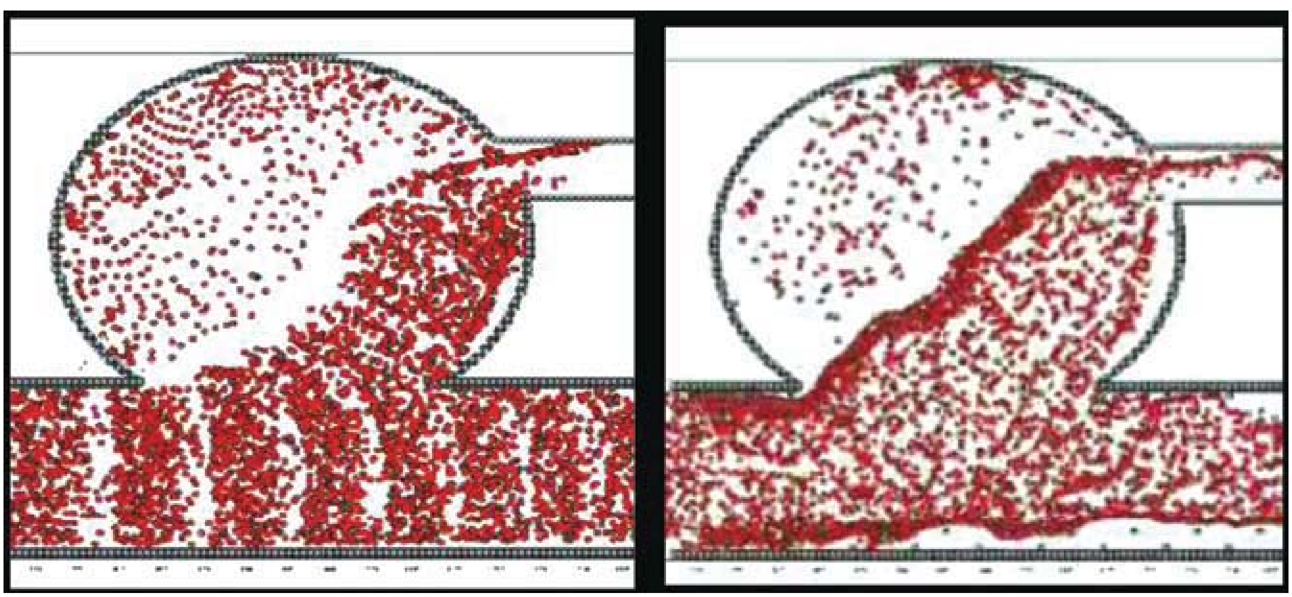

FIGURE 11. In an aneurysm with a branch the stent redirects the flow toward the ostium of the collateral by creating a kind of suction effect; the aneurysm collapses (shrinks) while keeping the collateral patent.

the side branches which remain patent and the aneurysm is excluded. The question remains about the time needed to achieve the exclusion of the aneurysm in large arteries such as the thoracic and abdominal aorta; we believe this is related to the number and size of the branches within the aneurysm as well as the size of the target vessel itself. A larger multicenter study is needed to confirm the suitability of the multilayer stent for the large thoracic, abdominal and thoraco-abdominal aneurysms.

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