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Angiographic analysis of animal model aneurysms treated with novel polyurethane asymmetric vascular stent (P-AVS): feasibility study

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Abstract

Image-guided endovascular intervention (EIGI), using new flow modifying endovascular devices for intracranial aneurysm treatment is an active area of stroke research. The new polyurethane-asymmetric vascular stent (P-AVS), a vascular stent partially covered with a polyurethane-based patch, is used to cover the aneurysm neck, thus occluding flow into the aneurysm. This study involves angiographic imaging of partially covered aneurysm orifices. This particular situation could occur when the vascular geometry does not allow full aneurysm coverage. Four standard in-vivo rabbit-model aneurysms were investigated; two had stent patches placed over the distal region of the aneurysm orifice while the other two had stent patches placed over the proximal region of the aneurysm orifice. Angiographic analysis was used to evaluate aneurysm blood flow before and immediately after stenting and at four-week follow-up. The treatment results were also evaluated using histology on the aneurysm dome and electron microscopy on the aneurysm neck. Post-stenting angiographic flow analysis revealed aneurysmal flow reduction in all cases with faster flow in the distally-covered case and very slow flow and prolonged pooling for proximal-coverage. At follow-up, proximally-covered aneurysms showed full dome occlusion. The electron microscopy showed a remnant neck in both distally-placed stent cases but complete coverage in the proximally-placed stent cases. Thus, direct flow (impingement jet) removal from the aneurysm dome, as indicated by angiograms in the proximally-covered case, was sufficient to cause full aneurysm healing in four weeks; however, aneurysm healing was not complete for the distally-covered case. These results support further investigations into the treatment of aneurysms by flow-modification using partial aneurysm-orifice coverage.

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Keywords

Asymmetric Vascular Stent; AVS; Aneurysm treatment; hemodynamics; flow modification; angiography

Purpose

Novel intracranial aneurysms treatment methods using hemodynamics modifiers are intensely studied by various groups^{1–19}. Flow alteration induced by stents can induce intra-aneurysmal thrombus formation thereby resulting in exclusion from circulation. The stent treatment should achieve aneurysm exclusion while maintaining a low probability of perforator occlusion, in-stent restenosis, thromboembolic events, or vessel injury. Reduced procedure time, lower dome perforation risk, reduced aneurysm recanalization, and shorter recovery time compared to other treatments, are potential benefits of such a treatment.

We developed a new stent, called an Asymmetric Vascular Stent (AVS),^{3–7, 14, 16, 19–21} the device has extremely low porosity in a relatively small, specific region. The device is used to divert the flow from the aneurysm dome by covering the orifice with the asymmetric low-porosity part of the stent. The initial device was built by adding a fine, low-porosity stainless steel mesh onto an existing standard high-porosity stent structure.³ Preliminary and feasibility AVS in-vivo verification was done in a small pilot study using a canine aneurysm model³ and in a larger group study using an elastase aneurysm model in rabbits^{3, 22}. The studies indicated the potential usefulness of this treatment method in that the aneurysms treated with the AVS demonstrated thrombosis and complications were minimal.

Aneurysm models used in the animal studies have a relative simple geometry when compared with the complex geometry of many human cases. Building an AVS that could cover the entire orifice for complex cases could be cumbersome. For these cases, we propose a new approach where flow diversion by partial aneurysm neck coverage is used rather than full coverage. Such a treatment requires a priori aneurysm flow knowledge, such as the impingent jet direction, the presence of vortex flow, the number of vortices, etc. This information can be obtained via angiography or CFD calculations.¹ Once this information is known, a treatment plan using flow diversion via an AVS can be generated. This new approach was verified by Kim et al²¹ using idealized and patient-specific phantoms. Their results indicated that AVS placement and vascular geometry are strongly related. Distal and proximal aneurysm neck coverage was studied for both geometries. But the CFD yielded conflicting results: while distal placement gave good results for the idealized geometry, the results for the patient specific model showed presence of impingent jet, and high wall shear stress. In this work, we present an in-vivo feasibility study investigating the usefulness of partial-orifice coverage. We used four standard elastase rabbit model aneurysms. The impingent jet was removed by blocking the proximal flow in the aneurysms in two cases and distal flow in the other two.

Material and methods

Asymmetric Vascular Stent Manufacturing

The device used in this experiment was a stainless steel, balloon deployed stent¹⁴. The balloon deployed P-AVS (Figure 1) is created by partial stent dipping in a polyurethane mixture of Cronoflex AR (AdvanSource Biomaterials Corp. Wilmington, MA). After the stent dipping, the polyurethane is sprayed with water for neutralization and placed in an oven at 80° C for 24 hours to cure. Once crimped, the AVS has an average diameter of 1.1 mm. The patch shape was patterned to fit a typical, side-wall aneurysm geometry, and, therefore, stent positioning and deployment were performed under direct fluoroscopic guidance. Platinum markers label the patch edges to indicate the stent orientation (Figure 1) and allow accurate rotational placement with a precision of 12 degrees when a 5-inch image intensifier is used or 6 degrees when a microangiographic fluoroscope³ is used.

Aneurysm Creation and treatment

All procedures were approved by the Institutional Animal Care and Use Committee of the State University of New York at Buffalo and were conducted according to guidelines established by the Animal Welfare Act. Four New Zealand rabbits underwent aneurysm creation using previously described techniques.³ After three weeks of aneurysm maturation, the subjects underwent angiographic evaluation and treatment.

Animals received 1000 units of heparin intra-procedurally. A 6 Fr. Terumo Pinnacle sheath (Boston Scientific, Mountain View, CA) was introduced the femoral artery, and a 6 Fr. Envoy guiding straight-tip catheter (Cordis Endovascular Systems, Miami, FL) was advanced under road-mapped fluoroscopic guidance to the subclavian artery. The AVS was then advanced over a Synchro-14 guide wire (Boston Scientific, Mountain View, CA) and positioned so that the proximal and distal platinum markers were adjacent to and spanned the aneurysm neck area to be occluded, while the middle platinum markers were overlapping (Figure 1, bottom). The stent-delivery balloon was then inflated.

Angiographic Analysis

Angiographic data were acquired pre-procedure, immediately post-procedure (after stent deployment), and at four weeks follow-up. Contrast flow changes in the aneurysm dome were graded as follows, 0 - no contrast entered the aneurysm, 1 - slow contrast entering the aneurysm, no jet like flow observed, 2 - fast contrast entering the aneurysms, impinging jet. The flow data was correlated with histological and electron microscopy observations used to assess the aneurysm healing status.

Histologic Analysis

For histological evaluation, aneurysm domes were excised from the parent vessel, processed, embedded in paraffin, and three 2 µm thick adjacent slices were cut from the aneurysm midpoint in the coronal orientation (same direction as the parent artery) using a rotary microtome (Microm International, HM355S, Kalamazoo, MI). Slides were stained with Tri-chrome for overall structural analysis and determination of the aneurysm's thrombosed area.

Scanning Electron Microscopy Analysis

Scanning Electron Microscopy (SEM) analysis was performed on the P-AVS-stented artery specimens. The specimens were fixed using isotonic 2.5% glutaraldehyde in 0.1M sodium cacodylate (Polysciences, Warrington, PA). The artery was longitudinally cut opposite the aneurysm neck, the vessel walls were opened, and SEM of the parent vessel performed for an “in-vessel” view of the surface covering the stent and the stent patch. The samples were washed in distilled water, dehydrated in ethanol (70%–100%), dried with hexamethyldisilazane (HMDS) (Polysciences, Warrington, PA), and stored overnight in a desiccator. SEM was performed using a field emission scanning electron microscope (Hitachi #9000, Schaumburg, IL) in high vacuum mode. We investigated the amount of neck coverage with new tissue.

SEM imaging is very precise in giving details about the stent endothelialization status. For the current presentation our main interest was to verify the aneurysm orifice patency. So we used three grades to quantify the status of aneurysm orifice endothelialization. “Covered” means the aneurysm orifice was totally obliterated; partially-patent was when part of the aneurysm orifice was still visible and fully patent was used when the aneurysm neck was totally visible.

Results

Angiographic Analysis

All the initial angiographic flow sequences (pre-stented) were graded with 2 (Table 1, first column). The initial angiograms shown in Figures 2 and 3 revealed direct flow into the aneurysm with an evident jet impinging on the distal wall followed by a strong vortex. After bolus passage in the main artery, contrast clearance from the aneurysmal dome occurs through the proximal aneurysmal neck region. These observations indicate that the impinging jet originates at the proximal aneurysmal neck region.

Post stented angiographic analysis revealed some flow in all four aneurysms, the grade given in all four cases was one (Table 1). Both stenting methods induced significant modification of contrast flow into the aneurysms, and the impinging jet was removed in all four aneurysms after the treatment. Prolonged pooling was observed in all post-treated aneurysms. However, a large difference can be observed between the angiographic sequences of the two post-stented aneurysms in Figure 2 and Figure 3. The proximal stented aneurysm is characterized by a small perfusion area located around the uncovered distal area, followed by a rapid clearance. The distally placed stent revealed a more significant flow. The contrast slowly perfused into the entire aneurysm dome, followed by a prolonged pooling.

Follow-up angiograms were graded with zero (0) for the proximally placed stents, while the distally-covered aneurysms were graded with one (1), indicating contrast flow in both distally-treated aneurysms. The angiographic sequence in Figure 3 reveals a remnant aneurysm, in which the flow is slow (no jet-like flow observed). However, at the end of the run there is no contrast left in the aneurysm, an indication of persisting relative strong flow in the dome.

Histology Results

Histology done on three aneurysms showed partial thrombosis in the case of the distally-placed patches and full thrombosis for the proximally treated aneurysm. One proximally-treated aneurysm was damaged during the sample preparation process and could not be evaluated by histology. The results for the others are presented in Table 1 and in Figure 4. When using tri-chrome stain, unorganized thrombus will have a pink or red color while organized thrombus will be light blue. The color of the histology slides for the proximally-covered aneurysms at four-week follow-up was primarily blue (lighter color in the Figure 4), indicating an advanced process of thrombus organization, i.e., fully thrombosed. The distally-covered aneurysms (Figure 4 (right)) showed large areas of the aneurysms still patent. Substantial amounts of unorganized thrombus were present; presence of structured lines (lamina), referred to as Lines of Zahn, indicate successive deposition of cell layer.

Scanning Electron Microscopy

Results for SEM are summarized in Table 1 and Figure 5. The large overview, Figure 5 top-left, showed a smooth layer covering both the stent and the solid polyurethane patch; this is a sign of an advanced process of endothelialization. For the proximally-covered aneurysms, the orifice was totally covered. For the distally-covered aneurysms, parts of the orifice were still open at the four-week follow-up as can be observed from the overview in Figure 5 top-right. The lower right picture in Figure 5 shows details of the remnant orifice, red blood cells are present in the area; some of them have a deformed shape, which is a sign of ongoing thrombogenic processes in the area. The orifice is about 0.5 by 1.00 mm. The longer dimension of the remaining orifice lies along the flow direction in the artery.

Discussion and future work

In this study, we collected and analyzed preliminary data for aneurysms treated by partial coverage of the aneurysm orifice using a new Polyurethane-Asymmetric Vascular Stent. The study motivation resides in the multiple constraints of intracranial EIGI's. The Circle of Willis where the intracranial aneurysms are located is a very tortuous arterial network that supplies blood to remote areas of the brain. The geometry or the locations of some of these aneurysms will make it impossible to place an asymmetric stent so that it will entirely cover the aneurysm orifice. Also, the device placement should avoid blockage of small side branches (referred to as perforators) to prevent brain function loss or even death. Last but not least, blood flow disturbances in main arteries by the stent structure should be kept at a minimum or not exist. We intended to simulate treatment of such situations by partially covering of the aneurysm orifice of an in-vivo aneurysm model placed on a curved vessel. We looked for those types of treatment that achieve flow stasis, thus eliminating risk of rupture and enabling thrombogenesis.

Flow through the aneurysm neck has two components, an inflow and an outflow area. The two components are directly interlinked and by significantly modifying one of them the other will be affected also. In our study we looked at both alternatives. For our particular model by analyzing the angiograms in untreated aneurysms, we concluded that the impingent flow originates in the proximal area of the neck, and impacts the aneurysm in the

distal wall or in the dome. Then the flow in the aneurysms follow a vortex like behavior and exits through the distal part of the aneurysm dome. Base on this observation we chose to alter either component by placing the P-AVS distally or proximally.

The proximal neck coverage appears to have been successful in treatment of the aneurysms in only four weeks. Once the impinging jet was modified, the amount of contrast entering the aneurysm was reduced dramatically, most of the flow observed was located at the area of the neck, and did not dissipate in the rest of the aneurysm. This indicates a very negligible exchange between the flow in the artery and the aneurysm dome. The blood trapped in the dome area has a long residency time and develops the chemical links leading to clot formation. These initial experiments point towards the hypothesis that impinging jet elimination can lead to thrombosis of the aneurysm.

Distal coverage creates hemodynamic changes significant enough to affect inflow. The experimental post-stented data showed prolonged contrast presence in the aneurysm dome, an indication of slower flow in the dome. However at four-week follow-up, we still had a remnant aneurysm. In this case, we cannot conclude with confidence that the aneurysm treatment was not optimal, since the histology shows a good portion of the aneurysm is thrombosed. Also the presence of lines in the unorganized thrombus indicates a gradual process of aneurysm occlusion. This particular aspect could be of interest for aneurysms with perforators in the dome. This gradual process versus total immediate obliteration needs to be further studied for longer periods of time before any conclusions can be derived. A solution to these unanswered questions is to design a longitudinal experiment that contains exclusively distally covered aneurysm orifices.

A note of caution is that it might be possible that thrombus could escape the aneurysm with partial orifice coverage and cause vessel occlusion in the distal vasculature. None of the subjects used in the experiment, however, showed any neurological or physiological problems under conditions of moderate to heavy anticoagulation medication.

Future Work

Finally, we would like to indicate the new advancement in the asymmetric vascular stent development. As we pointed out in this work as well as in previous published works⁶, balloon deployable stents are not suitable for placement in remote areas of the brain vasculature. The stents are too rigid and could cause severe injuries to the vessel walls. Also the balloon folding used for stent crimping can cause rotation of the stent during deployment.⁶ The new type of self deployable stent that we have developed will remove many of the issues characteristic to balloon deployable stents. Future experiments will focus on the usage of the new stents in phantoms and in vivo.

The new stent is made from Nickel-Titanium (NiTi) and is self-deployable. A model similar to current self-deployable neurovascular stents was designed using solid modeling software. The computer model was sent to a laser shop (Lasera Technology Corporation, Waukegan, IL) and the model was cut from NiTi tubing provided by NI-TI Tubes LLC (Fremont, CA). The stents were cut at a nominal diameter of 2.5 mm. Later they were expanded to 4 mm diameter by placing them on glass rods in an oven set at 525 degrees C.

They were kept for 5 minutes at the specified temperature and then dipped in an ice-water bath.

Next, the stents were chemically processed and electro-polished using chemical solutions provided by (RD Chemical, Mountin View, CA). Finally, we attached a low porosity PTFE (Millipore, Billerica, Ma) material and the platinum markers onto the stent (Figure 1, Self deploying stent)

The new trials with the new stent have started the in-vivo stage and the first angiograms acquired before and after stent placement are shown in Figure 6. In this particular case the flow in the aneurysm was almost completely removed, while the vessel keeps most of its initial shape. This is due to the increased flexibility of the new stents and the material used. We believe that the new asymmetric stent is the closest to the design that may be used in human cases.

Conclusion

Angiographic and histological data were analyzed in a feasibility study of partial-coverage treatment of aneurysms using an improved polyurethane-AVS. The results indicate that by appropriately analyzing the initial angiographic data and understanding the hemodynamic processes, an adequate treatment plan for flow modulation can be selected and implemented using a novel AVS device. Our results indicate that blockage of the initial impinging jet will create conditions for rapid aneurysm occlusion. These data support further investigation into this new type of treatment.

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References

1. Benitez RP, Silva MT, Klem J, Veznedaroglu E, Rosenwasser RH. Endovascular occlusion of wide-necked aneurysms with a new intracranial microstent (neuroform) and detachable coils. *Neurosurgery*. 2004; 54:1359–1367. [PubMed: 15157292]
2. Doerfler A, Wanke I, Egelhof T, Stolke D, Forsting M. Double-stent method: Therapeutic alternative for small wide-necked aneurysms. *Journal of Neurosurgery*. 2004; 100:150–154. [PubMed: 14743929]
3. Dohatcu A, Ionita CN, Paciorek A, Bednarek DR, Hoffmann KR, Rudin S. Endovascular image-guided treatment of in-vivo model aneurysms with asymmetric vascular stents (avs): Evaluation with time-density curve angiographic analysis and histology. *Proc SPIE*. 2008; 6916:69160P-1–12.
4. Hoi Y, Ionita CN, Tranquebar RV, Hoffmann KR, Woodward SH, Taulbee DB, Meng H, Rudin S. Flow modification in canine intracranial aneurysm model by an asymmetric stent: Studies using digital subtraction angiography (dsa) and image-based computational fluid dynamics (cfd) analyses. *Proc SPIE*. 2006; 6143:61430J.
5. Ionita CN, Hoi Y, Meng H, Rudin S. Particle image velocimetry (piv) evaluation of flow modification in aneurysm phantoms using asymmetric stents. *Proc SPIE*. 2004; 5369:295–306. [PubMed: 21572936]

6. Ionita CN, Pacioremek A, Hoffmann KR, Bednarek DR, Yamamoto J, Kolega J, Levy EI, Hopkins LN, Rudin S, Mocco J. Asymmetric vascular stent (avs): Feasibility study of a new low-porosity patch-containing stent. *Stroke*. 2008; 39:2105–2113. [PubMed: 18436886]
7. Ionita CN, Rudin S, Hoffmann KR, Bednarek DR. Microangiographic image-guided localization of a new asymmetric stent for treatment of cerebral aneurysms. *Proc SPIE*. 2005; 5744:354–365. [PubMed: 21311733]
8. Kallmes DF, Ding YH, Dai D, Kadirvel R, Lewis DA, Cloft HJ. A new endoluminal, flow-disrupting device for treatment of saccular aneurysms. *Stroke*. 2007; 38:2346–2352. [PubMed: 17615366]
9. Krings T, Busch C, Sellhaus B, Drexler AY, Bovi M, Hermanns-Sachweh B, Scherer K, Gilsbach JM, Thron A, Hans FJ. Long-term histological and scanning electron microscopy results of endovascular and operative treatments of experimentally induced aneurysms in the rabbit. *Neurosurgery*. 2006; 59:911–923. [PubMed: 17038956]
10. Krings T, Hans FJ, Moller-Hartmann W, Brunn A, Thiex R, Schmitz-Rode T, Verken P, Scherer K, Dreeskamp H, Stein KP, Gilsbach JM, Thron A. Treatment of experimentally induced aneurysms with stents. *Neurosurgery*. 2005; 56:1347–1359. [PubMed: 15918952]
11. Lieber BB, Gounis MJ. The physics of endoluminal stenting in the treatment of cerebrovascular aneurysms. *Neurological Research*. 2002; 24:S33–S42. [PubMed: 12074435]
12. Lieber BB, Livescu V, Hopkins LN, Wakhloo AK. Particle image velocimetry assessment of stent design influence on intra-aneurysmal flow. *Annals of Biomedical Engineering*. 2002; 30:768–777. [PubMed: 12220077]
13. Minsuok K, Ciprian I, Rekha T, Kenneth RH, Dale BT, Hui M, Stephen R. Evaluation of an asymmetric stent patch design for a patient specific intracranial aneurysm using computational fluid dynamic (cf) calculations in the computed tomography (ct) derived lumen. *Proc SPIE*. 2006; 6143:61432G.
14. Rangwala HS, Ionita CN, Rudin S, Baier RE. Partially polyurethane-covered stent for cerebral aneurysm treatment. *J Biomed Mater Res B Appl Biomater*. 2008 in-print.
15. Rudin S, Wang Z, Kyprianou I, Hoffmann KR, Wu Y, Meng H, Guterman LR, Nemes B, Bednarek DR, Dmochowski J, Hopkins LN. Measurement of flow modification in phantom aneurysm model: Comparison of coils and a longitudinally and axially asymmetric stent - initial findings. *Radiology*. 2004; 231:272–276. [PubMed: 15068953]
16. Sherman JR, Rangwala HS, Ionita CN, Dohatcu AC, Lee JW, Bednarek DR, Hoffmann KR, Rudin S. Investigation of new flow modifying endovascular image-guided interventional (eigi) techniques in patient-specific aneurysm phantoms (psaps) using optical imaging. *Proc SPIE*. 2008; 6918:69181V.
17. Wakhloo AK, Lanzino G, Lieber BB, Hopkins LN. Stents for intracranial aneurysms: The beginning of a new endovascular era? *Neurosurgery*. 1998; 43:377–379. [PubMed: 9696095]
18. Wakhloo AK, Schellhammer F, Devries J, Haberstroh J, Schumacher M. Self-expanding and balloon-expandable stents in the treatment of carotid aneurysms - an experimental-study in a canine model. *American Journal of Neuroradiology*. 1994; 15:493–502. [PubMed: 8197946]
19. Zhou W, Ciprian NI, Stephen R, Kenneth RH, Adam BP, Daniel RB. Angiographic analysis of blood flow modification in cerebral aneurysm models with a new asymmetric stent. *Proc SPIE*. 2004; 5369:307–318.
20. Ionita CN, Keleshis C, Patel V, Yadava G, Hoffmann KR, Bednarek DR, Jain A, Rudin S. Implementation of a high-sensitivity micro-angiographic fluoroscope (hs-maf) for in-vivo endovascular image guided interventions (eigi) and region-of-interest computed tomography (roi-ct). *Proc SPIE*. 2008; 6918:69181I.
21. Kim M, Rangwala HS, Ionita CN, Hoffmann KR, Taulbee DB, Meng H, Rudin S. Evaluation of the effect of partial asymmetric stent coverage on neurovascular aneurysm hemodynamics using computer fluid dynamics (cf) calculations. *Proc SPIE*. 2007; 6509:65092I.
22. Ionita CN, Pacioremek AM, Dohatcu A, Hoffmann KR, Bednarek DR, Kolega J, Levy EI, Hopkins LN, Rudin S, Mocco JD. The Asymmetric Vascular Stent. Efficacy in a Rabbit Aneurysm Model *Stroke*. January 8;2009 Published online before print.

Figure 1.

AVS Stents on top: balloon deployed P-AVS top-left figure shows the middle of the patch and top-right figure shows the edge of the patch. The left bottom figure shows a projection view, comparable to an x-ray view. The right bottom figure shows the cross-sectional view at the location indicated by the dotted line in the projection view.

Figure 2.

Angiographic snapshots, pre-and post stented in a proximally-placed stent. The white arrows indicate the location of the aneurysm. Pre-stented flow shows a direct jet impinging onto the distal wall. After 180 frames or 6 seconds, there is very little contrast left in the aneurysm. Post-stented cases show very small flow into the aneurysm dome in the angiographic snapshots. Follow-up sequence shows no flow in the aneurysms dome. During the stent placing procedure the right front leg of the rabbit was moved in order to facilitate the advancement of the stent, hence some of the geometry and the arteries in the angiographic

sequence were different or missing in the post stented images compared to the pre-stented images.

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Figure 3.

Angiographic snapshots, pre-and post stented in a distally-placed stent; images were acquired at 30 frames per second. Pre-stented flow shows direct jet impinging onto the distal wall. After 180 frames or 6 seconds, there is very little contrast left in the aneurysm. Post-stented sequence shows a reduced but significant direct flow into the aneurysm dome. After 180 frames there is still a significant amount of contrast due to gravitational pooling. Follow-up sequence shows a significant amount entering the aneurysm dome. Area of the inflow is indicated by the white arrows in the angiographic snapshots.

Figure 4.

Histology results for proximal-covered (left) and distally-covered aneurysms (right). The aneurysm neck is at the bottom of the figure. Pink indicates unorganized thrombus or thrombus in the initial stages of organization. Blue indicates an advanced process of thrombus organization.

Figure 5.

Scanning Electronic Microscopy of the artery wall at a location corresponding to the aneurysm orifice for the proximally-placed (left) and distally-placed (right) stent patch. The top shows a large overview of the orifice area (scale 1 mm). Details (scale 10 and 20 microns respectively) corresponding to the dotted ellipse are shown in the bottom pictures. For the proximally placed stent the aneurysm orifice has disappeared completely. The distally placed stent has a remaining aneurysm orifice.

Figure 6.

Top: New self-deploying AVS. Arrows show the location of markers on the periphery of the patch. Bottom: Angiographic snapshots of pre-stented (left) and post-stented (right) vessels. The angiograms are taken in the same subjects and the difference in the vasculature is due to a change in the C-arm orientation between images.

Table 1

Angiographic flow data, histology results, and SEM results for the treated aneurysms. Flow ratings: 0 - no contrast entered the aneurysm, 1 - slow contrast entering the aneurysm, no jet-like flow, 2 - impinging jet.

Subject No	Stent placement	Pre-stented Angiogram	Post-Stented Angiograms	Follow-up Angiogram	Histology	SEM
1	Distal	2	1	1	Partially thrombosed	Neck Partially Patent
2	Distal	2	1	1	Partially thrombosed	Neck Partially Patent
3	Proximal	2	1	0	Fully thrombosed	Covered
4	Proximal	2	1	0	N/A	Covered