Published in final edited form as:

Proc SPIE Int Soc Opt Eng. 2015 February 21; 9417: . doi:10.1117/12.2082079.

Angiographic analysis for phantom simulations of endovascular aneurysm treatments with a new fully retrievable asymmetric flow diverter

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Abstract

Digital Subtraction Angiography (DSA) is the main diagnostic tool for intracranial aneurysms (IA) flow-diverter (FD) assisted treatment. Based on qualitative contrast flow evaluation, interventionists decide on subsequent steps. We developed a novel fully Retrievable Asymmetric Flow-Diverter (RAFD) which allows controlled deployment, repositioning and detachment achieve optimal flow diversion. The device has a small low porosity or solid region which is placed such that it would achieve maximum aneurysmal in-jet flow deflection with minimum impairment to adjacent vessels. We tested the new RAFD using a flow-loop with an idealized and a patient specific IA phantom in carotid-relevant physiological conditions. We positioned the deflection region at three locations: distally, center and proximally to the aneurysm orifice and analyzed aneurysm dome flow using DSA derived maps for mean transit time (MTT) and bolus arrival times (BAT). Comparison between treated and untreated (control) maps quantified the RAFD positioning effect. Average MTT, related to contrast presence in the aneurysm dome increased, indicating flow decoupling between the aneurysm and parent artery. Maximum effect was observed in the center and proximal position (~75%) of aneurysm models depending on their geometry. BAT maps, correlated well with inflow jet direction and magnitude. Reduction and jet dispersion as high as about 50% was observed for various treatments. We demonstrated the use of DSA data to guide the placement of the RAFD and showed that optimum flow diversion within the aneurysm dome is feasible. This could lead to more effective and a safer IA treatment using FDs.

Keywords

Digital subtraction angiography (DSA); Intracranial aneurysm (IA); Flow diverter (FD); Uniform flow diverter (UFD); Asymmetric flow diverter (AFD); Retrievable asymmetric flow diverter (RAFD); Mean transit time (MTT); Bolus arrival time (BAT); parametric image mapping (PIM)

2. INTRODUCTION

Digital Subtraction Angiography (DSA) sequences are used to analyze vascular structure and pathology geometry. Within certain limitations, DSA is also used for qualitative evaluation of the contrast flow through the neurovascular network. Due to its inherent high spatial resolution, 200 micrometers, high signal-to-noise ratio and high temporal resolution (up to 60 frames/s), DSA application has been extended for quantitative estimation of the blood flow within the cerebrovasculature.^{1,2} For this proceeding we are particularly interested in DSA based quantitative estimation of the flow in intracranial aneurysms (IA) treated with flow diverters. We plan to use such information to optimize the IA treatment using a novel fully Retrievable Asymmetric Flow-Diverter (RAFD)

IA's are localized bulges with weakened walls of the cerebrovasculature which affects 5–8% of the general population. The IA formation occurs in three stages: a) initiation b) growth and c) position stabilization or undesired rupture. This entire process is a result of the intimate relationship between the arterial wall, flow dynamics and local artery geometry.^{3, 4}

Traditional treatment methods include coiling, clipping and application of liquid embolic. While these are reliable methods, they remain invasive and can lead to intra-procedural complications escalating chances of Intra Cerebral Hemorrhage or Sub Arachnoid Hemorrhage. In addition, complex geometries with large, wide neck aneurysms (10–25mm diameter) remain a challenge to be treated with such conventional techniques, making long term care of these aneurysms difficult.

Post -treatment pathologies that occur as a consequence of the above mentioned techniques are aneurysm re-growth due to coil compaction and aneurysm rupture.^{4, 5}

A recent advent, the concept of flow diversion (FD), was proposed to be an alternative solution to the conventional techniques for IA treatment. FD stents attempt to block the aneurysm neck by deflecting the main inflow jet to limit the cerebrovascular blood flow into the aneurysm sac. This lowers pressure on the walls of the aneurysm dome, to facilitate the progressive thrombosis of the lesion while keeping the adjacent vessels healthy and ensures safety with minimal device invasion. Flow diverters can be categorized as of two kinds: 1) uniform flow diverters (UFDs) and 2) asymmetric flow diverters (AFDs).

While UFDs such as Pipeline stents have proven to be effective in some side wall IAs, they are ideally not suited for cerebrovascular bifurcations and vessel sizes less than 2.5 mm. This is due to factors such as perforator occlusion or narrowing of the adjacent perforator orifice. Another major drawback is the need for device repositioning that complicates the procedures by additional application of further pipelines (flow-diverters) and coiling. Although flow diverters are clinically used, their effects remain sub-optimal due to limited torqueing ability, negligible re-sheathing properties, limitations on delivery wire rotation, low porosity zones occluding adjacent perforators that might lead to incidence of lacunar infarcts and insufficient perforations causing delayed ischemic events.^{6, 7, 8, and 9}

The second kind of FD is the asymmetric flow diverter. The concept of AFDs is being proposed for treatment of bifurcated IAs. The challenge being faced in this area is optimal

placement and delivery of the device which critically affects flow in adjacent perforators. Hence, design of an asymmetric flow diverter is highly dependent on the aneurysm geometry and vascular location.^{5, 6, 7}

This paper focuses on a unique possibility of utilizing DSA for optimizing the placement of a newly developed completely retrievable asymmetric flow diverter (RAFD) and studies its consequent effects on flow dynamics. The RAFD provides flexibility of re-sheathing and un-sheathing to attain the right alignment in the vessel. Deployment of the device involves the application of current between the actuator and the device to detach the stent diverter.

The quantitative analysis of RAFD is based on the correlation between parametric imaging maps derived from Time-Density-Curves plotted using DSA acquisition. We performed parametric imaging mapping, also referred to as color coded digital subtraction angiography, by analyzing the contrast behavior at each pixel in an angiographic image sequence while the asymmetric flow diverter was placed at proximal, middle and distal regions of the aneurysm neck.¹⁰ Some of the position naming conventions in the paper may slightly deviate from the ones mentioned above, based on the location of the device and the aneurysm geometry.

3. MATERIAL AND METHODS

This paper involves three parts: a) development of the device prototype (RAFD), b) Data acquisition using DSA in a clinical environment followed by c) data analysis.

3.1 Development of the Completely Retrievable Asymmetric Flow Diverter (RAFD)

The design of RAFD is such that it comprises of two regions: 1) the porous region and 2) a polymer patch that covers three quarters circumference of the stent just enough to deflect the main in-jet flow. We developed two prototypes. One of the prototypes has the patch placed at the edge of the stent on a tapered wing and the other has a patch placed on the center of the stent. (Refer to figure 1 (a))

The patch is made of a polymer that belongs to a family of bio-durable segmented polycarbonate polyurethanes (Chrono flex AR). This polymer offers good tensile strength, adhesion and elastic properties when compared to the other polyurethanes that succumb to enzymatic activity leading to formations of micro cracks and potential catastrophic failures. The polymer when tested proved to sustain its properties when stressed at 300% elongation and examined under scanning electron microscopy.¹¹

Using N-N dimethyl acetamide facilitated thin film deposition which allowed the RAFD to be delivered or re-sheathed using a 3Fr Catheter as shown in figure 1(b).

We deployed the prototypes (RAFD) in 3D aneurysm phantoms of varying geometry and evaluated its effect on flow using DSA. The naming conventions depend on the complexity of the vasculature and the device alignment. The RAFD placement and evaluation was conducted at three separate positions for both the prototypes. The RAFD with stent to patch bonding in the center was aligned at the proximal, distal and middle regions of the aneurysm neck facing the aneurysm dome and the RAFD with the stent-to-patch bonding at the

tapered edge was positioned in the centerleft, middle and center-right positions of the aneurysm neck. (Refer to figure 2(a) and (b)) For reference, Figure 3 depicts an image of the RAFD (with patch located on the center of the stent) being positioned in an idealized side wall aneurysm phantom during an ongoing procedure.

3.2 Experimental Set-up and DSA Data Acquisition

The experimental set up in Figure 4 was based on generating a real time flow model where the flow rate was maintained at 348 ml/min analogous to that of the carotid artery (375 $\pm$ 79 ml/min) using a flow pump. The experiment was done in three phantoms: an idealized simple side-wall aneurysm phantom, a 3 D printed patient specific aneurysm phantom, and an aneurysm occurring in a full 3 D printed patient specific Circle of Willis phantom.

The contrast bolus volume was kept constant at 5ml for every run. The RAFD was deployed by constant repositioning and re-sheathing using a 2.8-3F catheter while maintaining the integrity of the patch^{12, 13, and 14}. Given the complexity of the phantoms, DSA performed at 10 frames per second (f/s), guided the positioning of the prototypes at various positions of the aneurysm neck. This significantly affected the bolus inflow-jet and the redistribution of flow. Once the stent was placed in the required position, it was detached by applying a current between the actuator and the implant. The DSA acquired data in the treated and the untreated aneurysm were compared by deriving information about the Bolus-Arrival-Time (BAT) and the mean transit time (MTT) taken for contrast clearance in the aneurysm dome by plotting time-density-curves (TDC) and projecting the parameters in color coded scales of Parametric Image Map¹⁰.

3.3 Data Analysis

We analyzed the data using the sequence of steps in the diagram in Figure 5. To speed up the processing, the acquired images' size was reduced from 1024 $\times$ 1024 to 256 $\times$ 256 pixels using binning of adjacent pixels. Next, we recorded the intensity of each pixel (C_{ij}) individually during the entire sequence. In order to avoid the analysis of the background pixels and focus only on vessel pixels analysis, we set a calculation threshold. The threshold was based on RMS calculation of pixel variation during a sequence. The RMS limit was set to 10% above the background RMS, which was established by tracking background pixels (region excluding the vessel). For those pixels with RMS value below the threshold, the values of temporal parameters in the PIM were set to zero. For those pixels with RMS value above the threshold, we applied a Time Density Curve (TDC) correction for system sampling¹⁰:

$$g(t)=c(t)+\tau \cdot \frac{dc(t)}{dt}$$

Where $g(t)$ is the corrected TDC, $c(t)$ is the recorded TDC from the DSA sequences and τ is the exposure time per frame.

Next we fitted $g(t)$ data with a gamma variate function in order to calculate MTT (mean transit time) i.e. the time delay of the bolus contrast to leave the aneurysm dome which is

represented by intensities, BAT (bolus arrival time) and TTP (time to peak that is the. time at which the intensity of the contrast bolus is maximum in the aneurysm dome¹⁰. The gamma variate function is given by:

$$D(t)=K(t-t_0)^\alpha e^{-\frac{(t-t_0)}{\beta}}$$

where K is a constant scale factor, t_0 is the time of appearance of the contrast medium, and α and β are parameters of the distribution.

Using the definition of MTT and the properties of the gamma variate functions, it can be shown that¹⁰:

$$MTT=t_0+\beta(\alpha+1)$$

For our purpose we have used the MTT (Mean transit time) and BAT (Bolus Arrival Time) values.

4. RESULTS

We have demonstrated the use of DSA for RAFD placement and flow analysis in a simple idealized side-wall aneurysm, 3 D printed patient specific phantom with aneurysm at the ophthalmic vessel region and a patient specific aneurysm occurring in a full 3 D printed Circle of Willis phantom¹⁴. We conducted initial studies with a thick patch on the RAFD, retrievable in a 5F catheter and now have successfully made a finer patch that can be retrieved in a 2.8F micro-catheter. The data acquired using DSA is correlated with Parametric imaging that generate information about the flow dynamics that will act as a deciding factor for device positioning based on the aneurysm geometry. The results have given information about both flow in-jet deflection, about 50%, and stasis in the aneurysm dome, to about 75%¹⁰.

4.1 Flow analysis in a simple idealized side wall aneurysm phantom

DSA was used to confirm the positioning of the RAFD based on the quantitative analysis of data and its effect on flow dynamics. The RAFD dedicated for a side wall aneurysm model as shown in figure 6 contained the patch at the center of the stent. The data acquired was saved in the form of raw images.

Following this, DSA acquisitions were quantitatively analyzed using a parametric imaging algorithm that displayed DSA color coded images based on the contrast bolus intensity over a period of time (in seconds) This helped study the effect on flow dynamics based on the placement of the RAFD.

We have shown the initial overall results of the parametric image mapping of a side wall aneurysm phantom as shown in figure 7. Figure 7(a) displays the data about the bolus arrival time (BAT) and figure 7(b) displays the Mean Transit Time (MTT). The color scheme convention is the same for each particular parameters: 0 to 1.5 seconds for BAT and 0 to 3

seconds for the MTT. Overall, the inlet values were similar within 10% indicating similar flow conditions.

We narrowed the time window of the above mentioned results in Figure 8 to generate details of the effect of the treatment. Shorter BAT corresponds to the inflow jet. The proximal placement of the patch on the RAFD had the largest effect on the inlet, followed by the middle and distal placement, respectively as expressed in figure 8(a). The largest MTT was observed during the middle placement. This particular position affected the bolus contrast clearance time in the aneurysm dome as expressed in figure 8(b).

4.2 Flow analysis in a 3 D printed patient specific aneurysm geometry

Further quantitative studies were conducted on a patient specific aneurysm geometry occurring in the ophthalmic vessel region as shown in figure 9 with the tapered wing-patch RAFD model. The prototype was tested to generate more data on mean transit time (MTT) and bolus arrival time (BAT) using PIT. DSA-guided RAFD positioning was used to obtain patch placement in the center-left, center-right and distal regions of the aneurysm neck. Figure 10 shows the BAT and MTT results of the phantom. The parametric imaging technique (PIT) images have been enlarged to exemplify the flow redistribution that were recorded with the time frequency parameters set to 0–0.9 seconds for BAT and 2.1–2.5 seconds for MTT. The BAT images contribute for physiological information about the flow jet and its dynamics while the MTT images correspond to the time taken for contrast clearance from the aneurysm dome that will or stasis.

4.3 Flow analysis in a 3 D printed Circle of Willis phantom

Next, we tested a 3D printed Circle of Willis aneurysm phantom as shown in figure 11. The prototype with the effective patch-to-stent bonding was obtained in the center of the stent. The device was placed at the middle and proximal positions. The platinum markers as shown in figure 12 designate the position of the patch. The color coded images were acquired from an angiographic study on a 3D printed Circle of Willis. Figure 13 demonstrates the specific aneurysm being tested along carotid siphon, distal to MCA on the circle of Willis. All the values that have been generated were normalized to the bent region of the carotid siphon as represented by the yellow box. The images in figure 14 show the flow changes caused due to the flow jet being perturbed as a result of the RAFD positioning. The results generated in this study were significantly different from the previous ones. The maximum flow-jet dispersion occurred when the patch on the prototype was placed in the middle region of the aneurysm neck. Unlike the earlier images, here the MTT is maximum when the RAFD is positioned in a way such that the patch is placed in the proximal region of the neck with reference to the flow direction. This substantiates the fact that the complexity of the geometry plays an important role as a deciding factor for optimal positioning of the RAFD in order to achieve progressive thrombosis. The color scheme parameters were set as 0.1–0.9 seconds for BAT and 0.4–3 seconds for MTT.

5. DISCUSSION

We have used two RAFD prototypes to treat various aneurysm phantom geometries, with stent-to-patch bonding in the center of the stent and at the tapering wing of the stent. Both these prototypes can be used in all the geometries that have been mentioned in the paper. The naming conventions depend on the placement positions of the prototypes in the phantom geometries. Our results show the use of DSA that ensures safe RAFD placement with minimal intra-procedural complications attributing to the retrievable characteristic of the device. We have shown that DSA generated data can be used to study the modified flow dynamics as a result of RAFD positioning, thus, providing physiological information that can act as a reference for optimum RAFD positioning owing to the complexity of the aneurysm geometry.

This study can be compared with the earlier studies conducted by CN. Ionita et al in developing an Asymmetrical Vascular Stent (AVS)⁶. In that study, we demonstrated the development of a simple hemodynamic modifying device, the AVS to treat intracranial aneurysms as an alternative to coiling. The AVS consisted of low-porosity metal mesh in a relatively small, specific portion of the metal stent.^{6, 7, 15, and 16}. Although the initial studies on a side wall aneurysm model generated promising results, the AVS design had substantial mechanical limitations. The AVS prototype was not likely to be used for more tortuous aneurysm geometries due to its stiffness caused as a consequence of its design⁶.

The current results have overcome the drawbacks of the previous studies by supplementing the procedure with effective safety and optimal deployment technique using DSA guidance. The device prototype in its existing designs has demonstrated flow diversion that can be observed in the BAT (bolus arrival time) images. Although we have not tested these devices for adjacent branch occlusion, these stents are similar to the neuro-stents that have maintained a history of patent branches. We have generated data for aneurysm phantom models ranging from a simple idealized side wall aneurysm phantom to a complex 3 D printed patient specific circle of Willis to verify the effectiveness of the prototype and the system. DSA acquired data were used to generate BAT (bolus arrival time) and MTT (mean transit time) values to understand the flow changes effect while placing the device at various positions such as proximal, middle, center-left, center-right and distal regions of the aneurysm neck^{10, 14}. The color coded maps projected distinguished data for every given position in order to assist the optimal device placement. The re-sheathable navigation through tortuous cerebral vasculature and torquing characteristics of the RAFD helped maintain negligible intra-procedural complications and effective deployment.

Quantitative analysis using the PIT algorithm can sometimes generated unclear maps with a higher noise ratio but this challenge can be overcome in the future by working on optimization of the algorithm function.

6. CONCLUSION

Our initial studies have led to a RAFD deployment method using DSA guidance optimization for treatment of intracranial aneurysms (IA) of complex geometries.

Given the benefits of this technique, future prospect are that flow images will help clinicians guide RAFD placement and help determine their most effective positioning.

ACKNOWLEDGMENT

This work is supported by NIH Grant: 2R01EB002873 and an equipment grant from Toshiba Medical Systems Corporation.

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Figure 1.

a) Shows both RAFD prototypes, one with patch secured to the tapered wing and the other, with the patch on the center of the stent. The figure demonstrates the two regions of the device, the patch and the porous region. b) Illustration of the RAFD being retrieved with constant re-sheathing and unsheathing while maintaining the integrity of the patch. The black arrow indicates the position of the patch and the white arrow represents the point of dissociation when a current is applied for detachment

Figure: 2.

the schematic color coded representation of positioning of the RAFD prototypes. Blue stands for the patch, 'black' for the stent, green arrows represent the direction of flow and red represents the blood vessel. The positioning of the patch is in regards with the flow direction. (a) RAFD positioned in the proximal, center and distal regions of the aneurysm neck with stent-to-patch bonding in the center of the stent. (b) RAFD positioned in the center-left, middle and center-right regions of the aneurysm neck with stent-to-patch bonding at the tapering wing of the stent.

Figure 3. Shows an exploded image-version of the patch-orientation in a side wall aneurysm phantom during an ongoing RAFD deployment. Here, RAFD polymer-patch is positioned in the center of the aneurysm neck and the red arrow represents the orientation of the patch

Figure 4.

a) The Clinical Flow Set up model for the purpose of conducting studies and collecting data using DSA b) A DSA frame that illustrates the use of DSA for positioning of the flow diverter. The red arrow depicts the length of the patch on the stent and the markers designate the Nitinol stent. (c) A series of images derived from a DSA run showing flow diversion based on the positioning of the RAFD.

Figure 5.
Parametric Imaging Algorithm

Figure 6.
Simple idealized side wall aneurysm phantom treated with RAFD followed by DSA acquisition.

(a) Bolus Arrival Time

(b) Mean Transit Time

Figure 7.

Overview of the parametric imaging maps, containing the parent vessel where (a) depicts the Bolus Arrival Time window and (b) depicts the Mean Transit Time window

Figure 8.

Magnified view of the parametric image analysis done on a side wall aneurysm phantom where (a) compares the effect on the bolus contrast inflow jet between the control and the treated aneurysm while the patch is placed at distal, middle and proximal position to that of the flow. The control experiment was a DSA run conducted with no device. It can be seen that the size of the inflow jet (light blue) is reduced to minimum in the proximal followed by middle and distal position placement which is represented by red arrows.

(b) Represents the delay of the contrast to leave the aneurysm dome, the mean transit time (MTT). It can be seen that the maximum MTT was observed when the patch was placed in the medial position.

Figure 9.
Patient specific 3D printed aneurysm phantom of the ophthalmic vessel region

Figure 11.
3D printed patient specific Circle of Willis phantom. The region marked in red represents the aneurysm chosen for conducting flow studies

Figure 12.
The platinum markers (marked within the circle in red) placed on the RAFD patch being recorded using DSA

Figure 13. represents the region of interested being tested in the 3D printed Circle of Willis phantom. All the pixel values acquired are normalized to the value obtained in the region represented by the yellow box.

Fig 14.

The parametric images of a complex geometry emphasizing the carotid siphon and the MCA in the Circle of Willis. The RAFD deployments were only conducted in the proximal and center regions of the aneurysm model. The red boxes represent the aneurysm of interest and the yellow boxes depict the region of pixel values to which all the pixel values were normalized. The control experiment did not have the device. The arrows represent the reduced thinning of the flow jet in BAT images. The middle positioning of the RAFD results in maximum flow-jet dispersion. The MTT or the contrast delay in the aneurysm is maximum when the patch is placed in the proximal region of the aneurysm neck.