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Evaluation of an asymmetric stent patch design for a patient specific intracranial aneurysm using Computational Fluid Dynamic (CFD) calculations in the Computed Tomography (CT) derived lumen

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Abstract

Stenting may provide a new, less invasive therapeutic option for cerebral aneurysms. However, a conventional porous stent may be insufficient in modifying the blood flow for clinical aneurysms. We designed an asymmetric stent consisting of a low porosity patch welded onto a porous stent for an anterior cerebral artery aneurysm of a specific patient geometry to block the strong inflow jet. To evaluate the effect of the patch on aneurysmal flow dynamics, we “virtually” implanted it into the patient's aneurysm geometry and performed Computational Fluid Dynamics (CFD) analysis. The patch was computationally deformed to fit into the vessel lumen segmented from the patient CT reconstructions. After the flow calculations, a patch with the same design was fabricated using laser cutting techniques and welded onto a commercial porous stent, creating a patient-specific asymmetric stent. This stent was implanted into a phantom, which was imaged with X-ray angiography. The hemodynamics of untreated and stented aneurysms were compared both computationally and experimentally. It was found from CFD of the patient aneurysm that the asymmetric stent effectively blocked the strong inflow jet into the aneurysm and eliminated the flow impingement on the aneurysm wall at the dome. The impact zone with elevated wall shear stress was eliminated, the aneurysmal flow activity was substantially reduced, and the flow was considerably reduced. Experimental observations corresponded well qualitatively with the CFD results. The demonstrated asymmetric stent could lead to a new minimally invasive image guided intervention to reduce aneurysm growth and rupture.

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Keywords

Stent; Aneurysm; Computational Fluid Dynamics; Image guided interventions; Angiography; Asymmetric stent

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1. INTRODUCTION

An intracranial aneurysm is a bulge in an artery of the brain that is prone to rupture. A ruptured intracranial aneurysm may lead to subarachnoid hemorrhage (SAH) with a high mortality rate. More than 27,000 people in America suffer from ruptured intracranial aneurysms each year.¹ It is generally believed that the intracranial aneurysm is initiated and developed by the hemodynamic interactions between blood flow and vessel walls.

A stent is a less invasive endovascular intervention inducing aneurysmal hemodynamic alternations which might reduce wall shear stress or promote thrombosis in a cerebral aneurysm. However, results of aneurysm stenting have been inconsistent. Geremia et al.² deployed self-expanding, cobalt-alloy stents in sidewall aneurysms and fusiform aneurysms of canine models. Near-complete ablations were observed eight weeks after stent placement while the stented carotid arteries remained widely patent. They concluded that a woven wire stent can alter the aneurysmal blood flow patterns, and promote the formation of thrombus and fibrosis within the residual aneurysmal lumen. Vanninen et al.³ reported that complete thrombosis was induced by stent placement in three saccular aneurysms of patients, without additional packing of the aneurysm with coil. Recently, Krings et al.⁴ treated elastase induced rabbit aneurysms with covered stents as well as porous stents. Covered stents induced complete obliterations of the most aneurysms, but they found the parent vessel occlusion for one in the three-month follow-up group. Porous stents led to the aneurysm occlusion in two of five aneurysms in the one-month follow-up group, and four of five aneurysms in three-month follow-up group. Lanzino et al.⁵ originally treated four patients' aneurysms with porous stents solely. No evidence of aneurysm thrombosis was observed either immediately after the procedure or on follow-up angiographic studies.

Various ideas were introduced to increase the therapeutic efficiency of a stent placement.⁶⁻⁸ An asymmetric stent, minimally invasive endovascular flow modifier, is one of these approaches.⁸⁻¹¹ The aneurysm should be hemodynamically decoupled from parent vessels by this asymmetric stent. The asymmetric stent consists of a low porosity patch micro-welded on a highly porous stent. The low porosity patch of the asymmetric stent covers the aneurysm orifice to minimize the aneurysmal inflow. Outside of the patch region, the porous stent allows blood to flow through peripheral vessels without blockage. Therefore, the asymmetric stent patch must be accurately positioned over the aneurysm orifice to disrupt and weaken the aneurysmal flow. In an initial study, Rudin et al.¹¹ deployed an asymmetric stent in an elastomer vessel aneurysm phantom. The hemodynamic alterations in the aneurysm were assayed by both optical and radiological flow examination. The authors concluded that asymmetric stent created potentially favorable flow modification.

Aneurysm hemodynamics is known to be significantly affected by the arterial and the aneurysmal wall boundaries which vary from patient to patient.¹² Therefore, it is important

to consider the specific geometrical characteristics of an artery and an aneurysm to make hemodynamically favorable modifications using placement of an asymmetric stent. We designed an asymmetric stent patch for an anterior cerebral artery aneurysm of a specific patient. The patch porosity varied across the neck. The local porosity of the patch at the proximal neck was designed to block the strong inflow jet in this patient-specific aneurysm. The purpose of this study was to evaluate the hemodynamic effects of this patient-specific asymmetric stent patch using Computational Fluid Dynamics (CFD) as well as digital subtraction angiography (DSA).

2. METHODS

A cerebral aneurysm geometry of a patient was reconstructed from computed tomographic angiography (CTA) images of the patient's right anterior cerebral artery (ACA). The specific hemodynamic features of this geometry were investigated using Computational Fluid Dynamic (CFD) models under both steady-state and pulsatile flow boundary conditions. With these results, a patient-specific asymmetric stent patch was designed to minimize the aneurysmal flow activity to enable conditions that could induce thrombosis in the aneurysm. The porosity of the patch varied both longitudinally and axially. The patch was deformed by commercial CAD software to fit into the lumen then virtually placed across the aneurysm neck. CFD analysis for a stented model was performed as well as for an untreated model. After the virtual intervention, a physical patch with the same design was fabricated using laser cutting techniques and micro-welded onto a commercial porous stent, creating a patient-specific asymmetric stent. This asymmetric stent was implanted into a rapid prototyped phantom of the patient-specific ACA aneurysm, which was imaged with X-ray angiography. The hemodynamics of untreated and stented aneurysms were compared both computationally and experimentally.

2.1. Patient-specific aneurysm and stent

A 52 year old female patient's ACA aneurysm was selected for this study (Fig. 1). The anatomical geometry was reconstructed from CTA images for flow analysis. Bone structures were removed from vascular anatomy. The bone-removed aneurysm geometry was segmented and smoothed for rendering. Ujiie et al.^{13, 14} found that saccular aneurysms were more likely to rupture when the aspect ratios (AR) of the aneurysms were greater than 1.6. From the geometric analysis of the reconstructed aneurysm, the aspect ratio of this superior oriented ACA aneurysm was about 2.3, hence it would be in danger of rupture. Thus, we treated this aneurysm model using an asymmetric stent patch to investigate the hemodynamic modification to reduce the postulated chance of rupture.

The patient-specific stent patch for this ACA aneurysm (Fig. 1) was designed to minimize the flow activity in the aneurysm, but on the other hand not to block the flow to peripheral vessels that might arise from the vessel walls. The local porosity of the patch was 0% (solid) at the proximal side of the aneurysm to eliminate the strong impinging flow penetration in the untreated aneurysm model. The patch porosity was also controlled to interrupt the flow that had strong momentum along the longitudinal centerline of the aneurysm neck. Away

from this centerline, the patch had high porosity which allows the blood flow to the perforating arteries.

2.2. CFD simulation

The untreated and stented aneurysm geometries were meshed with 0.6 and 1.2 million tetrahedral volume elements respectively. The blood flow was calculated by a finite volume based CFD code, StarCD® (CD-adapco, Melville, NY) under the assumption of incompressible flow. The calculation was performed with both steady and pulsatile flow conditions (Fig. 2). In addition to solving the governing equations of the flow, the scalar transport equations, which is similar to the Navier-Stokes equations but describe the motion in a scalar were added for the virtual angiographic visualization. Therefore, sequential operations to solve the scalar transport equations were performed during each iteration. The second order accuracy was obtained by choosing a central differencing scheme for solving both flow and scalar equations. In this study, the average Reynolds number (Re) of the flow was 678, which is higher than normal but still in the range of typical flows known to occur in cerebral arteries.¹⁵ This Re is low enough to be considered laminar flow. The Womersley number of the pulsatile wave was 1.51. Blood was assumed to be Newtonian in this study because the shear rate in the artery was high, and the diameter of the artery was large.¹⁶ The viscosity and the density of blood in all models was 3.5cPs and 1056kg/m³ respectively.¹⁷ Scalar viscosity was 6.4cPs and density was 1320kg/m³. The aneurysm and vessel walls were assumed to be non-compliant as was the assumption in other studies.^{18,22}

2.3. Patient-specific phantom and asymmetric stent patch

The aneurysmal flow and the patch effect on this flow were investigated using DSA images from the patient-specific phantom model. A rapid prototype phantom model was created using a stereolithography apparatus (SLA) process. The photosensitive liquid photopolymer resins were solidified by a laser to generate the patient-specific aneurysm geometry. The surface achieved for this rapid prototype phantom had 0.15mm accuracy. Another pattern of the phantom geometry was made from wax. The wax pattern was created by a Thermojet wax printer (3D systems, Valencia, CA) using 0.025mm layers. This wax pattern was submerged in liquid silicon elastomer and the elastomer was solidified. Then a transparent elastic silicone casting was created using lost wax technique. The aneurysm in the casting was treated with an asymmetric stent.

We took the patch geometry used for the CFD simulations and created a file which reproduced the contour with a resolution of 25µm. This file was used in a LabView program to control the motion of a 2D motorized stage (Velmex, Bloomfield, NY) and a Nd:Yag laser. We synchronized the stage motion with the laser exposure in order to cut and vaporize a pattern on a stainless steel foil with 50 µm thickness thus creating the asymmetric patch (Fig. 3).

2.5. Angiographic flow visualization

The rapid prototype aneurysm model was inserted in a flow loop consisting of a waveform generator, a pump, and a flow meter; the flow was activated by a heart simulating pump (Vivitro Systems Inc., Canada). A 33% glycerin - 67% water mixture fluid was used to

achieve dynamic similarity with the blood flow in the CFD simulation. Prior to angiographic acquisition, we did 3D rotational angiography of the aneurysm using an Infinix angiographic C-arm (Toshiba Medical Systems Corp, Tustin CA). The volume rendering was done using a Vitrea 3D station (Vital Images Corp.). The 3D rendering was used to find the orientation of the angiographic C-arm which offered the same orientation of the aneurysm as used in the CFD simulation. Further, this view was used to acquire the angiographic runs. The contrast medium was a 50% solution of water and Reno iodine contrast agent (Bracco Diag. Inc, Princeton NJ). The flow patterns in the aneurysm were depicted by the images of contrast medium in the flow and recorded by a digital subtraction angiography system (DSA) which has thirty frames per second frame rate. The variation of the contrast medium concentration in the aneurysm indicated the flow stasis in the aneurysm. For this, the contrast medium integration in the aneurysm sac was obtained from the DSA data. The contrast medium concentration data was normalized for quantitative comparison of flow reduction in the aneurysm between untreated and stented case.

3. RESULTS

3.1. Analysis of the aneurysm hemodynamics in the CFD models

The computed aneurysmal flow patterns in the untreated and the stented models were compared. Shown in figure 4 are the particle paths in the steady state flow simulations. Initial points of these particles were identically selected at the inlets of both untreated and stented models. The particle paths in the untreated aneurysm showed that most of blood flow entered into the aneurysm through the proximal side at the aneurysm neck. Only a small part of the flow could bypass the aneurysm to go to the outlet in the untreated aneurysm model. Unlike the other studies,^{19, 22-24} the role of the distal neck as a flow divider was not clear in this geometry. A major part of the untreated aneurysmal inflow impinged on and reflected off the distal wall while a small part of the inflow directly impacted against the dome of the aneurysm. The vortex flows in the untreated aneurysm were intricate.

After the stent treatment, the blood flow pattern in the aneurysm was significantly changed. The strong inflow jet was blocked by a patch at the aneurysm neck and the direct impingement on the aneurysm wall disappeared. Most of the particle paths pass through the vessel without entering the aneurysm, and only a few of them directly penetrated the aneurysm neck. A lot of the momentum directed toward the aneurysm volume was lost during this process. Consequently, the weakened inflow lead to the reduction of the intra-aneurysmal flow activity. For example, the average flow velocity magnitude in the aneurysm was reduced by 93%, and the aneurysm flow turn-over time was increased by 483% after stenting. The hemodynamic stress exerted on the aneurysm wall is substantially linked to the aneurysm growth and rupture.²⁵ The instantaneous wall shear stress (WSS) distributions at peak systole for each aneurysm model are shown in figure 5. The asymmetric stent effect on aneurysm WSS is clearly demonstrated in this figure. In the untreated aneurysm, highly elevated WSS resulting from the strong impinging flow occurred at the distal wall and the dome of the aneurysm. The peak value for the untreated aneurysm WSS was 388 dyne/cm² at the distal wall. This values was about 19 times higher than normal WSS in cerebral arteries.²⁶ The asymmetric stent patch reduced the average

aneurysm WSS, and the elevated WSS zone was eliminated as well. It has been found experimentally that low shear rate which is directly related to low shear stress on the wall promotes more thrombus formation.²⁷ Therefore, there is a better chance of blood clotting in the stented aneurysm than untreated aneurysm.

3.2. Aneurysmal inflow patterns from DSA and virtual angiography

The aneurysmal inflow was visualized at the early stage of the radioopaque contrast agent injection. The contrast medium flow pattern in the untreated aneurysm is shown in figure 6. In the comparison of the angiographical and the virtual flow visualization, the inflow patterns were consistent. The main stream of the flow entered through the proximal side at the aneurysm neck when the aneurysm was untreated. This flow met the distal wall and dispersively reflected into the deep inside of the aneurysm. The concentration of the contrast medium in the proximal region in the aneurysm was relatively lower than the other regions at this stage. Therefore, one could conclude that the flow in this region was relatively slower and the shear rate was lower than the flow in the other regions of the untreated aneurysm. The asymmetric stent patch changed the flow direction at the aneurysm neck. As a result, the direct impinging flow was eliminated and the aneurysm was hemodynamically decoupled from the artery.

3.3. Flow reduction in untreated vs. stented aneurysms

The asymmetric stent effect on the aneurysm hemodynamics was investigated experimentally using the average concentration of the contrast medium in the aneurysm as well as the flow pattern. The contrast medium concentration in the angiogram of the untreated aneurysm and the stented aneurysm were compared with those of the CFD model. Figure 7 is an example of the DSA images of the instantaneous contrast medium in the aneurysm and the virtual angiographic CFD modeling results. From the image sequence, it was clear that the asymmetric stent interfered with the flow into the aneurysm. The contrast medium in the region near the aneurysm dome appeared to be somewhat trapped. The variation of the average contrast medium concentration in the aneurysm is shown in figure 8. In the angiographic visualization, the contrast agent was injected further upstream than in the CFD simulation and, therefore, the contrast flow duration was expanded. However, a comparison of the CFD to the angiogram shows a similar overall effect on the aneurysmal flow by the stent. By stenting, the maximum value of the average concentration of contrast medium was decreased about 44%, and 38% for DSA and CFD respectively. Conversely, the half-washout time of the contrast medium in the aneurysm was increased about 227% and 338%. From both DSA and CFD results, the aneurysmal inflow was significantly reduced and the aneurysm residence time was increased by stenting.

4. DISCUSSION

Aneurysm morphology is an important factor for predicting aneurysm rupture and in making a medical decision for an endovascular treatment. From the statistical analysis of ruptured and unruptured aneurysms, it has been postulated that aneurysms with large AR are more liable to rupture than those with small AR.^{14, 28} Ujiie et al.²⁹ found secondary flow circulation occurrence near the dome of an aneurysm which has a large aspect ratio

(AR>1.6). According to these authors, the critically slow flow circulation in the dome of the aneurysm may cause aneurysm rupture by following mechanism. In their discussion, the effect of enzyme digestion on the aneurysm wall remodeling was mentioned. They supposed that the low shear stress induced by the slow flow motion was correlated with atherosclerotic lesions which can degrade the integrity of the aneurysm wall and possibly cause its breakdown. We used an aneurysm having large AR in this study and hence it would be more probable to rupture. Therefore, an endovascular treatment to prevent this potential rupture was performed using a patient-specific asymmetric stent both virtually (with CFD) and experimentally.

Figure 9 illustrates the computed flow patterns in the untreated and the stented aneurysm. The flow in the untreated aneurysm was very complex and multiple vortex-like flows were found at various locations in this aneurysm. Also a strong jet-like inflow directly impinged on the confined regions of the aneurysm wall, when it was untreated. According to Cebal et al.³⁰, the flow in ruptured aneurysms is more likely to have disturbed flow patterns, small impingement regions, and narrow jets. These aneurysmal flow characteristics were similar with the findings in the untreated aneurysm in this study.

From the CFD analysis of an idealized aneurysm on various curved vessels, Hoi et al.²⁰ revealed that the aneurysm inflow and the flow impingement on the aneurysm wall increased with increasing parent vessel curvature. From similar CFD investigations, Meng et al.³¹ found that the inflow zone was shifted from the distal to proximal side on the aneurysm neck when the parent vessel curvature increased. As previously shown above, in the untreated aneurysmal flow, the vessel curvature of this aneurysm was large and the impinging flow entered through the proximal neck of this aneurysm. Therefore, the asymmetric stent patch was designed to block the strong inflow at the proximal neck and possibly modify the flow to a more favorable one in this patient-specific aneurysm.

The asymmetric stent patch totally changed the hemodynamics in the aneurysm. The aneurysm flow was stabilized, and the flow pattern was simplified by the asymmetric stent placement. These simple and stable flow patterns were commonly seen in unruptured aneurysms.³⁰ We modeled only the patch part of the asymmetric stent for CFD analysis, because the effect of the very porous part of the stent was assumed to be negligible. Since the role of the patch for aneurysm hemodynamic alteration was important, the asymmetric stent and in particular the patch must be properly placed to cover the aneurysm orifice and not to cover the terminal small perforator arteries, which could lead to local ischemia. Hence accurate stent deployment techniques would be required for the actual patient-specific stent.⁹ For the purposes of our CFD study, the virtual stent patch was deformed by computer software to fit into the artery and was almost perfectly placed at the aneurysm neck in the CFD model.

The endovascular treatment of the patient specific aneurysms using an asymmetric stent provided desirable results in this study. Nevertheless, the biological reactions caused by the asymmetric stent can not be overlooked. It was reported that a porous stent could promote neointimal proliferation and in-stent stenosis.⁴ Similar reactions might occur for an

asymmetric stent, but there is not enough evidence about this presently. Thus, further studies regarding the effect of asymmetric stents on the arterial wall are required.

5. CONCLUSIONS

We computationally and experimentally demonstrated substantial hemodynamic modifications to reduce aneurysm wall shear stress and increase residence times using the new asymmetric stents for a patient-specific cerebral aneurysm model segmented from CT image data. This could lead to a new minimally invasive image-guided patient-specific intervention to reduce aneurysm growth and rupture.

An asymmetric stent patch was designed for a patient-specific cerebral aneurysm, and virtually implanted into the aneurysm. The asymmetric stent patch effectively blocked the strong inflow jet at the aneurysm neck and significantly reduced the flow impingement on the wall of the aneurysm. Consequently, the highly elevated WSS on the distal wall and the dome of the aneurysm was lowered down to be comparable to the normal physiological range of WSS values in cerebral artery. The aneurysmal inflow pattern computed in the CFD model qualitatively agreed with that deduced from the DSA image of the visualized flow in the phantom model. The flow stasis in the untreated and the stented aneurysm was investigated using contrast medium concentration. The variations of the contrast medium concentration derived from DSA images and virtual angiography models were analyzed. Asymmetric stent patch designs specifically for a given patient significantly reduced the maximum concentration and increased the residence time of the contrast medium in the aneurysm. One can thus conclude that asymmetric stents may be a viable intervention for treating intracranial aneurysms. Additionally, the “virtual intervention” used in this study may provide valuable clinical feedback in treatment planning as well as a better understanding of possible new treatment options when the methodology is applied retrospectively to previous clinical cases.

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Figure 1. Geometries of an anterior cerebral artery aneurysm of a specific patient and an asymmetric stent patch designed to block the inflow jet at the proximal neck of the aneurysm.

Figure 2. Velocity wave of the pulsatile flow. The solid line indicates the contrast agent injection.

Figure 3.
Specially designed asymmetric stent patch for treatment of the patient-specific aneurysm.

Figure 4.
Particle path in the untreated and the stented aneurysm model.

Figure 5.
Instantaneous aneurysm wall shear stress distribution for the untreated and the stented aneurysm model.

Figure 6. Visualization of aneurysmal inflow using DSA and CFD virtual angiographic images: (A) Untreated-DSA, (B) Stented-DSA, (C) Untreated-CFD, (D) Stented-CFD

Figure 7. Visualization of the instantaneous images of the contrast medium in the aneurysm (at time = 0.5sec, systole): (A) Untreated-DSA, (B) Stented-DSA, (C) Untreated-CFD, (D) Stented-CFD

Figure 8.

Variation of the average concentration of the contrast medium in the aneurysm. DSA data was normalized for a comparison: (A) Untreated-DSA, (B) Stented-DSA, (C) Untreated-CFD, (D) Stented-CFD

Figure 9.
Velocity vectors on a plane across the middle of the patient-specific aneurysm.