Published in final edited form as:

J Biomech Eng. 2009 June ; 131(6): 061006. doi:10.1115/1.3118764.

Comparison of Near-wall Hemodynamic Parameters in Stented Artery Models

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Abstract

Background—Four commercially available stent designs (two balloon expandable - Bx Velocity and NIR and two self-expanding - Wallstent and Aurora) were modeled to compare the near wall flow characteristics of stented arteries using computational fluid dynamics (CFD) simulations under pulsatile flow conditions.

Method of Approach—The flow disturbance was characterized by the distributions of wall shear stress (WSS), WSS gradients, and flow separation.

Results—Normalized time-averaged effective WSS during the flow cycle was the smallest for the Wallstent compared to others. Regions of low mean WSS (<5 dynes/cm²) and elevated WSS gradients (>20 dynes/cm³) were also the largest for the Wallstent compared to others. WSS gradients were the largest near the struts and remained distinctly non-zero for most of the region between the struts for all stent designs.

Conclusions—The most hemodynamically favorable stents from our computational analysis were Bx Velocity and NIR stents, which were slotted tube, balloon-expandable designs. Since clinical data indicates lower restenosis rates for the Bx Velocity and NIR stents compared to the Wallstent, our data suggest that near wall hemodynamics may predict some aspects of in vivo performance. Further consideration of biomechanics, including solid mechanics, in stent design is warranted.

Keywords

Stent; Wallstent; Aurora stent; NIR stent; Bx Velocity stent; CFD; Strut; Wall shear stress; Wall shear stress gradients; Restenosis

INTRODUCTION

Angioplasty combined with stent deployment opens atherosclerotic vessels, but these stented vessels often undergo significant restenosis depending on stent design [1]. The process of restenosis, or neointimal hyperplasia (NIH), includes initial thrombosis, inflammation, proliferation, and eventual remodeling of the arterial wall [2]. Changes in stent design

parameters, such as increasing the strut-strut spacing, decreasing the strut width, and including fewer strut-strut intersections, has been shown to result in a reduction in the degree of restenosis [3,4,5]. This may be due to near wall fluid dynamics (like intrastrut flow patterns and/or wall shear stress (WSS)) and its effects on blood-borne and artery wall cells. Short term clinical results with stents coated with antiproliferative drugs indicate that the restenosis rate can be decreased by 85% or more. These drugs act by inhibiting cellular proliferation [6].

Unfortunately, late thrombosis has been considered to be an issue long-term in drug-eluting stents compared to baremetal stents [7]. Thus biomechanics is still an important consideration in stent design, irrespective of the application (coronary, carotid, or peripheral arterial flow).

The formation of NIH in stented arteries has been linked to persistence of low wall shear stress. Regions of low WSS are also slower to re-establish the endothelium, which could be important for NIH formation. The presence of NIH near the stent edges is likely related, at least in part, to flow patterns attributable to the local curvature of the arterial wall and/or the compliance mismatch [8,9]. This group showed an inverse relationship between WSS and NIH, but their flow models did not take into account the actual stent geometry; just the changes in overall arterial geometry (primarily curvature) due to stent implantation.

Stent design has a significant affect on near wall flow and wall shear stress. 3D computational fluid dynamic (CFD) modeling has shown that circumferential flattening of the artery wall after coronary stent implantation introduced areas of high WSS or high WSS gradients, absent in circular stented cross-sections under pulsatile flow conditions [10]. Regions of low WSS were larger with a greater number of struts, and with an increase in expansion ratio [11]. Using a parametric model of a generic stent design, we have previously shown that the mean axial WSS restoration between struts of parametric stent designs was larger for a stent with larger interstrut spacing and for a stent without longitudinal connectors [12]. Balossino et al. studied the spatial and temporal variations in low WSS (<0.5 Pa) of four different stents after deployment through an atheromatous plaque [13]. Highest WSS was found on the stent struts. They showed that thicker struts decrease the percentage area of low WSS in the vessel section between struts. One disadvantage of the study was that the hemodynamic behavior of the stents were compared using one single parameter only, namely low WSS.

The primary objective of this study is to characterize the flow disturbance induced by different commercially available stents by comparing the distributions of WSS, WSS gradients, and the flow separation regions in the various models, with corresponding implications for potential regions of NIH formation. This study compares the near wall flow characteristics of stented arteries using computational fluid dynamics simulations under pulsatile flow conditions. Four different commercially available stent designs were modeled. The results provide insight into how stent design affects fluid mechanical factors and potential for development of NIH.

METHODS

We have simulated three-dimensional models to study the blood flow patterns in stented arteries under pulsatile flow conditions using computational fluid dynamics. Our models use four specific designs currently on the market. Our evaluation criteria were specifically developed to quantify flow stagnation and WSS, as these have been shown to be important factors for platelet adhesion and endothelial cell growth in the near strut region of the arterial wall [14,15].

Computational domain

Rather than model the arterial cross-section, only a portion of the near wall section (see Fig. 1 for a sample) was modeled to resolve WSS accurately (similar to [12]). Previous studies show that flat wall models are able to predict the wall shear stress in a cylindrical model to within

10% [16]. Hence, the computational domain in the cross-stream direction was flat, rather than curved, since the maximum strut thickness is ~0.18 mm, or <=9% of a 2mm (height of the computational domain) arterial radius (in other words, flow disturbance only in the region near the artery wall). To avoid effects from the boundaries on flow in the region of interest, the inlet and outlet lengths proximal and distal to the stent struts were 9mm and 1-3mm respectively.

The models were created based on the digitization of images obtained from these stents balloon-expanded into an elastomeric cylindrical tube. See Fig. 2 for the specific stent designs modeled along with other details like strut height, linkage angle, etc (see table 1). Thus these configurations represent the approximate geometry of the stented artery in vivo. The strut height modeled was the same as measured, shown in table 1; however the strut thickness modeled (on the wall) was based on image digitization calculations. Note that the Wallstent is a braided stent and hence, the figures appear as such in the results. The computational domain was discretized using a structured hexahedral mesh (Fig. 3). The blood flow was modeled as a homogeneous Newtonian viscous incompressible fluid using the 3D Navier-Stokes and continuity equations with blood density of 1060 kg/m³ and dynamic viscosity of 4.0 mPa s.

Boundary and initial conditions

The artery and strut wall boundary regions were assumed to be rigid and defined with a no-slip velocity boundary condition. The XZ and XY planes corresponding to the side walls and bottom wall of the computational domain respectively (from Fig. 1) were treated as symmetric boundary conditions (normal velocity vanishes at boundary). A fully transient (pulsatile) sinusoidal loading was applied to the computational domain as velocity driven conditions corresponding to a normal level of flow in a mid-sized artery (nominal shear stress of 10±5 dynes/cm², loading conditions similar to [12]). This waveform provides a reasonable approximation of the physiologic flow patterns; any higher degree of specificity in the flow rate waveform could potentially limit the applicability of the results. The frequency of this sinusoidal velocity profile was 1.1Hz, corresponding to a heart rate of 70 beats/minute. The Reynolds number (Re) was 130 and Womersley number (Wo) was 2.8. The outlet flow boundary was described by a spatially and transiently uniform pressure distribution of 0. The initial conditions for the entire computational domain were determined from a steady state simulation using mean inlet velocity boundary conditions (inlet velocity of 0.125±0.0625 m/s).

Critical flow solution parameters

We have evaluated three blood flow parameters: separation parameter, wall shear stress, and

wall shear stress gradient. A flow separation parameter $\phi = \frac{T_s}{T}$ is defined, where T_s is the time the flow remains separated from the wall (flow stagnation) and T is the total time in the flow cycle; very low WSS (of the order of 0.005 dynes/cm² and lower) were neglected from the calculations for the separation parameter due to issues arising due to convergence. The parameter flow stagnation takes the value of 1 when flow separates from the wall (when WSS becomes negative) and 0 when flow reattaches to the wall. Previous studies have shown that spatial distributions of this separation parameter correlate well with those of oscillatory shear index (OSI) [17,18]. The normalized timeaveraged (or mean) WSS (defined below) has been considered as a useful parameter from a fluid dynamic point in several computational studies on stents previously [10,11,12]. An effective (or total) WSS is the combination of both axial and transverse WSS. The axial and cross-stream directional components of WSS (WSS_{zx} and

WSS_{zy}) were calculated using velocity gradients as $WSS_{zx} = \mu \left(\frac{\partial U}{\partial Z} + \frac{\partial W}{\partial X} \right)$,

$WSS_{zy} = \mu \left(\frac{\partial V}{\partial Z} + \frac{\partial W}{\partial Y} \right)$, where μ is the viscosity and (U, V, W) are directional components (X, Y, Z) of velocity. As a standard measure, effective (or total) WSS between struts was normalized by the effective (or total) WSS at the non-stented inlet; we call this normalized WSS. The normalized WSS was then displayed as a percentage. Spatial WSS gradient (WSSG)

magnitudes were defined as $WSSG = \sqrt{\left(\frac{\partial WSS_{zx}}{\partial x} \right)^2 + \left(\frac{\partial WSS_{zy}}{\partial y} \right)^2}$, after previous definitions [10,11]. Spatial and temporal gradients of WSS have been correlated with restenosis in other areas such as anastomosis and arteriovenous grafts [14,19]. Three of these hemodynamic parameters were processed further by determining which areas of the wall were subjected to values higher than a certain threshold in a binary sense. A value of 5 dynes/cm² has been proposed as a possible threshold as a low WSS leading to stenosis formation [20]; so we have determined the areas subjected to these conditions. Similarly, threshold values of $\phi = 0.5$, $\phi = 1.0$ and $WSSG > 20$ dynes/cm³ for >50% of the cardiac cycle were established. In order to facilitate the comparison between stents of low WSS areas, high separation parameter, and high WSSG, the areas subjected to these conditions were expressed as a percentage of the whole area between the struts.

Simulations

The governing equations for the blood flow were discretized using the finite volume method and solved using the CFD-ACE flow solver (CFDRC, Huntsville, AL) with a minimum residual of 1e-18 and a convergence tolerance of 1e-4 for the velocity and pressure variables. The upwind scheme was used for solving for velocity in most of our models, with default relaxation parameters for pressure and velocity in most cases. The time step size was fixed at 8.571 msec, or 100 steps for each cyclic period of the inlet velocity function ($\omega = 7.331$ rad/sec). The total number of cells in the models were 640008 in Wallstent, 212044 in Bx Velocity stent, 187544 in NIR stent, and 240876 in Aurora stent. With a dual processor machine, steady state simulations were performed in 2-4 hours, while transient simulations took 4-6 days. All simulations were carried out until a time periodic flow convergence (<5%) was established between successive oscillatory periods, typically just over 1 flow cycle (105 time steps) to remove the transients from the initial time steps. Mesh independence was determined from convergence (<10%) of the axial WSS along the length of the stented model. WSSG was not used for mesh convergence; the differences in WSSGs in the overall region between struts between successive mesh densities were 10% in Bx Velocity stent, 11% in Aurora stent, 5% in NIR stent, and 20% in Wallstent, after steady state simulations. The maximum percentage difference in WSSGs (in some cases about 60%) were concentrated in regions close to the struts and connectors. The WSSGs were ≥ 20 dynes/cm³ (nominal value proposed for NIH formation in the anastomosis) in these regions [19,20].

RESULTS

The stent strut geometry caused deviations in WSS based on the strut and the connector geometry. The axial WSS was low at the proximal and distal regions of the strut (Fig. 4). The mean WSS over the flow cycle at the inlet was 8.9 dynes/cm² for all models. The mean effective WSS between struts was 2.9 dynes/cm² for Wallstent, 5.8 dynes/cm² for Bx Velocity stent, 5.0 dynes/cm² for Aurora stent, and 5.3 dynes/cm² for NIR stent. The maximum axial WSS between struts was 8.67 dynes/cm² for Wallstent, 13.7 dynes/cm² for Bx Velocity stent, 12.1 dynes/cm² for Aurora stent, and 15.4 dynes/cm² for NIR stent. The minimum axial WSS between struts was -0.11 dynes/cm² for Wallstent, -1.89 dynes/cm² for Bx Velocity stent, -1.68 dynes/cm² for Aurora stent, and -1.83 dynes/cm² for NIR stent. The minimal axial WSS in Bx Velocity, Aurora, and NIR stents were negative, indicating regions of recirculating flow with

low velocities; these were primarily observed near the connector regions and at the concave and convex ends of the struts of models. Comparison of the steady results to the fully pulsatile results revealed that the near-strut flow phenomena were fairly quasi-steady.

Transverse WSS signifies regions of flow disturbance, as the flow near the struts deviates from the mainstream axial direction. Higher transverse WSS (of the order of 2-4.6 dynes/cm²), primarily at the ends of curved structures, were seen in all the models, as in Fig. 5. The maximum transverse WSS between struts was 46.5% (Wallstent), 49.2% (Bx Velocity stent), 29% (Aurora stent), and 48% (NIR stent) of the mean WSS at the inlet.

The WSSG was above threshold values (≥ 20 dynes/cm³) for most of the region between the stent struts at the point of mean flow rate in the cardiac cycle (Fig. 6). WSSG was highest near the struts. Flow stagnation at the mean flow rate of the flow cycle occurred mostly near the stent struts (as in Fig. 7). Flow remains fully recirculating during the entire flow cycle mostly at the proximal and/or distal ends of the concave and convex portions of the strut. In the Aurora stent, the struts were oriented more parallel to the flow, thus less flow stagnation was seen around the struts.

The normalized effective WSS for the Bx Velocity stent was the largest (65.6%), followed by NIR stent (59.2%), Aurora stent (56%), and Wallstent (32.2%, from Fig. 8a). Similarly, from Fig. 8b, the normalized average axial WSS followed the same pattern as the normalized effective WSS, as reported above. The normalized average transverse WSS was the largest for the NIR stent (7.9%), followed by Wallstent (7.5%), Bx Velocity stent (6.7%), and Aurora stent (4.6%) (Fig. 8c). Since the normalized average transverse WSS was similar in all stent cases, the ratio of normalized axial WSS to the transverse WSS was considered; this ratio was the largest for the Aurora stent (132% per dynes/cm²), followed by Bx Velocity stent (104.6% per dynes/cm²), NIR stent (81.3% per dynes/cm²), and the Wallstent (45.1% per dynes/cm², from Fig. 8d).

The Wallstent had the greatest area (90.46% of the area between struts) exposed to low WSS (< 5 dynes/cm²) for $> 50\%$ of the flow cycle (see Fig. 9a), followed by Bx Velocity, NIR, and Aurora stents (59.3%, 58.7%, and 57.1% of the region between struts respectively). Using a threshold of 2.5 dynes/cm² (see Fig. 9b), the Wallstent still had the greatest area (50.53% of the area between struts) exposed to low WSS for $> 50\%$ of the flow cycle. The Bx Velocity stent had larger area exposed to low WSS than the Aurora and NIR stents (47.2%, 35.6%, and 35.0% of the area between struts respectively). The low WSS areas in the NIR and Aurora stents were thus more sensitive to changing the threshold for low WSS than in the Bx Velocity stent.

All stent designs have a combination of partially and fully recirculating regions. The percentage of area between the struts over which the separation parameter indicated fully recirculating flow ($\phi = 1$) was the largest for the Bx Velocity stent, followed by Aurora stent (19.1%, 4.7% respectively, Fig. 10a). The Wallstent and NIR stents had negligible totally recirculating regions (0.4% and 0%) during the flow cycle. The percentage of area between the struts over which the separation parameter indicated partially recirculating flow ($\phi > 0.5$) was the largest for the Bx Velocity stent, followed by Aurora, NIR, and Wallstent stents (20.4%, 5.5%, 5.2%, 0.6% respectively, Fig. 10b). We see that Bx Velocity and Aurora stents have mostly fully recirculating regions, whereas the NIR stent has mostly partially recirculating regions for most of the flow cycle. Wallstent has 57% smaller number of partially recirculating regions compared to NIR stent and no fully recirculating areas within the stented section.

Elevated spatial WSSG were found in the near-strut region of stented arteries from Fig. 6. The Wallstent had the greatest area exposed to WSSG > 20 dynes/cm³ for $> 50\%$ of the flow cycle,

followed by NIR, Aurora, and Bx Velocity stents (see Fig. 11, 100.0%, 87.9%, 82.8%, and 75.0% of the region between the struts, respectively). The distribution of WSSG >40 dynes/cm³ was similar.

DISCUSSION

Restenosis is a common clinical problem in stented arteries of patients. Restenosis is dependent on stent design and a large number of stents are available in the market for this purpose [1]. A variety of techniques have been employed to provide a better understanding of stented artery hemodynamics and its influence on restenosis. The differences in the stent design indicate the need to model each stent design and makes a one-to-one comparison from results of other parametric studies difficult (see [10], [11], [12]). The primary objective of this study is to characterize the flow disturbance induced by different stents, with corresponding implications for potential regions of NIH formation. The flow characteristics of four different commercially available stent designs were studied using 3D computational fluid dynamics. The near-wall flow was characterized by specific fluid dynamic parameters that have been previously demonstrated to play a role in early intimal thickening and graft intimal hyperplasia: axial and transverse WSS, separation parameter, and WSS gradients [14,15,18-24].

The four different stents studied were Wallstent, Aurora, Bx Velocity, and NIR stents; the former two are self-expanded stents, while the latter two are slotted-tube and balloon-expanded stents. While there are no clinical trials that have compared the restenosis rates of all of these designs concurrently, data from different clinical trials suggest that there are significant differences in this important stent performance parameter. The angiographic binary restenosis rates at 6-month follow-up in a randomized study of long coronary disease showed 26% for NIR slotted tube stents vs 46% for Wallstent self-expanding stents [25]. In a study of the propensity to NIH formation with different stent designs, self-expanding stents had a greater restenosis rate compared to slotted tube stents [26]. Slotted-tube (cylindrical tubes having laser cut cells with straight struts) stent designs have shown increased restenosis compared to corrugated-tube (cylindrical tubes having laser cut cells with sinusoidally curved struts) stent designs [3,4]. The Wallstent more closely resembles the slotted-tube design with intermediate openings for fluid flow, while the Aurora, NIR, and Bx Velocity stents represent a corrugated-tube design. The slotted-tube stents had a greater restenosis rate compared to multicellular (multiple cells not connected) designs [26]. The only multicellular design in our case is the Aurora stent, but it is more slotted tube than a multicellular stent (see Fig. 2). The choice of open-cell (only some cells connected together like Aurora stents) versus closed-cell (cells connected together like Wallstent or slotted-tube stents like NIR, Bx Velocity stents) geometry depend on the lesion under consideration. For a tortuous geometry, stents with open-cell configuration (i.e. flexible stents) are preferred [27]. The more radially flexible the stent, the lower the stress on the arterial wall, and hence lower the restenosis [27]. In a randomized study assessing the effectiveness of paclitaxel-eluting stents (TAXUS-II), the average restenosis rates in the control population with bare-metal NIR stents (15mm stent length) for single lesions in the coronary artery was 22% [28]. In a randomized study assessing the effectiveness of sirolimus-eluting stents (RAVEL), the restenosis rate in the control population (of similar size) with bare-metal Bx Velocity stents (18mm stent length) for single lesions in the coronary artery was 26.6% [29]. Clinically, the NIR stent seems to perform marginally better than Bx Velocity stent; both of these stents seem to be better than the Wallstent and Aurora stents [25,28,29]. These clinical studies reiterate once again that restenosis is dependent on stent design and overall, but the variety of sources of these data point to the difficulty in assessing which stent would produce minimal NIH.

As per the hemodynamic indicator parameters such as low WSS, elevated WSSG, transverse WSS, and separation parameter, the Wallstent was hemodynamically disadvantageous. The

order of hemodynamically favorable performance was Bx Velocity, NIR, Aurora, and Wallstent stents. The comparison of each of these hemodynamic indicators with each stent type and whether they match the clinical results are summarized below.

Wall shear stress (WSS)

Since previous studies indicate that larger intrastrut spacing results in less NIH, it could be postulated that a higher normalized WSS value would enhance the hemodynamic performance of the stent [3,5]. From Fig. 8a, the normalized averaged effective WSS was the largest for the Bx Velocity, NIR, Aurora, and Wallstent stents. Hence, the Wallstent would then be concluded to not perform better than the other stents; this statement is based only on average WSS between struts and matches clinical results. From Fig. 8b and Fig. 8c, the pattern of axial and transverse WSS was similar as that of the effective WSS for the stents (since the averaged transverse WSS was much smaller in magnitude compared to averaged axial WSS). The transverse WSS was higher in regions of low axial WSS, particularly in the near-strut regions (Fig. 5). Hence, increased transverse WSS in the stented region led to larger low WSS regions. We still do not however know the effect of such low transverse WSS on NIH in vivo. Therefore, we considered the ratio of normalized axial to transverse WSS as the hemodynamic parameter; the larger this ratio, the lesser the flow disturbance (or transverse WSS) in the stented region. From Fig. 8d, this ratio still showed that other stents performed better than the Wallstent, the ratio being greatest for the Aurora stent. Further studies will tell us if this is a good parameter to use for predicting in stent restenosis.

Low WSS (<5 dynes/cm²)

NIH thickness in human coronary arteries has been shown to correlate inversely with overall WSS distribution in Wallstents, but the actual strut geometry was not included in the flow model [8]. In our study, low WSS appeared in the near-strut region of stented arteries. The area covered by low WSS (< 5 dynes/cm²) was the largest for the Wallstent, followed by the Bx Velocity, NIR, and Aurora stents (from Fig. 9a). The Wallstent has the smallest area between the struts. Since it also consists of cross-wires, the effective strut height (~0.18mm) is largest in the Wallstent. The increase in strut height increases the flow stagnation regions proximal and distal to the strut; this along with slowly moving fluid at the intermediate openings between the struts increases the regions of low WSS. The region of low WSS is the greatest in the Wallstent. Hence, NIH would be expected to be the largest in Wallstent. From Fig. 9b, the differences seen in low WSS between Bx Velocity, Aurora, and NIR stent designs became more clear by comparing between different threshold values of low WSS (i.e. <5 dynes/cm² and <2.5 dynes/cm²). In general, the Bx Velocity stent geometry had more significant low WSS region, compared to the Aurora and NIR stents.

Separation Parameter

Based on the observations of low WSS patterns, one would expect the flow separation regions for the Wallstent to be the largest. But from Fig. 10a and Fig. 10b, the Wallstent has negligible flow recirculating regions. Previous studies have shown that partially recirculating regions (with intermittent mixing from the mainstream flow) are prone to greater platelet accumulation and adhesion [30]. From Fig. 10b, Bx Velocity stent may be more subjected to thrombus and eventually NIH formation. However, the separation parameter has been a less significant hemodynamic parameter from previous studies for predicting NIH at the toe region of a distal anastomosis or an arterio-venous graft [19,20,24]. The flow separation regions are very small in these 3D stented cases, hence this parameter may be less significant for prediction of restenosis.

WSS Gradients (>20 dynes/cm³)

Disturbed flow results in local changes in WSS. One way of representing the nonuniformity in the flow patterns is through the WSS gradients (WSSG). WSSG above 20 dynes/cm³ has been correlated with cellular proliferation and NIH formation in graft anastomoses [19,20]. *From our theoretical calculations* (Fig. 11), the Wallstent had the largest area of elevated WSSG, followed by the NIR and Aurora stents, while the Bx Velocity stent had the lowest. This is most likely due to the Wallstent having the smallest area between the struts and a relatively large degree of flow disturbance.

Our results show that differences in hemodynamic parameters cannot be attributed to strut thickness or spacing alone, but rather the overall strut configuration. The strut thickness of Bx Velocity and Aurora stents are similar and the interstrut spacing in Aurora stent is more than that of Bx Velocity stent. One would have expected the effective (or total) WSS to be higher in the Aurora stent compared to the Bx Velocity stent. However, we find the effective (or total) WSS is greater in the Bx Velocity stent compared to the Aurora stent. This is primarily due to strut spacing and positioning relative to the principal flow direction. From the clinical data described before, we found that NIR and Bx Velocity stented patients had lesser NIH formation compared to Wallstent [25-27]. Our computational data showed Bx Velocity, NIR, and Aurora stents were more hemodynamically favorable compared to Wallstent. From normalized effective WSS (see Fig. 8), Bx Velocity and NIR stents were more favorable; from ratio of normalized axial to transverse WSS ratio, Aurora and Bx Velocity stents were more favorable; from low WSS and elevated WSSG parameters (see Fig. 9 and Fig. 11), Bx Velocity and NIR stents were more favorable; from separation parameter (see Fig. 10), Wallstent and NIR stents were more favorable. From a combination of all of them, NIR and Bx Velocity stents were the most hemodynamically favorable choices and seemed to agree well with the NIH results in vivo. Note although there are certainly other differences between self-expanding and balloon-expandable stents that could explain differences in their clinical performance. Aside, Bx Velocity (Cordis Corp.) stent is one of the most widely used stents for coronary artery disease today; our computational results show that this stent could be a favorable choice among those studied here.

Limitations

Accuracy from CFD results depends on computational domain and computational mesh size. The computational domain in the cross-stream direction was flat, rather than curved, since the height of the stent strut is <8% of the radius. Other studies indicate that the possible error associated with this assumption is less than 10% [16]. No repeating struts were considered for the simulation to save on computational mesh size and time. The stent geometry is just an approximation as provided from the digital images, hence the results may vary marginally from that of the actual geometry. The rigidity assumption of the artery wall is warranted as the stents are most often over-expanded inside the artery. Previous 2D simulations show that tissue prolapse does not significantly affect the estimation of WSS [31]. Our computational models were shown to be mesh independent based on convergence ($\leq 10\%$) of WSS values [10,11]. The present study did not vary the stent-to-artery expansion ratio. The assumption that blood is a Newtonian fluid, while generally valid in the medium to large size arteries that are typically stented, may have a minor effect on the flow patterns in the low shear regions near the stent struts. Nevertheless, the flow characteristics demonstrated in this 3D unsteady flow study would be expected to be indicative of the in vivo flow patterns to the extent that they are used to compare different stent designs. One of the major limitations of the study is the use of different stents with different strut heights and geometries and areas; in short, there is no optimization of geometrical strut features considered. Hence, it is difficult to say if the normalization of hemodynamic parameters with the area between the struts can accurately

predict clinical efficacy. We have not varied Reynolds number (Re) in our study, hence any speculation about flow patterns for Re greatly different from that used here would be baseless.

Based on our results, we conclude that the data from clinical and other in vivo animal studies seemed to match well with the computational data of low WSS and elevated WSSGs of the four different stent designs studied. The significance of the hemodynamic differences between the stent designs depends on physiologic processes that may in fact be highly sensitive to wall shear stress or other flow parameters. These fluid dynamic parameters, which concentrate on specific areas of interest in the stented region, are probably more indicative of potential for NIH formation than a single averaged parameter like WSS between struts. The differences though small may be significant to the artery. Still, one has to recognize that there are other factors that influence arterial reactions to stents (e.g., solid mechanical considerations). We know that the more radially flexible the stent, the lower the stress on the arterial wall, and hence lower the restenosis. The ability to correlate specific hemodynamic phenomena with NIH should be enhanced with sophisticated imaging modalities (such as optical coherence tomography). Stent-tissue interaction studies will also provide correlation to the spatial development of NIH in vivo, thus improving our understanding of the hemodynamic phenomena of restenosis.

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Fig. 1.
3D model of a Bx Velocity stent that would represent the near-strut flow characteristics.

Wallstent:

Bx Velocity stent:

Aurora stent:

NIR stent:

Fig. 2.

Four different stent designs - Wallstent, Bx Velocity, Aurora, and NIR stents were used. The strut thickness of Bx Velocity and NIR stents were 0.132mm, aurora stent was 0.12mm, and Wallstent was 0.09mm. The areas represented by the boxes indicate regions modeled in CFD.

Fig. 3.
Mesh design underlying the connector between the struts of the Bx Velocity stent.

Fig. 4. Axial WSS (dynes/cm²) taken at the mean flow rate for (a) Wallstent, (b) Bx Velocity stent, (c) Aurora stent, and (d) NIR stent during the accelerating phase of the flow cycle.

Fig. 5. Transverse WSS (dynes/cm²) taken at the mean flow rate (a) Wallstent, (b) Bx Velocity stent, (c) Aurora stent, and (d) NIR stent during the accelerating phase of the flow cycle.

Fig. 6. WSS gradients (dynes/cm³) taken at the mean flow rate for (a) Wallstent, (b) Bx Velocity stent, (c) Aurora stent, and (d) NIR stent during the accelerating phase of the flow cycle. Dark pink regions near struts show WSSG ≥ 20 dynes/cm³.

Fig. 7. Flow stagnation areas taken at the mean flow rate for (a) Wallstent, (b) Bx Velocity stent, (c) Aurora stent, and (d) NIR stent during the accelerating phase of the flow cycle; 0 indicates no flow separation and 1 indicates flow stagnation.

Fig. 8. (a) Normalized effective WSS, (b) normalized average axial WSS, (c) normalized average transverse WSS, and (d) ratio of normalized axial WSS to transverse WSS plotted for the different stent design types.

(a)

(b)

Fig. 9.

Percentage area of the region between struts, with averaged low WSS ((a) <5 dynes/cm², (b) <2.5 dynes/cm²) for >50% of the flow cycle in the different stent design types.

(a)

(b)

Fig. 10. Comparison of percentage area of the region between struts for (a) totally recirculating regions and (b) partially recirculating regions (with separation parameter ϕ) for the different stent designs.

Fig. 11.

Percentage area of the region between struts with the averaged WSSG > 20 dynes/cm³ for > 50% of the flow cycle in different stent design types.

Table 1

Geometric properties of the stents

Stent	Manufacturer	Diameter (mm)	Length (mm)	Strut Height (mm)	Interstrut Distance (mm)	Average Linkage Angle (wrt axial direction)	Interstrut Area (mm ²)
Wallstent Stent	BostonScientific	6	59	0.09	1.3	45°	0.9
Bx Velocity Stent	Cordis corp	5	25	0.132	3.1	30°	6.3
Aurora Stent	Medtronic	6	40	0.12	4.3	20°	2.95
NIR Stent	BostonScientific	6	19	0.132	3.3	25°	3.53