A Comparison Between the Dynamic Responses of Bare-Metal Wallstent Endoprosthesis and AneuRx Stent-Graft: A Mathematical Model Analysis

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Dynamics of Bare-Metal WALLSTENT Endoprosthesis and AneuRx Stent-Graft
Abstract

Purpose: The purpose of this study was to analyze the mechanical properties of bare-metal WALLSTENT endoprostheses and of AneuRx stent-grafts and compare their responses to the hemodynamics forces.

Methods: Mathematical modeling, numerical simulations and experimental measurements were utilized to study the two structurally different types of endoprostheses.

Results: Our findings revealed that a single bare-metal WALLSTENT endoprosthesis is ten times more flexible (elastic) than the wall of the native abdominal aorta. Graphs showing the change in the diameter and length of the stent exposed to a range of internal and external pressures were obtained. If the aorta is axially stiff and resists the length change, a force as large as 1 kg can act in the axial direction on the aortic wall. If the stent is not firmly anchored, it will migrate. In contrast, a fabric-covered fully supported stent graft such as AneuRx is significantly less compliant than the aorta or the bare-metal stent. During each cardiac cycle the stent frame tends to move due to higher elasticity while the fabric resists the movement, which might cause suture breaks. Elevated local transmural pressure along the prosthesis graft was detected. This contributes toward material fatigue.

Key words: blood vessel prosthesis, aortic abdominal aneurysm, optimal design, mathematical analysis, stents and stent grafts.
1 Introduction

Bare-metal stents such as WALLSTENT have been used for the treatment of occlusive diseases,\textsuperscript{1,2} and for the exclusion of abdominal aortic aneurysms (AAA).\textsuperscript{3-5} Although the use of bare-metal stents in the treatment of AAA is diminishing, their use as a skeleton for the composite stent-graft prostheses is increasing. One such prostheses is the AneuRx stent-graft (Medtronic, Sunnyvale, CA) with self-expandable nitinol stent rings sutured to the graft made of thin-walled noncrimped, woven polyester.\textsuperscript{6,7}

The purpose of this study was to analyze the mechanical properties of bare-metal WALLSTENT endoprostheses and of AneuRx stent-grafts and compare their responses to the hemodynamics forces. Novel information that might be useful for improved prostheses design is presented.
2 Methods

We used a mathematical model based on the incompressible, viscous, Navier-Stokes equations to describe the flow of blood in (large) compliant vessels\textsuperscript{8–10}. The incompressible, Navier-Stokes equations have been long known to be a good model for blood flow in medium-to-large arteries\textsuperscript{11,12}. We used the Navier equations for the elastic membrane with small, but non-negligible thickness\textsuperscript{12,13} to model the vessel wall behavior. These equations account for the “effective” response of the vessel walls to the forces induced by the pulsatile nature of blood flow. The fluid-structure interaction model describing the flow of blood in compliant vessels was tested experimentally at a Cardiovascular Research Laboratory. Excellent agreement with the experiment was obtained\textsuperscript{10}. The mechanical properties of bare-stents were described in\textsuperscript{14,15} using the slender rod theory\textsuperscript{15} and “beam on elastic foundation” model\textsuperscript{14} coupled with experimental, \textit{in vitro}, measurements at the Center of Mechanics of Solids, Structures and Materials at the University of Texas in Austin. The measurements were performed on the WALLSTENT endoprosthesis (Boston Scientific Corp., Natick, Mass) with stent diameter 0.01m, number of wires: 36, radius of the stent wire: 0.845 \(\mu m\), and on an AneuRx stent graft (Medtronic, Sunnyvile, CA). The mathematical equations, describing the response of a stent and of a stent-graft to the internal and external pressure were derived, and compared with experimental data. Excellent agreement was obtained\textsuperscript{14,15}. 
The methods, based on the mathematical and computational fluid-structure interaction calculation, enabled us to view the simulated rhythmic pulsation of the prosthesis and of the vessel wall during each cardiac cycle. A snapshot of the behavior at the systole/diastole is shown in the pictures below (Figures 4, 5, 6, 7).
3 Results

(1.) Compliant, self-expandable bare-metal WALLSTENT.

The response of the metallic WALLSTENT endoprosthesis with respect to the static pressure load was measured experimentally and modeled using the slender rod theory. The following are the findings.

(a) A single sheet of a WALLSTENT endoprosthesis is about ten times more elastic than is the wall of the aneurysmal abdominal aorta. The measured Youngs modulus of WALLSTENT endoprosthesis is $E = 8,700 \text{N/m}^2$. This should be compared with the in vivo measurements of the Youngs modulus of the abdominal aorta, which is in the range of $E = 40,000$ to $E = 300,000 \text{N/m}^2$ for a normal aorta and can be more than 300,000 $\text{N/m}^2$ in aorta susceptible to aneurysm.\textsuperscript{16,17} Detailed measurements data of the radial change of the WALLSTENT stent due to a range of exerted pressure forces is shown in Figure 1. When reading the diagram shown in Figure 1 one needs to keep in mind that the stent inserted in the aneurysm will have a prestressed diameter which is smaller than the unstressed diameter of 21$\text{mm}$. For those values of stent diameter, Figure 1 shows that small pressure will imply large radial displacements. When the diameter gets around 22$\text{mm}$ the stent becomes rather stiff and the radial displacement with respect to the exerted physiological pressure is small.
(b) When the stent expands due to the internal pressure exerted by blood flow at each systole, its length contracts significantly. If the aorta is axially stiff and resists the length change in the stent, then a force as large as $10N$ can act in the axial direction on the aortic wall. If the stent is not firmly anchored in the aorta, the stent will migrate. The precisely measured relationship between the change in the stent length and the exerted pressure load is shown in Figure 2.

For more details on the magnitude of the axial force at the anchoring sites see $^{14}$

We performed a numerical study of the dynamic response of the WALLSTENT endoprosthesis to the pulsatile forces exerted by the blood flow. Numerical simulations utilized the data from the *in vivo* measurements of the vessel wall properties corresponding to the aneurysmal aorta,$^{17}$ the flow rate at the proximal end of the abdominal aorta,$^{16,17}$ and the *in vitro* measurements of the mechanical properties of WALLSTENT.$^{14,15}$ We show here, in a series of pictures, the response of several configurations of stents at the systolic peak. At this point we are not interested in the precise, patient specific study of prostheses performance. Rather, we want to identify the general prostheses properties that could be improved for better performance.

**Case 1: One stent in curved patient geometry.**

A rough approximation of the patient’s aneurysm geometry was taken into account. The aneurysm is shown in Figure 3 (left). Numerical simulations were
obtained for a single sheet of WALLSTENT stent placed in the aneurysm. The stent position obtained using numerical simulation is shown in Figure 4. For the purpose of clarity the aneurysm sac was not shown in Figure 4. Figure 4 (left) should be compared to Figure 3 (right). Both the numerical simulation and the actual patient’s angiogram show that at the systolic peak the stent protrudes inside the aneurysm sac. This shows that indeed, a single sheet of WALLSTENT endoprosthesis is much more elastic (compliant) than is the wall of the native aorta. The drastic change in the diameter of the inserted stent inside the aneurysm causes the length of the stent to decrease, see the diagrams in Figures 1 and 2, thereby exerting high stresses and strains near the anchoring sites of the prostheses. This numerical experiment together with the measurements of the elastic properties of WALLSTENT presented in the previous section, and the patients angiogram shown in Figure 3 indicate that optimal stent design for endoluminal treatment of AAA needs to include stiffer prosthesis structure in the central section of a prosthesis. Multiple sheets of WALLSTENT, placed in the center of the prosthesis, should improve the performance of endovascular stenting of AAA. This is discussed in Case 3 below.

In the series of pictures below (Figures 5, 6, 7) the displayed data shows a three-dimensional section of a compliant channel corresponding to the abdominal aorta between renal and iliac arteries, a prosthesis inserted inside the aneurysm sac (the aneurysm is not shown), and the overlap between the prosthesis and the aorta. The six graphs on the right side of each figure show the
distribution of the (scaled) elasticity coefficient (Youngs modulus), calculated circumferential and axial strain (stretching), a magnified view of the radial displacement of the aorta/prosthesis along the channel and the pressure distribution along the aorta/prosthesis. The higher the Youngs modulus, the more rigid the response of the channel wall. The horizontal axis in the first five graphs describes the length along the vessel: zero marks the inlet and 100 (mm) corresponds to the outlet (distal) end of the channel. The last graph (bottom right) shows the proximal velocity profile in one cardiac cycle (the inlet velocity data). The circle at the top of the graph (systolic peak) shows the time in the cardiac cycle at which the data snap-shot is taken.

**Case 2: One stent in straight geometry.**

Figure 5 shows large radial displacement of a single sheet of WALLSTENT inside the aneurysm sac at the systolic peak. Pulsatile flow induces high periodic circumferential strain of a stent inside the aneurysm sac, and high periodic axial strain near the anchoring sites of the prosthesis. This weakens the vessel walls near the anchoring sites and may be a precursor for stent migration caused by distension of aortic walls at the anchoring sites. The systolic pressure distribution along the infrarenal section of the abdominal aorta is within the normal range (around 120 mmHg).

**Case 3: A prosthesis consisting of three superimposed WALLSTENT endoprostheses: one full length and two shorter centered stents.**

The purpose of this case is to increase stiffness of the prosthesis only in the
central section of the stent which lies inside the aneurysm sac. Considerable improvements over Case 2 can be seen in Figure 6. We see much smaller radial and axial strains near the anchoring sites thereby causing less damage to the native aorta and to the structure of the stent itself. The systolic pressure distribution along the prosthesis is still within the normal range (between 120 and 130mmHg).

(2.) **Rigid, fabric-covered stent-grafts.** We compared the dynamic behavior of bare-metal WALLSTENT with that of a fully stented AneuRx stent graft (Medtronic; fully stented graft with self-expandable nitinol stent rings; graft made of thin-walled noncrimped, woven polyester, sutured to the nitinol stent). The AneuRx stent-graft exhibited no compliancy, i.e., there is an insignificant change in the diameter of the prostheses during a cardiac cycle. Numerical results shown in Figure 7 show almost no axial or circumferential strains of the prosthesis. However, this causes large radial and circumferential strains of the native aorta at the anchoring sites, as can be seen in Figure 7 on the graphs showing circumferential strain, radius and axial strain. We also observe elevated local systolic blood pressure (around 140mmHg) induced by the stiffness of the prosthesis (see Figure 7, bottom left graph). High pressure exerted by the flow to the prosthesis’ walls, shown in Figure 7, indicate potential for fabric wear. If an elastic stent serves as a frame for the prosthesis, the tendency for expansion and contraction of a stent versus the noncompliant behavior of the fabric makes this prosthesis
particularly prone to material fatigue and suture breaks.
4 Discussion

Our study shows that self-expandable bare-metal WALLSTENT is exceedingly compliant. The radial and longitudinal displacements during each cardiac cycle of this prosthesis are large. Repeated pulsation of the prostheses and large magnitude forces measured and calculated near the anchoring sites might be responsible for weak anchoring and stent migration reported in\textsuperscript{19} for “softer” prostheses.

Fabric-covered fully supported stent grafts such as AneuRx (Medtronic) exhibit minimal compliancy. This causes high strains of the native aortic wall near anchoring. In addition, due to the stiff design, the calculated local transmural pressure along the prosthesis was elevated indicating potential for material fatigue. If the exoskeleton is flexible (such as the Nitinol stent support in AneuRx stent graft), the pulsation of the exoskeleton joined to the minimally compliant graft by polyester sutures might cause suture failure, as reported in\textsuperscript{18}.

This study was performed under the assumptions that the geometry of the abdominal aorta treated with an endoprosthesis is cylindrical and that the flow of blood through the cylinder is axially symmetric (angular velocity is negligible). Furthermore, it was assumed that the prostheses were non-permeable. To the leading-order approximation of the phenomena studied in this manuscript these assumptions are acceptable. However, improvements in the development of the software that would take into account the non-axially
symmetric flow and permeability of endoprostheses are desirable.

Future areas of application of the results and software used in this manuscript include the study of flow through bifurcated endografts such as the AneuRx Stent Graft System and the influence of hemodynamics factors such as the wall shear stress rates on graft limb occlusions. Preliminary results by the authors in this vein are encouraging. Improved bifurcated prosthesis design minimizing the probability of occlusion is under way. Further experimental validation is necessary for the results of this manuscript to be used in improved prosthesis design.
References


Figure 1: The pressure-diameter relationship for WALLSTENT stent and for the abdominal aorta.
Figure 2: The pressure-length relationship for WALLSTENT endoprosthesis.
Figure 3: Aneurysm (left) and bare-metal stent (WALLSTENT) inserted in the aneurysm (right). The angiogram shows that at the peak of a systole the stent expands more than the native abdominal aorta.
Figure 4: Numerical simulation of stent position in curved geometry.
Figure 5: The figure shows a single sheet of WALLSTENT endoprosthesis at the systolic peak.
Figure 6: The figure shows the performance of a configuration of three sheets of WALLSTENT: one full length and two additional sheets inside the aneurysm sac only.
Figure 7: The figure shows a rigid-wall endoprosthesis performance at the peak of a systole (AneuRx).