

Mathematical Model Analysis of Wallstent® and AneuRx®

Dynamic Responses of Bare-Metal Endoprosthesis Compared with Those of Stent-Graft

Suncica Canic, PhD
K. Ravi-Chandar, PhD
Zvonimir Krajcer, MD, FACC
Dragan Mirkovic, PhD
Serguei Lapin, PhD

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From: Department of Mathematics (Drs. Canic and Lapin) and Computer Science (Dr. Mirkovic), University of Houston; Leachman Cardiology Associates, P.A., an affiliate of Texas Heart Institute at St. Luke's Episcopal Hospital (Dr. Krajcer); Houston, Texas; and Department of Aerospace Engineering and Engineering Mechanics (Dr. Ravi-Chandar), University of Texas at Austin; Austin, Texas

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Address for reprints:
Suncica Canic, PhD,
Department of Mathemat-
ics, University of Houston,
4800 Calhoun Rd., Houston,
TX 77204-3008

E-mail: canic@math.uh.edu

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We performed this study in order to analyze the mechanical properties of bare-metal Wallstent® endoprostheses and of AneuRx® stent-grafts and to compare their responses to hemodynamic forces. Mathematical modeling, numerical simulations, and experimental measurements were used to study the 2 structurally different types of endoprostheses.

Our findings revealed that a single bare-metal Wallstent endoprosthesis is 10 times more flexible (elastic) than is the wall of the aneurysmal abdominal aorta. Graphs showing the changes in the diameter and length of the stent when exposed to a range of internal and external pressures were obtained. If the aorta is axially stiff and resists 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 the 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 its higher elasticity, while the fabric resists movement, which might break the sutures that join the fabric to the frame. Elevated local transmural pressure, detected along the prosthesis graft, can contribute to material fatigue. (*Tex Heart Inst J 2005;32:555-55*)

Bare-metal stents such as the Wallstent® Endoprosthesis (Boston Scientific Corp.; Natick, Mass) have been used for the treatment of occlusive diseases,^{1,2} and for the exclusion of abdominal aortic aneurysms (AAA).³⁻⁵ Although the use of bare-metal stents in the treatment of AAA is diminishing, their use as a skeleton for composite stent-graft prostheses is increasing. One such prosthesis is the AneuRx® AAA Stent Graft System (Medtronic, Inc.; Sunnyvale, Calif), which has self-expandable Nitinol stent rings sutured to a graft made of thin-walled, noncrimped, woven polyester.^{6,7}

We performed this study in order to analyze the mechanical properties of bare-metal Wallstent endoprostheses and of AneuRx stent-grafts and to compare their responses to hemodynamic forces. Novel information that might be useful for improved prosthesis design is presented.

Methods

To describe the flow of blood in (large) compliant vessels, we used a mathematical model based on the Navier-Stokes equations for an incompressible, viscous fluid.⁸⁻¹⁰ The Navier-Stokes equations have long been known to be a good model for blood flow in medium-to-large arteries.^{11,12} We used the Navier equations for this elastic membrane,^{12,13} in order to model vascular wall behavior. These equations account for the “effective” response of vascular walls to the forces induced by the pulsatile nature of blood flow. The fluid–structure interaction model that described the flow of blood in compliant vessels was tested experimentally at a cardiovascular research laboratory. Excellent agreement with the experiment was obtained.¹⁰ The mechanical properties of bare stents were described^{14,15} by using the slender rod theory¹⁵ and the “beam on elastic foundation” model,¹⁴ coupled with experimental, in vitro measurements that were conducted at the Center of Mechanics of Solids, Structures and Materials at the University of Texas at Austin. The measurements were performed on the Wallstent endoprosthesis (stent diameter, 0.01 m; number of wires, 36; ra-

dus of stent wire, 0.845 μm), and on an AneuRx stent-graft (diameter, 0.022 m). The mathematical equations describing the response of a stent and a stent-graft to internal and external pressures were derived, and the results were compared with experimental data. Excellent agreement was obtained.^{14,15}

Our methods, which had their basis in mathematical and numerical calculation of the fluid–structure interaction, enabled us to view the simulated rhythmic pulsation of the prosthesis and of the vascular wall during each cardiac cycle.

Results

Compliant, Self-Expandable Bare-Metal Wallstent

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

- A single sheet of a Wallstent endoprosthesis is about 10 times more elastic than is the wall of the aneurysmal abdominal aorta. The measured Young's modulus of the Wallstent endoprosthesis is $E = 8,700 \text{ N/m}^2$. This should be compared with the in vivo measurements of the Young's 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 an aorta susceptible to aneurysm.^{16,17} Detailed measurement data of the radial change of the Wallstent due to a range of exerted pressures are 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 has a pre-stressed diameter that is smaller than the unstressed diameter of 21 mm. For those values of stent diameter, Figure 1 shows that small pressure implies large radial displacement. When the diameter reaches approximately 22 mm, the stent becomes rather stiff and the radial displacement with respect to exerted pressure is small.
- 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 10 N 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 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 Wang and Ravi-Chandar.¹⁴

We performed a numerical study of the dynamic response of the Wallstent endoprosthesis to the pulsatile forces exerted by blood flow. Numerical simulations

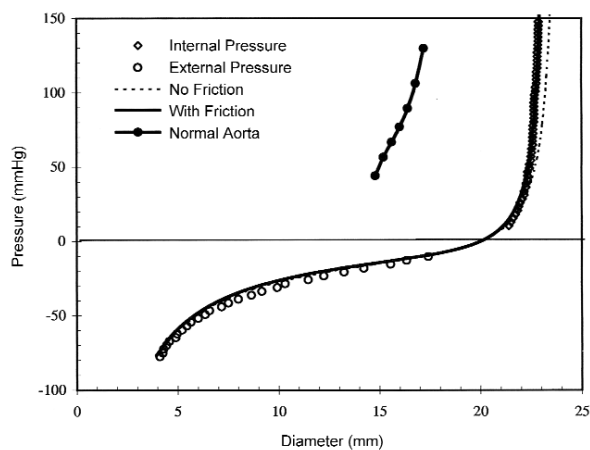


Fig. 1 The pressure–diameter relationships for the Wallstent® endoprosthesis and for the abdominal aorta.

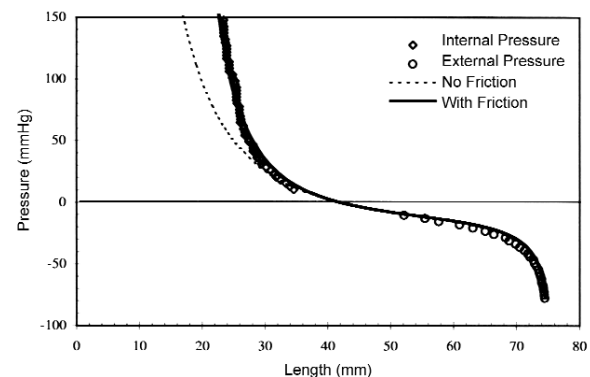


Fig. 2 The pressure–length relationship for the Wallstent® endoprosthesis.

used the data from the in vivo measurements of vascular wall properties that corresponded to the aneurysmal aorta,¹⁷ from the flow rate at the proximal end of the abdominal aorta,^{16,17} and from the in vitro measurements of the mechanical properties of the Wallstent.^{14,15} We show here, in a series of images, the response of several configurations of stents at the systolic peak. At this point, we are not interested in precise, patient-specific study of prosthesis performance. Rather, we want to identify the general properties of prostheses that can be improved for better performance.

Case 1: One Stent in Curved Aneurysm Geometry. A rough approximation of a patient's aneurysm geometry was taken into account. The aneurysm is shown in Figure 3A. Numerical simulations were obtained for a single sheet of Wallstent placed in the aneurysm. The stent position obtained by using numerical simulation is shown in Figure 4 (for the purpose of clarity, the aneurysm sac is not shown). Figure 4A should be compared to Figure 3B: both the numerical simulation and the patient's actual angiogram show that at

the systolic peak the stent expands inside the aneurysm's 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 causes the length of the stent to decrease (Figs. 1 and 2), thereby

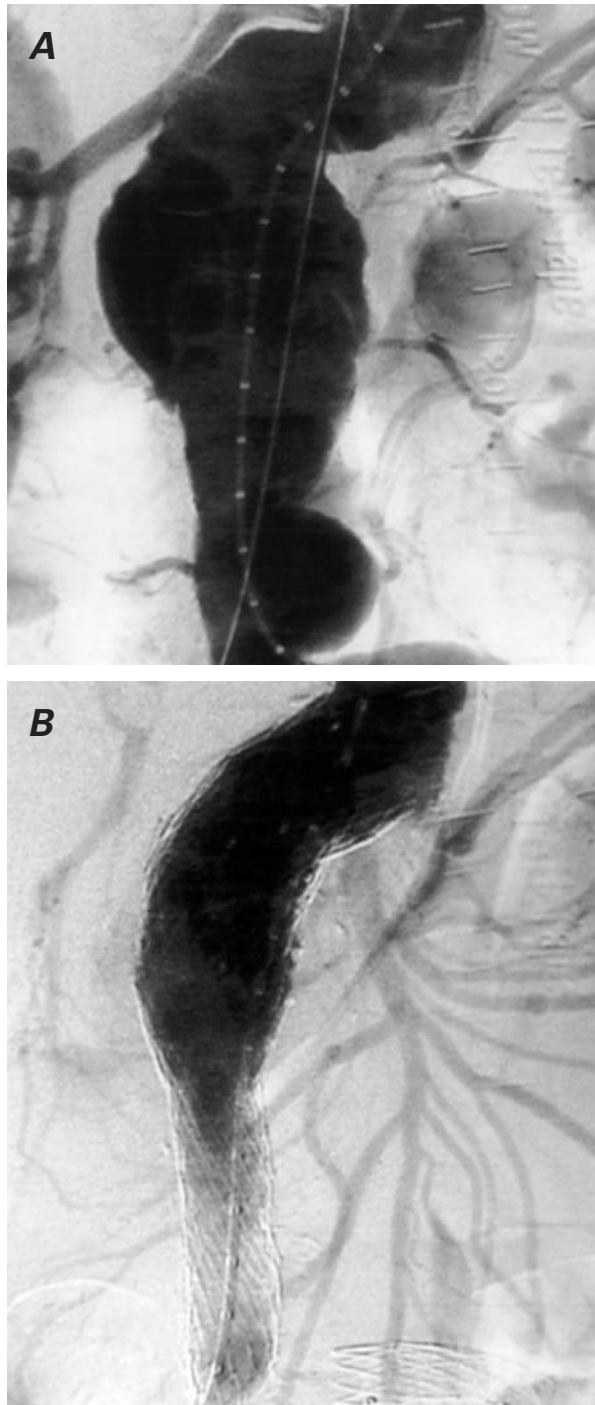


Fig. 3 A) Aneurysm and **B)** bare-metal Wallstent® inserted in the aneurysm. The angiogram shows that at the peak of systole the stent expands more than the aneurysmal abdominal aorta.

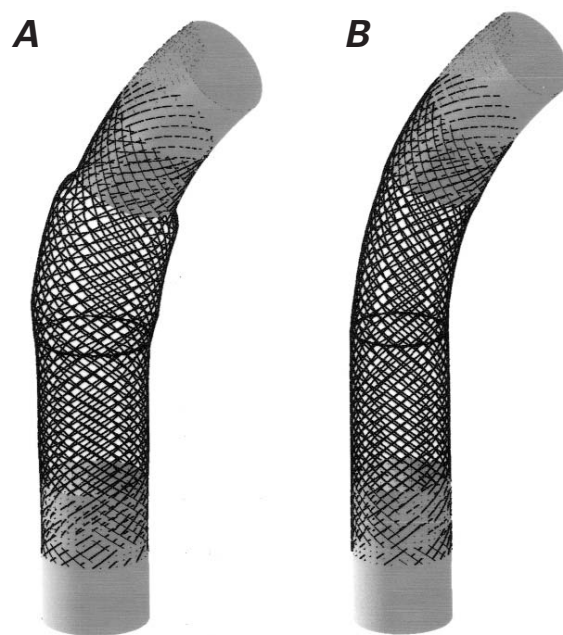


Fig. 4 Numerical simulation of stent position in curved geometry, systolic peak at left and diastole at right. Uses single sheet of Wallstent®.

Real-time motion image is available at texasheart.org/education/thijournal/canic324.html.

exerting high stresses near the anchoring sites. This numerical experiment, together with the patient's angiogram (Fig. 3) and our previous measurements of the elastic properties of the Wallstent, indicate that optimal stent design for endoluminal treatment of AAA needs to include stiffer structure in the central section. Multiple sheets of Wallstent, placed in the center of the prosthesis, should improve endovascular stenting of AAA. This is discussed in Case 3.

In Figures 5–7, the displayed data show a 3-dimensional section of a compliant channel corresponding to the abdominal aorta between the renal and iliac arteries, a prosthesis inserted inside the aneurysm's sac (the aneurysm is not shown), and the overlap between the prosthesis and the aorta. The 6 graphs on the right side of each figure show the distribution of the (scaled) elasticity coefficient (Young's modulus), calculated circumferential and axial strain (stretching), a magnified view of the radial displacement of the aorta and prosthesis along the channel, and the pressure distribution along the aorta and prosthesis. The higher the Young's modulus, the more rigid the response of the channel wall. The horizontal axis in the first 5 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 1 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 snapshot is taken.

Case 2: One Stent in Straight Geometry. Figure 5 shows large radial displacement of a single sheet of Wallstent inside the aneurysm's sac at the systolic peak. Pulsatile flow induces high periodic circumferential strain of a stent inside the aneurysm's sac and high periodic axial strain near the anchoring sites of the prosthesis. This weakens the vascular walls near the anchoring sites and may be a precursor to stent migration caused by distention 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 3 Superimposed Wallstent Endoprostheses: 1 Full-Length and 2 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's sac. Considerable improvements over Case 2 can be seen in Figure 6. Near the anchoring sites we see much smaller radial and axial strains, which would cause 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 130 mmHg).

Rigid, Fabric-Covered Stent-Grafts

We compared the dynamic behavior of the bare-metal Wallstent with that of the AneuRx stent-graft, a fully stented graft with self-expandable Nitinol stent rings. Made of thin-walled, noncrimped, woven polyester sutured to the Nitinol stent, the AneuRx exhibited no

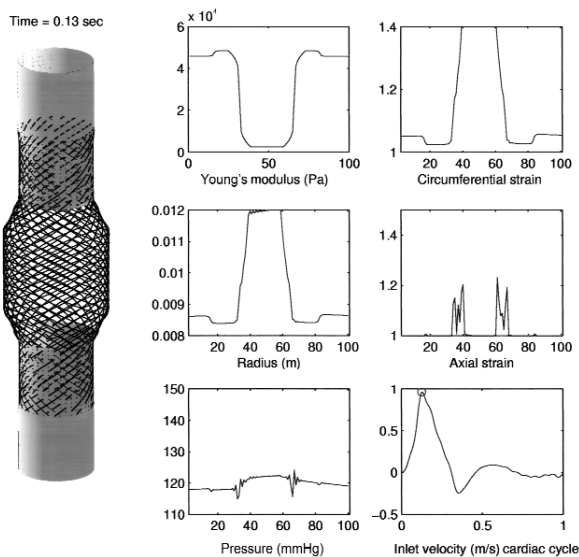


Fig. 5 A single sheet of Wallstent® endoprosthesis at the systolic peak.

Real-time motion image is available at texasheart.org/education/thijournal/canic324.html.

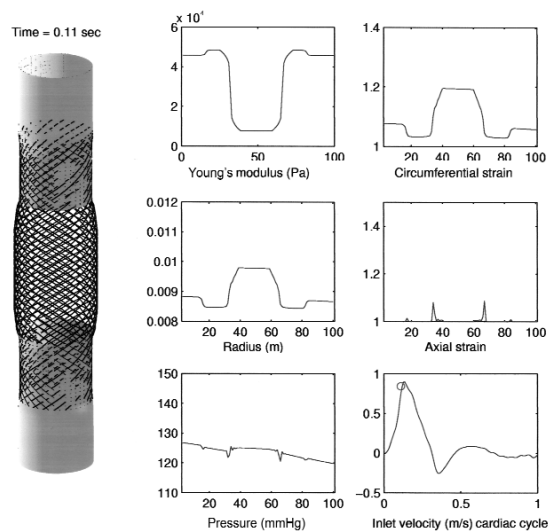


Fig. 6 The performance of a configuration of 3 sheets of Wallstent®: 1 full length and 2 additional sheets inside the aneurysm sac only.

compliance (that is, change in the diameter of the prosthesis was insignificant during a cardiac cycle). The numerical results (Fig. 7) demonstrate almost no axial or circumferential strains of the prosthesis. However, this inelasticity of the prosthesis causes large radial and circumferential strains of the native aorta at the anchoring sites, as can be seen on the graphs that show circumferential, radial, and axial strain (Fig. 7). We also observed elevated local systolic blood pressure (around 140 mmHg) induced by the stiffness of the prosthesis (Fig. 7, bottom left graph). High pressure exerted by the flow to the prosthesis walls (Fig. 7) in-

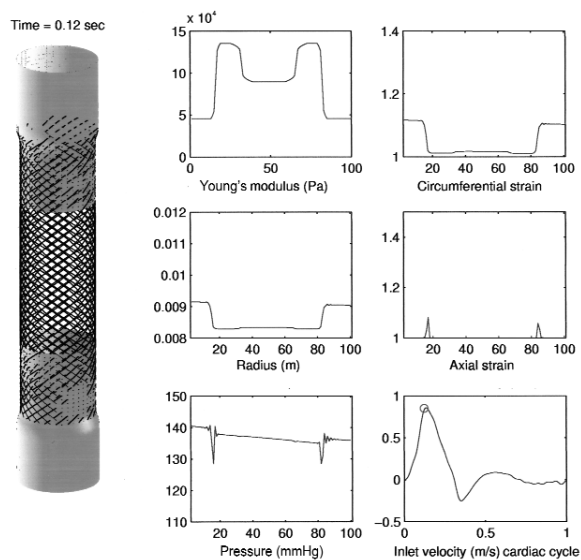


Fig. 7 The performance of a rigid-wall endoprosthesis (AneuRx®) at the peak of systole.

Real-time motion image is available at texasheart.org/education/thijournal/canic324.html.

dicates a potential for fabric wear. Because an elastic stent serves as a frame for noncompliant fabric, the expansion and contraction of the stent makes this prosthesis particularly prone to material fatigue and suture breaks.

Discussion

Our study shows that the self-expandable bare-metal Wallstent is exceedingly compliant. The radial and longitudinal displacements during each cardiac cycle are large. Repeated pulsation affecting the prosthesis and large-magnitude forces measured and calculated near the anchoring sites might be responsible for the weak anchoring and stent migration of such “softer” prostheses, which has been reported by Umscheid and Stelter.¹⁸

Fabric-covered, fully supported stent-grafts such as the AneuRx exhibit minimal compliancy. This causes high strain upon the native aortic wall at the anchoring sites. In addition, due to the prosthesis stiffness, the calculated local transmural pressure along the prosthesis is elevated, which indicates the potential for material fatigue. If the exoskeleton is flexible (such as the Nitinol stent in the AneuRx stent-graft), the pulsation of the exoskeleton against the minimally compliant graft, to which it is joined by polyester sutures, might cause suture failure, as reported by Zarins and colleagues.¹⁹

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 prosthesis is impermeable. For the leading-order approximation of the phenomena studied, these assumptions are acceptable. However, improvements in the development of the software, to account for the non-axially symmetric flow and for the permeability of endoprotheses, are desirable.

Future applications of our results and of the software that we used include the study of flow through bifurcated endografts, such as the AneuRx Stent Graft System, and the influence of hemodynamic factors, such as wall shear stress rates, on the occlusion of graft limbs. Preliminary results by the authors in this area are encouraging. Improvements in the design of bifurcated prostheses, which minimize the probability of occlusion, are under way. However, further experimental validation is necessary for the results of our study to be used in improving prosthesis design.

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