Design of Optimal Endoprostheses Using Mathematical Modeling

Are the mechanical properties of current-generation endografts suboptimal for AAA repair?

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Current-generation endografts for repair of abdominal aortic aneurysms (AAAs) have revealed deficiencies in their design and mechanical properties.[1,2] A mismatch in compliancy between the endoprosthesis and the arterial wall can lead to complications such as endograft migration, separation of modular components, and formation of aneurysms adjacent to the attachment sites. Suboptimal geometry of the endograft can also cause limb thrombosis. The predictors of endograft failure have been delineated in previous studies.[3,4] Some of the more common predictors of endograft failure are angulated and short infrarenal neck, large neck diameter, large maximal AAA diameter, and complex iliac artery anatomy.[5]

On the basis of their mode of fixation to the aortic wall, endografts for AAA repair can be divided into active and passive fixation devices. The active fixation devices use barbs or hooks for attachment, whereas passive fixation devices use their radial force for attachment. It has been previously shown that passive fixation devices are more prone to distal migration than active fixation devices (Figure 1).[3] The devices that do not have full body support are prone to extrinsic compression and thrombosis; however, this could occur with any endograft that has kinks or stenosis (Figure 2).[4]

Elevated shear stress rates have been implicated as the primary hemodynamic factor responsible for limb occlusion.[6,7] Suboptimal prostheses flexibility and wall shear stress have also been implicated as the primary factors responsible for distal migration, separation of modular components, and disruption of endograft components.[1]

It is now an FDA requirement to use computational

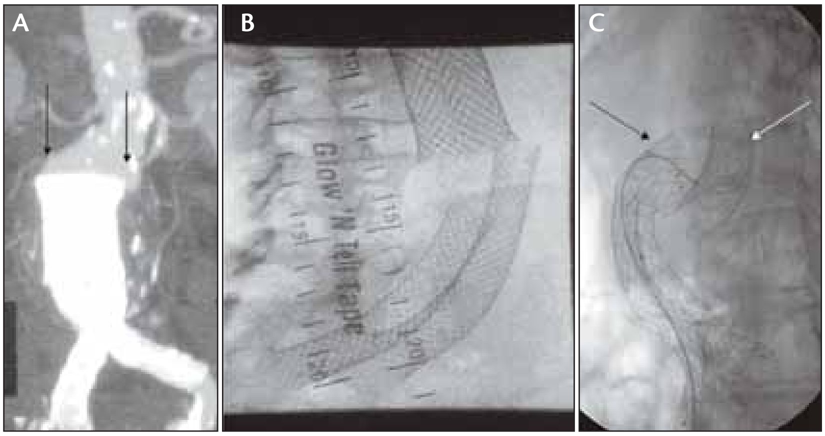

Figure 1. A CT angiogram of a patient 5 years after endoluminal AAA repair reveals distal migration of a Corvita stent graft (arrows) (Pfizer, New York, NY) (A). Fluoroscopic image of a patient 4 years after endoluminal AAA repair, revealing modular separation of the iliac limbs from the main body the Corvita stent graft (arrows) (B). Cineangiogram of a patient 3 years after endoluminal AAA repair revealing modular separation of aortic extension cuff and the main body of the AneuRx stent graft (arrows) (Medtronic Inc., Santa Rosa, CA).

Figure 2. Cineangiogram of a patient 5 years after endoluminal AAA repair revealing right limb thrombosis of the AneuRx stent graft.

Figure 3. Experimental model of a mock circulatory flow loop assembled to measure vessel wall and vascular prosthesis properties and behavior in different hemodynamic circumstances.

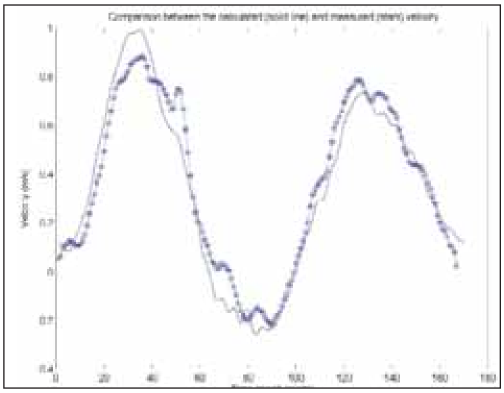

Figure 4. Doppler measurements of the pulsatile velocity of the flow and motion of the vessel wall reveal excellent agreement between the experimental measurements and our mathematical model.

models of human physiology to test peripheral vascular devices for potential failure before animal and human studies are undertaken. Previous studies have revealed that mathematical and computational modeling and simulation of arterial flow can be used to identify mechanical and geometric deficiencies when designing endovascular prostheses.[8] The purpose of this study was to analyze the influence of endoprosthesis design on prosthesis flexibility and shear stress rates. This study was done in an effort to design a computational model for an optimal endoprosthesis.

METHODS

We studied the performance of two passive fixation devices for AAA repair, with full body support. The main body diameters ranged from 22 mm to 28 mm, and the iliac limb diameters ranged from 12 mm to 16 mm. All the commercially available diameters of these endografts were analyzed in this study.

The computational method that was used in this study to analyze blood flow through a compliant artery and vascular prosthesis was developed and validated at our institutions and has been previously reported.[9] This computational model was used to analyze shear stress rates for a variety of endoprosthesis designs. The studied parameters included endoprosthesis flexibility (elastic Young's modulus) and geometric design (diameter of the main body component and the diameter of the iliac limbs). Using our computational method, the shear stress rates were obtained throughout the length of each endoprosthesis. The wall shear stress rates were measured as a potential indicator for development of focal stenosis, distal endograft migration, and modular component separation. The computational method was based on the finite element approximation of the Navier-Stokes equations for an incompressible, viscous fluid to model the blood flow in large arteries and on the viscoelastic membrane equations to model the vessel wall and vascular prosthesis behavior. We have previously tested our method using a mock circulatory flow loop assembled at our institutions (Figure 3).[10] Ultrasonic imaging and Doppler methods were used to measure the pulsatile velocity of the flow and the motion of the vessel wall. Excellent agreement between the experiment and the mathematical model was observed (Figure 4).

RESULTS

We found elevated shear stress rates in all the prostheses with limb diameters that were smaller than 14 mm. The observations in this study revealed that the shear stress rates at the peak systolic pressure were significantly higher for 12-mm iliac limbs than for 16-mm iliac limbs (Figure 5). The highest shear stress rates were found at the iliac attachment sites. Although lower shear stress rates were found in larger-diameter iliac limbs, they still remained significantly higher that the ones observed for the proposed optimally designed bifurcated endoprosthesis (Figure 5).

DISCUSSION

This study revealed that the endovascular prosthesis with smaller iliac limb diameters has elevated shear stress rates in the limbs. This may potentially lead to a higher risk of iliac limb thrombosis. Our findings concur with the experimental findings of others,[2,7,11] who found that the mean occluded diameter of the iliac limbs was 14 mm. Carrocio et al reported limb occlusions in both active and passive fixation devices with full body support.[2] The risk of thrombosis was more common with

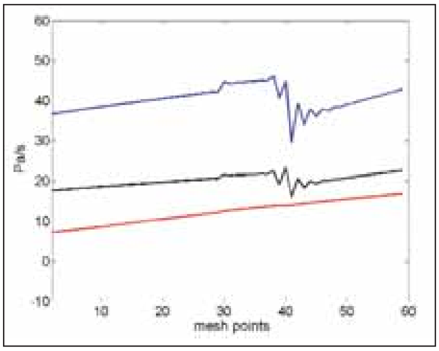

Figure 5. Measured shear stress rates for different iliac limb diameters reveal the highest value for 12-mm limb diameters (blue line) than for the 16-mm iliac limbs (black line). The shear stress rates were significantly lower for the proposed optimally designed bifurcated endoprosthesis (red line).

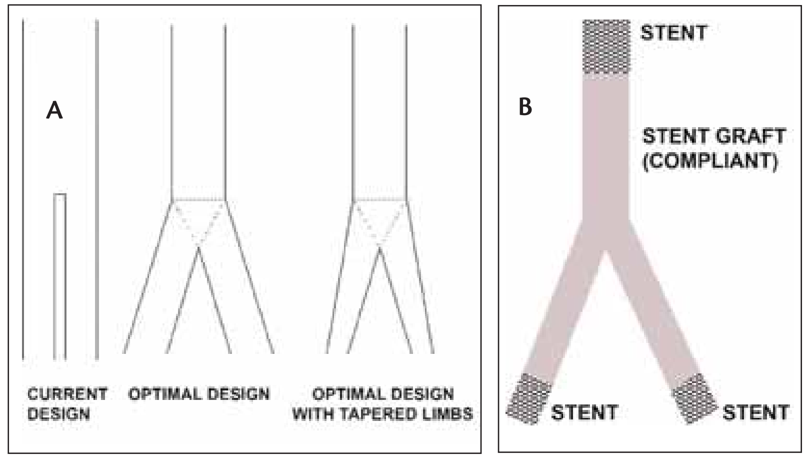

Figure 6. Sketch of a bifurcated endoprosthesis minimizing the shear stress rates (A). Geometric design of a bifurcated endoprosthesis (left), current design (middle), and optimal design (right). The optimal design has tapered limbs for small iliac artery diameters (B).

smaller limb diameters. In their study, thrombosis occurred in 5.5% of limbs that were 14 mm or less and in 2.4% of limbs that were greater than 14 mm.

Our observations revealed that the shear stress rates at the endograft limbs were the lowest when the diameter of the limbs was equal to $\sqrt{2}/2 \approx 0.7$ of the diameter of the main body component. This relationship is a consequence of the conservation of mass principle. Variable endoprosthesis flexibility was another factor that offers better performance. The prosthesis that is stiffer in its central section, where there is less support by the native aorta, and softer at the attachment site with the iliac arteries showed the lowest shear stress rates and the best performance. The stiffness of the composite endoprosthesis-vessel structure is equal to the combined stiffness of each structure. Therefore, the lower the stiffness of the endoprosthesis at the attachment site, the lower the difference will be between the stiffness of the native vessel and the endoprosthesis. A schematic rendering of the proposed optimal endoprosthesis representing these two properties is shown in Figure 6A. For practical purposes, in a patient whose iliac artery diameter is less than the optimal diameter, an endoprosthesis with tapered limbs would offer better long-term performance. Prosthesis design that minimizes the shear stress rates should also have variable prosthesis flexibility and limb diameter equal to 0.7 of the main modular component at the bifurcation, with limb diameters gradually decreasing toward the iliac attachment sites (Figure 6B). We hope that future designs will take into consideration the findings of this study to improve the outcomes and durability of AAA endografts. ■

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1. Umscheid T, Stelter WJ. Time-related alterations in shape, position, and structure of self-expanding, modular aortic stent-grafts. J Endovasc Surg. 1999;6:17-32.
2. Carrocio A, Faries PL, Morrissey NJ, et al. Predicting iliac limb occlusions after bifurcated aortic stent grafting: anatomic and device-related causes. J Vasc Surg. 2002;36:679-684.
3. Cao P, Verzini F, Zannetti S, et al. Device migration after endoluminal abdominal aortic aneurysm repair: analysis of 113 cases with a minimum follow-up period of 2 years. J Vasc Surg. 2002;35:229-235.
4. Sternbergh WC III, Carter G, York JW, et al. Aortic neck angulation predicts adverse outcome with endovascular abdominal aortic aneurysm repair. J Vasc Surg. 2002;35:482-486.
5. Cuyers PW, Laheij RJ, Buth J. Which factors increase the risk of conversion to open surgery following endovascular abdominal aortic aneurysm repair? The EUROSTAR collaborators. Eur J Vasc Surg. 2000;20:183-189.
6. Haidekker MA, White CR, Frangos JA. Analysis of temporal shear stress gradients during the onset phase of flow over a backward-facing step. J Biomech Eng. 2001;123:455-463.
7. Parent FN III, Godziachvili V, Meier GH 3rd, et al. Endograft limb occlusion and stenosis after ANCURE endovascular abdominal aneurysm repair. J Vasc Surg. 2002;35:686-690.
8. Frank AO, Walsh PW, Moore JE Jr. Computational fluid dynamics and stent design. Artif Organs. 2002;26:614.
9. Caniç S, Ravi-Chandar K, Krajcer Z, et al. A comparison between the dynamic responses of bare-metal (Wallstent) endoprosthesis and AneuRx Stent-Graft: A mathematical model analysis. Tex Heart Inst J. 2005;32:19-23.
10. Caniç S, Hartley CJ, Rosenstrauch D, et al. Blood flow in compliant arteries: an effective viscoelastic reduced model, numerics and experimental validation. Ann Biomed Eng. In press.
11. Carpenter JP, Neschis DG, Fairman RM, et al. Failure of endovascular abdominal aortic aneurysm graft limbs. J Vasc Surg. 2001;33:296-302.