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Type IIIb Endoleak and Relining: A Mathematical Model of Distraction Forces

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Abstract

Purpose: To examine the changes in distraction force following relining of a conventional abdominal aortic stent-graft with a type IIIb endoleak using the Nellix endovascular sealing device compared to a unilateral stent-graft.

Methods: Relining is often used to repair type IIIb endoleaks, but the consequences to graft stability are unknown. A mathematical model was constructed based on pressure and volume flow through the stent-grafts, incorporating recognized distraction force equations. Steady flow was presumed at peak systolic pressures to calculate the maximum distraction force, with gravity ignored. Distraction forces for 28- to 36-mm-diameter stent-graft bodies with 16-mm limbs were calculated and compared to forces following relining with single and double Nellix devices or the Renu unilateral device.

Results: Distraction forces for the 28-, 32-, and 36-mm stent-grafts prior to relining were 5.99, 10.21, and 14.99 N, respectively. Similar forces were reported after relining with bilateral Nellix devices (5.86, 10.08, and 14.86 N, respectively). However, use of a unilateral Nellix increased the distraction forces to 9.92, 14.14, and 18.92 N, respectively. These were comparable to the increase observed after relining with a Renu unilateral stent-graft (9.87, 14.09, and 18.86 N, respectively). The proportional increase in distraction force for a unilateral relining ranged from 26% to 66%, with the greatest increase noted in the smaller diameter main bodies.

Conclusion: Relining a stent-graft with a type IIIb endoleak using bilateral Nellix devices does not increase the distraction force. However, a unilateral Nellix device or the Renu system could theoretically increase the distraction force by up to 66%, potentially risking migration and type Ia endoleak. In clinical practice, these results suggest that a relining with bilateral Nellix may have benefits over the Renu unilateral stent-graft.

Keywords

abdominal aortic aneurysm, computational models, device failure, endoleak, endograft, endovascular aneurysm sealing, stent-graft

Introduction

Treatment of type IIIb endoleak after conventional endovascular aneurysm repair (EVAR) can take several forms. It may be treated through open operation and explantation of the original device, albeit with significant morbidity and mortality.¹ An alternative endovascular solution is to reline the original device with another bifurcated or aortouni-iliac stent-graft.² The endovascular relining technique may be complicated, however, due to the length of the original main body component, precluding incorporation of a standard graft. Fenestrated cuffed devices with or without internalized contralateral limbs may be required in order to reline the fabric defect while accommodating the dimensions of a short-bodied device.³

The Nellix Endovascular Aneurysm Sealing (EVAS) System (Endologix, Irvine, CA, USA) has been used to reline EVAR stent-grafts in the setting of endoleak and impending failure.⁴⁻⁶ We recently treated with success several cases of probable late type IIIb endoleak using the Nellix device.⁷ The insertion of the Nellix stent or a unilateral stent-graft within a standard stent-graft will inevitably change the hemodynamic forces experienced at the aortic neck and within the iliac vessels. There may be a disadvantageous increase in the distraction force, potentially causing subsequent migration of the combined stents and prompting type Ia endoleak. To investigate this hypothesis, a mathematical model was constructed to investigate the changes in distraction force following relining of a conventional aortic stent-graft using the Nellix EVAS device vs a Renu unilateral stent-graft (Cook Medical, Bloomington, IN, USA).

Methods

To model the hemodynamic forces both in a standard aortic stent-graft and in the Nellix Endovascular Aneurysm Sealing System containing endobags, one can, for the fluid forces, use a standard control volume approach⁸ based on the principles of conservation of mass and momentum. Such an approach, in combination with Bernoulli's equation to link velocities and pressures, has been successfully used by various authors⁹⁻¹³ to estimate distraction forces in endovascular⁹⁻¹¹ or endoluminal¹² stents or in modeling of hemodynamic forces in the aortic arch,¹³ for example. Hemodynamic distraction forces are generated by blood pressure and blood flow and may encourage migration of the

stent-graft. To calculate these fluid forces, a control volume was applied around the “wetted” part of the geometry under consideration, as shown schematically in Figure 1 by the blue dashed lines, and then apply equations (1) and (2) from Jones et al⁹ to determine the change in fluid momentum in the axial (flow) direction and hence the fluid component of the distraction force (shown in blue in Figure 1). The flow is assumed to be quasi-steady, gravity forces are neglected, and conditions are chosen to represent peak systole in the supraceliac aorta at rest, which included a constant pressure of 140 mm Hg and a constant volume flow rate of 8 L/min ($1.323 \times 10^{-4} \text{ m}^3/\text{s}$)¹⁴ assuming a density of 1098 kg/m^3 . Forces for different morphologies, ie, proximal and distal diameters, are shown in Table 1.

For the Nellix system, there are also forces exerted on the solid polymer endobags that need to be considered. To do so the pressure forces are resolved in the “vertical” direction (vertical as shown in Figure 1, but gravity forces are still neglected). At the proximal face, this pressure force acts downward and is equal to the peak systolic blood pressure multiplied by the endobag facial area A_N (eg, for the double stent case **Error! Objects cannot be created from editing field codes.**), whereas the force at the distal end pushes against this force in the upward direction and, for the double stent, is equal to the distal pressure (determined using Bernouilli’s equation) multiplied by twice the distal facial area A_n (**Error! Objects cannot be created from editing field codes.**) as there are two distal ends. For the single stent case, the proximal facial area is increased (**Error! Objects cannot be created from editing field codes.**), and it is assumed that the non-stented limb is occluded such that no pressure force can be exerted on this face.

The calculations for the aortouni-iliac stent of the Renu device replicate those for the standard bifurcated stent-graft but consider the upward force of only one of the iliac limbs, as the other has been occluded by the system.

Results

All forces, both the fluid control volume force and the endobag force, are shown for some representative morphologies in Table 1. Overall, it is apparent that for the Nellix double stent configuration, the overall distraction force is essentially the same as the

force in the standard aortic stent-graft case as the large reduction in fluidic distraction force is almost exactly balanced by a significant downward pressure force exerted on the endobag. For the Nellix single-stent configuration, which is assumed to be “missing” one half of the restoring pressure force acting on the distal ends as it is assumed occluded and at zero pressure, the distraction forces are significantly greater. The proportional increase in distraction force for a unilateral relining ranged from 26% to 66%, with the greatest increase noted in the smaller diameter main body. The same principle holds for the unilateral Renu system, which showed similar proportional increases in distraction force dependent on stent-graft diameter.

Discussion

The mathematical model indicates that the distraction force experienced by the combined original stent-graft and the Nellix stent is essentially unchanged following relining. This applies, however, only to the case of bilateral relining, with Nellix stents deployed in both iliac limbs. The situation is different if an aortouni-iliac relining is performed. In such circumstances, there is a significant increase in the distraction force experienced by the device, dependent on the original graft dimensions. The proportional increase in distraction force for a unilateral relining ranged to 66%, with the greatest increase noted in the smaller diameter main body. In clinical practice, these results suggest that a relining with bilateral Nellix is preferable to unilateral Nellix and may also offer some benefits over the Renu unilateral stent-graft, as it has a more favorable hemodynamic profile and avoids a femorofemoral crossover graft.

When the Nellix is deployed in an aortic aneurysm, the stability of the device is dependent on the cured polymer filling the entire aneurysm lumen and gaining support from the aortic bifurcation. However, when used for relining, the Nellix stents are entirely reliant on the original fixation of the primary stent-graft. It is therefore paramount that the quality of fixation must be carefully assessed, including close inspection for disengagement or shearing of the barbs before the relining is performed. If there has been proximal or distal stent migration, then the fixation may be inadequate, and relining with a sealing device may expose the patient to the risk of subsequent type I endoleak.¹⁵ The fixation of stent-grafts is variable depending on their design, with dislodgement

forces in an in situ bovine model reported as ranging between 10.7 and 20.8 N for 3 different commercially available stent-grafts.¹⁶ The original stent-graft fixation could be reinforced through the use of endoanchors prior to relining¹⁷; however, the validity of this method is unknown. Nellix associated with the chimney technique has been described in juxtarenal aneurysm treatment.¹⁸⁻²⁰ There is thus a potential for using chimneys in relining with proximal protrusion. Indeed, there is the possibility to extend the proximal and distal sealing zones by inserting sufficiently long Nellix stents (120–180 mm) to allow protrusion of the endobags beyond the top and bottom of the fabric of the original graft. This may allow treatment of type I endoleaks, however, the position of the renal arteries and iliac bifurcation is important if undertaking this repair. A concomitant treatment of unclear type IIIb and Ia endoleaks is therefore feasible.

According to EUROSTAR data,^{21,22} the incidence of late type III endoleak after successful EVAR is reported to be ~2% to 3%, and it has been reported with 3 commercially available endoprotheses.²³⁻²⁵ The source of these endoleaks is difficult to identify and often requires multimodal imaging, as demonstrated in the illustrated case (Figure 2A). Suspected type III endoleaks should be treated promptly, and in an analysis of preliminary EUROSTAR data, patients with late type III endoleaks had 9 times greater chance of aneurysm rupture compared with other registry patients.²⁶ Furthermore, type III endoleak is the second commonest cause of post-EVAR aneurysm rupture.²⁷ These studies do not necessarily differentiate between type IIIa and IIIb endoleaks; however, fabric degradation with type IIIb endoleak is becoming more recognized as a late failure modality.²⁸

Treatment of type IIIb endoleak can be endovascular or open. A conservative policy carries a definite but undefined rupture risk, while an open conversion has significant physiological implications due to the aortic clamping. Endovascular options can be limited due to the main body length of the original endograft being too short to allow deployment of a second standard bifurcated device. Insertion of a Renu stent-graft associated with a femorofemoral crossover bypass and a plug in the contralateral leg is an option.²⁹ The Nellix can seal any fabric defect (type IIIb and IV endoleak) but will not treat concurrent type II endoleak (Figure 2B, 2C). The use of sealing technology to reline grafts is very simple and the majority of the procedure can be done under fluoroscopic

imaging only, as the metal stent of the original graft will guide accurate placement of the Nellix stents. This offers clear advantages in terms of operative time, contrast medium load, and radiation dose over relining with fenestrated cuffs in short bodied stent-grafts, which is a complicated and long procedure.

Following relining, close surveillance is mandatory. Cessation of sac growth may confirm the diagnosis of type IIIb endoleak, and regular imaging can allay any concerns regarding fixation and migration. Early computed tomography angiography followed by regular duplex scanning and radiography may be sufficient since, following relining, the aneurysm repair is once again reliant on the original stent-graft.³⁰

Conclusion

Relining a stent-graft with a type IIIb endoleak using bilateral Nellix devices does not increase the distraction force. In theory, distraction forces on the original stent-graft remain unchanged if bilateral Nellix stents are deployed but are increased significantly if a unilateral procedure is performed. In clinical practice, these results suggest that relining with bilateral Nellix may offer benefits over a unilateral stent-graft.

Declaration of Conflicting Interests

The author(s) declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Legends

Figure 1. Schematic diagram illustrating control volumes (shown with blue dashed lines) for standard fenestrated endovascular stent-graft (“ORIGINAL”) and the Nellix Endovascular Aneurysm Sealing System containing endobags in the double (“NELLIX-DOUBLE”) and single stent (“NELLIX-SINGLE”) configuration together with the geometry of the endobags (black lines). Forces determined using conditions provided in Table 1.

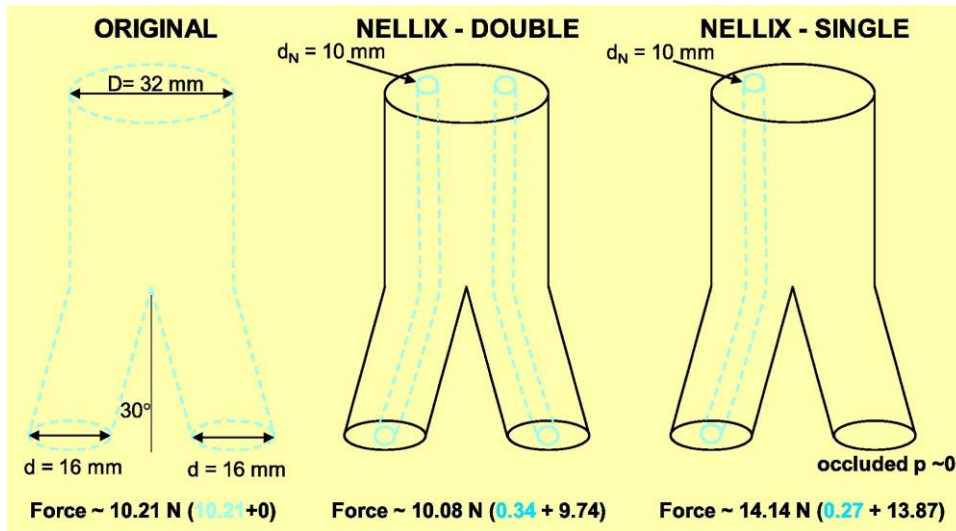


Figure 2. (A) Angiographic confirmation of a type IIIb endoleak arising from the fabric just above the top of the contralateral (left) limb; the catheter passed freely through this hole into the aneurysm. (B,C) Computed tomography angiography shows the absence of type IIIb endoleak after relining with 2 Nellix stents.

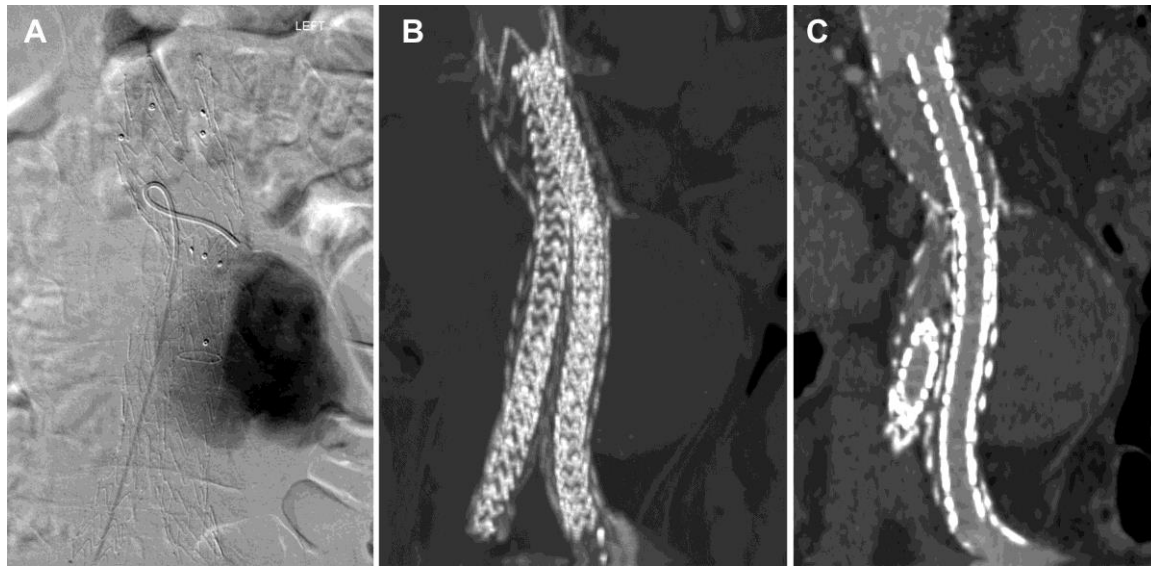


Table 1. Estimated Forces for Different Stent-Graft Configurations.^a

	Stent-Graft ^b Diameter, mm	Fluid Force, N	Endobag Force, N	Total Force, N
Original	28	5.99	—	5.99
Original	32	10.21	—	10.21
Original	36	14.99	—	14.99
Renu	28	9.87	—	9.87
Renu	32	14.09	—	14.09
Renu	36	18.86	—	18.86
Nellix (double)	28	0.34	5.52	5.86
Nellix (double)	32	0.34	9.74	10.08
Nellix (double)	36	0.34	14.52	14.86
Nellix (single)	28	0.27	9.65	9.92
Nellix (single)	32	0.27	13.87	14.14
Nellix (single)	36	0.27	18.65	18.92

^aAssuming fixed constant pressure of 140 mm Hg, fixed bifurcation angle of 30°, fixed 10-mm diameter of a Nellix stent, and a constant volume flow rate of 8 L/min assuming a density of 1098 kg/m³ in all cases.

^bAll stent-grafts had 16-mm limbs.