



To Print: Click your browser's PRINT button.

NOTE: To view the article with Web enhancements, go to:
<http://www.medscape.com/viewarticle/521159>

Aorfix Stent Graft for Abdominal Aortic Aneurysms Reduces the Risk of Proximal Type 1 Endoleak in Angulated Necks: Bench-Test Study

Jean-Noël Albertini, MD; Maria-Angela DeMasi, MD; Jan Macierewicz, MD; Redouane El Idrissi, MD; Brian R. Hopkinson, MD; Claude Clément, MD; Alain Branchereau, MD.

Vascular. 2005;13(6):321-326. ©2005 BC Decker, Inc.
Posted 01/11/2006

Abstract and Introduction

Abstract

Neck angulation (NA) is an important risk factor for type 1 proximal endoleaks following stenting of abdominal aortic aneurysms. The Aorfix (Lombard Medical, Oxon, UK) is a new flexible stent graft designed to overcome this issue. The aim of this study was to compare the endoleak flow rate (EFR) in relation to NA between the Aorfix and other manufactured stent grafts.

A flow model with silicone proximal and distal necks was used. EFRs corresponding to 10 neck angles between 0 and 70° were measured. Eight stent grafts were tested: Aorfix, Ancure (Guidant, Indianapolis, IN), Powerlink (Endologix, Irvine, CA), AneuRx (Medtronic, Sunnyvale, CA), Excluder (W.L. Gore & Associates, Flagstaff, AZ), Zenith and Zenith-Flex (Cook Inc., Bloomington, IN), and Lifepath (Edwards Lifesciences, Irvine, CA).

For all stent grafts except the Aorfix, the EFR was greater than at baseline for NA $\geq 30^\circ$ ($p < .01$). The EFR at NA $\geq 30^\circ$ was lower with the Aorfix compared with the other stent grafts ($p < .01$).

NA had no influence on the EFR with the Aorfix. The Aorfix may decrease the incidence of proximal type 1 endoleak in patients with a severely angulated aortic neck.

Introduction

Proximal type 1 endoleak is a dreaded complication of endovascular abdominal aortic aneurysm repair (EVAR). Left untreated, this complication usually results in the rupture of the aneurysm sac. It has been shown that proximal neck angulation was an important risk factor for proximal endoleak and other adverse outcomes following EVAR.^[1,2] A bench-test study identified that the relative stiffness of a stent graft was responsible for its inability to conform to neck angulation, therefore creating leaks through gaps between the stent graft and the neck.^[3] A development program was started in collaboration with Lombard Medical (Oxon, UK) to design a more flexible stent graft that would be able to overcome these issues. This program resulted in the development of the Aorfix stent graft. The aim of this study was to compare the bench-test performance of the Aorfix and other manufactured stent grafts in terms of leakage at the proximal end in the setting of angulated necks.

Methods

Bench-Test Design and Testing Methodology

Bench-test design and methodology of testing have been described in a previous publication.^[3] Proximal and distal necks were made of silicone cylinders, with internal diameters of 25 and 12 mm, respectively. These

cylinders were fixed to a frame by a system allowing them to be oriented in multiple directions. The length of the stent graft deployed in proximal and distal necks was 20 mm. The proximal and distal end diameters of the stent graft were 28 and 16 mm, respectively. As bifurcated stent grafts were used, one limb was deployed in the distal silicone tube and the other was totally obliterated. A pump generated continuous water flow in the system. For every run, the pump was switched on for 30 seconds and the corresponding amount of endoleak was collected and measured using a funnel and a graduated cylinder placed underneath the frame (Figure 1). This volume measured over 30 seconds was termed the endoleak flow rate (EFR). Angulation of the stent graft at the proximal neck was defined as the angle between the longitudinal axis of the proximal silicone tube and the longitudinal axis of the aortic body of the graft outside the proximal tube (Figure 2). Angulation at the proximal neck was gradually increased between 0 and 70° (at 10° intervals between 0 and 40° and 5° intervals between 40 and 70°). For each angulation, three runs of 30 seconds were performed. The entire manipulation was repeated three times for each stent graft, giving, overall, nine measurements for each angulation.

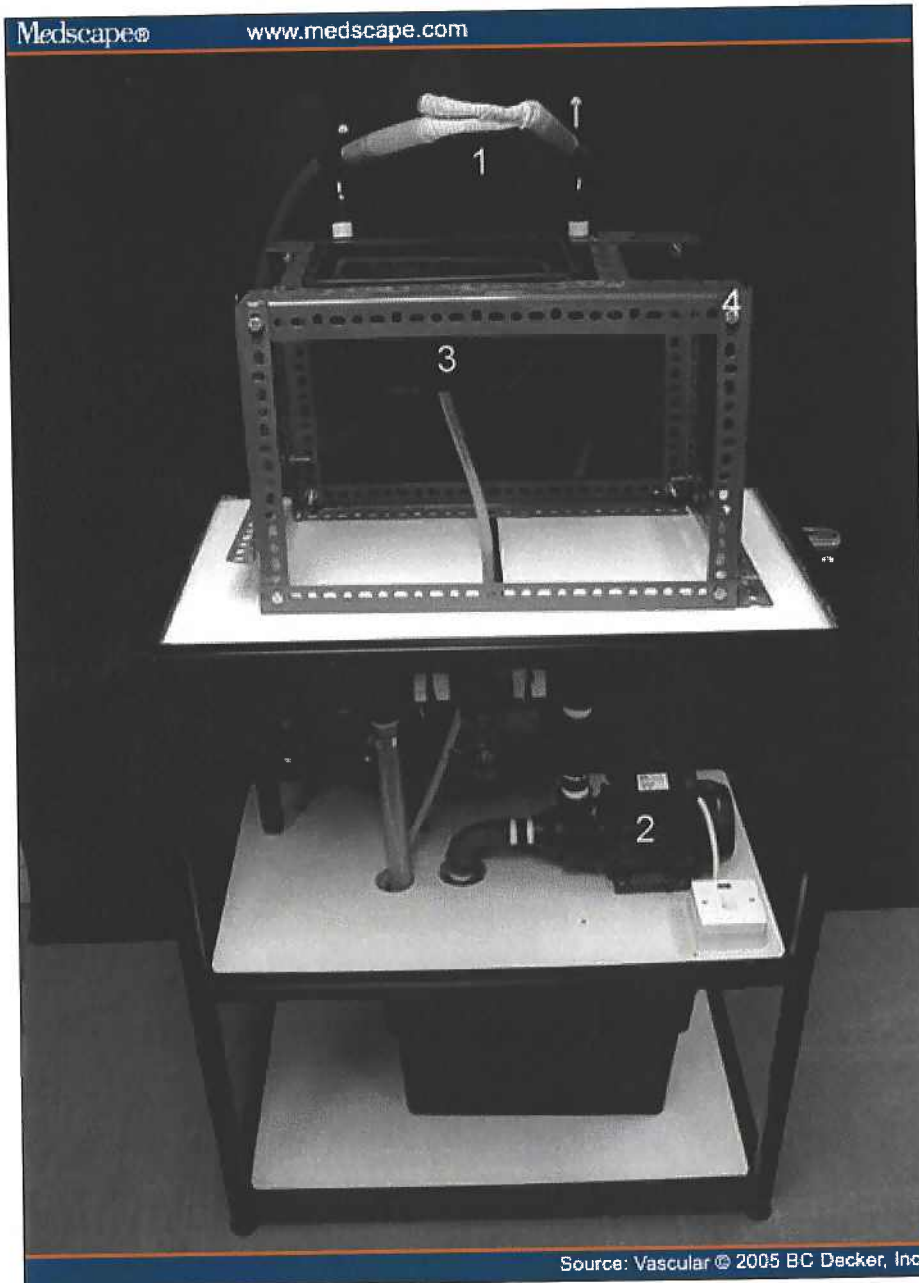


Figure 1.

Global view of the bench test showing a bifurcated stent graft (1) deployed in a proximal and distal tube. Water was pulsed into the circuit by an electrical pump (2). Proximal endoleak was collected by a funnel (3) placed underneath the frame (4) that supported the proximal and distal tube.

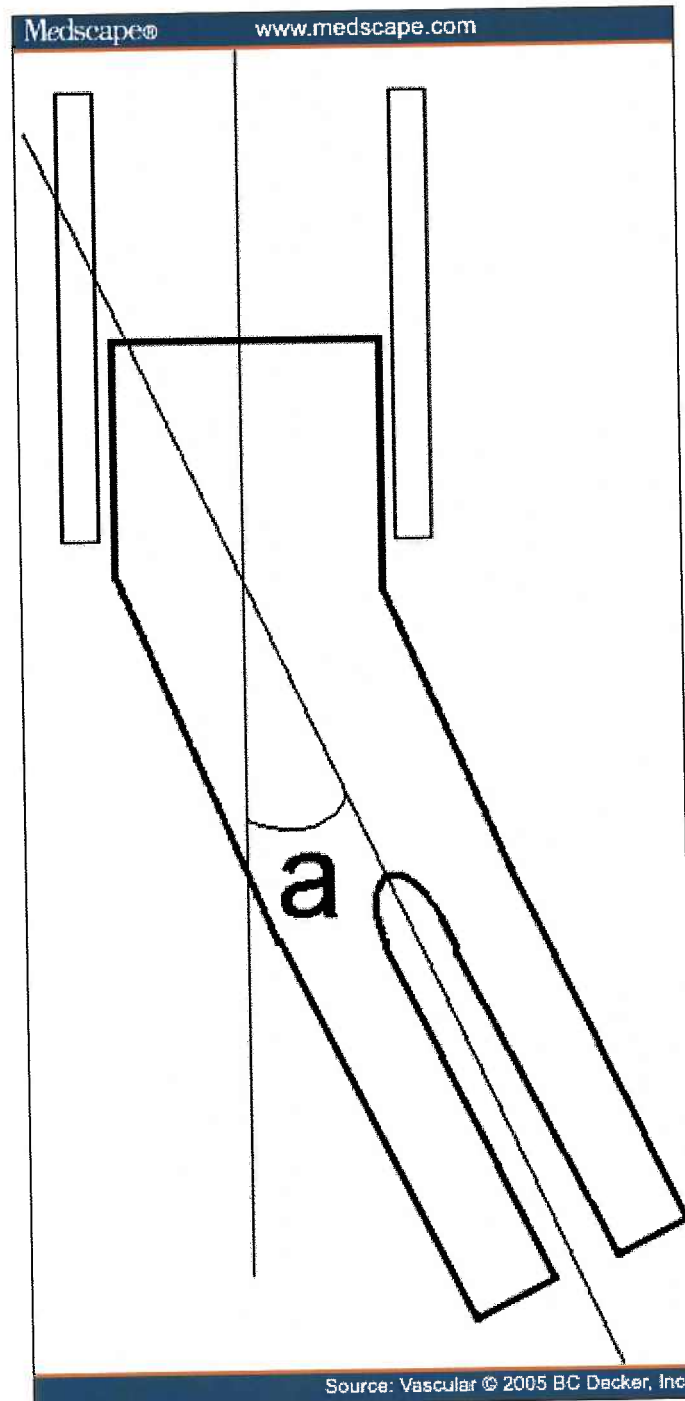


Figure 2.

Bifurcated stent graft deployed. Neck angulation was defined as the angle between the longitudinal axis of the proximal silicone tube and the longitudinal axis of the aortic body of the graft outside the proximal tube.

Description of Stent Grafts

Eight stent grafts were tested: Aorfix (Lombard Medical), AneuRx (Medtronic, Sunnyvale, CA), Ancure (Guidant, Indianapolis, IN), Zenith and Zenith-Flex (Cook, Bloomington, IN), Excluder (W.L. Gore & Associates, Flagstaff, AZ), Lifepath (Edwards Lifesciences, Irvine, CA), and Powerlink (Endologix, Irvine, CA). The design of the Aorfix stent graft has been reported elsewhere.^[4] Briefly, the fabric is made of polyester to which a continuous circular nitinol wire is embroidered along the entire length of the stent graft (Figure 3). To improve the seal, the number of turns of the nitinol wire is increased at the proximal and distal ends of the stent graft. The design of the other

stent grafts has been described in detail in previous publications.^[5-10] The Zenith-Flex stent graft has gaps of 6 mm between the proximal stents of the aortic body. The proximal end diameter was 28 mm for all stent grafts except the Lifepath, which was 27 mm. The distal end diameter was 16 mm except for the Ancure (13 mm) and the Excluder (14.5 mm). To reduce water leakage through the fabric, the stent grafts were covered by two thin layers of silicon spray.

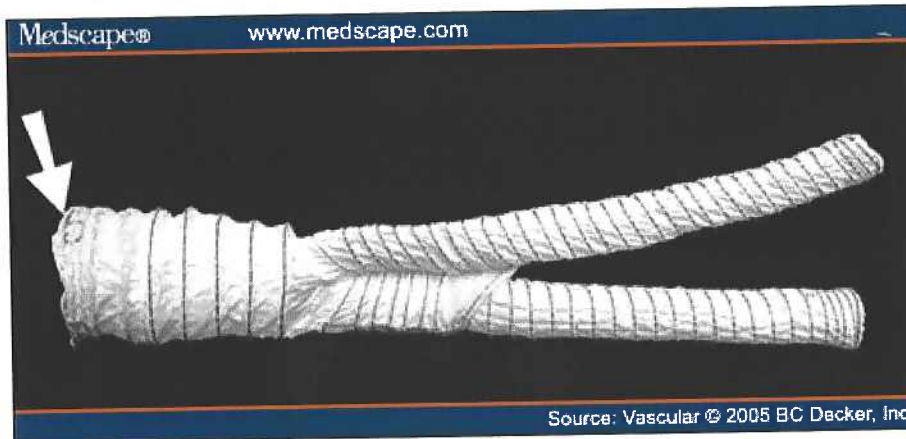


Figure 3.

Bifurcated Aorfix stent graft. Continuous nitinol rings are embroidered into the Dacron fabric, giving the stent graft its flexibility. The arrow indicates hooks at the proximal end of the stent graft.

Data Analysis

For any stent graft, the baseline EFR was defined as the flow rate measured at the 0° angulation. For each stent graft, the EFRs measured at angulations from 10 to 70° were compared with the baseline EFR using the Wilcoxon signed ranks test. Baseline EFRs were compared between the Aorfix and other stent grafts using the Mann-Whitney test. At every angulation greater than 0°, the EFR minus baseline was compared between the Aorfix and the other stent grafts using the Mann-Whitney U-test. A *p* value of .01 was considered statistically significant. Statistical tests were performed using *SPSS* (SPSS Inc., Chicago, IL).

Results

[Table 1](#) and [Figure 4](#) show the median value of the EFR for each stent graft at angulation, varying from 0 to 70°. The baseline EFR was significantly lower for the Aorfix compared with the other stent grafts.

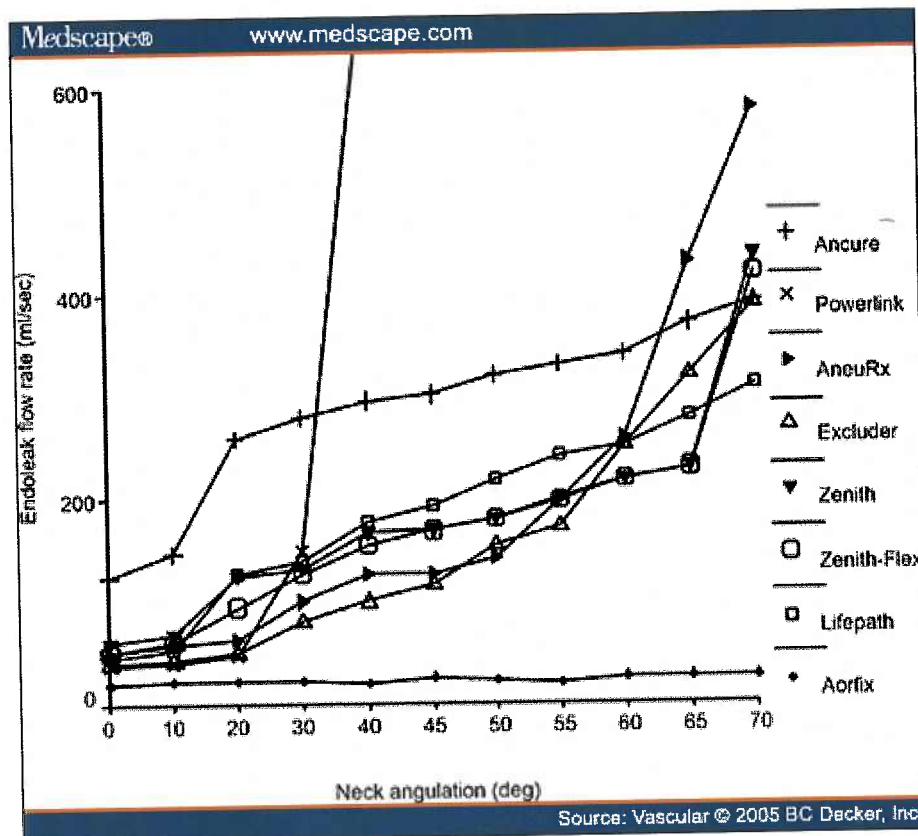


Figure 4.

Median endoleak flow rate at the corresponding angulation for each manufactured stent graft.

For all stent grafts except the Aorfix, the EFR at angulation $\geq 30^\circ$ was significantly greater than the baseline EFR (Table 2). Table 3 describes the EFR expressed as a ratio from the baseline value (endoleak ratio = EFR at any angulation/baseline EFR). For the Aorfix, the endoleak ratio did not exceed 1.3. For any other stent graft at an angulation $\geq 45^\circ$, the endoleak ratio was greater than 2 and increased in proportion to angulation. Depending on the stent graft, the maximum value for the endoleak ratio ranged between 2.6 and 46. The EFR at any angulation $> 20^\circ$ was significantly lower with the Aorfix compared with the other stent grafts (Table 4).

Discussion

This flow model study shows that proximal type 1 leakage can be related to increased angulation of the neck for all stent grafts except the Aorfix. Indeed, the Aorfix was the only stent graft for which increased angulation of the proximal neck did not affect the EFR. One issue in the interpretation of the results is that the baseline EFR differed significantly between the Aorfix and the other stent grafts. The baseline EFR reflected leakage around the proximal end of the stent graft through interstices that existed at the zero angulation, leakage through the fabric along the stent graft (which depended on the quality of the waterproofing process), and leakage (although minimal) at the distal attachment site. Baseline leakage was also different between other stent grafts. We assumed and observed that the baseline EFR was constant at any angulation and that further leakage was related to the effect of angulation. This assumption was confirmed by the results, which showed a good correlation between angulation and EFR for any type of stent graft except the Aorfix. The effect of different baseline values was corrected by subtracting the baseline EFR to every EFR at greater angulation. Analysis of the endoleak ratio was another way of showing that the EFR significantly increased with neck angulation independently from baseline for any stent graft except the Aorfix. Analysis of shape change at the proximal end confirmed the results of our previous study. All stent grafts showed some extent of distortion at the proximal end when neck angulation increased. In the case of the Aorfix, no shape modification was noted whatever the neck angulation (Figure 5). This is explained by the succession of embroidered nitinol rings, which give flexibility to the stent graft.

