Aortic and Iliac Fixation of Seven Endografts for Abdominal-aortic Aneurysm Repair in an Experimental Model Using Human Cadaveric Aortas

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Abstract  Objective: To evaluate the proximal and distal (iliac) fixation of seven self-expanding endografts, used in the endovascular treatment (EVAR) of abdominal-aortic aneurysm (AAA), by measuring the displacement force (DF) necessary to dislocate the devices from their fixation sites.

Methods: A total of 20 human cadaveric aortas were exposed, left in situ and transected to serve as fixation zones. The Anaconda, EndoFit aorto-uni-iliac, Endurant, Powerlink, Excluder, Talent and Zenith stent grafts were deployed and caudal force was applied at the flow divider, through a force gauge. The DF needed to dislocate each device 20 mm from the infrarenal neck was recorded before and after moulding-balloon dilatation. Cephalad force was similarly applied to each iliac limb to assess distal fixation before and after moulding-balloon dilatation.

Results: Endografts with fixation hooks or barbs displayed a significantly higher DF necessary to dislocate the proximal portion compared with devices with no such fixation modalities (p < 0.001). Balloon dilatation produced a significant increase in DF in both devices with (p < 0.001) or without (p = 0.003) hooks or barbs. Suprarenal support did not enhance proximal fixation (p = 0.90). Balloon dilatation significantly increased the DF necessary to dislodge the iliac limbs (p = 0.007).

Conclusions: Devices with fixation hooks displayed higher proximal fixation. Moulding-balloon dilatation increased proximal and distal fixation. Suprarenal support did not affect proximal fixation.

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Introduction

The proximal and distal fixation of an endograft following endovascular repair (EVAR) of abdominal-aortic aneurysm (AAA) is vital, to exclude endoleak, graft migration and sac repressurisation, all of which can prove catastrophic. The proximal fixation of a device depends on a number of factors relating to the aorta and the stent graft itself, such as the contour and size of the attachment zones, the presence of thrombus, the shape and size of the graft, the ability of the graft to provide radial spring force and various device specifications, including balloon or self-expanding deployment, the presence of fixation hooks and barbs and the configuration of the device’s skeleton.\(^1\)\(^2\)

Various investigators have attempted to evaluate the fixation force of the endografts used in EVAR, employing different models,\(^3\)\(^–\)\(^10\) in human cadaveric aortas or, most commonly, animal cadaveric aortas. However, some of these studies have only tested graft fixation in animals,\(^10\) while others have only assessed proximal fixation without taking distal fixation into account.\(^7\) Additionally, there are no studies focussing on graft fixation pre- and post- moulding-balloon dilatation. Moreover, there is insufficient data concerning the distal (iliac limb) fixation of the endografts against cephalad forces, similar to the forces causing type I distal migration seen in thoracic aortic endografts, which resemble the type of force that is applied to the distal (iliac) portion of any EVAR device.\(^3\)\(^,\)\(^9\)\(^–\)\(^15\)

This study aims to assess the proximal and distal fixation of seven commercially available aortic endografts (Anaconda (Vascutek, Inchinnan, Scotland, UK), EndoFit aorto-uni-iliac (LeMaitre Vascular, Burlington, MA, USA), Endurant (Medtronic, Minneapolis, MN, USA), Endologix Powerlink (Endologix, Irvine, CA, USA), Excluder (Gore Medical, Flagstaff, AZ, USA), Talent (Medtronic, Minneapolis, MN, USA) and Zenith (Cook Medical, Bloomington, IN, USA)) pre- and post- moulding-balloon dilatation in a model using human cadaveric aortas.

Methods

A total of 20 human cadavers (Department of Pathology, Aristotle University Medical School, Thessaloniki, Greece) were included (inclusion criteria: time of death \(\leq 18\) h; absence of intra-abdominal pathology or abdominal trauma; intact femoral and iliac vessels and absence of sepsis). Written informed consent was obtained in all cases by the family. Institutional Review Board approval was also obtained.

The Mecmesin Digital Basic Force Gauge (BFG) 200 and MultiTest stand (Mecmesin Limited, Newton House, West Sussex, UK) were employed to measure the DFs. The specific device has been previously validated.\(^16\)

The seven endografts included in the study were chosen as they have distinct characteristics aimed to enhance fixation, such as, proximal fixation hooks, unibody skeleton design and sophisticated proximal and distal fixation mechanisms using ring stents to enhance friction against the aortic wall. Table 1 summarises the characteristics of the endografts.

Through a midline laparotomy, the retro-peritoneum was uncovered and dissected, and each aorta was surgically prepared by displaying the vessel from the coeliac axis to the level of the internal iliac arteries. The actual diameter of the aorta was measured in the following manner, using a caliper: after the aorta was surgically exposed and prior to dissecting the vessel, arterial clamps were temporarily applied at the level of the suprarenal aorta, the renal arteries, the distal common iliac arteries and any patent lumbar arteries. The isolated abdominal aorta was sequentially dilated with saline using an inflation device at 100 mm Hg through the inferior mesenteric artery stump, to ensure that the aortic and iliac artery diameters correlated with the diameter of the vessels in vivo. The clamps were then withdrawn and the abdominal aorta was dissected from 20 mm below the origin of the most distal renal artery and up to the level of the aortic bifurcation to serve as proximal and distal fixation zones (‘experimental AAA’), as previously described in similar studies.\(^2\)\(^–\)\(^10\) The temperature of the cadaveric aorta was kept at 37 \(^\circ\)C by means of a warm normal saline bath (a probe was embattled into the saline bath, adjacent to the proximal aorta). Warmed normal saline was also used during the exposure of the femoral arteries and during endograft insertion and deployment to ensure adequate expansion of the self-expanding grafts. The femoral arteries were exposed and prepared in standard fashion. The endografts were deployed following femoral artery catheterisation in a standard fashion, according to the manufacturer’s specifications by NM and NS, both of whom have had previous experience (> 10 procedures for each device) using the specific devices. A 10–20% oversizing Tables 1 and 2 was employed in all cases (proximal and distal attachment zones), according to our department’s routine policy for EVAR and the manufacturers’ instructions. In general, we tested a total of three previously unused endografts of the same proximal and distal diameter for each device. The adequate proximal and distal fixations of the devices were confirmed macroscopically, without using fluoroscopy. Once the devices had been removed, the lengths of the proximal and distal fixation zones were measured, confirming that the affixed part was between 19 and 21 mm in all cases. A nonabsorbable coated braided polyester suture was attached to the flow divider of the graft Fig. 1. The suture’s elastic properties were tested prior to the experiments; a force \(>90\) N was necessary for the suture to deform. The distal end of the suture was attached to the Mecmesin BFG gauge in a 15\(^\circ\) angle.\(^11\) Incremental force was applied through a motorised displacement-measuring test stand at a speed of 100 mm min\(^{–1}\). The DF necessary to dislocate the graft from its proximal fixation site for 20 mm was measured following the full deployment (proximal and distal landing zones) of each device (for devices with and without fixation hooks or barbs). This DF represents the maximal force recorded by the gauge whilst applying incremental force at 100 mm min\(^{–1}\). Measurements were obtained for each graft prior and post dilatation using a Reliant moulding-balloon (Medtronic, Minneapolis, MN, USA). A manual inflation device was used to control inflation pressure. The DF necessary to dislocate the distal (iliac) part of each graft proximally for at least 20 mm was also measured in a similar manner following full deployment of the iliac legs pre- and post balloon dilatation; however, force was applied in the opposite direction (cephalad force, distal \(\rightarrow\) proximal) to simulate the type of force that would
be applied against the distal portion of an endograft when fully deployed in vivo. Each cadaveric aorta was used 2 or 3 times, as in previous studies. The intimal layer was considered as damaged if there was macroscopic disruption of the tissue. Grafts with fixation hooks or barbs were deployed last; no further measurements were obtained after a device with such modalities had already been deployed once. Additionally, when moulding-balloon dilatation had been employed, the cadaver was not used for any further measurements.

### Statistical Analysis

All analyses were made using the Statistical Package for the Social Sciences (SPSS) version 13.0 for Windows. All variables were analysed using the Shapiro–Wilk or Kolmogorov–Smirnov test (according to the size of the distribution) to assess the normality of each distribution. Median and range are given for non-normally distributed variables and mean and standard deviation (SD) or range are given for normally distributed variables. The Wilcoxon test (paired non-parametric data), Mann–Whitney test (independent non-parametric data) and Student’s t-test (paired parametric data) were used to compare differences between two groups. Differences among more than two groups were analysed using analysis of variance (ANOVA). A p value < 0.05 was considered as statistically significant.

### Results

The mean age of the cadavers was 57 years (range: 51–84 years; 14 men). Six patients were diagnosed with coronary artery disease (CAD), eight with arterial hypertension (receiving pharmaceutical treatment), nine had a history of hyperlipidaemia and 12 were smokers; none had a history of aneurysmal disease. The mean diameter of the aortas (infrarenal proximal neck) was 20.5 mm (range: 19.2–21.9 mm). The cadaveric aortas were divided into three groups according to the amount of calcification: (1) minimal (n = 6); (2) moderate (n = 7); and (3) heavy (calcified plaques extending ≥ 1/3 of the vessel’s perimeter; n = 7). Each endograft was deployed in all three types of aortas. None of the cadavers had excessive calcification; no thrombus was detected prior to graft insertion at the level of the attachment zones. Since three different endografts were available for each device, each separate graft was only deployed twice. Table 2 summarises the proximal and distal diameters of the devices used and the amount of oversizing applied in each case. Results are summarised in Tables 3 and 4.

The Zenith endograft recorded the highest DF necessary to dislocate the graft ≥ 20 mm from its proximal fixation site following full deployment of the main body and the iliac limbs and balloon dilatation (p < 0.001, ANOVA; mean DF: 39.30 ± 1.55 N); the Anaconda showed the second highest DF (mean: 36.16 ± 1.30 N); the aorto-uni-iliac EndoFit graft
displayed the lowest DF (mean: 13.20 ± 0.75 N) Table 3. Endografts equipped with fixation hooks or barbs (Zenith, Anaconda, Endurant and Excluder) displayed a significantly higher DF necessary to dislocate the proximal portion of the graft ≥ 20 mm compared with devices with no such fixation modalities (Talent, Powerlink, Endofit), following full graft deployment with balloon dilatation (p < 0.001, Mann–Whitney test, median: 36.10 N (range: 21.85–40.90 N) vs. median: 14.80 N (range: 12.50–16.65 N)). Balloon dilatation produced a significant increase in DF in both stent grafts equipped with hooks or barbs (p < 0.001, paired sample t-test, mean: 26.97 ± 6.44 N vs. 32.45 ± 6.71 N) and devices without such modalities (p = 0.003, paired sample t-test, mean: 13.58 ± 1.46 vs. mean: 14.72 ± 1.41) Table 4. Devices with suprarenal support did not exhibit an increased proximal fixation ability (p = 0.90, Mann–Whitney test, median: 16.20 N (range: 12.50–40.90 N) vs. median: 22.60 (range: 14.10–37.50 N)) Table 3.

Regarding distal fixation (iliac legs), the Anaconda device displayed the maximal DF necessary to dislocate the iliac limbs for ≥ 20 mm (p < 0.001, ANOVA, 14.58 ± 0.68 N),
followed by the Excluder (mean: 10.51 ± 0.40 N); the Endologix device displayed the lowest DF (mean: 4.93 ± 0.50 N) — Table 3. Balloon dilatation significantly increased the DF necessary to dislodge the distal fixation zones (p = 0.007, Wilcoxon test, median: 9.50 N (range: 4.55–15.30 N) vs. median: 9.05 N (range: 4.35–14.10 N)).

### Discussion

This analysis attempted to evaluate the proximal and distal fixation of seven endografts used in EVAR, all of which employ distinct fixation modalities. The Zenith, a modular three-piece bifurcated device with suprarenal support and 3 mm-long fixation barbs (‘anchors’), displayed the maximal proximal fixation capability. In general, devices incorporating hooks or barbs (Table 4) displayed significantly better fixation in the current model. Balloon dilatation also significantly impacted on proximal and distal fixation; however, suprarenal support did not have a significant effect (p = 0.90) among these devices.

Previous studies have shown that an endograft needs to withstand pulsatile drag forces of 3.8–6 N in an aneurysmal aorta with a friendly anatomy and drag forces up to 14 N in more hostile anatomies. All devices used in this analysis have exceeded these limits.

The fact that the Zenith and the Anaconda endografts displayed the maximal fixation can possibly be explained by the existence of rigid hooks and barbs at their proximal portion. Previous research has shown that such modalities significantly enhance fixation. The Zenith, in addition to its 10 fixation barbs (3 mm in length), offers suprarenal support through a 26-mm-long suprarenal fixation mechanism, significantly longer than the suprarenal stents of any other device. Suprarenal support has been shown to have a positive effect on graft migration even though this was not proven in the current study (Table 4). The long main body of the Zenith device may also play a role, as it provides a higher amount of columnar support. Resch et al. and Veerapen et al. have also shown that the Zenith has a high proximal fixation capability compared with other self-expanding devices. The Anaconda proved the second highest overall fixation. The specific device incorporates a sophisticated proximal fixation mechanism consisting of four pairs of 2-mm-long metallic hooks and double oversized stiff rings, which provide radial force as they expand against the aortic wall. Any attempt to migrate the stent distally produced a visible movement of these oversized proximal stents during our experiment. Bosman et al. recently included the Anaconda, Endurant, and the Excluder in a similar study showing a significantly higher DF for the Anaconda. The Endurant bears a proximal fixation mechanism with Z and M nitinol stents with five pairs of 2-mm-long hooks and a 15-mm-long suprarenal fixation stent. The fact that its proximal fixation is lower can probably be attributed to the smaller length of the suprarenal fixation stents (15 mm vs. 26 mm) and the anchoring pins (2 mm vs. 3 mm), as well as the different material of which the stents and pins are made (nitinol vs. stainless steel). The Excluder has been previously tested by Veerapen et al. and Bosman et al. and has been shown to necessitate a lower DF compared with the Zenith and the Endurant. The device incorporates eight pairs of 2 mm nitinol fixation barbs and no suprarenal support. Regarding the results for the Talent endoprosthesis, these are similar to the DFs seen in the studies by Veerapen et al. and Resch et al.; the device does not incorporate fixation hooks or barbs, but is equipped with a 15-mm nitinol suprarenal stent. As far as the Powerlink device is concerned, it needs to be noted that the major advantage of the prosthesis is the high amount of columnar support that it provides, given its unibody configuration. Due to lack of proximal aortic cuffs of adequate length, the device was not deployed as it would be in vivo, where the distal portion lies against the aortic bifurcation; therefore, supporting the main body of the prosthesis. As a result, the DF seen in this study does not probably correlate to the DF needed for the device to migrate in vivo. The EndoFit aorto-uni-iliac device does not have fixation hooks, but it does incorporate suprarenal

### Table 3

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SD: standard deviation.
fixation. Despite the relatively low DF seen in this study, in a group of 106 patients treated with the device in our centre, the rate of type I endoleak was 2.83% (long-term data)\textsuperscript{25} and it did not prove inferior compared with bifurcated prostheses over a midterm follow-up.\textsuperscript{26,27}

Overall, the presence of fixation hooks and barbs has significantly impacted on fixation. However, the presence of hooks, did macroscopically affect the integrity of the aortic wall. In vivo, we have not encountered any such complications in a cohort of 51 patients treated with the Anaconda over a midterm follow-up and we are not aware of any such complications in the literature.\textsuperscript{28,29} Moulding-balloon dilatation also had a positive effect, both proximally and distally. Balloon dilatation against proximal, distal and overlapping zones is applied when intra-operative type I endoleak has been encountered. This study suggests that it may in fact enhance fixation. However, we could not propose routine dilatation since, theoretically, it may lead to complications such as renal embolisation.

Regarding suprarenal support, it did not significantly affect fixation among these seven endografts; however, the device with the maximal fixation incorporates a long suprarenal support mechanism. It should be noted that suprarenal support has been linked with decreased renal function; however, most data so far are largely contradictory.\textsuperscript{10}

An important observation was the amount of force necessary to migrate the distal (iliac) legs of the prostheses, as iliac fixation does affect overall fixation.\textsuperscript{20,31} The Anaconda limbs recorded the maximal DF. This can probably be attributed to the fish-mouth ring stents, identical to the type of fixation mechanism incorporated at the Anaconda’s proximal portion. Any attempt to dislocate the iliac limbs produced a macroscopically visible movement of the ‘fish-mouth’ stents, which increased the friction of the vessel wall. The other devices incorporate iliac limbs made of Z stents.

The limitations of this study include the fact that the cadaveric aortas used were not aneurysmal, the proximal and distal necks were not mechanically connected, and the tortuosity—angulation of the aortas could not be adequately reproduced. Additionally, we only used uniaxial DF in a non-pulsatile manner. The DFs in vivo are rotational and pulsatile. However, previous investigators using similar models applying uniaxial forces have reported similar results with various endografts.\textsuperscript{3–10,19} Finally, force-displacement curves could not be obtained owing to the study’s design and the use of a force gauge and not a dynamometer to assess fixation. A significant advantage of this study is the fact that the aortas used were human and not animal and were tested, in situ. This allows safer conclusions to be made, especially since, besides the properties of the vessel’s wall, the proximal necks in all models using animal aortas are significantly smaller in diameter.

**Conclusion**

This study has attempted to assess the proximal and distal fixation of seven different endovascular devices used in AAA repair, in an experimental model using human cadaveric aortas. The Zenith and Anaconda devices displayed the maximal proximal fixation. Fixation hooks and moulding-balloon dilatation seem to increase fixation. Suprarenal support per se did not affect the overall fixation.

**Conflict of Interest**

None.

**Funding**

None.

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Endograft Fixation


