Helical EndoStaples enhance endograft fixation in an experimental model using human cadaveric aortas

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Objective: **This study evaluated the contribution of Aptus EndoStaples (Aptus Endosystems, Sunnyvale, Calif) in the proximal fixation of eight endografts used in the endovascular repair of abdominal aortic aneurysms (EVAR).**

Methods: **Nine human cadaveric aortas were exposed, left in situ, and transected to serve as fixation zones. The Zenith (Cook, Bloomington, Ind), Anaconda (Vascutek, Inchinnan, Scotland, UK), Endurant (Medtronic, Minneapolis, Minn), Excluder (W. L. Gore and Associates, Flagstaff, Ariz), Aptus (Aptus Endosystems), Aorfix (Lombard Medical, Didcot, UK), Talent (Medtronic), and AneuRx (Medtronic) stent grafts were proximally deployed and caudal displacement force (DF) was applied via a force gauge, recording the DF required to dislocate each device ≥20 mm from the infrarenal neck. Measurements were repeated after four and six EndoStaples were applied at the proximal fixation zone, as well as after a Dacron graft was sutured at the proximal neck in standard fashion. Finally, a silicone tube was used as a control fixation zone to test the DF of grafts with EndoStaples in a material that exceeded the integrity of a typical human cadaveric aorta and provided a consistent substrate to examine the differential effect of variable degrees of EndoStaple implantation using zero, two, four, and six EndoStaples.**

Results: **In the cadaveric model, the mean DF required to dislocate the endografts without the application of EndoStaples was 19.73 ± 12.52 N; this increased to 49.72 ± 12.53 N ($P < .0001$) when four EndoStaples where applied and to 79.77 ± 28.04 N when six EndoStaples were applied ($P = .003$). The DF necessary to separate the conventionally hand-sutured Dacron graft from the aorta was 56 N. In the silicone tube model, the Aptus endograft without EndoStaples withstood 3.2 N of DF. The DF increased to 39 ± 3 N when two EndoStaples were added, to 71 ± 6 N when four were added, and to 98 ± 5 N when six were added. In eight of the 13 cadaver experiments conducted with four and six EndoStaples, the displacement occurred as a result of complete aortic transection proximal to the fixation site, indicating that aortic tissue integrity was the limiting factor in these experiments.**

Conclusions: **The fixation of eight different endografts was increased by a mean of 30 N with four Aptus EndoStaples and by a mean of 57 N with six EndoStaples in this model. Endostaples can increase endograft fixation to levels equivalent or superior to that of a hand-sewn anastomosis. The application of six EndoStaples results in aortic tissue failure above the fixation zone, demonstrating fixation strength that exceeds inherent aortic integrity in these cadavers. (J Vasc Surg 2012;55:1726-33.)**

Clinical Relevance: **The proximal fixation of an endovascular device in the endovascular repair of abdominal aortic aneurysms (EVAR) is of crucial importance to avoid complications such as kinking, migration, and endoleak. This study represents the first attempt to quantify the effect of a new innovative device (Aptus EndoStaples) aimed to enhance endograft fixation. A cadaveric model, which resembles the forces applied onto the endovascular devices in vivo, was chosen to test the effect of the EndoStaples. The results suggest that endograft fixation is significantly better after the application of the EndoStaples, to an extent where it surpasses the inherent durability of the vessel wall.**

Proximal endograft fixation is a known determinant of chronic integrity and success of endovascular aneurysm repair (EVAR). Failure of proximal fixation as a result of longitudinal migration or aortic dilatation beyond the nominal diameter of the endograft can result in a late type I endoleak and aortic rupture. Other etiologies, such as unfavorable contour of the proximal neck, might lead to proximal endograft failure, but the experimental protocol in the following report does not address such issues because unfavorable necks (short, wide, highly angulated, and extremely tapered) are usually contraindications for EVAR. Failure of anastomotic integrity in open aortic reconstruction is typically not a result of suture or graft failure but rather failure of the tissue incorporated by the suture.[1-4]

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Conversely, endografts maintain their position in the aorta through a variety of features incorporated into the endograft design and procedure, including radial force, columnar rigidity, and suprarenal or infrarenal barbs.[5-7] The proximal fixation of typical endovascular grafts cannot be fully controlled by the operator during implantation and is maximized by a series of favorable anatomic features to include length of the nondilated aortic neck available for graft apposition, consistency of diameter (ie, lack of taper), lack of tortuosity, and the absence of mural thrombus or atherosclerotic plaque.[8,9]

Rarely are all of these conditions present in patients with aortic aneurysmal disease, resulting in a variable degree of compromise in endograft fixation dependent on the degree of compromise in each of these anatomic features. In some cases, however, molding balloon inflation against the proximal neck increases sealing of endograft; moreover, fixation, mostly of endografts that use hooks or barbs, is improved by balloon inflation. Additional stents or aortic extenders and mostly balloon-expandable cuffs assist sealing and apposition in some circumstances as well. Endograft fixation is therefore dependent on a variety of anatomic variables, and the degree of integrity achieved at the time of implantation can only be estimated in subjective terms.

The integrity of conventional hand-sutured grafts generally depends on the integrity of the tissue in which the sutures are placed, apart from the reliability of the surgeon's technical skills. The reproduction of the basic mechanism of suture fixation using an endovascular staple has the potential to allow endograft implantation to attain the integrity of a hand-sutured open anastomosis and to achieve this degree of fixation in different endograft designs not strictly dependent on their inherent fixation features.

To evaluate the contribution of various endograft features and designs to aortic fixation, prior investigators have used diverse experimental models[1,2,10-15] in human or animal cadaveric aortas to evaluate displacement force (DF). In a previous study[16] we assessed the proximal, distal, and overall fixation of seven aortic endografts (Anaconda [Vascutek, Inchinnan, Scotland, UK], Endofit aortouniiliac [Endomed, Phoenix, Ariz], Endurant [Medtronic, Minneapolis, Minn], Endologix Powerlink [Endologix, Irvine, Calif], Excluder [W. L. Gore and Assoc, Flagstaff, Ariz], Talent [Medtronic], and Zenith [Cook, Bloomington, Ind]) premolding and postmolding balloon inflation in a human cadaveric model. Hooks, barbs, anchors, and molding balloon inflation significantly increased fixation; the presence of a suprarenal stent did not affect fixation, except when the suprarenal stent also had hooks or barbs. Results from previous studies were consistent[10-14] with our findings. Endograft fixation in these studies did not exceed a DF of 40 N,[1,2,10-15] which is significantly inferior to the DF achieved in conventional hand-sewn vascular anastomoses, which ranged from 40 to 150 N.[1,2,14,16,17]

The helical EndoStaple (Aptus EndoStapling System, Aptus Endosystems, Sunnyvale, Calif) was designed to improve fixation and sealing for the Aptus Endosystems endograft and is also compatible for use with other commercially available endografts.[18,19] The Aptus EndoStaple is a helical "screw-like" metal alloy, 4.5 mm in length and 3.0 mm in diameter, made of a wire that measures 0.5 mm in diameter. It features a tapered needlepoint that allows penetration through nondiseased and diffusely calcified vascular tissue and prevents overpenetration. The operator chooses the location and number of EndoStaples based on clinical conditions and preoperative aortic imaging.

This study evaluated the effect of using four and six Aptus EndoStaples to augment the fixation of various endografts in a model using human cadaveric aortas. The fixation of the devices after the application of the EndoStaples was also compared with a hand-sewn anastomosis, acting as the standard reference.

METHODS

Human cadavers (Medical Anatomy Laboratory, University of Maryland Medical School, Baltimore, Md) without evidence of intra-abdominal pathology, sepsis, or abdominal trauma were used to conduct these experiments. Eight endografts were used: Anaconda, Endurant, Excluder, Talent, Zenith, Aptus Endovascular AAA Repair System, Aorfix (Lombard Medical, Didcot, UK), and AneuRx (Medtronic). These endografts represent a broad range of endograft fixation technologies and significantly different eras of endograft development. Table I summarizes the characteristics of the devices.

Through a midline laparotomy, the retroperitoneum was entered and the aorta was exposed from the diaphragmatic hiatus through the common iliac bifurcation. The diameter of the aorta was measured in the following manner: Arterial clamps were applied at the level of the suprarenal aorta, the renal arteries, the common iliac arteries, and any lumbar or other tributary vessels that would prevent aortic pressurization. The isolated abdominal aorta was pressurized with normal saline at 100 mm Hg through the inferior mesenteric artery stump, and the outer diameter of the vessel was measured to determine the physiologic diameter of the aorta at typical aortic intraluminal pressure and temperature. Unfortunately, the accomplished model was not a pulsatile one. The pressure we exerted was continuous because it represents an easier model to work with but still mimics a "high" normal mean aortic pressure.

The diameter was measured with a caliper at locations 0, 20, and 40 mm below the lowest renal artery. After measurement, the aorta was transected 40 mm below the origin of the most distal renal artery, producing the "experimental proximal fixation zone," as previously described.[1,2,9-14] Only proximal fixation was assessed, therefore, the iliac arteries were not surgically prepared.

Each endograft was deployed with 20 mm of longitudinal apposition in the proximal aorta. The infrarenal aorta was used for two separate tests, when possible, by using the distal 20 mm of the 40-mm section of infrarenal aorta for the first test and the more proximal 20 mm of the infrarenal aorta for the second experiment. A total of 18 infrarenal aortic fixation zones were used in these human cadavers.

Table I. Characteristics of the eight endografts used in the study

Name	*Fabric*	*Type of device*	*Proximal fixation*	*1st covered stent at sealing zone*	*Configuration of the skeleton*	*Fixation hooks, barbs, pins*
Anaconda Vascutek (Inchinnan, Scotland, UK)	Woven polyester	3 pieces, bifurcated	Infrarenal	2 independent SE nitinol fish-mouth ring stents with 8-mm gap	Exoskeleton	Yes on the second stent, 4 pairs (2 mm in length)
Zenith Cook (Bloomington, Ind)	Dacron	3 pieces, bifurcated	Suprarenal, 26-mm length	SE stainless steel Z stents, 17-mm (22) length	Exoskeleton (only stents at landing zones are internal)	Yes on the SR stent, 10 fixation barbs (3 mm in length)
Endurant Medtronic (Minneapolis, Minn)	Multifilament polyester	2 pieces, bifurcated	Suprarenal, 15-mm length	2 SE nitinol M stents, 8-mm length, 2-mm internal gap	Exoskeleton	Yes on the SR stent, 5 pairs fixation barbs (2 mm in length)
Talent Medtronic (Minneapolis, Minn)	Polyester	2 pieces, bifurcated	Suprarenal, 15-mm length	SE nitinol Z stent 15 mm + 8 mm with overlapping = 20 mm	Exoskeleton	No
Excluder Gore (Flagstaff, Ariz)	PTFE	2 pieces, bifurcated	Infrarenal	Independent asymmetric nitinol Z and M stents, approx 15 mm	Exoskeleton	Yes on the 1st stent, 8 pairs of 2-mm pins
AneuRx Medtronic (Minneapolis, Minn)	Woven polyester	2 pieces, bifurcated	Infrarenal	Unibody rhomboid skeleton (metal web), nitinol	Exoskeleton	No
Aorfix Lombard Medical (Didcot, UK)	Woven polyester	2 pieces, bifurcated	Infrarenal	Multiple fish-mouth ring stents (circular nitinol wire)	Exoskeleton	Yes, 4 pairs of anchors
Aptus Endosystems (Sunnyvale, Calif)	Woven polyester	3 pieces, bifurcated	Infrarenal with short transrenal stent	12-mm nitinol rhomboid stent	Exoskeleton	EndoStaples

PTFE, Polytetrafluoroethylene; *SE,* self-expanding; *SR,* suprarenal.

The temperature of the cadaveric aorta was maintained at 37°C with a warm normal saline, with irrigation consistently monitored with digital thermometry. Normal saline at 37°C was also used during endograft insertion and deployment to ensure adequate expansion of the nitinol components. The oversizing that was applied in each case is presented in Table II. The accurate positioning, deployment, and fixation of the devices were confirmed by visual inspection. After accurate deployment was achieved, a compliant Reliant molding balloon (Medtronic) was inflated at the fixation to reproduce the enhanced apposition and fixation of endografts demonstrated in prior work.[15]

A Chatillon Digital Force Gauge (DFS series; Chatillon, Largo, Fla) was used to measure DFs, in all cases. This DFS has been previously validated.[2,14] A Kevlar cord (DuPont, Wilmington, Del), able to withstand 150 N of force without deformation, was attached to the distal aspect of each endograft main body (Fig 1). The distal end of the Kevlar cord was subsequently attached to the Chatillon DFS gauge at a 15° angle.[6,15] A caudal manual distraction force was gradually applied. The DF necessary to dislocate (pull out) the graft from its proximal fixation site by at least 20 mm was measured after the proximal deployment of each device. Of the eight devices used in this analysis, five (Anaconda, Endurant, Excluder, Talent, and Zenith) were previously characterized for proximal fixation without EndoStaples using an identical protocol.[15]

The first set of measurements was obtained for the endografts fully deployed and fixated at the proximal zone without applying the EndoStaples (group 1). The Aptus endograft was also evaluated in this first group, but it should be noted that the Aptus endograft is not designed for use, nor is it indicated for clinical use, without the EndoStaples for fixation.

The next set of measurements was obtained after new endografts were deployed in new fixation zones with the addition of four EndoStaples applied circumferentially and transmurally through the aortic wall (Fig 2) using the Aptus Steerable EndoGuide and Aptus EndoStaple Applier (group 2). The diameter of the grafts and aortas did not differ between the two groups. Positioning and deployment of the EndoStaples was confirmed by visual inspection. Molding balloon inflation was used before EndoStapling as in all prior experiments without EndoStaples. The DF necessary to dislocate the graft from its proximal fixation site for at least 20 mm was measured.

The final set of measurements was made after six EndoStaples were deployed (group 3). Of the eight endografts used, five (Aptus, Talent, Zenith, Endurant, and

Table II. Sizes of the aortic necks, sizes of the devices deployed, number of staples applied to the proximal neck, and displacement force (*DF*) necessary to dislocate the device ≥20 mm from the proximal aortic neck

Device	*Device proximal diameter (mm)*	*Aorta size OD (mm)*	*EndoStaples applied (No.)*	*Migration resistance force (DF in N)*
Group 1				
Talent	24	20	None	9.10
Anaconda	23	20	None	35.70
Excluder	23	20	None	18.00
Zenith	24	20	None	36.80
Endurant	23	20	None	30.10
AneuRx	25	22	None	7.48
Aorfix[a]	24	16	None	10.07
Aptus[b]	24	23	None	10.59
Group 2				
Talent	26	23	4	41.12
Anaconda	23	18	4	49.12
Excluder	26	19	4	74.20
Zenith	26	22	4	57.42
Endurant	25	21	4	53.05
AneuRx	25	22	4	50.01
Aorfix	24	16	4	36.23
Aptus	24	23	4	36.60
Group 3				
Talent	26	22	6	56.68
Anaconda	25	23	6	80.61
Zenith	26	20	6	126.33
Endurant	25	21	6	76.24
Aptus	24	20	6	59.00
Hand-sutured anastomosis				
Dacron tube graft	20	20	Prolene 3-0 suture	56

OD, Outer diameter.
[a]Aorfix endograft was not matched to the aorta internal diameter, which may have inhibited the penetration of the fixation barbs into the tissue.
[b]Aptus endograft is not designed to be used or indicated for clinical use without the EndoStaples for fixation.

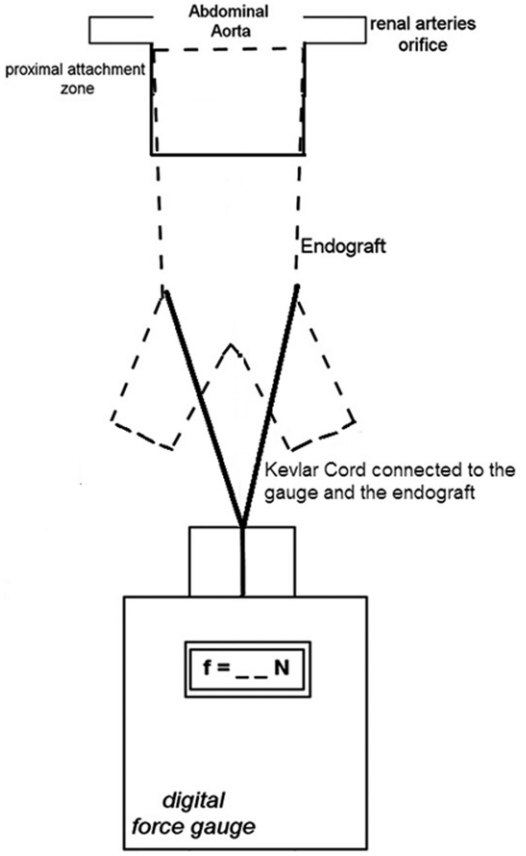

Fig 1. Schematic description of the experiment.

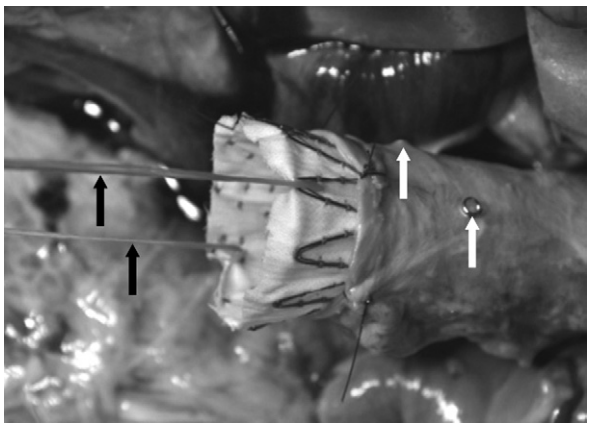

Fig 2. A Zenith endograft fixed with four EndoStaples (two of them shown by the *white arrows*). The *black arrows* indicate the Kevlar cord attached to the force gauge.

Anaconda) were assessed using six EndoStaples as a result of the limited endograft inventory available for testing.

A failure of aortic tissue integrity occurred in 100% of the experiments after implanting six EndoStaples. The ultimate fixation integrity of the EndoStaples could not be evaluated in these experiments because it exceeded the native integrity of the aorta. To assess the displacement force necessary to cause failure of the endograft and EndoStaple fixation rather than the failure of the substrate vessel, a silicone tube was used. This also allowed a better assessment of the potential degree of fixation for four and six EndoStaples in a consistent substrate able to withstand forces in excess of normal vascular tissue. Aptus endografts (24 mm in diameter) were deployed in 10-cm-long transparent silicone tubes with a 22-mm inner diameter and 3 ± 0.5-mm wall thickness. The method of endograft implantation, including molding balloon inflation was identical to all prior experiments.

In separate DF experiments, zero, two, four, and six EndoStaples were used. The DF necessary to pull out the graft from its fixation site by at least 20 mm was measured. Finally, a handsewn end-to-end anastomosis with a running 3-0 Prolene suture (Ethicon, Somerville, NJ) was performed between a 20-mm Dacron graft (DuPont, Wilmington, Del) and the aortic stump. Pull-out force was similarly applied to the Dacron graft.

Table III. Displacement force (*DF*) in Newtons necessary to dislocate the device ≥20 mm from the proximal cadaveric aortic neck

Device	*Self-fixed (group 1)*	*Reinforced by 4 EndoStaples (group 2)*	*Increase in DF between groups 1 and 2, Newton (%)*
Talent	9.10	41.12 (endograft pulled out)	32.02 (352)
Anaconda	35.70	49,12 (aortic tearing point)	13.42 (38)
Excluder	18.00	74,20 (aortic tearing point)	56.20 (312)
Zenith	36.80	57,42 (aortic tearing point)	20.62 (56)
Endurant	30.10	53.05 (endograft pulled out)	22.95 (76)
AneuRx	7.48	50.01 (endograft pulled out)	42.53 (569)
Aorfix	10.07	36.23 (endograft pulled out)	26.16 (264)
Aptus	10.59	36.60 (endograft pulled out)	26.01 (246)
Mean (SD)	19.73 (12.52)	49.72 (12.53)	$P < .0001$

SD, Standard deviation.

Table IV. Displacement force (*DF*) in Newtons necessary to dislocate the device ≥20 mm from the proximal cadaveric aortic neck

Device	*Self-fixed (group 1)*	*Reinforced by 6 EndoStaples (group 3)*	*Increase in DF between groups 1 and 3, Newton (%)*
Talent	9.10	56.68 (aortic tearing point)	47.58 (523)
Anaconda	35.70	80.61 (aortic tearing point)	44.91 (125)
Zenith	36.80	126.33 (aortic tearing point)	89.53 (243)
Endurant	30.10	76.24 (aortic tearing point)	46.14 (153)
Aptus	10.59	59.00 (aortic tearing point)	48.41 (457)
Mean (SD)	24.46 (13.59)	79.77 (28.04)	$P = .003$

SD, Standard deviation.

Statistical analysis. All analyses were made using SPSS 17 software (SPSS Inc, Chicago, Ill). All variables were analyzed using the Shapiro-Wilk test to assess the normality of each distribution. Mean and standard deviation are given for all variables. The paired and nonpaired *t*-test was used accordingly to compare differences between two groups. A value of $P < .05$ was considered statistically significant.

RESULTS

The cadavers (all men) were a mean age of 56 years (range, 51-84 years). The mean outer diameter of the aortas was 20.13 ± 2.03 mm for group 1, 20.5 ± 2.56 mm for group 2, and 21.2 ± 1.30 mm for the five cadaveric aortas in group 3. None of the exposed aortas was aneurysmal, tapered, or reverse-tapered in macroscopic anatomic configuration throughout the 40-mm proximal fixation zone. All cadaveric aortas had minimal to mild calcification macroscopically. No thrombus was detected before graft insertion. Table II summarizes the proximal diameters of the devices used, the diameters of the corresponding cadaveric aortas, and the amount of oversizing applied in each case. Overall results are summarized in Tables II, III, and IV.

The mean DF necessary to dislocate the graft ≥20 mm from the proximal fixation site was measured. In group 1 (Tables II and III), this was 19.73 ± 12.52 N (range, 7.48-36.80 N) after balloon inflation; in group 2, when the endografts were reinforced with four EndoStaples (group 2), the DF was increased to 49.72 ± 12.53 N (range, 35.23-74.2 N; $P < .0001$); and in group 3, when the endografts were reinforced with six EndoStaples (Tables II and IV), the DF was increased to 79.77 ± 28.04 N ($P = .003$ vs the five endografts in group 1 without EndoStaple fixation).

In all experiments using six EndoStaples (Tables IV and V, Fig 3) and in three of eight (37.5%) experiments using four EndoStaples (Tables III and V), the failure mechanism that allowed endograft displacement was aortic tissue failure (ie, transection) proximal to the fixation zone (Fig 3). In these cases, the DF was a measure of aortic integrity rather than fixation site integrity because the fixation integrity exceeded the inherent strength of the aortic substrate. For this reason, the actual DF value in these experiments represents the ultimate strength of the tissue and not the combined strength of the endograft and EndoStaples. To estimate the DF required for the failure of the EndoStaple–endograft combination rather than the substrate, a mechanical model of silicone was used. Table VI summarizes the results of the silicone tube model experiment.

In group 1, endografts equipped with fixation hooks, barbs, anchors, or pins (Zenith, Anaconda, Endurant, Excluder, Aorfix) displayed a significantly higher DF compared with devices without such fixation modalities (Aptus,

Table V. Displacement force (*DF*) in Newtons (*N*) necessary to disrupt a hand-sutured anastomosis—representative of the maximal endurance of the aortic neck

Studies	*DF, N*	*Surgical graft, type of anastomoses*	*Suture*	*Aortic model*
Veerapen[17]	85	Dacron, end-to-end	Running 3-0 Prolene	Human cadaveric
Resch[12]	150	Dacron, end-to-end	Running 4-0 Gore-Tex	Human cadaveric
Arko[1]	40	Dacron, end-to-end	Running 4-0 Prolene	Ovine alive
Murphy[2]	40.6	Dacron, unavailable	Running 4-0 Prolene	Ovine alive
Melas[14]	76.2	PTFE, end-to-end	Running 4-0 Gore-Tex	Human cadaveric

PTFE, Polytetrafluoroethylene.

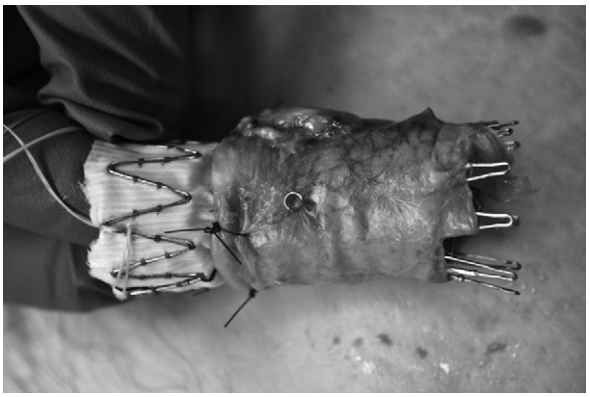

Fig 3. This Zenith endograft was reinforced with six EndoStaples before the application of displacement force (DF). The endograft was pulled out attached to the torn aortic tissue, proving the failure of the aortic tissue proximal to the fixation zone.

AneuRx, Talent) after proximal graft deployment with balloon dilatation (26.13 ± 11.67 vs 9.05 ± 1.55 N; $P = .03$).

In group 2 (four EndoStaples), endografts equipped with fixation hooks, barbs, anchors, or pins (Zenith, Anaconda, Endurant, Excluder, Aorfix) did not display a significantly higher DF compared with devices without such fixation modalities (Aptus, AneuRx, Talent; mean, 54 ± 13.78 vs 32.87 ± 22.4 N; $P = .24$).

In group 3 (six EndoStaples), endografts equipped with fixation hooks, barbs, anchors, or pins (Zenith, Anaconda, Endurant) did not display a significantly higher DF compared with devices without such fixation modalities (Aptus, Talent; mean, 94.39 ± 27.74 vs 57.84 ± 1.64 N; $P = .17$).

The DF required to dislodge the hand-sewn Dacron graft anastomosis was 56 N, which is lower than the mean DF for endografts stapled with six EndoStaples.

DISCUSSION

This analysis represents the first attempt to evaluate the effect of EndoStaple-assisted proximal fixation in various endografts using human cadaveric aortas. The findings suggest that the application of EndoStaples during EVAR may improve resistance to caudal DFs.

EndoStaples can be applied during the initial endograft deployment to enhance fixation, such as in the case of unfavorable aortic neck anatomy, or at a later date to treat device-related complications (endoleak type I, migration). Four to six EndoStaples have been deployed in previous studies.[18,19] The EndoStaples can be used in conjunction with the Aptus stent graft or with other commercially available devices (Zenith, Excluder, AneuRx, Endurant, and Talent).

The Aptus Endograft and EndoStapling System were used in a U.S. Food and Drug Administration (FDA) phase I U.S. trial in 21 patients, which completed enrollment in 2007, and in an FDA phase II U.S. trial in 155 patients that completed enrollment in 2009.[16,18] During these trials, 906 EndoStaples were deployed. At the time of writing, there were no known reports of EndoStaple fracture or EndoStaple migration with a follow-up of between 24 and 60 months.

Overall, this study included eight different commercially available endografts, each one using distinct modalities to enhance aortic fixation (Table I). So far, only a handful of studies have tried to assess the fixation of various EVAR devices, mainly in DF tolerance in human cadaveric,[11,14,16,17] in vivo ovine,[1,2] and cadaveric ovine[20] aortas, or in silicone models.[21] This is the first analysis to include the Aorfix and Aptus devices.

According to previous findings, three different modalities have been proven to significantly augment fixation: (1) hooks, barbs, anchors, or pins within the proximal fixation mechanism,[11,14,16] (2) molding balloon inflation at the attachment zone,[14,16] and (3) balloon-expandable stents at the proximal attachment zone.[17] The maximal DF that any device could tolerate in all these analyses was <40 N,[1,2,11,14,16,17,20] even when molding balloon inflation was used.[14,16,17] A traditional hand-sutured anastomosis can bear pull-out forces of 40 to 150 N in cadaveric or ovine models (Table V).[1,2,5,14,16,17]

Previous investigators have demonstrated that endografts are exposed to pulsatile drag forces of 3.8 to 6 N in an aneurysmal aorta with a friendly anatomy and up to 14 N in more hostile anatomies.[7,22] These figures represent only an acute estimate of the forces an endograft experiences and cannot account for the effects of these forces over extended periods of time. In addition, although current endografts can achieve resistance to caudal migration of 40 N, this only occurs in the most favorable anatomic conditions, so most clinical applications result in a resistance to caudal migration that is impaired to a minor or major degree, depending

Table VI. Displacement force (*DF*) in Newtons (*N*) necessary to dislocate the device ≥20 mm from the silicone tube fixation zone

	Endostaple pull-out force (N) in silicone tube model (Aptus endograft)			
Sample	*EndoStaples, No.*	*2 EndoStaples*	*4 EndoStaples*	*6 EndoStaples*
1	3	40	71	98
2	4	37	79	98
3	3	36	61	92
4	3	40	69	97
5	3	44	73	105
Mean (SD)	3.2 (.45)	39.4 (3.13)	70.6 (6.54)	98 (4.63)

SD, Standard deviation.

on a constellation of anatomic variables. For all of these reasons, some endografts will be vulnerable to caudal migration when exposed to continuous pulsatile blood flow, especially in unfavorable anatomies.[23-25]

In this study, we evaluated the contribution of the Aptus EndoStaples in improving the proximal fixation of almost every commercially available endograft. Four or six EndoStaples significantly increased proximal fixation against caudal DFs. In fact, the application of four EndoStaples produced a significant increase in fixation; a mean of 49.72 N was necessary to dislodge the devices, which is higher than the aforementioned 40 N (maximal DF that any endograft could tolerate in previous analyses, without the application of EndoStaples). Actually, after applying four EndoStaples to the proximal neck, the fixation of the weakest device in this series was higher than the fixation of the strongest nonstapled endograft.[7,22] The force necessary to dislodge the devices stapled with six EndoStaples (Table IV) was even higher (mean, 79.77 ± 28.04 N) than the force necessary to dislodge the hand-sewn graft (56 N), which comprises the gold standard for a vascular anastomosis.

When six EndoStaples were added to any of the endografts in group 3 (Table IV), the amount of fixation produced was higher than the aortic tissue structural integrity, leading to aortic tissue failure in all instances. The same phenomenon appeared using the Zenith, Anaconda, and Excluder devices when four EndoStaples were added (Table III). This implies that by adding EndoStaples to the proximal fixating zone of an endograft, fixation is increased to a level surpassing aortic tissue structural integrity. As a result, the fixation is no longer device-dependent with these devices but is related to the quality and strength of the aortic tissue.

In the model using a silicone tube, which is significantly more resistant to tearing than cadaveric aortic tissue, the mean DF necessary to dislocate the Aptus endograft without the application of EndoStaples was 3.2 N. The Aptus endograft is not designed for use without EndoStaples. The measurement in this model without EndoStaples serves only as a baseline value to show the difference from the next measurements. Adding two EndoStaples increased the DF to 39.4 N, adding four EndoStaples to 70.6 N, and adding six to 98 N (Table VI). The mean DF necessary to tear the cadaveric aortic tissue (mean aortic tearing point from Tables III and IV) in this analysis was 72.45 ± 24.45 N. Comparing this value with the DF in the silicone tube, it is implied that four EndoStaples offer fixation (70.6 N) similar to the mean aortic tearing point, whereas six EndoStaples offer fixation superior than the mean aortic tearing limit (98 N).

Another interesting observation is that endografts without proximal hooks, barbs, or other sophisticated mechanisms, which would be expected to withstand less force (AneuRx, Talent), also showed a significant increase in fixation after EndoStapling. There were no major differences between such devices and endografts that did not bear these mechanisms once staples were applied. The data suggest that EndoStapling transforms endografts with the lowest DF to the level of the best self-fixed endografts.

An important observation in this analysis was the DF necessary to dislocate the Aorfix device. The DF was as low as 10 N without the application of EndoStaples. This is probably a significant underestimation of the endograft fixation capability in vivo because it was deployed into a small (16 mm) aortic neck (Table II), and the significant oversizing did not allow adequate anchor penetration into the vessel wall. As a result, the endograft resistance to displacement was similar to endografts lacking barbs or pins.

The limitations of this study include the use of human cadaveric aortas and not animal aortas from living specimens, which was done because the latter are smaller in diameter and the required oversizing is unacceptable. The aortas were not aneurysmal, but instead, we used only the infrarenal neck as a fixation zone.

Only uniaxial DF in a nonpulsatile manner was applied, due to technical limitations owing to the study's design. The DFs applied on an endograft deployed in vivo are rotational and pulsatile. We did not have the ability to reproduce such a model in cadaveric aortas and still apply maximum load on the grafts to find out the ultimate pull-out force. However, previous investigators using similar models applying uniaxial forces have reported similar results with various endografts.[1,2,10-15,20]

Unfortunately, this analysis suffers from small sample size because we were unable to acquire many samples of each endograft type; however, the results are overwhelming

because they showed large increases in DF irrespective of endograft type. Our results imply that endostapling augments fixation in each competing endograft. More specimens and tests are needed for safer conclusions. Moreover, this protocol was unable to prove whether EndoStaples deal with apposition failure issues.

CONCLUSIONS

This study documents the effect of Aptus EndoStaples on the proximal fixation of various endografts in an experimental model using human cadaveric aortas. EndoStaples significantly increased endograft fixation in every case. So far, it is widely accepted that the fixation of current endografts is based on the structural and mechanical characteristics of a given design.[1,2,10,13,15,17,19] In most of the available endografts, six EndoStaples offered fixation that overwhelmed the mean aortic tissue integrity. This analysis suggests that the application of EndoStaples augments fixation to levels that may surpass the fixation of a conventional hand-sewn vascular anastomosis regarding pull-out resistance. It is implied that EndoStapling technology converts the device-dependant fixation of current endograft technology to an aortic tissue-dependant fixation similar to that observed in open aortic reconstructive techniques. If true, this would allow endovascular techniques for aortic reconstruction to mimic the failure characteristics of open aortic reconstruction, which are a function of aortic tissue integrity rather than device failure.

AUTHOR CONTRIBUTIONS

Conception and design: NM, TP, AS, DD
Analysis and interpretation: AS, NS
Data collection: NM, TP
Writing the article: NM, AS
Critical revision of the article: AS, DK
Final approval of the article: NM, TP, AS, NS, DK, DD
Statistical analysis: AS
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Overall responsibility: NS, DD

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