◆CLINICAL INVESTIGATION ◆

Primary EndoAnchoring in the Endovascular Repair of Abdominal Aortic Aneurysms With an Unfavorable Neck

Theodosios Perdikides MD[1]; Nikolaos Melas, MD, PhD[1]; Konstantinos Lagios, MD[2]; Athanasios Saratzis, MBBS, MRCS[1]; Athanasios Siafakas, MD[1]; Ioannis Bountouris, MD[1]; Nikolaos Kouris, MD[3]; Murat Avci, MD[4]; Danyel A.F. Van den Heuvel, MD[5]; and Jean-Paul P.M. de Vries, MD, PhD[4]

Departments of [1]Vascular Surgery, [2]Interventional Radiology, and [3]Anesthesiology, Hellenic Air Force Hospital, Athens, Greece. Departments of [4]Vascular Surgery and [5]Interventional Radiology, St. Antonius Hospital, Nieuwegein, The Netherlands.

Purpose: To investigate the feasibility and early results of endoanchoring (endostapling) using a new commercially available device as an adjunctive procedure during endovascular aneurysm repair (EVAR) of abdominal aortic aneurysms (AAAs) with an unfavorable proximal neck.
Methods: Between June 2010 and May 2012, 13 consecutive patients (all men; median age 73 years, range 62–82) were prospectively enrolled in a 2-center registry to follow outcomes of adjunctive primary endoanchoring (Aptus HeliFX Aortic Securement System) of the proximal endograft to enhance proximal graft fixation and sealing during EVAR. Indications for proximal neck endoanchoring included at least one of the following: neck angulation 45° to 90°, length 8 to 15 mm, diameter 29 to 33 mm, conical neck configuration, or an irregularly shaped neck. The median AAA diameter was 56 mm (range 50–98). The Endurant stent-graft was implanted in 4 patients and the Zenith device in 9.
Results: A median of 4 endoanchors were implanted per patient (range 3–10) in adjunctive procedures that required a median 12 minutes (range 7–20). Intraoperatively, 2 proximal type I endoleaks were present following endoanchor implantation (85% primary technical success); a cuff was deployed in 1 case, which successfully sealed the endoleak (92% assisted primary technical success). The second proximal type I endoleak was minute and sealed spontaneously within 30 days. No further major device-related complications occurred intraoperatively. In the 30-day perioperative period, the only procedure-related complications were 2 type II endoleaks, which required no intervention. Over a median follow-up of 7 months (range 2–17), no further complications occurred apart from an asymptomatic internal iliac artery occlusion and a non-lethal myocardial infarction at 9 months. The type II endoleaks spontaneously sealed. No endograft migration was noticed nor loss of endoanchor integrity. No deaths occurred throughout follow-up.
Conclusion: Primary endoanchoring using the HeliFX aortic securement system is feasible, and early results were promising in this series.

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Key words: abdominal aortic aneurysm, endovascular aneurysm repair, proximal fixation, proximal neck, angulated neck, short neck, conical neck, endoleak, type I endoleak, type II endoleak, endostaples, endoanchor

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Address for correspondence and reprints: Mr. Athanasios Saratzis, MBBS, MRCS, Department of Vascular Surgery, Hellenic Air Force Hospital, Athens, Greece. E-mail: *a_saratzis@yahoo.gr*

Proximal endograft fixation and sealing is a known determinant of chronic integrity and sac exclusion in endovascular aneurysm repair (EVAR) of abdominal aortic aneurysms (AAAs).[1,2] Compromised proximal fixation or sealing may lead to migration and type Ia endoleak, with subsequent sac repressurization necessitating secondary endoluminal interventions or even conversion to open repair.[2] These major complications usually increase morbidity, and if left undiagnosed, may lead to rupture, adding substantial mortality to the technique.

In order to achieve adequate proximal sealing and fixation, the length, diameter, angulation, contour, and tissue quality (calcification, thrombus) of the proximal aortic neck should conform to certain device-specific criteria.[3–6] The design of contemporary endografts involves specific mechanisms to help accomplish and maintain adequate seal and fixation, such as columnar strength, suprarenal bare stents, and suprarenal or infrarenal barbs, pins, hooks, and/or anchors.[7–9] However, when the morphology of the proximal neck is unfavorable, even these modalities cannot guarantee adequate fixation.[4,10]

Some manufacturers have recently developed endoluminal aortic staples (endostaples or endoanchors) to aid device fixation in unfavorable necks.[11–13] We studied one such new endoanchoring system[12] as an adjunctive fixation tool for use with various commercial endografts being deployed in hostile neck anatomy, with the goal of preventing acute and late migration, proximal endoleak, and late neck dilatation.

METHODS

Study Design

All patients undergoing EVAR of an infrarenal AAA aided by primary proximal neck endoanchoring using the HeliFX Aortic Securement System (Aptus, Sunnyvale, CA, USA) and who provided written informed consent were entered into a prospective follow-up registry at baseline. All procedures were performed in 2 tertiary referral centers by vascular surgeons with previous experience using all devices involved.

Preoperative assessment included computed tomographic angiography (CTA) acquired at 1-mm intervals with 2- and 3-dimensional reconstruction in all cases. M2S Planning Software (M2S, West Lebanon, NH, USA) was used for preoperative planning based on cross-sectional imaging. A full medical history was taken, and vascular assessment was performed at baseline for all patients.

Patient Selection

Patients were candidates for EVAR if they had an AAA with a transverse diameter $>$5 cm or a rapidly increasing sac (by $>$0.5 cm in the prior 6 months). Anatomical criteria for primary proximal endoanchoring at the level of the proximal neck were (1) length $<$15 mm; (2) diameter $>$29 mm (inner wall to inner wall) measured on axial CTA scans; (3) angulation $>45^\circ$; (4) conical configuration;[14] (5) irregular shape (tapered, hourglass, barrel, bulged);[14] or (6) a combination of the above characteristics. Exclusion criteria for endoanchoring in this study were (1) neck length $<$8 mm, (2) neck diameter $>$34 mm (inner wall to inner wall), (3) neck angulation $>90^\circ$, (4) circumferential neck calcification that could jeopardize the penetration of the endoanchors in the aortic wall, (5) circumferential aortic mural pathology $>$2 mm in thickness, or (6) general contraindications for EVAR.

Device Specifications

The HeliFX Aortic Securement System (Fig. 1) was initially designed to provide fixation and augment sealing of the Aptus aortic endograft (Aptus Fortevo). However, the system has recently been approved in Europe and the US for use with the AneuRx (Medtronic Cardiovascular, Santa Rosa, CA, USA), Endurant (Medtronic Cardiovascular), Talent (Medtronic Cardiovascular), Excluder (W.L. Gore & Associates, Flagstaff, AZ, USA), and Zenith (Cook Inc., Bloomington, IN, USA) devices as (1) an adjunctive measure during the primary procedure to enhance proximal fixation and sealing and prevent migration or endoleak (de novo use) or (2) during reintervention to repair endografts that have migrated or developed a type I endoleak.[15] Aptus

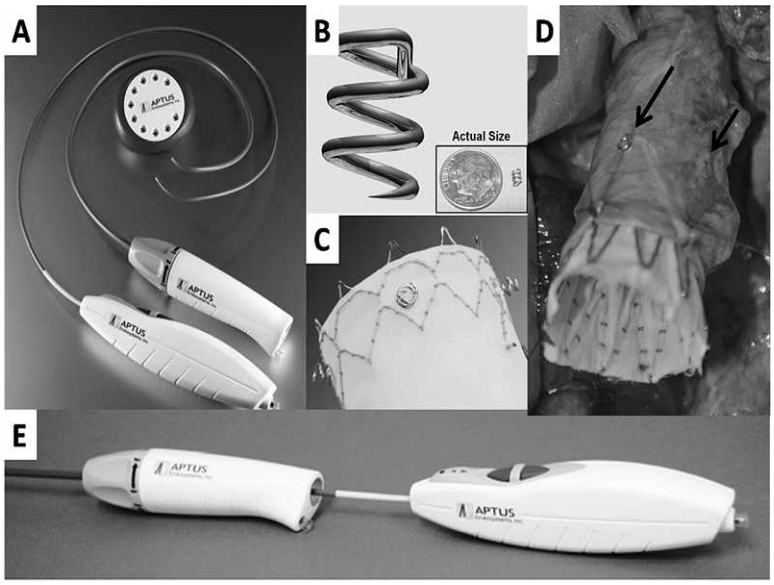

Figure 1 ◆ (**A**) Aptus Guide, Applier, and cassette. (**B**) The Aptus EndoAnchor. (**C**) The target zone for the anchors in an Aptus endograft. (**D**) Two EndoAnchors (or endostaples, arrows) have penetrated the aortic wall, fixing a Zenith graft in a cadaveric aorta. (**E**) Aptus electronically controlled applier inside the steerable guide.

EndoAnchors have already been described and analytically tested in a cadaveric protocol[13]; only a brief description is given herein.

The HeliFX Aortic Securement System consists of a deflectable 16-F Aptus Guide and an electronically controlled Aptus Applier (Fig. 1), with a 2-stage implantation sequence that allows retrieval and reimplantation of the endoanchor in a different spot. The Aptus EndoAnchor (Fig. 1B) is a 3.0-mm-diameter by 4.5-mm-long helix made of a metallic alloy (MP35N LT). The tapered needle point penetrates non-diseased vascular tissue, and the proximal cross bar is used to rotate the EndoAnchor during implantation and prevent over-penetration. The number of EndoAnchors required and site of implantation is based on the proximal diameter of the endograft and data from pre- and intraoperative imaging. Four endostaples is the minimum in most cases (anterior, posterior, and lateral); 6 are deployed in severely hostile necks. More can be deployed when proximal type I endoleak is documented intraoperatively.

Implantation Procedure

All procedures were carried out in a fully equipped angiographic suite under regional anesthesia and fluoroscopic control. Following femoral artery exposure, the main body delivery system of the endograft was inserted and advanced into position. The main body (top) of the endograft was deployed just distal to the orifice of the lowermost renal artery. Access was gained via the contralateral stump of the main body for application of the EndoAnchors. The iliac limb extensions were deployed as usual. Angiography and selective intraoperative DynaCT (Siemens, Erlangen, Germany) were used to confirm aneurysm exclusion and to verify adequate penetration of the EndoAnchors, but intraoperative CT is not a requirement for EndoAnchor deployment.

Patient Sample

Between June 2010 and May 2012, 13 consecutive patients (all men; median age 73 years, range 62–82) with unfavorable neck anatomies were prospectively enrolled in the 2-center registry. The median AAA diameter was 56 mm (absolute range 50–98). None of the patients was considered at high risk for surgical repair. Comorbidities included myocardial infarction (n=2), heart failure (n=2), atrial fibrillation (n=3), diabetes (n=1), hyper-

tension (n=7), and chronic obstructive pulmonary dysfunction (n=3). Median neck dimensions were 16-mm length (8–35), 32-mm diameter (26–34), and 55° angulation (15–85). In the entire cohort, 1 patient fulfilled 1 criterion rendering the proximal neck unfavorable, 7 patients had 2 criteria, 4 patients had 3 criteria, and 1 patient had 4 criteria. Thus, the configurations were 8 angulated, 7 conical, 7 wide, 5 short, 2 bulged, 1 barrel, and 1 irregular. Two different stent-grafts (4 Endurant and 9 Zenith) were deployed with primary adjunctive endoanchoring using the HeliFX Aortic Securement System.

Follow-up

A full clinical examination was performed on every follow-up visit; all patients had CTA in the 1st, 6th, and 12th month post EVAR and annually thereafter to determine device migration, proximal neck and aneurysm sac diameters, and the presence of endoleaks. The integrity of the EndoAnchors and any late anchor-related complications were assessed. Angiography was reserved for endoleaks or graft limb occlusions that required reintervention.

Definitions

Primary technical success was defined as successful endograft and EndoAnchor deployment to exclude the aneurysm and achieve a patent graft without the need for additional intervention. Assisted primary technical success referred to aneurysm exclusion and a patent graft after an adjunctive intraoperative maneuver, such as cuff deployment. All complications (deployment-related and implant-related) were defined according to Chaikof et al.[16] Endoleaks were classified according to definitions provided by White et al.[17,18]; type II endoleaks were not considered major deployment-related complications.[17,18] Migration was defined according to Greenberg et al.[19] as $\geq$10-mm movement in a caudal or cranial direction. Postoperative renal impairment was defined as an increase in plasma creatinine exceeding 30% above baseline.[20]

Statistical Analysis

Data are presented as the median (absolute range) as appropriate for non-parametric data. The Wilcoxon test was used to compare the neck diameter pre/post EVAR. $P<0.05$ was considered significant. All data were analyzed using SPSS software (version 17.0; IBM Corporation, Somers, NY, USA).

RESULTS

From 3 to 10 EndoAnchors (median 4) were deployed successfully in each patient (Fig. 2); none was misplaced or misfired. In operations that lasted a median 110 minutes (95–130), the stapling time was 12 minutes (7–20). In all, a median 110 mL (80–140) of contrast was used.

A proximal type I endoleak was detected in 2 patients on completion angiography (85% primary technical success), although all EndoAnchors had successfully been deployed in both patients. A cuff was deployed in 1 patient without using an additional EndoAnchor, which successfully sealed the endoleak (92% assisted primary technical success). The cuff covered a small accessory renal artery (unilaterally) without any effect on renal function (creatinine levels remained unchanged throughout follow-up).

The other intraoperative type I endoleak was minute and deemed insignificant; no

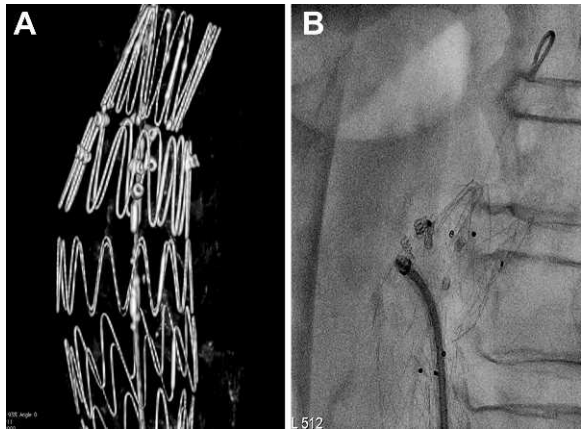

Figure 2 ◆ (**A**) Multiple Aptus EndoAnchors fixing a Zenith endograft. Notice the contour of the suprarenal and first sealing ring frame, which reflects the highly conical shape of this neck. (**B**) The implantation of EndoAnchors in an Endurant device.

further action was taken intraoperatively. Ten EndoAnchors had already been implanted, and the proximal neck could not accommodate a cuff due to its short length. Intraoperative DynaCT did not depict the endoleak, and it was not documented on the 30-day CT scan; the patient remained asymptomatic. Both patients had very challenging proximal neck anatomy, fulfilling 3 of the aforementioned criteria (wide, angulated, and conical in configuration). An intraoperative type II endoleak was also detected in 1 patient, but no intervention was deemed necessary. No further device-related events occurred intraoperatively.

Median hospital stay was 5 days (range 3–6). In the perioperative period ($\leq$30 days), another type II endoleak was detected on the 1-month CTA and was not treated. No migration, proximal endoleak type I, limb thrombosis, or any other major device-related complication occurred. Thirty-day mortality was zero. Post-implant syndrome complicated the postoperative period in 2 patients with a Zenith endograft; this resolved within hours with no further intervention.

During midterm follow-up (median 7 months, range 2–17), the 2 type II endoleaks sealed spontaneously. No further device-related complication occurred; no penetration of the EndoAnchors in adjacent structures was seen nor loss of EndoAnchor integrity. None of the patients developed an aortoenteric fistula secondary to the implantation of the EndoAnchors. There were no deaths; 1 patient suffered an acute myocardial infarction, and 1 asymptomatic occlusion of an internal iliac artery was detected on a follow-up CT at 12 months (no intervention). There was no migration; the overall longitudinal caudal movement of the endografts was zero. The diameter of the proximal infrarenal neck remained unchanged during follow-up (median 32 mm, range 26–34). None of the patients developed renal dysfunction throughout follow-up.

DISCUSSION

In our initial experience evaluating the use of EndoAnchors as a primary adjunctive procedure in EVAR for AAAs with a complex proximal neck, we found the implantation to be simple, relatively fast, and apparently effective over a median 7-month follow-up in which no migration, type I endoleak, or device-related complications occurred.

Proximal endograft fixation is crucial in EVAR to avoid migration or endoleak, both of which may have catastrophic sequelae. Most contemporary endografts incorporate various modalities to increase fixation, such as a design to increase radial force, columnar strength, suprarenal bare stents or crowns, and suprarenal or infrarenal barbs, pins, hooks, or anchors.[7,9,21] However, early or late type I proximal endoleak may still occur, especially in unfavorable necks. Deploying EndoAnchors at the proximal fixation zone during EVAR immediately increases proximal migration resistance of the endograft and can assist sealing, which may lower the possibility of early (intraoperative) type I endoleaks.[13]

Late type I endoleak is a different entity and represents a failure of the "anastomotic connection" of the endograft as a result of either continued neck dilatation beyond the nominal diameter of the endograft or a failure of endograft fixation, resulting in migration to a location that no longer provides adequate sealing. These two mechanisms of late type I endoleak (continued aortic dilatation and longitudinal migration) are dependent on the type of device being used, the configuration of the neck, technical expertise, and the disease process (continued dilatation of the neck). The adjunctive deployment of EndoAnchors may reduce the possibility of longitudinal migration, thereby decreasing the risk of late type I endoleak.

Current data suggest that unfavorable proximal neck anatomy is an independent predictor of adverse events following infrarenal EVAR, and these anatomies are associated with a higher incidence of endoleak or migration.[22,23] Albertini et al.[14] found that neck angulation and neck diameter were the risk factors most significantly related to proximal perigraft endoleak and migration. Similarly, in our series, both patients with a proximal type I endoleak had wide, angulated, conical necks. However, only one of the endoleaks required an additional cuff; the

other spontaneously resolved within a few days.

Proximal type I endoleak and migration have traditionally been repaired using balloon-expandable bare or covered stents as additional proximal aortic cuffs or inlay endografts.[24–26] Other investigators have used endografts able to sit onto the aortic bifurcation to address difficulties in proximal fixation.[27,28] Laparoscopic techniques have seldom been advocated and when used were generally in the setting of late neck dilatation.[29–31] Rarely has conversion with graft explantation been reported as the only definitive solution.[32]

Recently, other means of augmenting sealing and fixation have been proposed. van der Bas et al.[33] found that a Dacron endoprosthesis impregnated with collagen, heparin, and fibroblast growth factor is capable of inducing graft incorporation and healing in an in vitro model using cultures of pig and human aortas. Liu et al.[34] presented a novel magnetic device involving a ferromagnetic stent-graft (inside the vessel) and 2 magnetic rings (outside the vessel) to increase fixation. Unfortunately, neither innovation has yet been supported by other investigators and so remain experimental.

The TriVascular's Ovation Abdominal Stent Graft System is a new infrarenal AAA endograft that incorporates an inflatable (with biocompatible polymer) dual sealing ring to achieve proximal seal and a large suprarenal crown with anchors for fixation. The endograft is undergoing evaluation in the US and Europe. Similarly, Endologix's NELLIX fillable endograft consists of dual balloon-expandable endoframes surrounded by polymer-filled endobags that obliterate the aneurysm sac and maintain endograft position. Only limited data have been published to date.[35]

Endoclips and endostaples (or endoanchors) were introduced ~10 years ago to deal with acute and late proximal type I endoleak and to increase migration resistance of the endograft.[36] The "EVA staple" is a nitinol coil that resumes a coiled shape after deployment to "rivet" the graft onto the aorta. The catheter used to deliver this staple incorporates an optical fiber that is intended to transmit a laser that forms a hole through the graft and the aorta. There are no published results regarding this innovation.

Two more staple systems from Lombard Medical have been developed: one for open procedures (Anson Refix) and one for endografting (EndoRefix). The EndoRefix staple or endoclip is a "seagull"-shaped piece of nitinol wire. Clinical experience is very limited; Donas et al.[11] reported acceptable short-term results in 8 patients implanted with Zenith or Talent endografts.

The Aptus EndoAnchoring system was introduced in 2005 as the proximal fixation mechanism for the Aptus endograft (Fortevo).[12,13] However, it has since gained approval for use as an adjunctive fixation and sealing mechanism in several major endografts. The EndoAnchors secure the endograft by being rotated into the aortic wall, where the end of the anchor serves to hold the endograft in apposition to the vessel wall. When using the Aptus endograft, it is obligatory to use Aptus EndoAnchors to secure the graft to the aortic wall. On the other hand, when implanting endografts that already incorporate other proximal fixation mechanisms, the use of additional EndoAnchors would theoretically increase fixation, a hypothesis that is supported by a recent cadaveric study.[13] Additionally, helical Aptus EndoAnchors have the potential to secure the aortic wall to the graft (not only the graft to the wall), providing an added degree of "radial fixation." All other fixating mechanisms lack this ability, so late neck dilatation leads to proximal seal and fixation failure as the aortic neck becomes enlarged.[37–39] If the aortic neck is constrained by the helical EndoAnchors and is closely attached to the endograft, it is likely that it cannot enlarge more than the maximal diameter of the stent-graft. This assumption is supported by our early experience in which no neck expansion was seen at up to 17 months, though are cohort was very small and the follow-up interval minimal.

Our results using EndoAnchors in unfavorable necks compare favorably with outcomes using cuff deployment to secure proximal fixation. AbuRahma et al.[5,10] prospectively investigated 258 patients undergoing EVAR, 63% of whom had hostile neck anatomy (defined as length $<$10 mm, angulation $>$60°,

diameter >28 mm, ≥50% circumferential thrombus, ≥50% calcified neck, or reverse taper contour). Intraoperative proximal aortic cuffs were used in 22% of the hostile anatomy patients. For these, perioperative complication rates were 16%, with 3% mortality and a 22% intraoperative proximal type I endoleak rate. Though we cannot directly compare our results with this cohort since the definition for hostile neck anatomy is different, endoanchoring in hostile necks as defined in our series offered superior perioperative fixation. Thomas et al.[26] described an increased risk of fixation failure in patients treated with extender cuffs only due to persistent migration of the primary endograft, which led to secondary type III or type Ia endoleaks. Similar results have been published by van Lammeren et al.[40]

Fenestrated EVAR is another option in patients with an unsuitable proximal neck; however, the procedure is significantly more time consuming and complicated. A recent meta-analysis by Cross et al.[41] analyzing 660 fenestrated EVAR cases reported a procedure time ranging from 180 to 375 minutes and a 2% perioperative mortality. In our patients, mortality was zero throughout follow-up, the procedure time was shorter (range 95–130), and EndoAnchor deployment added only a median 12 minutes to the operation, although the comparison is unfair since the meta-analysis included type IV thoracoabdominal aortic aneurysms (TAAA) and supra/para/juxtarenal aortic aneurysms. Additionally, none of our patients developed renal dysfunction, a well-recognized sequela of fenestrated EVAR.[41] While endoanchoring endografts that are being deployed in unfavorable infrarenal neck anatomy is appealing and may offer better results than simple EVAR alternatives, the technique cannot be compared to fenestrated EVAR, which is mainly designed for complex AAAs and TAAAs in which endoanchoring is not (thus far) a viable option.

Limitations

The analysis included only 13 patients and follow-up was limited. However, this is a new device that has only recently become commercially available. Only 2 different endografts were used in this series among the 5 that have been approved for use with the EndoAnchors; the performance of the device in combination with the other 3 endografts should be investigated in a future study.

Conclusion

This analysis evaluates the feasibility and early performance of the Aptus HeliFX aortic securement system as a means of improving the proximal seal and longitudinal and radial fixation of various endografts in patients with unfavorable neck anatomy undergoing infrarenal EVAR. In this small cohort from two centers, EndoAnchoring appears to be feasible, efficacious, and safe. The short-term results are favorable, with limited device-related complications. EndoAnchors may broaden the applicability of infrarenal EVAR to include patients with unfavorable neck anatomy. Further long-term studies are necessary to verify the exact role of this new technique.

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