The phase I multicenter trial (STAPLE-1) of the Aptus Endovascular Repair System: Results at 6 months and 1 year

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Objective: **This phase I IDE study (STAPLE-1) evaluated the primary endpoints of safety (major device-related adverse events at 30 days) and feasibility (successful deployment of all endograft components) of the Aptus Endovascular abdominal aortic aneurysm (AAA) Repair System (Aptus Endosystems, Inc, Sunnyvale, Calif) to treat AAAs.**
Methods: **A prospective, single arm Federal Drug Administration (FDA) Phase I IDE study was performed. The Aptus endograft is a three-piece modular device with a flexible unsupported main body and two fully supported limbs in a 5.3 mm outer diameter (OD) (16F) delivery system for all iliac limbs and two of three main body sizes. The largest main body (29 mm diameter) is in a 6 mm (18 F OD) delivery system. EndoStaples measuring 4 mm (length) by 3 mm (diameter) designed to provide transmural graft fixation to the adventitia are applied independent of the endograft delivery system. Inclusion criteria included a proximal aortic neck length of 12 mm and iliac landing zone of 10 mm. Secondary endpoints included freedom from endoleaks, rupture, migration, and device integrity.**
Results: **Twenty-one (21) patients were enrolled at five centers. All patients received the Aptus Endograft and EndoStaples. Ninety-six EndoStaples (range, 2-10; median, 4) were implanted. All patients (n = 21) completed 1-month and 6-month follow-up evaluation and 14 completed 1-year follow-up. Two proximal cuffs and one limb extension were used as adjunctive endograft components at implantation. Three secondary interventions were performed in 2 patients for limb thrombosis. There were no EndoStaple-related adverse events, device integrity failures, migrations, or conversions.**
Conclusion: **These results of the STAPLE-1 trial document the acute safety and feasibility of the Aptus Endograft and EndoStaples. Early follow-up demonstrates excellent 6-month and 1-year results. A pivotal phase II trial is underway at 25 US centers. (J Vasc Surg 2009;49:851-8.)**

The therapy for infrarenal abdominal aortic aneurysm (AAA) in the United States was transformed in 1999 with the approval by the Food and Drug Administration (FDA) of the first two aortic endografts indicated for the treatment of infrarenal AAA.[1,2] Over the ensuing years, the vascular workforce in the United States has increasingly employed endovascular techniques to repair AAAs using a variety of different endograft technologies. Much of the enthusiasm for endovascular aortic grafting has been driven by the highly reproducible reductions of acute morbidity and mortality as well as a very high initial technical success rate.[1,2] The primary impediments to wider endovascular graft adoption over open surgical reconstruction include complications related to: (1) the relatively large size of the catheters required to implant endografts, (2) the significant increase in secondary interventions required to maintain the effectiveness of endografts, (3) the diminished reliability of the graft attachment to the aorta resulting in neck dilatation and/or graft migration and late aneurysm rupture, and (4) the requirement for long-term surveillance with computed tomography (CT) and intravenous (i.v.) contrast.[3-8]

This report documents the early results of a multicenter trial that represents the first human use in the US of a novel approach to an aortic endograft technique that utilizes a fixation technique completely independent of the endograft itself. While this fixation technology directly addresses migration and endograft sealing issues, its true significance is the freedom it allows for new developments in endograft design and delivery. It also enables the operator to determine the degree and location of fixation, essentially analogous to the process of suturing an open surgical aortic prosthesis.

Device description. The Aptus AAA Endovascular Repair System (Aptus Endosystems Inc, Sunnyvale, Calif) is a proprietary aortic endograft system comprised of three essential components: (1) a bifurcated modular endograft with two docking limbs, (2) a deflectable sheath specifically designed for EndoStaple delivery, and (3) an electronically-controlled EndoStaple applier and helical EndoStaples. The main body of the graft has a proximal nitinol self-expanding stent that functions to temporarily fix the endograft in the aorta upon deployment and as a target zone for proximal staple implantation to complete proximal fix-

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Competition of interest: Dr Deaton is a consultant to Aptus.

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0741-5214/$36.00

doi:10.1016/j.jvs.2008.10.064

Fig 1. The Aptus main body.

Fig 2. The Aptus Endograft main body and two docking limbs.

ation and sealing. The composite of this stent and staples applied across the stented portion of the main body create a proximal seal and fixation. The remainder of the body is unsupported polyester material that is designed to accommodate cyclic changes of aortic length during the cardiac cycle and enable the proximal stent to orient to the local axis of the aortic neck to allow a tension-free proximal attachment (Fig 1). The unsupported body of the graft is designed to also allow for compliance in the chronic remodeling of the aneurysm sac and aortic morphology. Two docking limbs are utilized to complete each endograft and are supplied in 2-cm length increments (Fig 2). All of the docking limbs are made of polyester supported by a full-length nitinol self-expanding stent that provides radial support while still allowing longitudinal flexibility (Fig 3). The deployment of the docking limbs into the main body results in a specific locking action between the main body and docking limbs so that limb distraction requires disruption of either the fabric or stents as opposed to a simple friction fit. This results in a functional unibody graft once implanted.

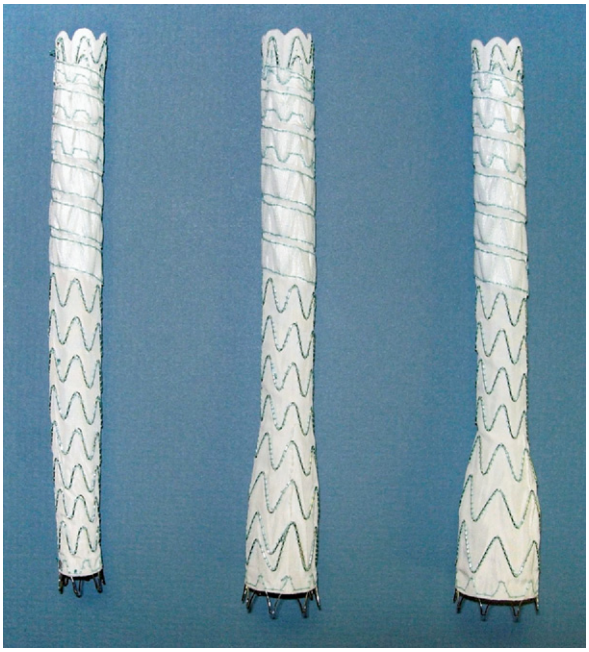

Fig 3. The Aptus Endograft docking limbs.

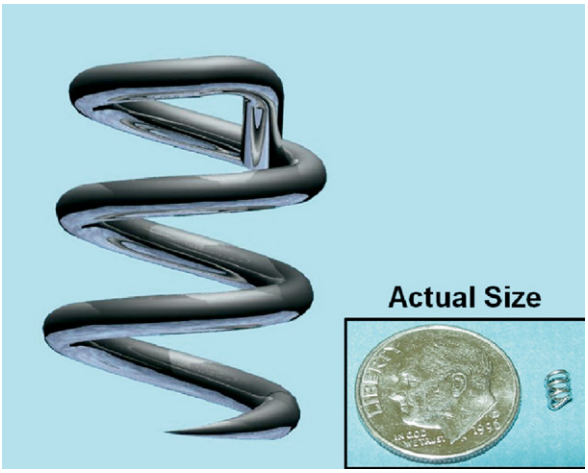

Fig 4. The Aptus helical endostaple.

The fixation of the endograft is achieved by the delivery of helical staples that measure approximately 3 mm in diameter by 4 mm in length. These staples are constructed of a metallic alloy (MP35N LT) which is similar to Elgiloy (Elgiloy Specialty Metals, Elgin, Ill). The wire used to construct the staples is approximately 0.5 mm in diameter (Fig 4). A deflectable guide sheath is positioned at 90° to the intended point of fixation. The stapler is then inserted into the flexible guide and the staple is deployed across the graft and aortic wall in a two-stage process intended to engage the full thickness of the vascular wall (Fig 5). The holding strength of the individual staple is ultimately dependent on the quality of the tissue into which it is de-

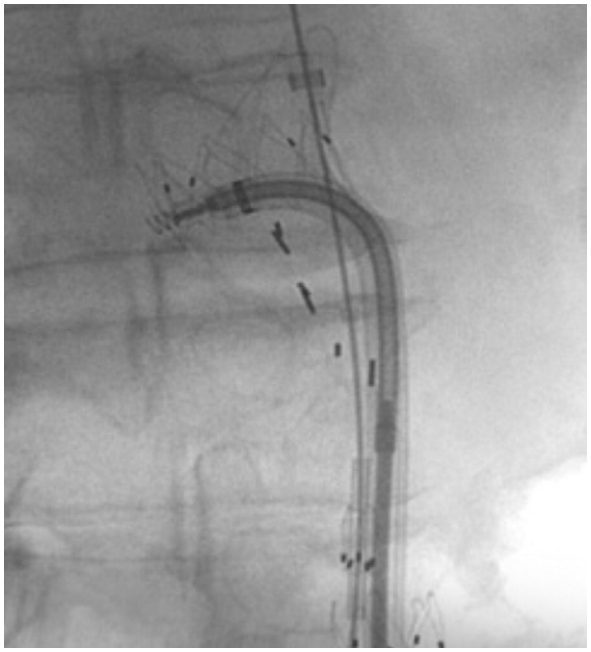

Fig 5. Fluoroscopic image of staple deployment and transmural aortic purchase.

Fig 6. The exterior profile of a barb vs a helical staple exiting an artificial vessel model.

ployed and its ability to engage the adventitia of the vessel. In a silastic model of a vessel wall, an individual staple attains a pull-out force of approximately 20 newtons.[9] The helical nature of the staple provides for a low-profile aspect on vessel penetration when compared to straight barbs or hooks (Fig 6). Four to six staples are recommended for fixation with variation in use based on the operator's discretion and appreciation of aortic neck morphology and tissue integrity.

The sequence of steps in the deployment of the graft is different from currently available endovascular technology. The initial step in deployment is the exposure of the main body of the graft once it is in a position near the renal arteries. This step does not result in proximal stent deployment. The next step in deployment is release of the proximal stent in a position determined to be optimal. While this is normally at the lowest renal artery, other positions that will generate sufficient seal can be chosen in the neck since fixation is independent of neck length. During the trial, different proximity to the renal arteries was occasionally chosen by investigators for anatomic reasons. After proximal stent release, the main body is still under positive control of the delivery catheter with nitinol stabilizing bars attached to the proximal stent and fixation of the ipsilateral limb to the main delivery catheter. This allows the operator to support the main body with the delivery catheter until staple fixation has been achieved. Cannulation of the contralateral limb is then performed and stapling is performed through the contralateral limb. After stapling, the contralateral limb is positioned and deployed. After the contralateral limb is in place, the main body-tethers to the proximal stent are released and the ipsilateral docking limb fixation to the main body delivery catheter is released to allow removal of the main body delivery catheter. The ipsilateral limb is then inserted and deployed.

The delivery systems required for the endograft and the stapling system are significantly smaller than those currently available. The endograft is delivered via a 5.3-mm (16F) outer diameter catheter for the 24.5 mm and 26.5 mm main body diameters and 6.0 mm (18F) for the 29 mm main body. During this study, 19/21 (90%) were implanted with the smaller delivery systems while 2 (10%) required the 29 mm main body diameter. The stapling system and endograft limbs also have a 5.3 mm (16F) crossing profile. The diminished diameter of the catheters required deploying and stapling the endograft to allow for both enhanced access in patients with smaller iliac vasculature as well as better control (ie, torque response and pushability) of the catheter in all vascular morphologies.

METHODS

A prospective, single arm FDA sanctioned phase I IDE study was performed in six centers. Inclusion criteria included a proximal aortic neck length of 12 mm and iliac landing zone of 10 mm. Proximal aortic diameters of 19-26 mm and iliac diameters of 11-14 were required for inclusion. All diameters were measurements of the inner diameter of the aortic or iliac lumen. The primary endpoints evaluated were safety (major device-related adverse events at 30 days) and feasibility (successful deployment of all endograft components). Secondary endpoints included freedom from endoleaks, rupture, migration, and device integrity. Inclusion and exclusion criteria are listed in Table I. Twenty-one patients were enrolled between July 2006 and May 2007. The primary endpoint of safety was defined by major adverse events (Table II). The baseline characteristics and co-morbid conditions of all patients enrolled were typical of the general population with aortic aneurysm disease and are listed in Table III. Anatomic evaluation for satisfaction of inclusion and exclusion criteria was accomplished with CT of the abdomen and pelvis with i.v. contrast acquired at 3 mm or less intervals. Follow-up evaluation consisted of plain x-rays of the abdomen in four views and a CT scan at 1 month, 6 months, and annually through 5 years. A core lab (M2S, Lebanon, NH) was utilized for

Table I. Inclusion and exclusion criteria

Inclusion criteria	*Exclusion criteria*
AAA diameter >5 cm or >4.5 cm with documented growth of >0.5 cm in the past 6 months	Circumferential thrombus or significant calcification in the proximal neck
Non-aneurysmal proximal neck length of at least 12 mm and between 19-26 mm in internal diameter	Ruptured or leaking AAA or requires emergent AAA surgery
AAA with an angle of ≤60° relative to the long axis of the aneurysm	Myocardial infarction within past 10 weeks
Bilateral iliac arteries between 11-14 mm in internal diameter	Requires chronic dialysis or creatinine >2 times the laboratory upper limit of normal
At least 1 cm of non-aneurysmal tissue in the iliac arteries for sealing	Active systemic infection
Bilateral femoral/iliac arteries with an internal diameter ≥5 mm	Previous AAA repair
Candidate for elective surgical AAA repair	Planned major procedure within 30 days of AAA repair
Life expectancy >2 years	Documented hypercoagulation condition

AAA, Abdominal aortic aneurysm.

Table II. Major adverse event criteria

Requires therapy/intervention with minor hospitalization <48 hours; or
Major therapy, an unplanned increase in level of care, prolonged hospitalization (>48 hours beyond expected hospital discharge); or
Permanent adverse sequelae; or
Death

radiologic measurements in addition to the measurements and evaluation of each investigator. Aneurysm baseline diameters were categorized as 45-49 mm through 80-89 mm category with 14 (67 %%) in the 50-59 mm category. Infrarenal aortic neck length ranged from 13 mm to 38 mm with a mean of 26 mm. Baseline anatomic features of the enrolled patients are listed in Table IV.

RESULTS

Twenty-one patients were treated for AAA with the Aptus Endovascular AAA Repair System over an 11-month period.

Technical success. Technical success was achieved in all 21 patients. All patients have 6-month follow-up and 14 have 12-month evaluations. No mortality, aneurysm rupture, or secondary intervention for aneurysm growth or endoleak occurred in the subject cohort. There were no acute or chronic conversions to open surgical procedures. There were no acute adjunctive open or endovascular procedures necessary to achieve vascular access (ie, surgical iliac conduit or iliac angioplasty). A total of 96 EndoStaples

Table III. Baseline patient characteristics

Characteristic	*n = 21*
Age (years)	
Mean	
Median (min, max)	75 (64-90)
Gender	
Male	20 (95%)
Female	1 (5%)
Co-morbid conditions	
Coronary artery disease	12 (57%)
Previous MI	5 (24%)
Congestive heart disease	1 (5%)
Valvular heart disease	5 (24%)
COPD	5 (24%)
History smoking	19 (90%)
Hypertension	15 (71%)
Stroke	2 (10%)
Renal failure/insufficiency	3 (14%)
Peripheral arterial disease	2 (10%)
Other significant medical conditions	21 (100%)

MI, Myocardial infarction; *COPD,* chronic obstructive pulmonary disease.

Table IV. Baseline aorta and aneurysm characteristics per investigator

Parameter	*n = 21*
Neck length (mm)	
Mean (min, max)	26.4 (13.0-38.0)
Neck angle (°)	
Mean (min, max)	25.3 (9.0-60.0)
Neck diameter (mm) – Aortic-renals	
Mean (min, max)	21.4 (15.9-24.0)
Neck diameter (mm) – Aortic-12 mm	
Mean (min, max)	22.4 (19.2-28.0)
Aneurysm maximum diameter range	
<45 mm	0 (0%)
45 mm-49 mm	2 (10%)
50 mm-59 mm	14 (67%)
60 mm-69 mm	3 (14%)
70 mm-79 mm	0 (0%)
80 mm-89 mm	2 (10%)
≥90 mm	0 (0%)

were implanted with a range of 2-10 staples per endograft. The median number of staples in each endograft was four. EndoStaple implantation was successful in all 96 staple implantations. Total device time averaged 58 minutes (range, 32-86) and stapling time averaged 17 minutes (range, 8-30). A total of four adjunctive prostheses were used in 3 patients. These included two aortic cuffs, one balloon-expandable stent used to address inadequate sealing, and one iliac extender for iliac tortuosity and potential graft kinking. There were no incidences of graft misplacement or migration that required extension or adjunctive devices. The mean and median intensive care unit (ICU) stay was 0 days and the median hospital stay was 1 day with a maximum of 10 days. Estimated blood loss intraoperatively had a median value of 100 cc with a range of 100-900 cc.

Clinical success. No measurable migration proximally, distally, or between graft components has been

Table V. Endoleak evaluation

Event	*3- days follow-up n = 21 n (%)*	*6-months follow-up n = 21 n (%)*	*1-year follow-up n = 14 n (%)*
Endograft leak			
Type I	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type II	4 (19%)	4 (19%)	1 (7%)
Type III	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IV	0 (0.0%)	0 (0.0%)	0 (0.0%)
Indeterminate origin	0 (0.0%)	0 (0.0%)	0 (0.0%)

Table VI. Major adverse events

Event category	*≤30 days N = 21*	*31 to 180 days n = 21*	*181 to 365 days n = 14*
Bleeding	3	0	0
Pulmonary	0	0	0
Cardiac	0	1	1
Renal	0	0	0
Bowel	0	0	0
Wound	1	2	3
Neurologic	0	0	0
Cardiovascular	0	0	0
Aortic & vascular	2**	0	1
Other*	8	2	0
Totals	14	5	4

*Other includes: chest pain, hypotension, urinary tract infection, febrile episode, decreased Hgb&Hct, tingling/numbness in hand.
**Two patients (three events) with iliac limb occlusion; one related to underlying hypercoagulable condition.

documented by either the core lab or investigators. Two patients experienced three limb thromboses. In one of these patients, a technical issue related to compression of a graft limb was deemed responsible. In this patient, the proximal portion of the iliac limb was not supported by the radial force of the docking limb and was also in a position of high angulation resulting in a focal stenosis of the proximal limb. This patient also had a thrombocytosis and was evaluated by hematology for this finding. In the second patient, a diagnosis of hypercoagulability requiring coumadin therapy was made in addition to a finding of tortuosity in the iliac vasculature. It is unclear whether or not the tortuosity of the iliac contributed to the thrombosis as there was excellent flow with normal ankle-brachial indices (ABIs) and the patient was able to run vigorously without claudication following implantation. This patient suffered an acute occlusion at 3 weeks and a second occlusion of the contralateral limb occurred 8 months later with no evidence of anatomic obstruction. This patient was diagnosed as hypercoagulable and coumadin therapy initiated. This patient also had portal vein thrombosis, as well as two children on chronic coumadin therapy for multiple thrombotic events, suggesting a familial disorder of hypercoagulability. Both of these patients were initially diagnosed in the first 30 days of follow-up. No further limb thromboses have occurred. As a result of the caliber of the metal in the staple, the morphology and integrity of each EndoStaple could also be evaluated throughout follow-up with plain x-ray. All staples remained in their original location throughout all follow-up evaluations. There was no change in any of the 96 staples' shape or any evidence of fracture throughout the follow-up period. No stent fracture in either the main body or iliac limbs was identified (Table V).

Endoleak and aneurysm size. There was no documentation of type I, III, or IV endoleaks at any follow-up interval. Type II endoleaks were documented in 4 of 21 (19%) patients at 30 days and 6 months, and in 1 of 14 (7%) patients at 12 months. At 6 months, 9 (42.9%) patients had a diameter reduction of >5 mm while 19 (90.5%) had a volume reduction of >5%. Enlargement of 5 mm in diameter was not detected in any patient at 6 months while a single patient (4.8%) had a greater than 5% volume increase. The remaining patients were categorized as no change. At 12 months, the 13 patients available for follow-up demonstrated a reduction in aneurysm diameter >5 mm in 9 (69.2%) with none enlarging and 4 (30.8%) remaining stable by diameter criteria. By volume criteria, 11 (84.6%) had a reduction of >5% while 2 (15.4%) demonstrated an increase of >5%. There have been no secondary procedures to address endoleak or aneurysm size changes.

Major adverse events. There were a total of 23 major adverse events cumulatively tabulated over 56 separate follow-up evaluations (Table VI). There were a total of 3 major adverse events related to the endograft. These three events occurred in 2 patients and all three were the limb thromboses detailed earlier in this section. There was no incidence of graft infection or any new morbidity related to the aortic aneurysm or the graft.

DISCUSSION

The results of this initial phase I trial validate the safety and feasibility of an endovascular grafting technique that employs a separate technique and device for fixation. Despite the widely-accepted improvements in acute outcomes associated with endovascular aortic grafting, migration and other endograft integrity failures continue to be a major impediment to long-term endograft clinical success[1,3,7,8,10-13] and more widespread clinical adoption. The radial force and lack of effective transmural fixation that characterize most endograft technologies today are largely responsible for the late complications related to migration and proximal neck dilatation.[4,6,14,15] Irrespective of the design,[16,17] any endostapling or independent endovascular fixation technology that allows the operator to securely attach a graft or other device to the load-bearing portion of the vascular wall, the adventitia, has the potential to change the nature of endovascular aortic grafting and potentially a variety of other endovascular procedures and devices. In addition to the secure attachment of the graft to the wall, the design of the helical EndoStaples described in this report have the potential to secure the aortic wall to the graft thus preventing one of the most insidious late complications of aortic aneurysm repair, namely continued aortic dilation at the proximal attachment site.[4,14,15] The discrete nature of EndoStaples al-

lows their use to treat focal defects including the effective address of type I endoleaks by creating apposition in an irregular area not sealed by the uniformity of a radial stent.[18] The independence of an endovascular stapling device from the primary graft also allows staple application at a time other than primary graft implantation. This allows future issues of fixation or other degenerative changes in the aorta to be addressed with a new endovascular procedure that directly addresses fixation rather than conversion to open surgery or simple endograft extension.[19] While the benefits of endovascular stapling are well demonstrated in the application of endograft fixation, there may well be other applications for independent and discrete fixation in a variety of vascular pathologies and new treatment paradigms may be made possible by this new endovascular modality.

The foundations of successful vascular reconstruction are based on the development of viable conduits and reliable techniques for vascular anastomosis.[20,21] While many endovascular therapies represent alternative methods to achieve revascularization (ie, endoluminal recanalization vs bypass), aortic endovascular graft therapy is a reproduction of open aortic grafting with the exception of endovascular delivery. The early success of endovascular aortic grafts satisfied the requirements for reductions in acute morbidity and mortality relative to the open procedure[22,23] but the inability to reproduce the transmural fixation and control of the open procedure resulted in long-term outcomes clearly inferior to open repair.[6,13] The potential for endovascular aortic grafting to surpass both the acute and chronic outcomes of open reconstruction rests on the development of technologies that effectively reproduce the principles of open reconstruction. While the graft materials of both open and endovascular grafts are similar, the fixation technologies are radically different. Enabling the surgeon to apply staples that represent the functional equivalent of a sutured anastomosis and the control inherent in that technique holds promise for a significant advance in both the acute and chronic success of aortic endografting. Such advances might well allow the endovascular technique to equal and potentially surpass the chronic performance of open surgical reconstruction and significantly reduce the current requirements for postoperative imaging. The capability to deliver a discrete fixation technology independent of the primary device will allow a new level of creativity in medical device design for aortic endografts and, potentially, a host of other devices and therapies.

CONCLUSION

These results document the acute safety and feasibility of the Aptus Endograft and EndoStaples. Early follow-up demonstrates excellent 6-month and 1-year results with no secondary intervention for aneurysm growth or endoleak. These data are the foundation for a pivotal phase II (STAPLE-2) trial that is underway at 25 US centers.

AUTHOR CONTRIBUTIONS

Conception and design: DD, RM
Analysis and interpretation: DD, MM, KK, MG, RF
Data collection: DD, MM, KK, EC, MG, RM
Writing the article: DD
Critical revision of the article: DD
Final approval of the article: DD, RM
Statistical analysis: Not applicable
Obtained funding: Not applicable
Overall responsibility: DD

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Submitted Jun 12, 2008; accepted Oct 31, 2008.

DISCUSSION

Dr Frank Arko (*Dallas, Tex*). Dr Deaton and coauthors discuss the early results of the phase I multicenter trial of the Aptus Endovascular Repair System. I congratulate the authors and the manufacturers for completing this initial phase. I have several questions for the authors.

Dr. Deaton, how many EndoStaples are actually necessary for each case to get a satisfactory outcome? What is the pull-out force for a staple in tissue as compared to a silicone model?

What is the learning curve on using these EndoStaples? I am the US principal investigator for a competitive endostapling device that's able to be used with any Dacron stent graft and I believe there is a learning curve to using these devices and I'd like to get your thoughts on what it is with this device.

Next, please comment on neck calcification, thrombus, angulation, and short neck length on the ability to accurately implant your EndoStaple and are any of these factors contraindications to using this endograft?

And then finally, with five currently approved devices within the United States, all of which have excellent 5-year results, can you elaborate on what you believe this repair system adds to the current treatment options?

Dr Deaton. The number of staples required in the phase I study was 2 but 4 was the number generally recommended and was the median number in the study. Only 1 patient received 2 staples and 1 patient had as many as 10. When more than 4 staples were applied, it was usually to address sealing issues. Fundamentally, the intention is to give the operator control over how many staples are needed in their clinical judgment.

While there is undoubtedly a learning curve, the controlled nature of this helical staple deployment provided for early success and no misdeployed staples throughout this initial experience. The positioning of the EndoGuide against the aortic wall followed by an electronically controlled and staged staple deployment made the initial learning curve for users fairly shallow.

With respect to the ability of the staple to penetrate aortic pathology, we don't have any evidence of staples that did not penetrate the tissue they were intended to penetrate. That being said, excessive calcification in the aortic neck is excluded in the trial. While there is ex vivo evidence of staple penetration through calcified aortic plaque, we will probably not understand the limitations of this helical staple until we have a much broader experience in less restricted clinical applications.

With respect to the pullout force, there is early work being done in a tissue model that I think will back up the numbers attained in an artificial silastic model. What is fundamentally different from most other endograft technologies is that the degree of fixation achieved by these staples appears to be related to the tissue into which they are implanted rather than the mechanical integrity of the staple itself. That is to say that what gives way is the tissue rather than the structure of the staple. So if it is weak tissue it will not achieve those high levels of pull-out force just as sutures in open surgery will tear through tissues with poor integrity. Another essential aspect of this type of fixation is that it is easily visualized on postoperative plain x-ray so we will be able to follow any compromise to the staple or any evidence of change in position of a particular staple.

Now, what did I miss?

Dr Arko. I think you got most of them. The last one is – and I'm going to add a little more to it since you made me stand up here – what do you think the advantages of this endograft is over other endografts?

And I'd like to ask you if you could describe the actual stent graft in some more detail including the distance from the top of the graft to the flow divider. I have found that with the shorter bodied stent grafts that it's actually a bit more difficult to implant the staples because I lose some ability to guide the catheter and in the shorter bodied stent grafts I have found it easier to go up both sides to implant the endostaples. Whereas with a longer bodied stent graft, I can really get the staples in from either side. Can you comment on that?

Dr Deaton. With respect to the staple implantation, on rare occasions we have used both limbs to implant staples, but in over 90% of the cases it is easy to implant staples circumferentially from one side. The main body in this study was 4 cm long. In the phase II study, there were 4, 5, and 6 cm body lengths to give the operator better sizing capabilities and to add flexibility to planning for unusual anatomic configurations. As for the body length inhibiting stapling, we have not seen that. The EndoGuide was specifically designed to work in the 4 cm length body and the unsupported nature of the main body also allows more flexibility in staple positioning and deployment.

One of the primary advantages of this endograft system is the possibility of achieving a degree of proximal fixation on a par with a hand-sewn anastomosis. If that proves to be the case, we may well be able to document a treatment paradigm that does not involve the lengthy and potentially dangerous necessity of annual CT scans. Another key advantage of a helical staple is the possibility of preventing future neck dilatation as the "bidirectional" nature of helical staple fixation should hold the aorta to the graft rather than just holding the graft up against the aortic wall. The separation of the fixation delivery from the graft delivery allows an entirely new approach to endograft design that maintains a very high degree of graft structural integrity while bringing the graft delivery catheter caliber down to 16F. There are a variety of other more nuanced features made possible by the design of the endograft that we are still learning about, the most prominent being the non-stented main body and the ability to treat angulated necks, facilitate contralateral cannulation, etc. Beyond the scope of this particular technology, I think any independent fixation technology will allow an entirely new approach to endograft design that will give the operator the ability to treat a broader group of patients more effectively with better long-term results.

Dr Wayne Zhang (*Loma Linda, Calif*). You use staples for proximal fixation. Do you have any migration after deployment of the stent graft before you put staples?

The second question is are you worried about bleeding? Can the staples cause penetration and bleeding? Do you need to do a CT scan immediately after the procedure?

And another question is, when you deploy the staples, if you have an angled neck, how do you position?

Dr Deaton. We don't see any bleeding from implanting the staples. We haven't seen it in an animal model. And it really is the helical nature of it is much less than what you would do in open surgery.

We do make a point to angle the C-arm so that we're looking straight across that proximal stent, because that is where we like to implant the staples.

And your first question again was?

Dr Zhang. Do you have any migration after deployment of the stent graft before you put staples?

Dr Deaton. Can you move the graft? It can move, but that proximal sealing stent has a fairly high radial force so it's done with some difficulty. But before you do that, when you uncover the entire graft, it's easily mobile at that point.

Dr Wesley Moore (*Los Angeles, Calif*). Does the device go up bare or are you putting it in through a sheath?

How far beyond the outer wall of the aorta does the staple go? Do you have any concern about puncturing the left renal vein or the cava when you put the staple in place?

Dr Deaton. As far as the staple penetration, it's 4 mm and it's designed to basically just go through the aortic wall. We've not seen any complications related to it. And I've neglected to show you a slide, but it's very different, when you penetrate a vessel with a barb, you have a barb sticking through the aorta. This helical screw has a much lower profile. It doesn't have something sticking up like a nail, if you will.

Dr Moore. Does this go bare or through a sheath?

Dr Deaton. It's designed to go bareback and it can. If they have adequate iliac access vessels, we do place a sheath just to facilitate exchanges and intraoperative imaging but there is no reason you have to place a sheath. The delivery system, as you can see, is tapered and we generally re-jacket the entire delivery system on removing it to prevent any iliac trauma.

Dr Moore. Finally, in one of the patients you mentioned that you placed one or two cuffs proximally. Was that because the graft moved before you had a chance to staple it, or did you staple it and had to place cuffs in addition to that?

Dr Deaton. It wasn't because the graft moved, but I think it was because of some irregularity in the neck that the short stent didn't fulfill the sealing requirements and so we added support to the main body to lengthen the sealing zone. In the phase II study, which is underway now, an aortic cuff designed specifically for this unique endograft system has been added to the portfolio of the system. This allows operators the ability to provide for a longer sealing zone in the main body with the fully-stented aortic cuff positioned within the main body or to extend the length of the main body cephalad when a more distal area is deemed more appropriate for staple implantation.

Dr Jean Panneton (*Norfolk, Va*). As a co-investigator in the Aptus trial, I can tell you all that it's actually a very slick device. I think the delivery is very intuitive which, as surgeons, we like. I think the learning curve for the EndoStapler is actually pretty short. I think it's also very intuitive to use and very user friendly.

One potential improvement would be shortening the radius of the EndoStapler, especially when there is angulation of the aneurysm neck; I think it would help the stapling.

My concern is the limb occlusion rate. I'm sure you have that same concern. I think you might explain this as technical difficulties or maybe from the iliac anatomy, but do you think there is a need to change the graft to try to prevent this problem? Is it because it is so flexible and does not have columnar strength that it's going to be more likely to kink or occlude in tortuous iliacs?

Dr Deaton. We've had 2 patients with limb occlusions and 1 of those was diagnosed with a severe hypercoagulability condition postoperatively. The other patient with a limb occlusion was likely the result of deploying the limb too low in the docking zone resulting in an unsupported proximal limb that happened to be at an angulated portion of the aorta where the neck terminated into the aneurysm sac. Having said that, there have been several design changes in the endograft system being used in the phase II to provide for better adaptation to tortuosity such that even acute bends of 90° can be accommodated by the graft limbs without luminal compromise.