Aptus Endovascular AAA Repair System

Report of the 1-year follow-up in a first-in-man study.

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Since 1991, when Parodi et al[1] described a minimally invasive alternative to open abdominal aortic aneurysm (AAA) repair via endovascular repair (EVAR), a variety of methods have been created to mimic principles of the traditional open AAA repair procedure. To date, all endovascular repair devices have a single method for delivery of an endograft into a diseased aorta. Additionally, each endograft relies primarily on the use of an oversized proximal stent, with or without a metallic barb, for fixation to the aortic wall. Experience has shown that these fixation methods can be prone to metal fatigue, as well as proximal stent migration. The Aptus Endovascular AAA Repair System (Aptus Endosystems, Inc., Sunnyvale, CA) divides the endovascular AAA repair procedure into two steps: (1) exclude the aneurysm with an endograft designed to provide radial support while maintaining longitudinal compliance and (2) secure the endograft to the vessel wall with an endovascular stapling system that provides transmural aortic fixation with a high pull-out force proportional to the number of EndoStaples (Aptus) deployed.

The Aptus modular endograft is designed specifically for use with the Aptus Endovascular Stapling System, which in turn is designed to provide secure fixation of the proximal edge of the endograft to the infrarenal aortic wall.

The modular endograft is designed to accommodate changes in aneurysm and/or aorta morphology without compromising graft integrity, graft patency, or arterial attachment and sealing. In addition, this two-step approach to endovascular AAA repair allows for a significant reduction in the profile and increased flexibility of the delivery systems (endograft and EndoStaples). The modular endograft and the EndoStaple Applier are delivered through a 14-F sheath (16-F outer diameter). These attributes may allow a broader range of patients to be safely treated with an endovascular procedure.

The Aptus Endovascular Repair System provides active fixation via an endovascular stapling system that allows placement of EndoStaples along the proximal edge of the main body endograft. The EndoStaple is a 4-mm helical staple manufactured from medical-grade wire designed to engage the full thickness of the aortic wall in an active fashion (Figure 1).

STUDY OBJECTIVE

The primary objective of this study was to evaluate the feasibility of the Aptus Endovascular AAA Repair System in treating infrarenal abdominal aortic or aorto-iliac aneurysms. A series of intensive bench, animal, and cadaver tests were completed. This first-in-man experience was designed to evaluate the acute safety of the device.

STUDY DESIGN

This study was a prospective, single-arm, ethics committee-approved study to evaluate the feasibility of the Aptus Endovascular AAA Repair System for treatment of infrarenal abdominal aortic or aorto-iliac aneurysms. No attempt was made to draw statistically valid conclusions regarding safety or performance from this small sample size. Postprocedure follow-up evaluations include 30 days, 6 months, 1 year, and 2 years.

Figure 1. The relative scale of an EndoStaple.

PREOPERATIVE ASSESSMENT

Each patient underwent a contrast-enhanced spiral CT scan with multiplanar reconstruction (M2S, Lebanon, NH) allowing precise measurement of anatomic features of the aneurysm. Patients meeting the inclusion and exclusion criteria and who signed the informed consent were considered candidates for the study.

The clinical team included José Antonio Condado, MD, along with Aptus Endosystems' clinical proctors Takao Ohki, MD, and David H. Deaton, MD. The first patient was treated by Dr. Condado and Dr. Ohki, and the second patient was treated by Dr. Condado and Dr. Deaton. Patient and case demographics are shown in Table 1.

MAIN BODY ENDOGRAFT

Two sizes of main bodies were used; the 29-mm endograft was used to treat patient 001, and the 24.5-mm endograft was used to treat patient 002. The Aptus main body endograft is a multilumen endograft composed of a woven polyester graft and nitinol stents. The proximal sealing stent, with diamond-shaped cells, is approximately 14-mm long and is sewn to the inside of the proximal edge of the endograft. It is designed to ensure secure apposition to the vessel wall just below the renal arteries, while being short enough to eliminate metal-fabric interaction. The distal portion of the main body has nitinol stents that function to accept and lock the modular iliac limbs.

IMPLANTATION AND ENDOSTAPLING

Using fluoroscopic guidance, the main body delivery system catheter was introduced into the vasculature via ipsilateral femoral artery access. The specially designed attachment mechanism allowed the proximal stent to open to its full diameter while remaining tethered to the delivery catheter. The tethered wires along with the radiopaque marker bands on the proximal edge of the main body endograft allowed repositioning of the proximal aspect of the endograft in relation to vascular landmarks. Repositioning is greatly enhanced by the small-diameter 14-F size of the delivery system.

Through contralateral femoral artery access, access to the contralateral gate was obtained in a standard manner utilizing directional catheters and guidewires. Under fluo-

TABLE 1. PATIENT DEMOGRAPHICS

	Patient 001	Patient 002
Age	71	72
Medical history	CAD, post-LAD PTCA+stent, hypertensive, past smoker, hypercholesterolemia, pulsatile AAA, ulcerative rectocolitis	CAD, post-RCA PTCA+stent, hypertensive, COPD, hypercholesterolemia, current heavy smoker, asymptomatic AAA with right aorto-iliac aneurysm, left popliteal aneurysm, claudication
AAA diameter	6.7 cm	4.3 cm
Proximal neck diameter*	26 mm	20 mm
Proximal neck length†	5 mm	9.9 mm
Angulation‡	63.5°	30°
R/L iliac diameter	11.5 mm/11 mm	16.5 mm/12 mm
Proximal neck shape	Reversed conical	Straight

*Proximal neck outer diameter as measured by core lab standards.
†Proximal neck length as measured by core lab standards; change in aorta diameter by 10%.
‡Angle of proximal neck to AAA body.

Figure 2. The EndoStaple Applier hand control.

roscopic guidance, a steerable EndoGuide with obturator (dilator) was positioned over a stiff, .035-inch guidewire within the proximal neck of the main body endograft. Once positioned, the obturator and guidewire were removed, and the distal tip of the steerable EndoGuide was directed toward the desired EndoStaple implant location.

A loaded EndoStaple Applier (Figure 2) was inserted through a port in the proximal end of the steerable EndoGuide control handle and advanced until it contacted the endograft wall, as evidenced by deflection of the main body endograft and aortic wall on fluoroscopy as well as by tactile feedback. The EndoStaple Applier is electronically controlled and allows partial deployment and subsequent retraction of the EndoStaple if the initial position of the EndoStaple is deemed unsatisfactory. After confirming that the EndoStaple is in good position, each EndoStaple was fully deployed with a second activation of the EndoStaple Applier (Figure 3). The EndoStaple Applier was then withdrawn from the steerable EndoGuide. The EndoStapling process is repeated by reloading and reinserting the Applier and repositioning the steerable EndoGuide. Initially, a total of four EndoStaples were deployed circumferentially in each patient.

Once stapling was complete, the EndoStaple Applier was removed, and the guidewire was re-inserted for placement of the contralateral lumen extension endograft. The contralateral lumen extension endograft was delivered and deployed into the contralateral gate using standard techniques.

At this time, attention was returned to the ipsilateral side. Deployment of the main body endograft was completed by releasing the tethered arms from the main body endograft via a control knob on the delivery system handle. The main body delivery system was retracted into the jacket and removed from the vasculature, leaving the .035-inch guidewire in place for placement of the ipsilateral lumen extension endograft. The ipsilateral lumen extension endograft was deployed in the same manner as described for the contralateral lumen extension endograft. A touch-up angioplasty was performed with large angioplasty balloons (Coda, Cook Incorporated, Indianapolis, IN) in both cases within the proximal sealing stent and the main body/lumen extension overlap junction. Finally, postprocedure angiography was performed. Table 2 summarizes the endograft components implanted in each case.

OPERATIVE RESULTS

Upon completion of postprocedure angiography in patient 001, a perioperative endoleak of undetermined origin was observed. Bilateral retrograde iliac contrast injections were performed to isolate and identify the source of the endoleak. A proximal contrast injection revealed a type 1 endoleak at the posterior wall of the proximal neck of the main body. Only four EndoStaples had been deployed at this point. Large-balloon angioplasty was performed with the Coda again in the proximal sealing stent without success. Upon further examination of the 3D CT reconstruction, it was realized that the proximal sealing stent was in a very irregular portion of the proximal neck (Figure 4). A decision was made to place three additional EndoStaples over the

TABLE 2. ENDOGRAFT COMPONENTS USED

	Patient 001	Patient 002
Main body size	29 mm	24.5 mm
Lumen extension endograft R/L size	16 X 12 mm 16 X 12 mm	16 X 12 mm 13 X 10 mm
Overall length R/L	160 mm/160 mm	160 mm/140 mm
Number of EndoStaples	7	4

TABLE 3. PREOPERATIVE AND POSTOPERATIVE DATA FOR PATIENTS 001 AND 002

Follow-up interval	AAA Diameter (cm)		AAA Volume (cm^3)		Proximal Neck Angle (°)	
	Patient 001	Patient 002	Patient 001	Patient 002	Patient 001	Patient 002
Preoperative	6.7	4.3	236.9	89.5	63.5	26.9
30 days	6.9	4	226.1	94.3	63.8	29.6
6 months	6.3	4.4	195.4	84.7	49	20.7
1 year	6.7	4.2	200	79.9	55.1	27
% change (preoperative to 1 year)	0%	-2%	-16%	-11%	-13%	0%

edge of the graft that was not closely applied to the wall. The implantation of three additional EndoStaples in the posterior segment of the sealing stent was performed. Final contrast injection revealed successful resolution of the endoleak. Patient 002 had no evidence of perioperative endoleak based on completion angiogram, and no further stapling was required. In both patients, the main body endografts as well as EndoStaples were deployed immediately below the renal arteries (Figure 3).

Acute technical success was achieved in both patients. Both devices were successfully implanted and secured with the EndoStaple system. Total procedure time was 2 hours 37 minutes, and 2 hours 1 minute, respectively (skin-to-skin). For patient 001, the EndoStaple time was 23 minutes for the first group of four EndoStaples and 14 minutes for the second group of three EndoStaples. For patient 002, the total EndoStaple time was 16 minutes. Estimated blood loss was 300 mL in each patient, and blood transfusion was not required.

POSTPROCEDURE DATA

Both patients recovered well. One patient exhibited mild atelectasis from anesthesia. Both patients were discharged on the second postoperative day.

Patient 002 presented preoperatively with a concurrent left popliteal aneurysm at the time of his AAA diagnosis. At the time of AAA treatment, the clinical plan was to treat the patient's popliteal aneurysm after the 30-day follow-up visit, after AAA repair. However, on day 27 after AAA treatment, the patient reported acute pain in his left leg and presented with ischemia, absent pulses, and numbness in the lower extremity. The symptoms were determined to be related to the pre-existing popliteal aneurysm. Revascularization with a femoropopliteal bypass graft placement was performed; however, the bypass graft occluded the next day resulting in the need for an above-the-knee amputation. There was no evidence to attribute the popliteal aneurysm thrombosis to the Aptus system or the AAA procedure.

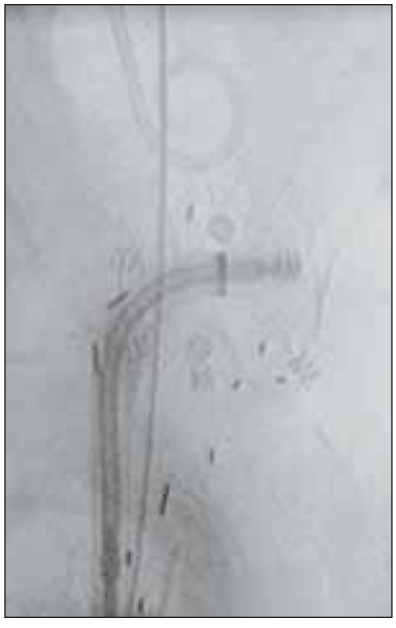

Figure 3. EndoStapling technique with 29-mm MB Endograft in patient 001. Seven EndoStaples were deployed.

FOLLOW-UP RESULTS

No endograft device complications have been documented perioperatively, postoperatively, or during follow up at 15 months. Figures 4 and 5 show the patients' preoperative and 1-year postoperative spiral CT scan reconstructions. Table 3 provides additional preoperative and 1-year postoperative data for each patient.

While the reported AAA diameter showed little change during the 1-year period, overall AAA sac diameter decreased 16% and 11%, respectively, in each patient. Over the same period, patient 001 showed a 13% decrease in proximal neck angle commensurate with the reduction in sac volume. In both cases, the proximal stent and the EndoStaples were located immediately below the renal arteries suggestive of the absence of proximal stent migration.

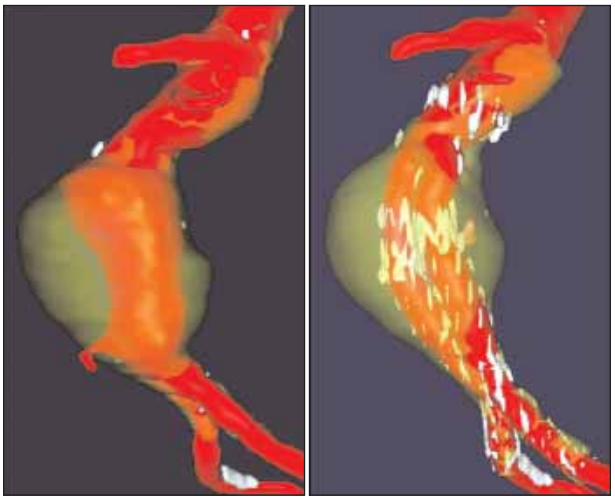

Figure 4. 3D CT reconstructions of preoperative and 1-year postoperative imaging for patient 001.

DISCUSSION

The Aptus Endovascular AAA Repair System was safely implanted in these two patients. Both patients tolerated the procedure well, and recovery through hospital discharge was unremarkable.

The CT evaluations through 1 year for both patients indicate stable device positioning (no migration) and good aneurysm exclusion. There were no type I, III, or IV endoleaks or device-related complications. At 6 months, a small type II lumbar endoleak (0.5 mL) was documented by CT scan in patient 001. At 1 year, the type II endoleak was reduced by 20% (0.2 mL).

EVAR has been established as an alternative to open surgical repair for the treatment of AAA. Its relative safety and reduction in aneurysm-related mortality has been proven in at least two randomized trials.[2,3] However, several factors continue to limit the wider use of EVAR, including the ongoing risk of proximal stent migration, durability, risk of vascular injury, and access-related issues due to the large-bore delivery system and inability to treat short and angulated proximal aortic necks. With the low-profile delivery system and unique fixation method of the Aptus Endovascular AAA Repair System, we believe this third-generation endovascular repair system has the potential to further improve the outcome and penetration of EVAR procedures.

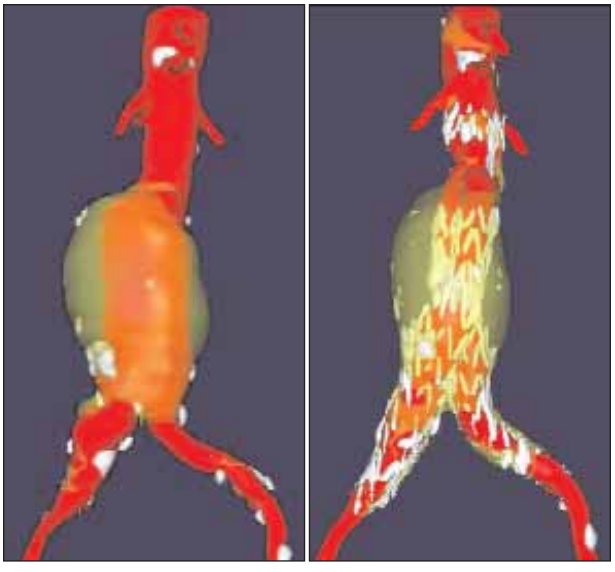

Figure 5. 3D CT reconstructions of preoperative and 1-year postoperative imaging for patient 002.

CONCLUSION

This initial experience established the feasibility of endovascular AAA repair using the Aptus Endovascular AAA Repair System. The data on these two patients support further clinical evaluation of this technology. A US Feasibility trial is currently underway. ■

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José Antonio Condado, MD, is with Hospital Centro Médico de Caracas in Caracas, Venezuela. He has disclosed that he received expense reimbursement from Aptus Endosystems for expenses related to the conduct of this study, as well as remuneration for consultation services. Dr. Condado may be reached at +58 (212) 552 5262.

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