

# Acute Descending Thoracic Dissection

A case with multiple complications and the failure of initial medical management was treated successfully using an endovascular stent graft.

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**A** 57-year-old man was admitted to the hospital with severe hypertension, severe persistent chest and back pain, and an acute descending thoracic dissection documented by CT. The

CT demonstrated an entry site distal to the left subclavian artery with the dissection ending above the celiac artery. After the patient was evaluated by medical and cardiovascular physicians, conventional medical management, including IV administration of three antihypertensive drugs, bed rest, and ICU monitoring, was selected.

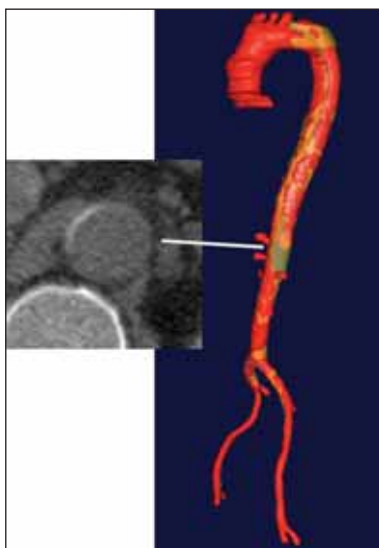
Approximately 6 hours after admission to the hospital, the patient became paraplegic with extension of the dissection into the abdominal aorta. There was no flow in the left renal artery, shown by CT, with onset of left flank pain. A lumbar drain was placed, resulting in reversal of the paraplegia within several hours, and there was loss of the left kidney function, shown by perfusion scan.

During the ensuing 6 days, the patient was treated medically with continuing moderate elevation in his blood pressure but showed no other symptoms. On the sixth day, he had

recurrence of uncontrollable systolic hypertension, developed diffuse abdominal pain, and had loss of pulses in the lower extremities with proximal extension of the dissection to between the left carotid and subclavian arteries. He also became anuric after his creatinine level elevated to 9, and he was started on dialysis.

Due to the severity of the patient's symptoms and the failure of medical management, intervention was recommended. The potential for endoluminal repair was discussed as a possible alternative to surgical repair. The concern for bowel ischemia and other peripheral ischemia was significant, and laparoscopy was considered to determine bowel viability, although he did not have an acute abdomen or serum lactate elevation.

The patient was re-evaluated by contrast CT scan after he was transferred to our institution and was found to have a near occlusion of the visceral segment of the aorta with extension of the dissection to the bilateral iliofemoral arteries (Figure 1). The patient's abdominal tenderness was moderate, but there was no evidence of ischemia. He was evaluat-



**Figure 1.** M2S reconstructions (M2S, West Lebanon, NH) of the thoracoabdominal aorta demonstrate the extent of the dissection and near occlusion of the true lumen in the visceral segment, shown on the axial CT image at this level.

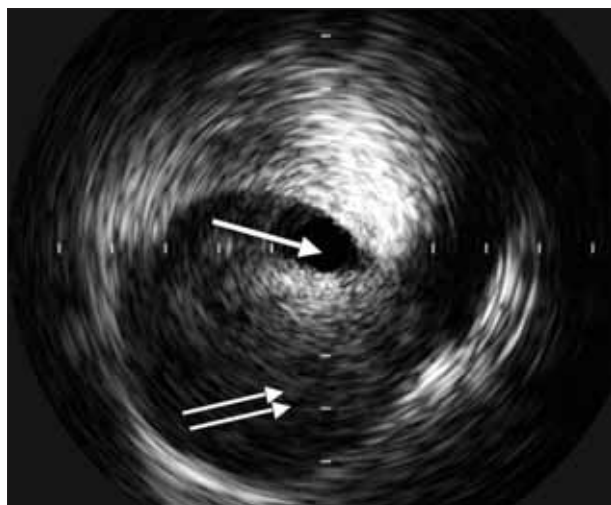


Figure 2. IVUS image shows the severely compromised true lumen at the level of the superior mesenteric artery (arrow) and sluggish flow in the false lumen where it appeared to be thrombosed on CT and on contrast angiography (double arrows).

ed in the endovascular suite for potential revascularization using an endoluminal device. The patient was treated as part of an FDA-approved, single-center-sponsored, investigator IDE with the Talent Thoracic Stent Graft (Medtronic CardioVascular, Santa Rosa, CA) for descending thoracic aortic pathologies, including dissection.

The endovascular procedure was begun by cannulation of the bilateral iliofemoral arteries, and a guidewire was passed atraumatically along the length of the thoracoabdominal aorta. Intravascular ultrasound (IVUS) interrogation demonstrated a very small, slit-like opening of the true lumen in the visceral segment, but there was obvious flow in the false lumen by IVUS that was not apparent on the contrast studies (Figure 2). The proximal entry site of the dissection in the descending thoracic aorta (DTA) was easily identified at approximately 3 cm distal to the left subclavian artery. The entry site was covered using the Talent Thoracic endoluminal prosthesis (34-mm internal diameter, 115-cm-long) in the true lumen. Immediately after the Talent device was deployed, there was return of pulsatility and enlargement of the true lumen at the visceral segment with reperfusion of the visceral vessels by shift of the true lumen. To enhance reperfusion of the visceral segments, two additional Talent Thoracic devices and a Talent Thoracic Distal Extension with an open distal wire configuration were extended across the celiac artery orifice (Figure 3).

After the endoluminal devices were deployed, pulses returned to both lower extremities and ankle-brachial indexes returned to 1 by 12 hours after deployment. In

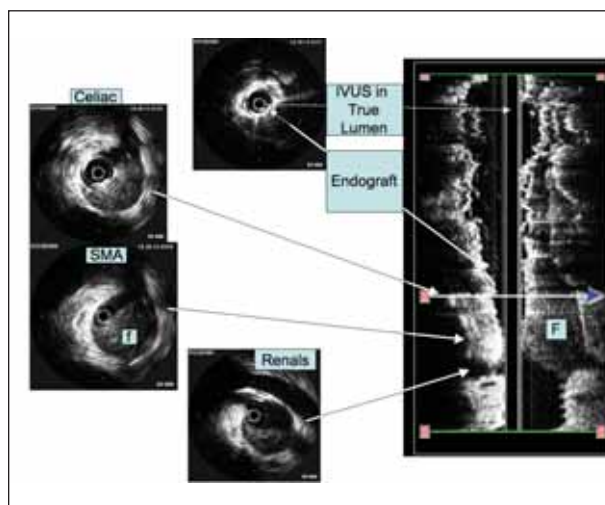


Figure 3. Axial IVUS images (left) and longitudinal grayscale reconstruction of IVUS images along the DTA segment that was covered by the endografts (top, DTA) near the subclavian artery and proximal entry site, and bottom visceral artery origins. There is immediate enlargement of the true lumen with a return of pulsatile flow and stagnation of flow in the false lumen after deployment of the endografts. All visceral artery orifices, except for the left renal, were perfused from the true lumen after coverage of the entry site. F indicates the false lumen.

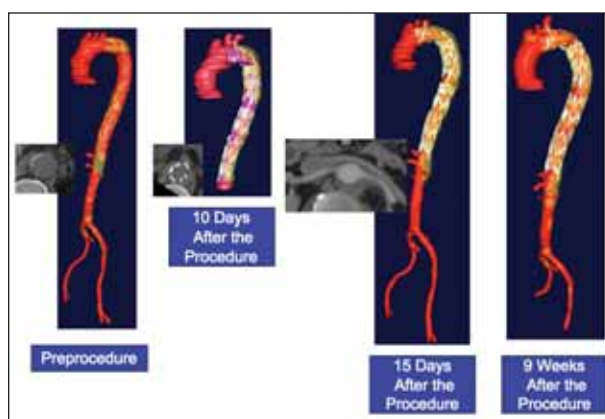


Figure 4. Composite M2S three-dimensional CT reconstructions and axial images of the visceral segment before the procedure and at intervals up to 9 weeks, demonstrating remodeling of the true lumen of the DTA with perfusion of visceral vessels from the true lumen, as the true lumen enlarged, and the septum of the dissection remodeled to an anatomically correct alignment.

addition, his abdominal pain resolved.

Eighteen hours after the procedure, the patient had recurrent paraplegia that reversed with placement of a lumbar drain. At 2 weeks after the procedure, the

patient's aorta completely remodeled with perfusion of all visual branches being from the true lumen (Figure 4). The left kidney had shrunk and did not perfuse on CT and was lost, but he had normal renal function with a creatinine level of 1 several days after the procedure.

## SUMMARY

This case demonstrates the potential for endograft treatment of acute aortic dissections with realignment of the true lumen, thrombosis, and regression of the false lumen over a fairly short interval. In this patient (who was clearly a failure of medical management, with complications including renal failure, impending visceral and peripheral ischemia, and paraplegia), endograft exclusion has provided an endovascular option for rapid recovery and reversal of the pathology, aside from loss of the left kidney. The benefits of this intervention compared to the complications associated with conventional surgical treatment of an acute dissection with failed medical management are obvious. This patient's outcome supports further clinical evaluation for potential treatment of all acute dissections with endografts, if consistent benefits compared to medical management can be demonstrated. ■

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## Indications

- The AneuRx Stent Graft System is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms having:
  - Adequate iliac/femoral access
  - Infrarenal nonaneurysmal neck length of greater than 1 cm at the proximal and distal ends of the aneurysm and an inner vessel diameter approximately 10-20% smaller than the labeled device diameter
  - Morphology suitable for endovascular repair
  - One of the following:
    - Aneurysm diameter of >5 cm
    - Aneurysm diameter of 4-5 cm which has also increased in size by 0.5 cm in the last 6 months
    - Aneurysm which is twice the diameter of the normal infrarenal aorta.

## Contraindications

There are no known contraindications currently associated with this device.

## Warnings and Precautions

FDA approval of the AneuRx device on September, 28, 1999 was based upon one-year follow-up data. The clinical information in this Brief Statement has been updated from the information originally submitted to the FDA for approval to include updated clinical information available to Medtronic as of August 1, 2003 (the clinical data freeze date for the 2003 PMA Annual Report).

The AneuRx Stent Graft is intended to prevent rupture of abdominal aortic aneurysms; however, this risk is not completely eliminated. Based on reports received for patients enrolled in all phases of the clinical study, through August 1, 2003, ruptures have occurred in 2/1193 (0.167%) patients during the operative period; in 3/1193 (0.251%) patients within 30 days of treatment; and in 15/1193 (1.257%) patients greater than 30 days after treatment. The one-year freedom from rupture rate for patients enrolled in all phases of the clinical study is 99.5%; the two-year freedom from rupture rate is 98.6%; the three-year freedom from rupture rate is 98.5%; the four-year freedom from rupture rate is 97.2%; and the five-year freedom from rupture rate is 97.2%. The long-term safety and effectiveness of this implant have not been established. All patients with endovascular aneurysm repair must undergo periodic imaging to evaluate the stent graft, aneurysm size, and occlusion of vessels in the treatment area. Significant aneurysm enlargement (>5 mm), the appearance of a new endoleak, evidence of perigraft

flow, change in aneurysm pulsatility, or migration resulting in an inadequate seal zone should prompt further investigation and may indicate the need for additional intervention or surgical conversion.

Exercise care in the handling and delivery technique to aid in the prevention of vessel rupture. If an AneuRx Stent Graft is placed with less than one centimeter length of nonaneurysmal tissue at the proximal or distal end attachment sites, there is potential for leaking or migration due to inadequate apposition of the stent graft.

- Inappropriate patient selection may contribute to poor device performance. Preliminary data indicate that patients with an aortic neck angle >45 degrees may have a higher likelihood of suboptimal outcomes compared to patients with an aortic neck angle <45 degrees. The same data indicate that patients with an aortic seal length of <15 mm and an iliac seal length of <25 mm may also have a higher likelihood of sub-optimal outcomes.
- This device should only be used by physicians and teams trained in vascular interventional techniques, including training in the use of the device.
- Do not use the AneuRx Stent Graft in patients unable to undergo the necessary preoperative and postoperative imaging and implantation studies.
- The results of the clinical studies indicated that patients who experience an unsuccessful endovascular repair attempt, and as a result undergo conversion to surgical Abdominal Aortic Aneurysm (AAA) repair, are likely to have increased complications arising from both procedures (i.e., cardiac complications, fever, infection, musculoskeletal complications, neurological complications, pulmonary complications, vascular disease, vessel dissection, wound healing issues, and mortality).
- The safety and effectiveness of the AneuRx Stent Graft System for the treatment of abdominal aortic aneurysms have not been evaluated in patients:
  - With aneurysms pending rupture
  - With connective tissue disorder
  - With hypercoagulability
  - With mesenteric artery occlusive disease
  - With ilio-femoral, thoracic, or inflammatory aneurysm
  - With juxtarenal AAA
  - With pararenal AAA
  - With suprarenal or thoracoabdominal aneurysms
  - Who are morbidly obese
  - Pregnant or nursing
  - Less than 18 years old

- With less than one-year life expectancy
- Always have a vascular surgery team available at institutions performing endovascular grafting in the event that conversion to open surgical repair is required.

## Patient Selection, Treatment and Follow-Up

- Do not use this device in patients having an active systemic infection.
- Do not use this device in patients with sensitivities or allergies to the device materials. The materials include: polyether block amide (PEBA); polyether block amide (PEBA) with tungsten filler; polyether block amide (PEBA) with barium sulfate filler; acrylonitrile-butadiene-styrene (ABS) copolymer; glass-filled acrylonitrile-butadiene-styrene (ABS) copolymer; polyetheretherketone (PEEK); polyvinyl chloride (PVC); stainless steel; ethylene propylene rubber; Nylon; silicone; polycarbonate; cyanoacrylate; nickel/titanium (nitinol); tantalum; and polyester. The AneuRx Stent Graft with Xcelarent Delivery System is latex-free.
- The results of the clinical study indicate that women treated with this device may have a higher mortality rate as compared to their male counterparts.
- The use of this device requires administration of radiographic agents. Patients with preexisting renal insufficiency may have an increased risk of renal failure postoperatively.
- Proper use of this device requires accurate fluoroscopic imaging. This device is not recommended for patients whose weight exceeds 350 lb (150 kg) or whose weight may impede accurate fluoroscopic imaging.
- Regular follow-up including imaging of the device should be performed every 3 to 6 months for patients in the enhanced surveillance group and at least every 6 to 12 months for patients in the routine surveillance group (see IFU for patient follow-up recommendations). During the recommended follow-up imaging schedule, patients should be monitored for aneurysm size, occlusion of vessels, change in pulsatility, migration, leaks, and device integrity.
- Additional treatment including endovascular treatment or surgical conversion should be strongly considered in the following cases:
  - Aneurysm growth >5 mm (with or without leak) since last follow-up
  - Change in aneurysm pulsatility (with or without growth or leak)

- Persistent endoleak with or without aneurysm growth
- Stent graft migration resulting in an inadequate seal zone

- The results of the clinical study indicate that subjects experiencing reduced blood flow through the graft limbs and/or leaks may be required to undergo secondary interventions or minor surgical procedures.
- Non-clinical testing has demonstrated that the AneuRx Stent Graft is MR Conditional. It can be scanned safely under the following conditions:
  - Static magnetic field of 3-Tesla or less
  - Spatial gradient field of 720 Gauss/cm or less
  - Maximum whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning.

## Adverse Events

Death, AAA rupture, bleeding, cardiac failure/infarction, edema, wound healing complications, impotence, pulmonary complications, renal failure, gastrointestinal complications, arterial vascular occlusion, and venous vascular occlusion. Potential adverse events include: arterial and venous occlusion (includes thrombosis and thromboembolism), arterial trauma/dissection/perforation, bleeding, cardiac failure/infarction, central or peripheral nervous system impairment, coagulopathy, death, edema, endoleak, erosion with fistula or pseudo-aneurysm, gastro-intestinal complications, graft dilatation, graft migration, graft occlusion, impotence, infection, loss of device integrity: stent fractures, graft wear holes, suture breaks, pulmonary/respiratory complications, renal insufficiency/failure, ruptured vessel/aneurysm, and wound healing complications. Please reference appropriate product *Instructions for Use* for a more detailed list of indications, warnings, precautions and potential adverse events.

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

