

Single-Center IDE Experience Treating Acute Traumatic Aortic Transection

Single-center data demonstrating the utility and midterm stability of thoracic endografts for traumatic aortic transection.

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The use of thoracic aortic endografts to treat patients with acute traumatic transection of the descending aorta has dramatically affected the outcomes of these critically injured patients. Current literature and expanding clinical use of thoracic endografts for this indication has near-uniform consensus regarding utility of this procedure. In the United States, expanded clinical indications for thoracic endografts to include traumatic transections are actively being pursued by several manufacturers, with Medtronic's Valiant® thoracic stent graft (Medtronic, Inc., Minneapolis, MN) recently approved for this indication.

During the evolution of this indication, we have prospectively treated 41 patients enrolled in either an FDA-approved single-center IDE or as part of a commercial IDE. The Harbor/UCLA single-center IDE began in 2003, with patients being treated with three different devices as the technology evolved. The devices were provided by Medtronic, Inc. and included 23 Talent® thoracic, 11 Valiant® thoracic, and one Valiant® Captivia® thoracic stent graft. An additional five Valiant® Captivia® stent grafts were implanted as part of the Medtronic RESCUE trial.

One patient in the single-center IDE died before the procedure could be initiated. All patients in the IDE were enrolled in a lifetime surveillance protocol to observe the immediate and long-term impact of

the thoracic endografts on severe descending thoracic aortic disruptions in a predominately younger patient population. Serial computed tomographic (CT) scans have been stored with M2S (West Lebanon, NH) with quantitative three-dimensional centerline measurement reconstructions providing aortic morphologic data, device stability, and adjacent aortic accommodation to the devices.

During the interval of the study, there has been 100% technical success in being able to deploy the device and exclude the injury, with the entry criteria being consistent across all of the studies. The length of the proximal landing zone was 15 to 20 mm, with individual patient considerations regarding coverage of the left subclavian artery being consistent with the SVS guidelines for treatment of acute, blunt descending thoracic aortic disruption. The data not only provide long-term surveillance regarding the performance of these devices but also demonstrate the utility of newer-design devices to better accommodate the arch anatomy in acutely injured patients.

CASE REPORTS

A 21-year-old man was treated 7 years ago with a Talent® thoracic endograft to exclude a descending thoracic traumatic injury (Figure 1). The patient sustained disability for several months related to his asso-

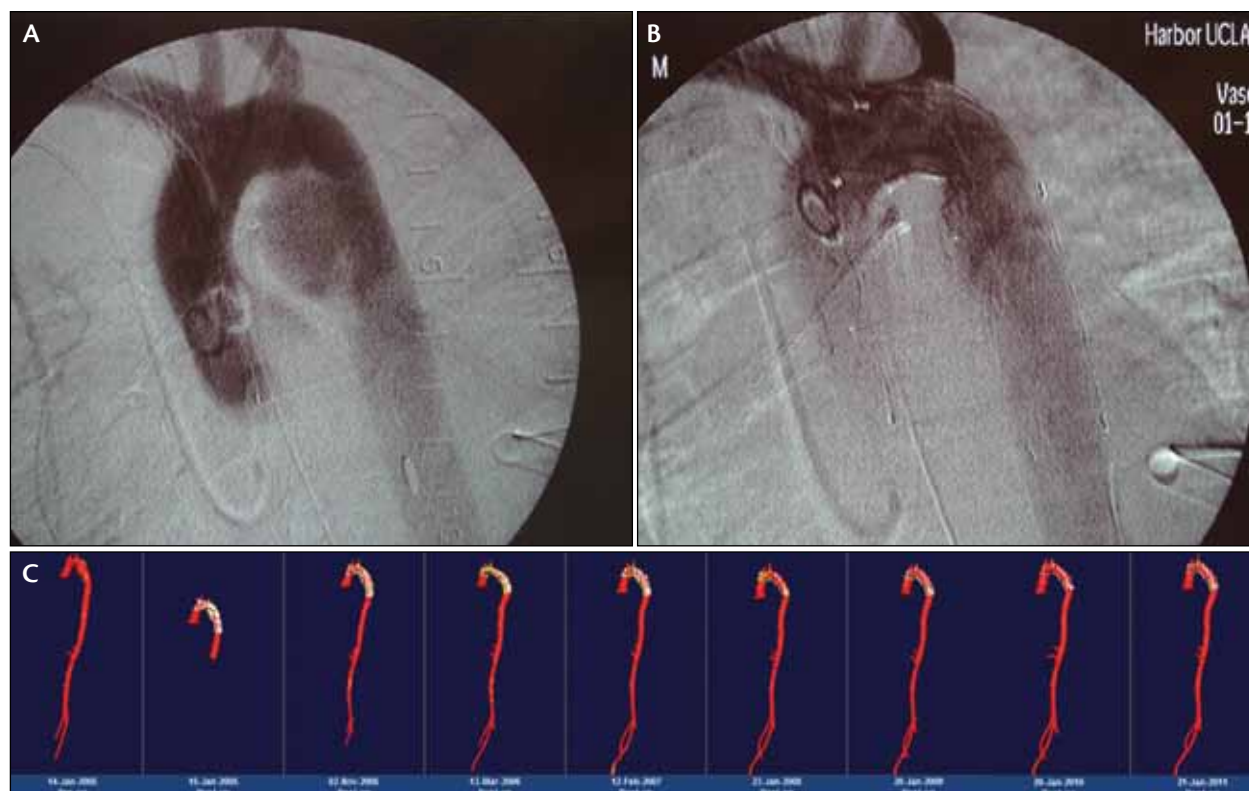


Figure 1. Angiography of a thoracic aortic injury prior to and following device deployment (A, B). Sequential M2S images of the aortic anatomy and device stability at yearly surveillance intervals (C).

ciated severe multiple organ injuries and head trauma. Yearly CT surveillance of the device has demonstrated continued stability of the endograft with no changes in the adjacent aortic anatomy.

With the development of improved iterations of the device, the IDE studies have included the evaluation of the Valiant® Captivia® thoracic endograft for this indication. We have found that the proximal portion of the device accommodates particularly well to acutely angled aortic anatomy, which is seen more frequently in younger patients and is easily deployed with controlled accuracy.

A recent patient treated with a Valiant® Captivia® stent graft was a 47-year-old man who sustained severe multisystem trauma. A CT scan before the intervention revealed an aortic hematoma with a severely disrupted aorta below the left subclavian artery. Additional injuries included blunt chest trauma with multiple rib fractures (first through ninth on the left and first and second on the right), bilateral pulmonary contusions, left hemothorax requiring a tube thoracostomy, complex pelvic fractures, a left acetabular fracture, and gross hematuria with bilateral renal contusions. The patient had a closed head injury with a CGS trauma score of 6

and a CT showing small punctuate hemorrhages but no cerebral swelling and normal-size ventricles. A ventriculostomy revealed normal intracranial pressures in the range of 6 to 7 mm Hg.

The preintervention aortic CT scan, angiography from the procedure, and accompanying intravascular ultrasound (IVUS) images of the proximal landing zone, site of the injury, and distal aortic anatomy emphasize the importance of IVUS as an integral part of the procedure (Figure 2A). By obtaining expedient access and wire passage through the injured segment, IVUS enhances rapid identification of the landing zones and aortic diameters, enabling rapid deployment. In approximately 25% of our patients, this technique allowed performance of the procedure without systemic heparin administration. Although the need for anticoagulation is determined for each individual patient based on the severity of injuries and concern for hemorrhagic complications, we have been able to deploy the devices with only heparin irrigation of the access sheaths and have not experienced any thrombotic complications.

An additional utility of IVUS is that the CT scan acquired at the time of patient admission is frequently performed when the patient is hypovolemic. In a signif-

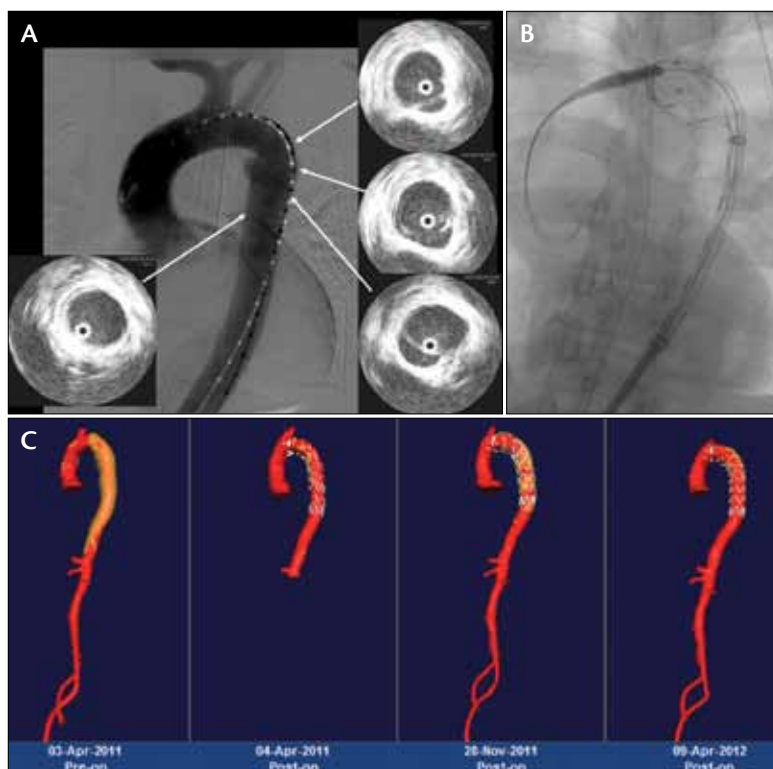


Figure 2. Angiography at the time of device deployment with corresponding IVUS images of the aortic injury (A). Controlled device delivery provided by the Captivia® device (B). Sequential M2S images after device deployment (C).

icant number of the cases, we have observed that once the patient has been transported to the endovascular suite and fluid resuscitation is performed, the aortic diameters are significantly larger in this predominately younger patient population with a compliant aorta. For this reason, we use IVUS to not only expediently identify the appropriate landing zones but also to determine the diameter. In a significant number of cases, we have used a larger device than would have been suggested from the initial CT.

Figure 2B shows the conformity of the device to the acute aortic anatomy and the controlled release provided by the Captivia® design. The Captivia® delivery system enables accurate positioning of the proximal fixation without requiring induced hypotension or asystole, a technique we used for many years to ensure accurate placement before the current design. Figure 2C shows the sequential follow-up CT images and demonstrates accurate deployment and accommodation of the device to the aortic anatomy.

DISCUSSION

Our 9-year experience with evolving thoracic endograft technology for treatment of patients with acute traumatic aortic transection demonstrates the utility and midterm stability of the device for this indication. ■

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