Acute descending thoracic aortic dissection is a dramatic and potentially catastrophic condition. The emergence of thoracic endovascular aortic repair (TEVAR) as a viable therapeutic option has the potential to revolutionize the treatment for complicated thoracic aortic dissections. TEVAR avoids morbidity of cardiopulmonary bypass, aortic cross-clamping and hypothermic circulatory arrest.

Uncomplicated type B dissection

Many patients with uncomplicated type B aortic dissection can be treated medically.1-3 Although short-term mortality rates are favorable, long-term mortality rates remain high, and successful management remains a challenge.4 Data from the International Registry of Acute Aortic Dissection (IRAD) indicates that the three-year survival of patients treated medically was only 77 percent.5 The role of TEVAR in patients with uncomplicated type B dissections may become better defined following completion of the ADSORB trial, a randomized European study comparing TEVAR to best medical therapy.7 The primary outcomes include false lumen thrombosis, aortic rupture and aortic dilation. The INSTEAD trial has demonstrated that aortic remodeling with false lumen thrombosis occurred in 91.3 percent of patients treated with TEVAR for uncomplicated type B dissections compared to only 19.4 percent with medical therapy.8 Patients with blood flow in the false lumen have a significantly higher growth rate of the aorta (3.3 mm/year) than patients without blood flow (<1.4 mm/year).9

Complicated type B dissection

Twenty percent of patients can present with a complicated type B dissection involving rupture, impending rupture with acute dilation of the false lumen or branch-vessel malperfusion.6 Surgical repair of such dissections is associated with significant morbidity and mortality of up to 40 percent.4,10,11 For this indication, TEVAR may soon become the standard of care due to improved outcomes. The goal is to exclude the primary entry site, maximize aortic true lumen diameter, enhance false lumen thrombosis, prevent aortic dilation or rupture and relieve lower body malperfusion (Fig. 1).

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The Cedars-Sinai Heart Institute is one of 12 national sites in the Valiant® Complicated Type B Aortic Dissection Trial* and is actively enrolling in the Cook Zenith® stent graft dissection trial (STABLE II). The Cook Zenith trial includes the “PETTICOAT” procedure, which eliminates the entry tear with a covered stent graft and increases the true luminal diameter in the distal aorta through bare-metal stenting of the visceral and infrarenal segments. These trials are considered pivotal for dissection-specific FDA approval for the treatment of complicated type B dissections. Cedars-Sinai is also part of the handful of U.S. aortic centers participating in the International Registry of Acute Aortic Dissection.

We reported our results with 28 patients undergoing TEVAR for complicated acute type B aortic dissection, with indications that include rupture in 14 percent, lower body malperfusion in 29 percent, visceral/renal malperfusion in 25 percent and impending rupture in 11 percent. Survival was 82 percent at one year’s follow-up and 78 percent at five years’ follow-up. The aorta-specific mortality was 10 percent. Aortic remodeling with complete thrombosis of the false lumen was observed in 85 percent.

Hybrid surgical/endovascular procedures

Some patients who are poor surgical candidates due to advanced comorbidities are also poor endovascular candidates due to the need to cover visceral branches in order to effectively exclude the diseased segment of aorta. For these patients, open debranching followed by TEVAR exclusion of the branched-aortic portion is performed (Fig. 3). We have successfully performed more than 50 such hybrid procedures with visceral debranching followed by TEVAR for
The landscape of transcatheter aortic valve replacement (TAVR) is changing dramatically. From only two first-generation devices, several new prostheses have emerged, some from the original manufacturers (Edwards Lifesciences and Medtronic) but many more from other companies.

**TEVAR for type A dissection**

While open repair remains the mainstay for patients with acute type A dissection, TEVAR may play an increasing role in specific indications. We have successfully performed TEVAR of an ascending aortic pseudoaneurysm in a patient following previous repair of a type A dissection utilizing an antegrade transapical left ventricular approach (Fig. 4). An antegrade approach via a left mini-thoracotomy may offer better access to enter the true lumen. We are currently testing a customized ascending aortic stent graft in collaboration with a U.S. manufacturer as part of an FDA investigational device exemption.

Endovascular repair has revolutionized our approach to acute aortic dissections. At Cedars-Sinai, we are effectively treating patients with complex aortic dissections and modifying our approach depending upon the specific needs of our patients.

Please see page 4 for publication references.

**Next-Generation Aortic Valve Devices**

Hasan Jilaihawi, MD; Raj Makkar, MD

The landscape of transcatheter aortic valve replacement (TAVR) is changing dramatically. From only two first-generation devices, several new prostheses have emerged, some from the original manufacturers (Edwards Lifesciences and Medtronic) but many more from other companies.

**Iterations of the first generation TAVR devices**

The Edwards-Sapien valve is the only FDA-approved device in commercial use today. Important iterations have been made in both the Medtronic CoreValve® and Edwards devices from their respective first generation devices. The Edwards Sapien® (stainless steel stent frame, RetroFlex 3 delivery system) has now been superseded in Europe by the Sapien XT (Cobalt chromium stent frame, NovaFlex delivery system), with access profile reduced from 22-24 Fr to 18-19 Fr.

The comparison between Sapien and XT valves and their delivery systems has been performed in randomized fashion in the PARTNER IIB transfemoral study, for which Cedars-Sinai Heart Institute was the largest enroller of patients. Data from this study demonstrated a reduction in vascular complications and was recently presented at the American College of Cardiology.

Forthcoming developments from Edwards Lifesciences include the Sapien 3 valve, an ultra-low-profile balloon-expandable platform with additional features designed for thoracoabdominal aortic dissections and aneurysms. Cedars-Sinai has one of the few aortic centers in the U.S. that is performing this complex procedure.

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to further reduce paravalvular regurgitation and a lower profile 14 Fr delivery system. Edwards Lifesciences has also developed the Centera™, a self-expanding, repositionable valve with a motorized delivery system and a 14 Fr eSheath.

With its self-expanding design, the Medtronic CoreValve® offered 18 Fr access early on but more recently has a stabilizing system (AccuTrak) for device positioning, which has some evidence of benefit in the accuracy of placement.

**Novel retrievable designs**

The first of these repositionable prostheses was the Sadra Lotus valve, with a first-in-man procedure performed in 2007. Boston Scientific completed acquisition of Sadra Medical in January 2011. The REPRiSE II study, an international registry in Australia and Europe, recently reported its six-month results.

The Direct Flow Medical (DFM) valve is a non-metallic repositionable and retrievable device that comprises bovine pericardial leaflets attached to an inflatable polyester fabric cuff; the cuff has independently inflatable ventricular and aortic rings which are first inflated with contrast-saline, then exchanged under positive pressure with a solidifying infusion media that hardens to form a permanent support structure. The first patient was treated in 2007, and a study for CE mark approval, DISCOVER, began in 2011.

Portico is a self-expanding, fully repositionable and retrievable device from St. Jude Medical. First-in-man was performed in June 2011 and a small 10-patient series was recently reported by two Canadian centers, with good clinical outcomes. The European clinical trial started in late 2011 and a U.S. trial is planned for this year.

**Novel transapical designs**

Three other designs, with present iterations delivered by transapical (TA) approach, have been developed that are specifically designed to conform to aortic annular geometry: JenaValve, Acurate and Engager. The JenaValve is a retrievable and repositionable device that is currently available in Europe for the TA approach. A slow pullback is performed during deployment, with tactile feedback when the aortic aspect of the paperclip-like active fixation mechanism makes contact with the aortic leaflets. CE mark approval was granted in September 2011.

Similarly, Symetis’ Acurate TA™ system is a transapical prosthesis with three sizes and anchors the aortic leaflets with tactile feedback to the operator during positioning. It is not retrievable but has a stabilization arch that anchors the device gently to the proximal ascending aorta. It received a CE mark in September 2011.

The Medtronic Engager is also a self-expanding, anatomically orientated device. Like the JenaValve, it comprises paperclip-like support arms that are positioned over the native leaflets but also incorporates rotational positioning, with prosthetic commissures that are orientated to correspond to the native commissures. Several additional prostheses exist and are at earlier stages of study (Fig. 1); these include Heart Leaflet Technologies, the AorTx valve, the Paniagua valve, the 3f® valve and the Palmaz-Bailey valve.

**Conclusions**

The next generation aortic devices offer considerable promise in standardizing and simplifying the TAVR procedure and reducing its complications. They are predominantly self-expanding devices, many of which have the additional feature of retrievability. Many of these prostheses will be the subject of randomized trials at Cedars-Sinai Heart Institute in the near future.

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