

Device Selection and Case Planning for the Treatment of Type B Dissections With the Conformable GORE® TAG® Thoracic Endoprosthesis

What to know regarding stent-graft sizing and patient selection for successful endovascular management.

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In recent years, the field of endovascular surgery has revolutionized the treatment of patients with acute and chronic type B dissections. Acute type B dissections are associated with significant morbidity and mortality related to complications that occur due to visceral malperfusion, paraplegia, limb ischemia, and retrograde dissection due to the unruly extension of the dissection flap. Thoracic stent-grafting has, in recent years, been utilized for the management of acute and complicated type B dissections with favorable results in comparison to open repair. Additionally, the INSTEAD XL trial has shown that thoracic stenting can improve outcomes in uncomplicated chronic type B dissections. Recently, the US Food and Drug Administration (FDA) approved the Conformable GORE TAG Endoprosthesis (Gore & Associates, Flagstaff, AZ) for use in aortic dissections—the first stent-graft to receive this approval. Device sizing and careful planning with consideration of patient-specific anatomy, dissection extent, need for brachiocephalic artery coverage, and location of tears all have to be taken into consideration for a successful repair.

BACKGROUND

A type B dissection is an intimal tear that develops distal to the left subclavian artery. Conversely, a primary intimal tear in the ascending aorta defines a type A dissection, which is a surgical emergency requiring ascending arch replacement. Type B dissections are broken into acute (< 2 weeks duration) and chronic. Patients with acute aortic dissection usually complain of excruciating, sharp chest or abdominal pain that is tearing in nature. Typically aided by

severe hypertension, these dissections spread distally. Acute type B dissections may be complicated by either rupture or malperfusion of the spinal cord, lower extremities, or visceral vessels. Malperfusion typically occurs when the dissection flap shears off and occludes the origin of the involved vessels or, less frequently, when compression of the true lumen compromises flow. Morbidity and mortality may be high in patients with acute type B dissections, with mortality rates in excess of 10% when complications occur.¹ In general, type B dissections are initially treated medically with anti-impulse hypertensive therapy and vasodilators. Operative management is reserved for complicated cases and usually involves exclusion of the primary entry tear and any aneurysmal degeneration with a stent-graft, which frequently requires coverage of the left subclavian artery.

The complicated type B dissection is an intricate, complex management problem that is patient specific. No two patients have the same location of the primary tear, proximity to the brachiocephalic vessels, aneurysmal degeneration, pattern of involvement of the visceral aorta, distal extension into the iliac arteries, or risk of spinal cord ischemia. Good cross-sectional imaging and 3D reconstructions are imperative for case planning. Emergent treatment is geared toward reopening a compressed true lumen and reestablishing flow to an underperfused branch vessel. Spinal cord ischemia, visceral malperfusion, and lower extremity ischemia are all surgical emergencies secondary to occluded, compressed, or thrombosed vessels. Aneurysmal degeneration and rupture make up the other component of complicated type B dissections requiring rapid intervention, typically by exclusion

with a stent-graft and covering the proximal entry tear. Careful examination of the renal vessels and the quantitative evaluation of renal perfusion and excretion should be followed for severe decline that mandates intervention.

Uncomplicated, chronic type B dissections have traditionally been treated with medical therapy. The INSTEAD trial evaluated best medical therapy compared to endovascular stenting for the management of patients with uncomplicated type B dissections, and at 2 years found no significant difference in mortality.² However, in extending the patient follow-up to 5 years, a significant improvement in patient aorta-specific survival was noted and delayed disease progression in the stenting group.³ The pendulum appears to be swinging toward more aggressive endovascular management of this aortic pathology once stabilized from the initial presentation, unless urgent repair is required for complications.

FDA APPROVAL OF THE CONFORMABLE GORE TAG DEVICE FOR MANAGEMENT OF AORTIC DISSECTIONS

The GORE TAG Thoracic Endoprosthesis was the first thoracic device on the market specifically for descending thoracic aneurysms approved by the FDA in 2005. It was further expanded to include lesions such as transections, penetrating atherosclerotic ulcers, and intramural hematomas. Since the introduction of thoracic stent-grafts, use in dissections has been off label. In September 2013, the FDA extended approval for a dissection indication. The GORE TAG Endoprosthesis has been vetted in the treatment of thoracic disease and the FDA felt that, given the diversity of descending thoracic pathology, a broad approval without individualized studies addressing each pathology was warranted. Given the approval, plans for postapproval studies evaluating the Conformable GORE TAG Endoprosthesis use in acute and chronic dissections are commencing.

ANATOMIC AND DISSECTION-SPECIFIC KEYS TO SUCCESSFUL ENDOVASCULAR MANAGEMENT

Initial management of a patient with an acute dissection or complicated chronic dissection is the lowering of the blood pressure via intravenous β -blockade and vasodilators. Symptom relief typically follows a reduction in blood pressure, however, it can lag several hours behind. Axial imaging of the entire aorta is imperative with fine cuts (1 mm), and 3D reconstruction ability is highly recommended. Careful identification of aneurysmal degeneration, location of the primary intimal tear—especially in regard to the left subclavian artery, presence and location of secondary tears, involvement and flow to the visceral vessels, ability to define true and false lumen, and distal extent and involvement of the iliac vessels are all imperative in case planning. Pressurization within the false lumen from the intimal tear can compress and cause thrombosis of branch

vessels, causing malperfusion of the legs, viscera, or spinal cord. Question of retrograde dissection or presence of a type A dissection should prompt further workup with a gated computed tomography (CT) scan of the chest or transesophageal echocardiogram.

The mainstay of endovascular therapy for the treatment of a type B dissection is to cover the proximal intimal tear. Due to the typical location of the proximal tear in close proximity to the left subclavian artery, intentional coverage of the vessel is often required. This, in theory, blocks the entry of flow into the false lumen, denying any further propagation of the dissection. Angiography is used to confirm improvement of flow to the vessels affected by malperfusion. If the placement of the thoracic stent does not improve the malperfusion, adjunctive measures are taken. Further stenting down to just above the celiac artery is indicated if there remains significant true lumen compression. If the true lumen appears patent and malperfusion of branch or visceral vessels remains, stenting or fenestration might be required.

Careful identification of true and false lumen, location, and number of fenestrations allows the surgeon to plan for arterial access location. A wire should be carefully advanced up into the aortic arch. Intravascular ultrasound (IVUS) use is highly recommended to identify position within the true lumen, location of tears, accurate determination of the flaccidity of the septum, and size of the true lumen for stent-graft sizing. IVUS allows avoidance of the misplacement of a stent within the false lumen, or identification of the wire traversing the tears incorrectly.

The Conformable GORE TAG Endoprosthesis does not have active fixation, which is a benefit in treating aortic dissection. Active fixation could potentially increase the risk of retrograde dissection and tearing of the fragile aorta. Coverage of the proximal tear typically involves the coverage of the left subclavian artery due to the usual proximity of the tear to the vessel. Careful consideration must be given to spinal cord perfusion with either spinal drain placement or extrathoracic revascularization. In the absence of aneurysmal degeneration, excessive stent-graft oversizing is not required, and most practitioners do not feel a full 2 cm of proximal fixation is needed. While staying within the instructions for use, most practitioners would tend to pick the smaller stent size. In the presence of aneurysmal degeneration, a full 2 cm of proximal fixation is recommended, and traditional sizing of stent-grafts is typical.

In acute dissections, where the septum is thin and mobile, sizing typically involves sizing the entire aorta (true and false lumen together) to achieve complete obliteration of the false lumen. In chronic dissections, where it is more likely that the septum is fixed, sizing must further take into account the size of the lumen to stent, with the understanding that the stent might compress the false lumen but not to the extent it does in an acute dissection.



Figure 1. CT angiogram showing a type B dissection from the origin of the left subclavian artery with proximal entry tear abutting the origin of the vessel (A, B). Additionally, the dissection extends to the left renal artery with no further fenestrations (C).

CASE 1: ACUTE DISSECTION

A 52-year-old man with a history of hypertension presented to the emergency room with a 5-day history of chest pain and severe hypertension (systolic blood pressure > 200 mm Hg). A CT angiogram confirmed a type B dissection. He was admitted to the intensive care unit and placed on intravenous β -blockade and vasodilators, and his systolic blood pressure was kept below 110 and heart rate, below 70. He had palpable pulses throughout and no abdominal pain. His creatinine level was 1 mg/dL. Over the next 48 hours, his chest pain was only slightly improved, his creatinine increased to 1.5 mg/dL and required higher doses of intravenous blood pressure medication. Repeat imaging revealed an increase in size of the proximal descending thoracic aorta by 9 mm. Immediate intervention was felt to be required.

Case planning was accomplished using 3D reconstruction with the AQUARIUS® INTUITION Viewer (Aquarius, TeraRecon, Foster City, CA). The dissection flap and aneurysmal degeneration started right at the left subclavian artery that had a size of 43 mm, with maximal aneurysm dimensions of 48 mm (39 mm 2 days prior). The diameter just distal to the left subclavian artery was 38 mm. The distance down to the celiac artery was 292 mm and tapered down to 27 mm (Figure 1). The dissection extended down involving the celiac artery with both true and false lumen flow, whereas the superior mesenteric artery and the renal vessels originated off the true lumen (Figure 2). The dissection stopped at the origin of the left renal artery with a distal fenestration noted. Endovascular management involved planned coverage of the proximal tear, requiring

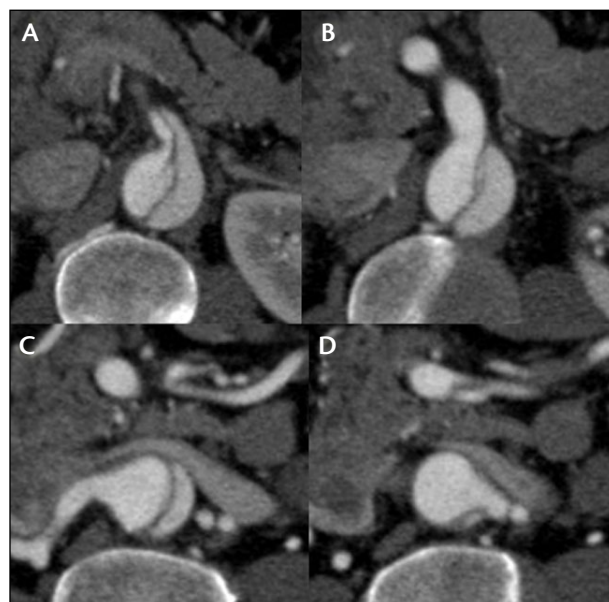


Figure 2. Axial images from a CT angiogram showing the visceral vessel involvement. There is true and false lumen involvement of the celiac artery (A). The superior mesenteric artery (B) and right (C) and left renal (D) vessels originate only in the true lumen, and the dissection ends at the left renal artery with a fenestration.

coverage of the left subclavian artery with coverage down to the celiac artery. Coverage all the way to the celiac was chosen due to aneurysmal degeneration and acute change in size of the descending thoracic aorta. The plan for left subclavian revascularization was decided upon because of the length of aortic coverage and the diminutive size of the contralateral vertebral artery, and this was performed initially. After wire access into the aortic arch was accomplished, IVUS was used to confirm diameters and ensure accurate location within the true lumen. As per the instructions for use, the choice of either a 40- or 45-mm Conformable GORE TAG Device was reasonable; however, due to the aneurysmal degeneration, the larger size was chosen. A 45-mm X 15-cm Conformable GORE TAG Device was placed proximally covering the left subclavian artery (Figure 3). A 34-mm X 15-cm Conformable GORE TAG Device was then deployed just above the celiac artery building up, and another 45-mm X 15-cm graft was used to bridge the two grafts.

The postprocedural course was unremarkable. The patient had no complaints of any further chest or back pain. His creatinine level remained stable and then dropped back to baseline. CT angiogram prior to discharge revealed adequate position of the stent-graft, primary tear coverage, and no extension of the dissection. On postoperative day 3, the patient was doing well on oral antihypertensive medication. Thirty-day postoperative CT angiogram revealed exclusion of the primary tear with aortic remodeling and false lumen thrombosis behind the stent (Figures 4 and 5).

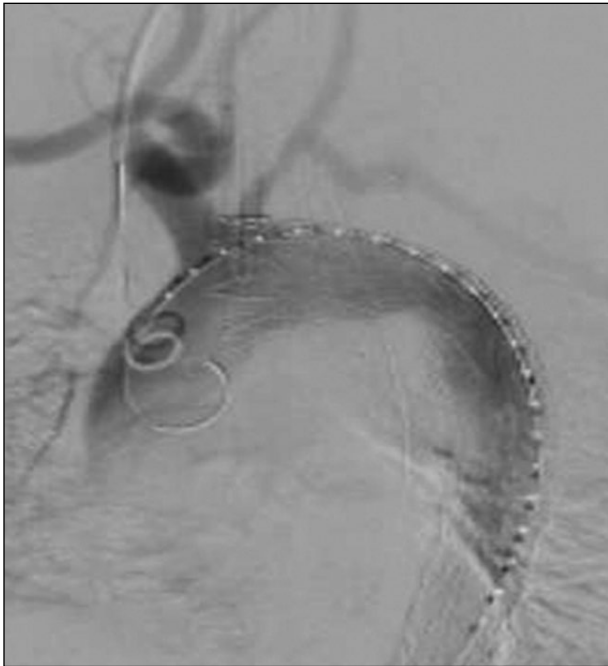


Figure 3. Intraoperative aortogram showing the placement of the Conformable GORE TAG Device with planned coverage of the left subclavian artery with excellent apposition and no bird beaking.

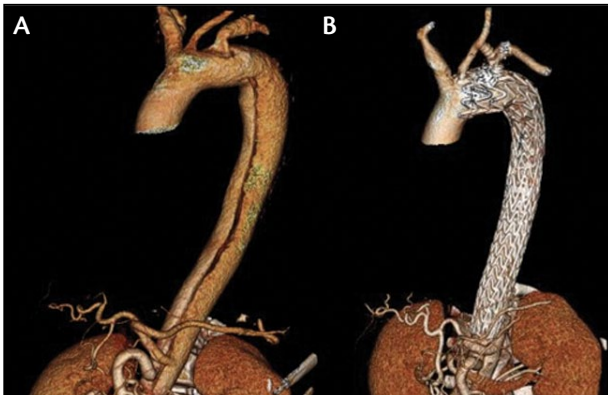


Figure 5. Pre- (A) and postprocedure (B) 3D reconstructions showing coverage of the left subclavian artery with stent coverage to above the celiac artery. A carotid-subclavian bypass supplies the left subclavian artery.

CASE 2: CHRONIC DISSECTION

A 57-year-old woman with a history of hypertension, autoimmune hepatitis, and a known type B dissection presented to the hospital with sharp back pain. She was followed at an outside hospital for a type B dissection down to the level of the renal arteries. She underwent a CT angiogram that revealed progression of the dissection down to the iliac bifurcation. She was admitted and placed on intravenous β -blockade with a reduction in her blood pressure and resolution of her pain. Over the next few days, the patient had difficulties transitioning to oral anti-hypertensive medications. The decision was made to treat her.



Figure 4. A CT angiogram 1 month after the procedure shows complete remodeling and thrombosis of the false lumen of the entire covered portion. Flow still remains in the visceral segment via a distal fenestration at the level of the left renal artery.

The CT angiogram with reconstructions revealed an aortic diameter at the left subclavian artery of 25 mm and a proximal entry tear 54 mm distally, where the true lumen was 24 mm X 16 mm, and the total aortic diameter was 30 mm. The dissection compressed the true lumen throughout the descending thoracic aorta for a total distance of 231 mm (Figure 6). All the visceral vessels appeared to come from the true lumen, which was fairly compressed through the paravisceral segment. IVUS was performed through the left femoral access, after wire access was navigated into the aortic arch, confirming the location within the true lumen. Additionally, IVUS confirmed an aortic diameter of 24 to 26 mm at the level of the left subclavian artery and true lumen diameter in the descending thoracic aorta of 19 mm. After performing an aortogram and identifying the left subclavian artery, a 31-mm X 15-cm



Figure 6. Axial cuts from a CT angiogram showing the extent of the dissection from just beyond the left subclavian artery (A) through the descending thoracic aorta (B, C), and just above the celiac artery (D).

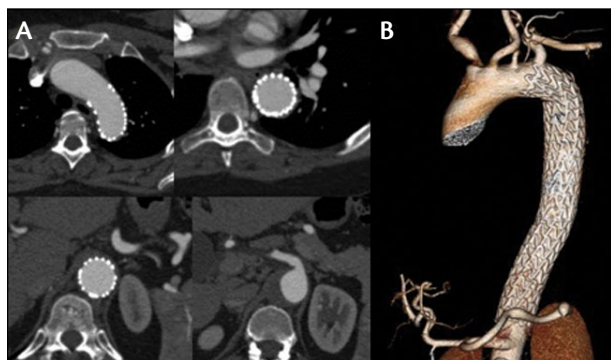


Figure 8. Axial images (A) and 3D reconstruction (B) from a 6-month repeat CT angiogram showing excellent stent apposition, true lumen expansion, and complete aortic remodeling and false lumen thrombosis.

Conformable GORE TAG Device was placed (Figure 7), with another 31-mm X 15-cm Conformable GORE TAG Device used to land just above the celiac artery. IVUS was used to confirm good stent apposition and no infolding and identified slight true lumen expansion.

The patient did well postoperatively and was discharged to home after 2 days. A repeat CT angiogram was obtained at 1 and 6 months showing full expansion of the true lumen, with complete aortic remodeling and false lumen thrombosis (Figure 8).

SUMMARY

Endovascular management of type B dissections appears to be the treatment of choice for acute, complicated, and select uncomplicated dissections. Immediate

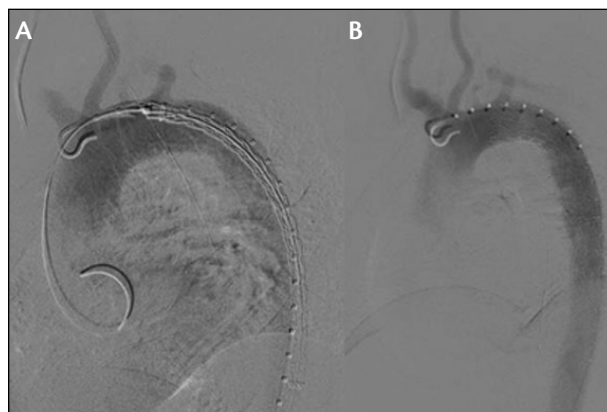


Figure 7. An aortogram confirming the location of the left subclavian artery (A), followed by graft deployment with excellent positioning at the left subclavian artery (B).

and lasting aorta-specific morbidity and disease progression are improved with thoracic stent-grafting. Careful patient-specific evaluation of preoperative imaging identifies potential pitfalls such as entry tear proximity to the left subclavian artery, aneurysmal degeneration, and true lumen size, which aids in successful placement of a well-sized stent-graft that covers the entry tear and causes false lumen thrombosis and remodeling. The Conformable GORE TAG Device is ideally suited for dissection pathology and should be the first-line therapy for repair. ■

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