

# Early results of bare metal extension stent for thoracoabdominal aortic dissection



Patrick R. Vargo, MD,<sup>a,b</sup> Christopher L. Tarola, MD,<sup>c</sup> Emily Durbak, MD,<sup>d</sup> Chang Yoon Doh, BS,<sup>e</sup> Francis J. Caputo, MD,<sup>a,f</sup> Christopher J. Smolock, MD,<sup>a,f</sup> and Eric E. Roselli, MD<sup>a,b</sup>

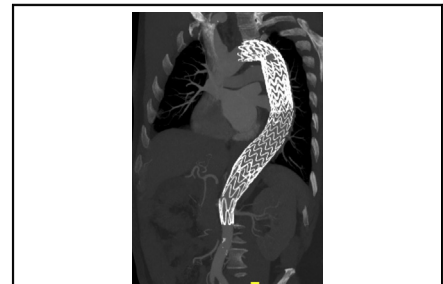
## ABSTRACT

**Objectives:** Debakey type I and IIIb aortic dissections are complicated by extension along the full length of the aorta. Over the long term, the thoracoabdominal aorta in these patients often continues to degenerate, requiring endovascular or open repair. The purpose of this investigation is to determine the early clinical outcome on aortic remodeling using a composite thoracic stent graft and thoracoabdominal bare metal extension stenting strategy.

**Methods:** From April 2019 to April 2021, 73 patients with Debakey I/IIIb aortic dissection underwent endovascular stent graft repair of the descending thoracic aorta and repair of the thoracoabdominal aorta using bare metal extension stenting. Pre-operative and follow-up surveillance computed tomography imaging scans were analyzed.

**Results:** Fifty-three (73%) patients had a Debakey I aortic dissection, and 50 (69%) patients underwent surgery during the chronic (time to surgery >30 days) dissection phase. Mortality at 30 days was 4% (3 hyperacute patients). Stroke occurred in 3 (4%), paraparesis in 2 (2.7%), and acute renal failure requiring dialysis occurred in 2 (2.7%) patients. On postoperative and follow-up computed tomography, there was a significant increase in false lumen thrombosis ( $P < .001$ ). This coincided with a significant increase in true lumen fraction suggestive of positive aortic remodeling ( $P < .001$ ) at the time of latest follow-up.

**Conclusions:** Altering the course of aortic remodeling, with placement of a dissection stent in the thoracoabdominal aorta simultaneous with descending thoracic aortic repair may promote true lumen re-expansion and false lumen thrombosis during acute and chronic dissection phases. (JTCVS Techniques 2022;14:1-8)



Computed tomography image of TEVAR with bare metal extension stent.

## CENTRAL MESSAGE

TEVAR with bare metal extension stent for thoracoabdominal aortic dissection promotes early positive remodeling and warrants further investigation.

## PERSPECTIVE

Thoracic endovascular repair of aortic dissections variably prevents further aneurysmal degeneration. Bare metal extension stenting of the thoracoabdominal aorta in conjunction with descending TEVAR for acute and chronic extensive aortic dissections is safe and promotes early positive remodeling. Late remodeling and the influence on survival will need continued study.

▶ Video clip is available online.

The treatment for complicated Stanford type B or DeBakey type III aortic dissections and those with high-risk features is thoracic endovascular aortic repair (TEVAR). Treatment goals are sealing the entry tear, expanding the

From the <sup>a</sup>Aorta Center, <sup>b</sup>Department of Thoracic and Cardiovascular Surgery, and <sup>c</sup>Department of Vascular Surgery, Heart, Vascular, and Thoracic Institute, Cleveland Clinic, Cleveland, Ohio; <sup>d</sup>Division of Cardiac Surgery, Sunnybrook Health Science Center, University of Toronto, Toronto, Ontario, Canada; and <sup>e</sup>Cleveland Clinic Lerner College of Medicine and <sup>f</sup>School of Medicine, Case Western Reserve University, Cleveland, Ohio.

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**Abbreviations and Acronyms**

CT	= computed tomography
PETTICOAT	= Provisional Extension to Induce Complete Attachment
TEVAR	= thoracic endovascular aortic repair

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true lumen, and depressurizing the false lumen.<sup>1</sup> Although TEVAR has been associated with reduced aortic-related death and reduction in early mortality, optimal management of subacute and chronic type B aortic dissection is an ongoing area of discussion and clinical investigation.<sup>2</sup> Similarly, after ascending and arch repairs, Debakey I aortic dissections are commonly left with residual thoracoabdominal aortic dissection. The progression of Debakey I and IIIb aortic dissections following TEVAR is complex, with persistent retrograde false lumen flow and late aneurysm degeneration requiring ongoing surveillance and surgical intervention.<sup>3-5</sup>

A strategy to positively influence aortic remodeling and true lumen perfusion, the bare metal extension stenting technique has evolved to support the delaminated segments of the thoracoabdominal aorta.<sup>6-8</sup> This approach utilizes an uncovered stent with low radial force deployed into the true lumen of the thoracoabdominal aorta, generally in the visceral segments. The purpose of this investigation is to determine the early clinical outcomes and changes in aortic morphology by managing the abdominal aorta with the bare metal extension stenting technique and report our experience in patients with acute and chronic thoracoabdominal aortic dissection.

**METHODS****Patients**

From April 1, 2019, to April 5, 2021, 73 patients underwent endovascular aortic repair for thoracoabdominal dissection with the bare metal extension stenting technique. The Food and Drug Administration-approved Zenith Dissection Endovascular Stent (Cook Medical) was used in conjunction with commercially available covered thoracic aortic stent grafts. Dissections were defined as acute <14 days, subacute 14 to 30 days, and chronic >30 days. Surgical indications included complicated acute Debakey IIIb dissection, true lumen compression and malperfusion, an increase in the adventitia-to-adventitia diameter of the descending thoracic aorta >5.5 cm, or an increase in the growth rate of the descending thoracic aorta by >10 mm/year. Patients were identified using the implant log of the Zenith Dissection Endovascular Stent since its availability at our institution in April 2019 and the electronic medical record, from which patient data was abstracted. Demographic and preoperative characteristics are presented in [Table 1](#). Follow-up information on patient clinical status and

**TABLE 1. Patient demographic characteristics (N = 73)**

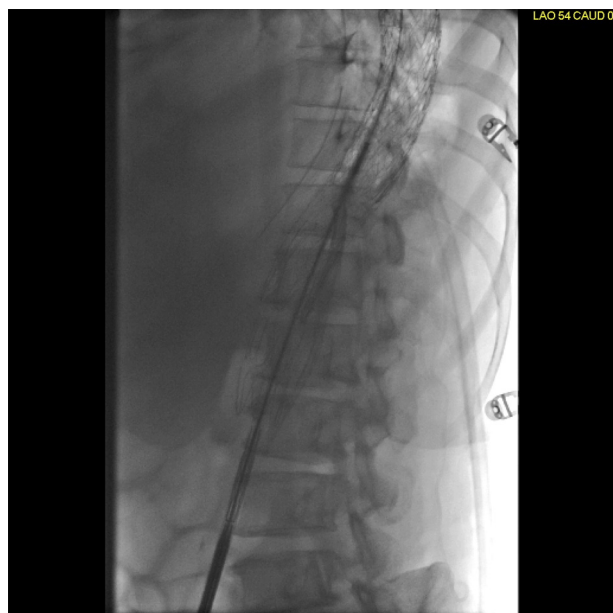
Characteristic	Result
Age (y)	58 (50, 69)
Female sex	25 (34)
Body mass index	28.6 (25.0, 33.7)
Comorbidity	
Coronary artery disease	16 (22)
Peripheral artery disease	19 (26)
Chronic obstructive pulmonary disease	8 (11)
Hypertension	61 (84)
Pharmacologically treated diabetes	8 (11)
Chronic kidney disease	13 (18)
Connective tissue disorder	8 (11)
Surgery indication	
Growth	51 (70)
Size	11 (15)
True lumen compression and/or malperfusion	11 (15)
Dissection classification	
Debakey type I	53 (73)
Debakey type IIIb	20 (27)
Dissection chronicity	
Acute	22 (30)
Subacute	1 (1.4)
Chronic	50 (68)

Values for continuous variables are presented as median (25th and 75th percentile) and values for categorical variables are presented as n (%).

the presence of surveillance imaging was obtained by chart review. Review of routine computed tomography (CT) angiography scans were analyzed to obtain aortic remodeling data. This single-institution, retrospective study was approved by the institutional review board at Cleveland Clinic, and informed consent was waived as Institutional Review Board No. 20-979 on September 15, 2020.

**Surgical Technique**

All procedures were performed under general anesthesia. Access was obtained via the common femoral artery, and was either percutaneous or via surgical cutdown. Intravascular ultrasound was used to identify and traverse the true lumen in conjunction with fluoroscopy. Commercially available thoracic stent grafts were selected to be used in the proximal descending aorta. Sizing was based on adventitial-to-adventitial diameters in proximal and distal landing zones, with <10% oversizing. The covered thoracic stent grafts were deployed in suprarenal position, followed by Zenith Dissection Endovascular Stent overlapping with the proximal stent grafts and extending through the abdominal aorta to the end of the dissection, typically the aortoiliac bifurcation ([Video 1](#)). The instructions for use for the Zenith Dissection Endovascular Stent recommend using the 36-mm device for true lumen diameters 20 to 30 mm, and the 46-mm device for true lumen diameters 31 to 38 mm. If the true lumen diameter exceeds 38 mm, this device should not be used. Similarly, the stent should not be used with total aortic diameter <20 mm. Regarding overlap with the proximal TEVAR endograft, in this study we use a minimum of 1 stent. In the setting of chronic dissection, adjunctive balloon fracture fenestration was employed to the thoracic stent grafts only.<sup>9</sup> Completion angiography and



**VIDEO 1.** Fluoroscopy-guided deployment of Zenith Dissection Endovascular Stent (Cook Medical) in aortic zones 5 through 9, extension of previously placed thoracic endovascular aortic repair (left anterior oblique view). True lumen course of wire and iliac bifurcation identified by intravascular ultrasound before deployment. Video available at: [https://www.jtcvs.org/article/S2666-2507\(22\)00237-1/fulltext](https://www.jtcvs.org/article/S2666-2507(22)00237-1/fulltext).

intravascular ultrasound confirmed satisfactory placement of the devices with branch vessel patency. Access was closed either using closure devices when performed percutaneously, or via primary repair of the femoral artery when performed via surgical cutdown. The surgery was considered a technical success if there was satisfactory positional deployment of the stent grafts in the true lumen without obstruction of branch vessels, no evidence of type 1 or 3 endoleaks, and survival at 24 hours postoperatively.

Cerebrospinal fluid drains were placed preoperatively in patients undergoing elective surgery considered to be at high risk for spinal cord ischemia, or as postoperative rescue in patients with signs of paraparesis (elective or emergency). High-risk patients were considered to be those with coverage of the T8 to L1 area, coverage of the entire thoracic aorta, prior infrarenal aortic repair, or presence of occluded left subclavian artery or internal iliac artery. If patients did not experience neurologic deficit on postoperative day 2, the drain was capped for 6 hours and then removed. Bare metal dissection stents do not directly seal off intercostal or lumbar arteries due to their uncovered design; however, they may result in false lumen thrombosis, which can occlude these arteries.

### Imaging Analysis

Multiphase (ie, noncontrast, arterial phase, and delayed venous phase) contrast-enhanced CT angiography was analyzed using 3-dimensional reconstructive software (Aquarius; TeraRecon). Centerline measurements of total aortic area, false lumen area, false lumen area, and the presence of patent, partially thrombosed, or thrombosed false lumen at zones 0 to 9 of the aorta were collected. CT scans were reviewed by a single interpreter (C.Y.D.), and supervised by a second expert reviewer (C.L.T. or P.R.V.). For each time point, area fraction was calculated for the true and false lumen by dividing the summed lumen area by the summed total area for dissected segments. Patent fraction was quantified by dividing the number of patent zones by the total number of dissected zones.

**TABLE 2. Postoperative outcomes**

Event	Result
30-d mortality	3 (4.1)
Spinal cord ischemia	2 (2.7)
Access site pseudoaneurysm	3 (4.1)
Limb ischemia	1 (1.4)
Stroke	3 (4.1)
Bleeding	2 (2.7)
Acute renal failure requiring dialysis	2 (2.7)

Values are presented as n (%).

### Data Analysis and Statistics

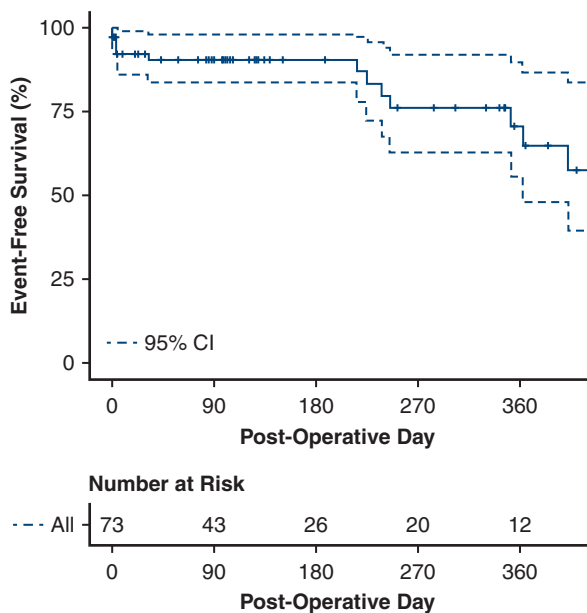
All statistical analysis was performed in R software version 4.1.0 (R Foundation for Statistical Computing). Continuous variables are summarized as median (25th and 75th percentiles); categorical variables are summarized as frequency (percentage) and were compared using the  $\chi^2$  test or Fisher exact test for frequency  $<5$ . A multivariable beta regression model with a logit link was used to assess change in true lumen and patent fraction. Covariates included postoperative day, age, baseline mean aortic area, indication for surgery, DeBakey classification, and dissection chronicity. Coefficient estimates and 95% CIs are reported with partial plots of selected covariate estimated marginal means. Freedom from reintervention and all-cause mortality was plotted as a composite end point using the Kaplan-Meier method.

### RESULTS

There were 73 patients in our study group, 20 patients had DeBakey class IIIb dissection (6 acute, 1 subacute, and 13 chronic). The remaining 53 patients had DeBakey class I dissection (16 acute and 37 chronic). Of those patients with DeBakey I dissection, 40 had proximal descending thoracic endograft (frozen elephant trunk in 37 patients and TEVAR in 3 patients) before PETTICOAT intervention. Of all patients, 46 had proximal descending thoracic endograft before PETTICOAT intervention. Patients were followed for a median of 104 days (25th and 75th percentile, 5 and 303 days): 70% were followed for 30 days or longer and 30% through 1 year. Sixteen patients were either lost to follow-up or chose to pursue care elsewhere, and the remaining patients that did not have CT scans at those intervals died or had not yet reached 1-year follow-up.

### Postoperative Outcomes

Technical success was achieved for all 73 patients undergoing TEVAR + bare metal extension stenting, and postoperative complications are presented in Table 2. A total of 5 (7%) patients died during the study period, with 3 (4.1%) occurring within 30 days. Two were in-hospital deaths resultant from multisystem organ failure after presenting with acute DeBakey class I dissections and malperfusion. Additionally, there was another mortality after acute



**FIGURE 1.** Freedom from reintervention and death following endovascular repair for thoracoabdominal aortic dissection with the provisional extension to induce complete attachment technique. Cumulative events (re-intervention or death) are displayed in 90-day intervals. *CI*, Confidence interval.

Debakey class IIIb with malperfusion occurring at 30 days, and of unknown etiology. Similarly, both patients requiring hemodialysis for acute renal failure presented with acute Debakey class I dissections. Retroperitoneal bleeding occurred after TEVAR + bare metal extension stenting procedure in 2 patients. One patient was managed nonoperatively with surveillance, and the other was diagnosed during exploratory laparotomy for mesenteric ischemia after presenting with intestinal malperfusion that eventually resulted in death.

**TABLE 3. Aortic reinterventions**

Indication	Procedure	Result
Root aneurysm and aortic insufficiency	Bentall + reverse frozen elephant trunk	1 (1.4)
New type A dissection	Ascending + reverse frozen elephant trunk	1 (1.4)
Persistent false lumen flow	False lumen embolization	4 (5.5)
Type 1a endoleak	Left subclavian transposition + thoracic endovascular aortic repair	1 (1.4)
Type 2 endoleak	Coiling or plug	2 (4.1)
Type 2 endoleak	Extension of left subclavian stent	1 (1.4)

Values are presented as n (%).

**TABLE 4. Preoperative aorta measurements (N = 73)**

Characteristic	Result
Mean aorta area (mm <sup>2</sup> )	1000 (750-1200)
Mean true lumen area (mm <sup>2</sup> )	370 (280-470)
Mean false lumen area (mm <sup>2</sup> )	550 (430-810)
True lumen fraction	0.37 (0.30-0.43)
False lumen fraction	0.62 (0.56-0.68)
Patent fraction	0.83 (0.56-1.00)

Values are presented as median (interquartile range).

**Reinterventions and Death**

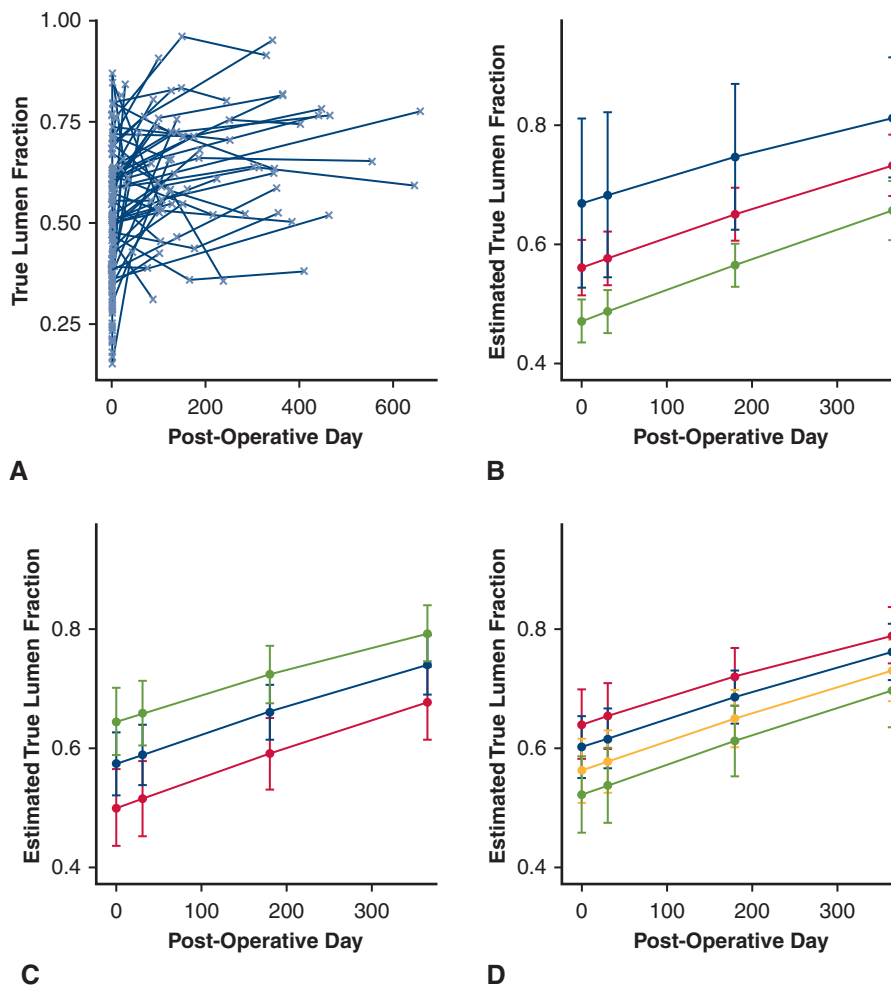
Freedom from reintervention and death remained high through the early postoperative period. Event-free survival was 92% (25th and 75th percentile, 86% and 99%) at 30 days and remained at 92% (25th and 75th percentile, 86% and 99%) through 180 days, after which it declined to 76% (25th and 75th percentile, 63% and 92%) at 270 days and 65% (25th and 75th percentile, 48% and 87%) at 365 postoperative days. Early events were largely attributable to 3 early deaths (30-day mortality, 4.1%) (Figure 1). There were 10 patients who required subsequent aortic interventions presented in Table 3. Most commonly, interventions were to treat continued false lumen flow or endoleak, and were endovascular in nature. Median time to aortic reintervention was 86 days.

**Aortic Remodeling**

Median preoperative cross-sectional area was 1000 mm<sup>2</sup> for the dissected aorta, 370 mm<sup>2</sup> for the true lumen, and 550 mm<sup>2</sup> for the false. Median preoperative area fraction was 0.37 for the true lumen and 0.62 for the false lumen. Mean preoperative patent fraction was 0.83 and 27 (37%) patients exhibited patent flow in all dissected areas (Table 4).

Postoperative true lumen area fraction was found to be significantly associated with increasing postoperative day ( $\beta = 0.0021$ ; 95% CI, 0.0015-0.0027;  $P < .001$ ), older age ( $\beta = 0.015$ ; 95% CI, 0.0088-0.022;  $P < .001$ ), and lower mean aorta area ( $\beta = -0.00056$ ; 95% CI,  $-0.00087$  to  $-0.00025$ ;  $P < .001$ ), and was negatively associated with chronic rather than acute or subacute dissection presentation ( $\beta = -0.36$ ; 95% CI,  $-0.58$  to  $-0.14$ ;  $P = .001$ ). Neither Debakey classification nor indication for surgery were found to influence postoperative true lumen area fraction (Figure 2).

Postoperative false lumen patent fraction was found to be inversely associated with postoperative day ( $\beta = -0.0040$ ; 95% CI,  $-0.0053$  to  $-0.0027$ ;  $P < .001$ ), and was lower in Debakey type III versus type I classification ( $\beta = -0.70$ ; 95% CI,  $-1.1$  to  $-0.29$ ;  $P < .001$ ), and lower for indications for surgery, including size and compression rather than



**FIGURE 2.** True lumen area fraction. A, True lumen fraction significantly increased over follow-up. Individual observations are indicated with blue *x*. B through D, Partial plots of estimated marginal mean true lumen fraction (circles) and standard error (error bars) stratified by (B) dissection chronicity (red = acute, blue = subacute, and green = chronic), (C) age (red = 40 years, blue = 60 years, and green = 80 years), and (D) mean aorta area (red = 500 mm<sup>2</sup>, blue = 800 mm<sup>2</sup>, yellow = 1100 mm<sup>2</sup>, and green = 1400 mm<sup>2</sup>).

aortic growth. Age, mean aortic area, and dissection chronicity were not found to be associated with decreasing false lumen patent fraction (Figure 3).

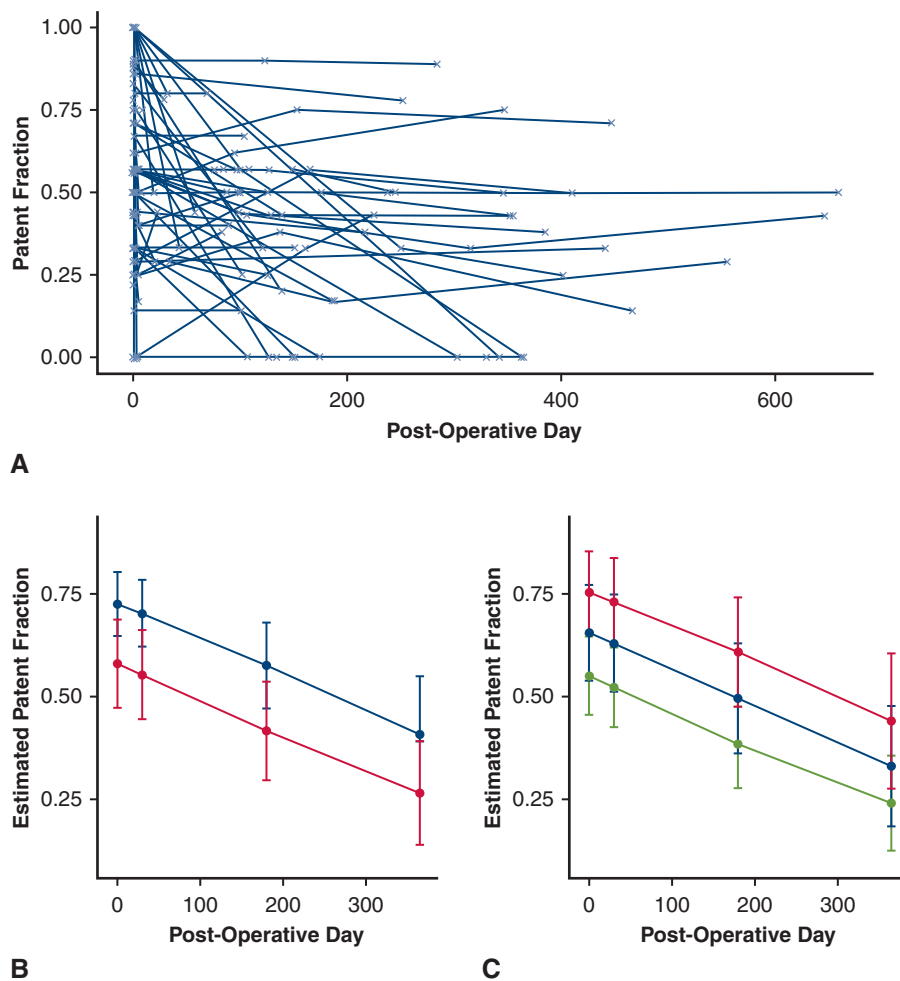
## DISCUSSION

This investigation demonstrated positive remodeling of the descending thoracoabdominal aorta following endovascular repair of acute and chronic Debakey I or Debakey IIIb aortic dissection using commercially available stent grafts within the descending thoracic aorta, and a bare metal extension stent technique in the thoracoabdominal aorta (Figure 4). The long-term outcomes on aortic remodeling are yet to be determined; however, our early results demonstrate an increase in true lumen fraction, and an increase in false lumen thrombosis. These findings were accomplished

in the setting of low morbidity and mortality across a large-sized, single-institution experience, demonstrating the safety of this technique in both the acute and chronic dissection settings.

TEVAR has become the accepted method of treating complicated acute Debakey IIIa/IIIb aortic dissections. We published our experience in 2016, reporting on aortic remodeling after TEVAR in patients with acute Debakey IIIa versus IIIb dissection, and demonstrating 91% false lumen thrombosis among patients with the former.<sup>1</sup> However, several studies have demonstrated ongoing aneurysmal degeneration of the distal thoracoabdominal aorta, and we similarly demonstrated increased false lumen diameter in the abdominal aorta among patients with type IIIb dissection, although there was little difference in early and late





**FIGURE 3.** False lumen patent fraction. A, Patent fraction significantly decreased over follow-up. Individual observations are indicated with *blue x*. B, Estimated patent fraction by Debakey classification (*red*, I; *blue*, III). C, Estimated patent fraction by indication for surgery (*red*, compression; *blue*, size; *green*, growth). Error plots are shown with estimated marginal mean indicated by the *circle*; error bars indicate mean  $\pm$  SE.

morbidity and mortality outcomes.<sup>1,10,11</sup> Notably, false lumen thrombosis was 62% in Debakey IIIb dissections, suggesting that favorable aortic remodeling is limited to the thoracic aortic segment, and that there is a need for an alternative approach to managing Debakey type IIIb aortic dissection, particularly with respect to improving remodeling of the abdominal aorta. The bare metal extension stent technique was developed to extend thoracic TEVAR devices; however, it has been mainly used in acute settings because encouraging aortic remodeling is particularly challenging in the subacute/chronic state when the intimal flap is thicker, and obliterating the false lumen is more difficult.<sup>8</sup>

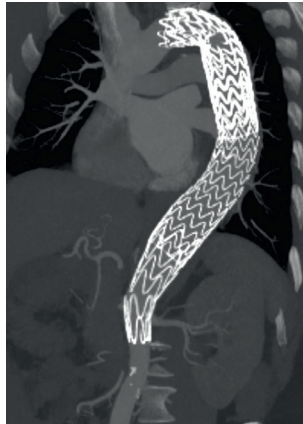
The provisional extension to induce complete attachment (PETTICOAT) stent technique to treat acute type B aortic dissection has demonstrated efficacy in expanding the true lumen in the abdominal aorta.<sup>12,13</sup> Systematic reviews by Rong and colleagues<sup>13</sup> and Bertoglio and colleagues<sup>14</sup>

both reported improved remodeling of the distal thoracoabdominal aorta at 12 months using the PETTICOAT technique, although studies were nonrandomized and primarily focused on patients with acute Debakey IIIb dissection with malperfusion. Few studies have focused on utilizing the PETTICOAT technique in chronic Debakey I/IIIb dissections to encourage distal thoracoabdominal aortic remodeling and reduce the need for thoracoabdominal aortic surgery or branched thoracoabdominal endovascular repair. Given the low radial force of the Zenith Dissection Endovascular Stent, it might be expected that there would be little effect in re-expanding the true lumen against a chronically thickened intimal flap. Faure and colleagues<sup>7</sup> and others<sup>15</sup> have had success with balloon fracturing the chronic flap after deployment of the PETTICOAT stent. This approach also required the stenting of visceral arteries and iliac arteries in more than half of the

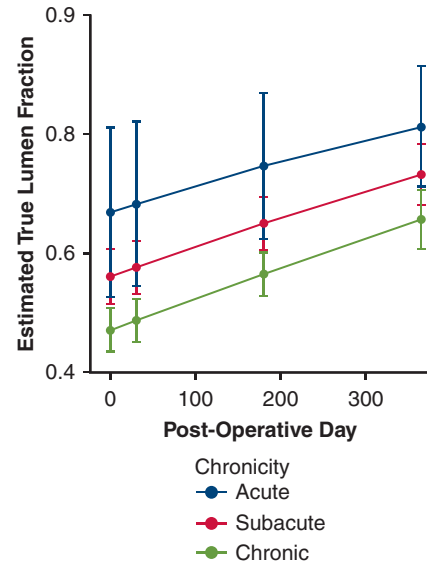
### Early Results of Bare Metal Extension Stent for Thoracoabdominal Aortic Dissection



April 2019 – April 2021  
Patients with DeBakey I/III  
• Acute: 22 patients  
• Subacute: 1 patient  
• Chronic: 50 patients



Treated with thoracic stentgraft  
and thoracoabdominal bare  
metal extension stent



**\*TEVAR with Bare Metal Extension stent placement for acute or chronic thoracoabdominal aortic dissection resulted in increased true lumen fraction and positive aortic remodeling.**

\*TEVAR, Thoracic Endovascular Aortic Repair

**FIGURE 4.** Seventy-three patients with acute, subacute, and chronic thoracoabdominal aortic dissection underwent endovascular repair with bare metal stent extension of thoracic endovascular aortic repair (TEVAR). Early outcomes demonstrated positive aortic remodeling with increase in true lumen fraction and decrease in false lumen patency fraction.

patient cohort. Continued patency of the false lumen, particularly a partially thrombosed false lumen, has been demonstrated as a major predictor of aortic enlargement after aortic dissection, and our goal was to encourage true lumen expansion and reduce the incidence of repeat thoracoabdominal open or endovascular procedures.<sup>10,15</sup> In this study, two-thirds of patients had chronic thoracoabdominal aortic dissection, and we demonstrated an increase in false lumen thrombosis and an improvement in thoracoabdominal aortic remodeling, suggesting that in addition to the acute phase, a composite stenting technique combining thoracic stent grafts with a distal thoracoabdominal bare metal extension stent technique may encourage distal aortic remodeling in the chronic phase of aortic dissection. The use of the bare dissection stent as an adjunct to descending TEVAR in the setting of chronic dissection may also prevent the occurrence of distal malperfusion secondary to distal stent induced new entry tears.

In total, 10 patients in this series required reintervention. However, 2 patients underwent surgery of the ascending aorta or aortic root, and the remaining required endovascular coiling for proximal to mid-descending aortic endoleaks and retrograde false lumen perfusion. Given the complex, high risk, and morbid nature of open and endovascular

thoracoabdominal aortic repair, utilization of this composite technique may offer a lower-risk therapeutic option, regardless of whether or not additional endoleak coiling is required, and particularly if we can reduce the long-term need for complex open thoracoabdominal completion repair.<sup>16</sup>

These findings are very early and follow-up at 1 year was incomplete. Ongoing follow-up with serial CT is necessary to further investigate the long-term effect of this strategy on distal aortic remodeling in chronic state disease. Because a large proportion of these patients were treated during the chronic phase, they did not present with early malperfusion syndromes, and therefore a large proportion had mesenteric vessels originating from both true and false lumens. This is important given the number of vessels originating from the false lumen has been identified as an independent predictor of aortic growth following aortic dissection.<sup>17</sup> Therefore, this technique may be most effective in patients whose mesenteric vessels originate from the true lumen. This investigation is further limited by its retrospective nature, although our routine is to follow patients with dissection with anniversary serial imaging, regardless of whether or not they have undergone surgical repair. TEVAR alone can promote positive remodeling aortic dissection. This

study cannot discern which remodeling was associated with the addition of bare metal extension stent, but rather report our early experience with TEVAR and bare metal extension stent.

## CONCLUSIONS

This analysis of composite TEVAR proximal endograft and distal bare metal extension stenting demonstrated an increase in true lumen fraction, and increase in false lumen thrombosis among patients with DeBakey type I/IIIB aortic dissection, with the majority of patients in the chronic phase. These results are promising in offering an alternative option to managing this complex pathology, and long-term follow-up in conjunction with ongoing investigation will determine whether or not this strategy reduces the incidence of late aortic reintervention, and whether or not the early benefit of this endovascular strategy toward aortic remodeling persists over the long term.

## Webcast

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## Conflict of Interest Statement

Dr Roselli serves as a speaker, investigator and consultant for Artivion, Cook, WL Gore, Medtronic, and Terumo Aortic. The other authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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