# **Toward the Uniluminal State**

Evolving concepts in the endovascular elimination of aortic dissection.

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# BACKGROUND AND RATIONALE

Appreciation of the need to repair the entire dissected aorta in the setting of dissection initiated our evolution

of the endovascular approach to aortic dissection in all its forms over a decade ago. Although placement of a proximal endograft to seal the primary entry tear reduces the risk of rupture and leads to shorter-term expansion of the true lumen in the thoracic aorta, the presence of more distal reentries is not addressed. The presence of persistent false lumen flow drives possible true lumen under perfusion and dynamic branch compromise and may increase the likelihood of further distal aortic degeneration in the longer term. This has been demonstrated in a number of studies relating to conventional thoracic endovascular aneurysm repair (TEVAR) for aortic dissection<sup>1</sup> and has been confirmed by computation fluid dynamics modeling.<sup>2</sup>

With this in mind, the aim of stent-assisted reconstruction beyond a proximal endograft to complete aortic dissection repair came about. The primary aims were multiple: to improve short-term outcomes in dissection management by reducing the chance of postoperative malperfusion, particularly for visceral and spinal circulations; to initiate acute and subsequent longer-term remodeling of the true lumen; and in conjunction with ancillary endovascular techniques in a staged fashion, to eliminate false lumen flow. The overarching aim of stent-assisted reconstruction is to achieve improved early and long-term outcomes compared to best medical treatment or TEVAR alone.

# **STENT-BASED RECONSTRUCTION**

Staged total aortic and branch vessel endovascular repair, known as the STABLE concept, was first described in 2005<sup>3</sup> (Figure 1). Although isolated use of stenting for established malperfusion has been reported,<sup>4</sup> STABLE introduced the routine and novel use of an extensive self-expanding, dissection-specific stent scaffold to reexpand the true lumen and reestablish more normal flow dynamics.

Early experience also indicated that endograft and stenting in isolation was insufficient to fully eliminate



Figure 1. STABLE: Staged aortic and branch vessel endolumenal repair for aortic dissection. Ten-year follow-up computed tomographic angiography. Complicated type B dissection was treated with a TX2 endograft and distal dissection stents, in conjunction with branch vessel-covered stent repair.

residual inflows to the false lumen. An additional essential element of this approach involved adjunctive novel techniques for the endovascular elimination of residual false lumen flow. These techniques included closure of branch vessel reentries by focal branch-covered stenting reconnecting the stented aortic true lumen to the branch true lumen (Figure 2), much in the same way that a fenestrated endograft is connected to a native aortic branch. Selective embolization of the false lumen at the site of reentries was also found to be a useful adjunctive tool.

Usually after initial endograft and stent placement, in conjunction with elimination of any major branch perfusion abnormality or reentry, a period of follow-up was performed. Any subsequent persistent major entries or any evidence of false lumen growth were treated with



Figure 2. Staged total aortic and branch endolumenal repair. Following initial closure of primary entry tear (first stage), residual renal and iliac reentries are closed by branch-covered stents eliminating false lumen flow (second stage).

a staged intervention. Such procedures were generally preemptive and not indicative of reinterventions for aortic-related complications. When using such techniques to reconstruct the true lumen, it was found that aortic degeneration could be controlled. Hence, STABLE aims to achieve a more robust total aortic repair through application of a staged endovascular approach.

Subsequently, a number of small case series reported the use of bare-metal stents in the distal thoracoabdominal aorta, with favorable short-term results.<sup>5</sup> In 2008, Melissano and colleagues<sup>6</sup> reported early outcomes using the same Zenith (Cook Medical) dissection stent that was used in our cohort in 11 selected patients with chronic type B dissection. A clinical success rate of 91% was reported at 12 months, with 0% mortality, stroke, or paraplegia.

## **EARLY OUTCOMES**

Evaluation of the early outcomes of the first 31 patients treated using STABLE was encouraging, with 30-day rates of death, stroke, and paraplegia/paresis at 3% (n = 1), 0%, and 0%, respectively.<sup>7</sup>

#### Malperfusion and Spinal Cord Ischemia

The initial experience of stent deployment beyond a proximal endograft to cover the lower thoracic and abdominal aorta demonstrated reperfusion of the true lumen, thus correcting true lumen collapse and protecting against visceral malperfusion.

In particular, our aim was to limit the extent of aortic coverage by endograft and avoid coverage of the subclavian artery if at all possible (with coverage only after careful assessment of the circle of Willis). After stenting segments of the more distal aorta, follow-up angiographic assessment often indicated improved direct flow from the true lumen to those branches arising from the now much-narrowed or nonexistent adjacent false lumen. In particular, this was frequently seen in relation to intercostal and lumbar branch vessels. This improved direct flow, combined with a reduction of any pressure gradient down the aortic true lumen, may account for the absence of spinal ischemia in this study.

## **COMPARISON TO TEVAR**

STABLE was further validated by the first study comparing composite graft and stent treatment to conventional TEVAR alone. Between 2003 and 2010, 63 patients underwent treatment for acute and chronic dissection. They were divided into two groups: 40 underwent stent-assisted repair (STABLE), and 23 underwent proximal endograft repair alone (TEVAR).<sup>8</sup>

This study demonstrated that the addition of baremetal scaffolding in the distal thoracoabdominal aorta significantly reduced visceral malperfusion in the acute phase compared with standard endovascular repair (0% vs 17%; P = .02). Moreover, this was achieved without increasing periprocedural morbidity or mortality. Spinal ischemia did not occur in the STABLE group (0% vs 4%).

Late follow-up (mean, 49 months) showed that STABLE was superior to TEVAR with fewer late reinterventions (11% vs 43%; P = .007), no distal late aortic reintervention (0% vs 19%; P = .01), fewer late adverse events (3% vs 10%; P = .28), and lower late aortic mortality (3% vs 9%).

Significantly, while bare-stenting of the dissection was at the heart of this approach, it is considered that the ancillary endovascular repairs were also key in achieving the highest level of false lumen exclusion and hence the greatest likelihood of preventing further aortic degeneration.

## LONG-TERM OUTCOMES

#### **Remodeling STABLE**

Subsequent ongoing follow-up of aortic remodeling data (aortic dimensions measured at mid-descending and celiac) have also reflected aortic survival with thoracic and abdominal aortic dimensions remaining stable (Figure 3) over longer-term follow-up.

#### Survival

At a mean follow-up of 49 months, a cohort of 40 patients undergoing STABLE repair for acute and chronic dissection had an aortic-specific survival of 90%.<sup>8</sup>



Figure 3. Remodeling after STABLE (mean follow-up of 97 months, range 50–154 months). Thoracic and abdominal diameters were measured at mid-descending thoracic aorta and coeliac levels and at initial (mean, 1 month), mid-term (24 months), and latest follow-up (mean, 97 months), respectively.

More selective follow-up of 33 patients undergoing stent- and endograft-based reconstruction for acute and sub-acute type B dissection demonstrated overall survival of 91% at 97 months (range, 50–154 months), while aortic-specific survival was 94%. Four patients (13%) underwent device-related reintervention. One (3%) late aortic-related death occurred. Survival rates in this group were higher than similar studies in the literature, with survival rates ranging from 56.3% to 87% at 5 years.<sup>9</sup>

## INTIMAL DISRUPTION AND RELAMINATION: RECREATION OF THE UNILUMINAL AORTA

Although STABLE has demonstrated the utility of stentbased aortic reconstruction in both acute and chronic dissection, further evolution of the initial approach has

occurred over the last decade. The aim was the creation of a more rapid and complete method of repair for acute and chronic dissection, particularly in patients in whom early dilatation of the aorta postdissection had not yet occurred.

In further clinical evaluation of this concept, balloon expansion within the distal endograft at the thoraco-abdominal junction has been demonstrated to seal the upstream false lumen while initiating intimal fenestration, which can be propagated more inferiorly, allowing further stent expansion and intimal relamination. Stent-based reapposition of intima to the aortic wall with creation of a uniluminal aorta resulted in complete elimination of the false lumen space. Hence, mitigation of the significant hemodynamic drivers of false lumen expansion (ie, false lumen shear flow and pressurization) (Figure 4), is achieved. Furthermore, this approach appears feasible in at least 50% of acute dissections currently treated by our group.

## Early and Late Outcomes

Early and intermediate results of this investigational study were reported in 2012 in an initial 11 patients having appropriate morphology and undergoing repair of complicated aortic dissection.<sup>10</sup> There were no intraprocedural complications and no early incidence of stroke, spinal, or visceral ischemia. Median follow-up was 18 months (range, 4–54 months). No late adverse events or aortic-related deaths occurred. Complete false lumen obliteration occurred in 90% of patients.

Although limited in scope, this study suggests application in acute dissection may enable elimination of the entire false lumen space in up to 90% of treated cases either through false lumen thrombosis and remodeling of false lumen within the zone treated by endograft or through stent-supported relamination of the intima to aortic wall more distally.

The technique now has (subsequent to our initial report)<sup>10</sup> a maximum follow-up of 60 months (median, 33 months) in 21 patients and is associated with an aortic-specific survival of 95%. Stability or positive remodeling of both the thoracic and abdominal total aortic diameters has occurred in 90% of patients.

## CONCLUSION

In conclusion, it has been our contention that the false lumen should be considered a continuous single



Figure 4. Distal aortic dissection treated with a proximal TX2 graft; more distal intimal disruption and bare stenting (Gianturco Zenith Dissection Stent, Cook Medical) create the uniluminal aorta. Initial and 5-year follow-up CT shows complete elimination of the false lumen.

compartment that communicates with the true lumen via intimal fenestrations throughout the dissected aorta. Hence, proximal endograft treatment alone is incomplete in managing dissection in its totality. Stent-assisted reconstruction and intimal disruption eliminating the false lumen and restoring a uniluminal status give us the ability to address the entire aortic dissection.

Improved short-term clinical outcomes in comparison to conventional endovascular techniques, high rates of aortic stability, and high aortic specific survival suggest the significant potential value of stent-based reconstruction in aortic dissection management.

More significantly, the ability to convert the dissected lumen to a uniluminal state offers the prospect of complete endovascular elimination of aortic dissection.

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