Early Experience With a Novel Dissection-Specific Stent-Graft to Prevent Distal Stent-Graft-Induced New Entry Tears After Thoracic Endovascular Repair of Chronic Type B Aortic Dissections

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Background: The aim was to report short and mid-term outcomes of a novel, investigational, dissection-specific stent-graft (DSSG), specifically designed to address the features of chronic type B aortic dissection (CTBAD) and reduce the risk of distal stent-graft-induced new entry tears (dSINE).

Materials and Methods: A retrospective single center cohort study of all patients undergoing TEVAR with the DSSG for CTBAD from January 1, 2017 to January 31, 2020. The DSSG, which is a modified stent-graft based on the Cook Zenith Alpha Thoracic platform, has no proximal barbs, and a customized longer body length with substantial taper. The second and third distal Z-stents are sited internally to avoid any contact of the metal skeleton with the dissection membrane and have reduced radial force, while the most distal stent was removed creating a distal 30 mm unsupported Dacron graft.

Results: Sixteen patients (13 males, 3 females) with a median age of 66 years (range 31–79 years) underwent elective TEVAR of CTBAD using the DSSG. Six patients (38%) had an underlying connective tissue disorder. The median tapering was 10 mm (range 4 mm–21 mm) and median length 270 mm (range 210–380 mm). Technical success was achieved in all but one case (96%). One patient died within 30 days, due to retrograde type A dissection with cardiac tamponade. The 30-day rate of stroke, spinal cord ischemia, and re-interventions was 0%. After median imaging follow-up time of 17 months (range 1–31 months), one patient developed a dSINE 4 months after the index procedure. After median survival follow-up of 23 months (range 2–35 months), one late death occurred due to traumatic brain injury, while no aortic-related death occurred during follow-up. Complete false lumen (FL) thrombosis was achieved in 9 patients while the remaining 6 showed partial FL thrombosis. No instances of diameter increase at the level of

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treated aortic segment were noted with serial measurements showing either stable ($n = 7$) or decreased ($n = 8$) maximal transverse diameter.

Conclusions: Use of a novel DSSG with low radial force for TEVAR in the setting of CTBAD is safe and feasible. This early real-world experience shows promising mid-term effectiveness with low rates of dSINE or unplanned re-interventions and satisfactory aortic remodeling during follow-up. Longer follow-up is needed, however, before any firm conclusions can be drawn.

INTRODUCTION

Although best medical therapy of acute/subacute uncomplicated type B aortic dissection has long been regarded as the mainstay of treatment, 20–40% of these patients experience progressive aortic dilatation over time and freedom from aortic events ranges from 34% to 84%.[1] Therefore, a progressive role for thoracic endovascular aortic repair (TEVAR) has emerged, with the INSTEAD trial reporting higher incidence of positive aortic remodeling and reduced risk of aortic-related mortality and progression of dissection at 2–5 years.[2]

Currently, TEVAR is largely utilized to treat a variety of descending thoracic aortic pathologies, and its specific role in the management of chronic type B aortic dissection (CTBAD) usually relates to the presence of post-dissection aneurysms. Standard thoracic stent-grafts may induce high radial forces on the aortic tissue at the landing zones as a result of the oversizing needed to provide enough fixation and seal. Although beneficial to obtain a tight seal in healthy aortic segments, they may tear the dissection membrane and thereby carry the risk of distal stent-graft-induced new entry tears (dSINE), which in turn represent a significant factor contributing to recurrent or progressive disease.[3] Therefore, dedicated devices specifically designed to overcome this issue might represent a significant advancement to the endovascular treatment of CTBAD.

The aim of the study was to report short-term and mid-term outcomes of a novel, investigational, dissection-specific stent-graft (DSSG), specifically designed to address the features of CTBAD, and reduce the risk of dSINE.

METHODS

Device Description

A custom-made DSSG based on the Cook Zenith Alpha Thoracic platform (Cook Medical Europe, Bjaeverskov, Denmark) was developed in collaboration with Cook Medical engineers. This was custom-made designed for each patient, with appropriately tailored diameters, and lengths to accommodate individual anatomy. The DSSG has no proximal barbs and a customized longer body length to allow for substantial taper. The second and third distal Z-stents are sited internally to avoid any contact of the metal skeleton with the inner aortic wall (i.e. only the DSSG fabric is in direct contact with the inner aortic wall) and have reduced radial force, while the most distal stent was removed creating a distal 30 mm unsupported dacron graft; "endovascular elephant trunk" (*Figs. 1 and 2*). Each Z-stent was measured separately in a Radial Expansion Force Gauge testing equipment. The stents were measured at a temperature at 37 degree C +- 1 degree C. Each stent is compressed to the corresponding Introductions system size. In the most common configuration of 28 mm distal stent-graft diameter the radial force of the second and third distal Z-stents is 2.7–4.8 N (compared to 7.0–7.6 N in the standard Alpha Thoracic platform), which corresponds to 31–64% lesser radial force.

Study Design

A retrospective single-center cohort study of all patients undergoing TEVAR with the DSSG for CTBAD from January 1, 2017 to January 31, 2020 at University Hospital of Uppsala (Sweden). Presence of CTBAD was defined as dissection distal to the left subclavian artery, either primary (DeBakey type IIIa and type IIIb) or residual/progressive disease after proximal repair of type A dissection (DeBakey type I). Whilst all patients contributed to analysis of early outcome analysis, patients were excluded from long term follow-up if they died within 30 days or no computed tomography angiography (CTA) was available for review after the index procedure. Electronic patient records were reviewed to collect baseline characteristics, procedural details, re-interventions, imaging, complications, and survival. The electronic record of death is updated on a daily basis from the Nationwide Death registry, which makes it highly reliable. The study was approved by the ethical review board and all patients gave informed consent.

Surgical Practice

The main indication for treatment was maximal aneurysm diameter ≥6.0 cm or growth rate ≥1.0 cm

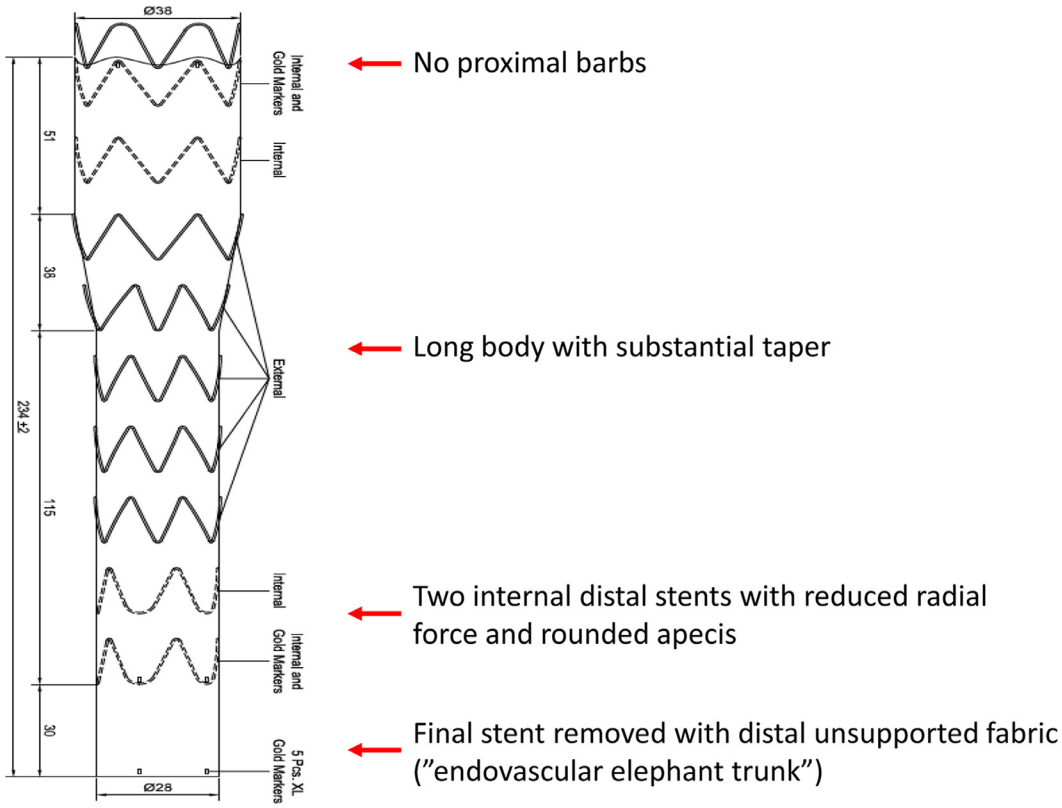

Fig. 1. Schematic drawing showing the main technical features of the custom-made Cook Zenith Alpha thoracic dissection-specific stent-graft.

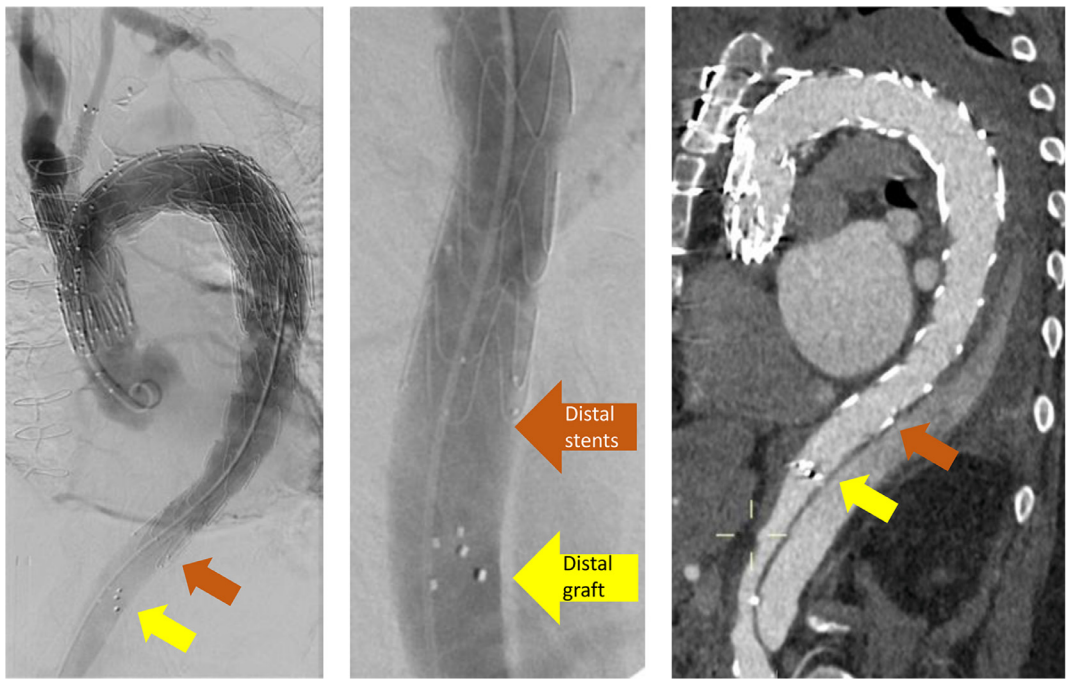

Fig. 2. Intraoperative angiography (*left* box; *middle* box) and pre-discharge CTA (*right* box) of a patient treated with the dissection-specific stent-graft in combination with a double branched arch device for post-dissection distal arch aneurysm. The distal stents (brown arrow) feature a low radial force while the distal graft (yellow arrow) is 30 mm long and made of unsupported fabric only ("endovascular elephant trunk"). CTA, computed tomography angiography (Color version of the figure is available online.)

on serial CTA measurements over 12 months. Use of DSSG was considered in the presence of one or more of the following risk factors for dSINE: i) narrow true lumen of the distal landing zone; ii) documented connective tissue disorder; and iii) history of dSINE from a previous procedure.

When obtaining an adequate proximal landing zone required coverage of the left subclavian artery by the stent-graft (Ishimaru's zone 2), the vessel was routinely revascularized (either in staged fashion with carotid-subclavian bypass prior to scheduled TEVAR or in concomitant fashion with use of a fenestrated/branched proximal device).

The DSSG was manufactured to achieve proximal seal with only minimal or no distal oversizing. In case of elliptical true lumen shape at the level of the planned DLZ, the average value of 2 perpendicular measurements was used. The DSSG taper ratio is given as percentage (%) and absolute number (mm). The length of the stent-graft was determined based on the goal of covering the entire descending thoracic aorta down to just above the coeliac trunk.

According to our institutional protocol patients were scheduled for outpatient visits and CTA imaging at 1 month, 6 months, and annually thereafter.

Endpoints and Definitions

The primary endpoint of the study was occurrence of any dSINE detected on follow-up CTA at any time after the index intervention.

Other outcomes were defined as early (<30 days) or late (≥30 days) as referenced to the day of DSSG deployment. Early outcomes included technical success, mortality, stroke, spinal cord ischemia (defined as either paraplegia or paraparesis, permanent or temporary), and re-intervention. Late outcomes included survival, false lumen (FL) status, aneurysm sac behavior, unplanned re-interventions, and aortic-related mortality. Accordingly, the following definitions were adopted.

- Technical success was defined as optimal graft deployment with complete exclusion of the aneurysm or full coverage of the target tear, without any unintentional supra-aortic trunk occlusion, conversion to open surgery, or retrograde type A dissection.
- Re-intervention (early) was defined as unplanned secondary surgical procedures required to correct procedure-related adverse events and/or graft-related complications (migration, endoleaks, occlusion, collapse, infolding or fracture).
- Survival was defined as the time between surgery and final follow up, or death from any cause.
- The FL status (at the level of treated aortic segment) was classified on a 3-point scale as completely thrombosed (no evidence of FL perfusion), partially thrombosed (<50% of FL area perfused) or nonthrombosed (≥50% of FL area perfused).
- Aneurysm sac behavior (at the level of maximal transverse diameter with outer wall to outer wall caliper using centerline measurements) was classified on a 3-point scale as decreased, stable or increased (defined as absolute increase or decrease ≥5 mm as compared with pre-operative maximal transverse diameter).
- Unplanned re-interventions (late) were defined as any unplanned aortic-related or graft-related surgical procedure that occurred after the index TEVAR with DSSG either at the intended treatment zone or at any separate aortic site.
- Aortic-related mortality was defined as death resulting from aortic-related (new dissection, rupture, organ malperfusion) or graft-related (occlusion, infection, components separation) complications or within 30 days of any unplanned late re-intervention (as defined above).

Statistical Analysis

Categorical variables were presented as numbers (with percentages) and continuous variables were presented as median (with interquartile range). Analysis was carried out using Microsoft Excel.

RESULTS

Study Cohort

Between 2017 and 2020, 16 patients (13 males, 81%) with a median age of 66 years (range 31–79 years) underwent elective TEVAR of CTBAD using the DSSG (*Table I*). In 4 patients (25%), there was an established dSINE after previous aortic procedure (2 cases of previous TEVAR, 2 cases of previous frozen elephant trunk -FET-), and the DSSG was inserted as a distal extension of the existing repair, whilst in the remaining twelve patients (75%) the DSSG was used as primary treatment for CTBAD-related aneurysms. Overall, 13 patients (81% of the study cohort) had received at least 1 prior aortic intervention. Six patients (38% of the study cohort) had an underlying connective tissue disorder (CTD); 4 cases of Marfan syndrome, 2 cases of Loeys-Dietz syndrome (Appendix Table I).

Table I. Baseline characteristics and operative details

Variable	*N* (%) or Median (range)
Baseline characteristics	
Age (years)	66 (31–79)
Males	13 (81%)
Connective tissue disorder	6 (38%)
Prior aortic repair	13 (81%)
Indication for repair	
- Aneurysm	12 (75%)
- Prior dSINE	4 (25%)
ASA class ≥3	16 (100%)
Operative details	
Proximal landing zone	
Zone 0	3 (19%)
- Zone 1	3 (19%)
- Zone 2	2 (12%)
- Zone 3	8 (50%)
Descending thoracic aorta coverage (mm)	270 (210–380)
DSSG characteristics	
- Proximal diameter (mm)	38 (28–44)
- Distal diameter (mm)	28 (17–32)
- Difference between proximal and distal diameter (mm)	10 (4–21)
- Taper ratio (%)	26 (13–55)
- Distal oversizing (%)	8% (0–33%)
Technical success	15 (94%)
Intraoperative conversion/death/retrograde type A dissection	0%

ASA, American Society of Anesthesiology; dSINE, distal stentgraft-induced new entry tear; DSSG, dissection-specific stentgraft.

Procedure Details & Peri-operative Morbidity

Two patients required a staged carotid-subclavian bypass in order to achieve a safe proximal landing zone in Ishimaru's zone 2 in the aortic arch, while another 3 patients received a fenestrated proximal component to achieve secure apposition in Ishimaru's zone 1 in the aortic arch. Three patients required complex repair of the aortic arch with a 2-branched or 3-branched custom-made arch stent-graft (Cook Medical) followed by distal placement of the DSSG. In the remaining patients, treatment was confined to the descending thoracic aorta, and was accomplished either by placement of the DSSG only or in combination with proximal extension of the repair using a standard commercially available thoracic endograft platform (Gore C-TAG or Cook Zenith TX2).

The median length of descending thoracic aorta coverage was 270 mm. The median proximal and distal stent-graft diameter was 38mm (range 28–44mm) and 28mm (range 17–32mm), respectively. The median taper ratio of the DSSG was 26% (range 13–55%) and the median difference between proximal and distal diameter of the DSSG was 10 mm (range 4–21 mm). Median distal oversizing was 2 mm (range 0–5 mm) corresponding to median 8% (range 0–33%).

Technical success at final angiogram was achieved in all but 1 case (94%). In the only case of technical failure recorded the DSSG did not achieve good distal apposition; this required distal extension across the celiac trunk ostium with a bare metal stent, and relining with a standard TEVAR endograft. Only 1 case of early death was recorded, occurring at 12 days after the index operation. Autopsy revealed retrograde type A dissection with cardiac tamponade (the patient was a 59-year-old man with without any evidence of CTD or genetically-triggered thoracic aortic disease, who received proximal zone 1 fenestrated TEVAR and distal repair with DSSG, referenced as patient no.14 in Appendix Tables I & II). In the remaining patients ($n = 15$), the 30-day rate of stroke, spinal cord ischemia, and unplanned re-interventions was 0% (*Table II*).

dSINE, Survival, Reinterventions & Aortic Remodeling

Two patients were excluded from analysis for dSINE occurrence (one case of 30-day death, 1 case of technical failure). The primary endpoint (i.e. absence of dSINE) was met in 13 out of 14 patients (93%). The median follow-up time for dSINE analysis was 17 months (range 1 –

Table II. Peri-operative morbidity and follow-up events

Variable	*N* (%) or Median (range)
Peri-operative morbidity	
30-day mortality	1 (6%)
30-day spinal cord ischemia	0%
30-day stroke	0%
30-day unplanned reinterventions	0%
Follow-up events	
Absence of new dSINE[a]	13 (93%)
Survival[b]	15 (94%)
Aortic-related mortality[b]	0%
Reinterventions[b]	1 (6%)
FL status[b]	
- Not thrombosed	0%
- Partially thrombosed	6 (40%)
- Completely thrombosed	9 (60%)
Ameusysm sac behaviour[b]	
- Regression	8 (53%)
- Stable	7 (47%)
- Increase	0%

ASA, American Society of Anesthesiology; dSINE, distal stentgraft-induced new entry tear; DSSG, dissection-specific stentgraft.
[a]Two patients were excluded from this analysis (1 case of 30-day death, 1 case of technical failure).
[b]Outcome(s) analyzed in all the 15 patients who survive the immediate post-procedural phase.

31 months). Only 1 patient developed a dSINE 4 months after the index procedure, which required the only unplanned late re-intervention recorded in the series. In this case, the DSSG landed in the mid descending thoracic aorta at the level of a marked angulation of the aorta in close proximity to a previous entry tear (*Fig. 3*). The patient presented acutely 4 months after index TEVAR with acute mesenteric and lower limb ischemia that required a complex hybrid repair (FL fenestration, redo TEVAR, right common iliac to superior mesenteric bypass and femoro-femoral crossover bypass). He survived the operation and was free from recurrent complications at 1-year follow-up. No other unplanned re-interventions were reported in the remaining subjects.

The median follow-up for survival and reinterventions analysis (after hospital discharge) was 23 months (range 2 – 35 months) with no aortic-related mortality. The following late events occurred:

- one patient underwent planned distal extension with fenestrated-branched endovascular aortic repair (F-BEVAR) of the visceral aortic segment;
- one patient died 14 months after the index TEVAR due to unrelated cause (traumatic brain injury) while waiting for a planned F-BEVAR procedure;
- one patient with scheduled F-BEVAR had the intervention postponed due to suspected infection of the thoracic endograft and is currently under suppressive oral antibiotic therapy and being followed with regular imaging and clinical assessments.

Complete FL thrombosis was achieved in 60% ($n = 9$) of the patients while the remaining 40% ($n = 6$) showed partial FL thrombosis (*Appendix Table II*). No instances of diameter increase at the level of treated aneurysmal aortic segment were otherwise noted, with serial measurements showing either stable ($n = 7$, 47%) or decreased ($n = 8$, 53%) maximal transverse diameter (*Fig. 4*).

DISCUSSION

It is well acknowledged that patients with CTBAD, including those with a residual distal dissection after repair of a type A dissection, may develop aortic-related complications requiring rehospitalization in up to 50% of cases, especially during the first 2 years of follow-up after the index event.[4,5] Aside from aneurysmal degeneration, aortic-related complications include recurrent symptoms, retrograde dissection, and FL rupture. The goal of TEVAR in the treatment of CTBAD is to cover

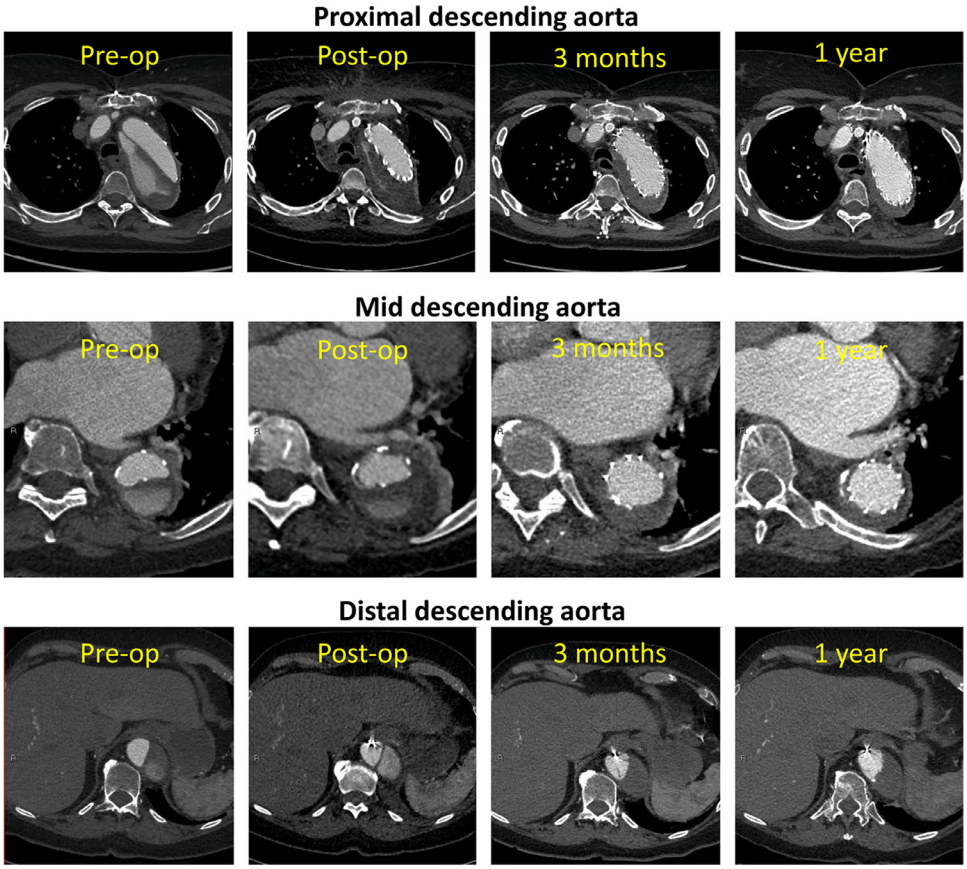

Fig. 3. Aortic remodeling after TEVAR with the dissection-specific stent-graft at the level of proximal (*upper* row), mid (*middle* row) and distal (*lower* row) descending thoracic aorta. At 1-year follow-up, CTA shows complete false lumen thrombosis, expansion of the true lumen and absence of any dSINE. TEVAR, thoracic endovascular aortic repair; CTA, computed tomography angiography; dSINE, distal stent-graft-induced new entry tear.

the proximal entry tear, facilitate FL thrombosis to achieve aortic remodeling and thereby reduce the likelihood of aortic rupture in the long run. However, TEVAR with standard thoracic platforms in the setting of CTBAD carries a significant risk of dSINE,[6] which in turn may lead to aneurysm expansion, and warrant re-intervention.[7–10] Furthermore, dSINE have been lately recognized as a potential complication also following deployment of FET devices in patients undergoing proximal repair for type A dissection[11,12] (as noted in 2 patients from the present series).

As the occurrence of dSINE is as high as 28%,[13] and has been mainly associated with the degree of distal oversizing,[14] various strategies including limiting oversizing[15] and the application of distal restrictive bare metal stents[16] have been proposed as possible alternatives to prevent dSINE, but the technical properties of commercially available stent-graft have not been specifically devised to address the needs of dissected aortas.[17,18] To date, TEVAR devices specifically designed to address this increasingly recognized issue have not been developed or used in clinical practice.

Conversely, the novel DSSG, presents technical features manufactured to address the anatomical challenges of TEVAR for CTBAD and primarily prevent the occurrence of dSINE. Indeed, although custom-made stent-grafts are frequently used for endovascular repair of complex aortic pathology, customization is usually done to the length/diameters/presence of fenestrations or branches, but not in terms of the radial force of the stents used, which is the main novelty of this approach. Use of the DSSG in sixteen consecutive patients with CTBAD, either as a stand-alone device or in combination with more proximal stent-graft(s) according to the individual patient's anatomy, resulted in 94% technical success rate with an excellent safety profile despite the extensive, and complex pathologies treated. Indeed, the only 30-

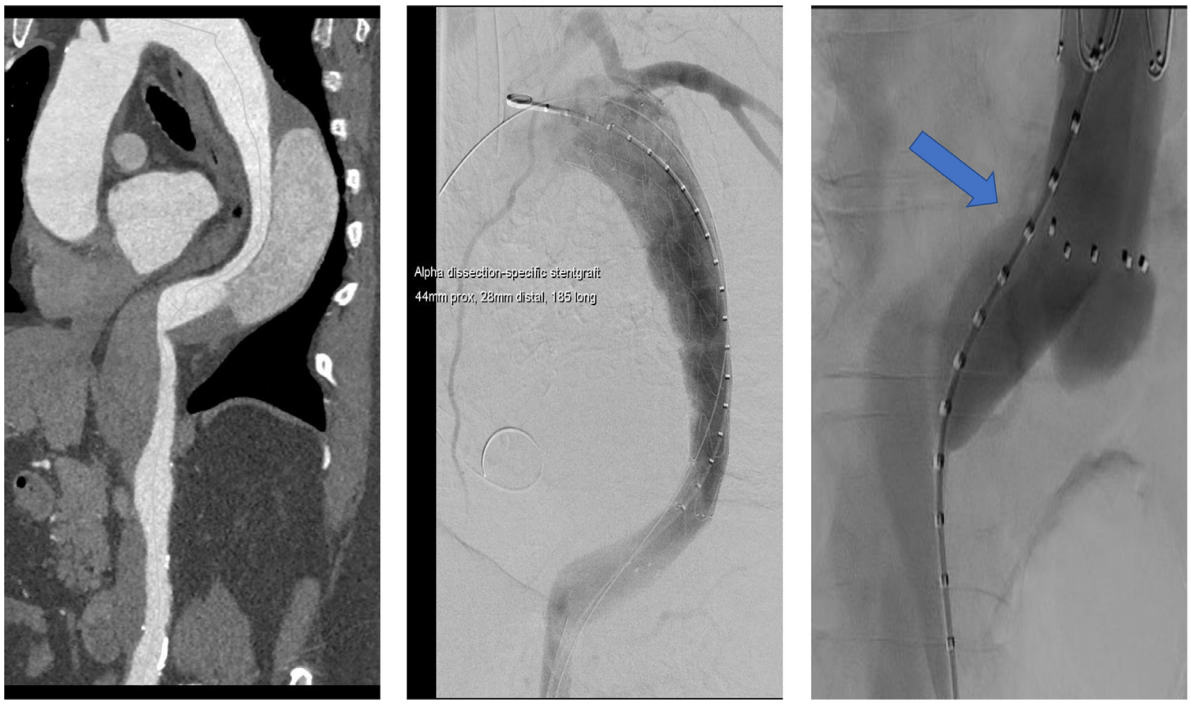

Fig. 4. Imaging from the only patient with dSINE in the series. Pre-operative CTA (*left* box) shows severe angulation at mid-distal junction of the descending thoracic aorta with narrow true lumen. Intraoperative angiography (*middle* box) shows good deployment of the dissection-specific stent-graft ending in the upper half of the distal descending thoracic aorta. Four months later the patient developed a dSINE (*right* box, blue arrow) that required emergent unplanned reintervention. dSINE, distal stent-graft-induced new entry tear; CTA, computed tomography angiography (Color version of the figure is available online.)

day death event recorded was due to retrograde type A dissection in a patient receiving totally endovascular arch replacement, thus not attributed to the design of the DSSG. Nevertheless, the risk of this serious, and potentially life-threatening complication after fenestrated endovascular arch repair in patients with native ascending aortas should be taken into account during the decision-making process.[19] Furthermore, promising mid-term effectiveness of the device was showed, as indicated by the extremely low rate of dSINE during mid-term follow-up, thereby showing the potential promise of this new treatment concept.

The described new DSSG is 1 way to reduce the radial force in patients with CTBAD requiring TEVAR and considered at high risk for dSINE, such as in presence of significant diameter mismatch between the proximal and distal landing zones, or in those with CTD. Due to the fragile aorta and their young age, TEVAR is usually considered unfavorable in individual affected by genetic aortic syndromes.[20] Nevertheless, it may sometimes be reasonable to treat such patients endovascularly, for example in emergency situations or complex re-do procedures. Indeed, presence of CTD has been suggested as a risk factor for SINE in general, and for dSINE specifically. Thus, the development of disease-specific devices that meet the mechanical challenges faced in these patients would represent a needed and significant advancement to the endovascular aortic field. We have previously shown the safety and feasibility of a physician-modified thoracic stent-graft with low distal radial force for preventing dSINE in a small case series of 3 patients with CTD[21]. In the present report, almost 40% of the patients had such a disease (Marfan syndrome and Loeys-Dietz syndrome), all with previous open ascending and/or total arch repair. While they were all deemed to be high-risk for redo sternotomy, presence of a previous proximal surgical graft allowed a safe and durable proximal landing zone for TEVAR (i.e. no retrograde type A dissections were noted in these cases). During follow-up, up till almost 3 years, all showed either a stable or shrinking aneurysm with a thrombosed or partially thrombosed FL, and none of them have developed dSINE or had any unplanned re-intervention.

Short stent-graft lengths (<145 mm) have also been reported to be a factor associated with dSINE by Li and associates.[22] Self-expanding TEVAR devices tend to "spring back" to their initial status if passively bent and it has been postulated that shorter stent-graft have greater spring-back force at their distal end.[23] This force may exert a particularly high mechanical stress on the stiff dissection membrane in the descending thoracic aorta and thereby contribute to the occurrence of dSINE. For that reason, our operative strategy has been relying upon long DSSG (always >150 mm) planned to land in a straight aortic segment. Careful retrospective review of the only dSINE case encountered showed that the DSSG was relatively short and landed in a marked angulated aortic segment in close proximity to a previous entry tear (Fig. 4). Although impossible to ascertain, it would be reasonable to assume that these factors may have contributed to the newly incident dSINE.

Whilst we saw no increase in aortic diameter during the follow-up period as well as no instances of completely nonthrombosed FL, and there were no un-planned re-interventions in all those without dSINE, up to 47% of the study cohort still had aortic diameter which remained unchanged while 40% of the patients only achieved partial FL thrombosis. It is well known that, despite TEVAR, progressive aortic dilatation may occur at the visceral segment, and distal extension is eventually required by means of F-BEVAR.[24,25] For that reason, strict lifelong surveillance is mandatory, and further refinement of endovascular aortic devices might help to facilitate target vessel catheterization in narrow aortic lumens[26-29] (as usually seen in CTBAD-related aneurysms).

Study Limitations

We acknowledge several limitations to our study including the retrospective design, small sample size, relatively short follow-up, and lack of comparison with a control group of subjects treated with standard devices. In addition, the extent of dissection and complexity of repair were variable between subjects and this might have a significant influence on the degree of aortic remodeling post-intervention. However, it should be borne mind that endovascular repair is the technique of choice for patients with a variety of aortic pathologies, and our study population can be considered representative of the wide spectrum of patients potentially likely to benefit from endovascular procedures in these clinical scenarios. Also, during the study period, the DSSG was our primary stent for patients treated electively with TEVAR on the indication of CTBAD, which limit the risk of selection bias. Furthermore, this experience reflects outcomes achieved by a team of experienced vascular surgeons at a single center, and the results might not be immediately extrapolated to other contexts. In order to further study the behavior of this specific stent-graft in aortic dissection, we now plan to introduce the device across several centers.

CONCLUSIONS

Use of a novel DSSG with low radial force for TEVAR in the setting of CTBAD is safe, feasible and effective across a wide range of anatomies. This preliminary experience shows promising mid-term effectiveness with extremely low rates of dSINE or unplanned re-interventions and satisfactory aortic remodeling during follow-up. Despite the satisfactory mid-term results, a larger cohort with longer follow-up on durability is required before any firm conclusions can be drawn.

CONFLICTS OF INTEREST

None, the authors were responsible for study design, patient selection, data collection and interpretation, and the drafting of the manuscript and the decision to submit the manuscript for publication, with no involvement by Cook Medical.

APPENDIX

Table A.I. Demographics, clinical history, extent of disease, and indication for repair, device characteristics and procedure of 16 patients with CTBAD treated with the novel DSSG.

Patient #	Age	Gender	CTD	Prior aortic repair	Extent of disease	Indication	DSSG characteristics (taper ratio/Δmm)	Procedure (Total DTA coverage)
1	55	Male	Yes	Ascending repair, FET	DeBakey type I	DTA aneurysm	21%, 6 mm	Zone 3 DSSG (260 mm)
2	31	Male	Yes	Ascending repair, FET	DeBakey type I	DTA aneurysm	26%, 10 mm	Proximal zone 3 TEVAR, Distal DSSG (260 mm)
3	78	Male	No	No	DeBakey type I	Arch aneurysm	26%, 10 mm	Proximal AIBSG, Distal DSSG (240 mm)
4	79	Female	No	Ascending repair	DeBakey type I	Arch aneurysm	35%, 14 mm	Proximal AIBSG, Distal DSSG (280 mm)
5	45	Male	Yes	Ascending repair	DeBakey type I	DTA aneurysm	26%, 10 mm	Proximal zone 1 fenestrated TEVAR, Distal DSSG (380 mm)
6	52	Female	Yes	Ascending repair	DeBakey type I	DTA aneurysm	26%, 10 mm	Proximal zone 1 fenestrated TEVAR, Distal DSSG (340 mm)
7	71	Male	No	Ascending repair, Infrarenal repar, TEVAR	DeBakey type I	dSINE from TEVAR	26%, 10 mm	Zone 2 DSSG + CS bypass (330 mm)
8	67	Female	No	TEVAR	DeBakey type I	dSINE from TEVAR	26%, 10 mm	Zone 3 DSSG (250 mm)
9	57	Male	Yes	Ascending repair	DeBakey type I	DTA aneurysm	21%, 6 mm	Zone 2 DSSG + CS bypass (270 mm)
10	64	Male	No	No	DeBakey type IIIB	DTA aneurysm	36%, 16 mm	Zone 3 DSSG (210 mm)
11	75	Male	No	Infrarenal repair	DeBakey type IIIB	DTA aneurysm	23%, 16 mm	Proximal zone 3 TEVAR, Distal DSSG (280 mm)
12	54	Male	Yes	Ascending repair, FET	DeBakey type IIIB	DTA aneurysm	55%, 21 mm	Proximal zone 3 TEVAR, Distal DSSG (300 mm)
13	70	Male	No	Ascending repair	DeBakey type I	Arch aneurysm	16%, 6 mm	Proximal AIBSG, Distal DSSG (270 mm)
14	59	Male	No	No	DeBakey type IIIB	DTA aneurysm	13%, 4 mm	Proximal zone 1 fenestrated TEVAR, Distal DSSG (260 mm)
15	68	Male	No	Ascending repair, FET	DeBakey type I	dSINE from FET	25%, 8 mm	Zone 3 DSSG (290 mm)
16	76	Male	No	Ascending repair, FET	DeBakey type I	dSINE from FET	18%, 6 mm	Zone 3 DSSG (220 mm)

CS, carotid-subclavian; FET, frozen elephant trunk; CTD, connective tissue disease; DTA, descending thoracic aorta; DSSG, dissection-specific stent-graft; CTBAD, chronic type B aortic dissection; TEVAR, thoracic endovascular aortic repair; dSINE, distal stent-graft induced new entry tear; Δmm, difference (in mm) between the proximal and the distal diameter of the DSSG.

Table A.II. Late outcomes and individual follow-up duration of 16 patients with CTBAD treated with the novel DSSG.

Patient #	dSINE FU (days)	dSINE	FL status	Aneurysm sac behavior	Survival FU (days)	Unplanned reintervention	ARM
1	614	No	Complete thrombosis	Decreased	693	No	No
2	589	No	Complete thrombosis	Stable	604	No	No
3	916	No	Complete thrombosis	Decreased	1036	No	No
4	811	No	Partial thrombosis	Decreased	1036	No	No
5	434	No	Complete thrombosis	Decreased	1064	No	No
6	448	No	Partial thrombosis	Stable	449	No	No
7	623	No	Complete thrombosis	Decreased	944	No	No
8	515	No	Complete thrombosis	Decreased	914	No	No
9	453	No	Partial thrombosis	Stable	489	No	No
10	116	Yes	Partial thrombosis	Stable	300	Yes	No
11	125	No	Complete thrombosis	Stable	105	No	No
12	100	No	Partial thrombosis	Stable	86	No	No
13	39	No	Partial thrombosis	Stable	49	No	No
14[a]	NA	NA	NA	NA	NA	NA	NA
15	623	No	Complete thrombosis	Decreased	748	No	No
16	547	No	Complete thrombosis	Decreased	748	No	No

FU, follow-up; FL, false lumen; ARM, aortic-related mortality; CTBAD, chronic type B aortic dissection; dSINE, distal stent-graft induced new entry tears; [a]Died within 30 days from index intervention

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