Featured Article

The soft elephant trunk: a new approach in the treatment of aortic dissection

Eduard Charchyan, Denis Breshenkov, Yuriy Belov

Department of Aortic Surgery, Petrovsky National Research Centre of Surgery, Moscow, Russia

Correspondence to: Denis Breshenkov, MD, PhD. Department of Aortic Surgery, Petrovsky National Research Centre of Surgery, 129343 Serebryakova Street, 11/1, Moscow, Russia. Email: denisbreshenkov@gmail.com.

Background: The frozen elephant trunk (FET) technique has revolutionized the surgical management of aortic dissection. However, distal stent-graft-induced new entry (dSINE) and reinterventions remain major challenges. This study presents the long-term results of a dissection-specific (DS) "Soft Elephant Trunk" (SET) (MedEng, Penza, Russia) hybrid prosthesis and its impact on distal remodeling compared to conventional hybrid prosthesis.

Methods: A retrospective review of hybrid aortic repairs from 2014 to 2024 identified 241 patients with aortic dissection. Patients were categorized into two cohorts: DS SET prosthesis (n=170) and conventional prosthesis (non-DS, n=71). Propensity score matching was performed. Primary endpoints included the incidence of dSINE and aortic reinterventions. Secondary endpoints evaluated perioperative complications and long-term survival. Cox regression analysis identified independent predictors of dSINE.

Results: Survival rates, freedom from reoperation, and the incidence of dSINE did not differ between the groups. However, cumulative incidence of new events—including distal aortic reoperations and dSINE—was significantly lower in the DS group versus non-DS both before matching (12.9% *vs.* 29.6%, P<0.001) and after matching (15.5% *vs.* 29.6%, P=0.04). Long-term endoleak rates (>5 years) were significantly higher in the non-DS group (31.4% *vs.* 7.1%, P=0.009). According to multivariable Cox regression analysis, the key predictors for dSINE included connective tissue disease [hazard ratio (HR) =3.22, 95% confidence interval (CI): 1.09–9.52, P=0.034], Stanford type B aortic dissection (HR =4.3, 95% CI: 7–14.61, P=0.019), and chronic phase of dissection (HR =7.8, 95% CI: 0.72–84.21, P=0.09). The highest dSINE risk was observed in non-DS patients with chronic dissection (P=0.009), Type B dissection (P=0.012), CTD (P=0.005), and aortic dilation >45 mm (P=0.004).

Conclusions: In comparison to conventional hybrid grafts, the SET graft exhibits a protective trend against dSINE, particularly in high-risk cases. This strategy may reduce distal complications and the need for secondary interventions, thereby improving long-term patient outcomes.

Keywords: Aortic dissection (AD); hybrid surgery; frozen elephant trunk (FET); soft elephant trunk (SET); aortic remodeling

Submitted Mar 05, 2025. Accepted for publication Aug 26, 2025. Published online Sep 18, 2025.
doi: 10.21037/acs-2025-evet-0046
View this article at: https://dx.doi.org/10.21037/acs-2025-evet-0046

Introduction

For 30 years, the hybrid approach to management of aortic dissection (AD) has been actively evolving. Despite progress of the frozen elephant trunk (FET) procedure, complications such as distal stent-graft-induced new entry (dSINE), negative remodeling and need for reoperation remain significant challenges. Conventional hybrid prostheses [E-Vita Open Plus (Jotec, Hechingen, Germany), Thoraflex Hybrid (Terumo, Inchinnan, Scotland), etc.] have limitations in adapting to dissected aortic anatomy, and a high rate of distal stent-graft related complications. This

study evaluates the long-term effectiveness of the "Soft Elephant Trunk" (SET) hybrid prosthesis (MedInzh, Penza, Russia) in reducing these complications and improving clinical outcomes.

Methods

This single-center retrospective cohort study included consecutive patients with AD treated between 2014 and 2024. Inclusion criteria were: (I) any type of AD; (II) age >18 years; (III) hybrid repair of AD propagating distal to the left subclavian artery; and (IV) prosthesis selection independent of patient-specific anatomy. Aortic dissection diagnosis was confirmed by computed tomography (CT) in all patients.

Study design

To evaluate the efficacy of the dissection-specific (DS) hybrid aortic prosthesis, patients were divided into two groups: DS group and non-DS group. To minimize selection bias, equal groups were formed using propensity score matching. The study was approved by the Local Ethics Committee of Petrovsky National Research Centre of Surgery (protocol#7 15.04.2021; #1 24.01.2025) and written informed consent was waived. The primary endpoint was any new distal aortic event. Secondary endpoints were mortality and postoperative complications. All patients underwent sequential CT scans according to the protocol. To ensure complete imaging data for the assessment of mid-term aortic remodeling, only those subjects who completed every scan at the specified intervals—preoperatively, during the hospital stay, at 6 months, at 1 year, and annually thereafter—with a minimum follow-up of 5 years were included in the analysis.

Aortic remodeling assessment

Aortic remodeling was assessed using an institutional protocol specifically developed for patients with AD. Planimetric analysis of the true lumen (TL), false lumen (FL), and total aortic lumen (AL) areas and perimeters was conducted at seven predefined aortic levels on all serial CT scans. Volumetric changes were evaluated at three levels: within the stent-graft, distal descending thoracic aorta (DTA), and abdominal aorta. The status of the FL (patent, partially thrombosed, or completely thrombosed) was assessed at five anatomical levels: within the stent-graft, distal DTA, level of visceral arteries, abdominal aorta, and iliac arteries.

Evolution of surgical technique

In our center, we utilize various cannulation options depending on AD anatomy and clinical context, though the right subclavian artery is preferred in most cases. The brain protection strategy relies on antegrade cerebral perfusion, typically bilateral. Neuromonitoring includes transcranial Doppler and cerebral oximetry. All surgeries are performed under moderate hypothermia (1). Temperature is routinely monitored at two sites: the urinary bladder and the nasopharynx. Distal first technique is used, beginning with aortic arch reconstruction and distal anastomosis, followed by stent-graft implantation. Distal perfusion is initiated after anastomosis with the left subclavian artery (multibranched prostheses) or after anastomosis with the brachiocephalic vessels (island technique). A guidewire was initially used for stent-graft implantation, but it is now reserved for complex cases. In all cases, we avoided excessive oversizing at the distal edge, especially in high-risk patients. All procedures were performed by a single surgeon. Prosthesis sizing was based on intraoperative TL measurement at zone 3 using a sizer, and on preoperative CT-based assessment at the level of the left atrium, guided by the TL perimeter.

- d TL = circumference length/π
- Acute AD: d SG = d TL + 10% (oversizing)
- Subacute AD: d SG = d TL (+10% oversizing in cases of malperfusion)
- Chronic AD: d SG = d TL.

In cases of narrow TL, we performed a wedge resection of the intima at the distal anastomosis, thereby eliminating the acute angle at the anastomosis. Before 2014, we primarily employed a hybrid technique that included the Elephant Trunk procedure with following TEVAR. We started using hybrid prostheses in our center in 2014, with the first prostheses being Thoraflex Hybrid and E-Vita Open Plus. Since 2019, we have introduced our own DS hybrid prosthesis, SET (MedEng, Penza, Russia) (2,3). The concept of SET is the progressive reduction of radial stiffness in the endovascular part. This is primarily achieved by decreasing the stiffness of the nitinol rings of the stent graft towards the distal end through a proportional reduction in the thickness of the nitinol rings. The final ring has been modified from an S-shape to a Z-shape, with its stiffness reduced by 50% compared to the first ring. Secondly, the distal end features a 2 cm vascular graft with

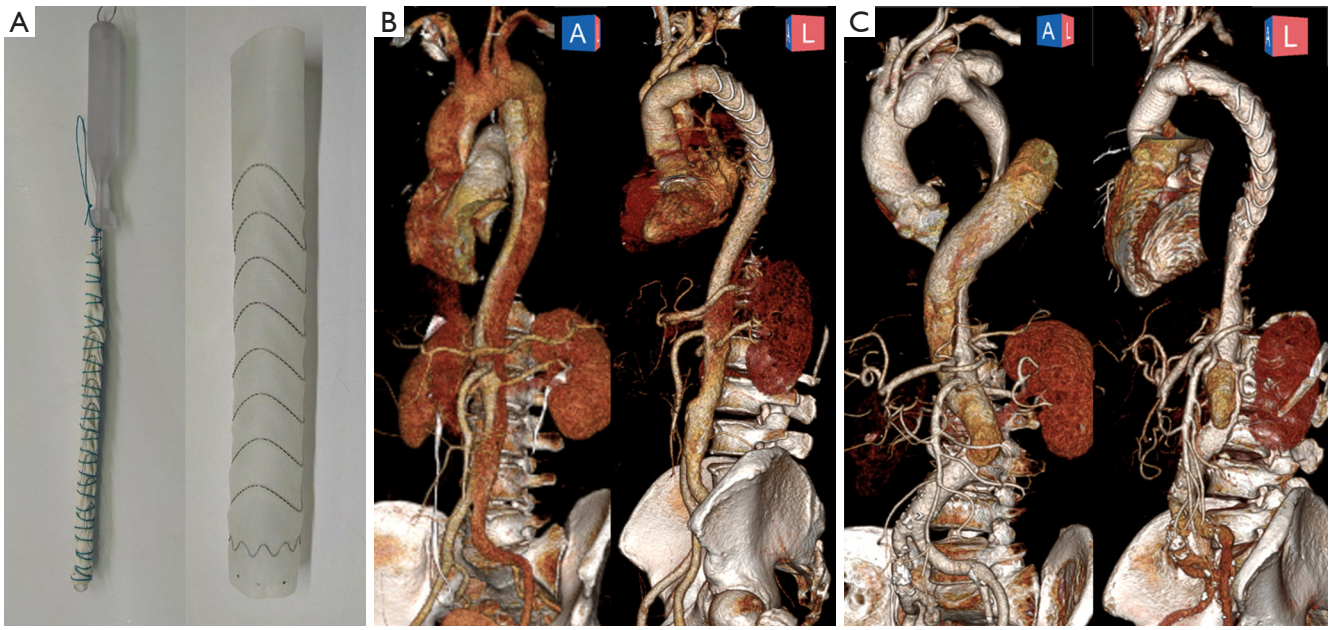

Figure 1 Soft elephant trunk. (A) dissection-specific "Soft Elephant Trunk" prosthesis (MedEng, Penza, Russia); (B) patient with acute Stanford type A aortic dissection before and after FET procedure using a DS stent graft ("SET"); (C) patient with chronic Stanford type non-A-non-B aortic dissection before and after FET procedure using a DS stent graft ("SET"). DS, dissection-specific; FET, frozen elephant trunk; SET, soft elephant trunk.

nine platinum markers. This design prevents the distal end from exerting pressure on the fragile intima, thereby preventing dSINE. The third important advantage is the length of the stent graft. The hybrid graft measures 200 mm in length and lacks a suture ring. This design feature, combined with a compact delivery system, facilitates implantation below Th8, effectively preventing distal fenestrations (*Figure 1*).

Statistical methods

Data analysis was conducted using parametric or nonparametric methods, depending on variable distribution. Quantitative variables are presented as mean (standard deviation) for normal distribution and median (IQR) for non-normal distribution. Qualitative variables are expressed as counts and percentages. The Shapiro-Wilk test assessed normality. Student's *t*-test was used for normally distributed continuous variables, with the Mann-Whitney *U* test applied otherwise. Categorical variables were compared using Fisher's exact test and Chi-squared test. Paired statistical tests were used where applicable, especially for comparisons between post-matching groups (McNemar's test quantitative variables, paired *t*-test or the Wilcoxon signed-rank test for qualitative variables). Propensity score matching (PSM) was performed using a Greedy algorithm with Euclidean distance to match treated units with control units on a one-to-one basis. A 95% confidence interval was used to ensure reliable estimates, and a strict tolerance threshold of 0.001 was applied to match units with highly similar propensity scores. We used sex, body mass index (BMI), AD type and phase, DTA dilation, prior aortic interventions, and CTD as covariates for PSM, which resulted in 71 matched pairs. The Kaplan-Meier method and log-rank test were used to analyze survival rate, aortic event-free rates, and negative remodeling. Multivariable Cox regression was used to identify the predictors of dSINE. Statistical analysis was performed using Jamovi version 2.3.21.0. PSM was performed using XLSTAT version 2024.4.1. A P value of less than 0.05 was considered statistically significant.

Results

Demographic data

A total of 323 patients underwent FET (2014–2024). Of these, 241 cases of AD were included. Patients were

divided into two groups: DS group (n=170) and non-DS group: (n=71). Median age was 53 [45, 63] *vs.* 52 [45, 62] years (P=0.6), respectively. There were no significant differences in sex, BMI, connective tissue disorder (CTD), hypertension, etc. between groups. A higher proportion of type A AD was observed in DS group: 122 (72%) *vs.* 63 (89%) (P=0.017), but after matching, this difference was non-significant. DS group had a significantly higher prevalence of aortic arch aneurysms (P=0.005 and 0.002 in both comparisons). DS group had a significantly higher rate of chronic kidney disease [51 (30%) *vs.* 9 (13%), P=0.005], and patients with malperfusion, which disappeared after matching (P>0.05) (*Table 1*).

Perioperative outcomes

The DS group typically had smaller grafts (26 mm; IQR: 24, 28 mm) compared to non-DS group, who were more frequently fitted with larger grafts (28 mm; IQR: 28, 30 mm) (P<0.001). Additionally, DS group had a longer graft length on average (P<0.001). DS group had significantly shorter CPB, aortic cross-clamp, circulatory arrest times, and hypothermia compared to non-DS patients, which we associate with the learning curve (*Table 2*). The incidence of pulmonary failure, stroke, and cardiac arrest was comparable across groups. Overall hospital mortality was similar between groups, at 5.3% in DS versus 7% in non-DS (P=0.56) and 5.6% versus 7% after matching (P>0.99) (*Table 3*).

Long-term outcomes

Late survival

We evaluated long-term outcomes in both overall and PSM groups. The follow-up duration significantly differed between the non-DS and DS groups [18 (7.9, 40) *vs.* 60 (34.3, 85.8) months, P<0.01], including after PSM adjustment [18 (9.2, 42.8) *vs.* 60 (34.3, 85.8) months, P<0.01]. In the DS group, late mortality (beyond 30 days) due to aortic-related causes occurred in three cases (1.7%): one case of aortic rupture in the visceral segment after TAAA replacement in a patient with Loeys-Dietz syndrome and two cases of aortic graft infection. In the non-DS group, late mortality due to aortic-related causes occurred in seven cases (9.8%): one case with dSINE complicated by distal aortic rupture, five cases of aortic graft infection, and one case of proximal aortic rupture. Survival rate was 85.4% (95% CI: 77.5–94.2%) *vs.* 90.5% (95% CI: 85.5–95.9%) and 78.5% (95% CI: 69–89.2%) *vs.* 76.5% (95% CI: 58–100%) at 3 and 5 years, in non-DS and DS groups (P=0.36), respectively (*Figure 2A*). In the matched cohort, survival rate was 85.4% (95% CI: 77.5–94.2%) *vs.* 92.3 (95% CI: 84.8–100%) and 78.5% (95% CI: 69–89.2%) *vs.* 73.9% (95% CI: 47.3–100%) at 3 and 5 years, in non-DS and DS groups (P=0.24), respectively (*Figure 2B*).

Late reoperations

Overall reoperation rates were significantly lower in the DS group compared to the non-DS group (10% *vs.* 24%, P=0.005), although this difference became non-significant after propensity matching (P=0.13). Non-staged reoperations were more frequent in the non-DS group (18% *vs.* 4.7%, P<0.001), while staged reoperations showed no significant difference between groups (P>0.99). After performing PSM analysis, the DS group demonstrated a significantly lower frequency of non-staged reoperations compared to the non-DS group (5.6 *vs.* 18%, P=0.02). Both groups had comparable frequencies and types of distal reoperations (*Table 3*); however, after PSM, there was a trend towards more frequent TEVAR procedures in the non-DS group (9.9% *vs.* 4.2%, P=0.326) and more frequent open surgeries in the DS group (11.3% *vs.* 9.9%, P=1.000). This shift is attributed to the evolving surgical strategy. These findings indicate that the DS group had a lower reoperation burden, particularly for non-staged procedures, but after adjusting for baseline differences, most comparisons lost statistical significance.

Freedom from reoperation was 89.5% (95% CI: 81.9–97.9%) *vs.* 91.3% (95% CI: 85–98%) and 86.56% (95% CI: 77.5–96.7%) *vs.* 91.3% (95% CI: 85–98%) at 3 and 5 years, in non-DS and DS groups (P=0.5), respectively (*Figure 2C*). In the matched cohort, freedom from reoperation was 89.5% (95% CI: 81.9–97.9%) *vs.* 91% (95% CI: 82.8–100%) and 86.56% (95% CI: 77.5–96.7%) *vs.* 91% (95% CI: 82.8–100%) at 3 and 5 years, in non-DS and DS groups (P=0.78), respectively (*Figure 2D*).

Aortic remodeling

To assess aortic remodeling, we selected 106 patients [non-DS (n=50) and DS (n=56) (Table S1)]. Type A AD was more prevalent in both groups but slightly lower in DS group (73.2% *vs.* 86.0%, P=0.105). Chronic AD was more frequent in DS group (62.5% *vs.* 54.0%), and non-DS group had a higher proportion of subacute AD (28.0% *vs.* 14.3%, P=0.216). Aortic diameters were measured at three key levels [stent-graft level (A), distal DTA (B),

Table 1 Comparison of baseline characteristics before and after matching

Variables	All included patients			Matched patients		
	Overall DS group, N=170 (71%)	Overall non-DS group, N=71 (29%)	P value	Matched DS group, N=71 (50%)	Matched non-DS group, N=71 (50%)	SMD
Age, years	53 [45, 63]	52 [45, 62]	0.60	51 [43, 60]	52 [45, 62]	0.059
Male sex	121 (71%)	53 (75%)	0.58	55 (77%)	53 (75%)	0.047
Height, cm	175.3 [11]	175 [10]	0.85	176 [11.5]	175 [10]	0.093
Weight, kg	85 [76, 96]	80 [75, 95]	0.34	85 [79, 96]	80 [75, 95]	0.270
BMI, kg/m^2	27.7 [25.2, 31.6]	27.4 [24.2, 31.2]	0.49	27.7 [25.2, 32.2]	27.4 [24.2, 31.2]	0.043
BSA, m^2	2 [0.2]	2 [0.2]	0.55	2.06 [1.90, 2.18]	1.99 [1.90, 2.12]	0.28
Type of dissection			0.017			
Type A	122 (72%)	63 (89%)		63 (89%)	63 (89%)	0
Type B	33 (19%)	6 (8.5%)		7 (9.9%)	6 (8.5%)	0.048
Type non-A-non-B	15 (8.8%)	2 (2.8%)		1 (1.4%)	2 (2.8%)	0.098
Phase			0.46			
Acute	48 (28%)	15 (21%)		15 (21%)	15 (21%)	0
Subacute	35 (21%)	18 (25%)		13 (18%)	18 (25%)	0.171
Chronic	87 (51%)	38 (54%)		43 (61%)	38 (54%)	0.142
Root aneurysm	43 (25%)	14 (20%)	0.35	17 (24%)	14 (20%)	0.097
Ascending aorta aneurysm	81 (48%)	32 (45%)	0.71	37 (52%)	32 (45%)	0.140
Arch aneurysm	34 (20%)	4 (5.6%)	0.005	17 (24%)	4 (5.6%)	0.697
TAAA dilatation more than 45 mm	33 (19%)	14 (20%)	0.96	14 (20%)	14 (20%)	0
DTAA	26 (15%)	9 (13%)	0.60	10 (14%)	9 (13%)	0
Type TAAA			0.33			
Extent I	12 (7.1%)	2 (2.8%)		5 (7%)	2 (2.8%)	0
Extent II	2 (1.2%)	2 (2.8%)		2 (2.8%)	2 (2.8%)	0
Extent III	1 (0.6%)	1 (1.4%)		1 (1.4%)	1 (1.4%)	0
Abdominal aortic aneurysm	1 (0.6%)	2 (2.8%)	0.21	1 (1.4%)	2 (2.8%)	0.182
CIA aneurysm	4 (2.4%)	0 (0%)	0.32	1 (1.4%)	0 (0%)	0.375
Mega-aortic syndrome			0.33			
I type	2 (1.2%)	3 (4.2%)		2 (2.8%)	3 (4.2%)	0.104
II type	2 (1.2%)	0 (0%)		1 (1.4%)	0 (0%)	0
III type	3 (1.8%)	2 (2.8%)		3 (4.2%)	2 (2.8%)	0.05
AV function			0.74			
Normal	105 (62%)	43 (61%)		38 (54%)	43 (61%)	0.155
AI	60 (35%)	28 (39%)		31 (44%)	28 (39%)	0.129
AS	2 (1.2%)	0 (0%)		1 (1.4%)	0 (0%)	0.04
MAVD	3 (1.8%)	0 (0%)		1 (1.4%)	0 (0%)	0.07

Table 1 (*continued*)

Table 1 (*continued*)

Variables	All included patients			Matched patients		
	Overall DS group, N=170 (71%)	Overall non-DS group, N=71 (29%)	P value	Matched DS group, N=71 (50%)	Matched non-DS group, N=71 (50%)	SMD
BAV	8 (4.7%)	0 (0%)	0.11	3 (4.2%)	0 (0%)	0.204
Redo cardiac surgery	12 (7.1%)	5 (7%)	>0.99	6 (8.5%)	5 (7%)	0.059
Redo aortic surgery	23 (14%)	15 (21%)	0.14	14 (20%)	15 (21%)	0.026
CTD	24 (14%)	12 (17%)	0.58	12 (17%)	12 (17%)	
Marfan	10 (5.9%)	7 (9.9%)	0.27	7 (9.9%)	7 (9.9%)	0.120
Elers-Danlos	1 (0.6%)	1 (1.4%)	0.50	0 (0%)	1 (1.4%)	0.048
Loyes-Dietz	1 (0.6%)	0 (0%)	>0.99	0 (0%)	0 (0%)	0
Terner	1 (0.6%)	0 (0%)	>0.99	0 (0%)	0 (0%)	0
Hypertension	147 (87%)	64 (90%)	0.49	59 (84%)	64 (90%)	0.167
CAD	28 (16%)	10 (14%)	0.64	11 (15%)	10 (14%)	0.042
History MI	8 (4.7%)	2 (2.8%)	0.73	5 (7%)	2 (2.8%)	0
LVEF, %	60 [55, 64]	58 [55, 62]	0.29	59 [55, 62]	58 [55, 62]	0.14
TI	13 (7.6%)	3 (4.2%)	0.41	6 (8.5%)	3 (4.2%)	0.184
MI	12 (7.1%)	4 (5.6%)	0.78	3 (4.2%)	4 (5.6%)	0.065
Stroke history	17 (10%)	7 (9.9%)	0.97	6 (8.5%)	7 (9.9%)	0.048
COPD	7 (4.1%)	2 (2.8%)	>0.99	1 (1.4%)	2 (2.8%)	0.098
Diabetes	5 (2.9%)	4 (5.6%)	0.46	1 (1.4%)	4 (5.6%)	0.230
AF	23 (14%)	5 (7%)	0.15	11 (15%)	5 (7%)	0.258
CKD	51 (30%)	9 (13%)	0.005	16 (23%)	9 (13%)	0.263
Class NYHA			0.86			
0	156 (92%)	64 (90%)		67 (94%)	64 (90%)	0.148
II	7 (4.1%)	3 (4.2%)		2 (2.8%)	3 (4.2%)	0.076
III	7 (4.1%)	4 (5.6%)		2 (2.8%)	4 (5.6%)	0.140
Coronary malperfusion	12 (7.1%)	0 (0%)	0.020	2 (2.8%)	0 (0%)	0.240
Visceral malperfusion	13 (7.6%)	1 (1.4%)	0.071	5 (7%)	1 (1.4%)	0.282
Tamponade	12 (7.1%)	3 (4.2%)	0.56	5 (7%)	3 (4.2%)	0.122
Nonstable	9 (5.3%)	3 (4.2%)	>0.99	3 (4.2%)	3 (4.2%)	0
Antiplatelets	8 (4.7%)	0 (0%)	0.11	1 (1.4%)	0 (0%)	0.169

Data are presented as mean [standard deviation], median [IQR] or n (%). AF, atrial fibrillation; AI, aortic insufficiency; AS, aortic stenosis; AV, atrioventricular; BAV, bicuspid aortic valve; BMI, body mass index; BSA, body surface area; CAD, coronary artery disease; CIA, common iliac artery; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CTD, connective tissue disorder; DTAA, descending thoracic aortic aneurysm; FET, frozen elephant trunk; IQR, interquartile range; LVEF, left ventricular ejection fraction; MAVD, mixed aortic valve disease; MI, myocardial infarction; Non-DS, non-dissection-specific; NYHA, New York Heart Association; SG, stent graft; SMD, standardized mean difference; TAAA, thoracoabdominal aortic aneurysm; TI, tricuspid insufficiency.

Table 2 Intraoperative data before and after matching

Variables	All included patients			Matched patients		
	Overall DS group, N=170 (71%)	Overall non-DS group, N=71 (29%)	P value	Matched DS group, N=71 (50%)	Matched non-DS group, N=71 (50%)	P value
FET type			<0.001			<0.001
FET	170 (100%)	59 (83%)		71 (100%)	59 (83%)	
ET + TEVAR	0 (0%)	11 (15%)		0 (0%)	11 (15%)	
Hybrid II type	0 (0%)	1 (1.4%)		0 (0%)	1 (1.4%)	
Prosthesis			<0.001			<0.001
E-Vita Open PLUS	0 (0%)	43 (59%)		0 (0%)	43 (59%)	
Thoraflex Hybrid	0 (0%)	15 (21%)		0 (0%)	15 (21%)	
Braile Medica	0 (0%)	2 (2.8%)		0 (0%)	2 (2.8%)	
Soft ET	170 (100%)	0 (0%)		71 (100%)	0 (0%)	
Medtronic Valiant Thoracic	0 (0%)	11 (15%)		0 (0%)	11 (15%)	0 (0%)
Size graft, mm	26 [24, 28]	28 [28, 30]	<0.001	26 [24, 28]	28 [28, 30]	<0.001
Length, mm	180 [160, 184]	150 [150, 150]	<0.001	180 [165, 187.5]	150 [150, 150]	<0.001
Distal end (type)			<0.001			<0.001
Z-shaped nitinol	0 (0%)	56 (79%)		0 (0%)	56 (79%)	
Ring-shaped nitinol	0 (0%)	15 (21%)		0 (0%)	15 (21%)	
Soft prosthesis	170 (100%)	0 (0%)		71 (100%)	0 (0%)	
Landing zone (thoracic vertebra)			0.023			0.12
Th 5	1 (0.6%)	0 (0%)		0 (0%)	0 (0%)	
Th 6	2 (1.2%)	5 (7%)		2 (2.8%)	5 (7%)	
Th 7	5 (2.9%)	3 (4.2%)		1 (1.4%)	3 (4.2%)	
Th 8	57 (34%)	27 (38%)		19 (27%)	27 (38%)	
Th 9	73 (43%)	20 (28%)		32 (45%)	20 (28%)	
Th 10	28 (16%)	10 (14%)		15 (21%)	10 (14%)	
Th 11	4 (2.4%)	5 (7%)		2 (2.8%)	5 (7%)	
Th 12	0 (0%)	1 (1.4%)		0 (0%)	1 (1.4%)	
Additional TEVAR	3 (1.8%)	2 (2.8%)	0.63	2 (2.8%)	2 (2.8%)	>0.99
Use of a guidewire	62 (36%)	67 (94%)	<0.001	26 (37%)	67 (94%)	<0.001
Intraoperative oversizing, %	100 [100, 100]	100 [100, 101.6]	0.85	100 [100, 100]	100 [100.0, 101.6]	0.66
Preoperative oversizing, %	112 [107, 133]	132 [116, 149]	0.93	111.9 [96.3, 117.5]	132.5 [116, 149]	0.75
Arch repair			0.008			0.15
Island	75 (44%)	25 (35%)		29 (41%)	25 (35%)	
Branched	95 (56%)	42 (59%)		42 (59%)	42 (59%)	
Lupiae	0 (0%)	4 (5.6%)		0 (0%)	4 (5.6%)	

Table 2 (*continued*)

Table 2 (*continued*)

Variables	All included patients			Matched patients		
	Overall DS group, N=170 (71%)	Overall non-DS group, N=71 (29%)	P value	Matched DS group, N=71 (50%)	Matched non-DS group, N=71 (50%)	P value
Zone anastomosis			0.10			0.061
Zone 0	1 (0.6%)	1 (1.4%)		1 (1.4%)	1 (1.4%)	
Zone 1	0 (0%)	1 (1.4%)		0 (0%)	1 (1.4%)	
Zone 3	13 (7.7%)	10 (14%)		3 (4.2%)	10 (14%)	
Zone 4	156 (92%)	59 (83%)		67 (94%)	59 (83%)	
Mini-sternotomy	5 (2.9%)	10 (14%)	0.002	1 (1.4%)	10 (14%)	0.005
Root repair			0.25			0.46
Supracoronary AAR	47 (28%)	20 (28%)		22 (31%)	20 (28%)	
Root repair	40 (24%)	8 (11%)		13 (18%)	8 (11%)	
Bentall-DeBono	32 (19%)	20 (28%)		11 (15%)	20 (28%)	
David	19 (11%)	11 (15%)		9 (13%)	11 (15%)	
Wolf	11 (6.5%)	3 (4.2%)		4 (5.6%)	3 (4.2%)	
Sandwich	20 (12%)	9 (13%)		12 (17%)	9 (13%)	
AVR + AAR	1 (0.6%)	0 (0%)		0 (0%)	0 (0%)	
Cannulation			<0.001			0.008
Aorta	32 (19%)	2 (2.8%)		9 (13%)	2 (2.8%)	
Femoral	5 (2.9%)	11 (15%)		2 (2.8%)	11 (15%)	
Subclavian	108 (64%)	52 (73%)		49 (69%)	52 (73%)	
BCT	8 (4.7%)	1 (1.4%)		1 (1.4%)	1 (1.4%)	
CCA	17 (10%)	5 (7%)		10 (14%)	5 (7%)	
CABG	25 (15%)	13 (18%)	0.50	9 (13%)	13 (18%)	0.37
MV repair			0.46			0.38
Prosthesis	2 (1.2%)	0 (0%)		2 (2.8%)	0 (0%)	
Repair	14 (8.2%)	3 (4.2%)		5 (7%)	3 (4.2%)	
TV repair	3 (1.8%)	3 (4.2%)	0.36	2 (2.8%)	3 (4.2%)	>0.99
Cardioplegia			<0.001			<0.001
Custodiol	4 (2.4%)	28 (39%)		3 (4.2%)	28 (39%)	
Blood	82 (48%)	43 (61%)		35 (49%)	43 (61%)	
delNido	84 (49%)	0 (0%)		33 (46%)	0 (0%)	
Cerebral perfusion			>0.99			>0.99
Unilateral	9 (5.3%)	4 (5.8%)		5 (7%)	4 (5.8%)	
Bilateral	161 (95%)	65 (94%)		66 (93%)	65 (94%)	
CPB, min	156 [134, 182]	182 [164, 205]	<0.001	160 [134, 192]	182 [164, 205]	0.001

Table 2 (*continued*)

Table 2 (*continued*)

Variables	All included patients			Matched patients		
	Overall DS group, N=170 (71%)	Overall non-DS group, N=71 (29%)	P value	Matched DS group, N=71 (50%)	Matched non-DS group, N=71 (50%)	P value
Aortic X-clump, min	94 [69, 118]	110 [85, 148]	<0.001	94 [77, 118]	110 [85, 148]	0.006
Circulatory arrest, min	32 [29, 39]	45 [38, 54]	<0.001	32 [28, 39]	45 [38, 54]	<0.001
T, ℃	28 [28, 28]	26 [26, 26]	<0.001	28 [28, 28]	26 [26, 26]	<0.001
Blood loss, mL	1,000 [800, 1,500]	1,000 [875, 1,500]	0.079	1,000 [700, 1,500]	1,000 [875, 1,500]	0.11

Data are presented as median [IQR] or n (%). AVR, aortic valve replacement; BCT, brachiocephalic trunk; CABG, coronary artery bypass grafting; CCA, common carotid artery; CPB, cardiopulmonary bypass; DS, dissection-specific; ET, elephant trunk; FET, frozen elephant trunk; IQR, interquartile range; MV, mitral valve; Non-DS, non-dissection-specific; TEVAR, thoracic endovascular aortic repair.

Table 3 Postoperative data before and after matching

Variables	All included patients			Matched patients		
	Overall DS group, N=170 (71%)	Overall non-DS group, N=71 (29%)	P value	Matched DS group, N=71 (50%)	Matched non-DS group, N=71 (50%)	P value
Pulmonary failure	24 (14%)	12 (17%)	0.58	7 (9.9%)	12 (17%)	0.22
Laryngeal nerve palsy			>0.99			>0.99
Unilateral	4 (2.4%)	3 (4.2%)		0 (0%)	3 (4.2%)	
Bilateral	3 (1.8%)	1 (1.4%)		2 (2.8%)	1 (1.4%)	
Lung ventilation time, hours	9 [7, 14]	11 [8, 19]	0.054	9 [7, 13]	11 [8, 19]	0.034
ICU stay, days	2 [1, 4]	2 [1, 4]	0.86	2 [1, 4]	2 [1, 4]	0.94
Paraplegia	1 (0.6%)	0 (0%)	>0.99	1 (1.4%)	0 (0%)	>0.99
Paraparesis	4 (2.4%)	3 (4.2%)	0.42	0 (0%)	3 (4.2%)	0.24
Re-exploration for bleeding	11 (6.5%)	5 (7%)	>0.99	4 (5.6%)	5 (7%)	>0.99
Tracheostomy	6 (3.5%)	6 (8.5%)	0.19	3 (4.2%)	6 (8.5%)	0.49
AKI	18 (11%)	10 (14%)	0.44	7 (9.9%)	10 (14%)	0.44
MOF	17 (10%)	7 (9.9%)	0.97	5 (7%)	7 (9.9%)	0.55
Temporary dialysis	7 (4.1%)	5 (7%)	0.34	3 (4.2%)	5 (7%)	0.72
Stroke	6 (3.5%)	3 (4.2%)	0.73	2 (2.8%)	3 (4.2%)	>0.99
Delirium	33 (19%)	19 (27%)	0.21	11 (15%)	19 (27%)	0.10
AV block (pacemaker)	1 (0.6%)	2 (2.8%)	0.21	0 (0%)	2 (2.8%)	0.50
AF	24 (14%)	8 (11%)	0.55	9 (13%)	8 (11%)	0.80
Malperfusion	4 (2.4%)	0 (0%)	0.32	2 (2.8%)	0 (0%)	0.50
Cardiac arrest	11 (6.5%)	5 (7%)	>0.99	2 (2.8%)	5 (7%)	0.44
Wound infection			0.28			0.12
SWI	5 (2.9%)	0 (0%)		2 (2.8%)	0 (0%)	
DWI	7 (4.1%)	5 (7%)		1 (1.4%)	5 (7%)	

Table 3 (*continued*)

Table 3 (*continued*)

Variables	All included patients			Matched patients		
	Overall DS group, N=170 (71%)	Overall non-DS group, N=71 (29%)	P value	Matched DS group, N=71 (50%)	Matched non-DS group, N=71 (50%)	P value
PGI	3 (1.8%)	2 (2.8%)	0.63	1 (1.4%)	2 (2.8%)	>0.99
Hospital stay, day	10 [8, 13]	11 [10, 15]	0.020	10 [8, 14]	11 [10, 15]	0.093
Hospital mortality	9 (5.3%)	5 (7%)	0.56	4 (5.6%)	5 (7%)	>0.99
Follow-up duration, months	18 [7.9, 40]	60 [34.3, 85.8]	<0.01	18 [9.2, 42.8]	60 [34.3, 85.8]	<0.01
Aortic reoperation			0.037			0.33
TEVAR	5 (3%)	7 (9.9%)		3(4.2%)	7 (9.9%)	
TAAA repair	9 (5.3%)	7 (9.9%)		6 (8.5%)	7 (9.9%)	
Arch repair	0 (0%)	1 (1.4%)		0 (0%)	1 (1.4%)	
Proximal homograft	1 (0.6%)	0 (0%)		0 (0%)	0 (0%)	
Abdominal aortic repair	2 (1.2%)	0 (0%)		2 (2.8%)	0 (0%)	
Reoperation	17 (10%)	17 (24%)	0.005	10 (14%)	17 (24%)	0.13
Non-staged	8 (4.7%)	13 (18%)	<0.001	4 (5.6%)	13 (18%)	0.020
Staged	9 (5.3%)	4 (5.6%)	>0.99	6 (8.5%)	4 (5.6%)	0.51
Proximal reoperation	3 (1.8%)	3 (4.2%)	0.36	0 (0%)	3 (4.2%)	0.24
dSINE	8 (4.7%)	14 (20%)	<0.001	3 (4.2%)	14 (20%)	0.004
New distal aortic event (composite endpoint)	22 (12.9%)	21 (29.6%)	<0.001	11 (15.5%)	21 (29.6%)	0.04
FU mortality	15 (8.8%)	16 (23%)	0.004	5 (7%)	16 (23%)	0.009
Aortic causes	3 (1.7%)	7 (9.8%)	0.0078	3 (1.7%)	7 (9.8%)	0.1656
Non-aortic causes	2 (1.2%)	2 (2.8%)	0.5834	1 (1.4%)	2 (2.8%)	1.000
Unknown cause of death	2 (1.2%)	2 (2.8%)	0.5834	1 (1.4%)	2 (2.8%)	1.000

Data are presented as median [IQR] or n (%). AF, atrial fibrillation; AKI, acute kidney injury; AV, atrioventricular; DS, dissection-specific; dSINE, distal stent-graft induced new entry; DWI, deep wound infection; FU, follow-up; ICU, intensive care unit; MOF, multiple organ failure; PGI, prosthetic graft infection; SWI, superficial wound infection; TAAA, thoracoabdominal aortic aneurysm; TEVAR, thoracic endovascular aortic repair.

and abdominal aorta (C)] with no statistically significant differences between groups (P>0.05), and the ratios of TL/AL also remained comparable (Figure S1A). The number of re-entries at various levels (A, B, C) was higher in DS group, but significance was only reached for re-entries >5 mm at Level A (P=0.023). Type II endoleak was more frequent in the DS group postoperatively (43.6% *vs.* 23.8%), but this difference diminished over time. Long-term endoleak rates (>5 years) were significantly higher in the non-DS group (31.4% *vs.* 7.1%, P=0.009) (Figure S1B). The incidence of dSINE increased over time, with a significantly higher rate in the non-DS group after 5 years (42.9% *vs.* 10.7%, P=0.002) (Figure S1C).

Patency of FL

FL thrombosis dynamics were evaluated across different anatomical levels (stent-graft, distal DTA, visceral arteries, abdominal aorta, and iliac arteries) over time (Table S2). At 1-year, complete thrombosis was higher at the stent-graft level in the DS group (55.4% *vs.* 34.8%, P=0.157), and by 5 years, complete thrombosis was 73.2% in DS *vs.* 47.8% in non-DS (P=0.057), showing a stronger remodeling effect in

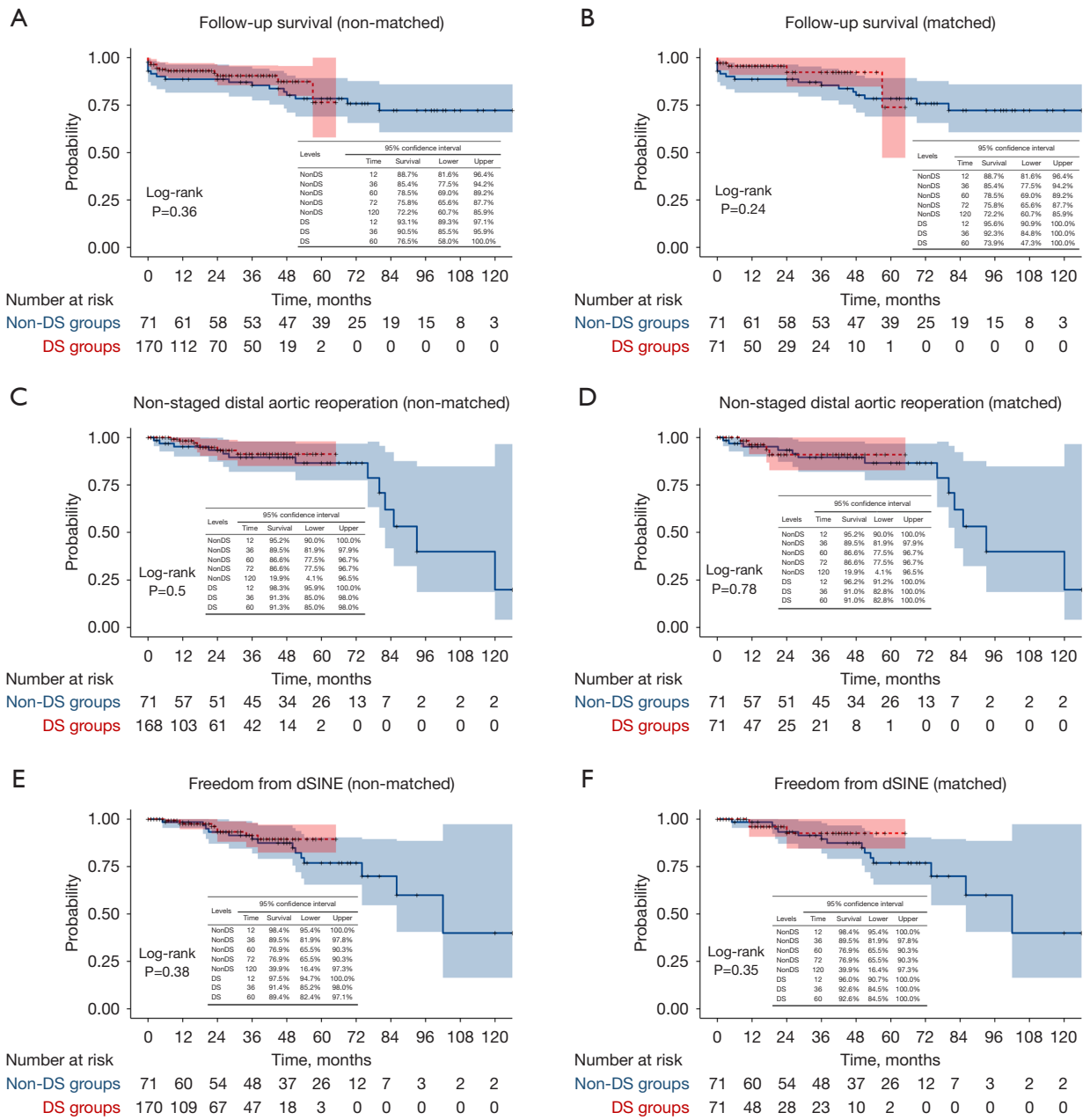

Figure 2 Follow-up outcomes stratified by DS and non-DS groups. Kaplan-Meier curves for (A) overall survival (non-matched cohort), (B) overall survival (matched cohort), (C) non-staged distal aortic reoperations (non-matched cohort), (D) non-staged distal aortic reoperations (matched cohort), (E) freedom from dSINE (non-matched cohort), (F) freedom from dSINE (matched cohort). DS, dissection-specific; dSINE, distal stent-graft induced new entry.

DS patients (Figure S2A). At 1-year, complete thrombosis at the level of distal DTA reached 8.7% and 3.6% in non-DS and DS groups, while partial thrombosis was higher in the DS group (82.1% *vs.* 52.2%, P=0.023). This difference persisted at 5 years (78.6% partial thrombosis in DS *vs.* 65.2% in non-DS, P=0.33) (Figure S2B). By 1 year at visceral arteries level, complete thrombosis remained low in both groups (2.6% *vs.* 4.3%), while partial thrombosis increased to 39.1% in non-DS *vs.* 33.9% in DS (P=0.703), showing a slower thrombosis effect in visceral arteries

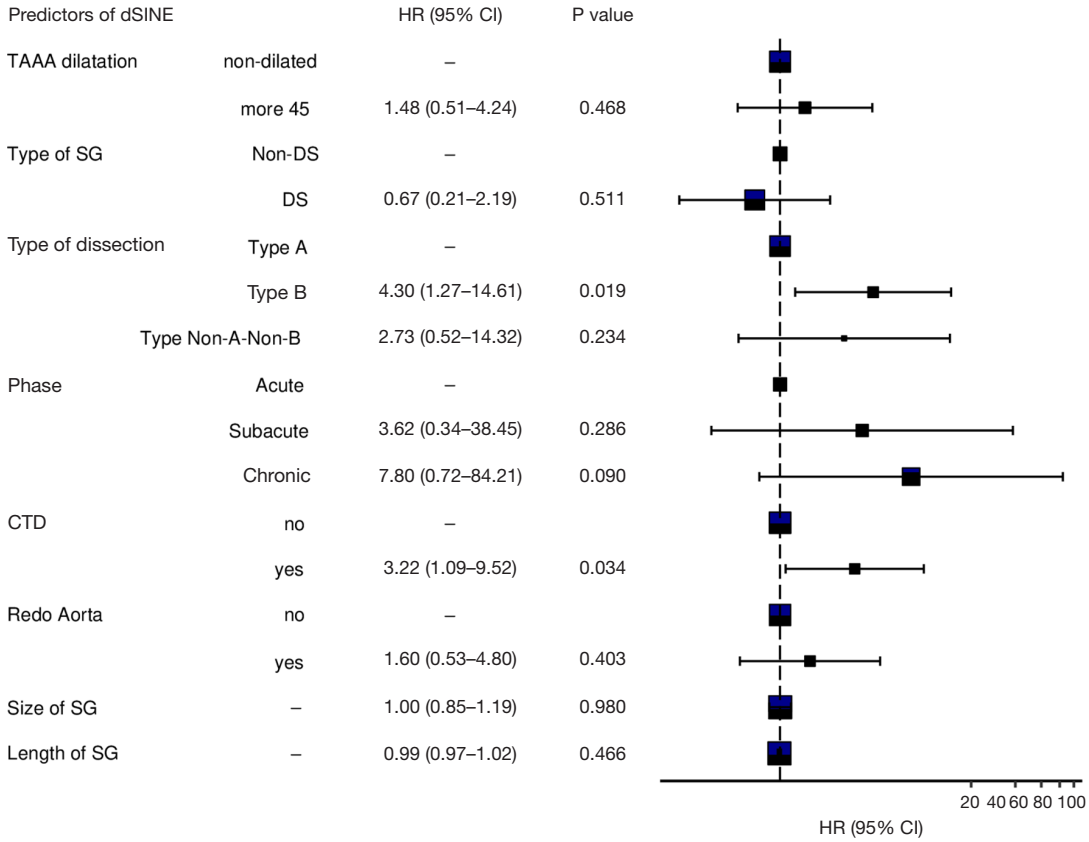

Figure 3 Predictors of dSINE. CI, confidence interval; CTD, connective tissue disorder; DS, dissection-specific; dSINE, distal stent-graft induced new entry; FET, frozen elephant trunk; HR, hazard ratio; PSM, propensity score matching; SG, stent graft; TAAA, thoracoabdominal aortic aneurysm.

(Figure S2C). At 1 year at level of abdominal aorta, complete thrombosis remained rare (1.8% *vs.* 0%), while partial thrombosis increased to 25% in DS *vs.* 26.1% in non-DS (P=0.811) (Figure S2D).

dSINE

Freedom from dSINE was 89.5% (95% CI: 81.9–97.9%) *vs.* 91.4% (95% CI: 85.2–98%) and 76.9% (95% CI: 65.5–90.3%) *vs.* 89.4% (95% CI: 82.4–97.1%) at 3 and 5 years, in non-DS and DS groups (P=0.38), respectively (*Figure 2E*). In the matched cohort, freedom from dSINE was 89.5% (95% CI: 81.9–97.8%) *vs.* 92.6% (95% CI: 84.5–100%) and 76.9% (95% CI: 65.5–90.3%) *vs.* 92.6% (95% CI: 84.5–100%) at 3 and 5 years, in non-DS and DS groups (P=0.78), respectively (*Figure 2F*).

Cumulative incidence of new events—including distal aortic reoperations and dSINE—was significantly lower in the DS group versus non-DS group both before matching (12.9% *vs.* 29.6%, P<0.001) and after matching (15.5% *vs.* 29.6%, P=0.04) (*Table 3*).

Predictors of dSINE and high-risk patients

Univariable Cox-regression analysis identified the risk factors for dSINE as TAA dilatation >45 mm (HR =3.36, 95% CI: 1.32–8.56, P=0.011), Stanford type B AD (HR =3.73, 95% CI: 1.36–10.18, P=0.01), and chronic AD (HR =12.95, 95% CI: 1.52–109.9, P=0.019). Based on multivariable Cox-regression data, the key predictors for dSINE included CTD (HR =3.22, 95% CI: 1.09–9.52, P=0.034), Stanford type B AD (HR =4.3, 95% CI: 1.27–14.61, P=0.019), and chronic AD (HR =7.8, 95% CI: 0.72–84.21, P=0.09). Other factors, including previous aortic repair, type of SG, SG length and size, etc., did not show strong statistical significance (P>0.05) (*Figure 3*). The Kaplan-Meier analysis demonstrated that patients from DS group had lower risks of dSINE even among high-risk subgroups (Figure S3). While freedom from dSINE was significantly lower in high-risk patients such as those with

chronic AD, type B AD, TAA dilation >45 mm, and CTD, the SET showed a protective effect, reducing the incidence of dSINE across all categories. The highest dSINE risk was observed in non-DS group with chronic AD (P=0.009) (Figure S3B), type B AD (P=0.012) (Figure S3D), and aortic dilation >45 mm (P=0.004) (Figure S3F). Additionally, non-DS group with CTD had significantly higher dSINE rates compared to DS group with CTD (P=0.005) (Figure S3H), reinforcing the protective role of SET in this subgroup.

Discussion

The SET graft features a tailored radial force distribution, allowing it to adapt to the weakened and fragile intima without exerting excessive pressure that could lead to new tears. The soft distal end, devoid of nitinol rings and featuring a gradual tapering in stiffness, enables deep prosthesis placement, ensuring optimal adaptation to the TL. In our study, we observed significantly lower rates of dSINE compared to conventional FET prostheses in high-risk patients. Although we did not find significant differences in long-term outcomes in the general and PSM cohorts, our subgroup analysis showed a significantly lower incidence of dSINE for SET in high-risk groups. Significantly higher dSINE risk was observed in non-DS group with chronic AD, type B AD, CTD, and TAA dilation >45 mm in comparison with DS group.

dSINE is a frequent complication of FET surgery, with an incidence ranging from 3.4% to 27% in the literature (4-7). The primary risk factors include CTD, chronic AD, and a mismatch between the stent graft size and the TL diameter (8). In most cases, dSINE occurs in the late postoperative period (11 to 36 months post-intervention) and is often asymptomatic, with mortality rates reaching up to 28.6% (9). The mortality rate for treating these complications remains high, reported at 14% in the literature (4). A study by Hiraoka *et al.* (10) reported a 23% incidence of dSINE after FET procedures for AD, identifying chronic AD and residual FL area as significant risk factors. A review by Jubouri *et al.* examined the incidence of dSINE and aortic remodeling associated with different FET devices. The study highlighted that Thoraflex Hybrid yielded the lowest incidence of dSINE while promoting favorable aortic remodeling through maximum FL thrombosis and TL expansion. The authors emphasized the importance of FET insertion length and graft size in optimizing outcomes and reducing complications (5). A study by Kreibich *et al.* evaluated the incidence and risk factors of dSINE after FET procedures. Among 126 patients treated with the Thoraflex hybrid graft, 13% developed dSINE, with a notable increase in risk over time—25% at 36 months. The study found no significant patient-related risk factors but suggested that the stiffer distal ring of the Thoraflex graft may contribute to dSINE. Additionally, patients treated with E-vita had a significantly lower reintervention rate than those with Thoraflex (0% *vs.* 22%, P=0.003), further supporting the role of graft design in dSINE occurrence (11). Additionally, a systematic review by Nakhaei *et al.* (12) assessed aortic remodeling, dSINE, and endoleak following FET procedures. The analysis, covering multiple studies, found a mean dSINE incidence of 15.2% post-FET, with the highest risk observed in patients with chronic AD and oversized stent grafts. The study emphasized that device-specific characteristics significantly impact remodeling outcomes, with stiffer grafts increasing dSINE rates. Endoleak occurrence was also linked to inadequate proximal sealing, reinforcing the importance of precise sizing and patient-specific graft selection. Our findings reinforce these observations, demonstrating that the SET prosthesis's enhanced flexibility and adaptability to the dissected aorta contribute to superior distal remodeling. These results align with recent studies advocating for graft modifications to minimize complications associated with FET.

Study limitations

This study is limited by its retrospective, single-center design. Despite propensity-score matching, some residual bias may remain; however, the density (Figure S4A) and scatter plots (Figure S4B) show good balance. Additionally, since the SET graft was introduced in 2019, follow-up data is relatively short, limiting the ability to assess long-term durability comprehensively. Larger, multicenter studies with extended follow-up are needed to validate these findings.

Future directions

Future research should concentrate on conducting multicenter studies to evaluate the long-term durability of the SET graft. A randomized controlled trial comparing the SET graft with conventional hybrid grafts would provide additional validation of its advantages.

Conclusions

The SET graft represents a substantial advancement in

hybrid aortic surgery. Although SET did not emerge as an independent predictor of dSINE in our multivariable analysis, the data demonstrates a protective trend—especially in high-risk subgroups—by addressing the anatomical and biomechanical challenges inherent to AD. Compared to conventional FET devices, the SET graft exhibits superior flexibility, conformability, and an optimized radial-force profile, collectively facilitating enhanced aortic remodeling and reducing the incidence of distal complications. While the overall long-term outcomes between SET and conventional hybrid grafts were comparable in the general and PSM cohorts, subgroup analysis revealed a significant reduction in dSINE rates among patients with chronic AD, CTD, and TAA dilation. These findings support the continued adoption of DS prosthesis as a means to enhance patient outcomes and reduce reintervention rates.

Acknowledgments

None.

Footnote

Funding: None.

Conflicts of Interest: The authors have no conflicts of interest to declare.

References

1. Yan TD, Bannon PG, Bavaria J, et al. Consensus on hypothermia in aortic arch surgery. Ann Cardiothorac Surg 2013;2:163-8.
2. Charchyan E, Breshenkov D, Belov Y. A new dissection-specific hybrid stent graft for patients with DeBakey type I aortic dissection. Eur J Cardiothorac Surg 2022;61:596-604.
3. Charchyan ER, Breshenkov DG, Belov YV. The Frozen Elephant Trunk Procedure Using New Russian Hybrid Prosthesis "Soft Elephant Trunk": the Early Experience. Kardiologiia 2023;63:29-37.
4. Kreibich M, Berger T, Rylski B, et al. Aortic reinterventions after the frozen elephant trunk procedure. J Thorac Cardiovasc Surg 2020;159:392-399.e1.
5. Jubouri M, Kayali F, Saha P, et al. Incidence of Distal Stent Graft Induced New Entry vs. Aortic Remodeling Associated With Frozen Elephant Trunk. Front Cardiovasc Med 2022;9:875078.
6. Murana G, Costantino A, Campanini F, et al. Distal stent graft-induced new entry (dSINE) after frozen elephant trunk: a scoping review. Cardiovasc Diagn Ther 2023;13:408-17.
7. Kozlov B, Panfilov D, Lukinov V. Frozen Elephant Trunk for Aortic Dissection Using Different Hybrid Grafts: Preliminary Results from a Prospective Study. J Pers Med 2023;13:784.
8. Li Q, Wang LF, Ma WG, et al. Risk factors for distal stent graft-induced new entry following endovascular repair of type B aortic dissection. J Thorac Dis 2015;7:1907-16.
9. Czerny M, Eggebrecht H, Rousseau H, et al. Distal Stent Graft-Induced New Entry After TEVAR or FET: Insights Into a New Disease From EuREC. Ann Thorac Surg 2020;110:1494-500.
10. Hiraoka T, Furukawa T, Imai K, et al. Distal Stent Graft-Induced New Entry After Frozen Elephant Trunk Procedure for Aortic Dissection. Ann Vasc Surg 2023;97:340-50.
11. Kreibich M, Bünte D, Berger T, et al. Distal Stent Graft-Induced New Entries After the Frozen Elephant Trunk Procedure. Ann Thorac Surg 2020;110:1271-9.
12. Nakhaei P, Bashir M, Jubouri M, et al. Aortic remodeling, distal stent-graft induced new entry and endoleak following frozen elephant trunk: A systematic review and meta-analysis. J Card Surg 2022;37:3848-62.

Cite this article as: Charchyan E, Breshenkov D, Belov Y. The soft elephant trunk: a new approach in the treatment of aortic dissection. Ann Cardiothorac Surg 2025;14(5):355-368. doi: 10.21037/acs-2025-evet-0046