Charchyan E.R., Breshenkov D.G., Belov Yu.V.
Petrovsky Russian Scientific Center for Surgery, Moscow, Russia

The Frozen Elephant Trunk Procedure Using New Russian Hybrid Prosthesis «Soft Elephant Trunk»: the Early Experience

Aim To present the first experience of performing the Frozen Elephant Trunk (FET) surgery in patients with thoracic aorta disease using a new Russian hybrid stent graft «Soft Elephant Trunk».

Material and methods Between 2014 and 2021, 170 patients with thoracic aortic disease underwent complete aortic arch replacement using the FET technique. In 70 of these cases (since June 2019), a hybrid graft «Soft Elephant Trunk» was used. A specific feature of this graft is the conical reduction of the radial force of nitinol crowns and the soft distal end without radial force. The study endpoints were early postoperative results, as well as the absence of reoperations on the aorta, absence of stent-graft-associated complications, including distal stent-graft-induced fenestration, and survival at a mid-term follow-up of up to 2.5 years.

Results Interventions were performed in patients with A type aortic dissection (n=51; 72.9%), type B aortic dissection (n=13; 18.6%), and thoracoabdominal aortic aneurysm (TAAA) (n=6; 8.5%). In 14 (20%) of these cases, interventions were performed after a primary intervention on the proximal aorta. Acute aortic dissection was diagnosed in 17 (24.3%) cases. Aortic root replacement was performed in 21 (30%) cases, David procedure in 5 (7.2%) cases, Bentall-DeBono procedure in 11 (15.7%) cases, and supracoronary graft placement in 33 (47.1%) cases. There were no cases of paraplegia or paraparesis. Respiratory insufficiency was observed in 8 (11.4%) cases. In one (1.4%) case, acute renal failure developed, which required renal replacement therapy. In-hospital mortality was 4.3% (3 patients died). Mean follow-up duration was 9 [4.25; 16] months. Three-year survival was 94% (95% confidence interval, CI: 88–99.9) and absence of reoperation was 96.6% (95% CI: 90.1–100). There were no cases of distal stent-graft-induced fenestration in this group.

Conclusion The new hybrid graft, due to its specific structure, provides prevention of distal stent-graft-induced fenestration and, thereby, a stable long-term result. Using this stent-graft is effective in patients with thoracic aorta pathology undergoing the FET surgery. However, further studies are needed to determine potential advantages and disadvantages of this new hybrid graft, to obtain long-term results and accumulate experience.

Keywords Aortic aneurysm; aortic dissection; aortic replacement; hybrid graft; mini-sternotomy; hybrid surgery

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Corresponding author Breshenkov D.G. E-mail: denisbreshenkov@gmail.com

Introduction

It has been more than 25 years since Kato et al. and Suto et al. [1, 2] first described the concept of a «frozen elephant trunk (FET)». As novel endovascular technologies appeared, the authors modified the original Borst technique by using an additional TEVAR prosthesis («elephant trunk») in order to exclude the proximal descending thoracic aorta (DTA) from the circulation. The good results of this technique promoted the rapid development of this technology, which led to the creation of the first hybrid prosthesis by Chavan et al. in 2003 [3]. Modern, more complex devices Cronus, Thoraflex Hybrid, Jotec E-Vita Open and others make it possible to safely perform a radical replacement of the aortic arch and isolate the affected part of the DTA [4–6].

One of the important advantages of the FET technique is manifested in patients with aortic dissection [7]. The total exclusion of primary entry, and the blood flow in false lumen (FL) thrombosis in the DTA allows in the most cases perform a single-stage repair of the extended thoracic aorta diseases. Subject to the right choice of patients, it is possible to achieve complete FL thrombosis and positive remodeling in the long term follow up, which reduces the risk of reoperation [8, 9]. However, new approaches give rise to new problems, which means that they require new solutions.

Objective

Present the first experience of performing the FET procedure in patients with thoracic aortic diseases using the new Russian dissection-specific hybrid prosthesis Soft Elephant Trunk (MedEng, Penza, Russia).

Material and Methods

The study included patients with a thoracic aorta disorders who underwent FET using the Soft Elephant Trunk hybrid prosthesis between July 2019 and 2021.

Postoperative outcomes were the study endpoints. The absence of distal aortic reoperations and stent-graft-related complications, including distal stent-graft-induced new entry (dSINE), were evaluated in the long-term follow up, as well as survival in the midterm follow-up period for up to 2.5 years.

All patients underwent computed tomography (CT) of the aorta during hospital stay, in 3 months (in acute dissection), 6 and 12 months, and then annually.

Surgical technique

All interventions were performed with using circulatory arrest and moderate hypothermia of 28 °C. Antegrade bilateral cerebral perfusion with monitoring of cerebral oximetry (rSO2) and blood flow in the middle cerebral arteries with transcranial Doppler were used for cerebral protection. The hybrid prosthesis was implanted via a guide wire pre-installed in the true lumen (Figure 1, A). The size of the hybrid prosthesis was selected based on preoperative planning according to the CT data using the following formulas:

Acute dissection: d prosthesis= d true lumen (TL) + 10%
Chronic dissection: d prosthesis=d TL
Aneurysm: d prosthesis=d aorta (+1 size),

with the TL diameter determined at the level of the left atrium using the following formula:

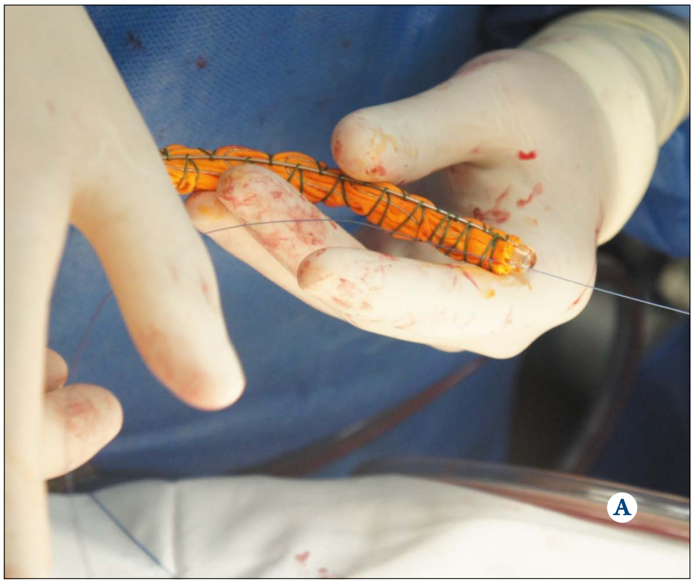
$$d\ TL = TL\ perimeter / \pi$$

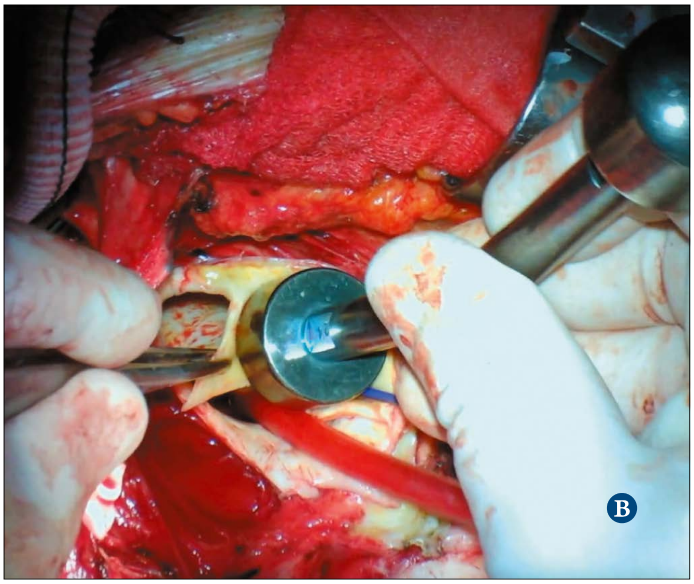
Measuring the TL diameter at the level of the aortic isthmus using a sizer was obligatory (yet less important, in our opinion, for this hybrid prosthesis due to the absence of radial force of the distal end of the prosthesis; Figure 1, B). In case of differences between the preoperative and intraoperative measurements, the latter were preferred. Then, the stent graft was deployed in the TL, the delivery system was removed, and an anastomosis was formed between the aortic isthmus, the soft part of the hybrid prosthesis, and the aortic arch prosthesis.

New hybrid prosthesis Soft Elephant Trunk

The novel dissection-specific hybrid prosthesis was developed by MedEng in cooperation with the Petrovsky National Research Centre of Surgery (patent RU196616U1) and was introduced into the clinical practice in the Aortic Surgery Department in June 2019. The need to create a dissection-specific hybrid prosthesis with a tapered decrease in radial force for the prevention of stent-graft-related complications was the main prerequisite for development a new prosthesis. The Soft elephant trunk prosthesis consists

Figure 1. Surgical technique for the implantation of a soft elephant trunk hybrid prosthesis





A – stent-graft implantation via the guidewire into the true lumen;
B – measurement of the diameter of the true lumen in the aortic isthmus using a sizer.

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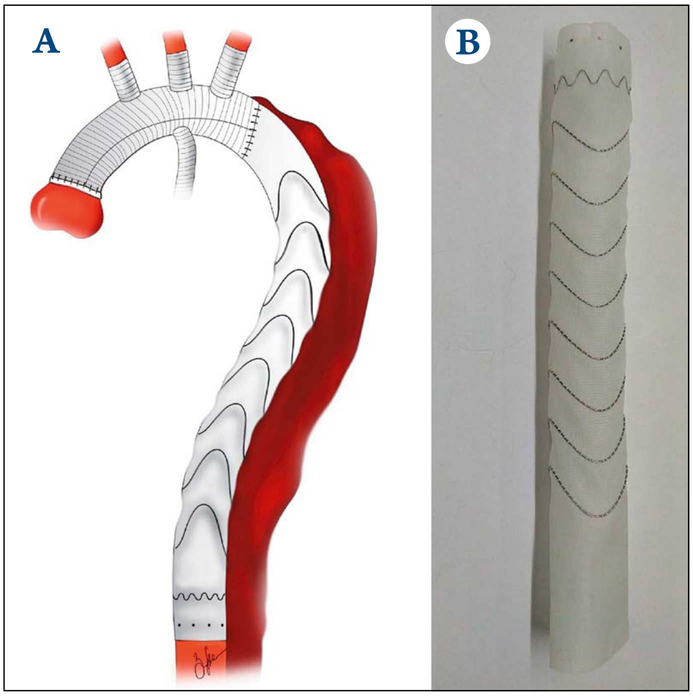
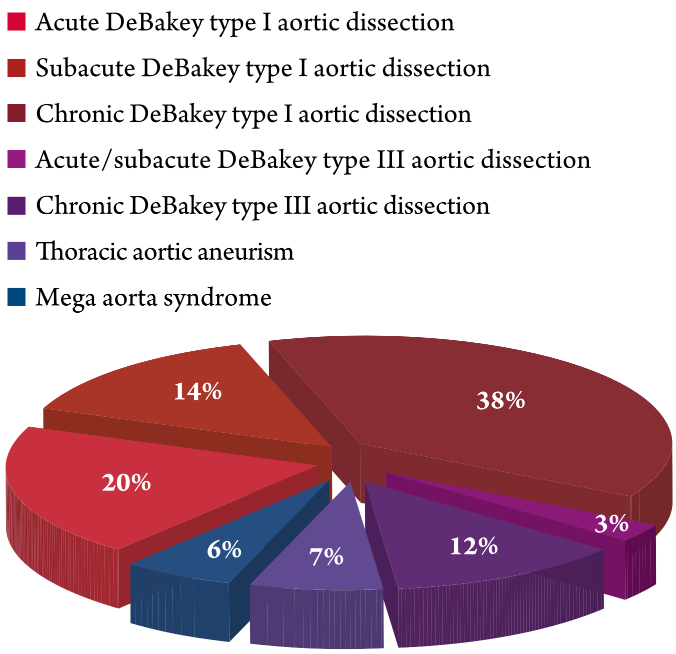
Figure 2. New «Soft Elephant Trunk» hybrid prosthesis



A – the prosthesis design scheme; B – open view.

Figure 3. Pathologies of the thoracic aorta in FET procedures



of a 5 cm dacron vascular part and a 15 cm long stent graft (Figure 2, A). The hybrid prosthesis absence a suture cuff, which allows it to be implanted depending on the dissection anatomy over a length of 15 to 20 cm. The diameters of the hybrid prosthesis vary from 24 mm to 30 mm.

The stent graft design includes 8 ring-shaped nitinol rings with nitinol thickness varying from 4.6 mm to 1.8 mm, which provides a tapered decrease in radial force and one Z-shaped nitinol ring without radial force (see Figure 2, B). There is a 15 mm long soft dacron part at the end of the stent-graft designed for the prevention of dSINE. Moreover, there are 9 radiopaque marks in this part to control the distal end, which also facilitate performing the second step, if necessary [6].

Statistical analysis was performed in Jamovi version 1.2 (Project, 2019). Normally distributed quantitative variables are presented as the means and standard deviations (M ± SD) and non-normally distributed quantitative variables are expressed as the medians and interquartile ranges (Me [Q1; Q3]).

Categorical variables are represented as numerical values and percentages of the total number. The sample distribution was evaluated using the Shapiro-Wilk test. The Kaplan-Meier method was used to analyze long-term survival and the number of cases without repeated procedures.

The study was approved by the local ethics committee. All patients signed the informed consent.

Results

From 2014 to 2021, a total of 170 FET procedures were performed using various types of hybrid prostheses (Figure 3).

According to the study design, 70 patients were selected since July 2019 (Figure 4).

Patients were divided to three groups: Group 1 – «A» with Stanford type A aortic dissection, Group 2 – «B» with Stanford type B aortic dissection, and Group 3 with thoracoabdominal aortic aneurysms (TAAA).

Preoperative parameters are presented per study groups in Table 1

The groups differed significantly in the duration of cardiopulmonary bypass, aortic cross clamp time, and circulatory arrest. There were no differences in the parameters of blood loss and cerebral perfusion time (Table 2). The types of complex repair of the aortic root and brachiocephalic branches, and the characteristics of the procedures are presented in Table 2.

The outcomes of the midterm period for up to 3 months were comparable between the groups and are presented in Table 3. During hospital stay, 3 patients died (mortality 4.3%), of whom 2 (67%) patients had acute Stanford type A aortic dissection with aortic rupture whom were admitted in an unstable and in a state of cardiopulmonary resuscitation. The re-intervention rate was 5.7% (n=4): in Group A, TAAA open repair from the distal end of the stent graft (Extent III) was required in 2 cases due to negative remodeling of the initially dilated distal aortic segments in a patient with Marfan syndrome

Figure 4. Study design

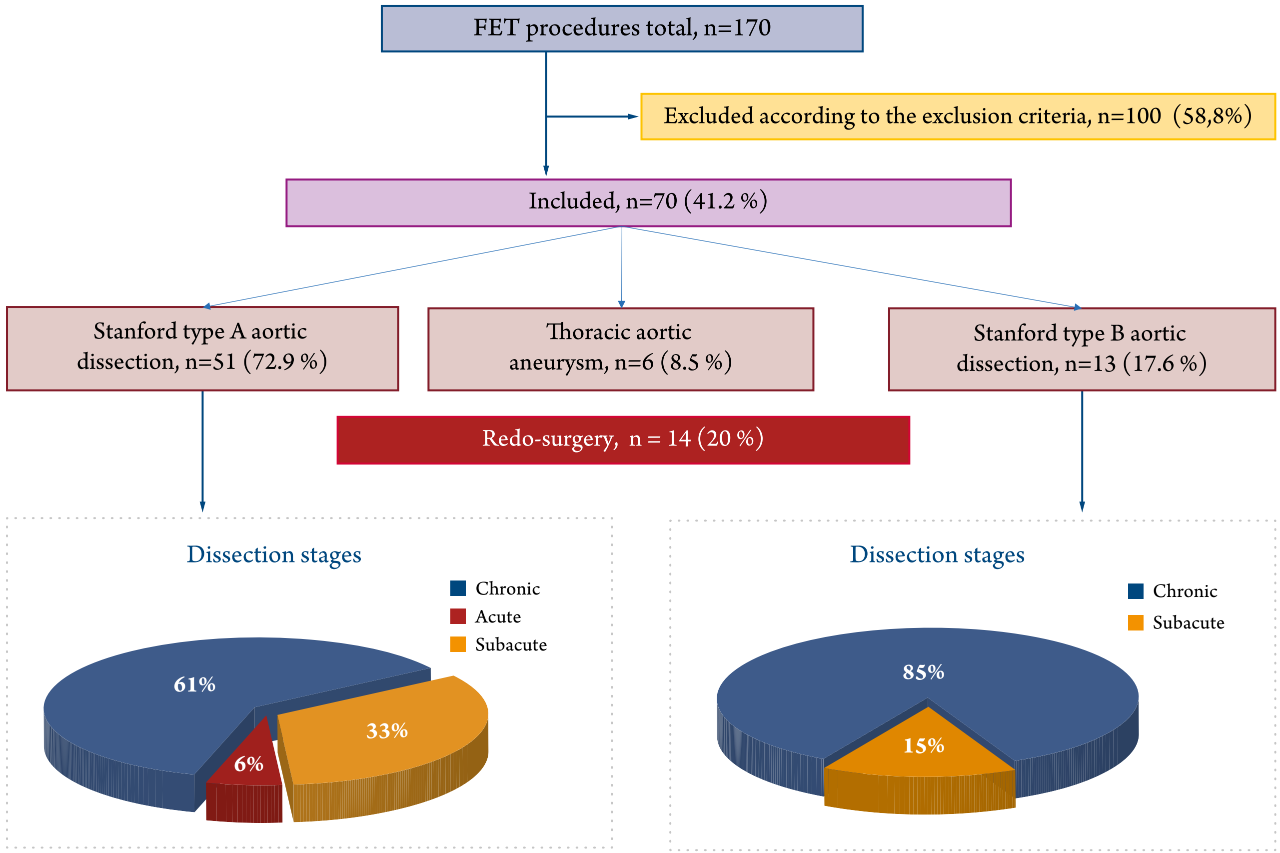


Table 1. Preoperative characteristics of the groups

Parameter	Group A (n=51)	Group B (n=13)	TAAA group (n=6)	p
Age, years	52.9±14	56.6±11	53.8±12	0.683
Male, n (%)	33 (64.7)	7 (53.8)	2 (33.3)	0.219
Redo-surgery	14 (27.5)	0	0	0.038
Dissection stage				
• Acute dissection, n (%)	17 (33.3)	0	–	
• Subacute dissection, n (%)	3 (5.9)	2 (15.4)	–	<0.001
• Chronic dissection, n (%)	31 (60.8)	11 (84.6)	–	
Connective tissue disorder, n (%)	7 (13.7)	0	1 (16.7)	0.349
Obesity, n (%)	18 (35.2)	4 (30.7)	2 (33)	1.000
DTA entries, n (%)	43 (84.3)	9 (69.2)	–	0.221
COPD, n (%)	9 (17.6)	1 (7.7)	1 (16.7)	0.677
Diabetes mellitus, n (%)	1 (2)	1 (7.7)	0	0.492
CKD, n (%)	11 (21.6)	3 (23.1)	1 (16.7)	0.954
CHF, n (%)	7 (13.7)	1 (7.7)	0	0.544
Malperfusion, n (%)	4 (7.8)	1 (7.7)	–	1.000
Unstable, n (%)	6 (9.8)	1 (7.7)	0	0.112
Stroke, % (n)	4 (7.8)	1 (7.7)	1 (16.7)	0.667
Narrow TL, n (%)	11 (21.6)	1 (7.7)	–	0.251

CT, connective tissue; DTA, descending thoracic aorta;
COPD, chronic obstructive pulmonary disease; CKD, chronic kidney disease; CHF, chronic heart failure; TL, true lumen.

in 13 months and another patient with Loeys-Dietz syndrome in 12 months (the second stage was successful in both cases).

In group B, additional TEVAR was required in the first case because pseudocoarctation syndrome developed due to a narrow TL with full resolution; in the second case, a patient with initial dynamic malperfusion and stenosis of a single renal artery and renal insufficiency, which required continuous hemodialysis, stenting of the renal artery was performed with full resolution of malperfusion.

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Table 2. Parameters of surgical interventions

Parameter	Group A (n=51)	Group B (n=13)	TAAA group (n=6)	p
Cardiopulmonary bypass, min	133 [114; 168]	124 [97; 143]	93.5 [86.3; 94.8]	0.017 p(A–TA-AA)=0.028
Aortic cross clamp, min	99 [81; 124]	72 [64; 90]	79.5 [71.8; 84.3]	0.013 p(A–B) =0.016
Circulatory arrest*, min	35 [30.5; 40]	41 [35; 46]	46 [35.5; 57.3]	0.036
Blood loss, mL	1000 [800; 1500]	1000 [800; 1000]	1000 [925; 1150]	0.127
Cerebral perfusion, min	44 [36; 52]	41 [34; 48]	56 [36.5; 59]	0.488
Mean stent graft diameter, mm	26 [26; 28]	26 [26; 28]	28 [28; 30]	0.195
Type of aortic root intervention				
Bentall-DeBono, n=11 (%)	11 (100)	0	0	0.005
David, n=5 (%)	4 (80)	1 (20)	0	–
Aortic root reconstruction, n=21 (%)	20 (95)	1 (5)	0	–
AAR, n=33 (%)	16 (50)	11 (31.3)	6 (8.8)	–
Re-implantation of branches				
Island technique, n=17 (%)	10 (62.5)	5 (25)	2 (12.5)	0.521
Branched prosthesis, n=53 (%)	41 (76.9)	8 (15.4)	4 (7.7)	0.459
Concomitant intervention				
MV repair, n=4 (%)	3 (75)	1 (25)	0	0.776
TV repair, n=2 (%)	1 (50)	1 (50)	1 (50)	0.459
CABG, n=5 (%)	3 (50)	2 (50)	0	0.204
Mini-FET procedure, n=5 (%)	0	4 (80)	1 (20)	<0.001

* Cardiovascular arrest. AAR, ascending aorta replacement;
MV, mitral valve; TV, tricuspid valve; CABG, coronary artery bypass grafting.

Table 3. Immediate postoperative outcomes

Parameter	Group A (n=51)	Group B (n=13)	TAAA group (n=6)	p
AKI, n (%)	5 (9.8)	2 (15.4)	1 (16.7)	0.782
AKI requiring dialysis, n (%)	0	1 (7.7)	0	0.555
Stroke, n (%)	1 (2)	0	0	0.828
Paraplegia, n (%)	0	0	0	1.000
Malperfusion, n (%)	1 (2)	0	0	0.833
Re-exploration for bleeding, n (%)	1 (2)	1 (7.7)	0	0.492
Respiratory failure, n (%)	7 (13.7)	1 (7.7)	0	0.544
Delirium, n (%)	9 (17.6)	1 (7.7)	1 (16.7)	0.981
Rate of re-interventions, n (%)	2 (3.9)	2 (15.4)	0	0.232
Mean follow-up time, months	7 [3; 13]	10 [7; 17]	12 [8.25; 15.8]	0.256
Atrial fibrillation, n (%)	6 (11.8)	0	2 (33.1)	0.104
False lumen thrombosis	**n=49**	**n=10**	—	
• Stent graft level, n (%)	33 (67.3)	6 (60)	—	
• Distal DTA level, n (%)	15 (30.6)	2 (20)	—	**0.233**
• Visceral branch level, n (%)	1 (2)	2 (20)	—	
Hospital mortality, n (%)	3 (5.8)	0	0	0.568
30 day mortality, n (%)	2 (3.9)	0	0	0.657

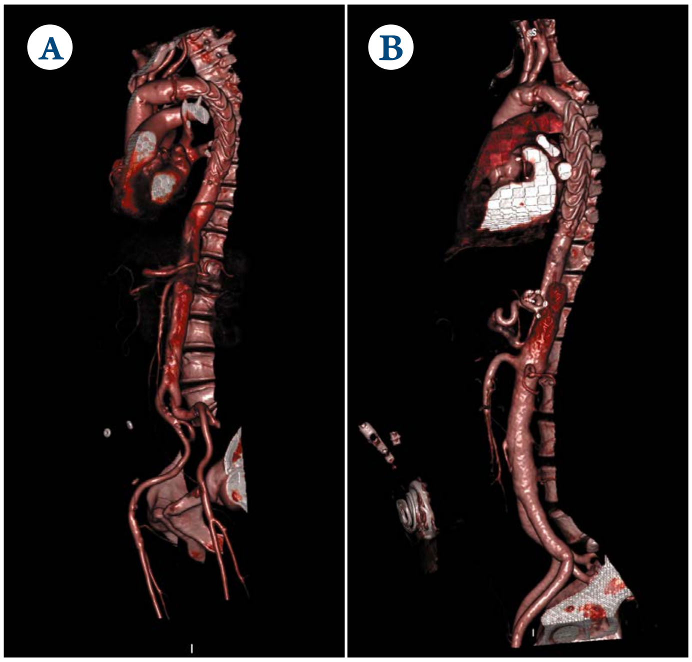
AKI, acute kidney injury; DTA, descending thoracic aorta.

There were no cases of severe complications as paraplegia and stent-graft-related complications in the groups.

The mean follow-up period was 9 [4.25; 16] months (7 [3; 13] months, 10 [7; 17] months, and 12 [8.25; 15.8] months in Group A, Group B, and TAAA group, respectively; p=0.256). False lumen thrombosis at the stent-graft level was achieved in 100% of cases in the postoperative period (Figure 5).

The overall long-term survival for up to 2.5 years was 94.2% and did not differ in the groups (92.2%, 100%,

Figure 5. False lumen thrombosis after FET using the hybrid Soft Elephant Trunk prosthesis



A – thrombosis at the level of the stent graft by 3D CT,
B – thrombosis to the level of visceral branches by 3D CT.

and 100% in Group A, Group B, and TAAA group, respectively (log-rank test p=0.46; Figure 6, A). In the long-term period for up to 2.5 years, the total percentage of cases without aortic reoperation was 97.1% and did not differ in the groups (90.5%, 100%, and 100% in Group A, Group B, and TAAA group, respectively (log-rank test p=0.58; Figure 6, B).

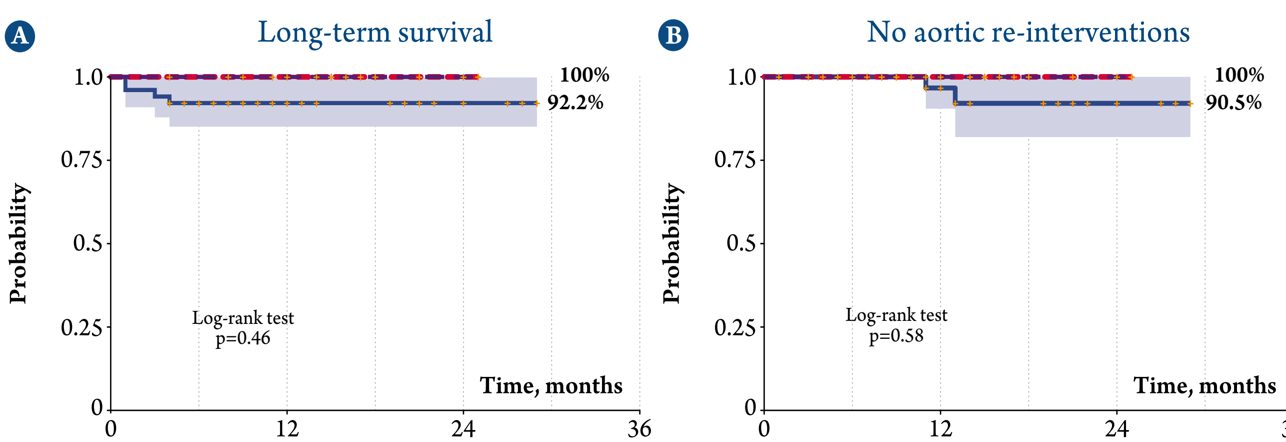
Discussion

The key results of the study can be summarized as follows:

- The novel hybrid dissection-specific prosthesis Soft Elephant Trunk (MedEng, Penza, Russia) is effective for extended diseases as thoracic aortic dissection and aneurysms;
- Soft elephant trunk allows achieving satisfactory midterm outcomes, frequency of total FL thrombosis, and the absence of midterm stent-graft-related complications;
- Despite the aortic dissection-specific design, patients need to be followed over time especially if they have connective tissue disorder syndromes;
- It is necessary to continue the follow up observation to obtain long-term results, gain experience, and compare with other devices to identify the potential benefits and indications for the use of the new hybrid prosthesis.

The main goal of the development of this prosthesis was the need to prevent stent-graft-associated complications and the appearance of blood flow of the FL [10]. This condition, also called dSINE, negatively affects the long-term outcomes, and relates with rapid negative aortic remodeling and the development of a new distal aneurysm [11]. The absence of specific clinical manifestations [12], the incidence (1.3–27%) [13], and the early onset (from 1.5 to 3 years) [10, 14] make the dSINE a tinderbox waiting to explode. According to many authors, distal graft stiffness and distal ring design play a major role in the development of this complication [15]. Despite natural remodeling process in a dissected aorta, the pulsating vibrations of the rigid end of the stent in contact with fragile dissected intima

Figure 6. Study design



Patients at risk	0	12	24	36	0	12	24	36
Group A	51	25	6	0	51	25	5	0
Group B	13	9	2	0	13	9	2	0
TAAA group	6	6	1	0	6	6	1	0

A – long-term survival in the groups; B – absence of the aortic interventions in the long-term period.

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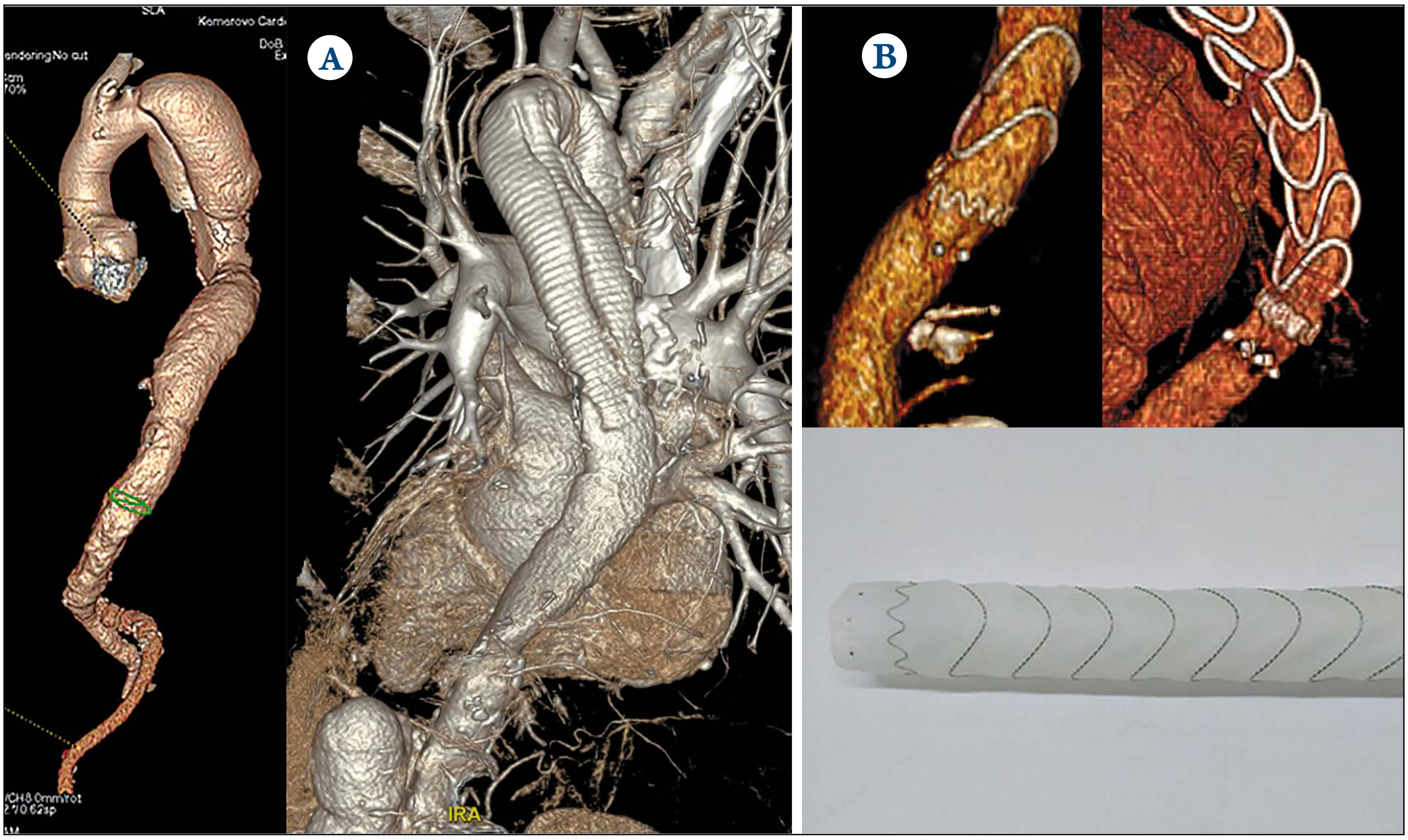
Figure 7. Soft distal dacron end of the hybrid prosthesis



A – 3D CT data of a patient with a long prosthesis implanted in the conventional elephant trunk procedure;
B – the distal end of the «Soft Elephant Trunk» hybrid prosthesis

can tear it. The state of intima is also important: in acute dissection, it is more fragile and at the same time pliable for pulsating stent vibrations [16]; however, despite greater strength in chronic dissection, it is more rigid and creates more conflict when in contact with the stent if there is no diastolic compliance [17, 18]. This conflict is prevented in the Soft elephant trunk prosthesis by a soft dacron distal edge without nitinol ring. The first developments were introduced in the conventional elephant trunk procedure using a long dacron prosthesis (more than 15 cm), which was implanted with a guide wire in the DTA TL (Figure 7, A). Based on the long-term outcomes of this patient group, a Soft elephant trunk design concept was developed (Figure 7, B).

The discrepancy between the distal end dimension of the stent graft and the TL dimension at the level of the distal end and more distally (the so-called aortic remodeling mismatch) is another important predictor of stent-graft-related complications [19]. This is due to the fact that according to the theory of elastic deformation force, the nitinol stent, when heated, tends at the level of the distal ring to recover its shape, and creates a radial force of impact on the fragile intima. The greater the mismatch between these parameters, the greater the radial force and the risk of stent-graft-related complications. The design of the Soft elephant trunk implements the concept of a tapered decrease in the radial force of the rings by reducing the diameter of the nitinol wire and the stiffness of the stent graft. Moreover, without radial force, the distal ring does not tend to recover its shape, which makes the stent graft compliant at the distal end and thus shapes a natural taper. This design allows increasing blood flow in the TL with the development of thrombosis in the proximal FL at the level of the stent graft and remodeling in the distal part without conflict and excessive radial force with a gradual deployment of the stent graft without sagittal straightening and thrombosis to the level of large residual fenestrations [20, 21]. The possibility of extended implantation up to 20 cm from the isthmus with the coverage of large DTA fenestrations can provide a stable long-term result and reduce the number of re-interventions in the distal aorta. Despite all the benefits of the novel prosthesis, we should not forget about patients at high risk. In our study, two patients with connective tissue disorder syndromes (Marfan syndrome and Loeys-Dietz syndrome) required open TAA replacement a year later due to negative remodeling and aortic growth. Despite the absence of stent-graft-related complications in these patients, the presence of residual fenestrations distal to the stent graft supports FL blood flow, which, together with the aortic wall weakness, leads to the distal aortic growth.

In this study, we present the first clinical experience of using the new hybrid prosthesis and the obtained results. We prospectively selected patients with various pathologies of the thoracic aorta who underwent a FET procedure with the Soft elephant trunk hybrid prosthesis. The obtained satisfactory results are consistent with the current literature data, and hospital mortality was associated in most cases with patient's initial unstable condition and the aortic rupture in acute dissection. High survival rate, low rate of re-interventions and of stent-graft-related complications should also be mentioned, which undoubtedly inspires optimism in the use of the novel hybrid prosthesis.

Limitations

Short follow-up period, a small patient sample, and the absence of a control group.

Conclusion

Given our findings, it can be concluded that the Soft elephant trunk hybrid prosthesis can be used for extended diseases of the thoracic aorta and provides satisfactory midterm results. However, it is necessary to accumulate experience and provide further observation of patients for long-term follow up results to identify the potential benefits and disadvantages of the novel prosthesis.

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