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The use of a new hybrid stentgraft for the repair of extensive thoracic aortic aneurysms with the frozen elephant trunk method – first Polish experiences

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Abstract

The frozen elephant trunk (FET) technique is a modification of the traditional elephant trunk method, which was introduced by Borst in 1983 in order to treat extensive thoracic aortic aneurysms. The crux of the new method is the different type of aortic prosthesis, consisting of a Dacron part (with or without branches leading to the arterial vessels which exit the aortic arch) and a port for extracorporeal circulation with a self-expanding nitinol stentgraft. This combination enables a complete one-stage treatment of the pathologies within the arch and the proximal segment of the descending aorta; moreover, it facilitates the performance of a two-stage hybrid treatment of extensive thoracic aortic aneurysms involving a significant part of the descending aorta. This article presents the cases of four patients with extensive aortic disease, who were implanted with Thoraflex prostheses (Vascutek, Scotland).

Key words: frozen elephant trunk, thoracic aortic aneurysms, aortic prosthesis.

Streszczenie

Technika *frozen elephant trunk* (FET) jest rozwinięciem klasycznej metody typu *elephant trunk* wprowadzonej w 1983 r. przez Borsta celem leczenia rozległych tętniaków aorty piersiowej. Istotą nowej metody jest odmienna proteza aortalna, która składa się z części dakronowej mającej – lub niemającej – odgałęzienia do naczyń tętniczych odchodzących od łuku aorty oraz port do krążenia pozaustrojowego, z samorozprężalnym, nitinolowym stentgraftem. Takie połączenie umożliwia kompletne, jednoetapowe leczenie patologii w obrębie łuku i początkowego odcinka aorty zstępującej, pozwala także na dwuetapowe, hybrydowe leczenie rozległych tętniaków aorty piersiowej obejmujących swym zasięgiem znaczną część aorty zstępującej. Niniejszy artykuł prezentuje cztery przypadki implantacji protezy Vascutek ThoraFlex u chorych z rozległą chorobą tętnicy głównej.

Słowa kluczowe: technika *frozen elephant trunk*, tętniaki aorty piersiowej, proteza aortalna.

Introduction

Frozen elephant trunk (FET), frst introduced in 1997 by Haverich, is an adaptation of the classical elephant trunk technique introduced by Borst in 1983 [1, 2]. A combination of a branched Dacron prosthesis, with branches for the individual cephalad vessels and an additional port for extracorporeal circulation with an aortic stentgraft enabled the creation of a hybrid stentgraft released by the surgeon during open heart procedures [3] (Fig. 1). Due to the direct and quick implantation of the prosthesis, its wide spectrum of use (acute and chronic conditions), and, most importantly, its good short- and long-term results, the FET technique gained acceptance as an effective and safe method for treating extensive pathologies of the ascending aorta, the aortic arch, and the proximal segment of the descending aorta, as well as for preparing patients for further endovas-

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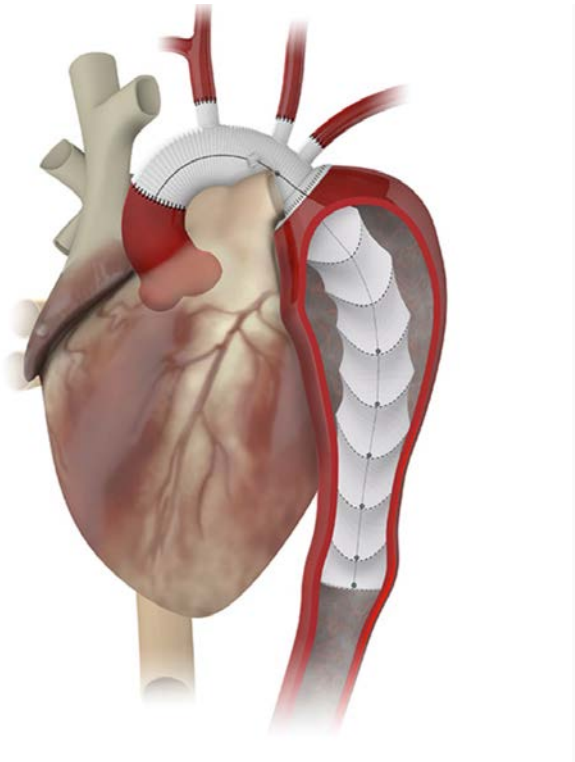

Fig. 1. Hybrid Vascutek Thoraflex Prosthesis

cular treatment [4-6]. The present article documents the cases of the first four patients in Poland in whom Thoraflex grafts were employed.

Case studies

All patients underwent planned surgery. After pre-medication with midazolam (Midanium, Polfa), two arterial catheters were placed into the right and left radial arteries at the operating theater. Anesthesia was induced using the intravenous agents etomidate (Etomidate Lipuro, Braun) and fentanyl (Fentanyl, Polfa). Relaxation of the striated muscles was achieved with pancuronium (Pancuronium, Jelfa). The patients were intubated with single-lumen tubes; mechanical ventilation was maintained in volume-controlled mode. Isoflurane (Aerrane, Baxter) was used for general inhalation anesthesia. Additionally, fentanyl was administered in the form of a continuous infusion. A large-diameter central venous catheter and a Swan-Ganz catheter were introduced. Furthermore, the parameters of pulmonary artery pressure, central venous pressure, cardiac output, and cerebral saturation (INVOS) were monitored. Although the

Tab. I. Technical details of the performed procedures

	Patient 1	Patient 2	Patient 3	Patient 4
	Reoperation St/p CoA		Reoperation St/p AAA	
ECC method (cannulation)	A: FEM V: RAA	A: RCCA V: RAA	A: RCCA V: FEM	A: RCCA V: RAA
Method of CNS perfusion	SACP – Kazui	SACP – RCCA	SACP – RCCA	SACP – RCCA
ECC time (min)	234	185	202	228 + 27
SACP time (min)	85	42	29	47 + 6
X-clamp time (min)	134	120	74	90
CA time (min)	85	42	29	47 + 6
Temperature (esophagus)	26°C	32°C	26°C	28°C
Stentgraft size	26/28/150	32/38/100	30/36/150	30/36/100
Stentgraft introduction	direct	direct	over-the-wire	over-the-wire
Additional procedures	Bentall m. Urbański On-X 25	CABG: Ao-RCA		concurrent coronarography

ECC – extracorporeal circulation, A – arterial cannulation, V – venous cannulation, CNS – central nervous system, FEM – femoral, RAA – right atrial appendage, RCCA – right common carotid artery, SACP – selective antegrade cerebral perfusion, X-clamp – aortic clamping, CA – cardiac arrest, CABG – coronary artery bypass grafting

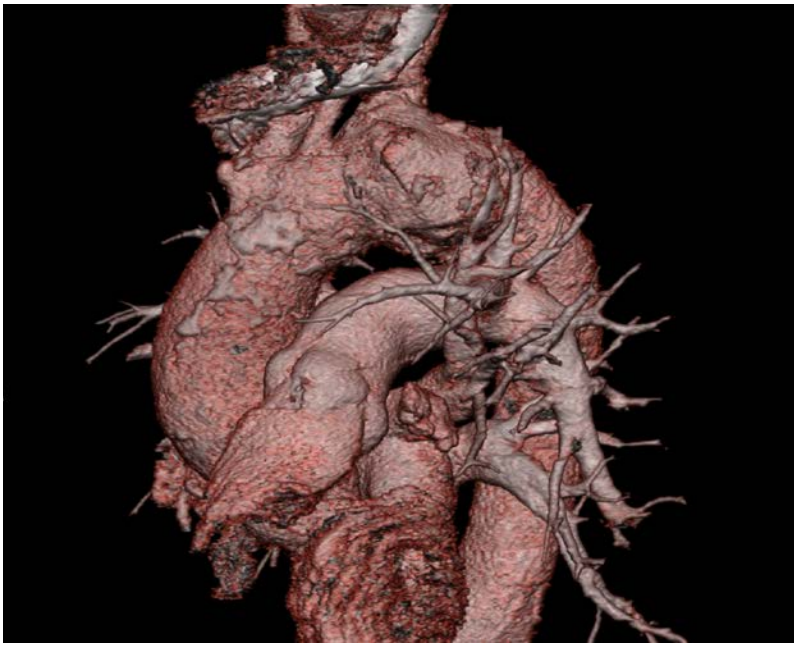

Fig. 2. Postoperative 3D reconstruction (CT) of the first patient

methods of maintaining extracorporeal circulation differed among the presented cases (Table I), selective perfusion of the central nervous system was conducted according to the binding standard of 10 ml/kg of body mass per minute. Perfusion pressure was maintained at the level of 40-70 mmHg. In all the cases, the heart was stopped with a cold blood cardioplegic solution, administered antegrade and retrograde in 20-30 min intervals. Coronary reperfusion was also conducted in all cases. During extracorporeal circulation and the period of its cessation, the central nervous system was protected using thiopental (Thiopental sodium, Hospira). Prevention of coagulation disorders was achieved by administering tranexamic acid.

Case 1

The first patient was a 39-year-old man, who had undergone a surgical repair of aortic coarctation in 1989. The procedure was conducted in a typical fashion, via left-sided thoracotomy, and the constricted location was widened with a Dacron patch. In 2013, the patient was diagnosed with a significant distention of the descending aorta at the surgical site. Moreover, distentions of the ascending aorta (to 50 mm) and the operated part of the aortic arch (to 55 mm) were described; in the vicinity of the bicuspid aortic valve, the planned procedure would involve the ascending aorta with the aortic valve, the aortic arch, and the proximal part of the descending aorta (Fig. 2).

The procedure was performed in January 2014. The ascending aorta and the aortic arch were exposed together with the brachiocephalic trunk (BCT) and the left common carotid artery (LCCA) via median sternotomy. After heparinization, extracorporeal circulation (ECC) was started; blood was received from the right atrium (RA) by a common cannula and administered to the right common femoral artery. After the heart was arrested, the ascending aorta and the aortic bulb were excised; a mechanical aortic valve prosthesis of low thrombogenicity (On-X 25) was sutured into a 26 mm prosthesis (Intervascular, La Ciotat) with a continuous suture, and this composite graft was sutured in place of the aortic bulb and the ascending aorta using the Bentall procedure. During the suturing, the patient was cooled to 26°C. Subsequently, circulation was stopped, and the Kazui method was used for starting CNS perfusion with the cannulation of the BCT and LCCA. The access to the sac of the descending aortic aneurysm was widened, and the opening of the left subclavian artery (LSA) to the aneurysmal sac was made visible. The opening was closed with a felt-pledgeted suture. After forming the Thoraflex prosthesis to fit the curve of the aorta, it was introduced directly into the descending aorta. Following the release of the stent-graft, the prosthetic sleeve was sutured to the aorta with 2-0 Prolene sutures, and the prosthesis of the ascending aorta was joined with the main part of the hybrid prosthesis. The heart and the aorta were deaired, and whole body and cardiac perfusion were resumed; while continuing the perfusion of the cephalad vessels, the branches of the arch prosthesis were sutured in, and selective antegrade cerebral perfusion (SACP) was ended. The procedure and the postoperative period were uneventful. The patient quickly regained consciousness and was soon able to begin rehabilitation. He was discharged on the 13th postoperative day in good general condition. During 6 months of postoperative follow-up, his health condition was assessed as good. Imaging examinations also indicated that the surgery was successful; no pathologies, leaks, or signs of prosthetic displacement were found (Fig. 3).

Case 2

The second patient, a 64-year-old man with single-vessel coronary artery disease (80% constriction in segment 1

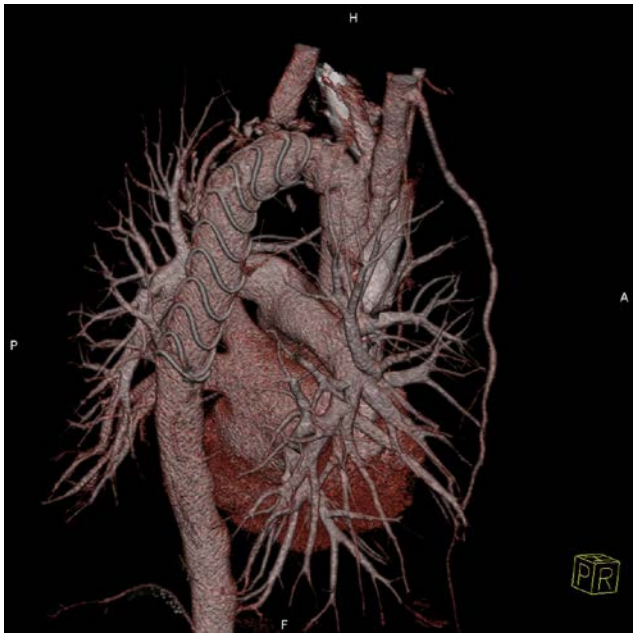

Fig. 3. Preoperative 3D reconstruction (CT) of the second patient

of the right coronary artery), type 2 diabetes mellitus, hypercholesterolemia, and obesity, was admitted with the diagnosis of a chronic post-traumatic dissection within the isthmus and the proximal segment of the descending aorta and a true aneurysm of the proximal segment of the aortic arch.

The procedure was also performed in January 2014. As in the case of the first patient, the aneurysmal sac involved the LSA branching point; its part involving the descending aorta underwent significant calcification. Extracorporeal circulation was established through the right common carotid artery (RCCA, arterial inflow through an 8 mm prosthesis) and a common venous cannula was placed in the right atrial appendage (RAA). Selective perfusion was maintained through the RCCA. The aneurysmal sac was opened and removed completely to the level of the aortic isthmus. After the vascular graft was introduced into the descending aorta and the stentgraft was released, LSA was anastomosed with the appropriate prosthetic branch, and systemic circulation was resumed. Joining the proximal end of the Dacron prosthesis with the aorta at the level of sinotubular junction (STJ) enabled the start of coronary perfusion. SACP perfusion was continued through the RCCA, while the cephalad vascular clamps were removed, and SACP was discontinued.

The patient's postoperative course was uneventful, and he was discharged in good general condition on the 10th postoperative day. After 6 months the patient continues to feel well, and the conducted imaging examinations indicated no pathology.

Case 3

The next patient was a 70-year-old man who had undergone a procedure of ascending aorta replacement (supracoronary graft) due to an acute aortic dissection (DeBakey type I) in 2012. Subsequently, a chronic aortic dissection reaching the renal arteries was found in the patient; the aneurysm of the arch and the descending aorta increased its size systematically (to over 6 cm). As the speed of aneurysm growth increased, the patient's clinical condition deteriorated, and he was qualified for expedited surgical treatment. Additionally, computed tomography revealed an anatomical abnormality of the aortic arch, as it gave off 4 arterial branches, including the abnormal right subclavian artery, branching off behind the LSA (ARSL, arteria lusoria – an abnormality occurring in approx. 0.5-1.5% of the population).

The surgical procedure was performed in May 2014. Extracorporeal circulation arterial inflow was maintained through an 8 mm prosthesis attached end-to-side to the RCCA, while a venous cannula was placed in the right femoral artery. As the aneurysmal sac was suspected to have adhered to the sternum, ECC and the induction of hypothermia were started before conducting sternotomy. As in the case of the 2nd patient, the stentgraft was implanted through a director placed into the right femoral artery immediately behind the LSA branching point, covering the ARSL opening. Subsequently, an anastomosis was performed with the previously implanted prosthesis of the ascending aorta. The cephalad arteries were attached to the prosthesis during systemic and coronary reperfusion.

During the first postoperative day, the patient regained consciousness as expected, and his respiratory capacity allowed for his extubation. He did not require catecholamine support; no neurological disorders or blood supply disturbances in the right upper extremity were noted during the following days. On the 5th postoperative day, the patient complained of strong and increasing abdominal pain with peristaltic arrest. An urgent ultrasonographic examination of the abdomen was performed, followed by computed

tomography, confirming the suspicion of an acute embolism in the superior mesenteric artery, diverging from the true lumen of the chronically dissected abdominal aorta. Thromboembolectomy of the superior mesenteric artery was successfully performed and supplemented with a partial resection of the distal segment of the small intestine due to the presence of necrosis. On the next day, a planned second-look laparotomy was conducted, revealing the spread of intestinal necrosis, requiring further resection. Due to the deterioration of the patient's general condition and the development of severe respiratory failure, despite mechanical ventilation, extracorporeal membrane oxygenation (ECMO) was employed in the venoarterial configuration; however, the development of multiple organ dysfunction syndrome resulted in the patient's death on the 8th postoperative day.

Case 4

The fourth patient was a 59-year-old man, whose medical history included many years of arterial hypertension. Three weeks before, the patient had gone through an incident of acute ascending aortic dissection with the development of a massive intramural hematoma. Curiously, despite hypertension and other reported ailments, the patient had not been previously hospitalized. The proper diagnosis was only reached after performing a chest CT scan, which not only confirmed the previous dissection and the presence of thrombus in the false lumen of the ascending aorta, but also visualized an extensive aneurysm of the aortic arch (81 mm) and a previous dissection in the same region.

The procedure was performed in May 2014. As there was no information concerning the condition of the coronary arteries, coronarography was performed on the operating table in the hybrid room after opening the chest and dissecting the heart and cephalad vessels. After the examination, which did not indicate any pathological changes, a guidewire was left in the aorta for the subsequent implantation of the prosthesis. ECC and SACP was maintained same way as in the case of the second patient. The aneurysmal sac was excised, and the prosthesis was implanted over-the-wire just below the aortic isthmus with the preservation of the left recurrent laryngeal nerve (LRLN), in accordance with the technique proposed by Cooley and modified by Onoguchi [7]. The stump of the thoracic aorta was anastomosed with the sleeve of the prosthesis; extracorporeal circulation was then started through the appropriate port of the prosthesis. Subsequently, the LSA, LCCA, and BCT were anastomosed, while rewarming and maintaining coronary reperfusion (Fig. 4). The perioperative and postoperative course was uneventful. The patient was discharged in good general condition on the 10th day.

Discussion

The hybrid Thoraflex aortic prosthesis manufactured by Vascutek is not the first device enabling the performance of the frozen elephant trunk procedure [5]. It is an adaptation and an upgrade of the well-known and valued E-Vita Open prosthesis (Jotek) and the subsequent modification of the Chavan-Haverich prosthesis (Curative Medical Devices GmbH, Dresden, Germany), which has a similar spectrum of use. The basic differences consist in the introduction of cephalad vessel lines and a port for ECC as well as a sleeve facilitating the fixing of the stentgraft. The former solution eliminates the requirement of using a second Dacron prosthesis, which, in the case of aortic arch reconstruction, would be sutured to the cut-to-size hybrid prosthesis. This results in the reduction of both the cost of the procedure (only one prosthesis) and the risk of bleeding or incompatibility between the prostheses. The second upgrade was

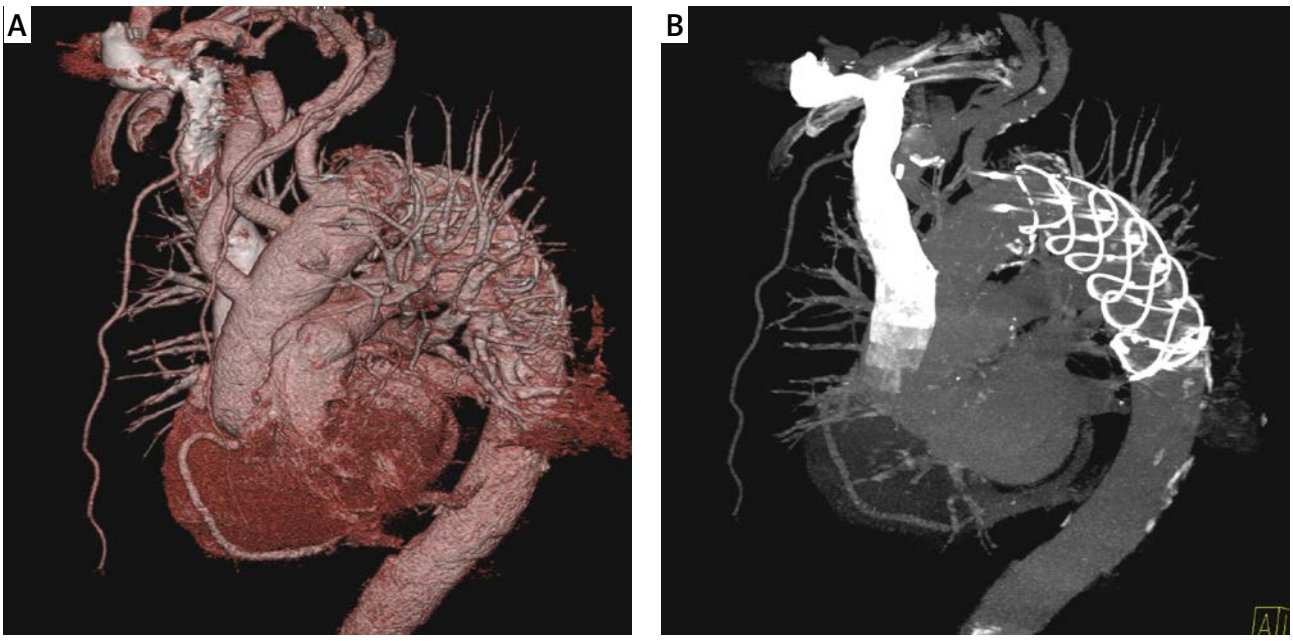

Fig. 4. Postoperative 3D reconstruction (CT) of the second patient

the introduction of a band consisting of a Dacron fragment at the point of contact between the prosthesis and the stent, which is meant to facilitate anchoring the stentgraft into the aorta and maintain tightness after suturing. At this point, it is worth mentioning the pioneering work of our team from the year 2004, when a hybrid prosthesis was created "ad hoc" in operating conditions by anastomosing arch prostheses with intra-aortic stentgrafts in patients with extensive aortic pathologies [8].

The published Thoraflex registry, including 90 patients treated in 14 European centers, indicates that the new prosthesis was successfully employed both in cases of chronic and extensive pathologies of the thoracic aorta (24.4%) and in cases of acute (34.1%) and chronic (36.6%) aortic dissection [9]. Our experience lacks cases with acute dissection, although the fourth patient, who had a type I dissection overlapping the chronically widened aortic arch, can serve as an example of such a condition. The authors of the multicenter and multinational registry underscore the ease of implantation and tightness of the prosthesis, at the same time pointing to the necessity of a guidewire (introduced through the femoral artery) during the introduction of the stentgraft into the lumen of the descending aorta. Even though we did not use it for the first two cases, we agree that introducing the stentgraft into the descending aorta safely and properly should be performed with the over-the-wire, especially in the case of a dissection. Among the most often reported intraoperative problems, the registry points to the moment of fixing the prosthesis to the aorta with the Dacron sleeve, which we believe to be one of the most important advantages of the new prosthesis. The short Dacron fragment should be attached to the internal wall of the aorta, which is often damaged or calcified; this may prove challenging and result in postoperative bleeding that is difficult to manage. Furthermore, the prostheses of the cephalad arteries are in the immediate vicinity of the sleeve, which may entail the need to modify the order of anastomosis. In the second case, LSA was anastomosed with the appropriate prosthesis immediately after the implantation of the stentgraft while systemic circulation was stopped, considering the expected difficulties associated with later access. Notwithstanding, the method's authors intended this solution to significantly reduce the time of systemic circulatory arrest and SACP. In the present material, the SACP time varied significantly, and its reduction could hardly be observed. We believe that this is a consequence of the learning curve and the encountered intraoperative conditions – in the case of the fourth patient, the longer time resulted from the fact that the aorta could not have been clamped, and the heart needed to be stopped simultaneously with the circulation. The reasons for this were the massive pericardial adhesions surrounding the recent dissection.

The prosthesis is available in a wide spectrum of sizes, ranging from 28 to 34 (proximal Dacron end) and from 32 to 40 (distal end of the stentgraft), with standard sizes of the cephalad vessel branches (10 mm, 8 mm, and 8 mm) and two stentgraft lengths: 100 mm and 150 mm. Experience gathered during endovascular procedures (TEVAR) and the first Thoraflex implantations indicates that the stentgraft should be oversized by approximately 15-20% in the case of chronic aortic pathologies. The registry data reveal that the largest size of the prosthesis (32/40/150) was selected most often when treating chronic dissections or true aneurysms of the thoracic aorta and when preparing patients for hybrid, two-stage treatment. In turn, the smallest prostheses (26/28/100) without oversizing were more often employed in the treatment of acute conditions. Due to the chronic character of the lesions and the fact that the procedures could not have been postponed until receiving a proper prosthesis, graft selection in our material was based on calculations conducted on the basis of CT examinations.

The authors of available publications recommend care when using the longer stentgraft (150 mm) in patients with acute type I dissection due to the increased risk of paraplegia [6, 9, 10]. No neurological complications were noted in our material (two short and two long prostheses). In the case of the third patient (chronic aortic dissection), the 150 mm prosthesis was used in order to completely cover the aneurysmal sac of the descending aorta up to the non-distended location, which facilitated one-stage aneurysm repair without the need for another intervention despite the chronic dissection in the more distal segment of the thoracic and abdominal aorta. It should be remembered that the area of the graft's adhesion to the non-distended aortic segment should be at least 4 cm, as in the case of endovascular stentgrafts.

The published registry data indicate good early and long-term results of the procedure. Although 31 adverse events (including 11 that were considered "serious") were noted in 23 out of the 50 analyzed patients, they were not directly associated with the prosthesis, but rather with the extensive surgical procedure. Five deaths were reported in the registry, including two early deaths caused by bleeding and acute heart failure. As in the case of our patient, the three remaining deaths occurred within 15-24 days after the procedure and resulted from multiple organ dysfunction syndrome or acute respiratory distress syndrome. Shrestha *et al*. from Hannover present a more detailed analysis of failed procedures [3]. Among the 52 patients undergoing the procedure, 7 died, including 5 within 30 days – all of them suffered from acute dissection of the thoraco-abdominal aorta; as in our material, one patient died during the hospitalization due to extensive intestinal necrosis in spite of an early intervention performed by an experienced surgeon.

Conclusions

The hybrid Thoraflex prosthesis enables the safe and efficacious treatment of extensive thoracic aortic pathologies, both as a single-stage, definitive treatment and as preparation for further endovascular treatment.

Patients who require aortic arch replacement while simultaneously suffering from pathological lesions within

the proximal segment of the descending aorta should be qualified for the FET procedure. FET may be successfully used in patients with acute type A dissection in whom the dissection extends from the ascending aorta, over the arch, to the descending aorta. In patients with chronic dissection, the FET procedure should be considered if the dissected fragment is distended, because of the possible difficulties in readapting the aortic wall and the stiff dissection flap.

Disclosure

Authors report no conflict of interest.

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