Aortic Arch Solutions

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NEXUS™ is manufactured by Endospan Ltd.
New solutions for aortic arch pathologies

Augusto D’Onofrio, Giorgia Cibin, and Michele Antonello outline the features and benefits of the JOTEC E-vita OPEN NEO and the NEXUS Aortic Arch Stent Graft System for the treatment of aortic arch pathologies.

AORTIC ARCH PATHOLOGIES are uncommon, but frequently pose relevant challenges in their management. Although open surgery remains the gold-standard treatment, new technological developments allow the performance of a total endovascular aortic arch replacement through a “micro-invasive” approach. Nowadays, the frozen elephant trunk (FET) represents one of the most widely adopted procedures for the surgical treatment of patients with aortic disease. In particular, FET is indicated in cases of involvement of the entire aortic arch and the proximal part of the descending thoracic aorta. This hybrid procedure allows one to replace the aortic arch using a non-stented conventional polyester vascular prosthesis starting from zone 0 and to treat or prepare the thoracic aorta for other possible future interventions deploying a stent graft using the same hybrid device via a single median sternotomy. The JOTEC E-vita OPEN family provides hybrid devices for FET procedures (Figure 1). The E-vita OPEN PLUS comes with a tubular vascular graft part in different lengths and sizes while the E-vita OPEN NEO is composed of a branched vascular graft part with different configurations, sizes, and lengths.

The endograft of the E-vita OPEN PLUS is delivered by a flexibleatraumatic introducer sheath through the open aortic arch into the lumen of the descending aorta. It is deployed with the proximal arch graft crimped and invaginated within the stent graft lumen. The release of the endograft is accurate thanks to the “Squeeze-to-Release” system and to the control handle that secures the position of the system during the procedure. After suture fixation of the graft to the distal aortic wall (usually zone 2 or 3), the incorporated vascular polyester prosthesis is released from the stent graft lumen into the arch and it is used for aortic arch replacement. The cylindrical shape of the prosthesis allows the reimplantation of supra-aortic vessels en bloc or separately with grafts interposition.

The E-vita OPEN NEO, which has recently obtained the CE mark, is produced with three different configurations: 1) a stent and an arch graft with a side branch for lower body perfusion; 2) a stent graft and the arch graft having individual branches for selective anastomosis to the supra-aortic arch vessels; 3) trifurcated configuration: this model has a ‘no-arch-touch’ principle with the suture line in Zone 0. The length of the stent-graft varies from 16–19cm. There is a trifurcated graft to perfuse the supra-aortic arch vessels adjacent to a separate perfusion port for the lower body. The introducer is shorter with maximum flexibility for ease of surgery. All these variants will help to perform a more tailored surgical repair of the aortic arch and to shorten the overall surgical time.

One of the greatest advantages of FET is that under rapid ventricular pacing, a simultaneous inflation of two molding balloons: one at the dock and lock section and the second at the side branch protruding to the arch, in order to stabilise the NEXUS system. The delivery systems of both stent grafts (20Fr compatible) have a hydrophilic coating and are pre-shaped to reduce manipulation and friction at the arch. This device comes with different sizes to fit the great majority of aortic anatomies. An ascending aorta diameter greater than 40mm, or a target supra-aortic vessel greater than 18.5mm are considered major contraindications. Since the NEXUS system is a single branch device, debranching of the supra-aortic vessels must be performed prior its implantation according to the planned strategy. This can

Nowadays, the endovascular stent-grafting of the aortic arch is a feasible solution.

False lumen thrombosis in patients with aortic dissection and aortic lumen remodelling. False lumen thrombosis can be as high as 89% at one year after FET and it has been shown to start immediately after surgery and to be progressive over time. FET is currently indicated in acute aortic dissection with primary entry tear in the in the distal aortic arch or in the proximal half of the descending aorta; in patients undergoing surgery for acute type A aortic dissection to prevent mid-term aneurysmal formation in the downstream aorta; in patients with complicated acute type B aortic dissection when primary thoracic endovascular aortic repair (TEVAR) is not feasible or the risk of retrograde type A aortic dissection is high and in patients with extensive thoracic or thoraco-abdominal aortic disease when a second procedure, either open surgical or endovascular in downstream aortic segments, can be anticipated. Although less invasive, patients undergoing FET procedures must still be assessed regarding prohibitive surgical risks.

Nowadays, the endovascular stent-grafting of the aortic arch is a feasible solution, using dedicated stent-graft. These devices are mostly produced with a process of customisation which requires time and cannot be used for urgent or emergent repair. The NEXUS Aortic Arch Stent Graft System (Endospan; hereinafter referred to as NEXUS) is the only CE-marked off-the-shelf endograft, developed specifically to address the morphology and haemodynamic challenges of the aortic arch.

The NEXUS system is made of two different components: a main module, for the aortic arch and the descending aorta with a side-branch for one of the supra-aortic vessels and a module for the ascending aorta which has two different configurations, tubular or oriented. The last one is the most used in our experience since its exclusive design allows conformity of the endograft accurately to the peculiar anatomy of the ascending aorta respecting the different curvature of the inner and outer profile improving sealing and avoiding “bird beaking”. The two modules are connected through a side-facing self-protecting sleeve and land in the sinotubular junction (Figure 2). After deployment, it is mandatory to perform, under rapid ventricular pacing, a simultaneous inflation of two molding balloons: one at the dock and lock section and the second at the side branch protruding to the arch, in order to stabilise the NEXUS system. The delivery systems of both stent grafts (20Fr compatible) have a hydrophilic coating and are pre-shaped to reduce manipulation and friction at the arch. This device comes with different sizes to fit the great majority of aortic anatomies. An ascending aorta diameter greater than 40mm, or a target supra-aortic vessel greater than 18.5mm are considered major contraindications. Since the NEXUS system is a single branch device, debranching of the supra-aortic vessels must be performed prior its implantation according to the planned strategy. This can
be an advantage because it may reduce the risk of periprocedural cerebral embolisation secondary to aortic arch manipulation since two of the three supra-aortic vessels have already been excluded. Moreover, there is no need for a retrograde deployment of bridging stents from the carotid vessels. This feature can be particularly effective in case of an aortic arch with ulcers and/or thrombus apposition. Technically the device is placed through a femoral artery access using a through-and-through guidewire, the first module lands in one of the supra-aortic vessels, usually the brachio-cephalic trunk, and then stent opening into the aortic arch and the descending aorta. The second module is then deployed into the ascending aorta during rapid pacing; the right landing zone is identified thanks to a radio-opaque ring placed into the module for the ascending aorta. In literature, there are just a few case reports or short series about the outcomes after this procedure, with initial promising results.

The selection of patients is mandatory to obtain a final good result. Endovascular repair provides a valid option for patients with high prohibitive surgical risks. An angio-computed tomography (CT) scan is absolutely required to identify potential candidates that could benefit from an endovascular procedure. Some anatomical characteristics make the aortic arch stent-grafting a suboptimal choice: a gothic arch is usually a contraindication for endovascular procedures. Also, length, size and take-off angle of supra-aortic vessels play a major role in the choice of the procedure.

The aortic team is the key to optimal procedural planning for all patients. Only in centres where cardiac and vascular surgeons work together there is the possibility to tailor the procedure on every single patient’s needs.

In conclusion, FET and endovascular total arch replacement with “ad-hoc” devices represent the best solutions for patients suffering from aortic arch pathologies. The choice of the most appropriate intervention for every single patient should be taken by a multidisciplinary aortic team taking into consideration patient’s comorbidities, clinical conditions and anatomical characteristics.

Figure 1. L–R: E-vita OPEN NEO device composed by a polyester stentless part for the aortic arch and a stented distal part to put into the descending aorta; intraoperative view after E-vita implantation, and post-operative angio-CT scan.

Figure 2. NEXUS™ device composed of a proximal module for the ascending aorta (A) and a main module for the arch and descending aorta with the branch for the supra-aortic vessel (B). The two modules are connected through a side-facing self-protecting sleeve (C). Final result after device implantation (D).

References

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FIFTEEN YEARS FOLLOWING THE first implementation of the E-vita OPEN prosthesis, a new generation of hybrid grafts was developed. In order to facilitate graft fixation in Zones 0–3, the novel E-vita OPEN NEO concept implements three different configurations of the arch graft: straight, branched, and trifurcated (Figure 1). When compared to the previous E-vita OPEN PLUS, the implementation of side branches for arch artery revascularisation and distal perfusion transformed the delivery and deployment technique of the graft. Indeed, in the E-vita OPEN NEO, the arch graft is delivered free in the arch position and it is not crimped within the stent graft as it was previously. The stent graft has been modified with a double Z-stent for distal sealing and a “tip-to-valley” orientation of the Z-stents for alignment over the aortic curves. The new delivery system is significantly shorter and enables the insertion of the graft in the descending aorta with or without a guidewire.

In May 2020, four E-vita OPEN NEO procedures were performed in Essen, Germany, including the first in-man worldwide implantation. This case report illustrates our first experience in Essen using the branched arch graft configuration of this novel frozen elephant trunk (FET) technology (Figure 1).

Case report
A 71-year-old male patient presented with recurrent nerve palsy and initial diagnosis of an 85mm aneurysm of the proximal descending aorta involving the distal aortic arch (Figures 3 and 4). Patient history reported cerebral stroke with residual minor hemiparesis, coronary artery disease, impaired renal function, and chronic pulmonary obstructive disease. As the computed tomography (CT) demonstrated a thick arch wall indicating the presence of “shaggy aorta”, we adopted an E-vita OPEN NEO treatment in arch Zone 2 with separate revascularisation of the innominate (IA) and left common carotid artery (LCCA). Debranching of the left subclavian artery (LSA) was performed using an extra-anatomic aorta-axillary bypass.

Since the diameter of the aorta at the distal landing zone was 28mm, we opted for a 30x30x120mm hybrid graft.

A guidewire (E-wire) within a pigtail catheter was placed into the descending aorta transfemoral via an 8mm sheath. Prior to sternotomy, the right axillary artery was cannulated for cardiopulmonary bypass (CPB) over an 8mm graft. Similarly, a T-anastomosis at the left axillary artery with an 8mm graft was performed for separate LSA perfusion during the hypothermic circulatory arrest (HCA). After median sternotomy, right atrial venous cannulation and left ventricle venting established CPB.

During cooling to 28°C bladder temperature, the left axillary artery graft was retrieved through the first intercostal space in the mediastinum and cannulated to a separate arterial pump. At the target temperature under cardiopulmonary arrest, clamping of the brachiocephalic trunk initiated selective cerebral perfusion (SACP) under near-infrared spectroscopy (NIRS) monitoring.

The proximal aorta was resected in arch Zone 2. Open cannulation of LCCA initiated the bilateral SACP. The LSA origin was closed by ligature and selective LSA perfusion was started via the left axillary graft. The E-vita OPEN NEO was guided downstream over the wire and deployed without manipulation of the intraluminal thrombus. The graft was fixed by circumferential 3–0 polypropylene suture with the collar inside and a Teflon strip outside the aorta. Selective distal perfusion via the side-branch was started after retrograde deairing and clamping of the arch graft. The 10mm and the 8mm proximal side-branches were used for the IA and LCCA revascularisation, respectively. The third arch branch was closed by ligature and suture. The replacement of the ascending aorta using a 28mm FlowWeave Bioseal graft (JOTEC-Cryolife) completed the procedure.

The left axillary graft was anastomosed end-to-end with the perfusion side-branch of the arch graft. The intraoperative times were CPB 195min, cardiopulmonary arrest 117min, SACP 60min, and HCA distally 41min. Postoperatively, no cardiocirculatory or neurological events occurred. The patient was extubated after 14 hours and stayed in the intensive care unit (ICU) for seven days for intermittent non-invasive positive pressure ventilation and medical treatment of a temporary renal insufficiency without need for renal replacement therapy. The postoperative CT angiography demonstrated the complete exclusion of the thoracic aneurysm (Figure 3).

References

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Figure 1. The E-vita OPEN NEO stent graft configurations.

Figure 2. E-vita OPEN NEO insertion over the wire under selective cerebral perfusion.

Figure 3. Preoperative CT imaging demonstrates an 8.5cm aortic aneurysm in the proximal descending aorta (A) and the atherosclerotic disease in the aortic arch (B). Postoperative CT demonstrated the exclusion of aneurysm (C) and alignment of the E-vita OPEN NEO stent graft (D). The 3D imaging (E) demonstrates the double Z-stent in the distal stent graft end and the position of the Z stents.

Figure 4. Intraoperative angioscopic imaging demonstrates the proximal neck of the aneurysm in the distal arch with atherosclerotic (“shaggy”) disease (A) and the intraluminal thrombus formation in the main body of the aneurysm (B). The distal landing Zone (C) for stent graft deployment was chosen in the mid part of the descending aorta. The control angioscopy demonstrates the E-vita OPEN NEO stent graft lumen after deployment (D).
First implantation of NEXUS in combination with inner branched endografts

Zbigniew Gałązka and Rafał Maciąg report on a successful total aortic endovascular reconstruction using the NEXUS Aortic Arch Stent Graft System and a thoracoabdominal inner branched JOTEC E-xtra DESIGN ENGINEERING stent graft.

Case presentation
The patient was a 42-year-old female with Marfan syndrome and a chronic residual ascending aortic dissection following aortic root surgery, dissection of the descending aorta with aneurysmal dilation of the false lumen above 55mm, and a fusiform infrarenal abdominal aneurysm above 75mm. The ascending aorta was dilated above 50mm with probable perianastomotic leaks identified on computed tomography angiography (CTA) imaging.

The major risk factor in this patient is Marfan syndrome. In a large study of patients with type B dissections treated by thoracic endografting (TEVAR) by Eggebrecht et al in 2009, the authors arrived at the conclusion that the most common complication in Marfan syndrome was a retrograde aortic dissection.

Retrograde aortic dissection carries the need for emergency ascending aortic surgery.

Stage one: Surgical debranching of the left common carotid artery and left subclavian artery and anastomosing them to the brachiocephalic trunk
The surgical debranching procedure was done in a typical manner 30 days prior to the endovascular stages of the procedure. The left common carotid and left subclavian arteries were anastomosed to the brachiocephalic trunk using a 7mm vascular graft.

Stage two: Endovascular reconstruction of the ascending aorta, aortic arch, and descending aorta
The NEXUS Aortic Arch Stent Graft System (hereinafter referred to as NEXUS) was used to reconstruct the aortic arch. NEXUS is a modular stent graft introduced via a 20Fr delivery system with double flushing ports, which guarantees efficient de-airing. The main module is deployed over an axillofemoral guidewire to extend from the brachiocephalic trunk to the descending aorta and is combined with a precurved ascending module that conforms to the ascending aorta.3

The surgery was carried out under general anesthesia. Systemic heparin was administered at a dose of 100 IU/kg with a target activated clotting time (ACT) throughout the procedure at >300s. Right femoral access was obtained using a 24Fr 65cm sheath for support and deployment of NEXUS Main Modul (NMM). Right axillary access was obtained using a 7Fr, 70cm sheath. The through-and-through wire technique and guidewire loop technique

Figure 1. Controls digital subtraction angiography (DSA). NEXUS stent graft system procedure.
were used to allow positioning of the Nexus Ascending Module (NAM) without damaging the mechanical aortic valve.

During implantation of NAM, rapid ventricular pacing (RVP) was used. The procedure was concluded without complications and with full technical success (Figure 1).

After an interim CTA was performed between stages two and three, a secondary dissection was observed. This was most likely iatrogenic and occurred during implantation of the NEXUS stent graft system. This caused significant changes in the relationship between the now multiple false and the true lumen (Figure 2).

Despite this, as there were no clinical sequelae of this newly observed dissection, stage three of the procedure was scheduled for seven days after stage two.

Stage three: Endovascular repair of aneurysmal thoracoabdominal dissection false lumen and the infrarenal fusiform aneurysm with a thoracoabdominal branched stent graft

Surgery was once again carried out under general anaesthesia. Systemic heparin was administered at a dose of 100 IU/kg with a target ACT throughout the procedure at >300s. Left femoral access was obtained using a 24Fr 33cm sheath. Right axillary access was obtained using a 12Fr 45cm sheath. The through-and-through wire technique to introduce multibranch stent graft was also used. With the technical support of JOTEC E-xtra DESIGN ENGINEERING, a thoracoabdominal multibranch custom-made device was manufactured, delivered and implanted. The E-xtra DESIGN ENGINEERING device (JOTEC-CryoLife) had four inner branches: three antegrade inner branches for the celiac trunk (CT), superior mesenteric artery (SMA), and left renal artery (LRA), and one retrograde inner branch for the right renal artery (RRA) with an integrated bifurcation (Figure 3).

Postoperative course

On the first postoperative day after the final stage of the procedure, the patient was transferred to the regular ward.

DSA and CTA imaging confirmed successful occlusion of the abdominal aneurysm with preservation of celiac trunk, superior mesenteric artery, and the right and left renal arteries (Figure 4).

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