The Thoraflex hybrid frozen elephant trunk device: the Bologna experience

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Aim. Extensive thoracic aorta lesions represent a challenging pathology in cardiac surgery. In the last years, hybrid procedures have been introduced for the treatment of these complex aortic diseases. The frozen elephant trunk (FET) procedure, combining conventional surgery with endovascular techniques, allows single-stage treatment for such pathology. Here we present our initial experience with the single-stage FET procedure using the latest commercially available hybrid prosthesis: the Thoraflex hybrid device.

Methods. Between March 2013 and March 2014, 11 patients underwent thoracic aorta surgery using the FET approach with the Thoraflex hybrid device. Indications for surgery were residual type A chronic dissection in 8 patients, chronic aneurysm of the distal arch in 2 patients and type B chronic aortic dissection in 1 patient. Eight patients had already undergone aortic interventions through a median sternotomy. Brain protection was achieved by means of antegrade selective cerebral perfusion (ASCP) and moderate hypothermia (26 °C) in all cases.

Results. Overall, in-hospital mortality was 0%. No patient presented spinal cord injury or major neurological events. Only one patient experienced transient ischemic attack. Two patients underwent reoperation for bleeding. One patient had renal failure needing temporary dialysis. All postoperative angio CT-Scans confirmed the desired results.

Conclusion. Our initial experience, although based on only eleven patients, showed excellent survival at 30 days with absence of paraplegia and major neurological events. Thoraflex hybrid prosthesis with the four-branched arch graft increases the spectrum of techniques available for the surgeon in the treatment of complex diseases of the thoracic aorta.

Key words: Aortic arch syndromes - Cardiac surgical procedures - Surgical procedure, operative.

Complex lesions of the thoracic aorta are defined as that aneurismal or dissecting pathology of the aorta starting from the ascending aorta or aortic arch and extending downward into the descending thoracic or thoracoabdominal aorta.

Patients with lesions which involve the entire thoracic aorta, acute and chronic, usually are treated with different surgical and hybrid procedures, in single or double stage approach.

Until the early 2000s, the extensive lesions of the thoracic aorta were treated by a two-stage approach, the elephant trunk technique. This approach, described in 1983 by Borst,1 facilitates the construction of the distal anastomosis during the first surgical step while in the second stage it avoids hazardous dissection of the distal aortic arch facilitating the prosthesis to prosthesis anastomosis.

Despite the excellent results obtained with this technique, providing its second surgical step, the technique has as main limitation the fact that more than half of the patients did not arrive at the second surgical step, both because they died between the first and the second step and because some patients refused to undergo another surgical operation in a few months from the first.

Along with the advent of transfemoral stent-graft
for the treatment of descending thoracic aorta aneurysms, it became possible to securely anchor a stent graft in a elephant trunk prosthesis, previously placed during the first step of the Elephant Trunk procedure, avoiding in this way the second surgical step.

In 1996 Suto in order to treat an extensive aneurysm involving distal aortic arch and descending aorta in one-stage approach, introduced a new technique by which he placed a stent-graft in the descending thoracic aorta in antegrade fashion directly from the arch. He called this new procedure “open stent-grafting technique”.

Some years later, Usui implanted an endovascular covered stent-graft for distal aortic arch aneurysm involving the left subclavian artery in 12 cases showing good results in terms of operative mortality and morbidity.

However, the most recent development of the classic elephant trunk technique is the so-called frozen elephant trunk (FET) and it is the combination of an endovascular stent graft with a conventional surgical graft for hybrid procedures of the entire thoracic aorta.

In this paper we present our initial experience, including the short-term follow-up, with the FET technique using the latest commercially available hybrid prosthesis, The Thoraflex hybrid device.

**Materials and methods**

**Patients’ profile**

Between January 2007 and March 2014, a total of 148 patients with extensive pathology of the thoracic aorta have been treated with the FET procedure in our Institution. Informed consent was obtained for each patient, and the data were acquired prospectively as part of the patients’ pathway.

Of these, 11 patients (7%) were treated by implantation of Thoraflex hybrid device (period: March 2013-March 2014).

Most of them were male (72.8%) and 3 (27.2%) female. The mean age was 63±9 years (range 51-78). Main risk factors were arterial hypertension in 9 patients (81.8%), previous aortic surgery in 8 patients (72.2%) and smoking history in 3 patients (27.2%). There were no patients with preoperative chronic renal insufficiency defined as preoperative creatinine >2 mg/dL.

Indication for surgery included: residual type A aortic dissection in 8 patients (72.8%), chronic aneurysm of the distal arch in 2 patients (18.2%) and chronic type B dissection in 1 patient (9%).

The preoperative characteristics of the patients are shown in greater detail in Table I.

**Hybrid endovascular device**

The Vascutek Thoraflex Hybrid device is a woven polyester prosthesis, with the addition of nitinol ring stents. The device is specifically conceived and designed for the treatment of extensive disease of the ascending aorta, aortic arch and descending thoracic aorta. The proximal part of the device consists of a four-branched vascular prosthesis with zero porosity, which is provided to accommodate reconstruction of the supraaortic vessels and intraoperative attachment of a perfusion cannula during cardio-pulmonary bypass in order to re-establish the antegrade perfusion. The stented portion of the graft enables treatment of the diseased descending thoracic aorta in a single-stage procedure without the need to anastomose a stented and unstented prostheses together. It is com-

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FET: frozen elephant trunk; CAD: coronary artery disease; Preop-RF: preoperative renal failure.
posed by gelatin sealed, polyester/nitinol supported prosthesis.

Operative technique

The operations were performed through a full median sternotomy in all patients using Cardio Pulmonary Bypass (CPB) and Antegrade Selective Cerebral Perfusion (ASCP) with moderate hypothermia as a method of brain protection.

Our technique was recently described. Briefly, after systemic heparinization, a guide-wire was inserted through the femoral artery in the descending thoracic aorta under transesophageal echocardiographic control. In case of aortic dissection (chronic type B dissection: 1 patient; residual type A dissection: 8 patients), the guide-wire was positioned in the true lumen of the aorta under the transesophageal control. For CPB institution, arterial cannulation sites were: right axillary artery in 9 patients and the innominate artery in the remaining 2. In all patients, right atrium cannulation ensured venous drainage. A left ventricle drainage was inserted through the right superior pulmonary vein. The cerebral protection method consisted of ASCP with moderate hypothermia, as previously described in greater detail.

Jugular bulb venous oxygen saturation and near infrared spectroscopy was utilized for monitoring the cerebral functions. A transcranial Doppler scan was never used. After the target nasopharyngeal temperature of 26 °C was reached, the circulatory arrest was instituted. Myocardial protection was achieved with infusion of cold crystalloid cardioplegia (Custodiol, Koehler Chemie, Alsbach-Haenlein, Germany). After circulatory arrest, the ascending aorta and aortic arch were opened, then a special catheter for ASCP connected to the oxygenator with a separate single roller pump head was inserted into the left common carotid artery and the perfusion of the left hemisphere was initiated with a flow rate of 5-10 mL/kg/min. The left subclavian artery was always clamped in order to avoid the steal phenomenon.

In all patients, the arch was completely resected and the proximal descending aorta was prepared using an external Teflon felt fixed with some (usually four) internal pledgetted U-stitches. In patients with aortic dissection, the false lumen was surgically obliterated at the level of the distal stump. The stent-graft system was then introduced in an antegrade fashion in the descending aorta over the previously positioned stiff guide-wire and released. The guide wire ensures that the correct lumen is being treated in case of dissection.

Once the device has been released from the system, the remainder of the system must be removed from the device in order to suture the collar to the previously prepared native descending aorta to provide fixation and stability of the implant. A circumferential anastomosis was performed to ensure that the implant was sealed correctly. The systemic perfusion was then antegradely restored through the side branch of the graft, while haemostasis at the distal anastomosis was performed in view of the following anastomosis. Then the supra-aortic vessels were separately reimplanted starting from the left subclavian artery. In some cases, the proximal repair was performed after the left subclavian artery reimplantation; in other cases all the supra-aortic vessels were first reimplanted and then the proximal repair was performed.

In all patients, the entire aortic arch and the proximal portion of the descending aorta were replaced. In 7 of them (63%) the ascending aorta was additionally replaced. One patient (9%), previously operated on for aortic valve replacement underwent prosthetic aortic valve sparing procedure and 1 (9%) underwent Bentall procedure. One patient (9%) needed additional revascularization as associated procedure. The operative procedures and data are summarized in Table II.

Results

The mean duration of cardiopulmonary bypass time was 226.9±98.4 min (range 139-463), with a mean ASCP time of 81.4±29.5 min (range 37-129). The myocardial ischemic time and the visceral ischemic time was 121.2±56.6 min (range 74-215) and 41.8±5.8 min (range 36-53), respectively.

There were no in-hospital deaths and no spinal cord injuries. No stroke occurred. Only one patient experienced transient ischemic attack. Two patients (18%) underwent rethoracotomy for surgical bleeding, 1 patient (9%) had pulmonary complication with prolonged mechanical ventilation. One patient (9%) had renal failure needing temporary dialysis.
Discussion

Complex lesions of the thoracic aorta is commonly treated with the two stage “elephant trunk procedure” described for the first time by Hans Borst in 1983. This approach facilitates the construction of the distal anastomosis during the initial operation and in the second stage avoids hazardous dissection of the distal aortic arch and facilitates the prosthesis to anastomosis.

In the first stage, via median sternotomy, the ascending aorta and arch are repaired, if necessary in combination with the aortic root or other cardiac interventions. During this stage a free-floating extension of the arch prosthesis, the so-called elephant trunk, is left behind in the proximal descending aorta. In the second stage through a left thoracotomy or thoracoabdominal aorta, the descending aorta or thoracoabdominal aorta can be replaced.

However, due to a significant mortality during the interval between the two stages ranging from 3% to 22% with only 45% of patients, who underwent first stage ET, returning for second-stage completion and because of some issues of the conventional ET such as a significant interval mortality between the first and the second stage (3-13%), the relatively high prevalence of left recurrent nerve injury (25%), the possibility of aortic rupture during the interval before the second stage of the operation and the high rate of patients who don’t arrive at the second stage (45%), different approaches have been proposed. In fact, in order to reduce the time interval between the two stages, with the advent of transfemoral stent-grafts for the treatment of descending aortic aneurysms, an endovascular completion of the first stage of the ET by implanting covered stent grafts retrogradely became possible. The main advantages of the retrograde placement of the stent graft are that it may allows patients to recover prior to the final exclusion of the aneurysm. However, despite a reduced rate of mortality and morbidity of this approach, also for endovascular procedures some issues remain open. In fact, the inability to revascularize the intercostal arteries with the risk of spinal cord ischemia, the risk of mobilization of thrombotic material during catheter manipulation, the development of endoleaks with the need of repetitive endovascular procedures, the risk of displacement and migration of the stent graft and the possible technical problems have raised some concerns about this approach.

For these reasons, some surgeons started to perform, whenever possible, a one-stage repair of complex disease of the thoracic aorta.

Kouchoukos started to treat extensive disease of the thoracic aorta in one step using a bilateral anterior thoracotomy, the “clamshell incision” and performing the arch anastomosis first during a period of hypothermic circulatory arrest to minimize the duration of brain ischemia.

He showed an in-hospital mortality rate of 7.2% and a very high rate of pulmonary complications:50% of mechanical ventilation for more than 72 hours and 13% of temporary tracheostomy. Survival at 5 years was 71%.

In 2009, Okada, with the extended replacement of the aortic arch through a left posterolateral thoracotomy, reported high rates of respiratory complications, spinal cord injuries and in-hospital mortality.

In a recent review by Kark, it has been showed...
that the mortality rate of the one-stage extensive aortic replacement by open surgery is relatively high, ranging from 0% to 14.7%.

During the last few years, another option has been considered to replace extensive aortic segments in one or two stages: the stent-grafting of the aortic arch associated to different forms of arch vessels revascularization basically depending on the location of the adequate stentgraft landing zone at the proximal thoracic aorta.

The arch hybrid procedure, is based on two main concepts: the debranching of the arch vessels allows to minimize cardiopulmonary bypass, aortic cross clamp, and circulatory arrest times, and to create an optimal proximal and distal landing zones for thoracic endovascular aortic repair (TEVAR) which can be performed concomitantly with the open surgery, or in a second step as a retrograde approach.

By reducing or avoiding the use of cardiopulmonary bypass, aortic clamping and hypothermic circulatory arrest, the aim was to extend aortic arch repair to patients not previously deemed candidates for conventional surgery.

Recently an interesting metanalysis reported the results of arch hybrid procedures from 15 studies. Thirty-days mortality ranged between 0 and 20%, stroke rate between 0% and 7.6%, the incidence of paraplegia between 0 and 8.9% and the incidence of endoleaks between 0% and 20%.17

Therefore, this approach is considered for patients with contraindications for traditional surgery, due to concomitant co-morbidity conditions, such as old age, chronic obstructive pulmonary disease, renal failure and previous cerebrovascular accidents.

However, in order to overcome the main limitations of the above mentioned techniques, starting from the early 1990s, new ET prostheses were developed, not only to treat concomitant aortic arch and proximal descending pathology in one step, but also to reduce the complications associated with the conventional ET. Therefore a one-step hybrid procedure was introduced. The technique, developed by some Japanese surgeons, initially was called “Open stent-grafting technique”2, 3 and consisted of treating the combined lesions of the thoracic aorta during a single-stage procedure combining endovascular treatment with conventional surgery.

The use of FET technique is increasing and early as well as midterm results are encouraging.18-21 This kind of operations are very complex and time demanding. Key points during this surgery are represented by an accurate assessment of the aortic anatomy, the employment of reliable methods of organ protection (myocardial, cerebral and visceral) and with effective surgical techniques and strategies. For myocardial protection, we have had very good experience with the Custodiol cardioplegia which allows long periods of myocardial ischemia (a single dose of 20-25 milliliters per Kg guarantees 3 hours of myocardial protection).22

As method of cerebral protection we use ASCP with a bilateral cerebral perfusion and a moderate systemic hypothermia. ASCP, as demonstrated by various authors 6, 23-25 is the best method of brain protection during surgery of the aortic arch and, in these challenging and time-consuming operations, its use is suggested.

FET is associated with a not negligible incidence of spinal cord injury (SCI) and various etiological factors have been advocated. In fact, extensive coverage of the descending aorta with excessive sacrifice of intercostal arteries represents a strong risk factor for SCI in patients undergoing this surgery 26 such as circulatory arrest, embolization and possible postoperative periods of hypotension can result in catastrophic spinal cord complications after FET.

In our limited series of eleven patients treated with the Thoraflex prosthesis, we have not had any case of SCI. All patients received a short stent graft (100 mm) and the mean visceral ischemic time was of 41 minutes.

SCI during FET surgery is multifactorial and probably, shortening the length of the descending aorta coverage and reducing the time of spinal cord ischemia, its incidence can be reduced.

Cerebrospinal fluid (CSF) drainage, even in for isolated endovascular surgery, has been demonstrated to be an effective means of preventing SCI 27, 28 and its use is always recommended during this kind of surgery.

We found the FET procedure very useful, above all in chronic dissection after acute type A aortic dissection repair or in the case of type B dissection associated with ascending or arch aneurysms. In type B aortic dissection, sealing of the primary tear is the goal of the endovascular procedure in order to restore the flow into the true lumen leading to thrombosis of the false lumen. This is the same objective we would like to obtain with the FET tech-
nique. Visceral ischemia after the complete sealing of the false lumen could occur if the abdominal arteries arise from the false lumen itself and no re-entry is present in the distal aorta. This is a very rare eventuality because there is always re-entry in the descending, abdominal aorta or in the iliac arteries. However, careful evaluation of the thoraco-abdominal aorta has to be carried out before surgery. In our experience we did not have any case of visceral malperfusion due to false lumen occlusion because of the known presence of re-entry sites in the distal aorta. We believe that the FET procedure should be contraindicated if re-entry sites are not visualized in the distal descending thoracic and/or abdominal aorta and the visceral arteries arise from the false lumen.

The correct positioning of the hybrid graft can be achieved using a guide wire positioned in the true lumen under transesophageal echocardiography before starting the cardiopulmonary bypass. Moreover, transesophageal echocardiography provides useful informations about the correct opening of the stent. Incomplete coverage of the primary entry-tear is not uncommon; however, in these cases, a complete or partial thrombosis of the false lumen can occur later, justifying a wait-and-see policy.

For these patients, a close follow-up is necessary. In case of persistent perfused false lumen, a further repair can be easily performed.

Conclusions

Concluding, the FET procedure represents an effective surgical option for the treatment of complex aortic disease of the thoracic aorta. Since prolonged period of circulatory arrest are required, an optimal method of cerebral protection is mandatory. Moreover, it offers a secure landing zone for an eventual secondary endovascular procedures. Thoraflex hybrid device facilitates the distal anastomosis and allows separate supra-aortic vessels reimplantation. One of the main advantages of the device is that, once the distal anastomosis is performed, it allows an immediate lower body re-perfusion through the cannulation of the fourth branch of the graft.

Despite imaging follow-up studies show satisfactory results in patients treated for acute and chronic dissection (thrombosis and diameter reduction of the false lumen), longer term follow-up is required.

References