Review Article

Implantation of frozen elephant trunk (FET)—surgical technique—Thoraflex

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Abstract: The development of the frozen elephant trunk (FET) prosthesis has revolutionised how we treat some of the most complex aortic pathology, including in the emergency setting of acute type A aortic dissection. The design of the prosthesis is fundamental to the success of the procedure in combination with the surgeon's skill in interpreting the pre-operative scan and procedural planning to juggling the technical aspects of the deployment and reimplantation of the supra-aortic vessels. Furthermore, organ protection strategies and techniques to reduce the complications of neurological and renal impairment are paramount. This article focuses on the Thoraflex Hybrid prosthesis including the evolution of the concept, design features unique to the device and surgical technique including fundamentals of sizing and implantation steps with illustrations. The Thoraflex Hybrid prosthesis provides an ergonomic and neat delivery system with a trusted gelatin coated surgical graft material making implantation and use as straightforward as possible. These features have meant that the device is a market leader in the field of FETs with outcome data and implant figures to support its efficacy globally. The success of the device is also reflected in the literature. For example, in the UK study from Mariscalco *et al.*, the mortality of FET implantation in acute type A dissection, of which most were using the Thoraflex device, was only 12%. This is comparable to leading centres in Europe with the inherent advantage of improving long-term outcomes in addition. Of course, this strategy is not appropriate in all cases and precise judgement of when to deploy a FET in both the emergency and elective setting is key to achieving good outcomes.

Keywords: Frozen elephant trunk (FET); aortic disease; arch of the aorta

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Introduction

The frozen elephant trunk (FET) procedure is the perfect example of a one stage hybrid operation and neat solution for complex arch pathology, combining the novel conventional elephant trunk (cET) procedure, first described by Borst in 1983 (1) with the innovative concept of Dake, first described in 1999, of endovascular stent placement to treat pathology in the descending thoracic aorta (DTA) (2). Observations that the dead space around a cET graft sitting within the proximal DTA could completely fill with clot, thereby negating the second stage operation reinforced the concept and long-term remodelling capabilities of the FET idea (1). Furthermore, concern regarding kinking of the floppy cET and flapping action of the graft were no longer applicable with the introduction of a fixed or 'frozen' stent graft within the DTA (3).

The FET has evolved to become an essential tool in the armamentarium of the modern aortic surgeon, refuting the inherent two stage risk of cET and marrying together technologies innovatively to treat a spectrum of complex pathology. A surgeon's instinct of knowing when and, importantly, when not to deploy the FET device is imperative and as important as the necessary knowledge required to size the device and technically implant the prosthesis safely. Furthermore, a robust strategy of organ

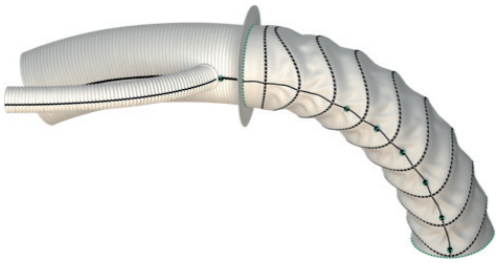

Figure 1 The Anteflow Thoraflex Hybrid device.

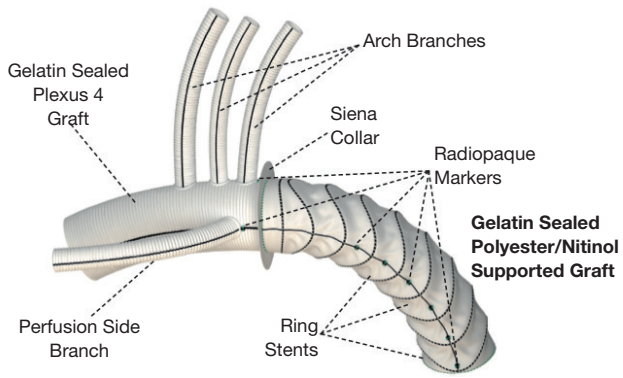

Figure 2 Configuration of the Plexus Thoraflex Hybrid device.

protection is paramount to the success of the procedure and minimising the morbidity for the patient.

Design of the Thoraflex Hybrid FET prosthesis

The unique design features and usability therefore of the Thoraflex Hybrid (Terumo Aortic, Glasgow, Scotland) have propelled the device to the forefront of the commercial FET market. After recently gaining Food and Drug Administration (FDA) approval in the US (4) and with over 900 implants in the UK as of 2019 (5) the success of the device is clear. There is further evidence to support its popularity in the setting of acute type A aortic dissection with a recent meta-analysis showing that the Thoraflex Hybrid prosthesis was clearly utilized more frequently in emergency settings across the studies that were pooled (6). Although this paper tries to correct for publication bias it is very difficult to draw conclusions about the superiority of one device over another and no direct statistical conclusion can be made.

The Thoraflex prosthesis was designed by Drs. Haverich, Shrestha, and Pichlmaier, and introduced by Vascutek Terumo. The proximal part of the graft is a conventional gel-coated woven polyester graft. The prosthesis is impregnated with bovine gelantin, which eliminates the need for pre-clotting and has zero permeability.

The stented section of the graft is a self-expanding endoprosthesis constructed of polyester and nitinol ring stents, which are attached to a fabric with braided polyester sutures. The unique design with independent, ring-shaped stents not only allows for better arch curvature and anatomic conformity to the descending aorta but also reduces the radial force on the aortic wall, thus minimizing the risk of intimal injury in patients with aortic dissection. Radiopaque markers are incorporated in both the proximal graft and the distal stented portion for radiological visualization to aid potential endovascular advancement of the stent.

There are two main designs, the Ante-Flo device with a single perfusion side arm and the Plexus graft with three additional arch branches (*Figures 1,2*). The grafts are available in different sizes (28–40 mm in diameter for the stented portion). The length of the stented part is either 100 or 150 mm. The prosthesis is mounted on a delivery handle with a compact design and importantly, an easy delivery sequence (*Figure 3*).

When to use the FET

The FET was touted as a potential standard approach to acute aortic dissection in the UK with a publication from the UK aortic group in 2019 presenting acceptable complication and mortality rates (7). However, there is no hiding the inherent increased risk associated with what is fundamentally a much bigger operation, with the additional risk of spinal cord injury for the patient. In the above series, temporary or permanent neurological injury occurred in 17% of patients and temporary renal replacement therapy in 20%. For these reasons a blanket policy of FET implantation for all, in the emergency setting, seems extreme.

Indeed, limited (hemiarch) versus extended (arch and FET) repair is much debated in the literature (8). A randomized controlled trial to compare the two mantras will likely never be commissioned from an ethical standpoint and therefore there is limited robust evidence to support either approach. The conventionalist aortic surgeon would argue that saving the patient's life is paramount, yet the stability of the dissected aorta of course relates to the location of the intimal tear and resultant pressure dynamics within the false lumen.

It therefore follows that where the FET technique really comes into its own is when it is truly indicated. Rapid

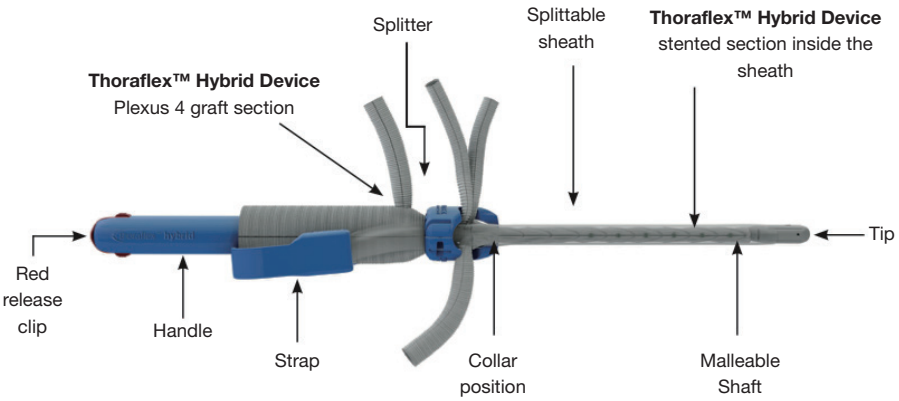

Figure 3 The Thoraflex Hybrid delivery system.

image transfer of computed tomography (CT) scans from a patient with an acute type A dissection is essential for planning and a tear in the arch, identified as a breach in the intima, is quickly recognised by the astute aortic surgeon. A theoretical advantage of the FET in this scenario is that the stented portion of the prosthesis depressurises the false lumen and therefore leads to less bleeding at the site of the collared anastomosis in the arch. A distal flap downstream in the DTA with compression of the true lumen would also favour a FET implantation to help re-expand the compressed lumen. Radiological and clinical malperfusion can be reversed dramatically with this therapy. However, in the event of leg ischaemia even after instituting cardiopulmonary bypass a femoral-femoral cross over graft, performed by the complete aortovascular surgeon, is essential to restore limb perfusion as a proximal repair even with a FET may not restore flow and would be too late.

The use of FET in chronic dissection allows for careful planning and can be as part of a staged procedure which could be either open or endovascular. Collaboration with vascular surgical colleagues therefore is imperative including sign off at a multidisciplinary meeting. Use of the hybrid operating room has meant that extending the stented portion of the FET at the time of surgery, even in emergency cases, is possible if deemed essential for sealing purposes in isolated cases.

Elective arch aneurysms which can be treated in one stage from a sternotomy approach is the natural evolution of the standard elephant trunk operation.

Surgical techniques

Thorough review of pre-operative CT imaging is essential to the use of and success of the FET. Analysis of the supra-aortic arch configuration is important in planning the zone of implantation with zone 3 being avoided where possible due to the risk of recurrent laryngeal nerve injury and technical difficulties of being so deep in the chest. With the zone of implantation known and knowing the stent lengths that are available, the surgeon can define the location of the landing zone for the stented portion of the graft. Generally, this is opposite the left atrium, although may vary, and enables the diameter of the aorta to be measured at this level. Zone 3 can be avoided by examining the CT scan carefully to ascertain the depth of the left subclavian from the front of the sternum and the extent of disease in proximity to the artery. If deemed difficult to mobilise and reimplant from the front of the chest, an extra-anatomical bypass can be performed using an 8 mm graft which is then brought back into the mediastinum and joined to the main graft.

In terms of sizing of the stent and in the event of an acute dissection, a true size would be taken (assuming the descending aorta is not dilated) to avoid the risk of implanting a larger stent than needed in acutely dissected tissues with the inherent risk of rupture. A shorter stent length would generally be preferred in these circumstances to reduce the risk of spinal cord injury. In the chronic case, a 10–20% oversize of the stent diameter is necessary to create the necessary seal to avoid a type 2 endoleak at the distal extent of the stented portion. Most surgeons performing FET in chronic dissection recommend sizing the stent graft according to the diameter of the true lumen because of the quality of the membrane. A longer stent length may be preferred here to give a greater chance of a seal, with the inherent spinal cord risk being reduced with the use of

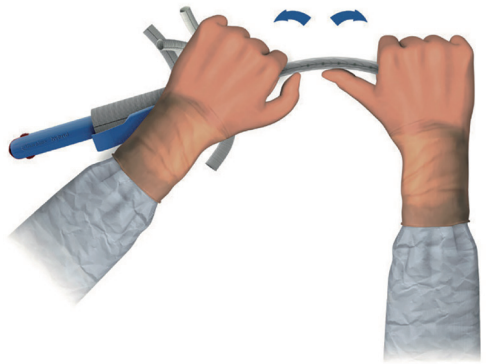

Figure 4 The sheathed section of the prosthesis is gently shaped to the desired curvature of the aorta to allow implantation, taking care to keep the orientation of the surgical graft correctly aligned. The arrows indicate the gentle shaping of the sheathed section of the prosthesis.

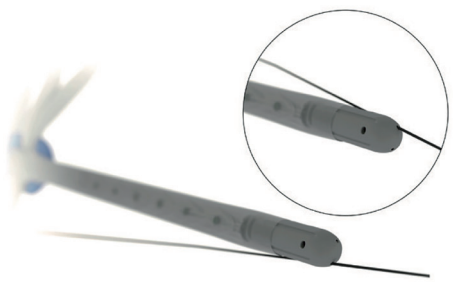

Figure 5 If a guidewire is used, it is fed through the port at the tip of the device as shown in the picture above. To note, the wire does not pass through the centre of the device but co-axially.

an electively placed spinal drain. However, if a seal cannot be achieved in the descending aorta, then consideration for endovascular extension into a suitable landing zone should be made. This could either be at the time of initial FET surgery (with a higher risk of spinal cord injury) or staged which is generally preferrable.

Internationally, there is considerable variation in sizing practices for FET prosthesis with variable evidence for its impact on clinical outcomes. Mohammed *et al.* published on this subject by sending an online questionnaire to 22 specialist aortic surgeons from 13 different countries inquiring about each surgeon's approach to FET prosthesis sizing (9). For example, the maximal diameter of the true lumen in the DTA is the most common index measurement with the stent graft diameter equalling this index. However, 59.1% of surgeons oversized the index diameter by 10%.

In terms of organ protection strategies and techniques to reduce the complications of neurological and renal impairment, a number of strategies are emerging as potentially very useful. For example, the experimental use of robotic transcranial doppler measurements in aortic surgery and hypothermic circulatory arrest have led to the hypothesis that traditionally accepted anterograde cerebral perfusion (ACP) rates of 8–10 mL/kg/min may be too high and lead to an increase in delirium and/or stroke. Early unpublished studies have demonstrated lower therapeutic targets for ACP flow in the middle cerebral artery at moderate hypothermia. An initial target flow of 6 mL/kg/min, for example, may paradoxically be more physiological at target circulatory arrest temperatures. There is also increasing confidence in the use of custodial cardioplegia use in complex aortic surgery including that of the arch. This has the obvious advantage of reducing cross clamp and cardiopulmonary bypass times in addition to the period of circulatory arrest to the body and organ ischaemia.

Deployment sequence

The Thoraflex device is pre-loaded on a neat and slim delivery device as mentioned previously (*Figure 3*). The product necessitates being pre-soaked in sterile saline and in addition at our institution we use rifampicin antibiotic to reduce the risk of graft infection. The sheathed section is then gentle shaped (*Figure 4*) to match the anatomy of the aorta keeping in mind the orientation of the plexus branches (if present) and side arm for perfusion. The system can be used with or without a guidewire but if used the guidewire should be inserted in a retrograde direction from the femoral artery into the true lumen under fluoroscopic guidance or if not available, transoesophageal echo (TOE) guidance (*Figure 5*). This is particularly useful is there is a risk of the device traversing the septum in a dissection case and landing into the false lumen which could be disastrous and result in visceral or limb ischaemia.

In acute dissection cases we invariably use Teflon inside and outside of the aorta as a sandwich which are held with four 4/0 prolene mattress sutures at 6, 9, 12, and 3 o'clock positions. We also take three 3/0 prolene sutures and pass this through the Teflon sandwich at equal intervals at the distal anastomosis site prior to implantation.

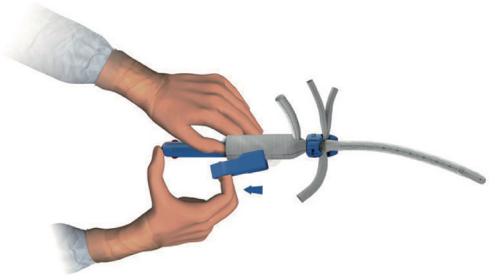

Figure 6 The handle is retracted to deploy the stent. Applying a syringe like grip to the system can provide greater control for the initial stage of the retraction process where a greater force needs to be applied. The arrow refers to the force applied to the blue handle to retract and deploy the stent.

Figure 7 The suture on the blue splitter collar is then cut with a knife and the collar released using either forceps or a Roberts.

The delivery system is then advanced into the open aorta so that the splitter release clip is accessible, and the collar is positioned correctly in relation to the anastomotic site. To unsheathe the device, the delivery system is stabilised with the left hand and with the other, the plastic strap handle is pulled firmly and slowly back (*Figure 6*). This manoeuvre will simultaneously retract and split the sheath allowing it to be completely removed from the delivery system. The suture on the blue splitter collar is then cut and the collar released (*Figure* 7). The sewing cuff is then retrieved and neatened ready for suturing. It is then grasped with forceps for the final two steps to fully release the device from the delivery system to keep the sewing cuff in line with the anastomotic site. The red release clip at

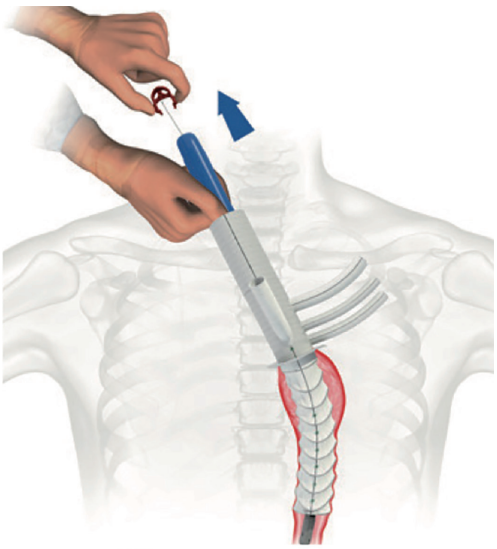

Figure 8 The red release clip at the end of the delivery handle is then squeezed and the fine wire removed from the delivery handle. The arrow refers to the direction the red release clip is pulled in to remove the wire.

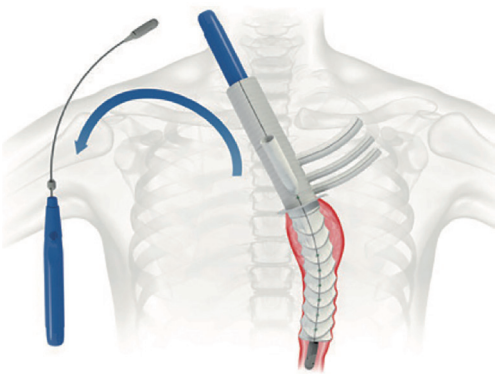

Figure 9 Finally, the handle is now removed from the fully deployed device. It is important to take account of the curvature applied to the delivery system before deployment as the removal will have to follow a similar path. The arrow depicts the direction that the handle must travel in to be removed from the device.

the end of the delivery handle is then pushed and the fine wire removed (*Figure 8*). Finally, the handle itself is gently teased out of the graft (*Figure 9*). The three 3/0 sutures are then sequentially passed through the sewing collar at equal intervals to minimise the pleating of the cuff and tied. The distal collar is then sutured in sequence. A second layer of pledgeted 3/0 sutures provides an additional haemostatic

safety net.

Outcomes

In the reflection from the UK aortic group paper, which included 66 patients in 4 years from 8 centres the mortality was 12% (7). Most of these implants were using the Thoraflex device. This is comparable to international data on the use of FET in acute type A dissections with Shrestha *et al.* reporting a 30-day mortality of 13% (8). In this paper of 52 patients, all had an intimal tear in the aortic arch and/or proximal descending aorta with the opinion of improving long-term outcomes. However, the authors caution that this strategy is not appropriate in all cases and only implemented in experienced centres if necessary.

In a joint paper from Bologna and Hannover, a large series of patients was reported with the aim to evaluate the early and midterm results for a variety of pathologies. Leone *et al.* looked at 437 patients between 2007 and 2017 who underwent total arch replacement using the FET technique. The main indications were thoracic aortic aneurysm (n=135, 31%), chronic aortic dissection (n=182, 41.6%) and acute aortic dissection (n=120, 27.5%). The overall in-hospital mortality was 14.9%, permanent neurological deficit 10.8% and spinal cord injury 5.5%. Chronic aortic dissections did better than the other two groups. A total of 86 patients (23.1%) required an additional procedure during the follow up with 61 patients (16.3%) requiring endovascular extensions and 25 patients (6.7%) requiring open surgery. This was over a median follow up time of 2.6 years (1.4–4.4 years) (10).

Ma *et al.* in Beijing, China, reported long term outcomes of FET beyond 10 years. The initial operative mortality in 518 patients was an impressive 7.5%. The follow up was complete in 98.7% of patients at a mean of 9±4.8 years with a late survival of 77.3% and freedom from distal reoperation of 69.8%. Marfans and malperfusion syndrome were risk factors for early and late mortality and distal reoperation (11).

Conclusions

The FET technique has evolved as an elegant solution for a one staged aortic repair in a variety of aortic pathologies. The Thoraflex Hybrid prosthesis provides an ergonomic and neat delivery system with trusted gelatin coated surgical graft material making implantation and use as straightforward as possible. These features have meant that the device is a market leader in the field of FETs with outcome data and implant figures to support its efficacy globally. The argument between limited and extended repair of type A aortic dissection continues but the indications for a FET and the ability of the prosthesis to treat complex dissections of the arch and completely remodel the downstream aorta is very compelling. Of course, there are still development and improvements in FET prosthesis to be made, particularly management of the left subclavian artery, reduction in the risk of stent thrombosis as well as strategies to reduce the risk of circulatory arrest and duration of ACP. Finally, the inherent risk of spinal cord injury is for many the Achilles heel of the procedure, however, with the use of adjuncts such as spinal drain insertion when feasible and higher mean arterial pressure targets in addition to increased awareness of the risk and expedient management then this can be reduced.

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Footnote

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Ethical Statement: The author is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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