Keynote Lecture Series

Rapidlink^{TM}: a new technology to simplify the supra-aortic vessel anastomoses in total aortic arch surgery

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Aortic arch surgery is associated with substantial perioperative risks. New techniques and novel prostheses have been developed to reduce the risks of these procedures. The application of these new techniques has helped to reduce the perioperative risk factors of aortic arch repair. From a technical standpoint, the supra-aortic vessel anastomoses, especially those to the left subclavian artery, can sometimes be technically challenging, resulting in the need for longer circulatory arrest. Therefore, various techniques and devices have been developed in recent years to simplify the supra-aortic vessel anastomosis. A new hybrid graft to simplify the supra-aortic vessel anastomosis during total arch replacement is described.

Keywords: Supra-aortic vessel anastomosis; aortic arch replacement; frozen elephant trunk (FET)

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The perioperative techniques of aortic arch surgery have undergone continuous evolution since its first description in 1956 (1). Nevertheless, multi-segment pathologies of the aortic arch remain a technical challenge. The perioperative risks of open total aortic arch replacement are still high (2,3). Over the past decades, several techniques, as well as grafts, have been developed to reduce the perioperative risks and to "democratize" open surgical repair of the aortic arch.

One of the technical challenges for open aortic arch replacement is the need for circulatory arrest. Hypothermic circulatory arrest as described by Dr. Griepp allowed these operations to be performed routinely (4). In addition, innovative cerebral perfusion techniques have been introduced, including retrograde cerebral perfusion, first described by Ueda and colleagues, and antegrade cerebral perfusion, first described by Bachet and colleagues (5,6).

One important surgical innovation was the elephant trunk technique to treat multisegment thoracic aortic disease. This technically simplified the second stage procedure (7-10).

Classically, an "island technique" was used to re-implant all the three supra-aortic vessels in the arch graft during total aortic arch replacement. Later, the branch graft technique was developed, in which each supra-aortic vessel was reimplanted separately into a special triple branch arch graft (11,12).

The advantage of this technique was that all the diseased aortic arch as well as the proximal parts of the supra-aortic vessels could be replaced. However, one of the disadvantages of this technique is the potential increase in circulatory arrest time due to the necessity of 3 separate anastomoses with the supra-aortic vessels (13,14). Another significant development was the frozen elephant trunk (FET) technique, which potentially allowed a single stage treatment of multisegment thoracic aortic disease (15-17).

Even with these modern techniques and grafts, open total arch replacement is still associated with significant risks (18).

Various novel innovative techniques have been described to simplify and reduce the perioperative risks during open aortic arch surgery.

Pichlmaier and colleagues used Gore Viabahn ('off label') to perform a stent bridging of the supra-aortic vessel anastomosis (19).

Folkmann and colleagues described a novel custom-made FET prosthesis with an endovascular side branch

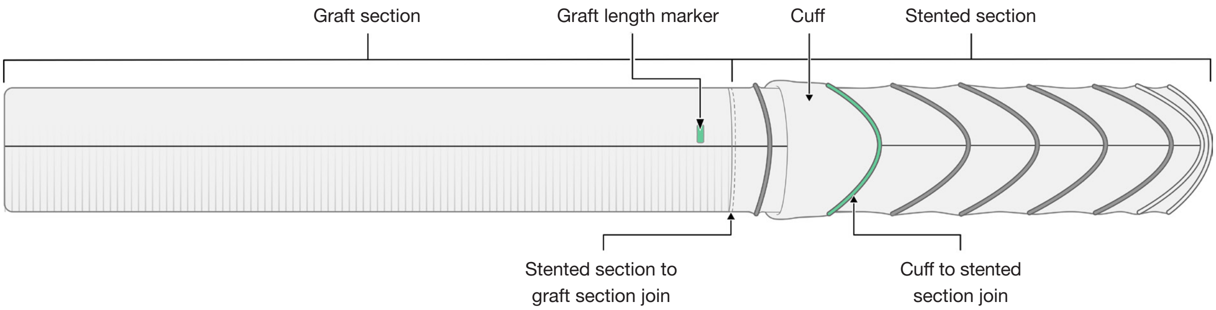

Figure 1 Rapidlink™ hybrid graft.

for left subclavian artery (LSA) connection. After successful pre-clinical testing, the feasibility and safety of implementing this innovative prosthesis in human subjects was investigated. They published their experience with four patients with this novel custom-made device (20).

This novel device is a custom-made FET prosthesis with an endovascular side branch for LSA connection. Morphological contraindications for the use of this device included an aneurysmatic or stenotic LSA or severe kinking of the LSA. Additionally, a separate take-off of the left vertebral artery from the aortic arch also prevents the use of this device.

Although implantation of this device was successful in all patients, endoleak of the side-arm stent in the LSA developed in all cases.

Therefore, endovascular extension of the LSA-side branch was necessary in all patients to cover the endoleak. The authors themselves admit that even though this novel custom-made FET-LSA prosthesis holds promise in streamlining and expediting complex aortic arch surgery, further refinement is imperative to enhance the device's usability and mitigate the incidence of LSA endoleaks.

The Rapidlink™ hybrid device

From 2015 onwards, the author, working with Terumo aortic (previously known as Vascutek Terumo), developed another normal hybrid graft to simplify the anastomosis to all three supra-aortic vessels.

The intended use of the device is to achieve faster and easier anastomosis of the supra-aortic arch vessels, particularly the LSA, during open repair of the thoracic aortic arch.

This unique hybrid device can be used during debranching procedures or in conjunction with triple branched aortic arch grafts, both FET and classical elephant trunk grafts.

Device information

The Rapidlink™ device is a conjunctive device, designed to simplify anastomosis of the main arch vessels to the graft being used to replace the aortic arch during open surgical repair (*Figure 1*). With the stented section secured in the target supra-aortic vessel, the graft section of the device can be attached to the arch graft at a location suitable for the user and/or patient.

Rapidlink™ is designed as a dedicated device for the aortic arch vessels, providing rapid anastomosis of the LSA, left common carotid artery and innominate artery. The Rapidlink™ hybrid device is designed to be used in conjunction with an aortic arch graft during aortic arch repair or replacement.

The device consists of a gelatin-coated vascular graft combined with a distal stented graft, supplied pre-loaded in a single use delivery system. The entire implant is coated with gelatin, loaded into a delivery system, and terminally sterilized.

Implant

The Rapidlink™ implant is comprised of a Dacron graft section (gelatin-sealed woven polyester) attached to a stented section (which utilizes nitinol ring stents), with a 'cuff' feature joined to the stented section of the implant. The implant is supplied pre-loaded in a single use delivery system which compacts the stented section within a polytetrafluoroethylene (PTFE) sheath at the front of the system.

The stented section of the implant consists of three

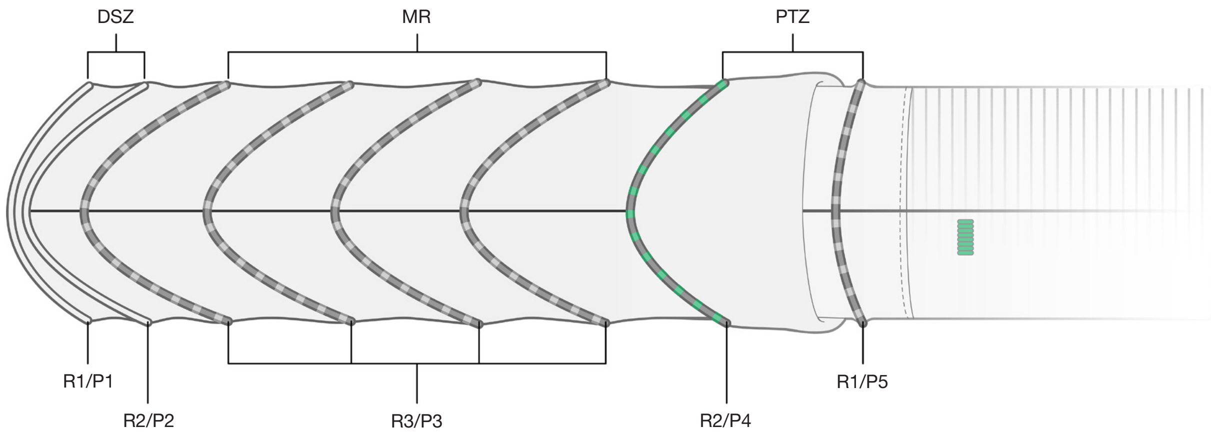

Figure 2 Rapidlink™ stented section. DSZ, distal sealing zone; MR, mid-rings; PTZ, proximal transition zone.

different types of rings split across three zones (*Figure 2*):

- The distal sealing zone (DSZ): made up of two rings (R1 and R2) which decrease in saddle height towards the distal end of the implant. The position of the rings is denoted as P1 (R1) and P2 (R2).
- The proximal transition zone (PTZ): made up of two rings (R1 and R2) which decrease in saddle height towards the proximal end of the implant. The position of the rings is denoted as P4 (R2) and P5 (R1).
- The mid-rings (MR): made up of a varying quantity of mid ring (R3) depending upon the diameter and length of the stented section, which are positioned between the DSZ and PTZ. The position of the rings is denoted by P3.

DSZ

The purpose of the DSZ is to provide a seal between the implant and the vessel. These rings are fully oversewn in order to provide an atraumatic tip to the delivery system once compacted within the PTFE sheath.

PTZ

The purpose of the PTZ is to ensure the join between the stented section and the graft section maintains its shape and does not impact the lumen of the implant. The PTZ is intended to be deployed such that P4 is within the vessel and P5 is outside the vessel (*Figure 2*). This ensures the ostia of the vessel is held open and improves the kink resistance of the implant at the transition between the graft section and the stented section. These rings are attached with suture spacing of approximately 1 mm.

MR

The purpose of the MR is to maintain the length of the implant during compaction and deployment, ensure a sufficiently patent lumen throughout the implant and allow the implant to conform to the vessel without kinking. These rings are attached with suture spacing of approximately 1 mm.

The cuff feature facilitates secure attachment between the implant and vessel. When implanted, the proximal edge of the cuff will protrude from the transected edge of the treated vessel, allowing the clinician to use the cuff to attach the implant to the vessel.

The graft section is joined to the stented section via a flat join, proximal to the PTZ. The Rapidlink™ implant is intended to be deployed such that the join between the graft section and the stented section is outside of the vessel. The graft section of the implant can be attached to the arch graft at a location suitable for the user and/or patient.

Alternatively, the graft section may be pre-attached to the arch graft prior to deployment. To aid in this process, a green suture marker is included to denote this area of the graft section, 3 cm away from the edge of the transected vessel.

Delivery system

The delivery system is comprised of a molded plastic handle, two malleable stainless-steel link pins and a device holder component with a pivotable lid (*Figure 3*). The device holder component contains the stented section of the implant, which is compacted within a PTFE sheath at the front of the system. Compacting the device within the

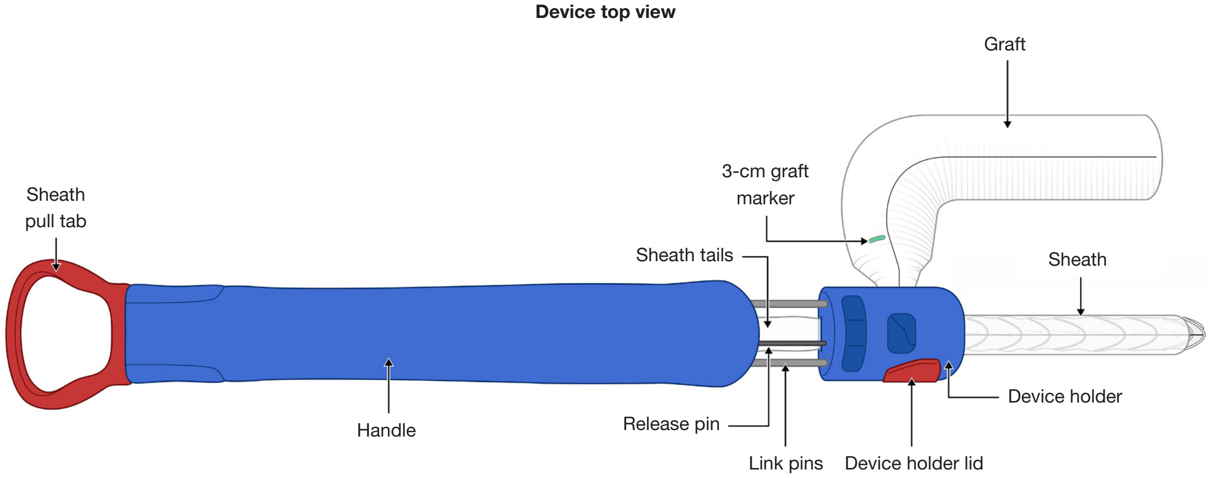

Figure 3 Rapidlink™ delivery system and graft.

PTFE sheath reduces the diameter of the stented section, allowing it to be placed within the vessel to be treated.

The two malleable link pins on the handle allow the user to shape the delivery system into a form which is appropriate for accessing the vessel, based on the specific constraints presented by the open chest cavity in each specific procedure.

The pull tab at the proximal end of the delivery system is removed to deploy the stented section of the Rapidlink™ implant within the target vessel.

To date, animal trials have shown promising results.

Conclusions

The novelty of this Rapidlink™ hybrid device is its versality. This device can be used in conjunction with either with an aortic arch graft (classical elephant trunk graft or FET) or with a debranching graft during open surgical repair of the thoracic arch.

This Rapidlink™ graft may also play a role in open thoracoabdominal aortic replacements by simplifying the anastomoses, especially those involving calcified Iliac vessels.

This Hybrid graft will add to the armamentarium to simplify and "democratize" open aortic arch surgery.

Future plan

This year we will be starting an Investigational device exemption trial both in the USA and Europe.

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Footnote

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