MONASH University

Inner-Branched Endoprostheses for the Treatment of Aortic Arch Aneurysms

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Abstract

In recent years, the successful application of fenestrated and branched endograft technology in the visceral aortic segment has been expanded to include treatment for aneurysms of the aortic arch. The inner-branched endograft (IBE) from Cook Medical (Bloomington, Ind) has been trialled in limited high-volume centers in Europe, the USA, and Canada. This is a third-generation aortic arch branched endograft which was designed to address specific challenges encountered with endovascular procedures in the aortic arch and lessons learned from earlier devices. Recently, a retrospective, multicenter analysis of the first 38 patients treated with the inner-branched endograft was published, confirming the feasibility and safety of the endovascular repair of arch aneurysms in selected high risk patients who may not have other conventional treatment options.

Other published data for the IBE is limited, with only small case series and short-term follow-up available. This thesis adds to the knowledge base and published literature about the use of the IBE for the treatment of aortic arch aneurysms.

Data for the thesis is derived from work performed at the following centres:

- The Aortic Centre, CHRU de Lille, Lille, France, a high-volume European centre for the treatment of complex aortic disease.
- The Vascular Surgery Unit, The Alfred Hospital, Melbourne, Australia, a high-volume Australian vascular and endovascular centre, and major state trauma centre.

This thesis establishes criteria for patient selection when using the IBE. The procedural technique is described in detail.

Results of a follow up study looking at mid-term outcomes for patients treated with the IBE confirm that the device is a feasible option. Outcomes compare favourably with open surgery and hybrid repair techniques for patients with significant comorbidities who are considered unfit for open surgery.

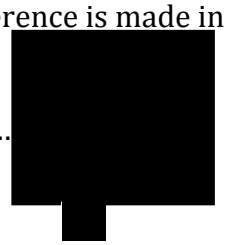
Results of a CT-based feasibility study indicate that approximately 70% of patients with arch aneurysm formation after open ascending aortic replacement for type A dissection are

anatomically suitable for treatment with the IBE. Guidelines on how to perform acute open Type A aortic dissection repair to allow for future endovascular repair of arch aneurysms are discussed.

Finally, results of a CT-based follow up study for patients having undergone thoracic endovascular aortic repair for blunt aortic injury indicate that this treatment is effective and durable in the long term. This analysis was done to better understand the long-term performance of endografts used in the aortic arch and thoracic aorta, an environment which exposes them to unique haemodynamic forces. Changes in aortic diameter and length measurements relative to the endograft exceeded those expected from age-related change alone. Despite this, diameter and length changes were overall small and caused no adverse outcomes.

Declaration

This thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

Signature: …  .

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Publications during enrolment

This thesis includes one original paper published in a peer-reviewed journal, one original published book chapter, and one original paper submitted for publication in a peer-reviewed journal. An additional original paper published in a peer-reviewed journal, for which I was a co-author, is included in the thesis. The core theme of the thesis is to examine the use of Inner-Branched Endoprostheses for the Treatment of Aortic Arch Aneurysms.

The development and writing up of these papers were the principal responsibility of myself, the student, working within the Department of Surgery, The Alfred Hospital, Monash University, Melbourne, Australia, under the supervision of Professor Wendy Brown. Additional content supervisors were Professor Stéphan Haulon and Mr Geoffrey Cox. The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team-based research.

Thesis Chapter	Publication Title	Status	Nature and % of Student Contribution	Co-author Name(s) Nature and % of Co-author's Contribution	Co-authors, Monash student?
1	**A Brief History of Time: The Evolution of Aortic Arch Intervention**	-	-	**-**	-
2	**Branched Endografts for Repair of Aortic Arch Aneurysms** **As part of: Endovascular Aortic Repair: Current Techniques with Fenestrated, Branched and Parallel Stent-Grafts**	Published Springer Publishing (New York, USA) 1st ed. 2017, XXIV, 747 p. 626 illus., 588 illus. in color.	Data C/A – 70% Manuscript – 70%	**Haulon S:** Data C/A – 20%, Manuscript – 20% **Oderich G S:** Data C/A – 10%, Manuscript – 10%	N N
3	**Editor's Choice - Subsequent Results for Arch Aneurysm Repair with Inner Branched Endografts.**	Published Eur J Vasc Endovasc Surg.	Data C/A – 5%, Manuscript – 20%	**Spear R:** Data C/A – 50%, Manuscript – 50% **Haulon S:** Manuscript – 20%	N N

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4	**Inner-Branched Endografts for the Treatment of Aortic Arch Aneurysms Following Open Ascending Aortic Replacement for Type A Dissection**	Published Ann Thorac Surg. 2016 Dec;102(6):2028-2035.	Data C/A – 70% Manuscript – 70%	**Amako M:** Data C/A – 17.5% **Spear R:** Data C/A – 2.5% **Clough R E:** Data C/A – 5% **Hertault A**: Data C/A – 2.5% **Sobocinski J:** Data C/A – 2.5%	N N N N N

				Brown W: Manuscript – 10% **Haulon S:** Manuscript – 20%	N N
5	**CT-Based Long-Term Follow Up After Thoracic Endovascular Aortic Repair (TEVAR) For Blunt Traumatic Aortic Injury.**	Submitted	Data C/A – 60% Manuscript – 80%	**Johnson N:** Data C/A – 10% **Claydon M:** Data C/A – 5% **D'Angelo A:** Data C/A – 10% **Tang J:** Data C/A – 10% **Paul E:** Data C/A – 5%, Manuscript – 5% **Cox G:** Manuscript – 5% **Brown W:** Manuscript – 10%	N N N N N N N

I certify that the above declaration correctly reflects the nature and extent of contribution from each author. I have re-numbered sections of submitted or published papers in order to generate a consistent presentation within the thesis.

Student signature:  **Date:** **11/4/17**

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- Professor Wendy Brown, for her enthusiasm and constant support as my supervisor for the Master of Surgery. Wendy has been a long-standing mentor for me since I was a medical student, and I am very grateful that she agreed to supervise my thesis.
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- Mr Geoffrey Cox, as my content supervisor, who has been a constant support and mentor to me throughout my vascular training and as a vascular surgeon. He is head of the vascular unit at the Alfred Hospital, which provided the essential data for publication of Chapter 5. He has acted as a content supervisor for the thesis and has encouraged the development of the Vascular Surgery Research Group at the Alfred Hospital.
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Introduction

Introduction

Open surgery for aneurysms involving the aortic arch is a significant physiological burden for the patient due to prolonged procedure time, requirement for sternotomy, aortic cross-clamping, cardiopulmonary bypass, and deep hypothermic circulatory arrest.

Endovascular techniques can be applied to the aortic arch to offer treatment to patients at high-risk for open surgery. 'Hybrid' procedures combine an open surgical procedure with an endovascular procedure. The open component is designed to 'debranch' the aortic arch to secure a proximal landing zone for the endovascular component (deployment of a tube endograft).

For distal aortic arch aneurysms, debranching can be done without sternotomy or aortic clamping (e.g. left carotid-subclavian bypass). For extensive aortic arch aneurysms, which still have a suitable seal zone for an endograft in the ascending aorta, a debranching procedure can be done, but requires sternotomy and a side-biting ascending aortic clamp to anastomose a branched prosthetic graft. A modified technique can also be performed via a right anterior thoracotomy. The advantage of this over conventional open repair of the arch is avoiding the need for aortic cross-clamping and cardiopulmonary bypass.

In recent years, the successful application of fenestrated and branched endograft technology in the visceral aortic segment has been expanded to include the aortic arch. The 'inner branched' endograft from Cook Medical (Bloomington, Ind) was developed to treat extensive aortic arch aneurysms without the need for sternotomy or an ascending aortic debranching graft, provided the ascending aorta offers a suitable seal zone. The endograft seals in the ascending aorta and has two inner side branches for the brachiocephalic trunk and left common carotid artery (left CCA). A left carotid-subclavian bypass is required prior to implantation of the endograft.

The procedure is currently restricted to high-volume endovascular aortic centres under trial conditions. It is approved for patients with aortic arch aneurysms ≥5.5cm, who are high risk for open surgery, and who fulfill specific anatomic and physiologic criteria.

At present, published data for the inner-branched endograft is limited, with only small case series and short-term follow-up available. This thesis adds to the knowledge base by expanding the published literature.

Data for the thesis is derived from work performed at the following centres:

- The Aortic Centre, CHRU de Lille, Lille, France, a high-volume European centre for the treatment of complex aortic disease.
- The Vascular Surgery Unit, The Alfred Hospital, Melbourne, Australia, a high-volume Australian vascular and endovascular centre, and major state trauma centre.

The thesis includes a review of the published literature, establishment of criteria for patient selection, and a detailed description of the procedural technique. Results of a follow up study looking at mid-term outcomes for patients treated with the inner-branched endograft are presented. Results of a CT-based feasibility study looking at the use of inner-branched endografts for the treatment of aortic arch aneurysms in patients following ascending aortic replacement for acute type A dissection are presented. Guidelines on how to perform acute open Type A aortic dissection repair to allow for future endovascular repair of arch aneurysms are discussed.

Finally, results of a CT-based follow up study for patients having undergone thoracic endovascular aortic repair for blunt aortic injury are presented. This is done to better understand the long-term performance of endografts used in the thoracic aorta, an environment which exposes these devices to unique haemodynamic forces.

CHAPTER ONE

A Brief History of Time:
The Evolution of Aortic Arch Intervention

A Brief History of Time:
The Evolution of Aortic Arch Intervention

Aneurysms involving the aortic arch have traditionally been treated with open surgery. For patients with limited comorbidities, it remains the gold standard. The first successful open aortic arch replacement was reported in 1957 by De Bakey and colleagues, using an early form of cardiopulmonary bypass. [1] Operative techniques evolved over the following decades, but the morbidity and mortality of arch surgery remained high. This improved significantly with the introduction of deep hypothermic circulatory arrest, first described by Griepp et al in 1975. [2] This offered a relative 'safe period' of cerebral ischaemia, which was built upon in later years by the use of retrograde and anterograde cerebral perfusion techniques.

Despite these advances, in association with improvements in anaesthetic and intensive care, contemporary open aortic arch surgery continues to be associated with significant complications, including death [5 – 20%] [3-5] and neurological impairment [5 – 18%]. [3, 4, 6, 7]

Open Aortic Arch Repair:

There are various approaches to open repair of the aortic arch, the selection of which depends on the nature of arch pathology, extent of arch involvement, and surgeon preference. Possibilities include replacement of the ascending aorta alone, hemi-arch replacement, or total arch replacement. Different methods are used to accommodate the supraaortic vessels during total arch replacement, the most common of which is a Carrel patch sewn in to the aortic graft. Alternatives include using individual grafts to sew each supraaortic vessel to openings in the aortic graft, or utilizing a pre-prepared branched aortic graft. [8] Any arch procedure may be combined with ascending aortic and/or aortic root surgery. [9]

The Elephant Trunk Technique:

The 'elephant trunk' technique for aortic arch replacement was first described by Borst et al [10] in 1983 as an approach to addressing extensive aortic pathology, involving both the aortic arch and descending aorta, in a 'two-step' fashion.

The first stage (*Fig 1*) involves open surgical repair of the ascending aorta and aortic arch. The distal anastomosis to the proximal descending thoracic aorta (just distal to the left subclavian artery [left SCA]) is performed first, using an intussuscepted tube graft. The double edge of the graft is sewn to the descending aorta, with the two free ends positioned distal to the anastomosis within the descending aorta. At completion of the anastomosis, the inner tube segment is reduced, forming a tube graft proximal to the anastomosis from which to complete the arch replacement. The outer tube segment is left floating in the descending aorta beyond the distal anastomosis – the 'elephant trunk'. [8]

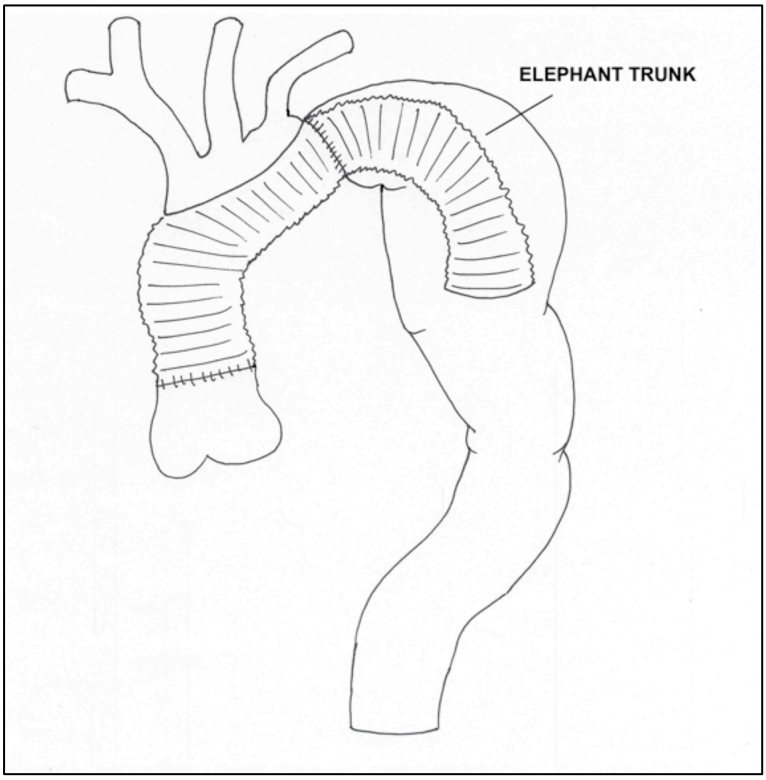

Figure 1: The Elephant Trunk Technique (First Stage)

The second stage (*Fig 2*) of the elephant trunk procedure is performed after recovery from the initial procedure. The elephant trunk acts as a platform from which to perform replacement of the remaining diseased segment of aorta, in either an open or endovascular fashion. If performed open, the elephant trunk obviates the need for proximal dissection and potential injury to the pulmonary artery.

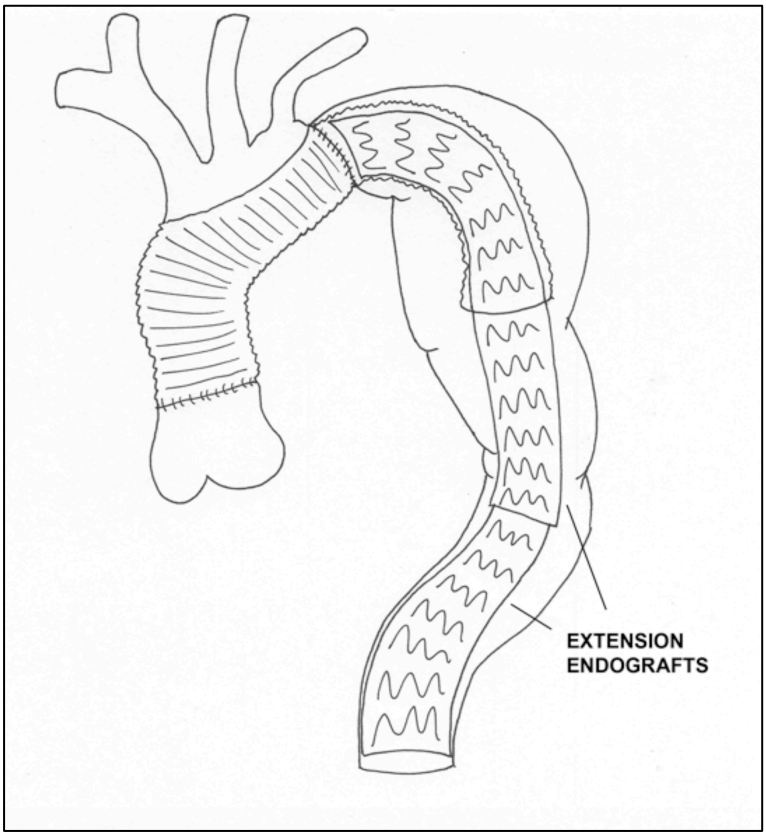

Figure 2: The Elephant Trunk Technique (Second Stage)

The Frozen Elephant Trunk Technique:

The 'frozen elephant trunk' technique is an adaptation of the original 'elephant trunk' technique, which involves treatment of arch and descending thoracic aortic pathology in a single procedure using a composite open/endovascular prosthesis. The endovascular portion of the graft is deployed in the descending thoracic aorta in an anterograde fashion. The 'open' portion of the graft is used to repair the aortic arch. [8]

Hybrid Procedures:

Whilst open repair remains the gold standard for treatment of aortic arch pathology in patients with limited comorbidities, alternative procedures have emerged to offer treatment to patients at high risk for open repair. Hybrid procedures use a combination of open and endovascular techniques in an attempt to lessen the overall risk of the operation.

Hybrid procedures are associated with shorter procedure times and reduced physiological burden by avoiding the need for sternotomy, deep hypothermic circulatory arrest and cardiopulmonary bypass. Despite this, clear evidence is lacking to show superiority of hybrid repair techniques over open repair. A meta-analysis conducted by Bernedetto et al comparing outcomes of open versus hybrid repair techniques demonstrated no significant difference in operative or late mortality, or permanent neurological deficit.[11] However, the authors acknowledged significant limitations of the meta-analysis, given the observational nature of the studies analysed. It is clear that cohorts of patients treated with open versus hybrid procedures are difficult to compare given the inherent differences in patient risk profiles.

<u>The Debranching Technique:</u>

The debranching technique is a type of hybrid repair which is particularly suited to aortic pathology involving the distal aortic arch and/or proximal descending thoracic aorta. It is used when the proximal seal zone for an endoprosthesis (≥20mm of the inner aortic curvature) cannot be achieved without partially or completely covering the origins of one or more of the supraaortic trunk origins.

The first step of the procedure aims to create an adequate seal zone for an endoprosthesis by performing one or more extra-anatomical bypasses between the supraaortic trunks. This ensures that perfusion is maintained to all supraaortic trunks once the endoprosthesis has been deployed. The second step of the procedure is to deploy the endoprosthesis in the arch of the aorta from a

femoral approach.

Debranching Options:

The choice of debranching procedure depends on the intended landing zone in the aortic arch, as described by Criado.[12] (*Fig 3*) 'Zone 0' extends from the coronary ostia to the distal margin of the innominate artery (IA). 'Zone 1' extends from the distal margin of the IA to the distal margin of the left CCA. 'Zone 2' extends from the distal margin of the left CCA to the distal margin of the left SCA. 'Zone 3' extends from the distal margin of the left SCA to the apex or 'arch knuckle' of the distal aortic arch. Some patients (in particular, young trauma patients with an aortic transection) lack a bend where the distal arch transitions in to the descending thoracic aorta, and therefore lack a zone 3.[12] They transition from zone 2 directly to zone 4. 'Zone 4' extends from the aortic knuckle to the level of approximately T8 in the descending thoracic aorta.

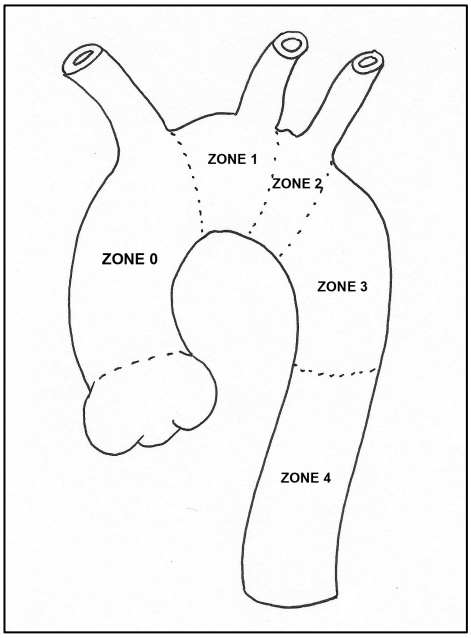

Figure 3: Landing Zones in the Aortic Arch

In order to create a seal for an endoprosthesis in zone 2, a left carotid-subclavian bypass (or transposition) is performed via a left supraclavicular incision. In order to create a seal in zone 1, a right-to-left carotid-carotid bypass is

performed (using a retrooesophageal or subcutaneous tunnel), in addition to the left carotid-subclavian bypass (or transposition).

The delivery of the endograft in to the newly created seal zone can be performed at the same time as the debranching procedure, or in a staged fashion. At some point, however, the proximal portions of the debranched supraaortic arteries must be occluded. This can be done by ligating the proximal artery or by embolization with an occlusion plug. Whilst ligation of the proximal left CCA is easily achieved during open surgery, the left SCA can be difficult to expose proximal to the vertebral artery. In this circumstance, our center (Aortic Centre, CHRU de Lille, Lille, France) prefers to deploy an occlusion plug in the most proximal portion of the left SCA (from either a femoral or subclavian approach). It is important to check for the presence of a coronary artery bypass graft using the left internal mammary artery, as this must also be preserved. If a staged procedure is planned and bypass grafts are used for debranching, occlusion of the proximal debranched arteries may be elected to take place at the first procedure in order to avoid competitive flow in the bypass grafts.

Debranching the Innominate Artery:

If the seal zone must extend across the IA, the only way of debranching the aortic arch is with a branched bypass graft from the ascending aorta to the supraaortic trunks.

Debranching of the IA should be considered separately to the other debranching techniques, as the need for a sternotomy (or a modified technique via a right anterior thoracotomy) adds to the physiological burden of the procedure. If the ascending aorta is of adequate length and non-diseased, a side-biting clamp can be used to perform the proximal anastomosis, thus avoiding the need for cardiopulmonary bypass and hypothermic circulatory arrest. However, if the ascending aorta is short and/or diseased, some form of limited aortic replacement may be performed in addition to the branched bypass graft to provide an adequate landing zone for an endoprosthesis.

Total Endovascular Repair of the Aortic Arch

In recent years, total endovascular solutions to aortic arch pathology have emerged with a view to offering even less invasive treatment options to patients at high risk of open surgery. Data available for these procedures is limited, as the published cohorts are small. Certainly, early data suggest that these procedures are technically challenging, and should be reserved for centres with particular expertise.

Scalloped and Fenestrated Endografts:

Scalloped and fenestrated endografts can be used to extend a seal zone from the descending thoracic aorta in to the aortic arch. They are ideally suited to aneurysms involving the descending thoracic aorta which arise close to the left SCA.

The use of a scallop or fenestration proximally allows for a single supraaortic trunk (e.g. left SCA) to continue to be perfused whilst extending the seal zone more proximally. However, concerns remain over the use of scallops in a seal zone, given that a large portion of the proximal sealing stent remains uncovered.[13] In addition, the procedures are technically challenging and require meticulous pre-operative planning. The technical demands increase if a combination of a scallop plus fenestration, or multiple fenestrations, is planned. As these devices are delivered from a femoral approach with a long delivery system, they are difficult to manoeuvre precisely when aligning scallops and fenestrations.[13]

Branched Endografts:

Branched endografts have emerged in recent years, and offer potential advantages over arch devices with multiple fenestrations.

The first series describing the use of branched endograft repair for treatment of

arch aneurysms was reported by Inoue and colleagues in 1999.[14] This demonstrated the technical feasibility of the procedure, but further use of the device demonstrated a procedure-related mortality of 23% (3/13) and a severe complication rate of 17% (including stroke, dissection and persistent endoleak).[13] Several models of arch branched endografts have been trialed since.

The first clinical experience with the Cook Aortic Arch Inner Branched Device (AIBD) (*Fig 4*) was reported by Lioupis et al in 2012.[15] This was a small series of six patients, where 11 out of 12 branches were successfully cannulated and preserved. This study demonstrated the technical feasibility of the device.

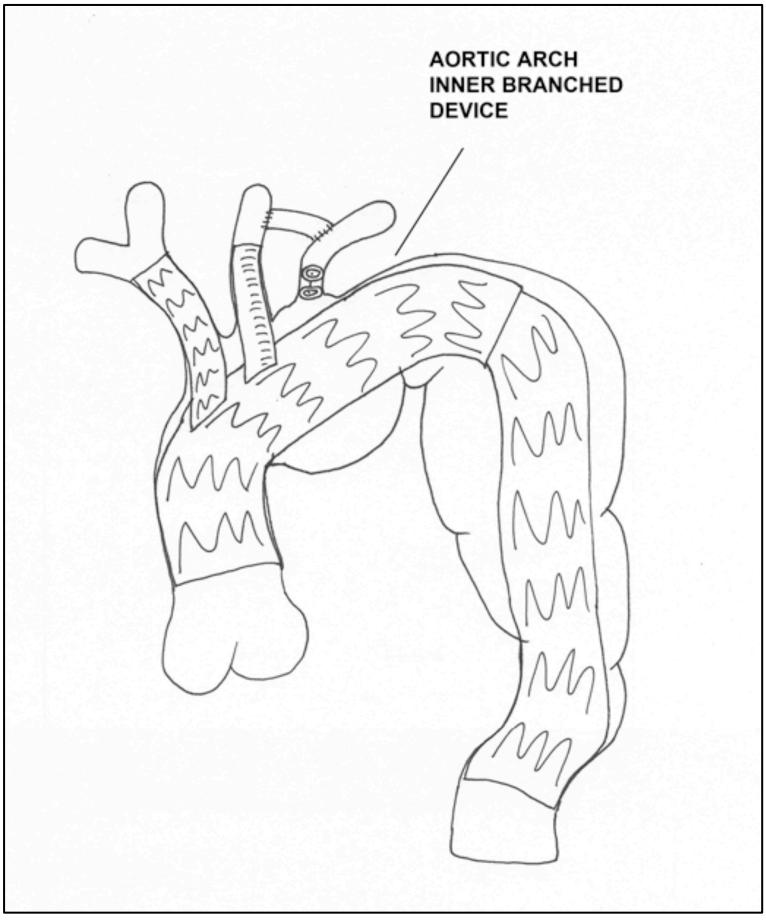

Figure 4: Aortic Arch Inner Branched Device

In 2014, a retrospective multicenter analysis of the first 38 patients treated with the Cook AIBD was published by Haulon and colleagues.[16] This series included the patients from the Lioupis et al series. Technical success was achieved in 32 of

38 patients (84.2%). Five patients (13.2%) died within 30 days of the procedure and six (15.8%) had cerebrovascular complications (four TIAs, one stroke, and one subarachnoid hemorrhage). The median follow up was 12 months. During this time, no aneurysm-related mortality was reported. When an analysis of the first 10 patients was compared with the latter 28 patients, early mortality appeared higher in the first 10 patients (30% vs. 7.1%), though the difference was not statistically significant (p=0.066). Interestingly, when early mortality was combined with neurologic complications, the difference between the two groups became significant (p=0.019). This likely represents the learning curve associated with the first patients treated with the graft. The combined endpoint of early mortality and neurologic complications was also significantly higher in those with ascending aortic diameters >38mm (p=0.026). The authors concluded that the study confirms the feasibility and safety of the endovascular repair of arch aneurysms in selected patients who may not have other conventional options.

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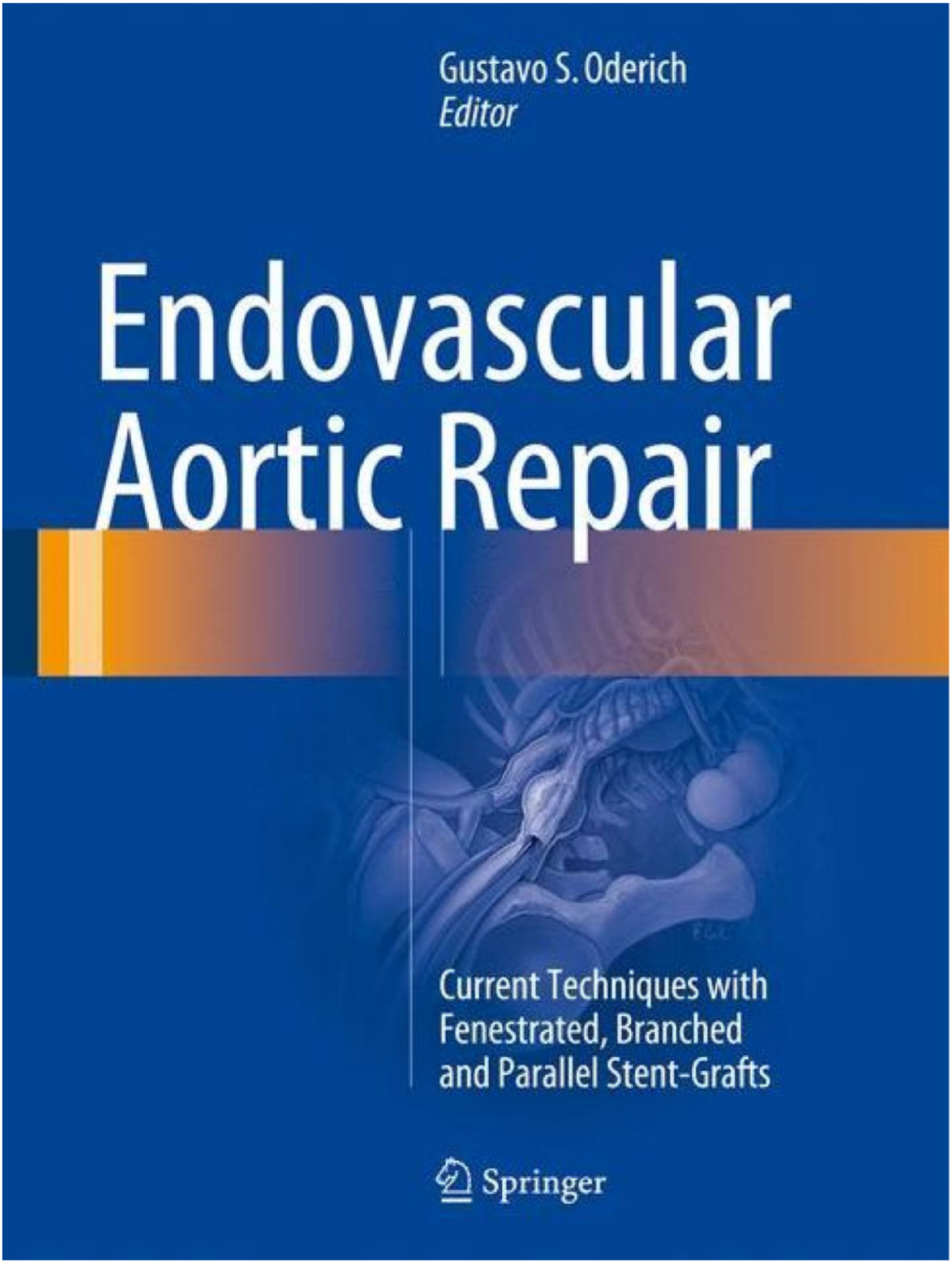
CHAPTER TWO

Branched Endografts for Repair of Aortic Arch Aneurysms

AS PART OF

Endovascular Aortic Repair:
Current Techniques with Fenestrated, Branched and Parallel Stent-Grafts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Branched Endografts for Repair of Aortic Arch Aneurysms

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Abstract:

In recent years, the successful application of fenestrated and branched endograft technology in the visceral aortic segment has been expanded to include the aortic arch. A number of challenges exist specific to endovascular procedures in the aortic arch, including issues associated with the seal zone, device durability, the aortic valve, device alignment, stroke and mortality. (2) In recent years, the Arch Branched Graft (ABG) from Cook Medical (Bloomington, Ind) has been trialled in limited high-volume centers in Europe, the USA, and Canada. This is a third-generation ABG, which was designed to address specific challenges encountered with endovascular procedures in the aortic arch and lessons learned from earlier devices. Recently, a retrospective, multicenter analysis of the first 38 patients treated with the Cook ABG was published, confirming the feasibility and safety of the endovascular repair of arch aneurysms in selected patients who may not have other conventional options. This chapter will discuss our approach to branched endograft repair of aortic arch aneurysms, including patient selection and steps of the procedure. We also describe potential solutions to issues associated with tortuous arch anatomy and previous prosthetic aortic valve replacement.

Introduction:

Open surgery for aneurysms involving the aortic arch remains the gold standard for patients with limited comorbidities. The need for sternotomy, cardiopulmonary bypass, and deep hypothermic circulatory arrest represents a significant physiological burden. Endovascular techniques have been applied to the aortic arch in order to offer treatment to patients at high risk for open surgery. Hybrid procedures combine an open surgical procedure to secure a proximal landing zone, together with deployment of an endograft. The open component of the procedure involves extra-anatomical 'debranching' of supra-aortic trunks, avoiding the need for sternotomy and cross-clamping of the aorta. Despite this, clear evidence is lacking to show superiority of hybrid repair techniques over open repair.(1) In recent years, the successful application of fenestrated and branched endograft technology in the visceral aortic segment has been expanded to include the aortic arch. This chapter will review early evidence for the use of branched endograft technology to treat aortic arch aneurysms. It will follow by discussing the technique used by our team for deployment of branched endografts in the aortic arch.

Challenges in the Aortic Arch:

A number of challenges exist specific to endovascular procedures in the aortic arch.(2) These include issues associated with the seal zone, device durability, the aortic valve, device alignment, stroke and mortality.

Seal Zone:

Adequate endograft seal zones are vital to ensure long-term success.3). Being strict with seal zone criteria is mandatory to achieve technical success and obtain positive midterm outcomes. In the aortic arch, the proximal seal zone should consist of parallel walls in relatively 'healthy' aorta, with a diameter <38mm. The neck should be at least 25mm in length, and free from excessive thrombus and calcification. Aortic angulation should be <60°.(2) For cases involving an arch branched graft, with proximal seal in the ascending aorta, we recommend a seal zone of at least 40mm length.

Durability:

Long-term durability data is available for standard thoracic and abdominal endograft designs. Mid-term data is also available showing that fenestrated and branched endografts are a durable option in the visceral aortic segment.(4) Mid to long-term follow up data is not yet available for aortic arch devices. Indeed, the arch represents a new horizon in terms of physiologic loads that will challenge endograft design. Increased aortic pulsatility along with significant motion of the supra-aortic vessels during respiration may increase complications related to graft wear and fatigue, including stent fracture and kinking.(2)

Aortic Valve:

Some endovascular arch repair procedures require passage of wires, catheters and the tip of the delivery system of the endograft through the aortic valve. This has the potential to damage the aortic valve. Graft design features must consider this, such as using shorter, lower-profile, more flexible nose cones on the delivery system, which will be better tolerated by the aortic valve. Until recently, previous aortic valve replacement (especially mechanical) was considered a contraindication to such procedures.(5)

Device Alignment:

Device positioning and alignment in the aortic arch is vital to ensure that the coronary arteries and supra-aortic trunks are preserved during deployment. As the arch is remote from femoral access, precise control of the device is limited. Therefore, arch endografts should be designed with specific 'auto-alignment' features.

Stroke:

Stroke rates of >6% have been reported for endovascular repair of the descending thoracic aorta.(6) Major contributing factors include manipulation of wires, catheters and the device in the aortic arch, air emboli released from the delivery system, and coverage of branch vessels.(2) Consideration of these factors and strict efforts to minimize their occurrence is vital.

Mortality:

Perioperative and 30-day device-related mortality has been reported at significant rates for current endovascular repairs of the aortic arch.(7) It should be considered that these procedures are mostly being performed on patients considered unfit for open surgery due to significant comorbidities. To minimize the perioperative complications and mortality, these procedures should be performed in high-volume, specialized centers, where complex open and endovascular aortic procedures are performed routinely.

Endograft Design:

Scalloped and Fenestrated Endografts:

Scalloped and fenestrated endografts can be used to extend a seal zone from the descending thoracic aorta in to the aortic arch. They are ideally suited to aneurysms involving the descending thoracic aorta, which arise close to the left subclavian artery (LSA).

The use of a scallop or fenestration proximally allows for a single supra-aortic trunk (e.g. LSA) to continue to be perfused whilst extending the seal zone more proximally. Concerns remain over the use of scallops in a seal zone, given that a large portion of the proximal sealing stent remains uncovered.(2) Proximal seal can be obtained after implanting a covered balloon-expandable bridging stent through a fenestration.

The technical demands of the procedure increase significantly when multiple fenestrations are used. The procedures are technically challenging and require meticulous pre-operative planning to ensure that fenestrations line up with the supra-aortic trunks. As the arch is curved, it is difficult to predict exactly how the device will sit, and thus the location of fenestrations when the endograft is deployed. Also, as devices are delivered from a femoral approach with a long delivery system, they are difficult to maneuver precisely when in the arch.(2) For these reasons, arch devices with multiple fenestrations are relatively unforgiving if problems arise with misalignment of target vessels. To overcome this issue, a wire advanced in a preloaded catheter positioned through a fenestration can be snared from a supra-aortic

trunk. Tension on this through and through wire while deploying the fenestrated endograft will ensure adequate positioning of the fenestration. Endovascular maneuvers in the arch to snare the wire (which can wrap around the nose cone of the delivery system) and tension on the wire increase the stroke risk.

Branched Endografts:

Branched endografts have emerged in recent years, and offer advantages over arch devices with multiple fenestrations. Modern arch endografts have branches located in a tapered, narrow segment of the endograft body. This ensures that the branches are positioned away from the origin of target vessels, simplifying the cannulation process and allowing for a device which is more forgiving in the event of misalignment with the target vessels (branch origins are positioned approximately 10mm proximal to their respective target vessels, whereas fenestrations need to be positioned accurately in front of their target vessels).

The first series describing the use of branched endograft repair for treatment of arch aneurysms was reported by Inoue and colleagues in 1999.(8) This demonstrated the technical feasibility of the procedure, but further use of the device demonstrated a procedure-related mortality of 23% (3/13) and a severe complication rate of 17% (including stroke, dissection and persistent endoleak).(2) The device itself had limitations, most important of which were *externally* located side branches, which complicated their cannulation and placement of covered stents.

Several models of arch branched endografts have been trialed since. In recent years, the Arch Branched Graft (ABG) from Cook Medical (Bloomington, Ind) has been trialed in limited high-volume centers in Europe, the USA, and Canada. This is a third-generation ABG, which was designed to address specific challenges encountered with endovascular procedures in the aortic arch and lessons learned from earlier devices.

<u>Design Features of the Arch Branched Graft:</u>

The device design varies significantly from early arch branched endografts (Fig 1).

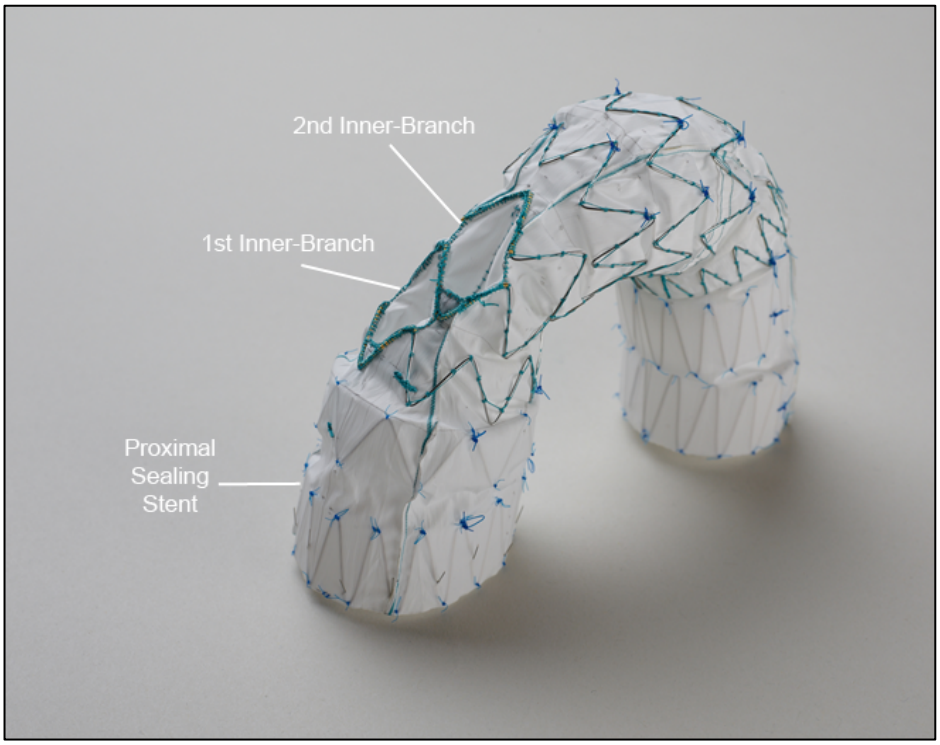

Fig 1: The Arch Branched Graft (ABG) from Cook Medical

It is designed to seal in the ascending aorta, with one or two proximal sealing stents and active fixation with circumferential barbs. There are two distal seal stents, but often the main body requires a distal extension to completely exclude an extensive aneurysm. The delivery system is pre-curved with a hydrophilic sheath. The nose cone is short, flexible and tapered, which allows for it to be advanced in to the left ventricle.

The device uses two *internalized* ('inner') side branches which are flush with the wall of the endograft, creating a smooth external contour. The branches have large openings at their distal end, making them easier to cannulate, and adaptable in the event of device misalignment. The number of inner branches is limited to two in order to simplify the procedure and allow for more flexibility of device alignment. The diameter is normally 12mm for the first branch, and 8mm for the second branch. In normal aortic arch anatomy, the presence of only two branches necessitates a left common carotid artery (CCA)-LSA transposition or bypass prior to deployment of the graft.

The proximal and distal ends of the device are wide and flexible, whilst the middle section of the graft (housing the branches) is narrow. This ensures that the distal ends of the side-branches are separated from the origins of the supra-aortic trunks, allowing for easier

cannulation of the branches, but also ongoing peri-graft flow (and perfusion of the supra-aortic trunks) during the procedure.

The inner branches are located on the outer curvature of the graft, which is attached to the inner cannula of the delivery system with a Nitinol wire. This acts as a rotational 'auto-alignment' feature of the device, which greatly facilitates alignment of the branches with the outer curvature of the arch. Markers are placed on the proximal and distal ends of the branches to further aid positioning under fluoroscopy and subsequent cannulation.

A total of four Nitinol wires attach to the graft and delivery system, which are removed using four handles located in sequence on the delivery system handle. In addition to the 'greater curvature' wire, the other wires provide proximal and distal attachment of the endograft to the delivery system, a 'proform' shape to adapt to the arch curvature, and release of the diameter-reducing ties.

A modified Zenith iliac limb component (Cook Medical), with a 14F delivery system, is used to bridge the proximal inner branch to the innominate artery (IA). A self-expanding fluency covered stent (Fluency, Bard Inc), is used to bridge the distal inner branch to the left CCA.

Early Results for the Arch Branch Graft:

The first clinical experience with the Cook ABG was reported by Lioupis et al in 2012.(9) This was a small series of 6 patients, where 11 out of 12 branches were successfully cannulated and preserved. This study demonstrated the technical feasibility of the device.

Recently, a retrospective, multicenter analysis of the first 38 patients treated with the Cook ABG was published by Haulon and colleagues.(7) This series included the patients from the Lioupis et al series. Technical success was achieved in 32 of 38 patients (84.2%). Five patients (13.2%) died within 30 days of the procedure and six (15.8%) had cerebrovascular complications (four TIAs, one stroke, and one subarachnoid hemorrhage). The median follow up was 12 months. During this time, no aneurysm-related mortality was reported. When an analysis of the first 10 patients was compared with the latter 28 patients, early mortality appeared higher in the first 10 patients (30% vs. 7.1%), though the difference was not

statistically significant (p=0.066). Interestingly, when early mortality was combined with neurologic complications, the difference between the two groups became significant (p=0.019). This likely represents the learning curve associated with the first patients treated with the graft. The combined endpoint of early mortality and neurologic complications was also significantly higher in those with ascending aortic diameters >38mm (p=0.026). The authors concluded that the study confirms the feasibility and safety of the endovascular repair of arch aneurysms in selected patients who may not have other conventional options.

Approach to Branched Endograft Repair of the Aortic Arch:

Patient Selection:

In general, patients diagnosed with an aortic arch aneurysm with a minimum diameter of 5.5cm who are deemed unfit for surgery, with appropriate anatomy to accommodate a custom-designed ABG, are potential candidates for total endovascular repair of the aortic arch.

In their global review of branched endograft experience, the authors describe a clear set of anatomic and physiologic criteria for patient selection.(7)

Anatomic Criteria	**Physiologic Criteria**
Arch aneurysm or chronic dissection Suitable iliac access to accommodate 22F - 24F sheaths No prior aortic valve replacement (biological or mechanical) Ascending aorta: - ≥50mm length (sinotubular	Minimum 2 year life expectancy Negative cardiac stress test - If positive, cardiology consult and clearance required No stroke or myocardial infarction within 12 months No class III or IV congestive cardiac

junction to origin of innominate artery) - ≥40mm sealing zone length - ≤38mm diameter Innominate artery: - ≤20mm diameter - ≥20mm sealing zone length	failure (NYHA criteria) No significant carotid bifurcation disease (<70%, NASCET criteria) eGFR ≥45ml/min/1.73m^2 * Exceptions to some physiologic criteria may occur based on surgeon discretion & anesthetic review

***Table 1.1: Anatomic and Physiologic criteria for selection of patients undergoing inner-branched aortic-arch endograft repair.*(7)**

Steps of the Procedure:

Preparation and Setup:

Our center performs all complex aortic procedures in a hybrid operating suite with the assistance of fusion imaging. Fusion is set by acquiring AP and lateral fluoroscopic images of osseous landmarks, which are registered to the pre-operative CT-angiogram.(10)

The patient is positioned supine, with arms by the side. The anesthetic team ideally achieves central venous access in the left upper internal jugular vein or right subclavian vein. Blood pressure is monitored using a right and/or left radial arterial line.

A diagram of the aortic arch anatomy and endoprosthesis is affixed to the lead screen adjacent to the operating table to allow easy reference throughout the procedure. All graft component sizes are labeled. The optimal angle for visualization of the proximal landing zone, IA and left CCA is also labeled (having been established pre-operatively using 3D workstation analysis).

Throughout the procedure, meticulous and thorough flushing of the endovascular equipment is performed to ensure that no air bubbles are introduced in to the aortic arch.

A left CCA-LSA transposition or bypass is performed prior to the arch branch graft repair. This can be done at the same time as the arch repair, or in a staged fashion (our preferred option). If performing a bypass, the most proximal aspect of the LSA should be occluded proximal to the vertebral artery origin (coils or Amplatzer plug) at the completion of the endovascular repair. This ensures that no type II endoleak from the LSA occurs after deployment of the arch graft. There is a risk of occlusion of the bypass by competitive flow if a staged approach is planned. We leave it open in case access to the internal branch from the left CCA is not possible, in which case we would switch to LSA access. This has not yet been required in our experience.

Access*:*

Three ports of arterial access are required:

- Open femoral access is used to deliver the main device to the aortic arch. The side which will best accommodate a 22 – 24F delivery sheath is chosen.
- Open right CCA exposure is used to deliver the modified iliac limb component between the proximal (first) inner side branch and the IA. An axillary approach can be used if the carotid territory is hostile (e.g. occlusive disease, previous carotid surgery or radiotherapy), but the angles are less favorable for delivery of the bridging stent. In addition, right CCA exposure gives us the opportunity to clamp the artery for embolic protection.
- Finally, a left open axillary approach is used to deliver the covered bridging stent between the distal (second) internal side branch and the left CCA. In this case, the bridging stent must be delivered via the LSA-left CCA transposition or bypass. If the transposition or bypass is performed at the same time as the arch branch graft, direct open left CCA access can instead be used.

A method of cardiac-output reduction is required for the procedure. We use rapid cardiac pacing to achieve this. Open common femoral vein access is gained on the same side as the open femoral artery exposure. Right internal jugular vein access can also be easily gained through the right cervicotomy. A trans-venous pacing probe is introduced and positioned in the apex of the right ventricle and a test run of rapid pacing is performed.

Establishing the Delivery Platform:

Systemic heparin is administered at a dose of 100 IU/kg. The target ACT throughout the procedure is >300 s.

Right CCA access is obtained using a short 5F sheath. A soft angled hydrophilic guide wire is advanced in to the ascending aorta to allow delivery of a pigtail side-hole catheter. This is advanced to make contact with the aortic valve and connected to the contrast power injector. The line is checked to ensure absence of air bubbles.

Left axillary artery access is obtained using a short 10F sheath. The hydrophilic guide wire is navigated through the LSA-left CCA transposition or bypass, and advanced in to the ascending aorta.

Femoral access is obtained using a short sheath. A long 260cm hydrophilic guide wire and 5F 100cm vertebral catheter are advanced in to the ascending aorta. The wire is used to gently navigate through the aortic valve and in to the left ventricle. The catheter is advanced in to the left ventricle and the wire is exchanged for a stiff Lunderquist (Cook Medical) wire, which acts as the platform for delivery of the branched device. The floppy tip of this wire should sit in the apex of the left ventricle. The position of the tip must be visualized during every step of the procedure so that inadvertent left ventricular perforation does not occur.

The gantry is positioned at the pre-determined optimal viewing angle for deployment of the endoprosthesis, and an angiogram performed (25ml at 10ml/sec). The fusion mask is adjusted to correspond to the angiogram.

Delivery and Deployment of Device:

The delivery system for the endoprosthesis is prepared by flushing the delivery sheath and inner lumen of the inner cannula. We use at least 120ml (six 20ml syringes) of heparin/saline solution to flush the delivery sheath to ensure the absence of air bubbles. Under fluoroscopy, the radio-opaque markers on the endoprosthesis are checked outside the patient. The short

femoral sheath is removed and the device is inserted over the Lunderquist wire and positioned in the ascending aorta. In order to position the proximal sealing stent at the level of the origin of the ascending aorta, the tapered short tip of the delivery system must be advanced through the aortic valve and in to the left ventricle.

A second angiogram is performed to check the position of the coronary arteries and supra-aortic trunks relative to the markers on the endoprosthesis. The markers for the inner branches are positioned upstream of the IA and left CCA.

Deployment of the graft is performed next under rapid pacing. The graft is unsheathed in its entirety and the first three trigger wires are pulled from the delivery device. (Fig 2) This must be performed quickly so that normal cardiac output can be resumed. The stiff wire and tapered delivery tip are then withdrawn from the left ventricle and positioned within the distal end of the endograft. The fourth trigger wire is intentionally left in place as it is attached to the distal end of the endoprosthesis. In cases of difficulty with cannulation of the inner branches, it can be used to provide traction on the endoprosthesis and move it away from the greater curvature of the arch to provide more working space.

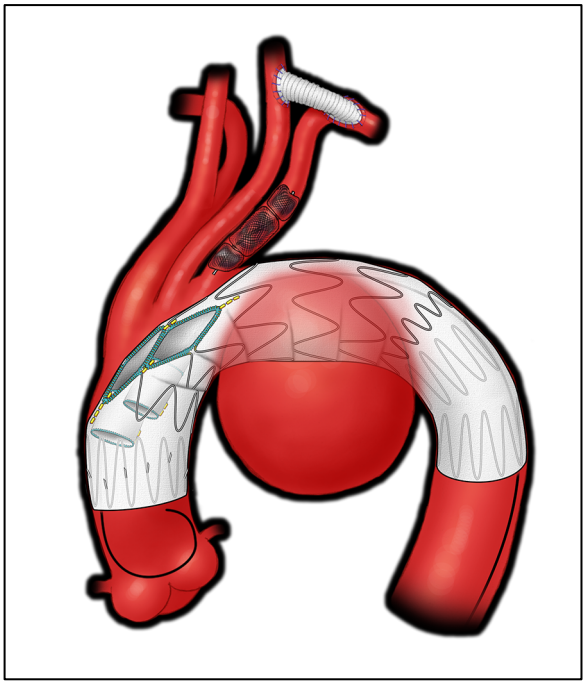

Fig 2: Main body of the ABG deployed in the aortic arch

Delivery and Deployment of Bridging Stents:

After removal of the pigtail catheter, the first inner branch is cannulated from the right CCA access using an 180cm 0.035 soft angled hydrophilic guide wire and 5F 65cm KMP catheter (Fig 3a). Wire and catheter are positioned in the left ventricle. The soft angled hydrophilic guide wire is replaced by an180cm 0.035 J-tipped Rosen wire. The catheter is then exchanged for a 12 x 40mm non-compliant balloon which is inflated in the first inner branch (Fig 3b). Multiple fluoroscopic views are obtained to ensure the wire is correctly positioned inside the branch, and not between the wall of the aorta and the endograft (Fig 3c). A retrograde angiogram is performed through the CCA sheath to identify the bifurcation of the IA (angulation of the C-arm is determined pre-operatively by analysis of the CT-scan on the 3D workstation). The distal CCA is clamped for cerebral protection, the short sheath removed and the modified Zenith iliac limb is advanced over the Rosen wire. The proximal edge of the limb is aligned with the proximal inner branch markers and the distal edge positioned proximal to the bifurcation of the IA. The limb is deployed (Fig 3d). The sealing zone between the inner branch and limb is ballooned using the 12 x 40mm balloon and a completion angiogram is performed through the delivery sheath to confirm good seal of the bridging limb, and to exclude technical issues such as kinking of the stent and target vessel dissection. The sheath is then removed, the CCA flushed, and the arteriotomy closed using interrupted prolene sutures. Right CCA perfusion is then restored.

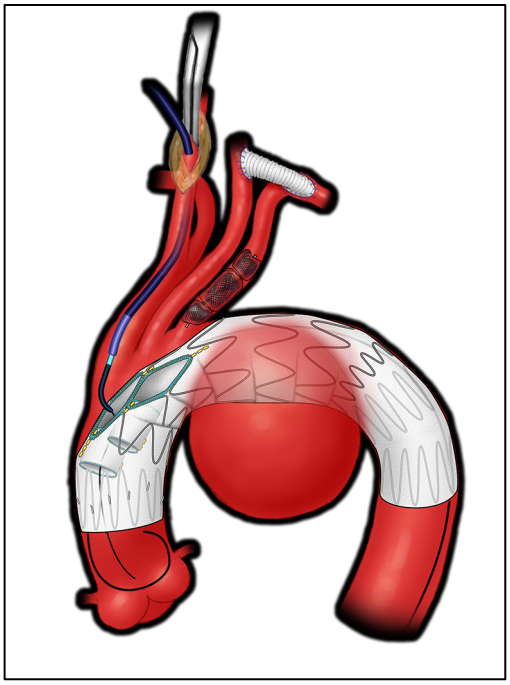

Fig 3a: Cannulation of the proximal inner branch

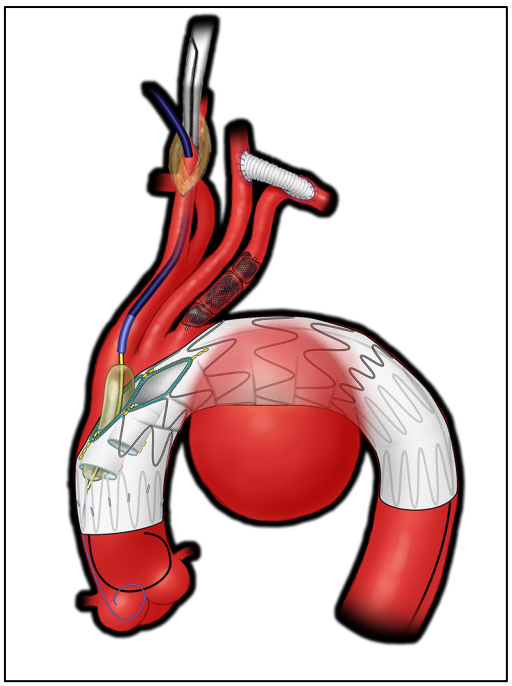

Fig 3b: Balloon inflation test in proximal inner branch (LAO)

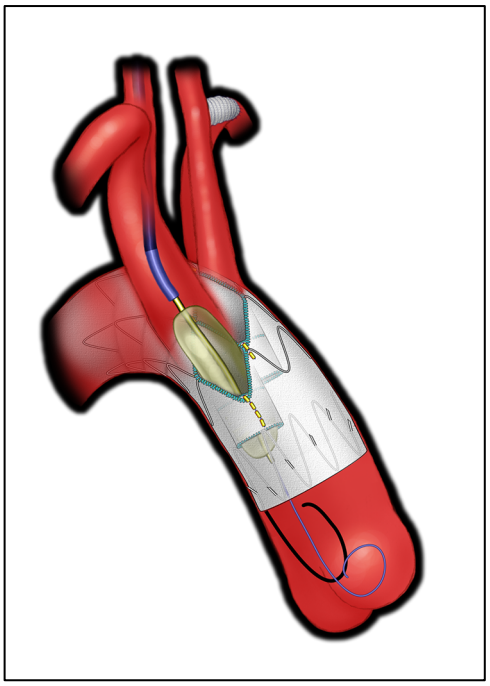

Fig 3c: Balloon inflation test in proximal inner branch (RAO)

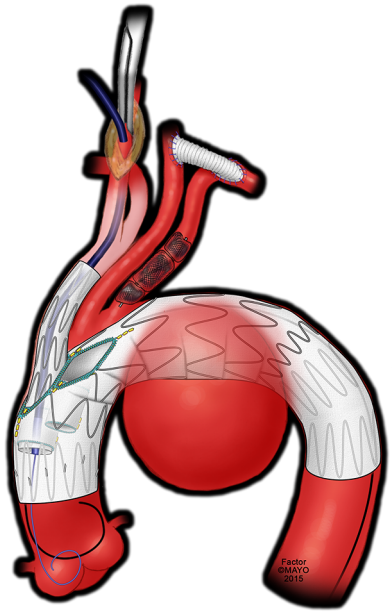

Fig 3d: Deployment of modified Zenith limb in proximal inner branch

The distal inner branch is next cannulated from the left axillary artery access using the same wire and catheter combination as previously (Fig 4a), and the balloon-inflation manoeuver is used to confirm correct cannulation using an 8 x 40mm balloon (Fig 4b & 4c). A 45cm 10F sheath is advanced over the Rosen wire in to the inner branch to facilitate the positioning of the bridging stent delivery system. An angiogram can be performed through the long sheath to identify the origin of the LSA-left CCA transposition or bypass. A self-expanding covered stent (Fluency, Bard Inc) is next advanced over the Rosen wire and the long sheath withdrawn to allow deployment of the stent. The proximal edge of the Fluency stent is aligned with the proximal inner branch markers and the distal edge positioned proximal to the origin of the LSA-left CCA transposition or bypass (Fig 4d). We routinely reline the bridging stent with a self-expandable uncovered Nitinol stent. A completion angiogram is performed through the delivery sheath. The sheath is then removed and the axillary artery repaired in the same manner as the right CCA.

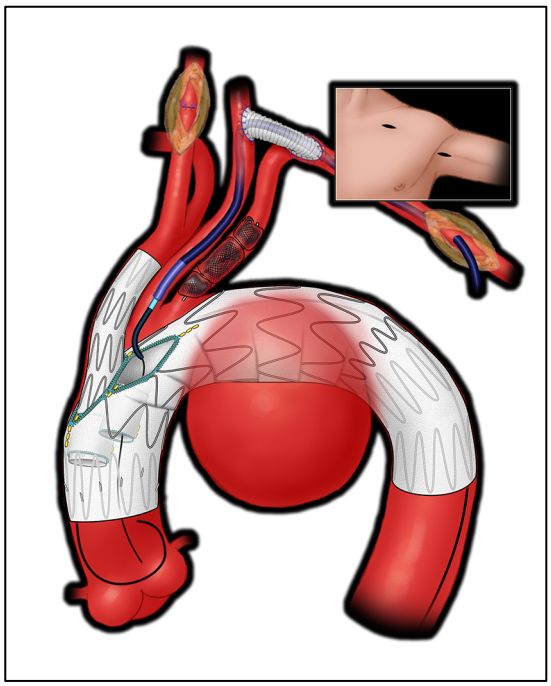

Fig 4a: Cannulation of the distal inner branch

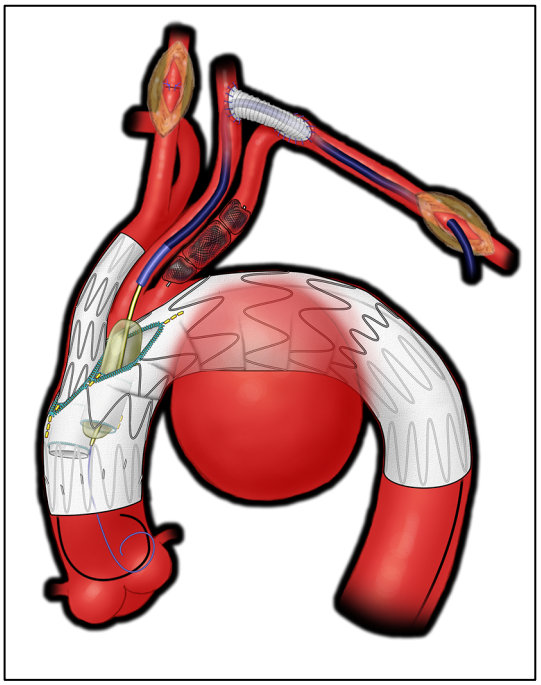

Fig 4b: Balloon inflation test in distal inner branch (LAO)

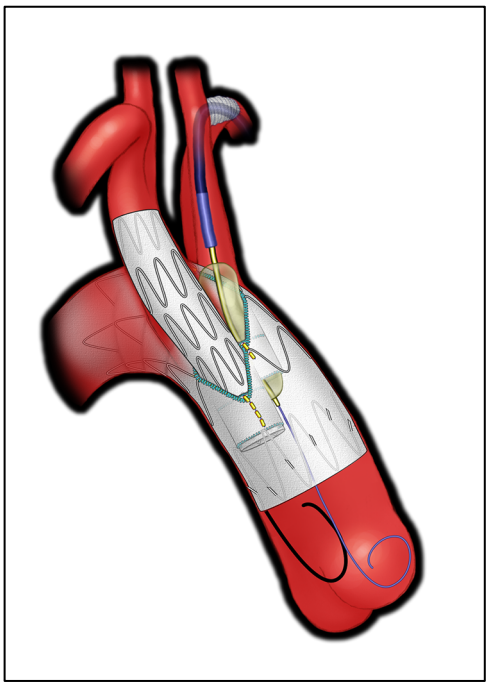

Fig 4c: Balloon inflation test in distal inner branch (RAO)

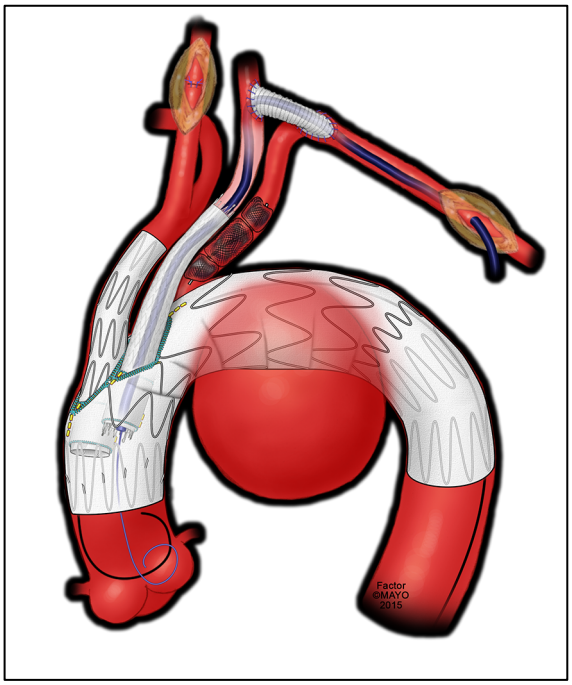

Fig 4d: Deployment of Fluency stent in distal inner branch

The distal end of the main body of the arch branch graft may need to be extended in to the descending thoracic aorta depending on the seal zone distal to the left CCA. In the setting of challenging tortuous arch and descending thoracic aorta anatomy, it is recommended to insert the delivery system of the distal thoracic extension from the contralateral groin. The trigger wire holding the distal aspect of the branched endograft is not removed until the extension

has been advanced in to position.

Completion:

The last trigger wire is removed. The pigtail catheter is advanced over the Lunderquist wire, in to the ascending aorta, and then connected to the power injector. Completion angiography is performed to confirm proximal and distal seal of the main body of the graft, as well as seal of the bridging stents between the inner branches and their corresponding target vessels. The supra-aortic trunks are again examined to ensure patency and exclude issues such as kinking and dissection.

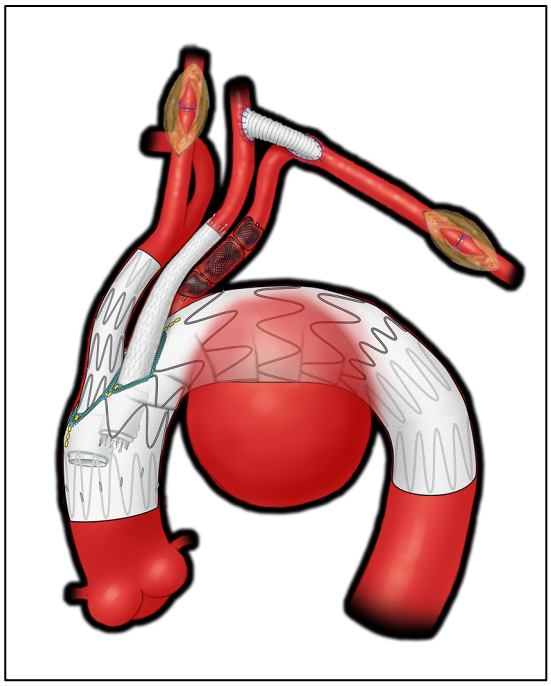

Fig 5: Final configuration of ABG

Special Situations:

Through-and-through Wire Technique:

In some situations, despite a stiff wire platform positioned in the apex of the left ventricle, an endograft is unable to traverse the arch due to hostile anatomy. One example is a large distal arch aneurysm in a 'gothic' arch, which promotes 'bowing' of the delivery system in to the sac of the aneurysm as it engages with the curve of the arch.

Rheaume et al describe a solution to this problem by using a through-and-through wire platform with an externalized transseptal guidewire technique.(11) The authors describe using a right common femoral vein access to establish a long sheath platform in the right atrium. Under transesophageal echocardiography guidance, the foramen ovale was punctured using a transseptal needle to access the left atrium. A steerable introducer and a 400cm long guide wire was then used to navigate through the mitral valve, left ventricle, aortic valve, and in to the aorta. The wire was snared from a left common femoral access to establish a stable through and through wire platform. The graft was successfully advanced and deployed using this system.

Other authors have described using a left ventricular trans-apical through-and through wire.(12) With this technique, needle access is obtained through the apex of the left ventricle, and the guide wire passed through the aortic valve and in to the aorta. The wire is then snared from the femoral access. Access to the left ventricle can be obtained via a mini-thoracotomy, or even using percutaneous techniques.

Modified 'Bullet' Nose Tip

As previously discussed, previous aortic prosthetic valve replacement was considered a contraindication to arch branched endograft repair. This is due to the inability to cross the valve with the tip of the delivery system.

Spear et al describe a solution to this problem by using a modified endograft delivery system with a short bullet nose tip.(5) The authors describe positioning a long 24Fr sheath just above the level of the aortic valve. The dilator of the sheath was withdrawn in order to advance the sheath to this level. The modified delivery system is loaded into a cartridge that is inserted and advanced through the long sheath. The modified short bullet nose tip is positioned against the aortic valve. The graft was successfully deployed 10mm distal to the coronary ostia.

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CHAPTER THREE

Subsequent Results for Arch Aneurysm Repair with Inner Branched Endografts

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Editor's Choice – Subsequent Results for Arch Aneurysm Repair with Inner Branched Endografts,☆

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WHAT THIS STUDY ADDS

This study reports early outcomes following endovascular repair of arch aneurysms in patients unfit for open surgery and is the first evaluation of arch aneurysm endovascular repair performed after the initial learning curve.

Objectives: The aim was to evaluate the current results of aortic arch aneurysm repair using inner branched endografts performed in three high volume aortic endovascular centers and to compare them to the pioneering global experience with this technology.

Methods: Included patients underwent repair of aortic arch aneurysms >55 mm in diameter using inner branched endograft technology between April 2013 and November 2014. All patients were deemed unfit for open surgery. Inner branches were designed to perfuse the brachiocephalic trunk and the left common carotid artery in all cases. A left subclavian artery (LSA) revascularization was performed prior to the arch endovascular repair. Data were collected retrospectively in an electronic database. Parameters included length of procedure, fluoroscopy time, contrast volume, technical success, presence of endoleaks, early and late complications, and mortality.

Results: Twenty-seven patients were included in the study. Technical success was achieved in all cases. No patients died during the 30 day post-operative period. Early neurologic events included two major strokes (7.4%) and one minor stroke (3.7%). Transient spinal cord ischemia with full recovery was observed in two patients (7.4%). Four patients (14.8%) underwent early (<30 day) re-interventions; these were for an access complication, an ischemic limb and exploration of the left ventricle through a sternotomy in two patients. During follow up (median 12 months), one patient (3.7%) died from a remote thoraco-abdominal aneurysm rupture. There were three Type 2 endoleaks (11.1%). Two re-interventions (7.4%) were performed, one to treat a Type 2 endoleak and one to treat a septic false aneurysm. A significant decrease in overall mortality was observed when comparing patients from the early experience with patients from the current report.

Conclusions: The early outcomes associated with this technology are favorable. Branched endografting of aortic arch aneurysms should be considered in patients unfit for open surgery.

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Keywords: Aortic arch aneurysm, Inner branched endograft, Endovascular repair

INTRODUCTION

Aortic arch aneurysm repair remains a major surgical challenge. Various strategies have been developed in order to limit the morbidity and mortality associated with open surgical repair, the major concern being neurologic morbidity with a reported rate of peri-operative stroke ranging from 5% to 12%.[1] Selective cerebral perfusion associated with deep hypothermia during circulatory arrest appears to reduce neurologic morbidity.[2] Hybrid[3] and endovascular techniques have been developed in an attempt to limit the morbidity associated with the treatment of arch aneurysms, especially in "high risk patients'. Although the hybrid technique is considered minimally invasive, because it avoids aortic cross-clamping and hypothermic circulatory arrest, the morbidity and mortality remains high, with a mortality rate ranging from 0% to 15% and a stroke rate from 0% to 11%.[3,4]

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The first multicenter study of endovascular repair with an inner branched device was published in 2014, and was performed for patients deemed unfit for open surgery.[5] This pioneering series reported a learning curve, primarily linked to patient selection (anatomic and physiologic criteria), and was associated with a high risk of stroke and mortality. To provide a dataset reflective of contemporary results of inner branched endograft procedures in high volume centers, the outcomes of this technique were assessed in the three aortic endovascular centers which have the largest experience worldwide subsequent to the initial series. The outcomes were compared with the outcomes of the pioneering experience.[5] All patients from the pioneering study were excluded from this current report.

METHODS

Population

Between April 2013 and November 2014, all patients who were treated for aortic arch aneurysms using the Cook Medical (Bloomington, IN, USA) inner branched arch endograft at three endovascular centers experienced in performing the procedure were included in the study. Of importance, all enrolled patients were separate from those analyzed in the 2014 paper evaluating the early arch branched endograft experience.[5] Indication for treatment was a maximal aortic diameter >55 mm, or rapid growth of an aneurysm (>10 mm over 12 months). All patients were ASA III/IV and deemed unfit for open surgery after multidisciplinary evaluation among cardiac and vascular surgeons, cardiologists, and anesthesiologists. Informed consent was obtained for each patient and the study was approved by the local ethics committee at each center.

Anatomic and physiologic inclusion and exclusion criteria are described below. They are similar to those published in the "early experience" paper, except for prior aortic valve replacement, which is no longer considered an exclusion criterion.[5]

Anatomic criteria

1. Arch aneurysms and chronic dissections
2. Sealing zone within the ascending aorta ≤38 mm in diameter and ≥40 mm length
3. Innominate artery ≤20 mm in diameter and ≥20 mm in sealing zone length
4. Iliac access able to accommodate 22F or 24F sheaths (conduits should be staged).

Physiologic criteria

1. Minimum 2 year life expectancy
2. Negative cardiac stress test (in the setting a positive stress test, cardiology clearance required)
3. No Class III or IV congestive heart failure (CHF)
4. No stroke or myocardial infarction within the last 12 months
5. No significant carotid bifurcation disease (≥70% stenosis by NASCET criteria)
6. Estimated Glomerular Filtration Rate (eGFR) by MDRD method ≥ 45 mL/min/1.73 m^2.

Analysis of pre-operative thoraco-abdominal computed tomographic angiography (CTA) was performed on a 3D workstation.

Device

The device implanted in all patients was a branched endograft manufactured by Cook Medical (Bloomington, IN, USA). It is a custom made device designed according to each patient's anatomy with two inner side branches for the innominate trunk (IT) and the left common carotid (LCC). The device is loaded in a 22F or 24F hydrophilic sheath. The sheath is curved in order to facilitate progression and self alignment in the aortic arch. The bridging component for the IT is manufactured with low profile graft fabric and loaded into a short 14F or 16F Flexor delivery system (Cook Medical). A commercially available self expandable covered stent, Fluency (CR Bard, Murray Hill, NJ, USA) or Viabahn (WL Gore, Flagstaff, AZ, USA), was used as the bridging component for the LCC.

A modified delivery system with a bullet nose tip inserted in a cartridge has been developed for patients with a mechanical aortic valve.[6]

Procedure

Procedure steps have not changed since the initial experience.[5] A left subclavian artery (LSA) revascularization (transposition or bypass to the LCC) is always performed before the arch endovascular repair in a one or two step procedure. In order to deliver the components, three arterial access sites are required:

1. Femoral access to insert the endograft over a stiff wire positioned through the aortic valve into the left ventricle.
2. Right common carotid or right axillary access to catheterize the innominate internal side branch and to insert the covered stent bridging the branch to the IT.
3. Left axillary or brachial access to catheterize the LCC through the LSA transposition or bypass, and the LCC internal side branch to deliver the covered stent bridging the side branch to the LCC.

After systemic heparinization with 100 IU/kg (target activated clotting time [ACT] > 300 seconds), catheters and/or sheaths are placed to mark the origins of the innominate artery and LCC or LSA, a catheter is positioned close to the apex of the left ventricle from the femoral access and a stiff wire (Lunderquist, Cook Medical) is advanced through this catheter. The position of the tip of the stiff wire is constantly visualized. Under fluoroscopy, the graft is verified outside the patient to get accustomed to the numerous radio-opaque markers and then delivered over the stiff wire to the aortic arch. The tapered short tip is brought through the aortic valve, into the left ventricle. An angiogram is performed. If the branches along with their associated markers are positioned adequately, the graft is deployed under cardiac output reduction using rapid

pacing, inferior vena cava occlusion or pharmacologic cardiac arrest. Normal cardiac output is resumed prior to withdrawing the tapered tip of the delivery system and the stiff wire from the left ventricle. The side branches are catheterized from the target vessels and sheaths are positioned into the inner side branches. Appropriate bridging limbs and covered stents are advanced through the access sheaths into the target vessels and deployed. On table angiography completes the procedure to confirm complete exclusion of the aneurysm and patency of the branches.

Data collection

Data were collected prospectively at each center and then retrospectively and anonymously gathered in a single electronic database. Early events are defined as events occurring within the first 30 post-operative days and late events as events occurring subsequently. Overall mortality includes both early mortality and mortality during follow up.

During follow up, clinical examination, neck vessel ultrasound, and CTA scan evaluation were scheduled post-operatively, at 6 and 12 months, and annually thereafter.

Technical success, clinical success, and intra-operative and post-operative morbidity and mortality were recorded according to reporting standards.[7]

A comparison of outcomes between the first 38 patients included in the early experience paper and the subsequent 27 patients presented in this study was performed. The median follow up of 12 months was similar in both groups.

Statistical analyses

Continuous variables are expressed as medians with interquartile ranges (Q1—Q3). Categorical variables are presented as percentages. Comparisons between categorical variables are performed using chi-square tests, or Fisher exact tests when fewer than five events were observed. When normality is not assessed and because groups are fewer than 30 patients, comparisons between continuous variables are performed with the Mann—Whitney test. A p-value $< .05$ is considered significant. Statistical analyses were performed using SPSS software.

RESULTS

Demographics

During the 18 month study period, 27 patients were treated in the three centers (Table 1).

The median age was 74 (69—77) years. The population exhibited a typical spectrum of cardiovascular risk factors (Table 2). Nineteen patients (70.4%) were treated for arch aneurysms and eight patients (29.6%) for arch dissection with development of a false lumen aneurysm, the majority (6/8, 75%) having already undergone open ascending aortic replacement for an acute type A dissection. Strict adherence to the inclusion and exclusion criteria was always observed.

Table 1. Inclusion of patients.

Aortic center	Patients included in current study	Total experience (November 2014)
Hamburg, Germany	12	15
Tokyo, Japan	9	9
Lille, France	6	16

Table 2. Population demographics (median [Q1—Q3] or n [%]).

	Group 1 ($n = 38$)	Group 2 ($n = 27$)	p
Gender: male	27 (71.1%)	22 (81.5%)	.34
Age	71 (64—74)	74 (69—77)	.74
High blood pressure	34 (89.5%)	21 (77.7%)	.20
Dyslipidemia	25 (65.8%)	16 (59.3%)	.60
Prior aortic surgery	21 (55%)	14 (51.8%)	.79
Prior ascending aortic surgery	12 (31.6%)	6 (22.2%)	.41
Smoking	20 (52.6%)	16 (59.3%)	.60
Coronary disease	15 (39.5%)	9 (33.3%)	.62
Dysrhythmia	14 (36.8%)	8 (29.6%)	.55
Chronic obstructive pulmonary disease	12 (31.6%)	9 (33.3%)	.88
Diabetes mellitus	11 (28.8%)	5 (18.5%)	.34
Coronary bypass or stent	9 (23.7%)	5 (18.5%)	0.62
Renal insufficiency	8 (21.1%)	7 (25.9%)	0.65
Prior cerebral event	7 (18.4%)	5 (18.5%)	0.99
Left ventricular ejection fraction $< 40\%$	5 (13.2%)	0	0.05
Valvular disease	4 (10.5%)	11 (40.7%)	0.004
Home oxygen	3 (7.9%)	0	0.14
Aneurysm	28 (73.7%)	19 (70.4%)	0.77
Chronic dissection	10 (26.3%)	8 (29.6%)	0.77

Group 1: early experience study.[4]
Group 2: current study.

Procedure results

Rapid pacing (14/27, 51.8%) or inferior vena cava occlusion (12/27, 44.4%) was performed to reduce the cardiac output during endograft deployment. One procedure was performed under pharmacologic cardiac arrest. LSA revascularization was performed during a first step procedure prior to the endograft procedure for 17 patients (63%). A transseptal guidewire was used in one case for a patient with challenging aortic anatomy.[8] The median procedure time (including the LSA revascularization in 10 patients) was 295 (232—360) minutes, and median X-ray time was 39.3 (34—61) minutes. The median volume of injected contrast media was 183 (120—290) mL.

Technical success was achieved in all cases. One unplanned iliac conduit was necessary to introduce the endograft delivery system. No intra-operative complications occurred.

Early post-operative period

The median length of stay was 13 (11—25) days, including a median intensive care unit stay of 4 (1—6) days.

No patient died during the 30 day post-operative period.

Early secondary interventions were performed in four patients (14.8%). Two sternotomies were performed to rule

out a left ventricular false aneurysm. In one patient no cardiac repair was necessary (i.e. required no cardiopulmonary bypass, deep hypothermic circulatory arrest, or cerebral perfusion). In the other patient cardiopulmonary bypass (CPB) was required; this patient experienced a major stroke. One case of acute limb ischemia secondary to occlusion of the limb of an aorto-bi-femoral bypass graft required revision surgery. One patient, on anticoagulation therapy for a mechanical aortic valve, was re-admitted three weeks after the procedure for evacuation of a hematoma in the cervicotomy access wound.

Brain magnetic resonance imaging (MRI)/computed tomography (CT) was not routinely performed after the procedure. Cerebrovascular events were clinically observed in three patients (11.1%), including two major strokes (one hemiparesis following a middle cerebellar stroke and one non-specified ischemic stroke following urgent open repair under CPB for LV perforation due to guidewire injury (described above)) and one minor stroke (asymptomatic left posterior cerebellar stroke shown on the post-operative CT scan). Two cases of transient spinal cord ischemia (SCI) were seen. Both were managed with cerebral spinal fluid drainage with complete long-term recovery. One patient required medical treatment for a myocardial infarction. This patient had a history of prior coronary bypass and stenting. The origin of the aorto-coronary bypass graft was close to the sino-tubular junction, and thus proximal to the landing zone. Two patients had transient impairment of renal function (>20% decrease in the estimated glomerular filtration rate). One patient required temporary dialysis, with return of renal function to baseline. This patient was one of the two patients with post-operative SCI described above. Micro-emboli were suspected for both the acute renal impairment and the associated SCI.

Follow up period

Median follow up time was 12 (6—12) months. During follow up, two secondary procedures (7.4%) were performed. One Type 2 endoleak required coil embolization. One patient presented with false aneurysms at the distal end of the IT branch and at the distal end of the endograft in the descending thoracic aorta (septic etiology not confirmed). Both false aneurysms were treated with extension of the endografts distally into the IT and the descending thoracic aorta; the 18 month follow up CT scan confirmed successful treatment.

One patient (3.7%) died during follow up from a remote thoraco-abdominal aortic aneurysm rupture. No aortic arch aneurysm related death or aneurysmal diameter evolution was observed on follow up.

Comparative analysis of patients from the early experience (Group 1, n = 38) and patients from this series (Group 2, n = 27)

Populations were similar when comparing median age, male gender and cardiovascular risk factors (Table 2). More patients had valvular disease diagnosed on the pre-operative cardiac ultrasound in Group 2, but all patients in group 2 had a left ventricular ejection fraction >40%. Indications for intervention (i.e. aneurysm vs. chronic dissection) were similar ($p = .77$).

Some differences in operative parameters were observed between the two groups (Table 3). There was a significant increase in the volume of contrast injected in Group 2 (183 [120—290] mL vs. 150 [95—207] ml, $p = .03$). Although not significant, there was a trend towards a decrease in fluoroscopy time (39.3 [34—61] minutes vs. 46 [32—84] minutes, $p = .07$) and a slight increase (though not significant) in length of procedure (295 [232—360] minutes vs. 250 [210—330] minutes, $p = .35$).

During the early post-operative period (<30 days), the rate of cerebrovascular events was comparable (6 [15.8%] vs. 3 [11.1%], $p = .6$) between the two groups. There was a trend towards a decrease in endoleak rate (11 (28.9%) vs. 3 (11.1%), $p = .08$) in Group 2. No early mortality was observed in Group 2, compared with five cases (13.2%) in Group 1 ($p = .05$).

During follow up (≥30 days), four patients (12.1%) died in Group 1, compared with one patient (3.7%) in Group 2 ($p = .24$). Group 2 showed a significant decrease in overall mortality when compared with Group 1 (1 [3.7%] vs. 9 [23.6%], $p = .02$).

DISCUSSION

The results of inner branched endograft repair of the aortic arch in this contemporary series from three experienced centers compares favorably with the early global experience of the technique published in 2014. The differences between the two groups in early mortality ($p = .05$) and mortality during follow up ($p = .24$) did not reach statistical

Table 3. Comparative analysis (median [Q1—Q3] or *n* [%]).

	Group 1 ($n = 38$)	Group 2 ($n = 27$)	*p*
Procedure			
Length (min)	250 (210—330)	295 (232—360)	.35
X-ray time (min)	46 (32—84)	39.3 (34—61)	.07
Volume of contrast (mL)	150 (95—207)	183 (120—290)	.03
Early post-operative			
Endoleaks	11 (28.9%)	3 (11.1%)	.08
Secondary procedures	4 (10.5%)	4 (14.8%)	.61
Cerebrovascular events	6 (15.8%)	3 (11.1%)	.60
Systemic complications	17 (44.7%)	13 (43.3%)	.79
Mortality	5 (13.2%)	0 (0%)	.05
Follow up ($n = 33$)			
Endoleaks	3 (9.1%)	2 (7.4%)	.82
Secondary procedures	3 (9.1%)	2 (7.4%)	.82
Mortality	4 (12.1%)	1 (3.7%)	.24
Overall mortality	9 (23.6%)	1 (3.7%)	.02

Group 1: early experience study.[4]
Group 2: current study.

significance, however the decrease in "overall" mortality ($p = .02$) did reach significance. It should be noted that the numbers in both series are relatively small, thus the power to demonstrate statistical differences between groups is limited. These results demonstrate an overall improvement in the safety profile of inner branched endograft repair of the aortic arch. Centers involved in both studies are endovascular centers performing routinely complex aortic repair. Despite the high level of expertise in all centers, the authors are still in the learning phase of this new endovascular procedure. Of note, half of the early secondary procedures required a sternotomy, and a cardiopulmonary bypass in one patient. Cardiothoracic surgeons should thus be involved in the whole process, from patient selection to post-operative care; centers with no on call cardiothoracic surgeon should not perform these repairs.

Interestingly, when the authors of the early global series analyzed the first 10 patients in their series and compared them with the latter 28 patients, they also found[5] a trend towards higher mortality in the first 10 patients (30% vs. 7.1%, $p = .066$). When early mortality was combined with neurologic complications, the difference between the two groups became significant ($p = .019$). It was also observed in the initial experience that many patients were treated outside the inclusion and exclusion criteria. For example, 11 of 38 patients had an ascending aorta diameter >38 mm; the early mortality and stroke risk was significantly increased in this subgroup of patients ($p = .026$). The inclusion and exclusion criteria have not changed since the initial experience, but strict adherence to these criteria was observed in the current report.

Peri-operative stroke remains the major issue with the procedure. Major potential contributing factors to stroke during procedures in the aortic arch include manipulation of wires, catheters and the device in the aortic arch, air emboli released from the delivery system, and coverage of branch vessels. Consideration of these factors and strict efforts to minimize their occurrence is vital. Stroke is also a major issue following open surgery with cardiopulmonary bypass. When evaluated prospectively by MRI and neurologists,[9] the incidence of clinical stroke and silent radiographic cerebral infarction complicating open surgical aortic valve replacement is more than double for this same cohort in the Society for Thoracic Surgery database. In the same study, silent cerebral infarctions were detected in more than half of the patients. Similar studies should be performed with every arch aneurysm repair technique, including inner branched endograft repair.

When comparing operative parameters between the two groups, there was a trend towards a decrease in fluoroscopy time in Group 2 (39.3 [34—61] minutes vs. 46 [32—84] minutes, $p = .07$) and a slight increase (though not significant) in length of procedure (295 [232—360] minutes vs. 250 [210—330] minutes, $p = .35$). Although these results may appear paradoxical, it could be explained by differences in practice between centers. In Group 2, one center performed the LSA bypass (or transposition) at the same time as the inner branched endograft procedure, thus increasing overall operating time without affecting fluoroscopy time. The other two centers performed the LSA bypass (or transposition) in a staged fashion, roughly 4—6 weeks before the inner branched endograft procedure. In Group 1, a staged LSA procedure was performed in 33 patients (86.8%), whereas in Group 2 it was performed in 18 patients (67%). Another comparison of operative parameters between the two groups reveals a significant increase in the volume of contrast media injected in Group 2 (183 [120—290] mL vs. 150 [95—207] mL, $p = .03$) despite the overall trend towards a decrease in fluoroscopy time. These results may again appear paradoxical, but could also be explained by differences in practice between centers. One center in Group 2 performs routine diagnostic aortic arch angiograms at the beginning of the case. The other two centers rely solely on the pre-operative CTA for arch analysis, using a 3D workstation. In Group 1, no patients received diagnostic angiograms, whilst in Group 2, 9/27 patients (33%) received them.

CONCLUSION

The results of inner branched endograft repair of the aortic arch in this contemporary series, from three centers experienced in performing the procedure, demonstrates an improvement in patient outcome when compared with the early global experience of the technique published in 2014. The results from this series confirm that inner branched endograft repair of the aortic arch is a feasible option and compares favorably with open surgery and hybrid repairs for patients with significant comorbidities who are considered unfit for open surgery. No early mortality was observed and technical success was always achieved in this latest experience with strict adherence to the inclusion and exclusion criteria.

CONFLICT OF INTEREST

Consulting and Intellectual property rights for Cook Medical: Stéphan Haulon and Tilo Kölbel.

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CHAPTER FOUR

Inner-Branched Endografts for the Treatment of Aortic Arch Aneurysms Following Open Ascending Aortic Replacement for Type A Dissection

Inner-Branched Endografts for the Treatment of Aortic Arch Aneurysms After Open Ascending Aortic Replacement for Type A Dissection

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Background. **The development of a postdissection aortic arch aneurysm after open ascending aortic replacement for type A dissection places the patient at increased risk for an open operation due to the need for redo sternotomy and total arch replacement. We conducted a computed tomography–based feasibility study to assess what proportion of these patients would be anatomically suitable for branched endograft repair of an arch aneurysm. We also aimed to identify ways to tailor the index operation to increase suitability for future endovascular repair.**

Methods. **Our study was conducted at the Aortic Centre, Lille University Hospital, Lille, France. Postoperative images were assessed for patients after open replacement of the ascending aorta for acute type A dissection in this center between 2009 and 2015 to determine suitability for use of an aortic arch inner-branched device.**

Results. **The assessment found 52 of 73 patients (71.2%) were anatomically suitable for treatment with the aortic arch inner-branched device. The only cause for absolute exclusion from suitability was the absence of a proximal landing zone in the ascending aorta. Reasons for this were the ascending aortic graft being too short (71.4%), the presence of a major kink in the graft (23.8%), and the graft diameter being too large (4.8%).**

Conclusions. **Approximately 70% of patients with arch aneurysm formation after open ascending aortic replacement for type A dissection are anatomically suitable for treatment with the aortic arch inner-branched device. In the future, surgeons will be able to fashion the prosthetic graft at the time of the index operation to ensure it fulfills criteria for an adequate proximal landing zone.**

(Ann Thorac Surg 2016;102:2028–35)

Open surgical intervention for aneurysms involving the aortic arch remains the gold standard for patients with limited comorbidities [1–5]. In recent years, the application of branched endograft technology has expanded to include the aortic arch to offer treatment to patients who are unfit for an open operation [6, 7] (Fig 1). A recent study confirmed the feasibility and safety of these procedures, provided they are performed in high-volume centers where fenestrated and branched endograft procedures are routine and that patient selection conforms to strict criteria [8].

Long-term survivors after open repair for type A aortic dissection have estimated rates of reintervention approaching 40% [9–11]. The development of a postdissection arch aneurysm places the patient at increased risk for open repair due to the need for redo sternotomy and total arch replacement, which is associated with lengthy procedure and circulatory arrest times [12, 13]. Traditionally, patients unfit for this type of operation would have no other treatment options, but branched endograft repair has become an option in recent years. Patients also lend themselves to endovascular repair after open ascending aortic replacement due the presence of a prosthetic graft in the ascending aorta acting as a proximal landing zone for an endograft. Currently, however, it

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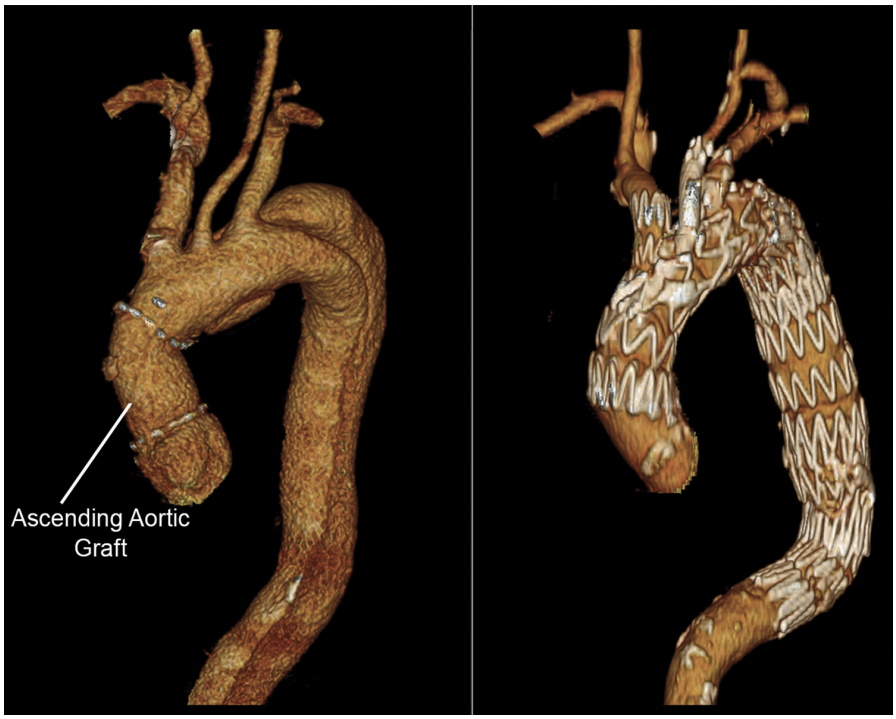

Fig 1. A three-dimensional reconstruction shows the aortic arch aneurysm in a patient (left) after open ascending aortic replacement for type A dissection and (right) after treatment with the aortic arch inner-branched endograft.

is unknown how many of these patients would fulfill the necessary anatomic criteria for the procedure.

We conducted a computed tomography (CT)–based feasibility study to assess what proportion of patients after open ascending aortic replacement for type A dissection would be anatomically suitable for branched endograft repair of an arch aneurysm. We also aimed to identify ways to tailor the index operation to increase suitability for future endovascular repair.

Material and Methods

The Aortic Arch Inner-Branched Endograft

The aortic arch inner-branched device (AIBD), manufactured by Cook Medical (Bloomington, Ind), is available as a custom-made device under special access or to physician-sponsored clinical trials in limited high-volume centers in Europe, the United States, and Canada (Fig 2) [14]. The AIBD seals in the ascending aorta with 1 or 2 proximal sealing stents with circumferential barbs. There are 2 distal seal stents, but often the main body requires distal extension to exclude an aneurysm. The delivery system is precurved with a hydrophilic sheath. The nose cone is short, flexible, and tapered, which allows it to be advanced into the left ventricle.

The inner branches are located on the outer curvature of the graft, which is attached to the precurved inner cannula. This acts to "autoalign" the branches with the outer curvature of the arch. The 2 internalized ("inner") side branches are flush with the wall of the endograft, creating a smooth external contour. The branches have large openings at their distal end for cannulation. The number of inner branches is limited to 2 to simplify the procedure and allow for flexibility with device alignment. The diameter is normally 12 mm for the first branch and 8 mm for the second branch. In normal aortic arch anatomy, the presence of only 2 branches necessitates a left common carotid artery (CCA)–to–left subclavian artery (SCA) transposition or bypass before deployment of the graft.

The middle section of the graft (housing the branches) is tapered. This separates the distal ends of the inner side branches from the origins of the supraaortic trunks and also permits perigraft flow during the procedure. Markers are placed on the proximal and distal ends of the branches to aid positioning under fluoroscopy and subsequent cannulation.

Data Collection and Analysis

The study was conducted at the Aortic Centre, Lille University Hospital, Lille, France. Ethics Committee approval was obtained before commencement, and individual patient consent was waived. An existing prospectively collected electronic database was used to identify all patients who underwent open replacement of the ascending aorta, with or without valve replacement, for acute type A aortic dissection in this center between 2009 and 2015. The maximum diameter of the aortic arch did not have to be at treatment threshold (≥5.5 cm) to be included in the study.

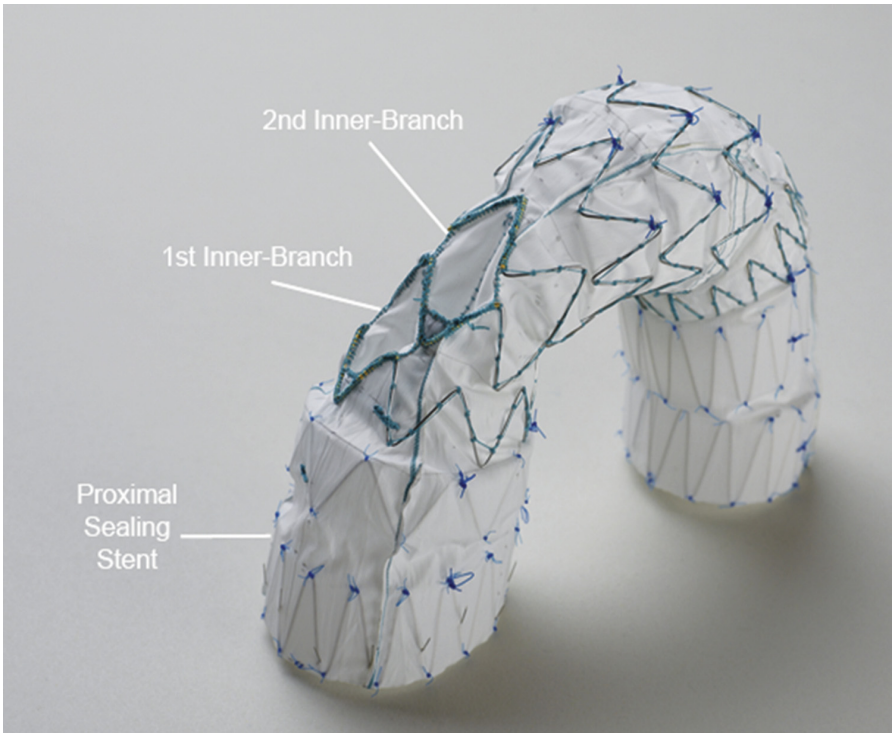

Fig 2. The aortic arch inner-branched endograft.

In their global review of early outcomes for the AIBD experience, Haulon and colleagues [6] describe a clear set of anatomic criteria for patient selection. The criteria for our study are based on this (Table 1), but exclude "absence of aortic valve replacement (biological or mechanical)." The latter was originally a criterion due to the necessity at the time to introduce the delivery system into the left ventricle for deployment. Since then, Spear and colleagues [15] have described a solution to this problem using a modified endograft delivery system with a short "bullet-nose" tip, thus avoiding the need to cross the aortic valve to deploy the AIBD.

Table 1. Anatomic Criteria for Use of the Aortic Arch Inner-Branched Endograft

Suitable iliac artery access to accommodate 22F–24F sheaths
- ≥7-mm diameter
- Absence of severe (≥90 degree) angulation

Ascending aorta:
- ≤38-mm diameter
- ≥40-mm sealing zone length (by true lumen centerline analysis), or
  - ≥24-mm inner curvature, ≥45-mm outer curvature (based on dimensions of the AIBD proximal sealing stent)

Target arteries for first and second branches:
- ≤20-mm diameter
- ≥20-mm sealing zone length
- Free from dissection and severe tortuosity/thrombus/calcification

AIBD = aortic arch inner-branched endograft.

Index operation reports and postoperative CT angiograms were collated, using a combination of electronic and hardcopy patient records. The only exclusion criterion from the study was the absence of high-quality CT angiograms suitable for analysis.

The most recent set of postoperative images was analyzed for each patient using the Aquarius 3D-Workstation (TeraRecon, Foster City, CA). If patients had undergone a secondary open or endovascular intervention after the index operation, the images before the secondary intervention were used. Analyses were performed by 4 vascular and cardiovascular surgeons with significant experience in endograft planning using the TeraRecon software. Multiplanar reconstructions were used to manually map and edit true-lumen centerlines of the aortic arch from the level of the aortic valve to the proximal descending thoracic aorta and the supraaortic trunks. The centerline reconstructions were then analyzed in a straightened (two-dimensional) format to allow for accurate assessment of diameters and lengths of landing zones to determine suitability for use of the AIBD (Fig 3).

The operation type and presence and type of valve replacement (bioprosthetic or mechanical) were recorded for each patient [16, 17]. The aortic arch types (ie, arch angulation and origin of supraaortic trunks), presence of variant anatomy, maximum arch diameter, maximum thoracic aortic diameter, and maximum abdominal aortic diameter were recorded. The minimum iliac artery

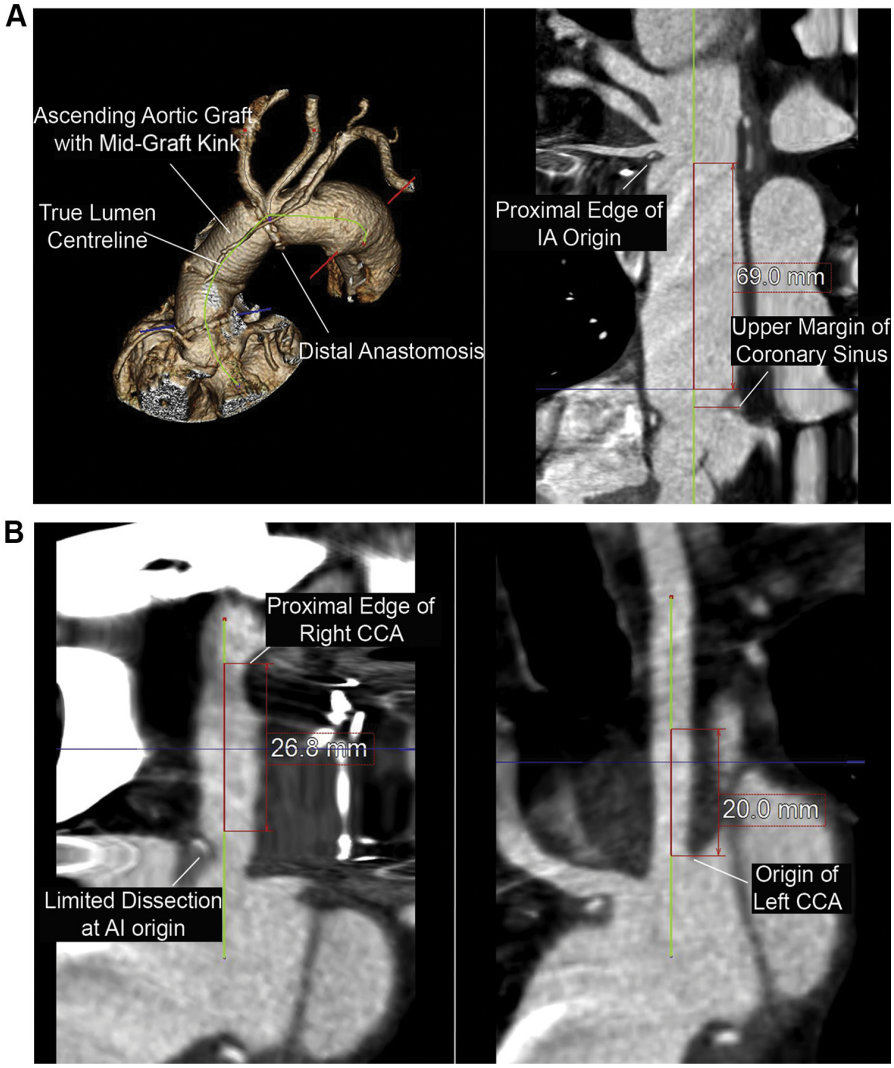

Fig 3. (A) Three-dimensional reconstruction shows (left) the true-lumen centerline of aortic arch and (right) the straightened centerline reconstruction for accurate measurements. (IA = innominate artery.) (B) The straightened centerline reconstruction of (left) the IA and (right) the left common carotid artery (CCA).

diameter was measured to assess whether there would be access issues for delivery of the endograft. If the AIBD delivery system could not be passed, these patients would require common iliac artery conduits to complete the procedure.

The ascending aortic prosthetic graft was analyzed to determine suitability as a proximal landing zone for the AIBD, including maximum diameter, distance from the coronary sinus (CS) to the distal anastomosis, distance from the distal anastomosis to the innominate artery (IA) origin, and graft angulation. The supraaortic target vessels were analyzed to determine suitability as landing zones for branches of the AIBD, including maximum diameter, presence and length of dissection, and length of the appropriate landing zone (ie, vessel diameter $\leq$20 mm, parallel healthy walls).

If the supraaortic target vessel did not have an appropriate landing zone, assessment of suitability for a debranching procedure was made to see if an AIBD branch could be extended in to a suitable landing zone. For example, if the IA was unsuitable, but the right CCA and SCA were free of disease, a CCA-to-SCA bypass could be performed, and the first branch of the AIBD could be extended in to the proximal CCA.

Note was made of patients with variant anatomy that would necessitate an adjunctive procedure before deployment of an AIBD. For example, the presence of a dominant left vertebral artery with an origin directly from the aortic arch would necessitate a vertebral artery transposition at the same time as the routine left CCA-to-SCA bypass was performed.

Adjunctive procedures were divided into simple or complex depending on anatomy. Simple adjunctive procedures were defined as right CCA/SCA debranching or left vertebral artery transposition. Complex adjunctive procedures were defined as right or left CCA/SCA debranching where the donor or recipient artery was partially or completely dissected.

If a bovine arch was present, assessment was made of the angulation of takeoff of the left CCA as well as the diameter of the common origin of the IA and left CCA to see if the two branches of the AIBD could be accommodated. If the angulation was too acute, or the common origin was too narrow (ie, <20 mm), the left SCA was assessed for suitability to deploy the second branch.

Parametric continuous variables are described using means and SD. Nonparametric continuous variables are described using medians with the 25th percentile (Q1) and 75th percentile (Q3). Categoric variables are described using numbers and percentages.

Results

Open replacement of the ascending aorta for acute type A aortic dissection was performed in 97 patients. We excluded 24 of these patients due to the absence of postoperative CT angiograms, leaving 73 patients with sufficient data for analysis in our study.

In addition to open replacement of the ascending aorta for acute type A aortic dissection, 41 of 73 patients (56%) also underwent valve-sparing operations, and 32 (44%) underwent valve-replacement operations. Of the latter, 19 of 32 (59%) received a mechanical aortic valve, and 13 (41%) received a bioprosthetic aortic valve. The mean age at the time of treatment was 56 years (SD, 11.5; range 31 to 80 years), 47 of 73 (64%) were men, and 26 (36%) were women. The median time between the initial operation and the most recent CT angiogram was 6 months (Q1, 0; Q3, 15; range, 0 to 98 months).

The mean diameter of the aortic arch was 40.4 mm (SD, 7.4; range, 28 to 63 mm). The mean diameter of the descending thoracic aorta was 41.6 mm (SD, 10.7; range 24 to 74 mm). A type I arch was present in 14 of the 73 patients (19.2%), a type II arch in 16 (21.9%), and a type III arch in 43 (58.9%). Appropriate CT imaging of the iliac system was available for 56 patients (76.7%), and the minimum external iliac artery diameter was less than 7 mm in 2 of these patients (3.6%).

Ascending Aorta

All measurements of the ascending aortic prosthetic graft, including assessment for suitability of a proximal landing zone for the AIBD are summarized in Table 2. Overall, 52 of 73 patients (71.2%) had a suitable landing zone in the ascending aorta. The reasons for an unsuitable proximal landing zone were the ascending aortic graft being less than 40 mm in length (71.4%), the presence of a major kink (≥90 degrees) in the graft (23.8%), and the graft diameter exceeding 38 mm (4.8%).

An assessment of the residual native ascending aorta (ie, between the distal anastomosis of the ascending aortic graft and the origin of the IA) is summarized in Table 3. The length of residual ascending aorta was 10 mm or more in 31 of the 73 patients (42.5%) and 20 mm or more in 12 (16.4%). In most cases, the residual native ascending aorta was unsuitable for a proximal seal due to a diameter exceeding 38 mm or the presence of dissection.

Table 2. Ascending Aorta (Proximal Landing Zone) Variables

Variables	No.	Mean	SD	Range
Measurements				
Maximum diameter of graft in AA, mm	73	33.4	3.2	26–42
Length from coronary sinus to				
Distal anastomosis, mm	73	42.1	20.4	2–85
IA, mm	73	52.3	19.7	9–99
		Median	Q1, Q3	Range
Length from distal anastomosis to IA, mm	73	7	0, 17	0–54
Landing zone characteristics		Yes No. (%)		No No. (%)
Suitable proximal landing zone?		52/73 (71.2)		21/73 (28.8)
Reasons for unsuitability				
AA graft too short (<40 mm)		15/21 (71.4)		
Major kink (≥90 degrees) in AA graft		5/21 (23.8)		
AA graft diameter too large (>38 mm)		1/21 (4.8)		

AA = ascending aorta; IA = innominate artery; Q1 = quartile 1 (25th percentile); Q3 = quartile 3 (75th percentile).

Innominate Artery

All measurements of the IA, including the presence of dissection and assessment for suitability of a landing zone for the first branch of the AIBD, are summarized in Table 4. Overall, 54 of 72 patients (75%) had a suitable landing zone in the IA. The reasons for an unsuitable landing zone were the presence of dissection (77.8%), a maximum IA diameter exceeding 20 mm (16.7%), and a conical IA (5.6%). One patient not included in the summary table had an aberrant right SCA (arteria lusoria) arising from the mid descending thoracic aorta, meaning that the landing zone of the first branch would have been in the right CCA. Measurement of this artery demonstrated a suitable landing zone.

Left CCA

All measurements of the left CCA, including the presence of dissection and assessment for suitability of a landing

Table 3. Residual Native Ascending Aortic Measurements

Variable	No.	Median	Q1, Q3	Range
Distance from distal anastomosis to IA, mm	73	7	0, 17	0–54
		Yes No. (%)		No No. (%)
≥10 mm residual native AA		31/73 (42.5)		42/73 (57.5)
Suitable for endograft seal?		8/31 (25.8)		23/31 (74.2)
≥20 mm residual native AA		11/73 (15.1)		62/73 (84.9)
Suitable for endograft seal?		3/11 (27.3)		8/11 (72.7)

AA = ascending aorta; IA = innominate artery; Q1 = quartile 1 (25th percentile); Q3 = quartile 3 (75th percentile).

Table 4. Innominate Artery (First Branch) Variables

Variables	No.	Median	Q1, Q3	Range
Measurements				
Maximum diameter of IA, mm	72	16	14, 17	9–25
Length of IA landing zone, mm	72	27	19, 36	0–85

	Yes No. (%)	No No. (%)
IA dissection?	18/72 (25)	54/72 (75)

	No.	Mean	SD	Range
Length of IA dissection, mm	18	27	13	6–58

Landing zone characteristics	Yes No. (%)	No No. (%)
Suitable landing zone?	54/72 (75)	18/72 (25)
Reasons for unsuitability		
Dissection	14/18 (77.8)	
Maximum diameter of IA >20 mm	3/18 (16.7)	
Conical IA	1/18 (5.6)	

IA = innominate artery; Q1 = quartile 1 (25th percentile); Q3 = quartile 3 (75th percentile).

zone for the second branch of the AIBD, are summarized in Table 5. Overall, 67 of 71 patients (94.4%) had a suitable landing zone in the left CCA. The only reason for an unsuitable landing zone was the presence of dissection

Table 5. Left Common Carotid Artery (Second Branch) Variables

Variables	No.	Median	Q1, Q3	Range
Measurements				
Maximum diameter left CCA, mm	71	9	8, 11	7–18

	Yes No. (%)	No No. (%)
Length of left CCA landing zone >20 mm?	67/71 (94.4)	4/71 (5.6)
Left CCA dissection?	5/71 (7)	66/71 (93)

	No.	Median	Q1, Q3	Range
Length of left CCA dissection, mm	5	76	68, 76	44–100

Landing zone characteristics	Yes No. (%)	No No. (%)
Suitable landing zone?	67/71 (94.4)	4/71 (5.6)
Reasons for unsuitability		
Dissection	4/4 (100)	

CCA = common carotid artery; IA = innominate artery; Q1 = quartile 1 (25th percentile); Q3 = quartile 3 (75th percentile).

involving a significant length of the left CCA, leaving a landing zone of less than 20 mm in length.

The 2 patients not included in the summary table had narrow bovine origins (<20 mm), meaning that the first and second branches would be unable to sit adjacent to one another. The second branch target artery for these patients would need to be the left SCA. Measurement of these arteries demonstrated suitable landing zones.

According to the anatomic criteria outlined in Table 1, 52 of 73 patients (71.2%) were suitable candidates for the AIBD. Of these, 73% were suitable for a standard AIBD procedure, 15.4% with a simple adjunctive procedure, and 11.5% with a complex adjunctive procedure (Table 6). A left SCA branch was required in 3 of 52 (5.8%), 2 due to a narrow bovine origin and 1 due to extensive left CCA dissection.

Comment

The only cause for absolute exclusion from an AIBD procedure was the absence of a suitable proximal landing zone in the ascending aorta. Issues with landing zones in the IA and left CCA could be overcome in all cases by adjunctive procedures.

A limitation of our study is that the maximum diameter of the aortic arch in 68 of 73 patients (93.2%) lay below the treatment threshold of 5.5 cm. Whether eligibility for these patients will change over time due to aneurysmal dilatation of the arch and distortion of the landing zones is unknown. The proximal landing zones will be somewhat protected due to the presence of the ascending aortic prosthetic graft; however, the supraaortic trunk landing zones remain vulnerable. If the latter become unsuitable, additional adjunctive (debranching) procedures would be required. Our center intends to perform a substudy to investigate this issue in future years once sufficient long-term follow-up imaging is available.

Interobserver variability is a possible issue associated with measurements performed by individual surgeon assessors.

Early Results for AIBDs

Haulon and colleagues [6] published a retrospective multicenter analysis of the first 38 patients treated with the AIBD in 2014. Technical success was achieved in 32 of 38 patients (84.2%). Cerebrovascular complications occurred in 6 patients (15.8%), and 5 patients (13.2%) died within 30 days of the procedure. The median follow-up

Table 6. Suitability for Aortic Arch Inner-Branched Endograft

Endograft Suitability	No. (%)
Suitable	52/73 (71.2)
Suitable (standard procedure)	38/52 (73)
Suitable (simple adjunctive procedure)	8/52 (15.4)
Suitable (complex adjunctive procedure)	6/52 (11.5)
Requirement for left subclavian artery branch	3/52 (4.1)
Not suitable	21/73 (28.8)

was 12 months. No aneurysm-related deaths were reported during this time. When an analysis of the first 10 patients was compared with the latter 28 patients, early mortality appeared higher in the first 10 patients (30% vs 7.1%), although the difference was not statistically significant ($p = 0.066$). Interestingly, when early mortality was combined with neurologic complications, the difference between the two groups became significant ($p = 0.019$). This likely represents the learning curve associated with the first patients treated with the graft. The authors concluded that the study confirms the feasibility and safety of AIBD repair of arch aneurysms in selected patients.

Spear and colleagues [8] recently published another retrospective multicenter analysis of the subsequent 27 patients treated with the AIBD after the first 38 patients. Technical success was achieved in all 27 patients (100%). Cerebrovascular complications occurred in 3 patients (11.1%), and no patients died within 30 days of the procedure. During 12 months of follow-up, 1 death occurred associated with a remote rupture from a thoracoabdominal aneurysm. When compared with the initial cohort of 38 patients, this study demonstrated a statistically significant reduction in overall mortality from 23.6% to 3.7% ($p = 0.02$) and a trend toward lower perioperative mortality from 13.2% to 0% ($p = 0.05$). The authors concluded that outcomes are favorable when the procedure is performed in experienced centers and that AIBD repair of arch aneurysms should be considered in patients unfit for an open surgical repair.

Where to From Here?

The feasibility and safety of the AIBD procedure has only been validated in the last 2 years [6]. Approximately 77% of the patients in our study underwent their index operation more than 2 years ago, before these data were available, and before anatomic criteria for use of the AIBD had been formalized. In the future, at the time of open ascending aortic replacement for type A aortic dissection, surgeons will be able to fashion the prosthetic graft to ensure that it fulfills criteria for an adequate proximal landing zone. This would involve, in order of priority:

1. positioning the distal anastomosis as close as possible to the IA to achieve a graft length of 40 mm or longer,
2. ensuring the graft is free from major laxity to prevent future kinking, and
3. trying to avoid the use of grafts with diameters exceeding 30 mm, where possible.

Our recommendation of avoiding graft diameters exceeding 30 mm where possible is based on work by Stollwerck and colleagues [18], which suggests that graft dilatation after open abdominal aortic operations is between 20% and 30% beyond 5 years, depending on the graft material.

More extensive arch operations at the time of acute type A aortic dissection is indicated in certain situations, such as exclusion of a primary or secondary arch tear and replacement of an aneurysmal arch [19]. However, total arch replacement increases operative time, morbidity, and death, without significant improvement in long-term outcome [20].

A recent analysis of the German Registry for Acute Aortic Dissection Type A (GERAADA) by Easo and colleagues [13] showed a trend toward lower postoperative mortality for hemiarch replacement of 18.7% compared with 25.7% for total arch replacement. Hemiarch replacement was significantly associated with reduced rates of repeat thoracotomy and excessive bleeding (>1,000 mL/d) as well as reduced circulatory arrest and procedure times.

When not absolutely required, less radical operations in the acute setting appear desirable. With this in mind, if long-term performance is favorable for the AIBD, it may be considered a compliment to open surgical intervention for the treatment of acute type A dissection to avoid extensive arch procedures in the emergency setting. This would involve open ascending aortic replacement only, with formal attention to valve reconstruction, coronary arteries, and pericardial effusion, followed by branched endovascular repair of the arch during follow-up, if required [9].

Conclusions

Approximately 70% of patients with arch aneurysm formation after open ascending aortic replacement for type A dissection are anatomically suitable for endovascular treatment with the AIBD. The major exclusion criterion was an unsuitable proximal landing zone in the ascending aortic graft. At the time of open ascending aortic replacement, surgeons should fashion the prosthetic graft to ensure it fulfills criteria for a suitable proximal landing zone. This will allow for use of the AIBD in a higher percentage of high-risk patients.

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CHAPTER FIVE

CT-Based Long-Term Follow Up
After Thoracic Endovascular Aortic Repair (TEVAR)
For Blunt Traumatic Aortic Injury

CT-Based Long-Term Follow Up After Thoracic Endovascular Aortic Repair (TEVAR) For Blunt Traumatic Aortic Injury

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Abstract:

BACKGROUND:

Thoracic Endovascular Aortic Repair (TEVAR) is the treatment of choice for blunt traumatic aortic injury. Despite this, there is limited data on long-term outcome of these patients.

METHODS:

We conducted a computed tomography (CT)-based long-term follow up study on patients having undergone TEVAR for thoracic aortic injury in our centre between October 2002 and July 2011.

RESULTS:

30 patients were identified. Mechanism of injury was dominated by motor car accidents (16/30, 53.3%) and motor bike accidents (7/30, 23.3%). The median patient age was 43 years (IQR: 27 – 64, range: 18 – 82). 22/30 (73.3%) were male.

3/30 patients (10%) required re-intervention in the early post-operative period. One required endovascular reintervention and two required open procedures. 1/30 patients (3.3%) died in the perioperative period (within 30 days). This death was unrelated to the aortic injury.

At 5 years post TEVAR, overall patient survival was 83.3% (25/30 patients). Of the four patients deceased between 30 days and 5 years, one was related to the aortic endograft (infection), two were unrelated to the aortic endograft, and one was of unknown cause.

Changes in aortic diameter and length measurements relative to the endograft exceeded those expected from age-related change alone. Contributing factors which might explain this include the influence of high radial force of the endograft on the walls of the aorta, hypotension in the trauma patient, changes in aortic arch flow dynamics following endograft deployment, and migration of the endograft. Despite this, diameter and length changes were overall small and caused no adverse outcomes.

CONCLUSION:

This CT-based follow up study indicates that TEVAR performed for BAI is effective and durable in the long term. Follow up of the patient cohort ranged between 4.5 to 12.6 years.

Background:

Thoracic Endovascular Aortic Repair (TEVAR) is the treatment of choice for blunt traumatic aortic injury. *(Figure 1)* When compared with open surgery, TEVAR is associated with a decreased risk of mortality, spinal cord ischaemia, renal injury, and graft infection.[1]

Blunt aortic injury (BAI) is the second leading cause of death in trauma patients, second only to head injury.[2] The mechanism of injury is most commonly sudden deceleration associated with motor vehicle accidents.[3] The most frequent site of injury is in the descending thoracic aorta, distal to the left subclavian artery, at the ligamentum arteriosum (Botallo's ligament). This is where the greatest strains are placed on the aorta during sudden deceleration.[4, 5] Injuries can be classified as grade 1 (intimal tear), grade 2 (intramural hematoma), grade 3 (aortic pseudoaneurysm), and grade 4 (free rupture).[6]

The 2010 Clinical Practice Guidelines from the Society for Vascular Surgery recommend TEVAR in the setting of thoracic aortic transection after stabilization of other injuries.[1] The guidelines also recommend observation of minimal aortic defects, selective (vs routine) revascularization in cases of left subclavian artery coverage, and that spinal drainage is not routinely required.

Despite the well-validated use of TEVAR for the treatment of traumatic aortic injuries, there is limited data on long-term outcome of these patients.[7] In Miller's paper on potential long-term complications of this technology, concerns are raised over accelerated aortic expansion and device durability.[8]

We conducted a computed tomography (CT)-based long-term follow up study on patients having undergone TEVAR for thoracic aortic injury in our centre between September 2000 and October 2011 with a median follow up time of 8.4 years (Range: 4.5 – 12.5 years). We aimed to assess changes in baseline aortic and endograft diameters, as well as changes in position of the endograft relative to the supraaortic vessels. We also aimed to identify incidence of endograft migration, fracture, and presence of thrombus within the endograft at long-term follow up. Calculation of 5-year survival in this patient cohort, and documentation of causes of death (aortic or non-aortic) was performed.

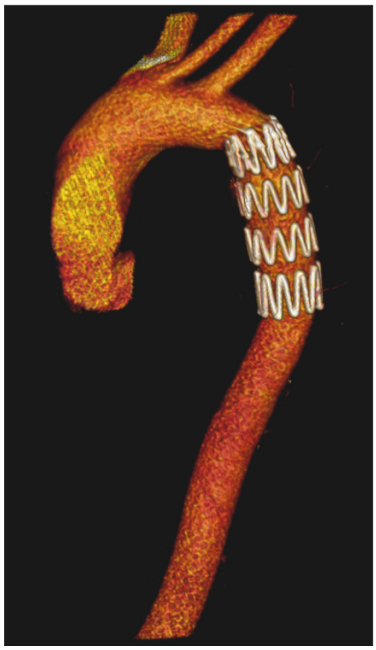

Figure 1: 3-D Reconstruction of CT-angiogram Following Thoracic Endovascular Aortic Repair (TEVAR) for Blunt Aortic Injury.

Methods:

The study was conducted at the Department of Vascular Surgery, The Alfred Hospital, Melbourne, Australia. Ethics committee approval was obtained prior to commencement and individual patient consent was waived. An existing prospectively collected electronic database was used to identify all patients having undergone TEVAR for blunt traumatic aortic injury in this centre between October 2002 and July 2016.

All patients underwent treatment with the Zenith TX2 endograft from Cook Medical (Bloomington, Ind).

The study focuses on CT-angiogram follow up of patients >5 years post TEVAR. At the time of collating data, patients were eligible for analysis if they had undergone TEVAR between October 2002 and July 2011 (i.e. ≥5 years post TEVAR). Some patients had already been followed up in vascular outpatients and had CT-angiogram images available. Others had been lost to follow up. For those lost to follow up, attempts were made to contact patients by

telephone to arrange a review appointment and CT-angiogram. If patients had moved interstate, they were offered a CT-angiogram from a local radiology provider and review with their local doctor. Patients were determined 'lost to follow up' if they refused follow up, failed to attend scheduled appointments or bookings for CT-angiogram on three or more occasions, were unable to be contacted due to change of contact details, or had moved overseas.

Some patients were scheduled for a 5 year review in outpatients, but had CT imaging done in preparation for the appointment, slightly before the exact 5 year post TEVAR date. Taking this in to account, patient images were assessed so long as the CT was performed within 6 months of the 5 year post-operative date.

The only exclusion criterion from the study was the absence of long-term follow up CT imaging.

Where possible, baseline images (within 12 months post TEVAR) were sourced to allow comparison with the long-term follow up images. Absence of baseline imaging was not an exclusion criterion.

For each patient, age, gender, mechanism of trauma, and injury severity score were recorded. Thoracic endograft diameter and length, and requirement for coverage of the left subclavian artery (no coverage, partial coverage, or complete coverage) were recorded. Hospital electronic records, records from general practitioners, and the Victorian Registry of Births, Deaths and Marriages were used to determine incidence of mortality and cause of death during follow up.

CT-angiogram images were analysed for each patient using the OsiriX MD (Pixmeo SARL, Bernex, Switzerland) Path Mode vessel analysis workstation. Analyses were performed by a single vascular surgeon with experience in aortic imaging analysis and endograft planning. Multiplanar reconstructions were used to manually map and edit luminal centerlines of the aorta and thoracic endograft (from the ascending aorta to the mid descending thoracic aorta). The centerline reconstructions were then analysed in a straightened (2-dimentional) format to allow for accurate assessment of aortic diameter, endograft diameter, and lengths between points of interest. *(Figure 2)*

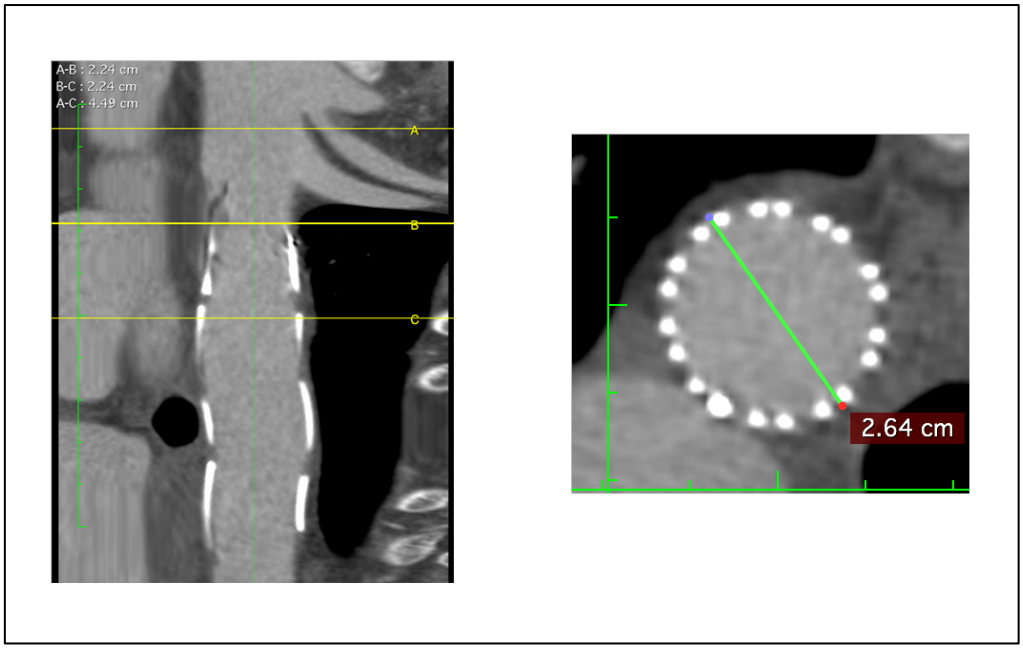

Figure 2: Left: Straightened Centerline Reconstruction of Aortic Arch and Endograft for Accurate Measurement of Length. Right: Cross-section of Centreline Reconstruction for Accurate Measurement of Diameter.

For each patient, maximum diameters of the aorta immediately proximal to the thoracic endograft (MD-P), the endograft itself (MD-E), and the aorta immediately distal to the endograft (MD-D) were recorded. Length between the *distal* edge of the left common carotid artery origin and the endograft origin (LCCA-E) was measured. Length between the *proximal* edge of the left subclavian artery origin and the endograft origin (LSCA-E) was also measured. The proximal edge of the subclavian artery was used as a reference point to allow length measurements for endografts which partially or completely cover the left subclavian artery.

The presence of malapposition of the proximal edge of the endograft to the inner curve of the aortic arch (*bird-beaking*) was recorded, along with the length of the leading edge of the endograft and angle of protrusion from the inner curvature of the arch.

Long-term follow up images were assessed for fracture of the metallic struts of the endograft or presence of thrombus within the endograft.

Baseline image data was compared with long-term follow up image data to look for significant differences. The length and angle of bird-beaking was assessed to look for influence on other variables.

Continuous variables were summarized using means and standard deviations, or medians and inter-quartile ranges (IQR), depending on the distribution of data. Categorical variables were summarized using numbers and percentages. Baseline imaging data was compared to follow-up imaging data using the paired Student's t-test, with results reported as mean differences and 95% confidence intervals. Correlation between diameter and length parameters was assessed using Spearman's rank correlation. All calculated P values were two-tailed. $P < 0.05$ indicated statistical significance. Analyses were performed with SAS version 9.4 (SAS Institute, Cary. NC, USA).

Results:

Between September 2000 and July 2016, 45 patients underwent TEVAR for BAI in our centre. Of these, 30 were performed between September 2000 and October 2011.

Aortic injuries were due to motor car accidents (16/30, 53.3%), motor bike accidents (7/30, 23.3%), pedestrian accidents (2/30, 6.7%), falls from a height (4/30, 13.3%), and a livestock farming accident (1/30, 3.3%). The median patient age was 43 years (IQR: 27 – 64, range: 18 – 82). 22/30 (73.3%) were male, 8/30 (26.7%) were female. The median patient Injury Severity Score (ISS) was 41 (IQR: 34 – 46.5, range: 29 – 75).

All cases of thoracic BAI were managed with TEVAR. Of the endografts deployed, median length was 78mm (IQR: 77 – 80mm, range: 77 – 134mm) and median diameter was 26mm (IQR: 26 – 31mm, range: 22 – 38mm). 1/30 patients (3.3%) had complete coverage of the left subclavian artery. 3/30 patients (10%) had partial coverage of the left subclavian artery.

3/30 patients (10%) required re-intervention in the early post-operative period. One required endovascular reintervention for a type I endoleak. Two required open procedures (one for migration and intussusception of the proximal sealing stent causing significant

luminal compromise, one for ongoing bleeding post TEVAR due to a type II endoleak). 1/30 patients (3.3%) died in the perioperative period (within 30 days). This death was unrelated to the aortic injury.

At 5 years post TEVAR, overall patient survival was 83.3% (25/30 patients). Of the four patients deceased between 30 days and 5 years, one was related to the aortic endograft (infection), two were unrelated to the aortic endograft, and one was of unknown cause.

CT Imaging Analysis:

Of the 30 patients who underwent TEVAR for BAI between October 2002 and October 2011, 13/30 (43.3%) had sufficient long-term follow up imaging data and 12 of these (40%) had sufficient baseline imaging data for analysis.

The median time between TEVAR and long-term follow up CT was 8 years 5 months (Range: 4 years 6 months – 12 years 6 months, Q1=4 years 11 months, Q3=8 years 7 months). 4/13 patients (30.8%) had a follow up CT between 4.5 to 5 years post TEVAR. 2/13 patients (15.4%) had a follow up CT >10 years post TEVAR.

Data for the aortic and endograft diameter parameters are presented in Table 1. There was a significant increase in MD-P, MD-E and MD-D between the baseline CT and follow-up CT. Mean increases in diameter were 2.63, 1.76 and 2.9mm respectively.

1/12 patients (8.3%) had an absolute change in MD-P and MD-D that exceeded 4mm and 6mm respectively, without clinical consequence.

Table 1. Maximum Aortic & Endograft Diameters				
	Baseline CT (n=12)	**Long-term F/U CT (n=12)**	**Difference (95% CI)**	**P value**
MD-P: Max Aortic Diameter Immediately Proximal to Endograft (mm)	25.62 ± 4.58	28.25 ± 5.40	2.63 (1.07-4.20)	0.006
MD-E: Max Endograft Diameter (mm)	28.86 ± 4.13	30.62 ± 5.86	1.76 (0.25-3.27)	0.04
MD-D: Max Aortic Diameter Immediately Distal to Endograft (mm)	23.88 ± 4.64	26.78 ± 7.27	2.90 (0.75-5.05)	0.02
Data presented as mean ± standard deviation (unless otherwise stated). CI: Confidence interval				

Data for length parameters between supra-aortic vessels and the endograft are presented in Table 2. LCCA-E and LSCA-E significantly increased between the baseline CT and follow-up CT. Median increases in length were 3.65mm and 3.6mm respectively.

1/12 patients (8.3%) had a change in LSCA-E that exceeded 10mm (11.2mm), without clinical consequence.

Table 2. Length Parameters				
	Baseline CT (n=12)	**Long-term F/U CT (n=12)**	**Difference (95% CI)**	**P value**
LCCA-E: Length from left CCA to Endograft (mm)	17.75 ± 6.09	21.80 ± 8.40	4.05 (1.63-6.47)	0.007
LSCA-E: Length from left SCA to Endograft (mm)	10.51 ± 7.73	14.68 ± 7.59	4.18 (2.21-6.14)	0.001
Data presented as mean ± standard deviation (unless otherwise stated). CI: Confidence interval				

Data for bird-beaking parameters is presented in Table 3. There was no significant difference in bird-beaking length and bird-beaking angle between baseline CT and follow-up CT.

Table 3. Bird-Beaking Parameters				
	Baseline CT (n=12)	**>5 year F/U CT (n=12)**	**Difference (95% CI)**	**P value**
Bird-Beaking Length (mm)	5.94 ± 1.95	6.77 ± 3.05	0.83 (-0.92 to 2.57)	0.36
Bird-Beaking Angle (°)	45.93 ± 13.96	51.40 ± 16.10	5.47 (-4.16 to 15.10)	0.28
Data presented as mean ± standard deviation (unless otherwise stated). CI: Confidence interval				

There were no cases of stent fracture or thrombus within an endograft at long-term follow up CT.

One patient developed a focal aneurysm around the endograft, with loss of contact of the endograft with the inner curvature of the thoracic aorta. The stent graft did not migrate, and the aneurysm was below threshold for treatment. This patient was an 82 year old female

involved in a high-speed motor-vehicle accident with an aortic transection and rupture. The stent graft was accurately placed, with no direct endoleak seen. The patient was unstable post-operatively and was found to have a type II endoleak (from bleeding intercostal arteries) on CT-angiogram. She proceeded to open repair with oversew of the aortic injury. The aneurysmal degeneration of the aorta over the subsequent years is thought to be related to a persistent type II endoleak from the intercostal arteries. She is now 91 years old and will continue with CT surveillance.

Correlations:

No significant correlation was found between the maximum aortic diameter measurements at baseline CT, and the magnitude of change of LCCA-E and LSCA-E between baseline CT and follow-up CT. However, there was a trend towards an association between MD-P and change in LSCA-E.

Table 4: Diameters vs Lengths		
MD-P: Max Aortic Diameter Immediately Proximal to Endograft (mm) at Baseline		
	rho	**p-value**
Difference in LCCA-E (mm)	0.27	0.398
Difference in LSCA-E (mm)	0.54	0.07
MD-E: Max Endograft Diameter (mm) at Baseline		
Difference in LCCA-E (mm)	0.36	0.252
Difference in LSCA-E (mm)	0.3	0.346
MD-D: Max Aortic Diameter Immediately Distal to Endograft (mm) at Baseline		
Difference in LCCA-E (mm)	0.42	0.174
Length from LSCA-E (mm)	0.38	0.229
rho – Spearman Correlation Coefficient, LCCA-E – Length from left CCA to Endograft, LSCA-E – Length from left SCA to Endograft,		

No significant correlation was found between birdbeaking angle or length, and the magnitude of increase of aortic diameters or aortic lengths between baseline CT and follow-up CT.

Discussion:

Overall, this study supports the long-term durability of TEVAR for BAI. Follow up ranged from 4.5 to 12.6 years. There were no cases of stent graft fracture. There were no cases of major endograft migration with clinical consequence. In the follow up period, there was one aortic-related death due to endograft infection, and one peri-endograft aneurysm formation thought to be due to a type II endoleak.

Diameter and Length changes:

The statistically significant increases in MD-P, MD-E, MD-D, LCCA-E and LSCA-E between baseline and follow up CT were small overall, and did not have clinical consequence.

Possible contributing factors to explain an increase in *aortic diameter* measurements are age-related change, the influence of high radial force of the endograft on the walls of the aorta, and a change in aortic arch flow dynamics following endograft deployment.[9-11] In addition, if the baseline CT was performed close to the time of trauma, hypotension in the trauma patient may influence diameter measurements.[12] 2/13 patients (15.4%) had a baseline CT within 72 hours of TEVAR.

Possible contributing factors to explain an increase in *length* measurements are age-related change, slight migration of the endograft, and a change in aortic arch flow dynamics following endograft deployment.[9, 10]

In their paper 'Age-Related Changes in Aortic Arch Geometry', Redheuil et al estimate an average annual increase in the length of the aortic arch of 0.6mm, and in the diameter of the proximal descending thoracic aorta of 0.08mm.[10]

Based on this, and taking in to account the median follow up time in our study of 8.4 years, maximum diameter of the descending thoracic aorta would be estimated to increase by ~0.67mm, and aortic arch length by ~5mm.

The median increases in MD-P, MD-E and MD-D were 2.63mm, 1.76mm and 2.9mm respectively. These appear to exceed age-related estimates, suggesting other factors play a role. The distances between the LSCA-E and LCCA-E are only a small fraction of the overall aortic arch length, however the median increase in these lengths were 3.6mm and 3.65mm respectively. Assuming age-related length changes occur over a uniform distribution of the aortic arch, the changes in LSCA-E and LCCA-E in our study also appear to exceed age-related estimates, suggesting other factors play a role.

Limitations:

The relatively small number of patients available for long-term follow up was a limitation of this study. Of the 25/30 patients (83.3%) alive 5 years following TEVAR, 12/25 (48%) were lost to follow up. Follow up of the trauma population has been shown to be difficult.[13] Of the 30 patients who underwent TEVAR for BAI in our centre between October 2002 and October 2011, 22/30 (73.3%) were male and 21/30 (70%) were <60 years of age. As previously reported, our data suggests that this young male cohort of trauma patients is difficult to follow up long-term.

Another limitation to the study was that all patients at 5-year follow up had been treated with the Zenith TX2 endograft from Cook Medical (Bloomington, Ind). In recent years, the TX2 has been superseded by the Zenith Alpha Thoracic (ZAT) endograft from Cook Medical (Bloomington, Ind). The ZAT has several design differences when compared to the TX2. It is delivered on a lower profile, pre-curved, more flexible system and has a wider range of diameters available. It has nitinol instead of stainless steel stents. The polyester fabric is thinner and more tightly woven. It also has a rounded, uncovered proximal stent, designed to minimize bird-beaking. It is unknown if these design changes will influence long-term performance.

CT analysis was performed by a single vascular surgeon with experience in aortic imaging analysis and endograft planning. There is potential for observational random error. In addition, some of the CT scans had only 5mm-thick slices available, with a subsequent loss in resolution during analysis. This may impact the accuracy of measurements.

Conclusion:

This CT-based follow up study indicates that TEVAR performed for BAI is effective and durable in the long term. Follow up of the patient cohort ranged between 4.5 to 12.6 years.

Changes in aortic diameter and length measurements relative to the endograft exceeded those expected from age-related change alone. Contributing factors which might explain this include the influence of high radial force of the endograft on the walls of the aorta, hypotension in the trauma patient, changes in aortic arch flow dynamics following endograft deployment, and migration of the endograft.[9-12] Despite this, diameter and length changes were overall small and caused no adverse outcomes.

As 75% of patients treated with TEVAR for BAI in our centre are ≤64 years of age, with a life-expectancy >15 years, an understanding of the long-term performance of TEVAR is important. We await with interest long-term follow up data from other major trauma centres.

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Conclusion

Conclusion

This thesis adds to the knowledge base and published literature about the use of the inner-branched endograft (IBE) for the treatment of aortic arch aneurysms.

Criteria for patient selection have been established and the procedural technique described.

Results of a follow up study looking at mid-term outcomes for patients treated with the IBE confirm that the treatment is a feasible option and compares favorably with open surgery and hybrid repair for patients with significant comorbidities who are considered unfit for open surgery.

Results of a CT-based feasibility study indicate that approximately 70% of patients with arch aneurysm formation after open ascending aortic replacement for type A dissection are anatomically suitable for treatment with the IBE. Guidelines on how to perform acute open Type A aortic dissection repair to allow for future endovascular repair of arch aneurysms have been established.

Finally, results of a CT-based follow up study for patients having undergone thoracic endovascular aortic repair (TEVAR) for blunt aortic injury (BAI) indicate that this treatment is effective and durable in the long term. Changes in aortic diameter and length measurements relative to the endograft exceeded those expected from age-related change alone. Despite this, diameter and length changes were overall small and caused no adverse outcomes.

This enhances our understanding of the long-term performance of endografts used in the aortic arch and thoracic aorta, an environment which exposes these devices to unique haemodynamic forces. This is encouraging when considering the long term performance of IBEs in the aortic arch, however, it must be acknowledged that the IBE is a more complex, modular device, and is likely more susceptible to long term haemodynamic forces when compared to the tube endograft used in TEVAR for BAI. Long term follow up of multicenter IBE series will shed more light on this potential issue in the future.

Overall, the IBE experience for the treatment of aortic arch aneurysms is in its early days, but the data thus far indicate that it is an effective treatment for carefully selected patients who are at high risk for open surgery. The procedures should be performed by experienced personnel in high-volume centers, where complex aortic endovascular procedures are considered routine.