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A New Modular Stent Graft to Reconstruct Aortic Arch

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Submitted 22 October 2008; accepted 24 January 2009

Available online 17 March 2009

KEYWORDS

Aorta;
Vessels;
Stents;
Grafting

Abstract *Background:* Endovascular repair by stent graft has been developed as a safe and less-invasive treatment for descending thoracic and abdominal aortic diseases. In case of involvement of the aortic arch, the challenge in endovascular repair is to maintain blood flow to the brain and upper extremities. Several studies have been done trying to repair this difficult part of the aorta with different stent grafts, and we have developed a new stent-graft device for aortic arch reconstitution. We implanted the new device in canine models to test its feasibility.

Methods and results: The new stent graft was composed of three components: parts I and II were both bifurcated, one with long, narrow limb and the other short and wide, and part III was a tubular component. Ten adult hybrid dogs were operated with the new stent-graft procedure, and eight were successfully implanted with the stent grafts. The technical success rate was 80% (8 of 10). Five dogs survived for 3 months without obvious cerebral, visceral or limb ischaemia. Autopsies showed that the implanted stent grafts were patent and the vital side branches of aortic arch were well preserved.

Conclusions: Our study demonstrates that it is possible to reconstruct aortic arch with the new branched stent grafts. The advantage of this device is that it is modular, more adaptable and surgical bypass could be possibly avoided.

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Endovascular aortic repair has been developed as a safe and effective treatment modality in various diseases of the descending thoracic aorta and abdominal aorta and has gained popularity for treating patients with a poor

conditioned.^{1,2,3,4,5,6,7,8} However, when the aortic arch is involved, endovascular repair turns to be very difficult. The main challenge lies in maintaining blood flow to the vital branches of brain and upper extremities while the aortic arch is being covered by the stent graft.

Some innovative studies have been done to reconstruct aortic arch by endovascular methods.^{9,10,11,12} Inoue et al. successfully treated a case of Stanford A dissection with

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a stent graft bearing side branches to the innominate, left carotid and left subclavian arteries.⁹ This was the first time a reconstruction of the aortic arch and its side branches was performed entirely by endovascular method. However, the Inoue device was custom-made, individually designed and the implantation procedures were rather complicated. Chuter et al. developed another method¹⁰ where they applied a bifurcated stent graft to repair aortic arch by maintaining blood flow to the innominate artery through one branch, and blood flow to the left carotid and subclavian arteries were supplied through extra-anatomical surgical bypass grafts. This method made stent-graft implantation procedure less complicated compared to that with the Inoue device, but the disadvantage was that surgical bypass was indispensable and therefore the corresponding operational risks increased.

Based on the Chuter device, we developed a new modular branched stent graft such that the whole procedure could be performed endovascularly, thus avoiding surgical bypass. In order to test the feasibility of this new device, we performed the implantation procedure in canine models.

Methods

Design and manufacture of the stent-graft system

The stent graft was manufactured from self-expanding Gianturco stainless steel Z stent covered with expanded polytetrafluoroethylene (ePTFE) grafts (Xianjian, China). The graft material was attached to the stent with 5/0 polypropylene sutures (Ethicon). Each stent graft was composed of three modular parts: parts I, II and III. Both parts I and II were bifurcated components with two limbs, one was a long narrow limb and the other was short and wide. Part III was a tubular component (Fig. 1). All three parts were inserted into an 18-Fr Teflon delivery sheath and deployed by withdrawing the outer sheath. It was planned

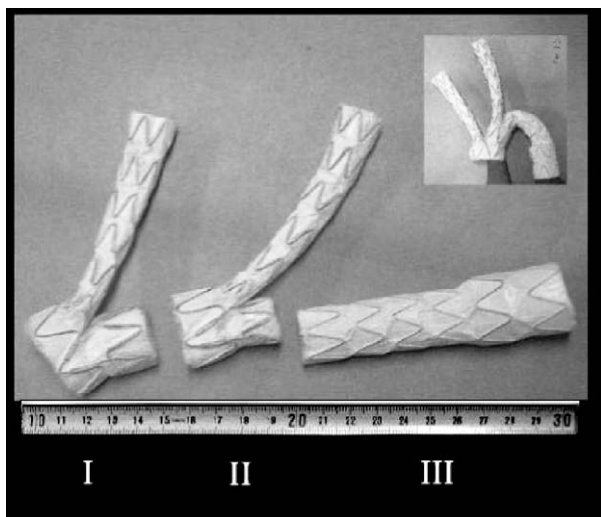


Figure 1 Modular parts of the new stent graft. From left to right are parts I, II and III, respectively. Upper-right corner is the assembled stent graft *in vitro*.

that, when the stent graft was deployed *in vivo*, both the innominate and left carotid arteries were to be preserved and the left subclavian artery was to be occluded in advance (Fig. 2A). This design is based on the well-accepted knowledge that the left subclavian artery can be covered in most people directly.^{13,14,15,16,17}

Aortography shows that a normal hybrid dog has two side branches on the aortic arch. One branch gives rise to bilateral carotid arteries and right subclavian artery, and the other branch is the left subclavian artery. Although the structure of canine aortic arch is a little different from that of humans, it is still an ideal substitute model for our new stent-graft deployment due to its two-branched configuration (Fig. 2B).

Aortography and target vessels measurement

To manufacture the stent grafts suitable for a canine model, we first performed aortography on hybrid dogs and data of the target vessels were recorded. The procedure of aortography is as follows.

A total of 10 adult, male, hybrid dogs (weighing 23.5–25.5 kg) were used in this study. All of the animals were cared for in accordance with the guidelines approved by the PLA General Hospital Animal Experiment and Care Committee. The dogs were sedated with an intramuscular injection of ketamine hydrochloride (10 mg kg⁻¹ body weight) and atropine sulphate (0.08 mg kg⁻¹). After sedation, the sheath catheter was inserted in the right femoral artery of the dog using the Seldinger method. An intravenous injection of heparin (50 UI kg⁻¹) was administered to each dog and a total of 12 ml of contrast agent (Ultravist300; Schering) was injected at a rate of 6 ml s⁻¹ using a 5-Fr marked pigtail catheter through the sheath. The length and diameter of target vessels were measured, and the data were recorded. The outer diameters of the stent grafts were set to be 1020% larger than those of the proximal and distal landing zones of target vessels.

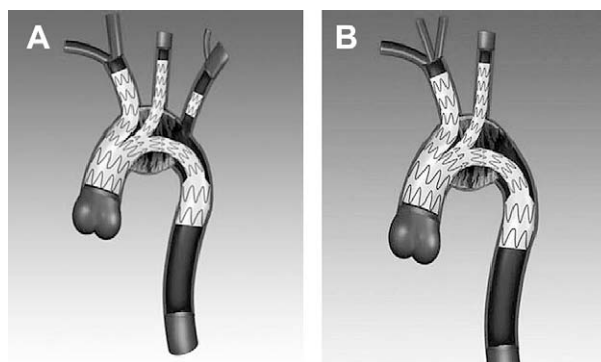


Figure 2 Scheme of aortic arch aneurysm repair with a new device in human being and canine model. (A) Endovascular repair in human being. Innominate artery and left carotid artery were preserved, and left subclavian artery was intentionally occluded. (B) Endovascular repair in canine model. There are two side branches on canine aortic arch. One branch is the innominate artery that gives rise to bilateral carotid and right subclavian arteries, and the other is the left subclavian artery.

Stent-graft implantation procedure on canine model

The dogs were sedated with an intramuscular injection of ketamine hydrochloride (10 mg kg^{-1} body weight) and atropine sulphate (0.08 mg kg^{-1}), and followed by endotracheal intubation and mechanical ventilation with 2 l min^{-1} of oxygen after induction with intravenous sodium thiopental (25 mg kg^{-1}). Anaesthesia was followed by intravenous pentobarbital and pancuronium administrations. Intravenous hydration with normal saline was maintained during the surgery, and antibiotics were given at the start and continued for 3 days. Heparin was given repeatedly throughout the operation to maintain activated clotting time of at least 300 s.

After skin sterilisation, both the bilateral subclavian and common femoral arteries were exposed. A short sheath and a 5-Fr marked pigtail catheter were introduced from left common femoral artery into the ascending aorta for real-time angiography. Right subclavian artery was punctured and a short sheath was introduced. A stiff guidewire (Lunderquist; Cook Inc., Indianapolis, IN, USA) was inserted from the right subclavian access into the ascending aorta, and the delivery system containing part I was introduced. The delivery system was advanced into the ascending aorta and positioned to avoid covering the orifice of the coronary arteries. The central pusher maintained the position of the device, while the outer sheath was withdrawn, thus releasing the stent graft part I with the short limb left inside the ascending aorta and the long limb left inside the innominate artery. Then the left subclavian artery was punctured, and a small sheath was inserted for access. A guidewire was advanced, together with a selective catheter, and the wire was accommodated into the short limb of part I. Then the delivery system containing part II was advanced over the stiff wire through the left subclavian artery access. The main body of part II was overlapped with the short limb of part I for at least 15 mm in length. Part II was positioned and released, and the long limb left was inside the left subclavian artery. The right femoral artery was punctured, and the short aortic limb of part II was cannulated with the same way mentioned above. The delivery system containing the tubular part III was advanced into the short limb of part II and released, with the distal part extending into the descending thoracic aorta. The overlapping length of parts II and III was also at least 15 mm. Each landing and overlapping area was expanded with a balloon to prevent endoleak. The whole implantation procedure was completed in this manner (Fig. 3A–D).

Results

Technical results

Ten adult hybrid dogs were operated with the endovascular procedure; of these, two died during the operation and eight were successfully implanted with the new stent grafts. One dog died of acute myocardial infarction because the coronary arteries were covered by part I accidentally. The other failure occurred due to rupture of the right subclavian artery during part I delivery, and the animal died of subsequent hypovolaemic shock. The technical success

rate was 80% (8 of 10), the average operation time was 320 min (270–400 min), and the average blood loss was 175 ml (30–350 ml) for each procedure.

Blood pressure difference across the new device

After stent-graft deployment, all the blood supply to the lower extremity and visceral arteries would pass through the short, wide limb of part II, which was the narrowest part of the whole stent-graft system with a diameter of 15 mm. To assess whether blood supply to these areas was sufficient, we measured the blood pressure difference between the ascending and descending aortas after the stent-graft deployment, which was also the blood pressure difference across the whole device system. The blood pressure was measured by connecting the angiographic pigtail catheter to a sphygmomanometer. Data are recorded as in Table 1.

Short-term outcome

Of the eight animals that were successfully implanted with stent grafts, three died within 24 h after the operation, and the remaining five dogs survived for 3 months without obvious cerebral or limb ischaemia. All the three deaths came at an early stage in the research because of the operators' lack of experience, especially since the cannulation of short limbs were time consuming and led to excessive loss of blood. In addition, after the operations, the three dogs, kept in hypovolaemic shock, did not recover from anaesthesia and the autopsies later showed that all the deployed stent grafts were patent. Four out of five dogs died early in the research, three were as mentioned above and the other failure was from a ruptured right subclavian artery due to a violent pullback of part I. With experience, we could control the operation time, avoid excessive blood loss and the latter five experiments worked well, except for one animal that died of unintentionally occluded coronary arteries. Computer tomography scan was performed on one surviving dog 2 weeks later, and it showed that the implanted stent graft was patent and no obvious endoleak or stent-graft migration was observed, and the vital side branches were well preserved (Fig. 3E). Three months later, the five animals were sacrificed for autopsy, revealing that the implanted stent grafts and all the vital branch vessels were patently conserved.

Discussion

Several studies have been done for endovascular reconstruction of the aortic arch. Chuter et al. method maintained blood flow to the innominate artery through a branch of the bifurcated stent graft, and blood flow to the left carotid and subclavian arteries were supplied by extra-anatomical surgical bypass grafts.¹⁰ Thus, median sternotomy is avoided and surgical risks are decreased, but the procedure still needs surgical bypass. Inoue et al. treated a case of aorta dissection involving aortic arch with a custom-made stent graft.⁹ This was the first time an entirely endovascular reconstruction of the aortic arch and its vital branches was undertaken. However, the Inoue device is custom-made and must be individually designed.

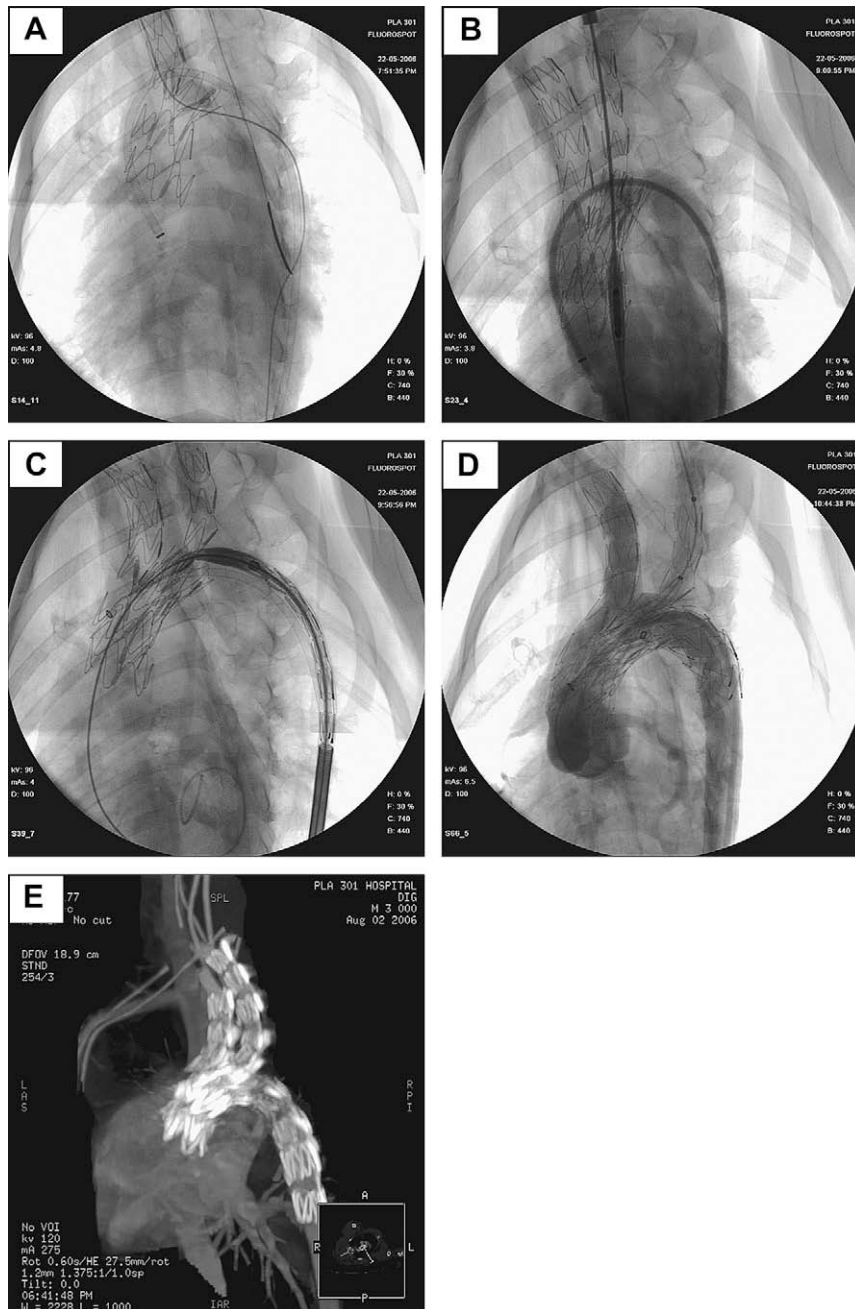


Figure 3 (A) Deployment of part I, (B) deployment of part II, (C) deployment of part III, (D) aortography after the whole procedure was completed and (E) CT scan 2 weeks after the stent-graft implantation.

An ideal stent graft should be adaptable and versatile enough to cater to the complex configuration and variation of aortic arch. Based on the Chuter device, we developed a new stent-graft device for aortic arch diseases, which was composed of three parts: parts I, II and III. Parts I and II were both bifurcated, one with a long, narrow limb supplying blood to the brain, and the other short and wide. Part III was a tubular component and could extend into the descending thoracic aorta. Similar to the Inoue device, our product also can be used to treat aortic arch diseases endovascularly, and surgical bypass could be avoided. However, the difference is that our device was modular and not custom-made, and the size of each modular part was

chosen according to angiographic measurement before the operation. In addition, the key techniques and the tools needed in our procedure, such as wires and catheters, were basically the same as that was widely used in the abdominal aorta aneurysm repair. No further special training on the implantation procedure was necessary.

However, several issues concerning this new device need to be elucidated.

Blood supply to the brain and upper extremities

It has been well accepted that left subclavian arteries of most people can be directly occluded as long as the right

Table 1 Systolic blood pressure difference between the ascending and descending aortas after stent-graft implantation in a canine model (unit: mmHg)

Number of dogs	SBP (ascending/descending aorta)	Blood pressure difference
1	—	—
2	130/125	5
3	108/105	3
4	95/90	5
5	110/105	5
6	115/110	5
7	—	—
8	106/100	6
9	135/130	5
10	125/119	6
Average	115.5/110.5	5

SBP (ascending/descending aorta): systolic blood pressure of ascending aorta and descending aorta, respectively. Animal Nos. 1 and 7 did not survive the procedure and no data were recorded.

vertebral artery and the vertebrobasilar system are normal.^{9–17} Our experience in endovascular treatment of Stanford type B dissection has also proved this.¹⁸ This knowledge laid the theoretical basis for our device, which preserved the blood flow to the innominate artery and left carotid artery, yet without a side branch to left subclavian artery.

Another issue concerns blood supply to the brain during stent-graft deployment. In the canine model, there are two branches arising directly from aortic arch, left subclavian artery and innominate artery. Aortography showed that the diameter of canine innominate artery was about 8 mm, and the outer diameter of the part I delivery system was 18-Fr (6 mm). Therefore, when the main body of part I was deployed through the innominate artery, the blood supply to the brain and upper extremity was not totally shut down and was still supplied by the remnant innominate artery cavity and left subclavian artery. However, this procedure should be concluded as early as possible to reduce the possible brain ischaemia time. When part I was deployed in humans, blood supply to the brain could be supported by left subclavian artery, left carotid artery and the remnant cavity of innominate artery. Therefore, the chances of brain ischaemia should be even lesser, as proved by the Chuter study¹⁰ and our own clinical experience.¹⁹

Blood supply of visceral organs and lower extremities

On completion of the procedure, all the blood supply to the lower extremities and visceral organs would flow through the trunk of the device. The diameter of the narrowest part of the device, which is the short wide limb of part II, is 15 mm. The average diameter of the descending aorta in the canine model in our experiment group was 29 mm. In order to evaluate whether the visceral organs and lower limbs received sufficient blood supply, we measured the blood pressure difference between the ascending aorta and

the descending aorta, which was the blood pressure difference across the whole stent-graft system. As a result, the average blood pressure difference was 5 mmHg, and this was not supposed to cause any serious ischaemia of distal organs.

In conclusion, our study demonstrates that it is feasible to reconstruct aortic arch with the new, modular, branched stent grafts. The advantage of this new device is that surgical bypass could be avoided and, compared with previous literature, our device was modular, seemed to be more adaptable and the implantation procedure be less complicated. More research and further improvements on this device are needed before its final clinical application.

Conflict of Interest/Funding

None.

Acknowledgment

We appreciate Dr. Allen Bray, Cardio vascular center, Newcastle, NSW, Australia, for giving valuable comments.

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