A Feasibility Study of a New Unibody Branched Stent Graft Applied to Reconstruct the Canine Aortic Arch

W. Li ², S. Zhai ³, K. Xu ⁴*, Q. Li ⁵, H. Zhong ⁶, T. Li ⁷, Z. Zhang ³

²Department of Vascular and Endovascular Surgery, Henan Provincial People’s Hospital, Zhengzhou University People’s Hospital, Zhengzhou, PR China
³Department of Interventional Radiology, First Affiliated Hospital of China Medical University, Liaoning, PR China
⁴Department of Medical Imaging, Henan Provincial People’s Hospital, Zhengzhou, PR China
⁵Department of Interventional Radiology, Henan Provincial People’s Hospital, Zhengzhou, PR China

WHAT THIS PAPER ADDS
Recently new endovascular devices have been developed to overcome the challenge of the aortic arch. The animal testing has demonstrated the safety and feasibility of the new unibody branched stent graft system, which can be used to reconstruct the aortic arch. The branched stent graft system is a new applicable device for total endovascular repair of the aortic arch.

Objectives: The aim was to evaluate the feasibility and safety of a new unibody branched stent graft for the reconstruction of the canine aortic arch.

Methods: The unibody branched stent grafts included single branched stent grafts and double branched stent grafts. The main stent graft and branched limbs were sutured together. The branched stent grafts were folded into the introducer system, which consisted of a double channel catheter, a detachable sleeve, and an introducer sheath. The branched stent grafts were introduced and deployed into the aortic arch by the delivery system. Twenty adult mongrel dogs were used for the experiments. Ten dogs were implanted with single branched stent grafts; the other 10 were implanted with double branched stent grafts. The surviving animals were followed up for 3 months. Computed tomography angiography (CTA) was performed to observe the status of the branched stent grafts.

Results: All the unibody branched stent grafts were successfully implanted into the canine aortic arches. The technical success rate was 100%. There was no cerebral infarction, paraplegia or incision infection. CTA showed that all the branched stent grafts were patent; there was no endoleak or stent migration.

Conclusions: The unibody branched stent graft system could be used to reconstruct the aortic arch. The animal experimental procedures demonstrated the safety and feasibility of the unibody branched stent graft system.

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INTRODUCTION
Aortic diseases (aneurysm and dissection) involving the aortic arch are usually associated with high mortality rates and remain a surgical challenge. ¹⁻² Endovascular thoracic aortic repair has been the most popular treatment for descending thoracic aortic diseases because of the lower incidence of procedure related mortality and morbidity.³ However, when the aortic arch is encroached upon, endovascular repair can be very difficult. The main challenge is to maintain the blood flow to supra-aortic vessels while the aortic arch is being covered by the stent graft. The branched stent grafts consist of the main stent graft and branched limbs, which are similar to the anatomical structure of the aortic arch. The branched stent graft may replace open surgery and hybrid repair in the future.⁴ It can be categorised as modular and unibody. The modular branched stent graft is assembled in vivo from several components,⁵ and this stent graft has been used in human patients.⁶,⁷ However, there is a risk of component separation in the long term.⁵ The unibody branched stent graft is implanted as a whole. Therefore it is theoretically much more stable.⁵ In this study, a new unibody branched stent graft system to reconstruct the aortic arch was designed.

MATERIALS AND METHODS
Unibody branched stent graft
The branched stent graft (patent number: ZL201020240888.3) consisted of a main stent graft and branched limbs (Fig. 1). The main stent graft and branched
limbs were made of stainless steel Z stents and polyethylene terephthalate (PET) graft (Chest Medical Technological Co., Shanghai, China). The PET graft was sutured to the Z stents with 5-0 Prolene (Ethicon, Somerville, NJ, US). The main stent graft and branched limbs were sutured together. The first Z stent of the main stent graft was a bare stent without barbs. The single branched stent graft consisted of a main stent graft and a branched limb (Fig. 1A). The double branched stent graft consisted of a main stent graft and two branched limbs (Fig. 1B). There are only two supra-aortic vessels in the canine aortic arch. Therefore the triple branched stent graft could not be tested in this study.

According to the pre-operative computed tomography angiography (CTA), the diameters of the main stent graft and the branched limbs were usually oversized by 10–20% to achieve better fixation and effective sealing. During animal testing, the main stent grafts were 20–25 mm in diameter and 100 mm in length. The branched limbs were 10–15 mm in diameter and 20 mm in length. The distance between the two branched limbs was 5 mm. The grafts between the branched limbs and the main stent graft were 5 mm in length.

**Introducer system**

The introducer system (patent number: ZL201210137457.8) consisted of the double channel catheter, a detachable sleeve and the introducer sheath (Figs. 2 and 3). The double channel catheter consisted of two parallel 5F catheters (Fig. 2A). It was used to parallel the guidewires in the aorta when they became entangled with each other. The

![Figure 1](image1.png)

*Figure 1.* (A) The single branched stent graft consists of a main stent graft and a branched limb. The first Z stent of the main stent graft is a bare stent without barbs. (B) The double branched stent graft consists of a main stent graft and two branched limbs.

![Figure 2](image2.png)

*Figure 2.* (A) The double channel catheter consists of two 5F catheters. (B) The detachable sleeve consists of a bridge wire, a PET sleeve, and a traction wire. (C) The introducer system of the single branched stent graft consists of a top cap, a detachable sleeve and an outer sheath. (D) The introducer system of the double branched stent graft consists of a top cap, two detachable sleeves, and an outer sheath.
detachable sleeve consisted of a bridge wire, a PET sleeve, and a traction wire. The bridge wire and the traction wire were two parts of one continuous wire. The bridge wire passed through the PET sleeve, which was sutured to the bridge wire (Fig. 2B). The PET sleeve was 4 mm in diameter and it was used to fold the branched limb. The bridge wire was designed to establish the pathway for introducing the branched limb into the supra-aortic vessel. The traction wire passed through the inner cannula of the introducer sheath, and the wire was fixed outside the handle using a fixing device (Figs. 2 and 3). The fixing device was to ensure the PET sleeve would not be accidentally detached from the folded branched limb.

The introducer sheath consisted of a top cap, an inner cannula, and an outer sheath (Figs. 2 and 3). The top cap was fixed to the tapered tip of the central cannula. The桥接线和牵引线是连续的两部分。桥接线穿过PET袖套，袖套被缝合到桥接线上（图2B）。PET袖套直径为4mm，用于折叠分支。桥接线设计用于建立通往椎前段血管的路径。牵引线穿过内导管，线绳被固定在手柄外的固定装置上（图2和3）。固定装置用于确保PET袖套不会意外从折叠的分支上脱开。

Assembling the stent graft system

The traction wire passed through the branched limb and the main stent graft. The branched limb was folded into the PET sleeve. The bare stent was folded into the top cap (Fig. 4A). The whole branched stent graft was folded into the outer sheath and the bridge wire was located outside the outer sheath (Fig. 4B). The assembly of the double branched stent graft was similar to that of the single branched stent graft. The two branched limbs were folded into two detachable sleeves. The bare stent was folded into the top cap (Fig. 4C) and the whole stent graft was folded into the outer sheath (Fig. 4D).

Implantation procedures

Twenty adult mongrel dogs (25.0–30.0 kg) were provided by the laboratory animal centre at the China Medical University. The single branched stent grafts were implanted in 10 dogs and the double branched stent grafts were implanted in the other 10 dogs. All the animals were cared for in accordance with the guidelines approved by the
After fasting for 12 h, the animals were anaesthetised with an intramuscular injection of sumianxin II at 0.1 mL/kg (Jilin Research and Development Centre of Veterinary Drugs, Jilin, China) and 3% pentobarbital sodium at 0.5 mL/kg (Kefeng Chemical Reagent Co. LTD, Shanghai, China). Anaesthesia was maintained with propofol 20 mL/hour (Xian Nippon Pharmaceutical Co. LTD, Xian, China) under mechanical ventilation (AM100B; Yishiheng Co., Beijing, China). The dogs were placed on the operating table in the supine position. Venous access was established through the superficial vein of the left hind leg. An 8F sheath was inserted into the left subclavian artery (LSA). The infrarenal abdominal aorta was exposed. A 260 cm standard super-slippery wire (Terumo Medical Corporation, Leuven, Belgium) was introduced from the 8F sheath to the abdominal aorta. The tip of the wire was pulled out from the abdominal aortotomy. A Lunderquist wire (Cook Medical Inc., Indianapolis, IN, USA) was introduced from the aortotomy to the left ventricle. The Lunderquist wire and the 260 cm wire might entangle with each other (Fig. 5A).

Under fluoroscopy, these two wires passed through the double channel catheter and were paralleled by rotating the double channel catheter (Fig. 5B). A 5F vertebral catheter (Terumo Medical Corporation, Leuven, Belgium) was introduced along the 260 cm wire from the 8F sheath which was inserted through the LSA. The tip of the catheter was outside the abdominal aortotomy (Fig. 5C). The bridge wire passed through the 5F vertebral catheter, and its tip was outside the 8F sheath. Before the introducer sheath was inserted into the abdominal aorta, the pathway of introducing the branched limb into the LSA had been established by the bridge wire (Fig. 5D). Then the introducer sheath was introduced from the abdominal aortotomy to the aortic arch along the Lunderquist wire (Fig. 6A). The outer sheath was retracted to the end of the second Z stent of the main stent graft. Then the branched limb folded in the PET sleeve was introduced into the LSA by pulling the bridge wire from the sheath in LSA (Fig. 6B). The bare stent folded in the top cap was released by pushing the central cannula forward. The main stent graft was released by further retracting the outer sheath (Fig. 6C). The fixing device at the end of the traction wire was removed. The branched limb was released by further pulling the bridge wire from the LSA to detach the PET sleeve. The whole detachable sleeve was pulled out from the 8F sheath. The introducer sheath was removed and angiography was performed (Fig. 6D). The 8F sheath was removed from the LSA. The aortotomy and the abdominal incision were closed and the operation time, fluoroscopy time, contrast load, and blood loss were recorded. All dogs were given penicillin (intramuscular injection, 1.6 million U/day) for the following 3 days.

The implantation procedure for the double branched stent graft was similar to that of the single branched stent graft. During the operation, two 8F sheaths were inserted into the right subclavian artery (RSA) and LSA. Two 260 cm guidewires were introduced from the RSA and LSA to the infrarenal abdominal aorta. The double channel catheter was used to parallel the Lunderquist wire and two 260 cm
wires by turns. Then two vertebral catheters were intro-
duced respectively along the 260 cm wires from the RSA
and LSA. The tips of the catheters were outside the
abdominal aortotomy. The two bridge wires were passed
through the two catheters to establish the pathways for
introducing the two branched limbs into the supra-aortic
vessels (Fig. 7A). The branched limbs were introduced into
the supra-aortic vessels by pulling the bridge wires (Fig. 7B).
Then the central cannula was pushed forward to release the
bare stent and the outer sheath was retracted to release
the main stent graft (Fig. 7C). The two branched limbs were
released by detaching the PET sleeves. The two detachable
sleeves were pulled out from the 8F sheaths and angiog-
raphy was performed (Fig. 7D).

All the surviving dogs were followed up for 3 months. At
the end of the follow up period, CTA was performed to
observe the status of the unibody branched stent grafts.

RESULTS
These procedures involved 20 mongrel dogs, 10 in each
group. All the single and double branched stent grafts were
successfully implanted into the canine aortic arches. All the
animals survived the operations. The technical success rate
was 100%. During the operation, the double channel cath-
eter successfully paralleled the Lunderquist wire and the
260 cm wires. There was no entanglement of the wires
when the introducer sheaths were pushed into the aortic
arch. There was no accidental detachment of the PET sleeve.

Figure 5. (A) The 260 cm wire was introduced from the left subclavian artery (LSA) to the abdominal aorta. Its tip was pulled out from the
abdominal aortotomy. The Lunderquist wire was introduced from the aortotomy to the left ventricle. (B) The Lunderquist wire and the
260 cm wire were paralleled by the double channel catheter. (C) A 5F vertebral catheter was introduced along the 260 cm wire from the
LSA. Its tip was outside the abdominal aortotomy. (D) The bridge wire passed through the vertebral catheter to establish the pathway for
introducing the branched limb into the LSA. Its tip was outside the LSA. 1. Lunderquist wire, 2. 260 cm wire, 3. double channel catheter, 4.
vertebral catheter, 5. introducer sheath, 6. bridge wire.
Figure 6. (A) The introducer sheath was introduced into the aortic arch along the Lunderquist wire. (B) The folded branched limb was pulled into the left subclavian artery by the bridge wire. (C) The bare stent was released by pushing the top cap forward. (D) Angiography was performed.

Figure 7. (A) The introducer sheath was introduced into aortic arch along the Lunderquist wire. (B) The two folded branched limbs were pulled into the supra-aortic vessels by the bridge wires. (C) The bare stent was released by pushing the top cap forward. (D) Angiography was performed.
from the folded branched limb. Angiography showed that the patency and location of all the branched stent grafts were satisfactory and there was no endoleak. The average operation time of the single and double branched stent grafts was 104.7 ± 9.3 and 111.8 ± 7.9 min, respectively; the average fluoroscopy time was 14.3 ± 2.4 and 20.3 ± 2.7 min; the average contrast load was 46.4 ± 18.4 and 57.6 ± 17.4 mL; and the average blood loss was 23.3 ± 6.6 and 32.8 ± 9.5 mL.

During the follow up period, there was no cerebral infarction, paraplegia, infection, or distal embolization. CTA showed that all the stent grafts were patent, and there was no endoleak, no fracture of the Z stents and no stent migration (Fig. 8).

DISCUSSION

Occurrences of aortic aneurysm and dissection involving the aortic arch are usually associated with a high mortality rate. The 5 year survival of untreated thoracic aortic aneurysm is 20%. The in-hospital mortality of type A aortic dissection is 32.5%. Currently open surgery remains the main treatment for aortic arch diseases. Although there have been advances in surgical techniques and anaesthetic management, open surgery of aortic arch diseases is still associated with a significant mortality (2–16.5%) and stroke rate (2–18%). The hybrid arch repair is a less invasive technique. However, there is no strong evidence indicating that hybrid repair is superior to open surgery. Recently hybrid repair was recommended as a viable option for higher risk patients.

Chimney and fenestration techniques have been used to treat aortic arch diseases, and the short- and mid-term results are favourable. However, the risk of endoleak from chimney and fenestration techniques is much higher in theory.

The branched stent graft consisted of the main stent graft and branched limbs, which are similar to the anatomical structure of the aortic arch. The branched stent graft may replace open surgery and hybrid repair in the future. The branched stent graft can be categorised as modular and unibody. The modular branched stent grafts are assembled in vivo from several components. There have been many reports describing modular branched stent grafts. Among these techniques, the modular branched stent grafts manufactured by Cook Medical (Bloomington, IN, USA) have been applied to human patients. However, the modular branched stent graft has a risk of component separation in the long term. The unibody branched stent grafts are implanted as an integral device and therefore they are theoretically more stable. The main stent graft and branched limbs of this unibody branched stent graft are sutured together. Therefore, the risk of component separation is lower than in modular stent grafts. During the follow up period, there was no endoleak, no fracture of the Z tents, and no stent migration.

For branched stent grafts, the most important procedure is to establish the pathway for introducing the branched limbs into supra-aortic vessels. Inoue et al. and Li et al. established the pathway using a goose neck snare wire to catch the branched limb. However, if the goose neck snare wire could not catch the branched limb, the partially deployed stent graft had to be taken out by open surgery. The detachable sleeve of the introducer system used in this

Figure 8. (A) Computed tomography angiography (CTA) showing the single branched stent graft was patent and did not migrate. (B) CTA showing the double branched stent graft was patent and did not migrate.
study could improve the safety of the operation. First, before the introducer sheath was inserted into the aorta, the pathway had been established by the bridge wire (Fig. 5D). There was no risk of transforming to open surgery. Second, the diameter of the canine (25–30 kg) supra-aortic vessels is about 8–12 mm. The branched limb was folded into the PET sleeve, which was 4 mm in diameter. It would not occlude the blood flow of the supra-aortic vessel during the operation. In addition, the surface of the PET sleeve was smooth. It would not damage the aortic intima. Third, the fixing device at the end of the traction wire could prevent the PET sleeve accidentally detaching from the folded branched limb.

During the operation, entanglement between the Lund erquist wire and the bridge wire results in the main stent graft and the branched limb becoming entangled. Yang et al.17 paralleled the wires by rotating the partially deployed stent graft system in the aortic arch. However, this could damage the aortic intima, especially by aortic dissection. A double channel catheter was used to parallel the entanglement of the wires. The double channel catheter was much thinner and softer than the partially deployed stent graft system. Therefore it was much safer to parallel the wires using the double channel catheter.

In the study, the unibody branched stent graft included single and double branched stent grafts. The single branched stent graft could be used to reconstruct the LSA. The double branched stent graft could reconstruct the total aortic arch in combination with the left common carotid artery (LCCA) to the LSA bypass. The double branched stent graft could also be used to reconstruct the LCCA and LSA. There is also a triple branched stent graft design, which could reconstruct the total aortic arch. However, the complexity of implantation of the unibody branched stent grafts increases exponentially with each additional branch.5

Animal testing had several limitations. First, the canine aortic arch is different from the human arch and therefore the triple branched stent graft could not be tested. Second, the aortic arches of the animal models were normal. There was no dissection or aneurysm. Third, the human arch anatomy has significant morphological differences.20 The unibody branched stent grafts have to be custom-made for apparent anatomical variability. Finally, the introducer sheath applied to human patients could be 22–24F and so the diameter of the stent graft system should be further decreased in future studies.

In conclusion, the unibody branched stent graft system could be used to reconstruct the aortic arch. Compared with modular branched stent grafts, the unibody branched stent graft is much more stable. The detachable sleeve and the double channel catheter could simplify and improve the safety of the implantation procedures.

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CONFLICTS OF INTEREST

None.

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A New Unibody Branched Stent Graft System


