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

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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

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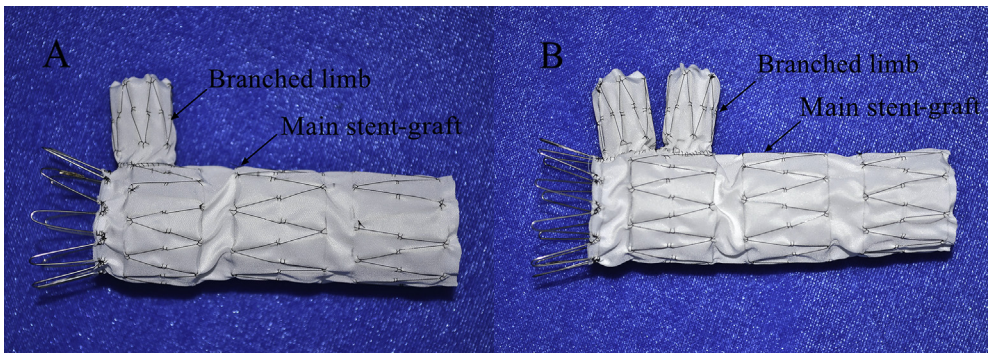

Figure 1. (A) The single branched stent graft consists of a main stent graft and a branched limb. The first Z stent of the main stent graft is a bare stent without barbs. (B) The double branched stent graft consists of a main stent graft and two branched limbs.

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

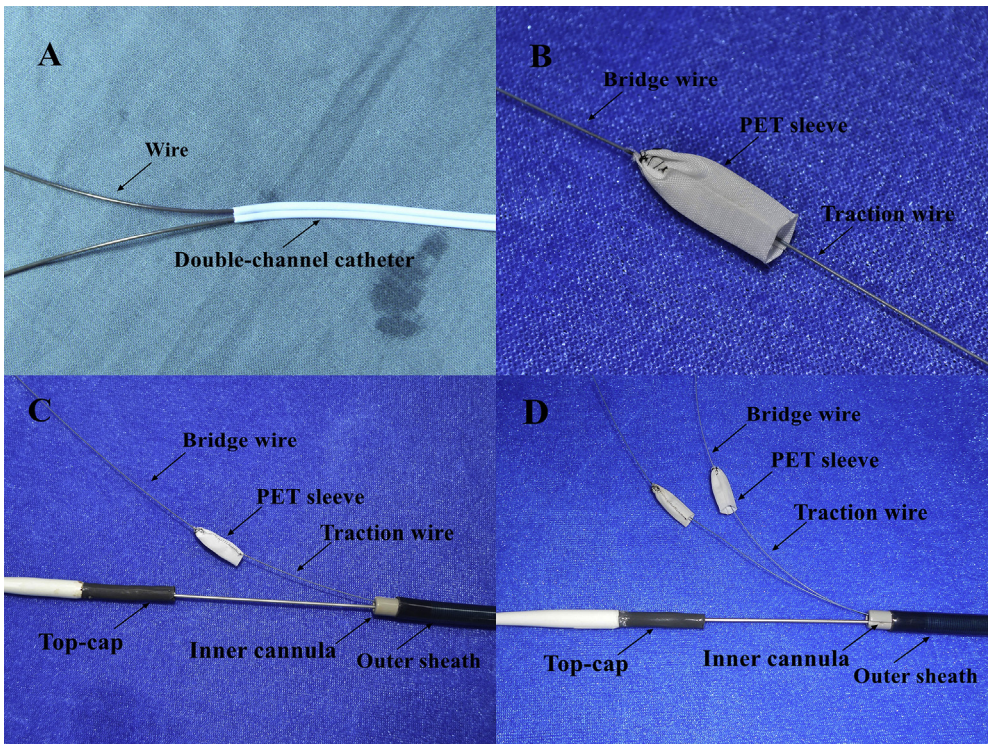

Figure 2. (A) The double channel catheter consists of two 5F catheters. (B) The detachable sleeve consists of a bridge wire, a PET sleeve, and a traction wire. (C) The introducer system of the single branched stent graft consists of a top cap, a detachable sleeve and an outer sheath. (D) The introducer system of the double branched stent graft consists of a top cap, two detachable sleeves, and an outer sheath.

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