

Experimental Assessment of Physician Modified Proximal Scalloped Stent Graft to Extend Proximal Landing Zone in the Aortic Arch

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WHAT THIS PAPER ADDS

A unique model of physician modified scalloped stent graft for one, two, or three supra-aortic trunks and its accuracy of placement over the supra-aortic vessel origins on human cadaveric aorta placed on a benchtop closed system pulsatile flow model was assessed. This model could provide an endovascular alternative to transposition with expansion of the proximal landing zone in zone 2, 1, or 0 for emergency cases with either short proximal zone 3 neck or injuries located at the inner circumference of the aortic arch.

Objective/Background: The aim of the study was to assess a model of physician modified scalloped stent graft (PMSG) on currently available thoracic aortic devices to extend the proximal landing zone in either zone 2, 1 or 0 of the aortic arch while preserving flow in the supra-aortic vessels on human cadaveric aorta.

Methods: Fresh human aortas were harvested at autopsy from adult subjects. A proximal scallop was made on the stent grafts based on direct measurements on the aortas to extend the proximal landing zone in zone 0 ($n = 5$), zone 1 ($n = 5$), and zone 2 ($n = 5$). A previously described benchtop closed system pulsatile flow model was used to mimic flow and pressure conditions in the aorta to deploy the stent graft as close to physiological conditions as possible. Deployment accuracy of the scallop opposite the aortic arch branch ostia was assessed by completion angiography and post-procedural analysis of the aortas.

Results: Fifteen proximal scalloped stent grafts were deployed in the aortic arch of 15 human cadaveric aortas under fluoroscopy. The expected proximal landing zone was achieved in all cases (zone 2 = 5; zone 1 = 5; zone 0 = 5). Post-procedural angiography and direct visual analysis showed supra-aortic vessel patency and deployment of the scallop opposite the aortic arch branch ostia in all cases.

Conclusion: PMSG to extend the proximal landing zone in zone 2, 1, or 0 in order to treat urgent diseases of the proximal descending aorta or the inner circumference of the aortic arch by a totally endovascular approach while preserving flow in the supra-aortic trunks is experimentally feasible.

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INTRODUCTION

Despite considerable advances in endovascular techniques over the last decade and the introduction of fenestrated and branched stent grafts to treat the entire abdominal aorta, treatment of the aortic arch remains one of the last barriers to providing patients with a total endovascular treatment option. Nowadays, hybrid techniques have commonly replaced open repair of the aortic arch. However, there are still significant morbidity and mortality rates with

these less invasive approaches, especially in acute thoracic aortic syndrome.¹ In emergency endovascular repair of the thoracic aorta, expansion of the proximal landing zone in zone 2, 1, or 0 is necessary to achieve a proximal seal in up to 50% of patients.² To date, there is a shortage of commercially available devices to offer these patients endovascular treatment.³ Proximal scalloped stent grafts have been manufactured by companies to overcome neck issues in the arch.⁴ However, construction of these custom made devices can take as long as 6–12 weeks. Patients who present with acute thoracic aortic syndrome cannot be treated with the current modified thoracic stent graft technology, while they are probably the ones who would benefit most from this new approach. Based on the concept of a physician modified fenestrated stent graft to treat an emergency aneurysm involving the visceral aorta,⁴ use of a

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physician modified proximal scalloped stent graft (PMSG) to extend the proximal landing zone in zone 2 have been reported in small case series with promising results.⁶

Enlargement of the physician modified scallop to include one, two, or three supra-aortic trunks could provide an endovascular alternative to transposition for emergency cases with either a short proximal zone 3 neck or in specific cases with aortic arch injuries located on the inner circumference of the aortic arch.

However, appropriate sizing of the scallop based on the targeted supra-aortic vessel origins and placement accuracy of the scallop over them should first be experimentally assessed. The aim of the pilot study was to assess a model of physician-modified scalloped stent-graft for one, two or three supra-aortic trunks and its accuracy of placement in front of the supra-aortic vessels on human cadaveric aorta.

METHODS

The study was approved by the authors' institutional review committee and the ethics committee.

Harvesting and preparation of aortas

With the permission of the department involved and in accordance with French regulations, 15 fresh human aortas were harvested at autopsy from adult subjects who had died a maximum of 4 days previously.

The aortas were procured from above the aortic valve to the coeliac trunk. The brachiocephalic artery (BCA), the left common carotid artery (LCCA) and the left subclavian artery (LSA) were harvested for their maximum length (from 2 cm to > 5 cm). The aortas were immediately placed in ice and maintained at 4 °C. Experiments were performed within 2 h of harvesting. Sections of the aortas were sent to the Department of Pathology for analysis (stained with haematoxylin and eosin) to ensure the presence of a three layer aortic wall comparable to a fresh aorta.

Bench test model

A previously described benchtop closed system pulsatile flow model was used to mimic flow and pressure conditions in the aorta to deploy the stent graft as close to physiological conditions as possible.^{7,8} The pump rate was maintained at 60 beats/minute and systolic/diastolic pressure at 100/60 mmHg. The benchtop pulsatile flow model simulated an aortic arch whose angulations were variable according to the position of the distal aortic connection. Common angulation of the aortic arch of 90° and extreme angulation of 140° were used to assess whether the deployment accuracy of the scallop was modified by the aortic arch angulation.

Experimental set-up

Aorta preparation. After aortic harvest, the BCA, LCCA, and LSA diameters were measured using a ruler, as well as the distance between each supra-aortic vessel. Then an 8 mm knitted Dacron graft was anastomosed to the distal end of

each of the supra-aortic arteries (BCA, LCCA, and LSA). The distal end of each graft was then connected to the closed circuit to ensure an antegrade circulation into the supra-aortic vessels during the experimental set-up. A 20 mm diameter, 30 cm long knitted Dacron graft was anastomosed to the distal end of the aorta to connect the aorta to the closed circuit and to extend the distal part of the aorta in order to reproduce the clinical catheterisation length of access to the aortic arch. Aortic arch curvature was reproduced using an external knob to create a 90° of curvature as previously reported.⁷ The intercostal and lumbar arteries were oversewn (Fig. 1).

Device preparation. The stent graft used was the Valiant Captivia (Medtronic, Minneapolis, MN, USA).

The stent graft was unsheathed for its four first stents. The first uncovered stent and tip capture was tightly surrounded by a surgical loop and put into a 2 mL needle (Fig. 2A). The size of the scallop was based on direct measurements on the aorta: 30% oversizing of the widest supra-aortic trunk diameter included in the scallop was applied to determine the width of the scallop, and the length of the scallop was determined by the measured length between the distal end of the LSA and the proximal end of the first supra-aortic vessel included in the scallop.



Figure 1. Model of human cadaveric aorta preparation.

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