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SHORT REPORT

A Clampless Aortoprosthetic End to Side Anastomotic Device with Large Diameter Aortic Puncher

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Introduction: To facilitate safe anastomosis of a vascular prosthesis onto the proximal ascending aorta without side clamping, a clampless anastomotic device with large diameter aortic puncher was developed.
Report: First, a vascular prosthesis is anastomosed onto the aorta without making a hole, then the aortic wall within the prosthesis is punched out using the device.
Discussion: After further refinement of the present device, endovascular surgery with debranching could be performed more safely and quickly.

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INTRODUCTION

Numerous attempts at automatic vascular anastomosis devices have been made since the end of the Second World War;[1—3] some of them were successful, especially for coronary artery bypass grafting (CABG), and now are commercially available. Side clamping of the aorta could carry a risk of embolic complications, and therefore clampless anastomotic devices have become widespread in the field of off pump CABG.[4—6] In the field of debranching endovascular surgery, ascending aortic side clamping carries more serious risks such as stroke, aortic dissection, or pseudeaneurysm because the aortic wall is more diseased than in patients requiring coronary artery bypass grafting.[7,8] To facilitate the safe anastomosis of a vascular prosthesis to the aorta without side clamping, a large diameter aortic puncher was developed.

TECHNIQUE

The anastomotic device (Japanese patent number 6010075) consists of three parts: (i) aortic wall fixation rod (AWFR) for the fixation of the target aortic wall; (ii) a 10 mm stainless steel blade covered with a protective pipe for cutting out the target aortic wall; and (iii) a suture guide pipe (SGP). As the first step, the AWFR is fixed to the target aortic wall using a polypropylene suture (Fig. 1A). Second, the AWFR is passed through SGP. Third, a 10 mm vascular prosthesis with sewing cuff is placed over SGP, and an anastomosis onto the adventitia to avoid tearing of the aorta is made using a running polypropylene suture (Fig. 1B). Then, the SGP is removed and the aortic puncher is inserted inside the prosthesis. The aortic wall is punched out by the rotating sharp blade inside the aortic puncher at the same time as providing counter traction to the aortic wall by pulling on the AWFR (Fig. 1B). Finally, the cut out aortic wall portion is removed with the fixation rod.

In vitro *assessment*

Using the prototype device, five *in vitro* assessments were performed in porcine aorta. As shown in Fig. 2, the watertight anastomosis could be performed in a clampless fashion. In the inner lumen of the aorta, there were no anastomotic failures and the surface of the anastomosis line was very smooth without any gaps (Video 1).

Supplementary video related to this article can be found at https://doi.org/10.1016/j.ejvsvf.2020.02.003.

The following are the supplementary data related to this article:video 1
video 2

In vivo *assessment using chronic canine model*

All animal procedures conformed to the Guide for the Care and Use of Laboratory Animals prepared by the National Institute of Laboratory Animal Resources and published by the National Institutes of Health (Publication no. 86-23,

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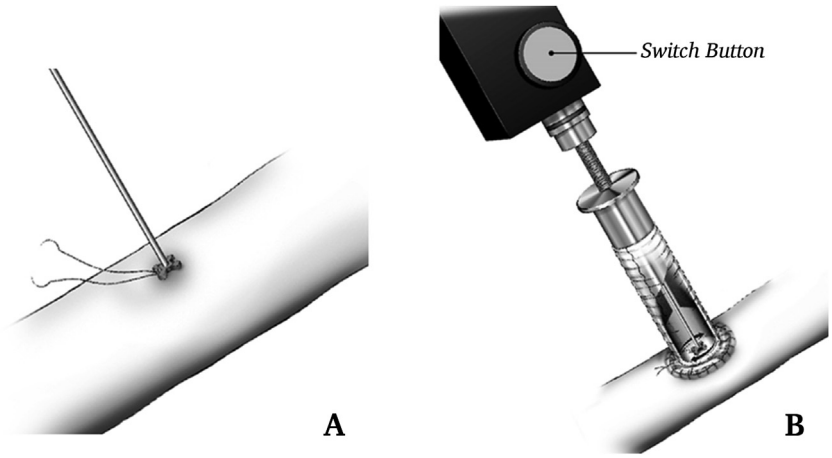

Figure 1. (A) The aortic wall fixation rod is fixed onto the target aortic wall using a polypropylene suture. (B) An adventitia sewn cuff anastomosis is made using a running polypropylene suture, the aortic puncher is inserted inside the prosthesis. The aortic wall is punched out by the rotating blade inside the aortic puncher.

revised 1996). The investigations were reviewed and approved by the local Ethics Committee for Animal Experimentation.

Based on the *in vitro* experiment, a descending aorto—aortic bypass with a 10 mm prosthesis was performed successfully in a canine model. General anaesthesia was induced in a 20 kg dog. The descending thoracic aorta was exposed through a left sided thoracotomy in the fifth intercostal space. Then, two anastomoses were made with the device after systemic heparinisation and the two prostheses were anastomosed together in end to end fashion. The post-operative course was uneventful without any complication and the animal was killed seven months after implantation.

The short descending aorto—aortic bypass was patent. There was no stenosis at either anastomotic site. Macroscopically, the junction between the vascular prosthesis and the native aorta was covered with smooth endothelium (Fig. 3A). This was also confirmed microscopically with Elastica van Gieson staining (Fig. 3B).

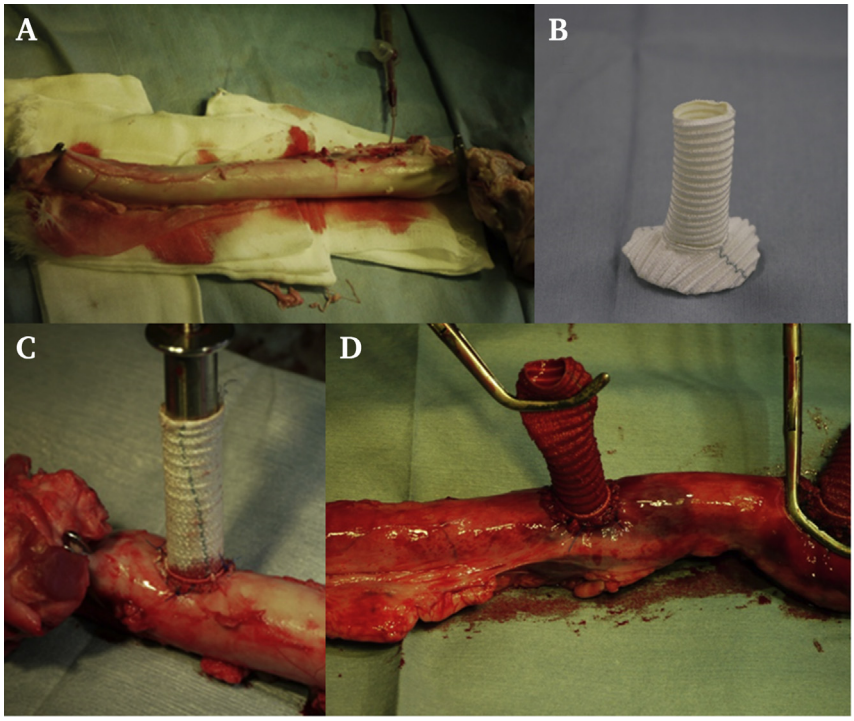

Figure 2. (A) The porcine aorta was filled with heparinised blood with an adequate pressure of 70 mmHg. (B) A vascular prosthesis with sewing cuff. (C) A 10 mm vascular prosthesis with sewing cuff was anastomosed onto the porcine aorta and the aortic wall inside of the vascular prosthesis was punched out by the aortic puncher. (D) Final finding with watertight anastomosis.

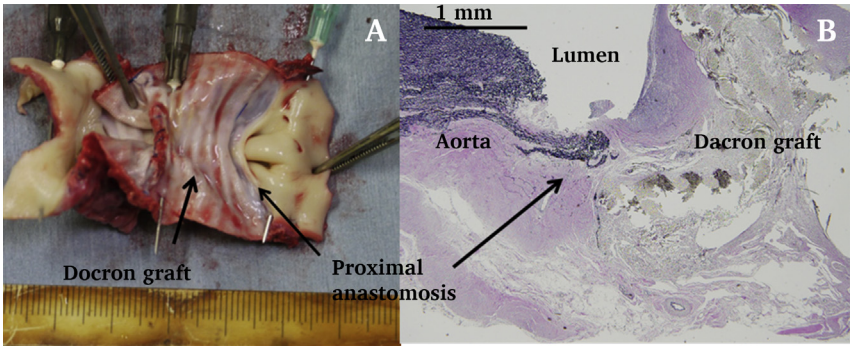

Figure 3. (A) Macroscopic finding of the inner lumen of the anastomotic site. (B) Microscopic findings of the anastomotic site.

In vivo *assessment using acute porcine model*

In the above experiment, the anastomosis was made on the descending aorta, but the ascending aorta is normally more pulsatile and therefore may be more dangerous for this anastomotic device. To confirm the safety of an ascending aortic anastomosis an additional experiment using a porcine model was done. General anaesthesia was induced in a 30 kg pig. The ascending aorta was exposed through a median sternotomy. After systemic heparinisation, an anastomosis was made using the device maintaining a systemic blood pressure of 100 mmHg (Video 2). This experiment demonstrated that no intimal damage occurred even if this device was applied to the ascending aorta.

CONCLUSION

In this study, a clampless watertight anastomosis between vascular prosthesis and the aorta has been demonstrated, using a novel anastomotic device with a large diameter aortic puncher. According to the current guidelines,[9,10] total debranching endovascular surgery with an anastomosis onto the ascending aorta is now only performed in very limited situations. This may be because of difficulty with making a safe aortic anastomosis. There have been some attempts at clampless aortic anastomosis combined with stent implantation through the sewn graft, known as “real chimney technique” in Japan, but these techniques have not been accepted widely.[11,12] However, after refinement of the present device with further assessment using diseased aortic wall, e.g. severe calcification, endovascular surgery with supra-aortic trunk debranching might become a more acceptable option.[9,10]

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