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ORIGINAL ARTICLE

Total aortic arch replacement with a novel four-branched frozen elephant trunk graft: first-in-man results†

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Abstract

OBJECTIVES: The combined disease of the aortic arch and the proximal descending aorta remains a surgical challenge. With the 'frozen elephant technique', the ascending aorta, along with the aortic arch, is replaced conventionally and an endovascular stent graft is placed into the descending aorta in the antegrade manner through the open aortic arch, thereby potentially allowing for a 'single-stage' operation. The purpose of this study was to assess the feasibility of a novel four-branched hybrid graft (Vascutek, Scotland).

METHODS: From April 2010 to August 2011, 34 patients (25 males, age 60 ± 14 years) were operated on [14 aneurysms, 20 dissections (18 acute)]. Ten of these patients had undergone previous cardiac operations. The collapsed endoprosthesis was deployed in the descending aorta through the opened aortic arch. A sewing collar between the graft segments simplified the 'distal' anastomosis. The four-branched graft segment allowed the replacement of the aortic arch and supra-aortic vessels individually. Concomitant procedures were performed if necessary.

RESULTS: There were three deaths within the 30 postoperative days. All of them were of AADA patients. The mean cardiopulmonary bypass time was 254 ± 53 min, aortic cross clamp time was 148 ± 48 min and circulatory arrest time was 48 ± 22 min. Aortic valve-sparing root surgery was performed in 12 patients, Bentall procedure in four, CABG in three and mitral valve repair in two. In one patient, a secondary endovascular extension of the stent graft was necessary to reach the landing zone. In all others, postoperative CT-Scans confirmed the desired results.

CONCLUSIONS: The graft adds to the 'frozen elephant trunk' concept for treating the arch and proximal descending aorta. Early experience demonstrates an excellent 30-day survival. Combining the frozen elephant with a four-branched arch graft increases the armament of the surgeon in the treatment of complex and diverse aortic arch pathology.

Keywords: Aortic arch aneurysm • Frozen elephant trunk • Acute aortic dissection

INTRODUCTION

The combined disease of the aortic arch and the proximal descending aorta (aneurysms and dissection) remains a surgical challenge. Various approaches have been used to treat these complex patients with the use of a deep hypothermic circulatory arrest (HCA) through a sternotomy, left thoracotomy, clam-shell incision or as a two-staged operation with both sternotomy and lateral thoracotomy (elephant trunk procedure and completion) [1–4]. In recent years, either hybrid operations or surgery with the frozen elephant trunk has been proposed [5–8].

The purpose of this study was to assess the feasibility of a novel branched hybrid graft for the treatment of combined diseases of the aortic arch and the proximal descending aorta.

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MATERIALS AND METHODS

Description of the novel hybrid graft

The novel hybrid graft (Vascutek, Scotland) consists of a four-branched arch graft with a stent graft at the distal end. The proximal part is a conventional gel-coated woven polyester graft. The stented section of the graft is a self-expanding endo-prosthesis constructed of polyester and nitinol ring stents, which are attached to a fabric with braided polyester sutures (Vascutek, Scotland) (Figs 1 and 2). The grafts were available in different sizes (28–40 mm in diameter for the stented portion). The length of the stented part was either 100 or 150 mm. Another unique feature of this graft is that the proximal unstented and distal stented parts are available in different sizes (e.g. unstented part with a 32-mm diameter and stented part with a 40-mm diameter).

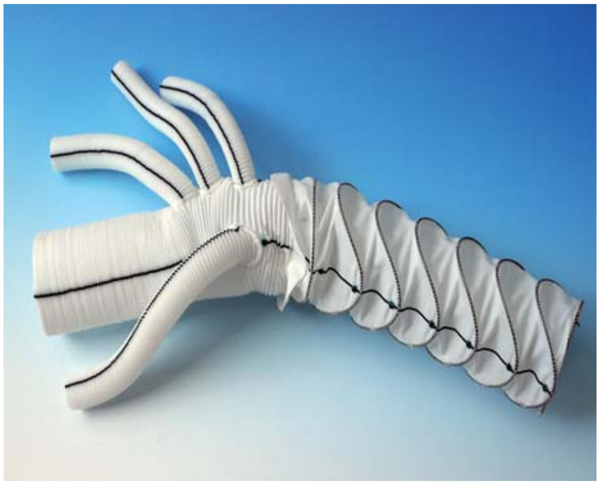

Figure 1: Hybrid graft with released stented section.

Figure 2: Hybrid graft with compacted stented section.

Patients

Between April 2010 and August 2011, 34 patients (25 males, age: 60 ± 14 years) with either aneurysms of the aortic arch and descending aorta or acute aortic dissection, type A (AADA) were operated on [14 aneurysms, 20 dissections (18 acute)]. Ten of these patients had undergone previous cardiac operations. Concomitant procedures were performed if necessary. Informed consent was obtained from all patients. The ethical committee of our institution gave their approval for the study. The patients' characteristics are given in Tables 1 and 2.

Coronary angiography, echocardiography and computer tomography scans were routinely performed in elective patients. In AADA surgery was performed on an emergency basis.

Statistical analysis

Given the heterogenecity of the patient cohort, no statistical analysis was performed.

Table 1: Patient demographics and preoperative clinical data

Number of patients	*n* = 34
Gender	25 males, 9 females
Age (mean)	60 ± 14 years
Aneurysm	*n* = 14
Acute aortic dissection: type A/AADA, DeBakey type I	*n* = 18
Chronic aortic dissection	*n* = 2

Table 2: Previous cardiac operations (10/34 patients)

Number of patients	*n* = 10
Bentall with proximal aortic arch replacement	*n* = 3
Isolated Bentall	*n* = 2
CABG	*n* = 2
Ascending aortic replacement	*n* = 2
Aortic valve replacement (AVR)	*n* = 1

Surgical technique

We have standardized the surgical technique as far as possible. After a standard median sternotomy, extracorporeal circulation was initiated with cannulation of the aorta and the right atrium. This technique of cannulating the ascending aorta even in AADA has been published by our group [9]. The left side of the heart was vented through the right superior pulmonary vein. Blood cardioplegia was our preferred method of myocardial protection. Cardioplegia was repeated approximately every 30 min.

Replacement of the arch was performed under moderate (22–25°C) HCA and selective antegrade cerebral perfusion (SACP).

During the time the patient was cooled to a nasopharyngeal temperature of 22–25°C, the aortic root/ascending aortic procedure was performed. Concomitant procedures (e.g. CABG) were also performed if necessary.

After the patient was cooled to the desired temperature, the systemic circulation was arrested and the aorta opened. With the patient in the Trendelenburg position, catheters (Medtronic DPL, USA) were introduced into the left carotid artery and the innominate artery for the SACP. The subclavian artery was clamped or occluded with a Fogarty catheter (Baxter, USA), thus avoiding the steal phenomenon as well as preventing blood flowing into the operative field.

Cerebral perfusion was initiated at a rate of 10 ml/kg/min. The blood temperature of the SACP was 20–24°C.

The aorta was transected either between the left common carotid artery and the left subclavian artery or distal to the left subclavian artery. The compacted endoprosthesis (Fig. 2) was placed through the opened aortic arch and deployed leaving the stented section positioned in the descending aorta. A sewing collar between the graft segments simplified the 'distal' anastomosis. In AADA patients in whom the distal aortic arch was not aneurysmatic, the distal anastomosis was done between the left carotid and the left subclavian arteries as described by Svensson *et al*. [3]. During open distal anastomosis, blood perfusion to the lower half of the body was either arrested (in AADA) or usually perfused via a Foley catheter placed in the descending aorta in aneurysm cases. The 'distal body perfusion' flow was between 2 and 3 l/min. After the distal anastomosis was completed, the left subclavian artery was anastomosed to the third branch of the hybrid graft. Distal body perfusion via the Foley catheter was stopped and the Foley catheter was then removed from the descending aorta. The perfusion to the lower part of the body and the subclavian artery was then restarted via the fourth branch of the hybrid graft. The proximal end of the hybrid graft was anstomosed, either to the native ascending aorta or the ascending aortic graft. After de-airing the heart, coronary circulation was started again. In this way, the myocardial ischaemia time was reduced to a minimum.

The first and the second branches of the hybrid graft were then anastomosed to the innominate and the carotid arteries, respectively. The patient was re-warmed and once the cardiopulmonary bypass (CPB) was discontinued, the fourth branch used for antegrade perfusion was ligated and resected.

RESULTS

The hybrid graft deployment was successful in all cases. There were no intraoperative deaths. Three patients died within 30 days postoperatively. All of them were AADA patients and died due to multi-organ failure. Aortic valve-sparing root surgery was performed in 12 patients, Bentall procedure in four, CABG in three and mitral valve repair in two. In the total collective, mean CPB time was 254 ± 53 min, aortic cross clamp time was 148 ± 48 min and circulatory arrest time was 48 ± 22 min. The intraoperative data are shown in Table 3.

Perioperative neurological symptoms were classified either as permanent neurological deficit (PND) or temporary neurological deficit (TND). Postoperatively, three patients developed PND, two of whom had preoperative neurological symptoms. Two patients developed TND. No patients developed paraplegia or paraparesis. Two patients developed recurrent nerve palsies.

Twelve patients underwent re-thoracotomy due to postoperative bleeding or cardiac tamponade. Six of them were AADA patients and another three re-do cardiac operation patients. Another five patients died post 30 operative days. Two of these patients could not be weaned from the ventilator. The first had a complex congenital problem of the aorta (right descending aorta) and the second was a 75-year-old patient with a huge arch aneurysm and a previous ascending aortic replacement. Another three patients died post-discharge. Two of these patients died due to the perforation of the down-stream aorta. Both of these patients had AADA. One patient died on postoperative day (POD) 80 POD and the other 245 days POD. In all

Table 3: Intraoperative data

Concomitant procedures (*n* = 14)	
Valve sparing aortic root replacement	*n* = 12
Bentall procedure	*n* = 4
CABG	*n* = 3
Mitral valve repair	*n* = 2
Intraoperative times in total cohort (*n* = 34)	
Cardiopulmonary bypass time (CPB)	254 ± 53 min
Aortic cross-clamp time (X-clamp)	148 ± 48 min
Circulatory arrest time (HCA)	48 ± 22 min
Selective antegrade cerebral perfusion time (SACP)	89 ± 40 min
Total operation time	377 ± 72 min

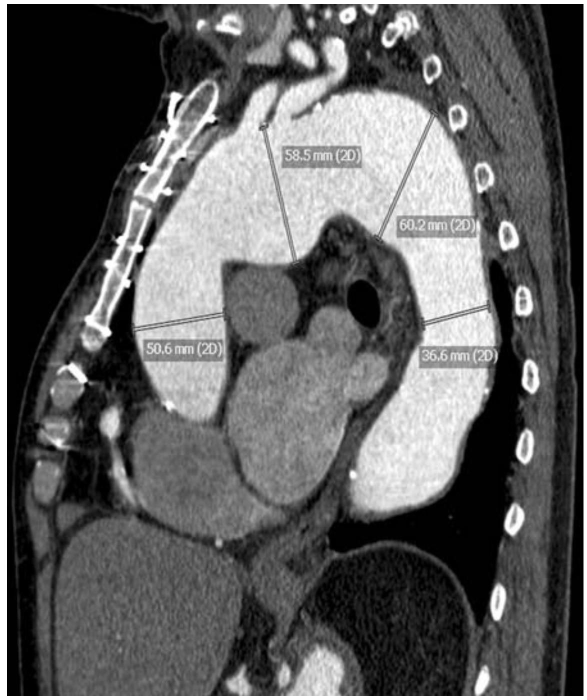

Figure 3: Preoperative CT scan of a patient.

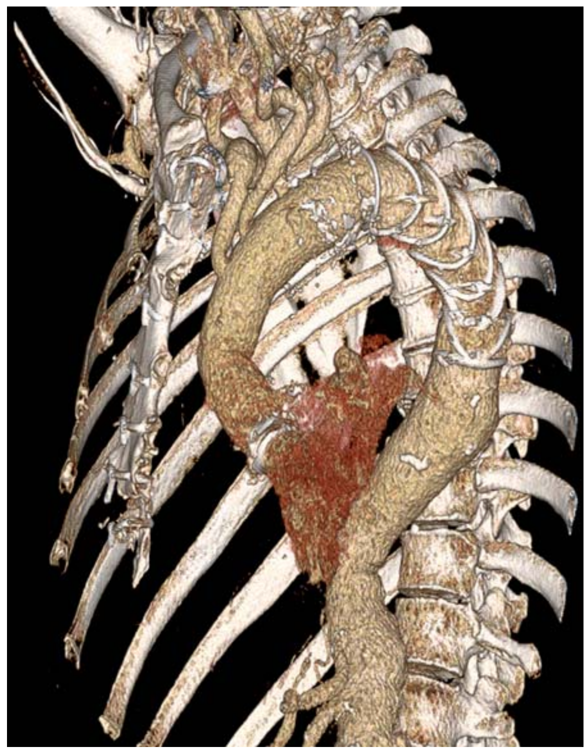

Figure 4: Postoperative CT scan of a patient.

of them, there was no graft dysfunction. In the follow-up, two patients were successfully operated on for their thoraco-abdominal aortic pathology. These two patients also had AADA. The first patient received a prolongation of the hybrid stent with an endovascular stent 208 days after the initial operation. The second patient was a Marfan patient and received a thoraco-abdominal aortic replacement 345 days after the initial operation. Figures 3 and 4 show a pre and postoperative CT of a patient.

DISCUSSION

The combined disease of the aortic arch and the proximal descending aorta remains a surgical challenge. Different techniques have been proposed. In patients with extensive aortic aneurysms, classically, a two-stage operation was performed. In the first stage, the ascending, as well as the aortic arch, was replaced through a median stenotomy. In the second stage, the descending thoracic aorta was replaced through a lateral thoracotomy. Borst *et al*. [1] introduced the so-called elephant trunk technique in 1983, greatly facilitating this two-stage technique. A significant disadvantage of this approach was the need for two operations with their associated mortality and morbidity as well as the fact that there was at least some mortality in the interval between the two operations due to the rupture of the untreated segment of the aorta. Some surgeons advocated a single-stage operation either through a clamp-shell incision or a combined median sternotomy and a lateral thoracotomy to repair the aortic arch as well as the descending aorta. Such a strategy is quite invasive for the patient and technically difficult for the surgeon and as such has been followed only by few centres [4].

The endovascular stent graft technology introduced by Dake *et al*. [5] in 1998 has facilitated the treatment of the descending aorta. However, a totally endovascular treatment of the aortic arch pathology is difficult because of the supra-aortic vessels. A combination of the classic 'elephant trunk' technique and the endovascular stent technology resulted in the so-called frozen elephant technique [6, 7]. In this potentially single-stage technique, the operation is performed through a median sternotomy. The ascending aorta along with the aortic arch is replaced conventionally and an endovascular stent graft is placed into the descending aorta in the antegrade manner through the open aortic arch. The non-stented part is used for the ascending aorta and the arch and a stented part for the descending aorta. The distal landing site of the stent graft can be placed at the non-diseased portion of the descending aorta.

In the classic elephant trunk technique, the graft portion forming the 'elephant trunk' in the descending aorta floats freely in the descending aortic lumen so that there is little or no thrombus formation between the graft and the aortic diseased wall. In the frozen elephant trunk technique, the stented segment allows for progressive thrombus formation in the peri-graft space up to the level of the landing site. This reduces the wall stress on the aorta and thus helps in preventing the subsequent growth of the aortic diameter. Owing to this reason, the frozen elephant trunk technique is becoming more popular. Initially, such operations were performed with a home-made 'hybrid prosthesis' with a stented and a non-stented segment [7]. At present, one 'off-the-shelf hybrid' prosthesis is available in the market. The advantages of the investigational device against the commercially available one are explained below.

It is controversial whether such an aggressive technique should be used in AADA patients. With the advances in diagnosis, surgical techniques, anaesthesia and perioperative care, the outcome of surgical repair in AADA has improved. Even then, AADA continues to be associated with high morbidity and mortality [10]. Therefore, some conservative surgeons advocate only an ascending aortic replacement with or without the replacement of the proximal arch. Kazui *et al*. [11] recommended a more aggressive strategy with total aortic arch replacement to improve the late surgical outcome. Ando *et al*. [12] proposed a total aortic arch replacement with a conventional elephant trunk to achieve a stronger distal anastomosis and facilitate possible subsequent operations on the downstream aorta.

Replacement of the arch with simultaneous antegrade descending stent-grafting using a hybrid prosthesis implantation can lead to the avoidance of late downstream complications after a classic DeBakey type I aortic dissection repair. This has been shown by the Essen group [13, 14].

Total replacement of the ascending and aortic arch in AADA patients does demand high technical skills [15]. Even then, we believe in such a strategy of total aortic arch replacement with a frozen elephant trunk to improve long-term outcome in cases of AADA with intimal tear or re-entry into the aortic arch or the descending aorta (DeBakey type I). Of course, such a strategy can only be implemented in centres of excellence and also if it is absolutely necessary and not routinely in all the acute dissection patients. In such situations, this hybrid prosthesis could play a positive role.

For the re-implantation of the arch vessels, currently either the en-bloc (island) technique or branched graft technique (BGT) is used. The BGT may have several advantages over the classical island technique. Di Eusanio *et al*. [16] showed that the perioperative risks are not increased with the BGT technique. The proposed advantages are:

(1) In atheromatous aneurysms, the cerebral emboli risk may be reduced by the replacement of the complete aortic arch and the proximal parts of the arch vessels that are normally left behind in the island technique.
(2) The CPB and especially the myocardial ischaemic times are shorter than in the island technique because after completing the distal anastomosis, the proximal anastomosis to the ascending aorta or the root (depending on the case), myocardial perfusion can be started. The arch vessels can be re-implanted with the myocardium perfused.
(3) The lower body ischaemia time as well as ischaemia of the left subclavian region can be reduced.
(4) Haemostasis is easier.

Despite these proposed advantages, currently no hybrid grafts with a branched unstented segment are available in the market. This investigational device combines the advantages of the frozen elephant technique with that of the branched plexus graft for the aortic arch and the supra-aortic vessels. Implantation of the stented portion of the graft into the proximal descending aorta is simple and can be done under direct surgical vision. Additionally, the grafts were available in different sizes and lengths. The fact that the proximal unstented and distal stented portions are available in different sizes excludes the necessity of having to replace the aortic arch with a large-sized graft when treating a large descending aorta. This is a big advantage over the commercially available hybrid graft.

We have standardized our technique. Our collective was operated on by three surgeons. Although technically demanding, this procedure is reproducible, with low mortality in experienced hands.

LIMITATIONS

Limitations of this study are the relatively small number of the patient cohort as well as a relatively short follow-up. Further evaluation and longer follow-up of this novel hybrid graft are warranted. Also, we do not have a control group to compare the study patients as this was primarily a feasibility study.

CONCLUSIONS

The graft substantially adds to the 'frozen elephant trunk' concept for treating the arch and descending aorta. Early experience demonstrates an excellent 30-day survival. Furthermore, the preoperatively set treatment goal was reached in all but one patient. Combining the frozen elephant with a four-branched arch graft substantially increases the armament of the surgeon in the treatment of the complex and diverse aortic arch pathology.

Conflict of interest: none declared.

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APPENDIX. CONFERENCE DISCUSSION

Dr H. Jakob *(Essen, Germany)*: I think it's an interesting tool and adds to our armamentarium to deal with the arch and the proximal descending aorta. But nevertheless, I have to ask you a couple of questions. And I play a little bit Jean Bachet, because I also was confronted with questions like 'what is the indication in the acute type A aortic dissection to implant the graft in your setup?'

Dr Shrestha: We in Hannover do not agree completely with Dr. Bachet. I think it's not enough to say type A dissection, it has to be type 1. Because if it is type 2, we don't need to do it. And I think the reason for this graft, I would say, is that if the aortic arch is circularly dissected, that would be one; and, second, I think if there is a reentry in the arch or the upper part of the descending aorta, of course. What we believe is that, at least in centres of excellence like yours where you do a lot of surgery, or in our centre where we do a lot of this type of surgery, I think it is safe to do total arch replacement with frozen elephant trunk even in type A, type 1 dissection. So I have to clarify that.

Dr Jakob: The second question, the last one, what about sizing? What I've learned from the paper you provided beforehand is that the graft starts out at 28 mm. So in acute situations sometimes the true lumen is quite narrow. So are you oversizing?

Dr Shrestha: No, the grafts go from 28 to 40, the stented parts, and the unstented part goes from 26.

Dr Jakob: But in the proximal descending aorta sometimes the true lumen is quite narrow. And we have learned in our series not to oversize more than 10% or so.

Dr Shrestha: Correct. But because the stent of this graft is not that stiff, I think even if you do a little bit of oversizing it doesn't press against it that hard. At least we haven't seen any rupture with this graft.