

Treatment of complex disease of the thoracic aorta: the frozen elephant trunk technique with the E-vita open prosthesis[☆]

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Abstract

Objective: The treatment of complex aortic pathologies of the thoracic aorta remains a challenging issue in aortic surgery. The most recent development of the classic elephant trunk technique, the ‘frozen elephant trunk’ technique, represents the combination of an endovascular approach with a conventional surgical treatment for a hybrid approach. **Methods:** Between January 2007 and July 2008, 34 patients were operated on for complex pathologies of the thoracic aorta using the frozen elephant trunk technique. There were 29 males (85.3%) and the mean age of 61.7 ± 9.6 years. The majority of patients ($n = 18$, 52%) presented type A chronic dissection, 7 (21%) patients had chronic aneurysm of distal aortic arch and 7 (21%) type B aortic dissection associated with ascending aorta/aortic arch aneurysm. There were two (6%) cases of acute aortic dissection. Nineteen patients (56%) underwent previous cardiovascular operations. **Results:** The overall in-hospital mortality was 6% (two patients). No patient developed postoperative stroke. Ischemic spinal cord injury occurred in three cases (9%) (two paraparesis, one paraplegia). There were five cases (15%) of renal failure (dialysis) and four patients (12%) had pulmonary complications with prolonged mechanical ventilation. Four patients (12%) needed rethoracotomy for surgical bleeding. Six patients (18%) required extension of the descending thoracic aorta repair with endovascular treatment for persistent perfusion of the dilated false lumen. **Conclusions:** The frozen elephant trunk technique with the new E-vita open prosthesis combines surgical and interventional technologies and represents a feasible and efficient option in the treatment of complex aortic pathologies. Strict monitoring of the patient has to be carried out in order to detect possible evolution of the aortic lesion, which can require prompt treatment. However, long-term follow-up is required.

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Keywords: Aortic aneurysm; Aortic dissection; Hybrid aortic surgery

1. Introduction

The surgical treatment of diffuse pathologies of the thoracic aorta remains a challenging issue in aortic surgery. Classically, they are treated with a two-step approach known as the ‘elephant trunk procedure’ [1]. Recently, a hybrid repair combining endovascular treatment with conventional surgery, the so-called ‘frozen elephant trunk’ (FET) technique [2–5], has been described as a single-stage procedure. Even if experience with this technique is very limited, early results, reported by various authors [6–10], seem to be encouraging.

In this paper, we present our early experience, including the short-term follow-up, with the FET technique using the E-vita open prosthesis.

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2. Materials and methods

2.1. Patients profile

From January 2007 to July 2008, 34 consecutive patients were operated on for complex pathologies of the thoracic aorta using the frozen elephant trunk technique. Informed consent was obtained for each patient. The data were acquired prospectively as part of the patients’ pathway and were presented as mean \pm standard deviation.

Twenty-nine (85.3%) patients were male and the mean age was 61.7 ± 9.6 years (range, 35–78 years). Main risk factors were arterial hypertension in 28 patients (82%), smoking history in 16 (47%). Four patients (12%) had preoperative chronic renal insufficiency defined as preoperative creatinine >2 mg/dl.

Eighteen patients (52%) presented with type A chronic dissection, 7 (21%) chronic aneurysm of distal aortic arch and 7 (21%) type B aortic dissection associated with ascending aorta/aortic arch aneurysm. There was 1 (3%) case of acute

Table 1
Patient characteristics.

Variable	No. of patients	Percent
Age (mean \pm SD)	61.7 \pm 9.6 years	
Gender (male/female)	29/5	85/15
NYHA classification		
I–II	29	85
III–IV	5	15
Hypertension	28	82
COPD	3	9
Smokers	16	47
Marfan syndrome	2	6
Dyslipidemia	5	15
CAD	4	12
Previous aortic surgery	19	56
Preoperative renal insufficiency	4	12
Disease of the aorta		
Chronic type A dissection	18	53
Chronic aneurysm of the distal arch	7	21
AscAo and arch aneurysm and type B dissection	7	21
Acute dissection	2	6
Type A	1	
Type B	1	

AscAo: ascending aorta; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease.

type A and 1 (3%) case of acute type B aortic dissection. Nineteen patients (56%) underwent previous aortic operations.

The preoperative details of the patients are shown in Table 1.

2.2. Hybrid endovascular prosthesis

The E-vita open prosthesis (Jotec Inc., Hechingen, Germany) consists of a single polytetrafluoroethylene graft encapsulating circumferential Z-shaped nitinol rings along its length and a Dacron prosthesis at the proximal end. There is no longitudinal support along the length of the graft, as the Z-rings are not linked together to provide exceptional flexibility inside the vessel. The length of the crimped Dacron part is 70 mm, and the length of the stent graft is 150 mm in sizes 24–30 mm and 160 mm in larger sizes. The stent graft is available in diameters of 24–40 mm.

2.3. Surgery

Operations were performed through a median sternotomy in all patients. After systemic heparinization, a guide-wire was inserted through the right femoral artery in the descending thoracic aorta under transesophageal echocardiographic control. In case of aortic dissection, the guide-wire was positioned in the true lumen of the aorta. Cardiopulmonary bypass (CPB) was instituted with an arterial cannula introduced into the right axillary artery and with a venous single two-stage cannula introduced into the right atrium. In only one patient (2.9%) we used ascending aorta as arterial inflow. Cerebrospinal fluid drainage was used in 13 patients (38%).

The cerebral protection method consisted of antegrade selective cerebral perfusion (ASCP) and mild hypothermia, as previously described in greater detail [11,12]. Cerebral

monitoring was achieved by means of jugular bulb venous oxygen saturation and/or near infrared spectroscopy. A transcranial Doppler scan was rarely used. After the target nasopharyngeal temperature of 26 °C was reached, the cardiopulmonary bypass was reduced to one liter per minute of flow and the innominate artery was clamped in order to obtain a unilateral brain perfusion. After circulatory arrest, the ascending aorta and aortic arch were opened maintaining the patient in the Trendelenburg position, then a special catheter for ASCP connected to the oxygenator with a separate single roller pump head, was inserted into the left common carotid artery and the perfusion of the left hemisphere was initiated with a flow rate of 5 ml/kg/min. In the case of ascending aorta cannulation, catheters for ASCP were inserted into the brachiocephalic trunk and left common carotid artery. The left subclavian artery was always clamped in order to avoid the steal phenomenon.

Myocardial protection was achieved using cold crystalloid cardioplegia (Custodiol, Koehler Chemie, Alsbach-Haenlein, Germany).

The distal aorta was prepared using a Teflon felt externally and fixed with some pledgetted stitches. The stent-graft system (E-vita open; Jotec Inc., Hechingen, Germany) was introduced in an antegrade manner in the descending aorta over the previously positioned stiff guide-wire and released with a pull back system. The proximal landing zone was approximately 2–4 cm distal to the left subclavian artery in order to have the distal end of the stent graft at T7 level or higher. The incorporated non-precoated Dacron graft was pulled back, cut to a minimum and sutured to the previously prepared descending aorta. A 14 mm Hegar dilator was inserted inside the E-vita prosthesis in order to check the opening of the stent-graft.

A vascular prosthesis was then prepared and anastomized with the cuff composed by the native aorta and the E-vita prosthesis. The systemic perfusion was then antegradely restored through the side branch of the graft, the epiaortic vessels were reimplemented and the correct opening of the stent was controlled with the transesophageal echocardiography.

In all patients the entire aortic arch and the proximal portion of the descending aorta were replaced. In 22 of them (65%) the ascending aorta was additionally replaced. Eight patients (24%) underwent aortic valve replacement and six (18%) underwent Bentall procedure. In 17 patients (50%) supra-aortic vessels were reimplemented as separated graft, while in the remaining 17 (50%) the 'en bloc technique' was used. Four patients (12%) needed additional myocardial revascularization as associated procedure. The operative procedures are summarized in Table 2.

3. Results

The mean duration of ASCP was 94.5 \pm 16.8 min (range 68–132) with a mean CPB time of 233.3 \pm 45.7 min (range 157–335).

The myocardial ischemic time and the visceral ischemic time was 164.1 \pm 43.5 min (range 105–296) and 78.7 \pm 16.1 min (range 44–109), respectively.

The overall in-hospital mortality was 6% (two patients). One patient died from cardiac arrest, due to ventricular

Table 2
Operative procedures.

Procedure	No. of Patients	Percent
Extension of aortic replacement		
Ascending aorta + Arch + FET	22	65
Arch + FET	12	35
Associated procedures		
AVR	8	24
Biological valve	5	15
Mechanical valve	3	9
Bentall	6	18
Biological conduit	4	12
Mechanical conduit	2	6
CABG	4	12

AVR: aortic valve replacement; CABG: coronary artery by-pass grafting; FET: frozen elephant trunk.

fibrillation, in the intensive care unit (ICU) a few hours after the operation. The other one with chronic aortic dissection type A, who sustained a postoperative pancreatitis, died from abdominal aortic rupture on 42nd postoperative day.

No stroke occurred. Ischemic spinal cord injury occurred in three cases (9%): two patients suffered from paraparesis and one from paraplegia. Five patients (15%) had renal failure (dialysis) and four patients (12%) had pulmonary complications with prolonged mechanical ventilation. Four patients (12%) underwent rethoracotomy for surgical bleeding. A coarctation of the stented segment of the hybrid prosthesis with a pressure gradient between the radial and femoral arteries of 52 mmHg occurred in a Marfan patient who presented a severe tortuosity of the true lumen on the dissected descending thoracic aorta. The patient was successfully treated with endovascular procedure. A Medtronic Valiant thoracic stent graft (Medtronic/AVE, Santa Rosa, Calif.) was placed and ballooned inside the E-vita open graft. A good angiographic result was achieved with the disappearance of the arterial pressure gradient.

3.1. Follow-up

Mean follow-up was 8.6 ± 4.7 months. Actuarial survival rate was $90 \pm 6\%$ at 12 months (Fig. 1). There was one death (3%) 7 months after the initial procedure. The patient died from rupture of the abdominal aorta after endovascular treatment for abdominal aortic aneurysm. Postoperative CT scans, performed in all discharged patients, revealed a complete thrombosis of the perigraft space around the stented segment of the E-vita open prosthesis in 25 patients (78%)(Fig. 2). Six patients (18%), four (13%) with chronic type A and two (6%) with chronic type B aortic dissection, required extension of the descending thoracic aorta repair with endovascular treatment for persistent perfusion of the dilated false lumen 1.7 months of mean after the initial operation (range 1–4 months) (Fig. 3).

4. Discussion

Diffuse aneurysmal disease of the thoracic aorta is traditionally treated with the 'elephant trunk' technique described by Borst and colleagues in 1983 [1]. This technique facilitates the construction of the distal anastomosis during

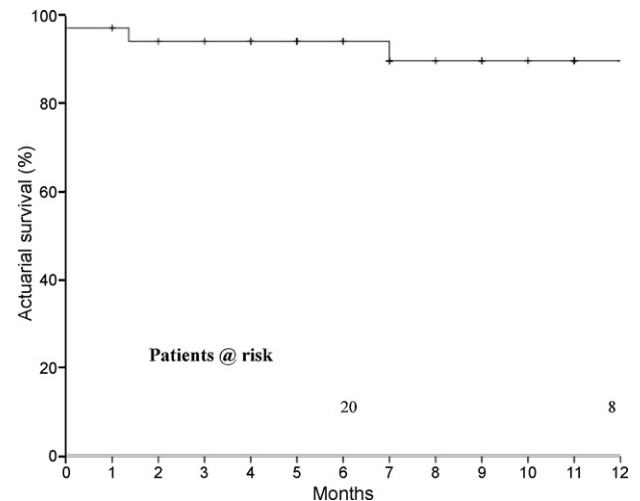


Fig. 1. Actuarial survival rate of overall patients.

the initial operation and avoids hazardous dissection of the distal aortic arch during the second step. However, this staged approach is associated with a considerable overall mortality and morbidity [13,14]. In order to improve the outcomes, few methods of single-stage repair have been proposed. Most of them are performed through a clamshell incision [15–17]. The surgical invasiveness of the bilateral anterior thoracotomy is not innocuous and it is potentially associated with a high incidence of pulmonary complications. With this technique Kouchoucos reported good results in terms of early mortality (7.2%) but he described a very high

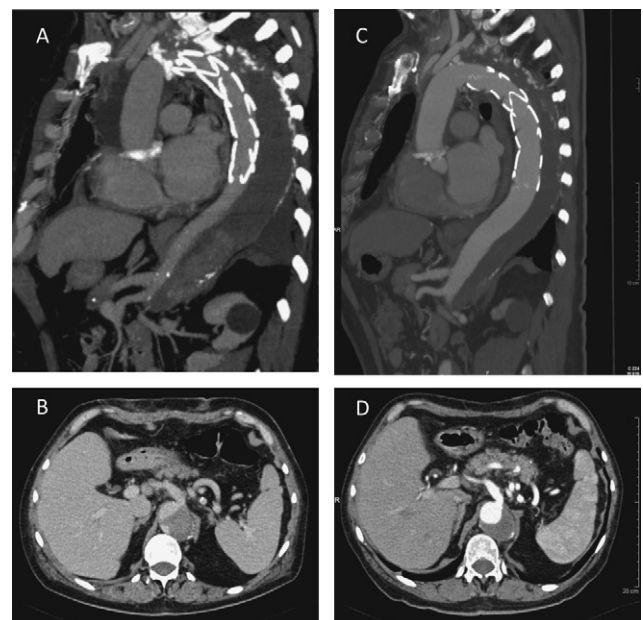


Fig. 2. Multidetector CT scans of a patient with chronic type A aortic dissection following frozen elephant trunk procedure 1 week (A, B) and 3 months (C, D) postoperatively. At 1 week postoperatively the false lumen around the stented segment of the E-vita open is totally thrombosed, while it remains partially perfused in the distal thoracic aorta (A, B). The false lumen is completely thrombosed down to the celiac artery at 3 months postoperatively (C, D). The diameter of the true lumen became wider at the level of the celiac artery when compared to 1 week postoperatively.

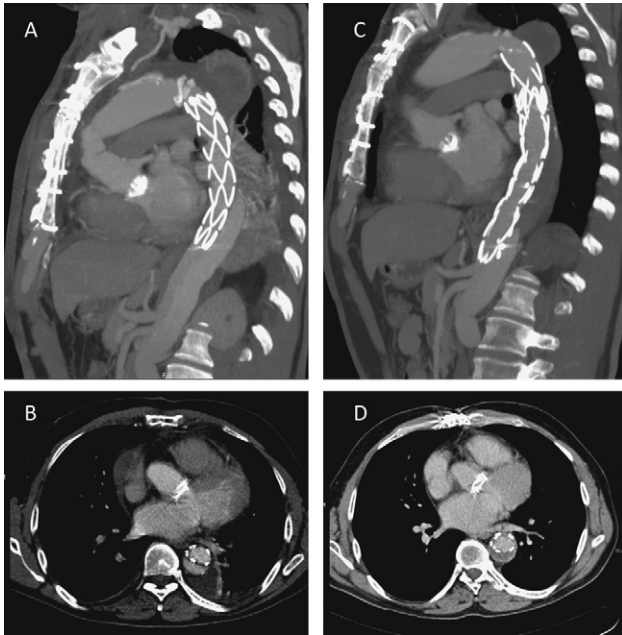


Fig. 3. Multidetector CTscans of a patient with chronic type A aortic dissection 1 week after frozen elephant trunk procedure (A, B), and after retrograde implantation of endovascular prosthesis (C, D). The dilated false lumen remains well perfused because of a large re-entry below the stented segment of the hybrid prosthesis (A, B). A complete thrombosis of the thoracic false lumen appears after endovascular repair with a persistent perfusion of the false lumen in the abdominal aorta (C, D).

incidence of postoperative pulmonary complications: a mechanical ventilatory support for more than 72 h was required in 50% of the operative survivors, and in 13% a tracheostomy was necessary [15]. A transmediastinal single-stage approach was also proposed by some authors [18,19]. Beaver et al. [18] presented a series of 14 patients who underwent single-stage transmediastinal replacement of the ascending arch, and descending aorta with an acceptable mortality (14%) but with a high incidence of paraplegia (14%).

We had a good experience with the anterior approach through a median sternotomy possibly associated to a small left thoracotomy for treatment of diffuse aneurismal disease of the thoracic aorta: we operated on 20 patients without any death and without any major neurological complication [19]. However, in some cases we found it very difficult to expose the distal aorta and to perform the distal anastomosis.

A new approach, the 'frozen elephant trunk' (FET) technique, developed by some Japanese authors [2–4] consists of treating the combined lesions of the thoracic aorta during a single-stage procedure combining endovascular treatment with conventional surgery.

Experience with the FET technique is limited but early results [5–10] seem to be encouraging.

Our experience confirms this trend; we had a mortality rate of 6% and a relatively low morbidity. However, these are very complex and time-consuming operations, and good results can be obtained only if good strategies of myocardial, cerebral and visceral protection are adopted.

Antegrade selective cerebral perfusion, as demonstrated by various authors [11,12,20–22], is the best method of brain protection during aortic arch surgery and, even if there are

surgeons who still propose deep hypothermic circulatory arrest as the sole cerebral protection method [23], in these challenging and time-consuming operations its use is essential.

No stroke developed in patients in our series. This rate is quite low compared with the stroke rate reported by Baraki et al. [6] with a similar approach. However, we had a relatively high incidence of spinal cord injury compared with that reported by the same authors: one case of paraplegia and two of paraparesis. This difference may be due to the higher rate of dissection of the descending aorta in our series (79% vs 54%). In fact, all three patients who sustained spinal cord injury (SCI) had a chronic type A aortic dissection involving the whole thoraco-abdominal aorta. The thrombosis of the false lumen on the descending aorta may lead to spinal cord ischemia with various degree of neuronal damage. Thromboembolism is also advocated to be a possible mechanism of ischemic SCI.

We did not find any correlation between ASCP and visceral ischemia times and SCI.

Cerebrospinal fluid drainage is a well known method of spinal cord protection during endovascular and surgical aortic repair. We use this technique in 13 patients and SCI did not occur in any of them.

Extensive coverage of the descending thoracic aorta during FET is associated with an increased risk of post-operative SCI [24]. For this reason we limited the deployment of the stent at the T7 level or higher.

We found the FET procedure very useful, above all in chronic dissection after acute type A aortic dissection repair or in the case of type B dissection associated with ascending or arch aneurysms. In type B aortic dissection, sealing of the primary tear is the goal of the endovascular procedure in order to restore the flow into the true lumen leading to thrombosis of the false lumen. This is the same objective we hope to obtain with the FET technique by positioning the stent of the E-vita open in the true lumen. Visceral ischemia after the complete sealing of the false lumen could occur if the abdominal arteries arise from the false lumen itself and no re-entry is present in the distal aorta. This is a very rare possibility because there is always re-entry in the descending, abdominal aorta or in the iliac arteries. However, careful evaluation of the thoraco-abdominal aorta has to be carried out before surgery. In our experience we did not have any case of visceral malperfusion due to false lumen occlusion because of the known presence of re-entry sites in the distal aorta. We believe that the FET procedure should be contraindicated if re-entry sites are not visualized in the distal descending thoracic and/or abdominal aorta and the visceral arteries arise from the false lumen.

The correct positioning of the E-vita can be achieved using a guide-wire positioned in the true lumen under transesophageal echocardiography before starting the cardiopulmonary bypass. Moreover, transesophageal echocardiography provides useful information about the correct opening of the stent.

Incomplete sealing of the primary tear is not uncommon; however, in these cases, a complete or partial thrombosis of the false lumen can occur later, justifying a wait-and-see policy [25]. For these patients, a close follow-up is necessary. In case of persistent perfused false lumen, a further repair

can be easily performed. In six patients of our series, an endovascular repair of the descending thoracic aorta was performed because of a wide perfusion of dilated false lumen.

In conclusion, the frozen elephant trunk represents an effective surgical option for the treatment of complex aortic disease of the thoracic aorta. Strict monitoring of the patient has to be carried out in order to detect possible evolution of the aortic lesion, which can require prompt treatment. A definitive single-stage treatment is achieved in case of aneurysm limited to the descending thoracic aorta. In case of dissection involving the entire thoraco-abdominal aorta, a further repair may be necessary. Long-term follow-up is required.

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Appendix A. Conference discussion

Dr C. Hagl (Hannover, Germany): We are all aware that the treatment of complex aortic arch pathologies can be challenging, especially if the disease extends into the descending aorta. In the early 80s, it was Professor Borst who invented the conventional elephant trunk technique which allows us to approach the arch and the descending aorta via a median sternotomy. In a second step through a lateral thoracotomy, the freely floating prosthesis could be used to attach another graft down to the desired level.

However, recent publications by Dr Etz and Dr Safi showed that the cumulative mortality for the two procedures as well as the risk of rupture in between can be substantial.

With an increasing expertise in stenting of the thoracic aorta in the late 90s, hybrid approaches became increasingly popular over time. The technique of the frozen elephant trunk allows us to perform the operation via a midsternotomy and to replace the complete aortic arch with the opportunity to guide the stented part into the descending aorta. Concomitant procedures such as coronary bypass surgery and/or AVR can be done easily.

The authors present the results after treatment of complex aortic arch pathologies with the commercially available frozen elephant trunk. Over a period of 18 months, they operated on 34 patients. The majority had chronic type A aortic dissection, but there were also two patients with AADA. More than 50% were reoperations, which is a remarkable number.

The overall in-hospital mortality was only 5.9%. Ischemic spinal cord injury occurred in three patients causing paraparesis in two and paraplegia in one. These results are in accordance with the results in the literature as Dr Karck showed in his wonderful review, which has been published in the journal earlier this year.

My first questions connect to each other and are addressing your concept of spinal cord protection. In your manuscript, I missed the information whether you performed CSF drainage or not. If so, I would ask you on the specific protocol of the target pressure and the time point when you place the catheter into a fully heparinized patient. In this context, what are your thoughts concerning the value of muscle evoked potentials?

Dr Pacini: Regarding your question about spinal cord protection, we had three cases of spinal cord injury, two cases of paraparesis, clinically improved before discharge, and one case of paraplegia.

One of our methods of spinal cord protection is the spinal fluid drainage. We were very afraid of doing spinal fluid drainage during this kind of operation,

so we did not start from the beginning of our experience putting the line in. However, after the first case of paraplegia, we start to use it. We drain the cerebral liquid in order to maintain an intrathecal pressure of 12 mmHg or less.

Another method of spinal cord protection we adopted is to reperfuse the distal thoracic aorta as soon as possible. So at the end of the distal anastomosis, we cannulate the new prosthesis, and we start the perfusion.

Recently, and we did it only in four or five patients, we started to perfuse the left subclavian artery in order to improve the perfusion of the spinal cord.

However, we really don't know the cause of the spinal cord injury. We compared our experience with the experience of your center: you did not have any kind of spinal cord injury even if you used the same degrees of systemic hypothermia and the time of visceral ischemia was almost the same; we had a visceral ischemic time just 7–8 min longer. So the only difference that I could find was that more than 80% of our patients had a dissection on the descending thoracic aorta. This finding may be related to the spinal cord injury.

Dr Hagl: How long do you keep your catheter in place?

Dr Pacini: How long? Up to the fifth postoperative day.

Dr Hagl: The second question is a more technical one. We probably both agree that sufficient circumferential mobilization of the proximal descending aorta is essential to avoid later bleeding complications. How do you perform your sizing in patients with chronic dissections?

Dr Pacini: So for the sizing, yes, in chronic aneurysm it is not a big problem. We always size the graft according to the preoperative CT scan, and we oversize for 10% the dimension of the distal descending aorta at the level of the pulmonary artery.

In chronic dissection, sizing is harder and more difficult. We try to size the prosthesis according to the hypothetical dimension that the aorta should have. I mean that we evaluate the preoperative CT scan, the axial CT scan, and we look at the true lumen and the false lumen, and we try to know how the aorta in that patient has to be. And then, during the operation, we also size the proximal landing zone, and we choose the size of the prosthesis according to these methods.

Dr K. Kallenbach (Heidelberg, Germany): I just would like to comment on the technique. How do you treat in the arch the prosthesis because this is not preclotted?

I realized in one of your slides that the ischemic time for the heart was pretty long, up to 295 min or something like that. We had exactly the same problem with a not preclotted graft. What we do is we leave the unfolded graft in the descending aorta and place the suture line around the descending aorta. Then we take the graft out, and we preclot then the Dacron-tube with fibrin glue via the blower.

This water seals the woven graft, and we can do meanwhile while it's drying an islet incorporation of the supra-aortic vessels. It saves a lot of time. The hybrid procedure itself takes time, and if you do a David or a composite replacement in an acute aortic dissection, you end up with a pretty long cumulative ischemic time for the heart.

Dr Pacini: Yes. These operations are very expensive for us. We use another graft, a precoated one. So we leave only 2 cm of the not precoated graft, take it out, and we put the precoated graft in.

Dr M. Schepens (Nieuwegein, Netherlands): Well, it's clear that this is another option to deal with the same problem, but it's a very elegant way to solve the problem of a non-coating prosthesis.

Dr E. Bachet (Abu Dhabi, UAE): A few technical questions. In all your patients, you cannulate the axillary artery, but most patients were elective patients. Why don't you cannulate the innominate artery, which is much simpler? You have it under your nose. It's just a suggestion as, personally, I do it very liberally.

Second question, how could you have a prosthesis in the false channel? As you open the aorta and you can see distinctly the true and the false channels, how can you get confused?

Dr Pacini: Regarding the first question, we have no experience with the cannulation of the innominate artery.

We have no experience and we are afraid of that.

Regarding the second question, you can see where you opened the aorta and where you performed the anastomosis, okay. But you couldn't see what happen below, here at this level.

We suppose that at this level there was a big tear. We went directly with the device in the tear and so we landed in this zone, the false lumen.

Dr Bachet: Yes, I understand.

Dr Pacini: We were lucky because the aneurysm at this level didn't grow in one year of follow-up.

Dr Bachet: Two other small questions. What is really the use of the E-Vita prosthesis which, I suppose, is expensive? Indeed, as far as I see in the meetings, most colleagues using the E-Vita prosthesis cut the non-stented part and then put another prosthesis? Why don't you just use a regular stent and then a normal prosthesis?

Dr Pacini: We did once. However performing the anastomosis between a regular prosthesis and a stent graft with the normal polypropylene suture, we can tear the Dacron of the stent. So we prefer the E-vita, we leave just 2, 3 cm of the Dacron, and we performed an anastomosis between two common prosthesis.

Dr Bachet: And finally, I know that Dr Kazui has a very great influence on your team. But in Europe in general about 90% of patients having a replacement of the arch have an island reimplantation of the supra-aortic vessels, which takes a short time, is safe and gives excellent results.

Why did you decide in all your patients to systematically reimplant separately all the vessels which results in a very long time of circulatory arrest, shifting of cannula, et cetera?

Dr Pacini: We choose the island technique to implant the supra-aortic vessel when the arteries are very close to each other.

These are very long operations, so to be faster, we perform only one anastomosis instead of three.

Dr Bachet: Yes, but why don't you do that more often?

Dr Pacini: Because sometimes, above all in chronic dissection, supra-aortic vessels are displaced and you cannot reimplant them all together.