Eur J Vasc Endovasc Surg **29**, 131–138 (2005)
doi:10.1016/j.ejvs.2004.12.005, available online at http://www.sciencedirect.com on SCIENCE DIRECT®

Endovascular Treatment of Aortic Arch Aneurysms

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Introduction. *The aim of this study was to review our clinical experience with endovascular treatment of aortic arch aneurysms using different commercially available grafts (Gore, Talent, Endomed, Cook).*
Methods. *From 1999 to 2004, 97 patients received endovascular treatment for diseases of the thoracic aorta. In 30 cases (26 males, 4 females) the aortic arch was involved.*
The left subclavian artery was overstented (Ishimaru zone '2') in 18 cases (60%). Only in the first three cases had the subclavian artery been revascularized. The left common and subclavian arteries were covered (zone '1') in 6 (20%) cases—all had the carotid artery reconstructed, either simultaneously (five cases) or as a staged procedure (one case). Finally, the whole aortic arch was over-stented (zone '0') in 6 (20%) cases, with simultaneous (five cases) or staged (one case) grafting of the supra-aortic vessels from the ascending aorta.
Results. *Perioperative mortality was 2/30 (7%), due to graft migration (zone '2') and intra-operative stroke (zone '0'), respectively. One minor stroke was observed. No cases of paraplegia were recorded. Three type I endoleaks were observed. Two resolved at 6 months follow-up; one zone '0' graft is still being followed. There was one surgical conversion for endograft failure 2 weeks after implantation. Thus, the technical success rate was 87% (26/30) cases. The mean follow-up time was 23±17 months. No new onset endoleaks or aneurysm-related deaths were recorded.*
Conclusions. *Currently available grafts may be deployed in the aortic arch in most instances. De-branching of the aortic arch with surgical revascularization for zone '0' and '1' seems to be adequate to obtain a satisfactory proximal landing zone.*

Keywords: Arch aneurysm; Endovascular; Supraortic vessels; Left subclavian artery; Arch de-branching.

Introduction

As soon as the endovascular deployment of stent-grafts was shown to be clinically feasible for the treatment of aneurysms of the descending thoracic aorta[1,2] it was apparent that the mid thoracic aorta represented an 'easy' area for deployment, whereas the procedure became more challenging if a short neck was present at either the distal or proximal landing zone.

In particular, at the proximal level two anatomical features posed significant challenges: the curvature of the aortic arch and the presence of the supra-aortic vessels. Technological improvements, namely more flexible sheaths and grafts, nowadays allow deployment in the arch in most instances. De-branching of the aortic arch with either intra-thoracic or extra-anatomic revascularization procedures appears to be the obvious solution for the second problem.[3–7]

However, in reality, endovascular treatment of aneurysms of the aortic arch, especially those that extend proximally to the origin of the innominate artery (zone '0'),[8] is not yet widespread for several reasons that will be addressed in this paper. The aim of this study is to review our clinical experience with endovascular treatment of aortic arch aneurysms and to describe the new problems encountered treating more proximal aneurysms and the suggested solutions.

Methods

Patient population

From 1999 to 2004, 97 patients received endovascular treatment for disease of the thoracic aorta at our

Paper presented at the XVIII Annual meeting of ESVS.
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1078–5884/000131 + 08 $35.00/0

Institution. In 30 cases the aortic arch was involved (proximal neck involving zones '0', '1', and '2').[8]

This series included 26 males and 4 females with a mean age of 71±7.9 years (range 56–86 years). Indications for treatment are listed in Table 1. All patients were treated electively; no ruptured aneurysm was treated in this series. Since we began employing this technique only two other patients, referred with aortic arch aneurysms anatomically feasible for endovascular treatment, did not receive an endovascular graft, due to the severity of co-morbid disease.

Device description

We employed several different types of commercially available prosthesis which obtained the CE marking:

Gore Excluder TAG (WL Gore and Ass. Flagstaff AZ): is an expandable polytetrafluoroethylene (ePTFE) prosthesis supported by self-expanding nitinol stents with no sutures.[9] The original graft also included longitudinal spines. This graft was withdrawn from the market in 2001. A modified version of the graft without the longitudinal spines is now commercially available in Europe.

Table 1. Demographic and clinical data

	N°	Sex	Age	Ø	Etiology	Device	Stent-graft size (mm)	Supra-aortic trunks	Outcome
Zone 0									
	1	M	71	71	ATS	Zenith TX1	42×36×194	AICB	OK
	2	M	74	62	ATS	Zenith TX1	40×160	AICB	OK
	3	M	80	59	ATS	TAG (N)	37×150	AICB	Stroke-death
	4	M	72	56	ATS	Zenith TX2	34×152+34×156	AICB	Type I EL
	5	M	73	66	ATS	Zenith TX1	40×160	AICB	OK
	6	F	80	68	ATS	Zenith TX2	34×150	AICB	Minor stroke
Zone 1									
	7	M	74	58	ATS	TAG (O)+Talent	Ø 37 (6 pieces)	CCSB	Type I EL-OK
	8	M	71	65	ATS	Endomed	38×160	CCSB	OK
	9	M	56	58	ATS	Zenith Cook TX1	37×150	CCB	OK
	10	M	69	69	ATS	Zenith Cook TX1	36×156	CCB+PLS	Type I EL-OK
	11	M	57	59	ATS	Zenith Cook TX1	36×156	CCB	OK
	12	M	63	65	ATS	TAG (O)	37×150	CCB	OK
Zone 2									
	13	M	77	54	ATS	TAG (O)	34×150	LSR	OK
	14	F	76	67	ATS	TAG (O)	34×200	LSR	OK
	15	M	61	59	ATS	TAG (O)	34×150	ICS	Conversion
	16	F	69	62	ATS	Talent	44×96	LSR	OK
	17	M	70	71	ATS	Endomed	40×140	ICS	Migration-death
	18	M	68	59	ATS	Endomed	38×160	ICS	Conversion
	19	M	77	68	ATS	Zenith TX1	40×140	PLS	OK
	20	M	76	61	ATS	Zenith TX1	36×230	ICS	OK
	21	M	56	–	Trauma	Zenith TX1	38×140	ICS	OK
	22	M	77	–	Trauma	Zenith TX1	36×106	ICS	OK
	23	M	86	56	ATS	Zenith TX1	38×100	PLS	OK
	24	M	66	39	Saccular	Zenith TX1	38×140	ICS	OK
	25	M	67	67	Chr Diss	Zenith TX1	26×150	PLS	OK
	26	F	83	–	PAU	Zenith TX1	40×198	ICS	OK
	27	M	58	55	Chr Diss	TAG (N)	37×150	PLS	OK
	28	M	78	–	PAU	Zenith TX1	34×156	ICS	OK
	29	M	74	61	ATS	Zenith TX1	36×156	PLS	OK
	30	M	72	51	ATS	Zenith TX1	40×139	ICS	OK

Abbreviations: penetrating aortic ulcer (PAU); left subclavian revascularization (LSR); carotid–carotid bypass (CCB); carotid–carotid-subclavian bypass (CCSB); ascending aorta-innominate artery-left common carotid bypass (AICB); intentional coverage of subclavian artery (ICS); pre-vertebral ligature of subclavian artery (PLS); first generation Gore stent-graft (TAG O); new Gore stent-graft (TAG N).

Talent (AVE/Medtronic Inc. Santa Rosa CA): is composed of polyester graft fabric sutured to nitinol Z-configured self-expanding stents.[10] Deployment is by manual retraction of the outer sheath of the delivery system while holding the stent graft in position.

Endofit (Endomed Inc. Phoenix AZ): is constituted of Nitinol stents blended with e-PTFE fabric, with an uncovered proximal stent. We used it in the year 2002 with unsatisfactory results.[11] Based on early clinical experience, the company have modified the device.[12] This new device however, was not used in this series. Due to insufficient evidence over the safety of the device when placed high up in the aortic arch, the manufacturer amended the Endofit instructions in January 2004, to restrict use of the device to the descending thoracic aorta only.[13]

Zenith TX1 device (William Cook Europe-Denmark): the endograft consists of self-expandable stainless steel Gianturco® Z-stents and woven polyester. An uncovered Z-stent with barbs is located at the bottom of the graft body for fixation. The first proximal covered stent also has barbs. A new modular device (TX2) that received CE marking in 2004 and is currently undergoing a trial for FDA approval is now available.

Procedures

Graft oversizing 15–20% was based on preoperative CT scans; aortograpy was performed in all patients. Mean aneurysm diameter was 61 ± 7 mm. All the procedures were performed in the operating room, using a portable digital C-arm image intensifier. General anaesthesia was the preferred method for zone 0 and 1 aneurysms, and was used in 21 cases; epidural anaesthesia was used in eight patients, and local anaesthesia in one. The contrast agent used was ioprimide (Ultravist, 300 mg/ml, Berlin, Germany) and the mean volume given during procedure was 156 ± 58 ml (range 60–370 ml). Cerebrospinal fluid drainage was not used in this series. The common femoral artery was used as the access site in 28 cases; one patient had the device inserted through the common iliac artery, another one through an infra-renal aortic tube graft during abdominal open surgery for combined AAA and thoracic aneurysm repair. All patients received prophylactic antibiotic therapy peri-operatively and a bolus of heparin (70 IU/kg).

Zone '2'.[8] Intentional over-stenting of the left subclavian artery (LSA) alone was performed in 18 cases. In the first three cases a prophylactic revascularization of the LSA was performed, whereas in the last 15 cases no additional revascularization procedure was performed.

Zone '1'.[8] Over-stenting of the origin of the left common carotid artery was performed in six cases. Extra-anatomical revascularization was performed as a staged procedure in one case and as a single procedure in five cases.

Zone '0'.[8] Over-stenting of the whole aortic arch was performed in six cases, in one case as a staged procedure and as a single procedure in five cases. Previous revascularization of the brachiocephalic vessels was performed from the ascending aorta, through a sternotomy or in one case a mini-sternotomy.

Follow-up

Ranged from 1.2 to 44.3 months (mean 23 ± 17) and was obtained in all patients. This was achieved with CT and chest X-ray controls every 6 months for 1 year, and then yearly.

Results

The mean time of fluoroscopy was 29 ± 18 min, with a mean radiation dose of 93 Gy/cm^2. Procedures had a mean duration of 137 ± 92 min.

In-hospital mortality was 2/30 (7%). One patient affected by a zone '2'[8] aneurysm died intra-operatively 1 h after successful endovascular procedure. Post-mortem examination revealed that the stent graft was completely kinked within the aneurysm.[11,12] No other case of graft migration was recorded in this series. The other patient developed an intra-operative stroke after technically successful treatment of a zone 0 aneurysm and eventually died on postoperative day 11 (Fig. 1); one further case of minor stroke was recorded. No paraplegia was observed in the other patients.

Primary technical success was achieved in 26/30 (87%) patients.[14] No procedure was aborted because of access difficulty, no complications relating to access vessels were observed. We successfully inserted and deployed the stent-graft in all cases. Two type I endoleaks following treatment of a zone 1 aneurysm were discovered at discharge and both resolved by 6 months follow-up (Fig. 2). One case of type I endoleak after a zone 0 aneurysm exclusion is still being followed. In five cases we observed a type II endoleak from the left subclavian artery (LSA) that resolved after pre-vertebral ligature of the vessel during the same procedure.

No patient required immediate conversion to open repair. We recorded one conversion in a patient with a zone '2'[8] aneurysm. Two weeks after a successful

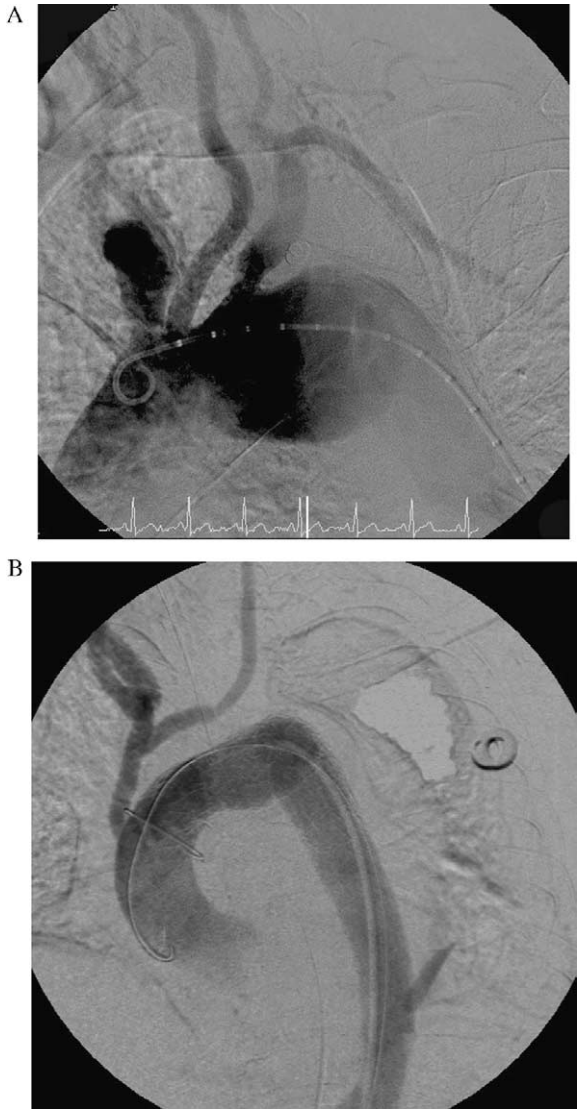

Fig. 1. (A) Preoperative angiogram of zone '0' aneurysm. (B) Revascularization of the brachio-cephalic vessels from the ascending aorta and exclusion of the aneurysm with new modified version of Gore TAG graft. In spite of uneventful deployment of the graft and technical success, this patients experienced a severe fatal intra-operative stroke and expired in postoperative day 11.

deployment of the graft, a routine chest X-ray study followed by CT scan showed total collapse of the graft and fracture of three stents that perforated the e-PTFE.[11,12] The patient had no symptoms. Open surgery for endograft removal and TAA repair was performed and the postoperative course was uneventful.

Five patients required packed red blood cells transfusion, and the mean volume of bleeding during the procedures was 253 ± 330 ml.

A patient undergoing complete aortic arch grafting for a zone '0'[8] aneurysm, experienced a short period of asystolic cardiac arrest during surgery.[15] The same patient experienced atrial fibrillation and pulmonary effusion, respectively, on postoperative day 2 and 3, which regressed after medical therapy. Another patient developed postoperative respiratory failure that required prolonged (20 days) mechanical ventilation.

Neither peripheral thrombo-embolism nor other cardiac, renal or other major respiratory problems were recorded in the remaining patients on the early postoperative period. In this series (zones 0, 1, 2), LSA intentional over-stenting without revascularization was performed in 20 cases with no clinically relevant adverse consequence.

At follow-up we recorded two late deaths unrelated to aneurysm repair (7.1%), at 24 and 39 months, respectively, after the procedure. Freedom from adverse device-related events was 100%. No cases of aneurysm sac enlargement were recorded and shrinkage[14] of aneurysm was observed in 15 cases (54%).

Discussion

Initially, overstenting of the left subclavian artery mandated revascularization. However, it is now generally accepted[16–18] that this may not be necessary, provided that the contralateral vertebral artery and the branches from which it originates are patent; vertebral territory stroke after LSA coverage is indeed a documented risk[19] Other reasons that suggest prophylactic revascularization of the LSA are the presence of a myocardial revascularization with the left internal thoracic artery, the presence of A-V access shunt for hemodialysis in left arm, the presence of a lusoria artery, and the patients being left handed professionals.[20] Moreover if the thoracic aorta is extensively covered with the endograft, especially with previous abdominal aortic surgery, prophylactic revascularization of the LSA may have a role in the prevention of paraplegia.[18]

Subclavian-carotid transposition or an extrathoracic bypass grafting is generally performed to revascularize the LSA.[21] Reconstruction of the first or second segments of the subclavian artery may be complicated by significant mortality and morbidity rates[16,22] and, to respond to this problem, a variety of endovascular procedures (scalloped,[23] fenestrated[24] and branched stent-grafts[25] or *in situ* fenestration[19]) are being investigated. We recorded five cases of type II endoleak from the left subclavian artery that were treated intra-operatively by pre-vertebral ligature of the vessel. As an alternative method, the left

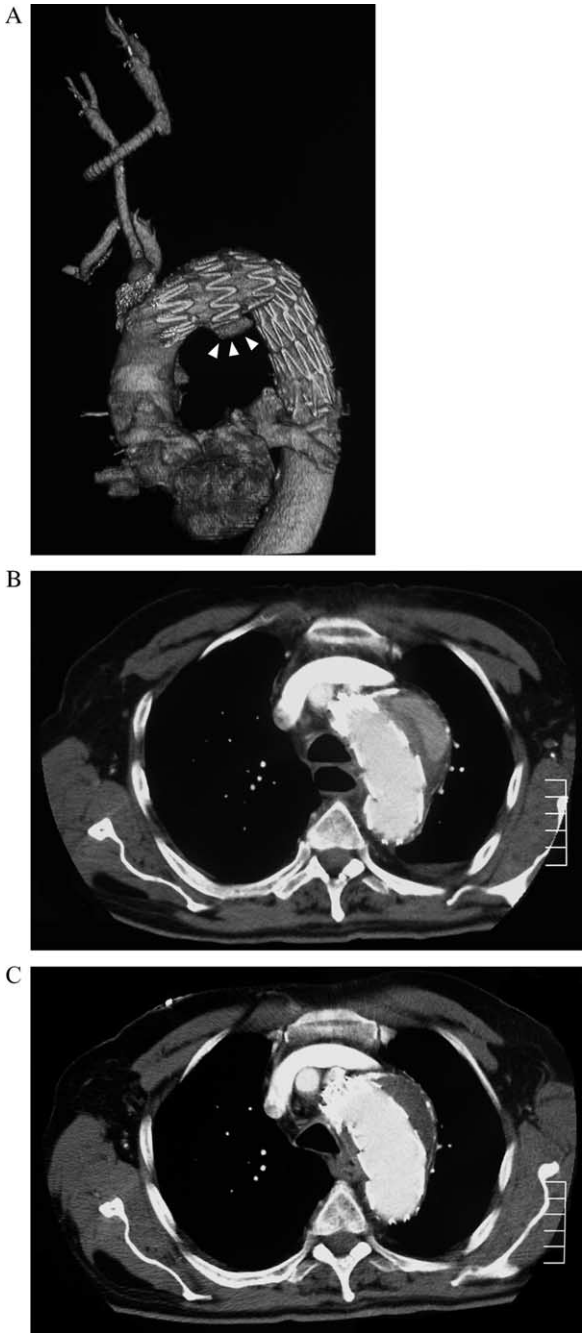

Fig. 2. (A) Postoperative Angio-CT scan showing type I endoleak (arrows) after deployment of graft (Zenith Cook TX1) for aneurysm of zone '1'. Note over-stenting of the origin of the left common carotid artery that was grafted to right carotid artery with ringed ePTFE bypass. (B) Axial scan view of the endoleak. (C) Axial CT scan taken at the same level 6 months later showing no endoleaks, expansion of the stent graft with initial shrinkage of aneurismal sac.

subclavian artery may be embolized with coils through a catheter placed in the subclavian artery from the arm.[3]

The largest clinical series published to date is that of Kieffer,[26] reporting on 16 patients (eight cases of zone 0, eight cases of zone 1 aneurysms) employing a home made device with mortality, perioperative morbidity and conversion rates of 25, 62.5 and 12.5%, respectively. Schumacher et al.[27] reported more encouraging results with commercially available endografts in eight high risk patients affected by an aortic arch aneurysm: however, one out of three patients with a zone 0 aneurysm died.

It is clear that the arch is the most challenging area for endograft deployment. Flexibility of both the sheath and the graft are crucial for a successful procedure. Pre-curved grafts are not commercially available at our institution. Gore grafts are advanced sheath-less into the arch. The Endofit grafts that we used were delivered through pre-curved commercial sheaths. The Cook TX1 sheath is pre-curved, the new TX2 idrophilic sheath (Flexor) is not pre-curved but it is so flexible that it advances into the arch without difficulty.

Our experience with the Talent graft has been limited mainly for logistic reasons (timely availability of the product). One of the characteristics of this widely used product is the high radial force of its stents, however, this also makes withdrawal of the sheath very hard or impossible in curved areas.[28]

Our overall experience with the Endofit graft, including three cases of arch deployment, have been reported elsewhere.[11,12]

The Cook TX1 is suitable for positioning in the arch, some problems may arise from a tendency to kink of the introducer sheath. The kinks in the sheath may prevent deploying in the arch (Fig. 3), if this is the case,

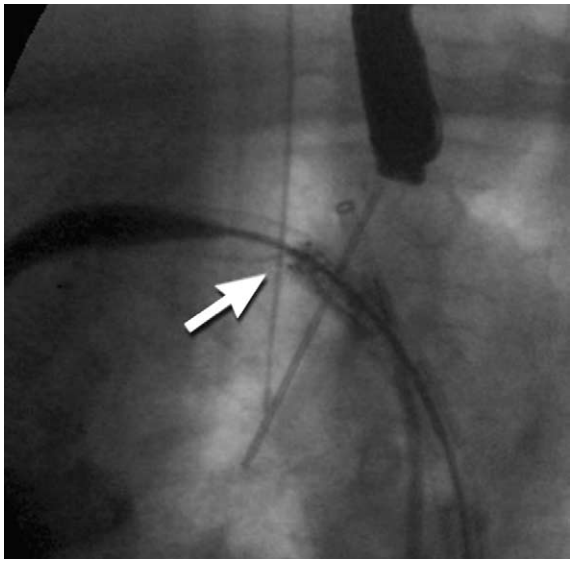

Fig. 3. Kinking of the introducer sheath may jeopardize release of the endograft (Zenith Cook TX1).

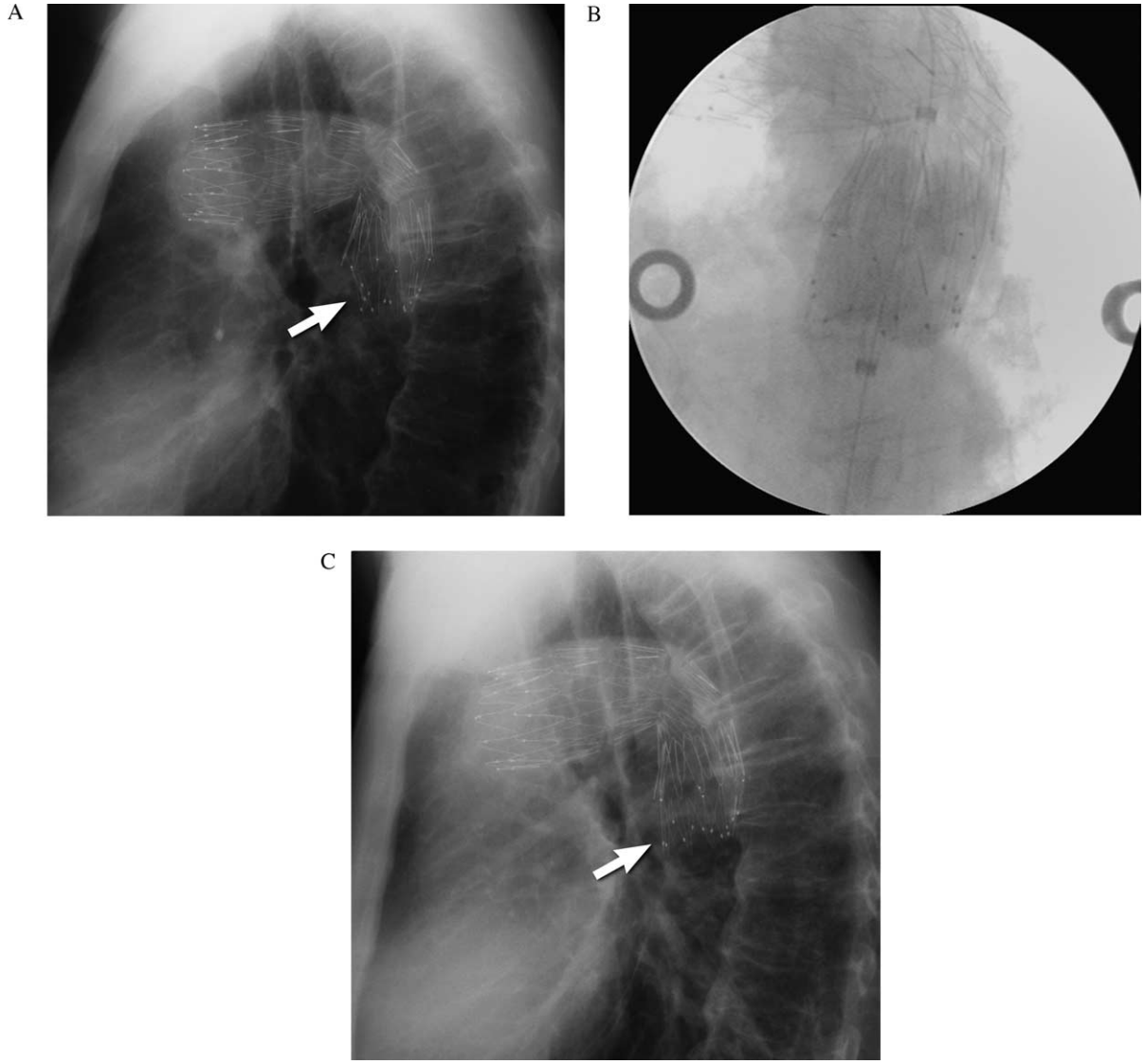

Fig. 4. (A) Chest X-ray shows incomplete opening of distal bare stent (Zenith Cook TX1). No endoleak was observed at CT or aortography (not shown). (B) Ballooning of the stent with a trilobated balloon (Gore WL Gore and Ass. Flagstaff AZ). (C) Complete opening of the stent after the procedure.

the device may be pulled back in the descending aorta, the sheath withdrawn a few centimetres in order to partially open the first stent and then the device pushed back in the desired position. The new, more flexible, introducer sheaths with hydrophilic coating now available (Flexor) seem to have resolved this problem. In one of our cases the distal bare stent failed to open completely at the time of implantation, simple ballooning was enough to overcome this problem (Fig. 4).

Gore TAG has been available only very recently. Its flexibility is satisfactory and it is advanced bare to its final position in the arch. It must be remembered however, that it opens instantly and a very accurate positioning is usually not possible. We used it in a single case of zone '0' landing, and in spite of a technically very satisfactory and uneventful procedure, the patient experienced a fatal stroke (Fig. 1).

In our experience the procedure was never a cause of aortic dissection, however, none of our patients was treated for acute dissection or intra-mural hematoma. These are the patients with the most friable aortas and retrograde dissection into the arch has been described in some cases, especially when a device with a proximal bare stent is used.[29]

So a decade after the introduction of this technique, we are still awaiting a graft that fulfils the need for flexibility, precise delivery, reliable fixation and sealing

and durability essential for deployment in the aortic arch. In spite of the apparently simple design needed for the thoracic aorta, unexpected problems arose in this area, possibly due to the larger diameters, to the curvature and tortuousity, to the incessant movements and to the high fatigue loads to which this grafts are exposed.[28] Migration and structural failures turned out not to be uncommon in this area.[30] The approval process for these devices needs to be rigorous. It is estimated that more than 21,000 patients are diagnosed with thoracic aortic aneurysms each year in the United States; AAA however, are much more prevalent and the effort of corporate companies is considerably greater in this area.

Fenestrated and branched grafts, may in the future avoid the need for hybrid endovascular procedures.[25,31,32] Currently however, these grafts are in an initial phase of their development and hybrid procedures may still be the only alternative to open surgery for the majority of patients.

In conclusion, currently available materials allow deploying in the arch in most instances. Surgical revascularization is needed for cases involving the right common carotid and the innominate arteries. The procedure is technically feasible; however, mortality and morbidity are not negligible.

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Accepted 2 December 2004