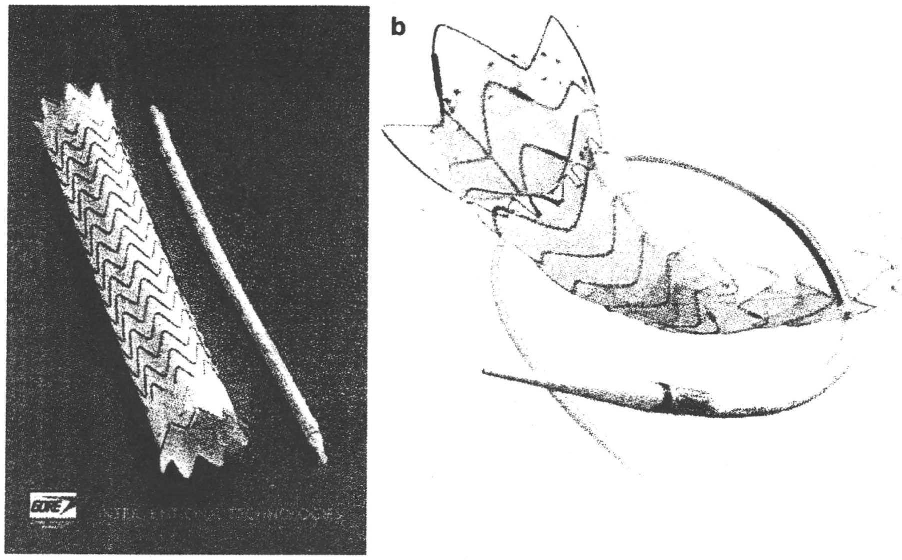

Fig. 1 Ready-made stent-grafts. **a** Gore thoracic aortic graft (TAG). **b** Talent (Medtronic)

Administration (FDA). In Japan, only TAG and Talent have been approved up to now (Fig. 1). TAG has wonderful flexibility and an unique deployment system, so this device may be applicable for almost all lesions of the aorta.[7] The new TAG devices are tapered with diameters >40 mm and may be developed within the next few years. Talent has a tapered type and has a diameter >40 mm. However, the flexibility of Talent is poor, so this device should be used only for straight lesions of the aorta.

Several new devices of endovascular aortic repair will be approved during the next few years, and TEVAR's success rate will improve with the new devices.

Thoracic descending aortic aneurysms

Degenerative aortic aneurysms

The pathological indication for using ready-made stent-grafts was originally only degenerated (true) aortic aneurysms. Therefore, we first described TEVAR for degenerated thoracic aneurysms. Almost all true aneurysms end in aortic rupture even if the best medical treatment is performed. Furthermore, the mortality rate associated with aortic rupture is >90% even if subsequent surgery is performed.[8] Unfortunately, conventional surgical treatment for thoracic aortic aneurysms is highly invasive, and the results are unfavorable for the elderly and high-risk patients.[9] As a result, less-invasive surgical techniques are necessary, and we believe that thoracic endovascular aortic repair serves such a purpose.

In Japan, we used only home-made stent grafts from 1993 to 2008.[10,11] However, so many doctors were not able to venture into the endovascular aortic repair field, the ready-made stent-graft called TAG was approved in 2008. Thus, treatment of true thoracic aortic aneurysms may be shifted from conventional surgery to TEVAR in the near future.

The thoracic aortic graft achieved excellent early and midterm results in some studies. A Phase II multicenter trial of TAG in the United States achieved excellent results: Brain infarctions were down to 4%, postoperative paraplegia was reduced to 3%, and the freedom rate of aortic-related death was 97% during the first 2 years.[12] In comparison to conventional surgery, the incidences of brain infarctions, paraplegia, mortality, and intensive care unit (ICU) stays after TEVAR were significantly lower. TEVAR also achieved better midterm results than did conventional operations.[7]

However, the access route for TEVAR was more troublesome than that of conventional surgery. The diameter of TAG's sheath is too large for Japanese people (and other Asian people). According to our data, the iliac artery or aortic approach was used in 45 of 112 cases (38%) treated with TAG. For our homemade devices, we usually use 20F (inside diameter) sheaths, so the iliac artery approach with homemade devices was used in <5% of patients. Rupture of an iliac artery is a serious problem, so when we have to use large sheaths we should select the iliac artery approach to prevent rupture of an iliac artery.

The incidence of endoleak by TAG was 5.6%–29.0% in the early results.[7,12,13] We advocate performing reintervention for type I endoleak; however, how to treat type II endoleak is controversial. As we had one aortic rupture with a type II endoleak, we have since aggressively performed interventions with the coiling method. Long-term results with type II endoleak are seriously needed.

Aortic dissection

Treatment strategy for acute aortic dissection may be similar worldwide. For type A dissection, almost all surgeons perform an emergency operation to close an intimal tear. For type B dissection, medical therapy is commonly selected, although complicated cases may require emergency operations. The results of type B aortic dissection after best medical treatment are not satisfactory.[14] Aneurysms expand in both transverse and longitudinal directions, and aneurysms involving visceral arteries have serious consequences for the patients. Finally, the true lumen becomes narrower. Hence, we need to operate during the chronic phase. In such a situation, however, the thoracoabdominal aorta might need to be addressed surgically. We think a less invasive operation at an earlier phase of aortic dissection is the best procedure.

We started to use TEVAR for type B aortic dissection with a homemade stent-graft in 1993 (Fig. 2). The device and technique have been improved since then, so we have been able to achieve excellent early and long-term results. For acute type B aortic dissection, based on our data, the pseudolumen might be expected to diminish when an intimal tear is closed by TEVAR. A Stanford University study during the 1990s reported similar long-term results after applying TEVAR for acute type B dissection.[15]

To achieve good results for TEVAR, strict measurement of the circumference is important. The proximal diameter of stent grafts was oversized 10%–20% of the native aorta, and the distal diameter was oversized 5%–10% so as not to create a new intimal tear; bare stents were never used. When there was a discrepancy of >120% between the proximal and distal diameters at the deployment area, we decided to use a tapered stent-graft.

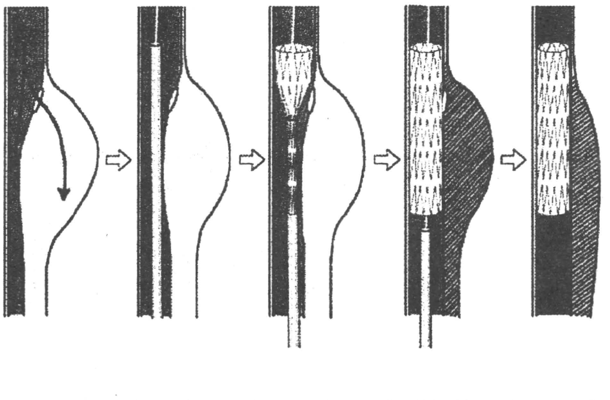

Fig. 2 Thoracic endovascular aortic repair (TEVAR) for type B aortic dissection with a homemade device

As for the treatment strategy for type B dissection, we usually select medical treatment for uncomplicated cases and surgery for those that are more complicated. However, the results of the surgery have never been satisfactory. In contrast, a recent compendium summarized the results of 39 published studies of TEVAR in 609 cases with type B dissections.[16–27] Procedural success was achieved in 96%, with only 2.3% of patients requiring in-hospital surgical conversion. The prevalence of neurological complications was remarkably low: brain infarction 1.2% and postoperative paraplegia 0.5%.

On the other hand, the treatment strategy for uncomplicated cases was controversial. Nienaber et al. conducted the INSTEAD trial for uncomplicated aortic dissections in Europe.[18] The study did not achieve favorable results owing to problems with the devices and trial institutions. Among our preliminary data of 12 acute uncomplicated cases, there were no operative deaths or postoperative major complications. The rate of freedom from aortic events was 100% for 3 years.

Currently, ready-made devices for aortic dissections, such as the Gore TAG, have diameters ranging from 26 mm to 40 mm, so it may be difficult to use them on aortic dissections. Talent has a large variety of diameters of stent-grafts, but Talent does not have enough flexibility for aortic dissections. Our treatment strategy of TEVAR for acute type B aortic dissection requires that we use short stent-grafts only when needed to cover intimal tears. hence, we have recently used the Gore aortic extender for aortic dissection because it comes in diameters of 23.0, 26.0, and 28.5 mm; and the length is only 3.3 cm. We used it in only a few cases, but the results were excellent.

TEVAR for type B aortic dissection is acceptable. Therefore, once companies develop next-generation devices for aortic dissection, TEVAR might be become the next major surgical treatment in this field.

Traumatic aortic aneurysms

The operative mortality rate for traumatic aortic transection is extremely high because these patients have multiorgan injuries and excess bleeding that might occur because of heparinization for cardiopulmonary bypass (CPB). However, the aorta must first be addressed surgically because other operations cannot be performed until the high risk of aortic rupture is averted. We are expecting TEVAR to perform well in this situation.

In a multicenter study,[28] 30 traumatic aortic transections were performed using TEVAR. All of the cases were successful, and only two ended in late death. One patient had a brain infarction, and the other experienced collapse of the device.

The main area of concern with traumatic aortic transection is the distal arch. Usually, these patients are young and have normal aortas that have smaller diameter than that of elderly patients. Therefore, bird's beak deformities at the lesser curve of the aorta are often seen, and an endoleak might occur. Finally, in the worst scenario, collapse of the stent-graft would lead to malperfusion of the spinal cord, visceral arteries, and legs in such patients.

We strongly recommend that new devices be developed that have excellent flexibility and smaller diameters. If these devices can be created, most traumatic aortic transections can be repaired with TEVAR.

Aortic arch aneurysms

It is difficult when TEVAR is used to address aortic arch aneurysms to achieve a landing zone large enough to prevent endoleaks and migration because there are three cervical arteries. We recommend that the landing zone of TEVAR be at least 2 cm. When a device is not flexible, however, it cannot adjust for aortic angulation. For example, the proximal 4 cm of TAG is not flexible, so the proximal end of TAG is not suitable for a tortuous aorta. Bird-beak deformities occur even if the landing zone is >2 cm. Therefore, we have to use the area in which cervical arteries are branched for the landing zone. In recent years, the reconstruction of cervical arteries for bypassing them with prosthetic grafts (debranching) may be the most useful technique.[10,29–31]

In our university hospital, we performed debranched TEVAR for elderly patients and patients who cannot undergo CPB because of some severe complications. Debranched TEVAR is the revascularization of cervical arteries with TEVAR to cover the entire aneurysm (Fig. 3).

We performed 87 debranched TEVAR operations from 1995 to 2008. The main procedure, performed in 43 cases, is to bypass from the right subclavian artery to the left subclavian artery and the left carotid artery. When the brachiocephalic artery has stenosis, we perform media sternotomy, and bypass from the ascending aorta to the left carotid artery and left subclavian artery or to three cervical arteries. The landing zone, zone 0, was used in 45 cases; and zone 1 was used in 26 cases. Thus, the incidence of the ascending aorta and proximal arch landing is >70%. The operative mortality was 1.5%, and there was no incidence of paraplegia or conversion to the conventional operation. We had two cases of brain infarction with the fenestrated devices.

When patients with aortic arch aneurysms have no proximal landing zone and can undergo CPB, we have performed the branched open stent grafting technique[32] (Fig. 4). The endoprosthesis is composed of the main body and cervical branches. Grafts are thin-walled woven polyester grafts, and the main body's stented portion is composed of a self-expandable Giantruco Z-stent. The cervical branches are composed of a balloon expandable Palmaz stent with a percutaneous transluminal angioplasty catheter, and they can be opened by inflating the balloon (Fig. 5). With the bladder temperature at 20°C and under CPB, deep-hypothermic circulatory arrest is introduced. The proximal aortic arch is

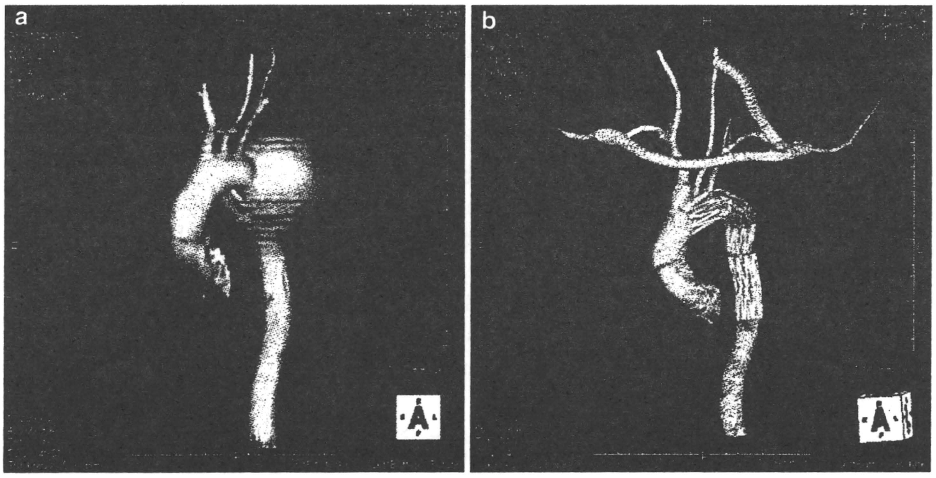

Fig. 3 Debranched TEVAR. **a** Large distal arch aortic aneurysm. **b** We performed the bypass (debranching) from the right subclavian artery to the left subclavian artery and left carotid artery and deployed a stent-graft from just below the brachiocephalic artery

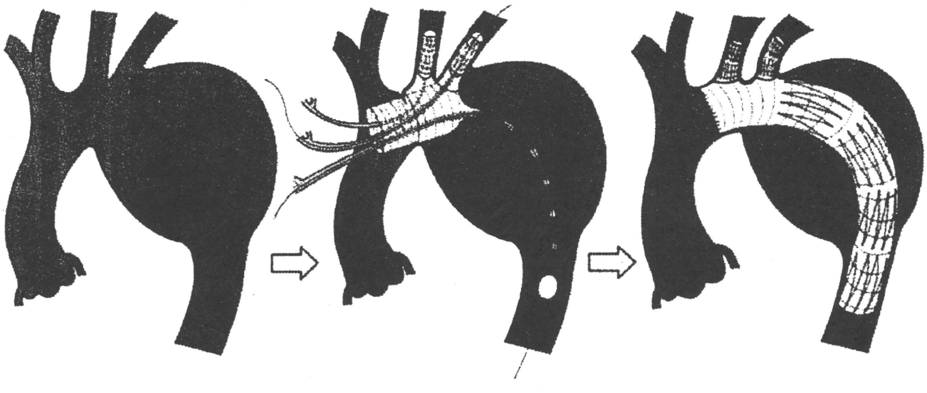

Fig. 4 Branched open stent grafting technique (BOS)

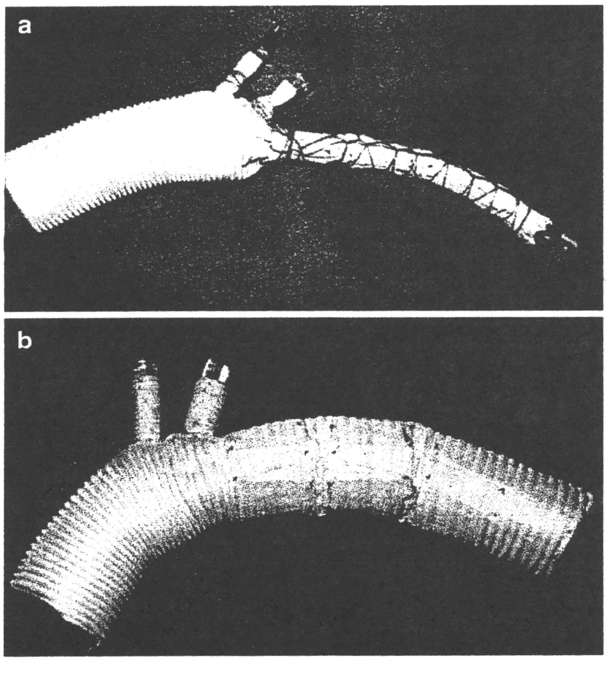

Fig. 5 Homemade device for BOS. **a** Before deployment. **b** After deployment

opened between the brachiocephalic artery and left carotid artery, and the stent graft is inserted through this incision. The main body, the left subclavian artery branch, is guided over the guiding wire. The stent-graft is deployed, and the suturing portion of the stent-graft is anastomosed to the aortic wall or the graft of an ascending aortic replacement by the inclusion technique. The operative mortality was 2.5%, and the incidence of paraplegia was 1.6%. The survival rate is 88% at 3 years. This procedure achieved good results, so we would like to use this procedure with these criteria until branched stent grafts are approved.

Recently, a new stent-graft named Najuta is being used in a clinical trial. This new stent-graft is a fenestrated device for aortic arch aneurysms. It is completely custom-made and has two or three holes to maintain blood flow to cervical arteries. Because it takes several weeks to make them owing to the need for precise adjustment for the holes, this device is not suitable for emergency operations. However, its use might someday replace conventional total arch replacement.

Conclusions

The efficacy of TEVAR for aortic pathology has been presented. Currently, TEVAR for the descending aortic aneurysm is the first line of treatment. In the future, TEVAR will be the first treatment strategy for aortic arch aneurysms. Furthermore, based on some reviews, TEVAR might be performed for aortic dissections because it is a less invasive treatment. We expect to see the development of next-generation devices in the future. Many companies will be competing for fenestrated or branched devices, new delivery systems, and new devices with adjunct treatment, such as a drug-eluting stent graft. We can look forward to the new developments over the next decade.

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Hybrid endovascular aortic arch repair using branched endoprosthesis: The second-generation "branched" open stent-grafting technique

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Objective: We advanced the open stent-grafting technique with a branched endoprosthesis, which reconstructs simultaneously the cervical branches and descending aorta within an acceptably short interval of deep hypothermic circulatory arrest. In this study, we evaluated the efficacy of this new technique and assessed the early and midterm results.

Methods: From January 2004 to September 2007, the branched open stent-grafting technique was performed in 69 cases (55 men, average age 66.2 years, 36 degenerative aneurysms and 33 aortic dissections, 13 [18.8%] in emergency, 7 [10.1%] redo cases). Under deep hypothermic circulatory arrest, the branched endoprosthesis was delivered through the opened proximal aortic arch, and total arch repair was completed. To avoid cerebral embolism, retrograde cerebral perfusion was performed at the end of deep hypothermic circulatory arrest.

Results: Average time of operation, cardiopulmonary bypass, and deep hypothermic circulatory arrest was 417, 130, and 36 minutes, respectively. A total of 124 cervical stent grafts were inserted and successfully delivered in 121 (97.6%). Operative mortality within 30 days was 3 (4.3%). The major postoperative complications involved 4 (5.8%) strokes and 2 (2.9%) spinal cord injuries. No aorta-related death was observed after discharge from hospital, and the survival was 90.9%, 88.8%, and 88.8% at 1, 2, and 3 years, respectively. Six (5.0%) cervical stent grafts showed endoleak; however, all these cases were successfully treated by additional endovascular repair.

Conclusion: Aortic arch repair with branched open stent grafting is an effective technique with satisfactory early results. In midterm analysis, cervical branch events were acceptably rare and controllable. This technique could be an attractive alternative to conventional total arch replacement.

Open stent grafting is a hybrid aortic arch repair method that involves stent grafting in conventional aortic arch surgery.[1] With this technique, surgeons can complete total arch repair by inserting a stent graft into the descending aorta through the opened proximal arch, which eliminates the difficulty of direct distal anastomosis in the deep portion beyond the left subclavian artery. The feasibility of this procedure as an alternative to elephant trunk technique was described, and also the long-term durability was reported.[1,2] The most outstanding results were presented when open stent grafting was applied to total arch repair in acute type A dissection, because it provided not only easy management of distal anastomosis but also excellent clotting formation of the false lumen in the descending thoracic aorta.[3-5] These results suggested that open stent grafting could be a powerful method to complete total arch repair in acute type A dissection; however, it is still a far more complex procedure than hemiarch replacement because it still requires cervical branch reconstruction of the same sort of conventional arch repair.

With the intention to make total arch repair a much simpler procedure, we modified the stent graft to the second generation and developed branched endoprosthesis. The branched endoprosthesis was designed to reconstruct the descending aorta and cervical branches simultaneously in a single circulatory arrest period through the opened proximal aortic arch, thus completing total arch repair by the same aortic incision line as hemiarch repair.

In this study, we describe the efficacy of aortic arch repair using the branched open stent-grafting technique by evaluating the early and midterm results.

MATERIAL AND METHODS

Patients

The branched open stent-grafting technique and the retrospective review of the records for publication were approved by the Institutional Review Board. From January 1994 to September 2007, 195 patients with aortic

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Abbreviations and Acronyms

3DCT	= 3-dimensional computed tomography
BCA	= brachiocephalic artery
DHCA	= deep hypothermic circulatory arrest
LCCA	= left common carotid artery
LSA	= left subclavian artery
RCP	= retrograde cerebral perfusion
TEVAR	= thoracic endovascular aortic repair

arch pathologies were operated using open stent-grafting technique in 2 centers (Osaka University Hospital, Osaka General Medical Center). Among them, 69 consecutive operations after April 2004 were the second-generation branched open stent-grafting technique. Informed consent was required in each case. The mean patient age was 66.2 years (range, 33–85 years), and preoperative comorbidities of the patients are listed in Table 1. The operation was performed for 36 (52.2%) degenerative/atherosclerotic aneurysms and 33 (47.8%) aortic dissections, including 13 (18.8%) emergency status (6 ruptured aneurysms and 7 acute type A dissections).

The selection criteria for branched open stent grafting were aortic arch/proximal descending aortic aneurysm and aortic dissections that necessitated aortic arch replacement to close the primary intimal tear. All these aortic pathologies were excluded from indication for thoracic endovascular aortic repair (TEVAR), mostly because an adequate proximal landing zone was not provided even by covering the left subclavian artery. Regarding the patient's condition (eg, instability, age, or comorbidities), inclusion criteria were the same as that of conventional ascending aortic repair. The aortic characteristics are listed in Table 2, and the specifics are indicated as follows.

Type A dissection. In acute (within 14 days from onset) type A dissection, we selected hemiarch repair or total arch repair with branched open stent-grafting technique to accomplish complete resection of the intimal tear. Patients in all 7 cases of branched open stent grafting had intimal tears in the aortic arch, which were unable to be resected by hemiarch replacement. Six patients with chronic type A dissection were operated with the branched open stent-grafting technique; all of these were redo cases (status of post–ascending aortic replacement/aortic root replacement in acute phase).

Type B dissection. All type B dissections had complicated status, which had been the indication for primary intimal tear closure (eg, aneurysmal enlargement of false lumen, malperfusion, intractable pain). In our institution, when proximal sealing was adequate, TEVAR with or without subclavian coverage was the first choice to close the intimal tear. When proximal sealing was not adequate (eg, tight arch angulation, aneurysmal dilatation of the arch), arch replacement with the branched open stent-grafting technique was performed. In this period, primary entry closure of type B dissection was performed by TEVAR in 28 cases and by branched open stent grafting in 20 cases.

Degenerative/atherosclerotic aneurysm. These aneurysms were also excluded from indication for TEVAR with cervical debranching because of lack of adequate proximal landing zone. In patients with extended aortic aneurysms (involving aortic arch and descending thoracic aorta more distally than 10 cm from left subclavian artery), 2-stage repair was performed (branched open stent grafting with distal flotage and delayed aneurysm exclusion, with extensional TEVAR in the next day).

Description of the Device

The branched endoprosthesis used in this study was a homemade device. It was made of a noncoated polyester fabric graft (main body: WSL graft, cervical branch: WST graft; Ube, Japan) with Gianturco stent (William Cook Europe A/S, Bjaeverskov, Denmark) for the main body and a Palmatz stent (Cordis Endovascular Systems, Miami Lakes, Fla) for cervical branches (Figure 1). The main body was composed of a suturing portion and a stented portion, and corresponding to the number of reconstructing cervical artery, 1 to 3 branches were attached. Normally, 2 branches (left subclavian artery [LSA] branch, left common carotid artery [LCCA] branch) were attached. The size of each part was determined by the measuring results using preoperative 3-dimensional computed tomography (3DCT). The diameter of each landing zone (descending thoracic aorta and cervical arteries) was calculated by tracing the intimal circumference, and an oversized graft (10%–15% in aneurysms, 5%–10% in dissections) was selected. The length of each part and distance between the branches were also designed according to 3DCT measurement. The stented portion of the main body was composed of self-expandable Giantruco Z stent and mounted on a balloon catheter (20F Silicon nephrostomy balloon catheter) with restraining silk string. The branches involved the Palmatz stent, and these were fixed on a balloon catheter (Powerflex, Cordis endovascular System; Figure 2). Assembly of the stent graft and preparation for insertion (mounting to the balloon catheter) were performed at the side table in

TABLE 1. Preoperative patient profiles

Demographic	
Gender	
Male	55
Female	14
Age (y)	
Mean	66.2
Range	33-85
Marfan syndrome	3 (4.3%)
Preoperative complications	
Stroke	7 (10.1%)
Spinal cord injury	2 (2.9%)
Coronary artery disease	10 (14.5%)
Chronic obstructive pulmonary disease	2 (2.9%)
Chronic renal failure (creatinine > 2.0 mg/dL)	7 (10.1%)
Hepatic failure	2 (2.9%)
Iliac artery malperfusion	3 (4.3%)

TABLE 2. Aortic characteristics

Pathology	
Aneurysm	36 (52.2%)
Atherosclerosis	35
Aortitis	1
Dissection	33 (47.8%)
Type A	13
Acute	7
Chronic	6
Type B	20
Acute	5
Chronic	15
Diameter of aneurysm (mm)	61.2 ± 10.6
Status of operation	
Emergency	13 (18.8%)
Rupture	6
Acute type A dissection	7
History of aortic repair	
Ascending/aortic root	7 (10.1%)
Descending/thoracoabdominal	4 (5.7%)
Abdominal	7 (10.1%)

ACD

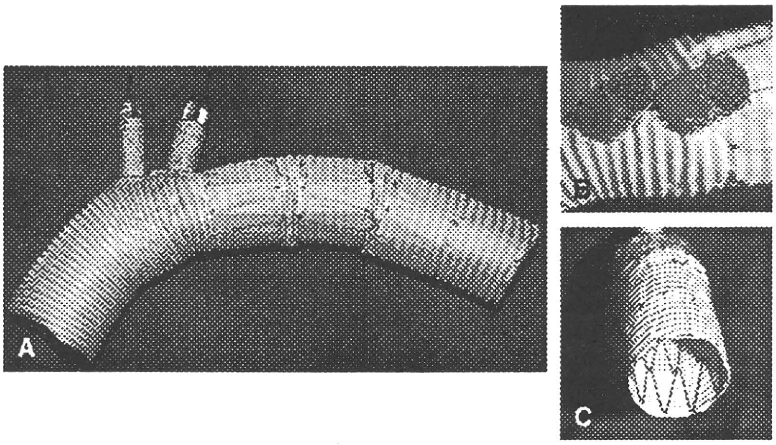

FIGURE 1. A, Whole image of the branched endoprosthesis, made up of a main body and cervical branches. B, The cervical branch is composed of a balloon-expandable stent. C, Stented portion of the main body. It is composed of self-expandable Z stent.

parallel with surgery. It could be completed within about 60 minutes, which was shorter than the time to establish deep hypothermic circulatory arrest at 20°C.

Surgery

After endotracheal intubation with a single lumen tube, the patient was positioned on the operating table in supine position with the right arm abducted on an armrest. The left arm was secured at the side, with rotation outward to expose the brachial artery. The left brachial artery was isolated with small incision, and a sheath introducer (Radiforcus introducer II, 5F, 10 cm; Terumo, Japan) was cannulated. The femoral artery was also cannulated by puncture with the same sheath introducer, and after administering heparin (100 U/kg), guide wires (0.035 inches, 260 cm, Radifocus guide wire) were advanced through these sheath introducers to the ascending aorta under the guide of fluoroscopy. Arterial pressure monitoring was also performed with these sheath introducers.

A median sternotomy was made, and the pericardial space was entered. Heparin (300 U/kg) was then administered. The right axillary artery and femoral artery contralateral to the sheath introducer were isolated and cannulated with a 16F or 18F cannula for blood return. Both venae cavae were cannulated separately through the right atrium, and cardiopulmonary bypass was established with right axillary artery perfusion. Perfusion cooling was initiated to bladder temperature of 20°C; the ascending aorta, brachiocephalic artery (BCA), and predetermined aortic incision line between BCA and LCCA were exposed.

In distal arch repair, with circulation arrest at bladder temperature of 20°C, aortic transection was made between the BCA and LCCA. Cardioplegic solution was administered antegradely using a balloon catheter. The guide wires from the femoral artery and left brachial artery were pulled out from aortic transection and led into the balloon catheter of the stent graft's main body and LSA branch, respectively. After inserting the branched endoprosthesis carefully, the LSA branch and LCCA branch were deployed by inflating the Powerfelx (Cordis Endovascular System) balloon with inflation device (8 atm, 5 seconds). Next, the main body was deployed by releasing the restraining silk string, and the stented portion was dilated with the balloon catheter to confirm the full opening of the stent graft. The suturing portion of the main body was trimmed and sutured to the transected aorta in inclusion fashion with continuous 3–0 polypropylene suture. Before finishing the suture, to flush out the air and debris in the cervical branches, retrograde cerebral perfusion (RCP) through the superior vena

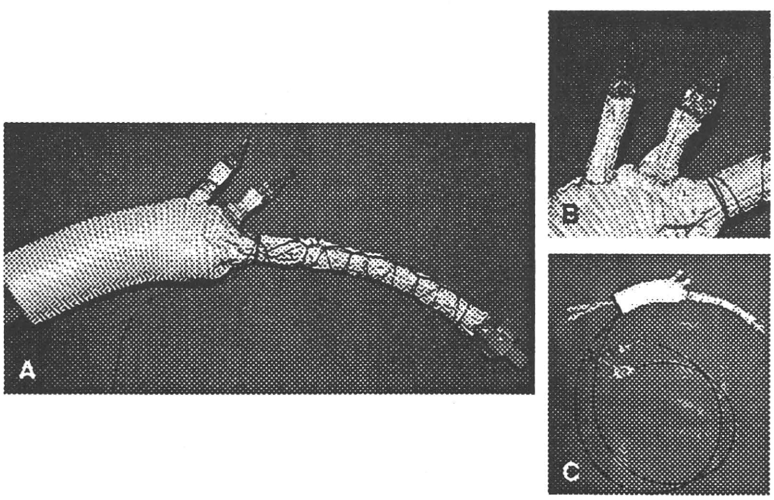

FIGURE 2. Delivery system. A, The stented portion of the main body is restrained with a silk string. B, The cervical branch is mounted on a balloon catheter. C, Whole image of the delivery system.

TABLE 3. Device size

	Average	Range
Main body		
Diameter (mm)	29.9 ± 5.9	20–40
Length (mm)	92 ± 18	75–145
Cervical branch diameter		
LSA	11.5 ± 1.1	8–14
LCCA	10.0 ± 1.0	8–12
BCA	13.0 ± 1.1	12–14

LSA, Left subclavian artery; *LCCA*, left common carotid artery; *BCA*, brachiocephalic artery.

caval cannula was initiated for 2 to 3 minutes at a flow of 600 to 900 mL/min, maintaining a central venous pressure of less than 25 mm Hg. RCP was also used when deep hypothermic circulatory arrest (DHCA) time exceeded more than 30 minutes. Then the descending thoracic aorta was flushed out by femoral blood return at a flow of 500 to 1000 mL/min for less than a minute, and finally antegrade reperfusion by axillary blood return was restarted.

In total arch repair, the ascending aorta and the root of the BCA were resected at the beginning of DHCA. After inserting the endoprosthesis, the suturing portion of the main body was sutured to the transected stump of the aorta with buttressing Teflon felt, and subsequently continuous anastomosis to a woven Dacron graft with 2 side branches (UBE Shield graft, UBE, Japan) was made.

Rewarming was initiated to rectal temperature of 35°C, and during this period, reconstruction of the BCA and proximal suture of the ascending aortic replacement were performed in total arch repair. Hemostasis was affected, and the patient was weaned from cardiopulmonary bypass.

Statistical Analysis

All data were reviewed retrospectively. Continuous variables are expressed as mean ± standard deviations and categorical variables as percentages. Survival and freedom from endoleaks and from aortic intervention were estimated by the Kaplan-Meier method. Data analysis was performed using SPSS 11.0 for windows (SPSS Inc, Chicago, Ill).

RESULTS

Operative Records

In this series, 41 (59.4%) total arch repairs and 28 (40.6%) distal arch repairs were performed. Nine (13.0%) patients required 2-stage repair. Other concomitant procedures included 2 (2.9%) aortic root replacements, 4 (5.8%) coronary artery bypass grafts, 4 (5.8%) tricuspid valvoplasties, 1 (1.4%) mitral valve replacements.

The branched endoprosthesis had 1 branch in 14 (20.3%) patients, 2 branches in 51 (73.9%), and 3 branches in 4 (5.8%). The size data of the device are listed in Table 3. A total of 124 cervical branches (1.79/case) were inserted, and 121 (97.6%) of them were successful. There were 3 (2.4%) branch insertion failures: 1 LSA branch slipped out from the orifice of LSA, 1 LSA branch did not fully open, and 1 LCCA branch was obstructed by unintended involvement to the aortic inclusion anastomosis. The 2 cases of failed LSA branch insertion required bypass grafting to LSA.

The overall average operation time was 417 minutes. In distal arch repair, operation time was shortened to an average 325 minutes (shortest time: 191 minutes). The mean duration of DHCA including terminal RCP was 36 ± 4 minutes (range 26–49 minutes).

Mortality and Morbidity

Operative mortality within 30 days was 3/69 (4.3%). The causes of deaths were 1 multiorgan failure, 1 acute subdural hematoma by accidental in-hospital fall over injury, and 1 massive progression of unfounded rectal cancer. There were 2 other hospital deaths (overall in-hospital mortality 5/69 [7.2%]); 1 was secondary aortoesophageal fistula and the other was drug-induced thrombotic thrombocytopenic purpura. The aortoesophageal fistula had occurred in a 67-year-old man who presented rapid expansion (>60 mm) of subacute type B dissection. The true lumen of the lower descending aorta was severely compressed, and as a consequence, malperfusion of the lower extremity and hepatic failure were observed. To repair the whole descending aorta, we planned to perform distal arch repair with branched open stent grafting and secondary TEVAR with visceral debranching for thoracoabdominal lesion. The postoperative course of the distal arch repair was uneventful; however, the thoracoabdominal aorta ruptured while waiting for the next surgery, and fatal aortoesophageal fistula developed.

Postoperative complications include 4 (5.8%) strokes, 2 (2.9%) spinal cord ischemias, 2 (2.9%) acute renal failures, 2 (2.9%) tracheotomies, 2 (2.9%) reexplorations for bleeding. Among 4 strokes, 2 were small multiple infarctions in both cerebral hemispheres in degenerative aneurysms with massive mural thrombosis. One was in the cerebellar hemisphere, and this patient also had severe mural thrombosis. One was observed in a patient with acute type A dissection with dissecting left subclavian artery, which showed infarcted left posterior cerebral artery lesion.

In our series, there were 7 (10.1%) cases of reoperative total arch repair and the results were satisfactory; mortality 0%, stroke 0%, spinal cord ischemia 0%, tracheostomy 0%.

Survival and Aortic Events

In average 20.3-month follow-up (range 1–41 months, 100% completion), there were 2 late deaths: 1 pneumonia and 1 malignant melanoma. No aorta-related death was observed, and actuarial survival estimates 1, 2, and 3 years after the procedure were 90.9%, 88.8%, and 88.8%, respectively.

There was no endoleak from the distal end of the main body, and also no new intimal tear creation by the edge of the stent graft. Four patients having dissection (3 chronic dissections and 1 acute dissection with Marfan syndrome) required intervention to control other intimal tears in the remaining dissected aorta (3 TEVAR of descending/thoracoabdominal aorta and 1 graft replacement of abdominal aorta). No patient with degenerative aneurysm required intervention for aortic pathology. The freedom from aortic

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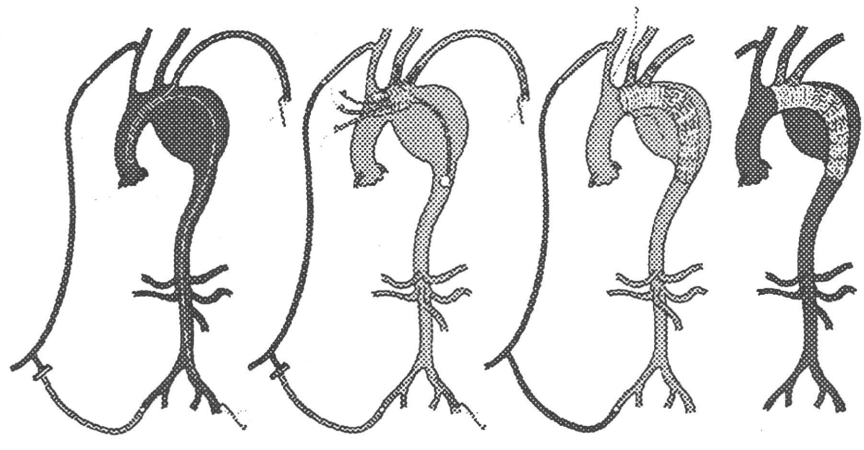

FIGURE 3. Distal arch repair with branched open stent-grafting technique.

intervention was 95.6%, 92.8%, 87.4% at 1, 2, and 3 years, respectively.

There were 8 (6.4%/branch, 11.6%/case) cervical branch events. Six showed endoleak from the distal end of cervical branches (5 in the LSA branch and 1 in the LCCA branch); however, all 6 patients underwent additional endovascular repair successfully (endovascular repair success: 6/6 [100%]). The freedom from endoleaks was 92.0%, 92.0%, and 84.4% at 1, 2, and 3 years, respectively. The remaining 2 patients had stenosis at the edge of LSA branch. One patient developed hypotension and coldness of left arm, so endovascular repair with bare stent was performed.

DISCUSSION

The branched open stent-grafting technique is an evolutionary hybrid aortic arch repair procedure that combines conventional aortic surgery and endovascular repair with branched endoprosthesis.

The outstanding point is that the branched open stent-grafting technique provides total arch repair without performing direct surgical reconstruction of the descending thoracic aorta and cervical branches. The distal aortic incision line is almost the same as in the hemiarch repair, and the branched endoprosthesis completes arch repair within an acceptably short interval of DHCA. In our series, all the maneuvers (insertion of the branched endoprosthesis, deployment, balloon attachment, inclusion anastomosis of the suturing portion and terminal RCP) took on average 36 minutes of DHCA. Terminal RCP was performed when DHCA time exceeded more than 30 minutes, which was also performed with the intention to eliminate debris and air in the cervical branches. We believe the duration of DHCA and addition of RCP was appropriate for brain protection,[6,7] and satisfactory results were achieved. In our series, the rate of stroke was 5.8%, which is acceptable when compared with previous arch replacement series reporting 3.0% to 7.0%.[8-11]

The branched open stent-grafting technique is best indicated in total arch repair for acute type A aortic dissection with intimal tear in the transverse arch or proximal descending aorta. It is emphasized that intimal tear resection is mandatory for better long-term results[12,13]; however, whether to include transverse arch in surgical resection in the acute setting is a long-lasting issue.[14] This means the increment of risk and complexity could be larger than that of benefit if the surgeon selects conventional total arch repair instead of hemiarch repair.

Our results suggested that the branched open stent-grafting technique could reduce the risk and technical difficulties of total arch repair to close to those of the hemiarch repair, although further controlled trials would be necessary to prove it. Also, excellent clotting formation of the false lumen

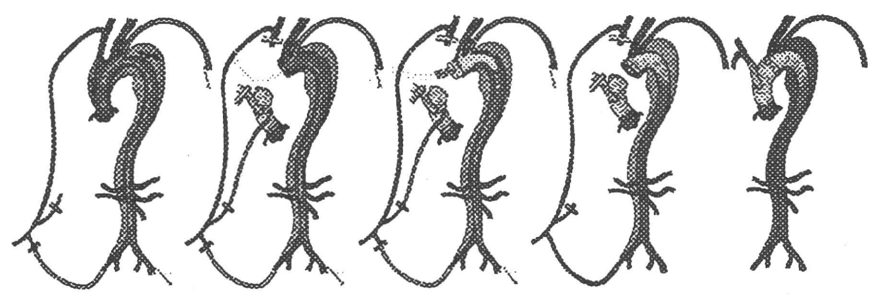

FIGURE 4. Total arch repair with branched open stent-grafting technique.

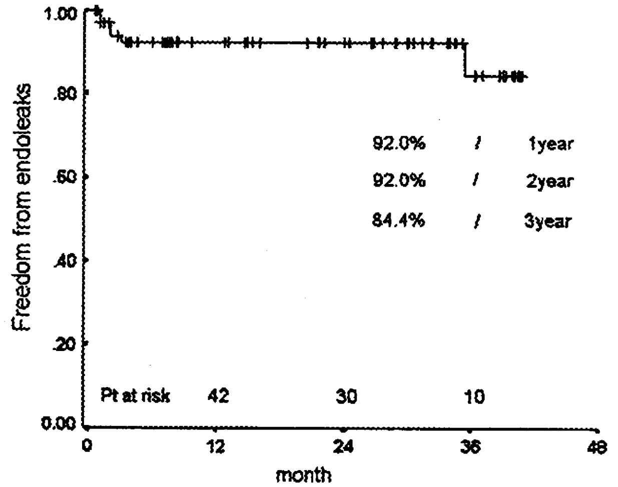

FIGURE 5. Freedom from endoleaks.

in descending thoracic aorta is expected. In this series, all 7 acute type A dissections showed complete thrombus formation in the false lumen at the level of stent graft distal edge; this result would be compatible with that of first-generation open stent grafting.[3-5]

Another good situation for the branched open stent-grafting technique is reoperative total ach repair. Operation of an enlarged residual dissection in the aortic arch after graft replacement of acute ascending aortic dissection is a formidable situation. Tight adhesion makes all the maneuvers (exposure, suture) in conventional aortic arch repair very difficult and subsequently has high mortality.[15] However, the branched open stent-grafting technique requires only median sternotomy, exposure of right atrium for establishment of cardiopulmonary bypass, and exposure of distal anastomosis site of the ascending aortic graft. Arch repair can be completed by inserting the branched endoprosthesis from the opened distal anastomosis site of the ascending graft during DHCA. Our results in reoperative cases were excellent, which suggests that branched open stent grafting can be a very attractive option in this situation.

On the other hand, branch open stent grafting should be used with discretion for degenerative/atherosclerotic aneurysms that have massive mural thrombosis around the cervical branch orifice. In this series, 3 patients with stroke in degenerative aneurysms had severe mural thrombosis in the ascending aorta and transverse arch. We think the technical advantage to prevent embolic events in this operation is to use adequate terminal RCP to eliminate embolic agents from cervical branches.

Cervical branch event would be a topic of discussion in comparison with conventional total arch repair. There were a total of 6 cervical branch endoleaks, and 5 of them were from the LSA branch. The LSA tend to have angulation, and its orifice is further than the LCCA from the aortic transection line, so it was technically not easy to insert the LSA branch. However, insertion became easier by using the guide wire, a minor modification of the device, and our learning. Also, it was not difficult to make additional endovascular repair when endoleaks were detected, and actually all endoleaks of the cervical branches were treated successfully by endovascular repair in this series.

The LSA is an important blood supply source not only of posterior cerebral circulation through the vertebral artery but also of anterior spinal circulation.[16,17] This would mean that sacrifice of the LSA could raise the risk of spinal cord injury, so we think LSA branch reconstruction during circulatory arrest is important.

There was no cervical branch occlusion in our study, but 2 stenoses were observed (2/124 [1.6%]). One was repaired in endovascular fashion. Of course, further observation is mandatory to argue about the patency of these cervical branches; it is expected to be satisfactory because simple endovascular stenting for cervical branch provides satisfactory patency (LSA stenting, 72%–89%/5 years[18,19], carotid stenting, 84%/4 years[20]), even in stenotic/obstructive pathologies.

Total endovascular arch repair with branched/fenestrated stent graft or TEVAR with arch debranching[21] would be another option to repair aortic arch pathologies. These can be performed off-pump, so would be less invasive than branched open stent grafting. We also performed these procedures in high-risk patients for cardiopulmonary bypass surgery. However, there were several problems. First was how to achieve proximal sealing. Aortic arch disease is often associated with diseased (dissected or atheromatously changed) ascending aorta, which is then not appropriate for use as a proximal landing zone. Second was how to prevent embolism in the cervical/cerebral artery. Protection methods such as using temporary balloon occlusion or using a filter protection device would be necessary; however, these technique are still not established in TEVAR.

Total arch replacement with branched open stent-grafting technique uses surgical graft replacement of the ascending aorta and direct anastomosis to secure proximal sealing and circulatory arrest with retrograde cerebral perfusion to prevent cerebral embolism. These methods are well established and time tested, so we believe branched open stent grafting has an advantage over totally endovascular arch repair with branched/fenestrated stent graft or TEVAR with arch debranching.

This study was a retrospective cohort study and the lack of concurrent control group restricts direct comparison with conventional total arch replacement. In order to elucidate the precise advantage of this technique, prospective case-control study would be required.

In conclusion, the branched open stent-grafting technique is an effective hybrid procedure using branched endoprosthesis to complete aortic arch repair, and it provides satisfactory early results. In the midterm, cervical branch events are observed; however, these are successfully treated with additional endovascular repair. This technique could be an very attractive alternative to conventional aortic arch surgery, especially for aortic dissections.

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Discussion

Dr Heinz G. Jakob *(Essen, Germany)*. I would like to congratulate Dr Shimamura and colleagues from Osaka for a great idea to facilitate and to horten aortic arch surgery by refining their own method of open stent grafting of the distal arch and the descending aorta, already published in the mid 1990s. Dr Kato's work certainly influenced my group as well as other European and probably American groups in adopting the principle of combining classical surgical methods with evolving interventional technologies to reduce the surgical dimension on one side but to simultaneously gain the treatment option for the descending aorta. Again, it is your group who demonstrates durability and low reintervention rates long term for this first-generation approach.

The inclusion of cervical branches into this concept seems logical, and you demonstrate how to securely place your main body graft as well as the left subclavian artery graft using a 2-wire guiding technique to guarantee landing within the true lumen in aortic dissection and to overcome kinking of the proximal subclavian artery. The procedural success rate of over 97% is impressive, as is your hospital mortality of 7.2% and your stroke rate of 5.8%, especially in light of the mean age of 66 years of your patient population. In addition, no aorta-related deaths occurred during a mean follow-up of 20 months, and reported survival is 88% at 3 years. I have 3 questions for you.

First, the construction of your "homemade" branch stent graft has to be done based on 3-D computed axial tomographic scan measurements and probably takes 30 minutes or more, either before surgery or at an early stage of the operation. What are you doing in the very acute situation of acute type A aortic dissection, for example, with pericardial tamponade? Can you use this method in this situation, too?

Dr Shimamura *(Osaka, Japan)*. Thank you for your very important question. I think we can use this technique even in that situation, because the insertion of the branched endoprosthesis is provided after establishing deep hypothermic circulatory arrest, and it required about 30 or 40 minutes to achieve core cooling to 20°C in the blood temperature. During this time we can make the stent graft in the side dish, and it is possible to do this procedure even in such a situation, I think so.

Dr Jakob. You state in your article that you don't oversize beyond 10% to 15% when designing the stent-graft dimension, and you are applying 8 atm balloon pressure over 5 seconds to deploy the cervical stent grafts. Is it the same balloon pressure in the descending aortic true lumen, and what about back bleeding during the reperfusion period and early after discontinuation of extracorporeal circulation, especially when you have tears in the aortic arch?

Dr Shimamura. We use a self-expandable type of stent for the main body. So we do not inflate at such a high pressure for the descending thoracic aorta. We only use the spontaneous opening of the self-expandable stent. In dissections, we insert very carefully and avoid the neointimal tear creation by overinflating. And we use the balloon-expandable stents for the cervical branch. Only in the cervical branch do we use the inflation device to achieve 8 atm pressure.

Dr Jakob. So you don't have back-bleeding problems?

Dr Shimamura. Because we do this procedure during deep hypothermic circulatory arrest, we do not have such a problem doing this procedure.

Dr Jakob. And not in the reperfusion period either? No bleeding problems during reperfusion?

Dr Shimamura. Oh, yes.

Dr Jakob. Probably not.

And a final question. You had 6 cervical endoleaks and 2 stenoses, which could be successfully treated by reintervention. You do not see persistent or distal descending aorta leaks, but you report freedom from endoleak is 84.4% after 3 years. Could you please explain this discrepancy?

Dr Shimamura. All the endoleaks were from the cervical branches, and there were no endoleaks from the distal end of the main body. All these endoleaks were detected in the primary computed tomography scan, and we think this is related to our technical immaturity to deliver the stent graft in our early experience.

Dr Jakob. But you state in the article that after 3 years, you have an 84% freedom from endoleaks. This means that you have 16% rate of endoleak.

Dr Shimamura. That may be because the number of cases is only 69 cases, and this is calculated by the Kaplan-Meier method. So the overall freedom from endoleak is calculated by that number.

Dr Jakob. Okay. Thank you. I think it is an important contribution.

Dr Shimamura. Thank you very much for your question.

Dr Jean E. Bachet *(Abu Dhabi, United Arab Emirates)*. I might fall in the category of the old conservative surgeons denounced this morning by Marko Turina, but I observed that in your method the length of the procedure was about 7 hours, that the duration of deep hypothermic circulatory arrest was also rather long, and that those lengths are clearly over the lengths observed, at least in my experience, in straightforward conventional replacement of the aortic arch. So my question is either naive or provocative, but what are the advantages of your method as compared with conventional replacement of the aortic arch, considering that your follow-up is quite short, that the procedure is not validated, and that the long-term outcome is somewhat uncertain?

Dr Shimamura. I think the biggest advantage of this procedure is that you can complete aortic arch replacement without manipulating distally to the left common carotid artery. So you do not need to perform anastomosis on a profound lesion, and you do not have an opportunity to make a recurrent laryngeal nerve injury. So this is the strongest point of this technique. However, as you pointed out, this technique should be more sophisticated, because the average deep hypothermic circulatory time is 36 minutes. So we have to improve the technique or the device to shorten the time of circulatory arrest to complete this procedure.

Dr Bachet. I have another question of the same kind. Considering now that it is highly demonstrated that antegrade selective cerebral perfusion and moderate hypothermia are much better than deep hypothermic circulatory arrest, why do you stick to this old technique of cooling down the patient to less than 20°C?

Dr Shimamura. Because to insert the cervical branches under direct visualization, we do need deep hypothermic circulatory arrest, but we are going to attempt selective cerebral perfusion, as you mentioned, after opening the cervical branches, and this could reduce the time of operation by raising the temperature of the circulatory arrest.

Dr Bachet. Thank you.

ACD

Long-term results of the open stent-grafting technique for extended aortic arch disease

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Objective: This report elucidates the long-term safety and effectiveness of extended aortic arch replacement with an open stent-grafting technique from our 12 years of experience.

Methods: From 1994 to 2004, 126 patients (mean age 67.8 years) with different pathologic conditions of the aortic arch with extension to the descending aorta (57 dissections [acute/chronic = 31/26] and 69 aneurysms) were operated on with an open stent-grafting technique. During deep hypothermic circulatory arrest with selective cerebral perfusion, the stent graft was delivered through the transected proximal aortic arch, and arch replacement with a 4-branched prosthesis was performed.

Results: Operative mortality within 30 days was 3.2%. Perioperative morbidity included 7 (5.6%) strokes and 8 (6.3%) spinal injuries (paraplegia in 3, transient paraparesis in 5). Sixty-three percent of the patients were extubated within 24 hours. In long-term follow-up (mean 60.4 ± 36.5 months, maximum 153 months), survival was 81.1%, 63.3%, and 53.7% at 1, 5, and 8 years. Five (3.9%) late endoleaks were observed but treated with successful additional endovascular repair. Freedom from endoleaks was 98.0%, 91.1%, and 91.1% for 1, 5, and 8 years, respectively.

Conclusion: Long-term observation showed safety and good durability of the open stent-grafting technique for aortic arch disease. This technique could be an attractive treatment option for aortic arch aneurysm with distal extension and aortic dissection requiring aortic arch replacement.

ACD

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Direct surgical approach to pathologic conditions of the aortic arch has been a time-tested, established procedure with satisfactory results and durability. Median sternotomy is the preferred and most advantageous approach. However, performing anastomosis and hemostasis at the deep portion beyond the left subclavian artery is often associated with difficulties and also could induce recurrent laryngeal nerve injury. Moreover, when the distal end of the disease extends to the descending aorta, surgeons have to select extensive exposure of the distal aortic arch or left thoracotomy, which could raise the risk of respiratory complications.

Several approaches such as the clamshell incision,[1] median sternotomy with left thoracotomy,[2] and 2-stage repair with elephant trunk[3,4] have been applied in this situation, but a less invasive procedure without left thoracotomy and with completion in a single stage is desired.

Meanwhile, as an emerging, less invasive alternative to conventional surgical repair, thoracic endovascular aortic repair (TEVAR) was brought into clinical use by Dake and his colleagues[5] and reported in 1994. Our group has also been using TEVAR since 1993 after animal experimentation,[6,7] and satisfactory early outcomes were achieved for type B aortic dissection.[8] This method yielded a less invasive alternative for high-risk patients. However, applying TEVAR to aortic arch diseases was difficult because the aortic arch could not provide an adequate proximal landing zone. To mitigate the difficulties in both the distal anastomosis in conventional arch surgery and the proximal landing zone in TEVAR for the aortic arch, our group[9] introduced

Abbreviations and Acronyms

CSFD	= cerebrospinal fluid drainage
CT	= computed tomography
TEVAR	= thoracic endovascular aortic repair
Th	= thoracic (vertebra)

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the open stent-grafting technique in 1994. This technique, which subsequently has been described as frozen elephant trunk technique or stented elephant trunk in some articles,[10-14] involves conventional replacement of the ascending aorta with a 4-branched graft and stent grafting into the descending aorta through the opened aortic arch. In 2002, we[15] reported that this technique is feasible for aortic dissection to obtain clot formation and shrinkage of the false lumen by closing the entry site in the aortic arch and providing continuous compression on the false lumen.

Previous reports[10-15] described relatively small series, and it is still controversial whether this technique is safe and useful for long-term results.

The objective of this current report is to elucidate the feasibility of this technique for extended aortic arch replacement and to investigate the long-term durability and efficacy of this hybrid procedure from our 12 years of experience.

Patients and Methods

Patients

The open stent-grafting technique and the retrospective review of the records for publication were approved by the institutional review board. From February 1994 to July 2004, 126 patients having pathologic conditions of the aortic arch with extension to the descending aorta were operated on in a single center (Osaka General Medical Center, Osaka Prefectural Hospital) by an open stent-grafting technique. The selection for open stent-grafting technique was aortic arch aneurysms with extension to the descending aorta or aortic dissections that necessitated aortic arch replacement. These indications are listed as follows:

Aortic Arch/Proximal Descending Aortic Aneurysms

- Involving proximal portion of left subclavian artery and unable to be treated with TEVAR
- Extending distally to descending aorta and difficult/unable to perform distal anastomosis in median approach.
- Expected tight adhesion around distal anastomosis site (eg, redo operation)

Aortic Dissection

- Type A dissection with intimal tear in transverse arch or proximal descending aorta that could not be resected by hemiarch replacement
- Type A/type B dissection with aortic arch enlargement/aneurysm
- Type B dissection with intimal tear in root of left subclavian artery (unable to close with TEVAR)

Informed consent was required in each case. Mean patient age was 67.8 years (range, 35–85 years), and 14 (11.1%) patients were older than 80 years. Thirty-seven (29.3%) operations were of an emergency status. Preoperative comorbidities are shown in Table 1. Ten (7.9%) patients had previous graft replacement of descending or thoracoabdominal aorta, and 18 (14.3%) had a history of abdominal aortic repair. There were 3 (2.4%) patients with Marfan syndrome.

TABLE 1. Preoperative patients profiles

Demographic	
Gender (M/F)	86 / 40
Age (mean)	67.8
>80 y	14
Pathology	
Degenerative/atherosclerosis	69
Aortic dissection	57
Type A (acute/chronic)	41 (29/12)
Type B (acute/chronic)	16 (2/14)
Diameter of aneurysm (mm)	63.6 ± 10.6
Preoperative comorbidities (%)	
Stroke	21 (16.7)
Coronary artery disease	28 (22.2)
Low LVEF (<40%)	5 (4.0)
Chronic obstructive pulmonary disease	10 (7.9)
Renal failure (crn > 1.5 mg/dL)	17 (13.5)
History of cancer	9 (7.1)
Previous surgery (%)	
Cardiovascular	6 (4.8)
Descending aorta	10 (7.9)
Abdominal aorta	18 (14.3)
Preoperative status	
Emergency (%)	37 (29.4)
Malperfusion with aortic dissection	
Cerebral artery	3
Coronary artery	4
Visceral artery	3
Lower extremity	7

LVEF, Left ventricular ejection fraction.

Fifty-seven (46.8%) patients had aortic dissection: among these patients, 29 (49.2%) had acute type A dissections involving malperfusion of organs in 10 and loss of conscious in 3. Twelve (24.4%) of the dissections were chronic type A dissections, including 5 redo cases with enlargement of patent false lumen of the aortic arch after ascending aorta replacement in the acute phase. Sixteen (30.5%) cases were type B dissections, involving 2 acute complicated cases and 14 chronic type B dissections with enlargement of the false lumen (average size 50.0 ± 7.7 mm, range 41–70 mm). Sixty-nine (53.2%) were degenerative/atherosclerotic aneurysms with 9 (13.4%) instances of rupture. The average diameter of the aneurysm was 63.6 ± 10.6 mm. All these aneurysms had distal extension to the descending aorta, which required stent graft delivery to the level of the sixth thoracic vertebra (Th6) in 21.4%, Th7 in 35.4%, and distally to Th8 in 44.2%.

Description of the Device

The stent graft was custom-made. It was composed of a Gianturco stent (William Cook Europe A/S, Bjaeverskov, Denmark) and a non-coated polyester fabric graft (WSL graft, Ube, Japan). The diameter of the polyester graft was selected with the measurement results of preoperative 3-dimensional computed tomography (CT). The diameter of the landing zone was calculated by tracing the intimal circumference, and a graft oversized by 10% to 20% was selected. These methods were described in detail in a previous study.[9] Average diameter of the stent graft was 25.9 ± 3.5 mm for dissections and 29.5 ± 3.2 mm for degenerative aneurysms. We first used the 30F sheath and pushing rod to deliver the stent graft into the descending aorta. Although this method did not fail to deploy the stent graft, inserting the rigid sheath into the descending aorta under the guidance of transesophageal echocardiography is not easy. In 2001 we developed a sheathless delivery method. The stent graft was mounted on a balloon catheter (20F silicone nephrostomy balloon catheter) and the stented portion was restrained by a silk string. After the stent graft had been inserted into the descending aorta through the transected aortic arch, withdrawal of the restraining string released the self-expandable stented part of the graft.

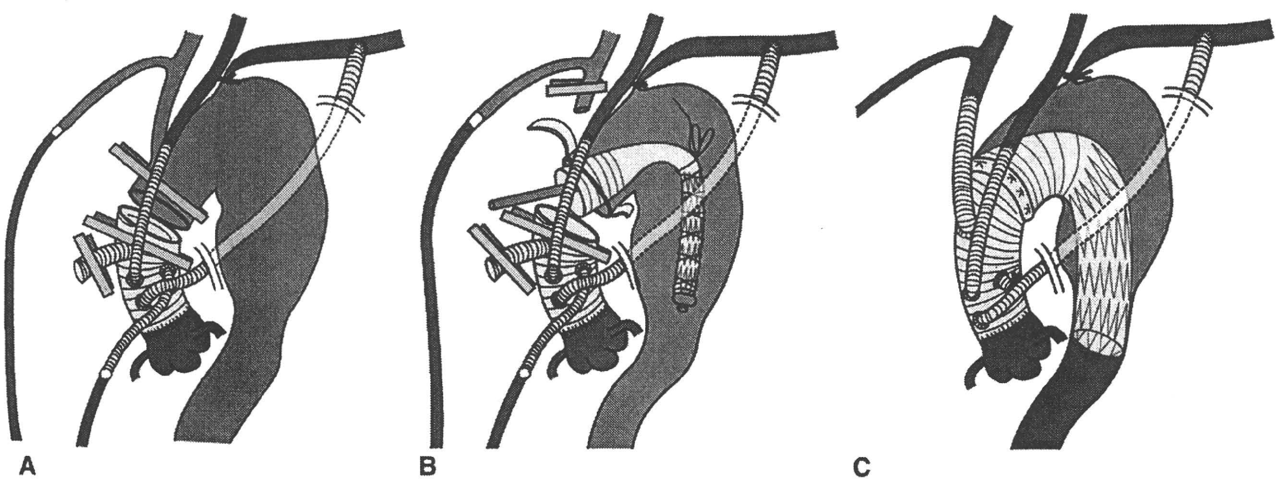
Surgery

The details of the operation have been described in previous reports.[9,15] Via a median sternotomy, the ascending aorta, brachiocephalic artery, and left common carotid artery were dissected. The arterial return cannula was placed in the right axillary artery and femoral artery. Cardiopulmonary bypass was initially started with right axillary perfusion. During core cooling to a 24°C bladder temperature, reconstruction of the left subclavian artery, left common carotid artery, and proximal anastomosis of the 4-branched graft was performed (Figure 1, *A*). The left subclavian artery was reconstructed in an extramediastinal fashion at the left infra subclavian space, with the graft branch passing through the second intercostal space. The proximal end of the 4-branched graft was anastomosed to the ascending aorta after cardiac arrest was achieved by cross-clamping the ascending aorta and antegrade administration of cardioplegic solution. Selective cerebral perfusion via the 4-branched graft and right axillary artery was established and the perfusion to the lower body was discontinued. The aortic arch was transected at a predetermined line between the brachiocephalic artery and left common carotid artery, and the stented portion of the stent graft was inserted to the descending aorta (Figure 1, *B*). After deployment, the stented portion was dilated with a balloon catheter under the guidance of transesophageal echocardiography to confirm that the stent graft was fully opened and not kinked. The nonstented graft portion was sutured to the transected stump of the aortic arch, and subsequently continuous anastomosis to the 4-branched graft was made in end-to-end fashion. The debris and air were carefully flushed out from the descending aorta with femoral blood return before this anastomosis was completed. During rewarming, the brachiocephalic artery was reconstructed and the procedure was completed (Figure 1, *C*). When the ascending aorta was intact and replacement was unnecessary, a bifurcated graft was anastomosed to the ascending aorta instead of 4-branched graft replacement. Reconstruction of the left common carotid artery and left subclavian artery was performed in the same fashion. To prevent ischemic spinal injury, when the time of lower body circulatory arrest extended over 30 minutes, blood return to lower body was established from femoral artery with occluding the stent graft by balloon catheter.

Spinal Protection

From January 1997, cerebrospinal fluid drainage (CSFD) was performed before the operation in elective cases with a history of aortic repair in the thoracoabdominal or abdominal aorta. CSFD was administered preoperatively in 16 (12.7%) cases. When the pathologic condition required stent graft delivery lower than the ninth thoracic vertebra, a short stent graft was delivered in the descending aorta without excluding the aneurysm, and additional endovascular grafting was performed the next day for complete exclusion (delayed exclusion technique). From 2001, to avoid spinal cord ischemia, we started to apply the delayed exclusion technique because of the following reasons:

1. *Technical reason.* A longer stent graft is hard to control under the guidance of transesophageal echocardiography, and



A B C

Figure 1. A, reconstruction of the left subclavian artery, left common carotid artery, and proximal anastomosis of the 4-branched graft. B, The aortic arch was transected at a predetermined line between the brachiocephalic artery and left common carotid artery, and the stent graft was inserted to the descending aorta. C, The brachiocephalic artery was reconstructed and the procedure was completed

there is a risk of kinking. From our experience, an easily manageable length of the stent graft is less than 15 cm, and this could reach around Th8 level.

2. *Preservation of the spinal circulation.* TEVAR provides excellent avoidance of spinal cord ischemia even when it covers the major intercostal artery connecting to the anterior spinal artery (Adamkiewicz artery). Delayed exclusion with additional endovascular grafting could maintain the spinal circulation, and we anticipate this technique could decrease the risk of spinal cord ischemia. Six (4.8%) patients were treated with the delayed exclusion technique.

Patient Follow-up

The follow-up with contrast CT imaging was obtained before hospital discharge, 6 months after the operation, and yearly thereafter. A follow-up CT image was available for 81.9% of patients who survived longer than 6 months. Follow-up clinical status was obtained by medical records from an outpatient clinic or by contacting surviving patients or family members and primary care physician. Follow-up was 92.6% complete, averaging 60.4 ± 36.5 months (maximal follow-up 153 month, total cumulative follow-up = 533 patient-years; 45 patient remaining at risk at 5 years).

Statistical Analysis

All data were reviewed retrospectively. Continuous variables are expressed as mean ± SD and categorical variables as percentages. Survival and freedoms from aortic arch–related death, freedom from endoleaks, freedom from aortic intervention, and freedom from major adverse events were estimated by the Kaplan–Meier method.

Results

Early Outcome

The stent graft delivery was technically successful in all 126 patients. In 6 (4.8%) patients kinking of the stent graft showed a pressure gradient greater than 20 mm Hg. All these patients were successfully treated intraoperatively by endovascular repair with additional bare stent deployment. Concomitant procedures included 4 aortic root replacements, 6 aortic valve replacements, and 8 coronary artery bypass grafts. There were 7 cases of type A acute aortic dissection with malperfusion of the lower extremity. To recanalized the malperfusion, we performed endovascular repair in 4 patients (3 iliac stenting and 1 stenting of the descending aorta) and bypass grafting in 3 (2 aortofemoral bypass and 1 femorofemoral bypass) intraoperatively. The average operative, cardiopulmonary bypass, and circulatory arrest times of the lower body were 401, 147, 31 minutes, respectively.

Operative mortality within 30 days was 4 of 126 (3.2%). Two death were in acute type A dissection (1 due to postoperative heart failure, 1 due to uncontrollable hemmorage from the aortic root with coagulopathy), and another 2 death were in degenerative aneurysm (1 due to stroke, 1 due to postoperative thoracoabdominal aneurysm rupture). There were 7 in-hospital deaths after 30 days (in-hospital mortality 5.5%). The causes of in-hospital mortality were brain infarction (n = 1), sepsis (n = 3), aortoesophageal fistula (n = 1), rupture of thoracoabdominal aortic aneurysm (n = 1), and acute myocardial infarction (n = 1). Aortoesophageal fistula occurred in a patient with ruptured type B aortic dissection with mediastinal hematoma. This patient was treated successfully with the open stent-grafting technique and the aneurysm was successfully excluded, but an aortoesophageal fistula developed after the mediastinal hematoma had absorbed at 38 days postoperatively. The causes of early death within 1 year are listed in Table 2. Perioperative morbidity included 7 (5.6%) strokes, 3 (2.4%) cases of paraplegia, and 5 (3.9%) cases of transient paraparesis. No spinal cord ischemia was observed in the patients treated by the delayed exclusion technique. The average number of packed red blood cells transfusions was 14.0 ± 3.1 units and re-exploration for bleeding was required in 3 (2.4%) patients. In 6 (4.8%) with renal failure, transient hemodialysis was required. The length of stay in the intensive care unit ranged from 0 to 60 days, median 4 days.

Postoperative hoarseness occurred in 12 (9.5%) patients; however, 7 (58%) of 12 were fully recovered before hospital discharge. Sixty-three percent of the patients were extubated within 24 hours, and 8 (6.3%) required tracheostomy.

The demographics of patients with paraplegia and transient paraparesis are shown in Table 3. All patients with transient paraparesis had recovered enough to be able to walk by themselves. The median hospital stay was 29 days, and 11 (8.7%) of the patients were discharged to an institution for rehabilitation.

TABLE 2. Causes of early and late death

Causes of death	Early (<1 y)	Late (>1 y)	Total
Aortic			
Rupture (treatment failure)	0	1	1
Aortoesophageal fistula	1	1	2
Rupture of other aortic aneurysm	3	1	4
Nonaortic			
Cancer	0	7	7
Brain infarction	3	2	5
Subarachnoid hemorrhage	1	1	2
Pneumonia	0	6	6
Sepsis	3	1	4
Renal failure	1	2	3
Acute myocardial infarction	1	1	2
Arrhythmia	0	1	1
Ischemic colitis	0	1	1
Ileus	0	1	1
Gastric bleeding	0	1	1
Cirrhosis	1	0	1
Suicide	1	0	1
Sudden death	1	0	1

Late Outcome

Survival. Actuarial survival estimates 1, 5, and 8 years after the procedure were 81.1%, 63.3%, and 53.7%, respectively (Figure 2). Causes of deaths are listed in Table 2. There

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TABLE 3. Demographics of spinal cord ischemia

Spinal cord ischemia	Pathology	Distal landing zone	Risk factor	Comment
Paraplegia	TAA	Th8	AAA repair	
Paraplegia	AD(A)	Th6	Hypotension	Stent graft stenosis
Parapleiga	AD(A)	Th6	Hypotension	Stent graft stenosis
Transient paraparesis	TAA	Th9	AAA repair	
Transient paraparesis	TAA	Th8	AAA repair	
Transient paraparesis	TAA	Th8		
Transient paraparesis	AD(A)	Th6	Hypotension	Preoperative malperfusion
Transient paraparesis	AD(A)	Th6	Hypotension	Preoperative malperfusion

TAA, Degenerative/atherosclerotic aneurysm; *AD(A)*, aortic dissection (type A); *AAA*, abdominal aortic aneurysm.

was 1 (0.79%) late death resulting from rupture of a treated aortic arch aneurysm that was caused by leaking from the proximal suture site of the stent graft. One (0.8%) late fatal aortoesophageal fistula had occurred. This case involved a huge degenerative aneurysm encompassing the whole thoracic aorta with chest pain and a hematoma around the aneurysm (sealed rupture). This patient was treated successfully by extended aortic arch replacement with the open stent-grafting technique; the stent graft was delivered to the 11th thoracic vertebra level by a delayed exclusion technique. The patient had an uneventful recovery, and CT 12 months after the procedure showed shrinkage of the aneurysm (70 mm to 61 mm). However, 28 months after the procedure, CT showed type III endoleak. Additional TEVAR was planned, but the aorta ruptured before treatment was instituted. Emergency TEVAR could have saved the patient's life, but fatal aortoesophageal fistula had occurred.

Brain infarctions as the cause of death within 1 year were promoted by the surgery, unfortunately. Two late brain infarctions were observed, but neither of them resulted from cerebral graft occlusion or graft thrombosis. Rupture of other aortic aneurysms had occurred while one of the patients was waiting for the next operation; the other patient had refused further treatment. All these patients showed complete exclusion of the treated arch aneurysm on postoperative CT scans, and none of these were associated with stent graft dislodgment or perforation.

Operative mortality, aortoesophageal fistula, stent graft–related mortality (perforation, occlusion, and thromboembolism), and cerebral graft–related mortality were defined as aortic arch–related death, and the freedom from aortic arch–related death was 95.8%, 92.4%, and 92.4% at 1, 5, and 8 years, respectively (Figure 3).

Endoleaks and aortic intervention. Follow-up CT was obtained in 81.9% of patients who survived longer than 6 months. In degenerative aneurysms, 68.3% of the aneurysms showed disappearance or shrinkage in late follow-up. In aortic dissections, 78.6% have achieved shrinkage of

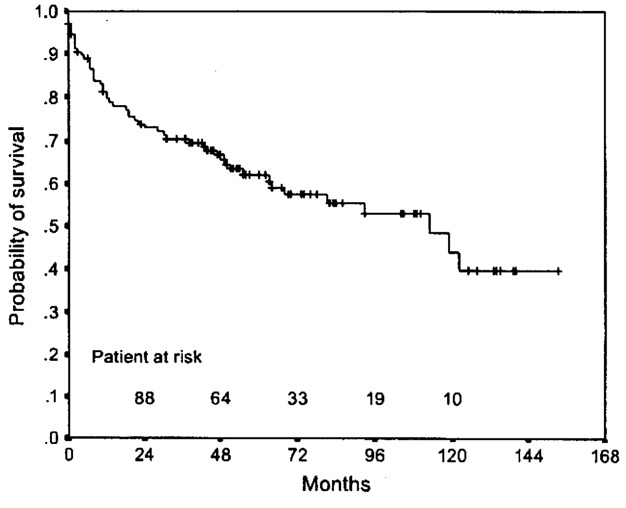

Figure 2. Overall survival of all 126 patients.

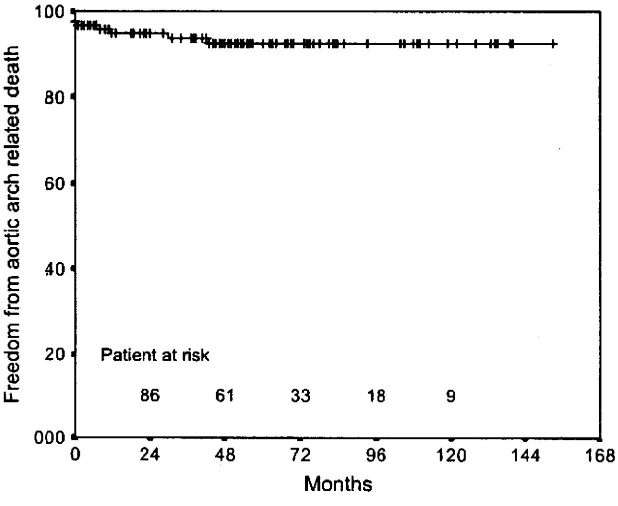

Figure 3. Freedom from aortic arch–related death.

the false lumen. Among these patients, 30.3% showed complete disappearance of the false lumen in the entire aorta, and 48.4% showed disappearance of the false lumen in the thoracic lesion. Creation of a new intimal tear by the edge of the stent graft was not observed in any case.

Late endoleaks were observed in 5 (3.9%) cases (4 in degenerative/atherosclerotic aneurysms, 1 in chronic type B aortic dissection). Type I endoleak from the distal end of the stent graft had occurred in 3 cases, and type III endoleak from the stent-in-stent site in 2 cases. Endoleaks were observed an average of 24.8 months postoperatively, and all of them were successfully treated with additional endovascular repair. Actuarial freedom from endoleaks was 98.0%, 91.1%, and 91.1% for 1 year, 5 years, and 8 years, respectively.

Intervention of another aortic lesion was administered in 10 (7.9%) cases. There were 7 TEVARs and 3 graft replacements (1 thoracoabdominal aortic aneurysm and 2 aascending aortic aneurysms). All of these cases that required intervention for other aortic lesions were aortic dissection cases. The average postoperative duration for intervention of other aortic lesions was 38.3 months (range 3–89 months). Actuarial freedom from aortic intervention (freedom from intervention of endoleaks and other aortic aneurysms) was 97.2%, 83.8%, and 75.4% for 1, 5, and 8 years, respectively.

Major adverse events. In-hospital death, stroke, spinal cord ischemia, aortic rupture, aortoesophageal fistula, and endoleak were defined as major adverse events, and the freedom from major adverse events was 79.9%, 73.8%, and 73.8% at 1, 5, and 8 years, respectively.

Discussion

The open stent-graft technique is a hybrid procedure that combines conventional aortic surgery and endovascular repair. By using the stent graft as an alternative to the distal anastomosis, surgeons can avoid extended dissection of the distal arch and left thoracotomy. This procedure could be completed by making the distal aortic incision between the brachiocephalic artery and left common carotid artery, which provides a better surgical view and hemostasis than traditional anastomosis in aortic arch replacement. Insertion of the stent graft could be performed in a few minutes. Thus this procedure has an advantage in arch aneurysms extending distally to the descending aorta, it being difficult or impossible to perform distal anastomosis by the median approach, or in aneurysms that are expected to have tight adhesion around the distal anastomosis site (eg, redo cases). It is also useful for type A dissections with an intimal tear in the transverse arch or proximal descending aorta that cannot be resected by hemiarch replacement.

In this cohort of 126 patients, the overall operative mortality within 30 days was 3.2%. In degenerative aneurysms, the operative mortality within 30 days was 2.9%. This is comparable with the operative mortality within 30 days of the first-stage operation with the elephant trunk technique in contemporary reports (2.1%–12%).[16,17] However, the elephant trunk technique requires a second-stage operation (mortality 4%–8.5%) to complete the procedure, and there are even a considerable number of patients who do not survive to the second operation. The open stent-grafting technique has an advantage over the elephant trunk technique in that it completes the procedure within a single operation.

In acute type A dissection, the entire intimal tear resection is desirable to achieve a good fate of the remaining dissected aorta.[18] However, extending the procedure to the aortic arch could be associated with increasing mortality.[18] In our series, the mortality in acute dissection is satisfactorily low (6.9%), and this could relate to the fact that this procedure could achieve total arch repair without manipulating more distally to the left common carotid artery, which facilitates the control of bleeding.

Postoperative occurrence of vocal cord paralysis after aortic surgery is considered to be an independent predictor of pulmonary complications and leads to a longer duration of hospital stay.[19] Even with preservation of the recurrent laryngeal nerve, vocal cord paralysis occurs in 21.9% to 32% of aortic arch operations and in most cases does not return to normal movement.[20] Our procedure does not require resection distally to the left artery, and it has the advantage of avoiding recurrent nerve injury. Postoperative vocal cord paralysis was observed in 9.5%, and 58% of them had fully recovered during hospitalization. Mechanical ventilation for more than 72 hours was required in 20.0% in our series and could be low in comparison with other series of aortic arch replacement through a left thoracotomy (36–50%).[21,22] These results suggest that the open stent-grafting technique could contribute to reduced postoperative respiratory failure.

Spinal cord ischemia is a devastating complication of aortic surgery. Our series showed 3 (2.4%) cases of paraplegia and 5 (3.9%) of paraparesis. Among the 3 patients with paraplegia, 2 had intraoperatively hypotensive perfusion of the lower body associated with stent graft stenosis. Inasmuch as hypotension is widely known to be a risk factor for the development of spinal cord ischemia,[23] stent graft stenosis is an important pitfall of this procedure. Designing the stent graft carefully is mandatory when custom-made stent grafts are used.

Among the 5 cases of temporal paraparesis, 2 were type A acute dissections with preoperative malperfusion. Both of them had a clotted false chamber and severely narrowed true chamber in the descending aorta associated with hypoperfusion of the visceral arteries and lower extremity, which raised concern about the occurrence of spinal cord ischemia. The remaining 3 cases except for the hypoperfusion cases were associated with a history of abdominal aortic repair. From 1997, we started to administer CSFD before the operation in cases of previous thoracoabdominal or abdominal aortic repair. No spinal cord ischemia was observed since then except the 2 cases of acute type A dissection with preoperative malperfusion.

In our study, survival at 1, 5, and 8 years was 81.1%, 63.3%, and 53.7%, respectively. Long-term results of extended aortic arch repair are not well described, but our result is comparable with those of other series of simple aortic arch replacement (5-year survival 46%–79%).[23-25]

Despite encouraging early results, there are few reports describing long-term results of endovascular stent graft repair. Demers and his colleagues[26] reported in their study of 103 TEVARs for descending thoracic aorta that freedom from endoleak was 78%, 64%, and 50% at 1, 5, and 8 years, respectively. Freedom from endoleak in this series was 98.0%, 91.1%, and 91.1% for 1, 5, and 8 years, respectively, which could be superior to TEVAR. TEVAR is inevitably associated with some frequency of proximal type I endoleak in the early and long-term follow-up periods, but this is avoidable in the open stent-grafting technique because the proximal end of the stent graft was sutured in a surgical fashion. All 5 patients who had a late distal endoleak were successfully treated with additional TEVAR, and there have been no secondary endoleaks.

Although shrinkage of the aneurysm sac after endovascular repair may be desirable, the persistence of the aneurysm does not represent a failure because a stable aneurysm without endoleak has not been linked to any untoward effects.[27]

On the other hand, sac enlargement implies increased pressure within the aneurysm sac and should be treated promptly. In our series, 3 aneurysms showed enlargement on late follow-up and all of them were associated with type I/type III endoleaks. Also, we have to consider that the intercostal arteries are opened to the excluded aneurysm (type II endoleak) and this requires that the transected stump of the aortic arch be sutured to the stent graft. Inasmuch as these issues should be carefully studied, we perform postoperative CT with contrast medium at the arterial phase and delayed phase to detect endoleaks.

However, type I/type III endoleaks can be treated with additional endovascular repair with a good result. According to type II endoleak, Ohki and colleagues[28] had reported a study using an implantable wireless aneurysm pressure sensor for endovascular repair of abdominal aorta. They showed that the postexclusion pulse pressure was significantly decreasing. In no patient in our series was trouble caused by the pressure inside the aneurysm, such as continuous leaking from ruptured aneurysm or enlargement of the aneurysm with type II endoleak. From these results, the pressure inside the aneurysm (endotension) could be low enough in the clinical point of view.

Limitation of the Study

This is a retrospective cohort study, and the lack of a concurrent control group restricts direct comparison with total arch replacement associated with left thoracotomy. For the precise advantage of open stent-grafting technique to be elucidated, a prospective case–control study would be required. This study includes our earliest experience with stent grafting, so both the technical immaturity and the lack of adequate spinal protection could have caused spinal ischemia. Improved stent graft design, delivery system, and consideration of spinal protection could be associated with better outcomes.

Conclusion

In this study of 126 patients treated with an open stent-grafting technique, satisfactory early results were obtained in both aortic dissections and aortic arch aneurysms with distal extension to the descending aorta. Regarding long-term outcomes, acceptable survival and good avoidance of aortic arch–related death was obtained. The incidence of endoleaks was satisfactorily low and the patients could be rescued by additional endovascular repair. In aortic dissection, this procedure could obtain good clot formation and shrinkage of the false lumen. These results suggest that the open stent-grafting technique is a safe and effective procedure and might be a good alternative to conventional prosthetic replacement for aortic dissections and arch aneurysm with distal extension to the descending aorta.

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