

Long-Term Results of Endovascular Repair for Distal Arch and Descending Thoracic Aortic Aneurysms Treated by Custom-Made Endografts: Usefulness of Fenestrated Endografts

Masakazu Matsuyama, MD,¹ Kunihide Nakamura, MD, PhD,¹
Hiroyuki Nagahama, MD, PhD,¹ Katsuhiko Nina, MD,²
Jouji Endou, MD, PhD,¹ Kazushi Kojima, MD, PhD,²
Masanori Nishimura, MD,¹ Hirohito Ishii, MD,¹
and Atsuko Yokota, MD²

Objective: We evaluated early and long-term results of atherosclerotic aneurysm repair with custom-made endografts.

Materials and Methods: Eighty-one consecutive patients underwent thoracic endovascular aortic repair with custom-made endografts. Fenestrated grafts were used in 37 patients (45.7%) to maintain blood flow of the neck and a landing zone for as long as possible for distal arch or proximal descending aneurysms. The rates of perioperative mortality, stroke, paraplegia, and primary endoleaks were assessed to evaluate in-hospital safety. The rates of endoleak development, survival, and freedom from aortic-related death were assessed to evaluate long-term efficiency.

Results: Twenty-four patients (29.6%) underwent urgent operations, and 38 (46.9%) underwent distal arch or proximal descending aortic aneurysm repair. There was one case (1.2%) of in-hospital mortality and no cases of stroke. Permanent spinal injury occurred in one patient (1.2%). Early and late endoleaks occurred in one and 16 patients, respectively. The actuarial survival rates were 88.9%, 64.9%, and 51.7% at 1, 5, and 10 years, respectively. The actuarial rates of freedom from endoleaks were 90.1%, 81.3%, and 68.6% at 1, 5, and 10 years, respectively.

Conclusion: Early results of custom-made endografts were excellent, and fenestrated endografts were safe for distal arch and proximal descending aortic aneurysms.

Keywords: long-term results, fenestrated endograft, custom-made, thoracic aortic aneurysm, distal arch aneurysm

¹Department of Cardiovascular, Thoracic and General Surgery, University of Miyazaki, Miyazaki, Miyazaki, Japan
²Department of Cardiovascular Surgery, Miyazaki Prefectural Nobeoka Hospital, Nobeoka, Miyazaki, Japan

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Corresponding author: Masakazu Matsuyama, MD. Department of Cardiovascular, Thoracic and General Surgery, University of Miyazaki, 5200 Kihara, Kiyotake-cho, Miyazaki, Miyazaki 889-1692, Japan
Tel: +81-985-85-1510, Fax: +81-985-85-5563
E-mail: mmatsuya@med.miyazaki-u.ac.jp

Introduction

In Japan, endografts for thoracic aortic aneurysms were not commercially available until March 2008. Thus, it was necessary to use custom-made endografts for high-risk patients. We designed precurved fenestrated endografts for distal arch or proximal descending aortic aneurysms and deployed them at the arch to preserve blood flow in the neck vessels and prevent stroke or paraplegia. Early clinical results of thoracic endovascular aortic repair (TEVAR) have

shown that this procedure is associated with significantly better quality of life and survival than is open surgery, and it is free from major complications.¹⁾ However, little is known about the long-term outcomes of TEVAR for treatment of thoracic aneurysms.

We used custom-made endografts with a fenestrated device for distal arch and proximal descending aortic aneurysms. Previous studies on the use of fenestrated endografts reported excellent perioperative results, but lacked long-term results.²⁻⁴⁾ The aim of this study was to evaluate the early and long-term results of our precurved fenestrated endograft and explain the advantages and limitations of this device.

Materials and Methods

We retrospectively studied 81 consecutive patients who underwent TEVAR for atherosclerotic thoracic aneurysms with custom-made endografts from 2000 to 2009 in the Department of Surgery 2 Faculty at The University of Miyazaki and the Department of Cardiovascular Surgery at Miyazaki Prefecture Nobeoka Hospital. All patients were followed up completely after TEVAR. The mean follow-up period was 90.9 ± 26.2 months (range, 36–164 months).

Anatomical indications

The anatomical inclusion criteria for endovascular aortic repair were a proximal and distal landing zone diameter of <38 mm and a proximal or distal landing zone length of >20 mm. When we used fenestrated endografts for distal arch aneurysms, the distance of the left common carotid artery and aneurysm was >20 mm.

Device details and methods of procedure

Our custom-made endografts comprised self-expandable stainless steel Gianturco Z-stents (Cook, Bloomington, Indiana, USA) covered with an ultrathin-wall woven polyester fabric (thickness, 0.1 mm; porosity; 200–250; Ube, Yamaguchi, Japan). The individually designed stent graft was constructed by connecting the peaks of the stents with struts, and the stent was shaped to achieve a relatively rigid great curvature that conformed to the contour of the individual aorta. The graft size was 10% to 20% greater than the diameter of the proximal and distal necks. The ideal landing zone length was ≥ 2 cm. Single or multiple fenestrations were created along its greater curvature to secure

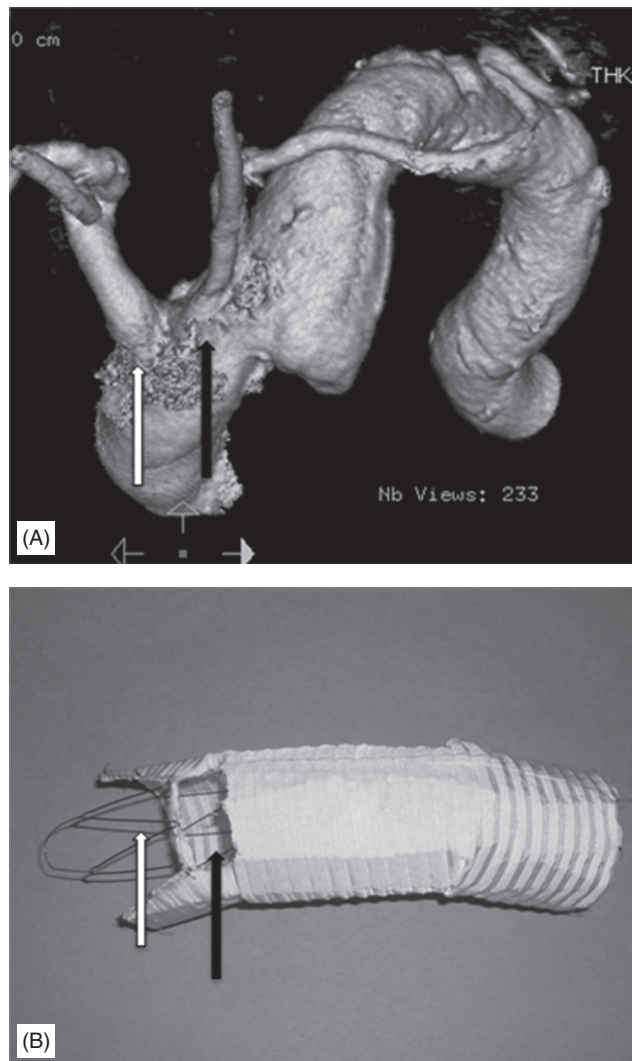


Fig. 1 Preoperative three dimensional computed tomography angiography (3D CTA) and custom-designed endograft. (A) Preoperative 3D CTA; white arrow is orifice of right brachiocephalic artery (RBCA), black arrow is orifice of left common carotid artery (LCCA). (B) Custom-designed endograft; white arrow is a fenestration for RBCA, black arrow is a fenestration for LCCA.

a blood supply via the arch vessels if the graft was landing at the arch.

At first we have to decide a position and the length of endografts from shape of arch and orifice position of neck vessels with information of three dimensional (3D) computed tomography angiography (CTA). If we make a fenestration on the graft, we predict the neck ramification origin part which will accord with the graft, and grant an open window to the department (Fig. 1). When we match the position of the fenestration with neck vessels, it is easier in longitudinal adjustment by the characteristic of device with

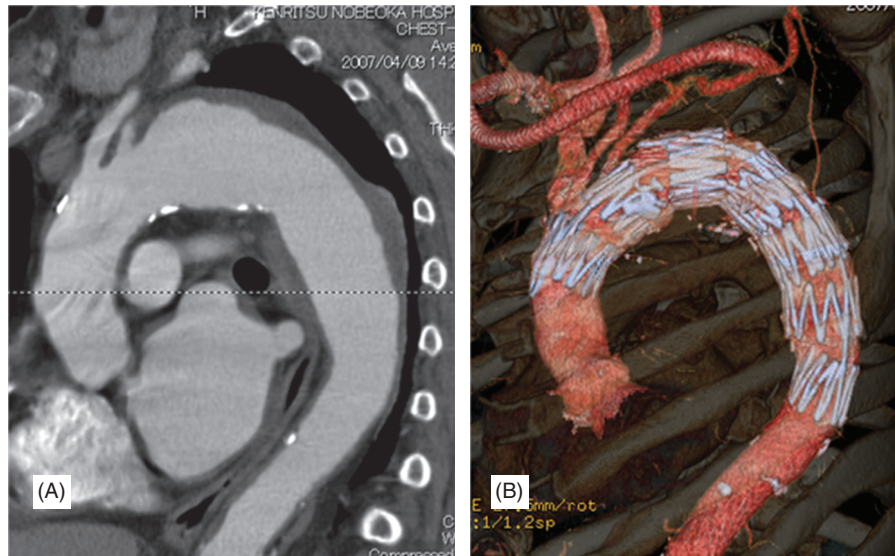


Fig. 2 Preoperative and postoperative images. (A) Preoperative two dimensional (2D) computed tomography angiography (CTA) image. (B) Postoperative 3D CTA image.

longitudinal stiffness and a pre-curved shape, but difficult in cross axis direction (Fig. 2). In actuality, the size of most fenestration for LCCA was 10 mm in length and 25 mm in width. And one for RBCA was 20 mm in length and 25 mm in width, to prevent blockade orifice of RCCA for migration of endograft (Fig. 1B).

When there was distance with LSCA and an aneurysm more than 20 mm, we kept flow of LSCA with fenestration. If there were fenestration for LCCA other than one for LSCA, we made two holes for each. When distance is thereunder, we must block up LSCA with graft.

Definitions

An endoleak was defined as radiological evidence of blood flow outside the endograft and was classified as primary (diagnosed within 30 days postintervention) according to a previously published classification.⁵⁾ An anatomical map was created of each landing zone bordered by lines delineating the distal sides of the branch arteries of the aortic arch. The position of the proximal end of the endograft was classified according to this system.⁶⁾ Aneurysm-related death was defined as any in-hospital death at the time of initial implantation or as a consequence of aneurysm rupture, conversion to open repair, or any other secondary endovascular procedure associated with the aneurysm at any time during hospitalization. Migration

was defined as >5-mm proximal or distal movement of the endograft relative to fixed anatomic landmarks. Chronic renal failure (CRF) was defined as an estimated glomerular filtration rate of <30 ml/min/1.73 m².

We defined a composite endpoint of “continued success” such as absence of type I endoleaks, procedural and aneurysm related deaths, migrations, and freedom from secondary interventions.

Initial patient demographics and perioperative variables and follow up

The preoperative variables recorded were age, sex, history of hypertension, history of smoking, coronary artery disease, history of central neurological event, cerebral infarction on preoperative brain computed tomography, chronic obstructive pulmonary disease, re-do operation, abdominal aortic aneurysm, diabetes mellitus, preoperative shock, CRF, and emergency operation. Perioperative variables were analyzed to identify associations with major adverse complications and in-hospital mortality. Major adverse complications included endoleaks, stroke, spinal injury, acute myocardial infarction, arterial injury, and prolonged ventilation.

The follow-up protocol involved the performance of contrast-enhanced computed tomography before hospital discharge, 6 months after endograft placement, and yearly thereafter. The follow-up clinical

status obtained in July 2013 was 100% complete; the mean follow-up period was 90.9 ± 26.2 months (range, 36–164 months) (maximum, 13 years; 72 patients [88.9%] remained after 5 years). The cause of death was determined from the patients' death certificates and medical records.

Statistical analysis

All variables underwent univariate analyses (unpaired two-tailed t test, χ^2 test, or Fisher's exact test, as appropriate) to determine any associations with endoleaks or mortality. Variables with a p value of <0.2 in the univariate analysis were examined using multivariate analysis by forward stepwise logistic regression to identify independent risk factors for endoleaks and in-hospital mortality. The rates of survival, freedom from aortic-related death, and freedom from endoleaks were estimated by the Kaplan–Meier method. Risk factors for long-term survival were identified using Cox's proportional hazards regression model. Statistical analysis was performed using JMP 6.1 for UNIX (SAS, Inc., Cary, North Carolina, USA).

Results

The mean patient age at the time of the operation was 72.6 ± 9.3 years (range, 44–93 years), and 53 (65.4%) of patients were male. Twenty-four patients (29.6%) underwent emergency surgery for a ruptured aneurysm. Disease locations were the distal arch in 32 patients, proximal descending aorta in 5, and middle and distal descending aorta in 44. Preoperative comorbidities included hypertension in 76 patients, coronary artery disease in 14 (17.3%), history of a central neurological event in 28 (34.6%), chronic obstructive pulmonary disease in 15 (18.5%), abdominal aortic aneurysm in 22 (27.2%), diabetes mellitus in 8 (9.9%), and CRF in 7 (8.6%). No patients had a history of hemodialysis. Twenty-one patients had undergone previous cardiac or aortic operations via median sternotomy. Fifteen patients (18.5%) had undergone previous abdominal aortic or intestinal operations via median laparotomy. Two patients had infected aneurysms; one was an aorto-brachial fistula, and the other was an aorto-esophageal fistula. The location of the aneurysm was the distal arch in 37 patients (45.7%). Nineteen patients (23.5%) had undergone previous rerouting and

Table 1 Demographics of rerouting, fenestrations for neck vessels

Manipulation for neck vessels	number
Fenestration for RBCA	15
Fenestration for LCCA	30
Fenestration for LSCA	12
Covered for LSCA	27
Reconstruction for LSCA	19
Anatomical landing zone map	
Zone 0	15
Zone 1	15
Zone 2	9
Zone 3	18

RBCA: right brachiocephalic artery; LCCA: left common carotid artery; LSCA: left subclavian artery

subsequent reconstruction by left subclavian artery (LSCA) bypass. Fenestrated endografts were placed in 37 patients. The endografts were placed in zone 0 in 15 patients, zone 1 in 15, zone 2 in 9, and zone 3 in 18 using the anatomical landing zone map.⁵⁾ The fenestrated endografts successfully preserved the head vessels in 57 patients, right brachiocephalic artery in 15, left common carotid artery in 30, and LSCA in 12. The LSCA was covered by endografts in 27 patients and revascularized by axilloaxillary or left common carotid artery–LSCA bypass in 19, but it was simply covered by the endograft as a sacrifice emergency procedure in 12 (Table 1). The mean operation time was 228.0 ± 112.6 min (range, 79–585 min), and the mean blood loss was 282.6 ± 263.2 ml (range, 5–1595 ml).

Early outcomes

The in-hospital mortality rate was 1.2%. One patient who underwent preoperative cardiopulmonary resuscitation caused by thoracic aortic aneurysm rupture died of multiple organ failure (Table 1).

The endograft was successfully deployed in 80 patients. Primary endoleaks were detected in the perioperative period in one patient, but this patient died and thus could not undergo secondary intervention.

No patients developed a stroke in the early postoperative period. One patient developed permanent paraplegia and one developed transient paraparesis after TEVAR.

Late outcomes

Thirty-two patients died during the follow-up period after hospital discharge. The cause of death was

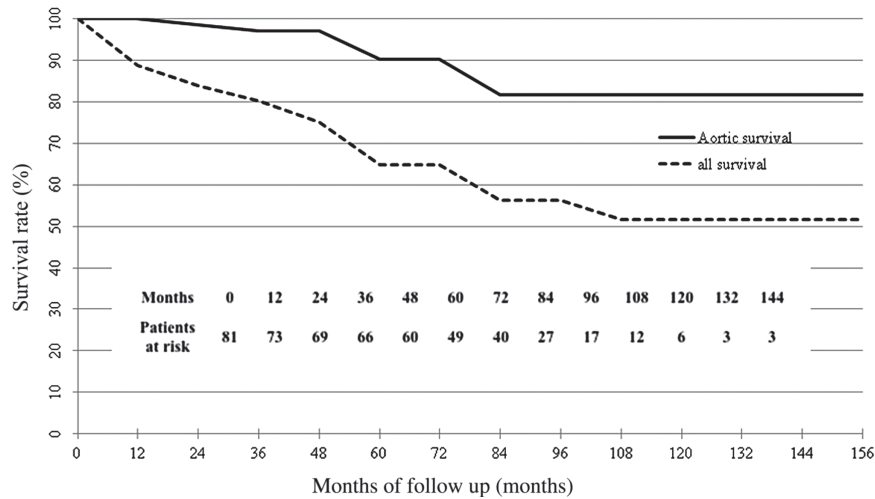


Fig. 3 Actuarial survival rate from all cause death and actuarial rate of freedom from aortic related death.

target aortic rupture in seven patients and secondary convert aortic operative death in one. Stroke occurred in two patients, pneumonia in seven, cardiac failure in three, malignancy in three, intestinal events in three, senile decline in four, and suicide in one (Table 1). Long-term survival rates, including in-hospital mortality, were $88.9\% \pm 3.5\%$, $64.9\% \pm 5.4\%$, and $51.7\% \pm 7.2\%$ at 1, 5, and 10 years, respectively (Fig. 3). Nine patients died of aortic-related causes. The actuarial rates of freedom from aortic-related death were $100.0\% \pm 0.0\%$, $90.3\% \pm 3.8\%$, and $81.6\% \pm 5.9\%$ at 1, 5, and 10 years, respectively (Fig. 3). Sixteen patients developed a new (or secondary) endoleak during the follow-up period. The actuarial rates of freedom from endoleaks, including primary endoleaks, were $90.1\% \pm 3.3\%$, $81.3\% \pm 4.6\%$, and $68.6\% \pm 7.0\%$ at 1, 5, and 10 years, respectively. The cause of all late endoleaks was dilatation of the proximal sealing zone. Eleven patients underwent secondary treatment. Seven patients required late surgical conversion; four of them had developed fabric erosions of the grafts. The actuarial rates of freedom from aortic reintervention were $91.4\% \pm 3.1\%$, $87.2\% \pm 3.8\%$, and $83.5\% \pm 5.1\%$ at 1, 5, and 10 years, respectively (Fig. 4). We recognized fabric erosion of the grafts in four of the seven patients who required open conversion. Univariate analyses showed that the following variables were associated with long-term mortality with a p value of <0.10 : age ($p = 0.060$), CRF ($p = 0.017$), congestive heart failure ($p = 0.072$), emergency operations ($p = 0.003$), endoleaks ($p = 0.003$),

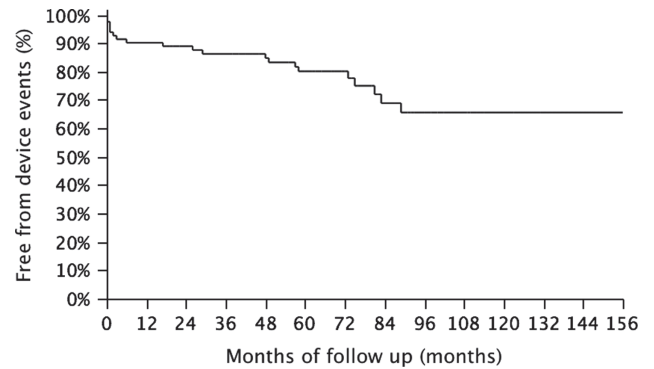


Fig. 4 Actuarial rate of continued success. We defined a composite endpoint of “continued success” such as absence of type I endoleaks, procedural and aneurysm related deaths, migrations, and freedom from secondary interventions.

and longer aneurysm length ($p = 0.030$). Multivariate analysis identified age (hazard ratio [HR], 1.08; confidence interval [CI], 1.02–1.15; $p = 0.012$), urgent or emergency operation (HR, 4.83; CI, 0.29–7.62; $p = 0.078$), and endoleaks (HR, 4.52; CI, 1.79–12.95; $p = 0.031$) as independent risk factors for long-term survival (Table 2).

Univariate analyses showed that the following variables were associated with endoleaks with a p value of <0.10 : CRF ($p = 0.001$), congestive heart failure ($p = 0.043$), larger aneurysm diameter ($p = 0.004$), and longer aneurysm length ($p = 0.077$). Multivariate analysis identified CRF (HR, 6.87; CI, 3.19–16.45; $p = 0.003$) and larger aneurysm diameter (HR, 1.06; CI, 1.01–1.12; $p = 0.003$) as independent

Table 2 Relationships between patient variables and long-term survival using Cox proportional hazards model

Predictor	Univariate analysis		Multivariate analysis	
	HR (95% CI)	p value	HR (95% CI)	p value
Age (years)		0.060	1.08 (1.02–1.15)	0.012
Female sex		0.242		
Arch involvement		0.367		
Fenestration		0.181		
Zones 0–2		0.261		
History of CVA		0.483		
CRF (CKD stage 3 or 4)		0.017		
CHF (NYHA class 3 or 4)	2.62 (0.96–7.11)	0.072		0.107
Emergency operation	2.87 (1.46–5.62)	0.003	4.83 (0.29–7.62)	0.008
Diameter of LZ (mm)		0.119		
Length of LZ (mm)		0.859		
Diameter of aneurysm (mm)		0.108		
Length of aneurysm (mm)	1.01 (1.00–1.02)	0.030	1.01 (0.99–1.03)	0.090
Endoleak development	3.78 (1.49–9.59)	0.0030	4.52 (1.79–12.95)	0.031

HR: hazard ratio; CI: confidence interval; CRF: chronic renal failure; CKD: chronic kidney disease; CHF: congestive heart failure; NYHA: New York Heart Association; CVA: cerebrovascular accident; LZ: landing zone

Table 3 Relationships between patient variables and endoleak development using Cox proportional hazards model

Predictor	Univariate analyses		Multivariate analyses	
	HR (95% CI)	p value	HR (95% CI)	p value
Age in years		0.938		
Female sex		0.269		
Arch involvement		0.234		
Fenestration		0.901		
Zones 0–2		0.947		
CRF	21 (2.70–13.32)	0.001	6.87 (3.19–16.45)	0.003
CHF (NYHA class 3 or 4)	2.1 (1.11–3.98)	0.043		0.061
Diameter of LZ (mm)		0.338		
Length of LZ (mm)		0.310		
Diameter of aneurysm (mm)	1.04 (1.02–1.06)	0.004	1.06 (0.01–0.12)	0.003
Length of aneurysm (mm)	1.01 (1.00–1.02)	0.077		0.177

HR: hazard ratio; CI: confidence interval; CRF: chronic renal failure; CHF: congestive heart failure; NYHA: New York Heart Association; LZ: landing zone

risk factors for endoleaks (**Table 3**). Arch involvement, fenestration, proximal landing in zones 0–2, landing zone length, and diameter did not affect the mortality or endoleak rates.

Discussion

Dake, et al.⁷⁾ reported the first custom-made endografts for thoracic aortic disease in 1994. The in-hospital mortality rate after TEVAR for descending aortic aneurysms was 0.0%, but the rate of primary endoleak development was 15.4%.

The early results of first-generation commercially produced devices were not good, the in-hospital mortality rate was 2.1%, 5.1%, paraplegia rate of

3.0%, 1.7%, stroke rate of 3.6%, 3.7%, primary endoleak rate was 11.0%, 9.6%, and rate of conversion to surgery was 2.2%^{7,8)} (**Table 4**).

In two recent studies of the Zenith TX2 endovascular graft and Medtronic Valiant thoracic endograft system, the 30-day mortality, stroke, paraplegia, and type I endoleak rates were 1.9%–3.1%, 2.5%, 0.6%–1.3%, and 0.0%–2.2%, respectively.^{9,10)}

The most significant complications of open surgery for thoracic aortic disease are stroke and paraplegia. In TEVAR, occlusion of the LSCA without previous revascularization and embolic phenomena from endovascular manipulation in the aortic arch are major causes of stroke.⁸⁾ Preservation of the vertebral artery is important to prevent stroke, axillary–axillary

Table 4 Summary of published series for thoracic endovascular aortic repair

Author Year	Device number	In- hospital death CVA paraplegia	Early EL Late EL	Overall survival Aortic related death Re-intervention	Follow (mo) Mean \pm SD
Dake ⁷⁾ 1994	Custom made 13	0% 0% 0%	15.4% 7.7%	0% 0% 7.7%	11.6
Demers ¹⁴⁾ 2004	Custom made 103	9% - -	20.4% 21.4%	27%/ 8y 20%/ 8y 29%/ 8y	54 \pm 31
Makaroum ¹³⁾ 2008	Gore TAG 140	3.0% 2.1% -	8.6% 4.3%/ 5y	68% 2.8% 3.6%	37
Fattori ⁸⁾ 2006	Talent 457	5.1% 3.7% 1.7%	9.6% 4.9%	77.5% 2.6% 30.0%/ 5y	24 \pm 19.4
Matsumura ⁹⁾ 2008	Zenith TX2 160	1.9% 2.5% 1.3%	12.6% 3.9%/ 1y	91.6% 5.8% 5.4%/ 1y	12
Fairman ¹⁰⁾ 2012	Valiant 160	3.1% 2.5% 1.9%	15.8% 13.0%	12.6% 4.0% 0%	12
Morales ¹⁵⁾ 2008	Zenith TX1 TX2 160	6.9% 3.1% 3.1%	9.4% 7.5%	70%/ 5y - 26%	36
Kawaguchi ²⁾ 2008	Custom made 1100 Fenestrated 288	- 3.8% 0.9%	4.8% -	62.4%/ 5y - -	-
Yokoi ⁴⁾ 2013	Najuta fenestrated 383	1.6% 1.8% 0.8%	4.2% -	- - -	-
Matsuyama 2014	Custom made 81 Fenestrated 37	1.2% 0% 1.2%	1.2% 20.0%	59.3% 8.6% 8.6%	90.9 \pm 26.2

CVA: cerebral vascular disorder; EL: endoleak; SD: standard deviation

artery bypass, carotid transposition,¹¹⁾ and carotid-to-subclavian artery bypass.¹²⁾ Kawaguchi, et al.²⁾ showed excellent initial results of fenestrated endografts for arch aneurysms. Among patients who received fenestrated endografts, primary endoleaks occurred in 1.0%, paraplegia in 0.9%, stroke in 3.8%, and aortic injury in 1.2%. Our device and the Najuta are totally different modality. The Najuta has ePTFE graft. But our device has a Dacron graft, the cloth which was not made for endovascular surgery. And the Najuta has an excellent proximal gimmick, so called stabilizer line. The line narrows the lead of endograft until the indwelling last. It assists an accurate landing of the endograft to prevent migration. We never had used our devices after the Najuta was released.

Paraplegia is multifactorial; its mechanisms include perioperative hypotension, embolic causes, aortic cross-clamping, insufficient collateral circulation, increased cerebrospinal fluid pressure, spinal edema,

and interruption of the intercostal arterial supply. The rate of paraplegia is about 2.8%–5.0% after TEVAR for thoracic aortic disease.^{10,12)} Long-segment thoracic aortic exclusion is reportedly the most important predictor of spinal cord ischemia in TEVAR.⁸⁾ Concurrent or previous abdominal aorta repair is another risk factor for paraplegia in TEVAR because of insufficient collateral circulation to the spinal cord by the loss of lumbar arteries.^{7,12)}

In patients whose LSCA orifice should be covered by an endograft, we are convinced that graft fenestration for LSCA or axillary–axillary artery bypass may help to protect against spinal cord ischemia by preserving important vertebral artery collaterals that contribute to spinal flow. In our study, the stroke rate was 0%, paraplegia rate was 1%, and transient spinal injury rate was 2%.

The rate of endoleak development is about 10%–20% in the literature, and the presence of an endoleak is associated with a constant risk of rupture.¹³⁾ In our

study, endoleak development was an independent risk factor for aortic-related death. An important report has been published on the proximal neck length necessary to prevent type I endoleak development with respect to the indications for TEVAR. Kawaguchi, et al.²⁾ showed that proximal and distal necks of ≥ 2 cm were required and that the performance of extra-anatomic revascularization of the subclavian artery increased the aortic neck length for endograft fixation. Proximal neck dilatation is recognized as another cause of late endoleak development. In our series, 16 patients developed postoperative endoleaks owing to dilatation of the landing zone, and 11 of them underwent secondary repair (secondary TEVAR in 8 and conversion to open repair in 7). Furthermore, seven patients died of aortic rupture and could not undergo re-intervention because of poor general and anatomical conditions. We can deal in additional endografting if caused by migration. But we have to convert to open if caused by dilatation of neck. Seven aortic ruptures in 81 patients appeared very high. Five cases had type I endoleaks, and other two cases ruptured another site of aneurysms. In all patients, it was impossible re-endografting for shorter neck length or larger neck diameter, and inoperative for co-morbidity such as chronic obstructive pulmonary disease (COPD) or congestive heart failure (CHF). In Japan, we could not use the commercially produced devices before April 2008. We had to use custom-made endografts. The graft was made to use open operation, so resistance of the graft for the friction with the metal was unidentified. The commercially produced devices have grafts and stents which were designed for endovascular treatment. It is clear that commercially produced devices are more excellent than our one. We had not used any custom-made devices after 2009. Four of the seven patients who underwent open conversion required stent graft extraction because of fabric erosion. Dake, et al.⁷⁾ reported the first TEVAR. They used custom-designed, self-expanding stainless steel stents covered with woven Dacron grafts. Demers, et al.¹⁴⁾ reported the midterm results of first-generation endografts. The overall actuarial survival rate was 27%, the actuarial rate of freedom from aortic rupture was 80%, and the actuarial rate of freedom from endoleaks was 50% at 8 years. Our results showed an overall actuarial survival rate of 51.7%, actuarial rate of freedom from aortic-related death of

81.6%, and actuarial rate of freedom from endoleaks of 68.6% at 10 years. Our late results are similar to those of the Stanford group.¹⁴⁾

Recent commercially produced thoracic endografts show improvements with respect to prevention of fabric erosion, migration, and type I endoleak formation. For example, the Zenith TX2 has barbs at the proximal edge to cope with extreme tortuosity, greater hemodynamic forces, remoteness from the vascular access site, and risk of iatrogenic injury. This graft was evaluated in terms of its ability to prevent migration.⁹⁾ The Valiant Thoracic Endograft System has nitinol scaffolding of the endograft and comprises a series of five-peaked serpentine springs stacked in a tubular configuration. This device also has a bare stent at the proximal edge.¹⁰⁾

Morales, et al.¹⁵⁾ reported the midterm results of the Zenith TX1 and TX2 in 160 patients with a mean follow-up period of 36 months. No patients died of aneurysm rupture, and endoleaks developed in 7.5% of patients. Secondary interventions were required in 26.3% of patients. Matsumura, et al.⁹⁾ reported the 12-month results of the Medtronic Valiant in 151 patients; the aneurysm-related mortality rate was 4.0%, endograft migration rate was 2.9%, and endoleak development rate was 13.0%. Throughout the 12 months, there were no ruptures, conversions to open surgery, secondary procedures owing to endoleaks, or loss of endograft patency. Makaroun, et al.¹³⁾ reported the long-term results of the Gore TAG device in 140 patients with a mean follow-up period of 37 months. The aortic-related mortality rate was 2.8%, endoleak development rate was 4.3%, and rate of conversion to open repair was 1.4%. The results of recent commercial devices have been good, but the mean follow-up period is about 3 years (Table 4).

Even if devices continue to evolve, if the aortic neck environment worsens, the incidence of endoleaks will increase. Hager, et al.¹⁶⁾ investigated the aortic size in 70 adults using helical computed tomography. That study delineated normal intrathoracic aortic diameters including relationships with male sex and age. Hassoun, et al.¹⁷⁾ investigated 139 patients who underwent successful endovascular repair. The mean proximal neck diameter increased from a baseline of 30.2 ± 4.6 to 32.0 ± 4.3 mm at 36 months ($p < 0.05$), and the annual diameter increase was 0.8, 0.4, and 0.6 mm at 12, 24, and 36 months, respectively. The mean distal neck diameter increased from 29.4 ± 3.8

to 32.1 ± 5.0 mm at 36 months ($p < 0.05$), and the annual diameter increase was 1.1, 0.4, and 1.2 mm at 12, 24, and 36 months, respectively. The rate of freedom from neck dilation of >5 mm was 87% at 36 months. They concluded that neck dilation was not associated with graft migration or endoleak development. In the distant future, however, the incidence of aortic neck dilatation will increase and become predictive of endoleak development.

In our study, the performance of an emergency operation was an independent predictor of mortality, but not of endoleak development. Kurimoto, et al.¹⁸⁾ showed that the choice of TEVAR as an emergency procedure requires that the LSCA does not originate from the ruptured aortic aneurysm. Serious endograft-related events are rare in the first few years after TEVAR. However, re-rupture secondary to endoleaks or endograft migration has been reported in the mid-term, especially ≥ 5 years after abdominal EVAR.¹⁹⁾

Renal insufficiency was shown to be an independent risk factor for mortality and an independent risk factor for stroke and paraplegia in the perioperative period of TEVAR.²⁰⁾ Mid- and long-term results of TEVAR showed that renal insufficiency was an independent risk factor of mortality.^{21,22)} Davies, et al.²³⁾ showed that independent risk factors for mortality were a large aortic size of >60 mm, female sex, renal insufficiency, hypertension, cardiac disease, pulmonary disease, carotid disease, prior cerebrovascular accidents, and a history of abdominal aortic aneurysm. Long-term results of TEVAR showed that male sex was an independent risk factor for late mortality, but that female sex was an independent risk factor for late endoleaks.²⁴⁾ In our study, advanced age and the presence of endoleaks were independent risk factors for mortality, and renal insufficiency and a large aneurysm diameter were independent risk factors for endoleaks. Renal insufficiency may cause aortic expansion and endoleak development secondary to neck dilatation.

Conclusion

Our method of preservation of neck blood flow with fenestration and rerouting was shown to be safe. A more proximal landing was effective in the short term. However, we found that advanced age, emergency operations, and the presence of endoleaks were

risk factors for late death in patients who underwent TEVAR for atherosclerotic thoracic aortic aneurysms. Additionally, CRF and a larger aneurysm diameter were risk factors for late endoleak formation. Thin-walled Dacron grafts for our custom-made endografts were erosion for tears sometime. And aortic necks for sealing were going to dilate. We should select open repair for low-risk patients with a better expected prognosis. Endografts must be improved with the use of long-lasting material and proximal features to resist migration, such as barbs, fenestrations, branching, and a proximal cuff.

Disclosure Statement

The authors declare no conflict of interest.

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