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Short-Term Results of Thoracic Endovascular Aortic Repair for Aortic Arch Aneurysm with a Fenestrated Stent Graft

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ABSTRACT

The purpose of this study was to review short-term results of aortic arch aneurysm treatment that were performed with fenestrated stent grafts (Najuta stent grafts) in our hospital. Nine patients of aortic arch aneurysm were treated with Najuta stent grafts between January 2015 and March 2018. Eight patients had a saccular aneurysm and one a dissecting aneurysm. A Najuta stent graft was deployed in the aortic arch in each patient. If necessary, a non-fenestrated stent graft was added, and bilateral axillary artery bypass or left subclavian artery embolisation was performed. Computed tomography (CT) examination was performed postoperatively, at 6 months, and yearly. In all patients, the stent grafts were deployed as planned. The blood flow of the brachiocephalic artery and left common carotid artery was maintained through fenestrations of the stent graft. Eight patients required occlusion of the left subclavian artery to get a sufficient proximal sealing zone; five of them were reconstructed. All patients were treated with fewer branch reconstructions than would have been required with conventional stent grafts. In one patient, a lower limb embolism occurred during the operation. On postoperative CT, endoleaks were observed in three patients. Coil embolisation of the left subclavian artery was performed within a year for two patients. The clinical course was evaluated for up to 4 years. Aneurysms shrank slightly in five patients, remained unchanged in three patients, and expanded in one patient. Najuta stent grafts performed well and enabled treatment of aortic arch aneurysms with minimal aortic branch reconstruction.

Key words: *TEVAR (thoracic endovascular aortic repair), Aortic aneurysm, Najuta stent graft*

INTRODUCTION

In thoracic endovascular aortic repair (TEVAR) for aortic arch aneurysms, if occlusion of branches of the aortic arch is necessary to obtain a proximal sealing zone of the required size, reconstruction of the branches would be indicated. Since the Najuta stent graft® (Kawasumi Laboratories, Inc., Tokyo Japan)[4,12)] includes fenestrations for the branches within the graft, aortic arch aneurysms can be treated with minimal branch reconstruction (Figure 1).

We reviewed the results for patients of aortic arch aneurysms that were treated with Najuta stent grafts in our hospital.

MATERIALS AND METHODS

From January 2015 to March 2018, nine patients of aortic arch aneurysm were treated at our hospital with Najuta stent grafts. All patients were males who ranged from 67–83 years old (75.9 ± 6.0, mean ± standard deviation [SD]). Eight patients involved saccular aneurysms, and one patient involved a dissecting aortic aneurysm that tended to expand six months after the onset (Debakey IIIa). Saccular type aneurysms existed on the lateral aspect of the minor curvature side of the aorta in seven of the patients. Three patients were just outside the instruction for use (IFU) for Najuta stent graft according to their proximal sealing zones (20 mm or longer) (Table 1).

All operations were performed under general anaesthesia. If necessary, the left subclavian artery was reconstructed by connection of the bilateral axillary artery

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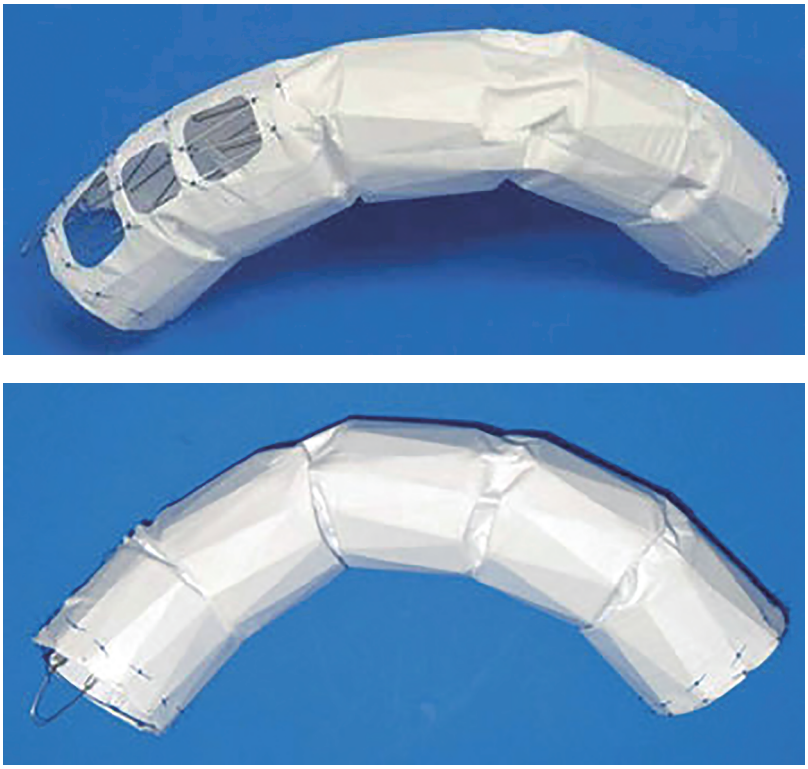

Figure 1 Najuta stent graft

Table 1 Preoperative conditions

Case No.	Morphology of aneurysm	Diameter of aneurysm (mm)	IFU of Najuta stent graft (proximal sealing zone)	Required debranches in Najuta stent graft	Required debranches in conventional stent graft	Previous aortic surgery
1	saccular	45	just outside the IFU	1	3	none
2	saccular	53	just outside the IFU	0	3	none
3	saccular	56	just outside the IFU	0	3	none
4	saccular	52	within the IFU	1	2	none
5	saccular	45	within the IFU	0	2	EVAR
6	saccular	50	within the IFU	1	2	none
7	saccular	48	within the IFU	1	2	none
8	saccular	47	within the IFU	0	1	EVAR, TEVAR
9	dissecting	55	within the IFU	1	2	none

IFU: instruction for use
TEVAR: thoracic endovascular aortic repair
EVAR: endovascular aortic repair

with an 8 mm expanded polytetrafluoroethylene GORE-TEX vascular graft (W. L. Gore & Associates, Inc., Flagstaff, AZ, USA) prior to stent graft deployment, with placement under the pectoralis major muscle.

An incision was made in the groin to expose the common femoral artery or external iliac artery on one side, and a 10-Fr sheath was inserted. A double-lumen sheath was inserted via the right brachial artery. An imaging catheter was inserted into the ascending aorta through one lumen of the 6-Fr double-lumen sheath.

In some patients, additional stent grafts were needed on the distal side due to the treatment length. In these patients, another stent graft was placed before deployment of the Najuta stent graft. A Lunderquist extra-stiff guide wire (Cook Medical Inc., Bloomington, IN, USA) was inserted via the sheath in the groin until reaching the ascending aorta, and a Zenith TX2 stent graft® (Cook Medical Inc.) that did not have a bare stent at the tip was inserted and deployed at the distal side of the aortic arch.

For deployment of the Najuta stent graft, another type of guide wire was required. The Lunderquist extra-stiff guide was removed, and a Radifocus guide wire (0.032 inch/400 cm) (Terumo Corporation, Tokyo, Japan) was inserted through the other lumen of the double-lumen sheath into the aorta, and the tip of the guide wire was taken out via the sheath in the groin. The guide wire could be operated from both upper and lower limbs. A Najuta stent graft was inserted into the aorta from the lower limb and deployed at the aortic arch using the guide wire. When significant leakage of contrast medium

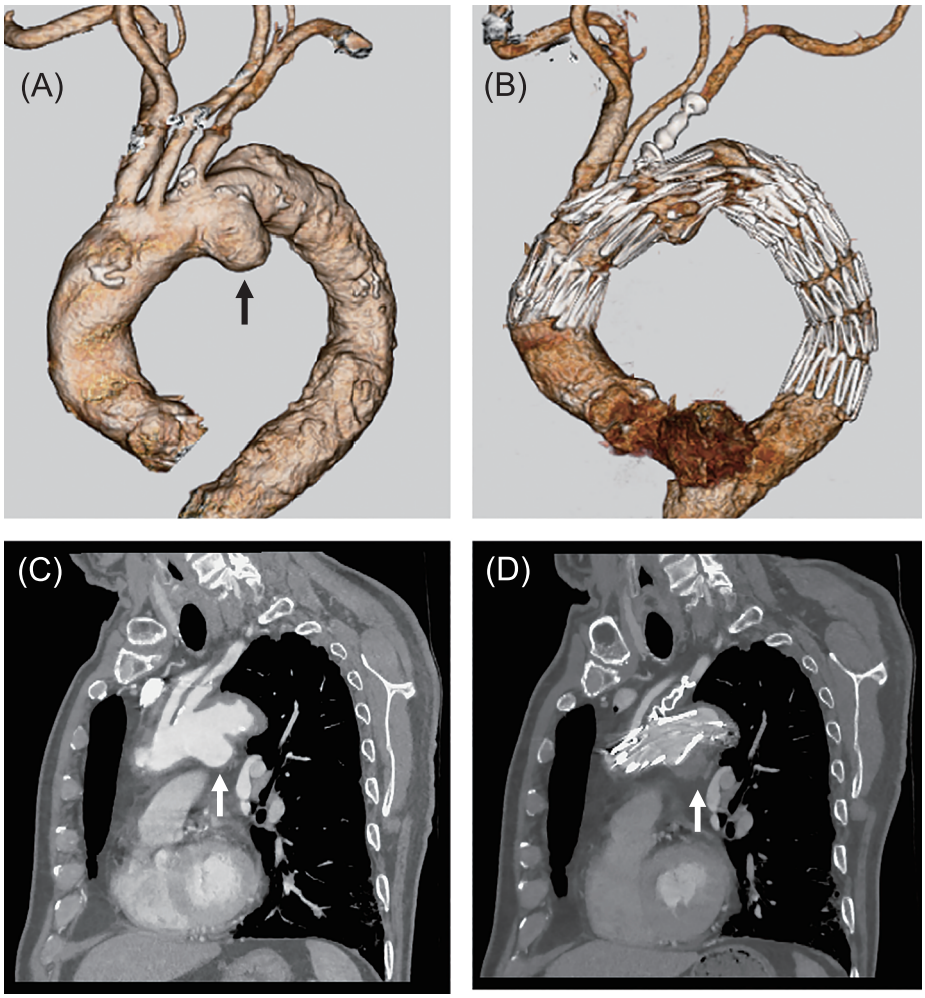

Figure 2 A saccular type aortic aneurysm that was treated with a Najuta stent graft. A saccular aneurysm existed at the lateral aspect of the minor curvature side of the aortic arch. A Najuta stent graft was deployed from the ascending aorta to the descending aorta. A non-fenestrated stent graft was added, and the left subclavian artery was embolised. The aneurysm was occluded with a thrombus. A, C: preoperative computed tomography (CT) image; B, D: postoperative CT image; arrow = aneurysm

from the left subclavian artery to the aneurysm was observed on aortography, embolisation of the proximal side of the left subclavian artery using a coil and/or vascular plug was performed (Figure 2).

In patients where there was an insufficient proximal sealing zone (just outside the IFU of Najuta stent graft), the Najuta stent graft was deployed first, followed by a Relay Plus stent graft® (Bolton Medical Inc., Barcelona Spain), which has a long bare stent at the tip. This was added to overlap with the Najuta stent graft from the distal edge of the left common carotid artery to the descending aorta as a reinforcement from inside. For this method, the guide wires were required in the reverse order of their use above[11].

CT examination was performed immediately postoperatively, six months later, and every year after that until March 2019 to investigate leakage of contrast medium into the aneurysm (endoleak) and other problems associated with the stent graft. Depending on the results, additional procedures were added, as necessary.

RESULTS

The Najuta stent graft was successfully deployed from the ascending aorta to the descending aorta in all patients. The blood flow of the brachiocephalic artery and left common carotid artery was maintained through fenestrations of the stent graft. In eight patients, the left subclavian artery was occluded by the stent graft, which was reconstructed by connection of the bilateral axillary arteries with vascular prosthesis in five patients. In the other patient, the blood flow of the left subclavian artery was maintained by the fenestration of the stent graft. In four patients, the proximal side of the left subclavian artery was occluded with a plug and/or coil intraoperatively to resolve the endoleak via the left subclavian artery.

Another stent graft was added in eight patients. In five patients, a Zenith TX2 stent graft was deployed in the descending aorta as required for the treatment length before Najuta stent graft deployment. In three patients, a Relay Plus stent graft was deployed that overlapped with the Najuta stent graft from the distal edge of the left common carotid artery to the descending aorta for reinforcement of the Najuta stent graft.

Although there were no problems related to the stent grafts themselves, there was one patient with a problem related to the insertion of the stent graft in the aorta.

Table 2 Postoperative results

Case No.	Fenestrations in the Najuta stent graft	Added stent graft	Reconstruction of Lt.SCA	Lt.SCA embolization	Timing of embolization	Intraoperative complications	Postoperative complications	Postoperative hospital stay (days)	Complications at discharge
1	2	Relay plus	Ax-AxA bypass	+	4 months later	none	none	11	none
2	2	Relay plus	—	–	—	none	none	11	none
3	2	Relay plus	—	+	1 year later	none	none	12	none
4	2	Zenith TX2	Ax-AxA bypass	+	intraoperative	embolization for right leg	incomplete paralysis in right leg	16	incomplete paralysis in right leg
5	2	Zenith TX2	—	+	intraoperative	none	fever of unknown origin	29	none
6	2	Zenith TX2	Ax-AxA bypass	+	intraoperative	none	none	16	none
7	2	—	Ax-AxA bypass	–	—	none	incomplete paralysis in right leg	7 + 31 (lung cancer)	incomplete paralysis in right leg
8	3	Zenith TX2	—	–	—	none	none	15	none
9	2	Zenith TX2	Ax-AxA bypass	+	intraoperative	none	none	17	none

Ax-AxA bypass: Axillary-axillary artery bypass
Lt. SCA: left subclavian artery

This patient had an abdominal aortic aneurysm with a mobile mural thrombus in the entire aorta. Arterial embolism occurred in the lower limb opposite to the stent graft insertion; hence, thrombectomy was required.

On the immediate postoperative CT, each arterial branch was properly maintained by the fenestrations of the Najuta stent graft, and the diameter of the aneurysm did not change in any of the patients. Endoleak was observed in three patients. In two patients, the endoleak occurred from the left subclavian artery, which did not have coil embolisation during the operation. In the single patient of aortic dissection, a small amount of contrast medium was observed in the false lumen from a small endoleak around the fenestration of the stent graft.

All patients were discharged without additional procedures at 11–38 days (18.3 ± 9.2, mean ± SD). In one patient with embolism of the lower extremity during surgery and another patient who subsequently required surgery for lung cancer, weakness of the lower extremity on one side was observed; however, there was no obvious cerebral infarction on magnetic resonance imaging. The patients were hospitalised for 16 days and 38 days, respectively, for rehabilitation after the operation. Another patient developed fever of unknown cause after the operation; the fever subsided, and the patient was discharged after 29 postoperative days.

After discharge, none of the patients had trouble associated with the stent grafts up to a maximum of four years (2.2 ± 1.2, mean ± SD). Aneurysm diameter was reduced in five patients, unchanged in three patients and increased in one patient. Although no new endoleaks appeared on CT, the endoleaks observed immediately postoperatively continued in three patients. Additionally, in two patients who did not have coil embolisation of the left subclavian artery during the operation, embolisation of the left subclavian artery from the left brachial artery was subsequently carried out at four months in one patient and one year in the other to prevent the expansion of the aneurysm due to the endoleak. Since a microcatheter could be inserted into the aneurysms, the space from the aneurysm to the branch was closed with coils in both patients. Thereafter, the aneurysm in one patient did not show any change for four years, while the caudal side of the aneurysm expanded in the other patient, in whom there was no endoleak on CT, and the patient developed hoarseness of voice due to paralysis of the recurrent laryngeal nerve. This patient is still under observation to avoid further treatments. In the patient with aortic dissection, the endoleak had continued in a part of the false lumen at one year after the operation. However, both the size of the enlarged portion of the distal arch and space in the false lumen shrank (Tables 2 and 3).

DISCUSSION

In the treatment of aortic arch aneurysm, endovascular repair using a stent graft is a minimally invasive therapy compared with open surgical repair[2,9,13]. In Japan, there are five types of commercially available stent grafts for aortic arch aneurysms. The Najuta stent graft[4,12] was developed at Tokyo Medical University and commercialised by Kawasumi Chemical Co., Ltd. It became amortised by health insurance in 2013 and is the only stent graft with fenestrations for the branches of the aorta that is covered by health insurance in Japan. It is manufactured in a semi-custom-made manner from the combination of 68 basic stent skeletons, with holes tailored to the branches, and vascular prosthesis adapted to the aorta, according to the morphology of the aorta on the CT images of each patient. The Najuta stent graft was granted Conformitè Europëenne (CE) certification in 2017, and can be used in Italy and Germany in addition to Japan; therefore, its utilisation rate is increasing (Figure 1).

In TEVAR for aortic arch aneurysms, if a conventional

Table 3 Postoperative course of the thoracic aortic aneurysms

Case No.	Preoperative	Before discharge	6 month		1 year		2 year		3 year		4 year	
	Diameter of aneurysm (mm)	Diameter of aneurysm (mm)	EL (type)	Diameter of aneurysm (mm)	EL (type)	Diameter of aneurysm (mm)	EL (type)	Diameter of aneurysm (mm)	EL (type)	Diameter of aneurysm (mm)	EL (type)	Diameter of aneurysm (cm)	EL (type)
1	45	45	2 (→CE :4 month)	45	none	45	none	45	none	45	none	45	P
2	53	53	none	44	none	43	P	43	P	43	P	43	none
3	56	56	2	56	2	56	2→CE	60	none	62	none		
4	52	52	none	45	P	42	none	42	P				
5	45	45	none	43	P	43	P	41	P				
6	50	50	none	50	none	50	none	50	P				
7	48	48	none	48	P	48	none						
8	47	47	none	47	P	45	P						
9	55	55	2	55	P	52	2						

EL: endoleak
CE: coil embolisation
P: plane CT

stent graft without fenestration is deployed, reconstruction of the branches would be considered[2,5,7]. Even if the left subclavian artery was occluded by the stent graft, reconstruction would only be required in special circumstances because the left and right vertebral arteries usually communicate well through the basilar artery[3,6,10]. The commonly used methods for reconstruction of the branches are the debranching[5] and chimney methods[7]. In the debranching method, a bypass surgery of these branches using vascular prosthesis is performed via sternotomy and/or some skin incisions at the chest and neck. In the chimney method, small stent grafts are deployed through the skin incision from the peripheral sites of the branches to the aorta along the main stent graft. In these methods, some problems related to the procedures might occur during and after the operation. However, the use of Najuta stent graft avoids these reconstructions due to its fenestrations[4,12].

In the treatment of aortic aneurysms with stent graft, it is very important to have a large enough proximal sealing zone. In patients with insufficient proximal sealing, problems such as endoleak, migration of the stent graft, and dilatation of the aneurysm could occur. With conventional stent grafts, the proximal sealing distance is determined using the longitudinal distance along the centreline of the aorta from the distal point of the reference branch to the aneurysm. However, with the Najuta stent graft, the proximal sealing distance is determined using the distance along the surface of the aortic wall from the distal point of the reference branch to the aneurysm. Therefore, the Najuta stent graft can sometimes be used for TEVAR within the IFU even if the conventional stent graft was not within the IFU. It is especially beneficial for obtaining a sufficient proximal sealing zone for a saccular aneurysm existing lateral to the minor curvature side of the aortic arch.

During the study period, we had eight patients of aortic arch aneurysm whose proximal reference point to determine the IFU was the distal point of the left common carotid artery. According to the proximal sealing zone, all eight patients were out of the IFU for conventional stent graft, whereas five patients were within the IFU, and three patients were only just outside the IFU for Najuta stent grafts. Therefore, we selected the Najuta stent graft for all patients. Because the Najuta stent graft was selected, reconstructions of the brachiocephalic artery and left common carotid artery were not required for any patient. Of these eight patients, five required reconstruction of the left subclavian artery to maintain circulation to the brainstem and the left upper extremity via the bilateral vertebral arteries and prevent paraplegia associated with extensive thoracic intercostal artery occlusion by the stent graft in this and/or a previous operation[3,6,10].

In one patient, the aneurysm was located distal to the left subclavian artery. This patient had undergone previous treatments for thoracic and abdominal aortic aneurysms using stent grafts. Since many intercostal and lumbar arteries were obstructed, spinal cord ischaemia was a concern. Therefore, we selected a Najuta stent graft for the reconstruction of the left subclavian artery. This enabled treatment of the aneurysm with only a stent graft.

In this series, if conventional stent grafts were selected, all patients would have required more branch reconstructions via the methods described above, additional surgical invasions, operative time, and a longer hospital stay. Thus, the Najuta stent graft made the treatments less invasive.

As noted, we had three patients that were just outside the IFU according to the proximal sealing length, even with the selection of the Najuta stent graft. Fortunately, since the Najuta stent graft is deployed from the ascending aorta to the descending aorta, there is a stent graft at the more proximal side of the left common carotid artery. For these patients, we used the Relay Plus stent graft®, which has a long bare stent at the tip, to provide reinforcement from the inside. This method was effective

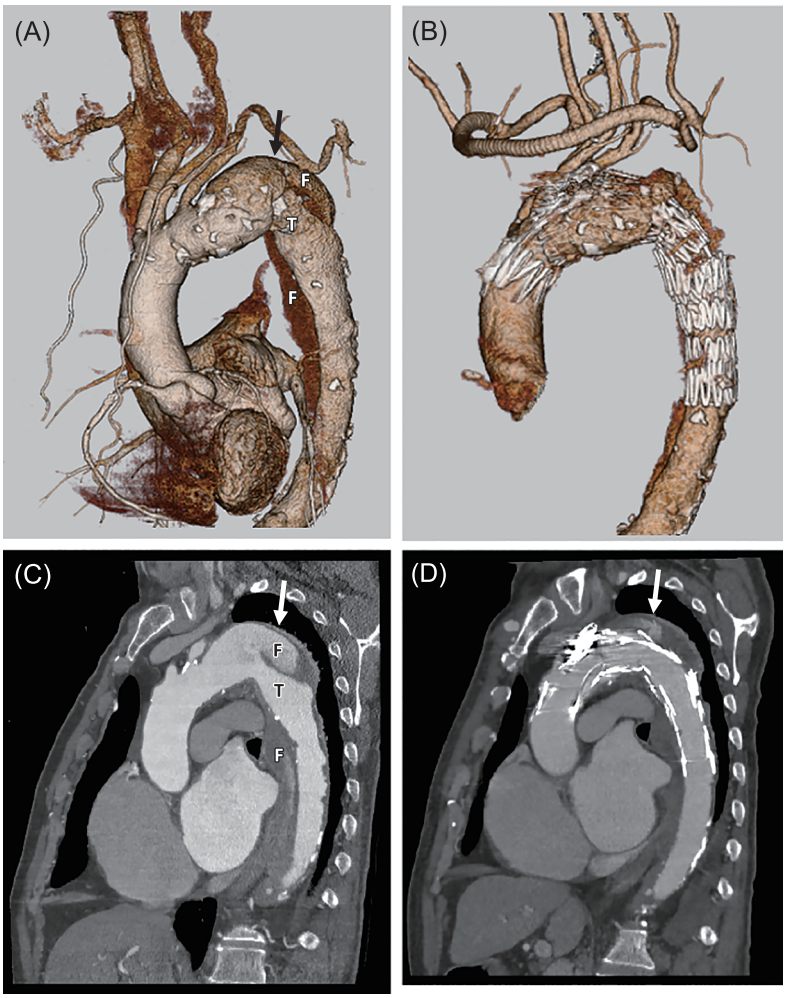

Figure 3 A dissected aortic aneurysm that was treated with a Najuta stent graft. A dissected aortic aneurysm existed at the distal aspect of the aortic arch with a false lumen from the distal edge of the left subclavian artery to the level of the diaphragm. A Najuta stent graft was deployed from the ascending aorta to the descending aorta. A non-fenestrated stent graft and a proximal extension of the Zenith TX2 stent graft were added, and bilateral axillary artery bypass and left subclavian artery embolisation were performed. Although minor endoleak in the false lumen remained, the aneurysm of the distal arch and the space in the false lumen shrank over the following year. A, C: preoperative computed tomography (CT) image; B, D: postoperative CT image; arrow = aneurysm, T = true lumen, F = false lumen

as a proximal sealing method for the Najuta stent graft. Two patients treated using this method yielded good results during the observation period[11].

However, because the Najuta stent graft has a three-dimensional stent skeleton inside the stent graft to maintain the shape, a problem with this method occurred later in another hospital. When the stents of the Najuta stent graft were compressed by another stent graft deployed inside, deformation of the Najuta stent graft was induced[8]. Thus, this method could not be used afterwards in any hospital. Therefore, in the next patient, a Relay stent graft was first deployed at the distal edge of the left common carotid artery, and the Najuta stent graft was deployed on the inside overlapping it. In this method, the long bare stent at the tip of the Relay Plus stent graft can support the Najuta stent graft from the outside. In this patient, although the diameter of the aneurysm was unchanged on CT one year later, endoleak via the left subclavian artery was shown to have continued. Subsequently, the left subclavian artery and aneurysm were embolised to prevent dilatation. Nevertheless, a part of the aneurysm gradually expanded. As the patient wishes to avoid further treatments, we are currently only conducting follow-up checks.

In this series, we encountered one patient with aortic dissection, which expanded over the six months after onset. The false lumen existed from the distal edge of the left subclavian artery to the diaphragm level. Since the patient was old and had severely impaired cardiac function, surgery with thoracotomy was considered a high risk. Accordingly, TEVAR was selected. However, we experienced a problem in treatment with a stent graft. Because the diameter of the true lumen of the descending thoracic aorta was small, the difference in the diameter of the non-dissecting part at the aortic arch had to be adjusted with a stent graft. In such cases, it is desirable to use a Zenith TX-D stent graft® [1], which has a large diameter difference between the proximal and distal side and is made for the treatment of aortic dissection. However, we selected the Najuta stent graft for this patient because it was necessary to secure sufficient sealing at the proximal side; the Zenith TX-D stent graft

could not be used for insurance reasons. We decided to adjust for the diameter difference by using a short stent graft that is ordinarily used for proximal extension of the Zenith TX2 stent graft. After deployment of a Zenith TX2 stent graft at the descending aorta, a proximal extension of the Zenith TX2 stent graft, which was bigger than the distal stent graft, was added overlapping it at the proximal part, similar to the Zenith TX-D stent graft. After that, the Najuta stent graft was deployed from ascending aorta to the Zenith TX2 stent graft. The stent grafts were deployed as intended. However, since these stent grafts overlapped around the enlarged portion of the aorta having the intimal flap, a part of them floated due to those structures. As a result, a minor endoleak via the fenestration occurred. One year after the operation, the endoleak to the false lumen remained, but the aneurysm of the distal arch and space in the false lumen shrank (Figure 3).

LIMITATION

This was a short-term study consisting of only nine patients and was not sufficient to be a full study of TEVAR using Najuta stent grafts. Accordingly, additional patients treated with Najuta stent grafts should be studied, with follow-up for longer periods.

CONCLUSION

The Najuta stent graft is useful in anatomically appropriate cases for the treatment of aortic arch aneurysms, with fewer branch reconstructions than would be required for conventional stent grafts.

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