The next generation of fenestrated endografts: results of a clinical trial to support an expanded indication for aortic arch aneurysm treatment†

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Abstract

OBJECTIVES: Short- and mid-term data regarding the use of precurved, fenestrated endografts have shown that these devices are both safe and effective in carefully selected patients. The first generation of the product was limited to patients with proximal landing zones (LZs) of >20 mm. The next generation of these endografts has been refined to enable the treatment of patients with shorter proximal seal zones (<20 mm), using smaller fenestrations and a greater diversity of skeletons. We reviewed the clinical studies involving the next-generation product and analyzed the morphological characteristics of aortic arch aneurysms that were successfully treated.

METHODS: Next-generation endografts were used to treat 393 patients with aortic arch aneurysms at 35 medical institutions during 2010 and 2011. There were 371 (94%) patients with sealing zones <20 mm and 244 (62%) with sealing zones <15 mm. The proximal sealing length was 2–35 (14.2 ± 5.1) mm.

RESULTS: Technical success was achieved in 390 (99.2%) patients. Of the treated patient population, 6 patients died, 7 experienced strokes and 17 were subsequently identified to have Type I endoleaks. In cases with proximal LZs <15 mm, the aneurysm was more likely to develop an endoleak. The proximal sealing zones (11 ± 12 vs 9 ± 13 mm) were not significantly associated with the development of endoleaks, but the proximal aortic diameters were (34.0 ± 13.3 vs 36.6 ± 6.3 mm; P < 0.01), in the univariate analysis. In the discriminant analysis, the maximum length of the aneurysm was the only factor that was predictive of Type I endoleaks (73 ± 55 vs 97 ± 59 mm; P < 0.001).

CONCLUSIONS: The next generation of precurved, fenestrated endografts shows promise as devices for aortic arch aneurysms with a <15-mm proximal sealing zone. These devices have a significant advantage in cases where the LZ has a short neck. However, more refinement is necessary to prevent Type I endoleaks, so that these devices can be used with aortic vessels with large proximal diameters and large aneurysms.

Keywords: Endograft · Endoleak · Aneurysm · Precurved · Fenestrated · Aortic arch

INTRODUCTION

The dimensions and shapes of an aortic arch are the morphological characteristics that are most affected by aging. These changes, combined with the observation that arch aneurysms are very common among the Japanese (43% of all thoracic aneurysms), indicate that an effective method for repairing these aneurysms is critical for Japan’s aging society [1]. Conventional repair of aortic arch abnormalities is significantly associated with high mortality (6–20%) and stroke rates (12%) [2]. Because endografting has shown excellent results for descending thoracic aortic disease, extension of thoracic endovascular repair (TEVAR) to the arch is a possible repair strategy. However, supra-aortic branches make the available landing zone (LZ) shorter. In addition, changes in the shape of the aortic arch, incident to aging [3], make aneurysms in the arch more difficult to treat. Hybrid debranching TEVAR [4, 5] and the ‘Chimney’ technique [6] are also possible solutions for repairing arch aneurysms. However, a simpler solution is the use of fenestrated endografts. A fenestrated device, instead of a branched stent graft, is preferred because it involves simpler, less-invasive therapy.

Precurved, fenestrated endografts were developed from a concept employed by a vascular surgeon who began to design and prepare ‘home-made’ endografts. As a result of experience with >1000 cases, the surgeon realized that most arch aneurysms can be repaired by an endograft involving a combination of skeletons and fenestration patterns. Thus, it became possible to expand the concept in order to make such endografts commercially available. The clinical trial of the first generation of precurved, fenestrated endografts (Najuta Stent-graft, Kawasumi Laboratories, Tokyo, Japan) was completed in 2008. Short- and mid-term data from the trials demonstrated that the device is both safe and effective in carefully selected patients. This device has Pharmaceuticals and Medical Devices Agency (PMDA) approval for use in Japan from January 2013. However, the first

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generation of the stent-graft system was limited to patients with a 
seal zone of >20 mm [7]. The second generation of the system has 
since been refined to enable the treatment of patients with short 
proximal seal zones (<20 mm), using smaller fenestrations and a 
greater diversity of skeletons. In 2010, a multicenter clinical study 
(the Next-gen Fenestrated TEVAR trial) commenced in 35 
Japanese hospitals, using the latest version of the precurved fene-
strated endograft.

The aim of this study was to evaluate the results of endovascular 
treatment with this next generation of the precurved fenestrated 
endograft (Next-gen-Najuta) for aortic arch disease and to identify 
the advantages and limitations of this device.

MATERIALS AND METHODS

The Next-gen Fenestrated TEVAR trial was a non-randomized, 
interventional study designed to assess the effectiveness of the 
advanced design of the new fenestrated endografts (Next-gen-
Najuta; Kawasumi Laboratories) when compared with first-
generation endografts. The next-generation endograft was refined 
to treat more challenging anatomies, including those with short 
proximal necks. Physicians in the participating institutions selected 
patients with arch aneurysms who were considered to have 
serious risk factors for open surgical repair and who were unsuit-
able for endovascular repair with commercially available devices, 
owing to inadequate proximal LZs. Angiographic computed tom-
ography (CT) was used to evaluate the arch anatomy of each 
patient and to propose a proper plan for TEVAR with the next-
generation endograft. All endografts were premade and shipped 
from the company. The duration from order to delivery was 2 
weeks. In the most challenging cases, the patients did not have 
access to any alternative methods for preventing aneurysm 
rupture, except through the use of the fenestrated stent graft.

This clinical study was organized by the Tokyo Women’s 
Medical University and included 35 Japanese institutes, including 
a mix of community hospitals, academic medical centres and 
private hospitals. Each participant was provided with sufficient 
information to enable him or her to provide informed consent for 
participation in this trial. The study protocol did not mandate 
or direct any concomitant surgical procedures, like debanding 
or bypass surgeries.

All patients were informed about the procedures and possible 
risks of the study as well as gave written informed consent. This 
study was performed in conformity with the Declaration of 
Helsinki and approved by our ethical committee.

Patients

In this 2-year clinical study, which ran from January 2010 to 
December 2011, 393 patients underwent endovascular repair 
with the Next-gen-Najuta. There were 338 men and 55 women 
(mean age, 76.1 ± 9.2 years; range, 23–93 years) who participated 
in the trial. Of the patients, 340 had degenerative aneurysms, 46 
aortic dissections, 5 traumatic transections of the aortic isthmus 
and 2 patent ductus arteriosus with congestive heart failure.

Indications

In a previous clinical trial using the first-generation fenestrated 
endograft (2008–09), the criteria for patient inclusion required a 
proximal LZ of >20 mm. In the present clinical study, the improved 
design made it possible to treat patients with an arch aneurysm LZ 
of ≥10 mm.

All patients underwent preoperative contrast-enhanced multi-
layered CT in order to plan the surgery and to select the appropri-
ate endograft components. The aortic arch configuration, 
including the angulation and the location of branches, was evalu-
ated by angiographic CT reconstruction. To ensure accurate mea-
surements, 1- to 2.5-mm thin slice CT data were required. The 
determination of a sufficient proximal sealing zone depended on 
the morphology of the pathological aortic arch. Therefore, patients 
were sometimes deemed to meet the inclusion criteria 
even if the target LZ was <10 mm. Patients with an LZ diameter of 
>42 mm were excluded because the diameter of the largest avail-
able endograft was 45 mm. The inclusion and exclusion criteria 
are summarized in Table 1.

Endograft preparation

A precurved, fenestrated endograft was created by suturing vascu-
lar graft material (expanded polytetrafluoroethylene membrane) 
to a self-expanding Z-stent. The precurved design was derived 
from the idea that there are connecting struts only in the greater 
curvature of the stent. Such a structure enables stents to overlap 
each other, with the stent-graft curve only in the lesser curvature 
of the aortic arch (Fig. 1A–C).

A customized endograft was made for each patient. The device 
has 19 types of curved stent skeletons and 8 types of graft fenes-
trations. Originally, 16 types of skeleton were adopted for use in 
the first clinical trial. In the current clinical study, three new types 
were developed for more proximal landings (Fig. 1C, E, and F). The 
device has a larger Z-stent and improved curvature-supporting 
struts to prevent the device from slipping down the aneurysm.

From the results of the first clinical trial, the design of the device 
was found to yield precise control over device rotation, and there 
were infrequent migrations of the device during the follow-up 
period. The current model has smaller fenestrations than the prior 
model, as well as a reduced number of fenestrations, which will 
final ensure the lack of migration (Fig. 2). According to the pre-
operative CT scans, an endograft, suitable for each patient, was 
fabricated by choosing from the available types of stent skeletons 
and graft fenestrations. The device design and implantation strat-
 egy are represented in Fig. 3.

The diameter of the endografts ranged from 24 to 44 mm, and 
their length ranged from 16 to 20 cm. Commercially available 
deices (Excluder TAG, W.L. Gore & Associates, Flagstaff, AZ, USA; 
Zenith TX2, Cook, Bloomington, IN, USA) were occasionally used 
to provide reinforcement in the distal portions of the aneurysms.

The purpose of using commercial devices was to fit the proximal 
stent to the greater curvature of the arch [8]. We use the bird-beak 
effect of current commercial devices to our best advantage.

Delivery system

This device has a stabilizing system for exact endograft positioning 
in the aortic arch, under normal blood pressure. During the de-
ployment period, the proximal end of the stent graft was gradually 
opened, and the second and third units of the Z-stent were 
atached to the aortic wall. The position of the endograft could 
still be finely adjusted during this stage of the implantation. To
Thoracic aortic aneurysm

Inclusion criteria

- Aneurysm enlarged by ≥5 mm in <12 months
- Saccular aneurysm >10 mm in the maximum transverse direction

Exclusion criteria

- <20 years old
- Pregnancy
- Estimated life expectancy <12 months
- Failure to indicate their intention to participate
- New York Heart Association Class IV
- Myocardial infarction within previous 3 months
- Cerebral vascular accident with previous 3 months
- Connective tissue disease (e.g. Marfans and Ehlers-Danlos syndrome)
- History of bleeding diathesis (including a coagulopathy or refusal to get blood transfusions)
- Sensitivity or allergy to stainless steel, ePTFE, PVDF, contrast media or heparin
- Unclear cerebellar arteries or Circle of Willis, requiring a stent-graft repair of the sub-clavian artery but without prior bilateral sub-clavian artery bypass
- No planned blockage of the LSA, with a <10-mm proximal LZ from the LSA to the aneurysm
- No planned blockage of the left carotid artery, with a <10-mm proximal LZ from the left carotid artery to the aneurysm
- No planned blockage of the brachiocephalic trunk, with <10 mm proximal LZ from the brachiocephalic trunk to the aneurysm
- Planned blockage of the celiac trunk, with an unclear connection between the SMA to the celiac trunk via the pancreaticoduodenal arcade
- Planned blockage of the celiac trunk, with a <15-mm proximal LZ from the SMA to the aneurysm
- No planned blockage of the celiac trunk, with a <15-mm proximal LZ from the celiac trunk to the aneurysm
- Unfavourable access route with calcification, stenosis and tortuous iliac
- Unfavourable LZ with calcification, mural haematoma and atheroma
- Significant formation of atheroma in the access route, with risk of atherothrombosis
- Thoracic aneurysm with a contained rupture
- Aortic diameter of <18 or >43 mm in the proximal LZ
- Active systemic infection
- Pregnancy
- Estimated life expectancy <12 months
- Failure to indicate their intention to participate
- New York Heart Association Class IV
- Myocardial infarction within previous 3 months
- Cerebral vascular accident with previous 3 months
- Connective tissue disease (e.g. Marfans and Ehlers-Danlos syndrome)
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- No planned blockage of the brachiocephalic trunk, with <10 mm proximal LZ from the brachiocephalic trunk to the aneurysm
- Planned blockage of the celiac trunk, with an unclear connection between the SMA to the celiac trunk via the pancreaticoduodenal arcade
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- Unfavourable access route with calcification, stenosis and tortuous iliac
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- Aortic diameter of <18 or >43 mm in the proximal LZ
- Active systemic infection

LZ: landing zone; SMA: superior mesenteric artery; DIC: disseminated intravascular coagulation; ePTFE: expanded polytetrafluoroethylene; PVDF: polyvinylidene fluoride.

**Table 1: Key inclusion and exclusion criteria**

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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</thead>
<tbody>
<tr>
<td>Thoracic aortic aneurysm &gt;50 mm wide</td>
<td>&lt;20 years old</td>
</tr>
<tr>
<td>Aneurysm enlarged by ≤5 mm in &lt;12 months</td>
<td>Pregnancy</td>
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<tr>
<td>Saccular aneurysm &gt;10 mm in the maximum transverse direction</td>
<td>Estimated life expectancy &lt;12 months</td>
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Facilitate safe access to the ascending aorta, the delivery sheath has a short, soft proximal tip and three types of precurved shapes, similar to the aortic arch. The outer diameter of the sheath ranges from 21 to 23 Fr in the proximal portion and is tightened to 18 Fr at the distal side. This characteristic assists in precise deployment when the patient has a severely angulated access route.

**Procedure**

Most of the patients underwent the procedure while under general anaesthesia; epidural anaesthesia was used in the case of 3 patients due to respiratory dysfunction. The deployment system was designed for a transfemoral approach. A ‘tag-of-wire’ method was the preferred guiding technique and was used to stretch the precurved device through the access route. Deployment of this device does not require blood pressure control using adenosine-induced cardiac arrest or rapid pacing during deployment. Device rotation was automatically controlled by the precurved shape of the stent graft and the dedicated stabilizing mechanism.

Reference digital subtraction angiography was performed immediately before and after deployment to confirm the proper positioning of the device and the absence of endoleaks. This simple procedure reduces the amount of contrast media and fluoroscopy time required. Touch-up ballooning is indispensable. The outer fabric immediately excludes the aneurysm and covers the left sub-clavian artery (LSA), if necessary. LSA revascularization was only performed in selected patients. A sub-clavian bypass was performed in patients with coronary artery bypass grafting using the left internal mammary artery; it was also performed in patients with insufficient connection to the vertebrobasilar artery and in those with a high risk of spinal cord ischaemia.

**RESULTS**

Technical success, defined as the successful deployment at the intended location of the aortic arch, was achieved in 390 of the 393 treated patients (99.2%); the procedure was unsuccessful in 3 patients due to poor access routes. The mean proximal aortic diameter was 33.7 ± 3.7 mm, the mean length of the pathological aortic arch was 79 ± 56 mm (without Type IIIb aortic dissection) and the mean length of the proximal sealing zone was 14.2 ± 5.1 mm. In all cases, the LZ was located in the aortic arch between Zones 0 and 2. The proximal end of the device was placed in Zone 0 in 376 patients, Zone 1 in 15 and Zone 2 in the remaining 2 patients.

Initial success, defined as the absence of Type I or III endoleaks on postoperative CT scan, was obtained in 375 (95.4%) cases. The hospital mortality rate was 1.5%; the causes of death were multiple embolisms, fatal stroke, ascending dissection, respiratory failure and aneurysm rupture with Type I endoleaks. In 1 case, the cause of death was not clear, but an impending rupture was identified. Cerebrovascular accidents occurred in 7 (1.7%) patients and permanent paralysis in 3 (0.76%). Ascending aortic dissection occurred in 3 patients, all of whom had previous aortic dissection, with an ascending aorta diameter of >40 mm. One stent-graft collapse occurred 4 days after the procedure in a patient with a small and tightly curved aortic arch. Three open surgical replacements were performed, 2 on patients with dissections and 1 on the patient who experienced the stent-graft collapse. As a salvage
procedure, the ‘chimney’ technique was unexpectedly required to preserve the perfusion of supra-aortic trunks in 3 patients, including 1 who experienced a minor stroke.

An LSA was intentionally covered in 281 patients without revascularization and in 17 with simultaneous revascularizations. The mean operative time was 161 ± 76 min (excluding LSA revascularization, with a duration of 146 ± 63 min), and the mean fluoroscopic time was 26 ± 13 min.

In the analysis of aortic arch morphology, 244 patients had proximal LZs of <15 mm. In such patients, the length of the proximal LZ was not related to the presence of Type I endoleaks (no endoleak vs endoleak, 11 ± 12 vs 9 ± 13 mm). However, the proximal aortic diameter and the treatment length were significantly related to Type I endoleaks. The proximal aortic diameter was significantly [34.0 ± 13.3 (without endoleaks) vs 36.6 ± 6.3 mm (with endoleaks); P < 0.01] related to the presence of endoleaks in the univariate analysis. Discriminant analysis revealed that the maximum length of the aneurysm was the only significant factor predictive of Type I endoleaks [73 ± 55 (without endoleaks) vs 97 ± 59 mm (with endoleaks); P < 0.001].

The results of clinical trials of the first generation revealed that technical success was achieved in 116 of the 117 treated patients (99.1%). The hospital mortality rate was 0.8%—1 patient died of MRSA (Methicillin-resistant Staphylococcus aureus) sepsis from wound infection, cerebrovascular accidents occurred in 7 (5.9%) patients, permanent paralysis in 2 (1.7%) and ascending aortic dissection in none. The absence of Type I or III endoleaks on postoperative CT scan was obtained in 101 (86.3%) cases.

A comparison between first- and second-generation endografts showed no significant differences in hospital mortality. Moreover, second-generation endografts resulted in significant reduction in cerebrovascular accidents and endoleaks in spite of a shorter LZ and more proximal landing.

**DISCUSSION**

The goal of aneurysm repair is to prevent aneurysm rupture during the patient’s lifetime; whether the aneurysm is resected is of little consequence. The endovascular approach has emerged as a valuable, less-invasive treatment for thoracic aortic disease. Endovascular aneurysm repair provides excellent results for descending thoracic aortic disease; repair of aneurysms of the aortic arch is still quite challenging. Some commercially developed devices, e.g. TX2 Pro-Form and c-TAG, require further enhancement in order to be fitted to a curved configuration [9, 10]. The anatomy of the aortic arch is complicated by the angularity of the arch and the involvement of supra-aortic branches. To overcome the angle-associated challenges, precurved, fenestrated endografts were developed. More proximal LZ and a precurved shape are critical for enhancing the stability of endografts in the aortic arch. With this part of the problem solved, the remaining challenge is how to overcome the difficulties associated with supra-aortic branches. Hybrid procedures with open surgical debranching constitute one potential solution to the preservation of perfusion to the supra-aortic branches. Recent reports have also demonstrated the feasibility of aortic arch hybrid repair [4–6]. Another possible approach is the use of branched endografts. Today, various medical manufacturers are competing to develop such branched endografts [11, 12]. However, these approaches bring
with them higher potential risks of embolic stroke than does the use of fenestrated endografts; we believe that simpler approaches, like the use of fenestration, are safer and less invasive.

The long history of the development of the precurved, fenestrated stent graft started at Tokyo Medical University. Ishimaru and colleagues [13] conducted a clinical study of TEVAR by using home-made endografts in 1995. Since then, they have been involved in efforts to improve TEVAR endografts, the delivery system and the necessary procedural techniques. One of the striking developments in the history of stent grafts was the concept proposed by Dr Yokoi, a vascular surgeon who prepared home-made stent grafts for >1000 patients, who used the variable shapes of individual aortic arches to create combinations of crooked skeletons and fenestration patterns. This made it possible to expand the use of individually designed endografts to a commercial level. The long-term effectiveness of the first generation of precurved, fenestrated endografts was reported by Kawaguchi et al. [7], and they indicated acceptable mid-term outcomes. Furthermore, the results of a multicenter clinical trial, involving endografts implanted from 2008 to 2009, confirmed the mid-term feasibility and the absence of proximal migration and branch occlusion.

We first studied the difference in arch anatomy between aged and young patients. The arch of a young patient is curved sharply like a C-curve. On the other hand, the arch of an aged patient is moderately curved back-and-forth and around like a twisted S-curve.

We then developed the precurved skeletons to fit various curved arches. Each skeleton was made of five Z-stents and connecting struts. Each Z-stent was joined with a couple of connecting struts. Two connecting struts were attached adjacent to each other. On the contralateral side of the connecting strut, the Z-stents crossed over and fit into the lesser curvature of the arch. To move the location of the connecting strut between junctions, we made a complex version of curved skeletons. In total, we made 16 types of precurved skeletons.

Further, this device had an outer graft and an inner skeleton system. The skeleton was sutured to the polytetrafluoroethylene (PTFE) graft at the top, bottom and around fenestrations. This device requires fewer suturing between Z-stent and graft, because the connecting struts support the shape of precurved skeletons. Moreover, minimizing suturing has two advantages. The first is that unfixed Z-stents can easily cross over and fit into the lesser...

Figure 2: Additional detail of endografts. (A) Skeleton with bigger Z-stent, (B) skeleton with lesser curvature support strut, (C) first-generation endograft with large fenestration, (D) second-generation endograft without insurance and (E) second-generation endograft with smaller fenestration.
The second is that the unfixed PTFE graft can fit the aortic wall according to the blood flow.

This device has eight types of fenestration. Every pattern fits each case. Fenestration is the simplest way to maintain steady blood flow to supra-aortic branches. This device has a stabilizing system for accurate endograft positioning in the aortic arch, under normal blood pressure. During the deployment period, the proximal end of the stent graft gradually opens, and the second and third units of the Z-stent get attached to the aortic wall. The position of the endograft can be finely adjusted during this stage of the implantation. The device contains two simple features to enable deployment. The first feature is the ‘fin’ that is on the proximal stent, which the distal stent is able to grasp until it is half-open. The ‘fin’ is attached to the opposite side of the connecting strut and functions to temporarily support the strut during deployment. This mechanism maintains the linearity of the stent graft and prevents it from curving too much towards the lesser curvature during deployment. The operator also supports and pushes the device against the blood flow with the help of the ‘fin’ structure. The second feature is the ‘traction suture’ that is similar to the trigger wire of the Zenith TX2 stent-graft system, but with a completely different function. The ‘traction suture’ ties up the first stent to prevent the opening of the stent mouth during the first part of the deployment process. The tip of the ‘traction suture’ is grasped by the second and third stents. When the third stent is half-open, the first stent opens gradually (Fig. 4). During the last half of the deployment, the system makes use of the blood flow to push the endograft into the greater curvature as it conforms to the aortic arch configuration, and the graft material then extends to the proximal LZ.

Moreover, the curved sheath and skeletons allow the sheath to pass easily during delivery into the aortic arch. This makes it possible to decide how much endograft must be preloaded into the sheath in the rotated position before shipping. In all cases, there are no fatal branch covering. We believe that fenestration is a safe technique.

It must be noted that this stent graft has extensive designing flexibility. We can choose the stent graft design that can be placed from Zone 0 or before. Zone 0 landing has a disadvantage of retrograde Type A dissection or brain infraction. However, Zone 0 landing has an advantage of decreasing the possibility of migration. This device makes it possible to approach Zone 0 through the arch, minimizing such disadvantages. Moreover, this device does not need large radial force for sealing, and ballooning is not always required. In our opinion, high radial force and touch-up ballooning lead to these potential risks. Moreover, outer graft system causes less compliance mismatch between graft and aortic wall in the ascending aorta. Less compliance mismatch leads to lower incidence of retrograde Type A dissection. Thus, this device opens the door for innovative implant strategy in arch aneurysm. Actually, in many cases, we place the first endograft in distal LZ in the beginning. Next, we put the second endograft in proximal LZ. Each precurved skeleton wall presses itself against the aortic wall in greater curvature. We call this ‘stepwise stent grafting’. This effect is similar to an arch bridge and decreases the endoleak from the supra aortic branch fenestrations in arch aneurysms.

The next generation of precurved, fenestrated endografts originated from the needs of patients with inadequate proximal Lzs. This model was limited to use in patients with serious risk factors for open surgical repair and who were unsuitable for endovascular repair using commercially available devices. These models feature...
refinements that allow for more proximal landings and smaller fenestrations. In the current study, the high rate of clinical success demonstrated that this model provides successful aneurysm repair despite the availability of poor LZs. Interestingly, the length of the proximal LZ was not determined to be a significant risk factor for endoleaks in the multivariate analysis. This result suggests that the Next-gen-Najutas have significant advantages in the case of patients with short-arch necks. On the other hand, this study also makes clear the limitations of the Z-stent-based fenestrated stent grafts. The results of analyses on patients with Type I endoleaks demonstrated two morphological risk factors. Both a larger aortic diameter in the proximal LZ and a longer aneurysm length were significant risk factors for the development of endoleaks. From these results, a decreased expansive force from the Z-stent is a possible reason for the development of endoleaks in the larger-diameter vessels. In addition, the endoleaks resulting from longer aneurysms appeared to occur most commonly as a result of the Z-stent slipping down the aneurysm. Although additional types of skeletons were developed in consideration of such endoleak scenarios, the Next-gen-Najutas could not completely prevent endoleaks in such cases. As previously noted, commercially available devices are occasionally used to reinforce the distal portion of the aneurysm, utilizing the bird-beak effect to prevent the Z-stent from slipping down the aneurysm by pushing both the proximal endograft and also the anterior wall towards the greater curvature of the arch. On the negative side, the proximal endograft separates from the posterior wall of the aortic arch. This is believed to be the reason why proximal endoleaks occur in cases with larger aortic diameters and longer aneurysms. In such cases, additional treatment with coil embolization between the graft and the aortic wall may be required. Currently, such a treatment is the best solution for stopping endoleaks, but the long-term effectiveness remains unknown.

In spite of the unfamiliar ‘tag-of-wire’ technique used in TEVAR, the mean fluoroscopic time was ~30 min. As noted previously, the ‘tag-of-wire’ technique was only used to stretch the precurved device through the access route. The surgeon does not need to do anything other than pull the endograft out of the sheath during the implantation procedure. This procedure does not entail a complicated catheter technique as is involved in cannulation or fenestration. The surgeon only positions the distal end of the fenestration with the left carotid artery or the LSA; the sheath can be easily supported against the blood flow. Re-positioning of the endograft is rarely required during the endograft procedure. Rotation of the device was controlled by the precurved shape, which was designed to be similar to the configuration of the aortic arch of each patient, and the fenestrations were automatically rotated and oriented towards the supra-aortic branches. This feature contributed to the decreased incidence of neurological complications.

In conclusion, the aim of surgical therapy for aortic pathologies was the prevention of aneurysm rupture, and the aim of the endovascular approach was to make the surgery less invasive and safer. Newer devices can not only extend the anatomical indications, but also minimize operative risks. The acceptable clinical success and low incidence of stroke and early death with Next-gen-Najuta demonstrate the progression of arch aneurysm repair. We are certain that this next-generation, precurved, fenestrated endograft has potential advantages in patients with short-arch necks. However, the long-term effectiveness of these devices is not yet clear. We can imagine that short LZs can easily degenerate and will not work as sealing zones in the future. Although there is some trepidation associated with additional treatments, such as coil embolizations, we are not concerned about endograft migration as a result of this procedure. Therefore, some salvage procedures are within sight.

Finally, we have to be aware of the limitations of this type of study. This study is non-randomized and prospective. This device was used only for patients with serious risk factors for open surgical repair and who were unsuitable for endovascular repair using commercially available devices.

The aim of this study was to determine the anatomical limitation of TEVAR using fenestrated endografts. The results have successfully shown the advantages and limitation of this device.

Conflict of interest: none declared.
REFERENCES


APPENDIX. CONFERENCE DISCUSSION

Dr M. Funovics (Vienna, Austria): I am an interventional radiologist and I also work in the ascending aorta, and we have some experience with stent grafts in zone zero. Yours is the best series and the best results in zone zero stent grafting that I have heard of; I encourage you to continue this work. However, from your data, the design of the stent graft doesn’t look too different from previous designs and I’m wondering how you really overcome some of the severe limitations that we experience in our way towards ascending aortic stent grafting. Most of all, do you think that the distribution of the radial force over the different stent segments contributes to some of the success that this device has?

Second, it seems that you do not go very far into the ascending aorta. The proximal neck seems to be very conservatively chosen. Did you do this on purpose to avoid retrograde dissection or any other traumatization of the ascending aorta?

Third, did you have difficulties with the proximal clamping? As we can clearly see with this very nice animation, they are clamped from the proximal lever, and this, in our experience, tends to pull the inner curvature forward. Did you get a very oblique depositioning result?

Finally, do you think that simple holes are safe enough? First of all, the holes are not much bigger than the exit points of the supra-aortic vessels, and, second, it seems that you go without any additional stent grafts to provide a tight seal. This cannot really be a tight seal in cases when the supra-aortic vessels come out of the aneurysm. Then you need some stent grafts to seal it and some branch inside the first stent graft. There are a lot of questions and maybe we cannot address all of these now.

Dr Azuma: We think a very simple answer for the repair of an aortic aneurysm is fenestration, as fenestration is sufficient to preserve the supra-aortic blood flow. In the case of an aneurysm that is more proximal to the brachiocephalic artery, we have a prototype of the branch stent graft, but we have the technology with fenestration, so we just put a branch to the brachiocephalic artery. That is very simple. This next generation endograft is very limited for a short proximal neck. What is the third question?

Dr Funovics: I think the main question is, do you think it is the way to go without any fixation stent grafts, and are you afraid of migration and catastrophic coverage of the supra-aortic branch?

Dr Azuma: Good question. In our results, we had four cases of retrograde type A dissection, which is 1.0% or less, and we believe this type of endograft has the smallest incidence of retrograde type A dissection.

Why do we put the stent graft in zone zero? The answer is that the ascending aorta has good compliance matching for this type of stent graft, as the graft is pre-curved and has ePTFE outside. The compliance is different in the ascending aorta and arch than in the descending aorta. The difference in the compliance is good for preventing migration. This is very difficult to explain, but the difference in compliance is the key reason for the successful use of this type of arch stent graft.

Dr Funovics: In other words, you think that if the compliance for the pulse wave of the natural aorta and of the stent graft is no big mismatch, then there will be no impedance break and the pulse wave will not be reflected and you will get very little retrograde dissection at this point. I agree with that. Obviously you came up with an ingenious solution.

When durability is overlooked

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The paper of Azuma et al. [1] described the results of a non-randomized, non-prospective, multicentre study (35 centres), in which the results of a so-called next generation, customized, pre-curved and fenestrated endograft were presented. The device was

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used for the repair of aortic arch aneurysms with challenging anatomy, that is to say, short proximal necks of <20 mm. All patients were operated upon electively. This homemade device consists of an inner skeleton (self-expandable Z-stents) sutured to an outer graft made from polytetrafluoroethylene. It possesses eight types of fenestrations. Deployment is facilitated by a number of peculiarities.

Concerning patient selection, the authors asserted that participating physicians selected patients with ‘serious risk factors for open surgical repair’. Given that pulmonary, cardiac and renal function was not specified or quantified in the manuscript, it is unclear exactly what this means. The fact that general anaesthesia was used in most of them probably indicates that their vital functions were not so deficient at all. I am surprised by the argument that in the most ‘challenging’ cases (for me entering the arch is always challenging), ‘patients did not have access to any alternative method for preventing aneurysm rupture except through the use of the fenestrated stent-graft’. This is, of course, the result of the specific study design, but it appears that the patients were not offered many alternatives. This is curious at the very least.

The paper starts with an introduction in which the authors announce that conventional repair of arch abnormalities is associated with a mortality of 6–20% and a stroke rate of 12%. In doing so, they refer to a paper that did not mention the words ‘mortality’ or ‘stroke rate’! It would be much more legitimate to refer to contemporary series with excellent and verifiable results, such as that of Yutaka et al. [2], who reported a mortality of 4.7%, with 3.5% permanent neurological deficit and 6.7% transient neurological deficit; or another recent paper of Zierer et al. [3], who reported 5% mortality, 3% permanent neurological deficit, 4% temporary neurological deficit and a freedom from reoperation of 97% at 8 years.

The significance of a 99.2% technical success rate is uncertain. If patients are well selected, one should reach 100% because, as I understand it, these devices are deployed with serious risk factors. Durability, the capability of maintaining the integrity of the structures to perform the functions for which they are designed and constructed, is overlooked here.

Thus this device opens the door for innovative implant strategy in arch aneurysms’. This statement is questionable based on the results of this study.

Making things easier, less invasive and less complex by introducing new techniques is one of the principal goals in surgery. It may even differentiate good surgeons from not so good surgeons. But the absolute condition is that the same excellent and durable results can be proved using the proposed new technique. In biology, ecology, finances, engineering, cancer prevention, energy problems, education and in life in general, long-term vision is critical. Here, there is no doubt that scrupulous follow-up was undertaken, but there is simply no follow-up mentioned.

As Dwight D. Eisenhower once said, the train of future will run over us if we lie down on the tracks of history. However, to me the introduction of fenestrated endografts for the treatment of arch aneurysms is only like the passing of an empty train; quick and without any impact for the future.

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REFERENCES

