for the type I EL can consistently achieve good results after the EVAR procedure.

The hostile neck, which is known to be a risk for perigraft leakage, is the focus of this study. The anatomical criteria, including the neck length and neck angulation, which are thought to be strongly related to the proximal type I EL, were set by the commercially available devices. We revealed the necessity of intra-op management, especially for those cases that did not fulfill the criteria regarding the aneurysmal neck. In addition, we retrospectively examined the EVAR cases, all of which were performed our simple algorithm against the intra-op type I EL and show the middle-term results.

Materials and methods

A series of 134 consecutive patients who underwent EVAR in Morinomiya Hospital (Osaka, Japan) between December 2006 and August 2008 were selected. Of these, 129 patients in whom contrast agents had been used intraoperatively were included in our study. Two kinds of commercially available devices were used: 72 cases (56%) were treated with the Gore Excluder™ AAA endoprosthesis (W.L. Gore & Associates, AZ, USA) and the remaining 57 cases (44%) were treated with the Zenith endovascular graft™ (COOK Medical, IN, USA). Follow-ups were performed until April 2010. Surveillance was performed with contrast CT scan at four days after the operation during in-hospital stay. After the discharge, patients were surveyed with CT at 6, 12, 24, and 36 month postoperatively.

Among the anatomical criteria documented in the instructions for use recommended by these companies, three factors considered to be strongly related to perigraft leakage were adopted in our study: a non-aneurysmal infrarenal aortic segment (neck) proximal to the aneurysms: 1) with a length >15 mm; 2) with an angle of <60° relative to the long axis of the aneurysm; and 3) with an angle of <45° relative to the axis of the suprarenal aorta. Eighty cases satisfied the criteria, and this group was classified as the on-label group. The 49 cases that did not satisfy the criteria were classified as the off-label group.

The off-label group included 14 cases of short aortic neck, 22 cases of severe suprarenal angulation, and 35 cases of severe aneurysm angulation. In cases where the distal landing area was too short, we usually extended the stent-graft leg to the external iliac artery with hypogastric artery coil embolization. If both the hypogastric arteries needed to be embolized, we performed a contralateral external iliac to hypogastric artery bypass. To avoid the difficulties encountered while accessing the aneurysm with the device, we often accessed *via* the retroperitoneal approach.

We evaluated the EL very carefully by performing a completion angiography, because the appropriate management of the proximal type I EL is extremely important for avoiding future reinterventions. We changed the angle of the C-arm and repeatedly checked the angiography. The angiography directly from the femoral sheath was useful for evaluating the distal type I EL. The retrograde flow from the lumbar artery, inferior mesenteric artery, and medial sacral artery into the aneurysmal sac in the late phase of the completion angiography was thought to indicate intra-aneurysm decompression, which meant successful exclusion.

When we found or suspected a type I EL during the completion angiography, we firstlyperformed a re-touch up with a semi-compliant occlusion balloon, then changed it to a PTA non-compliant balloon (balloon exchange), and finally used ancillary procedures, such as the use of aortic cuffs (Main body extension: Zenith™, or Aortic Extender Endoprosthesis: Excluder™) or a Palmaz™ (Cordis, Johnson & Johnson, Japan) stent insertion (Figure 1).

The TMP Lock-Balloon Catheter™ (Tokai Medical Products Co., Kasugai, Aichi,. Japan) and the Equalizer™ Occlusion Balloon Catheter (Boston Scientific Co., Japan) are the most frequently used semi-compliant occlusion balloons. Their material is relatively soft and their inflation pressure is low. The Maxi-LD™ (Cordis, Johnson & Johnson, Japan) is a non-compliant PTA balloon with a high inflation pressure. It is very important to consult the compliance chart before using this balloon. In order to avoid the risk of aortic dissection, one should select the balloon size whose diameter is less than the native aortic diameter. When using a palmaz™ stent, one should also take the balloon size into consideration. The use of too much pressure and repeated touch-up should be avoided.

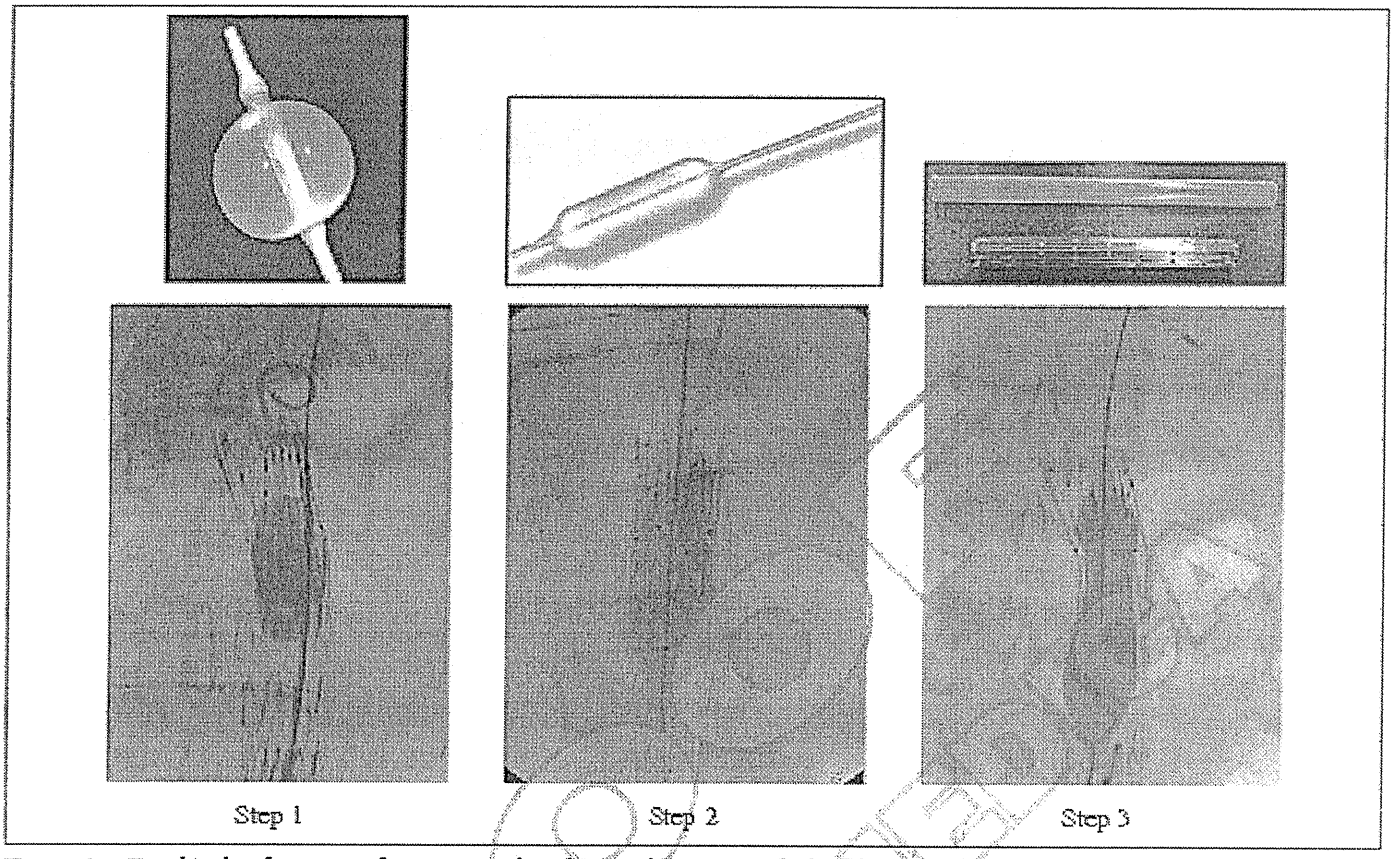

Figure 1.—Two kinds of stent-grafts were used in this study. Gore Excluder™ AAA endoprosthesis (W.L. Gore & Associates, AZ, USA) and the Zenith endovascular graft™ (COOK Medical, IN, USA). Step 1: re-touch up with semi-compliant balloon (The TMP Lock-Balloon Catheter™ [Tokai Medical Products Co., Kasugai, Aichi, Japan] or the Equalizer™ Occlusion Balloon Catheter [Boston Scientific Co., Japan]). Step 2: re-touch up with non-compliant balloon (The Maxi-LD™ [Cordis, Johnson & Johnson, Japan]). Step 3: Palmaz™ stent (Cordis, Johnson & Johnson, Japan) stent or aortic cuff (Main body extension: Zenith™, or Aortic Extender Endoprosthesis: Excluder™) insertion.

Where appropriate, unpaired Student's *t*-tests were used to make comparisons between the treatment groups. Significance was defined as $P<0.05$. The Kaplan-Meier life table analysis was used to estimate the overall survival, aneurysm-related mortality, and rate of freedom from re-intervention.

Results

During the follow-up period, which ranged from 12 to 40 months, no postoperative type I ELs were detected. A greater number of intra-op ELs were detected in the 27 cases of the on-label group (27/80: 33%) than in the 28 cases of the off-label group (28/49: 57%) ($P<0.01$). The intra-op type I EL was observed in a greater number of patients in the off-label group than in the on-label group (25 cases in the off-label group *vs.* 16 cases in the on-label group) (Table I). Ancillary procedures were also performed in a greater number of patients in the off-label group (Table I).

When we focused on the proximal type I EL, 78% (11/14 cases) of the patients who did not fit the proximal neck length criteria showed significantly higher proportion of early type I EL than those in the group that fit the criteria (Table II). The degree of neck angulation is a potential predictor for the proximal type I EL (Table II).

The aneurysm size decreased (>5 mm) in 70 cases (52%), unchanged (within 5 mm) in 63 cases (47%), and increased (more than 5 mm) in 1 case (0.7%).

Type II ELs were found in 33 cases. Although 2 type I ELs remained even after our 3 step algorithm, neither of these ELs was detected with the

TABLE I.—*The early type I EL was observed in a greater number of patients in the off-label group than in the on-label group. Ancillary procedures were also performed in a greater number of patients in the off-label group.*

		On-label group (80 cases)	Off-label group (49 cases)
Intraoperative type-I endoleaks	Proximal	16 (20%)	25 (51%)* (p<0.01)
	Distal	11 (13%)	3 (6%) (p=0.17)
	Total	27 (33%)	28 (57%)* (p<0.01)
Ancillary methods			
Palmaz™ stent or aortic cuff		9 (11%)	24 (48%)* (P<0.01)
Balloon Exchange		7 (8%)	1 (2%)* (P<0.01)

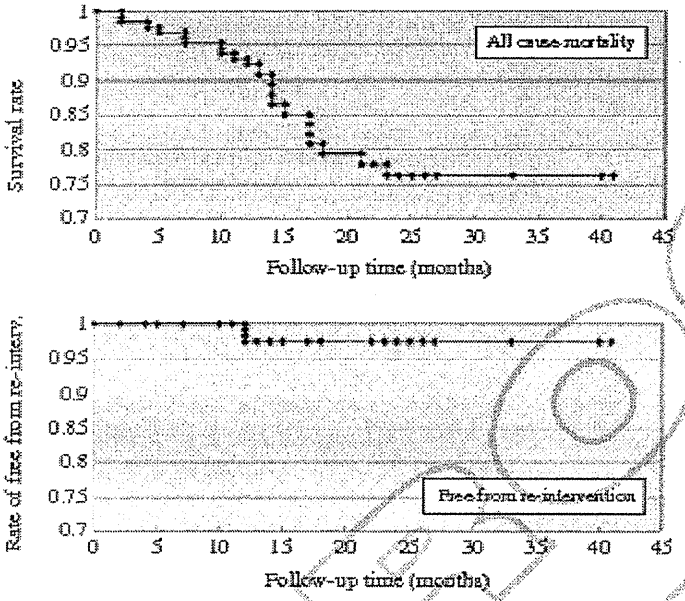

Figure 2.—All causes of mortality and the rate of periods free from re-intervention.

contrast CT performed at 4 postoperative days. Three type IV ELs were found. None of these cases showed any remnant of an EL after discharge.

The all cause mortality rate is shown in Table I. The aneurysm related death rate was zero. The aneurysm-related reintervention rate is shown in Figure 2. Four cases required reintervention (Table III). One graft limb occlusion and three graft migration-related complications are shown. The stent graft used for the reintervention was contralateral leg of Excluder™ because of its flexibility. There were no complications related to the proximal neck.

TABLE II.—*When focused on the proximal type I EL, a greater number of the patients who did not fit the proximal neck length criteria showed significantly higher proportion of early type I EL than those in the group that fit the criteria. The degree of neck angulation is a potential predictor for the proximal type I EL.*

Proximal neck length	Intra-op type1 EL
Neck length ≥ 15 mm (115 cases)	30 cases (26%)
Neck length < 15 mm (14 cases)	11 cases (78%)*
Neck angulation	*P<0.01 (X2=15.8)
Suprarenal < 45° and aneurysmal neck < 60°, (87 cases)	23 cases (26%)
Suprarenal ≥ 45° and/or aneurysmal neck ≥60° (42 cases)	18 cases (42%)**
	**P=0.06 (X2=3.5)

Discussion

The stent-graft was first approved in Japan in 2007, and the Japanese Committee for Stentgraft

TABLE III.—*Patients list of reintervention. All the stent grafts used for the reintervention was contralateral leg of Excluder™ because of its flexibility.*

Age and gender	Complication	Onset (month)	Treatment	Prognosis after the re-intervention
75 M	Graft limb occlusion	12	Thrombectomy and stent-graft insertion	Alive for 16 months
83 F	Graft migration and type1 and 2 endoleaks	12	Stent-graft insertion Coil embolization	Alive for 5 months
82 F	Graft migration and impending rupture due to type 1 endoleak	10	Stent-graft insertion	Alive for 9 months
75 M	Graft migration and type 1 endoleak	12	Stent-graft insertion	Alive for 5 months

Management (JACSM) was established with the aim of ensuring the safe and proper use of commercial stent-grafts following their regulatory approval.[5] Stent-graft materials have improved over the last two decades. Zenith™ and Excluder™ were the first two devices introduced to Japan. We were fully prepared to use these devices and aimed for procedural perfection in order to avoid the learning curve generally seen in the initial stages of implementation. In view of previous prospective studies of EVAR,[1-3] we focused on the importance of the type I EL and concentrated on its prevention. Therefore, we often used supportive devices, such as the palmaz™ stent or the aortic cuff, not only for cases of obvious intra-op proximal type I EL but also for remarkably difficult off-label cases (*i.e.*, neck length <10 mm, or neck angulation >90°) before completion angiography. Although in some cases this might mean oversurgery, we did not experience any complications caused by such procedures.

As Dias demonstrated, among the EVAR patients whose proximal type I ELs were treated with the palmaz™ stent, 10 out of 33 patients (30%) were treated for proximal perigraft leakage (9 intraoperatively and 1 postoperatively).[6] Non of these cases showed any anatomical difficulty regarding neck length (21 mm), neck angulation (30 degree), or conical neck. These cases corresponded to the off-label group in our study, and showed a relatively high rate of perigraft leakage. This may be due to the improvement of the endovascular device in this era.

Incomplete endovascular exclusion causes increases in intrasac pressure, which leads to a high risk of late rupture.[7,8] Parodi found that the intrasac pressure was close to the systemic pressure in the presence of the type1 EL.[9] We confirmed the absence of the type I EL by carefully observing direct leakage into the aneurysmal sac, and by confirming the retrograde flow from the branches of the aneurysm into the sac in the late phase of the completion angiography, which indicated the an intra-aneurysm decompression. We also employed completion angiography to reveal the stent-graft alignment.

Our endeavor to minimize perigraft leakage was partly grounded in the fact demonstrated by Li that sac pressure and AAA wall stress increased in proportion to the size of the leakage aperture.[10] On the contrary, Matsumura reported that 14 out of 28 cases that demonstrated initial ELs showed spontaneous sealing.[11] He indicated the beneficial effects of hemodynamical modification as a result of the stent-graft insertion itself. We also experienced one case in which we left an intraoperative type I EL and the leak spontaneously sealed postoperatively. We generally expected good results, however, by completing our algorithm.

An intraoperative evaluation of the proximal type I EL is difficult because the amount of contrast agent per cross-section area was less at the proximal site than at the distal one, and performing ancillary procedures near the renal arteries, such as the renal artery occlusion by the stent-graft, was sometimes troublesome. On the contrary, we did not focus on the distal EL in this study because an angiography directly from the femoral sheath can easily reveal a distal EL and defining a distal landing area can be ambiguous. Sometimes the common femoral artery has scattered sealing zones. If the distal EL was suspected, it is generally treated by the extension of the stent-graft leg to the external iliac artery.

In our study, about half of the off-label group patients required additional procedures at the proximal neck. This seemed to be a high additional intervention rate, and may be considered to be oversurgery. We are satisfied, however, with the result of no postoperative residual type I EL.

We revealed a higher rate for additional intervention of the short neck group and the tendency of the angulated group. This result was partly supported by the report of Albertini, who found that the neck angulation and neck diameter were significantly greater in patients who had a proximal type I EL, compared to patients who had none.[12] A short, heavily calcified and conical aneurysmal neck [6,13] was also reported as an increased risk of the type I EL, which corresponds with our results. Mohan pointed out that the stent-graft oversize, as well as short aortic neck, had close correlations with type I ELs.[7] Oversizing causes infolding of the stent-graft, which is sometimes difficult to mend without additional device such as the palmaz™ stent.[6] We did not experience such an infolding, however, possibly because we used a 64-slice CT and <3 mm slices for preoperative sizing in all of our cases.

The limitation of our study is that we did not take the multi-factors of hostile neck, such as

calcification or mural thrombus, into consideration. As such neck factors might be not independent, we should examine the data with a multifactorial analysis in the future, using a higher volume of patients.

The more than 97% free from reintervention rate at three years was satisfactorily high. The cause of postoperative reintervention in three cases was migration of the distal end attached on the common iliac artery. In our study, we performed coil embolization for the hypogastric artery, followed by extension of the stent-graft leg to the external iliac artery, for cases in which the landing zone was <15 mm. This is the reason that all cases fit the anatomical criteria of the distal landing. Some cases, however, including these three migration cases, had a tapered-shaped common iliac artery, whose landing condition might contain the risk of migration. We hypothesized that if severe aneurysmal angulation is remodeled, the inserted stent-graft might shift to the angulated site, resulting in the migration of the distal end of the stent-graft. We should take care in such angulated cases for the migration of the distal site rather than proximal one.

The all-cause mortality rate was similar to that of other high volume trials.[1,3] The mortality rate at three years was a little more than 70%. In spite of a good reintervention rate, the middle-term mortality rate did not surpass that of other reports. The causes of death were various, and we could not find any peculiar adverse factors. A higher volume of patients should be used in the future to examine the long-term results of these procedures.

Our strategy mainly included three steps, as mentioned above. A re-touch up with a semi-compliant occlusion balloon should be approached from the contralateral side. The direction of the radial force at the proximal landing site might change by a contralateral approach in the angulated neck. Although a PTA non-compliant balloon is certainly guarantees a firmer adherence to the aortic wall, it has the risk of dissection of the fragile atherosclerotic aortic wall. We referred to the compliant chart of the balloon and used an undersized one compared to the native aorta. A Palmaz™ stent was used as a last resort for persistent ELs.[6] We believe that the aortic cuffs, with its additional radial force, might be a good alternative to the Palmaz™ stent. However, we have experienced certain cases for which we could not use the cuffs because of the angulation and shortness of the neck.

We need to consider the cases of postoperative type I ELs that did not show any intra-op ones. Sampio demonstrated 8 cases of type I ELs among 202 EVAR patients.[13] Five cases did not show any intra-op type I ELs, and the time intervals after EVAR for these cases were 253, 155, 1, 1, and 21 days, respectively. We did not find any such cases in our study. However, we should pay specific attention to those patients with hostile neck in any future follow-up.

Conclusions

Off-label usage regarding aneurysm neck length and angle tends to be incomplete without ancillary procedures; the techniques we used for treating intra-op type I ELs produced good results. On the basis of the mid-term results, we should consider neck length and angulation when we expand the instructions for use. Furthermore, while aiming to perfect the intra-op procedure, we should have sufficient data regarding the various types of balloons and other supportive devices and also be skilled in using them in order to avoid intra-op complications such as aortic dissection.

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therapeutical impact. In all cases both the source of infection and the 'infected aneurysm' itself have to be addressed.

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Comments regarding "A Retrospective Study of Intravascular Ultrasound use in Patients Undergoing Endovascular Aneurysm Repair: Its Usefulness and a Description of the Procedure"

The use of Contrast Enhanced Ultrasound for Intra-procedural EVAR deployment completely eliminates the need for nephrotoxic iodinated intra-arterial contrast.

Dear Editor,

I was delighted to read your retrospective study using Intravascular Ultrasound (IVUS) during EVAR stent-graft deployment[1] and commend you for describing a technique to significantly reduce the intra-arterial contrast used. The availability of EVAR and the number of patients deemed suitable for these procedures is growing immensely. As techniques evolve and become more complex, such as fenestrated and branched grafts, the corresponding procedure times and thus exposure to greater volumes of nephrotoxic iodinated contrast and radiation[2,3] also increases.

I agree that your IVUS technique will help with these matters but will not eliminate them completely. In 2008 Dr Dirk Clevert first described the use of real-time intra-operative microbubble contrast-enhanced ultrasound for EVAR stent deployment and for post-procedural endoleak detection[4] (both immediate and late as part of a surveillance programme). I have visited Munich and witnessed this procedure that requires no intra-arterial contrast but does require the use of much reduced doses of intra-procedural angiographic fluoroscopy. More recently the German group has published their longer experience and refinement of the technique with a series of 17 patients[5] and compared this group with 20 treated using "conventional EVAR" consisting of iodine contrast media with intra-operative fluoroscopy.

The use of intra-operative microbubble contrast ultrasound for stent deployment completely eliminates to need for any completion angiography or the use of any intra-arterial contrast and significantly reducing the radiation exposure, which IVUS does not appear to match. I look forward to your further work that you allude to regarding the combined use of IVUS and ultrasound contrast, but suggest that this should not be limited to those with a contraindication to iodinated media but can be applied more widely.

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Response to comments regarding "A Retrospective Study Of Intravascular Ultrasound Use In Patients Undergoing Endovascular Aneurysm Repair: Its Usefulness And A Description Of The Procedure."

Dear Editor,

We thank Dr. Dindyal for his comments regarding our paper; we have provided a response regarding the issue that he had raised, mainly regarding the usefulness of contrast-enhanced ultrasonography (CEUS).

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We are extremely pleased to obtain his endorsement for our paper, which reports an intravascular ultrasonography (IVUS) technique for reducing the use of contrast agents. We agree that IVUS cannot completely substitute for contrast agents with regard to completion angiography for detecting endoleaks and that CEUS with second-generation contrast agents would be a powerful diagnostic method. The development of CEUS with second-generation agents would be a great boon for patients with renal dysfunction or allergy to contrast agents. Regretfully, in our country, health insurance coverage for CEUS with second-generation contrast agents has only been approved for hepatic diseases; this technique is a more practical one because of the clear images obtained and the durability of echo sound waves. Therefore, we plan to use it in the near future after it is approved.

The complete substitution of conventional contrast agents with CEUS has 2 disadvantages. Firstly, the resonance in ultrasonography (US) may not be adequate for detecting the orifices of the aortic branches.

CEUS appears to be adequate for detecting obvious perigraft leakage and the pooling of endoleaks in the aneurysmal sac. However, it is important to know which branch of the aorta is causing the endoleaks.

In addition, we usually check the route (collateral vessels) of backflow into the sac in order to prepare for future re-intervention.

The resolution of the currently used CEUS technique may not be adequate for detecting the lumbar artery or the median sacral artery, and the artifact of colon gas may impede precise examination. We agree with your recommendation of preoperative simulation with the US device; however, this requires skills and a lot of experience.

Secondly, evaluation of US imaging results is less objective than that of fluoroscopy imaging results, i.e. US imaging can be evaluated by only a small number of technicians. This is not desirable with respect to the training of vascular surgeons in our institute for this technique as well as with respect to the risk-management aspect such as overlooking minor endoleaks.

However, the combination of CEUS and IVUS would a powerful weapon for patients with aneurysms, in cases where there is a contraindication for the use of contrast agents. Our dream is the real-time three-dimensional construction of each US cross section during surgery. If this can be achieved, then CEUS can provide a complete and non-invasive alternative to contrast agents.

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