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Gap distribution mapping to visualize regions associated with type 1 endoleak in a fenestrated thoracic stent graft

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Key question

How can we predict the occurrence of TIEL after a TEVAR?

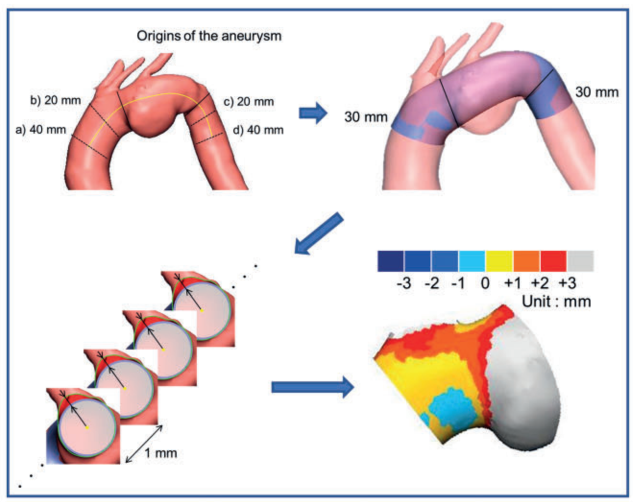
Key finding(s)

A continuously malapposed region at stent-graft landing zone defined using a novel gap distribution mapping was associated with TIEL region in all patients.

Take-home message

A preoperative gap distribution mapping may help to predict the occurrence of TIEL.

Gap distribution mapping



Gap distribution mapping visualizes the unevenness in the patient's aorta.

Abstract

OBJECTIVES: Our goal was to analyse the relationships between aortic surface irregularity and a type 1 endoleak (T1EL) after a thoracic endovascular repair using the Najuta fenestrated stent graft.

METHODS: The patients who were treated using the Najuta stent graft for an intact aortic arch aneurysm at the Saitama Cardiovascular and Respiratory Center between June 2013 and June 2017 were analysed retrospectively. The primary end point was the occurrence of a

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T1EL. The gap between a virtual aorta and the patient's aortic wall at the stent graft fixation was calculated over the whole circumference at 1 mm intervals, and gap distribution mapping was performed. The rate of freedom from a T1EL was estimated using the Kaplan–Meier method and compared between the patients with or without a continuously malapposed region of >1 mm from the branches to the aneurysm.

RESULTS: Twenty-one patients were analysed. During the mean follow-up period of 21.7 months, 4 patients were confirmed to have T1ELs. Three of the T1Els were detected during the perioperative period and occurred through a fenestration. The remaining patient had a T1EL 2 years postoperatively. The gap distribution mapping confirmed the presence of a continuously malapposed region of >1 mm from the cervical branch to the aneurysm postoperatively in 4 patients with T1ELs. Patients who had a continuously malapposed region of >1 mm showed a statistically lower T1EL rate than those without ($p < 0.001$). Malapposed regions defined using the gap distribution mapping were consistent with flow channels through T1EL fenestrations detected using the perioperative computed tomography data.

CONCLUSIONS: The gap distribution mapping could be useful to predict the occurrence of T1ELs in patients with the Najuta stent graft.

Keywords: Thoracic aortic aneurysm • endovascular aortic repair • fenestrated graft system • endoleak

ABBREVIATIONS

CT =	computed tomography
IFU =	instructions for use
LCCA =	left common carotid artery
LSCA =	left subclavian artery
SD =	standard deviation
TAA =	thoracic aortic aneurysm
T1EL =	type 1 endoleak
T1cEL =	type 1c endoleak
TEVAR =	thoracic endovascular aortic repair
VA =	vertebral artery

INTRODUCTION

Although open surgical repair remains the gold standard for treatment of arch thoracic aortic aneurysms (TAA), the outcomes of thoracic endovascular aortic repair (TEVAR) are excellent, particularly in patients with descending TAA [1, 2]. For surgically high-risk patients with arch TAA, TEVAR using the Najuta thoracic stent graft system (Kawasumi Laboratories, Inc., Tokyo, Japan), a semi-custom-made precurved fenestrated stent graft, is one of the less-invasive alternative treatment options [3]. The stent graft designs are customized for individuals from 19 types of curved stent skeletons and 8 types of graft fenestrations. The stent graft with various combinations of zigzag stent-frame designs and distances between adjacent stent frames allows adequate 3-dimensional (3D) curved conformations in accordance with an individual patient's arch anatomy. The location, size and number of fenestrations can be determined based on the patient's preprocedural computed tomography (CT) data to preserve the blood flow to the cervical branches. The excellent fit of the precurved Najuta stent graft for various arch anatomies has been demonstrated [4–6]. Some reports showed favourable clinical outcomes with the Najuta stent graft for arch TAA [3, 4, 7]. In contrast, 32.4% of patients with aortic arch aneurysms located within 15 mm from the left common carotid artery (LCCA) who used the Najuta stent graft developed type 1 endoleaks (T1EL) at discharge [8]. The authors reported that these endoleaks occurred through a space around the fenestrations [8]. Preoperative morphological evaluation of TAA and appropriate stent graft planning are critical to achieving good clinical outcomes for patients with complicated TAA using the Najuta stent graft. To provide a method to predict occurrence of continuously malapposed regions that may induce endoleaks, we developed a novel quantitative measurement method "gap distribution mapping", which shows the gap distribution between the virtual and actual aortic walls. We retrospectively analysed the gap distributions in patients treated with the Najuta stent grafts and investigated relationships between findings from the gap distribution mapping and presence/absence of T1EL after a TEVAR to evaluate applicability of the gap distribution mapping method for predicting the occurrence of T1EL.

PATIENTS AND METHODS

Ethical statement

This study was approved by the institutional review board of Saitama Cardiovascular and Respiratory Center (approval code: 2016024). The requirement for written informed consent was waived because of the retrospective design.

Patients

Patients who were treated for arch TAA using the Najuta stent graft at the Saitama Cardiovascular and Respiratory Center between June 2013 and June 2017 were retrospectively reviewed. These patients had no eligibility for open surgical repair due to their comorbidities. Patients with descending TAA or dissected TAA or treated for endoleak prior to TEVAR were excluded.

Characteristics of and deployment procedure for the Najuta thoracic stent graft system

All procedures were performed with the patients under general anaesthesia. The femoral artery was exposed, and a 6 Fr double-lumen introducer sheath (Medikit Co., Ltd. Tokyo, Japan) was inserted through the right brachial artery. An angiographic catheter was inserted through 1 of the 2 lumens of the 6 Fr sheath. A 0.032-inch Radifocus guide wire (Terumo Medical Co., Tokyo, Japan) was introduced through the exposed femoral artery site into the other lumen of the 6 Fr sheath. The Najuta stent graft was delivered using the tug-of-wire technique to stretch the precurved sheath, whose calibre ranged from 21 to 23 Fr at its proximal portion and narrowed to 18 Fr at its distal portion. The stent graft was deployed without cardiac arrest or rapid pacing. All cervical branch reconstructions were performed before the stent graft was deployed, whereas all embolizations of the left subclavian artery

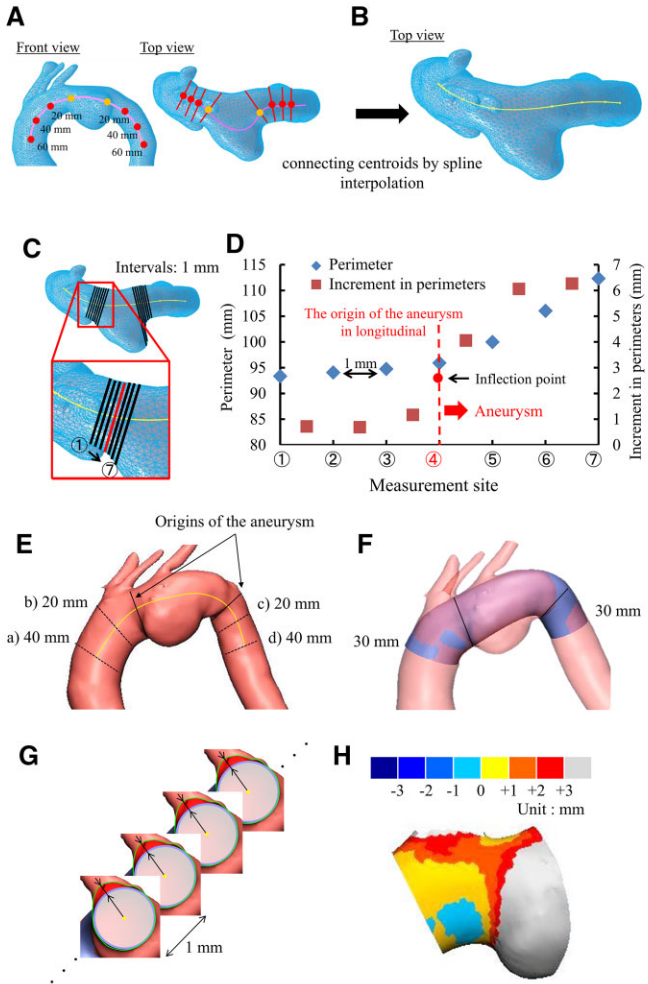

Figure 1: Definition of the centre line of an aorta, origin of an aneurysm and gap distribution mapping. (**A**) Two orange dots indicate the centroids of the 2 cross-sections initially set near the proximal and distal origins of the aneurysm. Red dots show the centroids of the cross-section at 20 mm, 40 mm and 60 mm proximal and distal along the centre line of the aorta from the orange dots. (**B**) The yellow line was drawn by connecting 8 centroids with spline interpolation as the centre line that was not affected by the aneurysm, whereas the pink line in (**A**) indicates the centre line affected by the aneurysm. (**C**) The perimeter of the aortic cross-section perpendicular to the centre line was measured at 1-mm intervals (**D**). Two inflection points of increased perimeters in the vicinity of the proximal and distal aneurysm were defined as the origins. (**E**) Diameters were calculated with the circle approximation method based on its perimeter at 4 points (a-d). The yellow line depicted the centre line. (**F**) The virtual aorta was created along the centre line. (**G**) The gap between the virtual aorta and the patient's aortic wall at the stent-graft fixation regions was calculated over the whole circumference at 1-mm intervals. The yellow point depicted the centroid of the aortic cross-section. The blue line depicted the virtual aorta, and the green line depicted the patient's aortic wall. (**H**) The gap distribution map was created.

(LSCA) were performed after deployment. Balloon dilatation was selectively performed after stent graft deployment.

All patients underwent contrast-enhanced CT at 1 week, 6 months and 12 months following TEVAR; patients without complications were checked annually thereafter.

Data collection

Age, sex, aneurysm diameter (mm), aneurysm shape, proximal neck length (mm) and violation of the instructions for use (IFU) in the proximal neck were obtained from a prospectively collected database. The IFU for the Najuta stent graft require 3 anatomical factors: (i) proximal neck length (direct length from the orifice of the preserved vessel to the proximal end of the aneurysm) of ≥20 mm, (ii) distal neck length (length from the distal end of the aneurysm to the coeliac artery) of ≥20 mm and (iii) diameters of both necks that are ≥20 mm and <38 mm. These anatomical measurements were performed preoperatively by the operators using SYNAPSE VINCENT (Fujifilm Medical Co., Tokyo, Japan) at the Saitama Cardiovascular and Respiratory Center. Intra- and postoperative data were obtained from the patients' operative notes, medical images and charts. Intraoperative data included the proximal landing zone based on the Ishimaru classification [9]; preservation of cervical branches; the procedure for cervical branch reconstruction; the presence or absence of LSCA embolization; and the presence of endoleaks on completion angiographic scans. Postoperative data included the presence of T1EL on postoperative CT scans. Definitions used in this study adhered to the Society for Vascular Surgery reporting standards [10]. A type 1a endoleak was defined as "a leak at the proximal graft attachment site", and a type 1c endoleak (T1cEL) was defined as a "leak around a fenestration".

Table 1: Patient characteristics, aneurysm morphology and intraoperative data

	n	(%)
All patients	21	(100)
Age, years, mean (SD)	77.3 (5.5)	
Male sex	16	(76.2)
Aneurysm diameter, mm, median (IQR)	56 (50-60)	
Aneurysm shape		
Fusiform	15	(71.4)
Saccular	6	(28.6)
Length of the proximal neck, mm, mean (SD)	18.4 (3.3)	
Violation of IFU in the proximal neck	11	(52.3)
Proximal landing zone		
0	20	(95.2)
1	1	(4.8)
Preserved the cervical vessel		
BCA only	2	(9.5)
BCA + LCCA	18	(85.7)
Three vessels	1	(4.8)
Reconstruction of the cervical vessel	9	(42.9)
RCCA-LCCA bypass	1	(4.8)
RCCA-LCCA-LSCA bypass	1	(4.8)
LCCA-LSCA bypass	1	(4.8)
RSCA-LSCA bypass	6	(28.6)
Embolization of LSCA	6	(28.6)
Type 1 endoleak at completion angiography	1	(4.8)

BCA: brachiocephalic artery; IFU: instruction for use; IQR: interquartile range; LCCA: left common carotid artery; LSCA: left subclavian artery; RCCA: right common carotid artery; RSCA: right subclavian artery; SD: standard deviation.

Gap distribution mapping to identify incompletely apposed regions at the stent graft fixation

We sought to distinguish normal aorta and aortic aneurysms based on the aortic cross-section perimeter of the inner surface of the aortic wall. CT Digital Imaging and Communications in Medicine data images were imported into the 3D construction software Mimics Research 17.0 (Materialize, Leuven, Belgium),

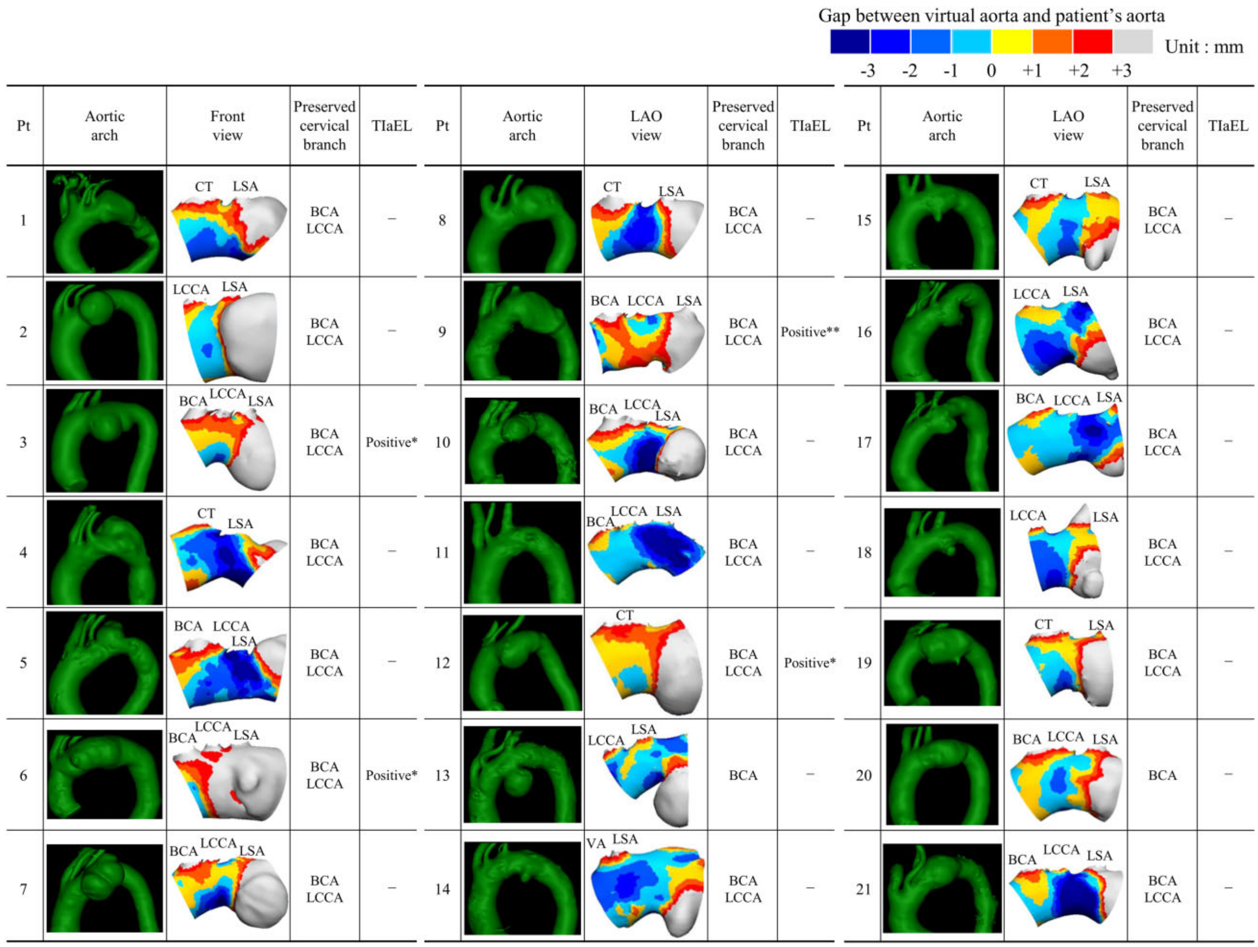

Figure 2: Aortic arch morphology and gap distribution mapping for all cases. BCA: brachiocephalic artery; CT: common trunk; LCCA: left common carotid artery; LSA: left subclavian artery; T1EL: type 1 endoleak; VA: vertebral artery. * Confirmed during the perioperative period. ** Confirmed during the remote period.

and an individual patient's aortic anatomy was reconstructed. First, 2 points near the proximal and distal origins of the aneurysm were set initially (Fig. 1A). A total of 8 aortic cross-section centroids at 20-mm intervals in the longitudinal direction, including those of the above 2 cross-sections, were obtained (Fig. 1A). The centre line through these 8 centroids was obtained by the spline interpolation using SolidWorks 2011 (SolidWorks Corp, Waltham, MA) (Fig.1B). Second, the perimeter of the aortic cross-section perpendicular to the centre line was measured at 1-mm intervals (Fig. 1C), and 2 inflection points of increased perimeters in the vicinity of the proximal and distal aneurysms were defined as the origins of the proximal and distal aneurysms (Fig. 1D).

The perimeters of the cross-sections located 20 mm and 40 mm proximal or distal from the aneurysmal origins were measured, and the aortic diameter (R) was calculated using the circle approximation method based on its perimeter (R = perimeter/π) (Fig. 1E). Then, the virtual aorta was created along the centre line from 30 mm proximal to 30 mm distal to the aneurysmal origin using 3-Matic Research 11.0 software (Materialize) (Fig. 1F). The gap between the virtual aorta and the patient's aortic wall at the stent-graft fixation regions was calculated over the whole circumference at 1-mm intervals (Fig. 1G), and the gap distribution mapping was created (Fig. 1H). The gap distribution mapping visualized the unevenness of the patient's aortic surface and quantitatively elucidated the location and degree of inflated or depressed regions. An irregularity on the aortic surface was colour-coded at 1-mm intervals. Positive values indicate inflated regions and negative values indicate depressed regions.

End point and statistical analyses

The primary end point was the occurrence of a T1EL. Continuous data were presented as the mean with standard deviation (SD) or median with interquartile range after assessing the normality. Categorical variables were presented as number and percent frequencies. Freedom from T1EL and overall survival rates were estimated using the Kaplan–Meier method. The T1EL event-free rates were compared between patients with or without a continuously malapposed region of >1 mm from branches to the aneurysm using the log-rank test. Statistical calculations were performed with STATA software, version 15 (Stata Corp, College Station, TX, USA). A *P*-value <0.05 was considered statistically significant.

RESULTS

After excluding 7 patients (1 with a descending TAA, 5 with dissected TAA and 1 with a secondary TEVAR), 21 were included in the analysis. Patient characteristics, aneurysmal morphologies and intraoperative data are shown in Table 1. The mean age was 77.3 (SD: 5.5) years; 16 (76.2%) were men; and the median aneurysm diameter was 56 (interquartile range: 50–60) mm. In 11

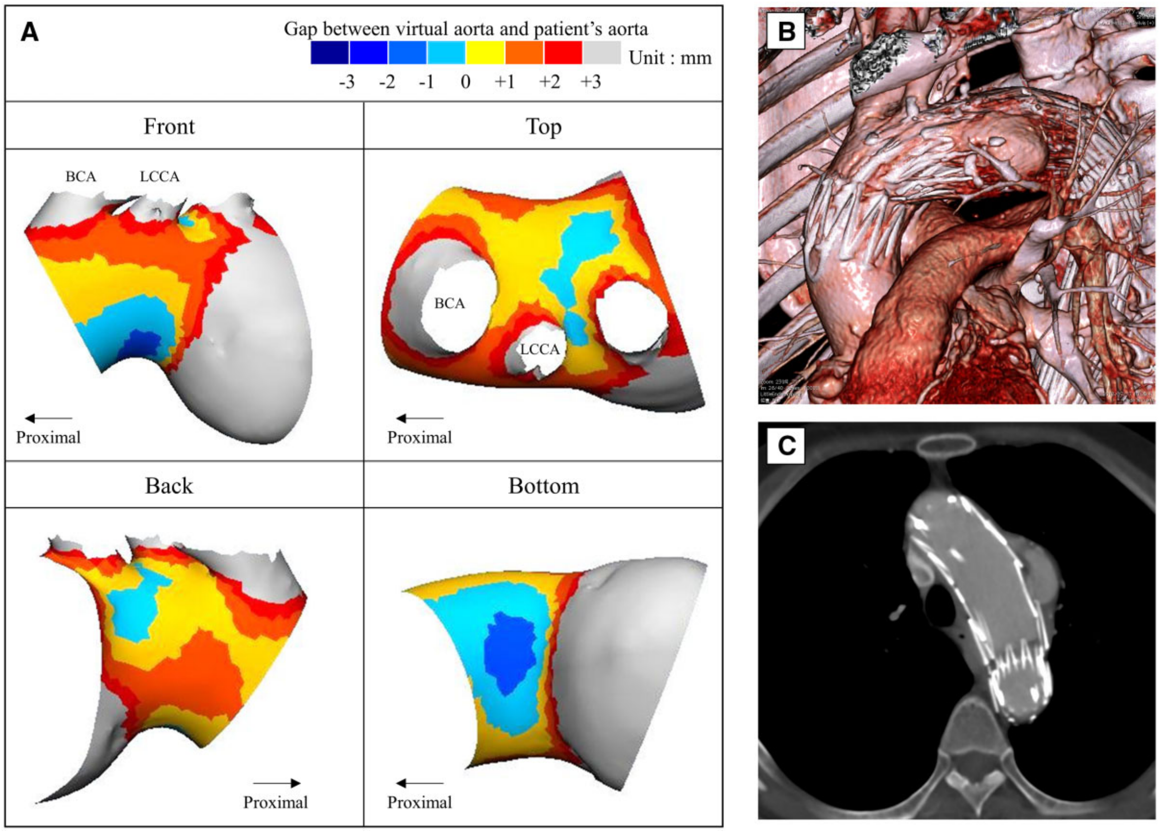

Figure 3: A 71-year-old woman (patient #3, Fig. 2) with a distal aortic arch aneurysm measuring 50 mm in diameter underwent TEVAR using the Najuta stent graft to preserve the BCA and the LCCA. (**A**) Gap distribution mapping. (**B, C**) Reconstructed 3-dimensional image and axial image of the postoperatively enhanced CT on postoperative day 7. The gap distribution mapping shows the region continuously malapposed more than 1 mm from the BCA and the LCCA to the aneurysm via the anterior wall of the aorta. Enhanced CT shows the T1EL through the fenestration of the stent graft via the anterior wall of the aorta. Because of persistent T1EL, the patient underwent an open conversion operation at another hospital 3 years postoperatively. BCA: brachiocephalic artery; CT: computed tomography; LCCA: left common carotid artery; TEVAR: thoracic endovascular aortic repair; T1EL: type 1 endoleak.

patients (52.3%), the procedure was performed outside the IFU. Cervical branch reconstruction was performed in 9 patients (42.9%). At completion angiography, T1EL was confirmed in 1 patient, who was followed and monitored conservatively.

Patients with type 1 endoleak

During a mean follow-up period of 21.7 (SD: 17.1) months, T1EL was confirmed in 4 patients (19.0%). In 3 of the 4 patients, T1cEL was confirmed during the perioperative period by CT angiography and was found to have occurred through a fenestration. One patient underwent conversion to open surgery in another hospital 3 years postoperatively; another died 4.5 years postoperatively of suspected aortic rupture; and the T1cEL in the third patient spontaneously disappeared 3 months postoperatively. The T1EL in the final patient developed 2 years postoperatively. In this case, although the aneurysm size had been stable for 2 years, it suddenly enlarged from 58 mm to 65 mm in diameter. Although no endoleaks were detected in the CT angiographic scans, a T1EL of unknown origin was confirmed by angiography. Therefore, an additional TEVAR was performed with in situ fenestration for the brachiocephalic artery with surgical bypass from the right common carotid artery to the LCCA. The aneurysm did not enlarge after the second intervention; however, the patient died 1 year postoperatively of chronic kidney disease. The freedom from T1EL and the overall survival rate were 85.7% and 94.7% respectively, 2 years postoperatively.

Gap distribution mapping

All aortic arch and gap distribution mappings are shown in Fig. 2. In all patients with T1EL (patients 3, 6, 9 and 12), a continuously malapposed region with a length >1 mm was confirmed postoperatively, connected from the cervical branch to the aneurysm. Although the same finding was observed in patient 1, who did not develop T1EL, the width of the malapposed region was significantly smaller than in those who developed T1EL. Patients 3, 6 and 12, with T1ELs confirmed during the perioperative period, had T1ELs consistent with the gap distribution mapping findings (Figs. 3–5). Patients with the presence of a continuously malapposed region of >1 mm from the cervical branch to the aneurysm showed a statistically lower rate of T1EL event-free survival than those without ($P < 0.001$) (Supplementary Fig. 1).

In the 56.3% (9 of the 16 remaining patients) patients without T1EL, the apposed region, a negative region in the gap distribution mapping, was confirmed over at least 1 entire circumference from the preserved cervical branch to the aneurysm. Three representative patients are shown in Fig. 6.

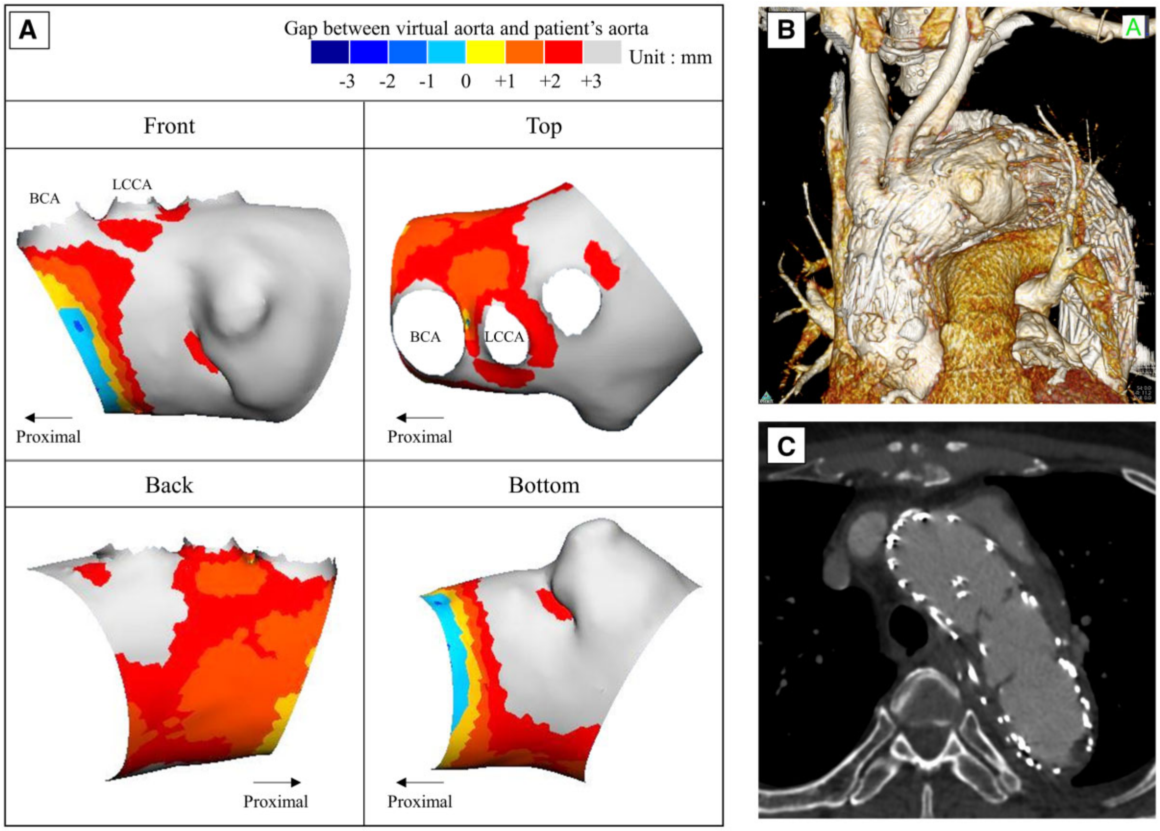

Figure 4: A 73-year-old man (patient #6, Fig. 2) with a distal aortic arch aneurysm measuring 60 mm in diameter underwent TEVAR using the Najuta stent graft to preserve the BCA and the LCCA. (**A**) Gap distribution mapping. (**B**, **C**) Reconstructed 3-dimensional image and axial image of the postoperative enhanced CT on postoperative day 7. The gap distribution mapping showing the region continuously malapposed more than 1 mm from the BCA and the LCCA to the aneurysm via both sides, especially the front side. The postoperative enhanced CT shows the T1EL through the fenestration of the stent graft via the anterior wall of the aorta. Although the T1EL was persistent, secondary intervention could not be performed because of patient opposition; finally, the patient died 4.5 years postoperatively of a suspected aortic-related death. BCA: brachiocephalic artery; CT: computed tomography; LCCA: left common carotid artery; TEVAR: thoracic endovascular aortic repair; T1EL: type 1 endoleak.

DISCUSSION

The results of this study suggested that the presence of a continuously malapposed region of >1 mm defined using the novel gap distribution mapping was associated with the occurrence and the portion of a T1EL in the Najuta stent graft. Endoleaks are a major complication: In particular, T1ELs that cause systemic pressure within the aneurysm may increase the risk of sac enlargement and rupture. The incidence of T1ELs after TEVAR was reported as 0.8%–18.9% [11–13]. Another study reported that the incidence of any endoleak after TEVAR was 19.4%, of which 71% were diagnosed on the first postoperative CT at 1 month [14]. Although some T1ELs diagnosed during the perioperative period spontaneously disappeared during follow-up [15], the TEVAR should be completed without T1EL. This study indicated that the use of gap distribution mapping for predicting the occurrence of T1EL preoperatively may improve the patients' overall outcomes.

In our cohort, 3 patients with TIcEL were confirmed during the perioperative period. Furthermore, in 4 patients, including 1 with newly developed T1EL at 2 years postoperatively, we found a continuously malapposed region with a length >1 mm connecting from the cervical branch to the aneurysm. Because the blood vessels are not a perfect circle, irregularities on the surface of the aorta might contribute significantly to the occurrence of perioperative T1EL when using an exoskeleton rather than endoskeleton-type stent graft. Although some newly developed T1ELs are caused by stent-graft migration in the remote period, anatomical factors, other than technical, are the main risk factors during the perioperative period. Although several studies reported the relationship between the proximal landing zone length and the occurrence of T1EL [16–18], there is no consensus on the optimal length of the proximal landing zone. In general, measurements on axial images and multiplanar reconstructions combined with centre-line analysis are used to plan TEVAR. However, these methods cannot quantitatively evaluate the 3D morphology of the aortic surface. Not only the landing length but also the aorta's surface properties could be associated with the occurrence of T1EL. Regarding the operative procedure, the brachiocephalic artery and the LCCA were preserved in all patients with T1EL. After the reconstruction of the cervical vessel, no patient developed a T1EL. However, in the group whose brachiocephalic artery and LCCA were preserved, the incidence of T1EL was 22.2%. Seven of 9 (77.8%) reconstructions were conducted for the LSCA reconstruction due to the insufficient connection between the bilateral vertebral arteries. The reconstruction of the LSCA was not associated with the stent-graft landing position. Although our cohort included 11 patients who violated the IFU-prescribed proximal length, the absence of T1EL throughout the follow-up period was confirmed in 8 patients. These data indicate the impact of the surface properties

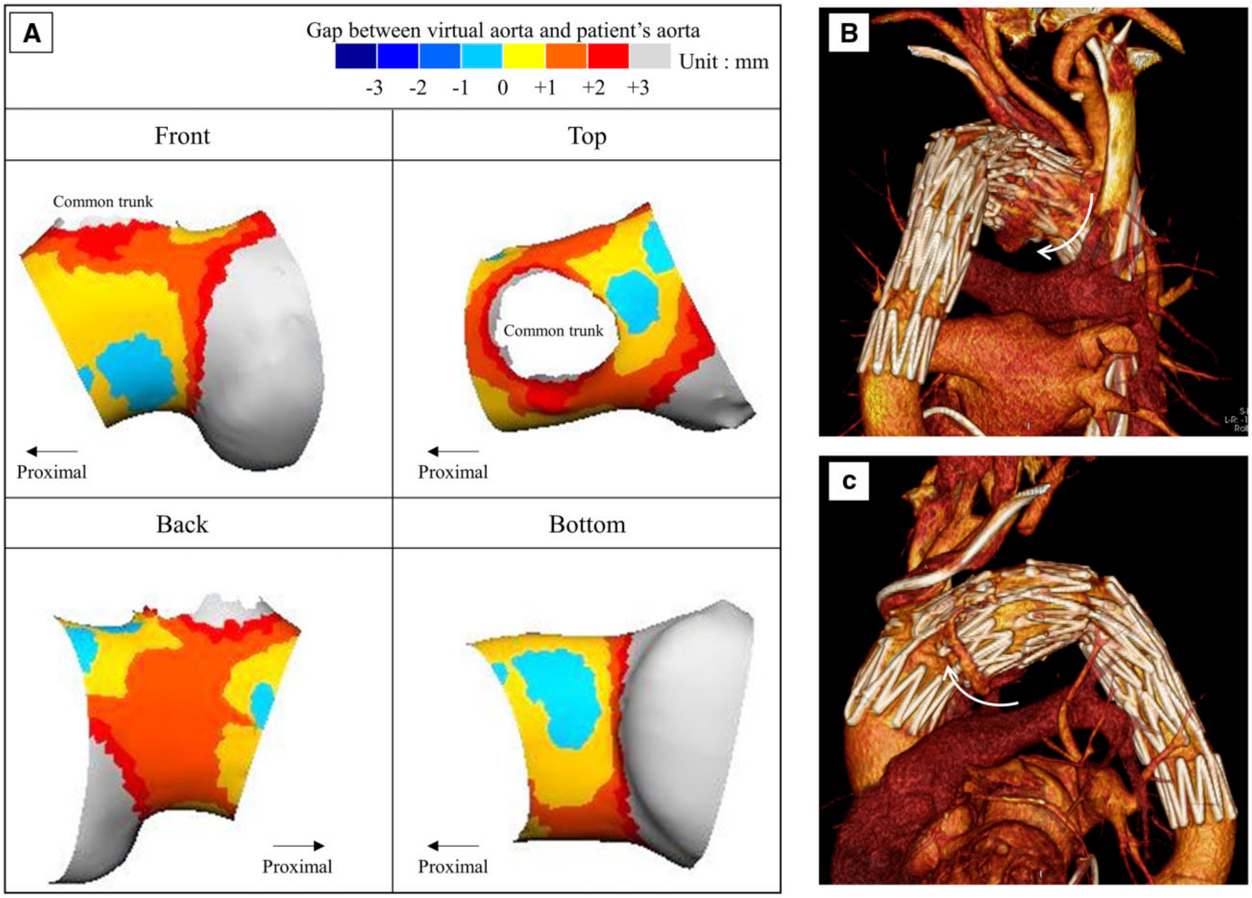

Figure 5: A 74-year-old man (patient #12, Fig. 2) with a distal aortic arch aneurysm measuring 65 mm in diameter underwent TEVAR using the Najuta stent graft to preserve the common trunk. (**A**) Gap distribution mapping. (**B, C**) Reconstructed 3-dimensional images of the postoperative enhanced CT on postoperative day 8. The gap distribution mapping showing the region continuously malapposed more than 1 mm from the common trunk to the aneurysm via both sides, especially the back side. The postoperative enhanced CT shows the T1EL through the fenestration of the stent graft via the posterior wall and the lesser curvature of the aortic arch to the aneurysm (white arrow). This T1EL disappeared spontaneously at 3 months postoperatively. CT: computed tomography; TEVAR: thoracic endovascular aortic repair; T1EL: type 1 endoleak.

of the aorta. Although further prospective study is warranted, surgical strategies based on preoperative gap distribution mapping may contribute to improving the overall patient outcomes associated with TEVAR.

One of the 3 T1cELs confirmed during the perioperative period spontaneously disappeared. Further accumulation of cases is required to determine which patients with T1EL and malapposed regions defined by the gap distribution mapping will experience spontaneous resolution, because persistent T1EL may be affected by the complex interactions among several factors, such as anatomical, patient-related (represented in blood coagulation ability) and technical.

The Najuta stent graft has the advantage of enabling a total endovascular repair for arch TAA while preserving the cervical branch flow without the need for a cervical cut-down, unlike other branched devices that require a cut-down to establish the side branches [19, 20]. The Najuta stent graft is particularly useful in patients with a bovine aortic arch [21] because crossing of the branches of the brachiocephalic artery and LCCA while using a branched device for a bovine aortic arch may lead to mutual compression of each branch [22]. On the contrary, T1EL through a fenestration in the Najuta stent graft is one of the major problems encountered. Further study using gap distribution mapping in combination with current clinical practices is needed to improve the outcome of thoracic endovascular repair using the Najuta stent graft.

Limitations

This was a retrospective study involving a single institution. A risk analysis was not conducted due to the small sample size. A prospective study to predict T1EL using preoperative gap distribution mapping should be warranted to assess efficacy in predicting occurrences of T1EL. Second, gap distribution mapping was based on preoperative CT scans that did not correspond to the postoperative wall abnormalities that may be changed due to the radial force and oversizing of the Najuta stent graft in the aortic arch. Third, the applicability of gap distribution mapping to other stent grafts was not evaluated. Nevertheless, our data suggest that gap distribution mapping can have an impact as an auxiliary tool in preoperative evaluation.

CONCLUSIONS

The results of this study suggest that the presence of a continuously malapposed region of >1 mm from the cervical branch to the aneurysm, defined according to novel gap distribution mapping, is associated with T1ELs in the Najuta stent graft. The findings encourage us to preoperatively use gap distribution mapping to predict the occurrence of T1EL and improve the patients' overall outcomes.

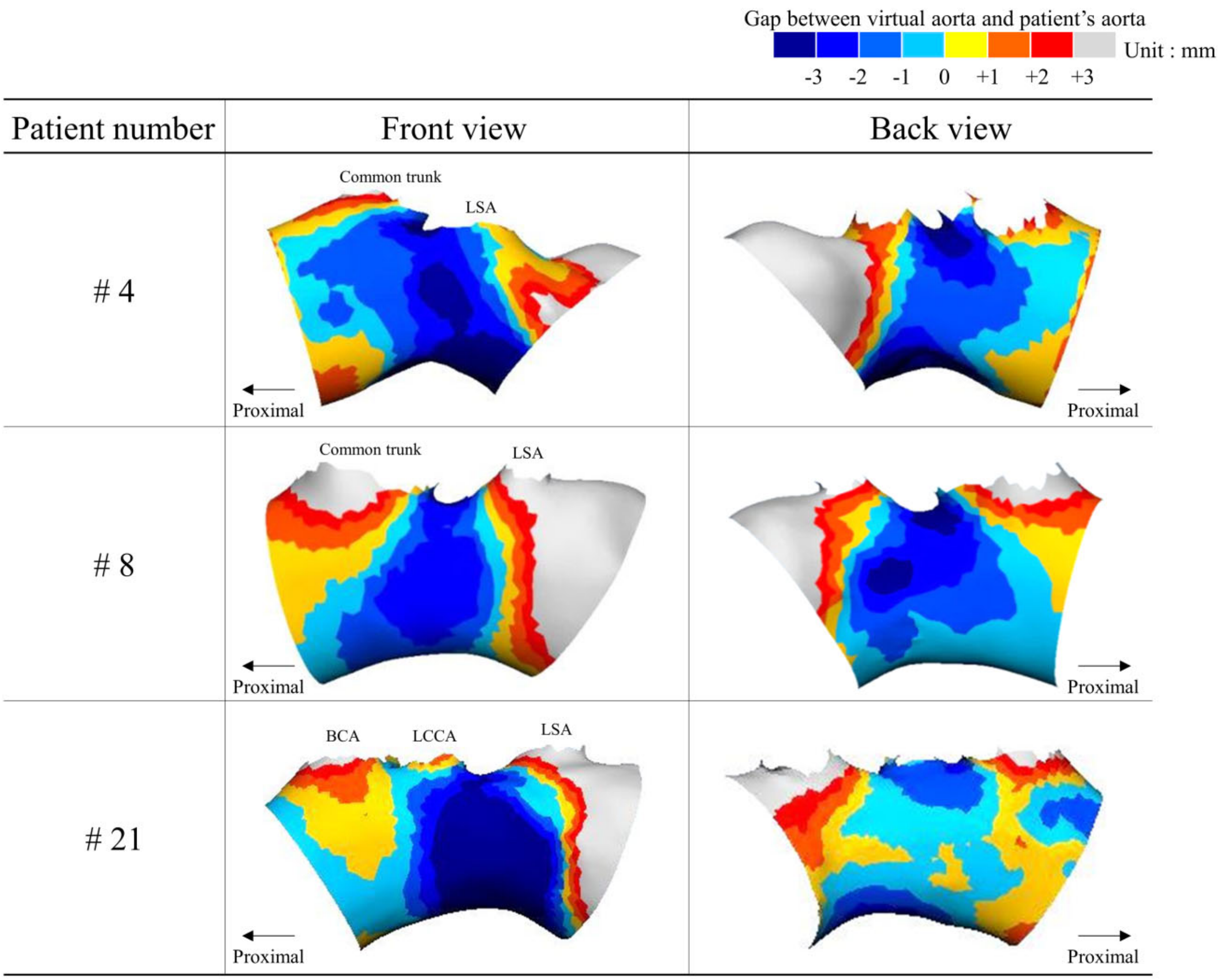

Figure 6: The gap distribution mappings of the 3 representative cases without T1EL. These mappings show minus regions over at least 1 entire circumference from the preserved cervical branch to the aneurysm. LSA: left subclavian artery; BCA: brachiocephalic artery; LCCA: left common carotid artery.

SUPPLEMENTARY MATERIAL

Supplementary material is available at EJCTS online.

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Conflict of interest: Dr. Takao Ohki is a consultant for W.L. Gore & Associates.

Data Availability Statement

The data underlying this article will be shared on reasonable request to the corresponding author.

Author contributions

Kota Shukuzawa: Data curation; Formal analysis; Writing-original draft. **Tomoya Fujii**: Data curation; Investigation; Formal analysis. **Makoto Sumi**: Data curation; Writing-review. **Junya Kozaki**: Investigation. **Mitsuo Umezu**: Project administration; Supervision. **Takao Ohki**: Writing-review. **Kiyotaka Iwasaki**: Conceptualization; Project administration; Writing-review; Supervision.

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