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ORIGINAL ARTICLE

Blood Vessel Prosthesis

Deployment of stent graft in an excessively higher position above the renal artery induces a flow channel to the aneurysm in chimney endovascular aortic aneurysm repair: an in vitro study

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Abstract
We aimed to investigate the influences of the sealing length above the renal artery (RA) on gutter formation, non-apposed regions between the aortic wall, stent graft (SG), and chimney graft and incidence of flow channel to the aneurysm in chimney endovascular aortic aneurysm repair (Ch-EVAR) using a juxtarenal abdominal aortic aneurysm model. Neck diameter and length of the silicone model were 24 and 4 mm, respectively. In double Ch-EVAR configuration using Advanta V12, 12 combinations were tested three times with two sizes [28.5 (20%-oversize) and 31 (30%-oversize) mm] of Excluder SG, three sealing lengths above the RA (10, 20, and 30 mm), and two deployment positions (anatomical and cross-leg). Gutter area, non-apposed region, and flow channels to the aneurysm were analyzed using micro-computed tomography. Average gutter area and non-apposed region of 30%-oversize SG were significantly smaller than those of 20%-oversize SG ($p = 0.05$). Furthermore, the non-apposed region of 30%-oversize SG with a 30-mm sealing length was significantly larger than that of the other sealing lengths. For 20%-oversize SGs, flow channel to the aneurysm was observed, except for the anatomical deployment with the sealing length of 10 mm. For 30%-oversize SGs, flow channel was absent, except for the SG with a 30-mm sealing length in both deployment positions. These flow channels were frequently formed through a valley space, existing in the lower unibody above the two limbs. Our data indicated that the optimal sealing length should be chosen in consideration of the device design difference due to the device diameter in Ch-EVAR.

Keywords Juxtarenal aortic aneurysm · Endovascular aortic repair · Chimney technique · Gutter · In vitro

Introduction

Although endovascular aneurysm repair (EVAR) has become standard for infrarenal abdominal aortic aneurysm (AAA), the recommended treatment for juxtarenal AAA (JRAAA) is surgical open repair [1]. EVAR for JRAAA should address the issue of short proximal neck sealing zone-inducing type I endoleak (EL) while maintaining flow to the renal artery (RA). For patients who are not eligible for surgical treatment, fenestrated EVAR (fene-EVAR) employing custom-made endografts or chimney EVAR (Ch-EVAR) deploying endografts both in the RA and abdominal aorta in parallel to each other are alternative treatment options. Good short- and long-term outcomes have been reported in fene-EVAR [2–4]. However, there is a disadvantage that fene-EVAR is unsuitable for emergency or urgent AAA because it requires a long manufacturing time of 4–8 weeks. The concept of Ch-EVAR is to achieve adequate sealing zone by deploying a main stent graft (SG) and a small-diameter chimney graft (CG) along the abdominal aorta and RA, which ideally leads to extension of the sealing zone.

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Although this technique gained popularity as an alternative option for high-risk patients after it was originally reported by Greenberg et al. as a bailout technique in 2003 [1, 5–7], a main disadvantage of Ch-EVAR is the development of type I EL from unsealed flow channels, so-called "gutter", among the main SG, CG, and aortic wall. Although type I EL through the gutter was seen in 5–33% of patients during follow-up, a previous study reported that in some cases the EL disappeared [5, 6, 8]. However, little is known about the mechanism of the disappearance of type I EL.

Some in vitro studies reported about gutter area [9–12]. These previous studies analyzed the effect of the oversizing of the SG types and combination with the CGs on the gutter area at the regions above the RA. However, no study focused on the apposition between native aortic wall and the SG at regions below the RA. Moreover, although it has been considered that the use of long CGs would contribute to preventing type I EL [13], the knowledge regarding optimal length of the sealing zone is lacking. The aim of this study was to investigate influences of the sealing length above the RA on the gutter formation, non-apposed regions between the aortic wall and SG at below the RA, and incidence of flow channel to the aneurysm.

Methods

Experimental model, stent graft, and experimental condition

Three JRAAA models were manufactured with elastic silicone. Stiffness parameter which represents luminal pressure and diameter relationship was adjusted between the JRAAA models (21.2 ± 2.48) and the reference human data (34.87 ± 24.46) [14, 15].

The aorta diameter above and below the RA was 24 mm, aortic neck length was 4 mm, and the inner RA diameter was 6 mm (Fig. 1a). The RAs branched out in a 70° angle from the aorta. Two sizes of Excluder® (W.L. Gore and Associates, Inc. Flagstaff, AZ, USA) with a diameter of 28.5 mm (20% oversizing) and 31 mm (30% oversizing) were used, and Advanta V12® (Atrium Medical Corporation, Hudson, NH, USA), which is a balloon expandable SG, was used as the CG (Fig. 1b). The Advanta V12 with a 6-mm diameter and 59-mm length was used. The influences of the two SG sizes, sealing lengths of 10, 20, and 30 mm above the RA, and two SG deployment manners with anatomical and cross-leg positions (90° clockwise rotation) (Fig. 1c, d) on the gutter and non-apposed regions were investigated (12 conditions in total). A total of 36 experiments were performed by doing the investigations three times for each combination.

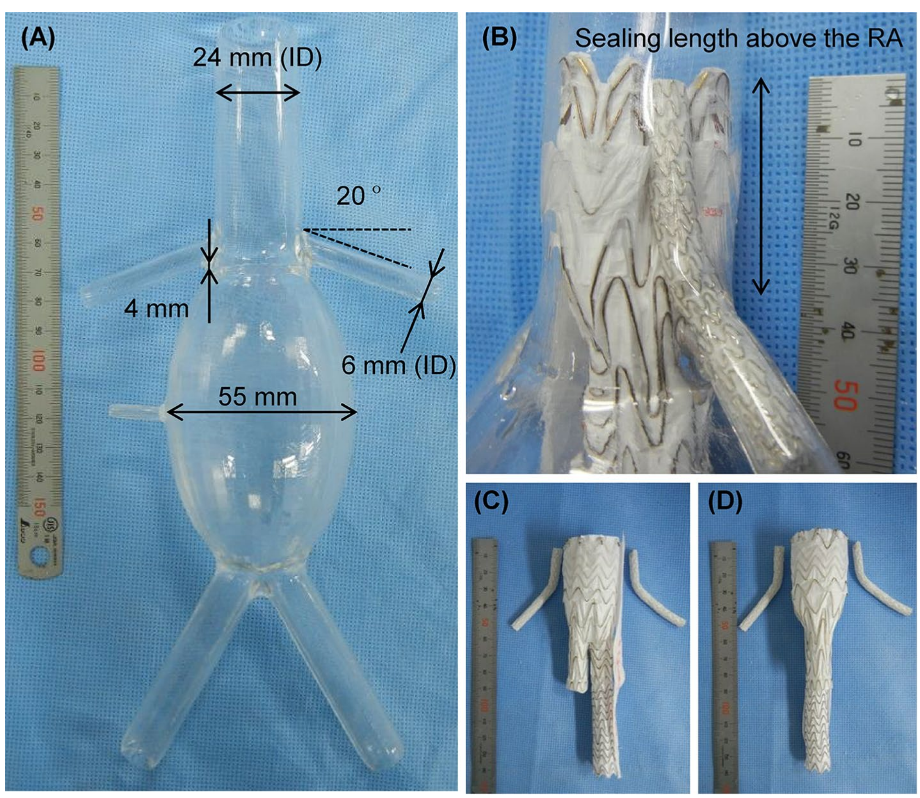

Fig. 1 Experimental model, stent graft, and experimental condition. **a** Juxtarenal abdominal aortic aneurysm model. **b** Endovascular aortic repair with chimney technique. **c** Anatomical position. **d** Cross-leg position. *ID* inner diameter, *RA* renal artery

Two SGs for each size and four CGs were prepared. We confirmed that there were no damages for SGs and CGs throughout the 36 experiments.

Stent graft deployment procedure

As in the actual procedure, CGs were introduced into each RA with an antegrade manner under the Amplatz Super Stiff® Guidewire (Boston Scientific, Natick, MA, USA), and inflated with 10 atm (nominal pressure 8 atm) at the intended position. After the deployment of the CGs, the SG was introduced in a retrograde manner and deployed. The top ends of CGs and SG were aligned. Finally, simultaneous balloon dilatation of the SG and CGs was performed using the Reliant® stent graft balloon catheter (Medtronic AVE, Santa Rosa, CA, USA) and the balloon that each CG was mounted on. To prevent compression of the CGs, balloon deflation was performed with the SG first, followed by CGs. All procedures were performed by a vascular surgeon (K.S.).

Measurements

The silicone JRAAA models with the SG and CG deployment (Fig. 2a) were filled with half-diluted Iopamiron® 370 (Bayer Healthcare, Berlin, Germany). Gutters and non-apposed regions were analyzed using a micro-CT (TDM 1300-IS, Yamato Scientific Co., Ltd., Japan) with a resolution of $91.5 \times 91.5 \times 91.5\ \mu m^3$ (Fig. 2b). Three-dimensional construction software (Mimics Research® ver. 17.0, Materialize, Leuven, Belgium) was used for quantification of the gutters (Fig. 2c) and non-apposed regions (Fig. 2d, e). The average gutter area (total gutter volume/sealing length) and minimum gutter area were measured between the top end of the SG and the bottom end of the lower RA orifice. The non-apposed region volume between the bottom end of the lower RA orifice and the origin of the aneurysm was measured (Fig. 2e). The flow channels from the gutter to the aneurysm were quantified.

Statistical analysis

Continuous data were presented as means ± standard deviations, and data between more than three groups and between two groups were compared using the Tukey's and Mann–Whitney tests, respectively. Statistical calculations were performed with JMP®, version 12.1.0 statistical software (JMP Statistical Discovery, North Carolina, USA). A p value ≤ 0.05 was considered statistically significant.

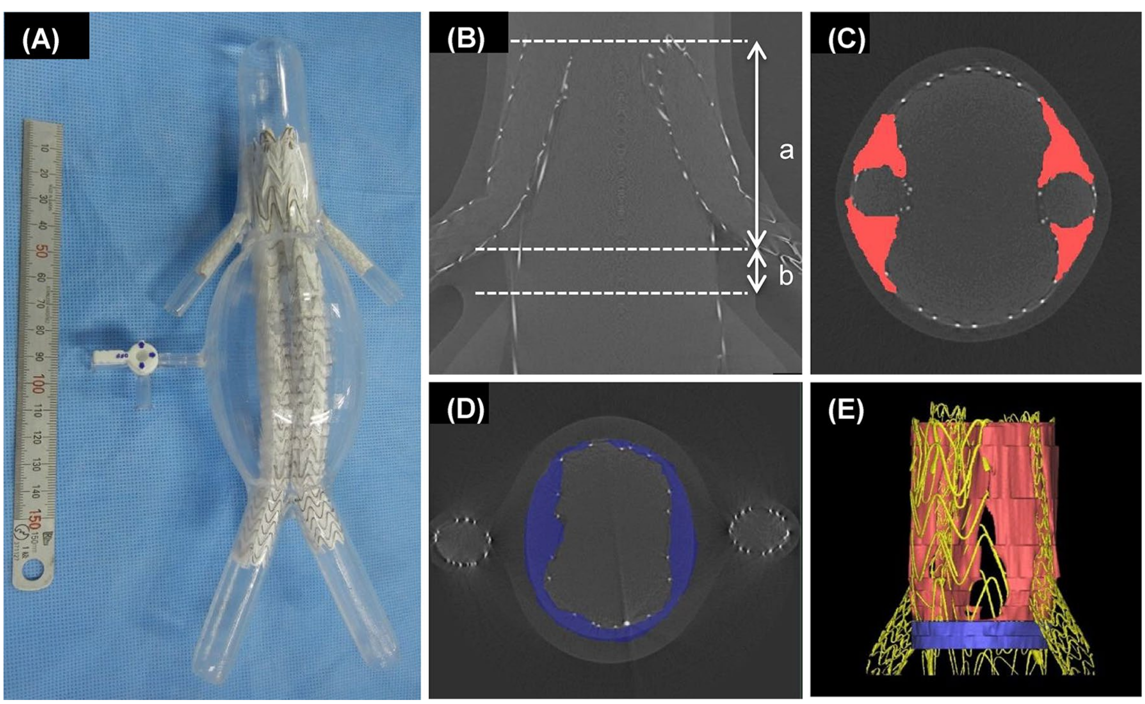

Fig. 2 Definition of the gutter and non-apposed region. **a** Silicone model with chimney EVAR. **b** Coronal plane image of the model. **a** Distance from the top of the main graft to the bottom of the lower renal artery. **b** Distance from the bottom of the lower renal artery to the top of the aneurysm. **c** Gutter area between the aortic model wall, chimney graft, and main graft in area (a). **d** Non-apposed area between the aortic model wall and main graft in area (b). **e** 3D reconstruction of the gutter and non-apposed region. *EVAR* endovascular aortic aneurysm repair

Results

Gutter area

The average gutter area of the 31-mm-sized SG (30% oversizing) was significantly smaller than that of the 28.5-mm-sized SG (20% oversizing) ($p = 0.050$) (Fig. 3a). The lower average gutter area of the 31-mm-sized SG was consistent regardless of the sealing length (10, 20, and 30 mm) both in the anatomical and cross-leg positions (Fig. 3a) compared with that of the 28.5-mm-sized SG. The minimum gutter area of the 31-mm-sized SG was also significantly smaller than that of the 28.5-mm-sized SG with the sealing lengths of 10, 20, and 30 mm in the anatomical position ($p = 0.050$) (Fig. 3b). However, in the cross-leg position, the minimum gutter area of the 31-mm-sized SG with a sealing length of 30 mm was significantly larger than those with a sealing length of 10 and 20 mm (30 mm vs 10 mm; $p = 0.014$, 30 mm vs 20 mm; $p = 0.021$).

Non-apposed region

The non-apposed region volume between the bottom end of the lower RA orifice and the origin of the aneurysm was significantly smaller in the 31-mm-sized SG (30% oversizing) than in the 28.5-mm-sized SG (20% oversizing) (Fig. 4, $p = 0.050$). The comparison among the 31-mm-sized SGs showed that the use of 31-mm-sized SG with a longer sealing length of 30 mm yielded a significantly larger non-apposed region volume compared with the SG with a sealing length of 10 and 20 mm, in both the anatomical and cross-leg positions (anatomical position: 30 mm vs 10 mm, $p = 0.034$; 30 mm vs 20 mm, $p = 0.050$; cross-leg position: 30 mm vs 10 mm, $p = 0.012$; 30 mm vs 20 mm, $p = 0.020$). The use of 31-mm-sized SG (30% oversizing) showed no significant differences among four conditions with the sealing length of 10 and 20 mm in both the anatomical and cross-leg positions.

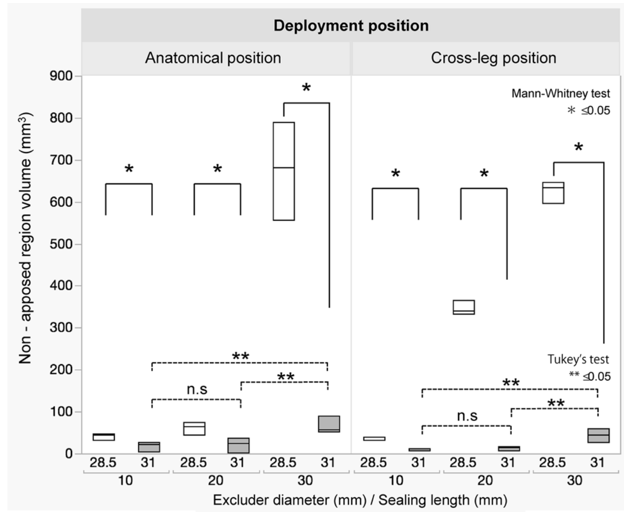

Fig. 4 Influences of stent graft oversize, sealing length, and deployment position on the non-apposed region volume (mm^3)

Flow channels from the gutter to the aneurysm

For the 28.5-mm-sized SGs, flow channels to the aneurysm were observed except for the anatomical deployment with the sealing length of 10 mm. For the 31-mm-sized SGs, the flow channel was absent, except for the SG with a sealing

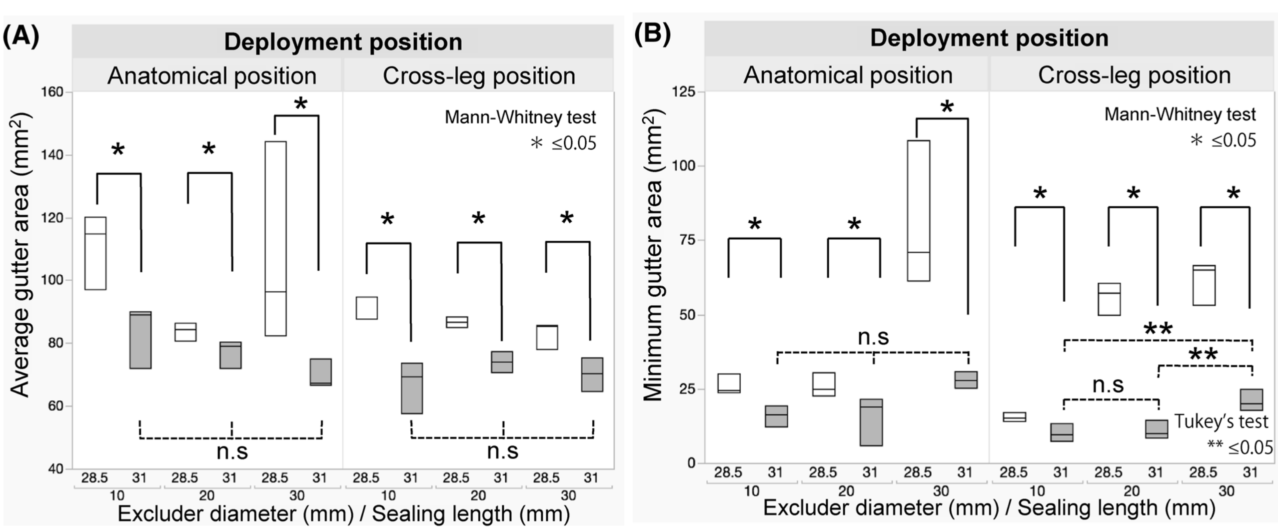

Fig. 3 Influences of stent graft oversize, sealing length, and deployment position on average and minimum gutter areas. **a** Average gutter area (mm^2), **b** minimum gutter area (mm^2)

length of 30 mm in both the anatomical and cross-leg deployment positions. In the 28.5-mm-sized SG with the sealing length of 30 mm in the anatomical position and with the sealing length of 20 and 30 mm in the cross-leg position, a completely circular non-apposed area was present (Fig. 5).

Discussion

The micro-CT analysis showed that excessive oversizing (30%) using 31-mm-sized SG significantly decreased the average gutter area and the minimum gutter area above the RA regardless of the sealing length, compared with the recommended oversizing (20%) using 28.5-mm-sized SG. The minimum gutter area was larger when the sealing length was 30-mm than when the sealing length was 10 and 20 mm. Previous studies showed the effectiveness of the larger SG oversizing on reducing the gutter above the RA [9, 10]. We confirmed that the presence of the CG inevitably increases the perimeter consisted of the aorta and the CG, which necessitates the larger SG size. In addition, the influence of the sealing length above the RA on the gutter was thoroughly investigated in this study.

Our study revealed that excessive oversizing (30%) of SG significantly decreased the non-apposed region volume below the RA communicated with the aneurysm, compared with the recommended oversizing (20%) of SG.

In 30% oversized SG with a sealing length of 30 mm, a significant increase in non-apposed volume below the RA was observed and the flow channel from the gutter to the aneurysm was present. In the 20% oversized SG, completely circular non-apposed flow channels below the RA communicated with the aneurysm were formed in the sealing length of 30 mm.

To investigate potential causes of the above findings, we focused on the three-dimensional configuration of the SG. The Excluder® has lineups in graft diameter of 23, 26, 28.5, 31, and 35 mm. The lengths of the unibody part are 4 cm in 23-, 26-, and 28.5-mm devices, 5 cm in 31-mm device, and 6 cm in 35-mm device. However, since the diameter of each

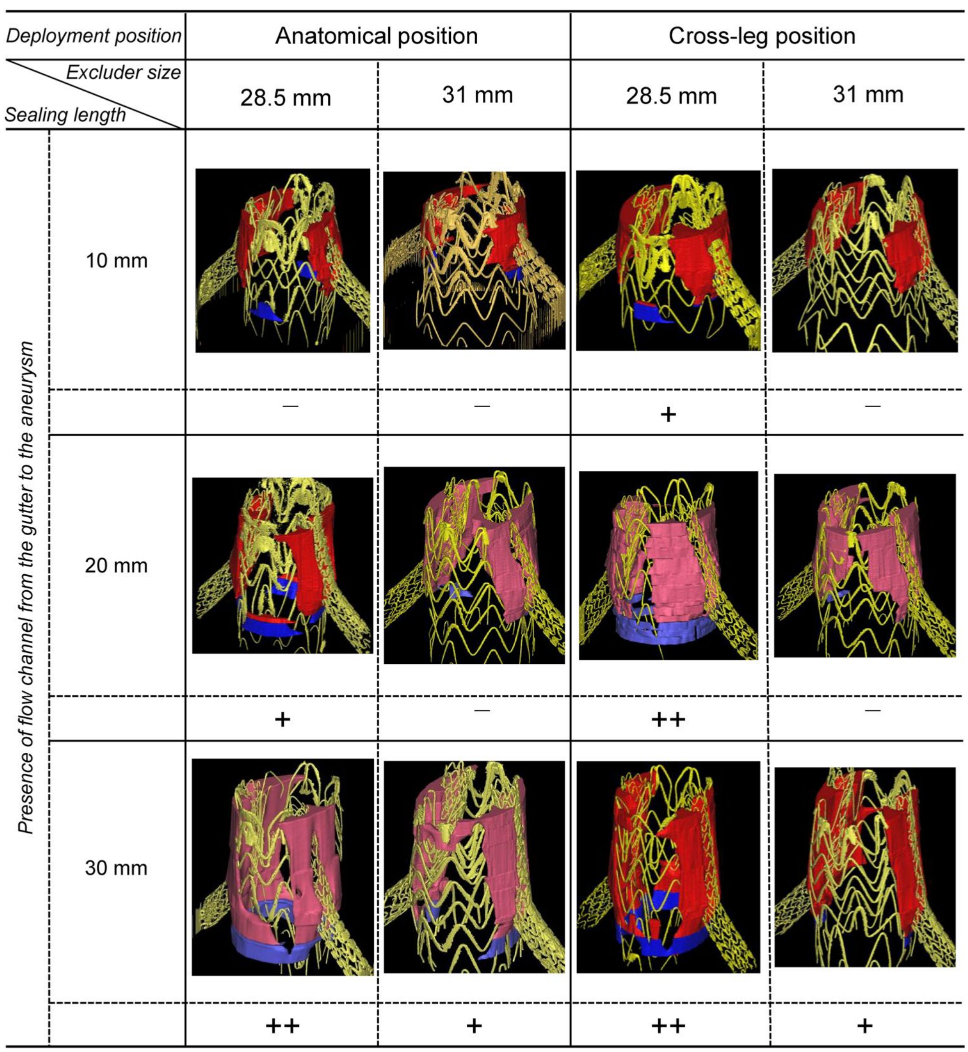

Fig. 5 Three-dimensional visualization of gutter and non-apposed regions in all the test conditions in Ch-EVAR. −, absence of flow channel from the gutter to the aneurysm; +, presence of channel from the gutter to the aneurysm; ++, presence of a completely circular non-apposed flow channel from the gutter to the aneurysm

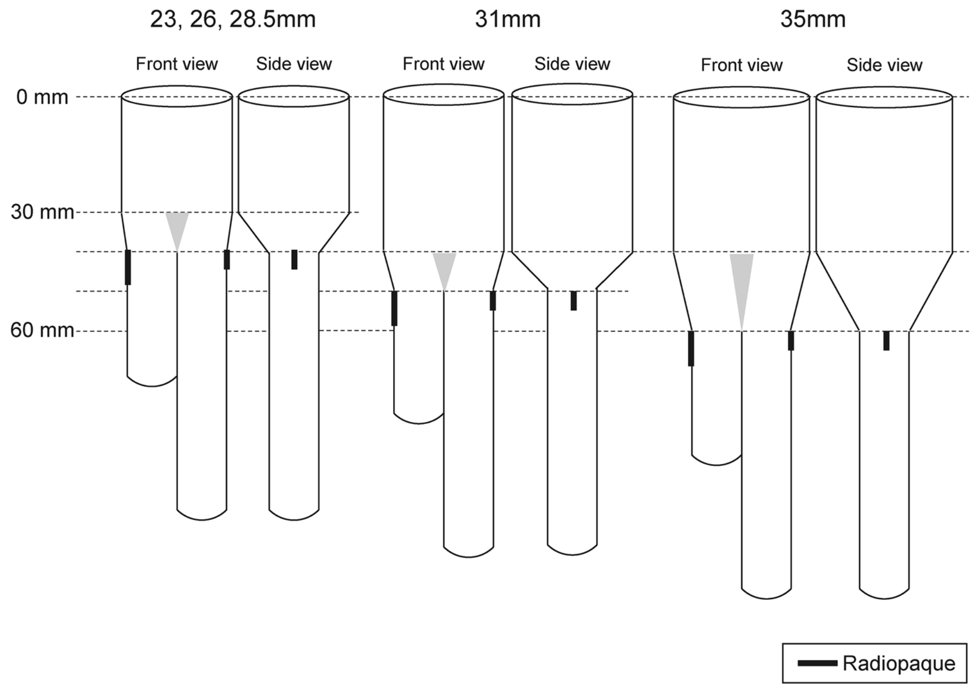

Fig. 6 Differences in design of the Excluder® due to the device diameter (W.L. Gore and Associates, Inc. Flagstaff, AZ, USA)

limb is 13 mm at the flow divider portion in all devices, all devices are tapered at the lower part of their unibody. In 23, 26, and 28.5-mm devices, tapering starts at 3 cm from the tip, whereas, in 31 and 35-mm devices, tapering starts at 4 cm from the tip (Fig. 6). As the device diameter becomes larger, the difference in diameter between the unibody and the limb increases. To connect the unibody and two limbs, the valley space is formed in the lower unibody above the two limbs. The flow channel from the gutter to the aneurysm was frequently formed through this valley to the aneurysm. Especially, the straight channel was formed in the cross-leg position. Our study revealed that the optimal sealing length should be chosen in consideration of the device design difference due to the device diameter. Because the SGs consisted of the unibody part and two limbs, all other endoprostheses need taper and valley design regardless of the size to compensate the diameter difference between the unibody and the limb. Therefore, our finding will be applicable to the other endoprostheses.

There is no radiopaque at the point where tapering starts on the unibody part of SG. In Ch-EVAR, the SG must be deployed with caution because it is impossible to accurately confirm the point where the tapering starts before the deployment. Applying long CGs or the triple Ch-EVAR with CG for the superior mesenteric artery may lose the appropriate sealing below the RA.

Ch-EVAR intrinsically induces the gutter above the RA. Filling the non-apposed region below the RA is difficult after performing the Ch-EVAR, although extending the sealing length above the RA is possible with the auxiliary device. Therefore, at the first Ch-EVAR, the effective use of the neck below the RA is crucial to prevent type I endoleaks.

Limitations

There are some limitations in our study. Firstly, we used only one kind of SG (Excluder®) and CG (Advanta V12) in one size JRAAA. Secondly, the neck morphology of our JRAAA model was straight. Nevertheless, the method presented here would be useful to investigate influences of device combinations and neck angulation on the gutter formation, non-apposed region, and incidences of flow channels from the gutter to the aneurysm in an actual AAA 3-D morphology.

Conclusion

Using micro-CT, the flow channel from the gutter to the aneurysm was successfully elucidated and influences of the SG size and the sealing length on the incidence of the flow channel were quantified. Our study suggests that the optimal sealing length should be chosen in consideration of the device design difference due to the device diameter in Ch-EVAR for JRAAA.

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Compliance with ethical standards

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

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