Pre-constrain technique using the Gore Excluder Conformable endograft for abdominal aortic aneurysm with severely angulated proximal neck

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ABSTRACT

Endovascular aneurysm repair for abdominal aortic aneurysms with a severely angulated proximal neck remains challenging because of the higher rates of type 1a endoleaks and secondary interventions. In this study, we reviewed six consecutive patients with a severely angulated proximal neck (>60°) treated with endovascular aneurysm repair at a single center. They were treated with a Gore Excluder Conformable endograft using a pre-constrain technique to prevent type 1a endoleaks. It is the unique deployment technique of the proximal trunk by pre-constrain of the proximal edge. This technique helps obtain optimal deployment of the proximal main body. (J Vasc Surg Cases Innov Tech 2024;10:101614.)

Keywords: Abdominal aortic aneurysm; Deployment technique; Endovascular aneurysm repair; Gore Excluder Conformable; Severe neck angulation; Type 1a endoleak

Endovascular aneurysm repair (EVAR) has become a standard therapy for abdominal aortic aneurysms (AAAs) since its introduction in 1991.[1] However, an unfavorable proximal neck-like severely angulated neck (>60°) remains challenging for EVAR because a severely angulated neck is associated with a high risk of incomplete wall apposition. Consequently, a severely angulated neck may lead to higher rates of proximal type 1 endoleaks and secondary interventions.[2] The Gore Excluder Conformable (W. L. Gore & Associates) is among the latest devices with an active control system designed to treat this type of anatomy. A recent study showed its safety and effectiveness up to 1 year.[3] However, the best practical use or technical tips for these new devices remain unclear. Herein, we report a small series of AAA cases with a severely angulated proximal neck treated with an Excluder Conformable endograft using a unique pre-constrain technique.

METHODS

Patient population. Between May and November 2023, a retrospective review was performed for six consecutive patients who underwent EVAR using the Gore Excluder Conformable endograft with pre-constrain technique at a single center. The indications for EVAR with this technique were AAA ≥55 mm or AAA with common iliac artery aneurysm ≥30 mm with a severely angulated proximal neck (>60°), proximal neck diameter from 16 mm to 32 mm, and proximal neck length ≥15 mm. We excluded patients who were expected to have less than 1-year survival. We treated the patients complying with the guideline of the Japanese Circulation Society.[4]

All patients were assessed preoperatively using a thoracoabdominal 320-detector row computed tomography (CT) angiogram. We determined proximal neck sizing in accordance with instruction for use (IFU) sizing. Heart team conferences with vascular surgeons were performed for all AAA cases, and all patients in this study were preoperatively classified as high risk for open surgery. Written informed consent and publication consent were obtained from all the patients.

Surgical technique. All procedures were performed by experienced endovascular operators in a hybrid operating room. The preemptive embolization of aneurysm side branches was performed for all patients to prevent type 2 endoleak during the EVAR procedure.[5] All patients were treated with a Gore Excluder Conformable endograft using the pre-constrain technique. The procedure steps were as follows: the Gore Excluder Conformable endograft was advanced to the infrarenal aorta over an Amplatz Ultra Stiff wire (Cook Inc), and the wire was pulled out until the proximal trunk was on the soft head of the wire, improving trunk flexibility. The angulation knob was rotated clockwise to advance the angulation wire and adapt the proximal trunk to the angulated proximal aortic neck. Next, optimal proximal

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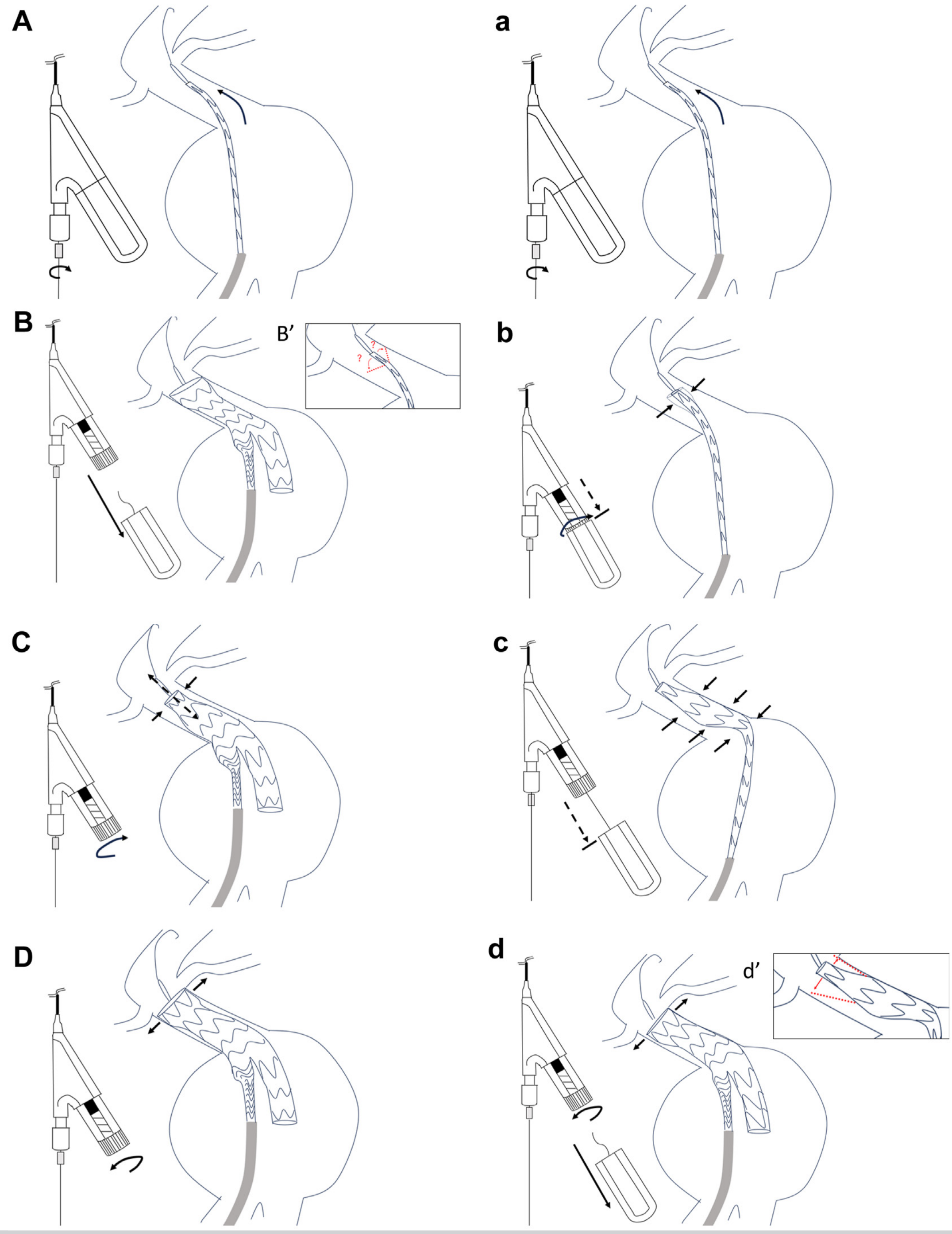

Fig 1. The comparison of traditional deployment **(A-D)** and pre-constrain technique **(A-D)** during proximal deployment of the Excluder Conformable endograft. After the Gore Excluder Conformable endograft was advanced to the infrarenal aorta, the angulation knob was rotated clockwise to advance the angulation wire **(A)**. The proximal deployment knob was pulled away for deploying the first sleeve **(B)**. At this point, predicting the behavior of proximal stent during deployment is difficult **(B′)**. Constraining and repositioning of the proximal trunk was performed **(C)**. The proximal deployment was completed after unconstraining of the proximal trunk **(D)**. The same steps were performed until advancing the main graft and angulation wire **(A)**. The proximal deployment knob was pulled carefully to the level where the constrain knob is visible, and the constraining dial was rotated for maximal constraining of the proximal edge **(B)**. The first sleeve was deployed to the level of the fourth or fifth stent from the top and position the proximal trunk properly **(C)**. The proximal deployment was completed after unconstraing of the proximal trunk **(D)**. At this point, predicting behavior of proximal stent during deployment is easy by slowly unconstraining.

Table I. Baseline characteristics of the six patients with severe neck angulation treated with the Gore Excluder Conformable endograft

	Patients					
Variables	1	2	3	4	5	6
Baseline characteristics						
Age, years	80	80	91	86	80	87
Sex	Female	Male	Female	Female	Male	Female
Aneurysm diameter, mm	35	55	77	42	90	57
Proximal neck						
Diameter, mm	17	23	20	20	21	23
Length, mm	32	58	15	44	48	29
Angulation, °	110	89	86	87	110	65
>50% calcification or thrombus	No	Yes (calcification)	No	No	No	Yes (thrombus)

Table II. Outcomes of the six patients with severe neck angulation treated with the Gore Excluder Conformable endograft

	Patients					
Variables	1	2	3	4	5	6
At final angiography						
Type 1a endoleak	No	No	No	No	No	No
Any endoleak at final	No	No	No	No	No	No
30-day outcomes						
Type 1a endoleak	No	No	No	No	No	No
Any endoleak	No	No	No	No	No	No
Endograft migration	No	No	No	No	No	No
6-month outcomes						
Aneurysm diameter change, mm	−9	−4	−15	−4	−4	−12
Aneurysm diameter shrinkage (≥5 mm)	Yes	No	Yes	No	No	Yes
Aneurysm diameter enlargement (≥5 mm)	No	No	No	No	No	No
Endograft migration	No	No	No	No	No	No
All cause death	No	No	No	No	No	No
Aneurysm-related secondary procedures	No	No	No	No	No	No

deployment was achieved using pre-constrain technique. Fig 1 and Supplementary Video 1 (online only) showed the steps of the pre-constrain technique. The most important difference in this technique compared with the traditional methods is constraining first before deploying the proximal trunk. During the pre-constrain technique, pushing the device properly improves the adaptation to the angulated proximal aortic neck. After the deployment of the proximal trunk, the usual procedure steps were performed to complete the endograft deployment.

Study outcomes. Technical success was defined as the ability to adequately deploy the endograft in the intended position and complete the procedure without type 1 or 3 endoleaks or complications, including artery injury, aneurysm rupture, distal embolization, and acute kidney injury. Migration was defined as ≥5 mm device displacement on a postoperative CT scan. Standard criteria were used to assess the presence of endoleak and need for secondary procedures.[6]

RESULTS

The characteristics and outcomes are shown in Tables I and II, respectively. EVAR was indicated owing to common iliac artery aneurysms in two cases (Cases 1 and 4). The averages of procedure time and radiation time were 233 and 130 minutes, respectively. Technical success was achieved in all the cases. In Case 3, the intended chimney stent for the left renal artery was used because of a relatively short proximal neck. The pre-constrain technique was effective for optimal proximal trunk positioning and adaptability to severe infrarenal aortic angulation (Fig 2). Furthermore, no endoleak or migration was observed on the final angiography and 1-month follow-up CT angiogram. The postoperative CT

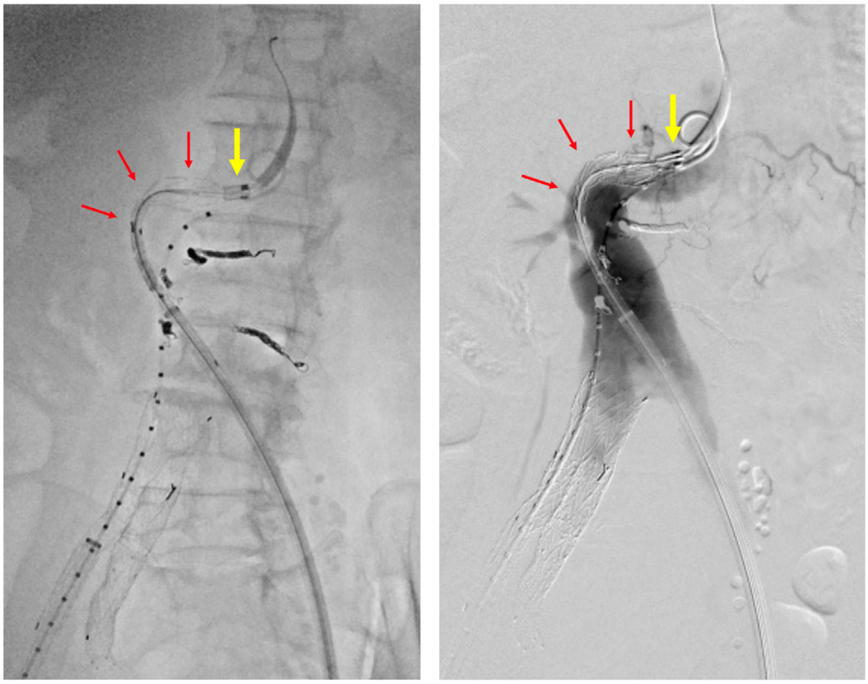

Fig 2. The pre-constrain technique for a severely angulated proximal neck (110°) in Case 1 is shown. The pre-constrain technique kept the proximal trunk narrow after deployment of the first sleeve (*yellow arrow*) and enabled it to achieve good flexibility in the proximal trunk (*red arrow*).

angiograms showed good adaptation to the angulated proximal aortic neck (Supplementary Fig, online only). The 6-month follow up revealed no expansion of aneurysm and no secondary intervention.

DISCUSSION

EVAR has a high technical success and low endoleak and secondary intervention rates under the IFU.[7-9] Recently, the number of EVAR procedures outside the IFU has increased, resulting in a higher rate of secondary interventions.[10-14] A crucial issue is type 1a endoleak due to challenging proximal neck anatomy. To prevent type 1a endoleaks, ideal positioning, coaxiality, and adaptability of the proximal trunk to the infrarenal aortic angulation are important. The concept of a Gore Excluder Conformable endograft with an active control system has been engineered to deal with severe infrarenal aortic angulation, although the optimal technical procedures for this newer device are unknown. Notably, Excluder Conformable endograft implantation may pose certain technical challenges. Predicting the behavior of proximal stent during deployment is difficult (Fig 1). Furthermore, the flexibility of the proximal trunk was relatively low before deploying the first sleeve because the shaft wrapped by the sleeve is rigid. This led to an insufficient angulation effect (Fig 3).

This study reported that the pre-constrain technique could be effective for solving these technical problems of Excluder Conformable. This technique has two advantages; first, this technique enables delicate proximal positioning by keeping the proximal trunk narrow for a while after the removal of the first sleeve (Fig 2). Although the proximal trunk was originally deployed to 70% immediately after the first sleeve was removed in a normal situation, the pre-constrain and maximal angulation keep the proximal trunk narrow. The proximal trunk was then slowly deployed to 70% by blood flow. Therefore, this technique enables predicting the behavior of the proximal trunk end during deployment (Fig 1), so that it is easier to deploy the proximal trunk properly in one go. Second, the proximal trunk became softer after removal of the first sleeve; hence, the proximal trunk showed better flexibility to the angulated aortic neck (Fig 2). As a minor tip, partial deployment of the first sleeve at the level of the fourth or fifth stent from the top was better for proximal repositioning because repositioning the proximal trunk may be difficult owing to the opened contralateral gate after the first sleeve was completely removed.

The top stent of the Excluder Conformable is not bendable structurally, so the short proximal neck is not a good indication for this device and this technique. A case of the short proximal neck needs some additional techniques or options like chimney stent, Endo Anchors, or fenestrated/branched endograft.

The soft guidewire technique is reportedly effective for a precise Excluder Conformable endograft deployment in severely angulated proximal neck AAA cases, although

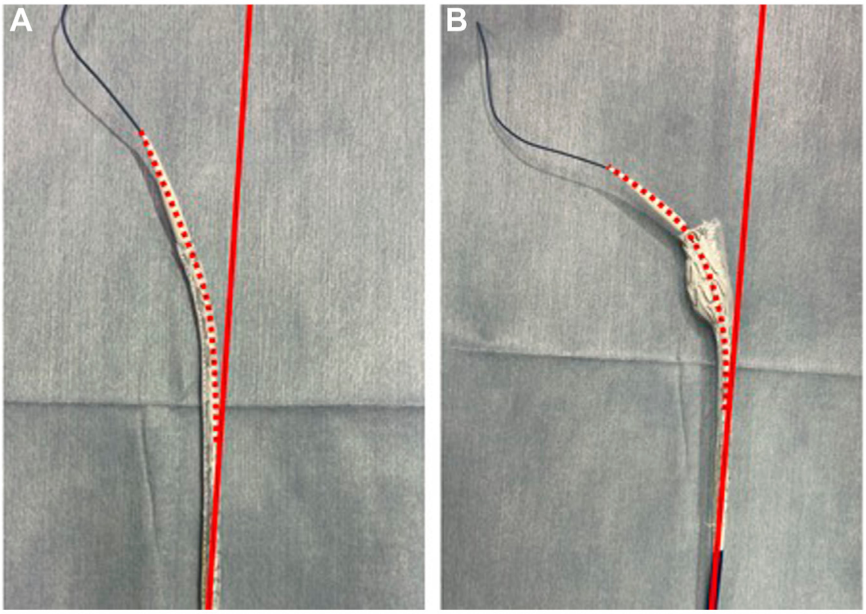

Fig 3. Maximal angulated proximal neck of the Excluder Conformable endograft before **(A)** and after the first sleeve is removed **(B)**. The proximal trunk is more angulated after the first sleeve is removed.

this technique requires a radial or brachial approach.[15] The purpose of the pre-constrain technique is almost similar to that of the soft guidewire technique; however, the pre-constrain technique is completed only via the percutaneous femoral approach. Furthermore, this study demonstrated the flexibility effect of the proximal trunk through the partial deployment of the first sleeve.

CONCLUSION

The pre-constrain technique using the Gore Excluder Conformable endograft appears feasible for treating AAAs with a severely angulated proximal neck. Nevertheless, this study had some limitations, such as a small sample size and unknown long-term outcomes. Therefore, the merits of this technique should be evaluated more rigorously in a larger and appropriately designed study.

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DISCLOSURES

None.

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