A Case of Folding Deformation of PROTÉGÉ Stent during Carotid Artery Stenting with Distal Embolic Protection

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Objective: A case of folding deformation of a PROTÉGÉ RX (PROTÉGÉ; eV3 Covidien, Irvine, CA, USA) stent during carotid artery stenting (CAS) with distal filter protection is reported. Folding deformation complicated retrieval of the filter device.

Case Presentation: A 67-year-old man was diagnosed with left asymptomatic cervical internal carotid artery stenosis, which gradually progressed despite medical treatment. The stenosis was long and eccentric, comprising soft plaque with partial calcification. CAS was performed under distal filter protection using a right brachial artery approach. After predilation, a PROTÉGÉ 10 mm × 60 mm stent was placed from the internal carotid to common carotid artery. Since the stent was not sufficiently dilated even after postdilation, additional balloon angioplasty was attempted. However, the balloon was trapped by the stent strut and could not cross the lesion. Cone-beam CT showed stent folding deformation extending from the internal carotid to common carotid artery. The deformed part of the stent was dilated with stepwise balloon angioplasty from proximal to distal, and the filter device was eventually retrieved. The patient showed no new neurologic symptoms after the procedure and no infarction was noted on postprocedural MRI.

Conclusion: In performing CAS using PROTÉGÉ for long, eccentric stenosis with calcification, the risk of stent folding deformation should be carefully considered.

Keywords ▶ stent folding deformation, carotid artery stenting, PROTÉGÉ

Introduction

In Japan, carotid artery stenting (CAS) began to be covered by the national insurance scheme in 2008. CAS has been performed widely as treatment for carotid artery stenosis due to its low invasiveness. Three types of self-expandable stents can be used for CAS in Japan: Precise Pro RX (Precise; Cordis, Miami, FL, USA) and PROTÉGÉ RX (PROTÉGÉ; Covidien, Irvine, CA, USA), as open-cell stents, and Carotid Wallstent Monorail (Carotid Wallstent, Boston Scientific, Natick, MA, USA), a closed-cell stent. A small number of reports have described stent deformation or fracture associated with placement, with a reported incidence of 1.9%–29.2%.1,2 A case of folding deformation of PROTÉGÉ stent during CAS with distal filter protection is presented. Retrieval of the filter device was difficult due to the folding deformation.

Case Presentation

A man had been hospitalized for cortical infarction of the right frontal lobe 8 years earlier. Follow-up carotid ultrasonography demonstrated stenosis in the left cervical internal carotid artery, which gradually progressed. As the lesion progressed despite medical treatment, he needed surgical treatment and was admitted at 67 years. Angiography revealed a long stenotic lesion (the North American Symptomatic Carotid Endarterectomy Trial [NASCET] 70%) in the left cervical internal carotid artery from the C2 to C4 level (Fig. 1A). Contrast-enhanced CT showed an area of
calcification extending longitudinally to the outermost layer of the vascular wall (Fig. 1B and 1C). On carotid ultrasonography, peak systolic velocity (PSV) was 295 cm/s and the stenosis was hypoechogenic with partial calcification. Mildly hyperintense was seen on MRI T1-black blood images (Fig. 1D). Based on these results, the stenosis was judged to consist of soft plaque with partial calcification.

Approaching the lesion via the femoral artery was difficult due to bilateral arteriosclerosis obliterans. The right brachial approach was therefore selected. A Simmons-type 6-Fr Axcelguide 80 cm (Medikit, Tokyo, Japan) was placed in the left common carotid artery. On preprocedural measurement, diameter of the internal carotid artery distal to the stenosed area was 5.9 mm, diameter of the common carotid artery was 9.2 mm, and the stenosis was 35 mm long. A Spider FX 6 mm (Covidien) was deployed for distal embolic protection and predilation was performed using a Coyote 3.5 mm × 40 mm (Boston Scientific) at 6 atm over 30 s (Fig. 2A). Since the stenosis was long, a PROTÉGÉ 10 mm × 60 mm (Covidien) was placed to sufficiently cover the stenosis (Fig. 2B). Postdilation was therefore performed using an Rx-Genety 4.5 mm × 40 mm (Kaneka Medics, Osaka, Japan) at 8 atm (Fig. 2C). The Rx-Genety was withdrawn to the common carotid artery proximally from the stent. Confirmation angiography showed residual stenosis in the distal portion of the stent (Fig. 2D). We tried to advance the Rx-Genety to the residual stenosis again for additional balloon angioplasty. However, the balloon became trapped at the stent orifice in the common carotid artery and could not be advanced into the stent. The balloon was replaced with an Aviator Plus 5 mm × 20 mm (Cordis), and maneuvers such as head rotation and manual compression of the neck were performed, but the balloon could not be guided to the residual stenosis.

At this point, we suspected stent deformation and performed cone-beam CT. Folding deformation was identified in the stent from the common carotid artery to the distal part of the residual stenosis (Fig. 2E), and the lumen through which the filter wire passed was severely narrowed due to the folding deformation (Fig. 2F). Since the filter had to be retrieved, expansion of the folded and markedly narrowed part of the stent was necessary. We considered that an intracranial percutaneous transluminal angioplasty (PTA) balloon with a small tip profile would probably be navigated to the residual stenosis. A Gateway 3 mm × 12 mm (Boston Scientific) was guided along the filter wire and advanced to the residual stenosis, then balloon angioplasty was performed at 10 atm over 30 s. Since the residual stenosis was slightly dilated, we again attempted to advance an Aviator Plus 5 mm × 20 mm to the residual stenosis. However, the balloon became trapped at the stent orifice and could not be advanced to the residual stenosis. Next, we attempted to directly advance the filter retriever, which also became caught at the residual stenosis and could not be passed through the stent. Next, stepwise balloon angioplasty from the proximal to the distal part of the folding deformation was considered, an Aviator Plus 5 mm × 20 mm was advanced to the stent orifice to the point of catching on the stent strut, at which point the balloon was inflated. The balloon was deflated, advanced further to the point where it was caught by the stent strut, and was again inflated. With stepwise balloon angioplasty, the narrow part of the stent folding deformation was gradually dilated from proximally to distally. After four dilations with stepwise balloon angioplasty at 10 atm, the narrow part of the stent folding deformation was sufficiently diluted (Fig. 3A–3D). The filter retriever was then able to pass through the stent and the filter device was retrieved. Cone-beam CT performed immediately after filter retrieval showed sufficient dilation of the lumen through which the filter wire had passed (Fig. 3E and 3F). Since blood flow in the two lumens created by the folded stent was confirmed adequately, we finished the procedure without additional treatment.

Postprocedural MRI showed no infarction. Antiplatelet therapy using aspirin (200 mg/day) and clopidogrel...
(75 mg/day) was continued after the procedure and the patient showed no new neurologic symptoms. Carotid ultrasonography 3 months after the procedure showed no structural changes to the stent or stent in thrombus. The two lumens created by the folded stent persisted and blood flow in each lumen was satisfactory (Fig. 4).

**Discussion**

Stent deformation was reported as tending to occur when the angle of the internal and external carotid arteries was more than 45° and heavy calcification was present around the stent.1,3,4) Stent fracture is reportedly associated with
closed-cell and stent deformation is associated with open-cell stents. Stent fractures are mostly caused by separation of the stent strut. Stent deformations are caused by distortion of the stent strut, particularly inwardly convex distortion. Two recent reports have described folding deformation of PROTÉGÉ. Seo et al. reported a case in which folding deformation was detected when a patient experienced cerebral infarction 4 years after stenting and considered that deformation was caused under the stress of neck movements and hemodynamic loads. Murakami et al. reported folding deformation that occurred after post-dilation in a patient who underwent CAS with embolic protection using Mo.Ma Ultra (MOMA; Medtronic, Minneapolis, MN, USA). According to results from experimental models, they suggested that folding deformation may be induced by postdilation when the stent folds inward in an insufficiently expanded part of an open-cell stent.

The open-cell stents presently available in Japan are PROTÉGÉ and Precise. To the best of our knowledge, no reports have described folding deformation of Precise. Precise uses a peak-to-valley structure, in which the strut peaks are arranged in a staggered manner between the upper and lower units, which are connected peak-to-peak via bridges. On the other hand, PROTÉGÉ uses a pantograph structure, in which the peaks are directly connected. Okamoto et al. performed an experiment using a silicone model of a stenotic vessel and reported that, with Precise, the stent cells expand uniformly during release, but the expansion in PROTÉGÉ is not uniform. Folding deformation is considered to occur due to such characteristics of PROTÉGÉ design.

In the present case, the stent was found to have expanded nonuniformly on fluoroscopy immediately after placement, and deformation is considered to have already occurred at this point (Fig. 2B). The presence of risk factors such as eccentric stenosis with partial calcification and vascular crank at the distal stenosis might have induced stent deformation, and postdilation might have exacerbated deformation to folding. No methods for managing folding stent deformation have been established. In the two previous cases of folding deformation of PROTÉGÉ 10 mm × 60 mm, no additional treatment was performed after confirmation of folding deformation, with conservative follow-up. In the present case, advancing the filter retriever across the stent was necessary to retrieve the filter device. Retrieving filter device is often difficult as the retriever is trapped by the struts of an open-cell stent. The retriever can often be passed by changing the stent position or vascular direction with neck rotation, manual compression, repositioning of the guiding catheter, and the buddy wire technique. In the present case, neck rotation or manual compression was ineffective. We considered that a device with a small tip profile, a 0.014 inch guidewire and intracranial balloon catheter might pass through the stenosis in the stent without catching on the strut. As expected, we could advance the device to the narrowest part of the stenosis, allowing perform balloon angioplasty. However, balloon angioplasty with a 3-mm balloon was insufficient.

Fig. 4 Follow-up carotid ultrasonography after 3 months still shows the fold deformation of the stent without any thrombus or flow restriction. (vertical [A], color-Doppler-mode vertical [B], and horizontal [C]).
Balloon angioplasty using a Gateway with a larger diameter might have been effective. In consideration of the risk of stent fracture and vascular injury, we performed stepwise balloon angioplasty from the proximal part to distal part of the folding deformation. In this maneuver, the filter retriever could be advanced passed and the filter device was retrieved.

Presently in Japan, only the PROTÉGÉ has an open-cell stents having 60-mm long model, and the PROTÉGÉ 10 mm × 60 mm is frequently used for long lesions. However, we should consider that the risk of folding deformation is higher when using a 60-mm PROTÉGÉ for long, eccentric, partly calcified lesions. Whether differences in the diameter on PROTÉGÉ 60 mm influence the risk of folding deformation is unknown. The evaluation of the use of a closed-cell stent should be used in patients with a risk of folding deformation in PROTÉGÉ. Since the filter retriever or aspiration catheter for distal balloon protection is difficult to advance beyond the stent folding deformation, we should select proximal embolic protection including flow reversal, rather than distal protection. However, MOMA has a thick shaft for the external carotid artery use of MOMA in itself may cause folding deformation. Care in using MOMA is therefore required.6)

Some accounts in the literature have reported that intraprocedural stent deformation or fracture had no direct influence on postprocedural incidence of cerebral infarction or re-treatment.2–4) However, as cases of cerebral infarction induced by delayed folding deformation of PROTÉGÉ have also been reported and strict follow-up is necessary.3) Since a folded stent protrudes into the vascular lumen, thrombus formation is more likely than in usual CAS and long-term intensive antiplatelet therapy is necessary. In the present case, dual-antiplatelet therapy should be continued for 1 year. If no problem is seen on re-evaluation by angiography, we may alter treatment to single antiplatelet therapy. Contrast-enhanced CT and carotid ultrasonography are useful modalities for outpatient follow-up. Carotid ultrasonography appears to be the most useful modality currently available, allowing visualization of the stent and evaluation of blood flow in the stent lumen and observing the dividing partition created by the folded stent. Long-term follow-up is necessary in the future.

## Conclusion

We encountered a case of stent deformation during CAS using a PROTÉGÉ 10 mm × 60 mm. We should be careful when using a 10 mm × 60 mm PROTÉGÉ for patients with stenosis that is eccentric, calcified and includes vascular crank.

## Disclosure Statement

Neither the first author nor any of the coauthors have any conflicts of interest to disclose regarding this article.

## References