



Folding Deformation of Open-Cell Stents in Carotid Artery Stenting: Report of Three Cases and Review of Literature

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Objective: We describe 3 cases with folding deformation of a PRECISE (Cordis, Miami, FL, USA) stent in carotid artery stenting (CAS).

Case Presentations: The 3 cases with cervical carotid stenosis consisted of 3 males around 80 years old and included 2 symptomatic lesions. During CAS, distal embolic protection was established using a Mo.Ma (Medtronic, Minneapolis, MN, USA) along with a filter device in 2 cases and an Optimo (Tokai Medical Products, Aichi, Japan) along with a filter device in 1 case. For the filter device, either FilterWire EZ (Boston Scientific, Natick, MA, USA) or Spider FX (Covidien, Irvine, CA, USA) was employed. In all cases, a PRECISE stent was deployed after pre-dilation performed using a percutaneous transluminal angioplasty (PTA) balloon with the diameter of 2.5 to 3 mm. Post-dilation was performed after the stent deployment using a PTA balloon whose diameter was about 80% of that of the normal distal internal carotid artery. In all cases, cone-beam CT taken after the deployment of a stent showed folding deformation of the stent. In 2 cases, heavily calcified plaque hampered self-expansion of the stent, which resulted in the stent deformation. On the other hand, in the remaining 1 case, a distal shaft of the Mo.Ma caused the stent deformation, which was likely accelerated by head rotation and cervical compression that was performed to resolve difficulties for a filter retrieval device to pass through the stent, and post-dilation after the stenting.

Conclusion: Heavily calcified plaque and a distal shaft of a Mo.Ma would result in stent deformation.

Keywords ▶ carotid artery stenting, folding deformation, open-cell stent

Introduction

Since the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST),¹⁾ carotid artery stenting (CAS) has been developed as a therapeutic alternative to carotid endarterectomy (CEA) for patients with carotid artery stenosis. Stent deformation or fracture is one of various complications in CAS,²⁾ with a reported prevalence rate of 1.9%–29.2%.^{3,4)} Although additional

treatment is not always necessary, stent deformation may result in restenosis and/or thromboembolic complications that bring sequelae.

In Japan, a PROTÉGÉ (Covidien, Irvine, CA, USA) and a PRECISE (Cordis, Miami, FL, USA) are available as open-cell stents. While several reports have described folding deformation of the PROTÉGÉ,^{5–7)} there are little information regarding folding deformation of the PRECISE.⁵⁾ Although none of the previous studies had clearly defined the term “folding deformation,”^{5–7)} we regarded that the term represents stent deformation protruding toward the vessel lumen, in other words, “inward convex distortion.” In this article, we describe 3 cases with the folding deformation of the PRECISE and present a review of the relevant literature.

Case Presentations

Before writing this report, a written consent form was obtained from each patient.

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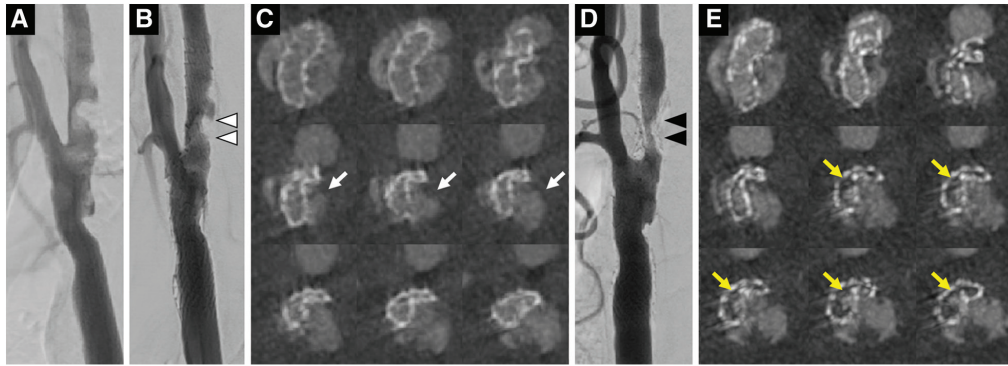


Fig. 1 In Case 1, right CCAG before CAS reveals a severe stenotic lesion at the right cervical ICA (A). Post-CAS CCAG shows improvement of the stenosis (B). However, cone-beam CT performed after stent deployment shows folding deformation of the stent caused by heavily calcified plaque (arrows, C). White arrowheads indicate the site of the stent deformation (B). The follow-up CCAG obtained 6 months after the CAS reveals a stenosis at the site of the stent deformation (black arrowheads, D). Cone-beam CT shows that the stent remains inwardly distorted; however, the residual vessel lumen becomes narrower likely due to neointimal proliferation (yellow arrows, E). CAS: carotid artery stenting; CCAG: common carotid artery angiography; ICA: internal carotid artery

Case 1

An 83-year-old man was referred to our hospital for asymptomatic progressive stenosis of the right cervical internal carotid artery (ICA). He had a medical history of hypertension, diabetes mellitus, and myocardial infarction. On carotid ultrasonography (US), calcified plaque caused the carotid stenosis with an increased peak systolic velocity (PSV) of 360 cm/s. MRA confirmed the presence of severe stenosis of the right cervical ICA. The plaque was iso-intense on the MRI T1-black blood method. Although cervical CT was not obtained, carotid US findings suggested that the plaque was composed of partial heavy calcification. Cerebral angiography (CAG) showed a severe stenotic lesion (North American Symptomatic Carotid Endarterectomy Trial [NASCET] 80%) at the right cervical ICA located between the third and fourth cervical vertebrae (Fig. 1A). The vessel diameter of the distal ICA and the common carotid artery (CCA) was 3.8 and 7.1 mm, respectively. Because the lesion was progressive despite the best medical therapy, CAS was planned. Dual antiplatelet therapy (DAPT; oral administration of aspirin 100 mg/day and clopidogrel 75 mg/day) was initiated 1 week before the CAS. Via the right common femoral artery, a Mo.Ma (Medtronic, Minneapolis, MN, USA) was deployed from the right CCA to the external carotid artery (ECA) to establish proximal protection, and a FilterWire EZ (Boston Scientific, Natick, MA, USA) was deployed in the proper position at the distal ICA for distal protection. Pre-dilation was performed using a SHIDEN 2.5 × 40 mm (Kaneka Medics, Osaka, Japan) inflated at 8 atm for 30 s. Thereafter, a PRECISE 8 × 40 mm was placed to sufficiently cover the

plaque. The stent was deployed only by unsheathing, and no excessive pushing was added. Finally, post-dilation was performed using a SHIDEN 3.5 × 30 mm inflated at 8 atm for 30 s. Confirmation angiography showed improvement of the stenosis (Fig. 1B). However, cone-beam CT performed after the stent deployment demonstrated folding deformation of the stent, which was likely due to the remarkable calcified plaque (Fig. 1C). The calcified plaque accounted for about 30% of the total circumference of the blood vessel but protruding into the vessel lumen. Because of the successful dilation of the stenotic lesion and improvement of run-off, the procedure was terminated despite the stent deformation. Postoperative course was uneventful and he was discharged with modified Rankin Scale (mRS) 0. However, 6 months after the procedure, he felt transient weakness of his left hand, especially when his systolic blood pressure dropped to less than 100 mmHg. Follow-up CAG showed stagnation of contrast media at proximal to the stenosis to the venous phase. Cone-beam CT obtained during the CAG indicated that the stent remained inwardly distorted and that the residual vessel lumen had become narrower likely due to neointimal proliferation (Fig. 1D and 1E). We attributed the restenosis to neointimal proliferation rather than thrombus because modification of antithrombotic therapy did not improve the patient's symptoms. It was considered that not only the heavily calcified plaque hampered self-expansion of the stent but also subsequent intimal thickening at the stenotic region led to the in-stent restenosis. The hemodynamic impairment due to the in-stent restenosis seemed to cause the transient ischemic attacks in spite of the best medical

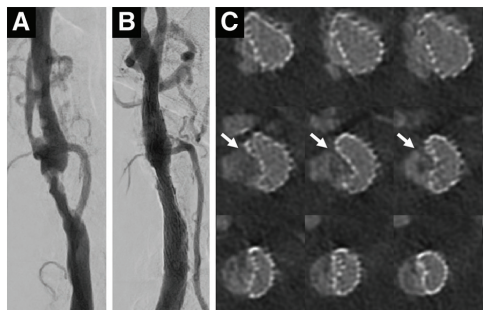


Fig. 2 In Case 2, right CCAG before CAS reveals a stenotic lesion at the right cervical ICA (A). Post-CAS CCAG shows improvement of the stenosis (B). After the stent deployment, cone-beam CT shows folding deformation of the stent due to heavy calcification (arrows, C). CAS: carotid artery stenting; CCAG: common carotid artery angiography

treatment. Three surgical options were discussed: 1) stent removal, 2) endovascular surgery including re-percutaneous transluminal angioplasty (PTA) and/or stent-in-stent, and 3) extracranial–intracranial bypass. We adopted 3) because the distal edge of the stent appeared too high for exposure for 1) and there was concern of acute occlusion for 2). Extracranial–intracranial bypass was performed 7 months after the CAS and the patient did not experience any transient ischemic attacks after the bypass surgery for 4 years of follow-up.

Case 2

An 81-year-old man was referred to our hospital for symptomatic stenosis of the right cervical ICA. He had a medical history of dyslipidemia. Carotid US revealed calcified plaque causing the carotid stenosis with an increased PSV of 359 cm/s. MRA confirmed the severe stenosis of the right cervical ICA. The plaque had iso-intensity on the MRI T1-black blood image method. Cervical CT revealed that the heavily calcified plaque accounted for about 80% of the total circumference of the blood vessel protruded into the vessel lumen. CAG demonstrated a stenotic lesion (NASCET 70%) at the right cervical ICA located between the third and fourth cervical vertebrae (Fig. 2A). The vessel diameter of the distal ICA and the CCA was 4.1 and 8.1 mm, respectively. CAS was planned, and DAPT was initiated 1 week before the stent deployment. Via the right common femoral artery, an 8 French (F) Optimo (Tokai Medical Products, Aichi, Japan) was deployed to the right CCA, and a FilterWire EZ was deployed at the distal ICA, both of which established embolic protection. Pre-dilation was performed using a SHIDEN 3.5 × 40 mm inflated at 8 atm for 30 s. Thereafter, a PRECISE 9 × 40 mm was placed to sufficiently cover the plaque. The stent was deployed only by unsheathing, and no excessive pushing was added. Finally, post-dilation was performed using an Aviator 4.0 × 20 mm

(Cordis) inflated at 8 atm for 30 s. Intravascular US revealed residual stenosis at the distal stent end, whose diameter was 2.5 mm. For the residual stenosis, additional post-dilation was performed using a Coyote 3.0 × 20 mm (Boston Scientific). Confirmation angiography showed that the stenosis improved (Fig. 2B). However, cone-beam CT showed folding deformation of the stent, which was likely caused by the heavily calcified plaque (Fig. 2C). The procedure was terminated because of the improvement in stenosis as well as run-off. No ischemic symptoms were observed during the postoperative course, and he was discharged with mRS 1. The patient remained free of serious complications for 1.5 years after the CAS.

Case 3

A 78-year-old man was referred to our hospital for asymptomatic progressive stenosis of the right cervical ICA. He had a medical history of hypertension, diabetes mellitus, and dyslipidemia. Carotid US showed a low echoic plaque partially covered by a thin fibrous cap that caused the carotid stenosis with an increased PSV of 397 cm/s. MRA also showed the severe stenosis of the right cervical ICA. The plaque had high intensity on MRI T1-black blood image. Preoperative cervical CT was not obtained; however, cone-beam CT obtained during CAG confirmed the absence of calcified lesion. These findings suggested that the plaque consisted of soft and fibrous components. The CAG revealed a severe stenotic lesion (NASCET 90%) at the right cervical ICA located between the third and fourth cervical vertebrae (Fig. 3A). The vessel diameter of distal ICA and CCA were 3.9 and 8.6 mm, respectively. CAS was planned, and DAPT was initiated 1 week before the stent deployment. Via the right common femoral artery, a Mo.Ma and a Spider FX (Covidien) were deployed to the proper position to establish double protection. Pre-dilation was performed using a Coyote ES 3.0 × 40 mm inflated at 8 atm for 30 s. Then a PRECISE 9 × 40 mm was placed at the proper position. The stent was deployed only by unsheathing, and no excessive pushing was added. Finally, post-dilation was performed using a Sterling 3.5 × 30 mm (Boston Scientific) inflated at 6 atm and deflated immediately due to bradycardia and hypotension. During the withdrawal of the Spider FX, a retrieval device could not pass through the stent strut at the site of the stenosis. Head rotation and cervical compression near the proximal part of the PRECISE were ineffective. Therefore, we employed a 4F TEMPO (Cordis) instead of the standard retrieval device, and along with the assistance of head rotation and neck compression, the Spider FX was successfully

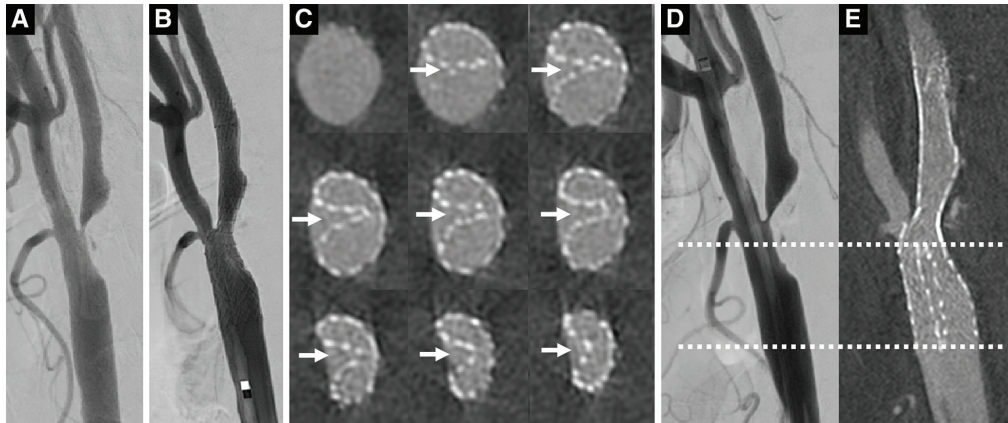


Fig. 3 In Case 3, right CCAG before CAS reveals a severe stenotic lesion at the right cervical ICA (A). Post-CAS CCAG shows improvement of the stenosis (B). However, cone-beam CT performed after the stent deployment shows folding deformation of the stent. Arrows indicate the site where a distal shaft of an Mo.Ma was located before obtaining this CT (C). The Mo.Ma is deployed from the right CCA to ECA during CAS (D). Cone-beam CT performed after stent deployment reveals that folding deformation of the stent occurs at the site where the distal shaft of the Mo.Ma contacts with the stent (between the dotted lines) (E). CAS: carotid artery stenting; CCA: common carotid artery; CCAG: common carotid artery angiography; ECA: external carotid artery

withdrawn. Confirmation angiography showed improvement of the stenosis (Fig. 3B). Cone-beam CT, however, showed folding deformation of the stent (Fig. 3C), which was at the CCA, not at the ICA with the narrowest lesion. Because the deformation did not cause flow restriction or thrombus formation, the procedure was terminated. Ischemic symptoms were not observed in the postoperative period, and he was discharged with mRS 0. Thereafter, he was uneventful for 2.5 years after the CAS.

Discussion

Open-cell stents have lower intensity of stent struts and more free cell areas than closed-cell stents,⁸⁾ which makes open-cell stents more flexible; further, open-cell stents possess torsional strength. These characteristics might contribute to the low prevalence of stent fracture and the ability to fit tortuous areas.⁹⁾ However, the stent flexibility can increase the risk of stent deformation due to mechanical forces such as heavily calcified plaque. In 2 of the 3 patients presented herein, the inward convex distortion of stents was likely caused by heavily calcified plaque. In contrast, the higher density of struts in closed-cell stents allows for increased rigidity and strength while rendering them less flexible and more brittle.³⁾ Stent fractures occur their inflexibility and brittleness in stents exposed to various external forces, such as compression.³⁾ This is why stent deformations are more common in open-cell stents and why stent fractures are more frequent in closed-cell stents. This was corroborated by Chang et al.,⁸⁾ who reported 27

cases of stent deformation and 5 cases of stent fracture. They found that deformation was more common in open-cell stents compared with closed-cell stents, while 4 of the 5 stent fractures occurred in closed-cell stents. In addition, they showed calcified plaque was a risk factor of stent deformation, although not all the stent fractures treated in this study were folding deformation because of the difference in definition.

Several studies have reported folding deformation of open-cell stents (Table 1). Seo et al.⁶⁾ reported that complex head and neck movements might cause deformation, whereas Tetsuo et al.⁵⁾ reported that long and/or eccentric stenosis with calcification was a risk factor for folding deformation. Additionally, Naraoka et al.¹⁰⁾ reported that the deployment of long stents, 40–60 mm in length, might be a risk factor for lesions with marked differences in diameter between the proximal and distal ends. Furthermore, Murakami et al.⁷⁾ reported the folding deformation of a PROTÉGÉ that occurred just after post-dilation in CAS where a Mo.Ma was employed for embolic protection. The authors confirmed that because open-cell stents, such as a PROTÉGÉ, were flexible and highly adhesive to the blood vessel wall, inward convex distortion of the stent occurred when a relatively thick device, such as a Mo.Ma, passed by the side. Moreover, they suggested that folding deformation was completed by post-dilation on the same site. Naraoka et al.¹⁰⁾ described a Mo.Ma case in whom a PRECISE was used, and pressure from the main shaft of the Mo.Ma might have caused folding deformation along with over-dilation. Therefore, they also discussed the need to restrict the balloon size for post-dilation.

Table 1 Overview of the reported cases with folding deformation of open-cell stents

Study	NASCET percent stenosis (%)	Length of stenosis (mm)	ICA diameter/CCA diameter (mm)	Heavy calcification	Embolic protection device	Stent (mm)	Pre-dilation balloon (mm)/expansion pressure (atm)	Post-dilation balloon (mm)/expansion pressure (atm) × time (s)	Presumed causes of stent deformation
Seo et al. ⁶⁾	80	40	NA/9.0	-	NA	PROTÉGÉ 10 × 60	NA/NA	NA/NA	Complex head and neck movement
Murakami et al. ⁷⁾	90	NA	NA	-	Mo.Ma	PROTÉGÉ 10 × 60	Coyote 3.5 × 30/NA	Aviator 6.0 × 40/NA Aviator 6.0 × 20/NA	Distal shaft of Mo.Ma
Tetsuo et al. ⁵⁾	70	35	5.9/9.2	+	Spider FX	PROTÉGÉ 10 × 60	Coyote 3.5 × 40/6	Rx-Genety 4.5 × 40/8 × NA	Heavily calcified plaque
Naraoka et al. ¹⁰⁾	80	24	3.9/7.4	+	Mo.Ma GuardWire	PRECISE 10 × 40	Sterling 3.0 × 30/NA	Aviator 5.5 × 20/12 × NA Aviator 6.0 × 20/NA	Heavily calcified plaque Distal shaft of Mo.Ma Over-dilation during post-dilatation
Naraoka et al. ¹⁰⁾	75	34	4.6/8.8	-	Mo.Ma GuardWire	PROTÉGÉ 10 × 60	NA/NA	Aviator 6.0 × 40/NA	Distal shaft of Mo.Ma Over-dilation during post-dilatation
Present case 1	80	35	3.8/7.1	+	Mo.Ma FilterWire EZ	PRECISE 8 × 40	SHIDEN 2.5 × 40/8	SHIDEN 3.5 × 40/8 × 30	Heavily calcified plaque
Present case 2	70	30	4.1/8.1	+	Optimo FilterWire EZ	PRECISE 9 × 40	SHIDEN 3.5 × 40/8	Aviator 4.0 × 20/8 × 30 Coyote 3.0 × 20/6 × 30	Heavily calcified plaque
Present case 3	90	30	3.9/8.6	-	Mo.Ma Spider FX	PRECISE 9 × 40	Coyote 3.0 × 40/8	Sterling 3.5 × 30/6 × a few	Distal shaft of Mo.Ma Head rotation and neck compression post-dilation

CCA: common carotid artery; ICA: internal carotid artery; NA: not applicable; NASCET: North American Symptomatic Carotid Endarterectomy Trial

In Case 1, the stenotic lesion was accompanied by marked calcification that protruded into the lumen of the blood vessel. It was unlikely that the Mo.Ma was responsible for the stent deformation because the deformation part was away from its distal shaft. In this case, calcified lesions were considered predisposing factors for the folding deformation. In Case 2, there was heavily calcified plaque protruding into the lumen of the blood vessel, as in Case 1. In this patient, a Mo.Ma was not used. Thus, heavily calcified lesions were considered risk factors for folding deformation. Different from these cases, calcified lesions were not present in Case 3. Because folding deformation occurred at the site of contact between a distal shaft of the Mo.Ma and the stent (**Fig. 3D** and **3E**), the use of the Mo.Ma was considered as a risk factor for the deformation. For reference, we introduce another CAS case in whom cone-beam CT obtained after a PRECISE stent deployment with the use of the Mo.Ma revealed that the distal shaft of the Mo.Ma prevented expansion of the

PRECISE and caused mild inward convex distortion at the site of contact between the distal shaft and the stent, which disappeared after the Mo.Ma withdrawal (**Fig. 4**). This case suggested that the inward convex distortion potentially occurred at the distal shaft of the Mo.Ma and this was completed if some additional factors were added. In Case 3, post-dilation, head rotation and cervical compression might be the additional factors for the deformation.

Although PRECISE stents do not generally exhibit inward convex distortion, it occurred in 3 cases in our series and the causes of the stent deformation were assumed heavy calcification in 2 cases and a distal shaft of a Mo.Ma in 1 case. Because heavily calcified lesion has been considered as a high risk for CAS due to inhibition of stent expansion,¹¹⁾ it is desirable to perform plain cervical CT preoperatively to evaluate plaque calcification in planning CAS. In our series, protrusion of calcified plaque seemed higher risk rather than the ratio of calcification to the total

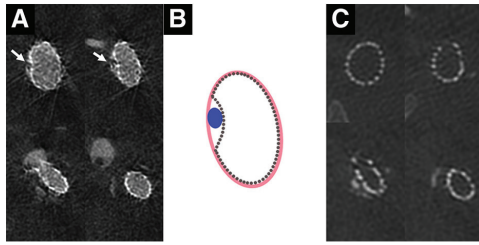


Fig. 4 In a reference case, cone-beam CT obtained after a PRECISE stent deployment shows that a distal shaft of a Mo.Ma hampers expansion of the PRECISE and causes inward convex distortion at the site of contact between the Mo.Ma and the stent (**A**, arrows). Schema of the cone-beam CT (**B**). A blue oval indicates the Mo.Ma and dotted lines indicate the PRECISE. Cone-beam CT after removal of the Mo.Ma reveals disappearance of the stent deformation (**C**).

circumference of the vessel. For lesions with such calcified plaque, it may be better to increase the pressure of pre-dilation to avoid stent deformation. After encountering these 3 cases, we have modified the pre-dilation policy: while PTA balloons with the diameter of 2.5 to 3 mm were previously selected for pre-dilation to obtain the smallest diameter for a stent system to pass the stenosis, after this series, the diameter of 3 to 4 mm with higher pressure has been selected for pre-dilation. In the Mo.Ma-related cases, because the stent exhibited an inward convex distortion along its distal shaft, it is important to avoid deployment of an unnecessary long stent into the CCA if the plaque is localized to the ICA or to consider the use of closed-cell stents. It is also important to choose appropriate-sized post-dilation balloons to avoid over-dilation, which might accelerate the stent deformation. With the recent discontinuation of supplying GuradWire PS (Medtronic), the frequency of the Mo.Ma use has been growing in CAS, which will require more attention to the folding deformation.

Seo et al.⁶⁾ reported cerebral infarction induced by the folding deformation of CAS stent. In response to this report, previous reports^{5,7,10)} have discussed the necessity of close follow-up and long-term intensive antithrombotic therapy. In all our cases, DAPT has been still ongoing beyond the usual 3 to 6 months after CAS in our protocol because of the risk of thromboembolic events due to the folding deformation. Thus, once the folding deformation occurs, the patients are forced to undergo longer-term antithrombotic therapy and occasionally additional treatments. Therefore, indication of CEA instead of CAS should be stressed in cases harboring high risk factors of strong predispositions to the stent folding deformation such as protruding calcified plaque along with the Mo.Ma use, and if CAS is still forced due to CEA high risks, the use of closed-cell stents along with pre-dilation by a PTA balloon with larger diameter and higher pressure should be considered.

Conclusion

Inward convex distortion of PRECISE stents can be caused by calcified plaque protruding into the vessel lumen or by a distal shaft of a Mo.Ma.

Disclosure Statement

The authors declare that there are no conflicts of interest.

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