Ex Vivo Release of Pipeline Embolization Device Polytetrafluoroethylene Sleeves: A Technical Note

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Objective: A method to deal with situations in which the protective sleeves of the Pipeline Flex embolization device (Medtronic, Minneapolis, MN, USA) cannot be released in its placement due to strong resistance to the delivery wire is presented.

Case Presentation: The patient was a 60-year-old woman with symptomatic aneurysm in the cavernous portion of the left internal carotid artery. We attempted to navigate the Pipeline Flex to, and place it in, the target vessel, but the resistance to the delivery wire in the microcatheter was so strong that it was totally impossible to expose the Pipeline Flex from the catheter tip. Therefore, we expanded the tip of the Pipeline Flex ex vivo, resheathed it after releasing the protective sleeves, and attempted to place the device again with success.

Conclusion: While this method cannot be recommended, it may be effective if there is strong resistance in releasing the protective sleeves.

Keywords ▶ Pipeline Flex, polytetrafluoroethylene sleeves, ex vivo release

Introduction

The Pipeline embolization device (PED, Medtronic, Minneapolis, MN, USA) has become a useful option for the treatment of large/giant intracranial aneurysm of the internal carotid artery (ICA),1,2) which used to be difficult to treat. In Japan, the Pipeline Flex with improved manipulability due to modifications of the tip protective function and delivery wire compared with the previous Pipeline classic type was approved in October 2015. With increases in cases treated using the Pipeline Flex, reports of its safety and efficacy are also increasing.3,4) However, technical problems may arise in its clinical use, but reports concerning technical tips are scarce. We encountered a case of left ICA-cavernous portion (cav) aneurysm in which the resistance to the delivery wire in the microcatheter was so strong that the deployment of the PED was difficult, but the device could be deployed after releasing the polytetrafluoroethylene (PTFE) protective sleeves ex vivo. This case is reported with a review of the literature.

Case Presentation

The patient was a 60-year-old woman presenting with diplopia as the primary complaint. She had a history of ovarian cystectomy at the age of 43 years.

History of the present illness: The patient consulted a local doctor as she noted double vision when she looked to the left. She was found to have unruptured aneurysm in the left ICA-cav on head MRI and referred to our department for treatment.

Neurologic findings: Neurologic examination revealed left abducens nerve palsy.

Imaging findings: Head MRI showed an aneurysm in the left IC-cav without findings of thrombus formation. On DSA, an aneurysm 14 mm × 12 mm × 11 mm with a neck about 7.4 mm long was observed in the left ICA from C5 to the curved portion of C4 (Fig. 1A and 1B). On balloon test occlusion (BTO) of the left ICA, no neurologic deficits
appeared during 30-minute occlusion, and a rich cross flow from the posterior communicating artery was noted, but Single Photon Emission Computed Tomography (SPECT) during BTO showed a slight decrease in the blood flow of the left hemisphere.

Periprocedural management: Oral administration of aspirin at 100 mg and clopidogrel at 75 mg was initiated 10 days before the procedure, and the VerifyNow (Medico’s Hirata Inc, Osaka, Japan) test was performed 2 days before the procedure. Since the effect of clopidogrel was slightly insufficient, the dose of clopidogrel was increased to 150 mg on the same day.

Endovascular treatment: Under general anesthesia, an 8 Fr sheath introducer was placed in the right femoral artery. Heparin was intravenously injected at a loading dose of 5000 U, and the activated clotting time (ACT) was adjusted thereafter at 2–3 times the baseline value by administering 1000 U at 1-hour intervals. An 8 Fr guiding catheter (GC) (Launcher; Medtronic) was placed in the left ICA, and a distal access catheter (Navien 5.4 Fr; Medtronic) was navigated to the closest possible point to the aneurysm. Then, a micro-catheter (MC) for stent navigation (Marksman; Medtronic) was advanced to the M1. The PED was planned to be placed from the C3 to C5 portion, and a PED 5 mm × 35 mm was selected because the diameter of the ICA was 4.6 mm in the distal portion, 5.3 mm at the neck, and 5.0 mm in the proximal portion. We first attempted to release the protective sleeves in the M1 but could not advance the PED due to very strong resistance to the delivery wire in the MC. Therefore, to increase the support force, the Navien was navigated to the terminal portion of the ICA, but the reattempt to deploy the PED failed again (Fig. 1C). When the PED was retrieved with the MC, the delivery wire was completely stuck even ex vivo. The system was replaced with a new one, and in vivo
Ex Vivo Release of Pipeline Flex

No clear neurologic symptoms were noted after the procedure, and the patient was discharged, capable of unassisted ambulation.

Discussion

In the Pipeline Flex, there have been improvements in the protective mechanism for the main body of the device, mechanism for its transmission, and delivery wire compared with the Pipeline Classic, which have not only facilitated the deployment and placement of the device but also made resheathing of the device possible. The protective mechanism was changed from a platinum protective coil to two feather-like PTFE sleeves. In the previous Pipeline Classic, a twist-stopper, which was the protective mechanism, was attached to the tip of the delivery system, and twisting of the wire clockwise released the lock on the tip and allowed it to expand. However, the resistance of the wire was strong, and there were times when the tip would not expand despite repeated attempts to twist or when the stent twisted itself and came off unintentionally. In the Pipeline Flex, on the other hand, as the protective sleeves are released spontaneously by the radial force of the stent itself, allowing the device to expand, the device can be deployed more easily by simpler manipulation than the previous model. In addition, the delivery wire was also changed to a thicker one in the Pipeline Flex, leading to improvements in the support ability and
pushability. With these improvements, the procedure time has been markedly shortened, and the accuracy of its positioning has been improved. According to the report of the use of the Pipeline Classic by Lin et al., it was necessary to retrieve the device due to poor deployment in 14.3%, but Pereira et al., who used the Pipeline Flex, reported that retrieval was unnecessary in all patients. Also, Le et al. reported that the operation time was shortened by 44 minutes with decreases in the radiation dose for fluoroscopy and the dose of the contrast agent in patients treated with the Pipeline Flex than in those treated with the Pipeline Classic. Moreover, they reported that failure in PED deployment also decreased from 23% to 7%. Concerning complications of Pipeline placement, the morbidity and mortality were 5.6% and 8.4%, respectively, and the incidence of ischemic complications was 4.7%, in PUFs and InterPED, in which the Pipeline Classic was used, but the morbidity and mortality were improved to 0% and 6.7%, respectively, in recent studies using the Pipeline Flex. However, despite the improvements in the device, strong resistance is felt in pushing the delivery wire, making the deployment of the PED difficult in not a few instances. According to our experience, the greatest resistance is felt in expanding the tip of the PED and releasing the protective sleeves, and we have the impression that the resistance is stronger as the PED is larger and longer and as the proximal portion of the vessel in which the device is placed is more tortuous. We have also experienced that, while the PED had been partially expanded, the protective sleeves could not be released, preventing expansion of the distal end of the PED. In this event, it is recommended to remove the protective sleeves by resolving twisting of the PED and stimulating the distal end by repeated resheathing. However, this increases the risk of thrombus formation or vascular damage as well as complications such as breakage of the PED itself. In addition, Tan et al. reported that complications increased with prolongation of the procedure time. In our patient, the resistance was so strong that we could not even advance the delivery wire let alone attempt the maneuver to release the protective sleeves. Martinez-Galdámez et al. recommended to recover the entire system if more resistance is felt in the manipulation of the delivery wire than usual. However, the PED is an expensive device, and repeated trials should be avoided also from the viewpoint of medical economy. In our patient, therefore, we attempted to place the PED after releasing the protective sleeves ex vivo and reducing the resistance in expanding the distal end of the device.

Griessenauer et al. reported that 25 PEDs could be safely and accurately placed in all 21 aneurysms by releasing the sleeves ex vivo. They placed PEDs after releasing the protective sleeves ex vivo only in cases that required accurate placement due to a very short distal landing zone. The protective sleeves cover the end of the PED and keep it closed to protect it from damages while the device is advanced in the MC. Therefore, if the sleeves are removed ex vivo, the tip may be damaged while it is advanced in the MC. Unlike our method, they first expanded PED from the accompanying introducer sheath ex vivo, released the protective sleeves, resheathed the device with the same introducer sheath, and advanced it in the MC by the usual
method (Fig. 3). For this reason, the device is advanced without the protection of the PTFE sleeves as mentioned above at the risk of damaging the tip. By our method, on the other hand, the protective sleeves are released after the PED is passed through the MC from the microcatheter, and the device is resheathed (Fig. 4). Then, the PED, inserted in the MC, is advanced in the Navien, so the possibility of damaging the tip is extremely low. Since the protective sleeves also serve as a mechanism that prevents expansion of the PED at an unintended site, caution is needed in advancing the device in the Navien. However, this risk is considered to be controlled by careful fixation with a torque device attached to the Y-connetcor part of the delivery wire. However, since this technique requires ascending of the MC with the PED inserted, the micro wire cannot be used. Therefore, it is necessary to place the Navien at a site sufficiently distal to the aneurysm in advance. Since this procedure of navigating the Navien involves the risk of complications, such as vascular damage, it must be performed with sufficient caution. Our patient was free of this problem because the Navien had been inserted safely to the terminal portion of the ICA for the IC-cav aneurysm.

Lastly, this method is not recommended by the manufacturer, and there has been no report concerning its safety. Also, as there is a possibility of unexpected complications, it cannot be recommended invariably. It should be regarded as an option for limited cases such as those that show strong resistance in advancing the delivery wire and difficulty in releasing the protective sleeves or, as reported by Griessenhauer et al., those that require accurate placement due to an extremely short distal landing zone.11)

### Conclusion

In a case in which strong resistance to the delivery wire was felt in PED placement, the PED could be placed safely and without resistance by releasing the protective sleeves ex vivo in advance. This method is not recommended by the manufacturer and lacks reports concerning the safety. Therefore, it cannot be recommended to all cases but is considered effective when there is strong resistance in releasing the protective sleeves.

### Disclosure Statement

Neither the first author nor any of the coauthors have any conflicts of interest.

### References


