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The Utility of the "LEONIS Mova" Steering Microcatheter in Flow Diverter Placement

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Objective: LEONIS Mova (SB-KAWASUMI LABORATORIES, Kanagawa, Japan, hereinafter called LEONIS Mova) is a steerable microcatheter (MC) that enables angle adjustment of the catheter tip using a hand-operated dial. LEONIS Mova may be useful for flow diverter placement when access to the distal parent artery with a conventional MC and microquidewire (MGW) is considered difficult or impossible. Here, we report three such cases encountered during flow diverter placement in large and giant internal carotid artery aneurysms.

Case Presentation: In Case 1, a strong S-shaped curve was observed in the proximal parent artery of a giant cerebral aneurysm, and the luminal structure of the parent artery was lost within the aneurysm. It was anticipated that the distal side of the parent artery would be difficult to access with conventional MC and MGW. By adjusting the tip of the LEONIS Mova toward the aneurysm outlet beyond the S-shaped curve, it was possible to induce the MGW to secure the distal parent artery easily. In Case 2, the inflow and outflow axes of the parent artery were completely misaligned at the site of the aneurysm, and stenosis was present in the distal parent artery. Firmly bending the catheter tip increased accommodation for the catheter, enabling the induction of an MGW to access the distal parent artery without kicking back. In Case 3, the lesion extended from the cavernous portion to the petrosal portion; however, by adjusting the tip of the LEONIS Mova toward the aneurysm outlet, it was possible to induce the MGW to secure the distal parent artery easily. In each case, the LEONIS Mova enabled more secure and prompt access to the parent artery than anticipated and facilitated flow diverter placement.

Conclusion: Encountering difficult-to-access lesions is one reason endovascular treatment may be unsuccessful. The LEONIS Mova is an excellent device that can overcome this obstacle, and its utility in certain applications should be recognized.

Keywords steering microcatheter, large and giant internal aneurysm, flow diverter, LEONIS Mova

Introduction

Flow diverter placement is an established treatment option for large or giant cerebral aneurysms of the internal carotid artery (ICA). Microcatheter (MC) access to the

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distal parent artery of the aneurysm is a requirement for stent deployment. However, this may be challenging in some cases due to anatomical reasons. Various techniques, including shaping and manipulation of the microguidewire (MGW), MC, and distal access catheter (DAC), have been trialed to overcome this, but are associated with prolonged procedural time, increased radiation exposure, increased contrast agent usage, and an increased risk of various complications.

The LEONIS Mova (SB-KAWASUMI LABORATO-RIES, Kanagawa, Japan, hereinafter called LEONIS Mova) (**Fig. 1**) is a steerable MC that enables angle adjustment up to 180° for 15 mm of the catheter tip via dial operation at the proximal end. It was initially designed to deliver or administer embolic materials, drugs, or contrast agents into peripheral vessels, and only one type was available (distal outer diameter 2.4F/proximal outer diameter 2.9F-effective length,

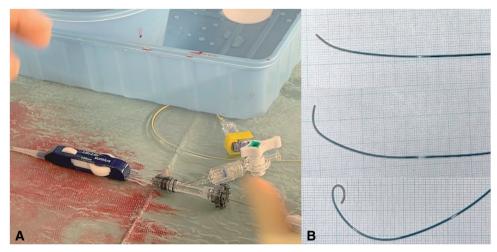


Fig. 1 LEONIS Mova SELECTIVE. (A) Image of the proximal end of the LEONIS Mova SELECTIVE, showing the rotating hemostatic valve with the microguidewire inserted, while the catheter lumen is perfused with saline. (B) Image of the tip of LEONIS Mova SELECTIVE, showing flexion at 45, 90, and 180 degrees.

125 cm). Recently, three new flow types have become available: SELECTIVE (2.0F/2.4F-125 cm, 150 cm), STAN-DARD (2.4F/2.6F-75 cm, 125 cm, 150 cm), and HIGH Flow (2.9F/2.9F-110 cm, 130 cm, 150 cm). The device obtained government approval and became reimbursed for neuroendovascular procedures in Japan from January 2023.¹⁾

In this paper, we report three cases of large or giant aneurysm treatment with flow diverters. In each case, the LEONIS Mova was used to reach the distal parent artery, as conventional MC + MGW was considered difficult or impossible.

Case Presentation

Case 1

A 70-year-old female presented with complaints of left ptosis and visual field impairment for approximately 3 years. Neuroradiological examination revealed a non-thrombosed giant cerebral aneurysm in the cavernous portion of the left ICA, with a maximum diameter of 45 mm and a neck diameter of 16 mm. Due to the presence of symptoms, treatment with a Pipeline Flex Embolization Device with Shield Technology (PED-Shield; Medtronic, Minneapolis, MN, USA, hereinafter called PED-S) was planned.

Under general anesthesia, an 8F FUBUKI 80 cm (ASAHI INTECC, Aichi, Japan) was guided into the ICA via the right superficial femoral artery, and a SOFIA 5F 125 cm (Micro Vention Terumo, Aliso Viejo, CA, USA) was used as the DAC. An S-shaped curve was observed in the ICA just proximal to the aneurysm, and the ICA lost its luminal structure. It was anticipated that the distal side of the parent artery would be difficult to access with conventional MC and MGW. Therefore, we decided to use a LEONIS Mova SELECTIVE (2.0F/2.4F, 150 cm). LEONIS Mova SELECTIVE and Synchro SELECT Standard 0.014" 215 cm (Stryker, Kalamazoo, MI, USA) were guided proximal to the aneurysm. Under fluoroscopy, the tip of the LEONIS Mova SELECTIVE was directed to the outflow orifice of the aneurysm, making it easy to advance the MGW into the distal parent artery. After navigating the MGW up to the M1 portion of the middle cerebral artery, the LEONIS Mova SELECTIVE, in which the tip angle was released, was guided up to M1 over the MGW, followed by a SOFIA 5F 125 cm (MicroVention Terumo) along the LEONIS Mova to M1. The LEONIS Mova SELECTIVE was then exchanged with Phenom 27 (Medtronic), and PED-S 4.5/35 mm was deployed from the IC top to the C5 segment. An additional PED-S 4.5/30 mm was deployed inside the first PED-S in an overlapping manner against the remaining jet flow after the first PED-S. The time required to guide the LEONIS Mova SELECTIVE from the aneurysm just the proximal side to the distal parent artery was 7 min and 39 s (Supplementary Video, Fig. 2).

Case 2

A 65-year-old male presented with the right ptosis and diplopia that had persisted for approximately 1 year. Neuroradiological examination revealed a large cerebral aneurysm in the cavernous portion of the right ICA with maximum and neck diameters of 19 and 14 mm, respectively. As the

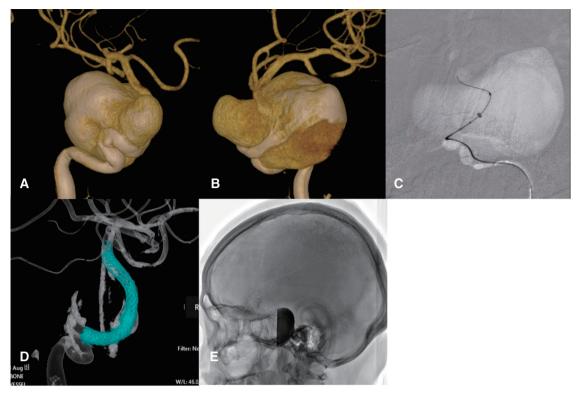


Fig. 2 Case 1: The right anterior oblique (A) and the left anterior oblique (B) views of the 3D DSA of the left ICA show a giant cerebral aneurysm in the cavernous portion of the left ICA, with a maximum diameter of 45 mm and a neck diameter of 16 mm. An S-shaped curve is noted in the ICA proximal to the aneurysm, with the fusiform expansion of the vessel at the aneurysm site, leading to a loss of the luminal structure. The tip of the LEONIS Mova SELECTIVE was directed to the outflow orifice of the aneurysm, making it easy to advance the MGW into the distal parent artery (C). After double overlapping stenting as shown on the translucent view of 3D DSA (D), the eclipse sign was confirmed in the delayed phase of the left internal carotid angiography (E). ICA: internal carotid artery

lesion was associated with symptoms, treatment with a flow diverter was planned. In addition to the loss of the luminal structure, similar to Case 1, there was a misalignment between the inflow and outflow axes of the vessel, accompanied by tortuosity and stenosis distal to the aneurysm. It was anticipated that the MC and MGW would be kicked back when passing through the tortuous part on the distal side of the aneurysm, and result in difficulty securing the distal parent artery. Therefore, we applied the same technique using the LEONIS Mova SELECTIVE as in Case 1. By strongly bending the tip of the LEONIS Mova SELECTIVE toward the outflow orifice of the aneurysm at the inflow orifice, it was possible to easily advance the MGW into the distal parent artery of the aneurysm. In the same manner, as in Case 1, a SOFIA 5F 125 cm (Micro-Vention Terumo) was advanced to the C2 segment of the ICA, and LEONIS Mova was exchanged for Phenom 27 (Medtronic), followed by the deployment of PED-S 4.5/35 mm from the C2 to C5 segment of the ICA. An additional PED-S (4.5/25 mm) overlapped inside the first PED-S. The time required to guide the LEONIS Mova SELECTIVE from the aneurysm just the proximal side to the distal parent artery was 4 min and 58 s (Fig. 3).

Case 3

A 76-year-old female presented with diplopia and left ptosis that had persisted for 6 months. The diagnosis was a large cerebral aneurysm in the left cavernous sinus (maximum diameter, 18 mm; neck, 23 mm), and treatment with PED-S was planned because of the symptomatic lesions. The aneurysm had a serpentine configuration. Similar to the previous cases, by directing the tip of the LEONIS Mova SELECTIVE toward the aneurysm outflow orifice upon surpassing the first curve within the aneurysm, it was easy to navigate the MGW into the distal parent artery. Because of the long distance from the distal landing zone to the proximal landing position of the ICA, telescoping stenting was performed by deploying PED-S 4.0/35, PED-S 4.5/35, and PED-S 4.5/30 from the C2 to C5 segment of the ICA. The time required to guide the LEONIS

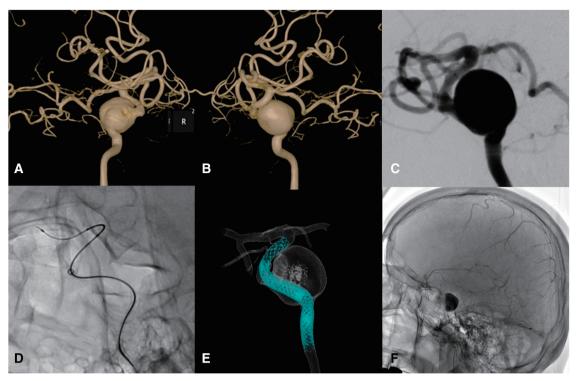


Fig. 3 Case 2: The right anterior oblique (A) and the left anterior oblique (B) views of the 3D DSA of the right ICA show a large cerebral aneurysm in the cavernous portion of the right ICA with maximum and neck diameters of 19 and 14 mm, respectively. In addition to the loss of luminal structure, there was a misalignment between the vessel inflow and outflow axes, accompanied by tortuosity and stenosis distal to the aneurysm. A working angle view of the right internal carotid angiography (C) also depicts these features. A craniogram during the procedure (D) shows a SOFIA 5F 125 cm advanced to the tortuous part in the distal ICA over the LEONIS Mova SELECTIVE, which reached the M1 portion of the middle cerebral artery. After forming an overlapping stenting as shown on the translucent view of 3D DSA (E), the eclipse sign is confirmed in the delayed phase of the right internal carotid angiography (F). ICA: internal carotid artery. SOFIA 5F 125 cm: MicroVention Terumo, Aliso Viejo, CA, USA

Mova SELECTIVE from the aneurysm just proximal side to the distal parent artery was 2 min and 33 s (Fig. 4).

A written consent was obtained from all patients for treatment preoperatively. Written consent for participation in this study was waived with the opportunity to opt-out posted on the institutional website due to retrospective analysis without disclosure of personal information. This study has been approved by the internal review board of our institution.

Discussion

The LEONIS Mova SELECTIVE is a low-profile steerable MC equivalent to 17 MCs with radiopaque markers 15 mm and 30 mm from the tip. Its unique feature is the ability to adjust the tip angle under fluoroscopy using a manual, proximally operated dial; by bending the tip angle, it is able to provide stronger support. In situations when the tip of the LEONIS Mova does not enter the distal target vessel, its fixation in the aneurysm near the desired outflow

orifice is still able to facilitate guidewire entry into the distal target vessel.

In Cases 1 and 3, with standard MC and MGW, operability might have been lost beyond the strong bend of the ICA just proximal to the aneurysm, making it difficult to access the distal parent artery to the aneurysm, which expanded like a saucer. Using the LEONIS Mova SELECTIVE, the angle of the catheter can be adjusted toward the aneurysm outflow orifice at a point just beyond the curve of the vessel, allowing the distal parent artery to be secured under MGW guidance. In addition, the LEONIS Mova SELEC-TIVE could be advanced sufficiently distal to the aneurysm along the MGW, and the DAC could be guided to the M1 segment over the LEONIS Mova SELECTIVE, making it possible to exchange the LEONIS Mova for the Phenom 27 (Medtronic) without wire exchange.

In Case 2, by bending the tip angle of the LEONIS Mova strongly, its supportiveness was enhanced, allowing for the guidance of the MGW to M1 without kicking back when passing through the tortuous portion distal to the aneurysm.

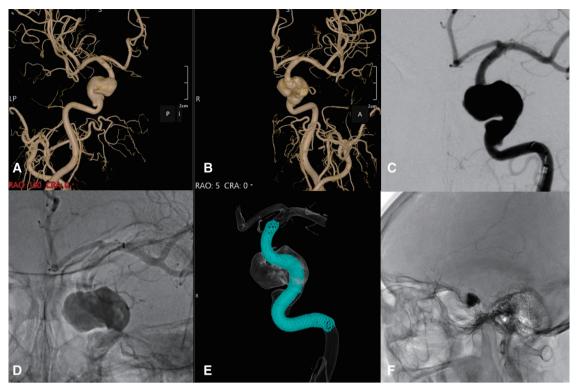


Fig. 4 Case 3: The right anterior oblique (A) and the left anterior oblique (B) views of the 3D DSA of the left ICA reveal a large cerebral aneurysm in the left cavernous sinus with a maximum diameter of 18 mm and a neck diameter of 23 mm. A working angle view of left internal carotid angiography (C) also shows the serpentine-like feature of the aneurysm as same as the 3D DSA. A SOFIA 5F 125 cm is advanced to the M1 proximal portion over the LEONIS Mova SELECTIVE (D). After forming telescope stenting as depicted in the translucent view of 3D DSA (E), the eclipse sign was confirmed in the delayed phase of the left internal carotid angiography (F). ICA: internal carotid artery. SOFIA 5F 125 cm: MicroVention Terumo, Aliso Viejo, CA, USA

In the treatment of large cerebral aneurysms, it is often necessary to navigate the MC and MGW along the inner wall of the aneurysm, looping around the aneurysm dome to pass over the neck. In such cases, complex techniques, such as the balloon anchor technique or stent anchor technique, are often necessary to relieve the looping of the MC and MGW inside the aneurysm. Similarly, these techniques are limited to cases with smooth aneurysmal walls without obvious fragile lobules or intraluminal thromboses. However, there are concerns about the risks associated with these techniques, such as aneurysm rupture during device induction and vascular dissection at the anchor site. ^{2,3)} However, the LEONIS Mova enables direct neck bridging without the need for the aforementioned techniques, thus simplifying the procedure.

Regarding steerable MCs, Berenstein et al. also reported the utility of Bendit (Bendit Technologies, Petach Tikva, Israel), which allows three-dimensional shape control of the tip. It has been reported for various applications, such as coil embolization for sidewall-type aneurysms, deployment of Woven Endobridge for aneurysms, and the use of aspiration catheters or guiding catheters during acute ischemic stroke.⁴⁻⁶⁾ Our experience also suggests that even if it is difficult to access the distal parent artery of the aneurysm with a conventional MC and MGW, the LEONIS Mova enables easy securing of the distal parent artery.

One limitation of this study is its limited scope, based on initial experiences with only three cases. Therefore, it may not be universally applicable to all formidable large and giant ICA aneurysms. In addition, influenced by our previous challenging experiences in similar cases, we opted for LEONIS Mova SELECTIVE as the primary treatment modality from the start, foregoing the standard use of MC and MGW in all three cases. Given the efficacy of this device, we believe it contributes to reducing procedural time, radiation exposure, and contrast agent use, thereby decreasing the risks associated with treatment.

Conclusion

In this study, we report the utility of the LEONIS Mova in flow diverter placement. Difficulty in accessing lesions, such as when the luminal structure of the parent artery is lost within the aneurysm when the axis of the parent artery is misaligned around the aneurysm when the parent artery is highly tortuous or stenotic, is one of the causes of endovascular treatment failure, and steerable MCs are an excellent option to overcome this issue.

Disclosure Statement

The authors declare no conflicts of interest associated with this manuscript.

Supplementary Information

Supplementary Video

An edited movie about the endovascular surgery of "Case 1."

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