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Surgical Neurology International

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Technical Notes

Some technical options for successful PulseRider procedures

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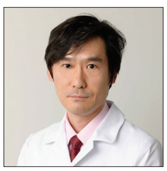

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Received: 04 August 2023
Accepted: 19 October 2023
Published: 17 November 2023

DOI
10.25259/SNI_656_2023

Quick Response Code:

ABSTRACT

Background: Unlike other conventional neck bridge stents, when using the PulseRider (PR), it is not necessary to introduce a microcatheter for stent delivery into the daughter branches from the neck, and it has less intraluminal metal. However, in some cases, securely introducing both leaflets into daughter vessels may be difficult, leading to coil herniation. This study aimed to present some technical issues in PR deployment.

Methods: Fourteen PR procedures were performed in our institution between August 2021 and June 2023, and T-type PRs were used in all procedures. Four technical points during PR procedures are presented from our experience, as "technical options (Options 1-4)". All procedures were carried out with T-type PR implants.

Results: The PR was successfully placed in all interventions; however, in seven cases (50%), some technique trials were necessary because the leaflets did not unfold in the optimal directions. In Option 1, an introduction procedure with transposition of the daughter artery using a microcatheter is presented. In Option 2, the method for correction of the unfolded leaflet angle is demonstrated. In Option 3, another method for correction of the leaflets is shown. In Option 4, an effective method for neck protection during PR procedures is shown.

Conclusion: Various options should be considered to achieve appropriate apposition of PR leaflets. These technical options may be safe and effective for successful PR deployment.

Keywords: Aneurysmal embolization, Leaflet, PulseRider

INTRODUCTION

The main advantage of the PulseRider (PR) implant (Cerenovus, Irvine, CA, USA) is that microcatheter introduction into the daughter artery is essentially unnecessary,[11] and it allows coverage of both daughter vessels without multiple stent placement, such as that using a Y-stent or T-stent.[5] However, to guarantee simultaneous coverage of both daughter arteries, both leaflets should be unfolded to an optimal angle, and thus, the PR may not be as appropriate as other conventional stents. For neck protection during the early phase of embolization, the PR system should not be used like other neck bridge stents. We believe aneurysm neck coverage by the PR may be more effective in extra-aneurysmal placement[11] than in hybrid- or intra-aneurysmal placement. Our PR procedures were aimed at extra-aneurysmal placement. This technical note demonstrates some technical options for PR procedures, mainly by extra-aneurysmal deployment.

In our view, PR deployment breakthrough is classified into three types of pattern. First is the case of breakthrough when extra-aneurysmal placement could not be achieved, such as when hybrid- or intra-aneurysmal deployment is possible but ineffective for safe coil embolization (demonstrated in option 1). Second is the case of a breakthrough with the inappropriate unfolding of the leaflets, which requires replacement (demonstrated in options 2 and 3). The third consists of circumstances that bring out the best performance of the PR during coil insertion and the first coil frame formation in particular (described in option 4).

METHODS

Fourteen PR procedures were performed in our institution between August 2021 and June 2023 [Table 1], and T-type PRs were used in all procedures. Four technical points during PR procedures are presented from our experience as "technical options." All procedures were carried out with T-type PR implants and were targeted to extra-aneurysmal placement because we considered the advantages of the PR to be maximized by extra-aneurysmal placement. A total of 121 cases (including 113 foreign cases) were collected from the literature[3,6,8,10,12] and data on 418 Japanese cases provided by Cerenovus, were also analyzed to clarify the safety and validity of the PR implant in aneurysmal embolization.

TECHNICAL OPTIONS

Option 1 (Case 5)

This option was employed in a case with a middle cerebral artery (MCA) aneurysm. The leaflets were unfolded in the proper directions, but one leaflet entered inside the aneurysm; hybrid placement was ineffective in this case. A microcatheter (Echelon 10 MicroCatheter, 90° angle; Medtronic, Dublin, Ireland) was introduced into the upper M2 trunk for transposition of the artery to reduce the acute angle of the branch, resulting in the successful introduction of the leaflet [Figure 1]. This method was also used in three other cases [Cases 7, 13, and 14; Table 1].

Option 2 (Case 10)

This option was employed in a case with an anterior communicating artery aneurysm. The leaflets were deployed with a tangent angle against the daughter arteries [Figures 2a-d]. In such situations, the delivery wire should be pulled back with torque inside the microcatheter and then pushed and deployed around the neck, but this does not guarantee the successful placement of the PR. In this case, as in similar cases, we pulled back the PR system outside the microcatheter and manually torqued the PR to the optimal degree using visual assessment. The stent was then carefully reinserted, resulting in successful deployment [Figures 2e-h]. In this method, all manipulation was performed outside the patient's body, which minimizes delivery wire or microcatheter damage compared to torquing the device inside the microcatheter [Figure 3]. We also used this approach in one other case (Case 9).

Option 3 [Case 4]

This option was employed in a case of recurrence of an MCA aneurysm after clipping. The leaflets were not unfolded properly despite several attempts. The microcatheter was introduced into a daughter artery and then gently pulled back with the opening of the tips of the leaflets, which resulted in the successful placement of the PR. We also used this method in one other case (Case 8).

Table 1: Summary of the authors' fourteen cases.

Case	Age	Sex	Location	PR	Deployment	Simulation	Trial
1	70	M	Acom	8T	Hybrid	○	
2	77	F	BA top	8T	Extra	○	
3	74	F	BA top	8T	Extra	○	
4	52	F	M1M2	10T	Extra	○	○
5	75	F	M1M2	8T	Extra	○	
6	67	F	BA top	8T	Extra	×	
7	77	F	M1M2	8T	Extra	○	○
8	73	F	M1M2	8T	Hybrid	○	○
9	67	F	M1M2	8T	Extra	○	○
10	60	F	Acom	8T	Extra	○	○
11	78	F	Acom	8T	Extra	○	
12	70	F	M1M2	8T	Extra	○	
13	54	F	M1M2	8T	Extra	○	○
14	81	F	ACAD	8T	Extra	○	○

A total of 14 procedures were performed at our institution. Technical trial for proper PR deployment was performed in 7 cases among these procedures. Fourteen PR procedures performed in our institution. Extra-aneurysmal deployment was performed in 12 cases. Pre-operative 3D simulation was carried out in 13 cases. An additional trial for proper PR deployment was performed in seven cases. Deploy: style of PR placement (extra-aneurysmal, hybrid-, or intra-aneurysmal), simulation: pre-operative simulation using a 3D model, trial: additional manipulation for proper PR deployment. Deployment: the style of PR placement (extra-aneurysmal, hybrid-, or intra-aneurysmal), Simulation: preoperative simulation using a 3D model, Trial: additional manipulation for proper PR deployment. PR: PulseRider, Acom: Anterior communicating artery, BA: Basilar artery, ACAD: Anterior cerebral artery distal, M1M2: middle cerebral artery bifurcation aneurysm, PR: PulseRider, M: Male, F: Female, ○: Yes, ×: No

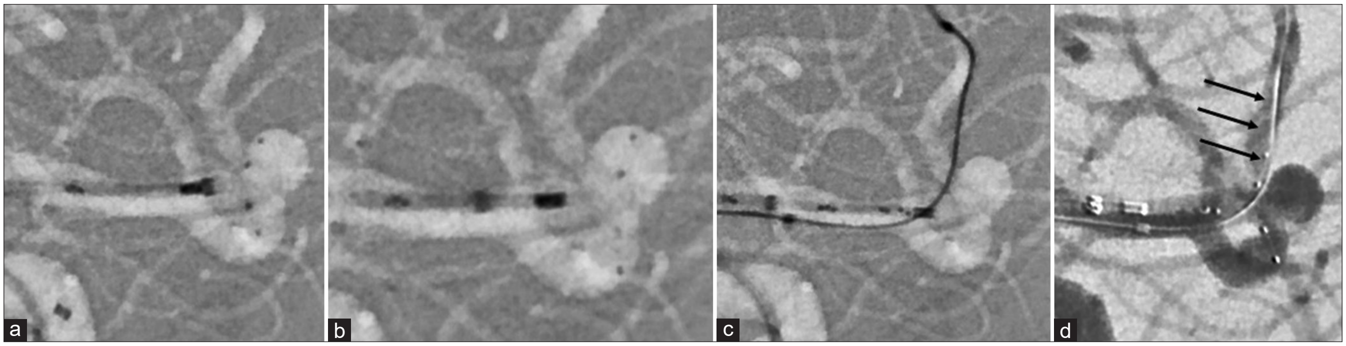

Figure 1: (a and b) Hybrid placement of the pulse rider (PR). Both situations are ineffective for aneurysm treatment. (c) Microcatheter insertion into the upper branch of the middle cerebral artery (MCA) for transposition of the branch. (d) Successful navigation of the leaflet is achieved. Arrows, (d) Reduction of the angle of the daughter artery origin is noted.

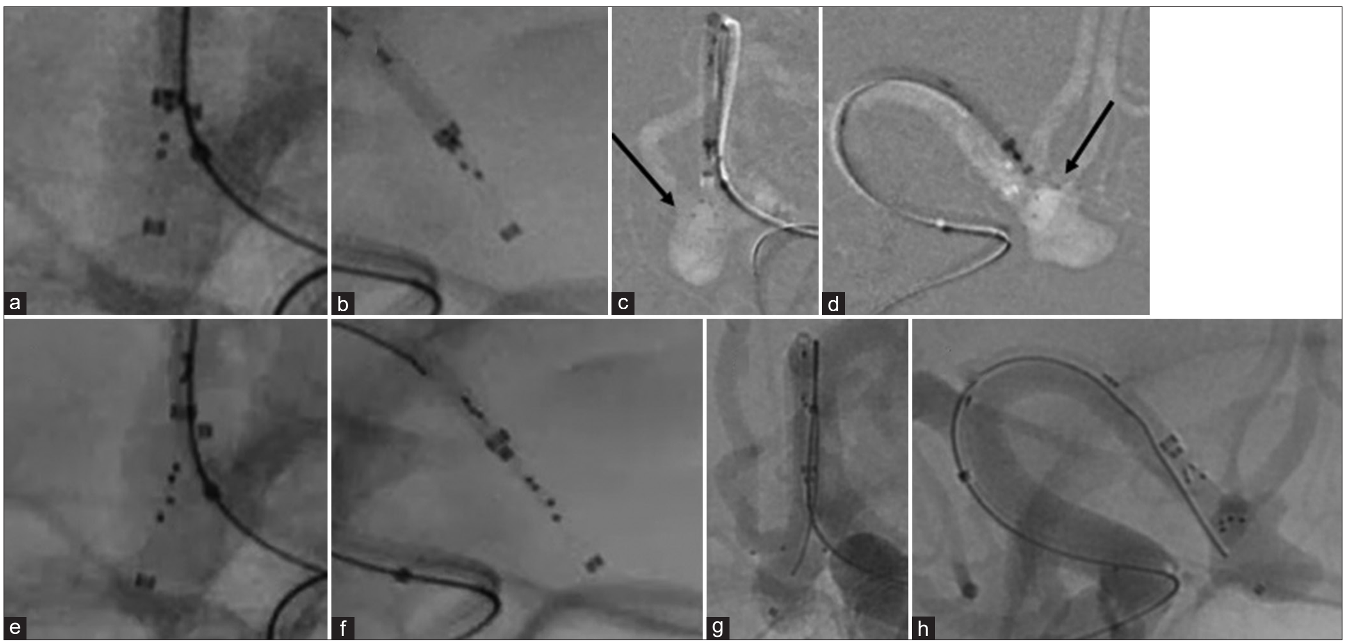

Figure 2: (a and b) Fluoroscopic image before PulseRider unfolding. Arrow, (c and d) Deployment to the tangent angle against the daughter branches during the first trial. (e and f) After rotating the stent 90 degrees outside the microcatheter, the second trial of PR deployment is performed. (g and h) Resulting in successful positioning of the implant.

This method may pose a severe risk of vessel rupture, so this should be attempted only when the space around the aneurysm neck and the daughter vessel is relatively large [Figure 4].

Option 4 (Case 5)

This option was employed in the case of a suspected MCA aneurysm. Inadequate neck protection can occur in PR procedures. Strict apposition of the PR to the neck during the first coil placement may result in coil herniation through the strut and entanglement of the coil and strut [Figures 5a-c]. Setting the PR proximal to the neck before the first coil insertion is essential in this situation. A gentle PR push toward the neck after the first coil placement may lead to contiguous coil frame formation, thus making subsequent coil embolization feasible [Figures 5d-f]. The preoperative simulation with the 3D model of Case 5 is shown for further explanation in Figure 6. On first coil placement, the PR is positioned proximal to the aneurysm neck [Figure 6a]. Gently pushing the neck forward after coil insertion allows for a contiguous coil frame [Figure 6b].

RESULTS

In our experience, the PR was successfully placed in all interventions; however, in seven cases (50%), some technique trials were necessary because the leaflets did not unfold in the optimal directions. The most important issue in PR deployment is whether the leaflets can be optimally unfolded toward each daughter's vessel. The leaflets unfolded successfully in Case 5 (Option 1). However, a leaflet could not initially be introduced into the M2 branch; inserting another microcatheter (Echelon-10) into the branch was performed to reduce the angle of the branch origin, resulting in successful navigation of the leaflet. This was an option when PR unfolding was optimal, but either leaflet was not in the daughter vessel. Echelon-10 was desirable for this situation because it is relatively stiff compared to other microcatheters. In Cases 9 and 10 (option 2), the leaflets were deployed at incorrect angles and needed to be adjusted. Pulling the delivery wire back with some torque and pushing the stent out again are recommended in such situations.[11] However, how much the device can be rotated with such manipulation is uncertain; in other trials, up to three rotations were possible.[11] We had never achieved successful deployment with this method before Case 9, and we, therefore, attempted to rotate the stent outside the patient's body manually as a test and adjust it visually as needed, which fortunately resulted in its successful placement in Case 9. Before the procedure in Case 10, we confirmed the comparatively high reproducibility of this method with a 3D model. Intraoperatively, similar results were achieved after a 1-time rotation of the stent, resulting in the optimal unfolding of the leaflets [Figure 2]. In this method, it is possible to rotate the PR outside the microcatheter, thus minimizing damage to the delivery wire or microcatheter and enabling more than three trials. Therefore, this method may be considered in similar situations. A challenging technique was demonstrated in Cases 4 and 8 (option 3), and we employed it successfully.

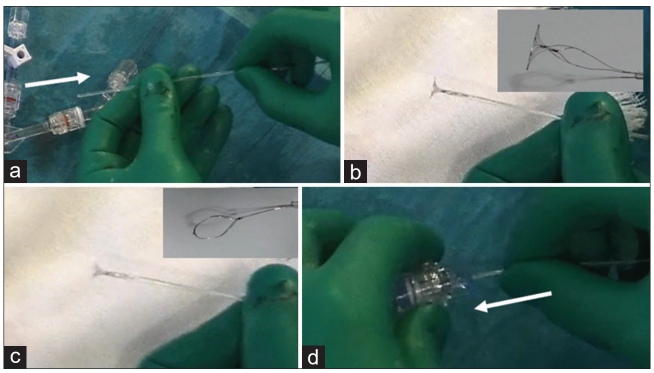

Figure 3: (a) Pulling the stent back into the introducer sheath (white arrow); (b)Pushing the stent without any torque; (c) Unfolded leaflets being rotated in the appropriate degree under visual confirmation; (d) The stent being re-inserted carefully without any rotation of the system (white arrow). Each photo above to the right of b (before rotation) and c (after rotation) shown for reference.

DISCUSSION

It is unnecessary to navigate the microcatheter for stent delivery into the daughter vessel during PR procedures.[11] PR implants are appropriate and effective for wide-necked aneurysms that need a T-stent or Y-stent[5] but have less intraluminal metal.[4,7,13] Some authors have reported promising midterm results.[1,2,9] However, the PR has a more limited range of applications than other conventional stents because both leaflets need to be simultaneously introduced into each daughter vessel. So far, we have performed 14 PR procedures using the T-type PR implant, and thus, our suggested technical options are related to the T-type PR.

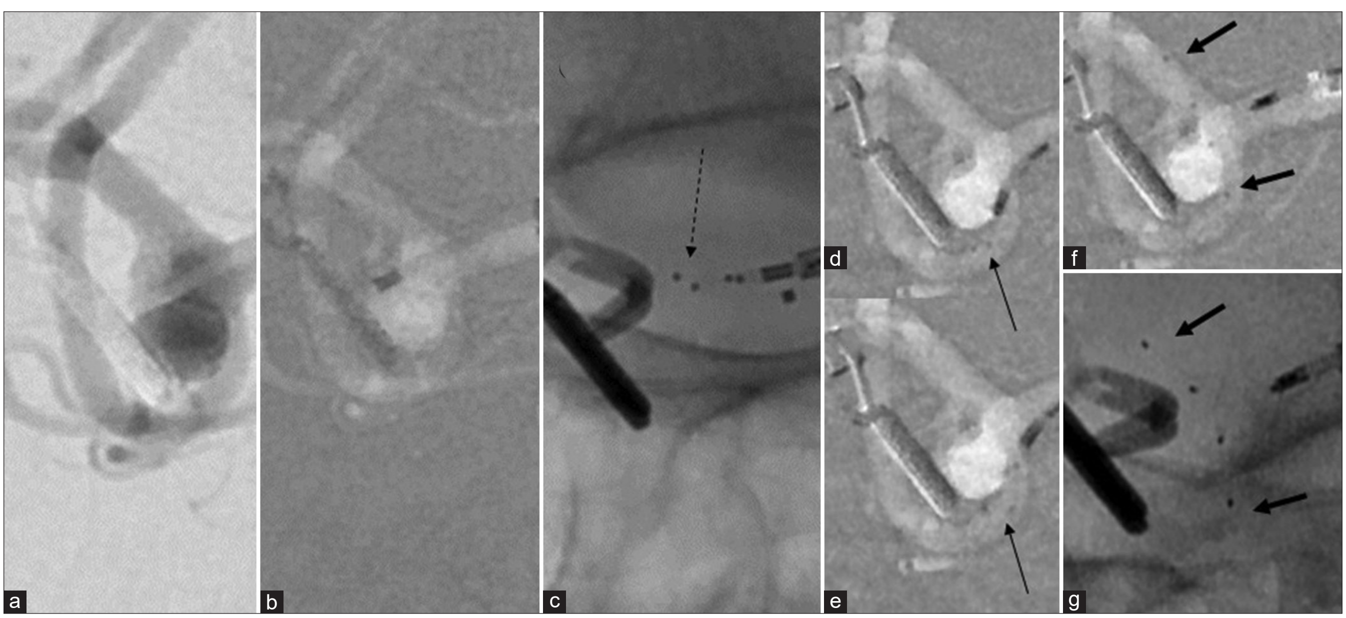

Figure 4: (a and b) Middle cerebral artery aneurysm recurrence 10 years after clipping. c: dotted arrow: The PR is not opened correctly. (d and e) thin arrow: Carefully and slowly pulling back the microcatheter being introduced to the daughter artery as the leaflets open slightly. (f and g) Bold arrows: Resulting in successful placement of the PR.

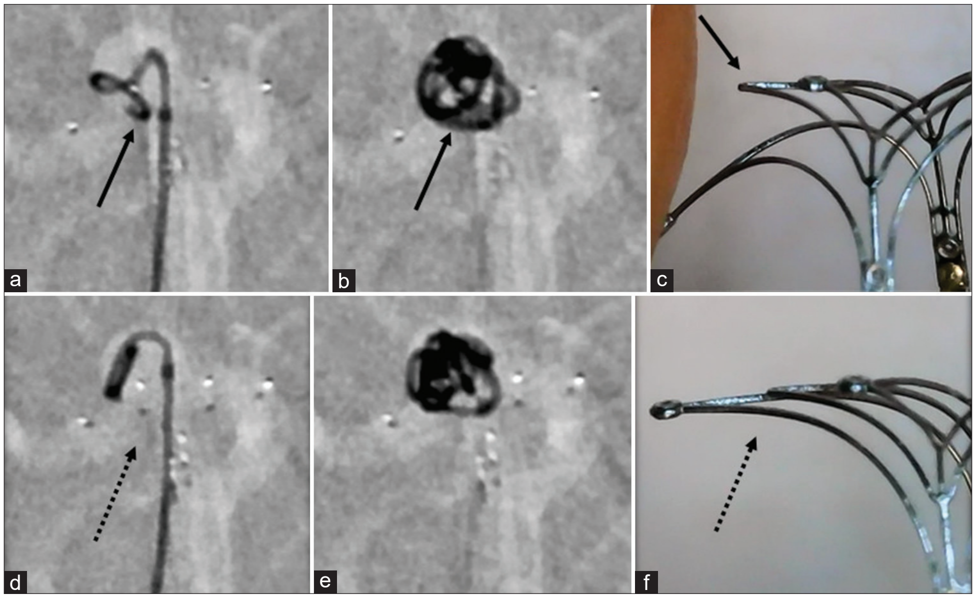

Figure 5: (a and b) The first coil herniating through the leaflet during PR placement at the neck before coil insertion (arrow); (c) Because of the loose leaflets (arrow); (d) Pulling the stent back from the neck appropriately (dotted arrow); (e) Effective and optimal situation for the neck protection is achieved; (f) Because of efficacious implant positioning (dotted arrow).

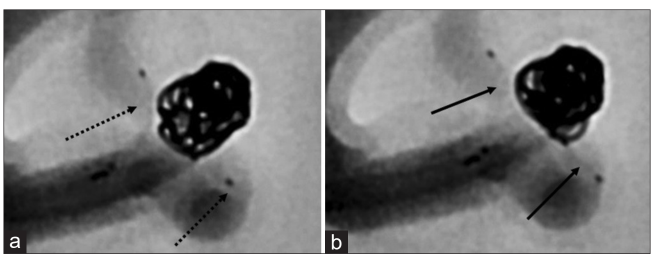

Figure 6: Dotted arrows, (a) The stent positioned proximal to the aneurysm neck until the first coil placement. Arrows, (b) Gentle pushing of the device toward the neck, allowing for the formation of a contiguous and desirable frame.

The PR deployment success rate was 97.5% in the surveyed literature, whereas in the Japanese cases, it was lower (372/418 cases, 90%; as of September 30, 2022) (data provided courtesy of Cerenovus). It is not clear why the rate of successful placement was lower in Japan than elsewhere. In Japan, surgeons can run simulations before the procedure using a 3D model of the patient. The rate of successful placement was 94% in cases with preoperative simulation, whereas it was 84% without such simulation (data provided courtesy of Cerenovus). Using such simulations, it is possible to attempt many technical scenarios that may occur during actual procedures, including what was presented in the present paper. In our opinion, surgeons should engage in technique trials as much as possible to maximize their chances of successfully deploying the PR. Such simulations may contribute to surgeons' ability to confirm the necessary technical manipulations and help them overcome difficulties encountered during procedures. In addition, the abovementioned technical ideas may contribute to successful PR procedures.

Options 1 and 2 may be worthwhile to obtain favorable PR leaflet placement. Option 1 is slightly complicated but maybe a breakthrough when the extra-aneurysmal placement is practical and essential. Option 2 presents a lower risk because whole steps are performed outside the patient's body. These may be suitable alternative methods for the correction of PR leaflets. On the other hand, Option 3 should be a last resort because it may be risky if there is not enough space around the aneurysm neck and daughter artery. A pitfall during the first coil insertion in PR procedures was shown in Option 4. Strict apposition of the PR to the aneurysm neck before the first coil placement is not desirable because the PR strut may loosen, causing coil herniation or entanglement of the stent and coil. To prevent this, the PR should be positioned slightly proximal to the neck and gently pushed forward to the channel after the first coil placement.[11] This enables the first coil frame to be tight, thus ensuring safe and effective coil embolization after that. Gentle pushing of the PR after first coil placement is a key point during PR procedures, and a half-release of the PR is essential for the smooth and safe mobility of the device. After the first coil, the PR placement onto the aneurysmal neck would draw out its capabilities and advantages.

CONCLUSION

The advantages of the PR may be maximized if each PR leaflet is navigated in the optimal direction. This paper presented four technical options for PR deployment with minimal trials. Technique trials were conducted in preoperative simulations before each procedure and were effective. Some technical options shown in the present study and preoperative practice using 3D models may be important for improving the success rate of PR procedures.

Acknowledgments

The authors would like to thank the radiologists at their hospital for their dedicated assistance during the procedures. The authors also wish to express their heartfelt thanks to Cerenovus staff for providing Japanese data.

Ethical approval

The author(s) declare they have taken the ethical approval from IIRB/IEC (NCH2023-4).

Declaration of patient consent

Patients' consent not required as patients' identities were not disclosed or compromised.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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How to cite this article: Kanazawa R, Uchida T, Higashida T, Watanabe S, Kono T. Some technical options for successful PulseRider procedures. Surg Neurol Int 2023;14:403.