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Operative Technique

Use of concentric Solitaire stent to anchor Pipeline flow diverter constructs in treatment of shallow cervical carotid dissecting pseudoaneurysms

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ABSTRACT

The flow-diverting Pipeline Embolization Device (PED; ev3 Neurovascular, Irvine, CA, USA) provides proven flow diversion for intracranial wide-necked and fusiform aneurysms. The tendency of the PED to migrate and foreshorten when its size is mismatched with the parent vessel makes its use more difficult for cervical carotid pseudoaneurysms, as the parent vessel regains its luminal diameter during the healing phase, and because of its mobility during head movement. We present a novel technique of using a Solitaire detachable stent (ev3 Neurovascular) to anchor PED constructs to mitigate these shortcomings. Two patients with shallow and broad-necked cervical carotid pseudoaneurysms with underlying parent vessel stenosis deemed poor candidates for conventional stent-supported coiling were treated using tandem overlapping PED centered over the neck of the pseudoaneurysm and a Solitaire concentric anchor was deployed to overlap distally and proximally. As predicted, both patients revealed carotid luminal gain after aneurysm thrombosis with attendant migration (3.8 and 2.8 mm) and expansion of the PED construct (14% and 7.8%) which remained constrained within the Solitaire anchoring device with persistent luminal patency and no evidence of endoleak at follow-up (3 and 5 months). The use of a concentric anchoring stent can mitigate the inherent tendency of the braided flow-diverting PED to migrate and foreshorten as the target vessel heals upon pseudoaneurysm thrombosis. This novel technique opens the possibility of using PED to treat shallow or fusiform lesions in mobile cervical arteries previously relegated to stent-supported coiling or surgical reconstruction.

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1. Introduction

Minimally invasive endovascular approaches are increasingly favored over microsurgical repair for the treatment of dissecting pseudoaneurysms of the cervical carotid arteries with results indicating encouraging clinical and radiographic outcomes [1]. An array of endovascular treatment options is currently available, including coil embolization, stent assisted coil embolization, dual-stent embolization, and the covered stent graft technique [2,3]. In cases of very shallow aneurysms with wide necks, coil only or stent-assisted coil embolization may lead to a poor angiographic result because of the oblong shape of the aneurysm. Covered stent grafts such as carotid or biliary-type stents used for carotid atherosclerosis are not as well suited for distal cervical internal carotid artery placement due to their lack of flexibility, and larger deployment catheters making navigation more difficult in tortuous vessels.

One endovascular option is the use of a flow-diverting stent such as the Pipeline Embolization Device (PED; ev3 Neurovascular, Irvine, CA, USA). Flow-diverting devices can cause thrombosis of the aneurysm in addition to remodeling of the parent vessel through neo-intimal proliferation [4]. The use of these devices has been described for the management of dissecting pseudoaneurysms involving the intracranial cerebral vessels, with promising radiographic and clinical results [4–7]. However, application of this technique to the extracranial vasculature has not been previously described to our knowledge.

The use of flow-diverting stents in the cervical internal carotid artery may be limited by the tendency of such stents to migrate once deployed, a phenomenon that has been reported by several groups [8–10]. This occurs more commonly than in the intracranial circulation due to the high mobility of the arterial system within the neck and the tendency of the cervical vessels to change their size and shape with turning of the head. We present a novel technique using a Solitaire FR detachable stent (ev3 Neurovascular) to anchor PED flow-diverter constructs for the successful management of dissecting extracranial carotid artery pseudoaneurysms in two patients.

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2. Technique

2.1. Bench-top testing

Prior to intervention, we sought to devise a construct that would mitigate the risk of PED construct migration or malapposition by utilizing a concentrically placed stent to anchor the PED using bench-top testing. We considered the range of available intracranial and extracranial carotid stents. The Solitaire stent was chosen because it is available in a 6 mm diameter, making it suitable for use in the larger extracranial internal carotid artery. Other currently available stents such as the Neuroform stent (Stryker Neurovascular, Fremont, CA, USA), and the Enterprise stent (Codman Neurovascular, Raynham, MA, USA) have 4.5 mm maximum diameters. Secondly, the Solitaire stent may be deployed using a 0.027 inch microcatheter system, the same system used for deployment of the PED. The use of the small 0.027 inch microcatheter allows for more delicate crossing of the PED construct prior to placement. A larger deployment system, as used for the currently available carotid stents, may dislodge the delicate PED from their position over the neck of the pseudoaneurysm. In the bench-top experiment, the stent was concentrically deployed within two PED (Fig. 1). As the photograph of the construct shows, the 6 mm Solitaire device is longer than the PED construct and additionally flares at the ends. Its greater radial force and 6 mm diameter were felt to make it an ideal option for holding the PED against the vessel wall.

2.2. Procedure description

The risks and benefits of the procedure were discussed with each patient, and informed consent was obtained prior to intervention. All interventional procedures were performed under general anesthesia in a biplane neuroangiography suite (Axiom Artis; Siemens AG, Munich, Germany). Each patient underwent diagnostic angiography of both anterior and posterior cerebral circulations for evaluation of collateral flow patterns. The patients were placed on dual antiplatelet therapy consisting of daily 325 mg aspirin and 75 mg clopidogrel (Plavix, Bristol-Myers Squibb, New York, NY, USA) 5 days prior to the procedure. On the day of intervention, platelet aggregation tests were performed to confirm adequate platelet inhibition. The procedures were performed under general anesthesia. At the start of the case, a baseline activated clotting time was obtained, and a weight-based bolus of intravenous heparin (70 units/kg) was administered after femoral arterial access had been obtained and before guide-catheter placement to achieve a target activated clotting time of greater than 240 seconds for the duration of the procedure. After femoral arterial access was obtained in a sterile fashion, a 6-French Shuttle Sheath (Cook Medical, Bloomington, IN, USA) was navigated under roadmap guidance into the internal carotid artery. A Marksman 0.027 inch microcatheter (ev3 Neurovascular) was advanced distal to the target site over a Synchro2 Soft wire (Stryker Neurovascular) under further roadmap guidance. The PED were deployed sequentially using the Marksman microcatheter, and positioned to optimally cover the pseudoaneurysm neck. Using the same microcatheter, a 6 mm × 30 mm Solitaire FR stent was then deployed so as to overlap the PED distally and proximally.

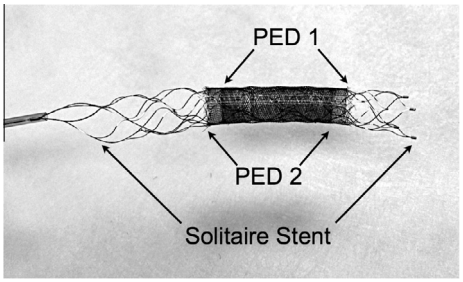


Fig. 1. Photograph of a bench-top model depicting the proposed stent construct. Two Pipeline Embolization Devices (PED; ev3 Neurovascular, Irvine, CA, USA) have been placed concentrically. A 6 mm Solitaire stent (ev3 Neurovascular) was then placed concentrically overlapping the proximal and distal ends of the PED.

3. Illustrative patients

3.1. Patient 1

A 66-year-old man was found to have a left high-cervical internal carotid artery dissecting aneurysm during work-up for near-syncope. Diagnostic angiography demonstrated a shallow but wide-necked dissecting aneurysm measuring 13 mm in width and 4.7 mm in depth with an 8 mm neck and a focal area of stenosis just distal to the neck of the aneurysm (Fig. 2A, B). The patient was considered high-risk for intervention because the left internal carotid artery was the sole feeder of both anterior cerebral arteries due to an azygous anterior cerebral artery, and the distal basilar artery was supplied via the posterior communicating artery due to right vertebral origin occlusion and left subclavian artery stenosis with a subclavian steal phenomenon. The shallow but wide-neck anatomy of the aneurysm was suboptimal for stent-mediated coil embolization, so a PED-Solitaire construct was planned. Two tandem-overlapping PED, measuring 5 mm × 18 mm, were delivered in succession to achieve optimal flow stasis in the aneurysm. Lastly, a Solitaire stent measuring 6 mm × 30 mm was delivered in a manner so as to overlap the proximal and distal ends of the PED, anchoring them to the vessel wall (Fig. 2C). The patient tolerated the procedure well and was discharged without complication. On routine follow-up 1 week later, computed tomography angiography demonstrated migration of the PED construct distally by 3.3 mm with respect to the Solitaire stent, and an average increase in the construct diameter of 10% (Fig. 3). Follow-up angiography 5 months later confirmed the stent movement. Cone-beam CT scan reconstruction analysis demonstrated the PED migration had increased to 3.8 mm from the initial placement, with an increase in the proximal stent diameter of 16% and an average construct diameter increase of 14% (Fig. 3C, F). The PED remained positioned to cover the neck of the pseudoaneurysm, which was completely occluded on follow-up. Clinically, the patient remained asymptomatic.

3.2. Patient 2

A 43-year-old woman was found to have a left high-cervical carotid artery dissecting aneurysm during work-up for severe headache. Diagnostic angiography demonstrated a shallow dissecting aneurysm with a wide neck measuring 5 mm deep by 11 mm wide with a neck of 5.2 mm, which was considered suboptimal to coil embolization (Fig. 4A, B). The pseudoaneurysm was compressing the internal carotid artery just distal to the neck, causing stenosis of the vessel. Three tandem-overlapping PED measuring 5 mm × 18 mm were deployed centered at the aneurysm neck. Finally, a Solitaire stent measuring 6 mm × 30 mm was delivered to provide anchoring of the deployed PED construct. The flow through the pseudoaneurysm was significantly reduced immediately following stent placement, and the area of stenosis was improved (Fig. 4C). At 3 month follow-up the artery remained patent, with no evidence of pseudoaneurysm filling and no residual stenosis (Fig. 4D). Cone-beam computed tomography angiography analysis of the PED demonstrated straightening of the vessel on follow-up and a similar foreshortening pattern seen in Patient 1 (Fig. 5).

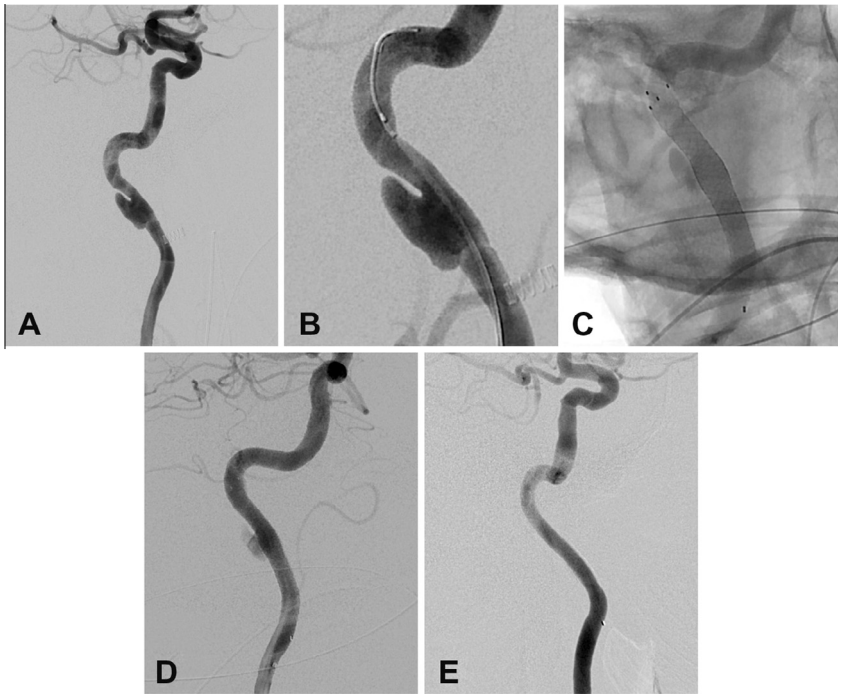


Fig. 2. Patient 1. (A) Digital subtraction angiography (DSA), lateral left internal carotid artery (ICA) injection with (B) magnified view, showing the crossing of the dissecting pseudoaneurysm with the stent delivery catheter. (C) Un-subtracted left ICA lateral angiogram after deployment of two Pipeline Embolization Devices followed by a Solitaire stent (both ev3 Neurovascular, Irvine, CA, USA). (D) DSA, lateral left ICA injection after completion of stent deployment. (E) DSA, lateral left ICA injection at 5 month follow-up.

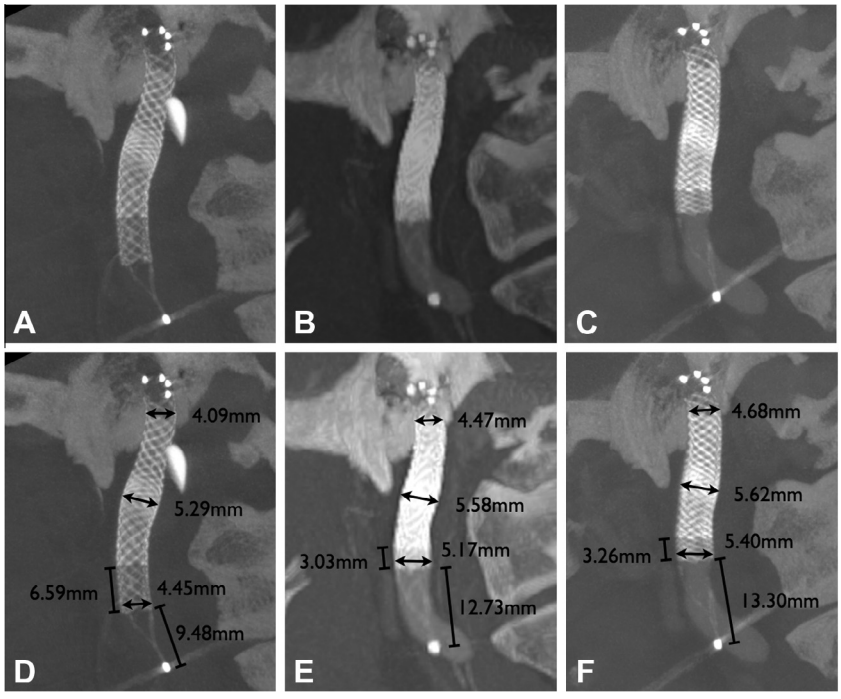


Fig. 3. Pipeline Embolization Device (PED; ev3 Neurovascular, Irvine, CA, USA) migration analysis for Patient 1. Maximum intensity projection multi-planar reconstructions through the stent construct with measurements of the width and relative distances of the three stents with respect to each other. (A, D) Cone-beam computed tomography angiography immediately after stent placement. (B, E) Computed tomography angiography 1 week after treatment. (C, F) Cone-beam computed tomography angiography at follow-up, 5 months later.

The proximal end of the PED construct was seen to move distally with respect to the vessel and the Solitaire stent by 2.8 mm, and the diameter of the proximal construct increased by 12%, with a mean construct diameter increase of 11% (Fig. 5C, D). The foreshortening of the PED also resulted in decreased porosity at the proximal end of the construct (Fig. 5B).

4. Discussion

Endovascular treatment of dissecting pseudoaneurysms of the internal carotid artery has been associated with excellent outcomes and low morbidity [11,12]. Surgical ligation and reconstruction may pose significant perioperative morbidity, primarily from

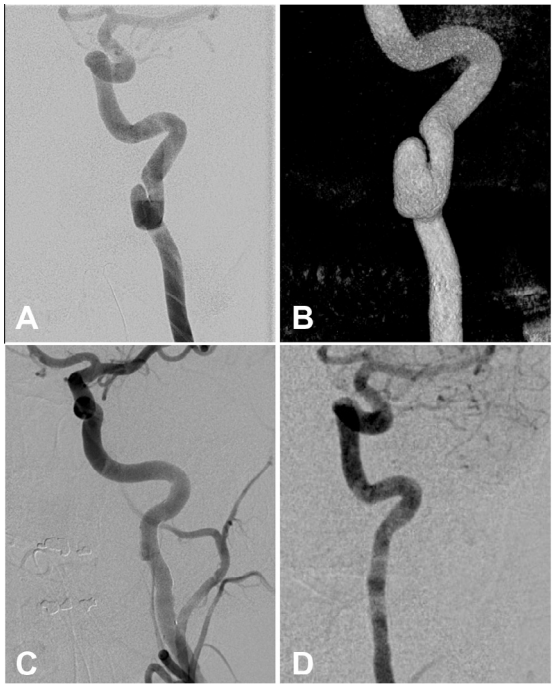


Fig. 4. Patient 2. (A) Digital subtraction angiography (DSA), left lateral internal carotid artery (ICA) injection and (B) three-dimensional rotational angiography reconstruction showing a shallow dissecting aneurysm suboptimal for coil embolization. (C) DSA, left lateral ICA injection immediately following stent placement showing significantly reduced flow through the pseudoaneurysm, and improved area of stenosis, and (D) at 3 month follow-up showing no evidence of pseudoaneurysm filling and no residual stenosis.

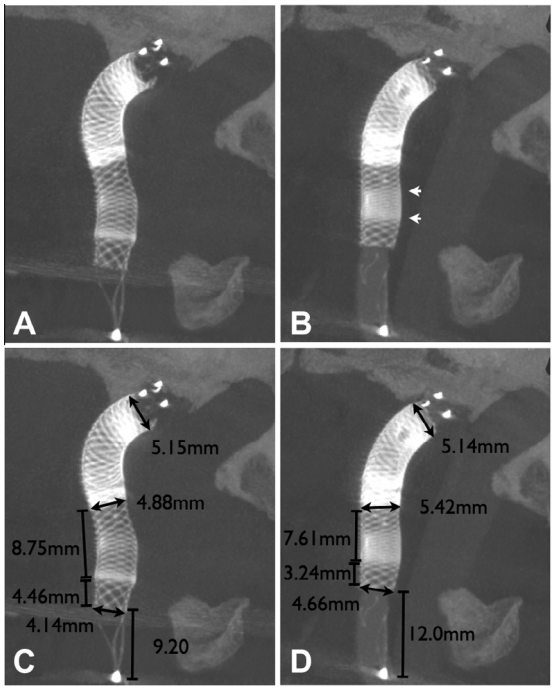


Fig. 5. Pipeline Embolization Device (PED; ev3 Neurovascular, Irvine, CA, USA) migration analysis for Patient 2. Maximum intensity projection multi-planar reconstructions through the stent construct with measurements of the width and relative distances of the three stents with respect to each other. (A, C) Cone-beam computed tomography angiography immediately after stent placement, and (B, D) at 3 month follow-up.

cranial nerve injury reported to occur in as many as 44% of patients [1,13]. These risks, in addition to a frequently inaccessible surgical location requiring a high cervical exposure, have increased the appeal of minimally invasive endovascular approaches.

Self-expanding, low-porosity stents have a promising theoretical role in the treatment of dissecting aneurysms. The PED is a flexible, self-expanding, microcatheter-delivered stent with a high metal to surface area ratio for aneurysm neck coverage that is designed to achieve aneurysm occlusion by promoting stasis of blood and intra-aneurysmal thrombosis. Composed of 48 individual cobalt chromium and platinum strands, it provides 30% to 35% metal surface area and promotes parent vessel remodeling via neointimal hyperplasia [14,15]. Several authors have reported high aneurysm occlusion rates at 12 months along with comparable periprocedural mortality with traditional stent assisted coil embolization [15–17].

The PED has been successfully applied for the treatment of intracranial dissecting pseudoaneurysms. Narata et al. described two patients with ruptured intradural vertebral artery dissecting aneurysms treated with overlapping PED leading to complete occlusion of the aneurysm at 3 months [18]. Similarly, de Barros Faria et al. reported a series of 23 patients with intracranial dissecting aneurysms (91% in the posterior circulation) treated with PED with an occlusion rate of 84% at 3 months [5]. Amenta et al. recently reported an iatrogenic case of a carotid dissecting aneurysm from a procedural complication during endoscopic ethmoidectomy; a PED was deployed, resulting in complete obliteration of the aneurysm at 4 month follow-up [4]. While these groups have demonstrated excellent outcomes when using the PED for intracranial dissecting aneurysms, to our knowledge there have been no reports of PED flow diverting stent being delivered for extracranial cervical artery pseudoaneurysms.

The relatively low radial force of the PED (approximately 2.0 mN/mm) poses the challenge of a need for appropriate size selection between the device and the artery that will contain it [19]. Mismatch between these diameters can lead to stretching of the PED (when the device is too large for the vessel) and foreshortening (when the device is too small for the vessel). These structural alterations and migrations of the PED can lead to decreased flow-diversion properties with lengthening and endoleak or malapposition with foreshortening. To decrease these phenomena, flow-diverting stents are available in 0.25 mm diameter sizing increments to allow for precise parent vessel–device match. While this is adequate in the intracranial circulation, the possibility of the vessel diameter in the neck changing makes accurate sizing more challenging.

Migration of the PED both distally and proximally has been reported in the literature. Chan et al. reported distal migration of an overlapping PED stent construct delivered over a right ophthalmic aneurysm [9] while Kerl et al. described distal migration of a PED delivered for a vertebral artery dissecting aneurysm at the V4 segment [8]. Interestingly, Chalouhi et al. reported proximal migration of the stent delivered for a large cavernous artery aneurysm [10]. In this particular patient, the difference in the diameter between the proximal and distal vessel was thought to cause the "watermelon seed" effect whereby the smaller diameter distal end of stent produces retrograde force on the proximal end, inducing proximal migration of the stent.

In light of these reports, we hypothesized that a PED construct might be at high risk for migration if delivered in the cervical carotid artery due to the high mobility of the artery and absence of bony structures in this region. To prevent migration of the PED, we opted to deploy a Solitaire stent in a concentric manner to provide anchoring of the PED at both the proximal and distal ends. The Solitaire stent is ideal not only due to its larger diameter (6 mm, typically required for cervical carotid arteries), but also its

comparatively high radial force during self-expansion. Additionally, the Solitaire stent can be deployed using the same 0.027 inch microcatheter used to deploy the PED, in comparison to the stents designed for extracranial carotid atherosclerotic disease, which require much larger deployment catheters. This decreases the chance of disrupting the delicate PED construct when attempting to deploy the anchoring stent. Despite the anchoring effect of the Solitaire device, in both of our patients follow-up imaging demonstrated foreshortening of the PED and increase in the proximal stent diameter over time (Fig. 3, 5). In Patient 2 straightening of the vessel was apparent, possibly because of alternate positioning of the neck or because of the effect of the stent-construct (Fig. 5). We hypothesize that without the Solitaire stent in place, the observed foreshortening could have been significantly worse, and may have also resulted in migration of the construct, exposing the aneurysm neck, or causing endoleak.

We have demonstrated the successful use of the PED combined with an anchoring Solitaire stent to treat shallow, wide-neck dissecting pseudoaneurysms of the extracranial carotid artery. In select patients where coil embolization or covered stent-graft placement are not optimal solutions, this novel technique may be considered.

Conflicts of Interest/Disclosures

The senior author (A.M. Malek) has received unrestricted research funding from Codman Neurovascular, Microvention, Stryker Neurovascular, Siemens, Ansys, and CD-Adapco for research that is unrelated to the submitted work. The other authors declare that they have no financial or other conflicts of interest in relation to this research and its publication.

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