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Spontaneous Trevo XP Stent-Retriever Fracture During the Mechanical Thrombectomy for Acute Ischemic Stroke Treatment: A Case Report of a Specific Device Variant and Literature Review

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Abstract

Background— The Trevo® XP stent-retriever (Stryker, Fremont, CA, USA), is a Food and Drug Administration (FDA)-approved device used in stent-assisted mechanical thrombectomy in patients with acute ischemic strokes secondary to large vessel occlusions. Reports of failure/fracture of these devices resulting in retention of the stent-retriever within the patient has led to a recent recall of Trevo® XP stent-retrievers with various sizes by FDA. However, Trevo® XP stent-retriever 3mm x 20mm variant is still considered approved. Here, a case of failure and retention of Trevo® XP stent-retriever 3mm x 20mm variant is presented.

Methods—FDA Manufacturer and User Facility Device Experience (MAUDE) database were searched using a combination of the terms "Trevo," "break," "fracture," and "stent."

Results— A total of 482 reports were scrutinized, which resulted in identification of 45 cases which described fracture in Trevo XP stent-retriever; none of these reports were regarding Trevo® XP stent-retriever 3mm x 20mm.

Conclusion— Stent-retriever failure and fracture is a potentially underestimated, yet serious, complication. Our case report demonstrates that even more recently released devices have the risk of this complication. This highlights the need for further precaution to minimize the risk and improve patient safety.

INTRODUCTION

Mechanical thrombectomy is now standard of care for patients presenting with acute ischemic stroke secondary to large vessel occlusion.[1] Numerous techniques for performing mechanical thrombectomy have been developed including those involving use of a stent-retriever.[2] Known complications of stent-retriever assisted mechanical thrombectomy include intracranial hemorrhage, vessel dissection, vessel perforation, vasospasm, and new emboli to previously unaffected territories.[3] Recently, various size variants of Trevo® XP stent-retriever have been recalled by Food and Drug Administration (FDA) due to reports of fracture and retention. However, Trevo® XP stent-retriever 3mm x 20mm is not particularly recalled and is still considered approved. Here we describe a case of mechanical failure of and retention of this particular product variant that warrants further attention from neurointerventionalists. We also review the incidence of similar Trevo failures as reported to the FDA.

METHODS

This study was conducted with the approval of the Institutional Review Board (IRB). The FDA Manufacturer and User Facility Device Experience (MAUDE) database was queried using a combination of the search terms "Trevo," "break," "fracture," and "stent." 482 relevant entries were accessed, and each one was reviewed for inclusion. Fifteen entries were excluded, as they described failures of a different device used in the same procedure as a Trevo. Out of the remaining 467 entries, 45 cases were identified which described instances of device failure of the Trevo XP stent-retriever resulting in breakage of the stent fragment. The remaining reports were submitted for reasons or failures other than device fracture. Pertinent information and characteristics from each of the 45 cases were then collated and are reported in the Results section.

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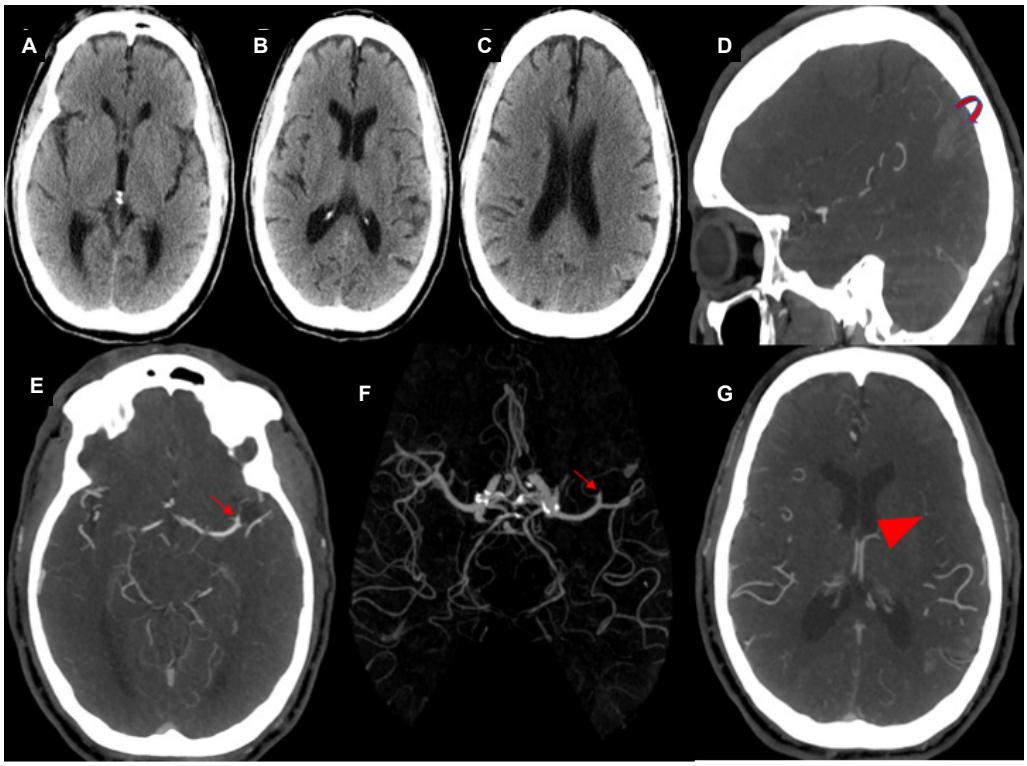

FIGURE 1: A, B, C – Images from initial Non-contrast CT head, demonstrating lack of early infarct changes. D – sagittal and E, F, G – axial images from CTA of the head and neck, demonstrating the occluded MCA branch (arrow), evidence for paucity of flow in the anterior division territory (arrow-head), and likely a small subacute infarct on the parietal lobe with enhancement (curved arrow)

CASE REPORT

A patient in their 50s with newly diagnosed congestive heart failure and atrial fibrillation presented to our center with acute onset right-sided hemiparesis, dysphasia, and confusion. The patient was last known well 5 hours prior and had recently been prescribed warfarin but was not therapeutic at the time. The national institutes of health stroke scale (NIHSS) score was 14 on presentation and emergent noninvasive imaging demonstrated a left middle cerebral artery occlusion with a favorable tissue perfusion profile (Figure 1). Recombinant tissue plasminogen activator was not administered as the patient was deemed outside the therapeutic window. The decision was made by the interdisciplinary stroke team to proceed with mechanical thrombectomy; informed consent was obtained from the family, and the patient was brought emergently to the angiography suite for revascularization.

General anesthesia was induced and transfemoral arterial access was obtained. A 6 French Neuron MAX guide sheath (Penumbra, Alameda, CA, USA) was advanced into the left common carotid artery. Initial angiography of the left internal carotid artery demonstrated an early left middle cerebral artery bifurcation in the horizontal/M1 segment with occlusion of the superior division at the M1 level. The Neuron MAX guide sheath was then advanced into the distal left internal carotid artery and a 5MAX reperfusion catheter (Penumbra, Alameda, CA, USA) and XT-27 microcatheter (Stryker Neurovascular, Fremont, CA, USA) were coaxially advanced over a Fathom-16 microwire (Boston Scientific, Marlborough, MA, USA) into the left internal carotid artery. The microcatheter and microwire were further advanced across the occlusion without difficulty and into the superior division of the left middle cerebral artery (MCA). A 4 x 20 mm Solitaire stent-retriever (Medtronic, Minneapolis, MN, USA) was then deployed across the occlusion and mechanical embolectomy was performed using combination stent-retriever and aspiration with the reperfusion catheter (Solumbra technique).[4] This first pass resulted in Thrombolysis in Cerebral Infarction (TICI) 2A reperfusion, with more distal occlusion still noted within the main trunk of the superior division, at the distal M2 level.

The microcatheter was then advanced across the residual M2 occlusion and a 3 x 20 mm Trevo XP stent-retriever (Stryker, Fremont, CA, USA) was deployed. Mechanical embolectomy was again attempted using a combination of this stent-retriever and aspiration, however upon retracting the Trevo stent-retriever, with minimal felt resistance and vascular distortion, the stent-retriever separated from the pusher wire, leaving the stent-retriever in the superior M2 division. The XT-27 microcatheter and Fathom-16 microwire were then advanced into the M2 branch, adjacent to the Trevo stent and the previously used 4 x 20 mm Solitaire stent-retriever was used in an attempt to retrieve the 3 mmTrevo stent retriever into the reperfusion catheter, without success. Unfortunately, this maneuver resulted in proximal migration of the retained Trevo stent retriever; with the proximal end of the Trevo device moving into the origin of the anterior temporal artery. The XT-27 and Fathom-16 were then advanced a second time into the MCA and an Amplatz Goose Neck microsnare (Medtronic, Minneapolis, MN, USA) was used in a repeat attempt to retrieve the Trevo stent retriever, again without success, primarily due to the inability to access either end of

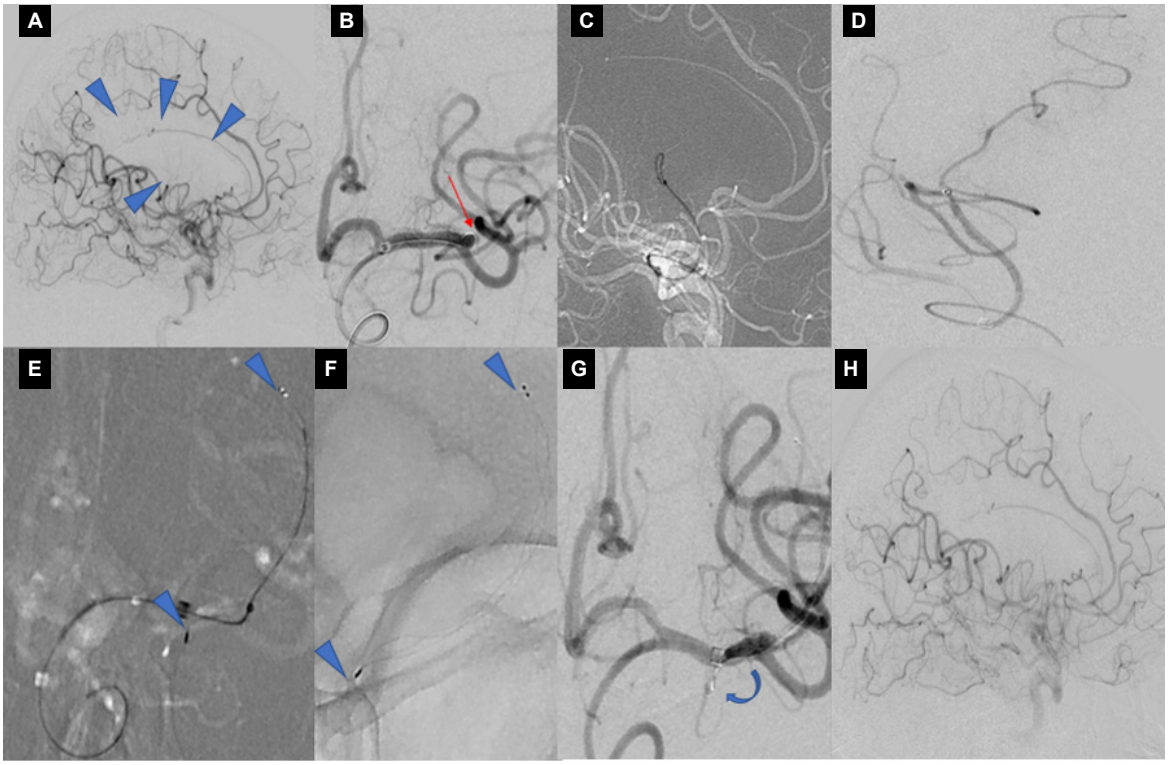

FIGURE 2: A – Lateral view of the left internal carotid angiogram, demonstrating the hypoperfusion in the territory of the occluded Lt MCA branch (arrowheads). B – Magnified AP angiogram, demonstrating the stump of the occluded MCA division (arrow). C – Lateral magnified roadmap, demonstrating the microcatheter placed through the occlusion, with microcatheter angiography. D - Demonstrating patency of the distal branches. E – AP magnified roadmap image and F – AP Fluoroscopic image, demonstrating the Trevo stent-retriever (proximal and distal ends marked by arrowheads). The microcatheter and microwire have been advanced along the stent-retriever, during the attempt to remove the stent-retriever. G – AP magnified angiogram, demonstrating the proximal tip of the stent-retriever (curved arrow) in the anterior temporal artery, with some flow through the stent-retriever. H – Repeat lateral view of L ICA angiogram demonstrating no difference in the area of original hypoperfusion.

the stent-retriever.

Control angiography at this point demonstrated a stable appearance of the intracranial vasculature, with no new occlusions, and stable hypoperfusion of the superior division past the occluded M2 segment (Figure 2). A decision was made to stop the procedure at this point, in order to prevent any vascular damage or perforation from additional attempts at manipulating the retained stent-retriever. All catheters, wires, and sheaths were removed and hemostasis was achieved at the groin puncture site. A flat panel computed tomography (CT) scan was obtained while on the angiography table, which demonstrated stable intracranial findings with no new intracranial hemorrhage (Figure 3). The patient was kept intubated, sedation was reversed, and a neurological examination with lightened sedation was obtained, which demonstrated stable right hemiparesis. The patient was then transferred to the intensive care unit (ICU) in critical but stable condition. Dual antiplatelet treatment (aspirin 325 mg and clopidogrel 75 mg) was initiated in the ICU. The patient's hemiparesis persisted after extubation. Magnetic resonance imaging (MRI) was not obtained due to the retained stent-retriever fragment; although the stent-retriever portion itself is MRI-compatible, the pusher wire contains ferromagnetic material and we could not determine if any of that material had been retained. Follow-up CT angiography demonstrated infarction within the left MCA territory supplied by the occluded M2 segment, with patency of the MCA trunk, posterior division and anterior temporal artery. The patient was ultimately discharged to a subacute rehabilitation facility after percutaneous gastrostomy and remained neurologically stable with little to no improvement. The patient was discharged to home with home health assistance after the rehabilitation period was completed.

RESULTS

Out of 482 reports submitted to the FDA MAUDE database, 45 described device failures similar to the present case. These cases spanned from 10/2012 to 2/3/2020. Twenty-six (57.8%) described incidents where device failure resulted in device retention within the patients' artery. A further 10 (22.2%) reported that the fragments were able to be retrieved, or were otherwise not retained within the patient. The remaining 9 cases (20.0%) did not specify whether the device was retained or not. Four entries (8.9%) reported that tortuous anatomy was encountered during the procedure. Nine cases (20.0%) reported entanglement or involvement of the Trevo device in a previously placed carotid stent resulting in breakage or device failure.

DISCUSSION

Recently, FDA issued a recall of Trevo XP stent-retrievers in 4mm x 20mm, 4mm x 30mm, and 6mm x 25mm due to fracture complaints of the flexible, tapered core wire, resulting in stent retriever separation, from the core wire, and eventual retention. However, 3mm x 20mm variant is not on this list and therefore, is still in use. To the best of our knowledge, there is no previously-reported incident of fracture and

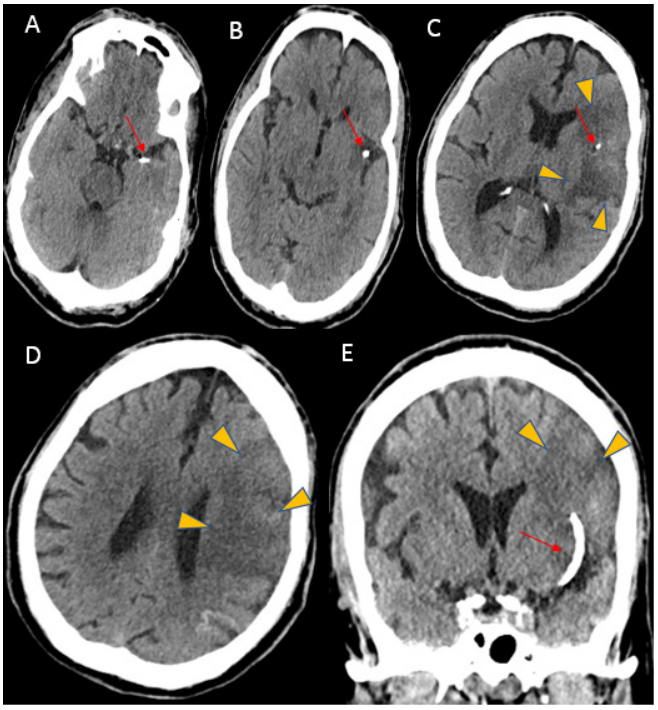

FIGURE 3: A, B, C, D – Axial, and E-Coronal NCCT images the day following the intervention, demonstrating the stent-retriever (arrows) and the area of completed infarction (Arrowheads) in the left frontal lobe, in the territory of the occluded branch

retention of this particular variant in the literature. This highlights further consideration by neurointerventionalists in utilizing this specific product to ensure safety of the patients.

The development of stent-retrievers and aspiration have made mechanical embolectomy much more effective at achieving successful recanalization. However, the addition of more devices adds procedural complexity and potential complications. Some Solitaire stent-retrievers are designed to be detachable, like the Solitaire AB device that is not available in the US, while others such as Solitaire FR are not purposed to be detachable. Notably Trevo stent-retrievers donot have a detachable model.[5] Whereas intracranial hemorrhage, vessel perforation, vessel dissection, and emboli to distant territories have all been described as complications from mechanical thrombectomy.[3] Reports of device failure and stent-retriever detachment has been limited to case reports and small case series.[6-11] Furthermore, all case reports and series have been limited to failure of Solitaire devices; there have been no published studies to date detailing the detachment and retention of a Trevo stent-retriever.

The Trevo Retriever Registry is a Stryker-sponsored, prospective, open-label, consecutive enrollment, multicenter, international registry which enrolled 2,008 patients between 2013 and 2017.[12] They reported only 9 device failures out of 2,008 cases (0.4%), with none having any adverse effect on the patients. Characterizations of each device failure or further details regarding the cases are not available from the publication. A follow-up study from the same registry examining 22 patients with posterior cerebral artery strokes arising from P1 and P2 occlusions, reported only one groin site complication (4.5% complication rate) and no device failures, concluding use of the Trevo stent retriever is safe in the posterior circulation as well.[13]

A Japanese group also reported a retrospective case series of 50 patients using the Trevo ProVue device in settings outside of a randomized controlled trial (i.e. "real-world" uses), and did not report any instances of device failure or detachment in their small sample set.[14] Their study included 24 cases where the large vessel occlusion was found to involve the distal M1 or M2, which are under-represented in the cohorts from randomized controlled trials. They reported inferior "complete revascularization" (as defined as TICI 3) when comparing use of the Trevo stent-retriever for proximal vs distal occlusions (73% vs 33%, p=0.01). However, there was similar "successful revascularization" (defined as TICI 2b or 3) when comparing use of Trevo for proximal vs distal occlusions (88% vs 75%, p=0.28). They also describe the "Half-Trevo" technique in distal M1 or M2 thrombectomies, to protect the fragile distal M1 and M2 vessels. Briefly, this technique involves deploying the minimal amount of stent-retriever to cover the clot and leaving the rest of the stent-retriever sheathed within the microcatheter. Furthermore, they specify that if a maximum of three passes of the Trevo device failed to revascularize the vessel, they would stop using the Trevo and would attempt additional endovascular procedures, such as transluminal angioplasty, direct aspiration by a reperfusion catheter, or mechanical disruption with a microcatheter and microwire, followed by intra-arterial chemical thrombolysis.[14]

Despite these postmarketing registry studies reporting the overall safety and efficacy specifically of the Trevo stent-retriever, there have been reports of device failure from other groups compiling their experience with stent-retriever assisted mechanical thrombectomy. The first report of inadvertent detachment of the Solitaire AB stent was in 2010, before the multiple randomized controlled trials 2015 demonstrated the efficacy of stent-retrievers and when use of stent-retrievers was still experimental or under humanitarian device exemption. This group reported a series of 7 patients who were treated with the Solitaire AB device to assist with mechanical thrombectomy.[15] Of these 7, they reported a device failure in one patient (14.2%); the patient had extreme vessel tortuosity and the Solitaire stent self-detached within the C7 segment of the internal carotid artery (ICA). The patient also demonstrated bleeding in the region of the basal ganglia.

Miteff and colleagues reported a series of 26 patients treated with the Solitaire AB device, of which two cases (7.7%) demonstrated technical difficulties and procedure-related complications associated with using the Solitaire stent.[16] During the second pass, while applying traction to the stent-retriever system, inadvertent stent detachment occurred in the MCA. It was noted that the patient had tortuous vessels and a large embolic burden within both the ICA and MCA. Ultimately, recanalization was achieved with intra-arterial urokinase in this case. The second complication was entanglement of the Solitaire device against a previously deployed carotid stent in the same procedure; this complication was managed by placing a third stent against the carotid wall, jailing the Solitaire stent against the carotid wall, resulting in

an unanticipated retained device.[16]

Dorn and colleagues also reported one case of a Solitaire stent-retriever being inadvertently detached during retrieval out of 104 total cases (0.96%), but this study also included patients in which Solitaires were intentionally detached to treat intracranial stenosis with stent-assisted angioplasty.[17] The SWIFT trial investigators also reported 1 incident of device separation out of 58 total Solitaire deployments (1.7%). The detached Solitaire fragment was retrieved with a rescue snare, with complete recanalization in all treatable vessels and no hemorrhagic transformation.[18] Gascou and colleagues reported device fracture and spontaneous release of the stent-retriever in 2 cases out of their 144 patient series (1.4%). They reported that in both cases, the device was left in place, the patients were placed on long-term antiplatelet therapy, and had a good neurological outcome on discharge. Further case details were not available.[19]

In addition to these reports of device failure from within larger cohorts looking specifically at results of mechanical thrombectomy, there have also been standalone studies detailing stent-retriever failure.[7,8,6,9-11] Thus far, all such studies report failure and detachment of the Solitaire stent retriever.

The first report details unplanned deployment of a Solitaire AB. in an M1 occlusion during the third thrombectomy pass, with resistance felt on retrieval of the stent through the carotid siphon.[6] The stent was detached and retained within the cavernous segment of the ICA along with thromboembolus. Microsnare retrieval and forced suction were both attempted to retrieve the stent, but were unsuccessful. Ultimately, open surgical removal was required; the cause of retention and stent detachment was postulated as part of a stent strut being caught in an atherosclerotic segment of the ICA.[6]

A second group described resistance on withdrawing a Solitaire AB stent deployed across an M1 occlusion; resheathing of the stent into the microcatheter was then attempted, after which spontaneous detachment was observed.[7] After multiple attempts to recanalize the occlusion as well as retrieval of the detached fragment with another Solitaire device, the detached fragment was able to be retrieved by deploying a second stent-retriever in the ipsilateral anterior cerebral artery (ACA). The distal marker of the second Solitaire device was deployed to overlap the proximal struts of the detached fragment; this technique was ultimately successful in removing the detached fragment.[7]

Kinariwala and colleagues reported a similar event, in which a Solitaire FR device was deployed in the M2 division distally into the M1 proximally on the second thrombectomy pass.[10] The middle cerebral arteries were noted to be atherosclerotic at baseline. A sudden loss of resistance was felt, the stent-retriever portion of the device was noted to have detached from the rest of the system, and the pusher wire was retrieved without the distal stent portion. Fragment retrieval was attempted with Amplatz gooseneck snares, but was unsuccessful. The stent fragment was left in situ spanning the M1 segment to the ICA terminus. The patient was started on dual antiplatelet therapy, but died from medical complications on postoperative day seven.[10]

In addition to the case reports above, there are three cases series specifically addressing inadvertent detachment of stent-retrievers.[8,9,11] These three series report failure rates ranging from 0.66%[11] to 3.9%.[9] Interestingly, two of the series, found that older age, vessel tortuosity, and number of passes all increased the likelihood of device failure.[8,9] All three of these series are all retrospective and non-blinded and therefore potentially prone to systematic biases.

Among all the reports above, most cases are related to detachment of the first-generation Solitaire FR device. One study did not specify the model of the solitaire device, while others reported the complication related to one specific model of the stent-retriever (with 2 studies reporting failure of Solitaire AB devices, 2 studies reporting the failure of first-generation Solitaire FR devices and 1 study reporting cases with both Solitaire AB and FR failures). As all the above studies were limited to the Solitaire system, we undertook a review of the FDA MAUDE for any device failures pertaining to the Trevo device, a device that was specifically designed to retrieve thromboembolus and not be detachable. We found 45 entries spanning eight years which described cases of device fracture or breakage similar to our case. Of these, a significant fraction (57.8%) required the device to be left within the patient's anatomy. Tortuous vascular anatomy (8.9%) and entanglement with previously deployed carotid stents (20.0%) were also important associated factors. A significant limitation of these findings is that the FDA MAUDE database is self-reported and has minimal systematization of its entries or data collection. There is also no standardization of the case data or patient characteristics that are submitted to the database. Finally, there are no radiographic images available for review in the dataset. The true number of device failures and fractures of the Trevo stent-retriever is undoubtedly larger than those deposited within the FDA database; the 45 cases we report here are by no means comprehensive.

CONCLUSION

The advantages of adding stent retrieval to direct aspiration during mechanical thrombectomy have been well-described in the literature. However, device failure or fracture of stent-retrievers is a potentially under-recognized complication which warrants further awareness and examination by the neurointerventional community. The cases and series we reviewed above, as well as the case we describe in this report, highlight the frequency with which device failure and fracture is encountered in the "real-world" setting. Furthermore, our case report details device failure with the 3mm x 20mm Trevo stent-retriever, indicating that even more recently released devices run the risk of fracture and retention within the patient. Further iterations of product improvement by medical device companies are needed to minimize such complications and improve patient safety.

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