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Study of Stent Deployment Mechanics Using a High-Resolution X-ray Imaging Detector

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Abstract

To treat or prevent some of the 795,000 annual strokes in the U.S., self-expanding endo-vascular stents deployed under fluoroscopic image guidance are often used. Neuro-interventionalists need to know the deployment behavior of each stent in order to place them in the correct position. Using the Micro-Angiographic Fluoroscope (MAF) which has about 3 times higher resolution than commercially available flat panel detectors (FPD) we studied the deployment mechanics of two of the most important commercially available nitinol stents: the Pipeline embolization device (EV3), and the Enterprise stent (Codman). The Pipeline stent's length extends to about 3 times that of its deployed length when it is contained inside a catheter. From the high-resolution images with the MAF we found that upon the sudden release of the distal end of the Pipeline from a helical wire cap, the stent expands radially but retracts to about 30% (larger than for patient deployments) of its length. When released from the catheter proximally, it retracts additionally about 50% contributing to large uncertainty in the final deployed location. In contrast, the MAF images clearly show that the Enterprise stent self expands with minimal length retraction during deployment from its catheter and can be retrieved and repositioned until the proximal markers are released from clamping structures on its guide-wire thus enabling more accurate placement at the center of an aneurysm or stenosis. The high-resolution imaging demonstrated in this study should help neurointerventionalists understand and control endovascular stent deployment mechanisms and hence perform more precise treatments.

Keywords

Neuro-imaging; Neuro-endovascular image guided interventions; Stent; EV3; Enterprise Stent; Pipeline Stent

1. INTRODUCTION

Approximately 795,000 strokes occur each year in the U.S. [1]. To treat or prevent stroke, self-expanding stents [2–3] can be used and, in the future, perhaps the asymmetric vascular stent [4] as well. The neurointerventionalist needs to know the deployment behavior of each stent in order to place it in the correct position. This study focuses on the deployment of two

important commercial self-expanding neuro-endovascular stents, the Pipeline (EV3 Inc.) embolization device, and the Enterprise stent (Codman and Shurtleff Inc.). The deployment mechanics of these two modern stents were compared using a high-resolution imaging detector, the Micro-Angiographic Fluoroscope (MAF).

2. METHODS AND MATERIALS

A typical stent deployment in a rabbit goes as follows[5]: First the FPD is operated in both fluoroscopy and angiography modes to bring the stent to the location of interest (stenosis or aneurysm) and place it in the center of the field of view and to determine the “optimum” x-ray parameters (as set by the automatic exposure control of the angiographic system). For example, the x-ray tube parameters in fluoroscopy (fluorography) mode were 80kV (80kV), 13mA (160mA), a pulse time of 2.6ms (9ms), and a pulse rate of 20fps (15fps). The MAF detector is then inserted in front of the FPD detector. For the MAF, the x-ray techniques were manually adjusted to provide exposures that were 2 to 3 times those of the FPD, e.g. for fluoroscopy: 80kV, 30mA, and 2.6ms, and for angiography: 80kV, 320mA, and 9ms; however, the exposure was for a much smaller field of view as the x-ray beam was collimated to the field size of the MAF. This increased exposure was used in order to reduce the observed noise for the small pixels. The imaging mode is set to fluoroscopy using CAPIDS (Control, Acquisition, Processing, and Image Display System) [5] and the patient table with the rabbit is slightly adjusted to center the aneurysm in the MAF's field of view. The mode is then set to Roadmap using CAPIDS and mask images are acquired while the contrast is injected into the artery near the ROI. The stent is then deployed using MAF's roadmap mode guidance.

2.1 Stents

The deployment behavior of the Pipeline and Enterprise stents were compared using a high-resolution imaging detector, the Micro-Angiographic Fluoroscope (MAF). The two stents are shown in Figure 1.

The delivery wire for the pipeline stent is shown in Figure 2. The pipeline stent is crimped inside a microcatheter between the proximal pusher and the distal cap. The distal cap captures the distal end of the pipeline stent.

The delivery wire for the Enterprise stent is shown in Figure 3. The proximal markers are crimped inside region "1" of the delivery wire, while the distal markers are crimped inside the distal end of region "2" of the delivery wire. The thick wire proximal to the proximal markers acts as a pusher for pushing the stent forward; the thick bullet shaped portion of the wire distal to the proximal markers acts as a puller to recapture the stent back to the microcatheter for repositioning the stent. Once the proximal markers are deployed, the stent is no longer recapturable.

2.2 MAF

The MAF detector has about 3 times higher resolution than the commercially available flat panel detector (FPD). The MAF detector consists of a 300 μm CsI(Tl) phosphor, a dual-stage micro-channel plate Light Image Intensifier (LII) coupled to a 2.88:1 fiber-optic taper

(FOT) and a fast frame rate, progressive scan, frame-transfer CCD camera. The MAF detector's field of view is nominally 4 cm in diameter and it provides 1024×1024 pixels resolution with 35 microns pixel size and 12 bit depth for each pixel [7–9]. A photo of the MAF is shown in Figure 4. Figure 5 shows the imaging system. The region-of-interest (ROI) detector, MAF, can be inserted in front of the FPD when higher resolution is needed during angiographic or interventional vascular imaging procedures using the detector changer [5].

3. RESULTS AND DISCUSSION

3.1 EV3 Pipeline Stent Deployment

The Pipeline stent consists of 48 braided nitinol strands and has a low porosity designed to divert the blood flow. The stent deployment shown in Fig. 6 was done in the air with the guidance of the high-resolution detector, MAF.

Figure 6 [2] shows that both the spring of the distal cap and the part of the stent inside the distal cap is clearly demonstrated by using MAF; the distal cap is not clearly seen when an FPD is used. During the distal stent deployment, the distal end of the stent retracts back to about 30% of the undeployed length and expands to about 10 times the diameter after the distal cap is removed. For the in-air deployment, the 30% retraction is substantially larger than stent deployment cases for patients. For patient cases, the distal cap is removed when only a small portion of the stent is pushed out of the catheter; in comparison, in our case, about 30% of the stent length is out of the stent-capturing catheter when the distal cap is removed. To avoid the sudden retraction of the distal end of the stent, the neurosurgeon tries to make a best estimate and compress the distal stent somewhat before removing the distal cap since the stent is not retrievable once it is released distally. After the distal cap is removed, the delivery system is advanced inside the microcatheter, and the stent is deployed by pushing the delivery system while retracting the microcatheter. The stent could be deployed shorter than its original length by pushing the stent more than the retraction of the catheter while the stent is covering the aneurysm areas. The proximal deployment of the Pipeline stent is shown in Figure 7.

During the stent proximal deployment, the proximal end of the stent retracts about the length of the expanded stent diameter. The retraction of the proximal end of the stent for in-air deployments is also larger than for stent deployment cases for patients. For patient cases, the neurosurgeon tries to make a best estimate and compress the proximal stent somewhat by pushing the stent more than the retraction of the catheter. The position of the distal part of the stent is not changed during the proximal deployment which means that the interventionalist has to correctly estimate the final central position prior to the release of the distal end and try to minimize the retraction at the proximal end as well.

3.2 Enterprise Stent Deployment

The Enterprise stent deployment is demonstrated inside the vessel of a rabbit. Figure 8 shows the distal deployment of the Enterprise stent. During the deployment, the pusher is kept still to keep the stent in the planned position while the catheter is being retracted. The relative position between the stent and the vessel does not change much longitudinally

which is a significant difference compared to the Pipeline stent deployment shown in Figure 6. Also the stent remains retrievable during the majority of the deployment procedure.

Figure 9 shows the proximal deployment of the Enterprise stent inside the vessel of a rabbit. Similar to the distal deployment, the relative position between the stent and the vessel does not change during the deployment because the stent does not retract longitudinally. Because the relative position between the stent and the vessel does not change during the whole deployment process, for the Enterprise stent, the distal part of the stent can be set to a position so the center of the stent is aligned with the center of the aneurysm or stenosis before deployment and the stent should maintain the proper alignment during the remainder of the deployment; however, retrieval remains possible as long as the proximal markers remain clasped by the extra guide-wire structures that only the MAF was able to visualize.

4. CONCLUSIONS

The deployment behavior of two important commercially available self-expanding endovascular stents was visualized for the first time under high resolution micro-fluoroscopy thus enabling better understanding and control of the stent release mechanisms. MAF high resolution images demonstrate in detail the different deployment behaviors of the Pipeline and Enterprise stents. Since the Pipeline stent is difficult to control and because it contracts in length so strongly, it should be positioned carefully, and pushing the pusher and pulling the catheter should be coordinated so as to avoid the sudden retraction of the stent. Once the distal end is released, it can no longer be retrieved or easily repositioned. The distal part of the Enterprise stent can be set to a position so as to align the center of the stent with the center of the aneurysm or stenosis before full deployment because the stent can be retrieved and repositioned until it is almost completely deployed as indicated by visualizing the proximal markers clasped onto a structure built into the guide-wire. This study demonstrates how neurointerventionalists can be aided in performing more precise stent deployments by visualization of detailed stent delivery mechanisms.

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Figure 1.
Pipeline stent (left), and Enterprise stent (right)[6].

Figure 2.
Pipeline stent delivery wire. Upper left: proximal pusher; upper right: guide wire tip; lower: distal cap.

Figure 3.
Enterprise stent delivery wire.

Figure 4.
MAF Detector.

Figure 5.
Imaging system for stent deployment.

Figure 6. Pipeline distal stent deployment. [1], [3]: before release from the distal cap; [2]: zoomed view of the distal cap; [4]: after sudden almost uncontrolled release from the distal cap the stent is no longer retrievable.

Figure 7.
Pipeline proximal stent deployment. Left: before the proximal deployment; Right: after the proximal deployment the stent is fully released.

Figure 8.

Enterprise stent distal deployment. Left: before deployment; Center: distal markers are seen leaving the deployment catheter; Right: full release of distal end of the stent. Stent is still fully retrievable.

Figure 9.

Enterprise stent proximal deployment. Left: before proximal deployment; Center: proximal markers are still clasped by guide wire structures, the stent is still fully retrievable; Right: full stent deployment with proximal markers hence complete stent is finally released.