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Original Article

Effect of False Lumen Occlusion Treatment With AFX VELA™, Candy-Plug Technique for Chronic Aortic Dissection

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Abstract

Introduction: We sought to examine midterm results and remodeling effect of false-lumen occlusion treatment using AFX VELA in case of chronic dissection repair. **Material and Methods:** From June 2019 to May 2022, we performed false lumen occlusion treatment using a modified Candy-Plug technique with AFX VELA on 8 chronic aortic dissection patients with a patent false lumen. We collected operative data, short-term clinical outcomes, mid-term clinical outcomes and imaging test results. We conducted follow-up examinations at postoperative, 6-month and 1-, 2- and 3-year intervals, including contrast-enhanced computed tomography to evaluate the diameter, false lumen thrombosis and any events. **Results:** The average time from the symptom onset to the thoracic endovascular repair was 81.5 (35-155) months. The aorta showed aneurysmal dilation with an average maximum short-axis diameter of 58.9 (41-91) mm. Two cases needed emergency surgery due to rupture and impending rupture. There were no postoperative deaths. Complete thrombosis within the false lumen was achieved in 6 cases (75%), but 2 cases had incomplete thrombosis, requiring additional treatment. The mean maximum diameter showed a significant decrease at 6 months, 1 year and 2 years postoperatively compared to preoperative measurements ($P < .05$). **Conclusion:** We showed the results of false lumen occlusion treatment using the AFX VELA cuff. We observed favorable clinical outcomes and remodeling effects. While the long-term durability and efficacy of this technique in aortic remodeling will need to be monitored with further observation, the use of this cuff is considered a reliable approach to false lumen occlusion treatment.

Keywords

chronic aortic dissection, thoracic endovascular repair, candy-plug technique, false-lumen occlusion, AFX VELA

Introduction

In Stanford type B aortic dissection, the position of endovascular stent graft treatment as a standard approach is being increasingly established. It is minimally invasive and provides excellent morphological remodeling.[1] However, the results tend to be less favorable in cases of chronic dissection than in acute or subacute cases.[2-4]

True lumen narrowing is often a problem, with a significant diameter difference developing between the proximal and distal treatment zones. Remodeling can be expected by placing a large-diameter device in the distal segment. However, there have been reports of stent graft-induced new entry (SINE),[5] which increases the risk of adverse aortic events due to blood flow into the aneurysmal false lumen.

The Candy-Plug technique, reported by Kölbel et al, involves occluding the patent false lumen with a large closure device to promote thrombosis.[6] The original method used the surgeon's modified ZOOK ZenithTX2 (Cook Medical, Bjæverskov, Denmark) device.

We sought to examine midterm results and remodeling effect of false-lumen occlusion (FLO) treatment using AFX VELA (Endologix LLC., Irvine, CA, USA) in case of chronic dissection repair.

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Material and Methods

From June 2019 to May 2022, we performed FLO treatment in our facility using an AFX VELA[7] on 8 patients with chronic aortic dissection accompanied by a patent false lumen. We performed regular imaging evaluations from the onset of aortic dissection, and surgical indication was determined for cases with a patent false lumen in which at least 3 months had passed since the onset and an increasing trend in the aortic maximum short diameter exceeding 50 mm was seen.

The surgical procedure involved closing the entry site using a stent graft, covering up to the level just above the celiac artery. The graft diameter was oversized by ≤10%, while the distal portion was sized according to the long-axis length of the true lumen. The FLO device was prepared by tying together the tip of the bare stent part and upper edge of the graft part of the AFX VELA (suprarenal proximal extension stent graft) with a 3-0 monofilament (Figure 1). It was guided and deployed into the false lumen to match the height of the distal end of the thoracic endovascular repair (TEVAR) graft. Table 1 shows the patient characteristics.

The patient inclusion criteria and requirements for the candy-plug technique are as follows: (1) patients with aortic dissection that has been present for at least 3 months with patent false lumen beyond the descending aorta, (2) access to the false lumen is possible, and (3) longitudinal length of false lumen just above the celiac artery is 32 mm or less. Exclusion criteria were as follows: (1) no reentry below the celiac artery that accesses the false lumen, (2) infection.

We assessed surgical outcomes and conducted follow-up examinations at postoperative, 6-month and 1-, 2- and 3 year intervals, including contrast-enhanced computed tomography (CT) to evaluate the diameter, false lumen thrombosis and events.

Data comparisons were performed using paired *t*-tests. *P* values <.05 were considered statistically significant.

Figure 1. Candy-Plug false-lumen occlusion device using AFX VELA.

Table 1. Patient Characteristics.

Patient number	N = 8
Age (years)	58 (43-71)
Sex (M:F)	6:2
Indication of treatment	Aneurysmal dilatation (6)
	Impending rupture (1)
	Rupture (1)
Time after onset to TEVAR (months)	81 (32-155)
Maximum diameter of aorta (mm)	57.5 (41-91)

Values are presented as the median (range).

Results

The median time from the onset of aortic dissection to TEVAR was 81.5 (range: 35-155) months, and the median maximum short-axis diameter was 57.5 (range: 41-91) mm. Six patients underwent scheduled surgery for diameter enlargement, while 2 patients required emergency surgery due to rupture and impending rupture. The median follow-up period was 36.5 (range: 13-49) months.

For all of these patients, this was their first TEVAR and they had no prior open procedure. FLO was also performed at the same time during this surgery. The placement of the devices was successful in all patients. The TEVAR devices used were the Medtronic Valiant Captivia (Medtronic Vascular, Santa Rosa, CA, USA) in 4 cases, Valiant Navion (Medtronic Vascular) in 1 case, Gore conformable TAG (W.L. Gore & Associates, Flagstaff, AZ, USA) in 2 cases and Terumo Relay Pro (Terumo Aortic, Sunrise, FL, USA) in 1 case. The FLO device used in all cases was an AFX VELA suprarenal extension 34 mm. In all cases, only 1 FLO device was implanted. Additional procedures included left subclavian artery reconstruction in 2 cases.

No complications related to the central nervous system, such as stroke or paralysis/paraparesis, were observed. There were no major aortic events, such as rupture, retrograde type A dissection (RTAD), or SINE. In this FLO device, most of the length of the graft can be used for sealing, with a 95 mm device allowing 85 mm of sealing. No other surgery-related complications or additional treatments were required during

hospitalization. Two cases had residual flow into the false lumen based on contrast-enhanced CT at discharge. All patients survived and were discharged home. The surgical outcomes are presented in Table 2.

There were no late deaths. At 2 years postoperatively, a type 3b endoleak due to graft failure of the Valiant Navion was observed in 1 case, which required additional treatment. Realigning was performed in this case 2 years after surgery. Two patients with incomplete thrombosis within the false lumen underwent embolization procedures at 6 and 26 months postoperatively. Two emergency surgery cases had good postoperative outcomes. In 1 case, coil implantation was added at 6 months postoperatively, but no additional treatment was given in the other case. In both cases, no postoperative aortic events occurred. Postoperative events are shown in Table 3.

A diameter reduction of ≥5 mm was observed in 4 cases at 6 months after the surgery. No enlargement of the aortic diameter was observed except in cases with EL3b findings. The mean maximum diameter, excluding a case with type 3b endoleak due to graft failure, showed a significant decrease at 6 months, 1 year and 2 years postoperatively compared to preoperative measurements ($P < .05$). There was no statistical difference at 3 years because the number of cases reaching observation was small, but diameter reduction was observed in all cases that reached it. The temporal changes in the maximum diameter of the aorta are shown in Table 4, and the trend in the mean maximum diameter is shown in Figure 2.

Discussion

Treatment for Stanford type B aortic dissection has changed with the introduction of TEVAR. There have been numerous reports highlighting the advantages of TEVAR in cases with rupture or complications.[3,4] Nienaber et al also reported a reduction in aortic-related mortality and events in cases with uncomplicated type B aortic dissection.[8] Furthermore, favorable remodeling effects have been observed. However, in the chronic phase, while the initial outcomes are favorable and the minimally invasive nature remains advantageous, simple closure of the major entry may not lead to favorable remodeling.[2,9-11] TEVAR alone can reportedly achieve complete thrombosis in the false lumen by approximately 55%-88%.[12] Incomplete thrombosis allows residual blood flow, which can maintain the pressure within the false lumen and lead to its expansion.[9,10] In cases where residual pressure persists within the false lumen after chronic TEVAR, expansion is observed in approximately 35% of patients, likely owing to retrograde blood flow from branches located distal to the TEVAR segment.[13]

It is believed that suppressing blood flow into the false lumen can be effective in decreasing the pressure. The Candy-Plug technique is 1 method for FLO treatment, as reported by Kölbel et al.[6] It involves occluding the false lumen with a homemade extra-large vascular plug. The central portion of the COOK Zenith TX2 distal extension stent graft (Cook Medical) was modified with a diameter-reducing suture and reloaded to be placed within the intended segment of the false lumen. After device retrieval, the central lumen was occluded using an Amplatzer Vascular Plug (Abbott, Santa Clara, CA, USA), promoting thrombosis within the false lumen. This technique is relatively simple in terms of procedure and is considered safer than other methods. However, with the Candy-Plug technique, there is a known issue of blood flow residue seeping through the gap between the false lumen wall and the deployed device, leading to gutter leaks. Although several modifications have been attempted,[14-20] the fundamental form remains similar, and this issue has not been completely resolved. Circular stent grafts have not been able to fully occlude this gap in cases of crescent-shaped false lumen morphology (Figure 3A).

Isomura et al reported a method of using the FLO plug with the AFX aortic cuff (AFX VELA).[7] AFX is an endoskeleton

Table 2. Surgical Outcomes.

Case	Indication	Emergency	TEVAR Device	Zone	LSA Reconstruction	Stroke	Paraplegia/ Paraparesis	RTAD	Distal SINE	Incomplete Thrombosis
1	Dilatation	-	Valiant Captivia	3	-	-	-	-	-	-
2	Dilatation	-	Valiant Captivia	3	-	-	-	-	-	-
3	Rupture	+	cTAG	2	+	-	-	-	-	-
4	Dilatation	-	Valiant Captivia	3	-	-	-	-	-	-
5	Dilatation	-	Valiant Captivia	3	-	-	-	-	-	+
6	Dilatation	-	Valiant Navion	3	-	-	-	-	-	-
7	Impending rupture	+	cTAG	3	-	-	-	-	-	+
8	Dilatation	-	Relay Pro	2	+	-	-	-	-	-

Table 3. Postoperative Events.

	Incomplete Thrombosis During Follow-up	EL	Additional Procedures	Reason for Additional Procedures	Months After Surgery When Events Occurred
1	-	-	-		
2	-	-	-		
3	-	-	-		
4	-	-	-		
5	+	-	Coil	Incomplete thrombosis	26
6	-	3b	Relining	EL3b	24
7	+	-	Coil	Incomplete thrombosis	6
8	-	-	-		

Table 4. Changes in Maximum Diameter.

Case	Pre	Post	POM 6	POY 1	POY 2	POY 3
1	59	57	50	49	48	46
2	53	52	47	49	49	49
3	52	52	53	51	51	51
4	41	40	38	38	38	38
5	60	61	52	52	44	41
6	56	57	58	59	63	
7	91	87	83	79	77	
8	59	56	55			
Mean maximum diameter (mm)	58.9	57.8	54.5[a]	53.9[a]	52.9[a]	45.0
Mean amount of decrease (mm)	-	−1.1	−4.4	−5.0	−6.0	−13.9

[a]Significant difference compared to "pre." ($P < .05$).

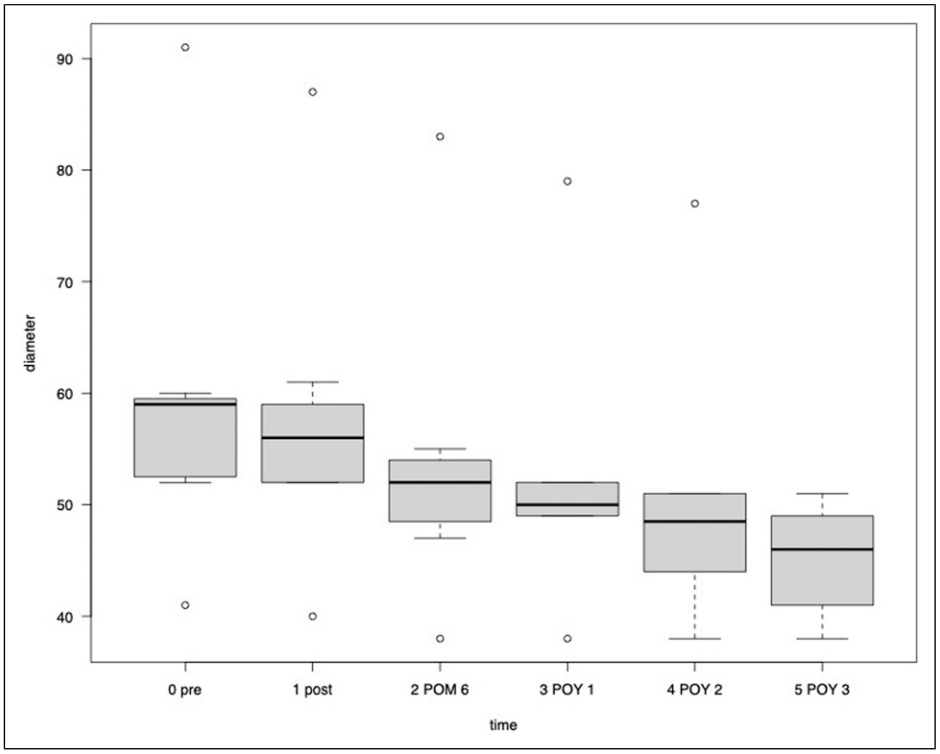

Figure 2. Box plot of changes in the maximum diameter without the EL3b case.

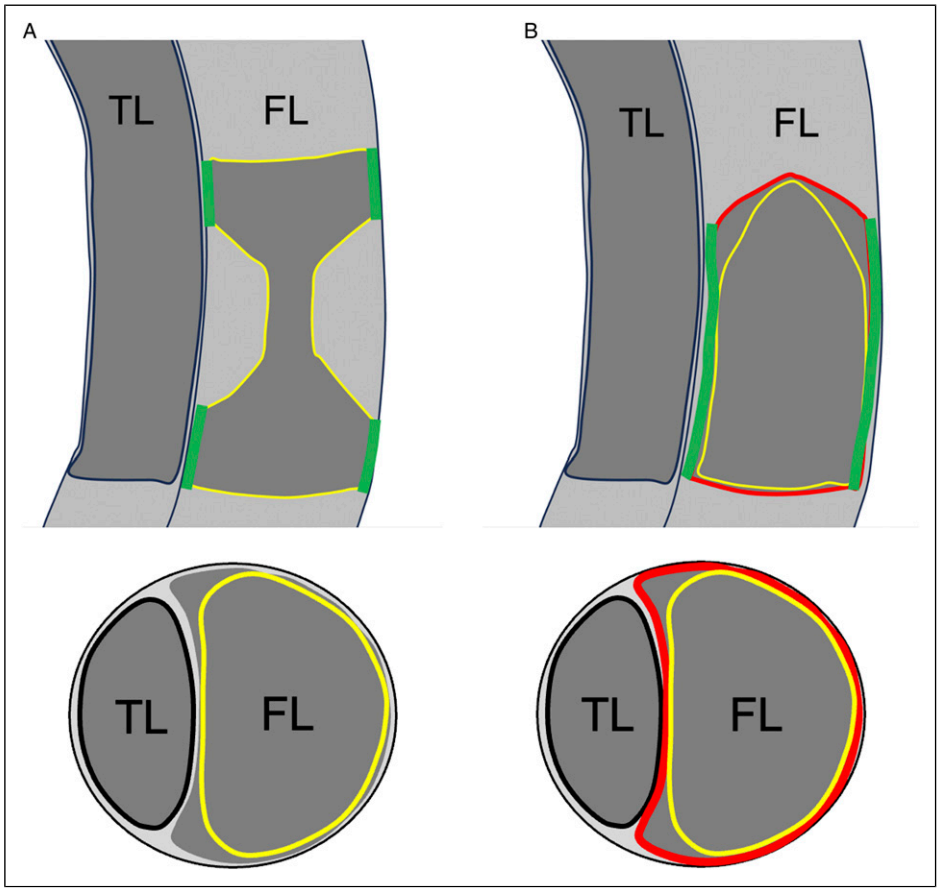

Figure 3. (A) Conventional FLO devices have not been able to fully occlude this gap in cases of crescent-shaped false lumen morphology. (B). This FLO device is an endoskeleton graft that expands like a sail when exposed to blood flow. By using this, the blood flow within the false lumen is blocked. The graft is adapted to fit a crescent-shaped lumen, and uses the reverse flow within the false lumen rather than relying on an endoskeleton structure. In addition, unlike the conventional Candy-Plug technique, the unligated central portion forms a long sealing area within the false lumen. Yellow line; Skeleton of FLO device, Green line; Attachment part to the wall of false lumen. Red line; Attachment part to the wall of false lumen using graft expansion.

graft that expands like a sail when exposed to blood flow due to its active seal. By occluding this homemade large plug, the blood flow within the false lumen is blocked. The graft is adapted to fit a crescent-shaped lumen, enhancing its adaptability, and uses the reverse flow within the false lumen rather than relying on an endoskeleton structure. In addition, unlike the conventional Candy-Plug technique, the unligated central portion forms a long sealing area within the false lumen (Figures 3B and 4).

In our study, we treated 8 cases of chronic dissection using this technique and conducted follow-up observations. Complete thrombosis was achieved in 6 out of 8 cases (75%) during the follow-up period, and at 6 months postsurgery, a reduction of ≥5 mm in the size of the false lumen was observed in 4 cases, indicating this approach to be extremely effective. We attribute this success to the excellent adaptability to the crescent-shaped lumen provided by the active seal.

However, 2 cases experienced incomplete thrombosis and required additional treatment. Complete thrombosis was achieved by occluding the gutter portion with coils or plugs in these cases. We believe that these cases had undersized AFX VELA devices (maximum diameter of 34 mm) compared to the false lumen morphology. Previous reports have used devices with diameters ranging from 36 to 46 mm. Despite the smallest diameter among the reported methods, the high rate of complete thrombosis achieved with the devices used in our study can be attributed to their unique characteristics. In addition, even in cases requiring additional treatment, it was very easy to occlude the gutter leak.

Furthermore, no cases of distal SINE occurred postoperatively. Although Furukawa et al expressed concerns about new intimal injuries at the lower edge of the candy plug,[21] we observed no such cases with our technique. This can be attributed to the ability of AFX VELA to seal without relying on the stent skeleton, as it maintains its seal using the patient's own blood pressure, avoiding unnecessary expansion force. In addition, by placing the device to match the height of the true lumen, the potential forces that could cause mutual intimal injuries are balanced.

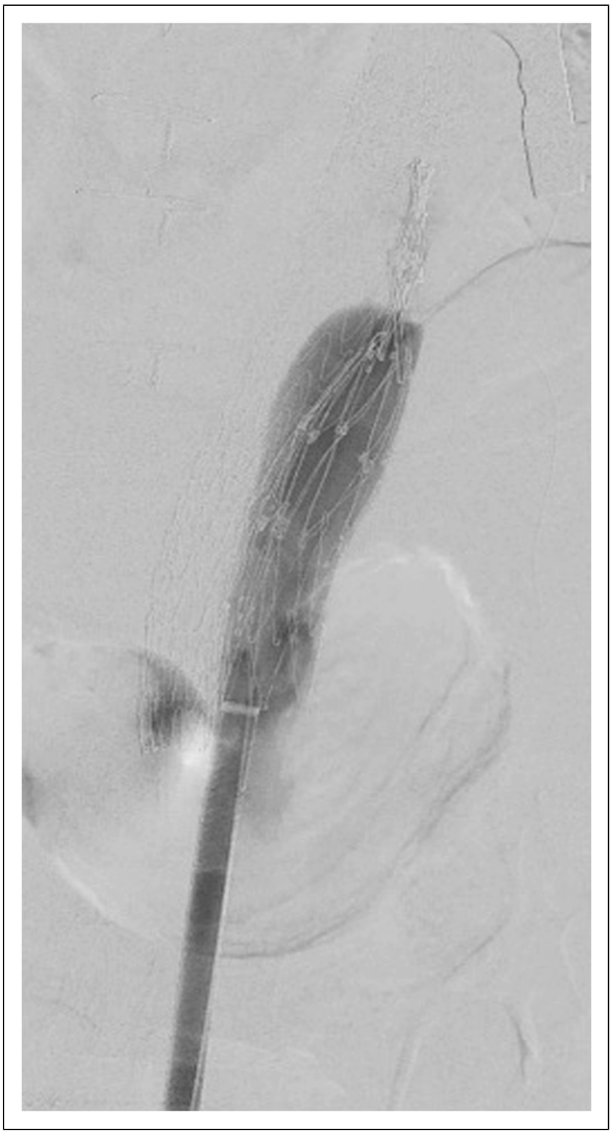

Figure 4. Intraoperative digital subtraction angiography of case 3: The FLO device had expanded in a sail-like fashion, completely blocking the retrograde blood flow into the false lumen.

However, it should be noted that the limited availability of cases due to the maximum diameter of 34 mm and the dependence on sealing using retrograde blood flow raise concerns about migration toward the central segment. Careful follow-up observations will continue to be necessary.

The modified Candy-Plug technique using AFX VELA achieved a high rate of complete thrombosis and reduction in the size of the false lumen, suggesting that it is a good approach to FLO treatment.

Conclusion

We performed the "Candy-Plug" technique and FLO treatment using the AFX VELA cuff and observed favorable outcomes and remodeling effects in this study. While the long-term durability and efficacy of this technique in aortic remodeling will need to be monitored with further observation, the use of this cuff is considered a reliable approach to FLO treatment.

Declaration of Conflicting Interests

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Informed Consent

Written informed consent was obtained from all patients.

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