

Initial clinical experience of CrossBoss catheter for in-stent chronic total occlusion lesions

A case report

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Abstract

Background: The CrossBoss coronary chronic total occlusion (CTO) crossing catheter has been demonstrated to have greatly improved the success rate of crossing CTO lesions, but there are no published data on its application for in-stent CTO lesions.

Methods: In the current study, we retrospectively reviewed the clinical data of 8 patients with in-stent CTO lesions that were managed with the CrossBoss catheter and herein we report the efficacy and safety of the CrossBoss crossing and re-entry system for this clinically challenging condition.

Results: The CrossBoss catheter was used for 8 patients with in-stent CTO lesions, which resulted in success in 6 cases and failure in 2 cases, with a 75% success rate. Of the 6 patients with successful treatment, 5 cases had the occlusive lesions crossed with the CrossBoss catheter through a proximal lumen-to-distal lumen approach, whereas the remaining case had his occlusive lesions penetrated by the CrossBoss catheter and the guidewire. Two cases failed in treatment as the CrossBoss catheter could not cross the occlusive lesions. The 6 cases with successful treatment included 3 cases with occlusive lesions in the left anterior descending artery, 1 case with occlusive lesions in the obtuse marginal branches, and 2 cases with occlusive lesions in the right coronary artery, and the 2 cases with failure in treatment had their occlusive lesions in the right coronary artery. In addition, patients with a higher Japan chronic total occlusion score were found to have a lower success rate of crossing the occlusive lesions. None of the patients developed complications.

Conclusion: Our study demonstrates that the CrossBoss catheter has a high success rate and is safe for in-stent CTOs and can be recommended for this rather clinically challenging condition.

Abbreviations: CABG = coronary artery bypass grafting, CTOs = chronic total occlusions, MACE = major adverse cardiac events, PCI = percutaneous coronary intervention.

Keywords: CrossBoss catheter, in-stent chronic total occlusion, intervention, percutaneous coronary, tortuosity

1. Introduction

There are 20% to 30% of coronary heart disease patients require percutaneous coronary intervention (PCI) because of chronic total occlusions (CTOs).^[1,2] Though an ever-growing and impressive array of dedicated guidewires have become available, the success rate still hovers around 70% in most studies^[3,4] and may be as low as 49% as reported in the SYNTAX trial,^[5] with failure to cross a wire being a major contributor to an unsuccessful PCI for CTO. Furthermore, the risk of stent

thrombosis after stent implantation remains high despite antithrombotic therapy and CTOs due to in-stent CTO lesions account for up to one-quarter of all PCI for CTO.^[6,7] However, PCI for in-stent CTO suffers from a low success rate due to challenges with wire and balloon crossing.^[8] Soft guidewire may fail to cross the fibrous calcified tissues in the occlusion, whereas hard guidewire may penetrate the stent mesh and even penetrate through the vascular wall due to poor controllability.

The Boston Scientific Coronary CTO Crossing System, which was first introduced in 2008, consists of the CrossBoss catheter, the Stingray balloon, and the Stingray guidewire.^[9] Unlike guidewires, the CrossBoss catheter has a hydrophilic coated shaft and a blunt 1.0 × 1.0-mm olive tip, which blocks the catheter tip from penetrating through the stent mesh. Furthermore, the visual structure of the stent guides the moving direction of the CrossBoss catheter. Even if penetrating through the stent region and entering the subintimal region to form a dissection, the CrossBoss catheter may re-enter the lumen by using the stingray balloon and the stingray guidewire.^[9] The CrossBoss coronary CTO crossing catheter has been shown to have greatly improved the success rate of crossing CTO lesions^[11] and even for patients refractory to conventional PCI, the CrossBoss catheter has achieved a high success rate without compromising safety as reported in the FAST-CTOs trial.^[10] Nevertheless, scant knowledge is available about the efficacy and safety of the CrossBoss catheter for in-stent CTO lesions. The FAST-CTOs trial also excluded this subset of patients from the study.

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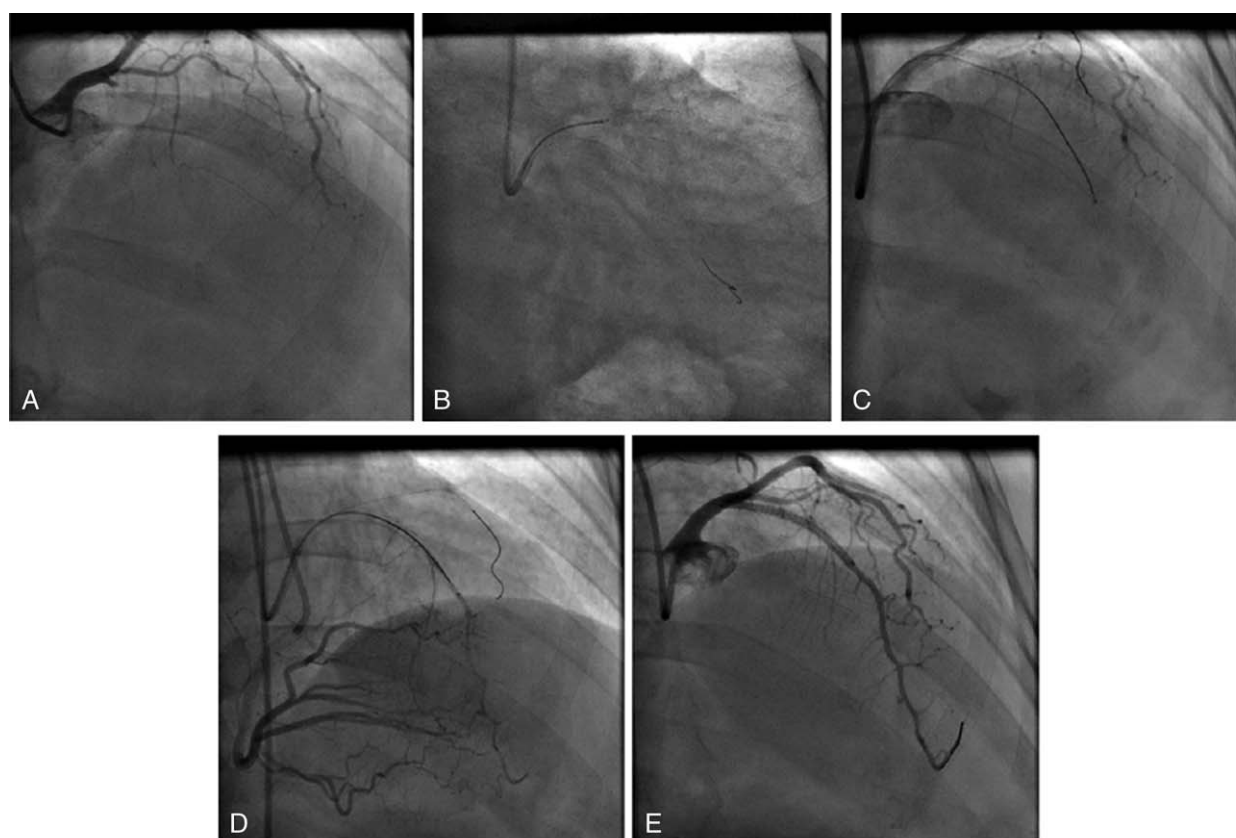


Figure 1. Procedure of a left anterior descending artery (LAD) in-stent CTO using the Corssboss catheter in 1 case. (A) Angiography shows that the proximal stent of the LAD is occluded in a 55-year-old male patient. CrossBoss is pushed to the proximal segment of the occlusion lesions (B) and then rapidly rotated to pass occlusion lesions completely (lumen-to-lumen) (C). Reverse angiography shows that the CrossBoss is in the true lumen (D). (E) Angiography after stent implantation. CTOs = chronic total occlusions, LAD = left anterior descending.

In the current study, we retrospectively reviewed the clinical data of 8 patients with in-stent CTO lesions that were managed with the CrossBoss catheter and herein we report the efficacy and safety of the CrossBoss crossing and re-entry system for this clinically challenging condition.

2. Patients and methods

2.1. Patients

In this study, we reviewed the clinical records of 2429 coronary heart disease patients who were seen at the Second Hospital of Jilin University between January 2015 and December 2015 and had undergone PCI due to in-stent restenosis and were managed with the CrossBoss catheter. In-stent CTO was considered present if the occlusion was located within a previously placed stent or within the 5-mm margins proximal and distal to the stent. The study protocol was approved by the local institutional review board at the authors' affiliated institution and no patient consent was required of the patients due to the retrospective nature of this study.

2.2. The procedure

Patients with in-stent CTO were treated with aspirin (100 mg/day) and clopidogrel (75 mg/day) before angiography for at least 5 days. During the procedure, intravenous heparin was given to maintain an activated clotting time of > 250 seconds. The radial or femoral approach and 6 F or 7F guiding catheters were left to

the operator. Corssboss was used initially or after the conventional method failed. When the wire passed the occlusion lesions, drug eluting stent or drug eluting balloon was used. Example of the procedure of a left anterior descending artery (LAD) in-stent CTO using the Corssboss catheter was shown in Fig. 1, with procedure of a right coronary artery (RCA) in-stent CTO using the Corssboss catheter shown in Fig. 2. After the procedure, patients were maintained on aspirin 100 mg and clopidogrel 75 mg daily.

2.3. Patient evaluation

The Multicenter CTO Registry of Japan J-CTO (Japan chronic total occlusion) score was calculated for each lesion based on occlusion length, stump morphology, the presence of calcification, presence of tortuosity, and prior attempt to open the CTO.^[3] Total procedure time and utilizing CrossBoss time were recorded.

Technical success was defined by a final TIMI 3 flow and <30% residual stenosis, whereas procedural success was defined as technical success without major adverse cardiac events (MACE). MACE (cardiac death, myocardial infarction, target lesion revascularization, or emergency bypass surgery) were recorded through 30 days post-procedure.

2.4. Statistical analysis

Continuous parameters were reported as median (range) if they were not normally distributed. Discrete parameters were reported

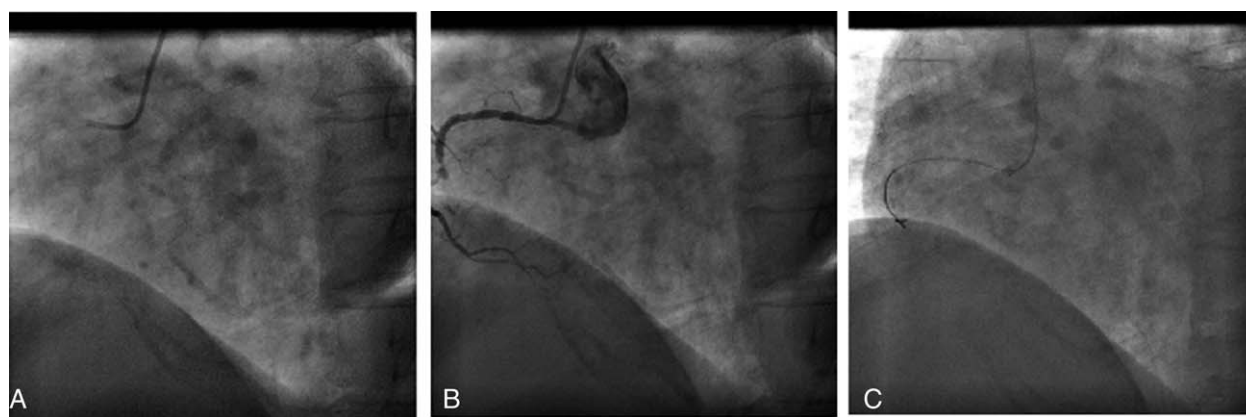


Figure 2. Procedure of a right coronary artery (RCA) in-stent CTO using the Corssboss catheter in 1 case. (A) and (B) The stent in the middle of the RCA is occluded in a 55-year-old male patient. The first turn of the RCA is highly tortuous (B, the bending degree is 63.8). The guiding catheter dropped from the opening of the coronary artery when the CrossBoss catheter was pushed forward. CTOs = chronic total occlusions, RCA = right coronary artery.

as percentages. Comparison between subgroups was made using the Mann–Whitney *U* test (Wilcoxon rank-sum test). All analyses were performed using SPSS 19.0.

3. Results

3.1. Demographic and baseline characteristics of the study subjects

Between January, 2015, and December, 2015, 2429 coronary heart disease patients underwent PCI at our hospital, of which 232 patients were attributable to CTO. Eight of them underwent revascularization with the CrossBoss catheter owing to in-stent CTO. The demographic and baseline data of these patients are listed in Table 1. Their median age was 60.8 (range 52–71) years and the majority of them (75%, 6/8) were male. The median duration of vascular occlusion was 14 (range 4–36) months. Occlusion existed in the left anterior descending artery in 3 patients, the obtuse marginal branches in 1 patient, and the right coronary artery in 4 patients. No

patients had a history of chronic kidney disease. None of the patients attempted to have the in-stent CTO lesions crossed, and none underwent Coronary Artery Bypass Grafting (CABG).

3.2. Treatment outcomes

The median total procedure time was 49 (range 20.0–86.4) minutes and the median duration of using CrossBoss time was 10.5 (range 1.65–45.0) minutes. The angiographic data of the patients are shown in Table 2 and imaging and surgical features of each patient are listed in Table 3. Both technical and procedural successes were achieved in 6 cases (75%, 6/8). Technical success was achieved in 5 patients via the lumen-to-lumen approach (J-CTO score = 1). For these patients, the median procedure time for using the CrossBoss catheter was 2.65 (range 1.65–5) minutes. In the remaining patient, the CrossBoss catheter partially crossed the occlusive lesion, and subsequent use of the guidewire finally resulted in successful crossing of the CTO lesions (J-CTO score = 2). The median

Table 1
Demographic and baseline characteristics of the study subjects.

	All subjects	Success	Failure	<i>P</i>
N	8	6	2	
Age, y				0.627
Median, range	60.8 (52–71)	61.8 (58–71)	57.5 (52–63)	
Male gender, N	6	5	1	0.641
Symptoms	8	6	2	
Tobacco use, N	2	1	1	0.641
LVEF, SD	59 (8.5)	57.5 (9.2)	63.5 (4.9)	0.699
Occlusive vessel, N				
LAD	3	3	0	–
OM	1	1	0	–
RCA	4	2	2	0.264
Duration of occlusion, months				0.577
Median, range	14 (4–36)	11.7 (4–21)	21 (6–36)	
Hypertension, N	2	2	0	0.641
Diabetes, N	3	3	0	0.449
Prior CABG surgery	0	0	0	
Prior attempt to recanalize CTO	0	0	0	

CABG = coronary artery bypass graft, CTO = chronic total occlusion, LAD = left anterior descending artery, LVEF = left ventricular ejection fraction, OM = obtuse marginal branches, RCA = right coronary artery.

Table 2

Angiographic characteristics of the study subjects.

	All subjects	Success	Failure	P
Duration of stenting, month	42.2 (13.7–82.4)	43.5 (15.0–82.4)	41.8 (13.7–77.9)	0.424
Occlusion length, mm				0.482
Median, range	45.2 (33.9–63.3)	42.5 (33.9–63.3)	53.4 (48.7–58.1)	
Bending, degree	28.3 (1.9–63.8)	18.1 (1.9–47.5)	58.8 (53.7–63.8)	0.085
Straight opening	2	1	1	0.641
Duration of surgery, min	49 (20.0–86.4)	47.2 (20.0–86.4)	54.5 (45.0–64.0)	0.922
Duration of using CrossBoss, min	10.5 (1.65–45.0)	5.7 (1.65–15.75)	25 (5–45)	0.272
7F catheter	7	5	2	0.827
J-CTO score				0.072
Median, range	1.5 (1–3)	1.1 (1–2)	2.5 (2–3)	

J-CTO = Japan chronic total occlusion.

procedure time for using the CrossBoss catheter was 10.33 minutes. All 3 patients who had in-stent CTO lesions at the left anterior descending artery and the patient who had in-stent CTO lesions at the obtuse marginal branches achieved technical success. Technical success was obtained in 2 patients (50%, 2/4) who had in-stent CTO lesions at the right coronary artery. Five patients who achieved technical success had a J-CTO score of 1 and 1 patient with technical success had a J-CTO score of 2.

The CrossBoss catheter did not manage to cross the occlusive lesions in 2 cases, and the procedure time for using the CrossBoss catheter was 15.75 and 45 minutes, respectively. Their J-CTO score was 2 or 3.

3.3. Safety

No MACEs were documented.

4. Discussion

PCI for in-stent CTO is clinically challenging and suffers from a low success rate. As a recently developed apparatus for CTO lesions,^[9] the CrossBoss catheter has a hydrophilic coated hollow metal shaft and a blunt 3F tip. When the apparatus at the tail of the catheter is rapidly rotated, the apparatus at the tip may cross the lesions without penetrating through the vascular wall, allowing the CrossBoss catheter to cross the lumen or subintimal region to reach the distal occlusive lesions.^[11] Though the CrossBoss catheter has been shown to improve the success rate of revascularization of CTOs refractory to conventional PCI in the FAST-CTOs trial, scant data are available on the efficacy and

safety of the CrossBoss catheter in in-stent CTO patients. We report in-stent CTOs treated with the CrossBoss catheter and achieved a technical success rate of 75% (6/8), which is comparable to the rate reported for in-stent CTOs.^[11,12] We also noted no MACEs in our patients. Our study demonstrates that in in-stent CTOs, the CrossBoss catheter has a high success rate and is safe.

The CrossBoss catheter may directly cross the lumen to reach the distal vascular lumen in ~20% to 30% of patients with coronary CTO.^[10] If the CrossBoss catheter crosses the occlusive segment via the subintimal region, combining stingray balloon and hard guidewires may re-enter the distal vascular lumen. After the CrossBoss catheter crosses the occlusive segment, the guidewire may reach the distal lumen via the hollow shaft of the catheter. In 5 of our patients, the CrossBoss catheter completely crossed the occlusive lesions. The CrossBoss catheter only partially crossed the occlusive lesions in 1 case and failed to cross the bending segment of the occlusive lesions in 2 cases with technical failure. Our success rate of 75% for crossing in-stent CTO lesions by the CrossBoss catheter was lower than that reported by Wilson and James (90%)^[11] and Papayannis et al (83%).^[12] Wilson and James^[11] reported that the CrossBoss catheter reached the distal lumen from the proximal lumen via the occlusive segment in 88% of patients with successful treatment, which is comparable to our data (83.3%, 5/6) but higher than that (41.5%) reported by Papayannis et al.^[12] In the remaining patients, the CrossBoss catheter crossed the occlusive segment with the help of guidewires after crossing the proximal fibrous cap, or the CrossBoss catheter entered the distal subintimal region and then re-entered the lumen by using the stingray balloon. In our series, the CrossBoss catheter did not enter the

Table 3

Imaging and surgical features of the study subjects.

Case	Target vessel	Calcification	CTO length, mm	Opening shape	CTO bending	Previous PCI	J-CTO score	Interventional approach	Collateral circulation	Retrograde radiography	Duration of surgery	Duration of CrossBoss	Lumen -to-lumen	Success
1	LAD	No	46.1	Sharp	18.1	No	1	Radial artery	Yes	No	27.1	1.92	Yes	Yes
2	LAD	No	63.3	Sharp	24.3	No	1	Radial artery	No	No	62.35	1.65	Yes	Yes
3	LAD	No	37.7	Straight	13.8	No	1	Femoral artery	Yes	Yes	45	5	Yes	Yes
4	RCA	No	34.1	Sharp	3.4	No	1	Femoral artery	Yes	Yes	86.42	1.78	Yes	Yes
5	RCA	No	33.9	Sharp	47.5	No	2	Femoral artery	Yes	No	37.8	10.33	No	Yes
6	OM	No	39.7	Sharp	1.9	No	1	Femoral artery	Yes	No	20.03	2.92	Yes	Yes
7	RCA	No	58.1	Sharp	53.7	No	2	Femoral artery	Yes	Yes	49.3	15.75	No	No
8	RCA	No	48.7	Straight	63.8	No	3	Femoral artery	Yes	No	64	45	No	No

CTO = chronic total occlusion, J-CTO = Japan chronic total occlusion, LAD = left anterior descending artery, OM = obtuse marginal branches, RCA = right coronary artery.

subintimal region in all subjects with successful crossing, and no re-entry technique was used. We speculated that the high success rate of our series was partially attributed to the low J-CTO score (mean 1.5; median, 1; range 1 to 3) of our patients, which is usually considered as a predictor of the outcome of interventional therapy.^[11] Patients who had their CTO lesions successfully crossed without resort to the use of the guidewire had a J-CTO score of 1 whereas those who failed in the attempt had a J-CTO score of 2 or 3.

All 3 patients with in-stent CTO in the left anterior descending artery achieved technical success. Only 2 (2/4) cases with in-stent CTO in the right coronary artery had technical success. Compared with the anterior descending artery, there are 2 turns in the right coronary artery, which has a high bending degree. In 2 cases with failure in treatment, the tortuosity of the lesions in the right coronary artery were more than 45 degrees, which has been reported to depress the success rate of crossing the CTO lesions.^[13] Tortuosity decreases the forward pushing force of the CrossBoss catheter, jeopardizing its ability to cross the occlusion. Wilson et al^[7] found that most patients with failure in crossing had extremely tortuous occlusions. One other contributor to our success rate is the lack of apparent calcification at the occlusion in our patients, which is a predictor of failure in interventional therapy. The CrossBoss catheter has difficulty penetrating severely calcified lesions.

In this study, no coronary artery perforation occurred, and the CrossBoss catheter did not cross the stent mesh to enter the subintimal region, indicating that the CrossBoss catheter is safe for in-stent CTO lesions. To date, there is but 1 case report describing the crossing of the CrossBoss catheter through the stent mesh to enter the subintimal region in a patient with in-stent CTO lesion.^[14] One limitation of our study is the small size of the study cohort and the applicability of our experience is restricted by the fact that the patients came from a single tertiary care center. Because financial factors, not all in-stent CTOs were managed with the CrossBoss catheter because the CrossBoss catheter is very expensive, contributing to the small size of the study cohort.

In conclusion, our study implied that the CrossBoss catheter has a relatively high success rate and is safe for in-stent CTOs and might have the potential to be recommended for this rather clinically challenging condition.

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