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STAR procedure becomes SAFER first-in-man case series of a new antegrade dissection re-entry technique

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Abstract

Introduction: Antegrade dissection and re-entry (ADR) is an integral part of the hybrid algorithm, which has allowed for improved outcomes in chronic total occlusion (CTO) coronary intervention (PCI).

Methods: A new ADR method, Subintimal Antegrade FEnestration and Re-entry (SAFER), is described. The results of a first-in-man series are presented.

Results: SAFER was performed on seven consecutive patients with angiographic and clinical success in all patients.

Conclusions: This first-in-man study has shown that the SAFER technique is feasible and effective with the possibility of improving the antegrade PCI CTO success rate.

KEYWORDS

antegrade dissection re-entry, chronic total occlusion, percutaneous coronary intervention

1 | INTRODUCTION

The last two decades have witnessed marked advancements in percutaneous coronary intervention (PCI) for chronic total occlusion (CTO) due to the development of dedicated devices and techniques, and procedural strategies, particularly the "hybrid algorithm."[1] Antegrade dissection and re-entry (ADR) is an integral part of the original hybrid algorithm and its subsequent modifications.[1,2] ADR involves crossing of a CTO lesion with a guide wire and/or equipment in the subintimal or extra-plaque space (EPS) followed by guidewire re-entry into the true distal lumen, with or without the assistance of dedicated device, followed with ballooning and/or stenting. ADR has helped to improve procedural success to approximately 90% compared with historical series where success rates has varied between 50% and 75%.[3,4] The first successful coronary wire-based ADR technique, adapted from peripheral CTO intervention, was described by Colombo as the Subintimal Tracking and Re-entry or STAR technique.[5] The technique was shown to be moderately effective but suffered from the unpredictability of the re-entry point into the true lumen and often resulted in a long EPS dissection with accompanying intra-EPS hematoma, which, in turn, generated permanent occlusion of side branches and impaired final TIMI flow. Early modifications in an attempt to improve outcomes, including contrast-guided STAR[6] and Mini-STAR[7] were ineffective because they did not resolve what is the main and most common cause of failure of ADR techniques, namely EPS hematoma.

An important evolution of the original STAR technique has been the concept of "deferred stenting." Carlino et al. demonstrated that suboptimal (less than TIMI 3) angiographic flow grade after stenting was the primary driver of restenosis after successful STAR.[8] In such cases with suboptimal flow after balloon angioplasty, a two-step strategy of deferred stenting was suggested. Visconti et al. found that if stenting was not performed immediately, 70% of patients maintained TIMI 3 flow at 3-month angiographic follow-up, with the frequent reappearance of side branches originating from the dissected segment.[9] This strategy led to confirmation of the importance of good TIMI flow at procedural completion, with subsequent reduction in total stent length required (as compared with the conventional one-step STAR technique) with improved clinical outcomes. Further confirmation of the utility of STAR as a "rescue strategy" without stent implantation after ballooning (in preparation for a repeated attempt of CTO PCI after 2–3 months) was confirmed by the description of the so-called "subintimal plaque modification" (SPM) also known as an "investment procedure."[10,11]

The next wire-based ADR development was the antegrade fenestration and re-entry technique (AFR) involving EPS ballooning at the level of the distal cap to create fenestrations, at least transiently, that could be traversed by a polymer-jacketed wire for true lumen re-entry.[12,13] In contrast to STAR and all the other wire-based ADR techniques (where the re-entry site is unpredictable), AFR was meant to allow for a more predictable re-entry in a targeted area (the balloon inflation site). When unsuccessful, this maneuver can still serve as a CTO modification procedure, as well as enlarging the EPS for a retrograde approach. While successful in many cases,[12,13] the limitation of AFR was that the fenestrations created by balloon inflation might only be transient and, therefore, less likely to be successfully engaged with a guidewire.

This report describes the first-in-man case series of a modification of the AFR technique that overcomes the limitations of previous ADR methods, which suffered from EPS hematoma formation, by eliminating it through the creation of larger and longer-lasting fenestrations between the false and the true lumen. We named this technique "Subintimal Antegrade FEnestration Re-entry (SAFER)."

2 | METHODS

2.1 | Rationale for a new ADR technique

Success in any ADR procedure relies upon two critical technical considerations: "inflow management" defined as blood ingress into the proximal connection (intentional or unintentional) between the true lumen and EPS and "outflow management," defined as optimal blood drainage from the EPS space into the true lumen. Excessive inflow and reduced outflow will interact to establish and maintain a large EPS hematoma. Current ADR techniques which fail to establish proper inflow will lead to an enlarging EPS hematoma formation driven by blood into the EPS under systemic pressure. Failure to provide adequate outflow will lead to progressive flow stagnation in the EPS, leading to further hematoma expansion and side branch pruning.

As the guidewire navigates the EPS through the full lesion length, unless spontaneous re-entry of the wire occurs, there will be no outflow into the true lumen: antegrade blood pools in the EPS, enlarging the EPS hematoma. Successful wire re-entry into the true lumen may not effectively drain the EPS because distal outflow is limited by the small size of the exit hole. Thus, it is intuitive that enlarging the outflow as early and as expansively as possible will improve EPS blood outflow into the true lumen, which may, in turn, prevent the loss of side branches and compression of the true lumen from the hematoma itself. All ADR techniques so far have focused their effort on distal wire re-entry and have not specifically addressed EPS hematoma drainage by relying on successful distal wire re-entry as the sole mechanism to clear hematoma.

The SAFER technique uses repetitive balloon inflations in the EPS along the entire length of the occlusion and across the distal cap of the CTO to establish multiple connections or fenestrations between the EPS and the true lumen through controlled tearing of the dividing layer, typically quite thin (~30 μm). By creating extensive connections as early and as widely as feasible, EPS blood will flow back into the true lumen with effective drainage of the hematoma responsible for the true lumen compression, clinically apparent as suboptimal or absent TIMI flow. Multiple EPS inflations of the balloon along the entire occlusion will generate multiple tears along the dissection flaps separating the false and true lumen, which will restore the blood flow into side branches and will provide the guidewire with several openings for successful re-entry into the true lumen. Balloon angioplasty in the EPS requires careful balloon diameter sizing to approximate 1:1 ballooning; as such, intravascular ultrasound may be utilized to define reference vessel diameter. The goal of repeated EPS balloon inflations is to make fenestrations larger and more "permanent." SAFER, as described herein, requires a systematic and meticulous effort to create multiple and persistent communication between the EPS and the true lumen.

This is a key modification that separates SAFER from AFR, where less extensive ballooning was proposed[12] and utilized only as mean to achieve distal re-entry, while here it should be performed throughout the entire length of the lesion for a different purpose (i.e., EPS hematoma management).

Another key modification that separates SAFER from AFR[12] stems from the lesson learned from AFR: failure of the wire crossing back into the true lumen after performing AFR have prompted us to revert the position of the crossing wire relative to the balloon. SAFER is a single wire technique, and the wire tip is maintained distal to the balloon tip to bypass the intricated network of the dissection area and to constantly remain adjacent to the barrier between true and false lumen before, during, and after performing controlled tearing caused by the balloon inflation.

2.2 | Step-by-step description of the SAFER technique

(1) Once guidewire advanced through a microcatheter has accessed the EPS (intentionally or unintentionally), every effort should be made to manipulate the wire tip to shape a "tight" knuckle. Based on our initial experience, the Gladius MG (or Mongo) wire is particularly suitable for this step due to its ability to maintain a short and small knuckled tip, good shaping memory, and steerability (Figure 1A).

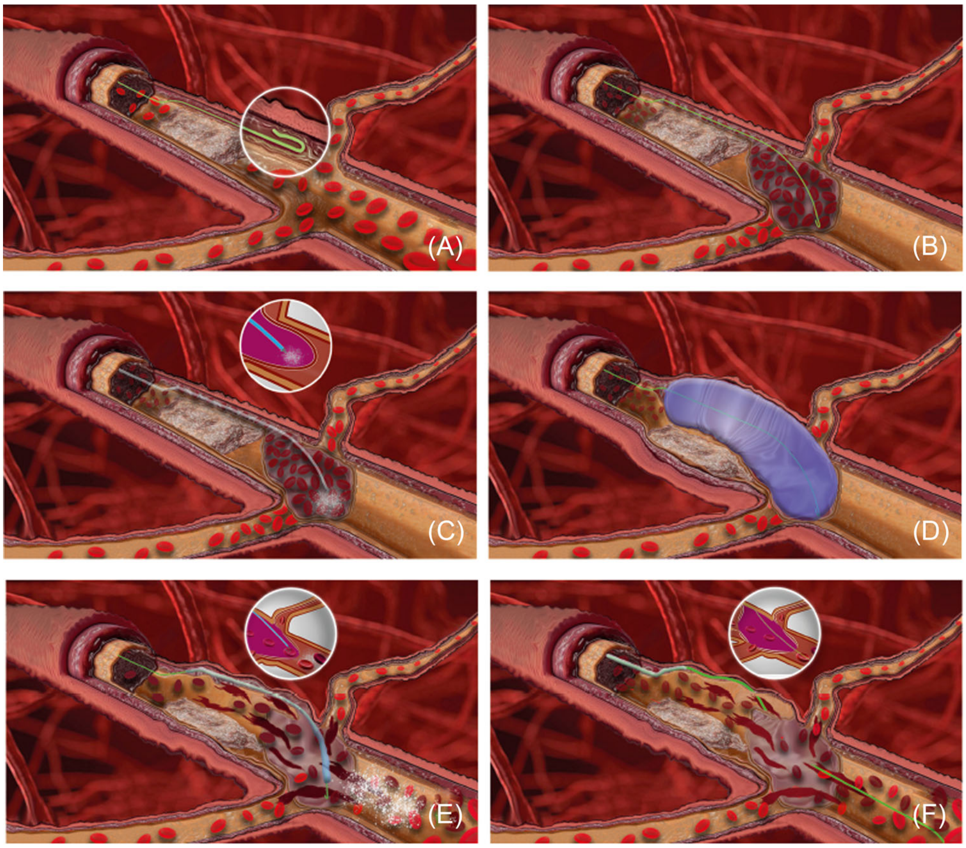

FIGURE 1 Schematics of SAFER: step-by-step visual description of SAFER. Panel A: Once wire is in the extra-plaque space (EPS), the guide wire with a tight knuckled tip (in the circle) is distal to the chronic total occlusion (CTO) site. Panel B: Additional wire manipulation at the distal end may result in more extensive false lumen dissection and side branch pruning due to side branch exclusion from an enlarging false lumen by blood flow at systemic pressure. Panel C: A suitable area to target a re-entry is confirmed by the combined visualization of the true lumen through a retrograde injection combined with a Carlino injection performed through an antegrade microcatheter distally to the distal end of the occlusion. Panel D: The balloon is delivered in the EPS space over the wire but distal to the occlusion guided by the persistent contrast. Subsequently, the balloon (previously sized 1:1 to the distal reference vessel) is inflated while maintaining the wire position to cause a rupture of the membrane dividing the true from false lumen. Panel E: The balloon is then deflated, and antegrade flow recanalization is confirmed by the disappearance of the previously injected contrast. As a byproduct of the effective fenestration, the side branch flow is also restored. The balloon is then retracted proximally to about the level of the proximal cap. Panel F: Wire is manipulated to pass through one of the fenestrations. Additional balloon angioplasty is performed with a 1:1 balloon-to-artery ratio distal to proximal followed by conventional (IVUS guided) stenting. [Color figure can be viewed at wileyonlinelibrary.com]

(2) Additional wire manipulation in the EPS may result in larger and/or longer dissection planes leading to hematoma expansion. Blood pooling in the EPS under systemic pressure progressively displaces the dissection flap in longitudinal and axial directions leading to true lumen compression and side branch exclusion, angiographically evident by side branches pruning) (Figure 1B; area shaded area represents hematoma).

(3) Once the wire reaches the distal cap of the occlusion and slightly passes it (confirmed through a contralateral injection), every effort should be made to stop wire progression and keep this area as the "base of operations" to target wire re-entry.

While maintaining the wire in this distal position, a microcatheter is advanced, and then the wire is temporarily withdrawn.

(4) It is next recommended to confirm a suitable area for a targeted re-entry by a "Carlino" contrast injection performed through the microcatheter in the proximity of the distal occlusion (Figure 1C). This step will serve the dual purpose of (1) guiding proper balloon position across the distal cap and (2) confirming the later occurrence of effective fenestrations (Figure 1E), demonstrated angiographically by the clearance of the contrast downstream.

(5) Next, the guidewire is advanced through the microcatheter within the contrast landmark, the microcatheter is removed, a rapid-exchange semi-compliant balloon, sized 1:1 to the presumed or documented size of the vessel, is delivered over the wire distal to the occlusion (but still in the EPS space) guided by the persistent contrast.

(6) Subsequently, the balloon is repeatedly inflated and deflated along the entire occlusion length while maintaining wire position (Figure 1D) to create multiple tears of the membrane dividing the true lumen from EPS as depicted in Figure 1E. This may result (Figure 1F) in the mixing of antegrade blood and the antegrade blood previously confined in the EPS (dark red) with the retrograde blood flow. In addition, the contrast stain from the Carlino injection is washed out as the fluoroscopic hallmark of the effective connection between the antegrade and retrograde flow (more evident in Figure 1E). As a byproduct of effective fenestration, the side branch flow is restored.

(7) The balloon is then slightly retracted.

(8) Next, the wire is also slightly retracted and subsequently manipulated to traverse one of the fenestrations (Figure 1F).

(9) Once the wire is documented to have successfully re-entered in the true lumen, additional balloon inflations are then performed with the same balloon distal to proximal CTO to prepare the lesion for proper stent implantation. Further confirmation of adequate preparation of the lesion and good outflow management is demonstrated with a gentle antegrade injection through the guiding catheter without the risk of hydraulic dissection in view of fenestration into the true lumen. The contrast disappearance confirms forward antegrade flow to the distal vessel. As a further sign of successful lesion preparation, injection of contrast through the guiding catheter demonstrates side branches within the occluded portion with the persistent flow as a result of extensive and stable connections between the true lumen and EPS through the disruption of the dissection flap at the level of the take-off of these side branches (Figure 2F).

(10) At this point, the wire can be exchanged for a workhorse wire through a microcatheter, delivered distally. We strongly recommend intravascular ultrasound (IVUS) imaging of the vessel at this point for stenting sizing.

(11) The balloon is then removed, and the subsequent decision of whether to implant the stent is left to the operator's judgment. As the entire path from initial EPS entry to re-entry into the true lumen has been ballooned, the likelihood of the side branches in this segment remaining open is high. As such, stenting may be performed immediately rather than delaying to a later procedure.

2.3 | Case series baseline characteristic and procedural results

This first-in-man experience was conducted in seven patients between January and March 2023 by three operators (MC, BF, CG) in two different centers. One of the operators (MC) was present in each case. The patient characteristics are shown in Table 1 and the angiographic and procedural characteristics are shown in Table 2. The technique was successful in all cases with successful recanalization and stenting with postprocedural TIMI 3 flow with no adverse events (Table 2).

A representative case (i.e., case #4) is shown in Figure 2.

Figure 3 (from case #7) demonstrates an optical coherence tomography (OCT) image of the distal re-entry zone. Note the extensive gap of the dissection flap at the point of re-entry. Dissection flaps of the fenestration are now well set apart, losing their transient nature as initially described in the AFR technique.[12] Fenestration in SAFER appears as a fracture of the EPS membrane that further facilitates distal wire re-entry and EPS hematoma drainage.

Supporting Information: Video S1 shows the OCT pullback from the true lumen through the EPS and into the true lumen from case #7.

3 | DISCUSSION

The SAFER technique has utilized lessons from previous wire-based ADR methods modifying inflow and outflow management to allow for a predictable ADR approach that maintains side branch patency through the EPS area and ensures excellent final TIMI flow.

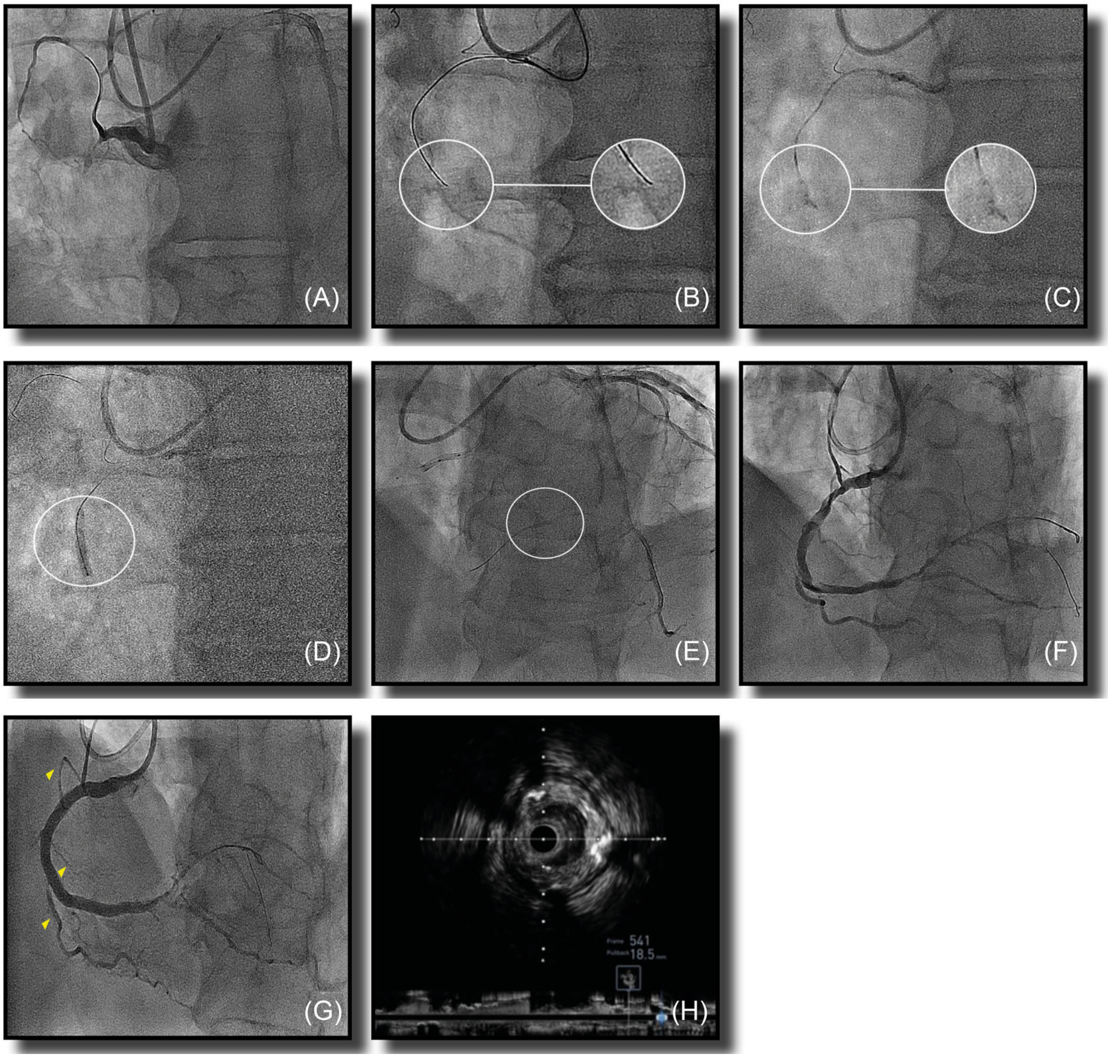

FIGURE 2 Representative case part 1. (A) Proximal RCA CTO. (B) Subintimal Gladius MG is shown in EPS through the retrograde injection (see in the circles). (C) Carlino injection (see in the circles) was performed through the microcatheter to guide proper balloon position across the distal cap and to confirm the occurrence of effective fenestrations. (D) Multiple balloon inflations (see in the circle) and deflations with a semi-compliant balloon 1:1 sized to the artery positioned across the re-entry zone previously (defined with contrast injection) and along the entire occlusion length. (E) Successful wiring into the true lumen (see in the circle). Note the disappearance of contrast stain with successful vessel recanalization. (F) Initial antegrade contrast injection shows preserved side-branches flow along the entire length of the occlusion and good distal contrast runoff. (G) Angiographic results obtained after stent implantation. Flow into the side-branches preserved after stenting (yellow arrow heads). (H) IVUS showing intraluminal wire position. [Color figure can be viewed at wileyonlinelibrary.com]

The "Achilles heel" of all ADR techniques has been the limited procedural focus on the EPS hematoma, which typically leads to an increased risk of procedural failure. AFR represented an ADR advance[12] as it included a solution to the EPS hematoma. As opposed to all the other wire-based ADR techniques previously described where the re-entry site was unpredictable, AFR was the first wire-based ADR technique that allowed a more predictable re-entry in a zone selected by the operator. The innovative aspect of AFR focused on EPS ballooning at the level of the distal cap to create fenestrations that, at least transiently, could be engaged and crossed by a polymer-jacketed wire back into the true lumen. The major limitation of AFR was that the fenestrations created by balloon inflation may have been transient in nature, and the complex geometry/shape of the dissection flap interposed between true and false lumen may have precluded successful re-entry. In addition, in AFR, the crossing wire was proximal to the balloon, required a parallel microcatheter, and the wire was advanced distally to the balloon once the balloon was deflated. With SAFER, the wire position is maintained distal to the balloon as the balloon position is already distal to the plaque edge, increasing the chance of crossing with less manipulation.

SAFER relies on more extensive and possibly longer-lasting fenestrations to effectively drain the hematoma, increasing the probability of wire re-entry, preserving side branches in the wire EPS area, and optimizing distal flow. SAFER is an efficient and technically

TABLE 1 Patient demographics.

	Patient #1	Patient #2	Patient #3	Patient #4	Patient #5	Patient #6	Patient #7
Age	64	80	69	72	77	69	53
Gender	M	M	M	M	M	M	M
eGFR	62	72	88	107	183	98	103
LVEF	60	50	60	50	50	55	55
Hb	15.6	12.4	14.2	13.2	11.1	12.8	14
Diabetes	1	0	0	1	1	0	0
Hypertension	1	1	1	1	1	1	1
CCS	2	3	2	2	2	2	1
ASA	Y	Y	Y	Y	Y	Y	Y
Plavix	Y	Y	Y	Y	Y	Y	Y
Beta-blocker	N	Y	Y	Y	Y	Y	Y
Oral DM medication	Y	N	N	Y	Y	N	N
ACEI/ARB	Y	Y	Y	Y	Y	Y	Y
Statin	Y	Y	Y	Y	Y	Y	N

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ASA, aspirin; CCS, Canadian Cardiovascular Society angina class; DM, diabetes mellitus; Hb, hemoglobin; LVEF, left ventricular ejection fraction; M, male; N, no; Y, yes.

TABLE 2 Procedural outcomes.

	Patient #1	Patient #2	Patient #3	Patient #4	Patient #5	Patient #6	Patient #7
J-CTO score	1	4	1	4	2	2	3
Lesion length (mm)	<10	>20	10–20	>20	<10	<10	>20
Radiation time (min)	30	53	32	51	42	38	36
Dose (mGy)	1228	2125	1317	3072	2820	2405	1478
Contrast (cc)	230	350	350	350	280	330	150
Number of implanted stents	2	4	2	5	3	1	2
Peak post-PCI Tn (ng/mL)	49	67	18	27	23	19	25

Note: Troponin levels are expressed in nanograms/L. Radiation time includes a combination of fluoroscopy and cine time.
Abbreviation: Tn, troponin.

simple procedure: (1) one-step, (2) predictable re-entry site, and (3) ability to inject contrast through guide catheter once outflow has been established.

Device-based ADR with a dedicated ADR device (Stingray; Boston Scientific) has been limited by the invariable challenge posed by the EPS hematoma compressing the true distal lumen. Its success rate has been reported to be around 70%–80%, thus illustrating the need for other techniques.[14] Recently a dedicated AFR device has been tested and shown a similar procedural success rate (71%) to Stingray but only a marginal improvement in the procedural success rate compared with the original AFR technique (66% vs. 71%), possibly highlighting the intrinsic limitations of AFR itself (due to the presumptive transient nature of the fenestrations and the proximal position of the crossing wire relative to the balloon responsible for the fenestrations).[15]

3.1 | Study limitations

This study is limited by the small number of patients and by the lack of long-term follow-up to assess whether restenosis/reocclusion rates are favorable. It is being presented at this early stage as a first-in-man case series description of a promising approach for the antegrade recanalization of a CTO. It requires testing by multiple operators in different programs to determine if the success rate can be replicated and to understand how further modifications may improve the technique: therefore, it will require reproducible results by other operators before this technique is adopted on a larger scale. However, this early experience provides evidence that SAFER can provide an additional option in CTO recanalization.

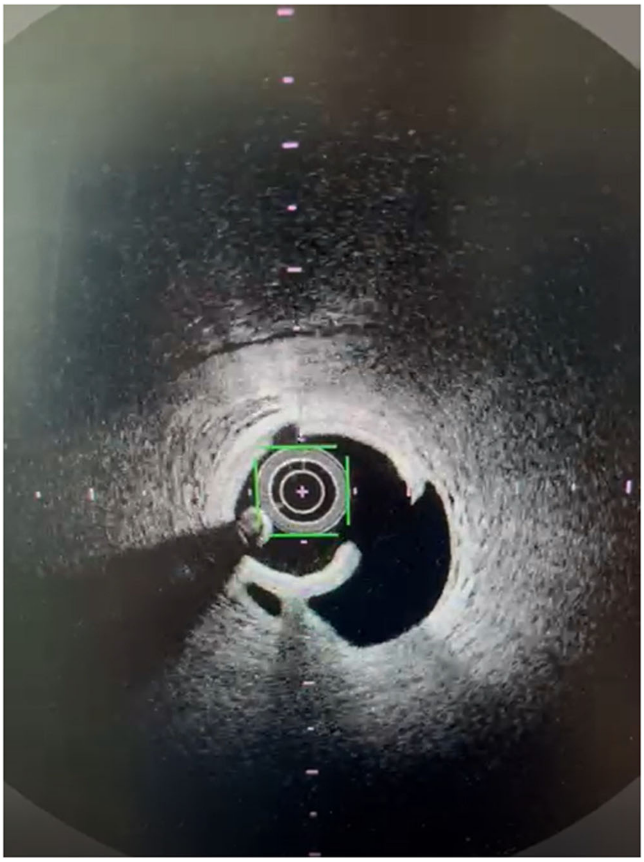

FIGURE 3 SAFER fenestration characteristic: OCT image of a distal fenestration from Case #7. Repeated EPS balloon inflations are performed in the SAFER technique to make fenestrations larger and more "permanent." Note discrete lesion and absence of collapsing flaps at the site of distal re-entry. [Color figure can be viewed at wileyonlinelibrary.com]

4 | CONCLUSIONS

This study has shown that the SAFER technique is feasible and effective with the possibility of improving the antegrade success rates. SAFER was successfully performed in all seven cases without any periprocedural complications. The SAFER technique eliminates the problem that had limited the success of other ADR techniques, namely large EPS hematoma. The SAFER technique is a refinement of the STAR technique that could become a primary rather than "last-resort" ADR technique if long-term follow-up confirms the favorable results of these initial data. It depends on the actuality of sustained fenestrations after repetitive EPS balloon dilatation. The results of the current study are consistent with this hypothesis. A larger clinical experience is necessary both in other centers and possibly in other vascular territories such as the lower limbs to confirm if results can be reproduced, if longer-term results can be acceptable and if the efficacy and safety of this technique can be confirmed.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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