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Antegrade fenestration and re-entry: A new controlled subintimal technique for chronic total occlusion recanalization

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Abstract

Objectives: To describe and evaluate the efficacy of a novel antegrade dissection/re-entry (ADR) technique, called antegrade fenestration and re-entry (AFR), for chronic total occlusions (CTO) percutaneous coronary intervention (PCI).

Background: The widespread adoption of ADR is limited by several technical, logistic, and financial factors. Therefore, novel ADR techniques are needed.

Methods: AFR consists in creating multiple fenestrations of the dissection flap separating the false and true lumen. This is achieved by advancing a balloon (sized 1:1 with the artery diameter) onto the antegrade wire into the subintimal space, and inflating it at the level of the distal cap. A soft polymer-jacketed guidewire is then advanced across the fenestrations created by balloon inflation from the subintimal space into the true lumen. Following its theoretical formulation, patients undergoing ADR-based CTO recanalization at our institution were considered for AFR treatment.

Results: Between November 2015 and October 2017, 279 CTO PCIs were performed. Of those, ADR was utilized in 33 (12%) cases, of whom AFR was used in 6 (18%). In all but one cases, AFR was performed after failed true-to-true lumen crossing, while in the remainder it was utilized after extensive subintimal space disruption following alternative ADR techniques. AFR was successful in all six cases and no complications were observed.

Conclusions: We have developed a novel ADR technique which aims at complementing the CTO operator's armamentarium. AFR requires no specific device, does not preclude alternative bailout techniques, and is inexpensive and easy to perform. A dedicated study should confirm our findings in a large cohort.

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

1 | INTRODUCTION

The introduction of subintimal techniques, also known as dissection/re-entry techniques, has allowed a remarkable improvement in the success rates of chronic total occlusions (CTO) percutaneous coronary intervention (PCI), especially in challenging lesions [1]. In particular, according to the "hybrid algorithm" [2], antegrade dissection/re-entry (ADR) is indicated in occlusions longer than 20 mm, with a non-ambiguous proximal cap, and a suitable distal landing zone.

Following the introduction of the CrossBoss/Stingray system (Boston Scientific, Marlborough, MA), the adoption and success rates of ADR-based CTO PCI has increased [1,3,4]. However, such approach is limited by high procedural costs, a steep learning curve, need for dedicated proctored training, and a non-negligible rate of failure secondary to inability to re-enter into the true lumen with the Stingray system

Mauro Carlino and Lorenzo Azzalini contributed equally and should be regarded as joint first authors.

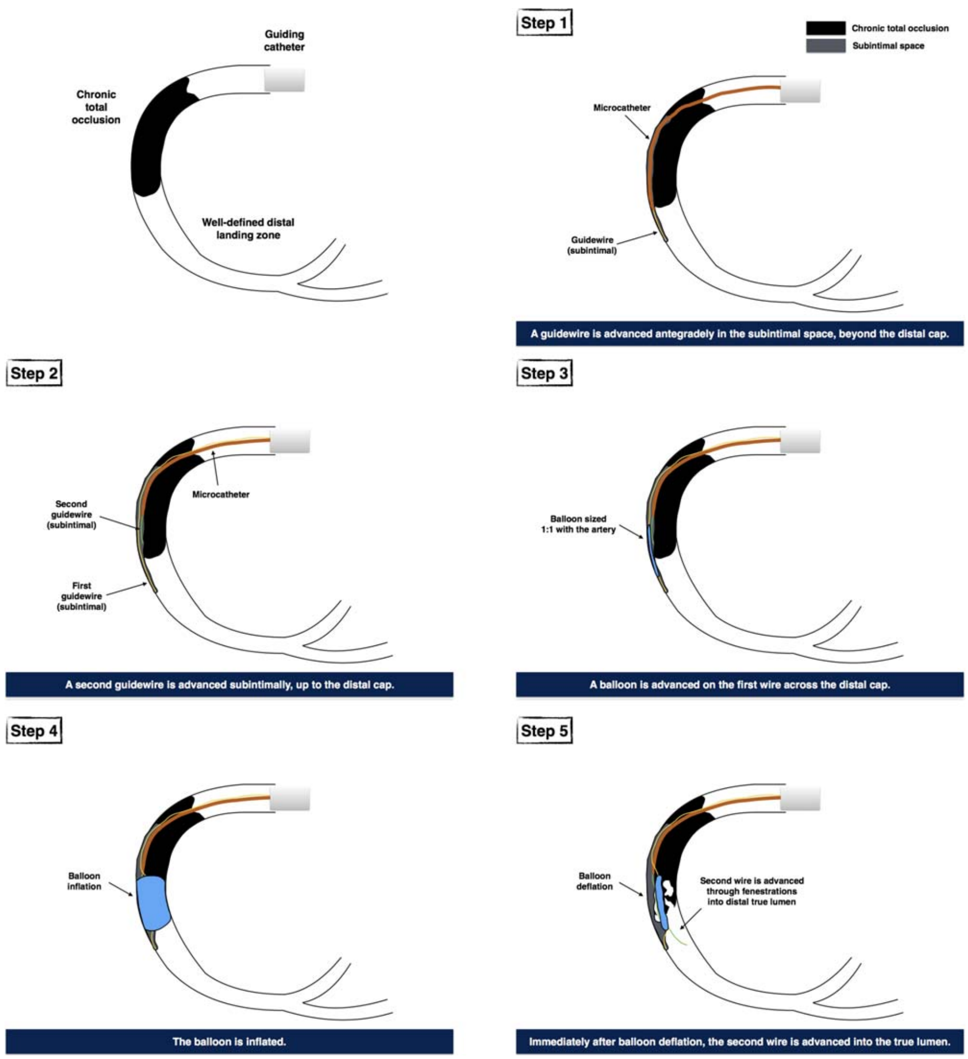

FIGURE 1 Procedural steps of the Antegrade Fenestration and Re-entry (AFR) technique [Color figure can be viewed at wileyonlinelibrary.com]

(usually due to compressive subintimal hematoma). For these reasons, alternative ADR-based techniques are required.

In this article, we introduce a novel ADR technique, named "Antegrade Fenestration and Re-entry" (AFR), which has the potential to represent an alternative to Stingray-based re-entry.

2 | METHODS

2.1 | Technique description

AFR can be utilized in three different settings: (1) as first-line ADR strategy; (2) as bailout of a failed true-to-true lumen approach; (3) as bailout of other ADR techniques (both wire- or CrossBoss/Stingray-based). For ease of presentation, the description of the most common scenario will be provided (bailout after failed true-to-true approach). As depicted in Figure 1, AFR consists of five steps. Step 1: the occlusion is inadvertently wired in a subintimal fashion, and the guidewire is located beyond the distal cap in the subintimal space. Step 2: the microcatheter is removed (with conventional techniques) leaving the first guidewire in place, and the occlusion is wired again, still through the subintimal space, although this time the second guidewire tip is kept as close as possible to the first wire (checking in multiple projections), inside the occlusion. Step 3: a balloon (sized 1:1 with the artery diameter) is advanced on the first guidewire, and is placed across the distal cap. Step 4: the balloon is inflated, at least up to nominal pressure (if a non-compliant balloon is used, higher pressures can be achieved, but never exceeding a balloon-to-artery ratio of 1, to reduce the risk of perforation). Step 5: while deflating the balloon, the second guidewire is rapidly advanced through the fenestrations created by the balloon (before the collapse of the dissection flaps) between the subintimal space and the true lumen, which is now accessible, since balloon dilatation took place across the distal cap.

A few fundamental aspects of this technique have to be kept in mind. First, while the operator can choose the first guidewire according to his/her preferences, the second guidewire should be a polymer-jacketed, low-tipload guidewire (e.g., Sion Black or Fielder family, Asahi Intecc, Nagoya, Japan; or Fighter, Boston Scientific). In fact, this guidewire must be manipulated quickly, to smoothly pass through the tears

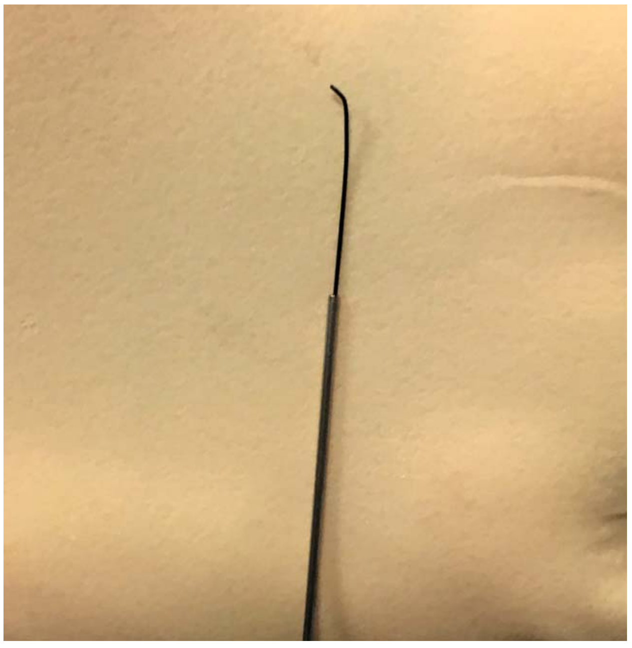

FIGURE 2 Shape of the tip of the polymer-jacketed guidewire used for re-entry. A 2-mm, 45° bend must be created to provide good maneuverability and maximize the chances of engaging a fenestration and entering into the distal true lumen [Color figure can be viewed at wileyonlinelibrary.com]

in between the false and true lumen, with low risk of perforating the vessel. Figure 2 shows the recommended guidewire tip shape to perform re-entry. Second, re-entry into the true lumen is an iterative process, and a few attempts might be needed before effectively crossing, as usually happens in conventional reverse controlled antegrade and retrograde subintimal tracking (CART). Third, re-entry should be attempted as close as possible to the distal cap of the occlusion, and far from the takeoff of side branches. This will allow minimizing the subintimal track and the risk of losing side branches, and maximizing the likelihood of achieving a good distal runoff, which are key aspect in ADR-based CTO PCI to ensure long-term patency rates [1]. Fourth, the second guidewire must initially be advanced as close as possible to the first guidewire, in order to increase the probability that the former engages a fenestration created by balloon inflation performed on the latter, similar to reverse CART. In case the two wires are too far apart from one another, and/or if there is a resistant calcified or fibrotic plaque in between them, it will be more difficult to cross through the connection between the false and true lumen.

2.2 | Study population

Following its theoretical formulation by these authors (MC and LA) in November 2015, the use of AFR at our institution was considered in procedures requiring ADR. Study period extended from November 2015 to October 2017. All procedures were indicated to treat angina, ischemia, or both, and were performed electively by two experienced operators (MC and LA) [5]. All patients signed an informed consent, approved by the local ethics committees, for procedural data collection and for the anonymous use of data for retrospective evaluation.

3 | RESULTS

As shown in Figure 3, a total of 279 CTO PCIs was performed at our institution during study period, of whom 33 (12%) were treated with ADR. Among those, AFR was attempted in six patients (18%), and was successful in all six. Procedural data of the six cases are shown in Table 1. The description of two of these cases will be provided as examples.

The first patient presented a mid-right coronary artery (RCA) CTO, longer than 20 mm, receiving septal collaterals from the left anterior descending and epicardial collaterals from the circumflex, as well as bridging collaterals from the proximal RCA. The distal landing zone was moderately diseased (Figure 4A,B; Supporting Information, Video 1). A 7F JR4 and a 7F XB 3.5 catheters were inserted transradially. An antegrade wire escalation strategy was initially attempted with a Gaia Second and subsequently an UltimateBROS3 guidewire over a Corsair Pro microcatheter (all by Asahi Intecc). However, the wires crossed the occlusion in a subintimal fashion, and a hematoma started to compress the distal true lumen (Figure 4C,D; Supporting Information, Video 2).

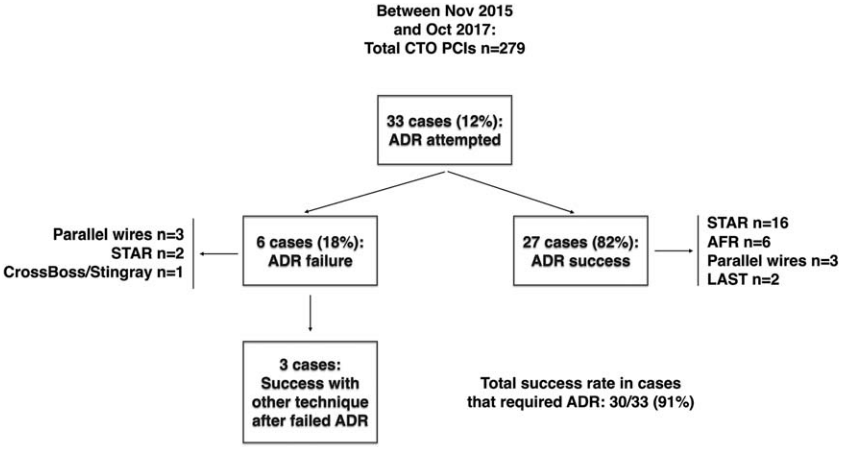

FIGURE 3 Study workflow. Abbreviation: ADR, antegrade dissection/re-entry; AFR, antegrade fenestration and re-entry; LAST, limited antegrade subintimal tracking; STAR, subintimal tracking and re-entry

TABLE 1 Clinical and procedural characteristics of the patients treated with the Antegrade Fenestration and Re-entry (AFR) technique

Case no.	Sex	Age	CTO vessel	J-CTO score	PROGRESS-CTO score	Indication of AFR	Micro-catheter	First guidewire (subintimal)	Second guidewire (re-entry)	Balloon size	IVUS	Contrast volume (mL)	Fluoroscopy time (min)	Dose-area product (Gy·cm^2)	Air Kerma (Gy)
1	M	50	Mid RCA	2	1	After failed TTT crossing	Corsair Pro	UltimateBROS3	Sion Black	2.0 × 15 mm (SC)	Y	300	37	185	2.3
2	M	70	Proximal circumflex	0	2	After failed TTT crossing and sub-optimal LAST+STAR-based recanalization	Finecross	UltimateBROS3	Sion Black	2.5 × 30 mm (SC)	Y	325	59	184	3.8
3	M	61	Mid RCA	1	0	After failed TTT crossing	OTW balloon	Fielder FC	Fielder XT-A	3.0 × 20 mm (SC)	N	500	88	411	5.2
4	F	76	Mid LAD	1	2	After failed TTT crossing	OTW balloon	Gaia First	Fielder XT-A	2.5 × 20 mm (SC)	N	600	50	416	6.6
5	M	74	Mid RCA	2	1	After failed TTT crossing	Corsair Pro	Gaia Third	Sion Black	3.0 × 20 mm (SC)	Y	400	80	223	3.5
6	F	71	Proximal RCA	2	1	After failed TTT crossing	Corsair Pro	Fielder XT-A	Sion Black	2.5 × 20 mm (SC)	N	408	26	49	0.6

Abbreviations: LAD, left anterior descending; LAST, limited antegrade subintimal tracking; RCA, right coronary artery; STAR, subintimal tracking and re-entry; OTW, over-the-wire; SC, semi-compliant; TTT, true-to-true.

At this point, AFR was performed: a Sion Black was carefully advanced over the microcatheter until a position in close proximity to the UltimateBROS3 was obtained (Figure 4E; Supporting Information, Video 3). A 2.0 × 15-mm semi-compliant balloon was inflated over the UltimateBROS3 (Figure 4F). Then, immediately after balloon deflation, the Sion Black was quickly advanced and reached the distal true lumen (Figure 4G; Supporting Information, Video 4), as confirmed by contralateral injection (Figure 4H). Intravascular ultrasound (IVUS) demonstrated a relatively short subintimal track (21 mm), and an otherwise true lumen situation of the guidewire (Figure 5A–F). The procedure was then successfully carried out as per standard practice, and two drug-eluting stents were implanted. Angiographic result was good (Figure 4I,J; Supporting Information, Video 5), also confirmed by IVUS (Figure 5A'–F').

The second case was a very short circumflex CTO with bridging but no interventional collaterals, and a moderately diseased landing zone (Figure 6A,B). A 7F XB 3.5 catheter was inserted transradially. The occlusion was wired with the intention to perform an antegrade true-to-true lumen strategy, using a Sion Black, a Gaia Second, and subsequently an UltimateBROS3 guidewire over a Finecross microcatheter (Terumo, Tokyo, Japan). All wires tracked in the subintimal space, and limited antegrade subintimal tracking (LAST) was attempted with the UltimateBROS3. The wire seemed to have achieved true lumen re-entry (Figure 6C), and the injection of a small amount of contrast through the microcatheter was performed for confirmation (Figure 6D). However, although microcatheter tip was located in the true lumen, contrast injection created a hydraulic dissection extending retrogradely (involving more proximal side-branches), likely due to extensive subintimal track and poor runoff. At this point, AFR was performed with a 2.5 × 30-mm semi-compliant balloon over the UltimateBROS3 in an attempt to achieve a more proximal true lumen re-entry. A Sion Black guidewire, supported by the Finecross, successfully achieved true lumen re-entry proximal to the circumflex trifurcation (Figure 6E). IVUS interrogation confirmed a much shorter subintimal track than initially achieved with LAST (18 mm; Figure 7A–F). Additionally, coronary angiogram showed minimal dissection and TIMI 3 flow (Figure 6F). The procedure was then carried out as per standard practice and one drug-eluting stent was implanted, with good angiographic result (Figure 6G, H), confirmed by IVUS (Figure 7A'–E').

4 | DISCUSSION

In this article, we have described AFR, a novel ADR technique that aims at complementing the CTO operator's armamentarium. AFR was conceived bringing some key concepts of retrograde dissection and re-entry techniques, and in particular reverse CART [6], to an ADR environment. Specifically, we have previously reported on an improvement of reverse CART, which we called Deflate, Retract and Advance into the Fenestration Technique (DRAFT) [7]. At the critical step of retrograde wire re-entry into the proximal true lumen, DRAFT (a two-operator maneuver) is performed by inflating and subsequently deflating and quickly retracting the antegrade balloon, creating a suctioning force that will facilitate the advancement of the retrograde wire across

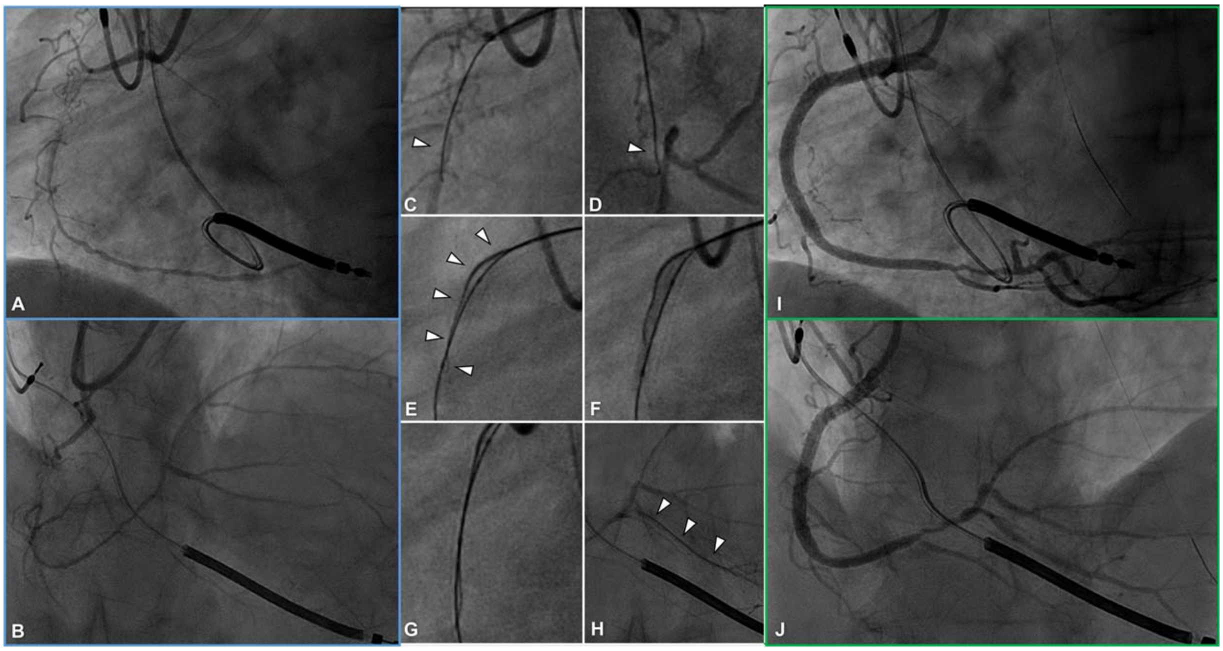

FIGURE 4 Right coronary artery CTO. (A, B) The occlusion is >20-mm-long, with proximal cap ambiguity, and the distal vessel is moderately diseased and visualized by bridging collaterals and contralateral collaterals. (C [LAO projection], D [RAO projection]) An UltimateBROS3 guidewire, supported by a Corsair Pro microcatheter, is advanced toward the distal landing zone but has a subintimal track (arrowheads). (E) A second guidewire, a Sion Black (arrowheads), is advanced through the microcatheter in close proximity to the UltimateBROS3, up to the distal cap. (F) A 2.0 × 15-mm semi-compliant balloon is advanced onto the UltimateBROS3 and inflated. (G) The balloon is deflated and the Sion Black is quickly advanced through into the distal true lumen, as confirmed by contralateral injection (H). (I,J) Final result, after implantation of two drug-eluting stents [Color figure can be viewed at wileyonlinelibrary.com]

the transient fenestrations just created. Similarly, AFR takes advantage of balloon inflation to create fenestrations between the subintimal space and the distal true lumen (since it is performed across the distal cap of the CTO). A second wire is therefore quickly advanced through the dissection tears and into the distal true lumen before the dissection flap collapses.

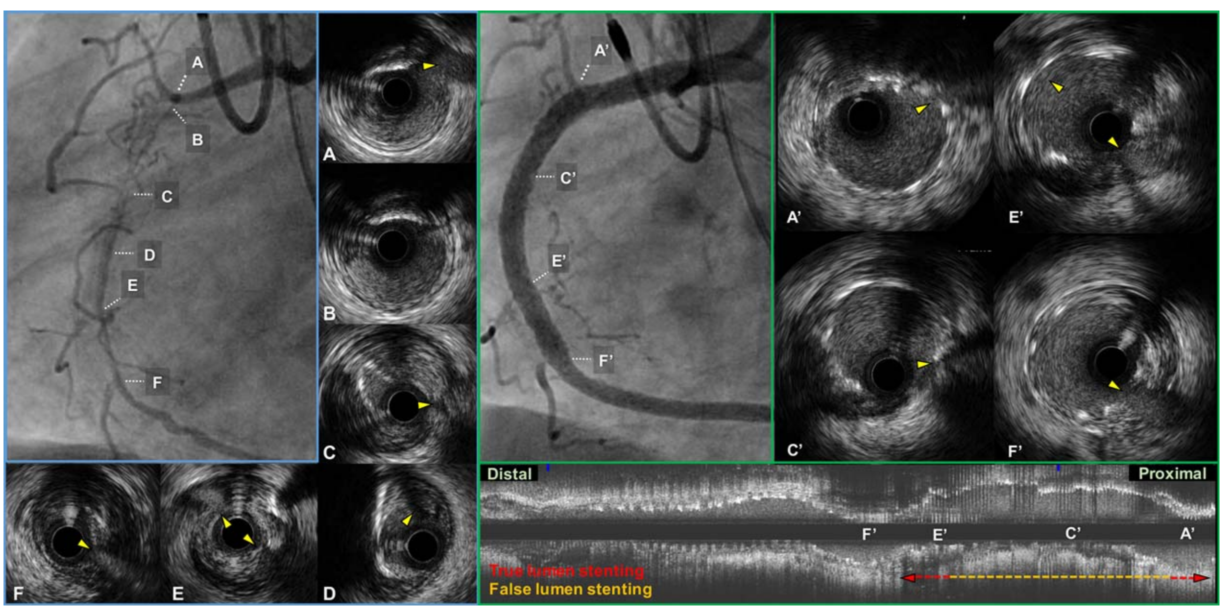

FIGURE 5 Intravascular ultrasound (IVUS) imaging immediately after antegrade fenestration and re-entry (left panel) and after stent implantation (right panel). (A) Proximal true lumen (arrowhead indicates side-branch ostium). (B) Entry point from true to false lumen (wire in false lumen). (C) Wire in false lumen (arrowhead indicates side-branch ostium). (D) Wire in false lumen (arrowhead indicates collapsed true lumen). (E, F) Wire in distal true lumen (arrowheads indicate ostia of side-branches). (A', C', E', F') Final result corresponding to the sites indicated in (A, C, E, F). Arrowheads indicate side-branches. The subintimal track measures 21 mm [Color figure can be viewed at wileyonlinelibrary.com]

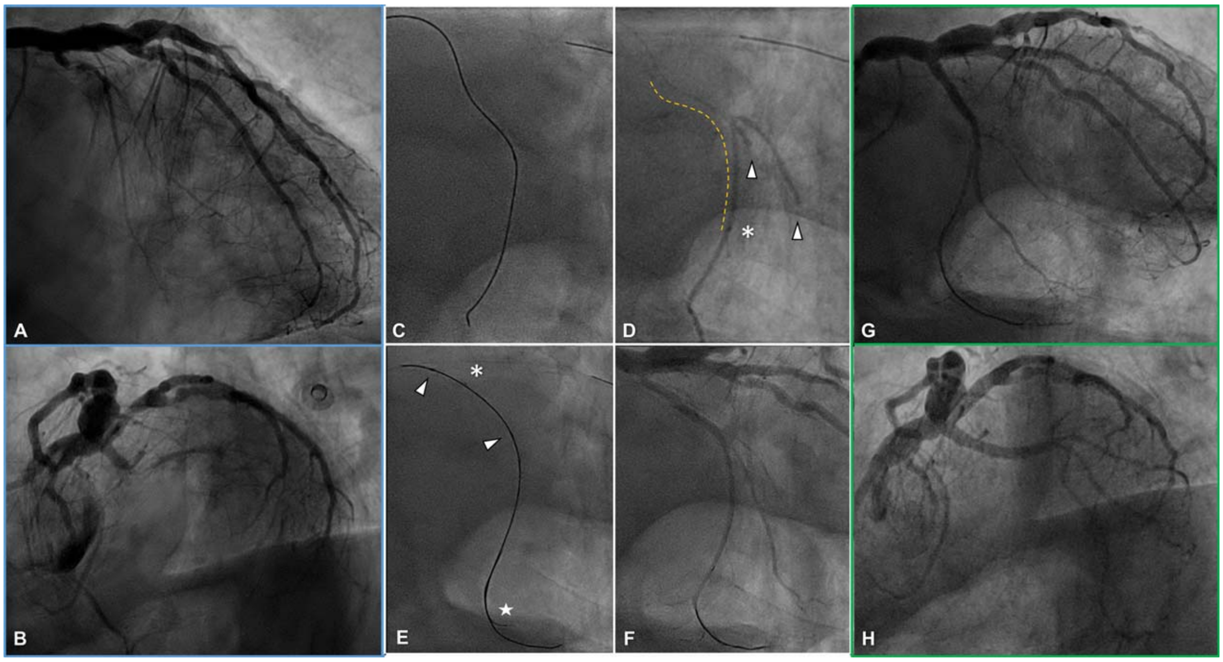

FIGURE 6 Circumflex CTO. (A, B) The occlusion is short and presents bridging but no interventional collaterals, and a moderately diseased landing zone. (C) An UltimateBROS3 guidewire over a Finecross microcatheter reaches the distal landing zone after a long subintimal track. (D) Injection of a small amount of contrast through the microcatheter (asterisk) confirms true lumen re-entry. However, contrast injection causes a retrograde hydraulic dissection (broken line) extending to side branches (arrowheads; this was likely due to suboptimal runoff). (E) A 2.5 × 30-mm semi-compliant balloon (arrowheads) is inflated at the occlusion site and a Sion Black guidewire is advanced into the true lumen at a much more proximal location than achieved earlier (asterisk indicates microcatheter; star points at Sion Black in the distal true lumen). (F) Result after predilatation. Note that the two proximal side-branches have now been recanalized. (G, H) Final result after implantation of one drug-eluting stent [Color figure can be viewed at wileyonlinelibrary.com]

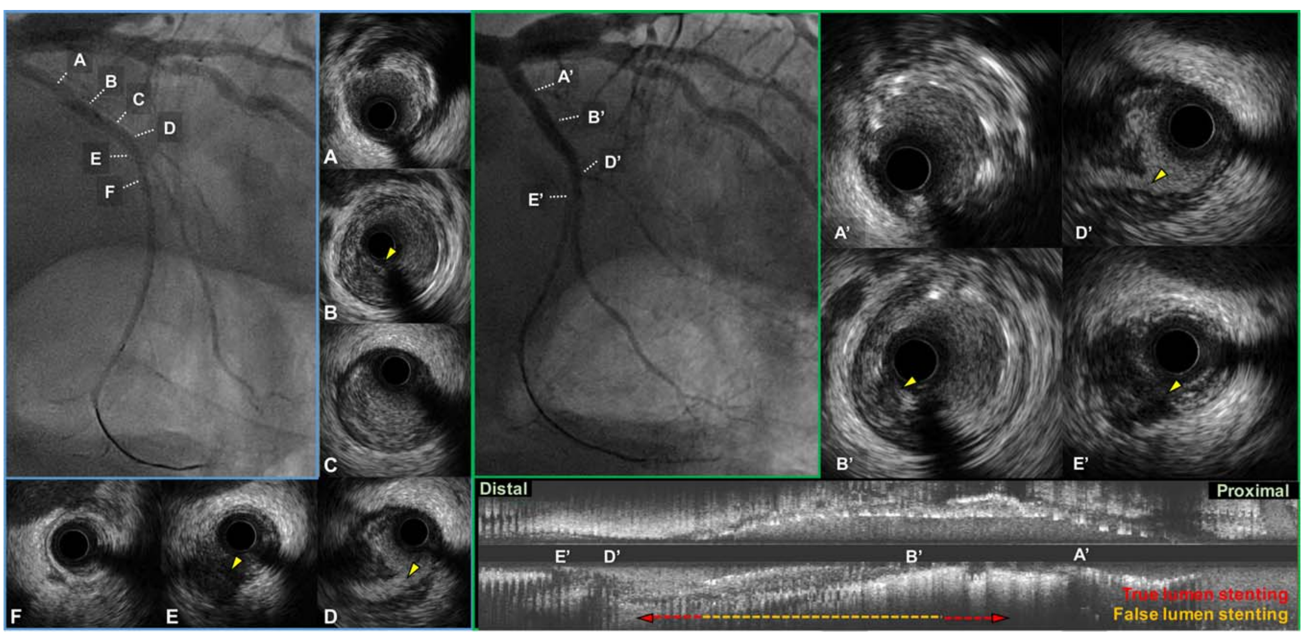

FIGURE 7 Intravascular ultrasound (IVUS) imaging immediately after antegrade fenestration and re-entry (left panel) and after stent implantation (right panel). (A) Proximal true lumen. (B) Wire in false lumen (arrowhead indicates collapsed true lumen). (C) Re-entry point from false to true lumen (wire is in true lumen). (D) Wire in true lumen (arrowhead indicates first marginal branch ostium). (E) Wire in true lumen (arrowhead indicates second marginal branch ostium). (F) Distal true lumen. (A', B', D', E') Final result corresponding to the sites indicated in (A, B, D, E). Arrowhead in (B') points at the compressed true lumen. Arrowheads in (D', E') indicate first and second marginal branches. The subintimal track measures 18 mm [Color figure can be viewed at wileyonlinelibrary.com]

AFR presents several strengths. First, it is inexpensive, since it can be performed with wires, microcatheters, and balloons already available in the catheterization laboratory, and which have possibly already been utilized earlier during the intervention. This aspect makes AFR particularly appealing in clinical practices with limited budget and/or where the CrossBoss/Stingray system is not available. Second, in our series AFR was effective in all six cases where it was attempted and no specific training or ex vivo testing was required. However, the experience with this technique is still in its infancy, and a much larger volume of cases should be evaluated before any solid efficacy claim can be made. Third, AFR appears relatively safe, provided that dilatation is performed with a balloon sized 1:1 with the artery diameter, and that a soft polymer-jacketed guidewire is utilized for re-entry. Additionally, although we did not observe any AFR failure in our series, we speculate that this technique is not destructive of vessel structure, and bailout techniques can still be performed in case of unsuccessful re-entry (e.g., the retrograde approach). In particular, dilatation of the distal cap in AFR would mirror the key step of antegrade balloon dilatation as performed in reverse CART. For this reason, we recommend that AFR be initially attempted by operators already experienced with both ADR and the retrograde approach, so that CTO recanalization might still be achieved with alternative, conventional techniques. Moreover, as shown by the second case example presented, AFR can be performed not only as first-line ADR technique or as bailout of failed true-to-true lumen crossing, but also in case of significant vessel disruption following alternative ADR techniques (in our case, LAST and, albeit unintentional, contrast-guided subintimal tracking and re-entry [STAR] [8]). Finally, although we could not evaluate this aspect in practice, AFR might have the potential to overcome one of the most common failure modes of Stingray-based re-entry, i.e. compressive subintimal hematoma [9].

Nonetheless, several specific limitations of AFR should also be described. First, it is important to underline that AFR should be attempted at the critical point of true lumen re-entry, which follows penetration into the subintimal space, navigation through the occlusion, and arrival at the re-entry zone. As such, AFR does not provide a solution to problems associated with other steps of ADR, namely dealing with an ambiguous proximal cap, avoiding bridging collaterals, and navigating through proximal and intra-occlusional tortuosity and calcification. Therefore, at present, AFR should be considered by experienced CTO operators. Second, as with any ADR technique, true lumen re-entry might be particularly challenging in small or severely diseased vessels, regardless of the extent and number of fenestrations created between the false and true lumen. In addition, in such cases, any subintimal technique might create significant outflow disruption that will compromise runoff, which has been associated with risk of reocclusion during follow-up [1,10]. Third, if balloon dilatation is unable to create sufficient fenestrations to perform re-entry, a large subintimal hematoma will develop and compress the true lumen, making further attempts at creating fenestrations and performing re-entry very challenging. To this regard, it is fundamental that a balloon sized 1:1 with the artery diameter is used for dilatation. Additionally, as previously mentioned, it is important to attempt re-entry with a wire that has previously been advanced in close proximity with the one that will bear the balloon used to create fenestrations. In case of excessive separation or if resistant tissue (e.g., calcified plaque) is present between the two wires, crossing through the connection between the false and true lumen will be challenging.

Alternative ADR techniques should also be discussed. The CrossBoss-Stingray system has proven to be associated with higher success rates [4] as well as better mid-term clinical outcomes [11], as compared with wire-based ADR, when performed by experienced hybrid operators. However, with the exception of North America and certain European countries, such device has had limited diffusion in the rest of the world, due to financial considerations and “philosophical” differences in the approach to CTO PCI (i.e., preference for techniques that preserve as much as possible vessel architecture and limit the extension of subintimal tracks). Additionally, even in experienced hands, CrossBoss-Stingray-based ADR is unsuccessful in about one fifth of cases, most frequently due to inability to perform re-entry secondary to subintimal hematoma [4]. To this regard, a few troubleshooting techniques have been described. Subintimal TRAnscatheter Withdrawal [12] utilizes an over-the-wire balloon inflated in the proximal occluded vessel to block inflow and allow aspiration of the blood from the subintimal space. Double-blind stick-and-swap [9] consists in a bidirectional “blind” puncture with the Stingray wire through both ports of the Stingray balloon, followed by exchange of the Stingray wire for a polymer-jacketed wire, thus achieving distal true lumen re-entry. Another alternative is represented by “bobsled” [9], in which the Stingray balloon is advanced to a different re-entry zone with a larger and more visible target vessel. Wire-based re-entry (STAR, LAST, etc. [1]) still represent valuable tools in the CTO operator toolkit. However, these should be considered as last resorts, due to little control over exact re-entry location, significant dependence on operator’s skills and experience, and inferior success rates and outcomes on follow-up compared with a CrossBoss/Stingray-based ADR [4,11]. Finally, IVUS-guided re-entry [13] is another technique that can be used to achieve true lumen re-entry, even if it requires significant operator experience and can be difficult to perform in case of important subintimal hematoma.

Although we did not experience any AFR-related complications, we speculate that a few issues can be associated with this novel technique. First, perforation can arise for two distinct mechanisms: balloon-induced or wire-induced. As previously detailed, choosing a balloon sized 1:1 with the artery diameter is important to decrease the risk of perforation. To reduce the odds of wire-induced perforation, a soft polymer-jacketed wire (Sion Black or Fielder family; Fighter) should be utilized, and highly penetrative wires (e.g., Confianza and Gaia families) should be avoided. Another possible complication is represented by unfenestrated subintimal hematoma. This might develop when too small a balloon is used to create fenestrations, or if resistant tissue is present between the balloon and the guidewire for re-entry. When concern exists regarding possible development of this complication (e.g., due to a very calcified or fibrotic occlusion), it is important to choose in advance a balloon of adequate size (ideally a non-compliant balloon inflated at high pressure) and to minimize the distance between the two guidewires. In case re-entry fails, IVUS might be useful to confirm that this is secondary to subintimal hematoma and to identify the optimal site for a re-entry attempt. Finally, polymer-jacketed guidewires with higher tipload (e.g., Pilot 200, Abbott Vascular, Santa Clara, CA) can be considered in scenarios of challenging re-entry due to non-negligible separation between the two guidewires (where a thicker layer of tissue must be crossed), although we did not have the chance to test this in practice.

5 | CONCLUSIONS

We have introduced a novel ADR technique which aims at complementing the CTO operator's armamentarium. AFR requires no specific device, does not preclude alternative bailout techniques, and is inexpensive and easy to perform. If our findings will be confirmed by larger (ideally multicenter) reports, AFR has the potential to become part of the expanded hybrid algorithm [2].

CONFLICT OF INTERESTS

None.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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