Forward-Looking IVUS in Chronic Total Occlusions

A new approach to an old problem.

BY JASON H. ROGERS, MD

hronic total occlusions (CTOs) are frequently encountered in clinical practice and are present in approximately 30% of diagnostic coronary angiograms. Successful percutaneous revascularization of CTOs has been shown to result in improved left ventricular function and angina relief, decreased mortality, and freedom from subsequent coronary artery bypass grafting.²⁻⁴ However, revascularization of less than 10% of CTOs are generally attempted and represent a minority (5%-15%) of interventional procedures currently performed in the United States. The reasons why CTO procedures are rarely attempted are because they are time-intensive and can result in significant contrast and radiation exposure. In addition, complications may include vessel dissection, perforation, guide injury, embolization, myocardial infarction,

Crossing Profile

3.2 F

Rotational IVUS Catheter (Atlantis SR, Revolution)

23 mm

Solid State Catheter (Eagle Eye Gold)

3.5 F

Figure 1. Characteristics of rotational IVUS catheters (the Atlantis SR [Boston Scientific Corporation, Natick, MA] and the Revolution [Volcano Corporation, San Diego, CA]) and solid state IVUS catheters (Eagle Eye Gold [Volcano Corporation]). The crossing profile of these catheters generally requires predilation of the subintimal tract. The length of the catheters distal to the imaging element requires extension of subintimal tract by 10.5 to 23 mm beyond the potential IVUS-quided true lumen re-entry point.

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and, rarely, death. Although numerous novel techniques have emerged to improve CTO crossing, many procedures still fail due to an inability to re-enter the distal true lumen. Even with advanced wire skills, maintaining or re-entering a true lumen location can be a formidable challenge. Forward-looking intravascular ultrasound (FL-IVUS) holds particular promise because it has the potential to visualize the vessel, plaque morphology,

and true and false lumens in front of the imaging catheter. This enhanced visualization could be used to improve CTO crossing by continually maintaining and directing the catheter or wire toward the true lumen.

USE AND LIMITATIONS OF CONVENTIONAL IVUS IN CTOS

The current use of IVUS, specific to CTO intervention, employs two basic techniques: (1) IVUS identification and differentiation of true vessel lumen from false lumen, thereby assisting re-entry into the true lumen with a guidewire; and (2) facilitating true lumen entry of a CTO when a side branch arises just proximal to the CTO. Once a CTO is successfully crossed, the utility of IVUS involves more traditional applications

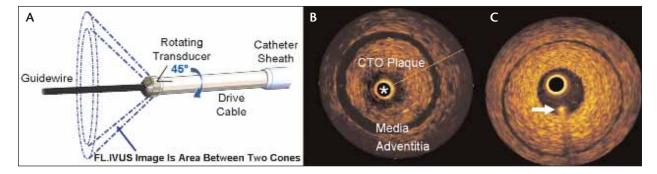


Figure 2. A 45-MHz transducer is oriented at a 45° angle at the tip of the catheter, which rotates to provide a forward-looking cone of visualization (A). A 0.014-inch guidewire can be advanced through the catheter, and true lumen position can be maintained under FL-IVUS guidance in an antegrade manner. An FL-IVUS view of the proximal end of CTO phantom model (B). The catheter (asterisk) is proximal to the occlusion, and the vessel layers are identified. A buddy guidewire (arrow) can be visualized in front of the FL-IVUS catheter (Volcano Corporation) and directed in real time to maintain a true lumen position (C).

that include precise vessel sizing and ensuring adequate stent expansion and apposition.

TRUE LUMEN RE-ENTRY METHOD

True lumen re-entry can be assisted with IVUS when the guidewire has passed into a subintimal space adjacent to the true lumen and attempts to re-enter the true lumen under fluoroscopic guidance are unsuccessful. In this situation, an IVUS catheter can be placed into the subintimal space after predilation with a 1.5-mm balloon catheter. The IVUS catheter can then be advanced into the subintimal tract and the true lumen visualized. A second guidewire can then be advanced alongside the IVUS catheter, and under IVUS visualization, the true lumen can be re-entered.

A limitation of this technique includes the fact that conventional IVUS provides only a thin cross-sectional view of the artery; therefore, the wire must re-enter the true lumen at a point directly adjacent to the imaging element. The need for subintimal dilation creates an unwanted larger

false lumen, and the monorail design of existing IVUS catheters precludes wire exchanges. In addition, because of the physical attributes of current IVUS catheters, the distal end of the IVUS catheter must reside approximately 10.5 to 23 mm distal to the imaging element, requiring a relatively longer subintimal tract to be made (Figure 1).

SIDE BRANCH TECHNIQUE

This technique takes advantage of the fact that CTOs often arise just distal to a branch artery. In the side branch technique, the IVUS catheter can be placed into this side branch just proximal to the CTO, whereby the proximal cap and true lumen of the CTO can be visualized. A limitation of this technique is that a precise anatomic arrangement of a side branch (such as a diagonal coronary artery) must exist just proximal to a complete occlusion (such as the mid left anterior descending coronary artery). The angle of the side branch relative to the parent vessel and CTO must also be favorable for cross-sectional imaging catheters.

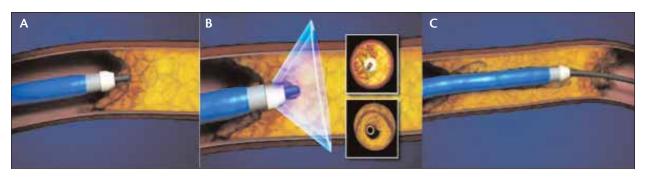


Figure 3. The key steps of the Preview catheter (Volcano Corporation) operation. The catheter is advanced over a guidewire to the proximal cap of the CTO (A). Under FL-IVUS guidance, the wire is advanced into the true lumen of the CTO (B). The catheter is then advanced over the wire, and additional imaging guides further guidewire advancement. The guidewire and FL-IVUS catheter are advanced in a step-by-step fashion through the CTO and into the distal true lumen (C).

GENERAL PRINCIPLES OF FL-IVUS CATHETERS

The procedural ideal of any CTO intervention is to enter the true lumen at the proximal cap of the occlusion, stay intraluminal, and re-enter the true lumen after crossing the distal cap. FL-IVUS catheter technology is currently being developed for clinical use with these goals in mind. The main innovation with FL-IVUS is the ability to image in an antegrade (forward-looking) manner distal to the catheter tip. FL-IVUS catheters have previously been developed with an annular ring array of 64 elements at the tip of the catheter.⁷ In other designs targeted for clinical use, there is a single 45-MHz imaging transducer oriented at a 45° angle at the end of the catheter. The catheter rotates within a polymer sleeve and provides a forward-looking cone of visualization. This should result in visualization of the proximal cap and facilitate entry into the true lumen through the proximal cap of the CTO. Once within the CTO, the vessel walls can be visualized in front of the FL-IVUS catheter. By keeping the catheter centered in the vessel, the guidewire can be directed to maintain a true lumen position. The potential advantages of FL-IVUS technology are listed in Table 1.

THE PREVIEW CATHETER

The Preview catheter is currently undergoing preclinical and early clinical evaluation. It is a single-use, overthe-wire imaging catheter, and the distal imaging tip is shown in Figure 2. This catheter is advanced over a conventional 0.014-inch guidewire to the site of occlusion. It rotates at a rate of 3 to 5 revolutions per a second at a frame rate of 3 to 5 frames per second. The current generation of this catheter has a 45-MHz transducer at the tip and is compatible with a 7-F guide. The catheter provides a unique forward-looking view at a depth of

TABLE 1. FEATURES AND POTENTIAL ADVANTAGES OF FL-IVUS TECHNOLOGY

- Ability to image immediately beyond the catheter tip (forward-looking)
- · Guidewire visualization beyond the catheter tip
- Imaging of the proximal cap will allow confirmation of guidewire entry into the true lumen
- Intraluminal passage of the wire reduces the risk of perforation
- Facilitation of true lumen re-entry antegrade to the FL-IVUS catheter
- Compatibility with existing CTO specialty guidewires

5 mm and allows visualization of the vessel borders distal to the tip of the catheter. Conceivably, the catheter can be advanced behind a guidewire into and through a CTO while maintaining a true lumen position. Figure 3 shows a schematic of the Preview catheter in clinical use.

FL-IVUS WITH RADIOFREQUENCY

A second-generation FL-IVUS catheter, which has not yet been named, is built on the Preview catheter platform, but also integrates a radiofrequency (RF) ablation element at the catheter tip. Therefore, in addition to imaging, it adds the elements of steering and tissue ablation. The tip of this catheter is angled, rotationally

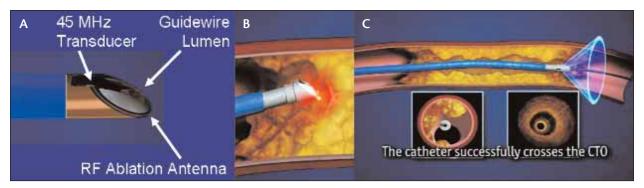


Figure 4. This second-generation catheter combines FL-IVUS technology with an RF antenna, which allows the operator to ablate CTO tissue under IVUS guidance (A). The catheter can be rotated, and under FL-IVUS guidance, RF energy can be applied to directionally ablate CTO tissue (B). The catheter is advanced in a step-by-step fashion after sequential applications of RF energy (C). In this manner, the CTO can be crossed while maintaining true lumen position.

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directable, and can be used to ablate CTO tissue under direct IVUS visualization; ablation time and power are user adjustable. Once the tissue is ablated, the catheter is gently advanced, and the vessel is reimaged. Sequential ablations can be directed to maintain an intraluminal position and avoid tracking toward the adventitia or subintimal space. The operation of the FL-IVUS catheter with RF is shown in Figure 4. This catheter has been used successfully in animal models of CTO, and early clinical evaluations are planned.

CONCLUSION

CTOs remain the most challenging subset of coronary percutaneous interventions with success rates averaging 50% in current practice. These procedures tend to be lengthy and require a high degree of operator skill, experience, and patience. The ultimate goal of any new CTO technology is to increase the procedural success rates of CTO crossing and to shorten the procedure time. FL-IVUS technology may provide an entirely new technique and approach to CTO intervention with direct visualization of the CTO distal to the catheter tip. Whether with guidewire-assisted or RF energy crossing, FL-IVUS has the potential to improve the ease and success of CTO interventions in the future.

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