Extravascular Ultrasound Guidance for CTO Crossing

Techniques to treat complex infrainguinal and tibial-pedal disease.

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he use of ultrasound (US) to visualize vascular structures and interventional devices has been a great addition in the evaluation and treatment of patients with critical limb ischemia (CLI). In an effort to standardize the treatment of chronic total occlusions (CTOs), this article describes the stepwise approach and US-guided techniques utilized to access vascular conduits, place and orient devices (sheaths, wires, catheters, crossing tools, re-entry tools, atherectomy devices, balloons, and stents) within vessels, cross the CTOs, and finally, treat the diseased segments.

Due to the evolution of medicine and technology, procedures continue to become less invasive, and the search for methods to increase safety and decrease complications has rendered US a time-honored tool that accomplishes these goals.¹⁻⁵ Patients with CLI have multilevel and multivessel disease, usually with severely calcified vessels and long lesions/occlusions, which translates to the need for multiple and lengthy revascularization procedures. On average, each CLI patient may require 1.9 to 2.4 procedures to achieve complete revascularization.⁶ However, even in this particularly high-risk population, the use of US has been shown to decrease the rate of femoral-arterial access-related complications to 1.1% and allow tibial arterial access with a complication rate of 0%.⁷

Patients with CLI tend to have multiple comorbidities, including obstructive sleep apnea, chronic obstructive pulmonary disease, and congestive heart failure, which all limit the amount of time they are able to tolerate a supine position. Additionally, many have advanced kidney disease, which comes with its inherent limitations in the amount of contrast that can be safely utilized. These challenges have led physicians to design new strategies in an attempt to circumvent

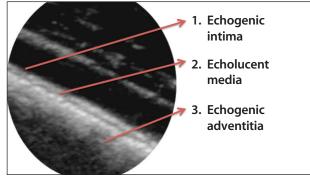


Figure 1. Long-access view of the anterior artery showing the three layers of the arterial wall.

these limitations, including the use of US-guided tibial-pedal arterial access and minimally invasive retrograde interventions (TAMI procedure).⁸ The TAMI procedure allows the patient to be propped at a 30° to 45° angle while the procedure is performed from a tibial-pedal access approach. Additionally, the use of extravascular ultrasound (EVUS) can be used to minimize radiation and contrast exposure during prolonged interventions in these complex patients.

ULTRASONIC FEATURES OF ARTERIES

Historically, interventionists have relied on angiography to delineate the vascular anatomy. However, we have come to learn that angiograms are merely "lumeno-grams," as the contrast column only defines the borders of the lumen. The arterial wall consists of three layers that can be readily identified by currently available EVUS probes (Figure 1), therefore EVUS provides the operator with the unparalleled ability to directly and simultaneously visualize the lumen, the entire arterial wall, plaque and calcium deposits and densities, as well

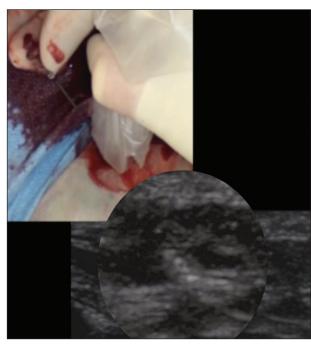


Figure 2. The needle tip "tents" the posterior wall.

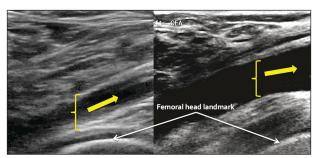


Figure 3. The femoral head as a landmark under EVUS. Bracket shows the CFA, and arrows signal the target access point.

as the interventional devices being used.

For the purpose of tibial-pedal access, the short-access view is typically utilized to identify the ideal puncture site. In CLI patients, these vessels tend to be calcified and have low intravascular pressure, which introduces two challenges. The calcification of these arteries leads to rolling of the target vessel to either side of the access needle when it comes into contact with the vessel wall. Direct EVUS visualization allows the operator to follow the vessel trajectory and simultaneously correct the angle of the needle tip. To gain access, the operator will have to apply a considerable amount of pressure to overcome the calcified barrier. The high pressure leads to puncture of both the anterior and posterior wall, consistent with the Seldinger technique. The issue of low filling pressures causes the

COMMON ULTRASOUND LANDMARKS

- · Inferior epigastric artery
- · Femoral head
- SFA/profunda bifurcation
- · Distal femur/proximal fibula
- Superior and inferior anterolateral branch of the anterior artery
- · Anterior communicating artery
- Posterior communicating artery

target vessel to collapse both walls until they come in touch with each other. This leads to penetration of both walls simultaneously and requires attentiveness to maneuver the access needle to the center of the vessel. These maneuvers are done by decreasing the angle of the needle, which will raise or "tent" the posterior wall (Figure 2), and gently withdrawing the needle while slowly advancing the access wire. When the posterior wall "falls," the tip of the needle is in the lumen, and the wire is advanced while being spun to increase its visualization.

ULTRASONIC LANDMARKS

For common femoral artery (CFA) access, we combine fluoroscopy to identify the femoral head and EVUS to identify the CFA bifurcation, superficial femoral artery (SFA), profunda femoral artery, and inferior epigastric artery (see the *Common Ultrasound Landmarks* sidebar). Accessing the CFA above the femoral head (or the inferior epigastric artery) increases the risk of a retroperitoneal bleed, whereas puncturing below the femoral head can increase the risk of hematomas and pseudoaneurysms (Figure 3).

ULTRASONIC FEATURES OF ENDOVASCULAR DEVICES

In order to proficiently perform endovascular interventions with EVUS guidance, operators must become familiar with the appearance of different devices under US.

Needles and Wires

Needles and wires have a bright echogenic appearance under US (Figure 4). Operators will be able to identify the access needle as a bright echogenic line, which should be the most reflective image within the field of view due to the serration of the distal tip of



Figure 4. The needle appears as a bright line under US (asterisk).

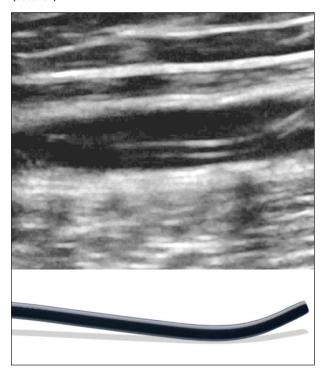


Figure 6. Catheter visualization under US.

the access needle. The wires typically used for tibial-pedal access and interventions are significantly thinner (0.014 and 0.018 inch) and therefore slightly more difficult to see. The recommendation is to constantly spin the wires to increase the reverberation artifact that is produced, which enhances their visibility while decreasing the likelihood of subintimal penetration (Figure 5). The ability to see the tip of the wires engaging the CTO cap, deviating to potentially enter the subintimal space, diverging into a side branch, or even trying to go across the adventitia is invaluable, as this allows operators to make specific corrections as they go, increasing the likelihood of remaining intraluminal and decreasing the likelihood of complications.

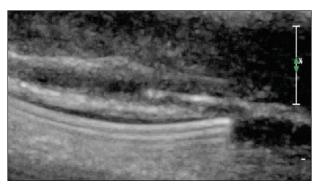


Figure 5. A wire with reverberation artifact.

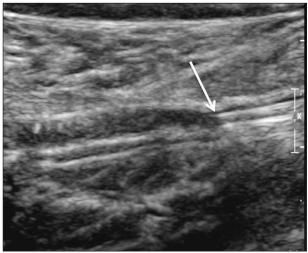


Figure 7. The tip of the pedal sheath within the anterior tibial artery (arrow).

Catheters and Sheaths

Catheters and sheaths are seen as two parallel lines. Larger-diameter catheters (0.035 inch) and those with a double stainless steel braiding have increased echogenicity, which enhances their visibility under EVUS (Figures 6 and 7).

Balloons

EVUS allows direct visualization of the distance between the balloon surface and the vessel wall, providing the operator with immediate feedback regarding the appropriateness of balloon sizing, adequateness of inflation, and the lesion's response to inflation, all of which are not feasible with fluoroscopic imaging (Figure 8).

Stents

Although stents vary in design, their appearance under EVUS is the same, as all we can see are the struts and the cells they delineate. EVUS allows direct visualization of wires, sheaths, catheters, and interventional devices as they are within the lumen of the stent, which

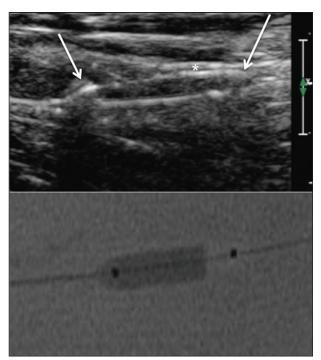


Figure 8. A balloon inflated under US and fluoroscopy. Arrows show the shoulders of the balloon under US. The asterisk shows the space between the balloon and the arterial wall.

is particularly helpful in situations when we are unable to determine whether or not we are behind a stent strut with fluoroscopic imaging. Sizing and apposition of the stent struts to the arterial wall can also be documented, which is particularly helpful when deploying stents in the infrapopliteal space. Figure 9 shows an example of an undersized stent.

Atherectomy, CTO Crossing, and Re-Entry Devices

Each one of these devices has its own unique and specific appearance under EVUS, as this is determined by their specific components and mechanism of action. The Viance CTO crossing device (Medtronic) appears as a catheter (two parallel lines) with a bright, echogenic reflective tip. The Crosser CTO crossing device (Bard Peripheral Vascular, Inc.) appears as a reflective tip, but its peculiar EVUS "signature" is the result of a unique phenomenon only seen with this device under EVUS visualization. Due to its mechanism of action (rapid mechanical vibration), it creates cavitations and microcavitations in the CTO caps, which in turn generate microbubbles that are seen as a "cloud" as the catheter finally crosses the cap (Figure 10). The TruePath CTO crossing device (Boston Scientific Corporation) appears as a rotating wire under US. Figure 11 shows an example of the Diamondback orbital atherectomy

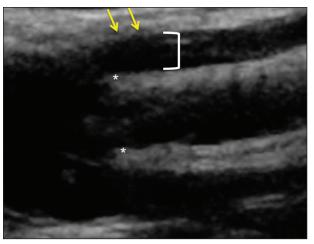


Figure 9. An undersized stent shown on US. The yellow arrowheads signal the arterial wall, the asterisks signal the stent borders, and the bracket signals the distance between the stent and the arterial wall.

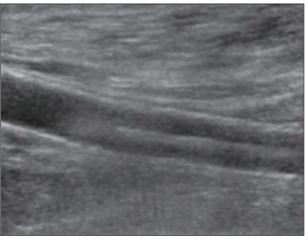


Figure 10. The Crosser device and the microcavitation "cloud" created by the device vibration.

crown (Cardiovascular Systems, Inc.) seen with EVUS. The crown is made of metal and is covered with synthetic echogenic diamonds.

ULTRASONIC FEATURES OF CHRONIC TOTAL OCCLUSIONS

All CTOs are composed of a proximal and distal cap. Depending on the length and chronicity of the occlusion, the segment in between the caps may either have a hibernating lumen, house multiple subtotal occlusions, or in extreme cases, the entire segment may be totally occluded.

We have observed that the composition and calcium content of each cap tends to differ greatly between patients. However, based on their distinct appearance

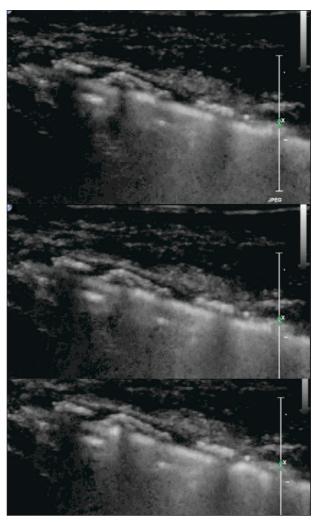


Figure 11. Orbital atherectomy.

under fluoroscopic or EVUS imaging, caps are classified as having either a concave or convex morphology. Caps are further classified by the direction in which they are approached (antegrade or retrograde). From these observations, we have created the proposed CTO classification shown in Figure 12, which grades the CTO types from simplest to most difficult (I-IV) under the assumption that the lesion is being approached from the traditional antegrade approach. Figure 13 shows a CTO cap that has been imaged with ultrasound (Figure 13A) and angiography (Figure 13B). If the operator chooses to approach the proximal CTO cap in antegrade fashion (white arrows), it will be classified as antegrade concave. However, if the operator chooses to approach the same cap in a retrograde fashion (red arrows), it will be considered a retrograde convex cap. The importance of this distinction lies in the increased complexity in crossing and treating lesions with convex caps. Convex caps are

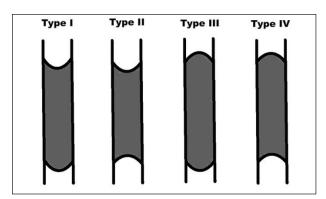


Figure 12. C-TOP classification for CTOs.

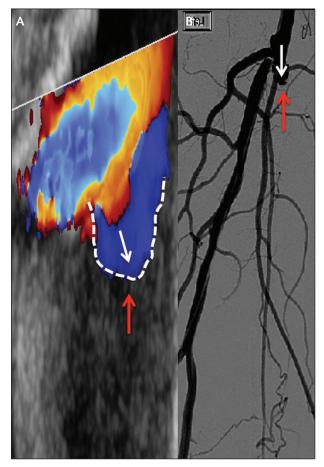


Figure 13. US with color showing an antegrade concave CTO cap (A). Angiographic view of the same antegrade concave CTO cap (B).

difficult to cross, as their morphology directs devices toward the arterial wall, increasing the likelihood of subintimal penetration, dissection, and perforations. Based on this classification, type III and IV CTOs are considered to be the most challenging to cross from an antegrade approach.

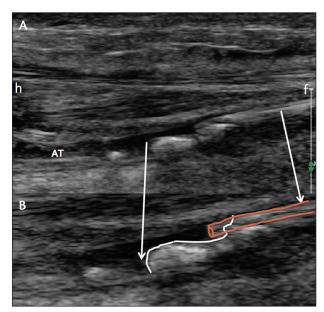


Figure 14. An antegrade convex cap and retrograde crossing catheter (h = head; f = feet) (A). A magnified drawing of the same segment (B).

In an effort to validate this classification, we are currently conducting the C-TOP (Chronic Total Occlusion Crossing Approach Based on Cap Morphology) trial, an ongoing analysis evaluating patients with infrainguinal CTOs. The objective is to determine whether the CTO cap analysis can influence decision making with regard to access and interventional device selection, as well as to evaluate technical and procedural outcomes.

EVUS-AIDED CTO CROSSING

EVUS provides the ability to visualize CTOs and identify the plaque composition of lesions and CTO caps. Figure 14 shows an example of the value of EVUS in a complex peripheral vascular intervention. The lesion shown in Figure 14A is composed of severely calcified plaque with eccentric origin that led to the CTO. The CTO cap is convex, which is associated with a higher crossing complexity, occasionally requiring re-entry devices or additional alternative access such as retrograde tibial access. In this scenario, as shown in Figure 14B, the retrograde catheter is across the calcified plaque, which was approached from a retrograde tibial access. The valuable real-time feedback information provided by EVUS increases the likelihood of crossing the CTO while remaining in the true lumen. Every step of retrograde CTO crossing is predetermined based on this visual feedback until the lesion is crossed. Intraluminal CTO crossing preserves significant therapeutic options, including atherectomy.

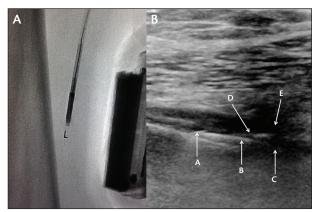


Figure 15. The Outback re-entry device seen under fluoroscopy (A) and US (B).

In Figure 11, orbital atherectomy is used to treat a severely calcified concentric CTO plaque. The figure shows the atherectomy device at different levels and stages of therapy. EVUS provides the opportunity to see the atherectomy device in direct contact with the calcified plaque while staying within the confines of the vessel lumen. In order to complete the endovascular therapy of this complex, severely calcified lesion, the operator has the ability to choose the adequate balloon size based on EVUS analysis of the vessel diameter (which is of paramount importance in the era of drugcoated balloons).

A commonly seen lesion in patients with peripheral arterial disease is the long CTO that involves the ostium or proximal segment of the SFA and reconstitutes at the level of the popliteal artery. EVUS plays a major role in access selection and crossing strategy of the proximal cap. Traditionally, the most common approach to this type of lesion has been to access the contralateral CFA and perform the intervention via the "up-and-over" technique. However, EVUS offers a valuable option as it facilitates (in select patients) EVUS-guided antegrade access, with the possibility of directly crossing the proximal CTO cap. When feasible, this alternative provides the best support, eliminates the loss of kinetic energy produced by the breakdown of the force vector at the level of the aortoiliac junction, and increases the pushability and torqueability of the devices being used, increasing the likelihood of successful crossing and treatment.

The process for this type of access and crossing begins with EVUS mapping of the target access point in the ipsilateral CFA in order to determine whether antegrade access is feasible and safe. After access is achieved and before initiating the intervention, it is recommended to further analyze the proximal and distal CTO caps with EVUS, as shown in Figure 14. The

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crossing tool is then advanced and engaged in the CTO cap under EVUS guidance, which provides visual feedback that favors intraluminal maneuvering and keeps devices within the confines of the vessel wall and close to the center of the CTO cap. As shown in Figure 15, the crossing tool is positioned in the center of the CTO cap and rotated both clockwise and counterclockwise to keep it centered while its forward motion is carefully controlled and visualized. These steps are sequentially repeated until the crossing tool is across the proximal CTO cap and obstructive plaque. Attention is then directed to the distal CTO cap. Figure 14 shows the extensive complexity of a convex, severely calcified CTO cap, which completely obliterates the arterial lumen. Not surprisingly (given its morphology), the peak of the convex cap deflected the crossing tool into the subintimal space, and due to the complete obliteration of the arterial lumen with dense and severely calcified plaque, alternative crossing methods (such as re-entry tools or alternative access) had to be utilized.

In this case, a re-entry device was selected, as shown in Figure 15. The re-entry wire was clearly seen entering the distal true lumen right next to the CTO cap, with only minimal loss of viable patent lumen. From this point, revascularization can be performed based on the operator's preference. As with any other procedure, experience will translate to significantly better images and success rates. Figure 15 shows the simultaneous visualization of the Outback re-entry device (Cordis Corporation) on both fluoroscopy (Figure 15A) and EVUS (Figure 15B). Notice the significant discrepancy in the amount of detail provided by both imaging modalities. EVUS shows the operator the location of the Outback, the orientation of the needle, location of the true lumen and subintimal space, as well as their relationship with the re-entry device. Combined fluoroscopic and ultrasound images provide the operator with more accurate visualization of the re-entry segment.

Traditional re-entry devices were designed for supratibial vessels and are too bulky for the tibial arteries.

The Enteer device (Covidien) has a lower profile and can be used for re-entry in the tibial arteries.

SUMMARY

EVUS-guided endovascular intervention is a viable option for patients with complex disease including multilevel and multivessel CTOs. Patients with advanced kidney disease can derive significant benefits from EVUS by receiving a decreased amount of contrast. Physicians, staff, and patients can also benefit by substantially decreased radiation times, especially during access and crossing of long, complex CTOs. Overall, the utilization of EVUS to guide arterial access and complex interventions should become an essential part of the interventionist's tool kit in order to increase success rates and decrease complications.

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