The TAPE Method

A novel intravascular ultrasound scoring system for peripheral CTO lesions.

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Chronic total occlusions (CTOs) represent the far end of a spectrum of peripheral arterial atherosclerotic disease and plaque burden. Clinical outcomes surrounding successful CTO crossing and treatment include improvement of symptoms, limb salvage, improved overall morbidity and mortality, and significantly reduced health care expenditures. Accordingly, large efforts are underway to define new technologies aimed at crossing CTOs with more safety, efficiency, and predictability.

Endovascular peripheral CTO interventions are fraught with unacceptably high rates of restenosis. Multiple strategies have been employed in superficial femoral artery (SFA) CTO interventions, including intentional subintimal angioplasty (SA), percutaneous transluminal angioplasty with bailout stenting, and CTO atherectomy with provisional percutaneous transluminal angioplasty. Long-term patency rates can vary between 57% and 70% at 1 year[1] and are thought to be due to the unfavorable SFA anatomical location, which undergoes torsional forces and repetitive flexion.[2]

The initial method of CTO crossing may have important implications on the amount of vessel injury that then guides further interventional strategies. Vessel perforation, embolization, dissection, hematoma, compromise of important collaterals, and prolonged lesion treatment length are inherent pitfalls of SA CTO crossings. The overall complication rate of the SA approach ranges between 6% and 17% due to the differing definitions.[3-8] Vessel injuries may contribute to an accelerated vessel healing response and restenosis.

We propose a novel intravascular ultrasound (IVUS) scoring system to assess vascular injury patterns (morphology) after successful CTO crossing. The scoring system is referred to as the *TAPE Method*. This method incorporates four concepts of vessel injury during CTO crossing. TAPE stands for: tears, axial (vs nonaxial), preservation (collaterals), and extension (treatment lesion length). Each characteristic is associated with a score ranging from 0 through 2 (Table 1).

Methods

The TAPE score was developed with no particular device in mind. This is a measurement assessing the anatomic status of a vessel that was previously occluded. For CTO crossing, our institution uses the Crosser catheter (Bard Peripheral Vascular, Inc., Tempe, AZ), the Wildcat catheter (Avinger, Inc., Redwood City, CA), and the standard SA technique. Patients who are analyzed with a TAPE score are those who have primary crossings without adjunctive devices or bailout SA/PIER (Percutaneous Intentional Extravascular Revascularization). At our institution, the primary approach centers on central lumen crossing, with PIER utilized as a bailout option. Future validation studies will determine a direct comparison between competing procedures.

We perform IVUS after CTO crossing, at which point the TAPE score is applied. Obtaining the imaging needed to determine a TAPE score can be acquired by either a phased-array or mechanical coronary IVUS catheter. Our institution uses a phased-array coronary IVUS catheter (Eagle Eye Platinum, Volcano Corporation, San Diego, CA).

The first reason we use this device is the ability to use ChromaFlo during image acquisition. ChromaFlo increases our ability to note collateral communication between the true versus the false lumen and the exit and entry points of dissection planes. A second advantage of phased-array coronary catheters over mechanical cath-

TABLE 1. TAPE SCORE

Score	Tears	Axial	Preservation	Extension
0	No dissection	Completely axial	Collateral preservation	No extension of treatment segment
1	Dissection	Between IEM and EEM	Loss of collaterals in the treatment segment	One reference segment extended
2	Hematoma	Between EEM and adventitia	Loss of collaterals in the reference segments	Two reference segments extended

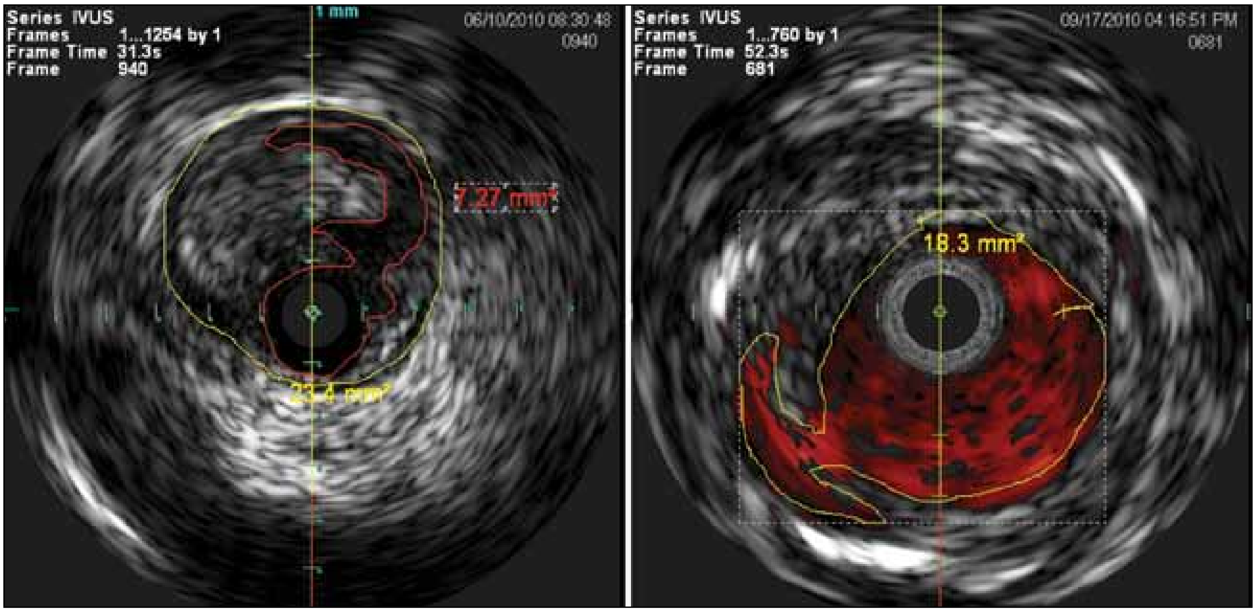

Figure 1. T1 level dissections, with and without ChromaFlo. No notation is made in TAPE score for the depth or severity of the dissections.

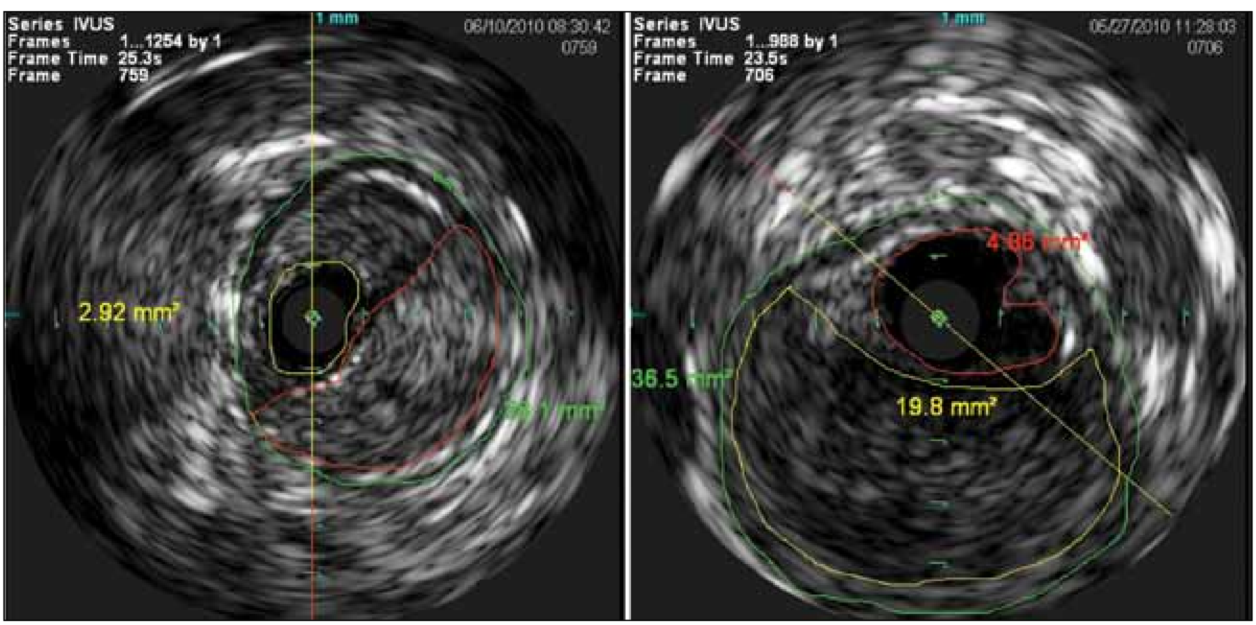

Figure 2. T2 lesion with an intravascular and an extravascular hematoma. Note the compression of the remaining lumen and the large size of the extravascular hematoma. All hematomas show the characteristic "D" or "helmet" shape.

eters is that the lumen is often easier to delineate due to less blood speckle or rouleaux formation. This can be pronounced in the peripheral vessels and makes delineation of the leading intimal edge very challenging when using mechanical coronary catheters.

Third, we have used Virtual Histology (Volcano Corporation) in patients who present with the appearance of medial calcinosis in order to ascertain the calcific content of the tunica media. This is a novel approach to diagnosing Monckeberg's medial calcinosis.[9] This condition seems uniquely suited to central lumen crossing technology and often garners more favorable TAPE scores due to the media deflecting the crossing catheter toward the center of the vessel. It would also appear to offer greater resistance to distal reentry during SA/PIER approaches.

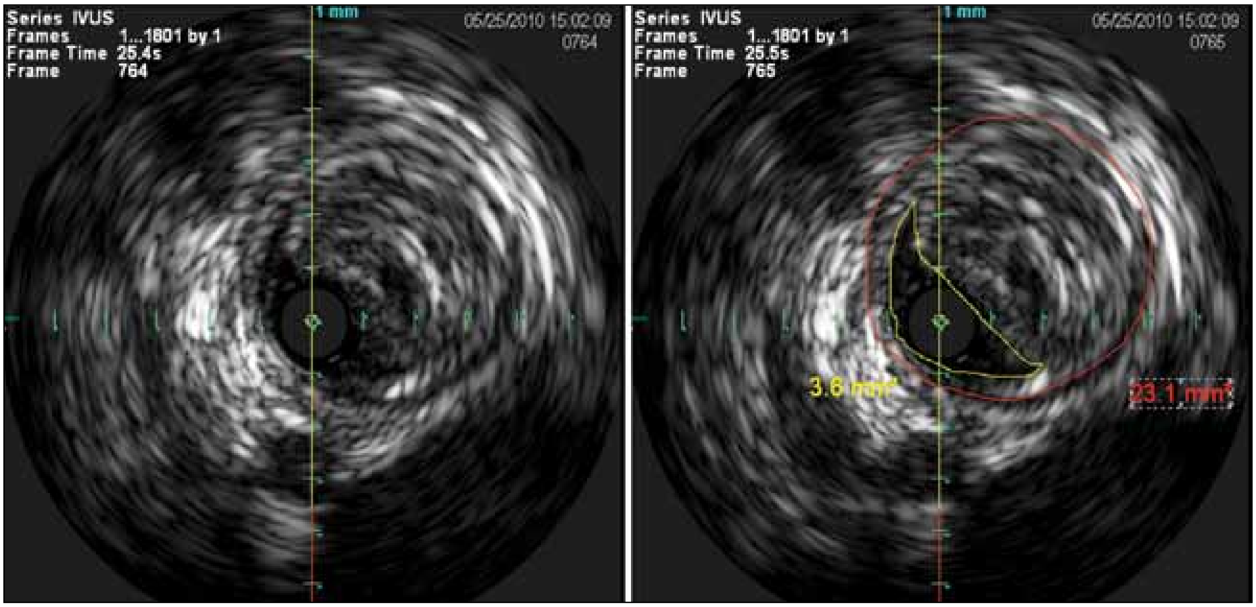

Figure 3. A1 level nonaxial line. The IVUS catheter sits between the IEM and EEM and displays the characteristic extension of the false lumen within the media in a semilunar shape.

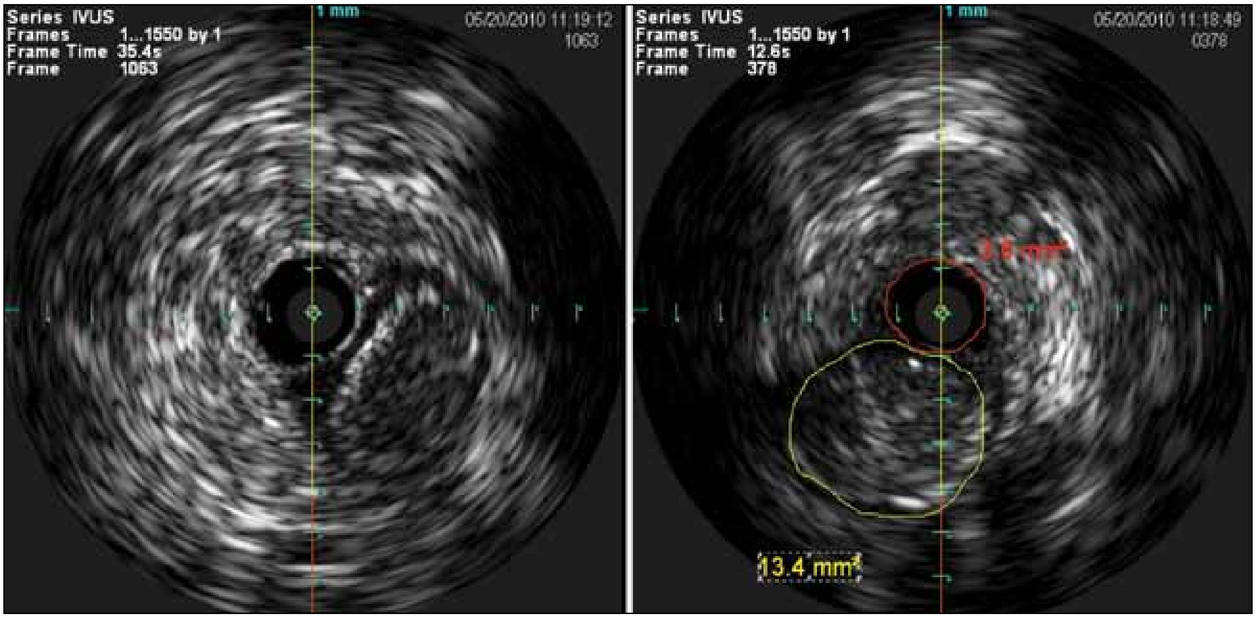

Figure 4. A2 level nonaxial lines. Note that the catheter now sits between the EEM and the adventitia and forms a "figure 8" shape.

A default grayscale setting is adequate, but it is advisable to set the range of the screen to 14 mm instead of the default 10 mm. This enables the practitioner to have a reasonable view of the perivascular field, even with large SFAs, which is important in diagnosing perivascular hematomas.

Motorized pullback at 1 mm per second can offer important information about the length of the lesion or dissection planes but is often impractical due to the extensive lengths of the total occlusions involved. In most typical occlusions, the video loop would reach the maximum frame rate before reaching the proximal reference, in which case, splicing segments would be necessary. For this reason, we typically manually pull through the study segment at a uniform and steady rate. The pullback is performed within a 90-second time period

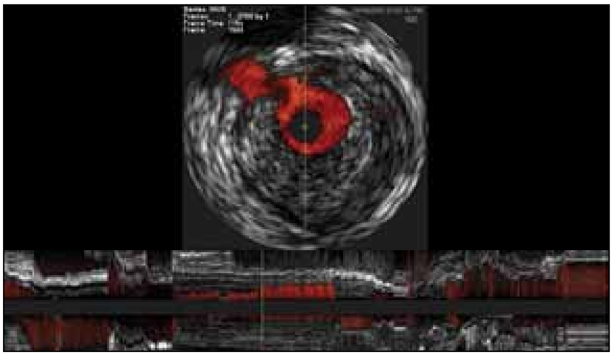

Figure 5. P0 lesion with a collateral seen connecting with the lumen of the crossing, indicating preservation of collateral.

from distal to proximal, which, at 30 frames per second, acquires approximately 2,700 frames to examine. Before the video loop is archived, a TAPE score is assigned as the name of the loop.

TAPE SCORE

Tears

In terms of tears, we look for evidence of dissection proximal to, within, and distal to the total occlusion. We quantify this as some investigators have—the proximal segment will be at the site of the lesion, within the lesion, and distal can be ≤ 5 cm as described by Lipsitz et al.[10] No evidence of dissection results in a score of 0. Any evidence of dissection results in a score of 1. We do not qualify whether the dissection is flow limiting or the size or depth of the dissection. Evidence of extravascular or intravascular hematoma, which often causes systolic compression of the new lumen and can extend longitudinally, will receive a score of 2 (Table 2, Tear score; Figures 1 and 2).

Axial

For axial assessment (Table 2, Axial score), we see if the IVUS catheter is inside the internal elastic lamina (IEL) border. If the catheter stays entirely within the lumen, this is scored as 0. In an A1 orientation, the catheter wedges itself between the internal elastic membrane (IEM) and the external elastic membrane (EEM), which will appear to not distort the outer wall of the vessel and will create a semilunar tear within the media (Figure 3). In an A2 orientation, the catheter wedges itself between the EEM and the adventitia, which will appear to distort the outer wall of the vessel and give the appearance of a "figure 8" shape (Figure 4).

Preservation

For preservation of collaterals, we look at the collateral circulation as it connects proximal to, within, and distal to the total occlusion. The loss of collateral circulation could mean increased risk of critical limb ischemia if and when the treatment segment undergoes restenosis. Lipsitz et al reported that up to 47% of the collaterals distal to and 26% of the collaterals proximal to subintimally treated CTOs of the lower extremity are lost after angioplasty.[10] There is evidence that loss of collaterals within the treatment segment can be critical when the vessel reoccludes due to the length of the occlusion often being shorter than the original occlusion and the

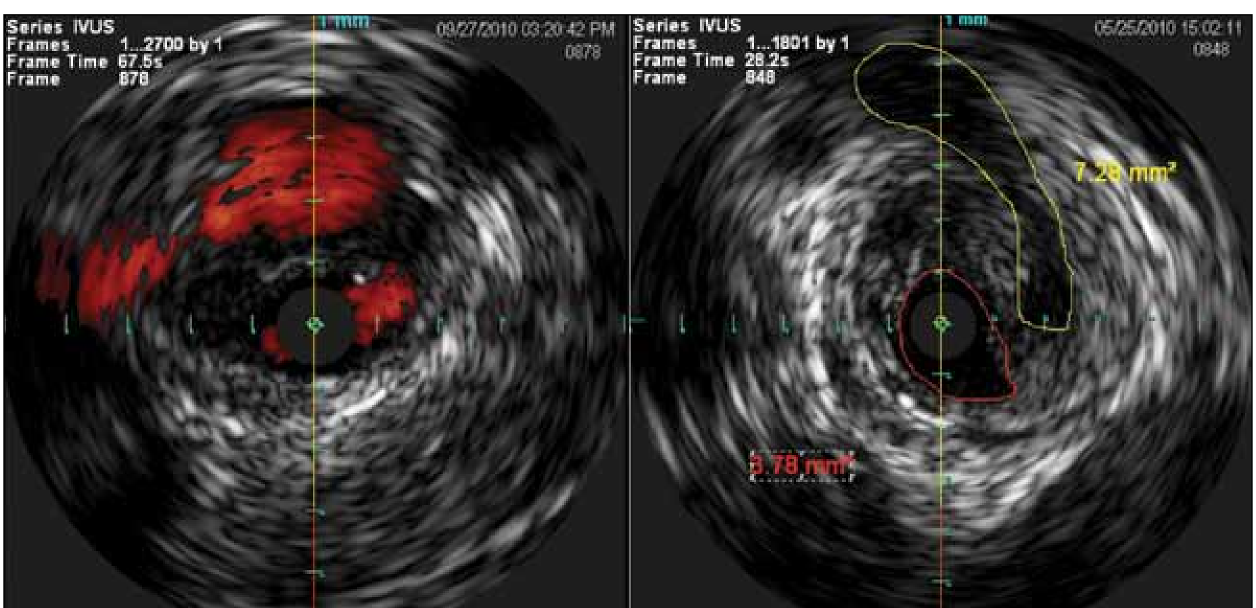

Figure 6. P1 in-lesion collateral loss with and without ChromaFlo.

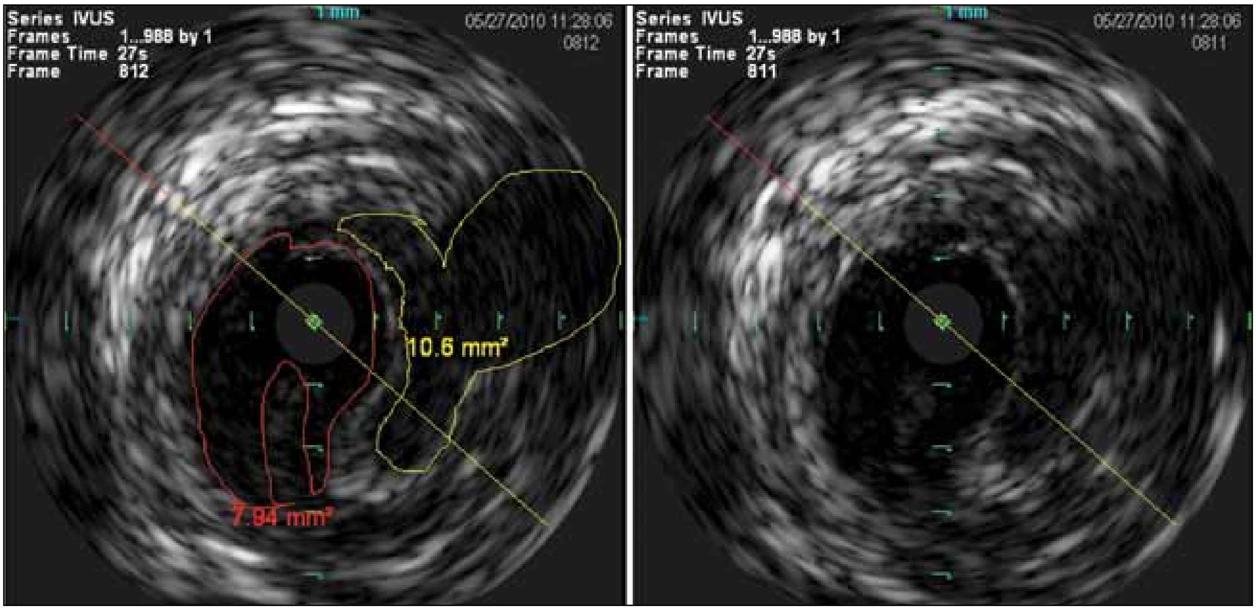

Figure 7. P2 lesion with reference collateral loss to the proximal reference with and without borders. Note a small dissection at 6 o'clock.

in-lesion collaterals becoming more relevant. The reference collaterals are still considered to be more important for limb preservation than the in-lesion collaterals and are graded accordingly.

No loss of collateral circulation yields a score of 0. If collaterals are seen to connect with an alternate lumen within the treatment segment alone, this results in a score of 1. If collaterals connect to alternate lumen in a reference segment, this is scored as 2 (Table 2, Preservation score; Figures 5 through 7).

Of note is that this score can be ameliorated by connecting the crossing lumen to the alternate lumen by adjunctive atherectomy before balloon-based interventions.

Angiography is insensitive for evaluating collaterals and the loss of collaterals postprocedure after CTO crossing. Although angiography may suggest that collateral preservation is intact, IVUS can show that the crossing may in fact be in a separate lumen from the one the collateral communicates with. Any additional balloon-based intervention (PTA or stenting) has a considerable potential to seal off this collateral. As previously stated, there is evidence that loss of in-lesion collaterals may have adverse effects due to the chance that a reocclusion may take place in a shorter segment, thus making the in-lesion collaterals the new reference collaterals.

Collateral circulation is easily identifiable by IVUS, especially when utilizing ChromaFlo. Collaterals do not display divergence (deferential shifting of plaque consistent with arterial bifurcations), and so they resemble septal perforators in their IVUS characteristics and patterns.

TABLE 2. THE TAPE METHOD

Tear score (Figures 1 and 2)	0	No dissection
	1	Dissection
	2	Hematoma
Axial score (Figures 3 and 4)	0	Completely axial
	1	Between IEM and EEM
	2	Between EEM and adventitia
Preservation score (Figures 5 through 7)	0	Collateral preservation
	1	Loss of collaterals in the treatment segment
	2	Loss of collaterals in the reference segment
Extension score (Figure 8)	0	No extension of treatment segment
	1	One reference segment extended
	2	Two reference segments extended

Extension

A common undesired effect of the PIER technique is the inability to re-access the true lumen at the exact site of the distal end of the lesion. This often leads to reentry at a distal site and extension of the actual treatment zone.

Limiting the extent of intimal dissection and angioplasty in such cases may preserve surgical options. For example, precise placement of the point of reentry into a reconstituted above-knee popliteal artery may preserve the option of an above-knee femoropopliteal bypass in the event of long-term failure of angioplasty or stenting of an SFA occlusion.[1]

We assess the distal and proximal reference vessels for extension of the treatment segment during the crossing attempt. If there is immediate entrance and exit from the total occlusion, the patient is given a score of 0. If one reference shows evidence of extension, the patient is given a score of 1. If both references show evidence of extension, we give the patient a score of 2 (Table 2, Extension score; Figure 8).

DISCUSSION

SA crossing of CTOs of the SFA is a common technique for treating peripheral vascular disease and can be seen as a competing approach to bypass grafting. Limb salvage rates at 5 years appear to be nearly identical between the two approaches.[3] A major advantage for the SA/PIER technique appears to be shorter length of hospitalizations, reduced costs in the short-term, and a lower risk of major adverse events.[1,3]

CTO crossing devices offer a clear alternative to the SA approach, but levels of technical expertise and/or financial constraints of strained cardiology institutions may influence the preference between these techniques. It is unclear if one method is superior to the other in influencing outcomes. The TAPE score is an attempt to assess and quantify the intravascular effects of different CTO crossing methods and their influence on vascular anatomy. Thus, according to the TAPE scale, an ideal crossing would garner a score of 0, and a very suboptimal crossing would merit a score of 8. The patient's score

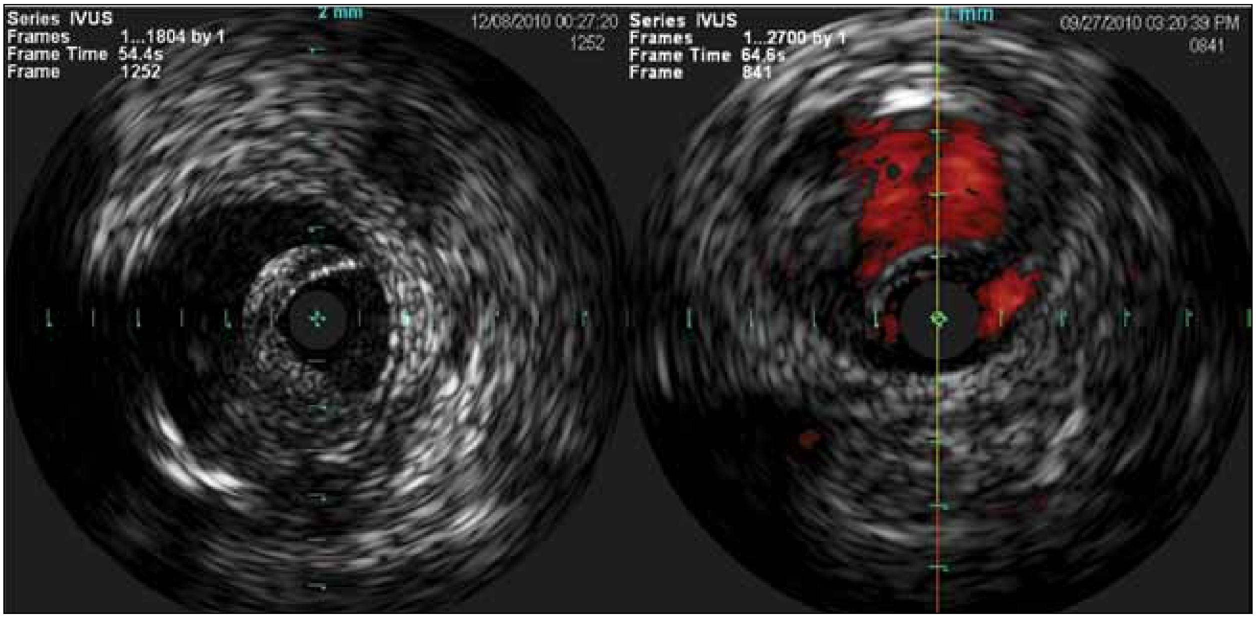

Figure 8. Extension (E1 lesion) of the crossing into the reference segments without and with ChromaFlo.

may determine long-term outcomes of the crossing and subsequent intervention device choice. For example, in the case of a lengthy nonaxial crossing, long bare-metal stenting may be seen as a less-optimal choice due to increased risks of under expansion, increased scarring secondary to subendothelial deployment, and increased risk of stent fracture.[11]

IVUS was chosen because the diagnosis of many complications may be grossly underreported or underappreciated due to the relative inability of angiography to detect all instances of perforations, dissections, perivascular hematomas, collateral compromise or treatment length extensions.

CONCLUSION

We propose the use of a novel IVUS scoring system to characterize SFA vessel injury after CTO lesion crossing. Clinical retrospective analysis and multicenter validation studies are currently in progress that implement this proposed scoring system. As we continue to understand the dynamic environment of the true and false lumens created during reconstitution of vascular flow, the TAPE score enables us to accurately classify and catalogue CTO crossings.

Current therapies for CTO crossing include techniques ranging from traditional looped guidewire passing to guidewire support catheters armed with IVUS, optical coherence tomography, radiofrequency, and laser technologies. Extrapolating TAPE scores with long-term clinical outcomes has the potential to highlight the safest and most effective CTO crossing interventions. ■

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