◆ CLINICAL INVESTIGATION

Novel Intravascular Ultrasound-Guided Method to Create Transintimal Arterial Communications: Initial Experience in Peripheral Occlusive Disease and Aortic Dissection

Ramin R. Saket, BA; Mahmood K. Razavi, MD; Arash Padidar, MD; Stephen T. Kee, MD; Daniel Y. Sze, MD, PhD; and Michael D. Dake, MD

Cardiovascular and Interventional Radiology, Stanford University Medical Center, Stanford, California, USA.

Purpose: To report our experience using a commercially available catheter-based system equipped with an intravascular ultrasound (IVUS) transducer to achieve controlled true lumen re-entry in patients undergoing subintimal angioplasty for chronic total occlusions (CTO) or aortic dissections.

Methods: During an 8-month period, 10 patients (6 men; mean age 73.4 years) with lower extremity (LE) ischemia from CTOs (n=7) or true lumen collapse from aortic dissections (n=3) were treated. Subintimal access and controlled re-entry of the CTOs were performed with a commercially available 6.2-F dual-lumen catheter, which contained an integrated 64-element phased-array IVUS transducer and a deployable 24-G needle through which a guidewire was passed once the target lumen was reached. The occluded segments were balloon dilated; self-expanding nitinol stents were deployed. In the aortic dissections, fenestrations were performed using the same device, with the IVUS unit acting as the guide. The fenestrations were balloon dilated and stented to support the true lumen.

Results: Time to effective re-entry ranged from 6 to 10 minutes (mean 7) in the CTOs; antegrade flow was restored in all 7 CTOs, and the patients were free of ischemic symptoms at up to 8-month follow-up. In the aortic dissection cases, the fenestrations equalized pressures between the lumens and restored flow into the compromised vessels. There were no complications related to the use of this device in any of the 10 patients.

Conclusions: Our preliminary results demonstrate the feasibility of using this catheter-based system for subintimal recanalization with controlled re-entry in CTOs and for aortic flap fenestrations in aortic dissections. This approach can improve the technical success rate, reduce the time of the procedure, and minimize potential complications.

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Key words: chronic arterial occlusion, aortic dissection, subintimal angioplasty, percutaneous intentional extraluminal recanalization, intravascular ultrasound, true lumen, re-entry

Chronic total occlusions (CTOs) pose a substantial challenge in the treatment of arterial occlusive disease. In the coronary arteries, angioplasty of CTOs has had only limited technical success (47% to 72%),[1–4] resulting in increased utilization of resources, prolonged radiation exposure, and higher complication rates as compared to the angioplasty of high-grade stenoses.[2,5,6] A similar problem exists in the peripheral circulation, where the re-

Address for correspondence and reprints: Mahmood K. Razavi, MD, Cardiovascular and Interventional Radiology, Stanford University Medical Center, Vascular Center H3651, 300 Pasteur Drive, Stanford, CA 94305 USA. Fax: 1-650-725-0533; E-mail: *mrazavi@stanford.edu*

ported technical success rate is only ~80%, with prolonged procedure times and poorer outcomes.[7–13]

Subintimal recanalization with distal re-entry, known as percutaneous intentional extraluminal recanalization (PIER), has been advocated as a solution to this problem. This approach, however, has been limited by the lack of controlled re-entry into the true lumen of the target vessel, achieving a technical success rate reported between 76% and 82%.[14–16] Similar to the treatment of CTOs, aortic flap balloon fenestration in patients with aortic dissection can be time consuming and associated with a high rate of complications and low yield.

The purpose of this study was to report our experience with controlled true lumen re-entry using a commercially available catheter-based system in patients with peripheral CTOs and aortic dissection.

METHODS

In a study approved by the Human Subjects Committee, 10 symptomatic patients (6 men; mean age 73.4 years, range 52–85) were treated for peripheral ischemia (Table): 7 due to CTOs in lower extremity (LE) vessels and 3 owing to aortic dissections compromising various vascular beds (renal, mesenteric, and LE). The presenting symptoms in patients with LE CTO included chronic lower limb claudication and rest pain (n=5), rest pain associated with a nonhealing foot ulcer (n=1), and a nonhealing decubitus ulcer (n=1). Patients with aortic dissection had LE ischemia (n=1), acute anuric renal failure and LE ischemia (n=1), and a combination of acute LE ischemia, ischemic paraplegia, renal failure, and mesenteric ischemia (n=1). Written informed consent was obtained from all patients or their legal guardians.

All endovascular interventions were performed under local anesthesia with 1% lidocaine; conscious sedation was achieved with intravenously administered fentanyl citrate (Abbott Laboratories, Chicago, IL, USA) and midazolam hydrochloride (Roche Laboratories, Nutley, NJ, USA). In the 7 CTOs, all attempts to recanalize the occluded segments using the standard catheters and wires were unsuccessful, so subintimal access and re-entry were attempted with the CrossPoint TransAccess catheter (Medtronic Inc., Santa Rosa, CA, USA). This 6.2-F dual-lumen catheter (Fig. 1) has a fully integrated 64-element phased-array intravascular ultrasound (IVUS) transducer that enables controlled targeting of structures, as well as 360° imaging of the area of interest. Using a retrograde approach for iliac lesions (n=4) and antegrade delivery for superficial femoral artery (SFA) occlusions (n=3), the catheter's integral 24-G needle was advanced under IVUS guidance to the desired position for re-entry, and a 0.014-inch guidewire was then delivered into the target lumen (Figs. 2 and 3). After recanalization, the occluded segments were balloon dilated in standard fashion, and self-expanding nitinol stents were deployed (Fig. 4).

In the aortic dissections, the intimal flaps were punctured from the true lumen into the false lumen using the CrossPoint TransAccess catheter with the IVUS unit of the device acting as the guide. The fenestrations were then balloon dilated. To improve flow into the ischemic beds after fenestration, stents were placed in the abdominal aorta (n=1), renal artery (n=1), aortic true lumen, iliac arteries, and left renal artery (n=1).

RESULTS

Recanalization of the lower extremity chronic total occlusions was successful in all 7 patients using the CrossPoint TransAccess catheter (Table). Technical success, defined as effective luminal re-entry and restoration of antegrade flow through the occlusion, was achieved in all patients. Time to recanalization (from insertion of the device to re-entry into the lumen) ranged from 6 to 10 minutes (mean 7) for the LE lesions, which measured 10, 13, and 20 cm in the femoropopliteal arteries and 3, 3, 4, and 7 cm in the iliac arteries. There were no procedure-related complications. Lower extremity symptoms resolved in all patients after the procedure. One patient expired a month later of unrelated causes, but the remaining 6 patients were asymptomatic with patent stents at follow-up ranging from 4 to 8 months.

In the aortic dissection patients, 3 fenestra-

TABLE
Patient Profiles, Procedures, and Outcomes

Age, y/ Sex	Pathology	Indication for Treatment	Comorbidity	Procedure*	Pre/Post ABI	Follow-up
85/F	13-cm SFA occlusion from the origin	Nonhealing foot ulcer; foot rest pain	Osteoarthritis	SFA-POP recanalization (A-C)	0.66/0.83	8 mo: Patent stents by duplex. No claudication or rest pain; foot ulcer healed
75/M	10-cm SFA-POP occlusion from adductor canal, with multiple proximal SFA stenoses	Foot rest pain; no Doppler-detectable pulses†	CHF, HTN, tobacco abuse, COPD, dementia	SFA-POP recanalization (A-I)	No Doppler signal/ 1.00	1 mo: Foot pain subsided immediately; expired at 4 weeks of unrelated causes
83/F	Focal, 3-cm CIA occlusion just proximal to hypogastric artery origin, with multiple distal SFA stenoses	Lower extremity rest pain and numbness	HTN, diabetes	Aortoiliac recanalization (R-I)	0.56/0.60	6 mo: Patent stents with 2 focal areas of velocity elevation by duplex. No rest pain or claudication; palpable femoral pulses
82/F	4-cm CIA occlusion	Buttock claudication	Occluded renal stent, CABG, malignant HTN	Aortoiliac recanalization (R-I)	—/Normal femoral pulses	4 mo: Symptoms resolved
64/M	7-cm CIA occlusion	Nonhealing decubitus ulcer	Paraplegia, CAD, diabetes, HTN, HL	Aortoiliac recanalization (R-I)	—/Normal femoral pulses	4 mo: Interval healing of decubitus ulcer
76/M	Bilateral 3-cm CIA occlusions	2-block claudication	HTN, diabetes	Bilateral CIA recanalization (R-I)	—/Normal femoral pulses	6 mo: No claudication; palpable distal pulses bilaterally
85/F	Chronic left FP segment occlusion	1-block claudication	HTN, CAD, HL, tobacco abuse	Antegrade FP recanalization	0.5/0.8	4 mo: Claudication resolved
52/M	Acute type B aortic dissection; left renal artery compromised by false lumen	Acute anuric renal failure (creatinine ↑ 1.1 to 4.7 in 72 h)	Right subdural hematoma, seizure disorder	Aortic fenestration ×3, renal stent	NA/NA	2 mo: Patent false lumen, no pressure gradient, and patent renal artery on aortogram. Dialysis dependent
68/M	Chronic type A aortic dissection after repair; no angiographic evidence of LE runoff compromise	Bilateral LE claudication	HTN	Aortic fenestration, distal aortic stent	0.58 and 0.46/Palpable femoral pulses	1 mo: No claudication with full exertional capability
64/M	Acute type A dissection with true lumen collapse and no false lumen reentry	Mesenteric, right renal, and bilateral LE ischemia	HTN, CAD, prior CABG, AAA, obesity	Aortic fenestration; aortic, renal, and iliac stents	NC/Palpable femoral pulses	10 days: Restoration of visceral and lower extremity blood flow. Multiorgan failure after sternotomy

AAA: abdominal aortic aneurysm, ABI: ankle-brachial index, A-C: antegrade contralateral, A-I: antegrade ipsilateral, CABG: coronary artery bypass graft, CAD: coronary artery disease, CIA: common iliac artery, FP: femoropopliteal, HL: hyperlipidemia, HTN: hypertension, LE: lower extremity, NC: noncompressible, POP: popliteal artery, R-I: retrograde ipsilateral, SFA: superficial femoral artery, NA: not applicable.

* All successful.

† Symptoms occurred after a hemiarthroplasty for a fractured hip on the ipsilateral side of the lesion.

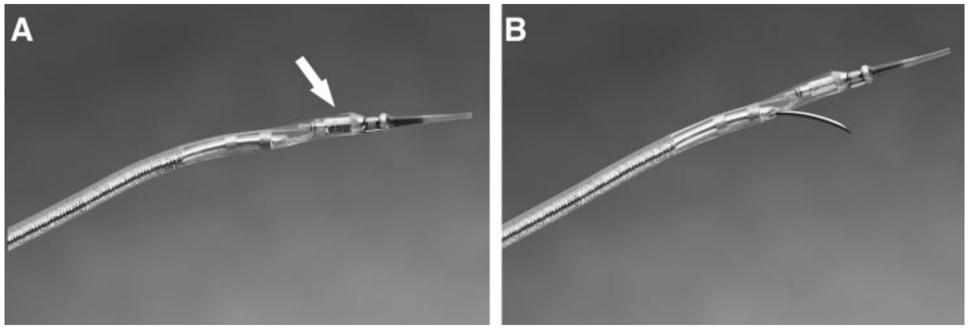

Figure 1 ◆ The CrossPoint TransAccess Catheter, shown here with the 24-G needle retracted (**A**) and deployed (**B**). The deployed needle permits the redirection of a second 0.014-inch guidewire back into the vessel to facilitate subsequent placement of catheters. The gold component (arrow in **A**) located between the deployed needle and the distal tip is the 20-MHz phased-array IVUS transducer.

tions were created successfully in the acute type B dissection at a level just above the renal arteries, which equalized pressures between the false and true lumens. Post-fenestration angiography revealed restoration of flow into both kidneys. Despite objective evidence of good renal perfusion, he remained dialysis-dependent at discharge.

The patient with a chronic type A aortic dissection had 1 fenestration created successfully, with equalization of pressures between the lumens. Immediately after the initial procedure, the patient developed claudication with worsening of the ankle-brachial indices. Repeat angiography revealed severe true lumen compression of the abdominal aorta just distal to the fenestration. A balloon-expandable stent was deployed across the narrowing, which reduced the mean pressure gradient from 61 to 7 mmHg and established good flow into both iliac arteries. The patient's symptoms immediately subsided, and he remained without any ischemic symptoms at follow-up.

The patient with an acute type A dissection underwent successful balloon fenestration supported by stents in the aorta and left renal and iliac arteries, which re-established flow in the mesenteric, renal, and LE vascular beds. The patient subsequently underwent repeat sternotomy for repair of his ascending aorta. One week after the sternotomy, he developed multiorgan failure and life support was withdrawn.

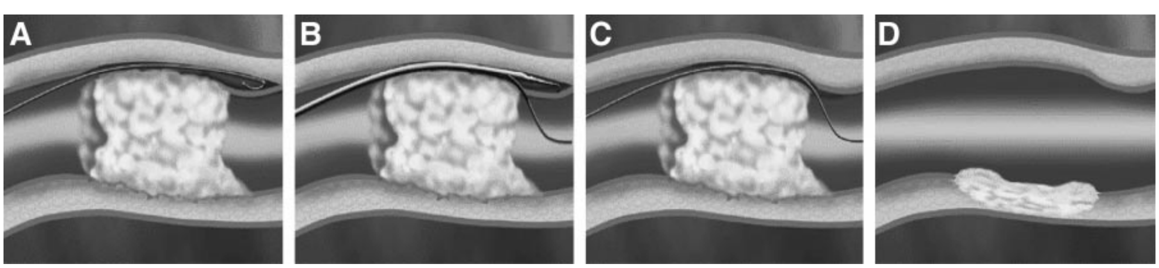

Figure 2 ◆ The CrossPoint TransAccess system facilitates the placement and positioning of catheters within the peripheral vasculature. In this series of illustrations, (**A**) a wire has become trapped in a subintimal location. Guided by a cross-sectional ultrasound image of the target area of interest, the CrossPoint (**B**) is guided to the target segment, where the needle is deployed. The guidewire is then passed through the needle. (**C**) With the wire securely placed into the target, the CrossPoint is removed. (**D**) The lesion is treated successfully with an angioplasty device delivered over the wire.

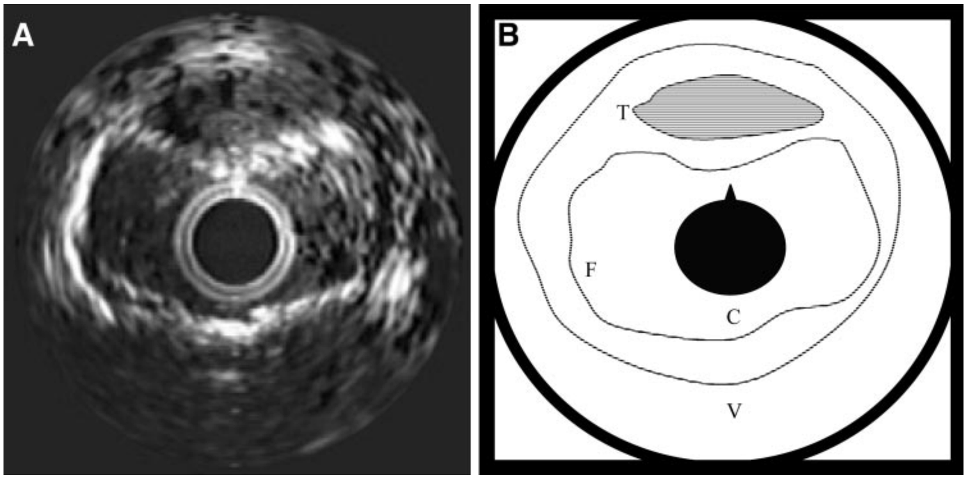

Figure 3 ◆ IVUS image (**A**) and diagram (**B**) showing the probe on the catheter (C in **B**) within the created false lumen (F) of the vessel. IVUS was used to guide the insertion of the needle, situated at the 12:00 o'clock position on the catheter, into the true lumen (T) distal to the occlusion. The outer edge of the vessel (V) can also be visualized.

DISCUSSION

In this study, we present the feasibility of using an IVUS-guided controlled re-entry system for subintimal recanalization of peripheral CTOs and fenestration in acute aortic dissections. The CrossPoint TransAccess catheter has been used experimentally to treat CTOs of the coronary circulation by percutaneous in situ coronary artery bypass (PICAB) and percutaneous in situ coronary venous arterialization (PICVA) with limited success to date.[17–19] In a preliminary study by Haskal et al.,[20] the same device was used to perform extravascular femoropopliteal bypass and in situ arterio-veno-arterial bypass of the tibial arteries in a cadaver model.

IVUS-guided subintimal recanalization appears to have 2 main advantages over the traditional guidewire-based subintimal dissection. First, it facilitates controlled re-entry into the true lumen of the vessel after subintimal recanalization of an occluded segment. Using the attached IVUS scanner, the reconstituted vessel lumen distal to the obstruction can be visualized and targeted for re-entry. The deployable 24-G needle is then advanced to a desired length sufficient to pierce through the intima and enter the flow lumen. A second wire advanced through the needle will then provide guidewire access into the targeted vessel. Our limited experience thus far suggests that this advantage optimizes the ability to create a subintimal path and re-enter into the reconstituted segment to re-establish antegrade flow, which should increase the overall technical recanalization rate of CTOs. Furthermore, re-entry under direct IVUS visualization has the potential to reduce the risk of vessel injury and perforation associated with recanalization attempts in CTOs.

The second advantage of this technique is the accelerated process of recanalization, which in our pilot series was 7 minutes among patients who had failed the standard guidewire attempts to cross the CTOs. Shorter procedure times may in turn lead to reduced radiation exposure and utilization of resources. Any savings in procedural costs may be partially offset by the added cost associated with its use, so this device may best be used selectively in cases where there is failure of conventional methods to re-enter the flow lumen.

The main advantage of the CrossPoint TransAccess catheter in fenestration of an intimal dissection flap is its ability to traverse from one lumen to the other under direct IVUS visualization, which obviates the need for difficult and time consuming access into both lumens. In addition, controlled passage of the needle across the flap reduces the risk of accidental injury to the aortic wall.

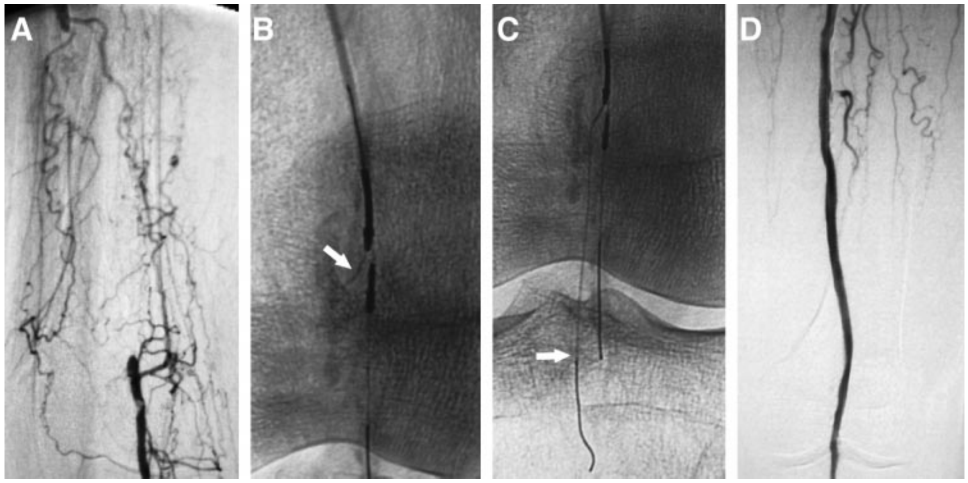

Figure 4 ◆ A 75-year-old man with a 10-cm occlusion (**A**) of the left femoropopliteal segment was treated with subintimal recanalization and stenting. (**B**) The CrossPoint TransAccess catheter was advanced subintimally over a 0.014-inch guidewire trapped in the created false lumen. The 24-G needle (arrow) was deployed into the true lumen beyond the occlusion under IVUS guidance. (**C**) A second 0.014-inch guidewire (arrow) was then advanced into the true lumen of the popliteal artery. (**D**) After balloon angioplasty and stenting of the subintimal tract, the arteriogram shows brisk flow through the previously occluded segment.

The main limitation of this device is that it does not have an ''over the wire'' capability. Its rapid exchange configuration, along with the 7-F size, reduces its ability to negotiate tortuous arteries over a 0.014-inch wire. The antegrade force that can be applied before the catheter buckles is also limited because of its rapid exchange design. Our initial attempts to recanalize the SFA occlusion in one patient from a contralateral retrograde approach were unsuccessful due to iliac tortuosity, necessitating an ipsilateral antegrade access.

Our preliminary results are promising using the CrossPoint TransAccess catheter for subintimal recanalization of chronic total occlusions and aortic flap fenestrations. Although our study sample was small, this approach appears to have the potential to improve technical recanalization rates for CTOs, reduce procedural time, and minimize complications. Additional experience is necessary to fully delineate the role of this device in endovascular interventions.

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