Percutaneous Recanalization of Chronically Occluded Coronary Arteries
A Consensus Document
Part II

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In Part I of this article, the definitions, prevalence, and clinical presentation of chronic total occlusions (CTOs) were reviewed, the histopathology of CTOs was examined, efforts to replicate human CTOs with experimental models were appraised, and the clinical relevance and rationale for CTO revascularization were evaluated.1 In Part II, we summarize the technical approach to and outcomes after percutaneous coronary intervention (PCI) of occluded coronary arteries, describe the novel devices and drugs approved and undergoing investigation for CTO recanalization, and conclude with practical perspectives on managing the patient with 1 or more chronic coronary occlusions.

Outcomes After PCI of CTOs
Patient Selection and Revascularization Strategies
PCI of CTOs constitutes as many as 20% of all angioplasty procedures at selected centers,2 although a rate of ≈10% is more typical,3–6 suggesting that CTO angioplasty is attempted in 50 000 to 100 000 patients per year in the United States. Many more CTOs are present for which PCI is never attempted, representing one of the most common causes for referral to bypass surgery rather than PCI.6–8 Furthermore, a large proportion of patients with CTOs are managed medically, the prognosis of whom may vary depending on the extent of viable myocardium and ischemia, concomitant atherosclerosis in other coronary and noncoronary vascular territories, and other comorbid conditions. The decision to attempt PCI of a CTO (versus continued medical therapy or surgical revascularization) requires an individualized risk/benefit analysis, encompassing clinical, angiographic, and technical considerations. Clinically, the patient’s age, symptom severity, associated comorbidities (eg, diabetes mellitus and chronic renal insufficiency), and overall functional status are major determinants of treatment strategy. Angiographically, the extent and complexity of coronary artery disease (eg, single-vessel versus multivessel disease, single versus multiple total occlusions, likelihood for complete revascularization), left ventricular function, and the presence and degree of valvular heart disease should be considered. The technical probability of achieving successful recanalization of the PCI without complications, as well as the anticipated restenosis rate, must also be strongly factored into the decision-making process.

In general, when the CTO represents the only significant lesion in the coronary tree, PCI is warranted when the following 3 conditions are all present: (1) The occluded vessel is responsible for the patient’s symptoms (PCI may also be considered in selected cases of silent ischemia if a large myocardial territory at risk is demonstrable); (2) the myocardial territory supplied by the occluded artery is
viable; and (3) the likelihood of success is moderate to high (>60%), with an anticipated major complication rate of death <1% and myocardial infarction <5%. If the PCI attempt is unsuccessful, then further management will depend on the symptomatic status and the extent of jeopardized ischemic myocardium. Repeated PCI (typically with an allowance of several months for vessel healing in the case of dissection) or surgical revascularization may be warranted if a large myocardial territory is ischemic or the patient is very symptomatic. Alternatively, conservative therapy may be appropriate if repeated PCI is unlikely to be successful and the patient’s symptoms can be controlled with antianginal medications.

In patients with multivessel disease and 1 or more CTOs, the relative risks and benefits of bypass surgery compared with interventional management should be considered. The presence of any of the following may favor surgical revascularization: (1) left main artery disease; (2) complex triple-vessel disease, especially in the patient with insulin-requiring diabetes, severe left ventricular dysfunction, or chronic renal insufficiency; (3) an occluded proximal left anterior descending artery (supplying a viable anterior wall), which is not favorable for PCI; and (4) multiple CTOs with a relatively low anticipated success rate. Other patients with multivessel disease, including a chronically occluded vessel, may be appropriately managed by PCI, with the goal being complete revascularization whenever possible. Typically, in patients presenting with an acute coronary syndrome or with stable angina in whom the nonoccluded vessels can be reliably stented with a low rate of complication, angioplasty of the CTO should be performed after PCI of nonoccluded lesions. The one exception to this rule would be in patients in whom failed PCI of the CTO would result in referral for bypass graft surgery, in which case the CTO should be approached first unless conditions dictate otherwise.

**Success Rates and Failure Modes for CTO Recanalization**

The technical and procedural success rates of PCI in CTOs have steadily increased over the last 15 years because of greater operator experience, improvements in equipment, and procedural techniques.\(^9\,10\) Despite this observation, CTOs remain the lesion subtype in which angioplasty is most likely to fail. In a series of 1074 consecutive patients undergoing PCI, the primary success rate was 90% in nonoccluded lesions, 78% in functional total occlusions (Thrombolysis in Myocardial Infarction [TIMI] flow grade 1), and 63% in true CTOs.\(^11\) In recent contemporary series, procedural success rates have ranged from 55% to 80%, with the variability reflecting differences in operator technique and experience, availability of advanced guidewires, CTO definition, and case selection.

The most common PCI failure mode for CTOs is inability to successfully pass a guidewire across the lesion into the true lumen of the distal vessel.\(^11\,12\) In a recent large series by Kinoshita et al,\(^12\) reasons for procedural failure included inability to cross the lesion with a guidewire (63% of cases), long intimal dissection with creation of a false lumen (24%), dye extravasation (11%), failure to cross the lesion with the balloon or dilate adequately (2%), and thrombus (1.2%).

Reifart et al evaluated the most common reasons for an initially unsuccessful percutaneous CTO recanalization in 200 consecutive patients referred for a second procedure during 1998–2002 at the Kardiologisches Institut in Bad Soden, Germany (N.J. Reifart, MD, et al, unpublished data, 2004). Failure to successfully cross the occlusion with the guidewire was the most common cause (89%), followed by inability to cross the lesion with the balloon (9%) and inability to dilate the lesion (2%). In an estimated 10% of cases, the operator aborted the procedure because of uncertainty regarding the vessel course.

The success rates for percutaneous CTO recanalization have undoubtedly improved over the last 5 years; a major reason is the introduction of stiffer, more powerful, and more supportive wires with greater torque response (eg, Asahi Intec Miracle Brothers 3- to 12-gram wires), tapered tip wires (eg, Asahi Intec Confianza and Confianza Pro 9-gram and Guidant Cross-It 100 to 400 wires), and wires with hydrophilic coatings (eg, Guidant Whisper and Pilot, Boston Scientific Choice PT and PT Graphics, Terumo Crosswire and Confianza Pro). Routine incorporation of novel or advanced procedural techniques, including contralateral injections to visualize the distal vessel via collaterals, and the parallel wire technique (in which a wire that has entered a dissection plane is left in place to serve as a marker and a second, usually stiffer wire with a slightly different tip bend is introduced alongside the first wire to interrogate the occlusion) have also contributed to the improving success rates in catheter-based CTO revascularization.

Failure to cross a lesion with a balloon angioplasty catheter is infrequent, accounting for failed PCI (principally in older, more fibrocalcific CTOs) in 2% to 9% of cases. Most of these failures can be overcome by one of several methods: switching the guide catheter “in situ” for more backup support (eg, Amplatz curves for the right coronary artery); placing a supportive “buddy wire” (eg, Guidant Ironman) into a branch proximal to the occlusion to increase guide support; inflating an angioplasty balloon proximal to the lesion or in a side branch to stabilize the guide; enlarging the lumen with a second wire passed parallel to the first; debulking with excimer laser; or using high-speed rotational atherectomy. The latter 2 devices are also the primary solutions in the 2% to 5% of cases in which the lesion is resistant to balloon dilatation.

In the aforementioned series by Reifart et al of failed CTO cases referred to a specialized interventional center for a second attempt, successful dilatation of the CTO was achieved in 71% of lesions, which was ascribed to use of stiffer and/or hydrophilic wires (in 61% of cases), over-the-wire catheters (54%), guide catheters with greater backup support and coaxial alignment (43%), careful analysis of the entry and exit sites in different views (41%), contralateral injections for better distal visualization (34%), use of the parallel wire technique (21%), support (buddy) guidewires (7%), and rotational atherectomy for resistant lesions (4%).

**Predictors of Successful Angioplasty of CTOs**

Most prior studies have consistently reported that increasing age of the occlusion, greater lesion length, presence of a
Complications of Angioplasty of CTOs
PCI of a CTO has traditionally (and mistakenly) been considered a low-risk procedure despite the fact that inhospital major adverse event rates may exceed 5%.\textsuperscript{9,14,23} Even with extensive operator experience, periprocedural myocardial infarction may occur in $>2\%$ of cases, emergency bypass surgery may be required in 1%, and death may occur in 1% of patients. In a series of 2007 angioplasties for CTOs, the PCI procedural success rate in cases with versus without bridging collaterals was 75% versus 83%, respectively ($P=0.07$), suggesting at most a modest adverse impact of bridging collaterals.\textsuperscript{12} Bridging collaterals may reflect the chronicity of the lesion and signify the requirement for stiffer and/or tapered tip wires to penetrate the occlusion. The availability of enhanced force wires with greater torque response has clearly increased the success rates in occlusions with bridging collaterals to the point where CTOs should no longer be avoided for this reason alone.

Angioplasty of Occluded Saphenous Vein Bypass Grafts
Approximately 25% of saphenous vein grafts (SVGs) have occluded within 5 years after surgery.\textsuperscript{29} Because SVGs lack side branches, distal occlusion results in stasis and thrombus formation throughout the vein graft body. The resulting large thrombotic burden significantly complicates the recanalization of occluded SVGs, resulting in lower procedural success and higher complication rates than after PCI of nonoccluded native coronary arteries.\textsuperscript{30} Reported success rates of intervention in chronically occluded SVGs have ranged from 58% to 77%.\textsuperscript{24,30–33} Myocardial infarction has been reported to occur in 17% to 22% of patients after PCI of occluded SVGs (often due to no reflow from embolization of thrombotic debris), whereas overall mortality occurs in 3.4% to 6.5% of patients.\textsuperscript{24,30–36} Efforts to enhance the safety of PCI in occluded grafts by reducing the thrombus burden with the use of local or systemic fibrinolytic therapy have not clearly improved success rates and result in major bleeding in 12% to 19% of patients and intracranial hemorrhage in 2% to 3%.\textsuperscript{33–35,37} Most studies have also demonstrated poor long-term results after recanalization of occluded SVGs,\textsuperscript{24,30–32} although stents are believed to enhance patency compared with balloon angioplasty in this setting.\textsuperscript{37} Many patients with chronic SVG
occlusions have excellent collateral vessels supplying the target territories and may thus have a favorable prognosis with conservative management. Careful consideration should thus be given to the risk/benefit ratio before PCI of an occluded SVG is undertaken, and, in general, consideration should be given to attempting to recanalize the underlying native coronary artery if possible rather than the CTO. If this is not possible, unless the patient has life-imparing symptoms or a very large myocardial territory of ischemia, medical management should initially be pursued for most occluded SVGs (especially when occluded at the aorto-ostium) rather than percutaneous revascularization.

Special Devices for CTO Recanalization

Despite advances in experience and equipment, CTO recanalization with the use of contemporary guidewires and techniques may still be unsuccessful in \( \geq 25\% \) of cases. Numerous devices have been developed to approach such refractory and complex cases. Many of these devices never progressed beyond the investigational phase because their use in small numbers of patients demonstrated either excessively high rates of complications (typically either dissection and/or perforation) or success rates not clearly greater than those achieved by standard equipment. Examples of failed CTO devices include the Magna/Magnarail system, the Kensey Catheter, the ROTACS Low Speed Rotational Atherectomy Catheter, and the Excimer Laser Wire.

Two devices specifically designed for refractory CTO recanalization have demonstrated sufficient safety and efficacy to have received approval by the Food and Drug Administration for sale in the United States: the Safe Cross-RF guidewire and the Frontrunner catheter. The Safe Cross-RF guidewire (Intraluminal Therapeutics) is a steerable 0.014-inch intermediate-stiffness guidewire incorporating optical coherence reflectometry, which measures the reflection of near-infrared light ahead of the wire tip. A visible and audible signal warns the operator when the wire tip approaches within 1 mm of the outer vessel wall, allowing the wire to be redirected before dissecting or perforating. With the system enabled, the Safe Cross-RF wire can also deliver a train of radiofrequency energy pulses to the wire tip to facilitate crossing hard fibrotic material within the occluded segment. Early pilot experiences and a subsequent controlled multicenter registry demonstrated that this active guidewire is able to cross 50% to 60% of lesions refractory to a 10-minute attempt with a standard guidewire. Perforations related to the device have occurred in <1% of patients. The Frontrunner Catheter (Lumend) is a manually operated device incorporating a bilaterally hinged distal tip assembly that, when activated, spreads tissue planes via the principle of blunt microdissection. The device is supported by a probing and recanalization catheter (the 4.5F Micro Guide Catheter) as it is passed across the occlusion. The current X-39 Frontrunner has an outer diameter of 0.03 to 0.04 inches, with a 2.8F distal tip. Lesion success rates with the Frontrunner have been achieved in \( \approx 50\% \) to 60% of refractory occlusions, although rates are slightly lower in tortuous right coronary arteries. Perforations have occurred in 0.9% of cases. This device may have a special role in refractory in-stent CTOs, wherein the stent serves to confine the device as it passes through the occlusion.

Several novel device-based and pharmacological strategies are currently under investigation for refractory CTOs. Prolonged infusions of fibrinolytic agents have been investigated to soften the thrombotic component that may be present even in very chronic occlusions, thereby facilitating wire crossing. Success rates of \( \approx 50\% \) to 60% have been reported with this technique in several series of refractory CTOs, with blood transfusions primarily from access site bleeding required in 0% to 15% of patients. Collagenase infusion in experimental models has shown promise in modifying the fibrotic, collagen-rich structure of occlusive plaque to facilitate successful guidewire passage; human studies are pending. The utility of therapeutic ultrasound in crossing vascular occlusions has been studied for many years, although the results with a first-generation system in coronary CTOs were suboptimal because of relatively high device profile and stiffness. Recently, a new 20-kHz ultrasound device (CROSSER, FlowCardia, Inc) is undergoing human investigation, with favorable preliminary results reported in refractory CTOs. Vibrational angioplasty (Medical Miracles) is a mechanical device that generates reciprocal and lateral movements in the distal end of a standard guidewire with frequencies of 16 to 100 Hz. The outcomes with this low-cost device have been favorable, although it must be used in a relatively large and nontortuous vessel given limited directional control. Lumen reentry devices have been developed to facilitate guidewire reentry into the true lumen after the creation of a dissection plane, including the ultrasound-guided Pioneer catheter (Medtronic AVE), and the fluorooscopically directed Lumend Outback catheter. An alternative approach to CTOs with the use of the Pioneer system also undergoing investigation is the creation of connections between a coronary artery and vein (percutaneous in situ coronary vein arterIALIZATION (PICVA)). Several intravascular ultrasound–guided methods have also been developed to perform true percutaneous in situ coronary artery bypass (PICAB), which, although technically complex, has been performed successfully in several patients. Finally, several novel guidance modalities are under development, including forward-looking ultrasound and magnetically enabled 3-dimensional wire guidance. It is likely that prospective, randomized trials comparing these novel approaches and devices with contemporary angioplasty equipment and techniques will be required before their widespread acceptance and utilization.

Late Patency and Restenosis After Successful CTO Angioplasty: Role of Bare Metal and Drug-Eluting Stents

Clinical and angiographic restenosis rates are increased after PCI of CTOs compared with nonoccluded lesions, possibly in part because of an increased incidence of diabetes; greater lesion length, plaque mass, and calcification; and more negative vascular remodeling of CTO lesions. Eight randomized trials of bare metal stent placement compared with balloon angioplasty have been reported (Table 2). Collectively, these trials have shown that stent implantation
achieves statistically significant and clinically meaningful reductions in angiographic restenosis, vessel reocclusion, and the need for repeated target vessel revascularization, results that persist ≥6 years.80–82

Despite the improved results with stenting compared with balloon angioplasty, restenosis and reocclusion remain a problem. In the Total Occlusions Study of Canada (TOSCA) trial,76 for example, restenosis and reocclusion rates after bare metal stent implantation in CTO lesions exceeded 50% and 10%, respectively. The occurrence of reocclusion was associated with a trend toward higher mortality and a significant increase in the need for repeated revascularization procedures at 3 years.81 Moreover, in most reports, long-term outcomes after stent implantation in patients with CTOs have not been as favorable after stenting nonocclusive stenoses. In the series by Elezi et al,82 the restenosis rate was 43% after stent implantation in CTOs versus 27% in nonoccluded lesions \( (P<0.001) \). Significantly more stents were required to treat the occluded compared with nonoccluded lesions in this series, and a smaller final postprocedure minimal luminal diameter was achieved in CTOs than after stent implantation in nonocclusive stenoses, both of which contributed to the higher restenosis rate. Lesion length has been reported to be a strong determinant of restenosis after stenting CTOs.83 Notably, however, the presence of collateral flow does not seem to predict late restenosis or reocclusion.84

Because of the high restenosis rate after bare metal stent implantation in CTOs, practice has shifted to routine drug-eluting stent implantation in these lesions, despite the absence of an adequately powered prospective, randomized trial. However, several single-center and multicenter registries of drug-eluting stents in CTOs have been performed with favorable results. Nakamura et al85 reported the results of a 5-center Asian registry in which 88 patients with successfully recanalized CTOs were treated with sirolimus-eluting stents. At 6 months, the major adverse cardiac event rate was 4.5% (all repeated target vessel revascularizations), and the angiographic restenosis rate was 3.4%. In the Rapamycin Eluting-Stent Evaluated At Rotterdam Cardiology Hospitals (RESEARCH) Registry from the Thoraxcenter in the Netherlands, sirolimus-eluting stents have been used exclusively in all patients since April 2002.86 During the initial 6-month study period, 56 (9.9%) of 563 stented patients had sirolimus-eluting stents implanted in a CTO. This cohort was compared with a similar group of patients \( (n=28) \) treated in the preceding 6-month period with bare metal stents. In this nonrandomized observational study of consecutive series of patients, implantation of sirolimus-eluting rather than bare metal stents was associated with a significantly improved event-free survival rate at 1-year (96.4% versus 82.8%; \( P<0.05 \)). In the sirolimus-eluting stent group, 1 subacute thrombosis occurred, and 2 patients required repeated target vessel revascularization (including the 1 patient with the stent thrombosis). In the bare metal stent group, all adverse events were related to repeated target vessel revascularizations. Among sirolimus-eluting stent patients with angiographic follow-up at 6 months (59% of the entire cohort), the binary restenosis rate was 9.1%, and in-stent late loss was 0.13±0.46 mm. Target vessel reocclusion was identified in only 1 patient (3.0%).

In the multicenter Sirolimus-Eluting Stent in Chronic Total Occlusion (SICCO) study, sirolimus-eluting stents were implanted in 25 CTO lesions after successful balloon angioplasty. At 6-month follow-up, target vessel revascularization was required in only 2 patients (8.0%), and no patient experienced a major adverse cardiac event or stent thrombosis.87 Angiographic follow-up at 6 months demonstrated essentially no in-stent late loss \(-0.1±0.3 \text{ mm}\), and in-stent percent plaque volume obstruction was only 13.1±18.3% by intravascular ultrasound imaging. In a study by Werner et al,88 paclitaxel-eluting TAXUS stents were implanted in 48 CTOs, and the outcomes were compared with a historical bare metal stent control group. Use of the paclitaxel-eluting stent was associated with reductions in angiographic restenosis at 6 months by 84% (8.3% versus 51.1%; \( P<0.001 \)), in angiographic target vessel reocclusion by 91% (2.1% versus 23.4%; \( P<0.001 \)), and in major adverse cardiac events at 1 year by 74% (12.5% versus 47.9%; \( P<0.001 \)). Finally, in the international WISDOM registry, implantation of paclitaxel-eluting stents in 65 CTOs resulted in freedom from major adverse cardiac events and repeated intervention in 93.3% and 98.3% of patients, respectively, at 12 months, with stent

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PTCA indicates percutaneous transluminal coronary angioplasty; SICCO, Stenting in Chronic Coronary Occlusion; GISSOC, Gruppo Italiano di Studio sulla Stent nelle Occlusioni coronariche; SPACTO, Stent per Percutaneous Angioplasty in Chronic Total Occlusion; TOSCA, Total Occlusion Study of Canada; STOP, Stents in Total Occlusion for Restenosis Prevention; and PRISON, Primary Stenting of Occluded Native Coronary Arteries.
thrombosis occurring in only 1 patient.89 Thus, emerging data suggest that drug-eluting stents may enhance long-term patency rates and freedom from restenosis and repeated revascularization compared with bare metal stents in patients with CTOs, although appropriately powered randomized trials are required to definitively prove the safety and efficacy of this new technology for this application.

Conclusions
For most interventional cardiologists, CTO angioplasty represents a challenge that is often avoided given the additional time required, radiation exposure, and contrast administration and the decreased procedural success compared with PCI of nonoccluded lesions. Moreover, there is general confusion regarding the accepted indications for PCI of chronic occlusions, the optimal technical approach, and the ultimate impact of revascularization on patient outcomes. The procedural complexity of angioplasty in CTOs and the lack of familiarity with new equipment and technique innovations specific to CTO intervention often prompt half-hearted prematurely aborted attempts at PCI, ensuring high failure rates and physician and patient frustration. As a result, patients with single-vessel disease and chronically occluded vessels are often managed medically regardless of the extent of ischemia, and those with multivessel disease with a CTO and lesions otherwise ideal for PCI are referred for bypass graft surgery.

With the marked reduction in restenosis being realized with drug-eluting stents in occluded as well as nonoccluded stenoses and emerging evidence that successful percutaneous recanalization of chronic coronary occlusions results in improved survival, as well as enhanced left ventricular function, reduction in angina, and improved exercise tolerance, PCI should be considered the preferred initial revascularization modality in patients in whom a high procedural success rate may be anticipated. Fortunately, the tremendous progress in guidewire technology and techniques developed in the last few years, coupled with the introduction of dedicated devices for refractory occlusions, has resulted in success rates of 80% to 90% being realized by experienced operators in true CTOs. It is hoped that the rationale for and principles of CTO recanalization discussed in this consensus document will provide a knowledge base for this emerging subspecialty of interventional cardiology and stimulate the dedication desired to develop the expertise to overcome the “last frontier” of PCI.

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References


