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Abstract

Purpose: To report experience with aggressive recanalization approaches in chronic total arterial occlusion (CTO). **Methods:** Chronic total arterial occlusion recanalization was attempted on 112 limbs in 99 consecutive patients between January 1999 and December 2006. **Results:** There were 63 iliac arteries, 45 femoropopliteal arteries, and 4 occluded stents. Mean occlusion length was 8.7 ± 4.7 cm. Conventional recanalization was attempted first and was successful in 71 limbs (70%). Probing with the guidewire's stiff end was attempted in 33 of the 41 procedures where conventional techniques failed and was successful in 18 (54%), improving the overall procedural success rate to 80%. For the remaining 15 limbs, home-made directional sharp needle recanalization was attempted in 11 and was successful in 9 (82%), further improving the overall recanalization success to 88%. Procedural complications were self-limited or managed nonoperatively. **Conclusions:** Aggressive recanalization techniques in CTO following failure of traditional means are safe and can substantially improve procedural success rates.

Keywords

endovascular, chronic total occlusion, recanalization, stenting, angioplasty

Introduction

Percutaneous endovascular techniques have revolutionized the management of symptomatic peripheral arterial occlusive disease when conservative medical management fails, allowing lower morbidity and quicker recovery compared to surgical bypass.¹ Chronic total occlusion (CTO) is a common lesion in patients presenting with limb ischemia, both in the iliac and femoropopliteal locations.¹⁻³ Endovascular methods have long been considered suboptimal in the management of CTO, with early series demonstrating disappointing outcomes and excessive complication rates.⁴⁻⁹ However, in recent years, the outlook of endovascular management of CTO has dramatically improved with increased experience with endovascular skills and improved tools and equipment allowing endovascular therapy now to be considered a viable first-line therapy in peripheral arterial CTO, especially when short in length.¹ Nevertheless, CTO remains a formidable obstacle to successful endovascular management of complex vascular occlusive disease, with its presence inherently implying a lower procedural success rate. Attempted recanalization can fail in 30% to 50% of peripheral arterial CTOs using standard guidewire and catheter techniques, which is usually the result of inability to cross the occlusion with a guidewire or false lumen passage

of the guidewire with inability to re-enter the true lumen.^{10,11} Various techniques have been developed to enhance the success of CTO recanalization with the most popular one based on the purposeful subintimal dissection at the leading edge of an occlusion and provisional true lumen re-entry at the reconstituted lumen, an approach termed percutaneous intentional extraluminal recanalization.^{3,10,12-14} Although useful, this approach remains limited by the uncontrolled manner of re-entry back into the true lumen of the target vessel and in most hands remain intimidating and associated with a relatively low technical success rate.

Our team has evolved an aggressive approach toward the endovascular management of CTOs in the iliac and femoropopliteal segments. This report represents a retrospective review

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Table 1. Demographics and Comorbidities in 99 Patients With 112 Chronically Occluded Limbs^a

		Conventional	Sharp (Wire-end/Needle)	P
Age	61 ± 13	60.0 ± 12.8	60.1 ± 13.4	.9
Male	66	44	22	.8
Vascular Risk Factors				
Smoking history	107	70	37	.5
Current smoking	65	44	21	.8
Hypercoagulability	5	3	2	.7
DM	32	24	8	.2
HTN	67	46	21	.5
HLP	97	65	32	.6
ESRD	8	6	2	.5
CHF	15	9	6	.6

Abbreviations: DM, diabetes mellitus; HTN, hypertension; HLP, ESRD.

^a The variables are also listed for both the conventional and sharp recanalization technique categories.

of our institutional experience with a number of aggressive approaches for iliac and femoral-popliteal CTO recanalization, including sharp recanalization methods.

Materials and Methods

Retrospective review of our departmental records between January 1999 and December 2006 identified 99 patients (age 61 ± 13; 59 males) in whom CTO recanalization was attempted on 112 limbs. The demographic characteristics and vascular comorbidities of the patients are listed in Table 1.

Technical success was defined as successful traversal of the occlusion into the distal patent segment with subsequent balloon angioplasty or stenting. We compared the success rates of the various recanalization techniques used, as well as the long-term patency. The following CTO recanalization techniques were used in our patients: (1) traditional catheter-guidewire probing, usually using a glide or regular directional catheter with a coaxial glide wire or spring coil guidewire; (2) balloon angioplasty in a wedged position at the occlusion leading edge followed by guidewire probing; (3) attempted traversal from a contralateral approach for iliac lesions; (4) open access into the diseased artery prior to guidewire probing under direct visualization; (5) directional puncture with the stiff end of a guidewire; And (6) directional sharp-needle puncture following multiprojection triangulation, using a home-made 21-gauge coaxial system (Figure 1). The last 2 classes were broadly labeled as sharp recanalization techniques whereas the others were labeled conventional techniques.

Several variables were evaluated for their effect on procedural success, long-term patency, and limb preservation. Technical variables included the approach (antegrade, retrograde), and the occlusion traversal technique including conventional recanalization, the use of the stiff end of the guide wire, or the use of directional sharp needle recanalization. Patient-related variables included gender, age, cardiovascular risk factors including diabetes mellitus, hypertension, current smoking, hyperlipidemia, uremia, prior myocardial infarction, and congestive heart failure. Variables related to disease pattern included the length of occluded segment, the anatomic location of the occlusion (iliac

vs femoropopliteal), and angiographic runoff score of outflow resistance distal to the treated lesion (1-3). The clinical presentation prior to the procedure was also evaluated, as assessed by the clinical ischemia grade according to the Rutherford-Baker classification.¹⁵ The effect of anticoagulants and antiplatelet agents following the procedure was also evaluated.

The follow-up protocol was dependant on the preference of the primary surgeon but included clinical assessment, and non-invasive hemodynamic evaluation (ankle arm index, pulse volume recordings, and toe pressures) on the follow-up visits, usually 1 month, 3 months, 6 months, 12 months, and yearly thereafter. Doppler waveform analysis of the common femoral artery was obtained in patients who underwent iliac segment interventions. Depending on the specific clinical situation or the preference of the surgeon, direct imaging was also obtained at various time points including duplex and color Doppler sonography. Restenosis was usually confirmed prior to secondary intervention using either catheter angiography and/or gadolinium-enhanced magnetic resonance angiography (Gd-MRA). Restenosis on follow-up was defined by angiographic or duplex documentation of stenosis ≥60% (peak systolic velocity (PSV) > 300 cm/sec or PSV ratio > 2.5). Primary patency was defined as maintained patency of the treated arteries in one limb as verified by duplex and/or angiography. Assisted patency referred to maintenance of patency following restenosis by endovascular means, using repeat balloon dilatation and/or stenting. Thromboses and recurrences that could not be treated by endovascular means or treated using bypass surgery were considered a patency loss. Primary and assisted patency were analyzed on an intent-to-treat basis.

Statistical comparison of the various variables was performed using a SYSTAT 11.0 software (SPSS, Inc, Chicago, Illinois). Univariate analysis of continuous numeric variables was done using the Student *t* test, whereas discrete numeric variables were compared using the Mann-Whitney nonparametric test. The Pearson chi-square probability test was used for comparing nonnumeric categorical variables. Multivariate analysis was also performed using Logistic regression analysis. Survival statistics with life-table analysis was also generated on the same software package.

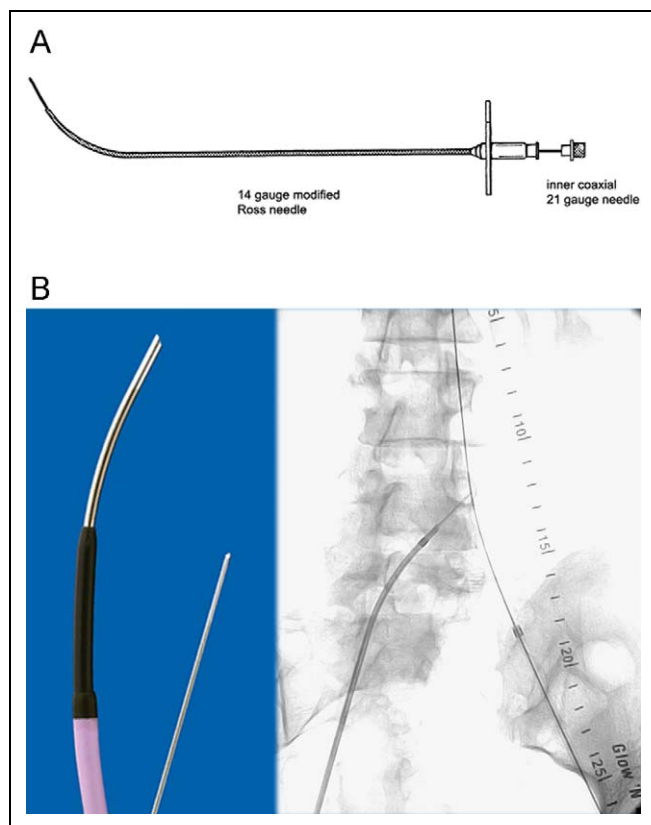


Figure 1. A, Home-made 21 gauge, coaxial, directional true-lumen reentry system. The system consists of 2 main components: (1) Modified Ross canula: curved blunt-tipped, directional metallic canula (Rosch-Uchida TIPS system, Cook, Bloomington, Indiana), and (2) 65 cm long 21-gauge Chiba needle (Cook). B, Following multiprojection fluoroscopic triangulation, entry into true lumen is made with the coaxial 21 gauge needle and verified by contrast injection. An 0.018-inch guidewire is then introduced into the true lumen before proceeding with angioplasty/stenting.

Results

The occluded conduits consisted of 66 iliac segments (including 3 occluded stents), and 46 femoropopliteal segments (including 1 superficial femoral artery stent). Mean occlusion length was 8.7 ± 4.7 cm. Conventional recanalization refers to using any variety of catheter–guidewire combinations and was attempted first in all patients. Failure of conventional attempts was nearly always due to subluminal passage and failure of true lumen re-entry. Depending on the operator's preference, the condition of the patient and the availability of resources, nonconventional methods were attempted next. The overall outcome of attempted recanalization as well as in the various recanalization technique groups and anatomic location of the occlusion are summarized in Table 2. Conventional recanalization techniques were successful in 71 (70%) limbs out of 112. Probing with the guidewire's stiff end was attempted in 33 of the 41 procedures where conventional techniques failed and was successful in 18 (54%), thus improving the overall procedural success to 80%. Of the remaining 15 limbs, sharp needle

recanalization was attempted in 11 and was successful in 9 (82%), further improving the overall recanalization success to 88%. The 2 failures of sharp needle recanalization occurred in 1 patient with bilateral iliac occlusions who had a heavily calcified aortic wall and thick atheroma at the puncture point. Successful conventional recanalization included the use of a contralateral femoral or brachial approach in 4 limbs (successful in all), and wedge-balloon angioplasty to assist recanalization in 3 procedures (successful in 2). A hybrid open approach allowing selective access across the atheroma was used in another 3 procedures (successful in all).

Overall success of CTO recanalization was independent of the length of the occlusion segment (7.9 ± 5.1 cm in successes vs 8.3 ± 2.9 cm in failures, $P = .6$). It was also independent of the lesion's anatomic location (Iliac: 85% (55 of 65) versus femoropopliteal: 91% (43 of), $P = .27$).

The mean follow-up duration was 20 ± 23 months (range 0–86 months). Over the follow-up period of the study, recurrences developed following 7 of 27 successful sharp recanalization procedures and 13 of the 71 successful conventional recanalization procedures. Endovascular reintervention was attempted in 4 restenoses in the sharp recanalization group and 4 in the conventional recanalization group, with all interventions successful. During the follow-up period, major amputations were required in 4 patients in the conventional intervention group compared to 6 in the sharp recanalization group. Using Kaplan-Meier survival table analysis the estimated overall primary and assisted patency rates ($\pm$ SEM) at 40 months were $63\% \pm 7\%$ and $81\% \pm 6\%$, respectively (Figure 2). The assisted patency rate was significantly better for iliac occlusions compared to femoropopliteal occlusions ($P < .005$). Although recanalization using conventional means was associated with a favorable primary and assisted patency trends compared to sharp recanalization, the trend did not reach statistical significance (Figure 3).

Complications were relatively uncommon and mostly mild, requiring either observation or additional therapy/brief hospitalization (Society of Interventional Radiology class B and C).¹⁶ Two instances of embolization treated with aspiration thrombectomy, 1 self-limited extravasation, 1 extraluminal passage of the needle with extravasation treated with stent graft placement (Figure 4), 1 access hematoma treated conservatively, and 1 instance of self-limited acute tubular necrosis.

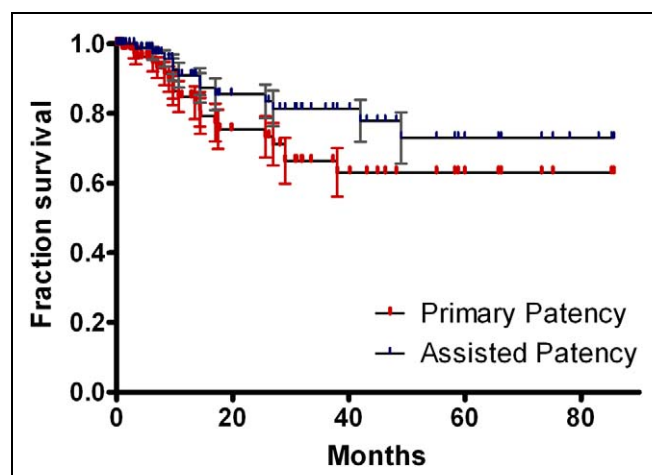
There was no procedure-related mortality, although 5 deaths occurred in the 30 days periprocedural period. Overall, 25 deaths occurred during the follow-up period of the study mostly due chronic illness (cardiac 11, pulmonary 5, cancer 6, other/unknown 3).

Discussion

The major limiting factor in the successful management of TransAtlantic Inter-Society Consensus (TASC) C and D aortoiliac disease is the presence of chronic total occlusions (CTOs), especially long segments with underlying calcified plaques. Previous studies evaluating endovascular therapy of iliac and

Table 2. Technical Details and Successful Recanalization Rates

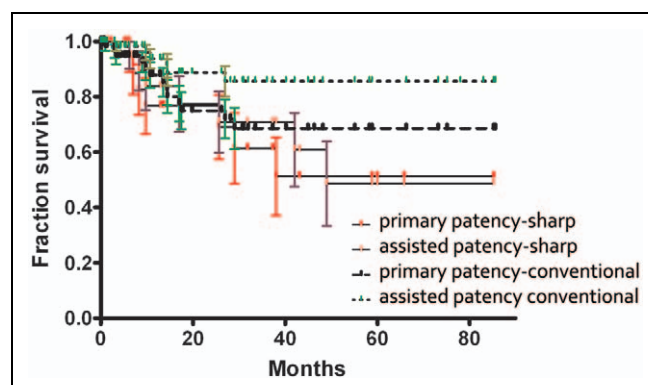
	Overall (112)	Conventional Alone (79)	+Wire-End Alone (22)	+Needle (11)
Successful recanalization	98	71 (63.4%)	18/33 (54.5%); (79.5%)	9 (81.8%); (87.5%)
Per segment				
Iliac (58)	48	31	9	8 (82.8%)
Stent (9)	8	7	0	1 (88.9%)
Fem-Pop (45)	42	33	9	0 (93.3%)

**Figure 2.** Kaplan-Meier survival curves of the overall primary and assisted patency rates following CTO recanalization. Primary and assisted patency rates at 40 months were $63\% \pm 7\%$ and $81\% \pm 6\%$, respectively. CTO indicates chronic total arterial occlusion.

femoropopliteal arterial occlusive disease reported significantly lower technical success rates for the treatment of occlusions (approximately 80%) compared with the success rates for the treatment of stenoses (approximately 90%).^{6,7,17-24} Other relevant observations included higher complication rates²⁵ and increased procedure duration in occlusions primarily attributable to the recanalization component of these procedures.²⁶ In a recent meta-analysis, one of the most significant predictors of failure during endovascular intervention was the presence of occlusion.²⁷

Reported overall success rate of transcatheter recanalization of CTOs in the iliac segments using conventional techniques average around 75% (33%-89%).^{6,9,17,28-34} In the femoropopliteal segment, the trend is generally slightly more favorable, with reported successful recanalization rates around 85% (76%-100%).^{3,10,14,35-40} Our data demonstrated comparable recanalization success rate in both iliac and femoropopliteal segments (Table 2).

Various approaches are currently available for CTO recanalization.¹¹ Accurate re-entry into the true lumen during subintimal recanalization is the most crucial component during the recanalization of aortoiliac and femoropopliteal CTOs. Entry into the leading segment of the reconstituted true lumen is important for preserving vital collaterals.⁴¹ Various methods have been implemented to allow re-entry into the true lumen, which vary in their aggressiveness. Careful atraumatic probing with the guidewire during the initial crossing attempt usually

**Figure 3.** Kaplan-Meier survival curves of conventional recanalization compared to sharp recanalization of CTO. CTO indicates chronic total arterial occlusion.

gives the best chance at crossing from the occluded lumen into the true lumen. The choice of catheter and guidewire varies based on the experience and preference of the operator but, by enlarge, the combination of a directional catheter with a hydrophilic guide wire seems to be most commonly used. Other experienced interventionists have maintained that the most optimal combination is to use a spring coiled tip guidewire of the long length taper variety (Newton LLT, Cook, Bloomington, IN),⁴² while others prefer to use softer small caliber guidewires.⁴³ We have also been successful at crossing into the true lumen using the back end of a guidewire, after careful fluoroscopic triangulation using multiprojection angiographic views. When all fails, we have increasingly adopted the use of a home-made sharp true lumen re-entry system using a combination of a curved blunt-tipped Colapinto metallic canula taken from the Rosch-Uchida transjugular intrahepatic portosystemic shunt (TIPS) system (Cook, Bloomington, Indiana) kit with a 65-cm long 21-gauge Chiba needle (Cook). Once entry into the true lumen is verified by contrast injection, a 0.018-inch guidewire is introduced into the true lumen before proceeding with angioplasty/stenting. A number of true lumen re-entry devices have been recently introduced into the market which allow reliable re-entry.^{11,44,45} These can be classified under 3 broad categories: (1) Controlled blunt microdissection devices (CMD type), which include the Fronrunner device (Cordis, Warren, New Jersey) which uses blunt microdissections inside the plaque, allowing passage of guidewire through the lesion and adjunctive angioplasty.⁴⁶ (2) True lumen re-entry catheters (LRE type),⁴⁴ which include the Outback catheter (Cordis), which allows fluoroscopically controlled re-entry

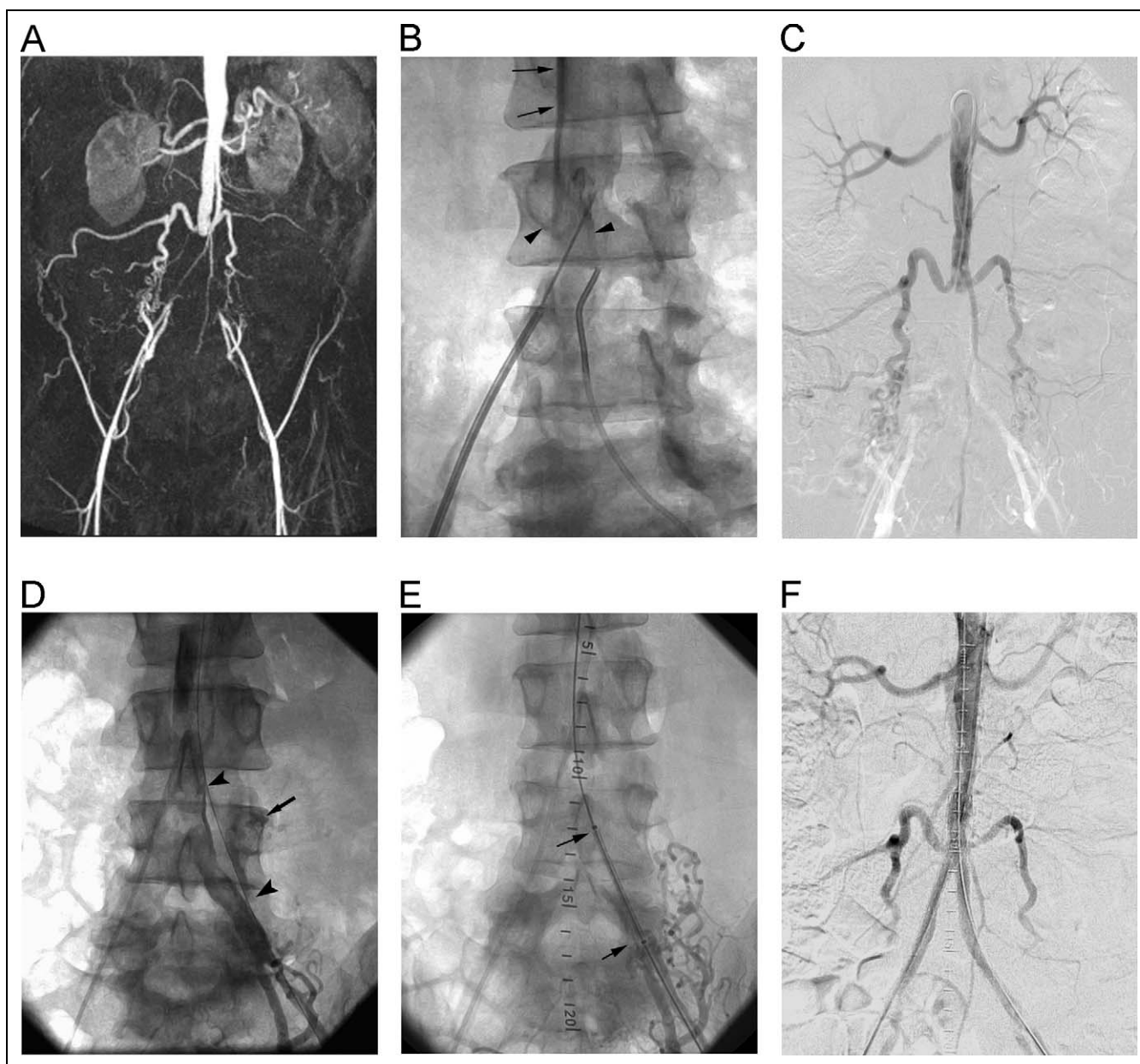


Figure 4. A, gadolinium-enhanced magnetic resonance angiogram demonstrating distal aortic and bilateral common iliac artery occlusion, with patency of the infrarenal aorta maintained through hypertrophied lumbar branches. B, Several attempts to cross the occlusions via bilateral transfemoral approach using conventional methods were unsuccessful (arrows depict residual subintimal contrast stain). Sharp puncture using a coaxial directional 21-gauge needle was then attempted. The needle has been advanced into the true lumen “ghost” following careful triangulation under fluoroscopy. Intraluminal position is confirmed by injection of contrast through the lumen of the 21 gauge needle (arrow heads). C, The occluded segment on the right was successfully crossed and a diagnostic angiographic catheter was advanced to obtain an aortoiliac angiogram. A similar approach was used on the left side although the puncture point was more distal than desired (ideally one should advance the sheath through the subintimal plane so that the directional needle and the coaxial puncture needle is as close to the downstream true lumen as possible). Contrast injection demonstrate an extraluminal path with eventual reentry into the true lumen above the bifurcation (arrow heads). Free extravasation of contrast into the retroperitoneum is demonstrated (arrow). E, The wire was withdrawn and another pass was performed following correction of the pathway. Once a satisfactory course was demonstrated, a balloon-expanded stent graft was deployed across the suspected area of extravasation (arrows). F, Completion angiography following aorto-bi-iliac reconstruction using kissing stents demonstrates wide patency and no extravasation. There was zero systolic pressure gradient across the reconstruction. The patient did well post-procedurally and was discharged home on the second postoperative day. She continues to do well 16 months later.

of the true arterial lumen after subintimal guidewire passage during recanalization procedures of arterial occlusions.⁴⁷ A newer refinement resulted in the Pioneer catheter (Medtronic,

Minneapolis, Minnesota), which uses a built-in cross-sectional Intravascular Ultrasound (IVUS7) transducer to guide puncture into the true lumen.⁴⁴ (3) Miscellaneous angioplasty

technologies including those that use radiofrequency energy (Safe-Cross CTO system (Kensey Nash Co, Exton, Pennsylvania),⁴⁸ or other that use mechanical or ultrasonic vibrations to recanalize occlusions (CROSSER catheter; FlowCardia, Sunnyvale, California).⁴⁹

A key limitation when attempting endovascular therapy in aortoiliac CTOs is the coexistent common femoral artery disease. Although we currently do not hesitate to extend the stents into the common femoral artery segment to cover any limiting underlying disease, we have also increasingly adopted hybrid strategies combining direct common femoral artery (CFA) repair with inline iliac stenting extending into the endarterectomized segment on an interposition graft, with excellent short- and intermediate-term outcomes.⁵⁰

We noted a nonsignificant trend toward lower delayed patency following sharp recanalization and wire-end techniques was appreciated on life-table analysis (Figure 3). This, however, likely reflects the complex associated anatomy of these lesions, and the small number of patients in the study. The adoption of routine pharmacologic modulation of aggressive atherosclerosis with the use statins and aggressive risk factor modifications should become routine counterparts of such aggressive interventions in our armamentarium. In addition, selective use of stent grafts in long-segment occlusions especially in young patients with aggressive atherosclerosis may be worth further exploration.⁵¹⁻⁵⁴

The only failures using directional needle recanalization occurred in 2 limbs in 1 patient, with heavily calcified aorta using the 21 gauge needle system. The needle could be seen bowing against the calcification on fluoroscopy and in both limbs. Conceivable this could have been circumvented by using a larger needle system such as the Rausch-Uchida kit using the 5-F sharp cannula or even using the 16 gauge Colapinto needle itself, although careful multiview triangulations must be undertaken to ensure proper orientation before the pass is made using this considerably larger bore needle. This may be an instance where IVUS may prove valuable. It should be noted that recanalization failures have also been reported with dedicated commercial devices, especially in the iliac segments. Failure was reported in 18 of 44 lesions using the CMD type, occurring more commonly in the iliac segments, highly calcified lesions, and longer occlusion length.⁵⁵

Our study has the traditional drawbacks of a small single-institution retrospective study, with the most important limitation is the nonstandardized approach used in the selection of recanalization method and approach. Also, personal preference of the operator, availability of simple surgical alternative options as well as time constraints may have played a role in the success rates of any of the methods that were compared in the study. We also did not have the ability to study the effects of specific features of the treated vessels such as calcifications and chronicity of the occlusions.

In conclusion, our experience demonstrates that adopting an aggressive approach in CTO recanalization can improve procedural success without compromising patients' safety. Our approach starts with a direct transfemoral approach using

standard catheter—guidewire technique, with selective use of retrograde recanalization if the direct approach fails, and progression into sharp recanalization techniques using the wire's stiff end, or directional needle puncture into the true lumen using a 21 gauge home-made system. Our experience indicates that aggressive recanalization techniques following failure of traditional means can improve procedural success from 70% to 88%, with comparable safety, clinical efficacy, and durability. Alternatively, commercially available true lumen re-entry systems can also provide valuable tools to allow successful management of aortoiliac disease with CTO albeit the added cost and complexity would need to be weighed in to the decision-making process, especially when simple surgical options are available, such as supragenicular femoropopliteal or femoro-femoral bypass. One must note, however, that substantial reduction in procedural time may be achieved if sharp recanalization approaches or devices are used early during difficult CTO recanalization procedures, with the potential for cost saving that may conceivably offset the cost of such devices. Home-made directional needle puncture systems are highly effective and safe if used properly, with success rates comparable to commercial devices.

Authors' Note

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Declaration of Conflicting Interests

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