13 Adjunctive Technologies (Rotablation, Excimer Laser, Aspiration Thrombectomy, Distal Embolic Protection)

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Key Points

Rotational Atherectomy

- Rotational atherectomy improves the procedural success rate of percutaneous coronary intervention (PCI) in heavily calcified lesions, but does not decrease restenosis. Late lumen loss was higher in patients treated with rotational atherectomy followed by drug-eluting stenting compared with patients without rotational atherectomy.
- Pericardiocentesis kits and covered stents should be readily available given the risk of coronary perforation.

Excimer Laser

- Excimer laser coronary atherectomy improves procedural success but does not decrease restenosis in moderately calcified lesions.
- Excimer laser coronary atherectomy can be used in situations that are difficult to treat including in-stent restenosis, suboptimal stent expansion, and subtotally occluded lesions uncrossable by exchange catheters.

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Aspiration Thrombectomy

- Routine use of thrombectomy for acute myocardial infarction (AMI) is not recommended.
- The benefits of up-front manual aspiration thrombectomy in AMI remain questionable, but the procedure may become necessary in bailout situations.

Embolic Protection Devices

- Embolic protection devices can capture liberated debris during saphenous vein graft (SVG) intervention to decrease the risk of distal embolization and periprocedural MI.
- Embolic protection devices do not appear to protect against no-reflow or improve clinical outcomes in PCI of native coronary vessels.
- Embolic protection devices provide clinical benefit in SVG intervention but remain underutilized.

Rotational Atherectomy

Synopsis

- Coronary artery calcification (CAC) increases the complexity of PCI. Severe CAC can create undilatable lesions, limit stent expansion, predispose vessels to dissection during high-pressure balloon inflations, and increase the risk of major adverse cardiac events (MACE).
- Rotational atherectomy (RA) (Boston Scientific, Maple Grove, MN, USA) is an invaluable tool for modifying severely calcified lesions.

Techniques to Quantify Degree of Coronary Artery Calcification

- Quantifying the degree of CAC is important, as appropriate patient selection is vital to RA success.
- Patients with moderate-to-severe CAC are appropriate candidates. Various imaging modalities are used to identify the presence of moderate-to-severe CAC (Table 13.1).

Fluoroscopy and Angiography

- Fluoroscopy and angiography are limited in their ability to identify and quantify CAC. Hazy angiographic images make distinguishing between thrombus, dissection, distorted lumen, and irregular plaque morphology difficult [1–3].
- Fluoroscopy cannot differentiate between medial calcification, superficial calcification, and calcification narrowing the lumen diameter [4]. Angiography cannot clearly visualize vascular wall components.

Table 13.1 Summary of coronary diagnostic techniques

	Angioscopy	Coronary arteriography	Intravascular ultrasound	Optical coherence tomography
Picture expression	3-dimension	2-dimension	2-dimension	2-dimension and 3-dimension
Color tone	Color	Black and white	Black and white	False color (e.g., sepia) or black and white
Quantification	–	++	++	++
High resolution	++	+	+	+++
General picture	–	–	++	++
Tissue characterization				
Plaque characterization	++	+	++	++
Intraluminal	++	+	+	++
Intramural	–	–	++	+
Calcification	–	+	++	+++
Thrombus	++	+	–	+++

++: excellent; +: good; −: poor

Adapted from Regar E, Weissman NJ, Muhlestein JB. Intravascular ultrasound, optical coherence tomography, and angioscopy of coronary circulation. In: UpToDate, Post TW (ed), UptoDate, Waltham, MA. (Accessed on November 2, 2016)

- These techniques alone are inadequate to determine whether lesions require plaque modification.

Intravascular Ultrasound (See Also Chap. 14)

- Intravascular ultrasound (IVUS) is superior to angiography alone in evaluating CAC [5]. IVUS can distinguish between discrete stenosis, dissection, plaque morphologies, and lumen irregularities [6].
- It provides a tomographic view of vessels with high resolution that improves delineation of the extent, composition, morphology, and distribution of arterial plaque [7, 8].
- The normal coronary anatomy produces a "three-layer appearance." The denser intima and adventitia produce a bright hyper-echoic appearance bordering the darker hypo-echoic middle media layer. Dense calcium also appears hyper-echoic on IVUS.
- Although IVUS cannot penetrate calcium itself, it helps quantify the arc and length of CAC. Atherectomy should be considered if the arc of calcium is ≥270°.
- Limitations include increased cost and duration of the procedure compared to angiography alone. Periprocedural risks, including vessel spasm and dissection, are uncommon.

Tips and Tricks

- Intracoronary administration of nitroglycerin can decrease the risk of coronary vasospasm.
- Vigorously flushing with normal saline can remove air from the catheter prior to insertion into the guiding catheter.
- The IVUS catheter should not be flushed due to the risk of air embolism once in the guiding catheter.

Optical Coherence Tomography (See Also Chap. 14)

- Optical coherence tomography (OCT) is analogous to pulse-echo imaging, but uses infrared light instead of sound [9].
- Its fiber-optic technology accurately characterizes the extent and morphology of CAC, limits artifacts, and produces a tenfold higher image resolution than IVUS [10–12].
- Two types of OCT include time-domain (TD-OCT) and Fourier-domain optical coherence tomography (FD-OCT). TD-OCT is the first-generation OCT, but has limited use given relatively slow data acquisition. FD-OCT has higher rates of wavelength scanning, faster image acquisition, and greater penetration depth.
- Typically, OCT penetrates 1–2 mm compared to 4–8 mm with IVUS [13]. Although OCT is inferior to IVUS in delineating reference vessel diameter given its limited range of visualization, it characterizes the structure of coronary artery disease in greater detail. Its ability to visualize calcification without blooming artifact prevents overestimation of CAC extent. Furthermore, it is superior in identifying neointimal hyperplasia, a surrogate marker for stent thrombosis [14].
- Limitations are similar to those of IVUS, increasing PCI cost and time. TD-OCT requires removal of blood during image acquisition to prevent red blood cell light scattering. Balloon occlusion of the vessel with subsequent saline irrigation can prevent this [12].
- The newer FD-OCT improves scanning times and pullback speeds, obviating the need for balloon occlusion [13]. Complication rates are similar to IVUS in head-to-head comparisons [15–17].

Tips and Tricks

- The catheter should be introduced distally into the coronary artery after administration of intracoronary nitroglycerin to minimize vasospasm.
- Some clinicians continue dual-antiplatelet therapy for 14 days to 1 month after OCT imaging due to endothelial damage observed in animal studies.

Indications for Rotational Atherectomy

- RA is reserved for selected patients with moderate-to-severe CAC. The decision to perform RA is based on clinical judgment and should be considered when there is a low likelihood of successful stent delivery and expansion without plaque modification.
- RA utilization is also determined by the degree of coronary calcium, as benefits are diminished

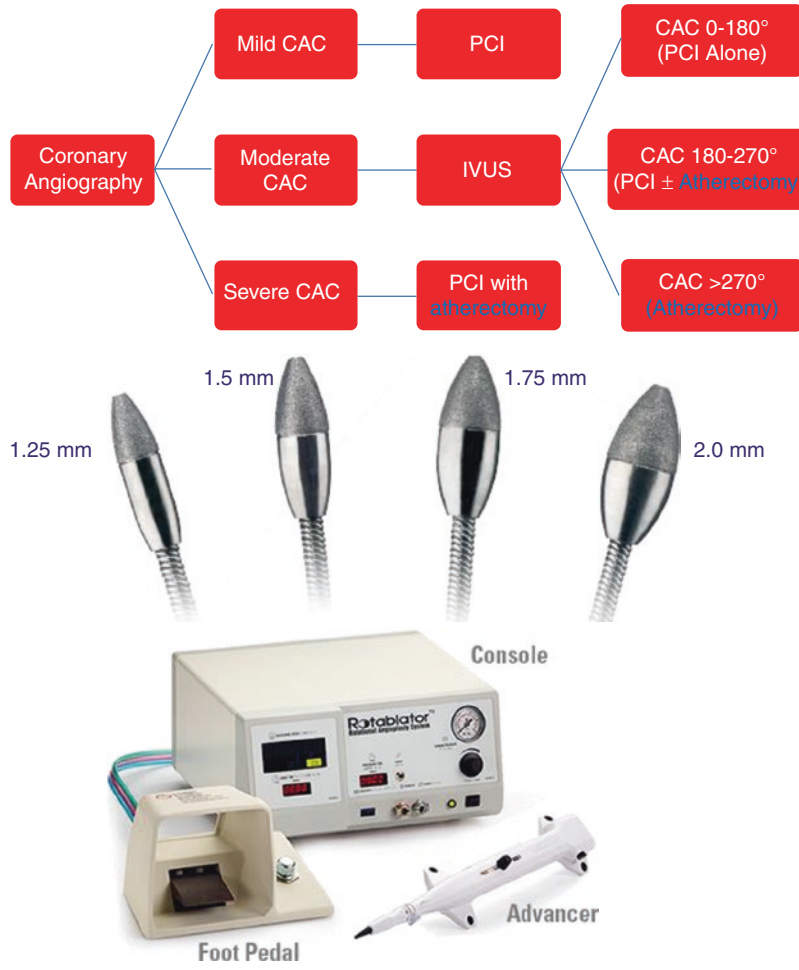

Fig. 13.1 Treatment algorithm for atherectomy (Plate A) and components of the rotablation system (Plate B = range of burrs available, also available in 2.15, 2.25, 2.38, and 2.50 mm; Plate C = system components). Adapted from Lee MS, Shah N. J Invasive Cardiol 2015

with minimal calcium (Fig. 13.1). The ACCF/AHA/SCAI guidelines for PCI provide a class IIa recommendation for utilizing RA for fibrotic or heavily calcified lesions that cannot be traversed by balloon catheters or adequately dilated before stent implantation [18].

- It should not be performed routinely for de novo lesions or in-stent restenosis (ISR) (class III recommendation) [18].

Tips and Tricks

- IVUS and OCT help determine CAC severity. Atherectomy should be used if the calcium arc is ≥270°.
- If coronary atherectomy for a calcified lesion is not the initial strategy, balloon inflation at nominal pressure should be performed to determine if the balloon fully expands without dissecting the vessel.
- If the balloon doesn't fully expand, coronary atherectomy can still be performed as long as a dissection has not occurred.

Contraindications for Rotational Atherectomy

- Absolute contraindications to RA include:
  - Presence of thrombus
  - Saphenous vein graft (SVG) lesions
  - Coronary dissection
- Relative contraindications in general include:
  - The lack of cardiothoracic surgery availability

  - Severe three-vessel or unprotected left main disease
  - Severe left ventricular dysfunction
  - Lesions >25 mm
  - Lesion angulation >45° [19]

Rotational Atherectomy Technique

- A rapidly rotating olive-shaped burr coated with 2000–3000 microscopic diamond chips modifies calcified plaque to facilitate stent delivery and expansion [20].
- The burr, which is bonded to the drive shaft, has a size range of 1.25 mm to 2.5 mm and is advanced over a 0.009 in. RotaWire (Boston Scientific). The other components include the console and turbine that is activated via foot pedal (Fig. 13.1).
- The mechanism of action is differential cutting, whereby the burr ablates inelastic tissue (calcium, fibrous tissue) and spares healthy tissue due to its elastic properties that deflect diamond microchip edges [20]. The differential cutting and longitudinal friction via changes in circumferential direction aid burr advancement through lesions. The typical burr-to-artery ratio is 0.5, as the purpose of RA is plaque modification rather than debulking.

Tips and Tricks

- A workhorse wire can traverse the lesion by swapping out the RotaWire through an over-the-wire balloon or any other exchange catheter, as the RotaWire is often difficult to advance across the lesion.
- Once the burr is advanced proximal to the lesion, the following maneuvers can be performed prior to ablation to reduce slack from the system and prevent the burr from jumping forward when activated: (1) gently pulling back the drive shaft and removing stored tension from the advancing shaft; (2) loosening the advancer knob and moving it back and forth; and (3) briefly activating dynaglide.
- Avoid adding vasodilators in the rota-flush solution to decrease the risk of periprocedural hypotension [21].
- A "single-operator" technique can be used to advance the drive shaft when a skilled assistant is not available to hold the RotaWire [22].
- If the RotaWire is inadvertently pulled back with the drive shaft on it, the RotaWire can be readvanced forward while activating dynaglide.
- Briefly tapping on dynaglide can facilitate the delivery of the burr that is difficult to advance.
- Constant normal saline flushes during each pass decrease heat generation.
- The burr should be advanced with a slow (1 mm/s) pecking technique.
- Each pass should be kept to a short duration (<15–20 s) to minimize excessive friction that can injure vessels, activate platelets, or release large debris [19].
- Burr deceleration of >5000 rpm indicates that it should be advanced more slowly or pulled back.
- Prophylactic placement of a temporary pacemaker should be considered if the patient has baseline bradycardia, a long diffuse lesion in the right coronary artery, or a dominant left circumflex artery [23].
- If a temporary pacemaker is not placed, nurses should have atropine readily available if heart block is induced.
- Nurses should have phenylephrine readily available if severe hypotension develops.
- Patients with left ventricular systolic dysfunction should be evaluated for a hemodynamic support device [24].

Clinical Data

- The ERBAC trial demonstrated that RA had the best initial procedural success rate compared to excimer laser and balloon angioplasty (89% vs. 77% vs. 80%, $p = 0.009$) [25].
- The COBRA trial reported that RA provided higher procedural success rates compared to balloon angioplasty (85% vs. 78%, $p < 0.05$) with no difference in rates of restenosis, target lesion revascularization, or symptomatic outcome at 6 months [26].

- The ROTAXUS trial showed that RA had a higher overall strategy success rate in patients with severe CAC lesions compared to PCI alone (92.5% vs. 83.3%, $p = 0.03$) [27]. The rates of in-stent restenosis, target-lesion revascularization, and MACE were similar between both groups at 9 months. There were also no differences in MACE rates at 2 years [28].

Complications/Troubleshooting

Vascular Complications

- The risk of coronary vasospasm can be reduced with prophylactic intracoronary nitroglycerin.
- A smaller burr-to-artery ratio (<0.7) may reduce angiographic complications compared to aggressive burr sizing (>0.7) [29, 30]. A smaller burr-to-artery ratio can additionally decrease the risk of coronary perforation.
- Coronary dissection is also concerning given its association with greater residual stenosis and greater need for surgical revascularization. Predictors of dissection include vessel tortuosity and angulation. Meticulous technique, slow burr movement, and avoiding atherectomy altogether in tortuous and angulated vessels will minimize both perforation and dissection risks.
- Larger catheters and frequent catheter exchanges increase the risk of cerebrovascular events possibly due to calcified arterial debris embolizing to the cerebral vasculature [31]. Careful advancement to minimize drop in speed, lower rotational speeds (150,000 rather than 180,000 rpm), and intermittent lesion contact may allow perfusion to better clear debris.

Slow/No-Reflow

- Reduced coronary flow (TIMI grade 2), or slow flow, is secondary to atherosclerotic debris showering followed by subsequent thrombotic phenomena, neurohormonal mediator release, and platelet activation in the absence of stenosis, thrombus, or dissection. No-reflow is TIMI grade 0–1 in the coronary vasculature without obvious secondary cause. The interplay of both local features at the level of the coronary artery and systemic pathophysiologic factors may cause these disturbances in coronary flow [32].
- To minimize the risk of slow/no-reflow, strategies such as prophylactic intracoronary administration of vasodilatory agents, appropriate device sizing, and slow and short-duration passes are recommended (Table 13.2).
- Treatment of slow/no-reflow includes intracoronary nitroprusside, adenosine, or calcium-channel blockade [33].

Table 13.2 Prevention and treatment strategies for slow or no reflow during rotational atherectomy

Mechanism of slow/no-reflow	Therapeutic options
Atheromatous debris embolus	Avoidance of significant deceleration Short duration of ablation Small burr sizing
Intraprocedural hypotension	Vasopressor: • Phenylephrine for immediate response • Dopamine or norepinephrine if sustained Intra-aortic balloon pump
Neurohormonal reflex bradycardia	Atropine
Microcirculatory vasospasm	Vasodilatory agents: • Nitroprusside • Nicardipine • Adenosine
Platelet activation, aggregation	Bailout glycoprotein IIb/IIIa inhibitor Optimal antiplatelet therapy

Adapted from Tomey M, Kini A, Sharma S. Current status of rotational atherectomy. JACC: Cardiovascular Interventions 2014;4:345–353

Burr Entrapment

- Burr entrapment is a rare phenomenon. The burr only ablates during advancement since only the distal half has diamond chips. The proximal portion of the burr can become entrapped in an incompletely ablated calcified lesion due to its inability to perform retrograde ablation.
- Various techniques can remove the entrapped burr, including deep intubation with the

guiding catheter or balloon angioplasty at the location of burr entrapment [34].
- Strategies to decrease the risk of burr entrapment include using smaller burrs with higher mobility and short-duration passes with intermittent advancement ("pecking" motion) to help avoid burr deceleration and stalling [19]. High-speed (>170,000 rpm) atherectomy may allow the burr to cross calcified lesions easier.
- Utilizing tactile, auditory, and visual senses can help minimize complications. Signs of impending entrapment include excessive vibration from the burr encountering extra resistance, changes in the pitch related to burr resistance, and poor burr advancement on fluoroscopy.

Summary

- RA is an invaluable tool to modify complex and heavily calcified coronary lesions.
- Intravascular imaging is a vital tool to identify the presence and degree of CAC and assist the operator in determining the need for atherectomy.
- Operator training, appropriate device selection, and experience are imperative to improving clinical outcomes in patients with complex coronary lesions.

Excimer Laser

Synopsis

Various coronary atherectomy methods are used to modify calcified lesions and reduce rates of PCI complications. One such technique is excimer laser coronary atherectomy (ELCA), a form of laser angioplasty (LA), which can improve successful stenting in lesions with CAC.

Techniques to Quantify Degree of Coronary Artery Calcification

Invasive imaging modalities like IVUS and OCT are used to quantify CAC and assist the operator in determining whether patients require adjunctive treatment with coronary atherectomy. These are covered in detail in the rotational atherectomy section previously (see also Chap. 14).

Indications for Excimer Laser Coronary Atherectomy

- The ACCF/AHA/SCAI guidelines for PCI provide a class IIb recommendation for utilizing LA in fibrotic or moderately calcified lesions that cannot be crossed or dilated with conventional balloon angioplasty [16].
- LA should not be used routinely during PCI (class III recommendation) [16].
- Procedural success using ELCA for crossing and debulking calcified chronic total occlusions and balloon-resistant lesions was high (>90%) with no perforation or no-reflow in the LEONARDO study and the study by Bilodeau et al. [35, 36].
- ELCA can also be used synergistically with RA in heavily calcified subtotally occluded lesions. If a standard 0.014 in. wire traverses the subtotally occluded lesion but an exchange catheter cannot cross, ELCA can modify the lesion to create a channel through which the RotaWire can subsequently be delivered distally through an exchange catheter [37]. This ELCA and RA combination is termed the RASER technique and is particularly effective for calcified stenosis during PCI [38–40].
- Suboptimal stent expansion can be treated with ELCA as it modifies the underlying resistant atheroma by delivering energy to the outer stent surface without disrupting stent architecture [41, 42]. This weakens plaque resistance behind the stent to facilitate further stent expansion.
- ELCA is effective in treating in-stent restenosis (see also Chap. 31). In a study of 107 restenotic lesions in 98 patients, lesions treated with ELCA had greater IVUS cross-sectional area and luminal gain compared to balloon angioplasty alone [43]. ELCA resulted in more ablation of intimal hyperplasia and a trend toward lower rates of 6-month

target-vessel revascularization (21% vs. 38%; $p = 0.083$). Data also support long-term efficacy of ELCA with balloon angioplasty in treating ISR, showing less frequent need for repeat target-vessel revascularization [44].

Tips and Tricks

- If the rate of advancement of the catheter distal tip does not correspond directly to the rate of proximal shaft advancement on fluoroscopy, reassess lesion morphology.
- The laser catheter tip should never pass the guide-wire tip.
- Avoid withdrawing the guide wire inside the laser catheter.

Table 13.3 Indications for excimer laser coronary atherectomy (ELCA) and the preferred laser catheter

ELCA indication	Preferred laser catheter (mm)
Acute myocardial infarct, intracoronary thrombus	0.9–1.4
Uncrossable lesions	0.9 × 80
Chronic total occlusions	0.9 × 80
Under-expanded stent	0.9 × 80
In-stent restenosis	0.9–2.0 (concentric or eccentric)
Saphenous vein grafts	0.9–2.0

Adapted from Rawlins J, Din J, Talwar S, O'Kane P. Coronary Intervention With The Excimer Laser: Review Of The Technology And Outcome Data. Interventional Cardiology Review 2016;11 (1):27–32

Contraindications for Excimer Laser Coronary Atherectomy

- An absolute contraindication to ELCA is the presence of coronary dissection.
- Relative contraindications to atherectomy are similar to rotational atherectomy.
- ELCA has minimal ablative effects on calcium and relies on ablation of more pliable lesion tissue, suggesting that severely calcified vessels may have less luminal gain following ELCA [45, 46]. Sequential IVUS analysis following ELCA has failed to demonstrate quantitative (measurable decrease in calcium arc or superficial calcium) or qualitative (visual evidence of reduced shadowing and increased ultrasound penetration) calcium ablation [46].

Excimer Laser Coronary Atherectomy Technique

- ELCA utilizes fiber-optic technology to produce monochromatic light energy to ablate plaque without directly affecting the surrounding healthy tissue [20]. Ultraviolet pulses debulk moderately calcified plaque, fibrous tissue, atheroma, and thrombus.
- Continuous versus pulsed laser waves affect the degree to which coronary plaque is affected. One of ELCA's initial limitations was the constant power output inducing significant thermal damage [47–49]. The current ELCA model delivers high energy in a pulsatile fashion, breaking chemical bonds in tissue without damaging surrounding material or causing heat damage [50]. ELCA can also vaporize concomitant thrombi, decreasing the risk of platelet aggregation [51].
- Coronary catheters are available in 0.9, 1.4, 1.7, and 2.0 mm diameters. Laser catheter size is primarily based on:
  - Lesion severity
  - Reference vessel diameter
  - Target-material consistency [37]
- The 0.9 mm X80 catheter is selected in most balloon failure cases because it provides the widest range of power and repetition (Table 13.3).
- The ELCA catheter is advanced on a short monorail segment, compatible with any standard 0.014 in. guide wire [37]. This is a major advantage over alternative coronary atherectomy techniques that require dedicated guide wires.

Tips and Tricks

- Operators control two factors during usage: wave frequency administered and amount of energy (fluence) [50]. There is a fine balance between the pulse repetition rate and fluence

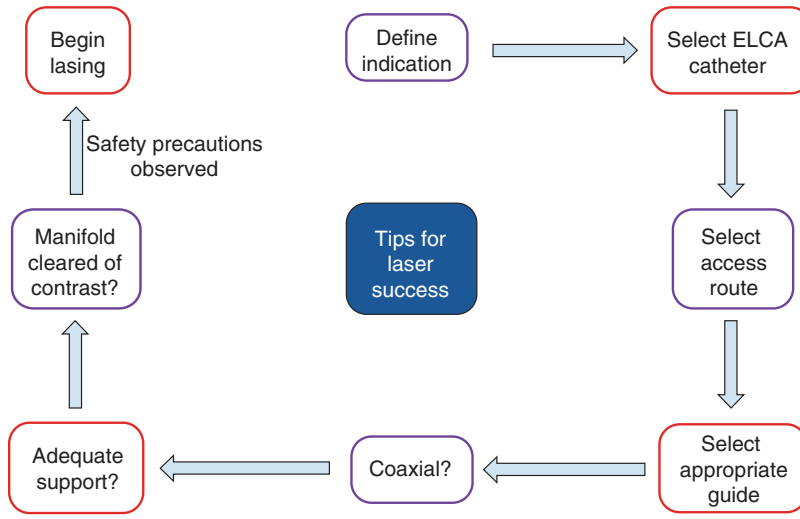

Fig. 13.2 Workflow for successful laser atherectomy. Adapted from: Rawlins J, Din J, Talwar S, O'Kane P. Coronary Intervention With The Excimer Laser: Review Of The Technology And Outcome Data. Interventional Cardiology Review 2016;11 (1):27–32

administered to minimize thermal effects during the procedure [52].

- A frequency/fluency of 40/40 is typically the initial setting. Settings can be increased after several passes.
- Effective plaque removal via slow advancement of the catheter (1 mm/s) creates a smoother, larger vessel diameter.
- ELCA should not be performed while injecting contrast media because contrast and blood have high absorption of emission light, increasing the risk of dissection and perforation [53, 54].
- Constant saline flushing during catheter advancement can decrease the risk of complications.
- A systematic approach improves the workflow for successful ELCA (Fig. 13.2).

Complications/Troubleshooting

Vascular Complications

- Coronary vasospasm occurred in 6.1% of cases in one multicenter analysis [36] but can be reduced with prophylactic intracoronary nitroglycerin. Coronary perforation and dissection are more troublesome complications.
- A 16-trial analysis reported high rates of dissection (22.0%) and perforation (2.4%) with LA [55]. Logistic regression analysis revealed a correlation between dissections and utilization of larger catheter sizes ($p = 0.0005$), lesion length > 10 mm ($p = 0.001$), and high energy per pulse levels ($p = 0.0001$ for native vessels) [55].

Slow/No-Reflow

Slow/no-reflow phenomena increase periprocedural complications due to induced ischemia and MIs. Their pathophysiology, prophylaxis, and treatment are covered in the rotational atherectomy section.

Summary

ELCA is used to modify complex and moderately calcified coronary lesions. Although its role is not as widely accepted as that of RA, it provides another option for treating undilatable lesions. Its versatility also allows operators to address difficult-to-treat lesions, including in-stent restenosis.

Aspiration Thrombectomy

Synopsis

- PCI is the preferred method of reestablishing coronary perfusion after thrombotic coronary occlusion in acute ST-elevation myocardial infarction (STEMI). However, PCI risks distal thrombus embolization.

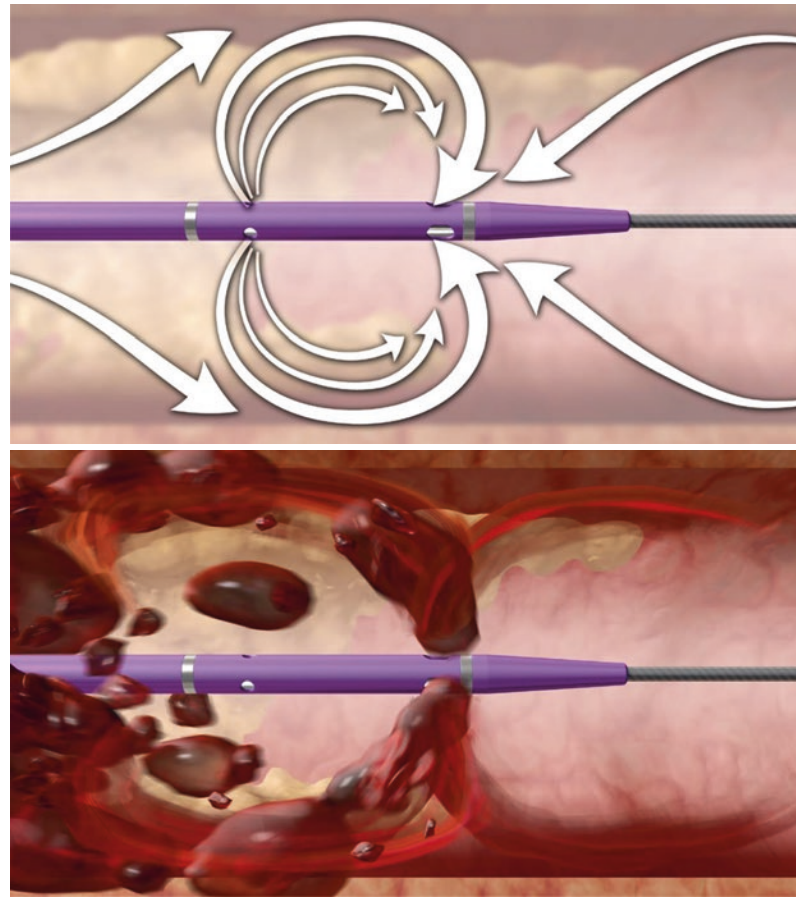

Fig. 13.3 Angiojet™ mechanical thrombectomy system. High-pressure saline jets create a vacuum effect that induces fragmentation and aspiration of large-volume thrombus (image courtesy of Boston Scientific, Inc.)

- Thrombectomy procedures have been studied in acute myocardial infarction (AMI), which includes completely occlusive STEMI or partially occlusive unstable angina and non-ST-elevation MI (NSTEMI).
- The goal of thrombectomy is to debulk intraluminal thrombus to improve flow and reduce distal embolization (Fig. 13.3). Early trials demonstrated mortality benefit with up-front routine thrombectomy in STEMI patients. However, subsequent trials have contradicted these findings.

No-Reflow Phenomenon

- No-reflow is a profound reduction in coronary blood flow (TIMI grade flow $\leq$ 2) in the absence of stenosis, thrombus, dissection, or spasm [56–58]. Thrombectomy may provide protective benefit against this phenomenon.
- A study of 260 patients undergoing primary PCI reported that no-reflow was most common in patients with large thrombus burden without thrombectomy, followed by those who underwent thrombectomy [59].
- A retrospective study of 116 AMI patients treated with conventional angioplasty and 89 AMI patients treated with angioplasty plus manual aspiration thrombectomy reported that no-reflow phenomenon was significantly lower in the thrombectomy group (8 vs. 18%, $p < 0.05$) [60]. Although this suggests that thrombectomy may decrease the risk of no-reflow, the reduction of adverse clinical events is not well

established since many higher risk patients did not benefit from the procedure, or were excluded from studies.

Thrombectomy

Large thrombus burden is associated with a higher rate of stent thrombosis and worse clinical outcomes [61]. Two types of thrombectomy have been studied in AMI patients: manual aspiration and mechanical thrombectomy.

Manual Aspiration Thrombectomy

- In aspiration thrombectomy, a dual-lumen catheter replaces a traditional balloon catheter. The catheters are deployed in rapid exchange or over-the-wire format with a second port connected to a vacuum syringe. The operator aspirates thrombus upon reaching the target lesion by turning the vacuum syringe stopcock.
- The 2015 ACC/AHA/SCAI primary PCI for STEMI patients' focused update does not recommend routine use of aspiration thrombectomy [62, 63]. Three large randomized studies provide the bulk of evidence for aspiration thrombectomy utilization (Table 13.4).
- The TAPAS trial, which randomized 1071 STEMI patients, reported that the primary endpoint of myocardial blush grade 0 or 1 occurred less frequently in patients treated with aspiration thrombectomy with the 6F Export catheter (Medtronic, Minneapolis, MN) compared with PCI alone (17.1% vs. 26.3%, $p < 0.001$) [64]. Although 30-day MACE rates were similar (6.8% vs. 9.4%; $p = 0.12$), MACE and overall mortality were significantly lower in those who achieved better myocardial blush. This benefit persisted at 1-year follow-up [65].
- The TASTE trial randomized 7244 STEMI patients to aspiration thrombectomy or PCI alone [66]. The primary endpoint of death from any cause at 30 days was similar in both groups (2.8% vs. 3.0%, $p = 0.63$), as were rates of 30-day MACE and 1-year mortality (5.3% vs. 5.6%, $p = 0.57$) [67].
- The TOTAL study, designed to clarify the mixed findings in the TAPAS and TASTE trials, randomized 10,732 STEMI patients to up-front manual aspiration thrombectomy with the Export catheter (Medtronic) versus PCI alone [68]. The primary outcome of the composite of cardiovascular death, recurrent MI, cardiogenic shock, or New York Heart Association class IV heart failure within 180 days occurred with similar frequency in both groups (6.9% vs. 7.0%, $p = 0.86$). Stroke within 30 days occurred more frequently with aspiration thrombectomy (0.7 vs. 0.3%, $p = 0.02$), as did stroke at 180 days (1.0 vs. 0.5%, $p = 0.002$). Outcomes at 1 year also showed a potential increase in stroke and no reduction in longer term clinical outcomes [69].
- Although aspiration thrombectomy showed promising clinical benefits in the TAPAS trial, the TASTE and TOTAL trials curbed early enthusiasm. Taking the cumulative data of these trials, the routine use of aspiration thrombectomy has been downgraded to bail-out in cases of heavy thrombus burden and poor flow.

Table 13.4 Major RCTs of manual aspiration thrombectomy (MAT)

Trial	Publication date	Size	Device	30-day MACE MAT arm (%)	30-day MACE control arm (%)	1-year MACE MAT arm (%)	1-year MACE control arm (%)
TAPAS	2008	1071	Export	6.8	9.4	5.6[a]	9.9[a]
TASTE	2013	7244	Multiple	3.3[a]	3.9[a]	8.0	8.5
TOTAL	2015	10,732	Export	6.9	7.0	8.0	8.0

MAT Manual aspiration thrombectomy, *TAPAS* the Thrombus Aspiration during Percutaneous Coronary Intervention in Acute Myocardial Infarction Study, *TASTE* the Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia trial, *TOTAL* the Trial of Routine Aspiration Thrombectomy with PCI versus PCI Alone in Patients with STEMI

[a]Mortality or myocardial infarction

Mechanical Thrombectomy

- Mechanical thrombectomy utilizes moving, machine-driven parts to macerate and aspirate thrombus. One such device is the Angiojet (Boston Scientific, Marlborough, MA), which uses rheolytic thrombectomy (RT). The 6F compatible system shoots high-pressure, high-velocity saline jets from its catheter tip to form a low-pressure zone, creating a vacuum that dissociates and aspirates thrombi via the Venturi-Bernoulli effect (Fig. 13.3). However, the AiMI and JETSTENT trials raised safety concerns.
- The AiMI trial randomized 480 patients presenting within 12 h of a STEMI to PCI alone versus RT [70]. The primary endpoint of infarct size was larger in the RT group (12.5% vs. 9.8%, $p < 0.02$). The RT group also had higher rates of 30-day MACE (6.7% vs. 1.7%; $p = 0.01$) and mortality (4.6% vs. 0.8%; $p = 0.02$) [70].
- The JETSTENT trial randomized 501 patients with STEMI in vessels >2.5 mm and visible thrombus to RT versus direct stenting [71]. The protocol required the device be activated prior to crossing the lesion. Although the rates of 6-month MACE (11.2% vs. 19.4%; $p = 0.009$) and 12-month event-free survival (85.2% vs. 75%; $p = 0.009$) were improved with Angiojet, the primary endpoint of infarct size was similar in both groups.
- A meta-analysis that included seven trials comparing mechanical thrombectomy to conventional PCI reported no significant difference in the incidence of MACE or death [72]. However, there was a trend toward a higher rate of all strokes with mechanical thrombectomy (1.3% vs. 0.4%, $p = 0.07$) [73].
- The manual devices in general are more user friendly with shorter learning curves. Despite effective thrombus removal, mechanical thrombectomy used during primary PCI does not appear to reduce infarct size or improve TMPG, TIMI flow grade, ST-segment resolution, or 30-day MACE [74].

Summary

- Thrombectomy during primary PCI does not provide benefit across most large randomized trials. The ACC/AHA/SCAI guidelines relegated routine aspiration thrombectomy utilization from class IIa to class III in 2015.
- However, its utility should be individually tailored for each case when flow cannot be restored with balloon inflation alone.
- Mechanical thrombectomy has yet to show equivalent benefits to manual aspiration. Thus, interventionalists must be familiar with aspiration thrombectomy techniques in complex reperfusion cases that may require adjunctive PCI treatment.

Distal Embolic Protection

Synopsis

- Reestablishing coronary perfusion after STEMI is crucial to improve patient outcomes. However, manipulation of culprit lesions with wires and catheters risks distal embolization of atheromatous material and thrombus.
- Embolic protection devices (EPDs) were designed for adjunctive use during PCI to address this issue. Early randomized trials analyzing EPD efficacy in native coronary vessels did not show additional benefit when used with primary or rescue PCI.
- Patients with SVG lesions have different risk factors and rates of vascular complications. Subsequent trials investigating EPD efficacy in SVG intervention demonstrated clinical benefits not seen in the native circulation.

Types of Distal Embolic Protection Devices (See Also Chap. 30)

EPDs capture and retrieve friable, lipid-rich plaque particles dislodged during PCI. EPDs can

Table 13.5 Embolic protection device type based on mechanism of action: strengths and limitations

	Proximal occlusion	Distal occlusion	Distal filter
Embolization on wiring/predilatation/device crossing	–	+	+
Failure to capture debris <100 μm	–	–	+
Failure to capture soluble mediators	–	–	+
Ischemia during balloon occlusion	+	+	–
Limited contrast opacification	+	+	–
Unlimited debris capture	+	+	–
Shunting of debris into proximal side branches	–	+	–
Graft lesion location			
Ostial (<12 mm)	–	+	+
Middle	+	+	+
Distal (<20 mm)	+	–	–

Adapted from Bangalore S, Bhatt DL. Embolic protection devices. Circulation 2014 Apr 29;129 (17):e470–6

be separated into three categories based on their mechanism of operation: proximal occlusion aspiration devices, distal occlusion aspiration devices, and distal embolic filters (Table 13.5).

Proximal Occlusion Aspiration

- A proximal occlusion aspiration device utilizes a guiding catheter with an inflatable balloon tip deployed proximal to the lesion. This occludes antegrade flow, creating a column of stagnant blood containing debris that is later aspirated through the guiding catheter.
- The Proxis (7F; St. Jude Medical, Minneapolis, MN), which is no longer commercially available, provides protection prior to crossing the lesion, potentially recovering all particles and vasoreactive substances, and can be used in lesions without a distal landing zone. The type of guide wire can also be tailored to procedural requirements.
- Disadvantages include limited contrast opacification and ischemia during balloon occlusion.

Distal Occlusion Aspiration

- A distal occlusion aspiration device contains an inflatable occlusion balloon attached to a hypotube (small tube acting as an interventional guide wire for balloon angioplasty or stenting).
- The occlusion balloon is inflated several centimeters distal to the lesion, obstructing antegrade flow and trapping plaque debris. Debris is subsequently removed via an aspiration catheter (Export or FlushCath).
- The PercuSurge GuardWire (6F; Medtronic, Minneapolis, MN) and TriActiv system (7F or 8F; Kensey Nash Corp, Exton, PA) are examples of such devices. These EPDs capture particles <100 μm and soluble vasoactive mediators with unlimited debris capture, but risk embolization during the wiring and device-crossing phase.
- Other disadvantages include ischemia during balloon occlusion, limited contrast opacification, and risk of shunting debris into proximal side branches. Operators also cannot tailor the guide wire type to procedural requirements.

Distal Embolic Filter

- A distal embolic filter has a filter bag attached to the distal portion of a 0.014 in. guide wire with a delivery sheath (3.2F). The filter bag has 100–110 μm pore sizes to filter particles >100–110 μm. The filter bag with debris is later retrieved with a retrieval catheter (4.2F–4.9F).
- Devices that work with this principle include the FilterWire (Boston Scientific, Natick, Mass.), Interceptor Plus Coronary Filter System (Medtronic Vascular, Santa Rosa, CA), and the Spider (Medtronic, Minneapolis, MN).

- Advantages include the ability to maintain perfusion and contrast opacification during the procedure.
- Disadvantages include the potential risk of distal embolization during the wiring and device-crossing phases, inability to filter soluble vasoactive substances, large-diameter delivery sheath requirement, and embolization of debris during filter retrieval.

Clinical Data in Native Coronary Circulation

- Data on EPD efficacy in STEMI patients have failed to consistently demonstrate significant benefit on clinical outcomes or myocardial reperfusion (Table 13.6) [75].
- The EMERALD trial analyzed EPD efficacy in 501 STEMI patients who underwent

Table 13.6 Major trials of embolic protection devices for ST-segment-elevation myocardial infarction involving the native coronary arteries

Trial	Device	Patients (*n*)	Primary endpoint	Result (%)	*P*-value
Proximal occlusion device					
PREPARE	Proxis vs. conventional PCI	284	Complete ST-segment resolution at 60 min	80 vs. 72	0.14
Distal occlusion device					
EMERALD	GuardWire Plus vs. conventional guide wire	501	ST-segment resolution at 30 min Infarct size	63.3 vs. 61.9 12.0 vs. 9.5	0.78 0.34
ASPARAGUS	GuardWire Plus vs. conventional guide wire	329	TIMI grade 3 flow TMP grade 3	77 vs. 78 25.2 vs. 20.3	0.73 0.26
MICADO	GuardWire Plus vs. conventional guide wire	167	No-reflow TIMI grade 3 flow TMP grade 3	4 vs. 3 80 vs. 76 58 vs. 44	0.73 0.182 0.054
Ohala et al.	GuardWire Plus vs. abciximab	120	TIMI grade 3 flow	89 vs. 89	>0.05
Tahk et al[a]	GuardWire Plus vs. conventional guide wire	116	TIMI grade 3 flow TMP grade 3 Hyperemic average peak velocity	96 vs. 81 65 vs. 38 39.2 ± 16.7 vs. 30.6 ± 10.8 cm/s	0.016 0.001 0.014
Distal filter device					
DEDICATION	FilterWire vs. conventional PCI	626	ST-segment resolution at 90 min	72 vs. 76	0.29
PROMISE	FilterWire EX vs. conventional guide wire	200	Maximum adenosine-induced flow velocity	34 ± 17 vs. 36 ± 20 cm/s	0.46
PREMIAR	SpiderRX vs. conventional PCI	140	ST-segment resolution at 60 min	60 vs. 60	0.99
UpFlow MI	FilterWire EX vs. conventional guide wire	100	TIMI grade 3 flow TMP grade 3 ST-segment resolution at 60 min	88.2 vs. 93.9 68.1 vs. 66 9.4 vs. 10.7	>0.05 > 0.05 > 0.05

ASPARAGUS Aspiration of Liberated Debris in Acute Myocardial Infarction With GuardWire Plus System, *DEDICATION* Drug Elution and Distal Protection During Percutaneous Coronary Intervention in ST Elevation Myocardial Infarction trial, *EMERALD* Enhanced Myocardial Efficacy and Removal by Aspiration of Liberated Debris, *MICADO* Multicenter Investigation of Coronary Artery Protection With a Distal Occlusion Device in Acute Myocardial Infarction, *PREPARE* Proximal Embolic Protection in Acute Myocardial Infarction and Resolution of ST-Elevation, *PREMIAR* Protection of Distal Embolization in High-Risk Patients with Acute ST-Segment Elevation Myocardial Infarction, *PROMISE* Protection Devices in PCI Treatment of Myocardial Infarction for Salvage of Endangered Myocardium, TIMI Thrombolysis in Myocardial Infarction, *TMP* Thrombolysis in Myocardial Infarction myocardial perfusion, *UpFlow MI* Use of Protective FilterWire to Improve Flow in Acute Myocardial Infarction study
Adapted from Bangalore S, Bhatt DL. Embolic protection devices. Circulation 2014 Apr 29;129 (17):e470–6
[a]No difference in major adverse cardiac events at 6 months

primary PCI or rescue intervention after failed fibrinolysis [76]. There was no significant difference in the co-primary endpoint of infarct size between patients randomized to PCI with a GuardWire and those randomized to primary PCI alone (median, 12.0% vs. 9.5%, $p = 0.15$). The secondary endpoint of MACE at 6 months was also comparable in the two groups (10.0% vs. 11.0%, $p = 0.66$).

- The PROMISE and DEDICATION trials were of similar design to the EMERALD trial, but used the FilterWire rather than the GuardWire [77, 78]. The two groups (PCI with and without EPDs) were equivalent in infarct size, maximal adenosine-induced flow velocity, and 30-day mortality in the PROMISE trial. Likewise, complete (≥70%) ST-segment resolution was similar between the two study arms in the DEDICATION trial. In fact, 15-month follow-up results of the DEDICTATION trial suggest an increased incidence of stent thrombosis and target-vessel revascularization with routine EPD use [79].
- It is hypothesized that the native coronary circulation may have smaller embolic burdens than SVG, accounting for the apparent lack of benefit with EPD utilization. There is no role for EPD use during PCI of native coronary vessels in STEMI.

Clinical Data in Saphenous Vein Grafts

- The ACCF/AHA/SCAI guidelines provide a class I indication to the use of EPDs during SVG intervention when technically feasible [18]. EPDs may have a greater impact on SVG lesions given their potentially higher embolic burden compared to native vessels.
- Degenerated vein grafts have more friable lipid-rich plaque, more diffuse lesions with thinner fibrous caps, and thus a greater propensity to embolize distally [80, 81]. In fact, MACE rates double in SVG intervention compared to those in native coronary vessels [82].
- The SAFER trial randomized 801 patients with SVG stenosis to stent placement over the shaft of a GuardWire device or a conventional angioplasty guide wire [83]. EPD utilization significantly reduced the frequency of no-reflow (3% vs. 9%, $p = 0.02$) and MI (8.6% vs. 14.7%, $p = 0.008$).
- The FIRE trial compared the PercuSurge GuardWire against the FilterWire Ex in 651 patients who received SVG stenting [82]. Equivalent results were recorded for the 30-day composite endpoint of death, MI, or target-vessel revascularization (11.6 vs. 9.9%, $p = 0.53$).
- The PRIDE trial compared the TriActiv System to both the PercuSurge GuardWire and the FilterWire Ex system [84]. The TriActiv System was not inferior to the other devices in terms of MACE, but may be associated with more bleeding complications.
- In-stent restenosis of SVG lesions consists primarily of neointimal proliferation and may have lower embolic potential, potentially negating the need for distal embolic protection. A study of 54 patients undergoing PCI for SVG in-stent restenosis without EPDs showed no procedure-related MI or no-reflow episodes during the procedure [85]. More data are needed to clarify the role of EPD in the treatment of SVG in-stent restenosis.
- The PROXIMAL trial evaluated the use of the Proxis device in 594 patients undergoing stenting in 639 SVGs [86]. Patients were randomized to either current care (distal EPD whenever possible, no EPD when not) or a test arm (proximal protection device whenever possible, distal embolic protection when proximal protection not feasible). The test arm was noninferior to the current care in the primary composite endpoint of death, MI, or target-vessel revascularization at 30 days (10.0% vs. 9.2%, $p = 0.0061$).
- Overall, the trials above demonstrate the efficacy of all three EPD classes in minimizing adverse outcomes in PCI for SVG stenosis (see also Chap. 30). Other studies comparing newer devices against the GuardWire reference standard have also been found to be noninferior in efficacy (Table 13.7). Although these devices have become part of a more common standard of care, they are currently underutilized in SVG intervention [87].

Table 13.7 Major trials of embolic protection devices for saphenous vein graft intervention

Trial	Device	Patients (*n*)	30-day MACE (%)	*P*-value	Design
Proximal occlusion device					
PROXIMAL	Proxis vs. FilterWire or GuardWire	594	9.2 vs. 10	0.006	Noninferiority
Distal occlusion device					
SAFER	GuardWire vs. conventional guide wire	801	9.6 vs. 16.5	0.004	Superiority
PRIDE	TriActiv vs. GuardWire	631	11.2 vs. 10.1	0.02	Noninferiority
Distal filter device					
AMEthyst	Interceptor PLUS vs. FilterWire or GuardWire	797	8.0 vs. 7.3	0.025	Noninferiority
SPIDER	SPIDER vs. FilterWire or GuardWire	732	9.1 vs. 8.4	0.012	Noninferiority
CAPTIVE	CardioShield vs. GuardWire	652	11.4 vs. 9.1	>0.05	Noninferiority
FIRE	FilterWire vs. GuardWire	651	9.9 vs. 11.6	0.0008	Noninferiority
TRAP	TRAP vs. conventional guide wire	358	12.7 vs. 17.3	0.24	Superiority

AMEthyst Assessment of the Medtronic Ave Interceptor Saphenous Vein Graft Filter System trial, *CAPTIVE* CardioShield Application Protects During Transluminal Intervention of Vein Grafts by Reducing Emboli trial, *FIRE* FilterWire EX Randomized Evaluation trial, *MACE* major adverse cardiac event, *PRIDE* Protection During Saphenous Vein Graft Intervention to Prevent Distal Embolization trial, *PROXIMAL* Proximal Protection During Saphenous Vein Graft Intervention trial, *SAFER* Saphenous Vein Graft Angioplasty Free of Emboli Randomized trial, *SPIDER* Saphenous Vein Graft in a Distal Embolic Protection Randomized trial, *TRAP* Trap Vascular Filtration System to Reduce Embolic Complications During Stenting of Diseased Saphenous Vein Grafts trial
Adapted from Bangalore S, Bhatt DL. Embolic protection devices. Circulation 2014 Apr 29;129 (17):e470–6

Summary

Routine EPD use as an adjunctive therapy to primary PCI in patients with acute STEMI in the native circulation is not recommended. However, evidence supports the routine use of EPDs in the setting of PCI for SVG lesions.

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