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Coronary Atherectomy, Atheroablation, and Thrombectomy*

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Unlike balloon angioplasty (Chapter 23) or stent placement (Chapter 25), which widen the coronary lumen by merely displacing atherosclerotic plaque, the family of atherectomy techniques seeks to widen the lumen by actually removing tissue (plaque or thrombus) from the vessel wall. A variety of specific devices and mechanisms of action are available, ranging from cutting and retrieval (directional [1,2] and transluminal excisional atherectomy [3]) to atheroablation without recovery of the resulting debris (rotational [4,5] and laser atherectomy [6]). Also included are the recently approved Possis AngioJet thrombectomy suction catheter (which has no cutting elements but uses a highly efficient vacuum generation system to provide efficient removal of intracoronary thrombus) and the new class of embolus containment devices (which do not act on the lesion itself, but rather trap and recover atheroembolic debris liberated from the lesion by other devices).

The proportion of interventions involving atherectomy has diminished (to roughly 20% in our laboratory) since reaching its zenith (at about 30%) from 1992 to 1994, largely because stenting generally provides a simpler, easier, and often less costly option. But atherectomy continues to be used for indications that are unfavorable for stenting, or where atherectomy before stenting improves results. It is therefore important to understand the techniques available and how to match available devices to patient and lesion characteristics, so as to optimize the final posttreatment lumen diameter and procedural safety. Given the wide variety of devices and associated mechanisms, the design, technique, results, and applications of each will be reviewed separately.

DIRECTIONAL CORONARY ATERECTOMY

Device Description

The directional coronary atherectomy (DCA) catheter, also called the Simpson AtheroCath (Guidant, Santa Clara, CA), was first used in human peripheral vessels in 1985 (1) and in coronary arteries in 1986 (7). The coronary device was approved in 1990, following a large multicenter experience (8). Despite several minor improvements, the basic concept remains intact—awindowed steel housing is pressed up against the lesion by a low-pressure positioning balloon. Any plaque that protrudes into the window isthen shaved from the lesion and trapped in the device nose cone by a spinning cup-shaped cutter that is advanced across the window opening. The coronary device tracks over a 0.014-inch guidewire (Fig. 24.1), and wire braid allows the shaft to be rotated to reduce friction as the device is advanced across the lesion and to allow precise rotational orientation of the cutting window. During cuts, a separate battery-powered motor drive unit spins the cup-shaped cutter at approximately 2,500 rpm, as it is advanced manually by a small lever on the motor drive unit.

FIG. 24.1.

Directional coronary atherectomy. Left coronary angiography (lateral view) reveals a long eccentric stenosis in the mid–left anterior descending (LAD) artery (A). After atherectomy, the lumen is smooth, and there is no significant residual stenosis or dissection (B). A 7F AtheroCath was employed (C), and several pieces of atheroma were retrieved (D).

Three different sizes of housing are available for coronary use, with diameters of 5F, 6F, and 7F (1.7, 2.0, and 2.3 mm, respectively). A 7F-graft device with a larger-diameter positioning balloon is also available. A newer design
Guiding catheters for directional coronary atherectomy (devices for vascular intervention) are constructed with gentle curves rather than sharp angles to facilitate passage of the rigid housing (Fig. 24.2). Some large-lumen 9F catheters are capable of delivering the 6F and 7F devices, and a new flexi-cut design promises 8F guiding catheter compatibility. The size of the atherectomy device is determined by the size of the normal vessel adjacent to the stenosis (the reference segment). The 6F device is generally used when the reference diameter is less than 3 mm, and the 7F device, when the reference diameter is between 3 and 4 mm or when a residual stenosis remains despite use of the 6F device with balloon inflation pressures up to 40 psi. The 7F graft device uses a larger-diameter positioning balloon on the 7F housing to treat vessels of more than 4 mm. A smaller, 5F device may be used rarely (e.g., subtotal lesions in calcified or moderately tortuous vessels) to partially debulk the plaque and thereby facilitate passage of an alter (definitive) device. Predilation with a small (e.g., 2-mm) conventional balloon also may be used to facilitate passage of the AtheroCath, but larger predilating balloons should not be used to avoid causing dissections or making recovery of tissue more difficult during subsequent atherectomy cuts.

**FIG. 24.2.**

Guiding catheters for directional coronary atherectomy (devices for vascular intervention) are constructed with gentle curves rather than sharp angles. **Left:** The 11F JCL 3.5 guiding catheter for coronary atherectomy. **Right:** The 9F JCL 4 guiding catheter for conventional PTCA.

After flushing the central lumen and filling the balloon lumen with dilute contrast material, the device is passed into the guiding catheter over an exchange-length guidewire that has been positioned well across the target lesion through a large-bore rotating hemostatic valve. To advance the device across the target lesion, the device is gently advanced until its nose cone passes into the proximal portion of the vessel. Gentle withdrawal or rotation of the guiding catheter helps align the device with the long axis of the vessel, and gentle forward pressure is applied during continuous rotation of the atherectomy catheter. If the device does not pass easily, attempts to force it into the lesion or around curves in the vessel should be avoided, since forceful advancement of the rigid housing through a stiff, calcified, tortuous vessel could traumatize the vessel wall. Likewise, deep seating the guiding catheter (a common maneuver in PTCA) should be avoided during atherectomy, since the stiff guiding catheter itself may cause injury to the coronary ostium or proximal vessel.

Once the device is in position at the target lesion, a fluoroscopic projection is utilized that maximizes visualization of the target lesion and its eccentricity. In that projection, the device is rotated until the cutting window is seen to point toward the greatest plaque burden. The cutter is withdrawn to the proximal end of the window, and the positioning balloon is inflated to 10 to 20 psi. The motor is activated, and the cutter is advanced slowly (>5 seconds) across the window. After each cut, the balloon is deflated as the device is rotated by 45° to 90° to reorient it toward additional plaque burden. To prevent embolization of plaque, the balloon is inflated to 10 psi during cutter withdrawal prior to making the next cut. Higher balloon inflation pressures (30 to 40 psi) may be used on subsequent cuts to retrieve remaining plaque, but cuts oriented toward nondiseased walls should be avoided to minimize the risk of vessel perforation. After four to six cuts, or if incomplete cutter advancement indicates that the nose cone collecting chamber is full, the device should be removed and emptied before additional cuts are made.

The number of passes and the final size of the device are determined based on the size of the reference segment and the presence of any angiographic residual stenosis. Intravascular ultrasound (Chapter 19) may be helpful in assessing the lumen diameter as well as the amount and location of residual plaque burden. Atherectomy is considered successful if there is tissue removal, a residual stenosis is less than 50% after atherectomy, and there are no major complications (death, Q-wave myocardial infarction [MI], or emergency coronary bypass surgery).

**Mechanisms of Lumen Enlargement**
Directional atherectomy was designed to excise atherosclerotic plaque (2). While lumen enlargement is predicated on plaque removal, the acute result is actually due to a combination of plaque removal and dilation. Early data showed that the amount of plaque removed (averaging 18.5 mg) accounts for less than half the observed gain in volume seen at the lesion site (9),(10), with the rest resulting from “facilitated angioplasty” (Fig. 24.3). Even after a successful atherectomy that has normalized the angiographic vessel lumen relative to that of the adjacent reference segments, a substantial amount of plaque (40% to 50% of the outer vessel [external elastic lamina, or EEL] cross-sectional area) remains, reflecting the substantial Glagov remodeling that typically has taken place at the lesion site (11).

FIG. 24.3.

Schematic representation of mechanism of directional coronary atherectomy and the concept of “facilitated angioplasty.” **Left:** Concentric stenosis in a coronary artery. The shaded area represents intimal plaque contained within the internal elastic lamina (wavy line). **Center:** Excision of plaque and media at 8 o'clock results in thinning of the vessel wall; subsequent cuts at 1 and 4 o'clock do not penetrate the media. **Right:** With disruption of the internal elastic lamina, radial compliance increases so that subsequent balloon inflations cause focal stretching of the vessel wall within the channels produced by previous atherectomy cuts (“facilitated angioplasty”). The resulting lumen appears smooth and free of residual stenosis in any angiographic projection, despite only partial atherectomy with the continued presence of residual intimal plaque.

Since atherectomy improves the radial compliance of the diseased and stiff coronary segment and since the mechanism of lumen enlargement is due in part to dilation, it stands to reason that post atherectomy balloon angioplasty should impart additional volume expansion. Although early studies considered such an application of balloon angioplasty after successful atherectomy to be tantamount to a “crossover,” current “optimal” atherectomy practice makes routine use of low-pressure postdilation to further enlarge the treated lumen (12–14).

**Procedural Results**

There has been considerable experience with directional coronary atherectomy (with the Simpson AtheroCath), with more than 200,000 procedures performed worldwide. Published experience includes single-center reports (15),(16) and results from two multicenter registries (8),(17), five multicenter randomized trials (Tables 24.1 through 24.4) (13,14,18–20). Device success rate (defined as achievement of more than 20% gain and less than 50% residual stenosis with tissue removal) is greater than 95%, with overall procedural success (defined as less than 50% residual stenosis, with adjunctive post atherectomy balloon angioplasty or other device) greater than 98%. Major complications are generally quite similar to balloon angioplasty except for the higher incidence of perforation (approximately 1%) and CK elevation greater than three times normal (approximately 15%). The importance of the high incidence of clinically silent elevations in creatine kinase myocardial band (CK-MB) enzymes following directional atherectomy remains unsettled and controversial, but in the Balloon versus Optimal Atherectomy Trial (BOAT) (14) there was no association with deaths at 1 or 3 years and there tended to be more late deaths by 1 year in the balloon angioplasty arm compared with the DCA arm (eight deaths vs. three deaths, p = .14).

The main differences among trials concern the residual stenosis and the subsequent rate of angiographic restenosis. For the two early (1990 to 1991) randomized trials, high (>25%) residual stenoses (29% for CAVEAT I and 26% for CCAT) (18),(19) reflected cautious tissue removal and the discouragement of adjunctive balloon postdilatation. In contrast, more recent experiences utilizing the optimal atherectomy technique have used more aggressive tissue removal and routine (75% of cases) adjunctive postdilatation angioplasty to obtain much lower residual stenoses (<15%). The benefit of this approach in lowering restenosis compared with stand-alone balloon angioplasty has been confirmed in the OARS (13), BOAT (14), and ABACAS (20) studies with angiographic restenosis rates of 21% to 31%, compared with the 46% to 50% restenosis rates in the earlier trials. In BOAT, the lower residual stenosis for DCA versus PTCA (14% vs. 28%) led to significantly lower angiographic restenosis rates (31% vs. 40%).

The mechanism of late lumen narrowing has been carefully evaluated for directional atherectomy using intravascular ultrasound (IVUS). Analysis of the OARS multicenter registry IVUS substudy (11) and the Serial Ultrasound Restenosis (SURE) trial (21) demonstrated that lumen renarrowing following directional atherectomy occurs between 1 and 6 months after the procedure and is due primarily to shrinkage (negative remodeling) of the external elastic
membrane as well as some neointimal hyperplasia. The results of the OARS intravascular substudy are summarized in Table 24.4.

Tissue Analysis and Consequences of Deep-Wall Resection

Atherectomy provides a unique opportunity for studying the pathophysiology of atherosclerosis and coronary restenosis in human coronary arteries (22). Standard light microscopy demonstrates that atherosclerotic plaque (97%), media (66%), adventitia (30%), and thrombus (43%) are commonly recovered. Remarkably, retrieval of deep-wall components seems to be well tolerated acutely, and at 6 months, angiographic follow-up (23),(24) shows no relationship between deep-wall resection and restenosis, although the risk of late aneurysm formation may be increased (25),(26).

Histologic analysis of DCA specimens shows intimal hyperplasia in 93% of restenotic lesions, with proliferating-phenotype smooth muscle cells interspersed with ground substance. Surprisingly, however, 44% of primary (de novo) lesions have intimal hyperplasia that is histologically indistinguishable from intimal hyperplasia seen in lesions with prior restenosis (27).

Use in Specific Lesion Types

Bifurcation Lesions

Plaque obstruction in large epicardial coronary arteries that involves the origin of a large branch, such as the left anterior descending/diagonal branch bifurcation, presents a special problem to the interventionist. The treatment of such true bifurcation lesions using conventional balloon angioplasty techniques is limited due to plaque shifting that occurs between the parent vessel and the ostium of the branch vessel (Chapter 23). In contrast, directional atherectomy provides superior treatment of bifurcation lesions, since the mechanism of lumen enlargement includes excision of the tissue that might otherwise be displaced into the branch ostium (28–30). The preferred technique involves sequential atherectomy of the main vessel and its branch, if the branch is large enough to accommodate the device (Fig. 24.4).

FIG. 24.4.

Bifurcation atherectomy. Upper left: “Mercedes Benz” lesion involving the bifurcation of the left anterior descending (LAD) and diagonal branch (arrow). Upper right: Directional atherectomy of LAD, leaving tight stenosis of the diagonal origin (right center, arrow). Lower right: Atherectomy of the diagonal origin leaves excellent result (lower left). (From Friedman HZ, et al. Mechanical rotatory therectomy: the effects of microparticle embolization on myocardial blood flow and function. J Interv Card 1989;2:77, with permission.)

The acute and long-term results of directional atherectomy for the treatment of true bifurcation lesions were compared with balloon angioplasty by Dauerman (31). The atherectomy group had lower acute residual diameter stenosis and lower target vessel revascularization rate (28% for atherectomy vs. 53% for balloon angioplasty. P = .01). DCA should only be performed in noncalcified bifurcation lesions where the main vessel and involved side branch are larger than 2.5 mm (otherwise, rotational atherectomy should be used). We first position the 0.014-inch guidewire into the distal parent vessel and perform initial cuts directed toward the ostium of the branch vessel in an effort to minimize “snowplow” branch compromise. Next, the guidewire is withdrawn and redirected into the branch vessel, where additional cuts are performed. Finally, kissing balloon inflation in the parent and branch vessel is performed, with stent placement reserved for situations in which there is excessive recoil or dissection.

Aortoostial Stenoses

The ostium of the right coronary artery or saphenous vein graft is located within the thick-walled aorta, where substantial elastic recoil makes the use of stand-alone balloon angioplasty problematic (see Chapter 23). Such recoil has been overcome by tissue excision using directional atherectomy (Fig. 24.5) (32),(33). This requires delivery of
the device coaxially with the proximal portion of the target vessel. The guiding catheter must be disengaged before performing atherectomy cuts (to avoid cutting the tip of the guiding catheter itself). This requires use of bony landmarks for positioning the device at the ostium, since the disengaged guide can no longer provide adequate contrast angiography. Generally, postatherectomy balloon angioplasty or stent placement may be used to further “upsize” the lumen result beyond the working diameter of the AtheroCath. The presence of intracoronary calcium, especially at the lumensurface, is a relative contraindication for directional atherectomy of ostial stenoses, and such lesions are more suited for rotational atherectomy (see later discussion).

**FIG. 24.5.**

Aortoostial saphenous vein graft atherectomy. **Left panel:** Ostial stenosis of saphenous vein graft (arrow) represents stenosis within the wall of the aorta, based on its location between the aortic lumen and the ring marker. This was refractory to dilatation with a 5-mm balloon (center, top) but responded to directional atherectomy (center, bottom) with favorable results (right panel). Such lesions are currently treated with stent placement (see Chapter 25).

**Salvage Atherectomy**

Directional coronary atherectomy can be used successfully to rescue failed or suboptimal balloon angioplasty (34),(35), particularly when plaque recoil results in plaque avulsion into the intraluminal space. This application has become quite rare with the widespread use of stent placement to stabilize abrupt or threatened closure after balloon angioplasty and should not be attempted when there are deep spiral dissections in which attempted resection may result in perforation.

**In-Stent Restenosis**

Although coronary stenting has been proven to reduce the incidence of restenosis compared with balloon angioplasty, the high recurrence rate (50% to 80%) of treating diffuse restenosis within stent in-stent restenosis has become evident. Debulking techniques using laser, rotational atherectomy, or DCA have been shown in case-matched series to cut this recurrence rate roughly in half (36–38), although further substantial reductions in recurrence have now been seen with beta or gamma radiation of the in-stent restenosis (39). Directional atherectomy, which offers potentially the highest debulking capacity of the atherectomy and atheroablative devices, has been shown to be safe and effective in achieving less than 20% residual in-stent diameter stenoses and subsequent clinical restenosis rates of less than 30% (Fig. 24.6). In some atherectomy procedures for in-stent restenosis, the tissue sample may include a small section of strut, although without apparent clinical consequence.

**FIG. 24.6.**

Directional atherectomy of in-stent restenosis. **Top:** Restenosis within stent in the mid-left anterior descending artery (arrows denote test strut). **Upper center:** Directional atherectomy catheter positioned within stent. **Lower center:** Enlarged lumen following atherectomy (arrow). **Bottom:** Final result after balloon dilatation.

**Debulking Before Coronary Stenting**

The concept of stand-alone “optimal” atherectomy was validated in the OARS, BOAT, and ABACAS studies (13,14,20). Recent studies have suggested that performing directional atherectomy before stenting may improve long-term stent results. In the Stenting after Optimal Lesion Debulking (SOLD) study (40), 71 patients underwent directional atherectomy of coronary lesions before stenting, achieving an angiographic restenosis rate of 11%. Interestingly, this was due both to a slightly larger acute result reduction and to a reduced late loss index (33% vs. the more typical 50%) compared with stenting alone. A similar experience has been reported by Kiesz and coworkers (the ADAPTS study), in which 89 lesions in 60 patients were treated with a combination of DCA debulking followed by stenting (41). Two more definitive randomized trials, AMIGO and DESIRE, are currently under way to test the hypothesis that directional coronary atherectomy before stenting may result in a lower restenosis rate than stenting alone.
TRANSLUMINAL EXTRACTION CORONARY AHERECTOMY

Device Description

The transluminal extraction catheter (TEC) (Interventional Technologies, Inc., San Diego, CA) uses a tip-mounted cutting blade and an external vacuum source to macerate and aspirate thrombus and soft plaque material (Figs. 24.7 and 24.8). A trigger on the handle of the motor drive unit activates shaft and blade rotation at 750 rpm, and a sliding lever on top of the motor drive unit permits advancement or retraction of the cutter over the 300-cm-long 0.014-inch guidewire. Warm, heparinized lactated Ringer's solution is infused during atherectomy passes to produce a thin slurry of blood and tissue that is then continuously aspirated into the external suction bottle during cutter activation.

FIG. 24.7.

Components of the transluminal extraction catheter (TEC), including the cutter, motor drive unit, battery pack, and vacuum bottle. (Reproduced with permission from Interventional Technologies, Inc., and Physician's Press.)

TEC Atherectomy Procedure

Device selection remains empirical, with the largest cutter being 1 to 1.5 mm smaller than the normal vessel diameter. For coronary use, TEC cutters range from 5.5F (1.8 mm), 6F (2 mm), 6.5F (2.15 mm), and 7F (2.3 mm) to 7.5F (2.5 mm). The larger cutters (7F or 7.5F) should be reserved for vessels greater than 3.5 mm in diameter or for lesions associated with large amounts of thrombus. Special 10F tungsten-braided soft-tip guiding catheters are recommended for all TEC atherectomy procedures, but a 9F guiding catheter can be used for TEC cutters of 6.5F or less. Guiding catheters with an inner diameter of more than 0.105 inch are required for 7F or 7.5F cutters.

After engaging the vessel ostium with the guiding catheter, the target lesion should be crossed with the special TEC guidewire using a bare-wire technique. The floppy tip of the guidewire should be positioned in the distal vessel so the stiff shaft of the wire is across the lesion. If difficulty is anticipated crossing the lesion, a conventional wire may be used first and then exchanged for the TEC wire using a transport catheter that will accommodate the 0.021-inch ball at the tip of the special TEC guidewire. Once the guidewire is in proper position, the TEC cutter should be advanced up to the lesion, and the infusion of warmed lactated Ringer's is begun through the guiding catheter. The operator then depresses the trigger to activate cutter rotation and slowly advances the lever to traverse the entire lesion. Two to five passes should be made slowly through the lesion (15 to 30 seconds per 10-mm segment) until there is no further resistance to cutter advancement. After retracting the cutter into the guiding catheter, repeat angiography should be performed to determine the need for a larger device or adjunctive angioplasty.

Mechanism of Action

TEC atherectomy theoretically enlarges the lumen by cutting, aspirating, and removing thrombus, plaque, and other debris. In contrast to the discrete tissue fragments commonly retrieved by directional atherectomy, TEC results in a slurry of blood and debris that does not lend itself easily to tissue analysis. In angioscopic studies of saphenous vein grafts, TEC resulted in partial or complete removal of fresh thrombus in more than 75% of lesions in which thrombus was identified (42, 43) but was less effective in removing laminated thrombus. Other angioscopic findings included the frequent development of intimal flaps and dissection. By intravascular ultrasound, plaque fissures and residual plaque were identified in 100% of lesions after TEC, and intimal dissections were identified in 36% of lesions (44). Others have suggested that most of the improvement results from mechanical dilatation rather than removal of plaque or thrombus (45).

FIG. 24.8.
Close-up view of the conical cutting head and stainless steel blades of the transluminal extraction catheter (TEC) and special 0.014-inch TEC guidewire. (Reproduced with permission from Interventional Technologies, Inc., and Physician's Press.)

Results

The treatment of saphenous vein grafts with luminal irregularities or the presence of frank thrombus is unfavorable for any coronary device, because of high rates of distal embolization, no reflow, and recurrent ischemia and restenosis, but may be suited for the TEC device with its potential to cut and aspirate thrombus and “grummos” material (Fig. 24.9) (Table 24.5). The overall procedure success rate ranges from 80% to 90% (3, 46, 47; Table 28.4), but modest quantitative angiographic improvement in lumen diameter immediately after TEC required adjunctive balloon angioplasty in approximately 90% of cases (48). Although lesions containing thrombus have been shown to be associated with lower procedure success for the TEC device than that achieved in lesions without thrombus (49), TEC atherectomy before stenting may be better than conventional balloon or stent treatment alone for thrombotic lesions (50).

Bypass graft angiography (left anterior oblique [LAO] projection) and angioscopy before and after TEC atherectomy. A: Angiography of a vein graft to the obtuse marginal branch reveals a tubular stenosis in the midbody of the graft. There is no definite thrombus by angiography. B: TEC atherectomy is performed with a 6.5F cutter. C: Angiography immediately after TEC reveals a complex residual stenosis with dissection and/or thrombus. D: A single Palmaz-Schatz P204 biliary stent is inserted and further dilated to 14 atm. After adjunctive angioplasty, there is no residual stenosis, dissection, or filling defect.

The incidence of death (0 to 5.9%), emergency bypass surgery (0.7% to 3.9%), and MI (2% to 7.8%), however, is generally similar to the incidence of death (0 to 5%), emergency bypass surgery (0 to 3%), and MI (0 to 9%) for patients with vein graft lesions treated by conventional angioplasty (3, 17, 44, 46). Angiographic follow-up confirmed the high incidence of restenosis, with 52% to 69% of lesions having a follow-up diameter stenosis of more than 50% (44), (46), and late vessel total occlusion in 29% of lesions.

In native coronaries, the TEC device has a procedure success rate that ranges from 85% to 95%, with adjunctive angioplasty required in approximately 80% (Table 24.5) (51). The final incidence of major in-hospital complications was death in 2.3%, emergency bypass surgery in 2.8%, and Q-wave MI in 3.4%, which was somewhat higher than the incidence of major complications for comparable lesions treated with balloon angioplasty. Other TEC-induced angiographic complications included side-branch occlusion in 2.7%, distal embolization in 0.5%, guiding catheter dissection in 2.2%, coronary artery perforation in 2.2% of lesions (Figs. 24.10 and 24.11).

Perforation of the right coronary artery (RCA, LAO projection) after TEC atherectomy. Baseline angiography reveals a long stenosis in the proximal RCA (left panel, black arrows). After TEC atherectomy with a 7F cutter, there is a jet of free contrast extravasation into the pericardium (middle panel, open arrowheads) and deep
periadventitial contrast staining (middle panel, open arrow). After prolonged inflation with a perfusion balloon and pericardiocentesis, there is no residual contrast extravasation (right panel, open arrowhead), although there is a mild residual stenosis at the site of the original lesion (right panel, black arrows).

Since TEC atherectomy has not been shown to consistently remove plaque, the immediate angiographic results of TEC atherectomy in native coronary arteries do not appear to be superior to balloon angioplasty, and most lesions were treated with adjunctive angioplasty after TEC, the value of TEC in native coronary arteries remains uncertain. Procedural costs for TEC are also significantly higher than those for conventional angioplasty of similar lesions (52). One exception may be the use of TEC to remove thrombus in the setting of acute MI, especially where large thrombus burdens are present (53). (54).

Randomized Trials

Thrombus-Containing Lesions Trial

The TEC or PTCA in Thrombus-Containing Lesions (TOPIT) Trial was a 245-patient multicenter randomized trial comparing TEC plus optional balloon angioplasty with balloon angioplasty for patients with either a clinical likelihood for coronary thrombus (unstable angina or postinfarction angina) or angiographically apparent thrombus (55). The procedure success rate was 97% for both groups, owing to the frequent (35%) rate of stent use to repair dissections. The primary end point-composite rate of in-hospital major adverse cardiac events (death, MI, bailout intervention, or emergent surgery)—was noted in 11.2% of patients randomized to balloon angioplasty versus 4.5% for those randomized to TEC (p = .06). A secondary end point of CK-MB isoenzyme peak elevation greater than three times normal was observed more frequently in the balloon angioplasty group (15.4% vs. 4.5%, p = .03).

FIG. 24.12.

Close-up view of the Rotablator burr embedded with diamond chips and special 0.009-inch guidewire. (Reproduced with permission from Heart Technology, Inc., and Physician's Press.)

Transluminal Extraction Coronary... (TECBEST)

The Transluminal Extraction Coronary (TECBEST) trial examined the potential role of TEC compared with balloon predilation before stenting in saphenous vein grafts (56). There was no improvement in acute angiographic results by TEC pretreatment, and the incidence of distal embolization and periprocedural MI was not reduced.

Contraindications and Limitations of TEC

TEC is contraindicated for the treatment of dissection caused by other devices and should not be used in cases of extreme angulation or calcification and where vessels are less than 2.5 mm in diameter. The theoretical benefits of TEC atherectomy suggest that its benefit is generally limited to thrombus-containing vein grafts. Published data disclose inadequate lumen enlargement as a “stand-alone” device, a high incidence of serious angiographic complications, frequent need for adjunctive angioplasty, high procedural cost, and high incidence of clinical and angiographic restenosis (57). Even in the cases of large thrombi, the use of newer thrombectomy devices (see later discussion) may offer safer and more efficient thrombus removal.

HIGH-SPEED MECHANICAL ROTATIONAL ATERECTOMY (ROTABLATOR)

Device Description

The high-speed mechanical rotational atherectomy device, or Rotablator (Boston Scientific, Boston, MA) (4,5,58),
consists of an olive-shaped stainless steel or brass burr whose surface is embedded with diamond chips measuring 30 to 120 mm in diameter (Fig. 24.12). The burrs attached to a hollow, flexible drive shaft that permits passage of a steerable, movable 0.009-inch guidewire with a 0.014-inch platinum coil at its tip. The drive shaft is encased within a Teflon sheath through which warm, heparinized Ringer's lactate solution is pumped into the sheath to lubricate and cool the drive shaft and burr. A compressed-air turbine rotates the drive shaft at 150,000 to 200,000 rpm (Fig. 24.13). Burrs for coronary use are available in diameters of 1.25, 1.5, 1.75, 2.0, 2.15, 2.25, and 2.5 mm (Table 24.6).

**FIG. 24.13.**

Schematic overview of the original Rotablator assembly. (Reproduced with permission from Boston Scientific, and Physician's Press.) In the current Rota-link design, the drive unit is separate and can be used with a series of different burr cables.

**Rotablator Atherectomy Procedure**

As with conventional balloon angioplasty, all patients should be pretreated with aspirin at least 24 hours before the procedure, and intravenous heparin adequate to maintain the activated clotting time at approximately 300 seconds. Intracoronary nitroglycerin (100- to 200-(g bolus), and intravenous nitroglycerin (20- to 100-(g/min infusion) should be administered as tolerated. For patients with target lesions in the distribution of the right coronary artery, prophylactic temporary pacemaker insertion is recommended, frequently in the form of a right heart catheter that combines capabilities for pacing and monitoring pulmonary artery pressure. Conventional angioplasty guiding catheters maybe used for Rotablator atherectomy as long as their lumens is at least 0.020 inch larger than the largest burr to be used (Table 24.6). Two guidewires are available, a floppy guidewire and an extra-support guidewire. The floppy wire has the advantage of minimizing guidewire bias-aphenomenon in which a stiff guidewire tends to straighten out curved vessel segments and cause deep cuts or dissection as the burr is forced against the tautly stretched lesser curvature of the vessel. On the other hand, the floppy guidewire may fail to adequately control the travel of the burr around tight bends, leading to uncontrolled cutting on the greater curvature of the vessel. If difficulty is anticipated crossing the target lesion with the Rotablator guidewire using a bare-wire technique, the lesion may be crossed with a conventional angioplasty wire and exchanged for the Rotablator guidewire using a suitable transport catheter.

Once the guidewire is across the lesion, the burr should be advanced to within a few centimeters of the rotating hemostatic valve, with the lines for compressed air supply and tachometer readout attached to the drive console. The system should be tested by depressing the foot pedal adjusting the turbine to maintain burr speeds of 140,000 to 160,000 rpm. During the test, the operator should also confirm adequate flow of heparinized flush through the Teflon sheath, free motion of the advance lever, and a firm grip of the wire brake. Once this test has been completed, the burr can be advanced into and through the guiding catheter. Any resistance encountered as the burr is passed around the primary curve of the guiding catheter can be overcome by firm traction on the guidewire, but this is less common with the use of gentle (“Q”) curves analogous to those used for DCA. The guiding catheter must be well seated in the vessel ostium while advancing the burr to prevent kinking of the guidewire in the aortic root. Once the burr has been advanced to 1 to 2 cm proximal to the target lesion, the advancer lever should be unlocked and pulled all the way back to its proximal limit so as to take up any slack in the drive shaft that might otherwise cause the burr to lurch forward into the lesion upon activation.

Under fluoroscopy, the burr is then activated by stepping on the pedal, and adjusted to the desired “platform” speed (160,000 rpm for smaller burrs and 140,000 rpm for burrs bigger than 2 mm) before engaging the lesion. Advancement of the lever then brings the spinning burr slowly into contact with the lesion. It is important to be aware of the sound of the turbine, the rotational speed display, and tactile feedback during “rotablation,” to avoid speed drops of more than 5,000 rpm during advancement. Greater speed drops caused by excessive pressure on the burr may result in the liberation of larger particles, frictional heating of the plaque, or torsional dissection. Brief (1- to 3-second) periods of plaque contact should be alternated with longer (3- to 5-second) periods of reperfusion provided by pulling the burr back from the plaque face, to aid in clearance of particulate debris through the distal circulation. After 15 to 30 seconds of operation, the device should be withdrawn into the proximal vessel and rotation.
should be suspended for a similar time before reactivating and advancing the burr again. This sequence should be repeated until the device can be advanced through the full length of the lesion without any fluoroscopic or tactile resistance to burr advancement and with no audible change in the pitch of the turbine or reduction in burr speed. If a second, larger burr is to be used, the initial burr is then removed during continuous rotation (decreased to 90,000 rpm, in the “dynaglide” mode).

The selection of burr sizes is largely empirical but should progress to a final burr/artery ratio of roughly 0.7 (e.g., 2.15-mm burr in a 3-mm vessel). In treating long segments of disease, heavily calcified lesions, and subtotal de novo lesions, it is generally a good idea to start with a smaller (1.5 or 1.75 mm) burr and step up to the final burr size in 0.5-mm increments. With the Rota-Link system, this involves changing only the burr with reuse of a single-drive turbine throughout the procedure. With a maximum burr-to-artery ratios of 0.7, optimal improvement in vessel lumen requires liberal use of adjunctive angioplasty (or other devices). When adjunctive post dilation is desired, most operators use low inflation pressures (<2 atm) to minimize barotrauma, but there are no published data to suggest that this technique results in lower residual stenoses or fewer complications than other approaches.

**Mechanisms of Rotablator**

Unlike other atherectomy devices, which rely on tissue cutting and retrieval (directional atherectomy) or cutting and aspiration (TEC atherectomy), high-speed mechanical rotational atherectomy relies on plaque abrasion and pulverization. By the principle of differential cutting, the Rotablator tends to selectively abrade inelastic tissue (i.e., plaque) while elastic tissue (i.e., normal vessel wall) is deflected away from the burr (59). The abraded plaque is pulverized into particles 20 to 50 μm in diameter that pass through the coronary microcirculation and undergo phagocytosis in the liver, spleen, and lung (4, 60, 61). Although these particles have long been felt to not interfere with the coronary microcirculation (62), the reported benefit of glycoprotein IIb/IIIa receptor blockers against transient hypoperfusion suggests a role for platelet-mediated microvascular flow reduction during rotational atherectomy (63). Reisman has confirmed ex vivo platelet activation, with greater activation at higher burr speeds (64), as well as greater vessel heating. These findings have encouraged the use of lower (<160,000 rpm) speed during rotational atherectomy, although this necessitates longer cumulative burr time.

Although two independent studies demonstrated no immediate or long-term impact on left ventricular ejection fraction (65, 66), other studies show a significant incidence of non-Q-wave MI and no reflow (67), particularly in longer lesions (>2 mm). These problems could be secondary to particle embolization, spasm, microcavitation caused when the burr surface velocity exceeds the speed of sound in water (Bernoulli phenomenon) (68). Microcavitations or hemolysis of red blood cells may also contribute to transient bradycardia and atrioventricular (A-V) block, whereas mechanical stimulation and the loss of endothelium in the lesion and adjacent normal wall may explain the propensity for severe vasoconstriction during rotational atherectomy. Accordingly, liberal use of nitroglycerin and calcium channel blockers is routine, and temporary pacing should be considered, as discussed earlier.

**Results**

**Immediate Results**

Following Rotablator, the average residual diameter stenosis was 37% to 54% (65, 67, 69–73), but this high residual diameter stenosis may reflect an increase in vessel tone after rotational atherectomy. Reisman thus demonstrated that the lesion site diameter was significantly larger 24 hours after rotational atherectomy than it was immediately after the procedure (74). IVUS maybe useful for identifying which lesions are best suited to Rotablator and for guiding the use of larger burrs, balloon angioplasty, directional atherectomy, or stenting (75). In general, superficial calcium deposits are most amenable to Rotablator, since deep calcium deposits do not come in contact with the burr surface. Hoffman and coworkers demonstrated that treatment of calcified lesions with rotational atherectomy before stenting resulted in larger post treatment lumen diameters and higher 9-month event-free survival than with stenting alone (76). The use of adjunctive low-pressure balloon angioplasty is frequent after Rotablator (70) (Table 24.7), and Rotablator pretreatment improves vessel compliance and therefore stent expansion (77). This “rota-stent” approach is our standard technique for calcified ostial and left main lesions (78), (79) although it showed no significant advantage in the randomized SPORT trial of non- or minimally-calcified lesions. Rotablator is also an effective technique for debulking in-stent restenosis (Fig. 24.14) (36).
Rotablator atherectomy may be particularly indicated for specific lesion subsets where balloon angioplasty is known to be associated with suboptimal angiographic results. For calcified lesions, ostial lesions (Fig. 24.15), nondilatable lesions, and chronic total occlusions, Rotablator success has been reported to be 92% to 97%, with an acceptably low incidence of major clinical complications (80) (Table 24.7). Quantitative angiographic studies using matching lesion subsets suggest that pretreating many types of lesions with Rotablator can facilitate the results of adjunctive angioplasty (81) (Fig. 24.16).

While early studies indicated significant angiographic complications in nearly 40% of lesions after Rotablator—including angiographic dissection in 29%, side-branch occlusion in 1.8%, distal embolization in 0.9%, no reflow in 6.1%, abrupt closure in 11.2%, and severe spasm in 13.8%, and perforation in 1% to 2% of lesions-current technique has made the complication rate comparable to other catheter-based techniques (81a). Like DCA, there is a higher incidence of non–Q-wave MI after Rotablator, which was 19% in one study of long lesions (67).

FIG. 24.14.

Rotablator for in-stent restenosis (upper left). Severe restenosis is present in the proximal left anterior descending (note stent struts, small arrows). Upper center and upper right: Rotational atherectomy with 1.75- and 2.15-mm burrs. Lower right: Appearance post-Rotablator. Lower left: Appearance after final balloon dilatation.


FIG. 24.16.

Resistant calcified lesion becomes responsive after Rotablator. Upper left: Severe stenosis in the proximal left anterior descending artery (arrow). Upper right: Persistent waist despite inflation of angioplasty balloon to 10 atm. Center left: Advancement of a 1.5-mm Rotablator burr (note the heavy calcium shadows). Center right: Modest lumen enlargement following Rotablator. Bottom left: Following Rotablator, however, the same balloon now expands completely at 6 atm. Bottom right: Final result after stent placement.

Late Results

In the Excimer, Rotablator, Balloon Angioplasty for Complex Lesions (ERBAC) study, a randomized trial of rotational atherectomy, excimer laser angioplasty, or balloon angioplasty (see later, in the laser section), the final diameter stenosis after Rotablator and adjunctive angioplasty was significantly lower than that for adjunctive angioplasty after excimer laser or balloon angioplasty alone, but angiographic restenosis at 6 months was not significantly different at 45% to 50% (82). Other observational studies suggest a clinical restenosis rate of 38% and an angiographic restenosis rate between 31% and 59% (Table 24.6). The 500-patient randomized STRATAS trial compared aggressive rotational atherectomy, defined as high (>0.75) burr-to-artery ratio, with standard burr sizing (<0.7) to evaluate the impact of greater debulking (83). There was no difference in acute outcomes (except for a higher trend of non–Q-wave MI in the aggressive arm), with 6-month restenosis rates of 58% for the aggressive arm versus 52% for the conventional arm; \( p = \text{NS} \).

Recommendations for Use of Rotablator Atherectomy

Although detailed randomized trial data are limited, we recommend the use of Rotablator for those lesions that are least likely to benefit from conventional angioplasty, such as long, ostial, and heavily calcified lesions, including protected left main arteries calcified bifurcation lesions (84), as well as the rare (1% to 2%) lesion that cannot be dilated successfully at inflation pressures of 12 atm (Table 24.8). Lesions that cannot be crossed with a balloon catheter due to lesion rigidity or excessive tortuosity of the proximal vessel may also be amenable to Rotablator (80).
Rotablator has also proven to be an excellent tool for the debulking of in-stent restenosis, with some studies suggesting a substantial reduction in recurrence rates after Rotablator plus balloon dilatation of such lesions (36,85–87).

Rotablator should be avoided soon after attempted angioplasty, particularly if there is any evidence for local dissection. Other contraindications to Rotablator include the presence of visible thrombus or extremely eccentric lesions in a severe bend in which the normal vessel wall lies on the outer curve of the bend. Although Rotablator is technically feasible in long lesions, it may be associated with a significant incidence of no reflow or non–Q-wave MI, and there areas yet no data to suggest superiority to conventional angioplasty using long balloons.

Despite its ability to facilitate the immediate results of balloon angioplasty for a variety of lesions, Rotablator has a clear learning curve for safe use. It is further limited by the maximum 2.5-mm burr diameter, the frequent need for adjunctive balloon angioplasty or stenting, the high cost of procedures, and the lack of a confirmed impact on restenosis. While the complications of distal embolization, no reflow, severe coronary vasospasm, bradycardia, and perforation are uncommon with refinement in Rotablator technique as described earlier, they can clearly occur and stand as a reason that Rotablator use is uncommon for low-volume operators.

ABLATIVE LASER TECHNIQUES

It was hoped that laser angioplasty would permit precise plaque removal with fewer acute complications and lower incidence of clinical restenosis (88). Despite the evolution of catheter system designs over the years, restenosis rates following laser angioplasty have not been lower than those with balloon angioplasty alone (6),(82). Given the lack of clinical benefit over other mechanical therapies and the significant capital cost ($100,000 to $250,000) for acquiring a laser system, hopes for laser angioplasty have shifted from a mainstream stand-alone therapy to an infrequently used adjunctive treatment to debulk plaque before balloon angioplasty or stenting in coronary lesions with large atherosclerotic and restenosis plaque burdens, or to debulk in-stent restenosis. Because laser systems are still in use in some laboratories, newer applications may still be found. The body of theoretical and clinical data will be reviewed.

Laser Generation

Light amplification by stimulated emission of radiation (LASER) is the process of creating an in-phase (coherent) beam of monochromatic light with high energy. The lasing medium is “pumped” by an external energy source to force most of the atoms or molecules from their lower-energy ground state to a higher-energy excited state. After a brief time-measured in nanoseconds—the atoms begin to relax to their ground state by giving off a photon whose wavelength is determined by the energy difference between the excited and ground states, by the equation $E = hn$, where $h = $ Planck's constant and $n = v/l$ ($c$, speed of light; $l$, wavelength). One spontaneously released photon of precisely matched energy ($hn$) can induce other excited atoms in the lasing medium to relax to the ground state and emit photons that are identical in direction, wavelength, and phase to the stimulating photon (stimulated emission). As this wave passes through the laser cavity, light coalesces into a single wave front whose intensity increases exponentially as it travels along the optical axis of the laser cavity and is reflected back and forth between the mirrors positioned at either end of the chamber. This standing wave of intense, monochromatic, coherent light then permeates the optical coupler, from which it travels down the optical fibers within the multifiber laser catheter whose other end is positioned within the coronary artery lumen so as to illuminate the obstructing plaque with a burst of laser light.

Laser/Tissue Interactions

The interaction between laser light and biologic tissue depends on the wavelength, the mode of laser operation (continuous-wave or pulsed), the energy density of the laser light (fluence), any interposed fluid medium (saline or blood) and the tissue's intrinsic absorption characteristics. For coronary laser angioplasty, lasers can be divided into ultraviolet lasers (e.g., XeCl excimer lasers, 300 nm) in which ablative energy is absorbed directly by atherosclerotic plaque absorption, and near-infrared/infrared lasers (e.g., holmium or neodymium YAG trium-aluminum-garnet), 2,000 nm) in which thermal energy produced by water absorption leads to secondary photocoagulation. It is also important to distinguish continuous-wave laser systems, in which laser light is emitted in an uninterrupted manner, from newer pulsed systems that deliver peak laser over a very short pulse followed by a long interpulse interval to reduce heating of surrounding tissue. Despite these theoretical advantages, all pulsed laser systems still produce some thermal effects that are detectable with histologic examination after holmium and excimer laser radiation (89),(90).
While water is almost completely transparent to ultraviolet light at wavelengths greater than 193 nm, it absorbs infrared light strongly due to excitation of the translational, vibrational, and rotational frequencies of the Hz/O bond. On the other hand, blood, x-ray contrast agents (such as ioxaglate), and tissue DNA absorb ultraviolet (UV) light avidly. When laser light encounters biologic tissue, tissue vaporization occurs if the light contains wavelengths that are absorbed by the tissue, and if the absorbed energy exceeds the threshold for triggering a phase transformation. Tissue ablation then takes place through one of three mechanisms: vaporization of tissue (photothermal effects), ejection of debris (photoacoustic effect), or direct breakdown of molecules (photochemical dissociation).

Because early experimental studies involving free-laser beams in air showed tidy ablation of biologic tissue with clean margins and no histologic evidence of thermal injury (Fig. 24.17), it was initially thought that photodissociation was the predominant mechanism of excimer laser ablation of atherosclerotic plaque. Studies under saline or blood, however, disclosed less efficient plaque ablation and significant dissection of adjacent tissue due to formation and implosion of vapor bubbles at the impact site. This observation has immediate implications for excimer laser angioplasty. The use of intracoronary saline infusion to displace blood and radiographic contrast in the excimer laser field may thus reduce the risk of vessel dissection during excimer laser angioplasty (Fig. 24.18).

**FIG. 24.17.**

Ablation of postmortem human aortic tissue with pulsed excimer laser radiation at 193 nm in air.

**FIG. 24.18.**

Ablation of porcine aortic tissue after pulsed excimer laser angioplasty at 308 nm with multifiber laser catheters under saline (A) or blood (B). (Photomicrographs courtesy of L. Wells, Spectranetics, Colorado Spring, CO.)

**Catheter Delivery Systems**

The history of laser angioplasty includes experimentation with bare laser fibers, coaxial fiber-centering balloons, laser-heated metal tips, the laser balloon for local vessel heating, and “smart” laser systems that used a diagnostic laser to interrogate the vessel and confirm the presence of plaque rather than normal vessel wall before firing the therapeutic laser. None of these techniques have survived clinical investigation. All current clinical laser systems share common elements: a laser generator, an energy coupler, and a catheter delivery system—a trackable, flexible, over-the-wire or monorail catheter that contain several hundred optical fibers. Each optical fiber is composed of a transmitting material (such as a purified silica for excimer laser angioplasty) surrounded by a cladding. Since the cladding and silica fibers have different refractive indices, this creates an interface that promotes internal reflection and transmission of light down the length of fiber with negligible energy loss. The brittle fiber and cladding materials are surrounded by a flexible protective coating to allow bending without fissuring. Efficient coupling of energy between the laser generator and the optical fibers requires critical tolerances for alignment and precise polishing of the fiber ends.

**The Technique of Laser Angioplasty**

Conventional, commercially available guiding catheters can be used for excimer laser angioplasty. Because laser catheters are stiffer than balloon catheters and have difficulty negotiating acute angles into the target vessel, coaxial alignment is imperative. A stiff guiding catheter helps delivery, but firm guide support theoretically is not needed to advance the activated laser catheter through the target lesion, and excessive pushing of the catheter across the lesion may increase the risk of vessel dissection.

To maximize the likelihood of a safe outcome and reduce the risk of vessel perforation with excimer laser angioplasty, it is important to select a laser catheter with a diameter at least 1 mm smaller than the reference diameter.
of the target vessel (e.g., a 2-mm catheter for a 3-mm vessel). For diffuse disease or total and subtotal occlusions, an even smaller laser catheter (1.3 or 1.4 mm) should be used initially to cross the lesion. The current recommendation is thus to limit ablation to one pass of a laser catheter per lesion.

After the target lesion is crossed with the guidewire, the laser catheter is advanced to lie at the proximal end of the lesion. This catheter position should be documented on cine. Before activating the laser and beginning ablation of the lesion, every effort must be made first to remove all contrast medium from the target vessel by flushing the guide catheter with at least 30 mL of saline. This is important because the interaction between excimer laser radiation and any retained contrast medium may increase the generation of shock waves with disruption of adjacent tissue planes.

During pulsed excimer laser angioplasty, laser energy is delivered at a fluence of 40 to 70 mJ/mm² at a frequency of 20 to 25 Hz for a duration of 1 to 5 seconds as the tip of the catheter is advanced through the lesion. For soft lesions such as saphenous vein graft lesions and restenosis lesions, laser ablation may commence at fluence of 40 mJ/mm², but for calcified lesions and de novo lesions in the native coronary arteries, the initial fluence should be 50 mJ/mm². As the laser is activated, the catheter is advanced slowly under fluoroscopic guidance through the lesion at an average rate of 0.5 to 1 mm/sec. After each 1- to 5-second train of laser pulses, the laser catheter should “rest” for 10 seconds, to avoid potential attenuation of energy transmission through the optical fibers. If the laser catheter meets resistance and cannot pass through the lesion at the initial fluence, the energy output should be increased by increments of 10 mJ/mm² to a maximum of 60 or 70 mJ/mm². If the laser catheter still cannot be advanced at higher fluence levels, the repetition rate also can be increased by increments of 5 Hz to a maximum of 40 Hz. If the laser catheter still fails to make progress through a stenotic segment after 15 seconds of laser time, the temptation for forceful advancement of the catheter should be avoided, since this will only increase the risk of vessel perforation. Once the laser catheter has been advanced completely through the stenotic segment, adjunctive balloon postdilatation will be required in about 90% of laser angioplasty procedures to reduce the residual stenosis to below 30% (93–95). Further improvement can be achieved by following excimer laser angioplasty by stent placement or directional atherectomy in selected cases.

FIG. 24.19.

Coronary artery dissections after excimer laser angioplasty. Treatment of a long lesion in the left anterior descending artery (A, proximal arrow) was associated with propagating dissection (distal arrow). Treatment of a total occlusion in the midportion of the right coronary artery (B, proximal arrow) was associated with propagating dissection to the distal right coronary artery (distal arrow).

Clinical Results of Laser Angioplasty

Clinical success with the excimer laser, defined as less than 50% residual stenosis (after all treatments) and absence of major in-hospital complications, has been reported in 84% to 94% of patients with saphenous vein graft lesions, aortoostial stenoses, total occlusions, long lesions, and undilatable lesions (82,93–95). Early clinical experience with holmium laser coronary angioplasty in 331 patients demonstrated a procedural success rate of 94% and a perforation rate of 1.9% (96). Because of the similarities for both excimer laser and holmium laser interaction with tissue, the clinical results for the two systems are probably quite similar.

Despite increased clinical success with catheter improvements, the rates of vessel dissection and perforation have remained constant. Indeed, the incidence of propagating dissection as high as 22% (Fig. 24.19) has continued to limit the usefulness of excimer laser angioplasty (93,95). Although coronary artery dissection is not unique to laser angioplasty, extension of the dissection beyond the treated site is probably more common following laser angioplasty than after use of balloon angioplasty or other devices. Vessel perforation occurs during laser angioplasty in 1% to 2% of patients treated (97) and commonly leads to a major complication (death, MI, cardiac tamponade, or bypass surgery). Risk factors for perforation include the use of oversized laser catheters, bifurcation lesions, and diabetes mellitus (98). The use of a saline flush during lasing has been shown to reduce the incidence of dissection and perforation both experimentally (99) and clinically.
Although laser angioplasty was developed initially to reduce restenosis by ablating atheromatous plaque without injuring the normal components of the arterial wall, restenosis has been reported in approximately 50% of patients (100).

**Undilatable Lesions**

Some fibrotic and calcified lesions cannot be dilated with balloon angioplasty at high pressures. Excimer laser angioplasty is associated with successful treatment in 89% of 36 patients with lesions that could be crossed with a guidewire but could not be dilated with balloon angioplasty (101). Although the excimer laser angioplasty is of value, rotational atherectomy is more commonly used for this indication. Neither should be attempted, however, in cases where dilation attempts resulted in local vessel dissection. Under such circumstances, excimer laser angioplasty is invariably associated with worsened dissection or perforation.

**Total Occlusions**

Total occlusions crossable with a guidewire are associated with procedural success rates of 84% to 90% with excimer laser angioplasty (102),(103). Many dissections that occur with excimer laser angioplasty, especially in the treatment of total occlusions, arise because the guidewire has traveled along an extraluminal course. It is therefore important to ensure that the guidewire is in the true lumen of the vessel by frequent contrast injections and confirming that the distal tip remains mobile, before advancing the laser catheter. The long-term success after excimer laser treatment of total occlusions is limited by the development of restenosis in approximately 50% of patients. In the randomized Amsterdam-Rotterdam (AMRO) trial (94), no restenosis benefit was seen for excimer laser compared with balloon angioplasty in a subset of 103 patients who presented with total occlusions.

For total occlusions not crossable with a conventional guidewire, a new approach with an excimer laser-based guidewire recently has entered clinical investigation. The Prima laser guidewire system (Spectranetics Corp., Colorado Springs, CO) consists of an 0.018-inch fiberoptic bundle coupled to a pulsed excimer laser operating at a tip fluence of 60 mJ/mm² at 25 to 40 Hz. The system uses a centering balloon for blinded tissue ablation through the obstruction.

The Prima system was also evaluated more formally in two prospective trials in which the laser guidewire was used only after conventional guidewire techniques were performed and documented to fail. The U.S. TOTAL trial evaluated the learning phase of the lasing strategy in a 179-patient registry (104). Using the Prima catheter alone or in combination with a conventional guidewire, 61% of the refractory total occlusions were successfully crossed. Major complications were low, with a 1.1% death rate and a 1.7% rate of perforation leading to tamponade. A similar European feasibility trial demonstrated a 59% successful recanalization rate in 39 patients who could not be treated with conventional guidewire techniques (105). The European TOTAL surveillance study was a multicenter trial done to evaluate the safety and performance of the excimer laser system among 345 patients with a median occlusion age of 29 weeks (106). The recanalization rate was 59%, with no deaths, emergency surgery, or Q-wave MIs. While coronary perforations (laser “exits”) were seen in 21% of cases, only 1% had tamponade. The independent covariates associated with success were occlusion age less than 40 weeks and lesion length less than 30 mm.

**Calcified Lesions**

Calcified lesions initially were thought to be an indication for excimer laser angioplasty (107), but results of more recent studies have tempered the enthusiasm for this indication. In the Excimer Laser Rotational Atherectomy Balloon Angioplasty Comparison (ERBAC) trial involving 620 patients (82), excimer laser angioplasty was compared with conventional balloon angioplasty and percutaneous transluminal rotational atherectomy for type B and C lesions and a high proportion of calcified lesions. The procedural success rate was 84% for balloon angioplasty, 88% for excimer laser angioplasty, and 93% for rotational atherectomy. The incidence of major complications (death, MI, or bypass surgery) was greater after excimer laser angioplasty than after rotational atherectomy or balloon angioplasty (6.2% vs. 2.3% and 4.8%, respectively). At 6-month follow-up, the incidence of clinical events (death, MI, bypass surgery, or repeat intervention) was greater after treatment with rotational atherectomy than after balloon angioplasty (53% vs. 45%; p < 0.05), whereas treatment with excimer laser angioplasty was associated with an intermediate rate of clinical events (49%). This does not support the use of laser in calcified lesions.
Long Lesions

Although long lesions were identified initially as the most promising indication for excimer laser angioplasty (93–95), recent analyses have suggested that long lesions are associated with trends toward reduced success, and strategies using long balloons and selective use of coronary stent placement (108) may result in superior success rates.

In a randomized comparison of excimer laser angioplasty with balloon angioplasty for lesions greater than 10 mm in length in 308 patients, the AMRO trial reported equivalent results for both types of treatment (109). In 151 patients randomly assigned to excimer laser angioplasty, 126 patients (80%) had procedural success and 50 (33%) experienced at least one cardiac event (death, MI, bypass surgery, or repeat angioplasty) within 6 months of the procedure. In 157 patients assigned to balloon angioplasty alone, 132 patients (79%) had procedural success and 47 (30%) experienced at least one cardiac event (death, MI, bypass surgery, or repeat angioplasty) within 6 months. Laser did not appear to confer a better acute or long-term benefit than balloon angioplasty for patients with lesions greater than 10 mm in length.

In-Stent Restenosis

Laser angioplasty may be used successfully as a debulking treatment for in-stent restenosis. Excimer laser angioplasty with adjunctive balloon dilatation was evaluated in 527 in-stent lesions in 440 patients previously treated with a variety of coronary stents (110). There was a 92% laser angioplasty success, with serious adverse events, including death (1.6%), Q-waveMI (0.5%), perforation (0.9%), and dissections after laser (4.8%) or postdilatation (9.3%). Mehran and coworkers compared the results of balloon angioplasty alone with excimer laser followed by balloon angioplasty in 98 cases of in-stent restenosis (111). By quantitative angiography and intravascular ultrasound, excimer laser was found to safely provide greater acute gain, plaque reduction, larger cross-sectional lumenarea, and a trend for lower clinical restenosis than seen with balloon angioplasty.

MECHANICAL THROMBECTOMY

The pathogenesis of acute myocardial ischemic syndromes in native coronary arteries and saphenous aortocoronary vein grafts clearly involves thrombus formation (112–114). Often the small amount of thrombus formation at the surface of a ruptured plaque is sufficient to interrupt coronary flow, may not be evident by coronary angiography, but may permit larger thrombi to propagate beyond the culprit plaque or into a proximal area of stagnant flow. Such large thrombi may be evident on angiography, and attempted intervention in such lesions tends to produce significant clinical problems (distalemboiliation, no reflow, abrupt closure). They were previously treated by infusions of thrombolytic drugs, but these large thrombi—recognized by certain angiographic and clinical clues (recent onset of symptoms, a mobile, rat-tail filling defect)—are now considered to be suitable targets for mechanical thrombectomy devices.

Earlier Pharmacologic Strategies to Remove Thrombus

Before the development of mechanical thrombectomy, standard therapy involved direct intracoronary or intragraft infusion of urokinase (115–117). The safety and efficacy of this approach was evaluated in the ROBUST trial (118), in which 107 patients were treated with direct urokinase infusion through a 0.035-inch infusion wire. After 25.4 hours of urokinase infusion to a mean dosage of 3.7 million units, 69% recanalization success rate was observed with major complications, including a 3% stroke rate and a 6.5% death rate. Broader use of adjunctive urokinase infusion during intervention has, however, been associated with a worsening of clinical outcomes (119).

In an attempt to avoid systemic lytic complications, urokinase has also been delivered directly to the thrombus surface using specialized delivery catheters. The Dispatch (Boston Scientific, Natick, MA) catheter is an over-the-wire, nondilatation catheter with a 20-mm spiral inflation coil whose inflation creates an external space apposed to the vessel surface into which urokinase may be infused. The initial experience showed complete dissolution of thrombus in patients with angiographically evident thrombus invasive coronary and vein graft obstructions (120), (121). Urokinase may also be absorbed into a hydrogel balloon coating to transfer urokinase locally to the site of thrombotic obstruction (122).
Principle of rheolytic thrombectomy with the Possis AngioJet. High-speed saline jets exit orifices near the catheter tip and spray back into the mouth of the catheter. This creates intense local suction by the Venturi effect, which pulls thrombus into the jets, where the thrombus is macerated and propelled down the catheter lumen for external collection.

Mechanical Thrombectomy

The limitations in speed, efficacy, and bleeding complications have fostered the development of catheter-based techniques for direct thrombus removal. Catheter-based systems can be categorized broadly into systems designed to disintegrate thrombus (e.g., the therapeutic ultrasound Acolysis device and the vortex-creating rotational Amplatz device), and systems designed to aspirate and remove thrombus from the body (e.g., the Possis AngioJet, the Hydrolyzer, TEC [see earlier discussion]).

The mechanical cutting and aspirating TEC device (see earlier discussion) has been advocated as a potential strategy for the treatment of thrombus-containing native coronaries and vein grafts (46–50), but has problems with distal embolization and vessel injury. The Cordis Hydrolyzer has had limited European exposure in humans in peripheral vessels (123), hemodialysis shunts (124), and coronary arteries and vein grafts (125). The Amplatz thrombectomy device is another mechanical thrombectomy device that macerates thrombus. There is limited experience in peripheral artery thrombosis and occluded hemodialysis shunts (127–130). The Acolysis system employs therapeutic coronary ultrasound (at 41.9 kHz) to produce thrombolysis by fragmentation (131), (132). Of 20 patients treated with the coronary ultrasound thrombolysis for vein graft disease (75% had total occlusions), there was a 70% device success (defined as final Thrombolysis in Myocardial Infarction [TIMI] 2 or 3 flow in occluded vessels or reduction in thrombus in patent vessels) with only one patient (5%) having evident distal embolization.

Possis AngioJet Catheter Design and Technique

The AngioJet is a 5F catheter with a stainless steel tip connected to a high-pressure hypotube (Fig. 24.20). Saline is injected into the tip via the hypotube, where it exits as three high-speed jets directed back into the main catheter lumen. By the Venturi-Bernoulli principle, this creates a low-pressure region at the tip (Fig. 24.21) that approaches a perfect vacuum (-760 mm Hg). With a normal pressure in the arterial lumen of +100 mm Hg, this produces a driving pressure of 860 mm Hg that pulls surrounding fluid (blood, thrombus, and saline) into the tip opening. There the jets break the thrombus into subcellular-sized particles and propel them proximally through the catheter lumen and out of the body. A hemostasis valve allows for the evacuation lumen to be sealed around a 0.014- to 0.018-inch diameter guidewire, over which the catheter is advanced down the coronary vessel. Previous *in vivo* histologic studies have shown that the catheter produces minimal or no vessel wall damage (133).

Rheolytic thrombectomy with the Possis AngioJet in a patient with an occluded saphenous vein graft (*upper left, insert*). **Upper left:** Following balloon angioplasty of the graft ostium, a large filling defect (*open arrow*) is apparent in the body of the graft. **Lower left:** The AngioJet (*arrow*) is advanced beyond the presumptive thrombus, activated, and pulled back slowly. **Upper right:** Following AngioJet treatment, only small defects remain. **Bottom right:** Placement of Palmaz-Schatz biliary stents in the ostium and body of the graft provides near-normal appearance and antegrade flow.

Once the culprit lesion is identified, it is crossed using a 0.014- to 0.018-inch guidewire. The 5F AngioJet is then advanced over the wire and distal to the thrombotic lesion. The saline jets are then activated and the catheter is withdrawn slowly across the lesion at 0.5 to 1 mm/sec. Angiography is then performed after the first such withdrawal, and repeated passes of the AngioJet may be performed until angiography shows no further evidence of improvement in the lumen diameter or thrombus burden. The AngioJet has been used successfully to remove...
thrombus in elective situations such as thrombotic vein grafts (Fig. 24.21) and acute coronary ischemic scenarios, including acute MI (Fig. 24.22) (134–136).

FIG. 24.22.

AngioJet for AMI. Upper left: Primary angioplasty for acute anterior wall myocardial infarction shows thrombotic occlusion of the proximal left anterior descending. Bottom left: Passage of the AngioJet distal to thrombus. Top right: Following aspiration with the AngioJet, the thrombotic filling defect is gone. Bottom right: Following stent placement, a large, smooth lumen and brisk antegrade flow are present.

Studies

VEGAS I

The Vein Graft AngioJet Study (VEGAS I) consisted of multicenter registry of 90 patients with acute ischemic syndromes demonstrated. It showed that the AngioJet rheolytic thrombectomy catheter system reduced the angiographically measured thrombus burden within native coronary arteries or saphenous vein bypass grafts by an average of 86% (137).

VEGAS II

The Vein Graft AngioJet Study randomized trial (VEGAS II) was designed as a 500-patient multicenter randomized trial comparing the AngioJet rheolytic thrombectomy system with direct urokinase infusion for safety and effectiveness of thrombus removal before stenting for the treatment of saphenous vein grafts or native coronaries with angiographically apparent intraluminal thrombus (138). Because the 30-day event-free survival for major adverse cardiac events (defined as freedom from death, MI, emergent bypass surgery, target lesion revascularization, or stroke) was significantly lower for the AngioJet group after enrollment of 300 patients, the data safety committee recommended early termination at a final enrollment of 349 patients (180 in the AngioJet arm and 169 in the urokinase arm). The results of VEGAS I and VEGAS II were used by the Food and Drug Administration to approve the device in June of 1998.

DISTAL EMBOLIZATION PROTECTION DEVICES

Each of the devices discussed earlier actively seeks to remove plaque or thrombus from the target lesion, but it is now clear that even such interventions as balloon angioplasty or stent placement may break free fragments of friable plaque. This appears to be one of the main causes of no reflow during saphenous vein graft intervention, and may cause distal embolic events during carotid artery intervention (see Chapter 27). Various devices have been introduced recently for clinical trial evaluation that seek to trap such embolic material and remove it from the circulation (Fig. 24.23). As such, they are technically members of the “atherectomy” family. As their development progresses, it is likely that distal embolus protection will be used in combination with a broad variety of interventional devices (such as thrombectomy and stent placement, Fig. 24.24) to protect the distal circulation from embolization and consequent no-reflow.

FIG. 24.23.

Distal embolus retrieval devices. Upper left: The PercuSurge Guardwire shown during inflation of the low-pressure distal occlusion balloon and passage of the Export aspiration catheter to aspirate liberated debris. Lower left: The MedNova filter device shown open with collected debris in the filter, and the AngioGuard filter shown collapsed during delivery (upper right) and expanded (lower right) for collection of embolic material.

FIG. 24.24.
Combination of distal protection and rheolytic thrombectomy. **Upper left:** Severe stenosis and adherent distal thrombus are present in this vein graft to the right coronary artery. **Upper center:** The PercuSurge Guardwire has been passed into the distal vessel and inflated, with advancement of the AngioJet over the Guardwire. **Upper right:** After removal of the thrombus, the Guardwire is deflated, and injection shows the residual stenosis. **Lower left:** Reinflation of the Guardwire allows placement of a stent. **Lower right:** Following aspiration of any liberated atheroembolic debris, the Guardwire is again deflated to restore flow.

The Guardwire (PercuSurge, Sunnyvale, CA) is a compliant balloon mounted on a hypotube that can function as a 0.014-inch steerable guidewire (139). Once it is positioned across the target lesion, the balloon can be inflated to block the flow of blood in the vessel, as the mechanical intervention is performed. With any liberated debris still trapped by the inflated Guardwire, an aspiration catheter is brought into the vessel and removes the blood and suspended debris. The Guardwire is then deflated to restore flow into the distal vessel. Preliminary analysis of the aspirate shows extensive plaque debris, and a randomized trial (SAFER) is now under way to evaluate whether performing vein graft angioplasty with such protection is associated with a lowering in the incidence of periprocedural slow flow and CK release. Preliminary results in the carotid artery is also encouraging.

There are also a series of semiporous filter devices that can be advanced into the distal vessel and deployed during intervention, to catch and remove liberated emboli. The first devices that will undergo clinical trial evaluation are the Emboshield (MedNova), the AngioGuard, and the Filter Wire (Embolic Protection Inc., SanCarlos, CA). All (Johnson & Johnson Medical) devices are nitinol expandable polymer filters located on the distal end of a modified 0.014-inch guidewire, which is deployed using specialized delivery and retrieval catheters. The shaft of the device can then function as a rail for advancement of over-the-wire platform for percutaneous coronary devices. After intervention, the filter is collapsed and withdrawn with any trapped debris.

**SUMMARY**

Although they have proven no more effective than stenting for the treatment of routine lesions, mechanical and laser-based atherectomy techniques continue to play an important adjunctive role in coronary intervention. These techniques are of particular value in treating ostial, bifurcation, or in-stent restenotic lesions, in debulking before stenting, and in treating long, fibrotic, or calcified lesions. In general, they are more challenging to use than balloon and stent techniques, and frequently carry a higher cost and an increased risk of some complications (such as per-procedure CK elevation, perforation, or dissection). But they have survived as important parts of interventional cardiology simply because they extend the range of lesions treatable by catheter-based therapy. The newer devices for thrombus removal and distal embolic protection also extend the range of treatable lesions and improve procedural results. Still newer atherectomy concepts are under development, including some with on-board ultrasound guidance to facilitate safe and more complete plaque removal, making it likely that atherectomy will remain as a strong minority player in an interventional world dominated by stenting.