

Atherectomy and the Role of Excimer Laser in Treating CAD

Atherectomy has an increased importance in the percutaneous treatment of anatomically complex coronary artery disease.

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The last 5 years have seen the increasing influence of drug-eluting stents (DES) in the invasive treatment of patients with coronary artery disease (CAD). Despite some early concerns regarding their safety, DES continue to demonstrate a dramatic reduction in restenosis and repeat revascularization procedures.^{1,2} In addition, interventional cardiologists are faced with treating older and more complicated patients, which could be a result of improved medical therapy for CAD and an aging patient population. In this new and ever-changing world of complex coronary intervention, I believe that atherectomy devices, such as excimer laser (CVX-300, Spectranetics Corporation, Colorado Springs, CO) and rotational atherectomy (Rotablator, Boston Scientific Corporation, Natick, MA), have a pivotal role to play in treating more complex lesions and facilitating stent delivery, thus benefiting patients who may not have otherwise been candidates for percutaneous coronary revascularization.

Furthermore, percutaneous treatment of patients with acute myocardial infarction (AMI) using the gold standard strategy of percutaneous transluminal coronary angioplasty and stent placement is far from ideal. This is because of the potential for distal embolization and microvascular plugging, leading to unsuccessful myocardial reperfusion despite a newly opened artery.³ Excimer laser is a technology with unique properties that render it very valuable in treating acute thrombotic occlusions, as in AMI.

Currently, laser is indicated and FDA approved for use in certain complex coronary lesions, as depicted in Table 1. This article discusses the role of atherectomy,

TABLE 1. INDICATIONS FOR USE OF ELCA

- Long lesions
- Moderately calcified lesions
- Chronic total occlusions (CTOs)
- Undilatable lesions
- Ostial lesions
- Saphenous vein grafts
- In-stent restenosis prior to brachytherapy

and more specifically, the use of laser in these lesion subsets. It also discusses the practical considerations of choosing such a strategy, and contrast laser to rotablator when appropriate, as well as the special role of excimer laser coronary atherectomy (ELCA) in the treatment of AMI.

LASER MECHANISM OF ACTION

ELCA has been performed since the late 1980s as part of percutaneous coronary intervention (PCI).⁴ Unlike percutaneous transluminal coronary angioplasty and stenting, which modify obstructions through stretching of vessel intima and media and longitudinal and circumferential plaque displacement, ELCA works by photoablation (vaporization) of tissue.⁵ ELCA is applied using a catheter that contains optical fibers



Figure 1. ELCA-assisted PCI of the left circumflex obtuse marginal 1 (OM1) total occlusion in an 82-year-old man with chronic stable angina and lateral ischemia. Left circumflex OM1 at baseline (A). Contralateral simultaneous right coronary artery injection to help direct an Asahi Miracle Bros 3 wire (Abbott Vascular, Santa Clara, CA) into the OM1 CTOs (B). Angiogram after successful wiring and ELCA of the OM1 using a 0.9-mm laser catheter (C). Final result after implantation of a 3- X 28-mm Cypher stent (Cordis Corporation, Warren, NJ).

and transmits pulses of ultraviolet light at 308 nm from a laser system to the target coronary obstruction. The ultraviolet pulses penetrate into 50 μ m of tissue and cause photothermal and photochemical dissociation of carbon-carbon bonds in the cells contained within the coronary lesion. Additionally, photothermal energy generates molecular vibrations leading to the repeated breakdown of cells. This action causes water vaporization and a subsequent vapor bubble at the tip of the catheter, which amplifies plaque ablation through a photomechanical effect. The majority of the degradation particles are <10 μ m (red blood cell size), which wash out into the microcirculation. The magnitude and degree of photoablation can vary depending on the energy and pulse repetition settings that can be set at the laser console. In this way, ELCA can vaporize plaque in complex coronary anatomy containing fibrous tissue, calcium, soft atheroma, or thrombus, all of which present challenges to the operating physician.

LESION SUBSETS

Long Calcified Lesions, CTOs, and Ostial Disease

Prospective randomized trials, such as the Amsterdam-Rotterdam trial, failed to demonstrate the superiority of ELCA over balloon angioplasty in lesions >10 mm in length, with comparable 6-month procedural success and complication rates.⁶ These results were in part due to first-generation devices used in relatively noncomplex disease without a developed saline flush technique during the laser procedure. The ERBAC (Excimer Laser, Rotational Atherectomy, and Balloon Angioplasty Comparison) study, comparing ELCA, rotablator, and balloon angioplasty in 620 patients with type B and C lesions, demonstrated procedural success of 84% with balloon angioplasty, 88% with ELCA, and 93% with rotablator, and clinical adverse event rates of 45%, 49%, and 53%, respectively.⁷ Based on a perceived lack of clinical benefit in the present era, ELCA was subsequently restricted to niche applications such as in-

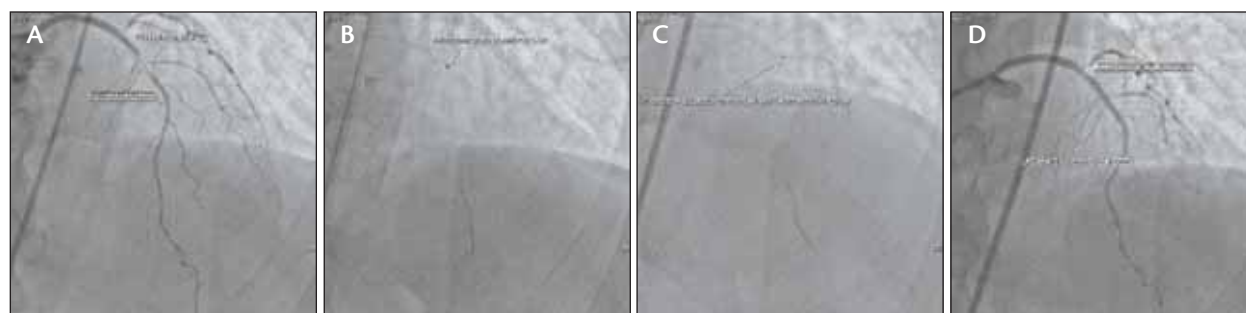


Figure 2. ELCA-assisted PCI of a left anterior descending (LAD)/diagonal lesion in a 65-year-old obese woman with severe chronic obstructive pulmonary disease. Example of ELCA enabling diagonal branch wiring and preservation. Baseline 90% mid-LAD and 90% angulated second diagonal ostial lesion (A). Use of 0.9-mm laser in the LAD after unsuccessful wiring of the second diagonal branch (B). Wiring and balloon angioplasty of the second diagonal branch using a 1.5- X 15-mm Maverick balloon (Boston Scientific Corporation) after ELCA (C). Final LAD/second diagonal result after placement of a 3- X 18-mm Cypher stent in the LAD and preservation of the second diagonal (D).

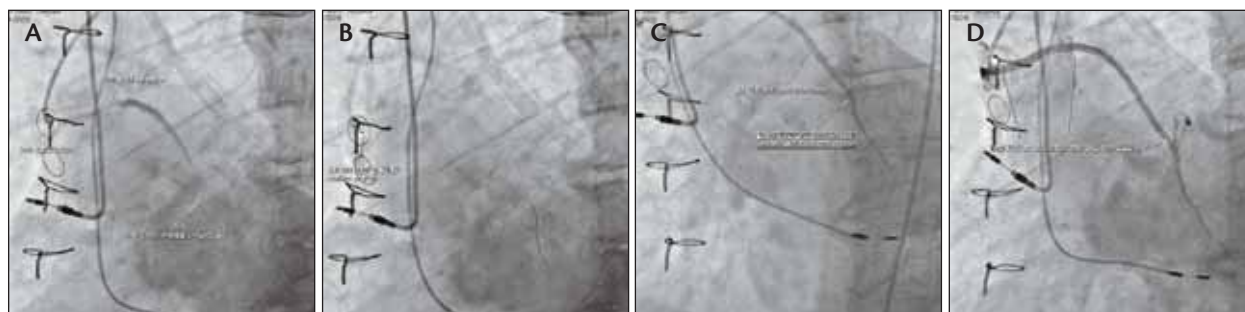


Figure 3. Example of laser-assisted PCI of an 85-year-old man with non-STEMI and a 25-year-old SVG with subtotal occlusion. Laser was used to enable delivery of distal protection device and final stent. Baseline subtotally occluded SVG to LAD. There is an ostial 95% lesion, a proximal 80% lesion, and a 90% distal anastomotic lesion (A). Laser using a 0.9-mm laser catheter at the SVG ostium and proximal portion (B). Angiogram after laser, deployment of a 3-X 8-mm Cypher stent at the anastomotic site, and subsequent delivery of an EZ filter wire (Boston Scientific Corporation) (C). Final SVG result after placement of stents (D).

stent restenosis and undilatable or uncrossable lesions.

However, with the advent of the 0.9-mm laser catheter and its higher fiber density, energy settings, and ablative power, subsequent registries have challenged this limited use. Bilodeau et al studied the use of the 0.9-mm laser catheter in a prospective registry of 100 complex lesions, one third of which had failed previous balloon angioplasty, one third of which were CTOs, and 80% of which were calcified lesions.⁸ The investigators demonstrated a high laser success rate of 92%, allowing for adjunctive therapy such as balloons and bare-metal stents in 93% of lesions.

CTOs are encountered frequently in patients undergoing cardiac catheterization, yet, they form a small minority of PCI procedures and are the most common reason to refer the patient to coronary artery bypass graft surgery. This is because they are inherently technically complex, time consuming, and have a lower procedural success rate. However, potential benefits of percutaneous revascularization of CTOs include relief of angina, reduction of arrhythmic burden, and a mortality benefit. In approximately 2% to 10% of cases, balloon delivery is not possible, despite the crossing of the lesion with a wire. The properties of laser make it an excellent tool in successful ablation of organized thrombus, connective tissue, and calcium contained within the CTOs. As demonstrated in several single-center registries, laser can enable successful completion of the procedure.⁸ This can be potentially accomplished with less distal embolization, easier stent delivery and expansion, and reduction of future risk of stent thrombosis and restenosis. An example of CTOs revascularization using ELCA is depicted in Figure 1.

Ostial lesions tend to be fibrocalcific in composition and resistant to full dilatation, despite the use of high-pressure, noncompliant balloons. High-pressure inflations can result in unwarranted dissection. Based on previous

registry data and our experience, ELCA can help prepare the lesion for stent delivery and allow for full stent expansion.⁹ From a practical standpoint, avoiding nose-diving of the guiding catheter (backing it out of the ostium with a second wire against the aortic cusp) can be helpful.

Bifurcation Lesions

The treatment of bifurcation lesions remains controversial. Bifurcation stenting, including the crush and culotte techniques, have been associated with relatively high restenosis and increased major adverse cardiac event (MACE) rates. Recently, the single or parent vessel stent strategy with preservation of the side branch and bail-out of the side branch in case of compromised flow, has been advocated based on trials that have shown reduced MACE rates with use of this simplified approach.¹⁰ However, in certain true bifurcation lesions, the side branch can be extremely difficult to wire. In these instances, we have found that debulking the parent artery with ELCA is a simple and effective strategy, enabling easy wiring and balloon angioplasty of the side branch (Figure 2). Alternatively, when the side branch is >2.5 mm in diameter and does not have an angulated takeoff, debulking of both branches can be performed before either a bifurcation stent technique or the single stent strategy. This can be performed while both parent and side branch arteries are wired and protected. ELCA does not affect the side branch wire and can be performed with a buddy wire in difficult cases.

Saphenous Vein Grafts

Percutaneous treatment of saphenous vein grafts (SVG) is problematic because of the risk for atheroembolic events during stent deployment, leading to

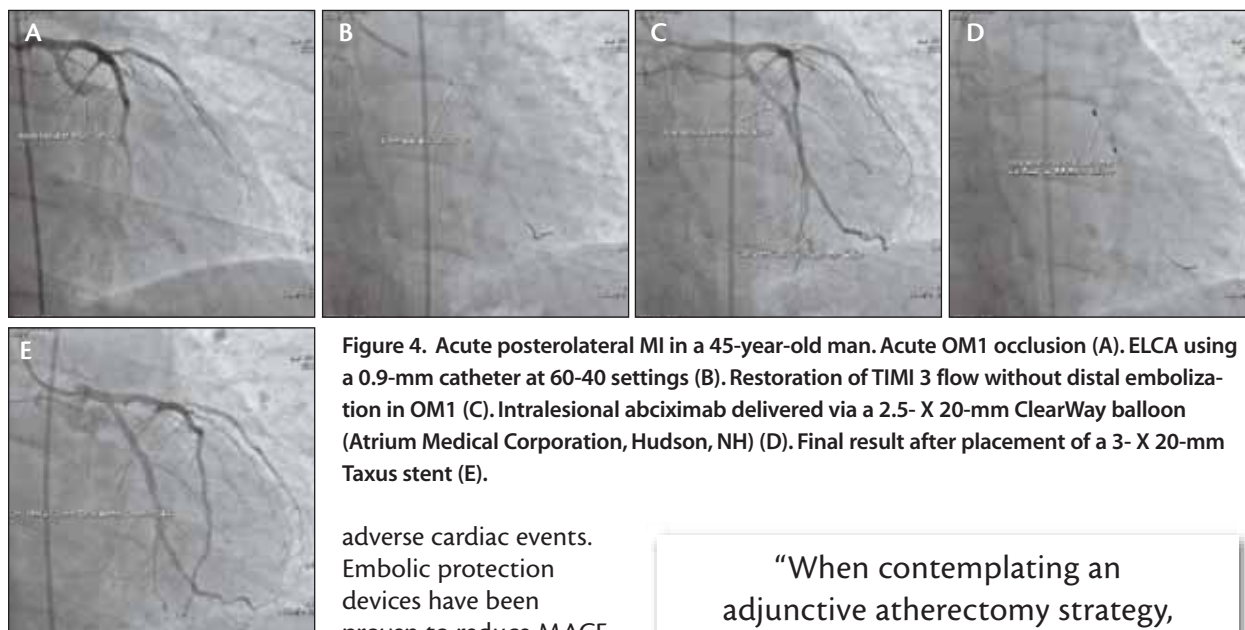


Figure 4. Acute posterolateral MI in a 45-year-old man. Acute OM1 occlusion (A). ELCA using a 0.9-mm catheter at 60-40 settings (B). Restoration of TIMI 3 flow without distal embolization in OM1 (C). Intralesional abciximab delivered via a 2.5- X 20-mm ClearWay balloon (Atrium Medical Corporation, Hudson, NH) (D). Final result after placement of a 3- X 20-mm Taxus stent (E).

adverse cardiac events. Embolic protection devices have been proven to reduce MACE

in randomized controlled trials and are the gold standard therapy to prevent these complications.^{11,12} However, these devices can be difficult to deliver in severely stenosed vein grafts. Laser has demonstrated its safety and efficacy in SVG intervention through multiple single-center registries with very low clinical event rates.^{13,14} Registry data tend to underestimate these events, and we would therefore not advocate the use of laser as the sole PCI strategy. Nonetheless, laser can be very valuable in enabling delivery and deployment of a distal protection device prior to stent implantation (Figure 3). In these cases, larger laser catheters such as 1.4-, 1.7-, or 2-mm catheters can be used because SVGs tend to be large in diameter and straight in configuration.

CLINICAL AND PRACTICAL CONSIDERATIONS FOR ELCA

When contemplating an adjunctive atherectomy strategy, the interventionist has to consider various lesion, vessel, and patient characteristics. In our experience, rotational atherectomy, with the unique property of differential cutting, is best suited for the treatment of diffuse, severely calcified CAD in patients with chronic stable angina. Alternatively, laser should be the preferred atherectomy device in vessels with up to moderate calcification, especially in the clinical setting of acute coronary syndrome, in which the interventionist has to be mindful of the possible presence of thrombus-laden plaque and the potential for distal embolization. Laser also has a special role to play in the treatment of ST-elevation MI (STEMI), even in patients

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with hemodynamic instability and cardiogenic shock (see subsequent section regarding AMI).

In terms of vessel selection, tortuosity can present a risk for dissection. Small burr sizes with gradual upsizing and the use of a floppy RotaWire (Boston Scientific Corporation) to help avoid wire bias are some of the techniques used during rotablation of vessels with tortuosity. When using ELCA in angulated vessel segments (ie, proximal bend of the right coronary artery), laser energy and repetition rate should be reduced, because ultraviolet light cannot be bent, and this maneuver can help reduce the risk of dissection. Supportive guides and wires should be used when performing ELCA to enable catheter delivery. Continuous intracoronary saline flush should be applied during ELCA, because ultraviolet light travels through saline in order to ablate the target lesion. Side-hole catheters should therefore be avoided. In our experience, automated flush systems such as the Medrad (Medrad, Inc., Warrendale, PA) or Acist (Acist Medical Systems, Inc., Eden Prairie, MN) devices, which provide an auditory feedback during saline infusion, help the physician to follow the sequence of fluoroscopy-flush-laser, therefore avoiding complications.

Vessel size and matching the catheter to the vessel, as well as the fluency and pulse repetition settings, are key considerations to laser success. Instead of the standard

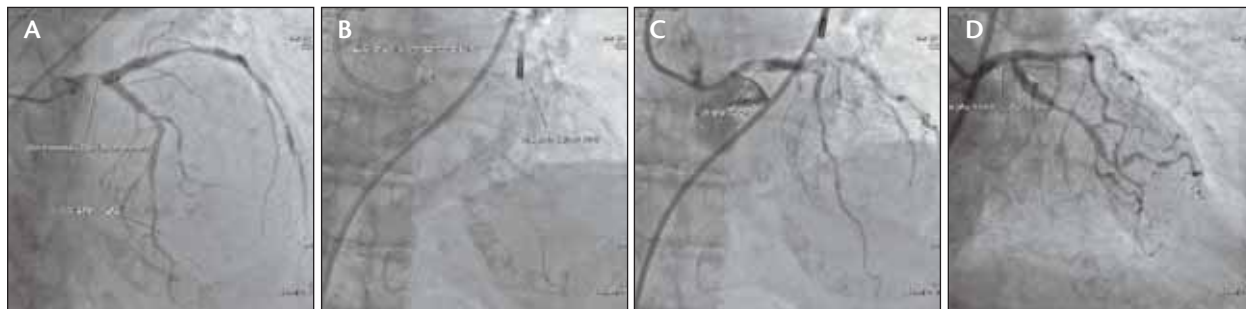


Figure 5. An 85-year-old woman with non-STEMI. A 95% moderately calcified left main (LM) lesion (A). ELCA using a 0.9-mm catheter at 50-40 settings (B). Angiogram after LM laser (C). Final result after placement of a 3.5- X 13-mm Cypher DES in the LM (D).

two-thirds atherectomy rule of catheter-to-vessel size, we have followed a more pragmatic approach to catheter selection. We have used the 0.9-mm catheter as the workhorse catheter and reserved the larger catheters for more niche applications, such as SVGs, in-stent restenosis, and large vessels. This is especially true for CTOs and long fibrocalcific disease, in which tracking and delivery of the 0.9-mm catheter is superior. If in doubt, such as in tortuous vessels, angulated segments, or small vessels, downsizing to the 0.9-mm catheter is the safest approach. With the advent of DES, the goal should not be the perfect atherectomy result, but rather facilitation of DES delivery. The 0.9-mm catheter can be versatile in helping achieve this goal by delivering the highest energy and repetition levels.

AMI

Balloon angioplasty and stenting are established as the gold standard percutaneous therapy for patients with AMI. However, it has long been recognized that the balloon and stenting approach in the setting of thrombotic arterial occlusions has limitations, such as distal embolization, microvascular plugging, and failure to successfully reperfuse the myocardium despite a newly opened artery. These untoward effects have been shown to correlate with increased morbidity and mortality. Therefore, the treatment paradigm has shifted from restoration of TIMI 3 flow in the infarct-related artery (the open artery), to additionally, the restoration of adequate myocardial perfusion (the open muscle) in the hopes of improved patient survival.

In the past, multiple trials involving active mechanical thrombectomy and distal protection devices had failed to improve on balloon and stenting results. More recently, there has been a renewed interest in the field, triggered by positive trials involving passive aspiration.¹⁵ These trials have reiterated the important correlation between improved TIMI myocardial perfusion grades and mortality in AMI.

Excimer laser has unique properties that render it very valuable in the treatment of thrombotic arterial occlusions. In a patient with AMI, the light energy mediates photochemical, photothermal, and photomechanical dissolution of thrombus and plaque to particulate material, the majority of which is the size of red blood cells. This mechanism of action allows for rapid clearance of thrombus and restoration of TIMI flow within the infarct-related artery with limited distal embolization. This approach can help assess the true length of the lesion related to plaque rupture and potentially allow for shorter stent length. It may also allow for stent deployment in much less of a thrombotic milieu and can serve to alleviate some of the concerns regarding DES malapposition in AMI. Furthermore, high-energy laser parameters have been demonstrated in *in vitro* studies to decrease platelet aggregation.¹⁶ In a world of an increasingly complex, aging patient population and doubts over the net clinical benefit of systemic IIb/IIIa inhibitors in AMI (secondary to bleeding concerns), this localized antiplatelet effect becomes very relevant.

Although the use of laser in AMI should be based on an individual patient basis, trials validating the safety and efficacy of laser in AMI include CARMEL and Extended FAMILI. The CARMEL trial enrolled 151 patients with AMI, including patients with cardiogenic shock, failed thrombolytic therapy, and occluded SVGs.¹⁷ In this high-risk population, the trial demonstrated laser, angiographic, and procedural success rates of 97%, 95%, and 92%, respectively.

More recently, the Extended FAMILI registry studied the effects of excimer laser in 100 AMI patients with respect to myocardial perfusion and ST-segment resolution¹⁸ and demonstrated an impressive rate of 92% in TIMI myocardial perfusion grade 2 and 3. Larger randomized studies evaluating the strategies of laser/stenting versus balloon/stenting are pending (TAAMI study) (for an example of AMI, see Figure 4).

During the last 24 months, we have treated numerous patients presenting at our institution with AMI using laser atherectomy and direct stenting. We have also used laser to treat patients with AMI and fibrotic, calcified, type C lesions and patients with critical left main stenosis and cardiogenic shock, which had good results despite their high risk (Figure 5). The collection of data from this single-center laser experience is ongoing in the GREECE study.

The AMI protocol developed at our center includes:

- The laser is turned on upon catheterization lab staff arrival.
- Clopidogrel 600 mg is administered in the ER; heparin is administered in the lab after femoral sheath insertion.
- If there is a thrombotic occlusion with TIMI flow ≤ 2 , a 0.9-mm ELCA is initiated, starting at 60-40 (catheter of choice because of deliverability and energy delivery).
- Localized, intralesion IIb/IIIa administration via the ClearWay balloon.
- Passive aspiration using the QuickCat (Spectranetics Corporation), Pronto (Vascular Solutions Inc., Minneapolis, MN), or Export (Medtronic, Inc., Santa Rosa, CA) catheter if there is still significant residual thrombus.
- Direct DES whenever possible. Balloon angioplasty is used if stent delivery is not possible despite the previously listed steps.

SUMMARY

The percutaneous treatment of patients with CAD is constantly evolving. Multiple studies have demonstrated the superiority of DES in terms of reduction of restenosis and repeat revascularization procedures in comparison to bare-metal stents. Additionally, recent 1-year interim data from the SYNTAX trial, which studied stents versus coronary artery bypass graft surgery in patients with complex multivessel CAD, demonstrated that the hard endpoints of death, MI, and stroke were very similar.¹⁹ Based on these data and his own clinical experience in an increasingly older and more complex patient population, it is this author's belief that atherectomy has a newly gained importance in the treatment of anatomically complex CAD.

Finally, I believe that the percutaneous treatment of AMI remains extremely challenging. The "squeeze-and-pray" approach of balloon and stenting clearly needs to be challenged, given the potentially dire consequences of distal embolization. ELCA has the mechanistic basis to improve outcomes in AMI, and registry data suggest excellent myocardial perfusion with this approach. Randomized data of laser versus traditional approaches in AMI are eagerly awaited. ■

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