Revascularization of LAD

OPERATOR / FACILITY

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Case History

- History: 61-year-old male, chronic fatigue immune deficiency syndrome, fibromyalgia, prostate problems, dyslipidemia, family history of CAD, 36 years of cigarette smoking, hypertension.
- Current: Patient presents with marked EKG changes including up to 2mm of ST depression noted in almost every lead post exercise, jaw discomfort with exertion, and blood clots in urine.

Significant Angiographic Findings

- Mild diffuse disease in left main
- 99% subtotal occlusion in proximal LAD and 99% single discrete vessel in mid vessel; TIMI 2 flow noted in distal vessel
- Mild diffuse disease in left circumflex
- RCA with mild diffuse disease, 80% lesion in the acute marginal branch

Intervention

- CLS 3.5 guide taken to left main
- Hi-Torque Pilot wire advanced into distal LAD
- ELCA 0.9mm catheter advanced into proximal and mid LAD for atherectomy
- Endeavor 3.0 x 12mm drug-eluting stent deployed at 16 atmospheres in proximal LAD, followed by 3.0 x 30mm stent in mid LAD
- Overlap dilated to 18 atmospheres
- Laser settings: 45/25; Pulses: 1,500; Time: 3 min

DEVICES

Access

- CLS 3.5 guide

Support Catheter

- N/A

Wires

- Hi-Torque Pilot 0.014 (Abbott Vascular®)

Balloon

- N/A

Stents

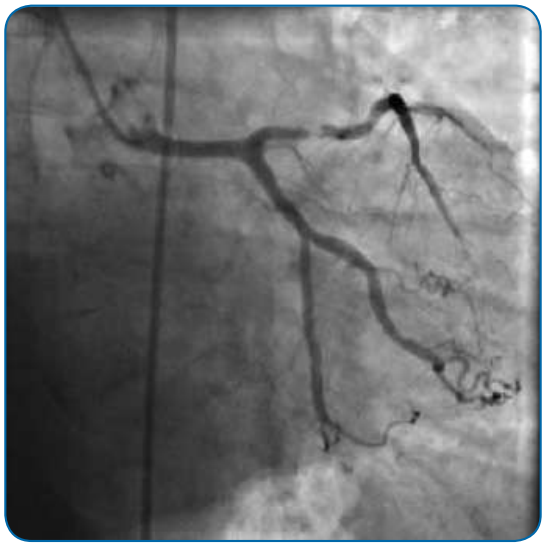
- 3.0 x 12mm Endeavor (Medtronic®)

Anticoagulation

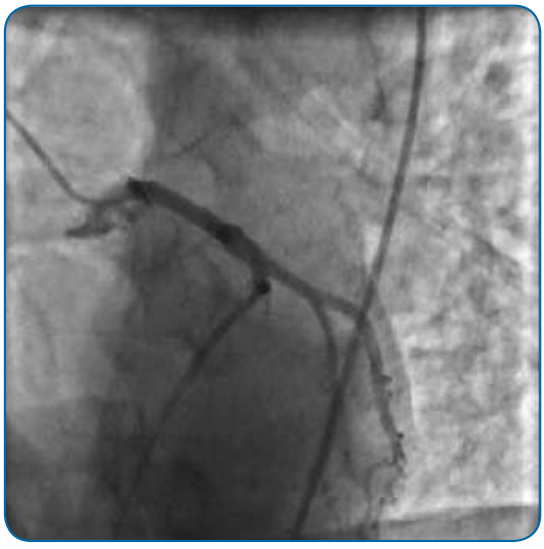
- Angiomax

FEATURED SPECTRANETICS PRODUCT

- ELCA® Coronary Laser Atherectomy Catheter



Pre Laser



Pre Laser

Spectranetics®

Always Reaching Farther

Laser Ablation for Coronary Intervention: Case Study

Revascularization of LAD

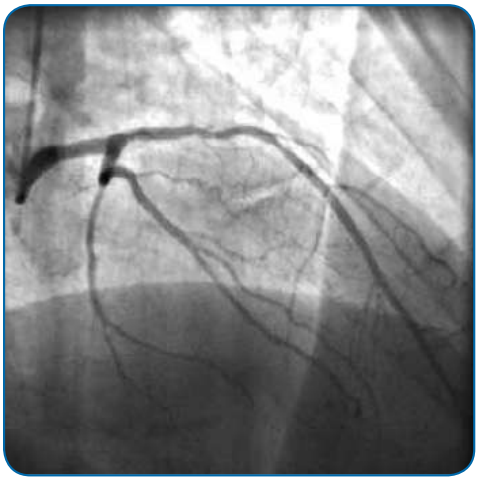
Results / Conclusions

- Post procedure, no residual stenosis, EKG changes or dissection noted
- Successful revascularization of left anterior descending artery with laser atherectomy and drug-eluting stent
- After two passes with the 0.9mm X-80 ELCA Catheter, the blood flow through the lesion was improved

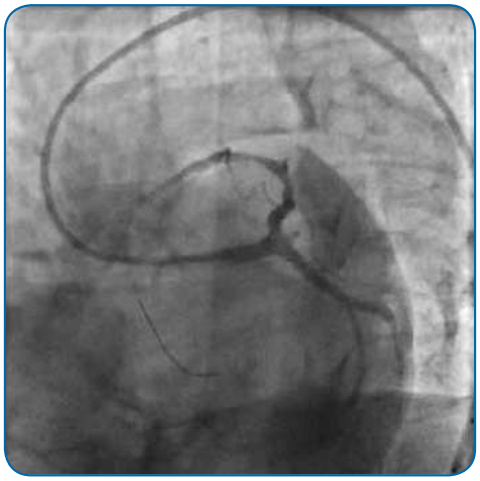
[The 0.9mm X 80 ELCA Catheter] Provided an option to debulk the lesion in order to obtain excellent stent apposition.

– Gaurav Aggarwala, MD

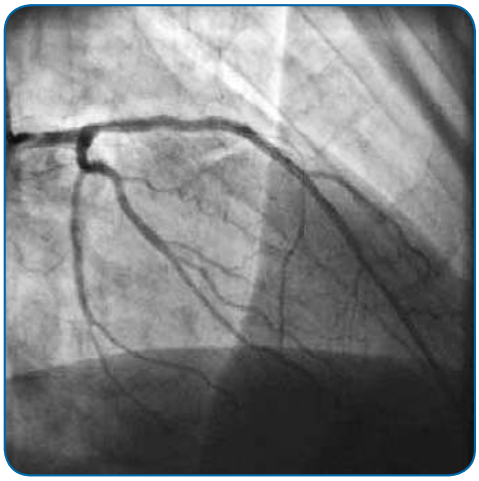
At the time of publication, Dr. Aggarwala has a consulting agreement with Spectranetics.



Post Laser



Post Laser



Final

Important Safety Information

ELCA® X-80 Coronary Laser Ablation Catheter

INDICATIONS

The X-80 Laser Catheters are intended for use as a stand-alone modality or in conjunction with Percutaneous Transluminal Coronary Balloon Angioplasty (PTCA) in patients who are acceptable candidates for coronary artery bypass graft (CABG) surgery. The following Indications for Use, Contraindications and Warnings have been established through multicenter clinical trials. The Spectranetics CVX-300® Excimer Laser System and the multifiber laser catheter models are safe and effective for the following indications:

- Occluded saphenous vein bypass grafts
- Ostial lesions
- Long lesions – (greater than 20mm in length)
- Moderately calcified stenoses.
- Total occlusions traversable by a guidewire.
- Lesions which previously failed balloon angioplasty - This includes those lesions that were treated unsuccessfully by PTCA. Lesions that have undergone a complicated PTCA procedure are not included in this category.

These lesions must be traversable by a guidewire and composed of atherosclerotic plaque and/or calcified material. The lesions should be well defined by angiography.

CONTRAINDICATIONS

- Patient has acute thrombosis.
- Lesion is in an unprotected left main artery.
- Patient has experienced an acute myocardial infarction.
- Patient has ejection fraction of less than 30%.
- Lesion is beyond acute bends or is in a location within the coronary anatomy where the catheter cannot traverse.
- Guidewire cannot be passed through the lesion.
- Lesion is located within a bifurcation.
- Patient is not an acceptable candidate for bypass graft surgery.

See complete IFU for more information before attempting use of ELCA X-80.

WARNINGS

Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training. A clinical investigation of the Spectranetics CVX-300® Excimer Laser System did not demonstrate safety and effectiveness in lesions amenable to routine PTCA or those lesions not mentioned in the Indications for Use, above. The effect of adjunctive balloon angioplasty on restenosis, as opposed to laser alone, has not been studied. The use of the CVX-300® Excimer Laser System is restricted to physicians who are trained in the use of the product.

PRECAUTIONS

This device has been sterilized using Ethylene Oxide and is supplied STERILE. The device is designated and intended for SINGLE USE ONLY and must not be resterilized and/or reused. Store in a cool, dry place. Protect from direct sunlight and high temperatures (greater than 60°C or 140°F). During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient. Anticoagulant therapy should be administered per the institution's PTCA protocol for a period of time to be determined by the physician after the procedure. Percutaneous Excimer Laser Coronary Atherectomy (ELCA) should be performed only at hospitals where emergency coronary bypass graft surgery can be immediately performed in the event of a potentially injurious or life-threatening complication. The results of clinical investigation indicated that patients with the following conditions are at a higher risk for experiencing acute complications:

- Patients with diabetes.
- Patients with a history of smoking.
- Lesions with tortuous vessels.

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