Laser Atherectomy of LAD and Ostial Diagonal Lesions with 2 Wires in Place

OPERATOR / FACILITY
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Case History

- 50-year-old male
- History: HCAD, Diabetes, Hypertriglyceridemia
- Current: Patient presents with chest pain into arm and jaw

Angiography

- IVUS reveals diagonal to be 3.0mm with a 90% ostial lesion
- IVUS to proximal LAD shows a 60% lesion and a luminal area of 5.5mm^2
- IVUS to mid LAD measures 3.5mm with significant plaque burden and luminal area of 4mm^2

Intervention

- 2 BMW wires utilized to gain access to both LAD and Diagonal
- 0.9mm X80 ELCA was used to perform atherectomy to proximal LAD and Diagonal
  - 2 passes to each artery at fluence of 45 and rate of 25 Hz and then 60/40
- 2.75 x 12mm stent to ostium of the Diagonal – deployed to 3.01mm diameter
- AngioSculpt PTCA to mid and proximal LAD
- 3.5 x 12mm stent to mid LAD – deployed to4mm diameter
- Angiography revealed TIMI 3 flow
  - IVUS revealed no dissection and 60% stenosis mid LAD and luminal area greater than 5mm^2 - was felt not to be flow limiting

DEVICES

Access

- Short 6F Sheath, right femoral artery
- 6F EBU-3.5 Guide

Wire

- 0.014 BMW® guidewire x 2 (Abbott Vascular®)

IVUS

- 014 Eagle Eye® Volcano®

Lasers

- 0.9mm X80 ELCA® (Spectranetics®)

Balloons

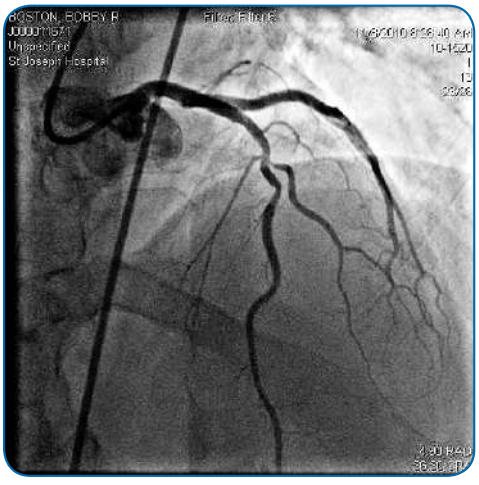
- 3.5 x 15mm AngioSculpt Balloon (AngioScore®)
- 3.0 x 10mm Quantum Apex™ (Boston Scientific®)

Stents

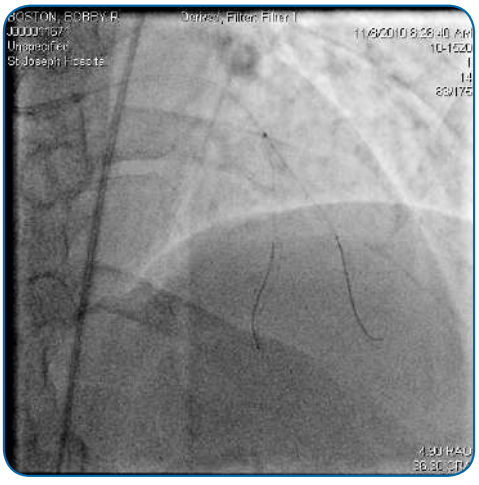
- 2.75 x 12mm PROMUS® (Boston Scientific®)
- 3.5 x 12mm PROMUS® (Boston Scientific®)

FEATURED SPECTRANETICS PRODUCT

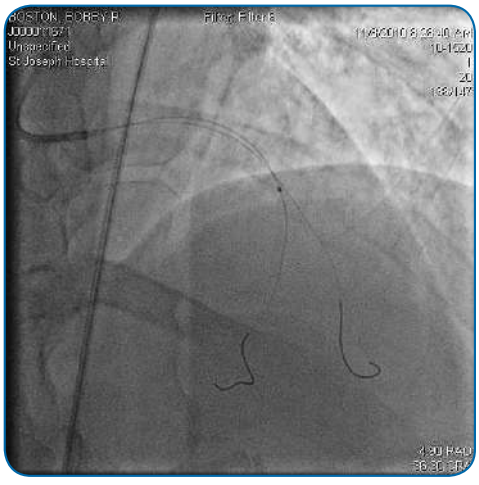
- ELCA® Coronary Laser Atherectomy Catheter



Mid LAD and Ostial Diagonal lesions



ELCA to Diagonal



ELCA to LAD

Spectranetics®
Always Reaching Farther

Laser Ablation for Coronary Intervention: Case Study

Laser Atherectomy of LAD and Ostial Diagonal Lesions with 2 Wires in Place

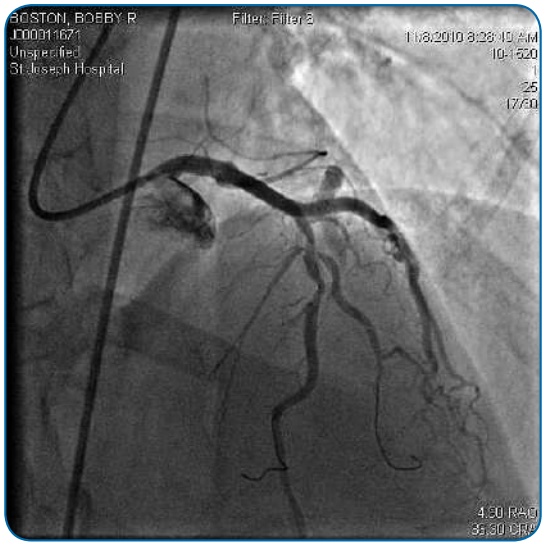
Results / Conclusions

- Successful revascularization of the LAD and Diagonal
- No complications and the patient tolerated the procedure well

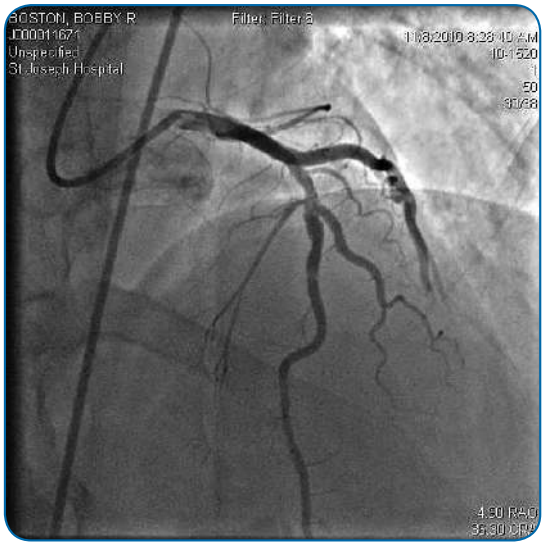
In a high grade ostial lesion, laser is ideal. Atherectomy can be performed with a 2nd wire in place and plaque shifting is minimal.

– Jack Casas, MD, FACC

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



Post-Laser to LAD and Diagonal



Final Angiogram Post ELCA and Stents

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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