Laser Ablation for Coronary Intervention: Case Study

Recanalization of a CTO in the LAD

OPERATOR / FACILITY

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Case History

- 58-year-old male
- History: c/o CP. HTN, SOB, dyslipidemia. Stress Echo showed exercise induced wall motion abnormality of anterior wall.
- Current: Patient presents with CP and no previous cardiac history.

Angiography

- RCA – large, dominant and patent
- LAD – totally occluded after 1st septal
- CX – Moderately large with no significant disease

Intervention

- LAD was engaged with a 6F AL1 Guide
- 0.014 Shinobi wire with a 0.014 Quick-Cross catheter used to cross proximal CTO cap
- Shinobi exchanged for 0.014 Choice PT (via Quick-Cross) to get down to distal vessel
- Choice PT exchanged for 0.014 BHW wire (via Quick-Cross)
- 0.9mm X 80 ELCA Laser Catheter was used to debulk and modify the LAD lesion
- 1st pass @ fluence of 50 and rate of 40
- 2nd pass @ fluence of 60 and rate of 60
- PTCA performed to the LAD with a 2.5 x 20mm Maverick balloon at low pressure with no plaque shift to the Diagonal
- PTCA was also performed on the Diagonal with a 1.5x15mm Maverick

Final angiogram revealed excellent angiographic results with TIMI 3 flow and no residual dissection.

DEVICES

Guide

- Right Radial Access, 6F AL1 guide

Wires

- 0.014 Shinobi® (Asahi®)
- 0.014 Choice PT® (Boston Scientific®)
- 0.014 BHW® (Abbott Vascular®)

Crossing Solution

- 0.014 Quick-Cross® (Spectranetics®)

Lasers

- 0.9mm X80 ELCA® (Spectranetics®)
  – 2 Passes @ settings of 50/40 and 60/60

Balloon

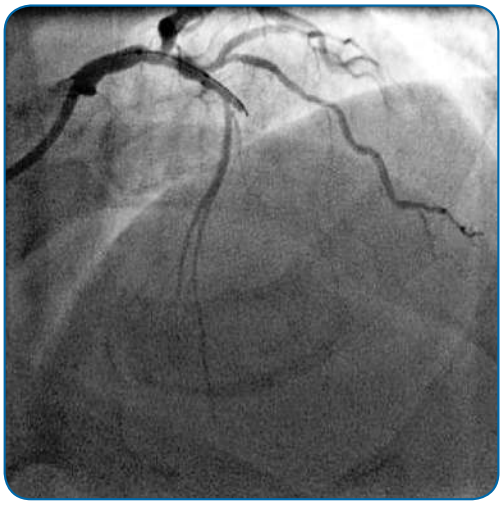
- 2.5x15mm Maverick® (Boston Scientific®)

Anticoagulation

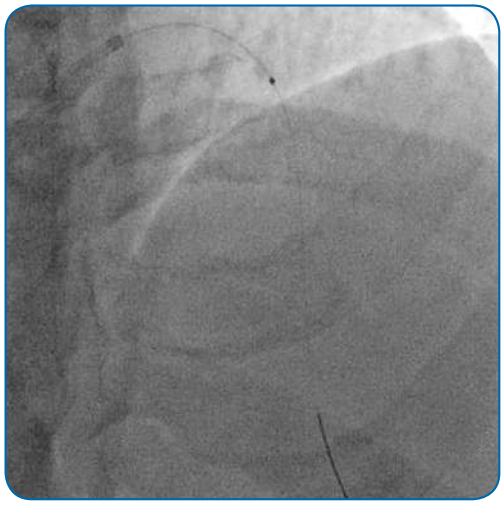
- Angiomax® (The Medicines Company®)

FEATURED SPECTRANETICS PRODUCTS

- ELCA® Coronary Laser Atherectomy Catheter
- Quick-Cross® Support Catheter



LAD CTO with Quick-Cross



LAD with 0.9mm X 80 Laser

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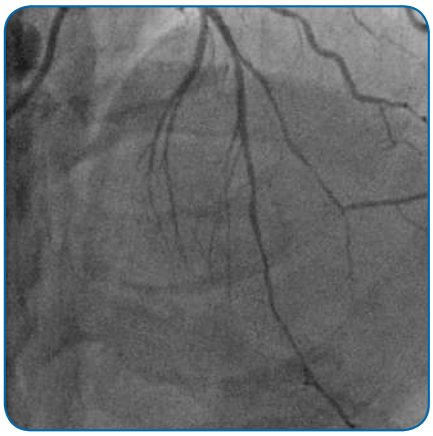
Results / Conclusions

- CTO of LAD treated successfully with laser atherectomy and PTCA
- Excellent angiographic results with TIMI 3 flow. Less than 5% residual stenosis and no dissection
- The patient was brought back 4 months later for routine followup

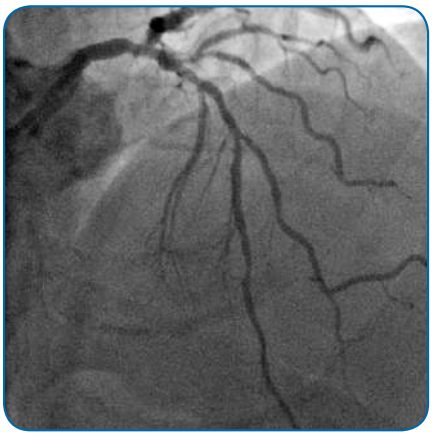
ELCA is novel strategy dealing with CTO in the coronary circulation and allows you to debulk the plaque burden and makes it easy for eventual delivery of the stent with better expansion and long term patency.

– Rakesh Bhan, MD

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



LAD Post-Laser, pre balloon



4 month post follow up

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.

Quick-Cross® Support Catheter

INDICATIONS

Quick-Cross Support Catheters are guidewire exchange and infusion devices designed for use in the vascular system. The catheters are intended to support a guidewire during access of vasculature, allow for exchange of guidewires and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

CONTRAINDICATIONS

None known.

See complete IFU for more information before attempting use of Quick-Cross.

ADVERSE EVENTS

Atherectomy or any other surgical procedure has inherent risks. For a completing listing, see the IFU.

WARNINGS

Maximum infusion pressure is 300 psi. The catheter is designed and intended for intravascular use only. This catheter is designed and intended for one-time use only. Do not re-sterilize and/or reuse. Careful inspection before use should verify that the catheter has not been damaged in shipment and that its condition is suitable for the procedure. The catheter should not be advanced through an area of resistance unless the source of resistance is identified by fluoroscopy and appropriate steps are taken to reduce or remove the obstruction. Catheter manipulation should occur only under fluoroscopy. If the catheter is used for infusion, reference the table of flow rates and ensure infusion pressure does not exceed the recommendations. Avoid introducing air or any other gas through the catheter into the vascular system.

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