Laser Ablation for Coronary Intervention: Case Study

Excimer Laser Atherectomy for a CTO of the Circumflex Artery

OPERATOR / FACILITY

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Case History

- 67-year-old male
- History: Hypertension, hyperlipidemia, and diabetes; family Hx of CAD, with a positive stress test.

Angiography

- LAD: Patent
- Circumflex: CTO in proximal segment
- RCA: Stenoses Patent collaterals to the Circumflex

Intervention

- LAD was engaged with a 8 Fr JL4 guide
- 0.014" Asahi guidewire was inserted into the circumflex
- RCA was engaged with a 6 Fr JR 4 guide
- Simultaneous injections performed to assess collateral circulation and evaluate the distal circumflex, as well as facilitate wire crossing
- 0.9mm X80 was used at 50 fluence/40Hz used in the circumflex
- PTCA post laser was performed with a 3x20mm Quantum Maverick
- Xience 3x23mm was deployed in the proximal circumflex

DEVICES

Guide

- 8F JL4 guide catheter (Boston Scientific®)
- 6F JR4 guide catheter (Boston Scientific®)

Wire

- 0.014" Grandslam Wire® (Asahi®)
- 0.014" Prowater Wire® (Asahi®)

Support Catheter

- 0.014" X 135cm Quick-Cross® (Spectranetics®)

Lasers

- 0.9mm X80 ELCA® (Spectranetics®)

Balloon

- 3x20mm Quantum Maverick® (Boston Scientific®)

Stents

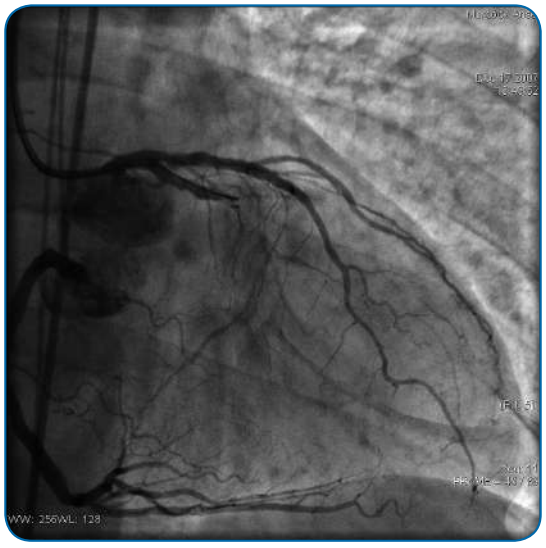
- 3.0x23 Xience® (Abbott Vascular®)

Anticoagulation

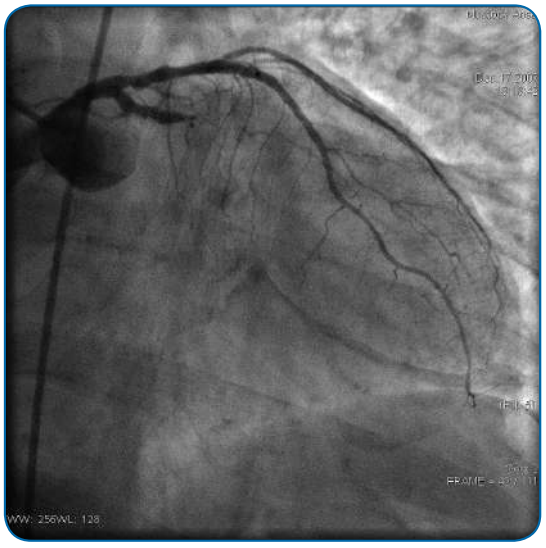
- Integrilin® (Millenium® Pharmaceuticals)

FEATURED SPECTRANETICS PRODUCT

- ELCA® Coronary Laser Atherectomy Catheter



CTO Simultaneous Injections



ELCA CTO

Spectranetics®
Always Reaching Farther

Excimer Laser Atherectomy for a CTO of the Circumflex Artery

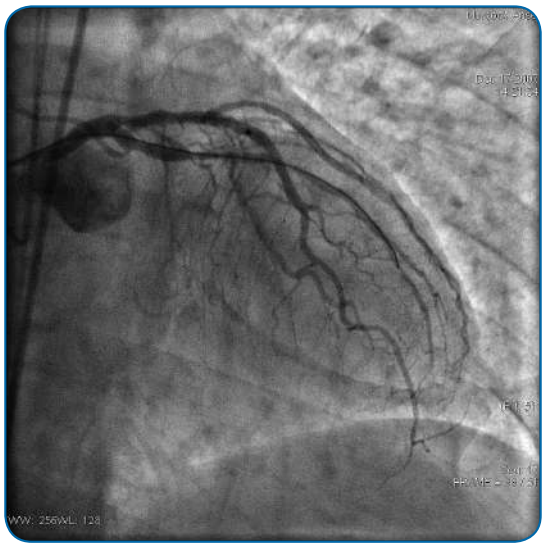
Results / Conclusions

- As demonstrated in this case, laser ablation was performed to treat a CTO in the Circumflex artery
- The 0.9mm X80 ELCA was used to create pilot channel restoring flow to the distal circumflex artery
- The laser allowed definitive therapy which included the placement of a DES

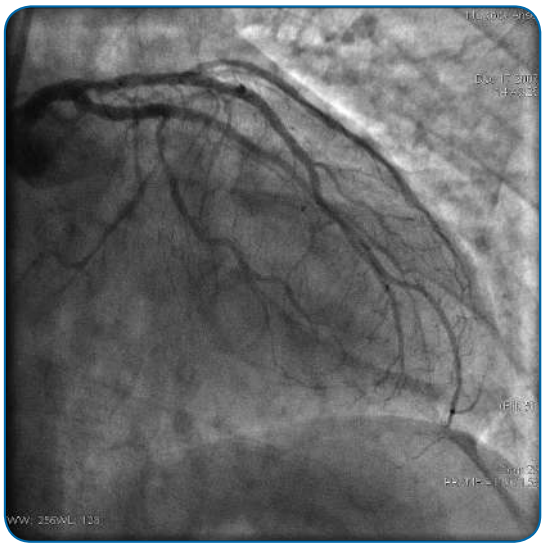
The 0.9mm X80 created a channel in the circumflex, restoring flow and allowing placement of a DES.

– Antonis Pratsos, MD

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



CTO Post Laser



CTO 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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