

Excimer Laser Atherectomy & Bifurcation Stenting for a Subtotal Occlusion of the CFX Artery

OPERATOR / FACILITY

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Case History

- 51-year-old male
- History: Diabetes, hypertension, history of mild CAD documented three years earlier on angiography; presented in clinic with crescendo angina of 3-months duration, outpatient nuclear stress demonstrated a new inferior scar with ischemia, and mild anterior ischemia, LVEF 48%.

Angiography

- LM: Mild disease
- LAD: Ostial 60%
- CFX: Dominant, 99% proximal occlusion extending to first OM, which was also subtotally occluded; TIMI 1 flow
- Left-to-left & right-to-left collaterals noted to small left PDA
- RCA: Non-dominant
- LV Gram: Posterior-basilar akinesis and moderate infero-apical hypokinesis
- EF: 45%

Intervention

- Left main was engaged with an 8F XB 3.5 Cordis guide
- 0.014" PROWATERflex Asahi guidewire was advanced into the first OM branch, and a second 0.014" PROWATERflex Asahi guidewire was successfully crossed with some difficulty into the native CFX artery
- Excimer laser coronary atherectomy of the proximal CFX, first OM and distal CFX was performed utilizing the Spectranetics 0.9mm X80 and 1.4mm ELCA catheters in a sequential fashion
- Subsequent injections revealed restoration of TIMI 3 flow in the dominant CFX artery
- 2.75x20mm Maverick balloon was used to sequentially dilate the first OM and the proximal and distal CFX artery
- First OM was stented with a TAXUS 3.0x32mm DES at 24 ATM. Then a 2.75x16mm TAXUS DES was placed in the distal CFX artery
- 3.0x20mm TAXUS DES was placed in the proximal CFX overlapping with the OM1 stent

DEVICES

Guide

- 8F XB 3.5 Cordis guide (Johnson & Johnson®)

Wire

- 0.014" PROWATERflex Asahi guidewire (Abbott Vascular®)

Lasers

- 0.9mm X80 and 1.4 mm ELCA® (Spectranetics®)

Balloons

- 2.75x20mm Maverick® (Boston Scientific®)
- 3.5x15mm and 3.0x12 Quantum® (Boston Scientific®)

Stents

- 3.0x32mm, 2.75x16mm, and 3.0x20mm TAXUS™ (Boston Scientific®) DES

Anticoagulation

- Heparin
- Integrilin® (Millennium® Pharmaceuticals)

FEATURED SPECTRANETICS PRODUCTS

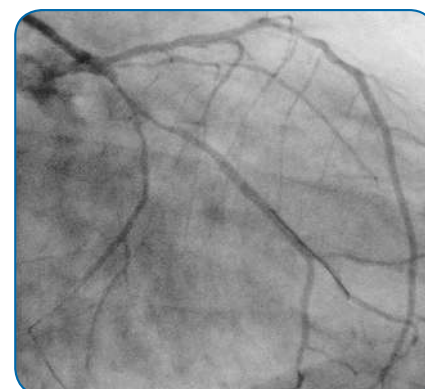
- ELCA® Coronary Laser Atherectomy Catheter



Subtotal CFX Artery



Subtotal CFX Artery



Post 0.9mm X80 & 1.4mm ELCA

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Intervention (continued)

- CFX/OM1 stent was then deployed at 20 ATM utilizing a “crushing stent” technique. The distal CFX was then re-wired and final “kissing balloon” inflations were performed using a 3.5x15mm Quantum balloon in the OM1-CFX and a 3.0x12mm Quantum balloon in the distal CFX at 12 ATM each.
- Final angiographic images indicated an excellent result with no residual stenosis in the CFX or OM branch. TIMI 3 flow was noted. A PCI was performed five days later to the LAD artery lesion.

Results / Conclusions

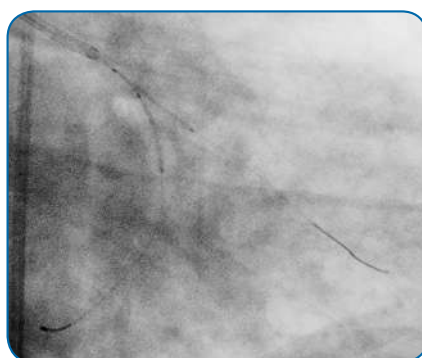
- Adjunctive use of excimer laser ablation in sub-total occlusions is valuable to establish improved coronary flow while minimizing distal embolization in the process
- As demonstrated in this case, laser atherectomy is the only device that enables debulking while maintaining “buddy wire” access to both major branches in a complex bifurcation lesion. In a complex intervention, such as a reverse T-stent with crush technique, sidebranch rewiring and high-pressure balloon inflations are paramount to achieving complete stent apposition and minimizing sidebranch restenosis and target vessel failure.

When contemplating multi-vessel intervention, it is important to consider the subtotal or total occlusion first. Using this strategy, had PCI been unsuccessful then surgical revascularization would still have been a viable alternative.

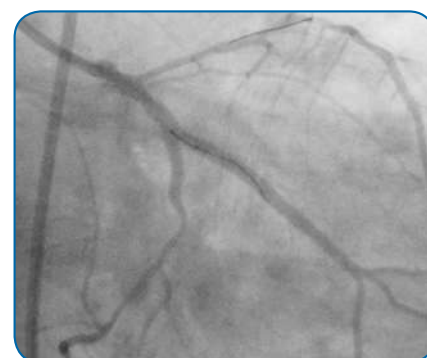
In this case, one could argue that the successful percutaneous approach resulted in a more complete revascularization given the ensuing excellent perfusion of the left PDA, which was angiographically a very poor surgical target.

– Antonis Pratsos, MD

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



Stents Positioned in OM1 and CFX



Final Images Post Stent Deployment

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.