

Excimer Laser for Coronary Intervention: Case Study

RADIAL APPROACH: CORONARY LASER ATHERECTOMY FOR CTO OF THE LAD FOLLOWED BY PTCA – NO STENTING



Clinical History & Angiography

- 58 year-old male
- c/o CP, HTN, SOB
- Stress echo showed exercise induced wall motion abnormality of anterior wall
- RCA large, dominant and patent
- LAD totally occluded after 1st septal
- CX moderately large with no significant disease



Devices

- ACCESS: 6F Sheath Right Radial Artery
- GUIDE: 6F AL1
- WIRES: 0.014 ASAHI Shinobi® (Abbott Vascular®), Choice PT® (Boston Scientific®), BMW (Abbott Vascular®)
- Crossing Solution: 0.014 Quick-Cross[®] (Spectranetics[®])
- LASER: 0.9mm X 80 ELCA® Catheters (Spectranetics®)
 - 2 passes @ 50/40 and 60/60
- BALLOON: 2.6x 15mm Maverick™ (BSC®)

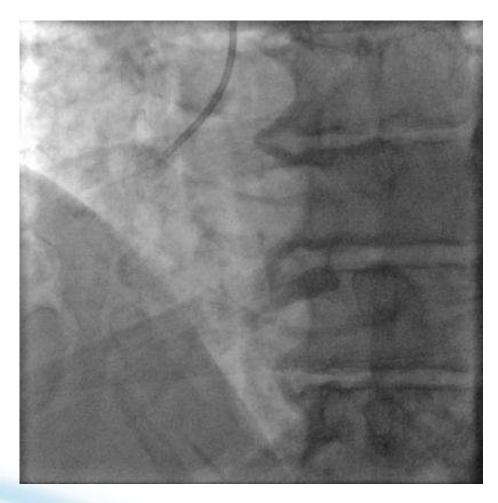


Procedure

- Difficult guidewire placement multiple wires attempted
- Crossed lesion with 0.014 Quick Cross and Shinobi wire
- Shinobi exchanged for Choice PT and later for BMW
- Atherectomy completed with the 0.9 x 80 ELCA Catheter
 - 2 runs of 50/40 and 60/60
- PTCA of LAD and Diagonal
 - No stent placed due to diffuse LAD disease
- TIMI 3 flow and no evidence of dissection
- Pt. returned 4 months later for follow up angiogram

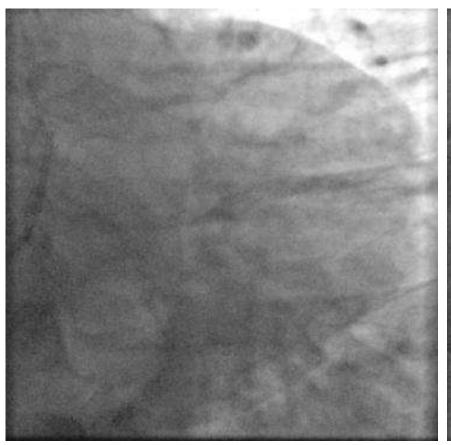


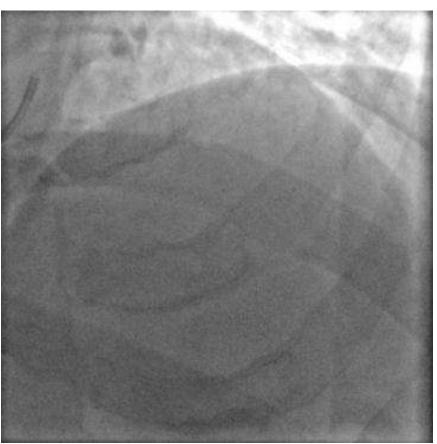
DX Angio





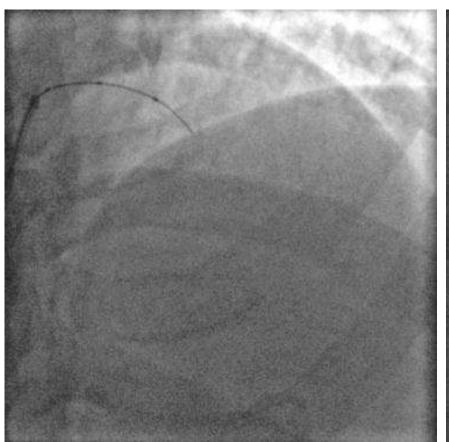
DX Angio

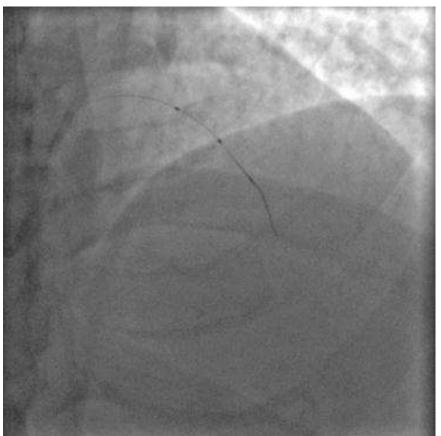




CTO of LAD

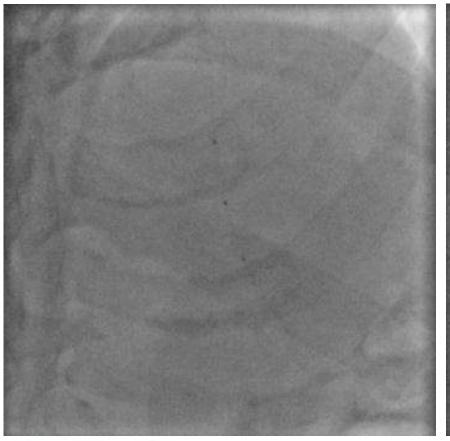






Quick-Cross facilitating crossing and guidewire position



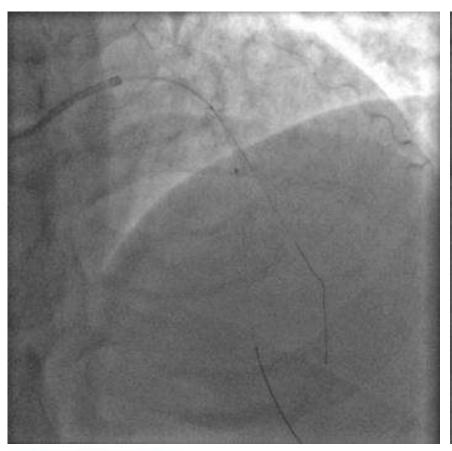


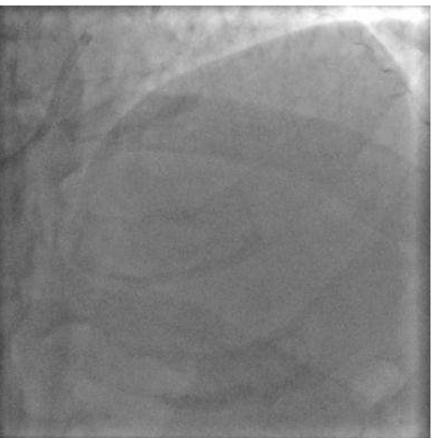


Quick-Cross completely across CTO

0.9 x 80 laser – 2 passes @ 50/40 and 60/60





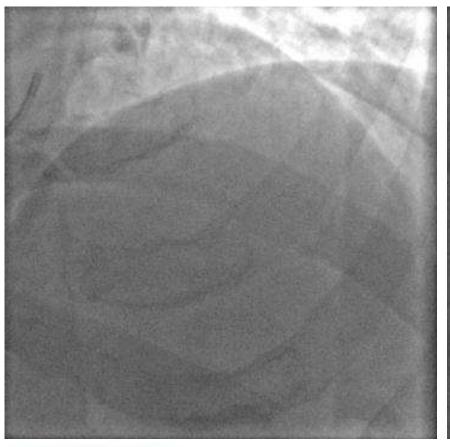


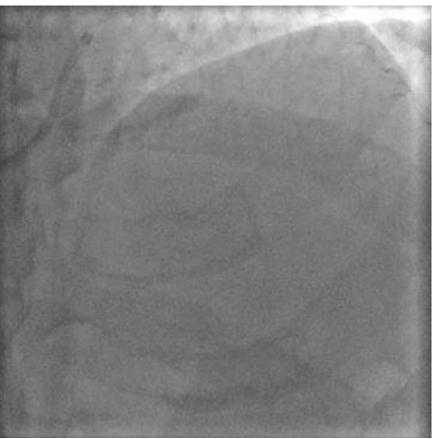
LAD and Diagonal wired – PTCA to LAD

No stent due to diffuse disease in LAD

Final Angio





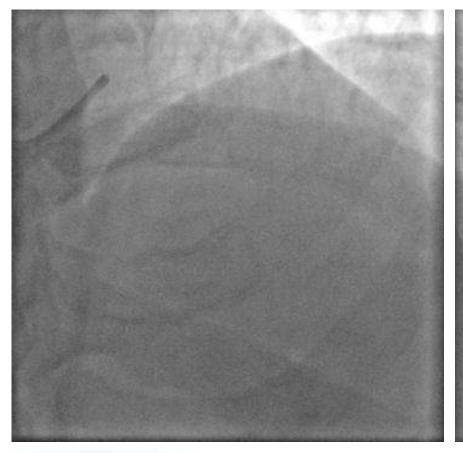


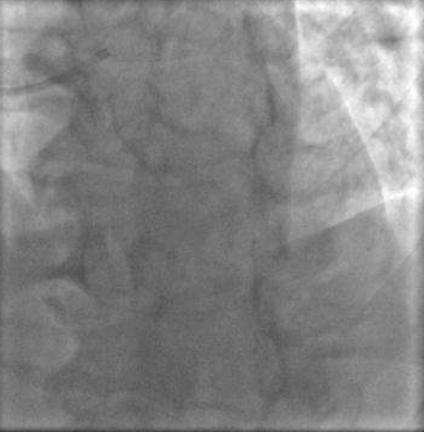
Pre Angio

Final Angio



4 Month Post Procedure Angios







Conclusion

• Successful laser atherectomy and PTCA of an LAD CTO.



ELCA® Important Safety Information

Indications

The Laser Catheters are intended for use either 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.
- Moderately calcified stenoses.

Ostial lesions.

- Total occlusions traversable by a guidewire.
- Long lesions—(greater than 20mm in length).
- Lesions which previously failed balloon angioplasty.
- Restenosis in 316L stainless steel stents, prior to the administration of intravascular brachytherapy.

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

Lesion is in an unprotected left main artery.

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.



ELCA® Important Safety Information

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® Important Safety Information

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.

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.

