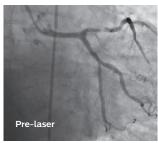
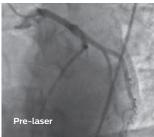
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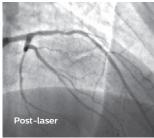
ELCA

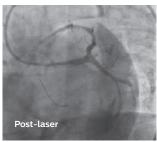
Coronary laser atherectomy catheter

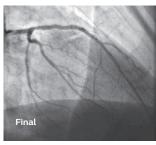
Revascularization of LAD











Images courtesty of Dr. Aggarwala

Operator and facility

Gaurav Aggarwala, MDDavis Hospital and Medical Center, Layton, UT

Case history

- · 61-year-old male
- History of chronic fatigue immune deficiency syndrome, fibromyalgia, prostate problems, dyslipidemia, family history of CAD, 36 years of cigarette smoking, and hypertension.
- Currently, patient presents with marked EKG changes including up to 2 mm of DT depression noted in almost ever lead post exercise, jaw discomfort with exertion and blood clots in urine.

Angiography

- · Mild diffuse in left main
- 99% subtotal occlusion in proximal LAD and 99% single discrete vessel in mid-vessel;
 TIMI flow noted in distal vessel
- · Mild diffuse disease in left circumflex
- $\cdot\;$ RCA with mild diffuse disease, 80% lesion in the acute marginal branch

Intervention

- · CLS 3.5 guide taken to left main
- · Hi-Torque pilot wire advanced into distal LAD
- ${}^{\centerdot}$ ELCA 0.9 mm catheter advanced into proximal and mid LAD for atherectomy
- Endeavor 3.0 \times 12 mm drug-eluting stent deployed at 16 atmospheres in proximal LAD, followed by 3.0 \times 30 mm stent in mid LAD
- · Overlap dilated to 18 atmospheres
- · Laser settings: 45/25; Pulses: 1,500; Time: 3 minutes

Results and conclusion

- · Post procedure, no residual stenosis, EKG changes or dissection noted.
- Achieved successful revascularization of left anterior descending artery with laser atherectomy and drug-eluting stent.
- After two passes with the 0.9 mm X-80 ELCA catheter, the blood flow through the lesion was improved.

"(The ELCA catheter) provided an option to debulk the lesion in order to obtain excellent stent apposition."

-Gaurav Aggarwala, MD

Dr. Aggarwala has been compensated by Philips for his/her services in preparing this material for Philips' further use and distribution.

The opinions and clinical experiences presented herein are for informational purposes only. Individual results may vary depending on a variety of patient-specific attributes and related factors. Results from this case study are not predictive of future results.

Devices

Access	CLS 3.5 guide
Wire(s)	Abbott Vascular Hi-Torque Pilot 0.014
Laser(s)	Philips ELCA 0.9 mm catheter
Stent(s)	Medtronic Endeavor 3.0 x 12 mm
Anticoagulation	Angiomax
Featured Philips product	ELCA coronary laser atherectomy catheter

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 Philips CVX-300 Excimer laser system and the multi-fiber 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 stenosis, total occlusions traversable by a guidewire, 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.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Potential adverse events: Use of the Philips CVX-300 Excimer laser system may contribute to the following complications: dissection of the arterial wall, perforation, acute reclosure, embolization, aneurysm formation, spasm, coronary artery bypass graft surgery, thrombus, myocardial infarction, arrhythmia, filling defects, death. No long term adverse effects of ELCA are known at this time.

Risks: The primary endpoint defined in the laser angioplasty of restenosis stents (LARS) randomized trial was the absence of major adverse cardiac events (MACE) at 6 months: Death; myocardial infarction; coronary artery bypass surgery. Procedural complications include: any dissection, acute thrombus, haziness, no reflow, arrhythmia, acute vessel closure, occlusion of side branch, occlusion non-target, coronary spasm, coronary embolism, coronary perforation, laser/stent damage, balloon/stent damage, and other serious complications.

