PHILIPS

ELCA

Coronary laser atherectomy catheter

Recanalization of LAD









Operator and facility

Robert Lee Jobe, MD

WakeMed Health & Hospitals, Raleigh, NC

Case history

- 85-year-old male with history: significant for essential hypertension, chronic lymphatic leukemia, peptic ulcer disease, bilateral cataract surgery, chronic sinusitis. Father died of myocardial infarction at 60.
- Current: patient presents with chest tightness and dyspnea on exertion, dizziness cardiolite stress test shows mild ischemia of the apex and inferior apex. Left ventricular function was normal. Due to symptoms and abnormal stress test, patient referred for cardiac catheterization to fully define cardiac status.

Angiography

Heavily calcified 95% stenosis at bifurcation of LAD and first diagonal branch

Results and conclusions

- Successful laser atherectomy and stent angioplasty of the left anterior descending and diagonal branch.
- Final angiography demonstrated excellent angiographic result, with 0% residual stenosis at the site of angioplasty and no evidence of dissection, distal embolization or loss of side branch
- "In this case, treatment with the laser catheters modified and converted a nondilatable coronary lesion into a dilatable lesion, even without the laser catheter fully crossing the lesion."
- Robert Lee Jobe, MD
 Dr. Jobe has been compensated by Philips for his/her services in preparing this material for Philips' further use and distribution.

Intervention

- LCA cannulated using 7F Judkins left #4 angioplasty guiding catheter.
- Angiomax anticoagulation administered.
- LAD lesion easily crossed with short 0.014 Luge guidewire.
- The first intervention attempted was with the Quantum Maverick noncompliant balloon, which could not dilate the lesion even at over 20 atmospheres pressure.
- Initial attempt at laser coronary atherectomy using Philips ELCA 1.4 mm atherectomy catheter, for 33 seconds at 45/25 for a total of 1,075 pulses, then for 1 minute 15 seconds at 60/40 for a total of 2,400 pulses.
- Laser then exchanged for 0.9 mm ELCA RX catheter and LAD lesion treated for 4 minutes at 60/40 and 80/80 for a total of 12,306 pulses.
- Over the LAD guidewire a 2.5 mm Quantum Maverick angioplasty balloon was used to easily dilate the lesion at 20 atmospheres.
- Another short 0.014 Luge guidewire was placed in the diagonal branch for side branch protection and the LAD was stented with a 3.5 mm Boston Scientific Promus 12 mm drug-eluting stent, delivered at 20 atmospheres.
- The ostium of the diagonal branch was then dilated using a 2.5 mm Abbot Voyager 12 mm angioplasty balloon at 10 atmospheres.
- Final inflation performed with stent delivery balloon in diagonal branch and a 3.5 mm Quantum angioplasty balloon in LAD, both at 6 atmospheres.

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.

Images courtesy of Dr. Jobe

Devices

Access	7F Judkins left #4 angioplasty guiding catheter
Wires	0.014 Luge guidewire (Boston Scientific)
Lasers	 1.4 mm ELCA (Philips) 0.9 mm X80 ELCA (Philips)
Balloons	 2.5 mm Voyager 12 mm angioplasty balloon (Abbott Vascular) 3.5 mm Quantum Maverick balloon (Boston Scientific)
Stents – Endeavor	3.5 mm Promus 12 mm drug-eluting stent (Boston Scientific)

Important safety information

ELCA laser atherectomy catheter

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.

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.

Caution

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

