PHILIPS

Coronary intervention

Case study

The advantage
of plaque modification

Case history

- 84-year-old white male with known multi-vessel CAD
- Undergone CABG and subsequent multi-vessel PCI
- Present with recurrent angina
- Referred for catheterization

Angiography

- Left main was heavily calcified 80% terminal stenosis
- LAD: 90% stenosis, patent LIMA graft
- LCx: 90% stenosis
- RCA: occluded proximally

Intervention

- Treated protected left main coronary artery *(figure 1)* **AngioSculpt PTCA** 3.5 x 10 mm up to 22 atm lesion did not yield *(figure 2)*
- 1.4 mm **ELCA coronary laser** was used for 29 seconds; multiple passes *(figure 3)*
- Post laser returned with the 3.5 x 10 mm **AngioSculpt PTCA** at 16 atm resulting in full lesion expansion *(figure 4)*
- Stented left main using a 4 x 8 mm Promus PREMIER DES and distal circumflex with a 3 x 16 mm Promus PREMIER DES *(figure 5)*

Results and conclusion

Final angiograms confirmed excellent angiographic result.

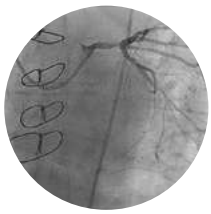

Figure 1

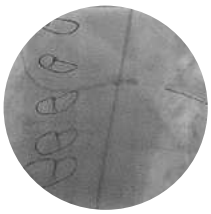

Figure 2

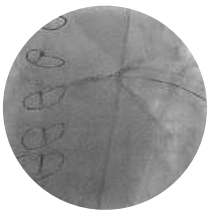

Figure 3

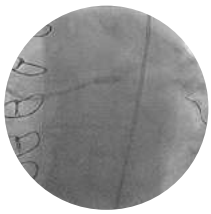

Figure 4

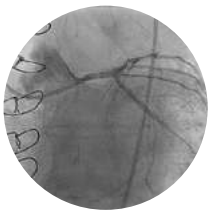

Figure 5

Operator/facility

Dr. Jaikirshan (Jai) Khatri, MD, FACC, FSCAI
Cleveland Clinic, Cleveland, Ohio

Devices

ELCA coronary laser atherectomy catheter	1.4 mm x 135 cm
AngioSculpt PTCA scoring balloon catheter	3.5 x 10 mm
Promus PREMIER DES	4 x 8 mm LMCA
Promus Premier DES	3 x 16 mm LCX

Images provided courtesy of Allen Jeremias, MD.

Important safety information

ELCA 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-30 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 20 mm in length).
- Moderately calcified stenoses.
- Total occlusions traversable by a guide wire.
- 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 guide wire 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.
- Guide wire 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.

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 Philips 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.

AngioSculpt PTCA indications

The AngioSculpt scoring balloon catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis and complex type C lesions, for the purpose of improving myocardial perfusion.

Warnings: Administer appropriate antiplatelet, anticoagulant and coronary vasodilator therapy, consistent with institutional practice for coronary stent procedures, during and after the procedure. This device is intended for single (one) use only. Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination. For use in de novo or in-stent restenosis (ISR) lesions, the inflated diameter size of the balloon should approximate the vessel diameter size just proximal and distal to the stenosis, in order to reduce potential vessel damage. When used to pre-dilate the lesion prior to pre-planned stenting, the catheter should be one size smaller than the estimated vessel diameter (e.g., a 2.5 mm diameter device should be used in a vessel estimated to have a 3.0 mm diameter). PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery require careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk. When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Do not exceed the rated burst pressure (RBP) during balloon inflation. The RBP is based on results of in-vitro testing. At least 99.9% of the balloons (with 95% confidence) will not burst at or below their RBP. Use of a pressure monitoring device is recommended to prevent over-pressurization. PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potential cardiovascular injury or life-threatening complication. Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon. Use the device prior to the expiration date specified on the package.

Precautions: Take extra care when using the AngioSculpt catheter to treat a lesion distal to a freshly deployed stent. This precaution is particularly applicable to a drug-eluting stent so as to minimize the risk of damage to the stent coating. Prior to angioplasty, examine the catheter to verify functionality, catheter integrity and to ensure that its size and length are suitable for the specific procedure for which it is to be used. Only physicians trained in the performance of percutaneous transluminal coronary angioplasty should use the AngioSculpt catheter. Do not rotate the catheter shaft in excess of 180 degrees when the tip is constrained. Do not rotate the catheter luer hub in excess of five (5) turns during use. Do not advance or retract the AngioSculpt catheter over the floppy portion of the guide wire. Catheter manipulation, including advancement and retraction, should be performed by grasping the hypotube shaft. If unusual resistance is felt when the catheter is being manipulated or if it is suspected that the guide wire has become kinked, carefully remove the entire catheter system (AngioSculpt catheter and steerable guide wire) as a unit. If fluoroscopic guidance indicates that the AngioSculpt catheter has advanced beyond the end of the guide wire, withdraw the catheter and reload the wire before advancing again.

Possible adverse effects: Death; Heart attack (acute myocardial infarction); Total occlusion of the treated coronary artery; Coronary dissection perforation rupture Emergency artery dissection, perforation, rupture, or injury; Pericardial tamponade; No/slow reflow of treated vessel; artery bypass (CABG); Emergency percutaneous coronary intervention; CVA/stroke; Pseudoaneurysm; Restenosis of the dilated vessel; Unstable angina; Thromboembolism or retained device components; Irregular heart rhythm (arrhythmias, including life-threatening ventricular arrhythmias); Severe low (hypotension)/high (hypertension) blood pressure; Coronary artery spasm; Hemorrhage or hematoma; Need for blood transfusion; Surgical repair of vascular access site; Creation of a pathway for blood flow between the artery and the vein in the groin (arteriovenous fistula); Drug reactions, allergic reactions to x-ray dye (contrast medium); Infection.

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D030163-01 072016

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