

# Early outcome of high energy Laser (Excimer) facilitated coronary angioplasty ON hARD and complex calcified and balloonOn resistant coronary lesions.

## Overview

The 0.09 mm X-80 xenon-chlorine (excimer) laser coronary atherectomy catheter (ELCA X80) was used to pretreat a series of complex coronary lesions, including calcified stenoses, chronic total occlusions and non-compliant plaques. Such complex lesions can be difficult to adequately treat with balloon angioplasty and/or intracoronary stenting alone, due to initial device crossing or balloon dilatation failure.

## Objective

To examine the acute procedural outcome of ELCA-facilitated coronary angioplasty in a cohort of patients presenting with chronic total occlusions, calcified plaques and/or balloon-resistant lesions.

## Methods

Eighty patients with 100 lesions were enrolled by four centers, and ELCA was performed on 96 lesions. Safety and effectiveness data were compared between patients treated with standard laser therapy (SLT = 60 fluence @ 40 hertz) and those treated with increased laser therapy (ILT = 60 fluence @ 80 hertz and/or 80 fluence @ 80 hertz). The primary endpoint (laser success) was defined as the ability of the X80 catheter to cross the lesion. The secondary endpoints included:

- Procedural success, defined as reduction of the target lesion to < 50% residual diameter stenosis after adjunctive therapy, as measured by quantitative coronary analysis (QCA)
- Clinical success, defined as reduction of the target lesion to < 50% residual diameter stenosis after adjunctive therapy as measured by QCA with absence of major adverse cardiac events (MACE) at hospital discharge.

## Results

Overall, laser success, the primary endpoint of the study, was obtained in 90 lesions (93.7%). Furthermore, dividing the study's population according to the indicated lesion type at laser angioplasty:

- The primary endpoint was reached in 96.4% of the cases with calcified lesions (53/55)
- 93.7% of the cases with initial balloon dilatation failure (30/32), and
- 77.8% of the cases with chronic total occlusion (7/9)
- Of the 6 failures to cross, 4 lesions were subsequently crossed with balloons and/or stents suggesting laser induced plaque modification (94/96 total lesions crossed 97.9%)

Regarding the secondary endpoints:

- 91.7% procedural success
- 90.6% clinical success
- 1/96 (1%) MACE reported – NQWMI - post ventricular fibrillation /CPR

## Conclusions

ELCA X80 catheters delivering the currently approved SLT and/or ILT levels of energy output demonstrate safety and effectiveness in the treatment of CTO, calcified and non-dilatable lesions. If required by dense lesion morphology, the ILT energy levels delivered by this catheter seem to improve device ablation performance without increasing procedural complications. The range of energy delivery capability of the X80 catheter allowed for successful percutaneous coronary intervention (PCI), with low procedural complication, in the complex lesion types presented in this study, including 33% of lesions presenting as prior balloon dilatation failures.

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## Prospective Study Summary

### Principle Investigator

- Vittorio Ambrosini, MD

### Atherectomy Devices

- 0.09 mm ELCA catheter (SPNC)
- CVX-300 XeCl Excimer Laser System (SPNC)

### Study Overview

#### Inclusion Criteria

- Target lesion with ≥80% stenosis by visual examination
- Angiographic evidence of calcification or a CTO
- Absence of acute coronary syndrome 3 months prior to index procedure

### Procedural Success

- Procedural success defined as reduction of the target lesion to < 50% residual diameter stenosis after adjunctive therapy, as measured by QCA

### Conclusions

- ELCA X80 catheters operated at maximum energy output levels is safe and effective for calcified lesions, CTO and non-balloon dilatable lesions.
- Use of the higher energy output levels (ILT), using 60-80 fluence at a frequency of 80 Hz, improved ablation performance without increasing procedural complications.

## **Important Safety Information**

### **ELCA & ELCA X-80**

The Excimer Laser Coronary Atherectomy Catheters (ELCA) are used in conjunction with the Spectranetics CVX-300® Excimer Laser System and are intended for use in patients with a variety of blockages in single or multivessel coronary artery disease. ELCA is usually used in conjunction with other therapies, such as balloon angioplasty or stenting. The use of ELCA may be unsafe in some patients or in treating certain types of blockages. The ELCA X-80 catheter should not be used in patients with weakened heart muscles (ejection fraction <30%) or in cases of acute heart attacks. Rarely a patient undergoing ELCA may require urgent surgical treatment for a complication; therefore, patients who are not candidates for coronary bypass graft surgery should not undergo treatment with ELCA. Ask your doctor if you are a candidate for ELCA.

Potential adverse events associated with procedures used to treat coronary artery disease may include: a tear, rupture, damage to the artery; a sudden, temporary or ongoing reclosure of the treated artery; blood clot or obstruction of the artery by plaque debris. Other complications may occur.

Rare but serious potential adverse events include: the need for urgent additional procedures or surgery due to bleeding, vascular damage, loss of blood flow or other complications; and irregular heartbeat, heart attack or death.

This information is not intended to replace a discussion with your health care provider on the benefits and risks of this procedure to you.

### **CVX-300**

The CVX-300 is an excimer laser system approved for use in minimally invasive interventional procedures within the cardiovascular system and for the removal of problematic pacemaker and defibrillator cardiac leads.

Potential adverse events associated with procedures used to treat PAD may include: a sudden, temporary or ongoing re-closure of the treated artery; blood clot or obstruction of the artery by plaque debris; a tear, rupture or damage to the artery (or nearby vein or nerve); minor bleeding or bruising at the entry site. Other complications may occur.

Potential adverse events associated with procedures used to treat coronary artery disease may include: a tear, rupture, damage to the artery; a sudden, temporary or ongoing re-closure of the treated artery; blood clot or obstruction of the artery by plaque debris. Other complications may occur.

Potential minor adverse events associated with lead extraction procedures that may or may not require medical or surgical treatment include: a tear or damage to the blood vessels, the heart or its structures; bleeding at the surgical site; or collapsed lung.

Rare but serious adverse events that require emergency medical or surgical procedures may include: a tear or damage to the blood vessels, the heart, lungs or their structures; blood clot or obstruction of the blood vessels or lungs by debris or lead fragments. Other serious complications may include: irregular heartbeat, weakened heart muscle, infection, respiratory failure or complications associated with anesthesia, stroke or death.

This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you.

For important safety information, please visit [www.spnc.com/IFU](http://www.spnc.com/IFU).