Percutaneous Bypass: Rebirth as Treatment for CTO

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Percutaneous Bypass Procedures Under Development for the Last 5 years

• Percutaneous In-Situ Coronary Venous Arterialization (PICVA)
• Percutaneous In-Situ Coronary Artery Bypass (PICAB)
PICVA - Basic Concept

Percutaneous In-Situ Coronary Venous Arterialization

- Anastomosis made between diffusely diseased coronary artery and adjacent vein
- Venous egress to coronary sinus is blocked
- Arterial blood then perfuses myocardium retrograde through distal vein
**PICAB Basic Concept**

**Percutaneous In-Situ Coronary Artery Bypass**

- Coronary vein acts as "jump" bypass graft
- Two anastomoses made percutaneously
- Vein isolated percutaneously
PICVA Clinical Experience

- Clinical Target
  - No-Option Patients With Class III/IV Angina
  - Viable Ischemic Target In Anterior/Septal Area
- Initial Trial Suspended – 2002
  - IVUS-based TransAccess, Self-expanding Occluder
  - 11 Patients Enrolled, 5 completed procedures
  - 2 deaths led to voluntary trial suspension to revise devices
- Trial Re-Initiated – 2003
  - NOGA-based TransAccess, Balloon-expandable Occluder
  - 1 Patient Enrolled, Successfully Treated – Milan [Colombo]
  - TCT follow-up, Channel closed
Lessons learned

• Difficult procedure in best of hands
• Arterial to Venous anatomy unpredictable
• Venous blocker size changes with higher pressure load condition (may continue to change)
• AV connector needs to be covered and drug eluting
Coronary True Lumen Return (TLR)

- CTO Target Population
  - 10 – 20% of all angiographic cases
  - 80% of all failed angioplasty

- More CTOs will be intervened on with the availability of Drug Eluting Stents

- Subintimal Wire Trapping
  - Approx 20 - 40% of all CTO attempts
  - Remains the major failure mode for new approaches

[Lumend, Intraluminal Therapeutics, New Wires]
Coronary True Lumen Return

• CrossPoint® TransAccess
  • 2 mm Tip
  • 6.2 Fr Shaft
  • Requires 9 Fr Guide

• Coronary TLR TransAccess [under development]
  • 1.2 mm Tip
  • 5 Fr Shaft w/ 4 Fr Distal Shaft
  • Requires 8 Fr Guide
Subintimal CrossPoint® IVUS Image

CrossPoint® Catheter IVUS image from within a dissection of the SFA
CrossPoint® Catheter

Key Features:

• 24G needle allows for delivery of a 0.014” guidewire

• Flexible shaft allows for contralateral approach

• 7F Introducer sheath compatibility (0.087” I.D.)
  • Exception: Compatible with Medtronic 6F Input PS Sheath
CrossPoint® Catheter

Key Features:

- 6.9F catheter tracks over 0.014” guidewire.
- Catheter length: 120cm
- Integrated 64-element, phased array IVUS with 20 MHz transducer.*
- Solid state versus mechanical

* For use with the Volcano/JOMED In-Vision IVUS console
True Lumen Return
Step 1: Guide Wire Entrapment
True Lumen Return
Step 2: Catheter Insertion
True Lumen Return
Step 2: Catheter Insertion

Using an exchange catheter, exchange the 0.035” wire for 0.014” extra-support HTF guide wire (190cm);
Pass CrossPoint catheter over subintimal guidewire*.

*Note: DO NOT use the CrossPoint catheter without a guide wire in place. Heavily calcified vessel wall may require small 20 mm diameter balloon dilation prior to CrossPoint catheter use. The CrossPoint catheter is not intended to be used as a tunneling device through a total occlusion.
1. Using IVUS component-orient catheter toward true lumen by rotating the entire catheter.

2. Verify position with fluoro.
Orient catheter toward true lumen

- Rotate CrossPoint catheter using ChromaFlo and ‘comet tail’ as guide*.

*Note: Comet tail will remain in 12:00 position and anatomy will rotate. Rotate the catheter no more than 180° in clockwise or counterclockwise direction. Change direction as required.
True Lumen Return
Step 3: Catheter Rotation
True Lumen Return
Step 3: Catheter Rotation

Platinum iridium needle housing facilitates catheter orientation toward true lumen.
True Lumen Return
Step 4: Deploy Needle
True Lumen Return
Step 5: Pass Guide Wire

Pass 0.014” extra-support guide wire (300cm) through CrossPoint needle into vessel lumen.

Note: The needle may need to be withdrawn slightly in order to advance the guide wire. DO NOT use plastic or hydrophilic coated wires.
True Lumen Return
Step 6: Remove the CrossPoint
True Lumen Return
Step 7: Treat the Vessel

Treat the vessel with a PTA balloon and/or with stent placement.
True Lumen Return:
Controlled Re-entry: Case Presentation
**True Lumen Return:**
**Controlled Re-entry: SFA**

Figure 1 and 2: Total occlusion of the left SFA with dense calcification

* Images courtesy of Dr. Michael Dake, Stanford University Medical Center
True Lumen Return: Controlled Re-entry: SFA

Figure 3 and 4: LuMend’s Frontrunner® CTO Catheter-unable to cross calcified lesion

* Images courtesy of Dr. Michael Dake, Stanford University Medical Center
True Lumen Return: Controlled Re-entry: SFA

Figure 5: Guidewire subintimal

Figure 6: CrossPoint catheter around bifurcation

Figure 7: CrossPoint catheter in subintimal space

* Images courtesy of Dr. Michael Dake, Stanford University Medical Center
True Lumen Return: Controlled Re-entry: SFA

Figure 8: IVUS image for needle deployment

Figure 9: Needle deployed

Figure 10: Guidewire into true lumen

* Images courtesy of Dr. Michael Dake, Stanford University Medical Center
True Lumen Return: Controlled Re-entry: SFA

Before

After

* Images courtesy of Dr. Michael Dake, Stanford University Medical Center
Myocardial Delivery Devices
Myocardial Repair

TransAccess® Delivery System
TransAccess® Delivery System

- **TransAccess® Catheter**
  - 6.2F Catheter with Integrated IVUS
  - Tracks over .014 Guide Wire
  - Pre-Shaped 24G Nitinol Needle

- **IntraLume™ Microcatheter**
  - 27G Injection Catheter
  - Delivered Through TransAccess Needle
  - Radiopaque Beveled Tip
On-Board IVUS Orientation

Anterior Wall

Septum

Pericardium

Needle Trajectory

AIV

LAD

OM

PLV

PDV

PDA
**Pre-Clinical Testing:**

**Efficiency and Retention**

- **Erasmus University Study**
  - Porcine model
  - N = 4 Animals
  - N = 10 injections total
  - TC⁹⁹-labelled VEGF₁₆₅

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Potential Advantages Over Endocardial Approaches

- Long, contiguous tracks
  - (2-6 cm, rather than 2-6 mm)
- Lower bleedback creates higher injection efficiency
- Any injection losses go into venous return, rather than bleedback into arterial circulation
- Access to entire left ventricle
Pre-Clinical Validation
- Contiguous Tracts -