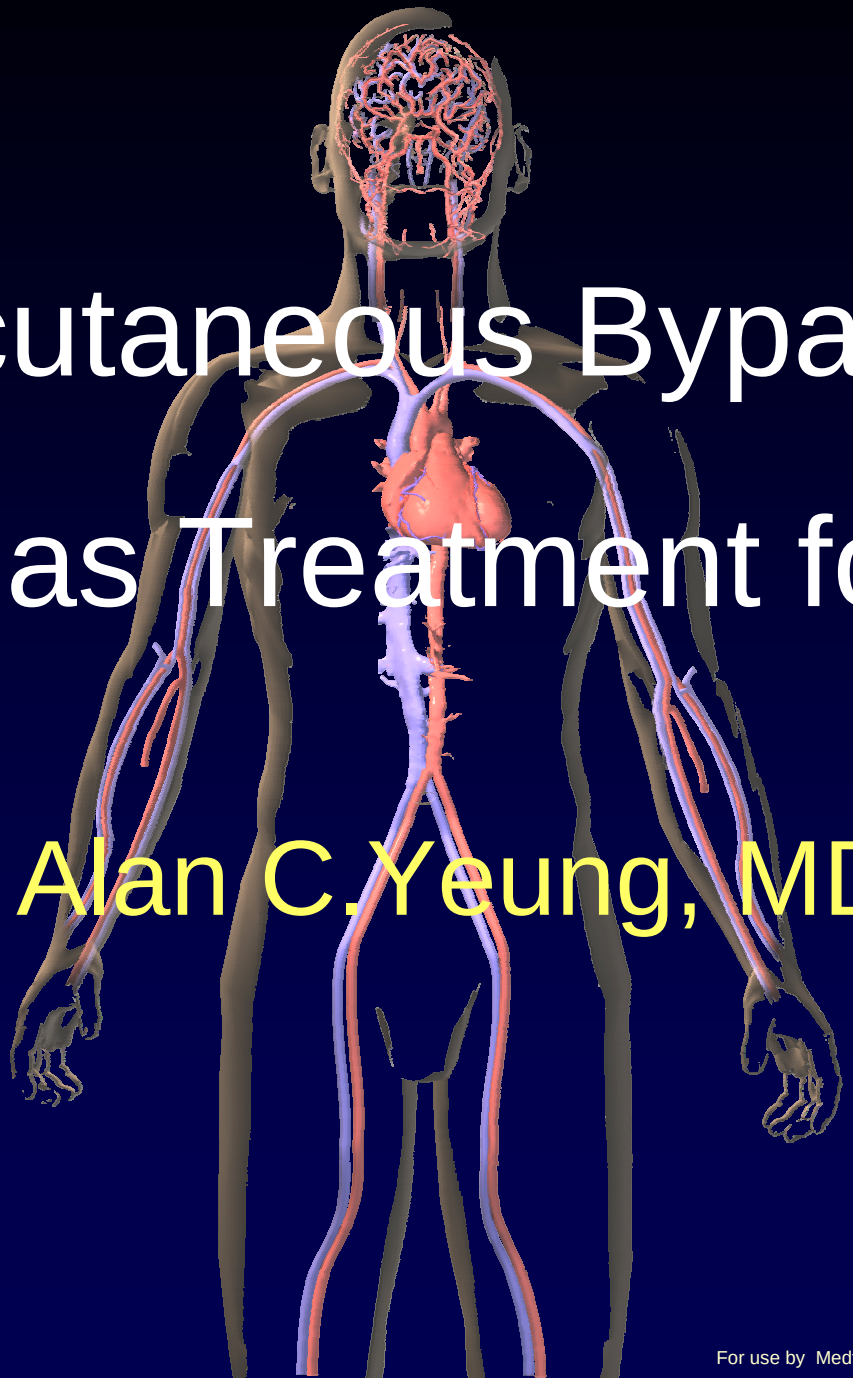
Percutaneous Bypass: Rebirth as Treatment for CTO



Alan C. Yeung, MD

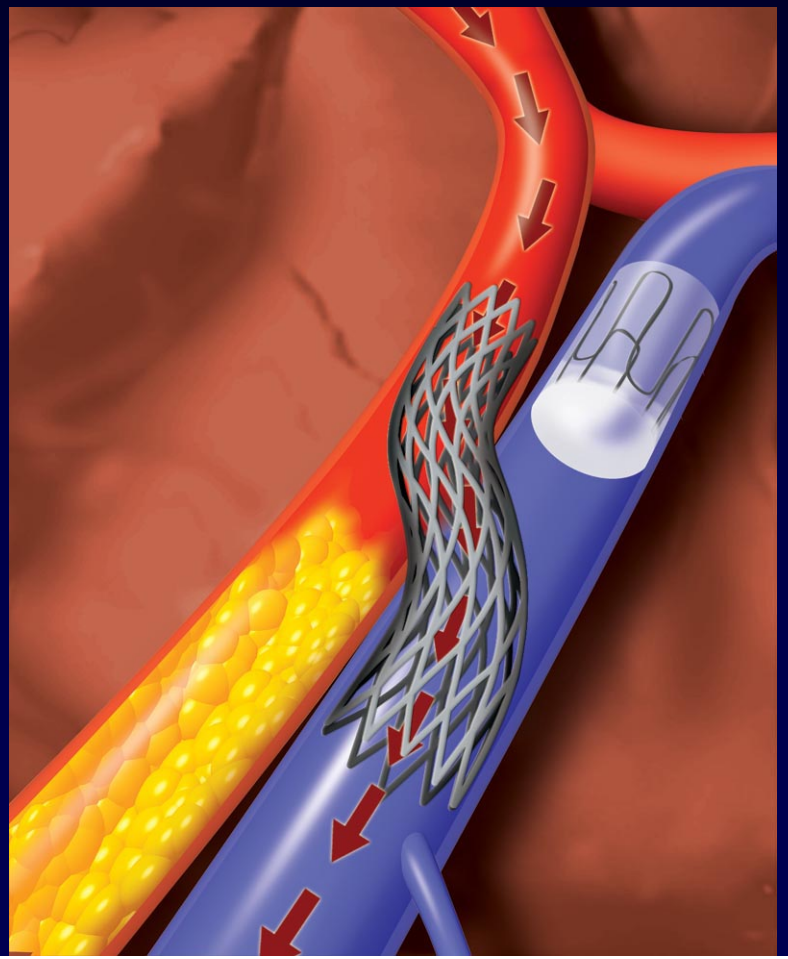
Percutaneous Bypass Procedures Under Development for the Last 5 years

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

PICVA - Basic Concept

Percutaneous In-Situ Coronary Venous Arterialization

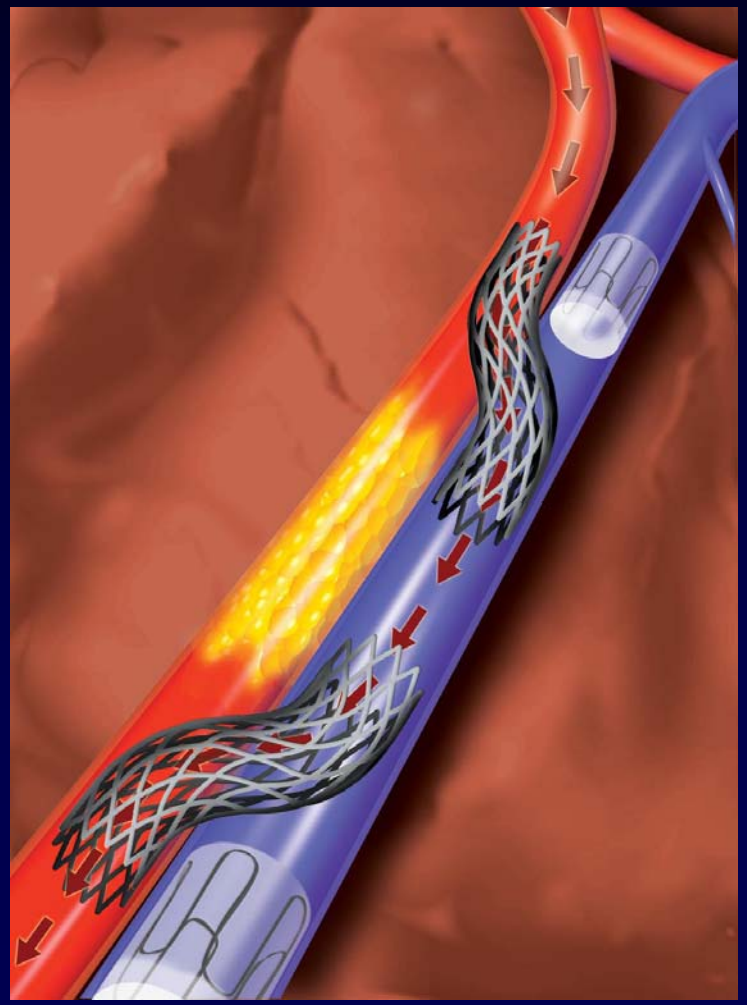
- Anastomosis made between diffusely diseased coronary artery and adjacent vein
- Venous egress to coronary sinus is blocked
- Arterial blood then perfuses myocardium retrograde through distal vein



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]

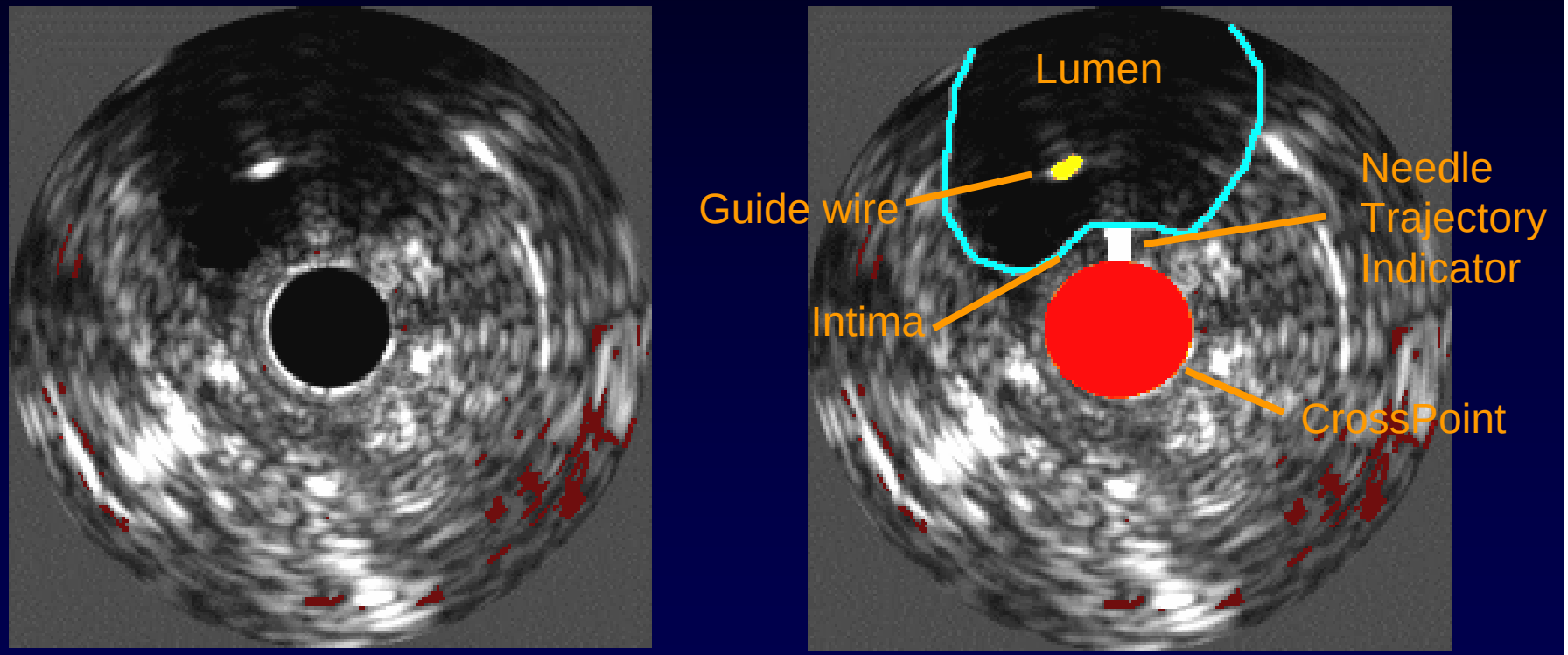
Coronary True Lumen Return

- 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

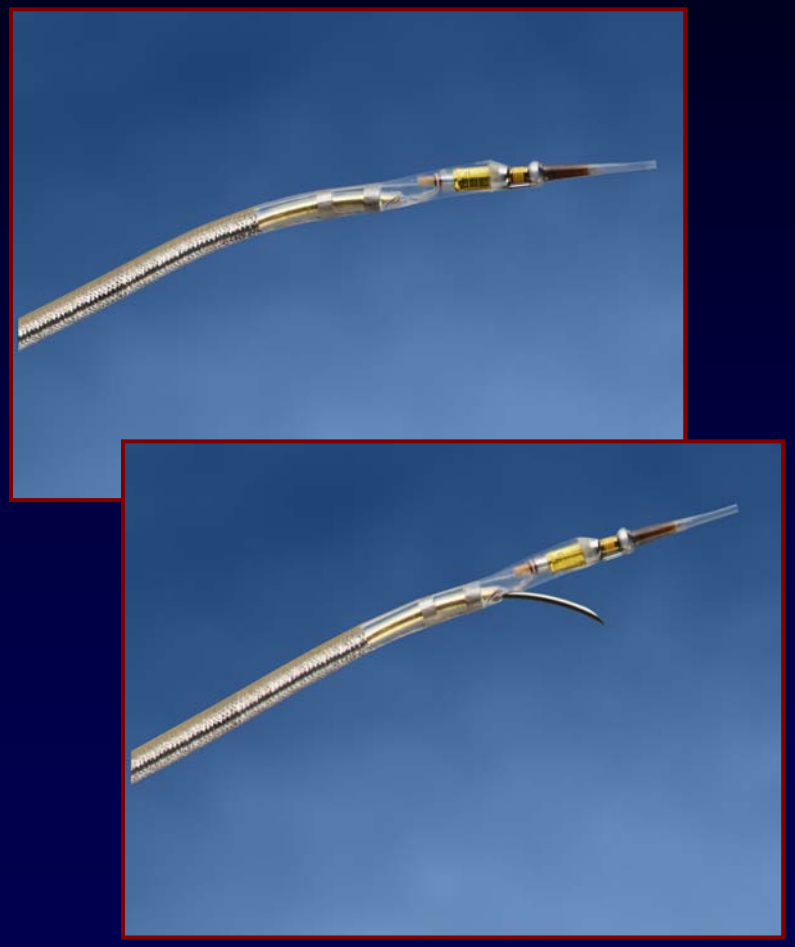


CrossPoint® Catheter IVUS image from within a dissection of the SFA

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



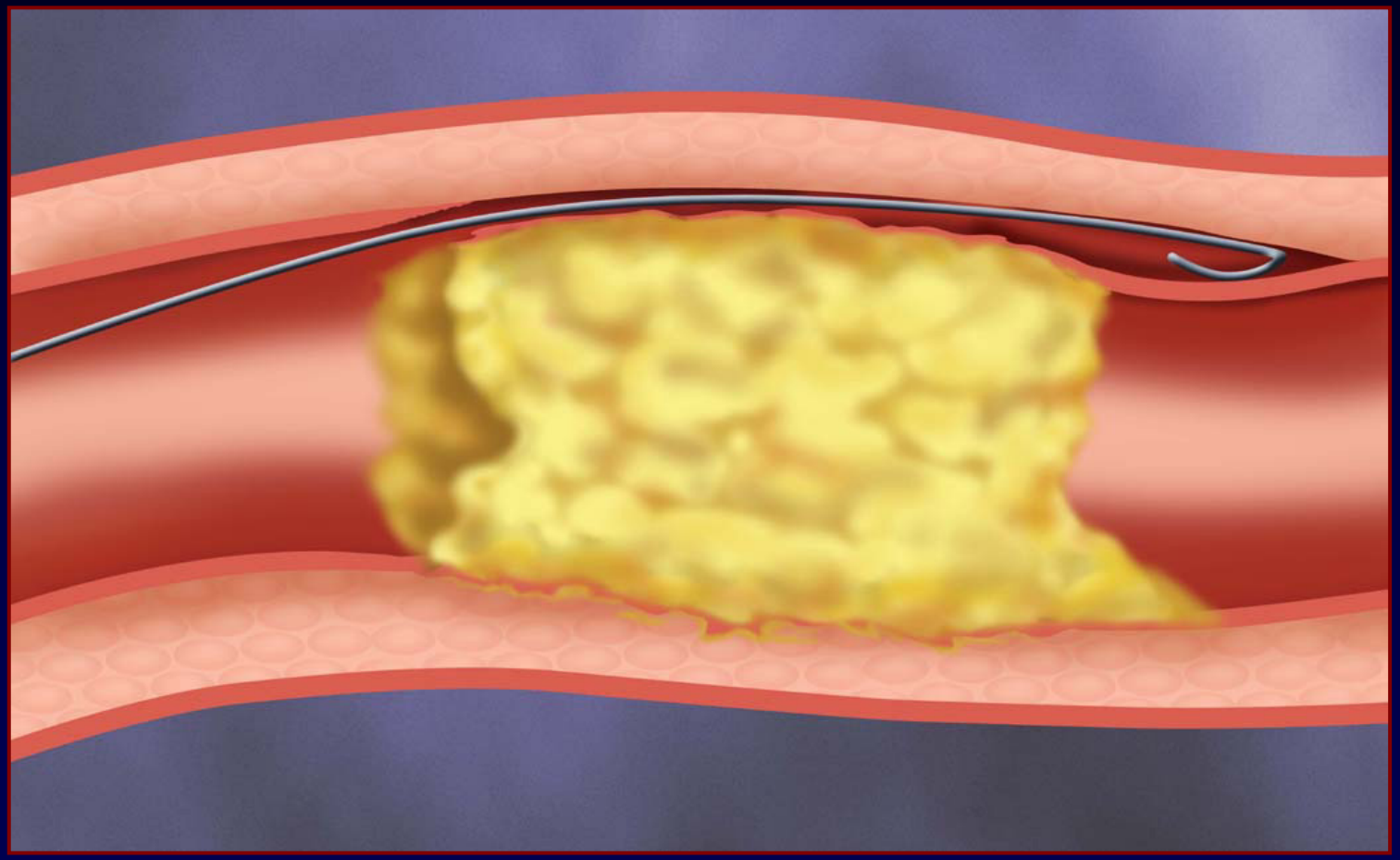
CrossPoint® Catheter

Key Features:

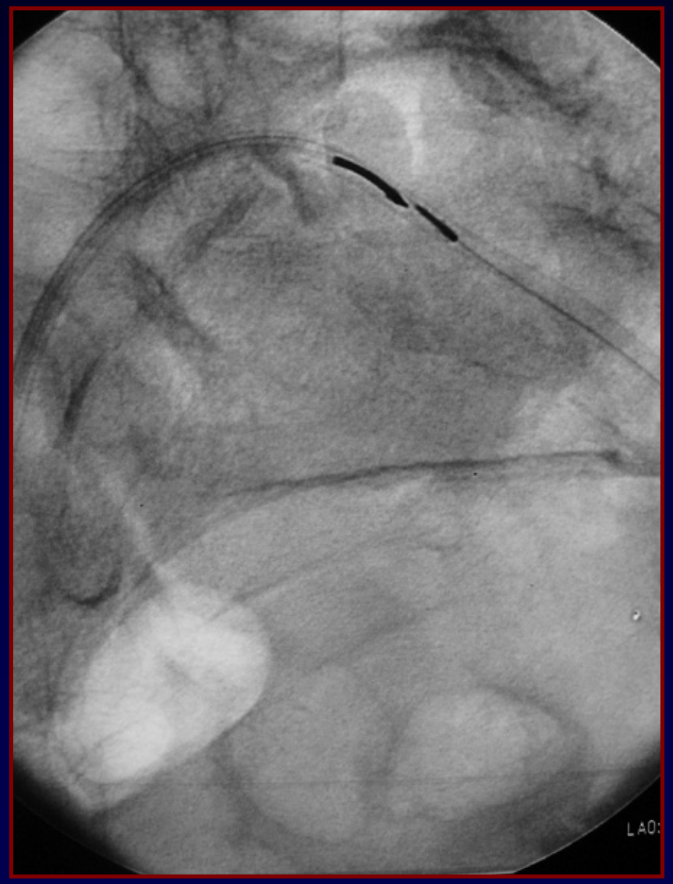
- 6.9F catheter tracks over 0.014” guidewire.
- Catheter length: 120cm
- Integrated 64-element, phased array IVUS with 20 MHz transducer.*
- Solid state versus mechanical

* For use with the Volcano/JOMED In-Vision IVUS console

True Lumen Return
Step 1: Guide Wire Entrapment



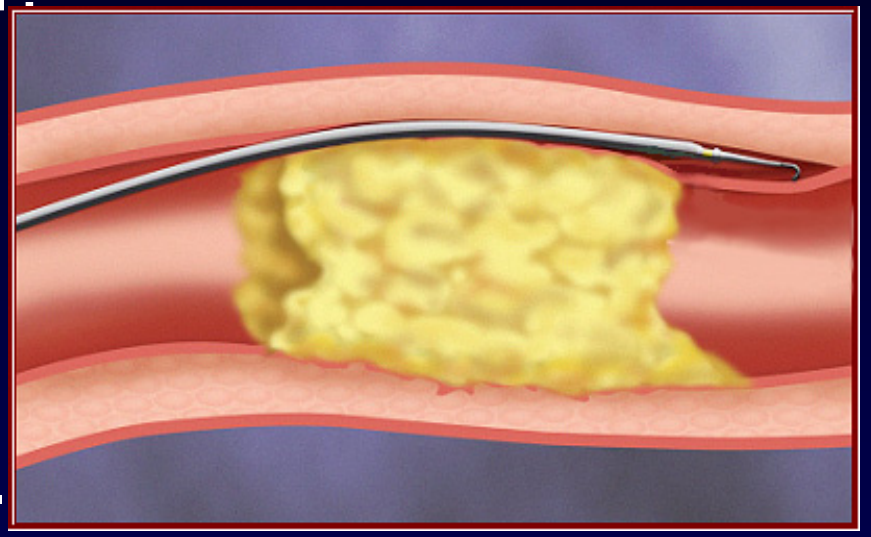
True Lumen Return
Step 2: Catheter Insertion



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*.

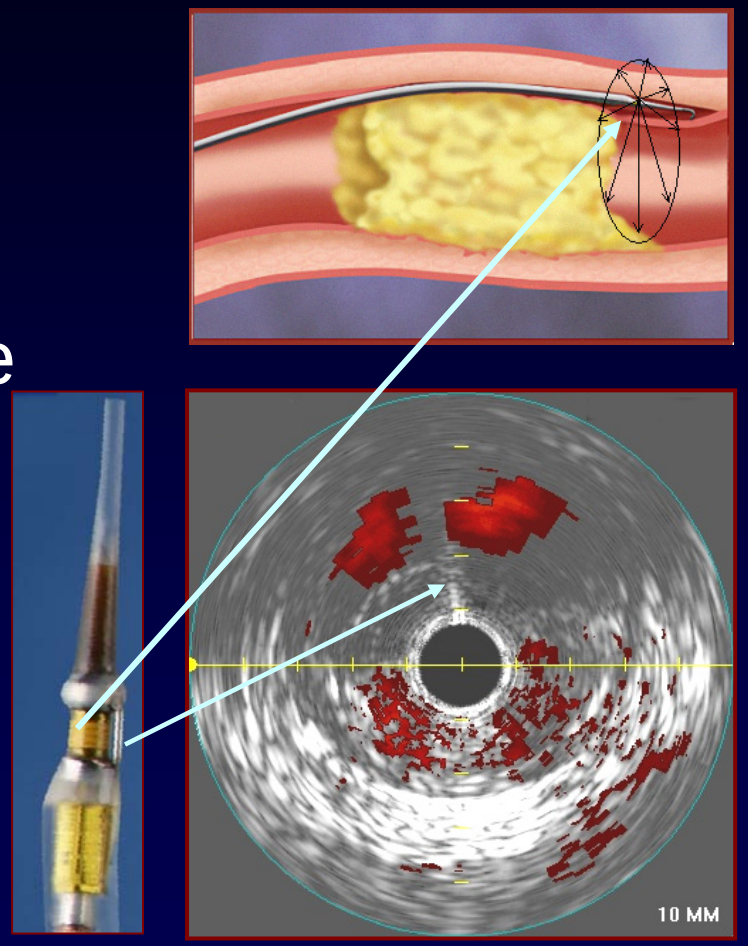


*Note: DO NOT use the CrossPoint catheter without a guide wire in place. Heavily calcified vessel wall may require small 20 mm diameter balloon dilation prior to CrossPoint catheter use. The CrossPoint catheter is not intended to be used as a tunneling device through a total occlusion.

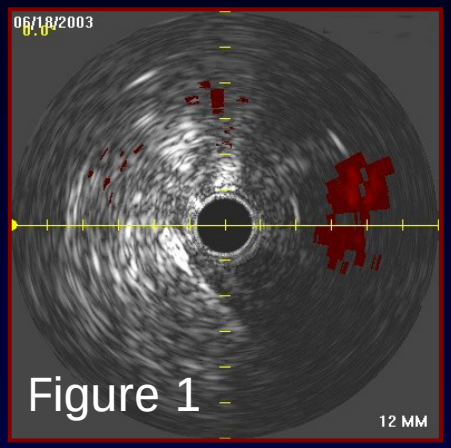
True Lumen Return
Step 3: Catheter Rotation

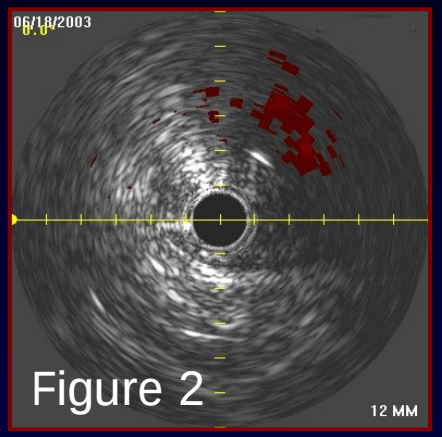
1. Using IVUS component-orient catheter toward true lumen by rotating the entire catheter.

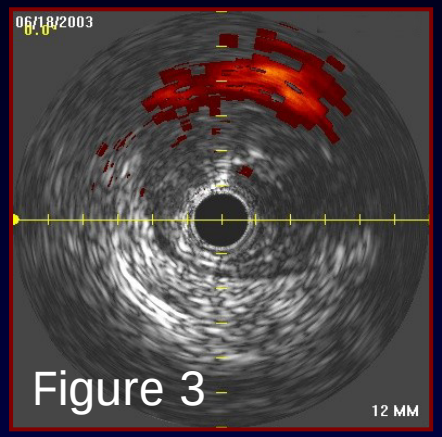
2. Verify position with fluoro.



True Lumen Return
Step 3: Catheter Rotation





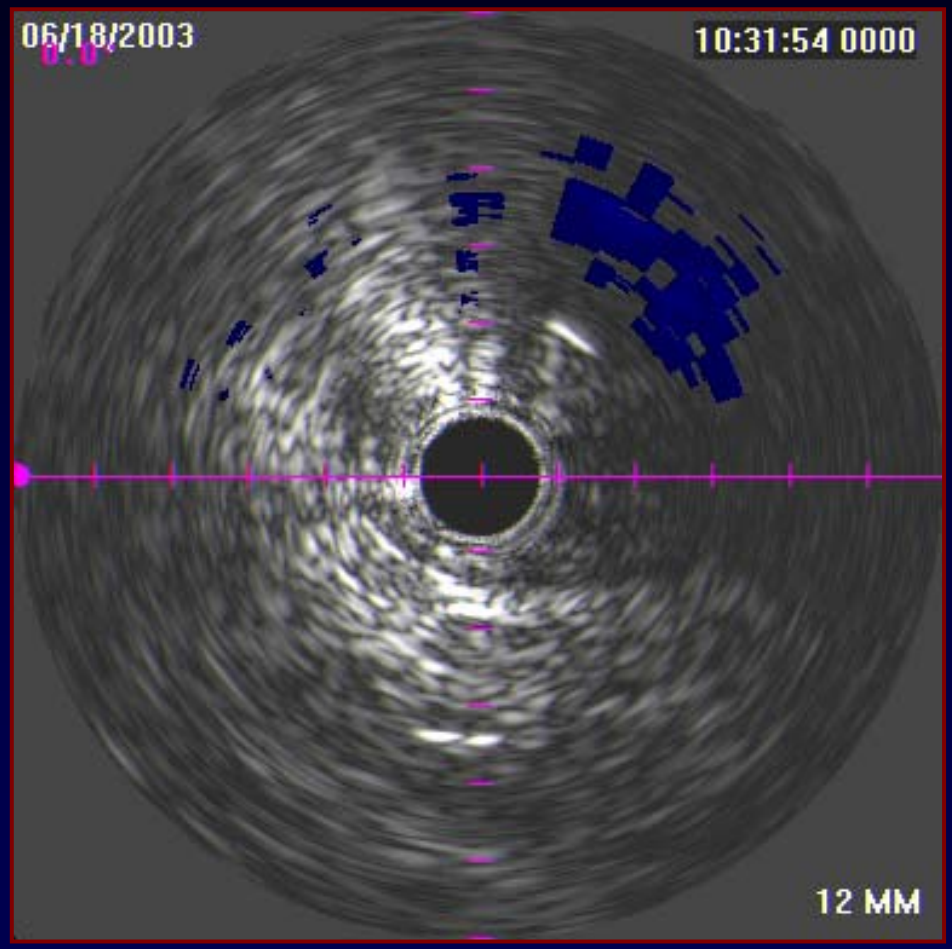


Orient catheter toward true lumen

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

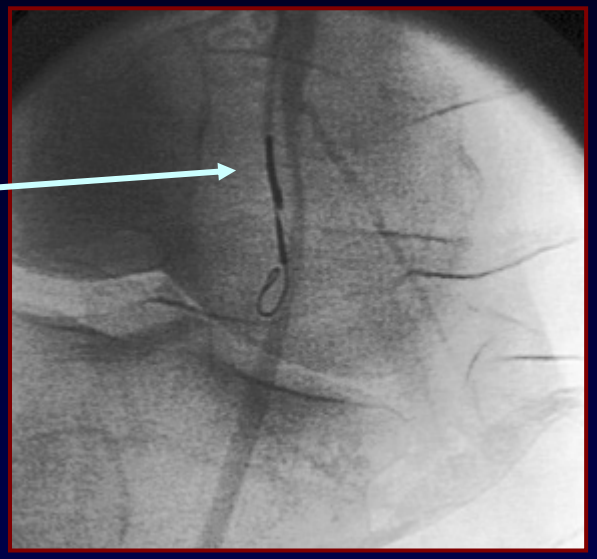
*Note: Comet tail will remain in 12:00 position and anatomy will rotate. Rotate the catheter no more than 180° in clockwise or counter-clockwise direction. Change direction as required.

True Lumen Return
Step 3: Catheter Rotation

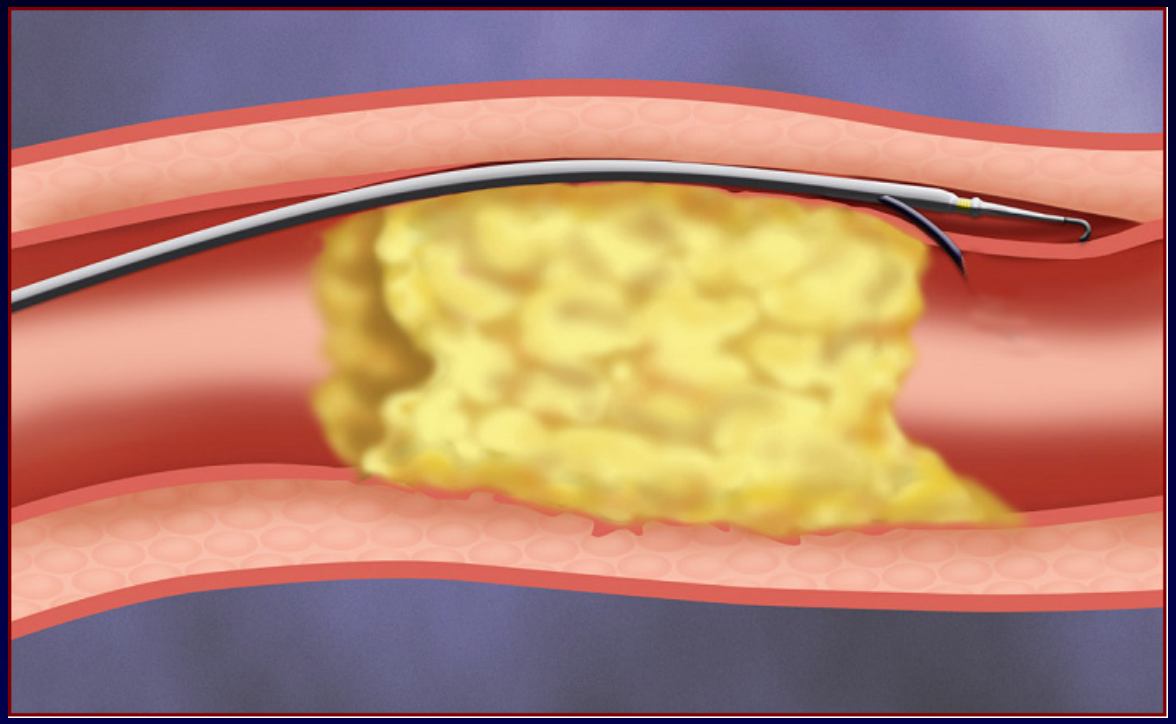


True Lumen Return
Step 3: Catheter Rotation

Platinum iridium needle housing facilitates catheter orientation toward true lumen



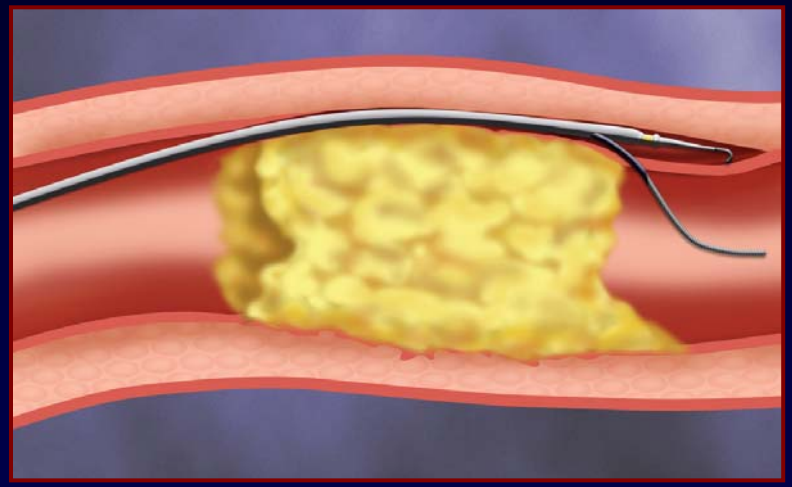
True Lumen Return
Step 4: Deploy Needle



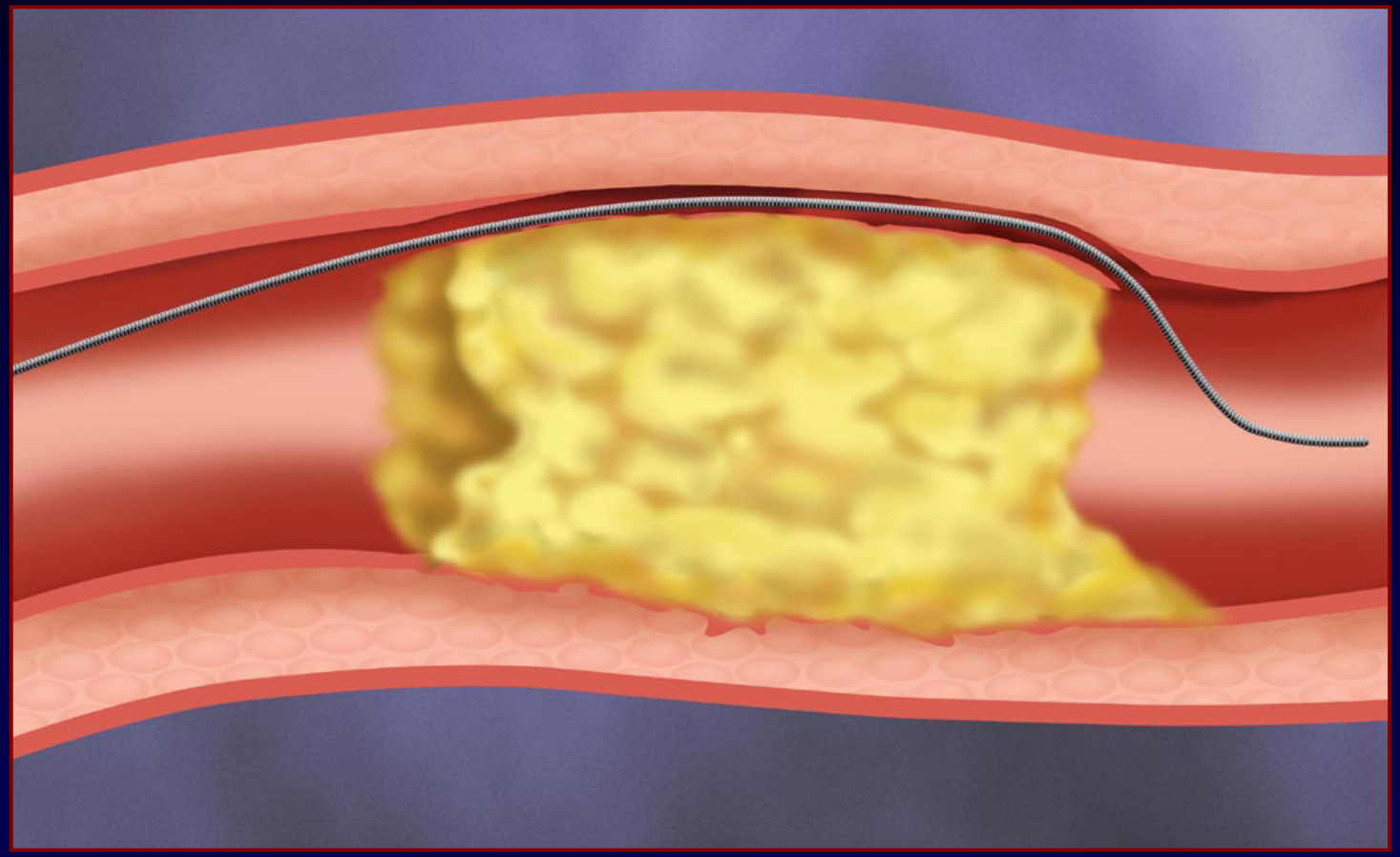
True Lumen Return
Step 5: Pass Guide Wire

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.

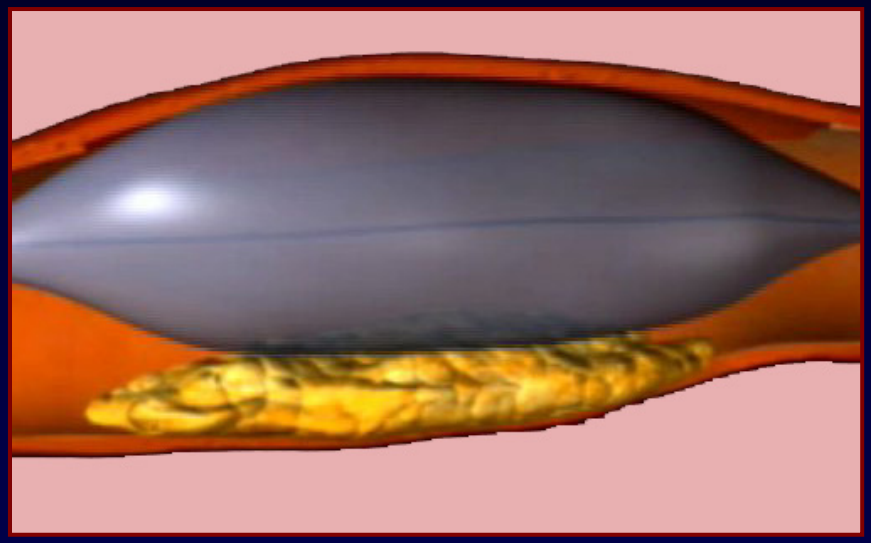


True Lumen Return
Step 6: Remove the CrossPoint



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

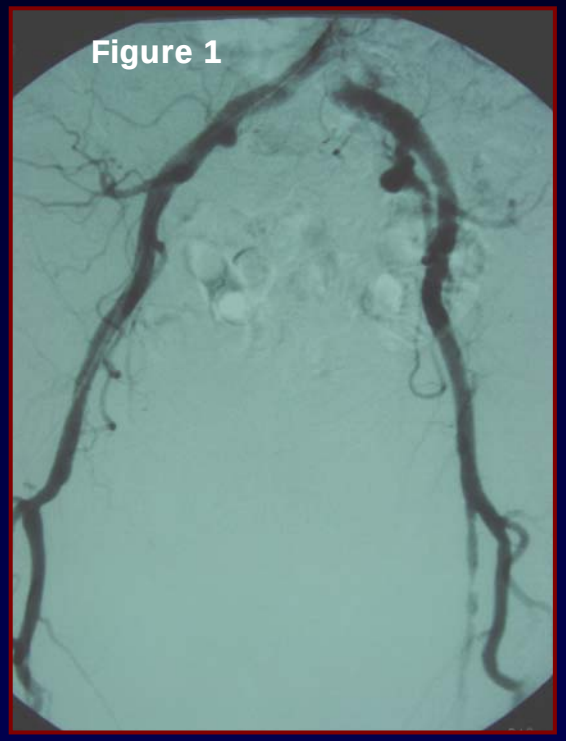
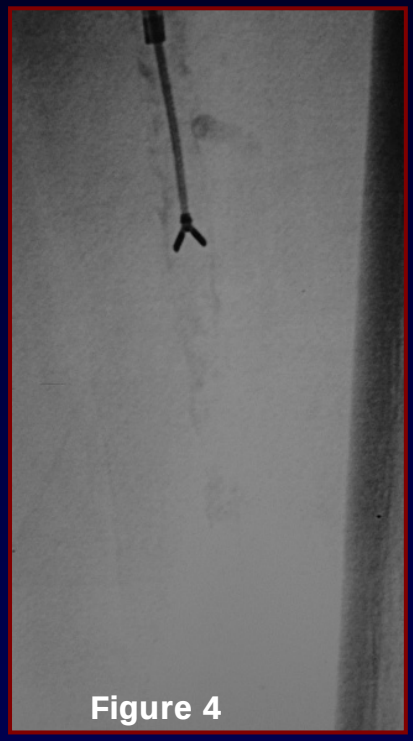


Figure 1 and 2: Total occlusion of the left SFA with dense calcification

* 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

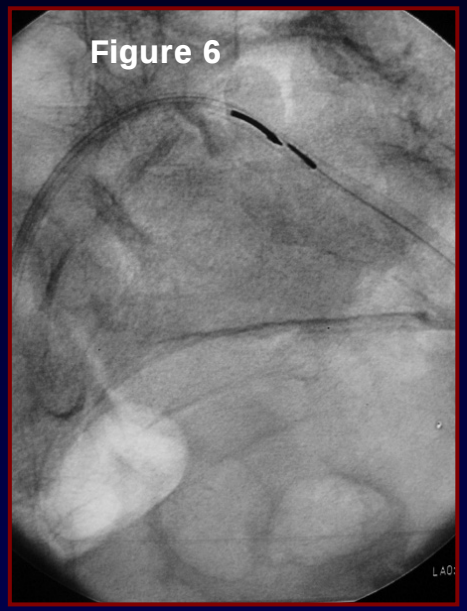


Figure 6: CrossPoint catheter around bifurcation

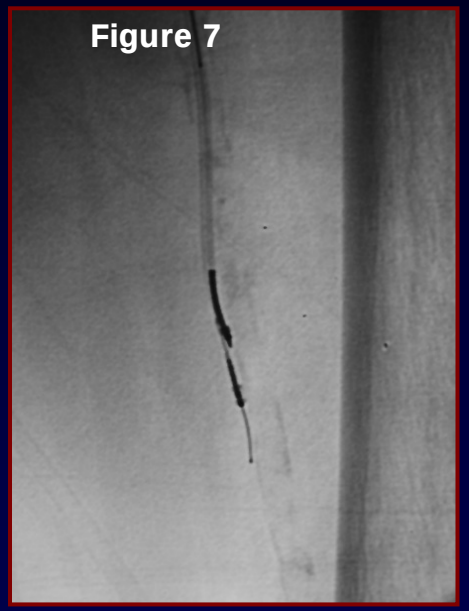


Figure 7: CrossPoint catheter in subintimal space

* Images courtesy of Dr. Michael Dake, Stanford University Medical Center

True Lumen Return: Controlled Re-entry: SFA

Figure 8: IVUS image for needle deployment

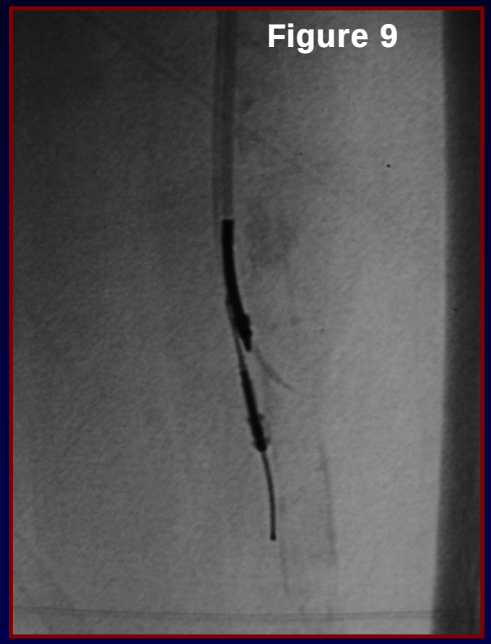


Figure 9: Needle deployed

Figure 10: Guidewire into true lumen

* Images courtesy of Dr. Michael Dake, Stanford University Medical Center

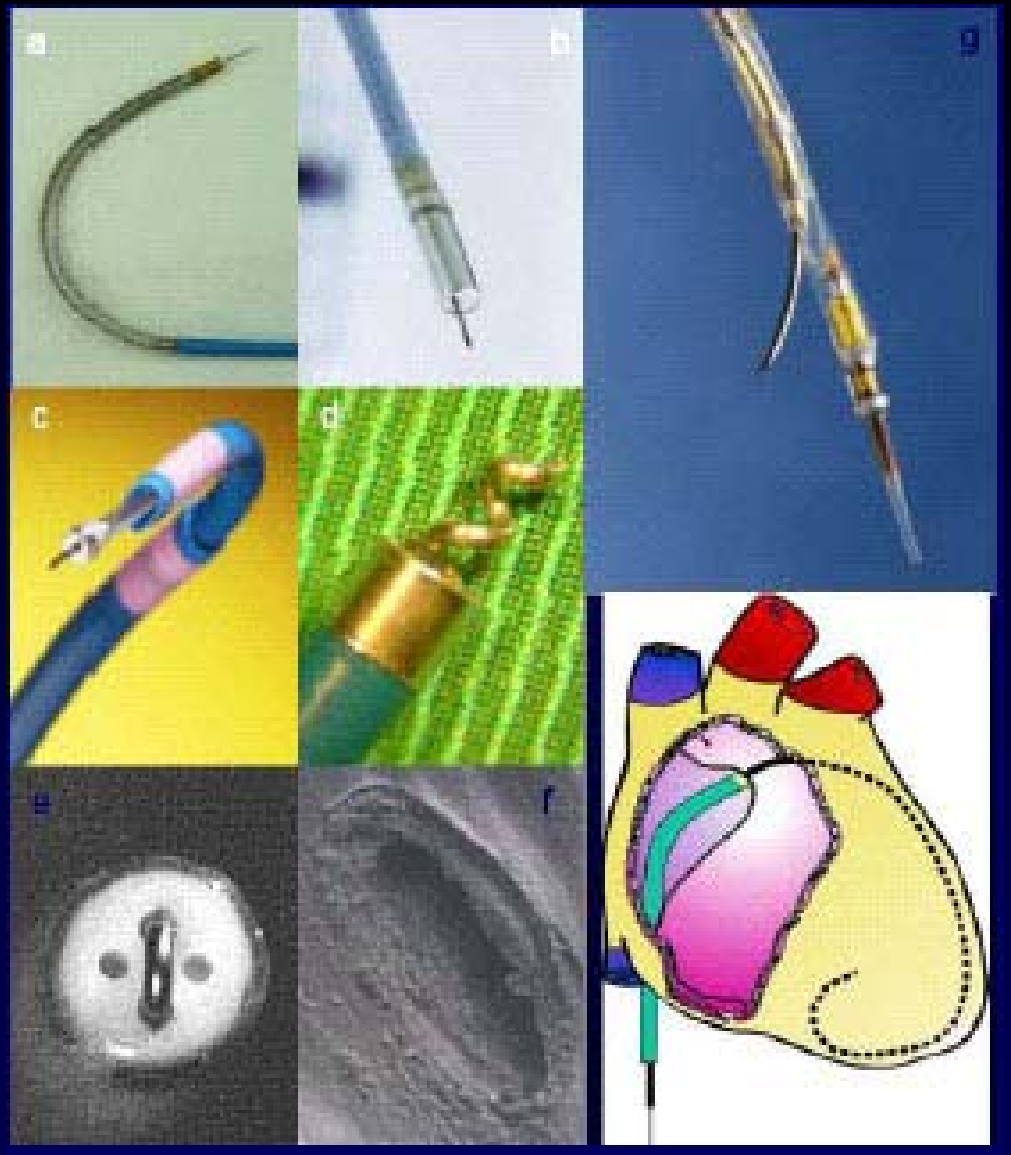
True Lumen Return: Controlled Re-entry: SFA

Before

After

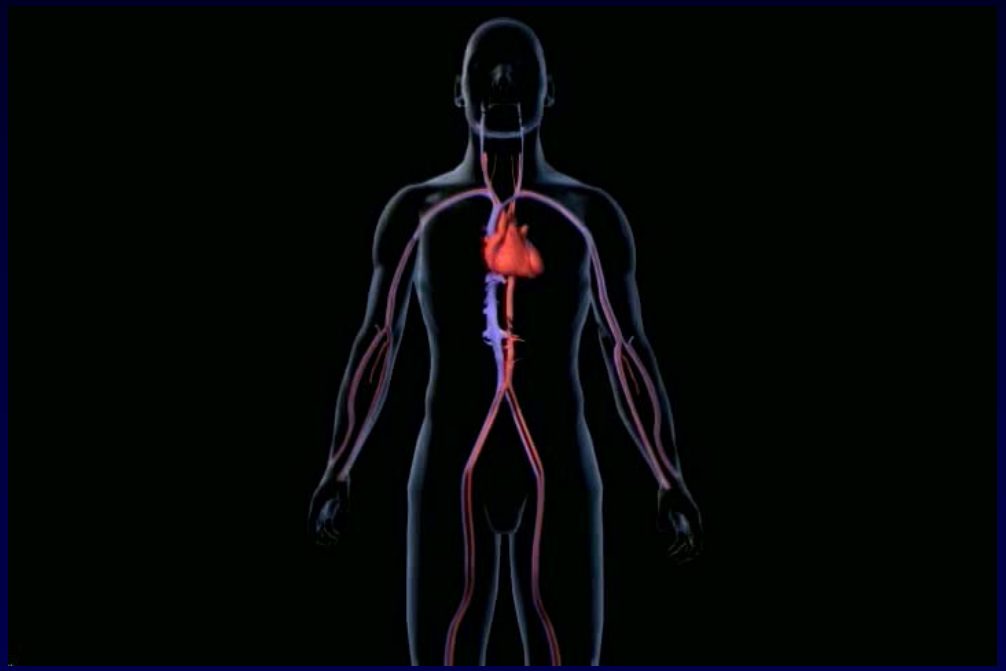
* Images courtesy of Dr. Michael Dake, Stanford University Medical Center

Myocardial Delivery Devices



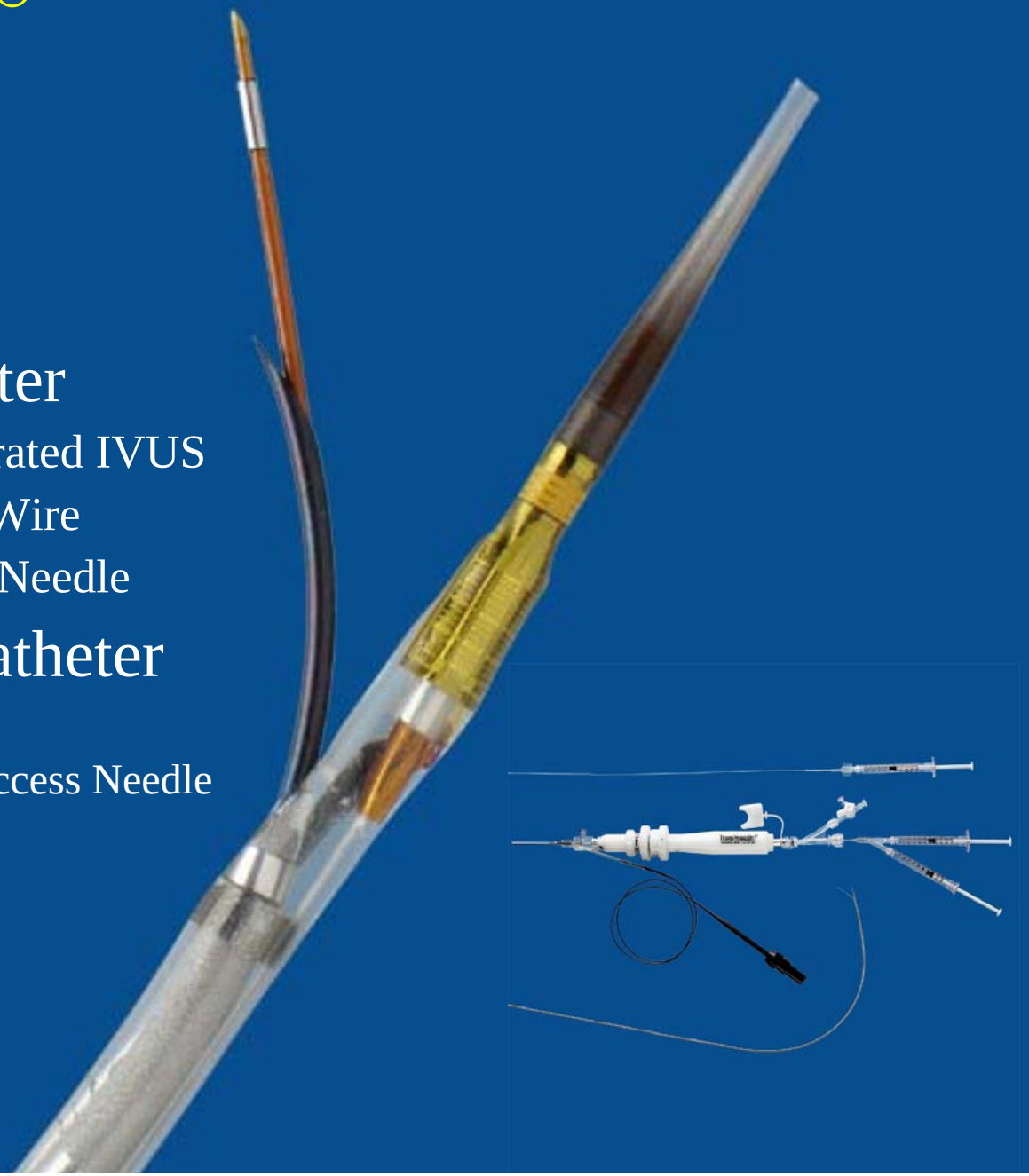
Myocardial Repair

TransAccess® Delivery System

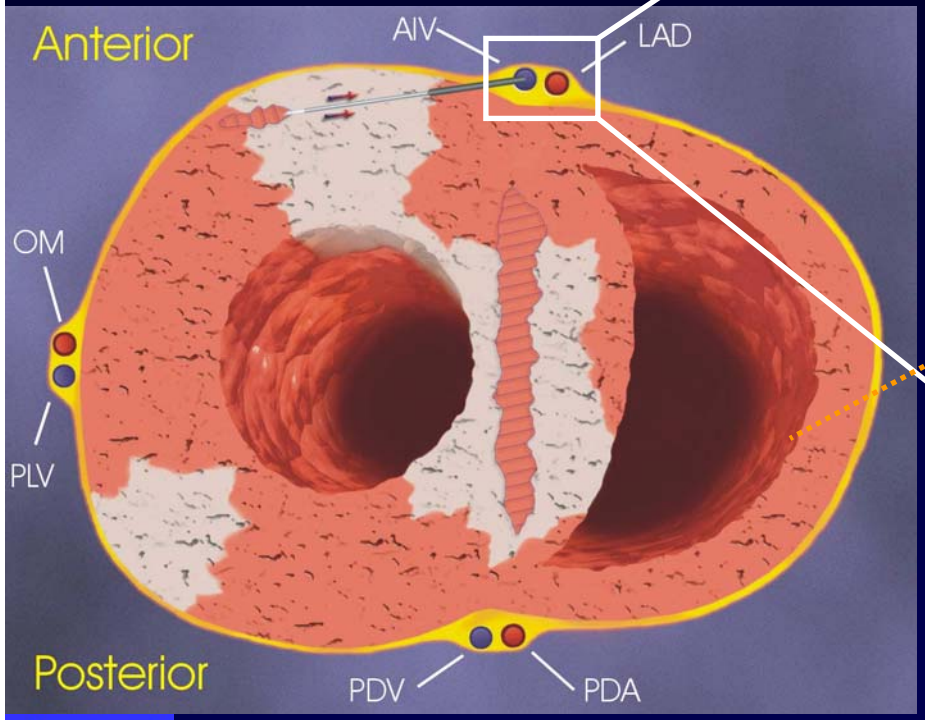


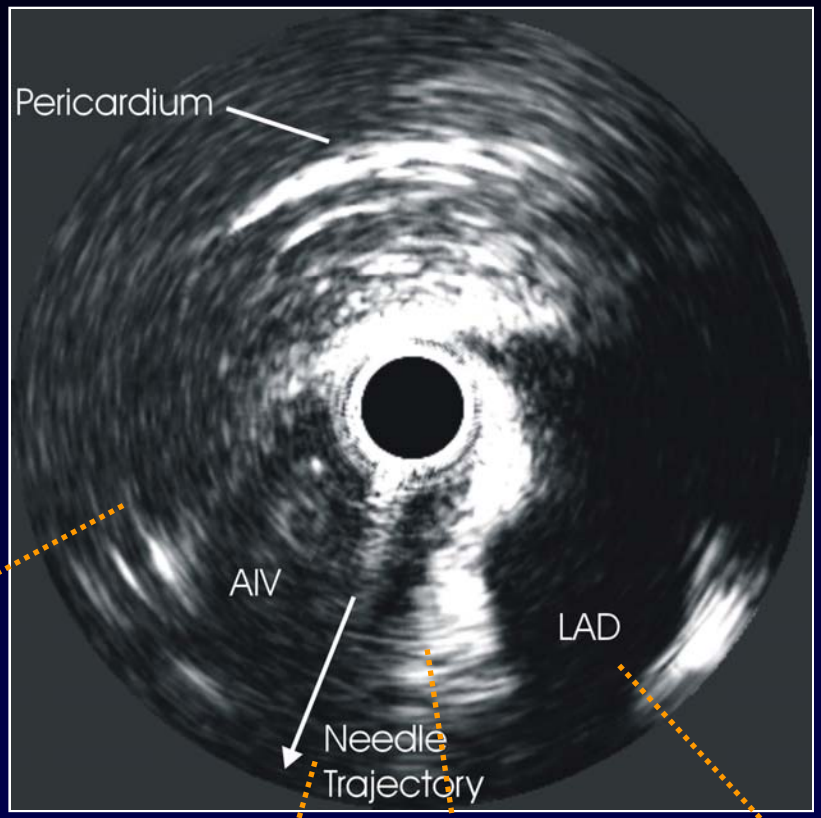
TransAccess® Delivery System

- 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



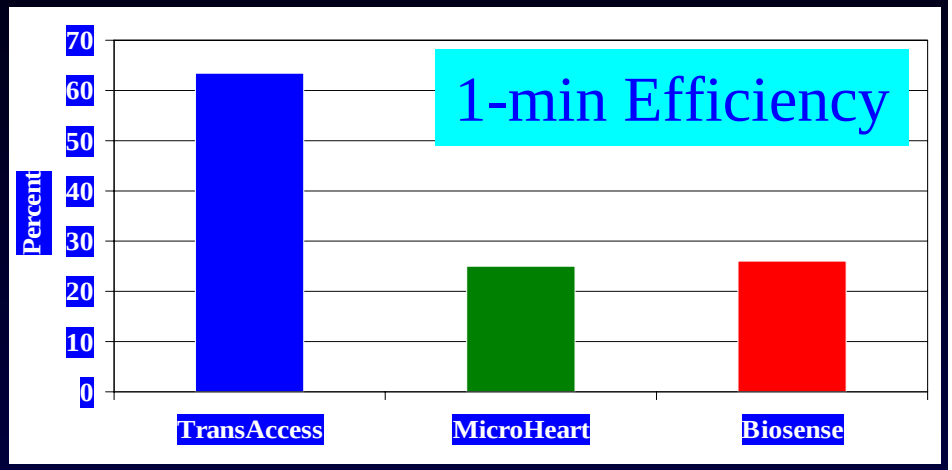


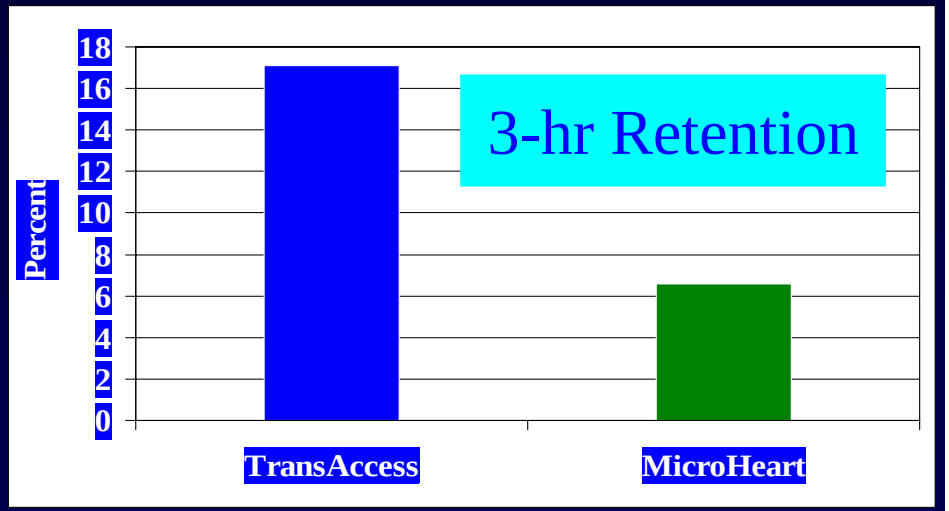
Anterior Wall

Septum

Pre-Clinical Testing: Efficiency and Retention

- Erasmus University Study
  - Porcine model
  - N = 4 Animals
  - N = 10 injections total
  - TC^{99}-labelled $VEGF_{165}$

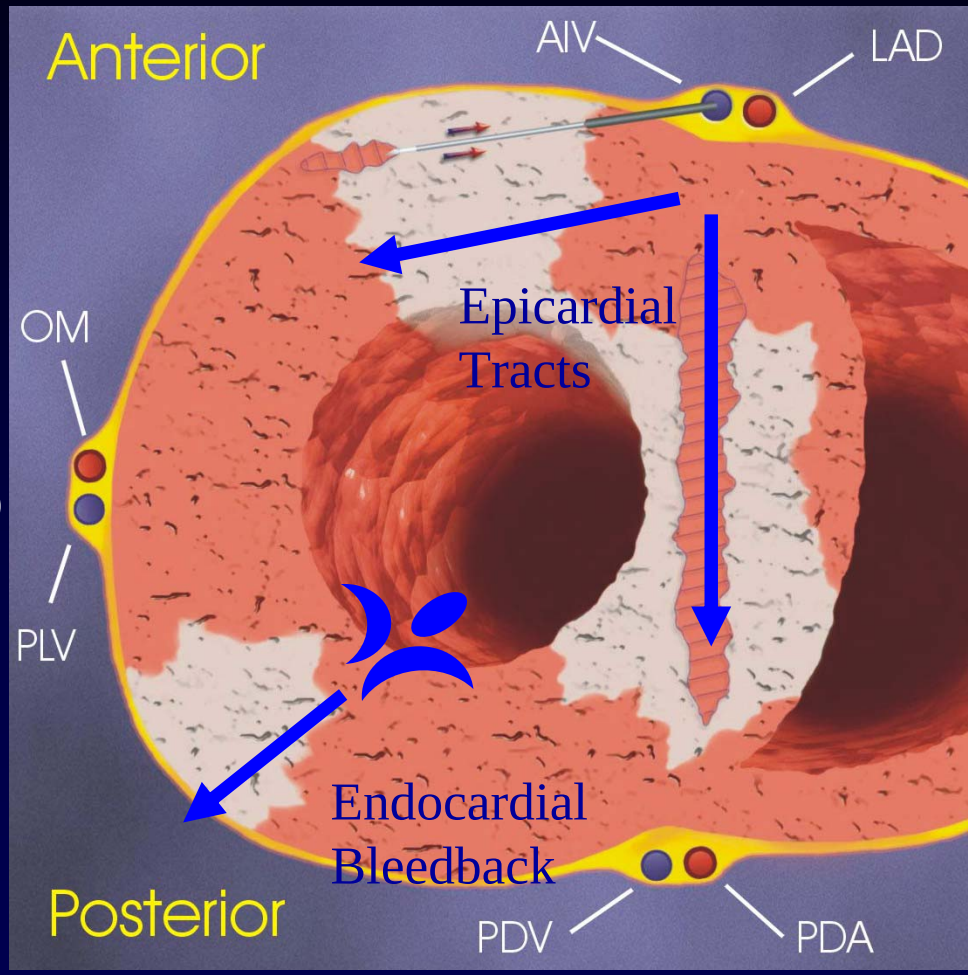




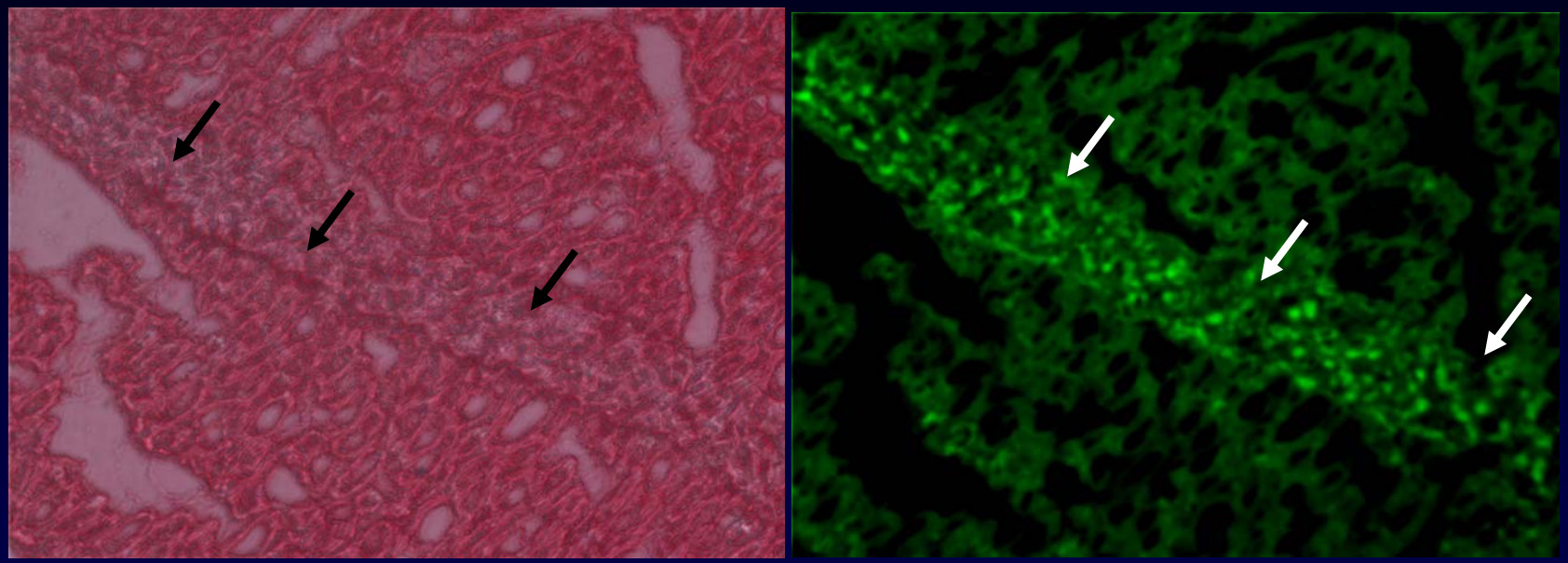
PCR 2002 by P. Smits with data obtained via same protocol from AHA Abstract entitled "Efficiency Between a NOGA and a Fluoroscopy Guided Transendomyocardial Injection Catheter," AHA Abstract: Scientific Conference On Therapeutic Angiogenesis & Myocardial Laser Revascularization, Jan. 2001

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 -



- ***Thompson et al.*** Percutaneous transvenous cellular cardiomyoplasty: A novel nonsurgical approach for myocardial cell transplantation. *J Am Coll Cardiol,* 2003, 41:11.