2022 MID-ATLANTIC CONFERENCE

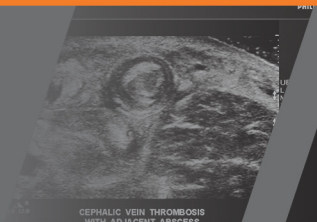
10th ANNUAL CURRENT CONCEPTS IN

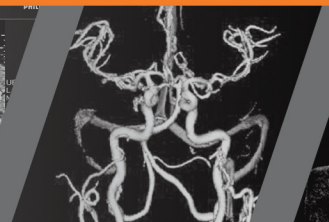
VASCULAR THERAPIES

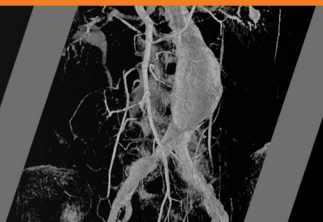
2022

Hilton Virginia Beach Oceanfront
Virginia Beach, Virginia

APRIL 28-30







Sentara Vascular Specialists

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VASCULAR THERAPIES

2022

Robotic Intervention

Lessening radiation exposure & lead time, while improving precision

Dr. Ron McKechnie, FACC, FSCAI

Interventional Cardiologist

Sentara Cardiology Specialists

Occupational Hazards in the Cath Lab

Interventional cardiologists have the highest radiation exposure of any medical professional[1]

CAROTID DISEASE[4]

- Accelerated vascular aging and early atherosclerosis in the carotid vessel
- Mean age of exposed workers was 45 years

10-15 YEARS IN PRACTICE

CATARACTS[7]

- 3X relative risk of posterior subscapular lens changes compared to nonexposed individuals
- Changes due to radiation exposure and not aging

16 YEARS IN PRACTICE

ORTHOPEDIC INJURIES

- **60%** incidence of spine issues after 21 years in practice[5]
- **28%** report hip, knee or ankle problems[6]
- **33%** miss work due to orthopedic issues[5]

21 YEARS IN PRACTICE

BRAIN TUMORS[8]

- In a study of brain tumors in interventionalists, where tumor location is known, **86%** occur on the left side.

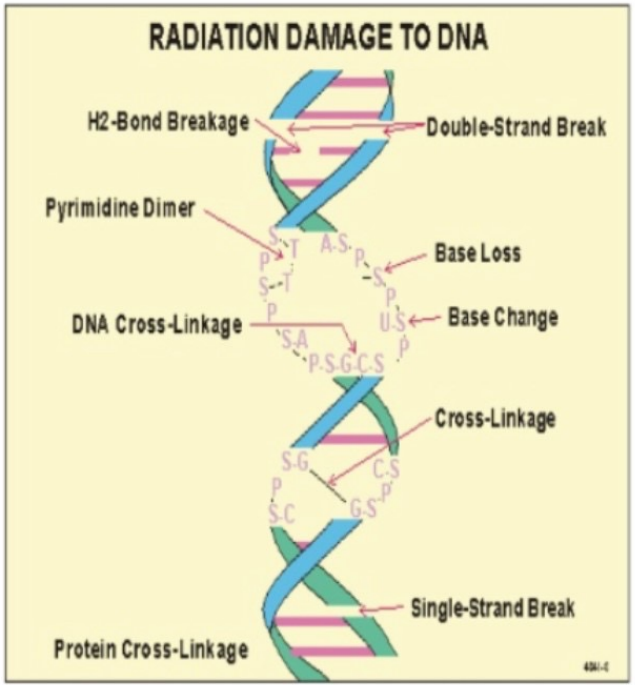
12-32 YEARS IN PRACTICE

LEFT BRAIN
RADIATION EXPOSURE

4.7X
Higher than Right Brain Exposure[9]

DNA Damage

Relevance



Physical Mutagens

Radiation was the first mutagenic agent known; its effects on genes were first reported in the 1920's.

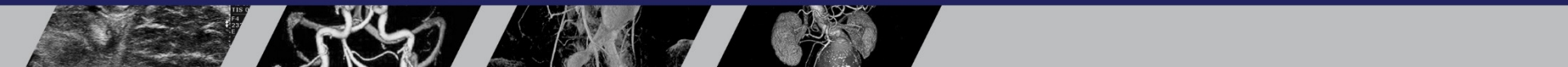
Radiations are of two types.

I. EM radiations

II. Ionizing radiations

Radiation Exposure

- Annual Average: 50-200mSv, (Cosmic = 3mSv/year)
  - 500-2,000 chest x-rays in a year
- Career exposure to Brain: 1,000mSV
  - 10,000 chest x-rays in a career
- ALARA: “As low as reasonably achievable”
  - Guiding principle of diagnostic and interventional procedures using radiation, including fluoroscopy.



Reducing exposure to the physician and staff

Corindus GRX Robotic System
-
95%

DoseAware instant feedback system
-
30%

Eggnest™ table mounted system
-
92%

Zero-Gravity
-
97%

Ceiling mounted shield
-
80%

Vertical shield
-63%

2020

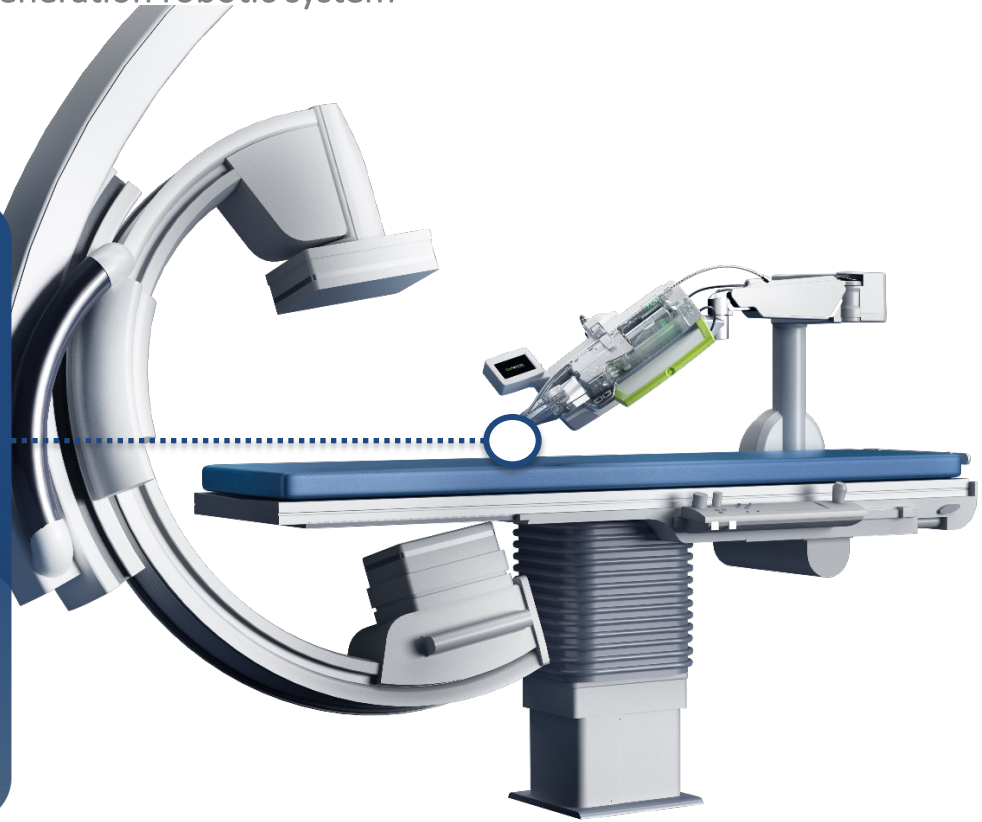
Robotics in the Interventional Suite

Second-generation robotic system

Corindus – CorPath GRX

BEDSIDE UNIT

- Optimized bedside unit for radial access
- Simple setup & in-procedure workflow
- Devices fixed during intervention
- Imaging and device agnostic



INTERVENTIONAL WORKSTATION

- Precise robotic control of
  - ✓ Guide catheter
  - ✓ Guidewire
  - ✓ Rapid exchange catheter
- Radiation-shielded workstation
- 4K resolution monitor

CorPath GRX Protection

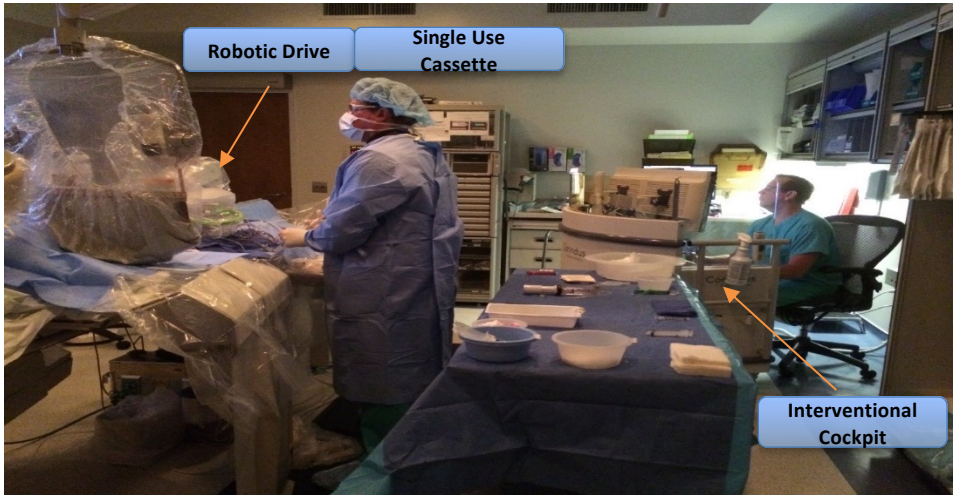
95.2% radiation reduction to the physician when using CorPath Robotic System[1^]

- Radiation shielded work station reducing radiation exposure
- Comfortably seated, without lead, potentially reducing orthopedic injury
- Enhanced visualization with physician's close proximity to the monitors

1Weisz G, et al. Safety and Feasibility of Robotic Percutaneous Coronary Intervention. J American College of Cardiol, 2013, Vol 61, No. 15: 1596-1600

^Data gathered using CorPath 200

Cath Lab layout/
with a Robotic System



CorPath vs Manual Staff Radiation Exposure[1]
- 91% reduction in physician radiation exposure (P=0.015)
- 15% reduction in technician radiation exposure (NS)

1 Campbell P., et al. Staff Exposure to X-ray during PCI: Randomized Comparison of Robotic vs Manual Procedures. Catheter Cardiovasc Interv April 2016; 87: S80-81.

Radiation & Orthopedic Protection in Robotic-assisted PVI

- Results of the RAPID II Study show significant benefit to physicians & staff

Problem

- Long, complex procedures result in significant:
  - Radiation exposure
  - Time in heavy lead protective gear
- Occupational hazards of peripheral interventions include:
  - Radiation damage (cancer, cataracts, vascular disease)
  - Severe orthopedic injuries

Solution

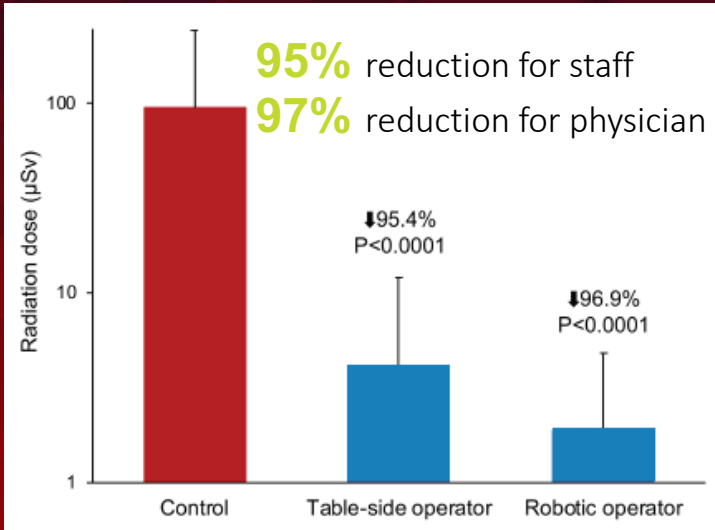
- Position physician in a radiation-free environment
- Reduced time in lead may reduce orthopedic burden
- Enhanced visualization and close up view of angiography

Rapid II Results

- 20 subjects with PAD treated via robotic-assistance
- Measured radiation dose for physician and tableside operator
- Average fluoroscopy time 7.3 ± 3.3 minutes
- Achieved significant radiation reduction by modifying tableside operator position & workflow

Mahmud,E et al. JACC 72, 13 Supp, B178, 9/2018

Radiation Reduction for Physician & Staff



Robotic precision

Modifiable Physician-dependent procedural factors

–***Measurement*** *(*Submillimeter)
–***Placement*** (One-millimeter Advancement/Retraction)
–***Control*** (Device fixation-Controlled movement)

Procedural Automation

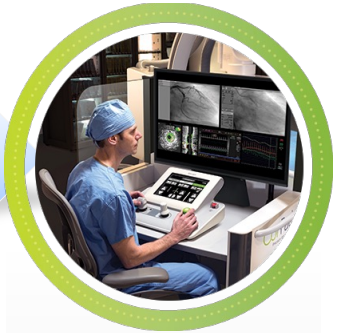
- Automating what were previously manual procedures and incorporating them into the control system
  - *May lead to improvements by:*
    - Improved procedural efficiency (reduction in time/ labor savings)
    - Improved proficiency/elimination of mistakes
    - Improved outcome consistency and equipment reliability
    - Capturing, analyzing and preserving operator knowledge
    - Enhancing patient outcomes

Traditional vs. Robotic Intervention

Today's Cath Lab Environment

- High radiation exposure
- Significant fatigue and orthopedic strain

Manual Intervention	STEPS	Robotic-assisted Intervention
Struggle to see angiography	Assess Anatomy	Close proximity, ergonomic visualization
Trial & error, wire spinning	Navigate	Automated robotic techniques
'Eyeball' estimate	Measure Anatomy	Sub-millimeter measurement
Manual adjustment	Position Stent	1mm precise positioning
Devices loose during inflation	Deploy Stent	Devices fixed during deployment



Robotic Cath Lab

- Shields from radiation
- Potential to reduce fatigue and orthopedic strain

technIQ™ Series

NEW

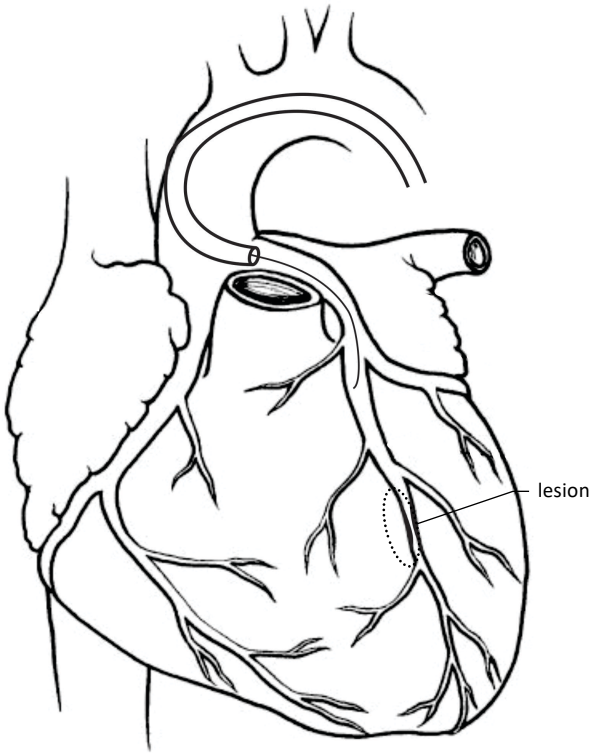
The **technIQ** Series is a set of automated robotic movements designed for the CorPath GRX System. Rotate on Retract (RoR) is the first automated move in the series.

Rotate on Retract (RoR)

- RoR allows the physician to quickly navigate to a targeted lesion by automatically rotating the guidewire upon joystick retraction.

Iterative approach improves navigation and variability

- Superb Rotation
- Patent pending



RoR: How it Works

Challenge

How to navigate the guidewire to the target location effectively, predictably and quickly?

RoR Joystick Control

System will perform an automated rotation on next retraction if the guidewire has first been advanced

First retraction automatically rotates GW clockwise

RoR: How it Works

Workflow

- User advances guidewire
- IF guidewire misses target branch
- User retracts while system automatically rotates
- User advances guidewire
- Repeat as necessary

Additions to techniQ Series

- Performance in models demonstrates standardization potential

Spin
Lesion crossing algorithm that automatically rotates guidewire in an oscillating motion while driving forward.

Dotter
Lesion crossing algorithm that incrementally advances and retracts working device while driving forward.

Wiggle
Navigation algorithm that automatically rotates guidewire in a reciprocating motion while moving forward (RoR enabled).

Constant Speed
Measurement algorithm that allows user to select a single, constant drive speed (selectable at 2 mms and 5 mms).

technIQ - Smart Procedural Automation

Spin

New introduction

SPIN

LESION CROSSING

To efficiently cross lesions in complex cases and difficult anatomies , Spin utilizes clockwise and counterclockwise rotations of the guidewire.

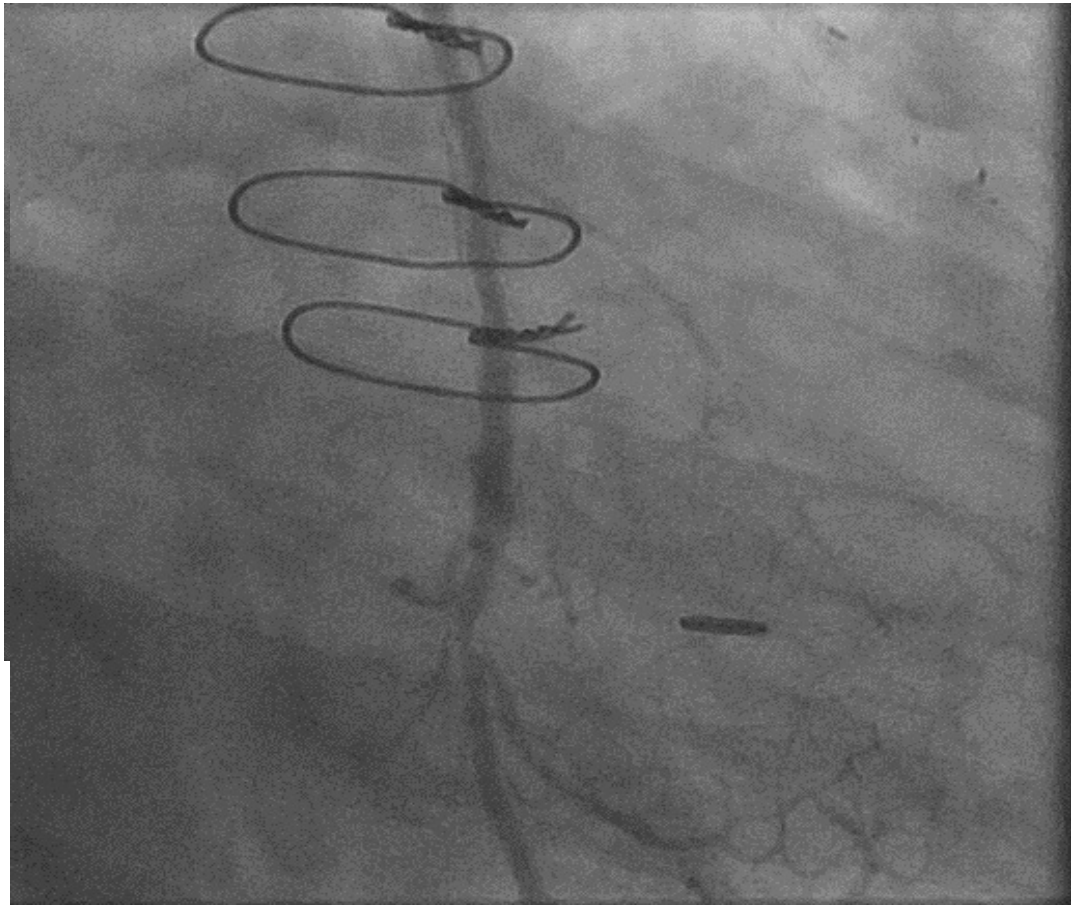
*technIQ is not commercially available in all countries. Their future availability cannot be guaranteed.

Case

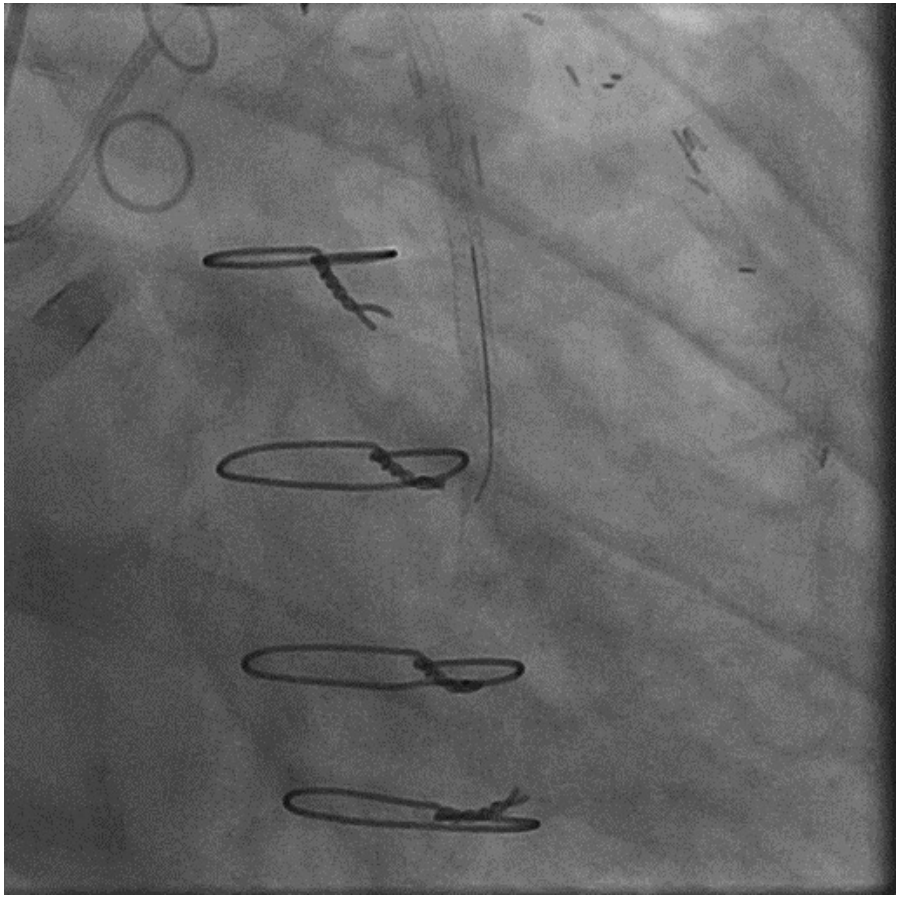
75% OM1 just beyond anastomosis of SVG

Stenting with CorPath GRX Robotic System (Corindus Vascular Robotics)

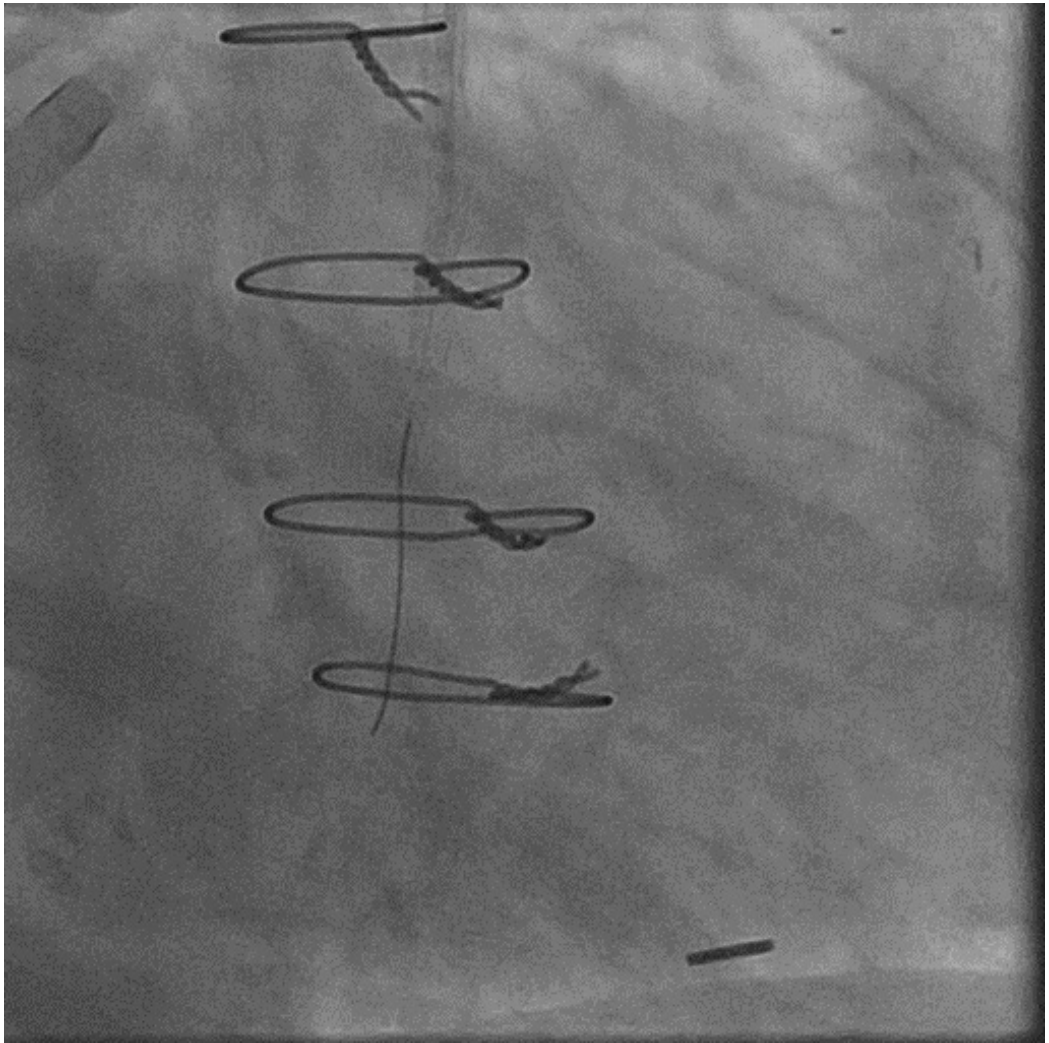
6 Fr RunWay AL2 SH Guide via L Radial approach (Boston Scientific)



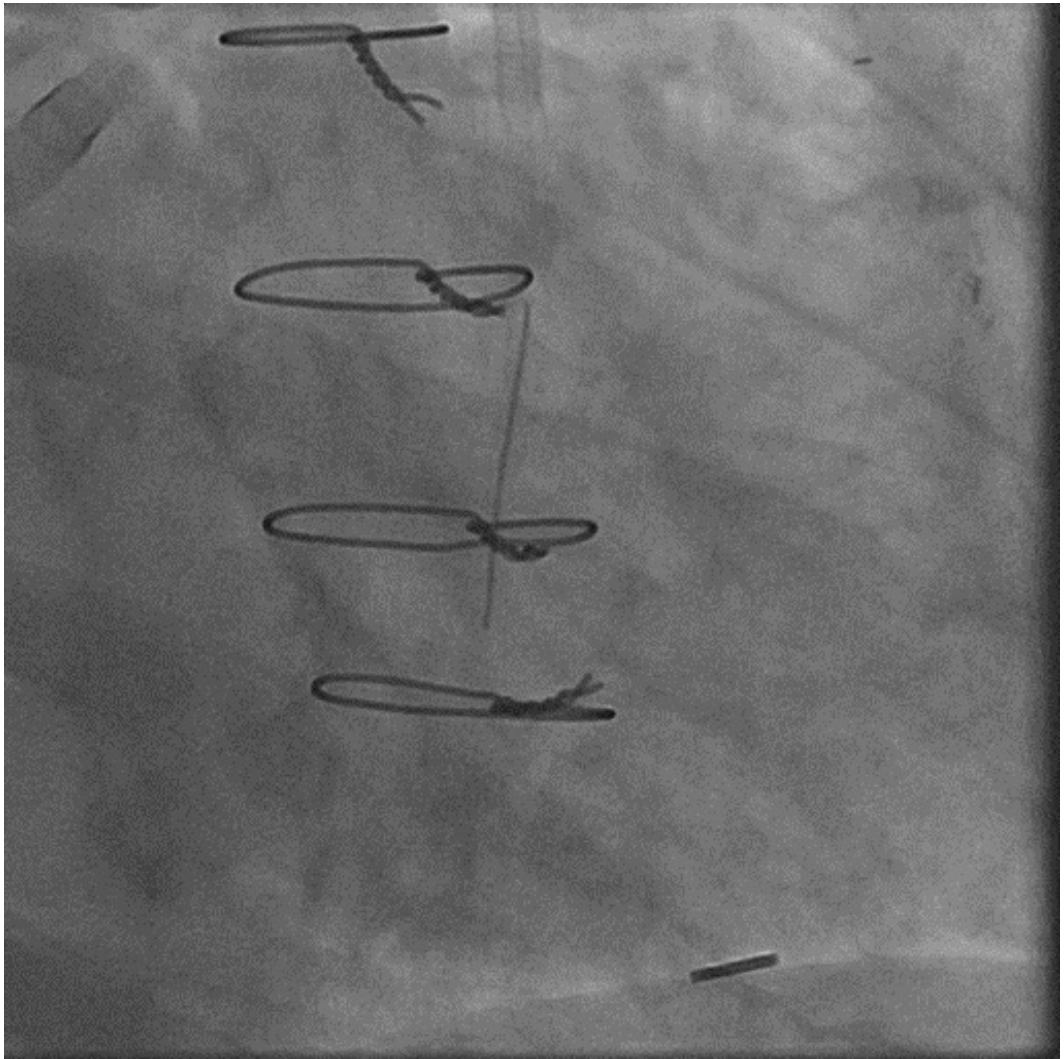
.014/180cm Runthrough NS Guide wire (Terumo) loaded into the CorPath
cassette drive unit robotically driven through the SVG



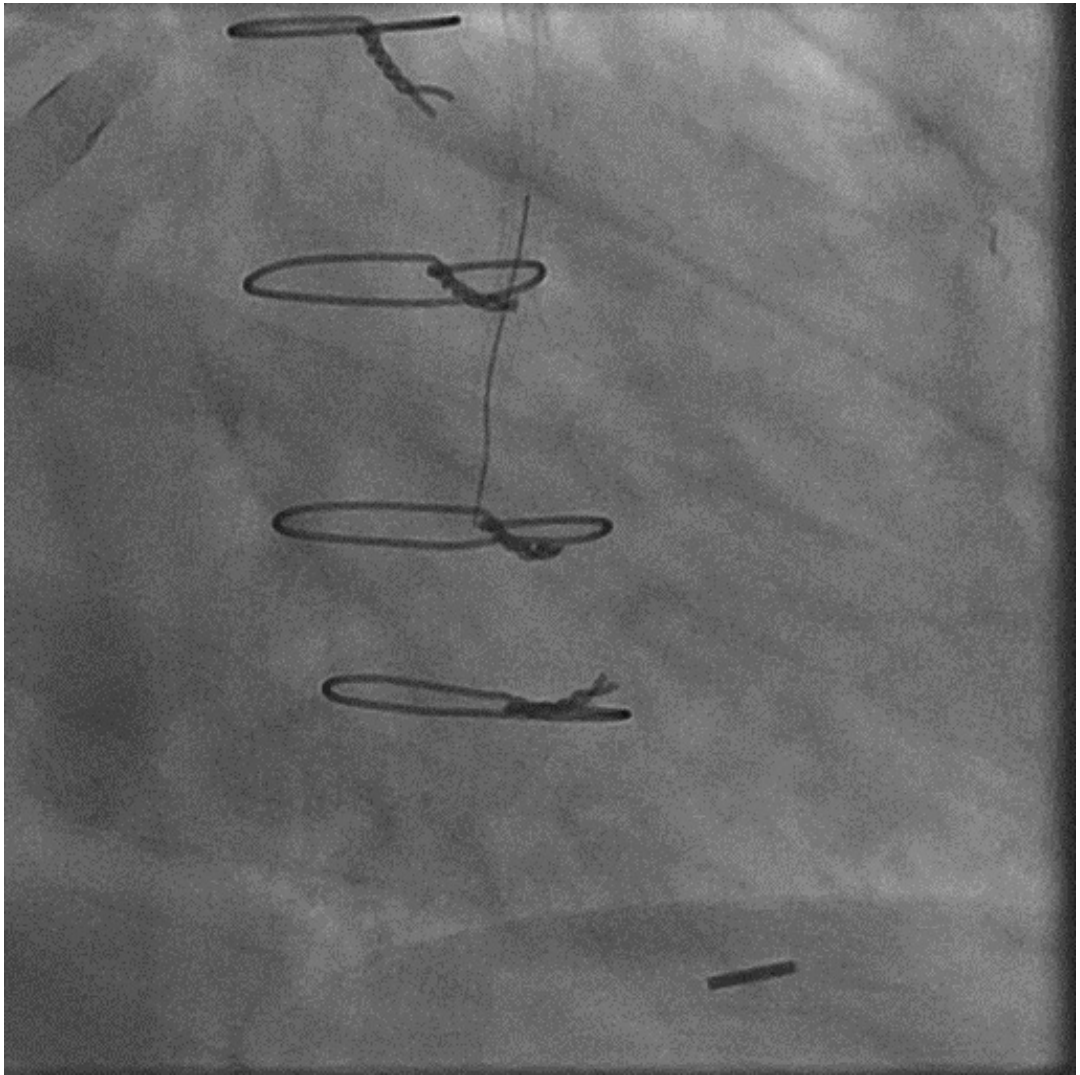
Guide wire enters a small distal branch vessel



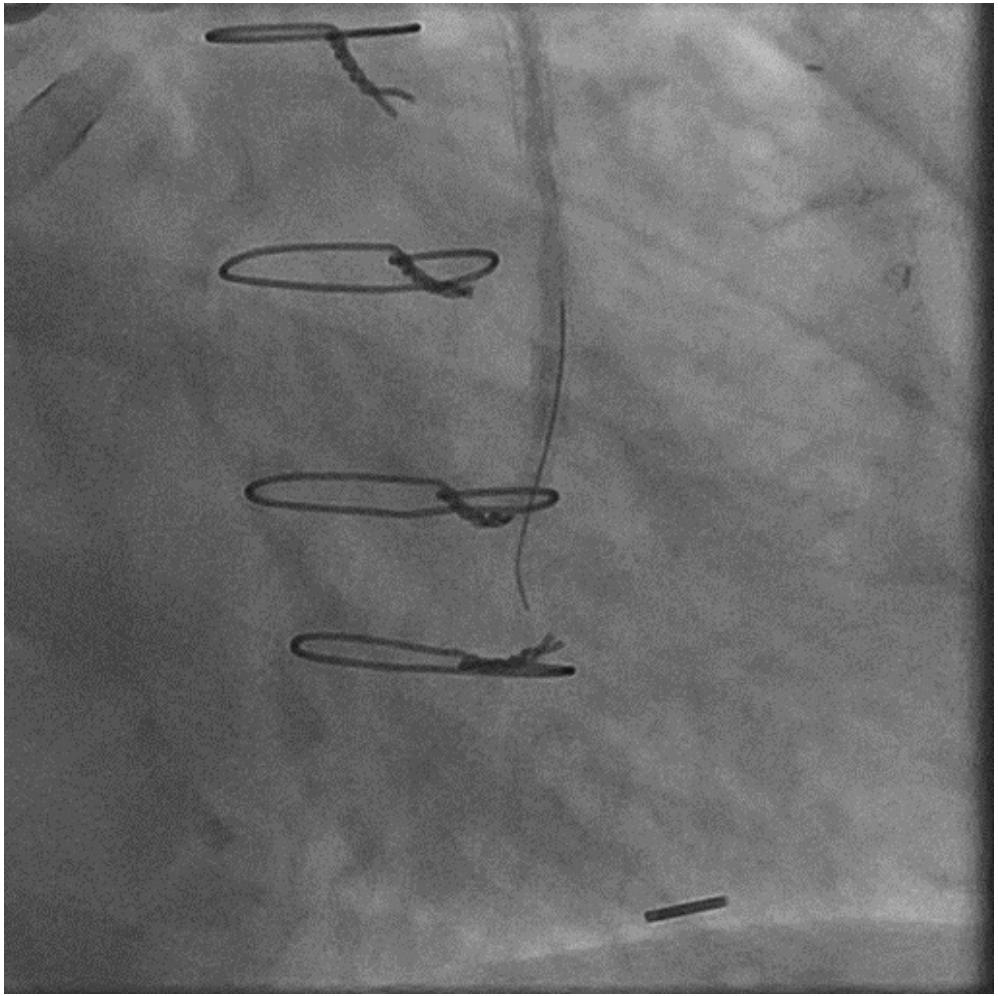
Guide wire retracted robotically



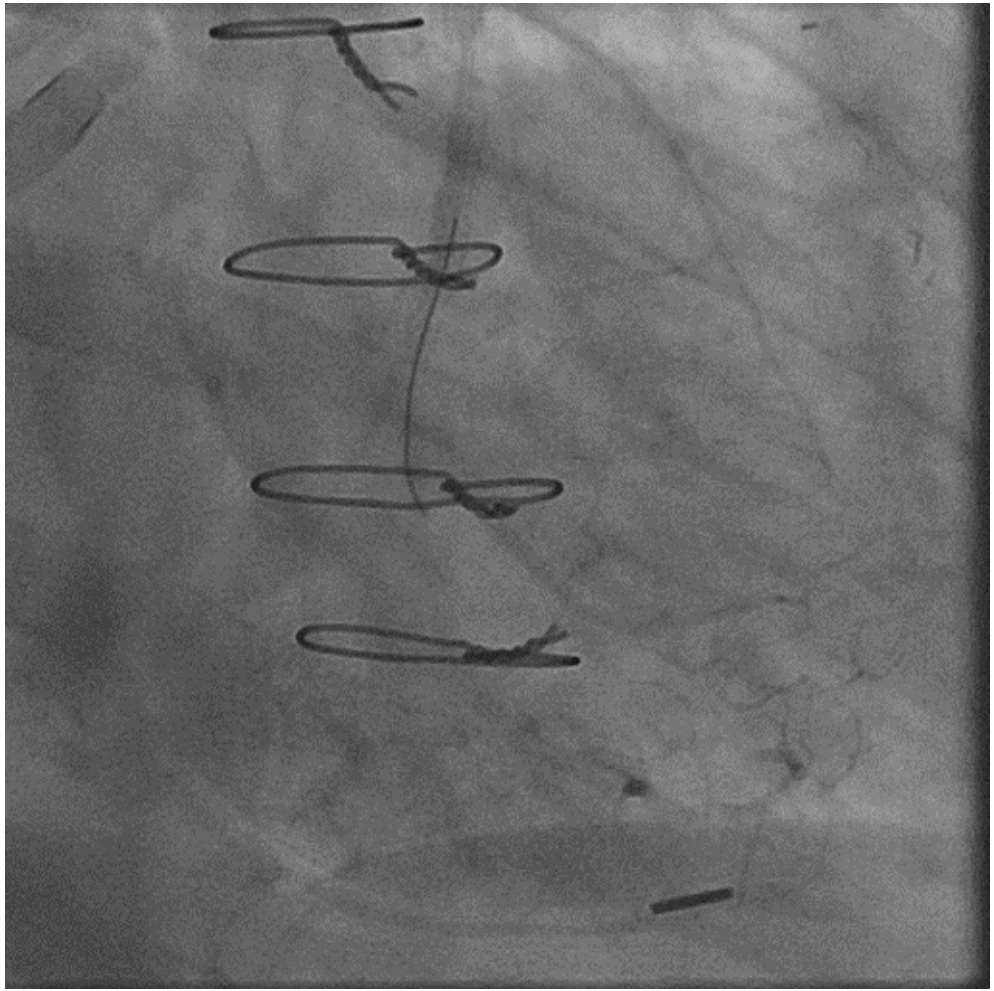
Guide wire retracted robotically with RoR on, wire rotates a set amount clockwise



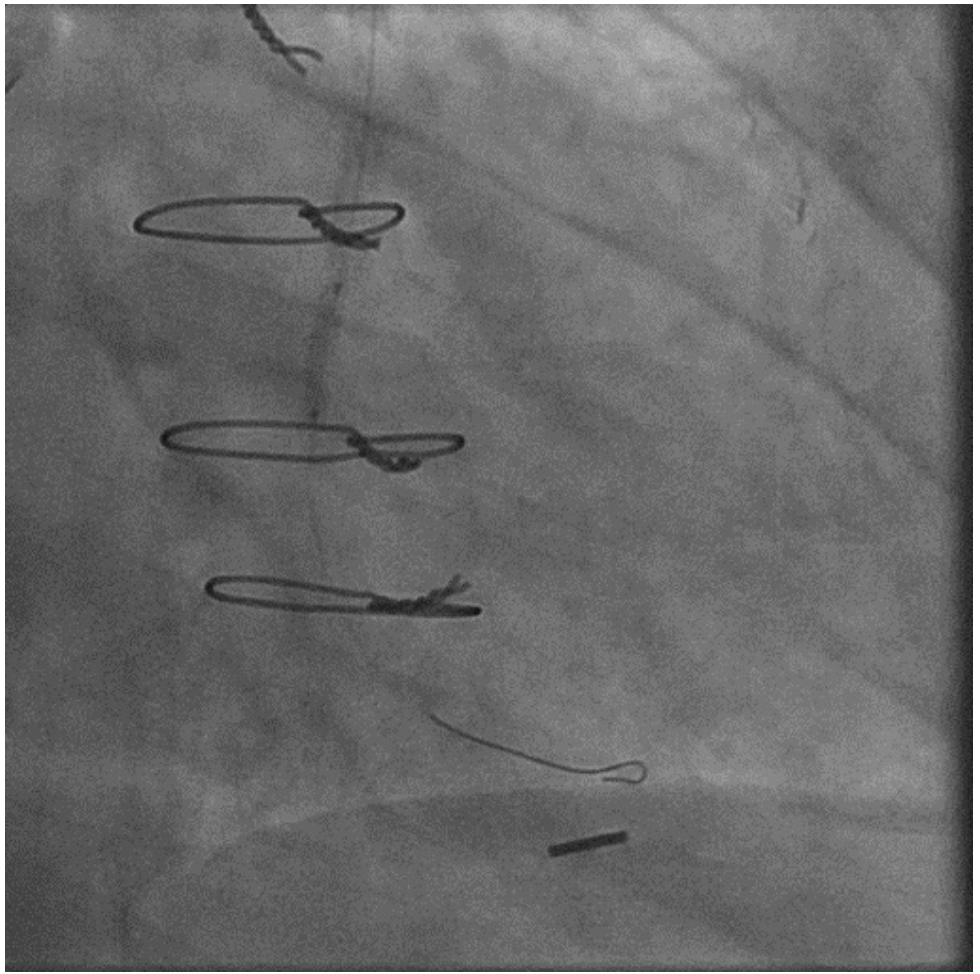
Guide wire retracted robotically
with RoR on, wire rotates a set amount clockwise – enters the
OM1 branch



Guide wire advanced robotically through the CM1 branch



- Lesion measured robotically using the radiopaque wire tip (mandrel)
  - Retract proximal edge of radiopaque tip to distal edge of lesion-mark as “0” on touch screen
  - Retract wire in sub-millimeter increments
  - When wire at proximal edge, a measurement of distance traveled displayed to provide lesion length



- Lesion measured 8.8 mm
- 2.5 x 12 mm Xience Alpine DES (Abbott Vascular) placed robotically over the Runthrough NS guidewire (Terumo) dilating the OM1 to 16 atmospheres (ATM)

Corindus Robotic Technology

Potential to be first disruptive treatment option in vascular medicine in 40+ years

Cleared | **In Development**

PCI

- **1st generation cleared in 2012, GRX in 2016**
- Used in clinical practice for simple to complex PCI
- Over 7,500 robotic-assisted PCIs performed

PVI

- **CorPath GRX cleared in 2018**
- Focused on below-the-knee interventions including CLI as well as renal interventions

NEURO

- **FIH neurovascular procedure performed November 1, 2019[1]**
- Regulatory approval received in select markets[2]
- Steering committee established in 2018[1]

NEURO + REMOTE

- **Potential disruptor to stroke therapy with remote access capabilities[1,3]**
- First in human remote PCI case completed in Dec 2018[3]

1 CorPath GRX for use in neurovascular interventions is currently under development; it is not for sale in the U.S.A. Its future availability cannot be guaranteed.
2 CorPath GRX has CE mark and TGA approval for use in neurovascular interventions.
3 Remote capabilities are currently under development; it is not for sale. Its future availability cannot be guaranteed.

Expanding Capabilities in Peripheral Intervention

Additional compatibility may increase applicability in PVI

Current GRX Experience

Clinical Case Experience

- SFA
- Popliteal
- Tibial PTA
- Renal PTA/Stent
- Carotid Artery Stenting (hybrid approach)

Benefits

- Automation has allowed for crossing of difficult lesions without a support catheter

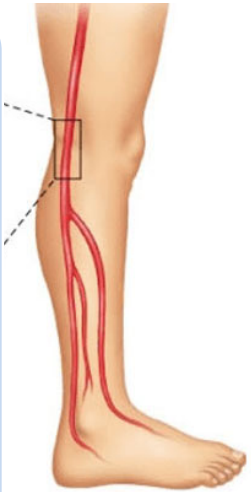
Potential Capabilities with GRX Upgrades[1]

Potential Clinical Opportunities

- Additional CLI work with less manual intervention
- Peripheral Embolization

Potential Capabilities & Benefits

- Expanded device compatibility
- Expanded indication for microcatheters and greater working length to accommodate
- May reduce need for manual intervention and associated occupational hazards



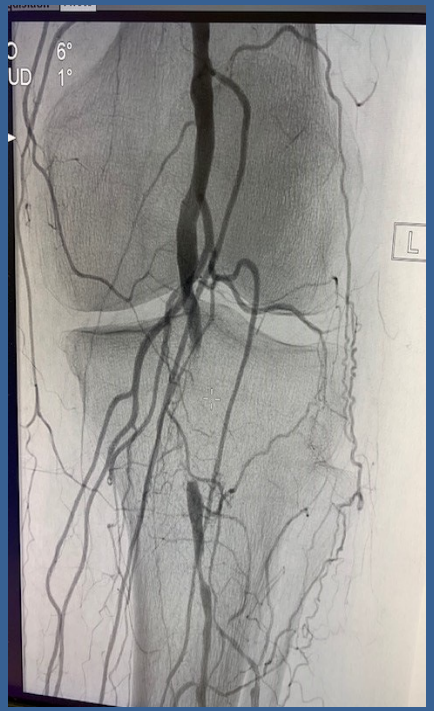
[1] Future enhancements to CorPath GRX are currently under development; it is not for sale in the U.S.A. Its future availability cannot be guaranteed.

Overview

Robotic-Assisted CTO Left Popliteal Artery

Patient Information

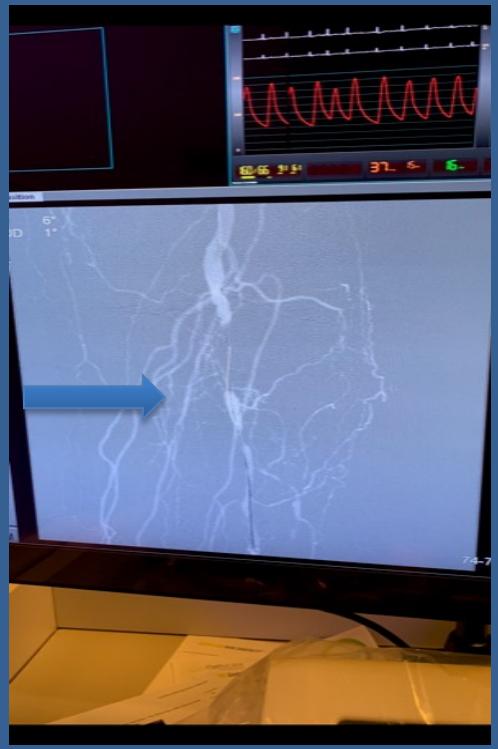
- Patient presented with left lower extremity claudication and non healing wound
- CTO Mid left Popliteal and Tibial Peroneal trunk



Pre angio

Case Strategy

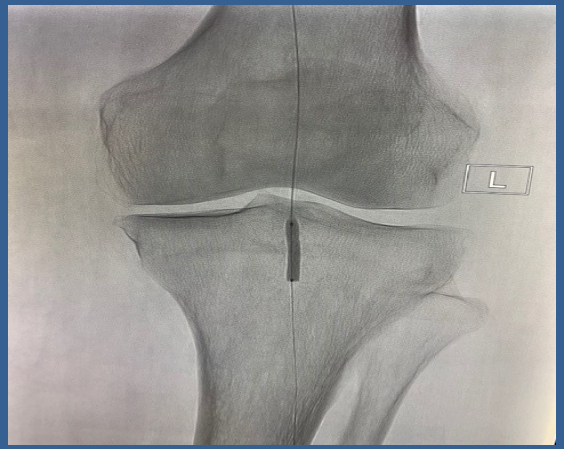
- Physician approach
  - Left femoral
  - Antegrade access
- Devices used
  - CorPath® GRX Vascular Robotic System
  - Cook 6Flexor 45cm
  - .014” Command Guidewire 300cm
- How the devices complement the strategy
  - Parked 45cm sheath in distal SFA
  - Was able to wire lesion RA only
  - Crossed lesion without catheter support to the ankle

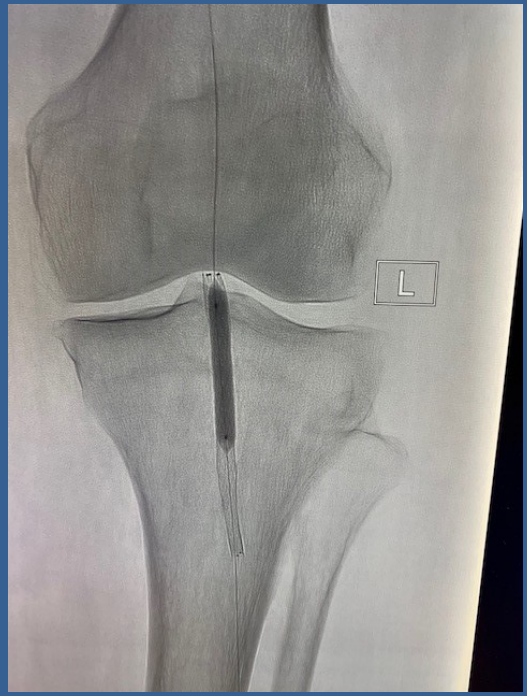


Crossed lesion without support catheter

Case Strategy

- Devices used
  - 2 RX BSC Coyote balloons and a Chocolate balloon were RA used:
  - 3.0mm x 20mm, 2.0mm x 60mm & 3.0mm x 20mm Chocolate Balloon
  - Manually deployed a Cordis Smart Flex SE stent 5.0mm x 60mm





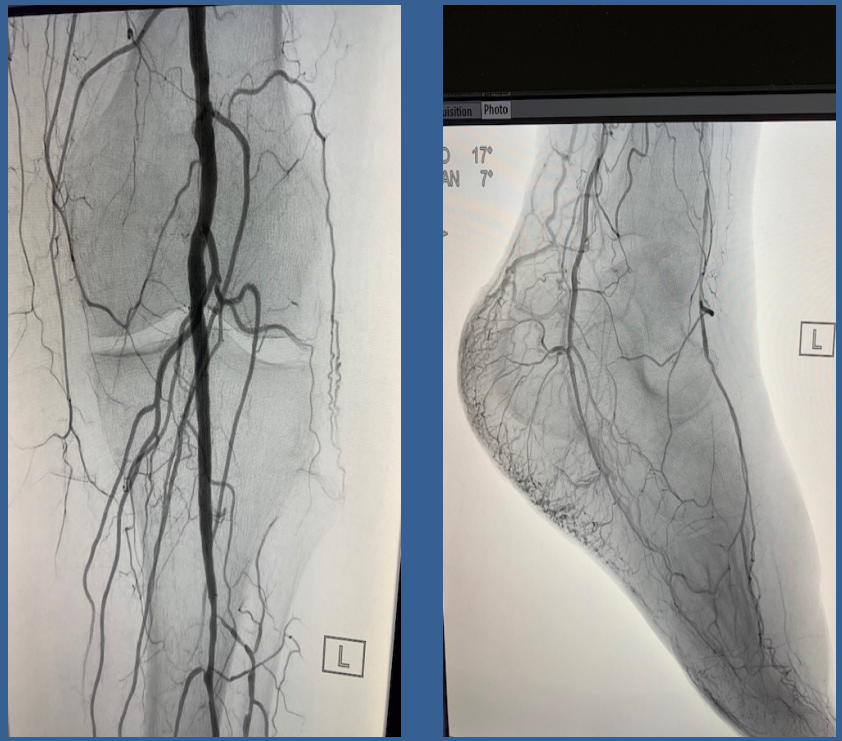
Ballooned robotically

Final Result

Robotic-assisted Popliteal CTO

- Physician gained access manually
- Following access, was able to wire; utilizing ROR and balloon lesion leveraging .014”/RX platform

- End result
  - Successful 100% robotic



Post-interventional angiogram of popliteal and distal flow to DP

Next level: Telerobotics

The Problem

Emergent procedures: Time to treatment is critical

Access to expertise & treatment is geographically limited

Shortage of skilled specialists

Incidence of STEMI & stroke on the rise due to aging patient population

Our Strategy

Reduce time to treatment for emergent procedures such as STEMI and stroke

Increase access to care globally

Expand intervention- & thrombectomy-capable facilities

Enable tele-proctoring & scale tele-diagnostic capabilities to tele-treatment

1 Remote capabilities are currently under development; it is not for sale. Its future availability cannot be guaranteed.

Evolution of Remote Intervention[1]

Under development

Same Hospital – Procedure Room	Same Hospital – Control Room	Same Hospital – Multiple Room Control	Different Hospital – Remote Site
			
Connection technology			
Hardwired 8’ from patient	Hardwired 30’ from patient	Fiber 200’ from patient	WiFi/Fiber 20 miles from patient

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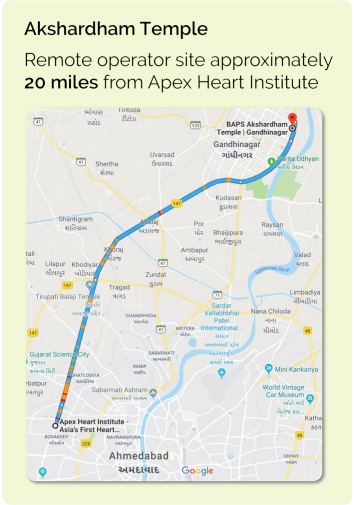
Remote Technology Development

Dr. Tejas Patel conducting first-in-human telerobotic procedures from Ahmedabad, India



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Long Distance Tele-Robotic-Assisted Percutaneous Coronary Intervention: A Report of First-in-Human Experience

Tejas M. Patel [a,*], Sanjay C. Shah [a], Samir B. Pancholy [b]

[a] Apex Heart Institute, Ahmedabad, India
[b] The Wright Center for Graduate Medical Education, Geisinger Commonwealth School of Medicine, Scranton, PA, USA

Published on September 2, 2019 in The Lancet journal eClinicalMedicine

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Multi-City, Cross-Country Remote Simulation

Remote Cross-Country Study Summary

Dr. Ryan Madder completed 36 simulated PCI procedures on a vascular simulator using CorPath GRX with prototype remote technology[1]

3 Network Connections Evaluated

Remote sites were connected over three connection types:

- 5G development connection
- Direct, dedicated fiber connection
- Public internet connection

Dr. Ryan Madder, Interventional Cardiologist from Spectrum Health, conducting trans-continental telestenting procedures via 5G, direct fiber, and public internet from Waltham, MA to New York City and San Francisco

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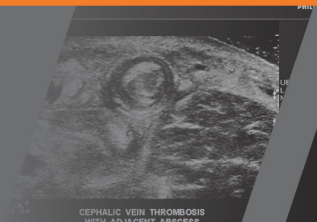

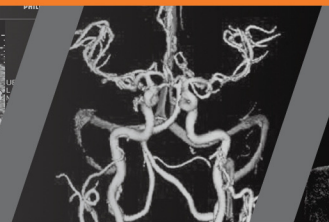

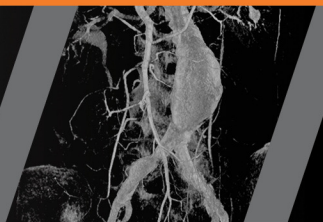

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