

Future of Coronary PCI: Robotics & Artificial Intelligence

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Disclosures

- Consultant
 - Abbott Vascular
 - Boston Scientific
 - Medtronic
 - Philips
 - Siemens



Evolution of Technology

“What a computer is to me is the most remarkable tool that we have ever come up with. It’s the equivalent of a bicycle for our minds.”

-Steve Jobs



The New Frontier of Healthcare Delivery

ITS GOALS ARE STRAIGHTFORWARD



Technological enablement, digitalization, and automation are affecting healthcare today in profound ways

Some of the biggest challenges in healthcare



43

million

Avoidable injuries*¹

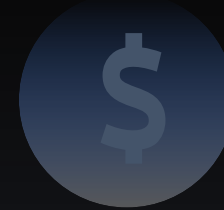
Burden of preventable medical errors



Average of
17 years

for acceptance*¹

The slow diffusion of medical knowledge



Up to **\$550**

billion

Spend too much on healthcare*²

Healthcare spending is increasing consistently

Sources:

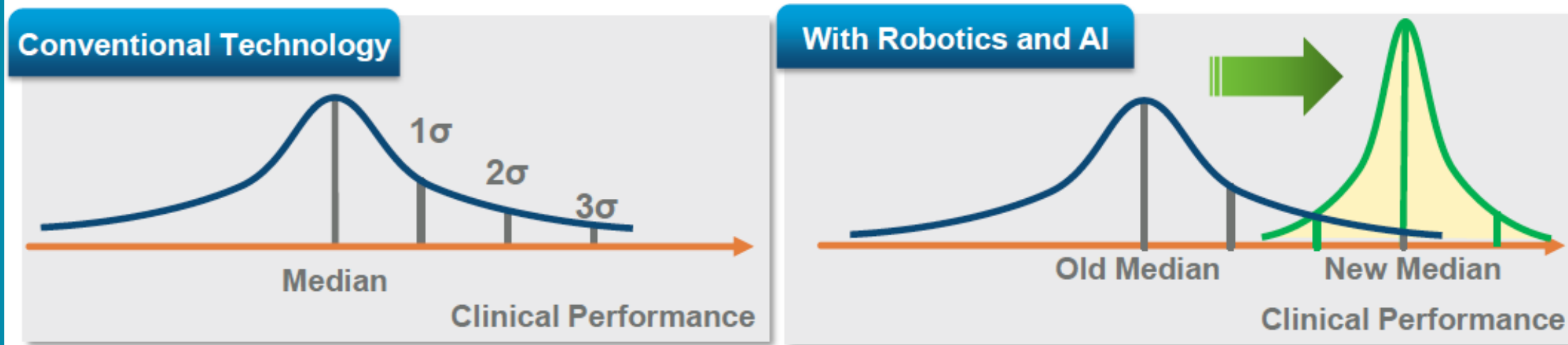
*¹ Elsevier Australia: <https://www.elsevier.com/en-au/connect/what-are-the-4-biggest-challenges-facing-the-healthcare-sector> 2018

*² McKinsey on

Healthcare: <https://www.mckinsey.com/~media/McKinsey/Industries/Healthcare%20Systems%20and%20Services/Our%20Insights/McKinsey%20on%20Healthcare%20Best%20of%202019/McK-HSS-Best-of-2019.pdf> 2020

Robotics and Artificial Intelligence

- In Medicine, Artificial Intelligence and Robotics offer to *Empower, Enhance, and Improve* Human Performance.
 - Opportunity for freedom and flexibility to treat patients with substantially better and more consistent outcomes.



Interventional Procedures Today

How the procedure is performed hasn't changed in 40+ years

- Performed with more predictability in recent years but optimization at a “hard stop”
- Innovation has been constrained to implantable devices (stents)
- Today's interventional procedures remains largely unchanged
 - Radiation and orthopedic risk
 - Limits on the precision required in today's complex cases

Dr. Andreas Gruentzig
Performs 1st Angioplasty



Traditional Intervention



AI & Robotics
Assisted Intervention



FUTURE

Robotic First In Man Series 2006

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Remote-Control Percutaneous Coronary Interventions Concept, Validation, and First-in-Humans Pilot Clinical Trial

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- OBJECTIVES** This study was designed to assess the feasibility and safety of a Remote Navigation System (RNS, NaviCath, Haifa, Israel) in which the angioplasty guidewire, the balloon, and the stent are navigated via a computerized system.
- BACKGROUND** Percutaneous coronary interventions (PCIs) are manually performed under fluoroscopic guidance, requiring lead protection for the operators. A system in which the operator can remotely, safely, and precisely navigate the procedure during PCI would have clear advantages.
- METHODS** The RNS involves a computer-controlled wire and delivery system navigator. Following preclinical validation, the system was assessed in patients undergoing single-vessel PCI.
- RESULTS** The study involved 18 patients (age 55.9 years, 16% women). The RNS successfully crossed lesions with the guidewire in 17 patients. The stent was then advanced by the advance/rotate mode and adequately positioned in 15 of 17 cases. Technical malfunction was encountered in three patients in whom the procedure was successfully completed manually. Direct stenting was employed in 10 of 18 patients, pre-dilation in 7 patients, and after-stent balloon dilation in 5 patients. The total fluoroscopy time for 17 RNS patients was compared with the corresponding time of 20 consecutive patients who underwent standard single-lesion PCI. Fluoroscopy time was similar for both procedures, with 8.8 ± 4.8 min with the RNS versus 9.1 ± 3.5 min with the standard techniques ($p = \text{NS}$). Clinical success was 100% and technical success 94% for the guidewire and 83% for the overall procedure.
- CONCLUSIONS** The use of the RNS for guidewire, balloon, and stent manipulation during PCI appears safe and feasible for the treatment of patients with coronary stenosis. The system offers operator radiation safety and may enhance precision of stent placement and balloon dilation strategies. (J Am Coll Cardiol 2006;47:296-300) © 2006 by the American College of Cardiology Foundation



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CorPath GRX Robotic System



Strategy to address unmet needs with automation



Create algorithms based on the techniques of highly skilled operators



Aim automation at improving:

- Navigation
 - Lesion crossing
 - Delivery of therapy
-

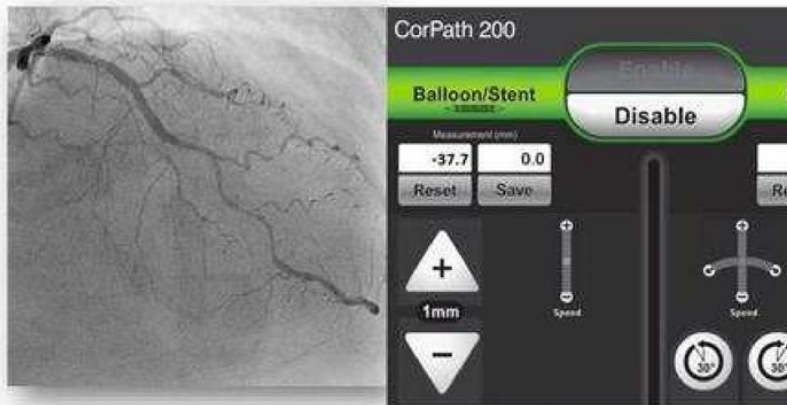


Faster procedures may reduce contrast & radiation and positively impact patient outcomes

Accuracy and Precision

Robotics Showed Reduction in 8.3% stent reduction¹

- We know challenging visual estimation leads to
- Manual assessment of lesion length significantly
- Treatment plan changed from two stents to one
- PRECISE trial also reported a reduced number



Visual estimate = 52mm
Initial treatment plan = 24 +
28mm stents

CorPath measurement = 37mm
Revised treatment plan = 3



¹Campbell P.T., et al. The Impact of Precise Robotic Lesion Length Measurement on Stent Length Selection: Ramification For Stent Savings. Poster Presentation CRT 2015.

²Campbell, P. T et al (2015). Interoperator and intraoperator (in)accuracy of stent selection based on visual estimation. Catheterization and Cardiovascular Intervention. doi: 10.1002/ccd.2578 ; Study sponsored by Corindus Inc.

³PRECISE cases averaged 1.1 stents per lesion vs. national average of 1.2 stents per lesion, PRECISE data compared to historical control (Nikolsky et al.)

Automation

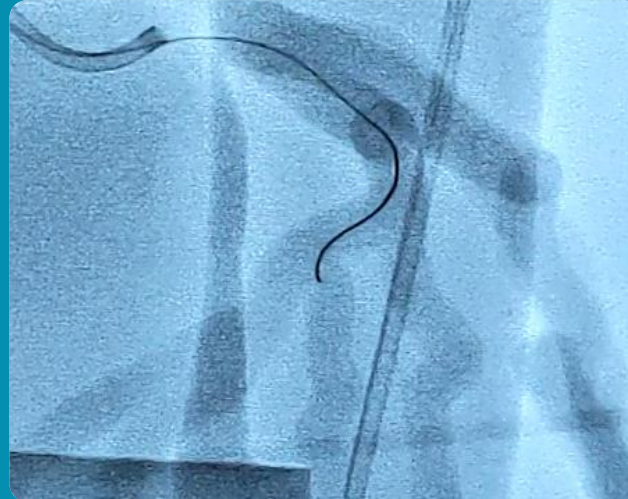
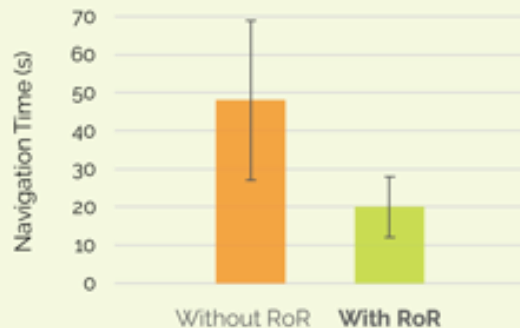
Jul 2017 TCT Abstract

Impact of a Novel Advanced Robotic Wiring Algorithm on Time to Wire a Coronary Artery Bifurcation in a Porcine Model

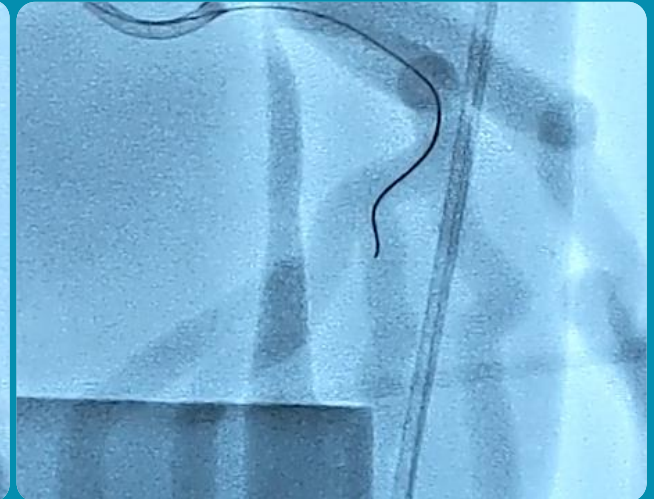
Madder, Lombardi, Parikh, Kandzari, Grantham, Rao

Standardized protocol of robotic guidewire advancement from the tip of the guide catheter into the anterior, then posterior branch of the first OM in live porcine model.

53% reduction in wiring time with reduced variability



Without Automation



With Automation



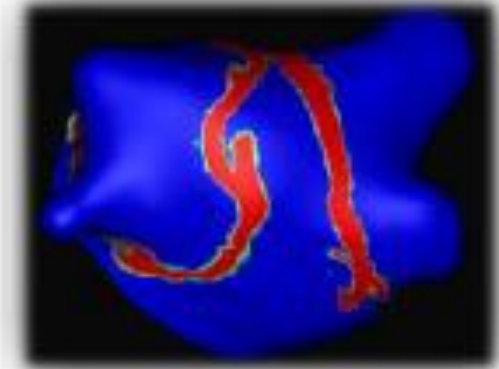
Machine Learning



Lesion Analysis



Machine Learning



Lesion Prediction



Equalizing Operator Skill & Experience



ROTATE ON RETRACT (ROR)

GUIDEWIRE
NAVIGATION



WIGGLE

GUIDEWIRE
NAVIGATION



SPIN

LESION
CROSSING



DOTTER

LESION
CROSSING



CONSTANT SPEED

ANATOMY
MEASUREMENT

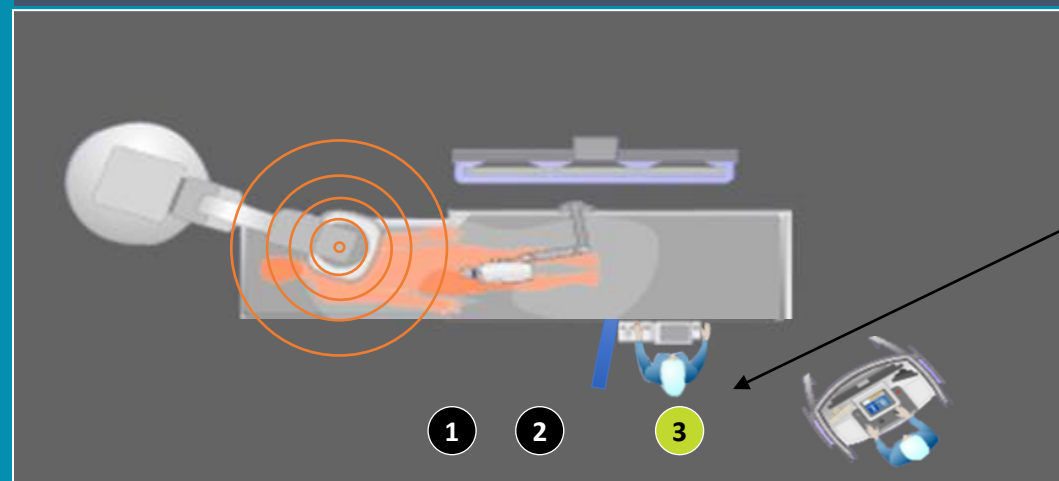


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Reducing Radiation Exposure

Robotic-assisted PCI is correlated with reduced staff radiation dosage¹

As staff distance doubles, exposure is decreased x4



- Robotic PCI personnel location
- Devices held in place in the CorPath cassette

Physician in Interventional Cockpit and tech behind shield at table

Mean Radiation Dose (per procedure) at Head Level By Position (μSV)²

POSITION	1	2	3
Radiation Dose	18.6	7.86	0.543

Radiation measured using a phantom and without a shield



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¹ Campbell P., et al. Staff Exposure to X-ray during PCI: Randomized Comparison of Robotic vs Manual Procedures. Presented at SCAI 2016.

² Böttcher H, Meenen C, Lachmund J, Hoffmann W, Engel HJ Strahlenexposition des Personals im Herzkatheterlabor. Z Med Phys 2003; 13: 251–256

Finish Line

October 2022

Bucket List

Mt Everest
Base Camp



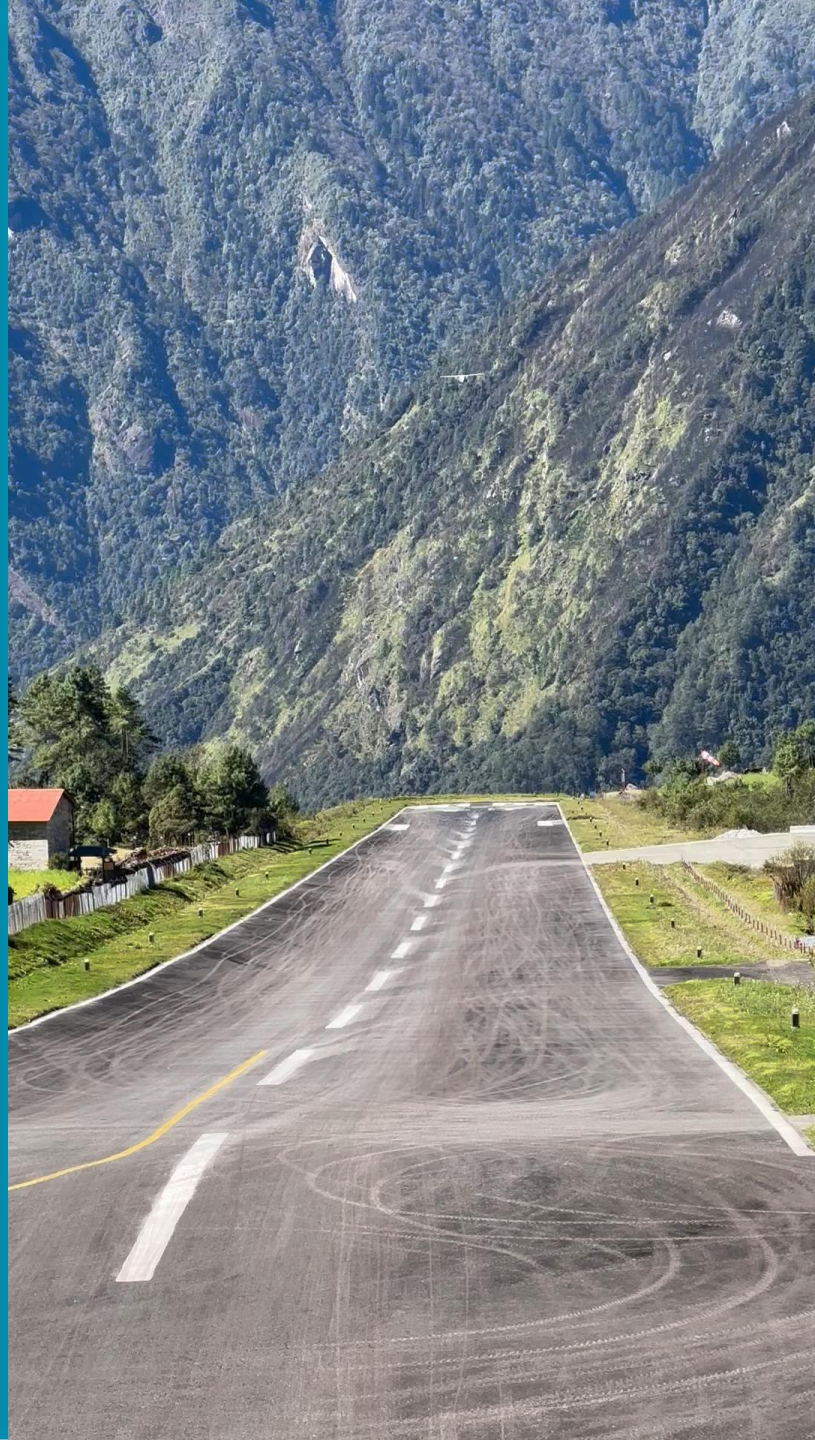
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Starting Point



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< Landing

Takeoff >



Success



@jcgeorgemd



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Summary

- Consistency & reproducibility with robotics
- Broad spectrum of lesion knowledge with machine learning
- Optimization of algorithms with artificial intelligence
- Reduced dependence on operator skill and experience
- Minimal radiation exposure with procedural distancing

