Application of AI and Robotics for Cardiovascular Care

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Disclosure

- Young-Hak Kim, MD, PhD
  - Co-founder & medical advisor of LN Robotics Corp.
  - Medical advisor of Medipixel Corp.
  - Founder & CEO of InMed Data Corp.

Topics

- Interventional robotics for coronary artery disease treatment
- AI for assistance of coronary intervention

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- **Interventional robotics for coronary artery disease treatment**

- AI for assistance of coronary intervention

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Remote-Control Percutaneous Coronary Interventions

Concept, Validation, and First-in-Humans Pilot Clinical Trial

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Haifa and Jerusalem, Israel; and Bucharest, Romania

Remote Navigation System (RNS, NaviCath, Haifa, Israel)

The potential advantages of a remote catheterization system can be summarized as:

- reduced operator radiation exposure and spine problems;
- provision of a convenient working environment;
- enhanced precision of balloon and stent positioning which may translate to clinical benefit;
- future inclusion of semiautomatic, robotically controlled functions and
- minimizing operator-based errors.

CorPath 200 System (Corindus,Inc., Natick, Massachusetts)

: US FDA approval in 2012

- Corindus Corp. was acquired by Siemens in 2019
- Currently 2nd generation system is available

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First-in-Human Evaluation of a Novel Robotic-Assisted Coronary Angioplasty System

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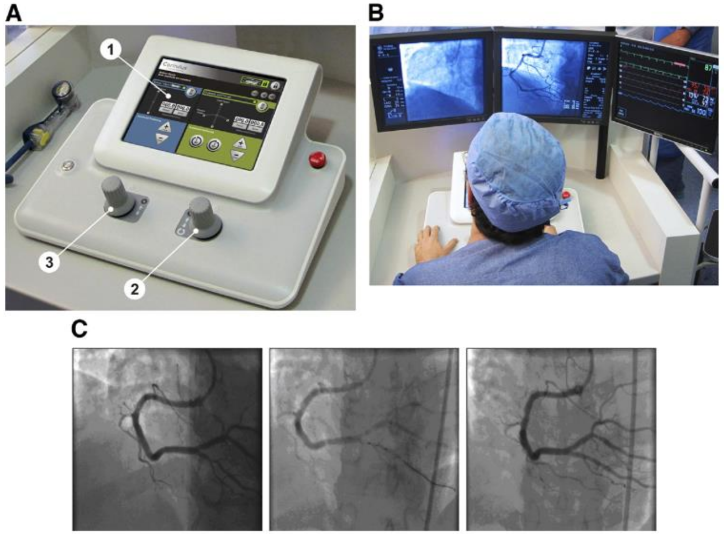
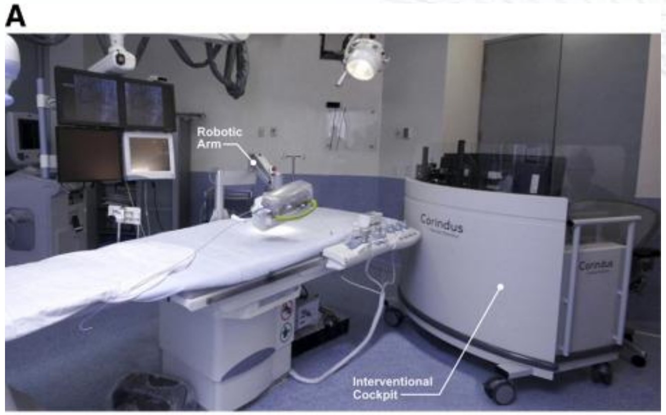
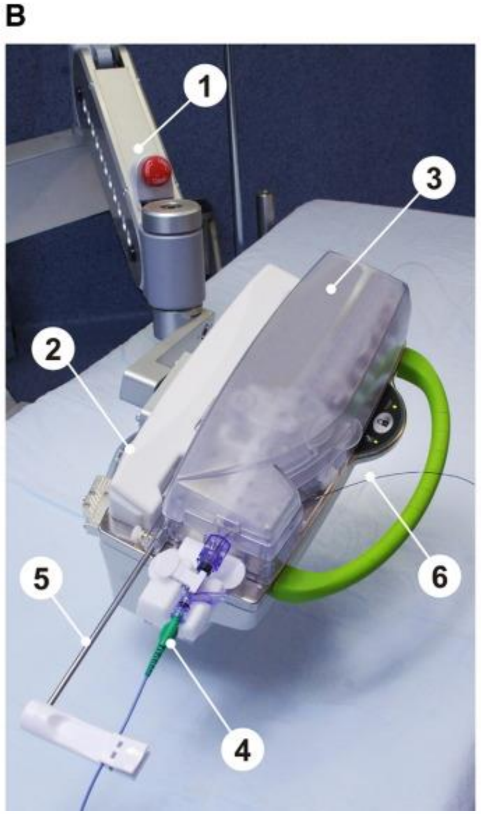




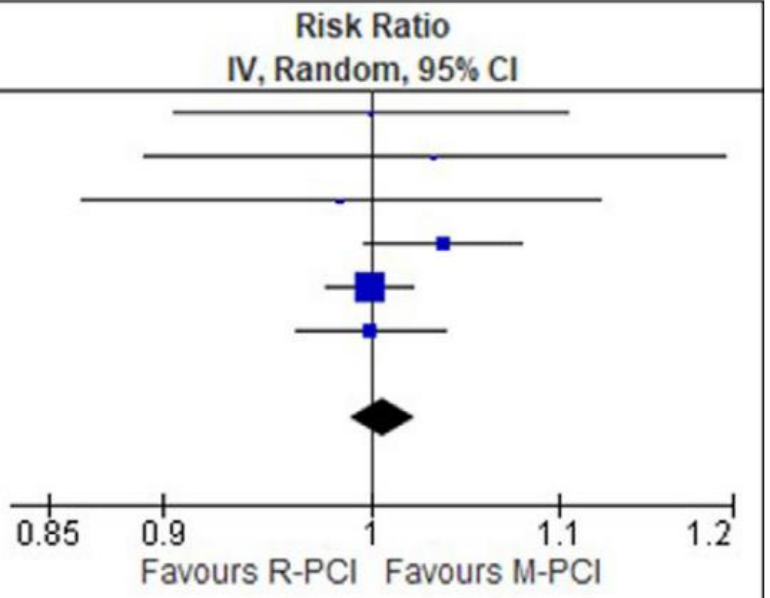


Meta-analysis

- Clinical Success of Robotic vs. Manual PCI

Study or Subgroup	R-PCI Events	R-PCI Total	M-PCI Events	M-PCI Total	Weight	Risk Ratio IV, Random, 95% CI
Beyar 2006	18	18	20	20	2.8%	1.00 [0.91, 1.10]
Hirai 2020	44	49	40	46	1.3%	1.03 [0.89, 1.20]
Kagiyama 2021	26	28	33	35	1.6%	0.98 [0.86, 1.12]
Madder 2017a	45	45	278	291	17.8%	1.04 [1.00, 1.08]
Mahmud 2017	107	108	224	226	57.3%	1.00 [0.98, 1.02]
Smilowitz 2014	40	40	80	80	19.1%	1.00 [0.96, 1.04]
Total (95% CI)		**288**		**698**	**100.0%**	**1.01 [0.99, 1.02]**
Total events	280		675			

Heterogeneity: Tau² = 0.00; Chi² = 2.94, df = 5 (P = 0.71); I² = 0%
Test for overall effect: Z = 0.76 (P = 0.45)



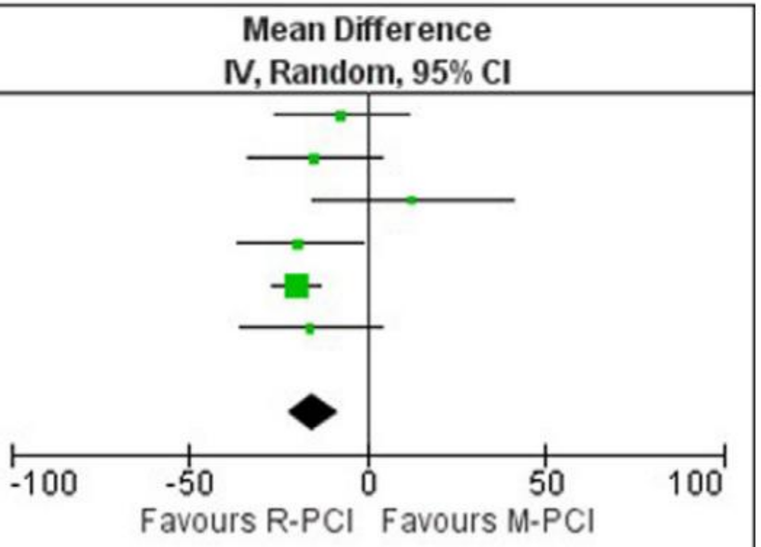
Mona JK et al. J Cardiol 2022;80:495

Meta-analysis

- Contrast Volume of Robotic vs. Manual PCI

Study or Subgroup	R-PCI Mean	R-PCI SD	R-PCI Total	M-PCI Mean	M-PCI SD	M-PCI Total	Weight	Mean Difference IV, Random, 95% CI
Hirai 2020	111	39	49	118	53	46	12.1%	-7.00 [-25.81, 11.81]
Kagiyama 2021	93.2	44.5	30	107.8	43.4	77	12.3%	-14.60 [-33.24, 4.04]
Madder 2017a	167	89	45	154.2	94.5	291	5.9%	12.80 [-15.38, 40.98]
Mahmud 2017	183.4	78.7	108	202.5	74	226	13.4%	-19.10 [-36.80, -1.40]
Patel 2020	133.3	52.1	310	153.3	52	686	45.4%	-20.00 [-26.98, -13.02]
Smilowitz 2014	121	47	40	137	62	80	11.0%	-16.00 [-35.92, 3.92]
Total (95% CI)			**582**			**1406**	**100.0%**	**-15.27 [-22.37, -8.18]**

Heterogeneity: $Tau^2 = 16.21$; $Chi^2 = 6.21$, df = 5 (P = 0.29); $I^2 = 20\%$
Test for overall effect: Z = 4.22 (P < 0.0001)



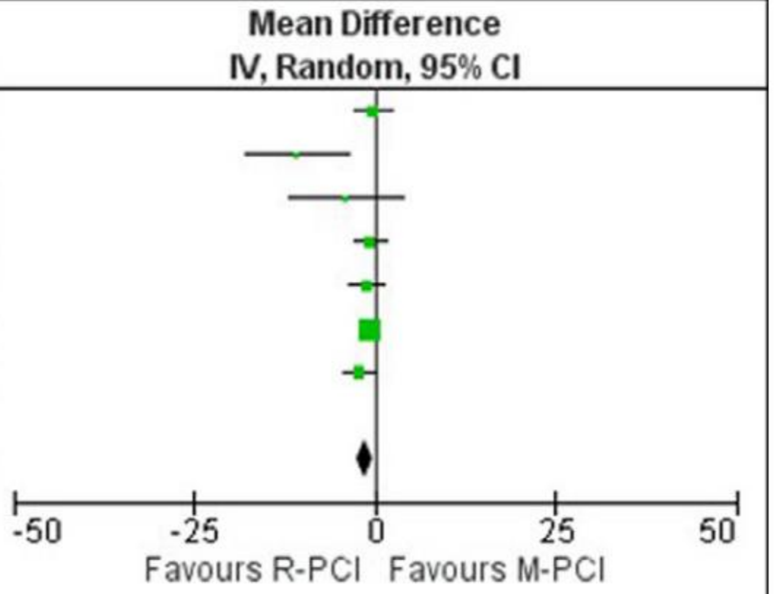
Mona JK et al. J Cardiol 2022;80:495

Meta-analysis

• Fluoroscopy Time of Robotic vs. Manual PCI

	R-PCI			M-PCI				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Beyar 2006	8.8	4.8	18	9.1	3.5	20	12.1%	-0.30 [-3.00, 2.40]
Hirai 2020	37.9	17.9	49	48.6	17.1	46	2.3%	-10.70 [-17.74, -3.66]
Kagiyama 2021	27.5	18.9	30	31.5	18.9	77	1.8%	-4.00 [-11.97, 3.97]
Madder 2017a	11.7	6.8	45	12.4	9.4	291	15.4%	-0.70 [-2.96, 1.56]
Mahmud 2017	18.2	10.4	108	19.2	11.4	226	13.8%	-1.00 [-3.46, 1.46]
Patel 2020	5.9	4.4	310	6.7	4	686	38.7%	-0.80 [-1.37, -0.23]
Smilowitz 2014	10.1	4.7	40	12.3	7.6	80	15.8%	-2.20 [-4.41, 0.01]
Total (95% CI)			**600**			**1426**	**100.0%**	**-1.26 [-2.37, -0.16]**

Heterogeneity: Tau² = 0.74; Chi² = 9.69, df = 6 (P = 0.14); I² = 38%
Test for overall effect: Z = 2.24 (P = 0.03)



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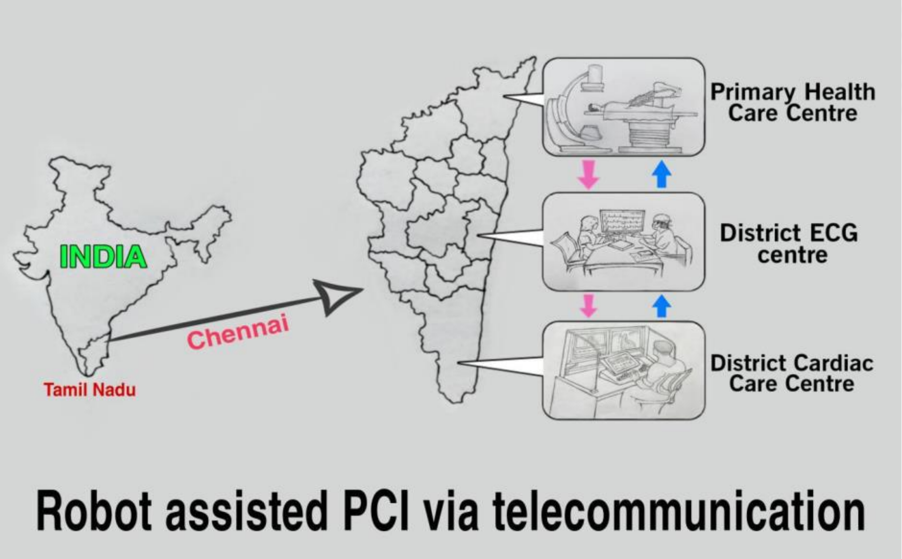
Remote Tele-Robotic PCI

- 20 miles away
- CorPath GRX for 5 patients
- LAN/MAN/WAN connectivity



"Remote tele-R-PCI through the telerobotic platform for STEMI patients in rural areas and during pandemic scenarios such as infectious disease transmission(Covid-19) may be viable."

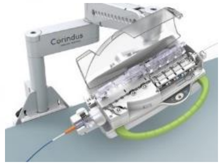
Thirumurugan E, et al. Indian Heart Journal 2023 (e-pub)

Robotic Angioplasty Devices

Year | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023

Corindus: Giemens

CorPath 200



CorPath GRX

Catheter control added

Robocath

[R-One™

1st clinical system

LN Robotics

AVIAR 1.0

1st clinical system

AVIAR 2.0

Multi-set instrument / haptic interface / AI

Korean startup

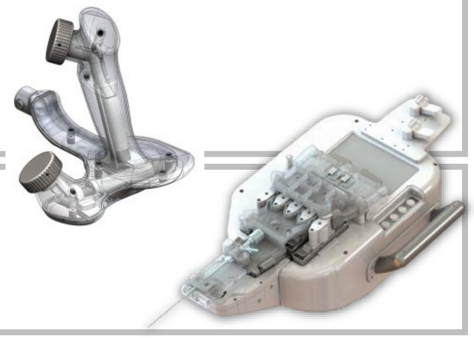
MFDS approval

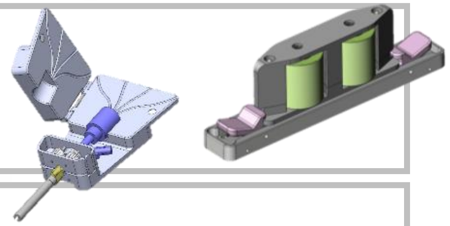
First in Man with AVIATOR 1

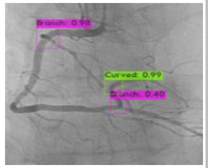
AVIATOR 2 for Commercial Use

Key Advantages of Aviator 2

Technical Advancement	Clinical Advantages
1.'One-Hand' haptic control 5 DOF haptic interface	Enhanced haptic rendering (virtual force field)
2. Complex PCI Multi-channel mechanism	Enhanced multi-channel mechanism
3. Easy control modules Unique design disposable set	Enhanced usability of the disposable set
4. Smart UI/UX & AI assistance Semi-automatic / autonomous wire navigation	Semi-automatic / autonomous wire navigation
	3D dynamic "roadmap"







Registry for Safety & Feasibility Assessment

- A multicenter registry for 200 patients who are planned to receive coronary stenting
- Study purpose: To assess the feasibility and safety of AVIATOR 2.0 robotic systems
- The first patient is scheduled to be enrolled in autumn 2023.
- PI: Seung-Whan Lee, MD, PhD, Asan Medical Center

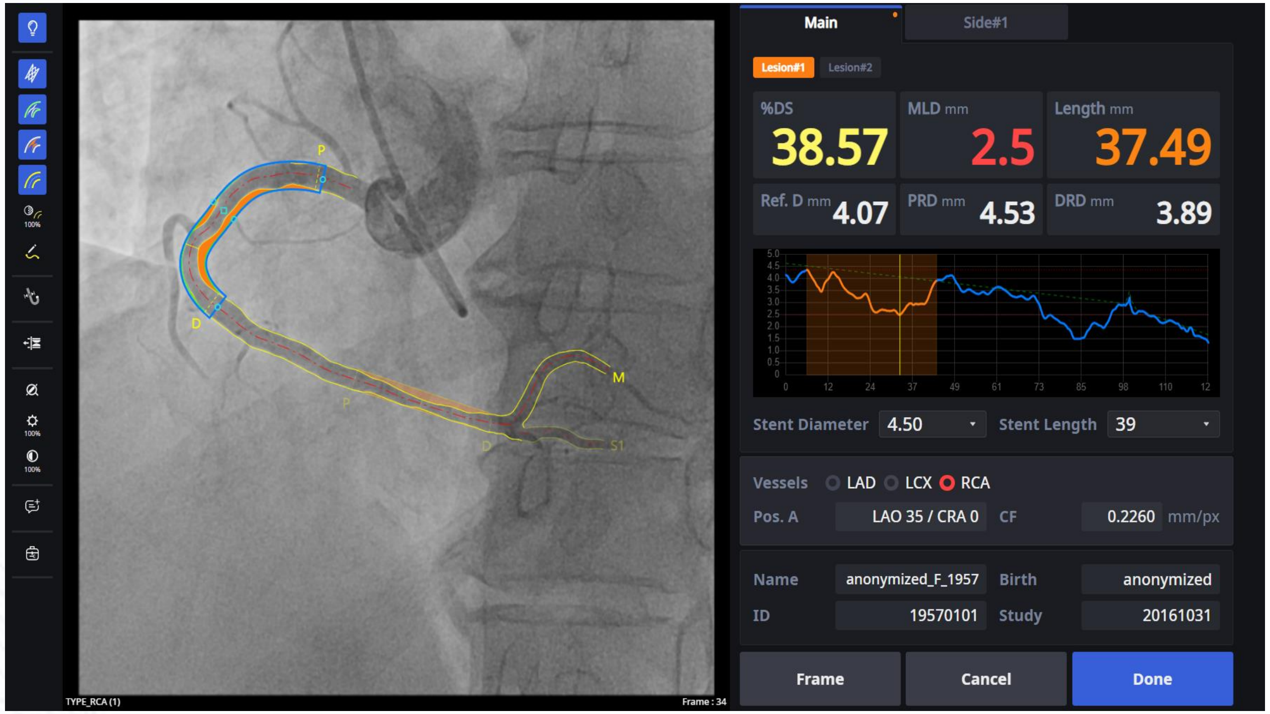
Topics

- Interventional robotics for coronary artery disease treatment
- **AI for assistance of coronary intervention**

AI-QCA for PCI Assistance: MPXA by MEDIPIXEL Corp.

- Provides detailed information on the target lesion in real-time
- Supports physicians' decision-making for PCI
- Provides more accuracy and consistency than visual estimation

What AI-QCA can do



Lesion information provided

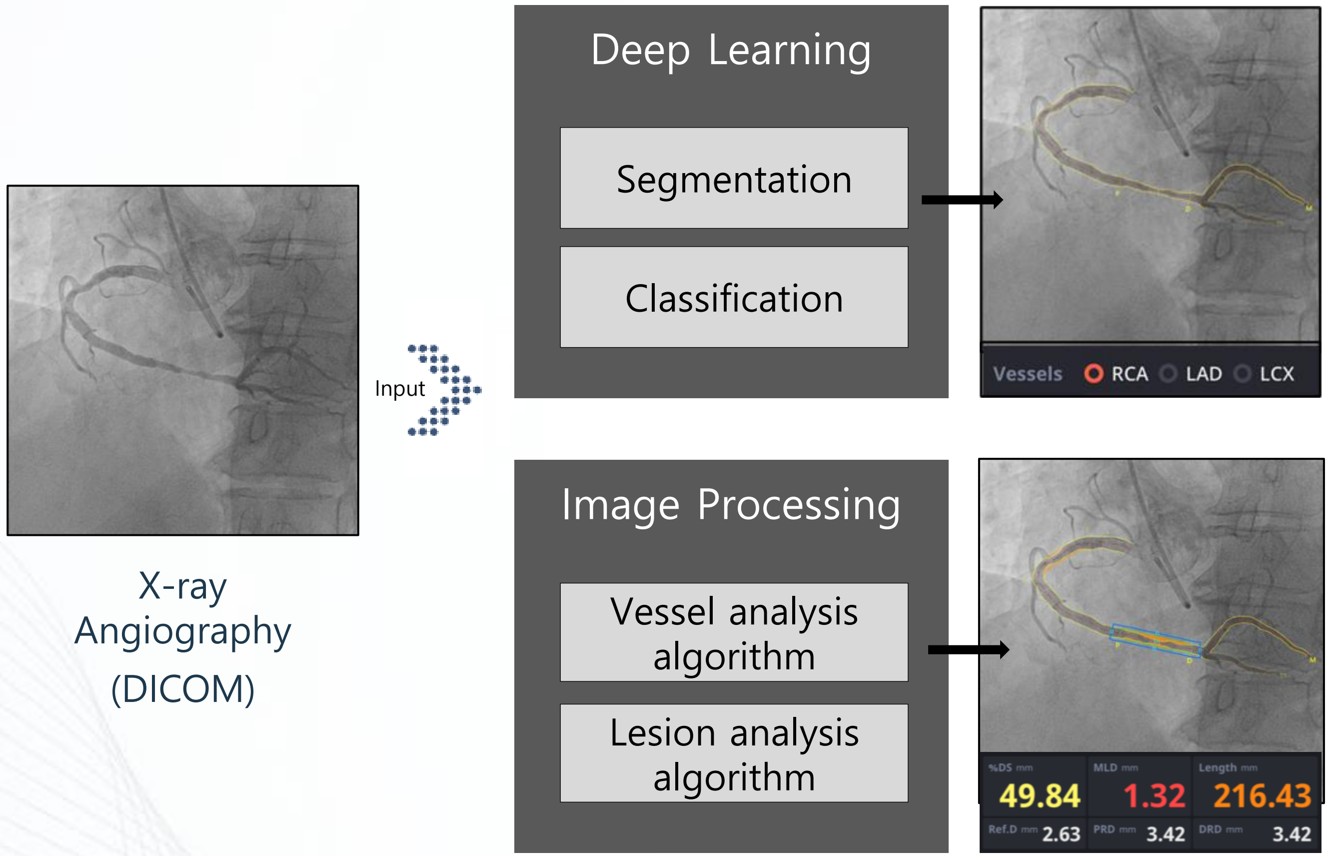
- %DS of the lesion
- Lesion length
- MLD, etc.

Scope of the analysis

- Multi-lesions
- Multi-vessels
  - Main and Side branches

AI-QCA allows you to obtain all necessary QCA information within a couple of seconds.

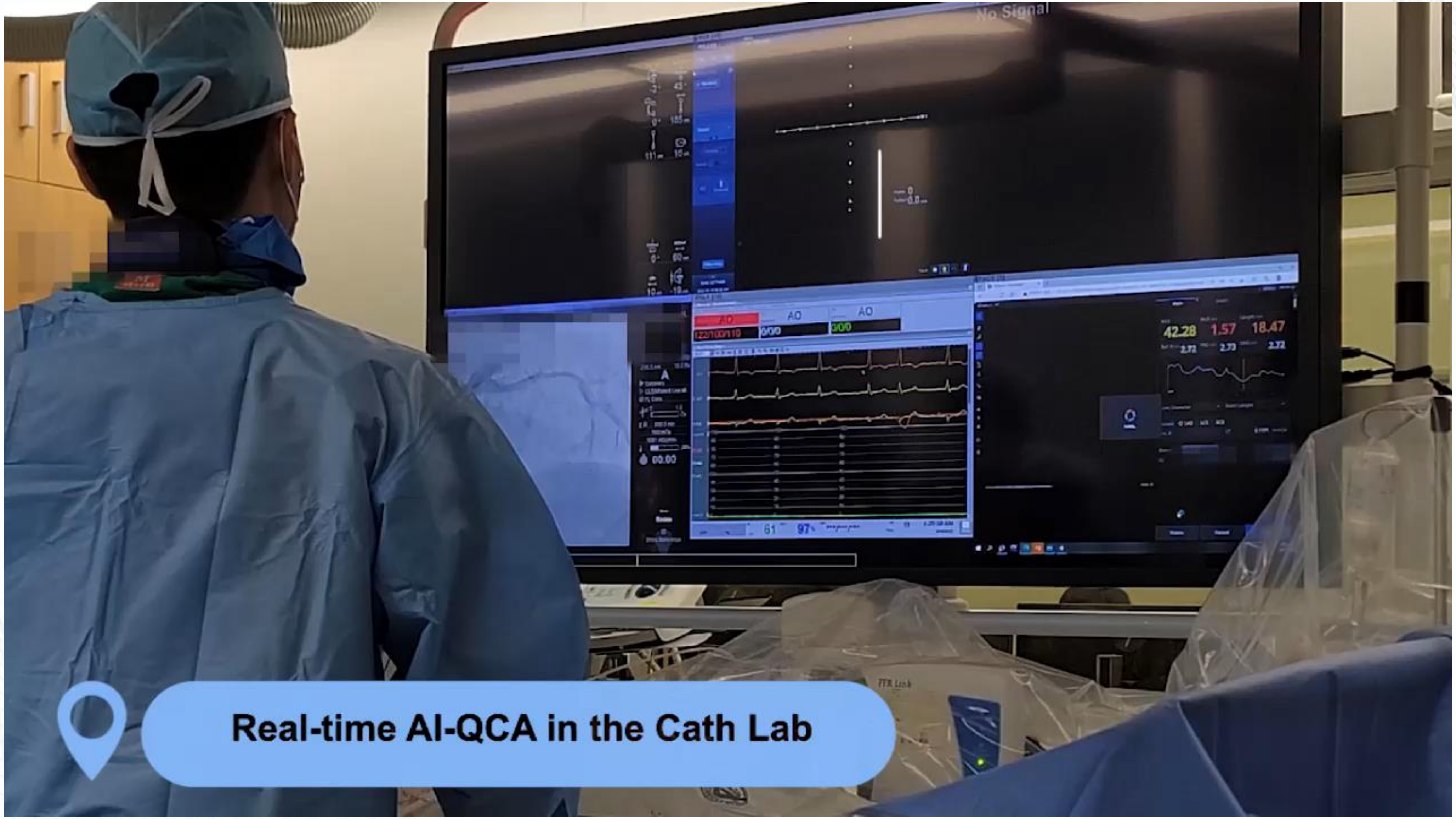
Well trained AI Engine



- DL-based segmentation
- AI trained with about 10,000 patients' data
  - Accuracy increases with more data
  - Data include patients with complex lesions
- Dataset used for learning reflect the real patient pool

Yang S. et al Scientific Report 2019;9:16897

How it works



FLASH Multicenter Randomized Trial

***F**u**l**ly **A**utomated Quantitative Coronary Angiography versu**S** Optical Co**H**erence Tomography Guidance for Coronary Stent Implantation*

Planned coronary stenting (N=400)

Random

MPXA-2000B Guided PCI (N=200)	OCT Guided PCI (N=200)

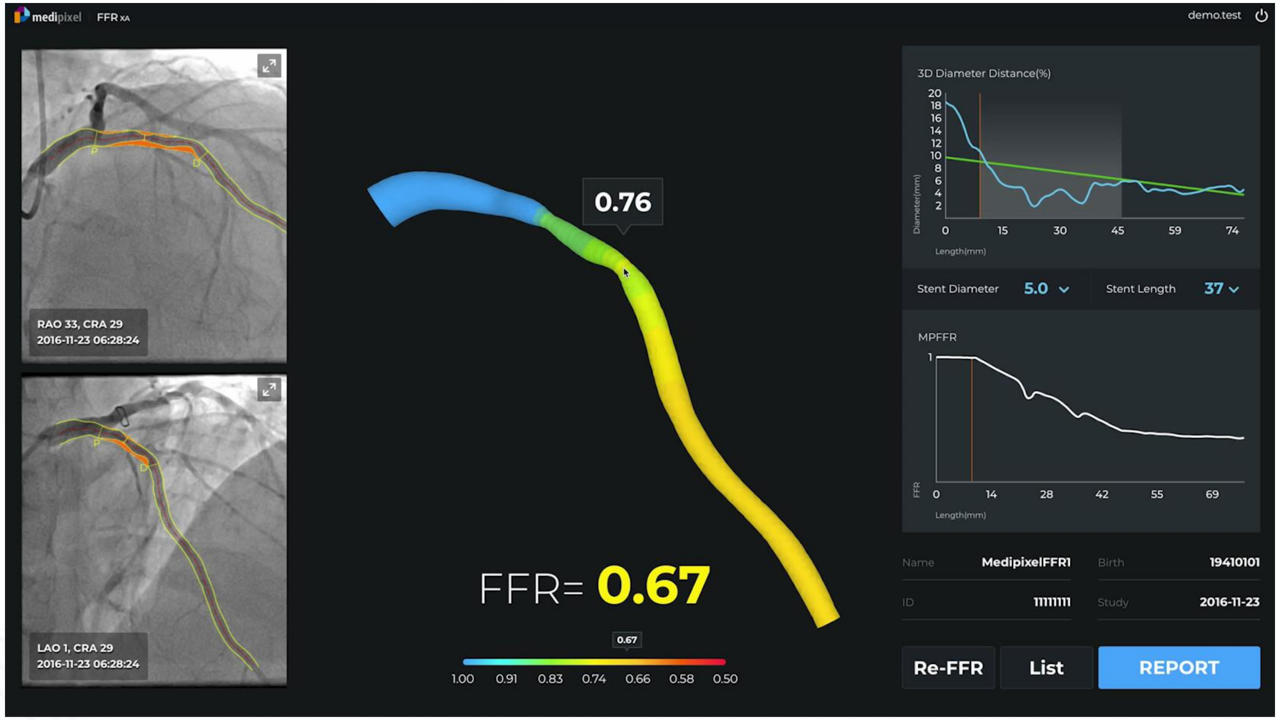
OCT after coronary angioplasty

- **Primary efficacy end point:** Stent MLA by OCT estimation (mm^2)
- **Primary efficacy end point:** Procedure-related complication
- **Secondary efficacy end points**: death, ST, revascularization, MI at 1 year
- **Cost-effective analysis**: At 1 year

▪ **Procedure-related complication: dissection, perforation, thrombosis, acute closure**

PI: Jung-Min Ahn, MD, PhD

Upcoming Program of AI-FFR: MPFFR$_{XA}$



MPFFR$_{XA}$ expands the FFR market

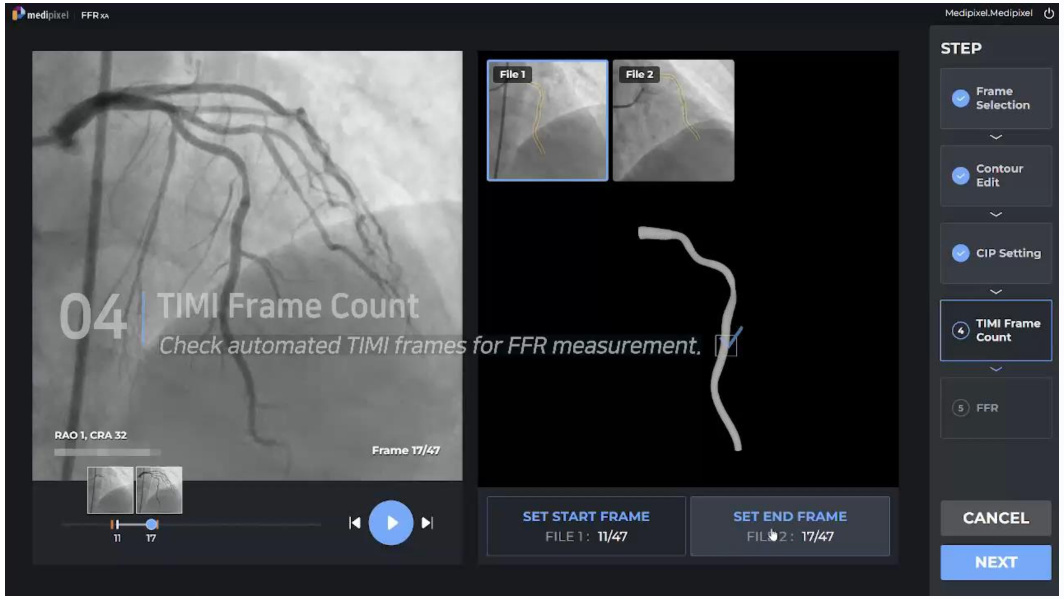
- ✓ Less than one minute
- ✓ Affordable cost
- ✓ No patient discomfort
- ✓ Reimbursement opportunity

Performance
(Internal data;
clinical trial result
Data coming soon)

- ✓ Segmentation 0.92 (f1 score)
- ✓ 3D modeling 0.96 (f1 score)

Automated Features

Frame Selection | Contour Segmentation | CIP Estimation | TIMI Frame Selection | FFR Value Estimation | 2D QCA Info Display

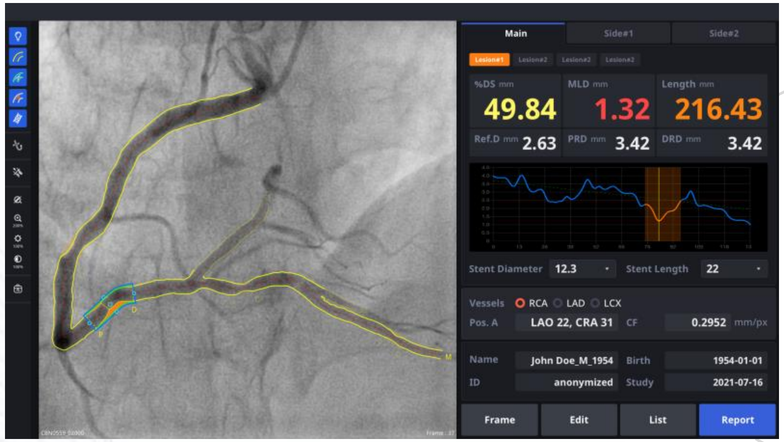


trained with more than 10,000 angiograms for additional automation features such as CIP estimation, FFR value estimation, etc.

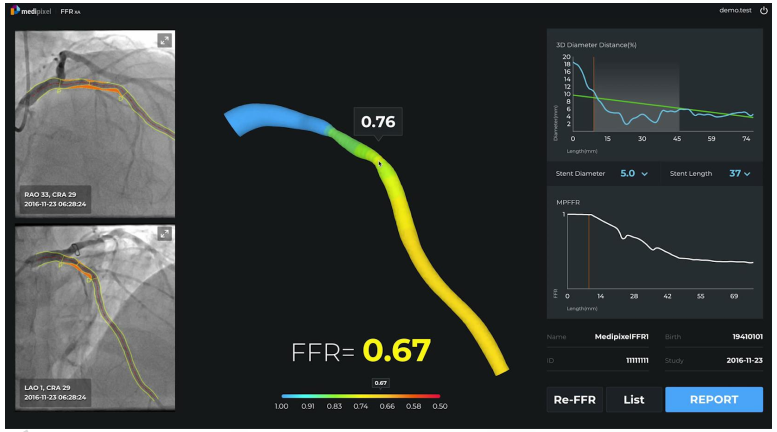
Synergistic Role of AI-QCA and AI-FFR

Both morphological and functional information at a time

AI-QCA with MPXA



AI-FFR by MPFFR$_{XA}$

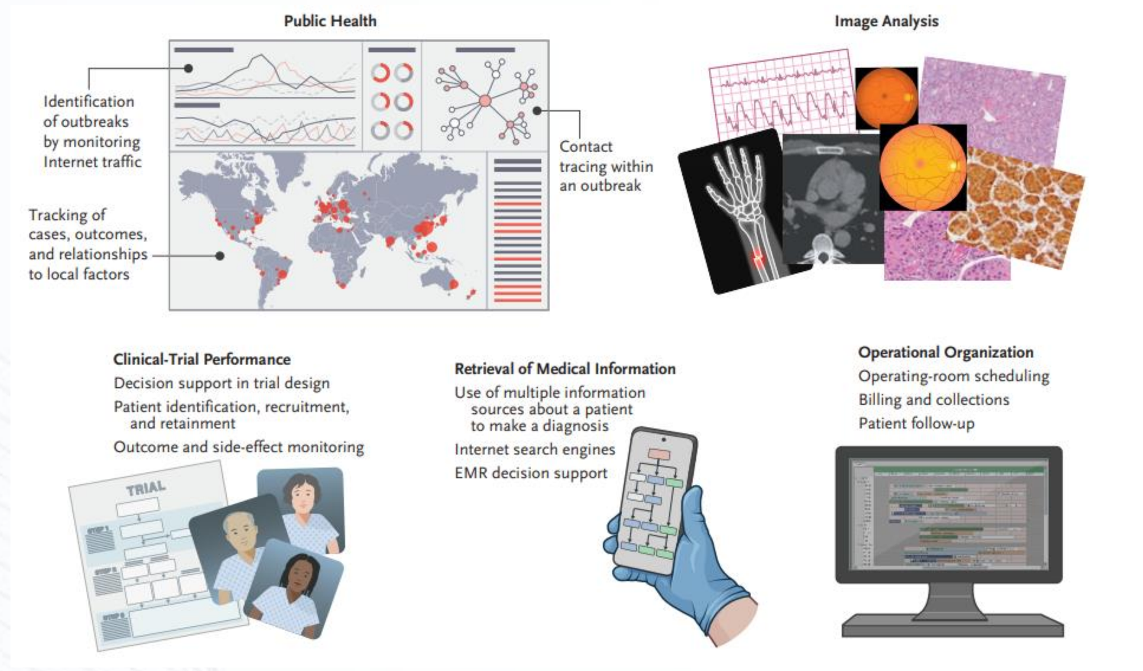


Sharing core technologies

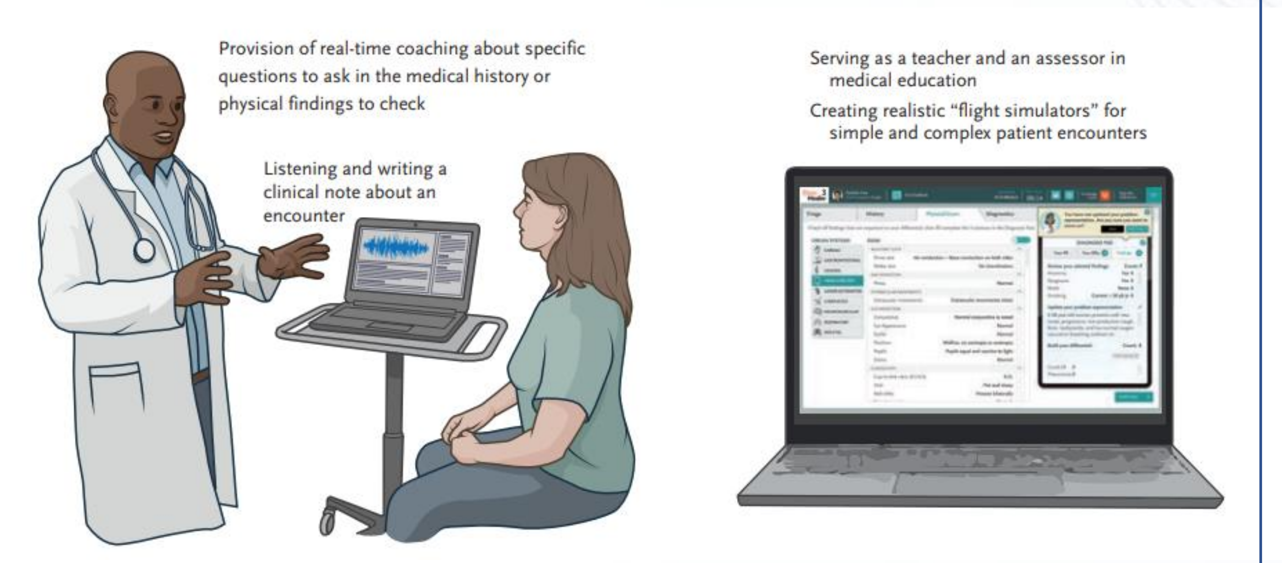
- Frame selection
- Contour segmentation
- Calibration
- Access control …

AI in Medicine

Present



Future



Charlotte J. Haug et al. N Engl J Med 2023;388:1201

Summary / Conclusion

- **Robotic angioplasty**
  - It reduces occupational hazard of radiation exposure and orthopedic injuries of operators.
  - Procedural outcomes are comparable as reference to the standard manual PCI.
  - Potential benefit for complex PCI with a new PCI robotic system will be tested by future clinical studies.

- **AI for interventional cardiology**
  - AI may be used to better predict possible adverse events and outcomes of patients.
  - AI-assisted real time QCA can assist operators to determine coronary lesion morphology and select appropriate devices.
  - Its benefit will be tested with a randomized clinical trial in Korea.