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

Topics

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

- AI for assistance of coronary intervention

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

: US FDA approval in 2012

- Corindus Corp. was acquired by Siemens in 2019
- The second generation system was released.
- Siemens discontinued the business for cardiovascular intervention in 2023, but it is still used for neurovascular treatment

JACC: CARDIOVASCULAR INTERVENTIONS
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PUBLISHED BY ELSEVIER INC.
VOL. 4, NO. 4, 2011
ISSN 1936-8798/$36.00
DOI: 10.1016/j.jcin.2010.12.007

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

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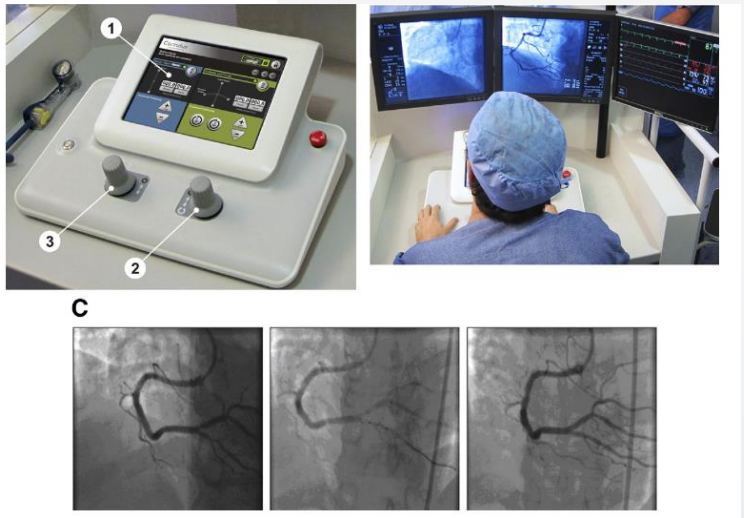
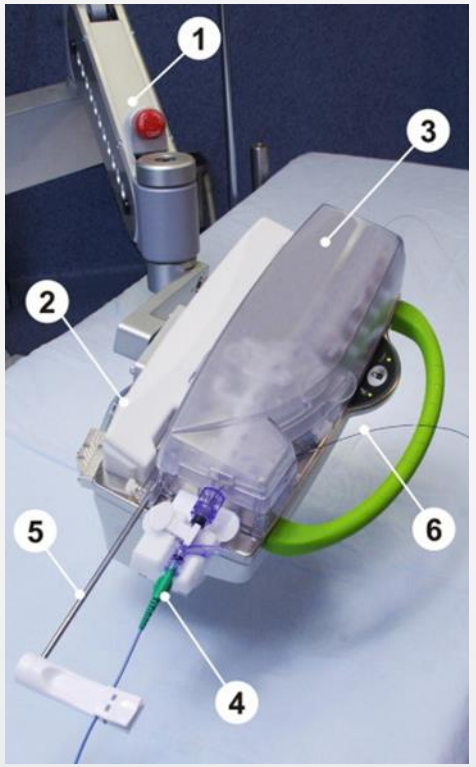




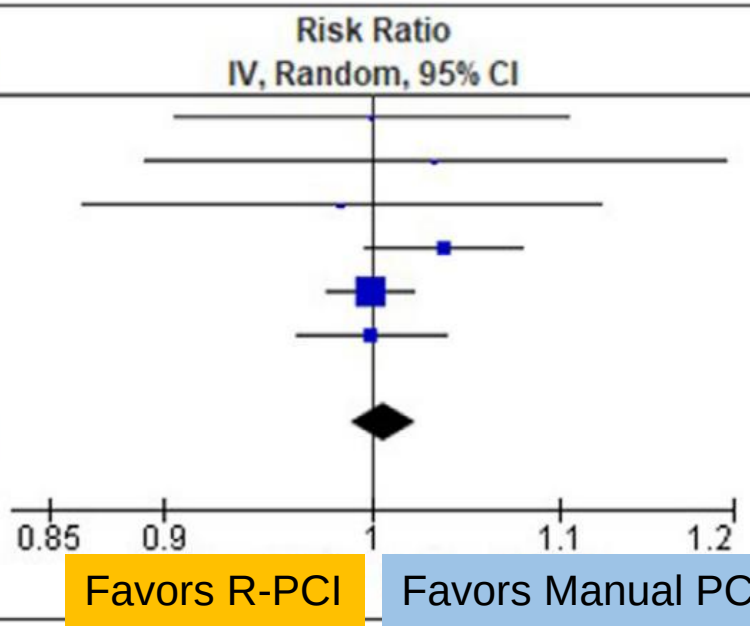
Meta-analysis

- **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

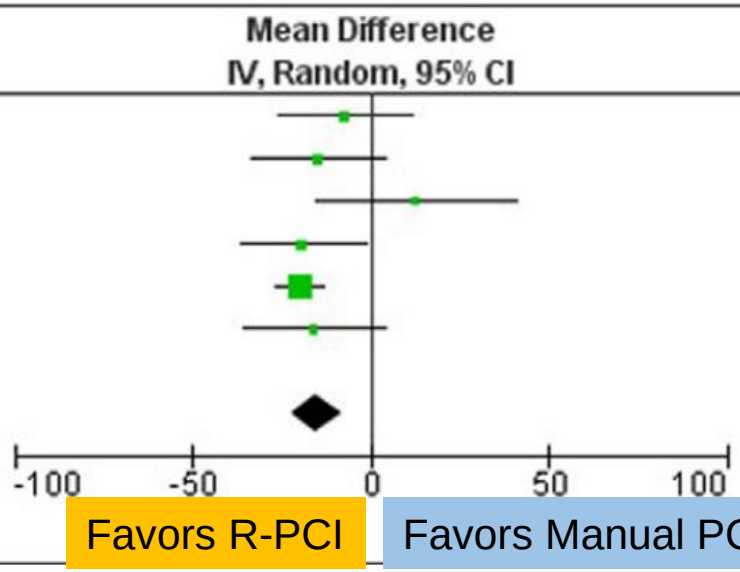
Meta-analysis

- **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: Tau² = 16.21; Chi² = 6.21, df = 5 (P = 0.29); I² = 20%

Test for overall effect: Z = 4.22 (P < 0.0001)



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

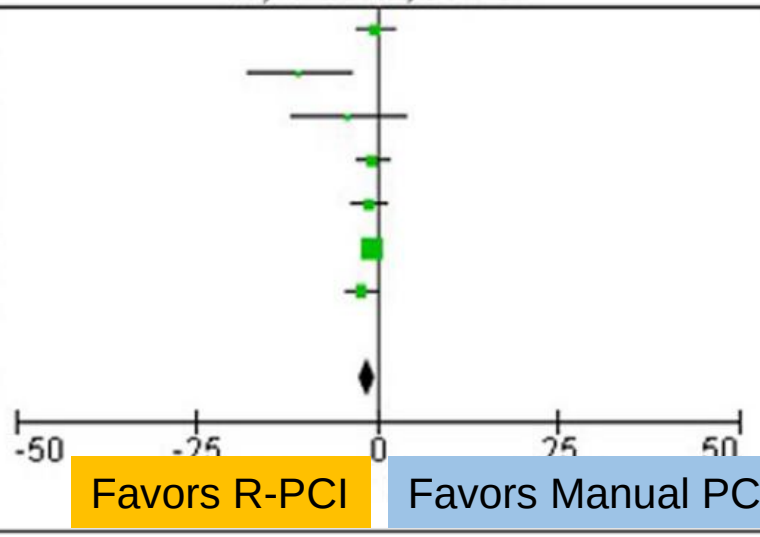
Meta-analysis

- **Fluoroscopy Time** of Robotic vs. Manual PCI

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
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%

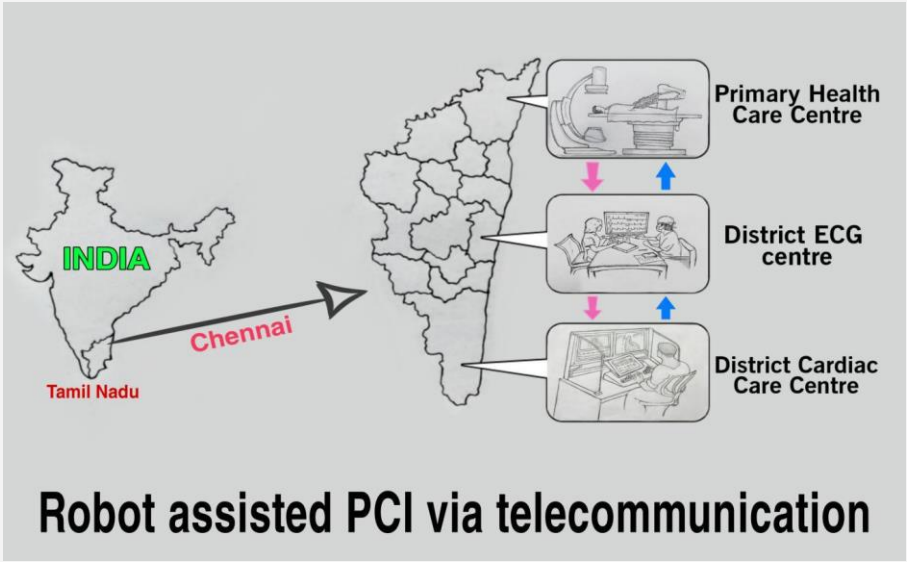
Test for overall effect: Z = 2.24 (P = 0.03)



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

Remote Tele-Robotic PCI

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



"Remote tele-R-PCI may be viable through the telerobotic platform for STEMI patients in rural areas and during pandemic scenarios."

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

Pro & Con of Corpath

- Pro
  - Reduction in radiation exposure and orthopedic injuries: operator benefit
  - Potential reduction in radiation exposure and contrast volume: patient benefit
  - Possibility of tele-PCI

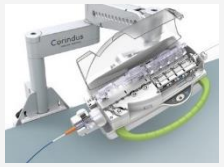
- Con
  - Incompatibility with intravascular imaging devices
  - Inability to manipulate multiple guidewires and stents
  - Lack of clinical evidences

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

Stop for CV

Robocath

R-One™

1st clinical system

LN Robotics

AVIAR 1.0

1st clinical system

AVIAR 2.0

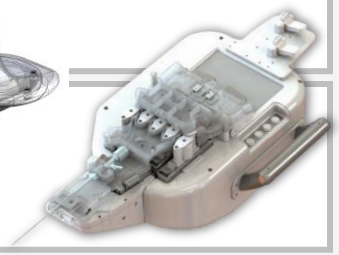
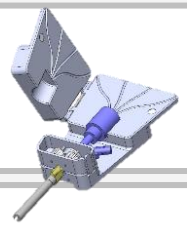
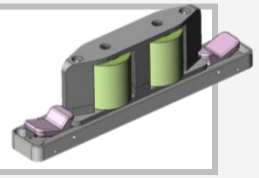
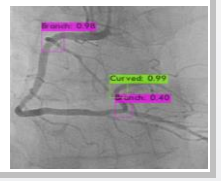
Multi-set instrument / haptic interface / AI

Korean startup

MFDS approval

AVIAR 2 for Commercial Use

Key Advantages of AVIAR 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"

Procedure of AVIAR 2

A Initial Registry for Safety & Feasibility Assessment

- Two cardiac centers included **20 cases of stable patients** receiving coronary stenting with R-PCI using AVIAR 2.0 by Dr. Lee SW in Asan Medical Center & Dr. Lee JH, MD in Eunpyeong St. Mary's Hospital

- No crossover case from R-PCI to manual PCI
- 100% clinical success rate
- Significant reduction of radiation time
- Plan of next clinical studies to assess the efficacy of AVIAR 2.0 R-PCI for complex lesion PCI

Topics

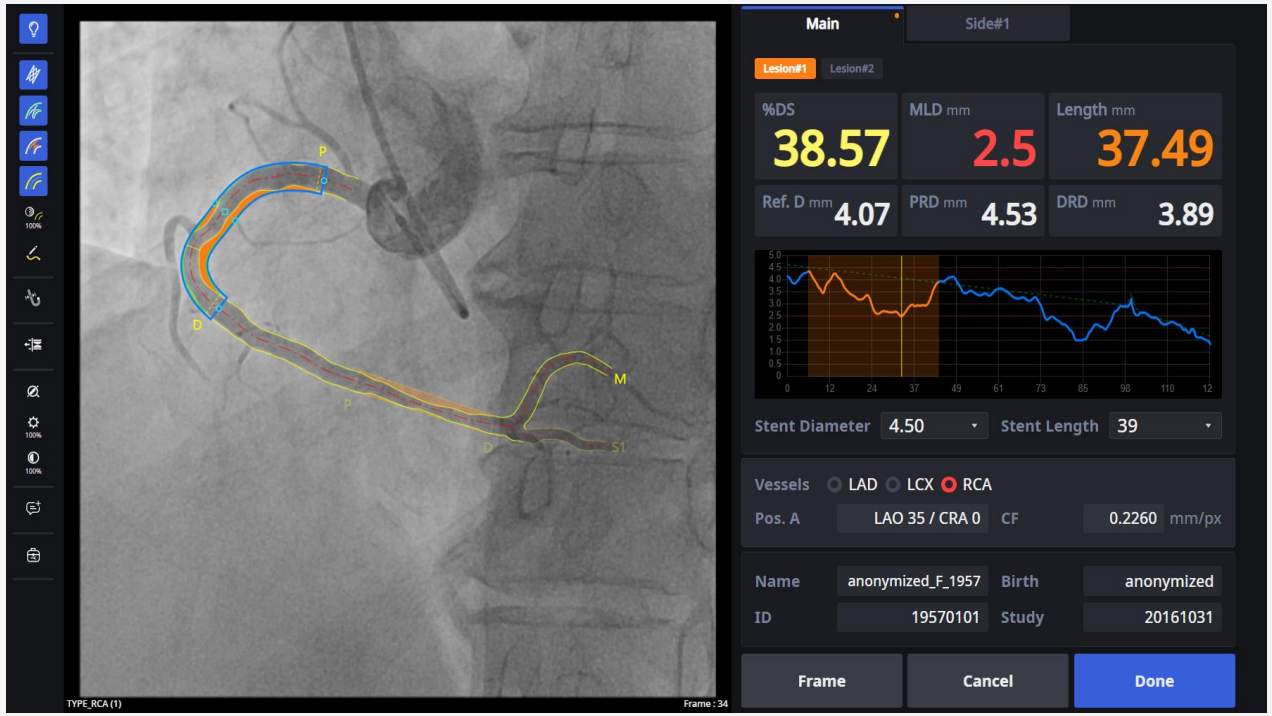
- Interventional robotics for coronary artery disease treatment

- **AI for assistance of coronary intervention**

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

- 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

X-ray Angiography (DICOM)

Input

Deep Learning

Segmentation

Classification

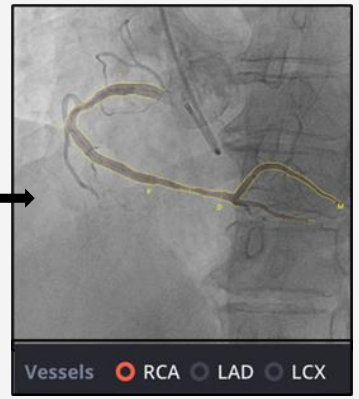


Image Processing

Vessel analysis algorithm

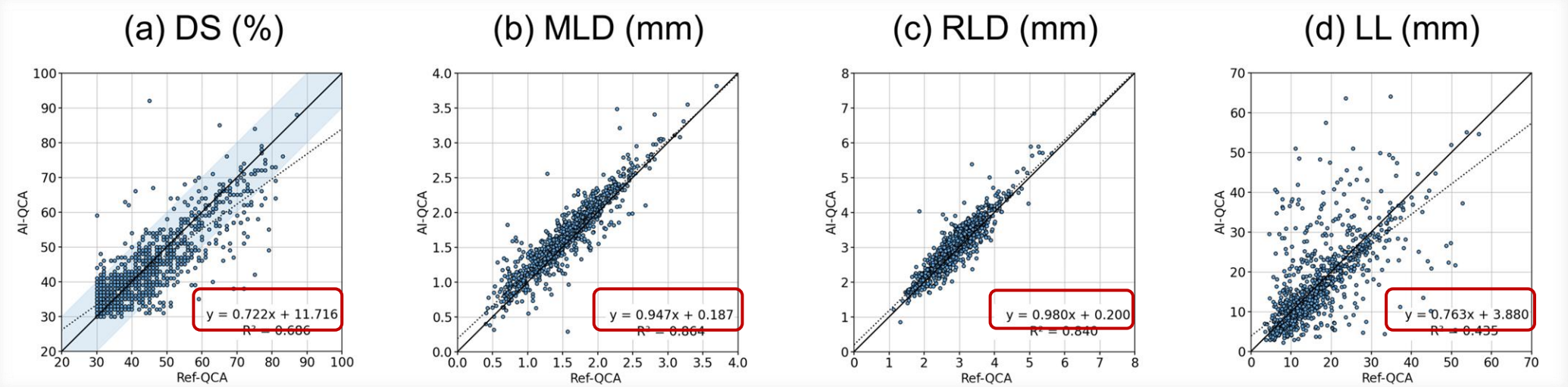
Lesion analysis algorithm

- 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

Accuracy Validation btw AI- vs. Manual-QCA

- MPXA-1000 AI-QCA analysis :
- Retrospective analysis of 676 coronary angiography images at two major hospitals in South Korea (Asan, Sejong Hospital)
- AI-QCA vs manual QCA comparison



Scatter plots of AI-QCA vs. Ref-QCA (upper row) and the corresponding Bland-Altman plots (bottom row). Each dot indicates a lesion.

- AI-QCA lesion detection sensitivity: 89.2%
- Strong correlations for DS, MLD, RLD, LL

YI Kim, et al. Int J Cardiol. 2024 Mar 11:131945.

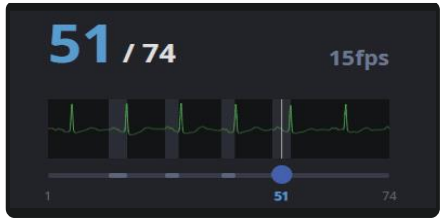
How it works

1 Toolbar Panel
2 Visual Output
3 Measurement Result
4 Vessel Information

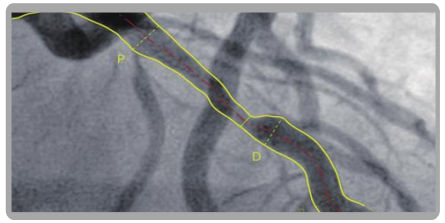
trained with more than **10,000** coronary angiography images

FDA

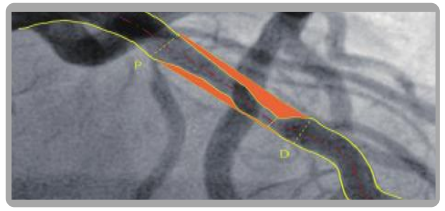
Automated frame selection



Automated segmentation



Automated lesion analysis



Perfromance

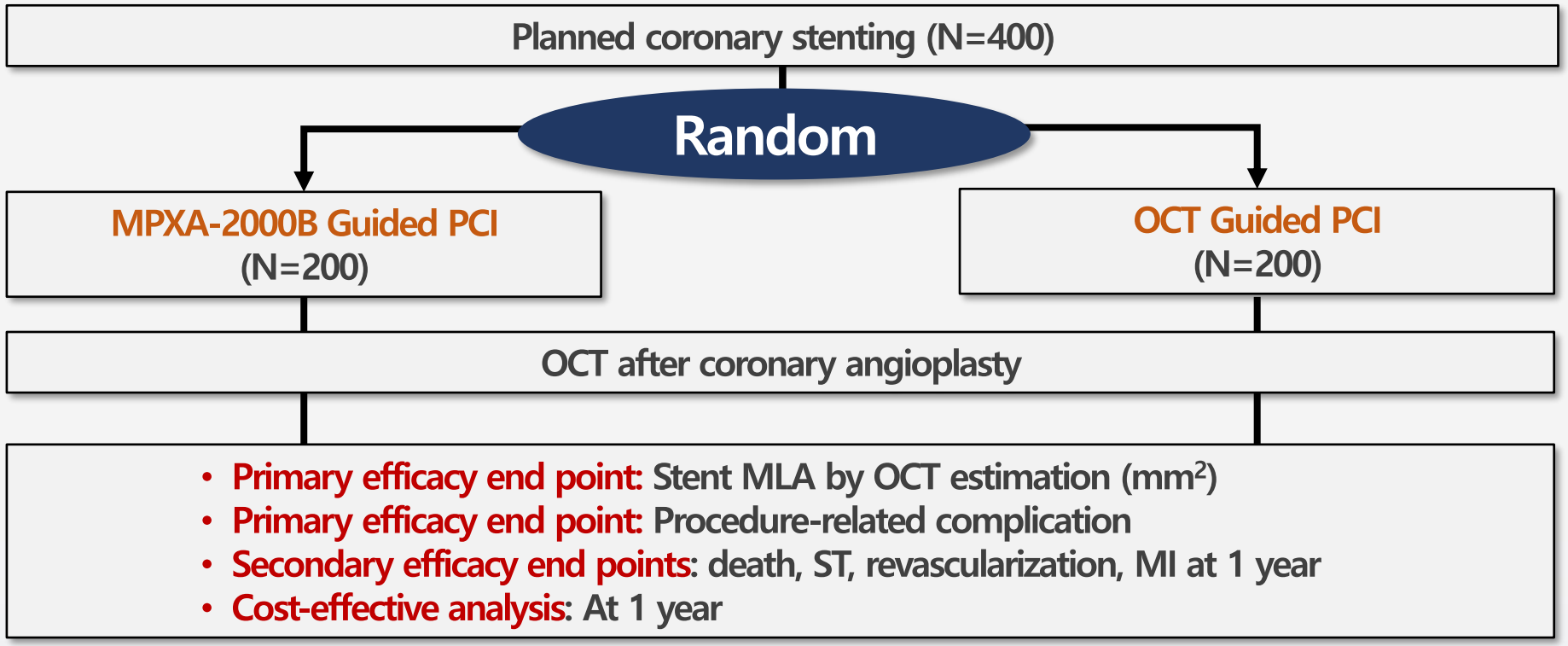
0.91
F1 score
segmentation

0.99
Accuracy
classification

< 2 seconds

FLASH Trial: AI- vs. OCT-guided PCI

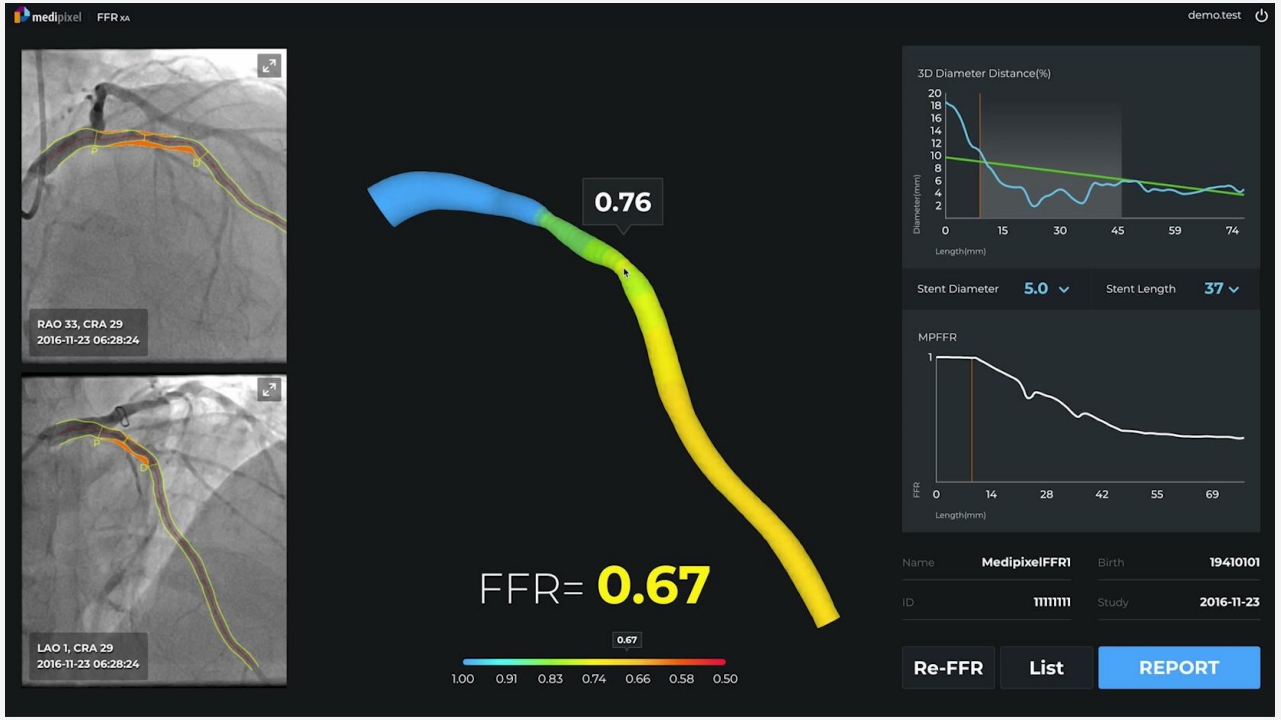
***Fu**l**l**y **A**utomated Quantitative Enrollment was finished! Co**H**erence Tomography Guidance for Coronary Stent Implantation*



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

PI: Jung-Min Ahn, MD, PhD

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

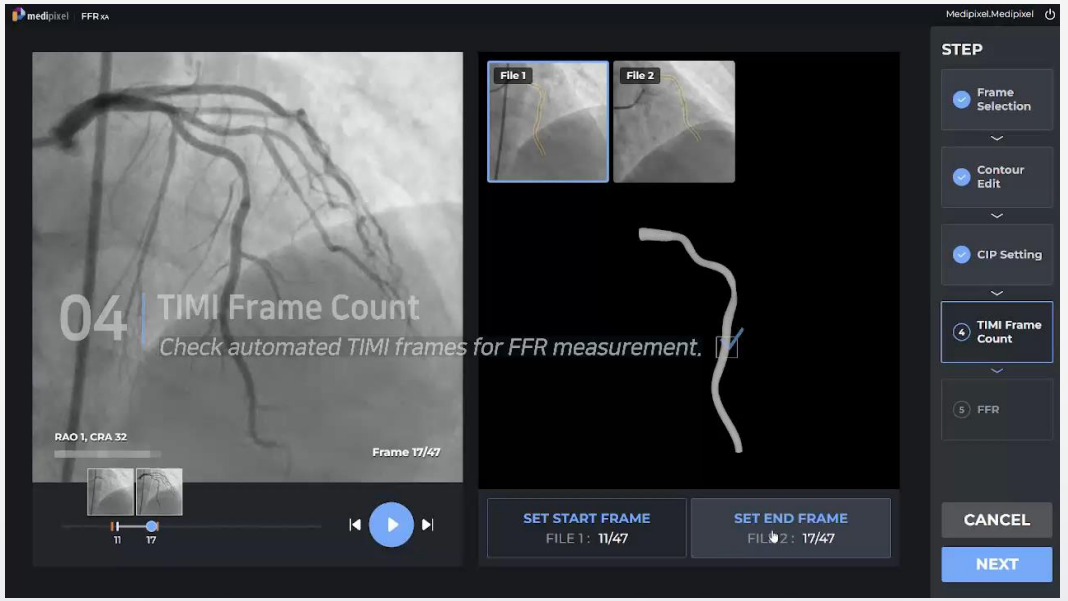


MPFFR$_{XA}$ expands the FFR market

- ✓ 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

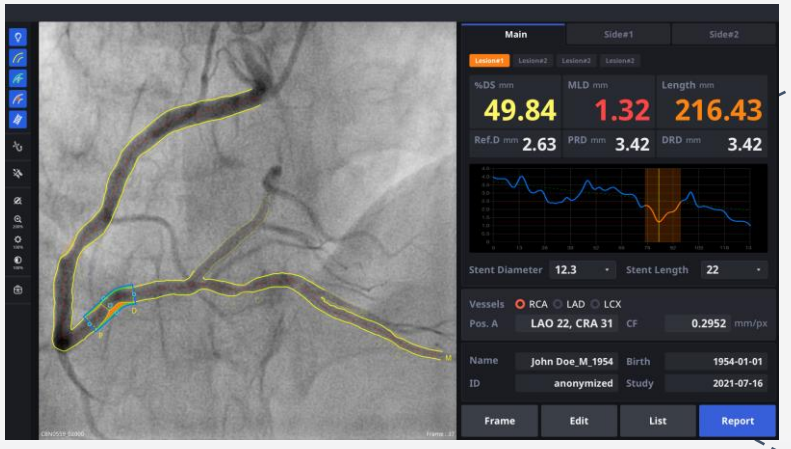
Frame Selection	Contour Segmentation	CIP Estimation	TIMI Frame Selection	FFR Value Estimation	2D QCA Info Display

AI 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

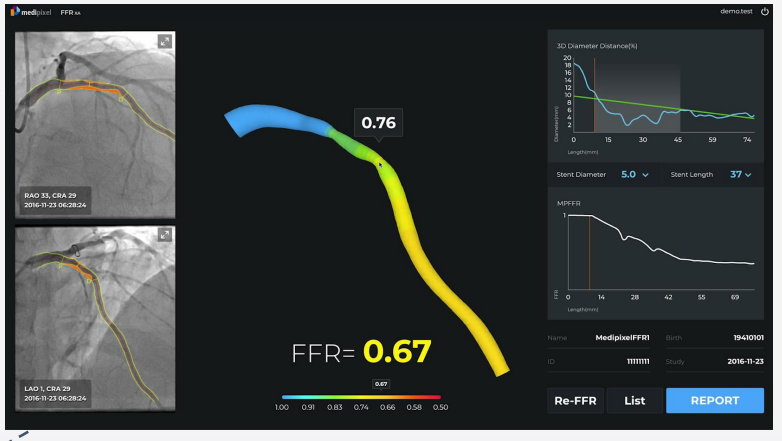
AI-QCA with MPXA



Sharing core technologies

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

AI-FFR by $MPFFR_{XA}$



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.
  - FLASH clinical trial will present the efficacy of AI-QCA-guided PCI as compared with OCT-guided PCI.