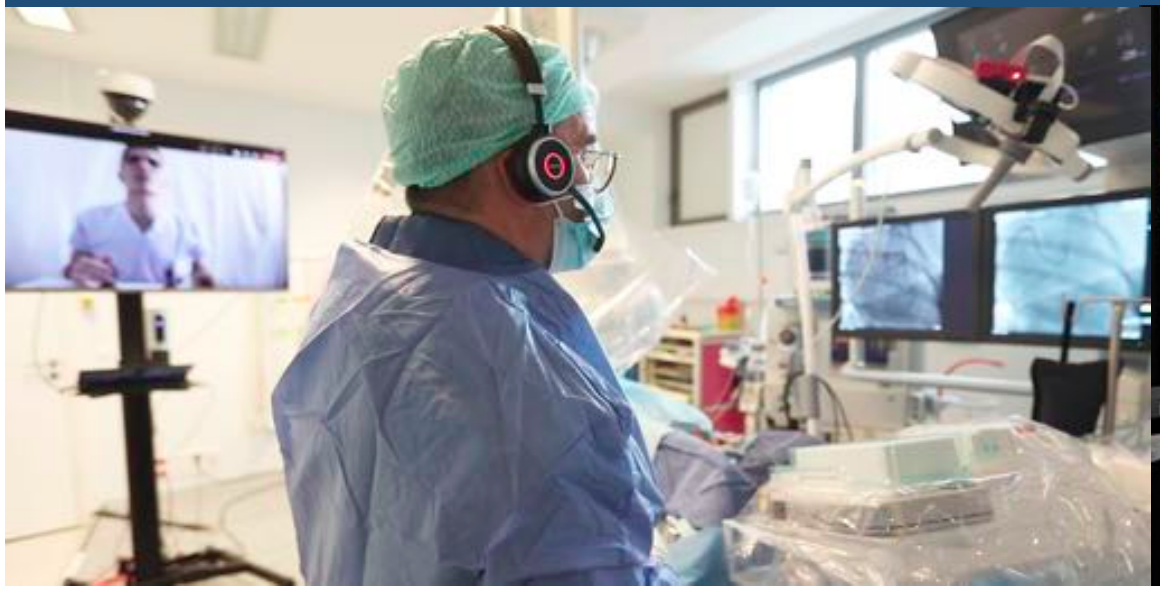
# Le futur : la robotique



Rémi Sabatier, CHU Caen
Eric Durand, CHU Rouen

# Liens d'intérêt

R Sabatier

**Consultant**: Robocath

**Honoraires**: Abbott, Amgen, Boston, Novartis, Sanofi-Aventis

# Le futur: la robotique ?

**Des progrès majeurs en angioplastie coronaire** depuis 1977:

- Amélioration des dispositifs (sonde, guide, ballon, stent,…)
- Optimisation de la pharmacothérapie
- Optimisation du confort et des risques patients (Radial…)

**Peu d'évolution des aspects pratiques de l'angioplastie par l'opérateur**
(manipulation des guides, des ballons et des stents sous Rx)

→ **Risques professionnels pour les opérateurs**
**Inhomogénéité des pratiques**
**Workflow du CathLab dépendant du temps opérateur**

# Risques professionnels pour les opérateurs

| Hazards of Radiation Exposure | Hazards of Protection from Radiation Exposure | Other Hazards |
|---|---|---|
| 1. Cancer<br>• Basal cell skin cancer<br>• Chronic myelogenous leukemia<br>• Thyroid cancer<br>• Brain tumor<br>Am Heart J 2009;157:118-24 | 1. Orthopedic Injury<br>• Lumbosacral spine<br>• Cervical spine<br>• Hip<br>• Knee<br>• Ankle | Exposure to blood-borne infections |
| 2. Cataracts | 2. Operator Fatigue | |
| 3. Effects on reproductive health<br>• Low sperm count<br>• Teratogenesis | | |
| 4. Accelerated atherosclerosis | | |

Andreassi et al. JACC cardiovasc Intv 2015

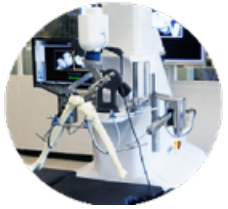
# LA ROBOTIQUE, une place croissante en chirurgie

## UROLOGIE/GYNÉCOLOGIE

**1999**
**DA VINCI**
Intuitive Surgical

**2016**
**ALF-X**
Transenterix

## NEURO



Zimmer

**2008**
**NEUROMATE** Renishaw
**ROBODOC** Think Surgical

**2011**
**ROSA**
Medtech

## ORTHOPÉDIE

Stryker

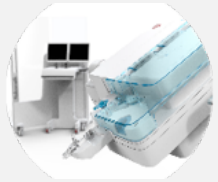
Medtronic

**2006**
**RIO**
Mako Surgical

**2011**
**RENAISSANCE**
Mazor robotics

## CARDIOLOGIE INTERVENTIONNELLE

Siemens

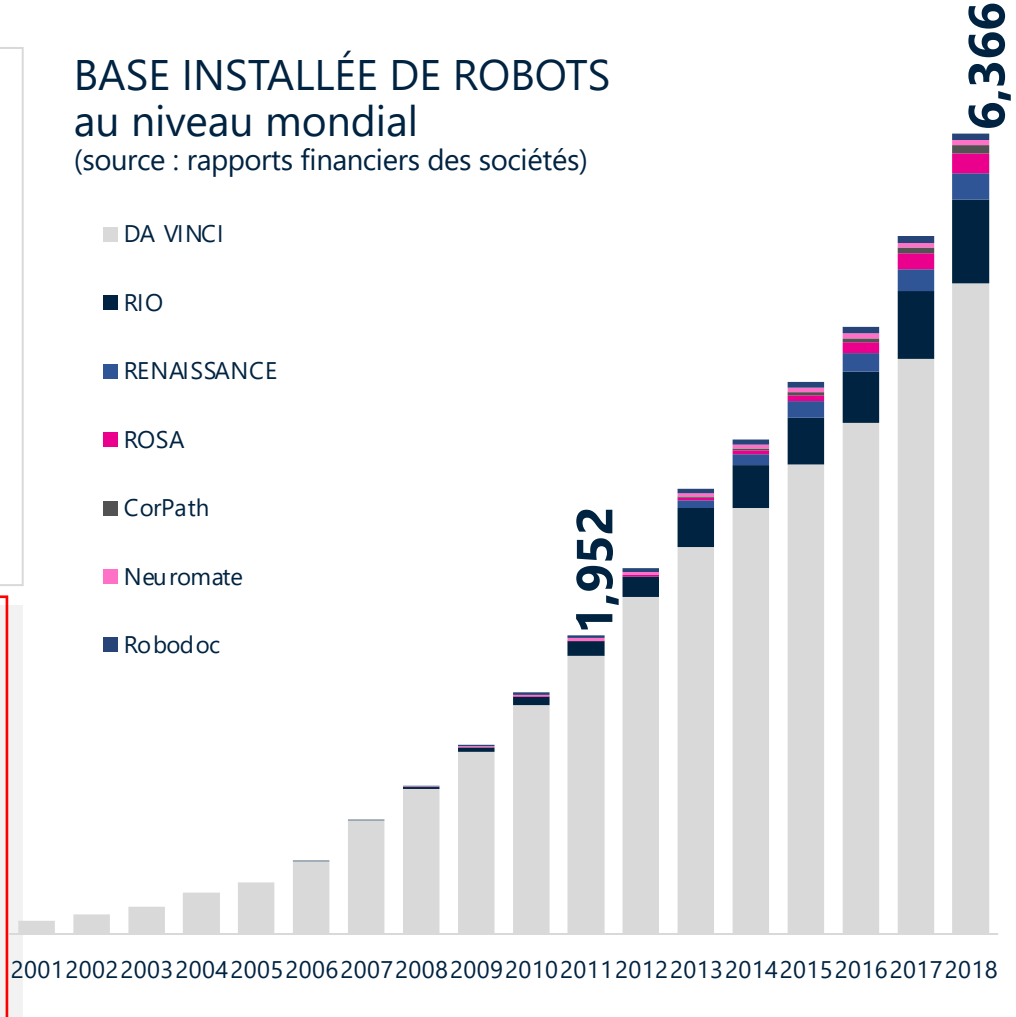


**2011**
**Corpath GRX**
Corindus

**2019**
**R-One™**
Robocath

## BASE INSTALLÉE DE ROBOTS au niveau mondial

(source : rapports financiers des sociétés)



# Rationnels de la robotisation de l'angioplastie coronaire

## Prévention

**Réduire l'exposition des opérateurs aux RX**

- ↓ Irradiation
  - Cataracte
  - Cancer
  - Athérome

**Réduire les équipements de protection des opérateurs**

- ↓ Troubles musculo-squelettiques

## Optimisation

- Précision de la procédure (contrôle)
- Courbe d'apprentissage rapide
- Optimisation Workflow CathLab
- Bénéfice Patient ? (précision, scopie, contraste)

## Autres méthodes préventives d'exposition aux RX

**Dose reduction (cathlab improvement)**

> **AlluraClarity** launched in 2012 by Philips is an interventional X-ray system that provides high quality imaging at low X-ray dose levels

> **Artis Q.zen** launched in 2014 by Siemens also aims at reducing radiation dose

**Apron improvement**

> **Zero Gravity launched in 2010[6] by CFI Medical & Biotronik** is a suspended body shield that provides following improvements:
- increased radiation protection (protects all areas except hands)
- increased comfort (suspended apron)

**Apron emancipation**

> **CathPax** launched in 2012 by Lemer Pax is a mobile radio-protection cabin that allows:
- increased radiation protection (protects all areas except hands)
- total comfort (no apron, seated position)

# Bénéfices en termes de radioprotection

## Sans robot

Temps d'exposition aux rayons X plus important [1,2,3,4]
(plus de procédures complexes, croissance de la population, obésité)

Protections contre les rayons X non efficaces à 100% [5, 6, 7, 8]

Taux d'exposition plus élevé par voie radiale [9,10, 11,12]

Taux d'exposition aux rayons X pour 100 PCIs [13]

> 2000 µGy

## Avec robot

Position assise

Proximité visuelle des écrans

Radio-stop®: protection totale des rayons X

Taux d'exposition aux rayons X pour 100 PCIs [13]

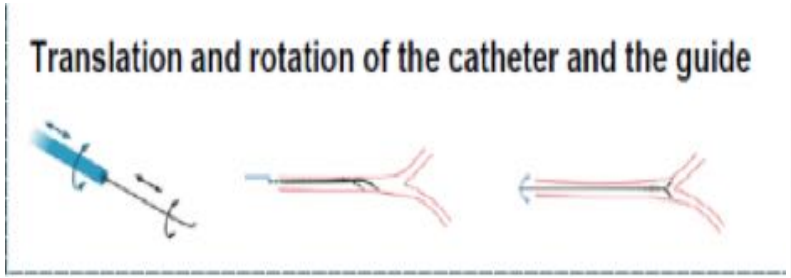
98 µGy

1 an d'exposition (approche manuelle) = 20 ans d'exposition (approche robotique)

[1] Kim, K.P., Miller, D.L., Balter, S., et al., 2008. Occupational radiation doses to operators performing cardiac catheterization procedures. Health Phys. 94, 211–227 ; [2] Payvar S, Kim S, Rao SV, et al. In-hospital outcomes of percutaneous coronary interventions in extremely obese and normal weight patients: Findings from the NCDR. J Am Coll Cardiol. 2013; [3] Buschur ME, Smith D, Share D, et al. The burgeoning epidemic of morbid obesity in patients undergoing percutaneous coronary intervention: Insight from the Blue Cross Blue Shield of Michigan cardiovascular consortium. J Am Coll Cardiol. 2013 ; [4] Madder RD, Van Oosterhout S, Mulder A, et al. Patient body mass index and physician radiation dose during coronary angiography: is the obesity epidemic impacting the occupational risk of physicians in the catheterization laboratory? Circ Cardiovasc Interv. 2019 ; [5] Peter Kamusella, Fabian Scheer, Christopher Wilhem Lütke, Philipp Wiggermann, Christian Wissgott, Reimer Andresen, Interventional Angiography: Radiation Protection for the Examiner by using Lead-free Gloves, Journal of Clinical and Diagnostic Research. 2017 Jul, Vol-11(7): TC26-TC29 ; [6] Fetterly, K., Schueler, B., Grams, M., et al., 2017. Head and neck radiation dose and radiation safety for interventional physicians. JACC Cardiovasc. Interv. 10, 520–528 ; [7] Papadopoulos, N., Papaefstathiou, C., Kaplanis, P.A., et al., 2009. Comparison of lead-free and conventional x-ray aprons for diagnostic radiology. International Federation of Medical and Biological Engineering (IFMBE) proceedings 25/III, 544–546 ; [8] Gabriel Bartal, MD, Anna M. Sailer, MD, Eliseo Vano, PhD, Should We Keep the Lead in the Aprons?, Techniques in Vascular and Interventional Radiology Volume 21, Issue 1, March 2018, Pages 2-6 ; [9] Brasselet C, Blanpain T, Tassan-Mangina S, Deschildre A, Duval S, Vitry F, Gaillot-Petit N, Clément JP, Metz D., Comparison of operator radiation exposure with optimized radiation protection devices during coronary angiograms and ad hoc percutaneous coronary interventions by radial and femoral routes, Eur Heart J. 2008 Jan;29(1):63-70 ; [10] Mann JT, Cubeddu G, Arrowood M. Operator Radiation Exposure in PTCA: Comparison of Radial and Femoral Approaches. The Journal of Invasive Cardiology [01 Jan 1996, 8 Suppl D:22D-25D] ; [11] Samir B.Pancholy MD, Panka jJoshiMD, Sanjay Shah MD, Sunil V.RaoMD, Olivier F. Bertrand MD, PhD, Tejas M.Patel MD, Effect of Vascular Access Site Choice on Radiation Exposure During Coronary Angiography: The REVERE Trial (Randomized Evaluation of Vascular Entry Site and Radiation Exposure, JACC: Cardiovascular Interventions Volume 8, Issue 9, 17 August 2015, Pages 1189-1196 [12] Hibbert B, Simard T, Wilson KR, et al. Transradial versus transfemoral artery approach for coronary angiography and percutaneous coronary intervention in the extremely obese. J Am Coll Cardiol Intv. 2012;5:819-826 ; [13] Ryan Madder talk during SCAI 2017, Cardiology interventions Journal, July-August 2017, Pages 20-24

# Angioplastie coronaire assistée par Robot

**CorPath 200** et **CorPath GRX**
*Corindus/Siemens*

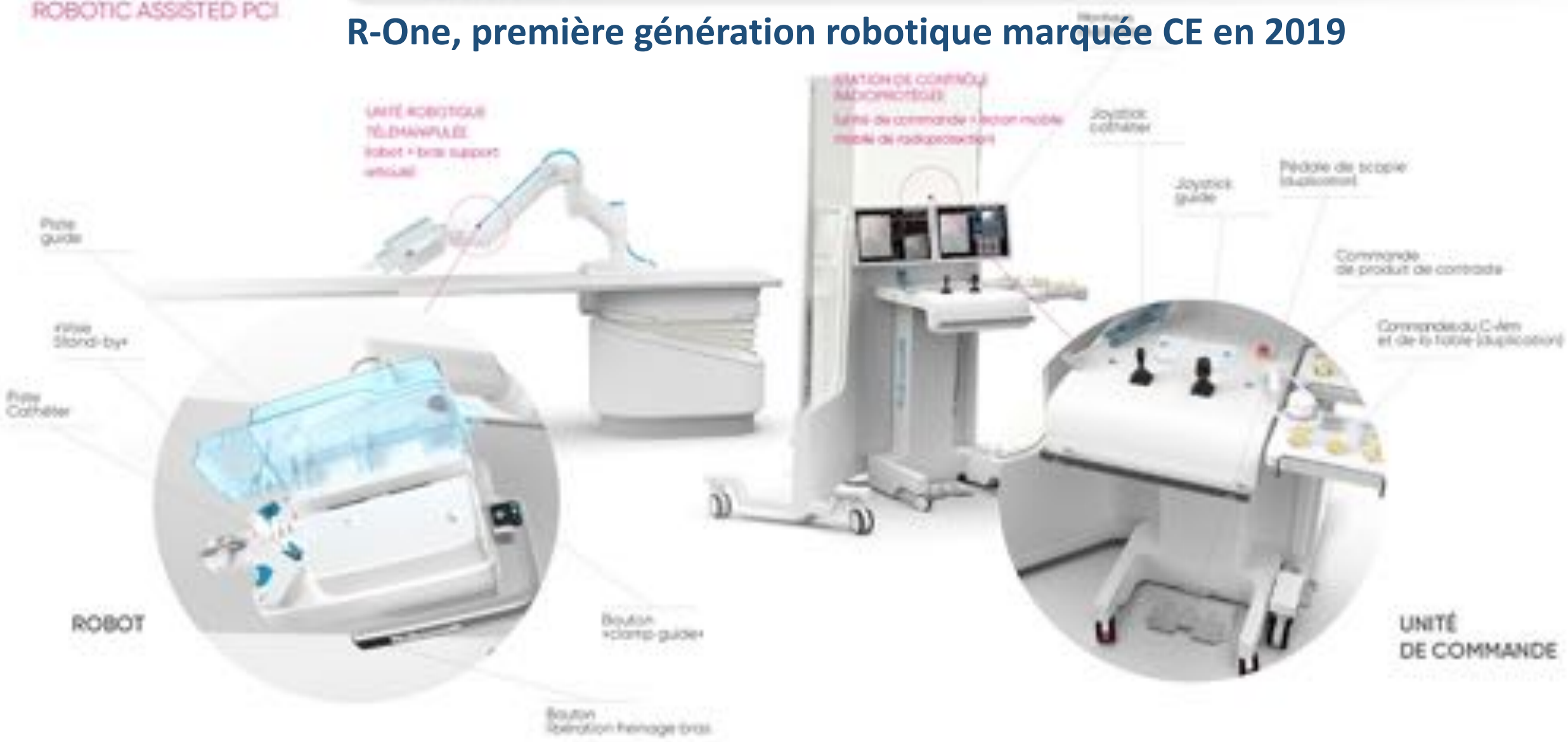




technIQ - Smart Procedural Automation


**R-One**
*Robocath*
*Rouen, Normandie, France*


R-One
ROBOTIC ASSISTED PCI
by Robocath

# R-One, première génération robotique marquée CE en 2019



# Angioplastie robotique: Données de la littérature

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 4, NO. 4, 2011

PUBLISHED BY ELSEVIER INC.
ISSN 1936-8798/$36.00
DOI: 10.1016/j.jcin.2010.12.007

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

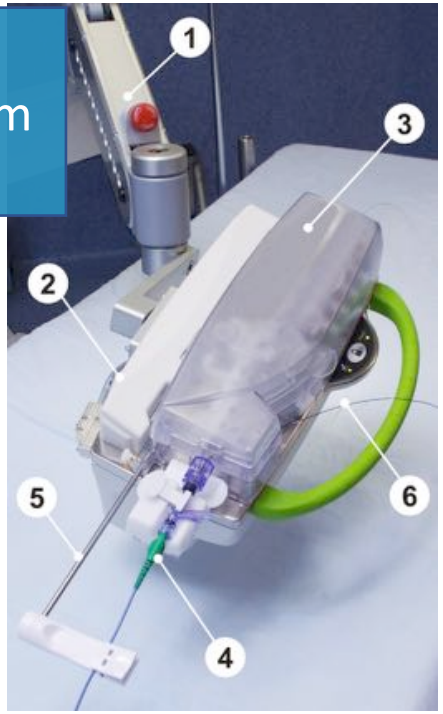
Juan F. Granada, MD,*‡ Juan A. Delgado, MD,† Maria Paola Uribe, MSCE,†
Andres Fernandez, MD,‡ Guillermo Blanco, MD,‡ Martin B. Leon, MD,§
Giora Weisz, MD§

*New York, New York; and Envigado, Colombia*



CorPath 200 System
CORINDUS

8 Lesions type A(6) ou B1(2)
Stenose 63% D3.0mm L11mm
6F Predilatation



# Angioplastie robotique: Données de la littérature

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ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2012.12.045

## Safety and Feasibility of Robotic Percutaneous Coronary Intervention

PRECISE (Percutaneous Robotically-Enhanced Coronary Intervention) Study

Giora Weisz, MD,* D. Christopher Metzger, MD,† Ronald P. Caputo, MD,‡ Juan A. Delgado, MD,§
J. Jeffrey Marshall, MD,‖ George W. Vetrovec, MD,¶ Mark Reisman, MD,# Ron Waksman, MD,**
Juan F. Granada, MD,§ Victor Novack, MD, PHD,†† Jeffrey W. Moses, MD,* Joseph P. Carrozza, MD‡‡

CorPath 200
CORINDUS

- Etude non randomisée, prospective, multicentrique en ouvert

- Une seule lésion: (<24mm, 2.5 à 4 mm)
- Un seul stent

Exclusions:
ATCD de stent Rotablator, Thrombus, Tortuosités ou calcifications sévères, occlusion totale, Ostium, Bifurcation, TC

**Réduction de 95% de l'exposition aux Rx (0.98 vs 20.6 uGy)**


Résultats:

- 164 patients/ 23 opérateurs
- Voie Fémorale
- 68% Lesion A-B1
- Pas de complications
- 2 procédures converties en manuel (Buddy wire, Guideliner)
- ***98.8% sans assistance ou conversion manuelle***

# Angioplastie robotique: Données de la littérature

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 10, NO. 13, 2017
ISSN 1936-8798/$36.00


## Demonstration of the Safety and Feasibility of Robotically Assisted Percutaneous Coronary Intervention in Complex Coronary Lesions

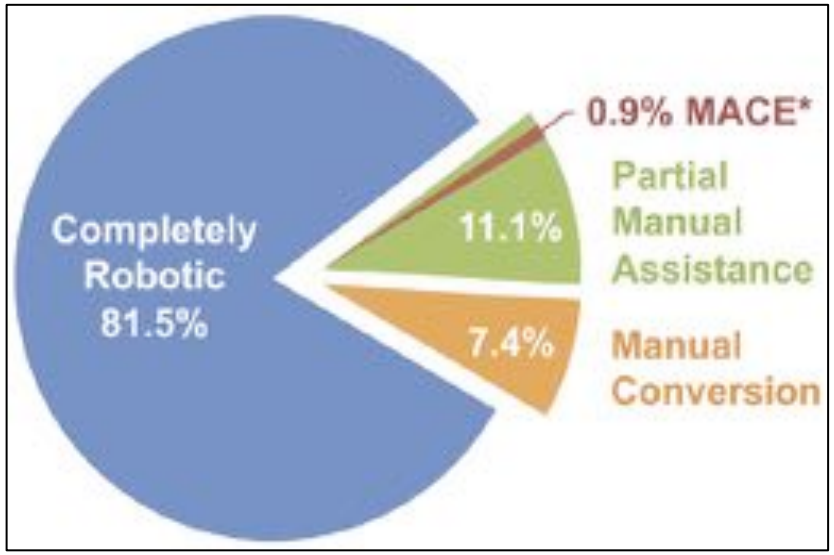
### Results of the CORA-PCI Study (Complex Robotically Assisted Percutaneous Coronary Intervention)

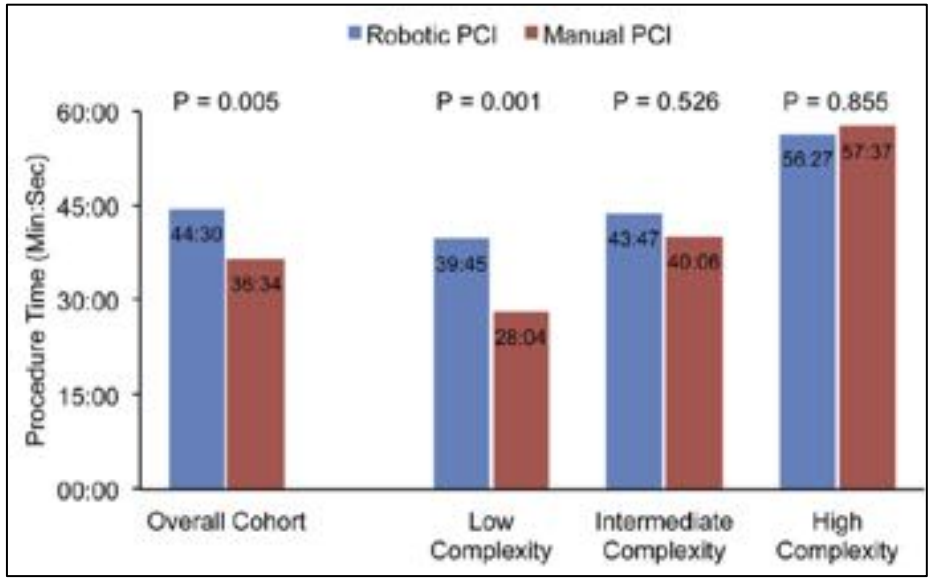
CorPath 200
CORINDUS

Ehtisham Mahmud, MD, Jesse Naghi, MD, Lawrence Ang, MD, Jonathan Harrison, MD, Omid Behnamfar, MD
Ali Pourdjabbar, MD, Ryan Reeves, MD, Mitul Patel, MD

| | Robotic Group (n = 108) | Manual Group (n = 226) | p Value |
|---|---|---|---|
| Target vessel | | | |
| Left main coronary artery | 3.2% | 3.3% | 0.96 |
| Left anterior descending coronary artery | 47.1% | 38.1% | 0.06 |
| Left circumflex coronary artery | 19.7% | 22.6% | 0.46 |
| Right coronary artery | 27.4% | 32.7% | 0.23 |
| Saphenous vein graft | 1.3% | 2.1% | 0.5 |
| Ramus intermedius | 1.3% | 1.2% | 0.94 |
| Lesion type | | | |
| A | 1.9% | 5.1% | 0.09 |
| B1 | 19.7% | 26.2% | 0.12 |
| B2 | 8.9% | 2.4% | 0.001 |
| C | 69.4% | 66.4% | 0.50 |
| Primary lesion stenosis (%) | 84.9 ± 9.2 | 85.9 ± 9.8 | 0.22 |
| Primary lesion length (mm) | 22.2 ± 10.6 | 19.4 ± 9.5 | 0.02 |
| Primary lesion type B2/C | 81% | 69% | 0.03 |
| Lesion complexity score | 5.0 ± 2.3 | 4.9 ± 2.7 | 0.40 |
| SYNTAX score | 19.6 ± 13.0 | 15.7 ± 10.9 | 0.01 |

| | Robotic Group (n = 108) | Manual Group (n = 226) | p Value |
|---|---|---|---|
| Access site | | | |
| Femoral | 88% | 87.6% | 0.93 |
| Radial | 12% | 12.4% | 0.93 |
| Stents deployed | 1.59 ± 0.79 | 1.54 ± 0.75 | 0.73 |
| Lesions treated | 1.47 ± 0.69 | 1.49 ± 0.67 | 0.78 |
| Procedure time (min:s) | 44:30 ± 26:04 | 36:34 ± 23:03 | 0.002 |
| Fluoroscopy time (min) | 18.2 ± 10.4 | 19.2 ± 11.4 | 0.39 |
| Dose-area product (cGy · cm²) | 12,518 ± 15,970 | 14,048 ± 18,437 | 0.045 |
| Contrast volume (ml) | 183.4 ± 78.7 | 202.5 ± 74 | 0.031 |
| MACE* | 0.9% | 0.9% | 1.00 |
| CK-MB >3 times ULN | 5.6% | 7.5% | 0.51 |



# Angioplastie robotique: Données de la littérature

*Circ Cardiovasc Interv.* 2020;13:e008888. DOI: 10.1161/CIRCINTERVENTIONS.119.008888

## Comparison of Robotic Percutaneous Coronary Intervention With Traditional Percutaneous Coronary Intervention

### A Propensity Score–Matched Analysis of a Large Cohort

CorPath GRX
CORINDUS

Tejas M. Patel, MD, DM; Sanjay C. Shah, MD, DM; Yash Y. Soni, DRT; Rajni C. Radadiya, DA; Gaurav A. Patel, MD; Pradyot O. Tiwari, MD; Samir B. Pancholy, MD

| Characteristics | T-PCI (n=280) | R-PCI (n=280) | *P* Value |
|---|---|---|---|
| Target vessel | | | 0.171 |
| LM | 0 (<0.1) | 1 (0.4) | |
| LAD | 205 (73.2) | 187 (66.8) | |
| LCX | 24 (8.6) | 43 (15.4) | |
| RCA | 46 (16.4) | 44 (15.7) | |
| Grafts | 1 (0.4) | 2 (0.7) | |
| Bifurcation | 4 (1.4) | 3 (1.1) | |
| Chronic total occlusions | 13 (4.6) | 11 (3.9) | 0.676 |
| Severe tortuosity | 1 (0.4) | 2 (0.7) | 0.5 |
| SYNTAX score* | 14 (10–21) | 13 (9–17) | 0.433 |
| No. of cineangiogram acquisitions* | 18 (14–24) | 17 (11–24) | 0.2 |

| Characteristics | T-PCI (n=280) | R-PCI (n=280) | *P* Value |
|---|---|---|---|
| AK, mGy | 1110 (699–1498) | 884 (537–1398) | 0.002 |
| Dose-area product, cGycm$^2$ | 5746 (3751–7833) | 4734 (2695–7746) | 0.003 |
| Fluoroscopy time, min | 5.51 (3.53–8.31) | 5.48 (3.31–9.37) | 0.936 |
| Contrast volume, mL | 130 (103–170) | 140 (100–180) | 0.905 |
| Total procedural time, min | 27 (21–40) | 37 (27–50) | <0.0005 |

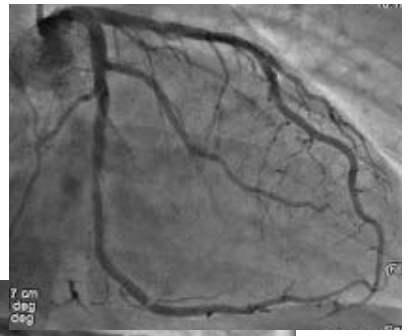
# FIM en 2019 avec R-One Robocath

CHU de Rouen
E. Durand
R. Sabatier

- Patient de 57 ans
- Sténose bissectrice > 20 mm
- Voie radiale droite 6F, EBU 3,5
- Guide Sion Blue (Asahi Intecc)
- Ballon SC Ryujin Plus 2.0X30mm (Terumo)
- Stent Onyx 2.5X34mm (Medtronic)

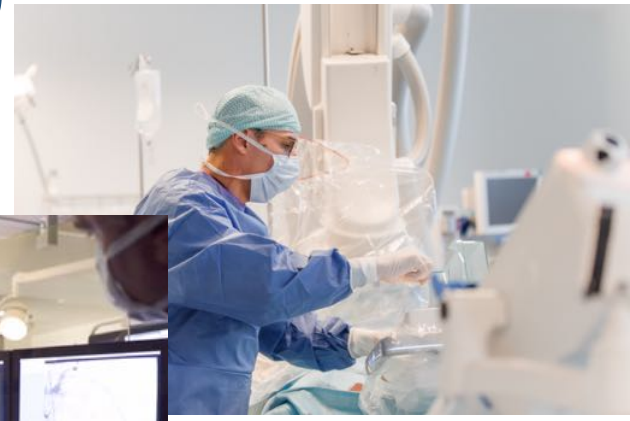
Clinique Pasteur, Toulouse
J. Fajadet

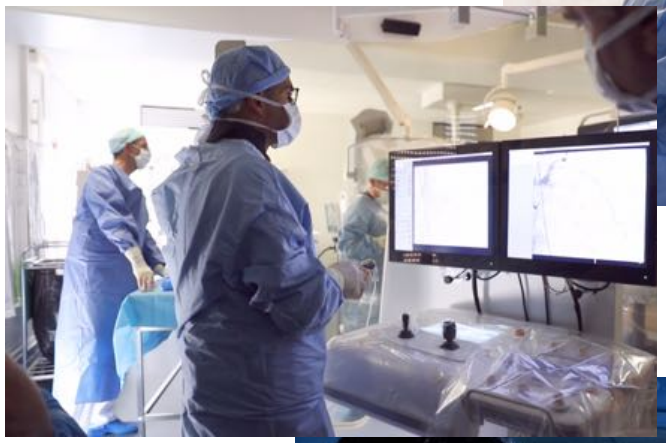
- Patient 57 ans
- Sténoses Mg2 > 20 mm
- Voie radiale 6F, EBU 3,75
- Guide BMW (Abbott)
- Ballon SC Sprinter 2.5X30mm (Medtronic)
- 2 stents Synergy 2.75X28mm et 2.5X28mm (Boston)
- Ballon Euphora NC 3.0X30mm (Medtronic)



# Zoom sur l'étude R-Evolution (R-One, Robocath)

- Etude prospective, multicentrique
- 60 patients
- 6 Centres :
  - CHU Rouen, E. Durand (PI),
  - Clinique Pasteur Toulouse, J. Fajadet (PI)
  - CHU Caen, R. Sabatier
  - ZNA Middelheim Anvers, S. Verheye
  - Maastaad Rotterdam, P. Smits, M. Van der Ent
  - INCCI Luxembourg, B. Pereira
- Lésion de novo < 38mm, 2.5 à 4mm, 1 stent/ lésion, 1 lesion/artère, tortuosité/calcification légère à modérée
- Primary endpoints : Succès de la procédure
- Follow-up : 1 mois- Monitoring : CERC
- Début d'inclusion: Q4 2019 / Fin d'inclusion: Q3 2021





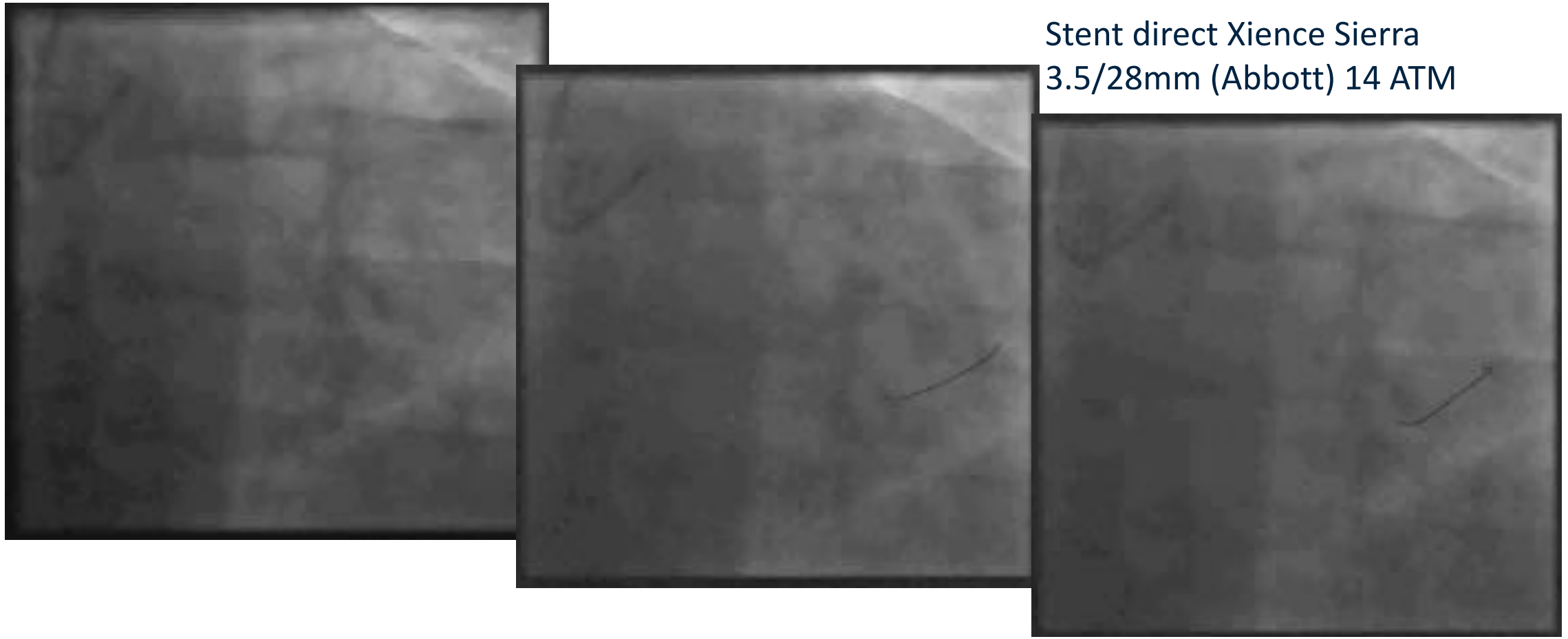
- To date : 20 patients inclus
- Taux de succès technique*: 100%
- No MACE

* Technical Success: defined as successful completion of the robotic-assisted PCI without total manual conversion for guidewire or balloon/stent catheter (inability to navigate vessel anatomy) during procedure time (T0= robot guidewire introduction → Tend= balloon/stent catheter removal)

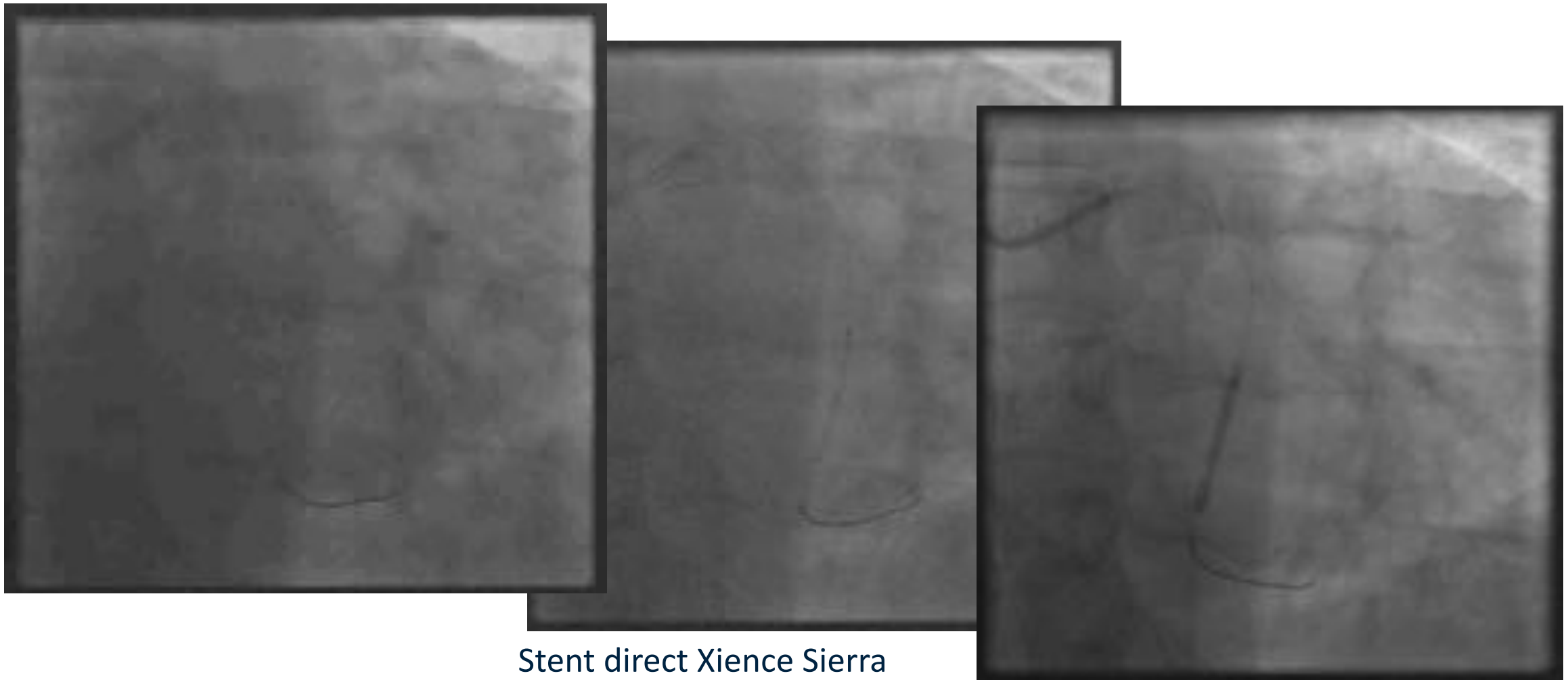
# Quelques exemples

Mr G, 56 ans, BMI 39, Ischémie inférieure et latérale
Sténoses Mg 1 et Cx 2

Stent direct Xience Sierra
3.5/28mm (Abbott) 14 ATM



Mr G, 56 ans, BMI 39, Ischémie inférieure et latérale
Sténoses Mg 1 et Cx 2



Stent direct Xience Sierra
2.5/23mm (Abbott) 14 ATM

Mr G, 56 ans, BMI 39, Ischémie inférieure et latérale
Sténoses Mg 1 et Cx 2

Post-dilatation Accuforce
2.5/15mm (Terumo) 20 ATM

# Angioplastie robotique à « longue » distance

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

C.

*Background:* Robotic-assisted percutaneous coronary intervention (R-PCI) has been successfully employed in the United States since 2011. Performing R-PCI from a remote location has never been reported but if feasible would extend availability of treatment to many patients with coronary artery disease (CAD) who would otherwise go without.
*Objective:* To assess the feasibility of remote tele-R-PCI with the operator 20 miles away from the patients.
*Methods:* Five patients with single, type A coronary artery lesions treatable by PCI consented to participate. The primary endpoint was procedural success with no major adverse cardiac events (MACE) before discharge. Procedural success was defined as achieving < 10% diametric stenosis of the occluded target vessel utilizing tele-R-PCI balloon angioplasty and stent deployment (CorPath GRX®, Corindus Vascular Robotics, USA) without converting to in-lab manual PCI by an on-site standby team. Procedural, angiographic, and safety data were collected as were questionnaire scores from the remote operator evaluating the robot-network composite, image clarity, and overall confidence in the procedure.
*Results:* The primary endpoint was achieved in 100% of patients. No procedural complications or adverse events occurred, and all patients were discharged the following day without MACE. The operator scores were favorable with the operators rating the procedure as equivalent to an in-lab procedure.
*Conclusions:* Performing long distance tele-R-PCI in patients with CAD is feasible with predictably successful outcomes if reliable network connectivity and local cardiac catheterization facilities are available.

Pattel MT et al. EClinicalMedecine 2019

# Zoom sur l'intervention robotique à grande distance avec R-One Robocath

- **Première démonstration de faisabilité en décembre 2020**
  - >120 km de distance (CHU Caen → Medical Training Center Rouen) : Première en Europe
- Prochaines étapes:
  - Etude pré-clinique sur animal avec variabilité de plusieurs paramètres (distance, réseau, communication)
  - Etude clinique sur l'Homme
- **Bénéfices attendus :**
  - Dimimue le temps d'accès au meilleur traitement
  - Répond au manque à venir de cardiologues interventionnels
  - Meilleur accès aux soins pour les personnes vivant dans des zones reculées (en Europe, 40% des infarctus du myocarde ne sont pas traités par angioplastie primaire, essentiellement en raison des temps de transport vers un centre de cardiologie interventionnelle*)

* Widimsky P, Wijns W, Fajadet J, et al., Reperfusion therapy for ST elevation acute myocardial infarction in Europe: description of the current situation in 30 countries, Eur Heart J, 2010;31:943–57 ; Grønborg Laut K., Becic Pedersen A., Lash T., and Dalby Kristensen S., Barriers to Implementation of Primary Percutaneous Coronary Intervention in Europe, European Cardiology, 2011;7(2):108–12

# R-One Remote Robotic PCI

# Prochains développements de la robotique en angioplastie

- **Registre observatoire** pour tous les centres impliqués dans un programme robotique
- **Intervention depuis la salle de contrôle**
- **Prochaine génération robotique**:
  - Repositionnement robotisée du cathéter guide
  - Management de plusieurs devices (rapid-exchange & over-the-wire)
  - Intégration complète dans le cathlab
  - Mouvements autonomes du guide (IA)
- Intervention à grande distance

# En conclusion : Bénéfices de la robotique en angioplastie coronaire

## Opérateurs

- **Position ergonomique** (meilleure visualisation, prévention des TMS)
- **Protection totale des Rx**
- **Courbe d'apprentissage rapide** (simplicité/sécurité)
- Guide verrouillé
- **Conversion manuelle rapide** et intuitive (R-one)

## Patients

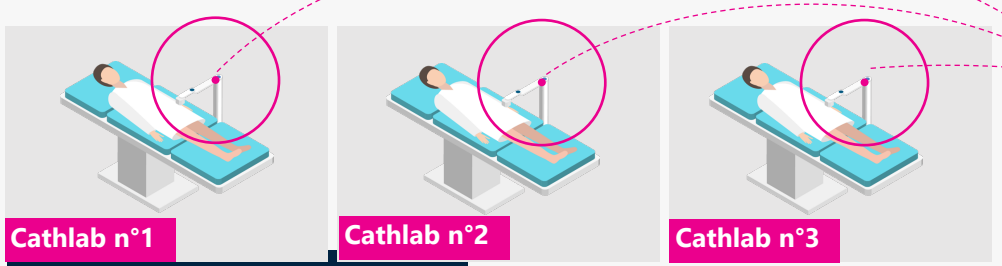
- Précision (positionnement du stent)
- Diminution de l'exposition aux Rx
- Moins de fatigue pour l'opérateur/meilleur résultat ?
- Augmentation du temps de procédure sans Rx ?

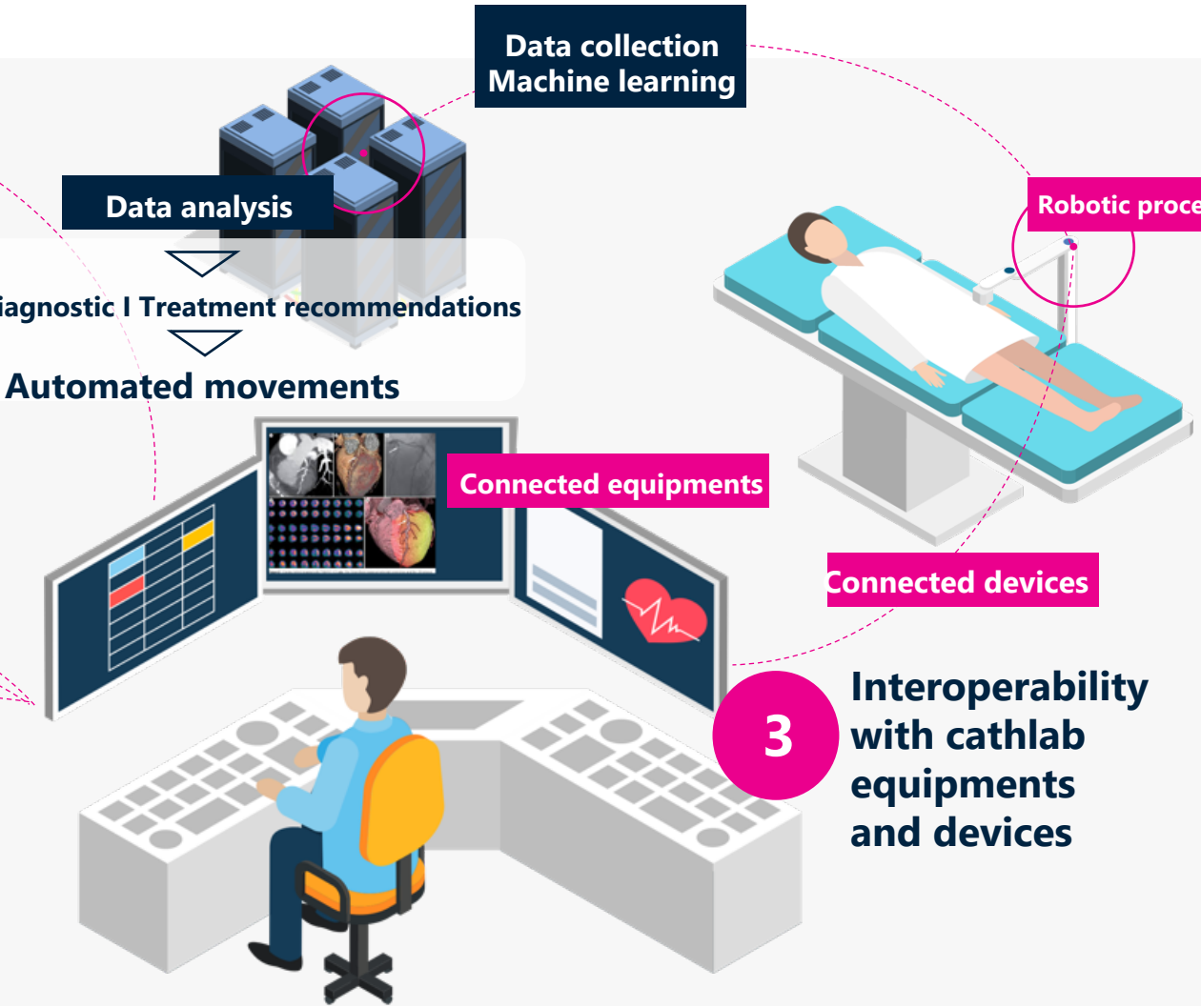
## Hôpitaux

- Visibilité/Innovation
- Attractivité Patient
- Attractivité Praticien
- Optimisation CathLab?/ coût de la procédure (Robot+ consommables)

# Future generation of cathlabs ?

**2** **Remote procedures**


**3** **Interoperability with cathlab equipments and devices**