HIGH TECH MARSEILLE

1·2·3 FÉVRIER 2023

MARSEILLE·PALAIS DU PHARO

6 minutes pour convaincre

L'angioplastie robotisée

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Liens d’intérêt

- Robocath, Edwards Lifesciences: consultant

1. Parce que pas grand-chose n'a changé ?

- ✓ **Des progrès majeurs en angioplastie** coronaire depuis 1977:
  - Utilisation de la voie radiale
  - Amélioration des dispositifs (sonde, guide, ballon, stent,…)
  - Optimisation de la pharmacothérapie
  - Amélioration de l'évaluation des lésions (FFR, IVUS, OCT)

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

1. Parce que la robotique occupe une place croissante en médecine !

UROLOGIE/GYNÉCOLOGIE

1999
DA VINCI
Intuitive Surgical

2016
ALF-X
Transenterix

NEURO

2008
NEUROMATE
Renishaw

ROBODOC
Think Surgical

2011
ROSA
Medtech

ORTHOPÉDIE

2006
RIO
Mako Surgical

2011
RENAISSANCE
Mazor robotics

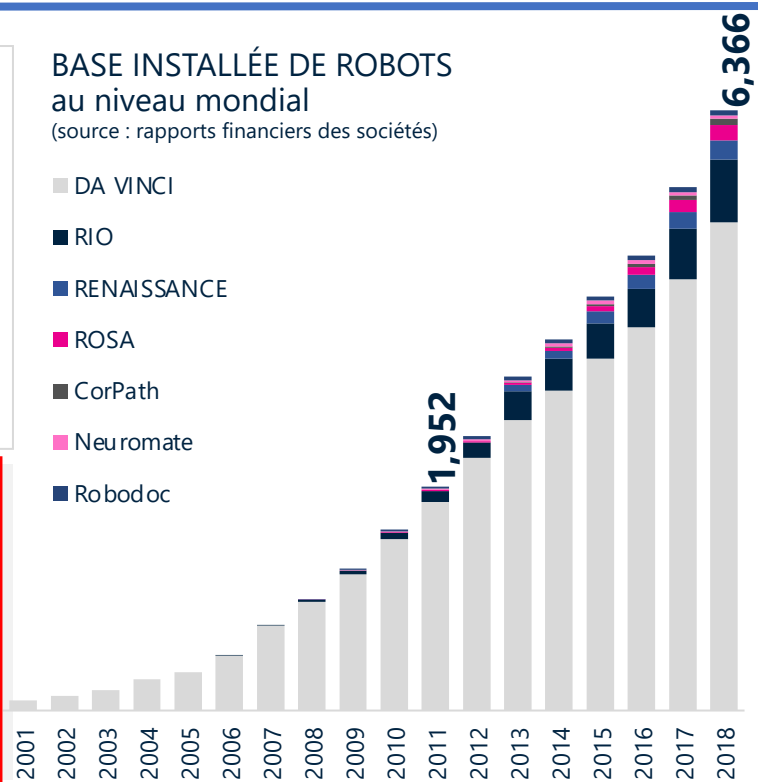
CARDIOLOGIE INTERVENTIONNELLE

2011
Corpath GRX
Corindus

2019
R-One™
Robocath

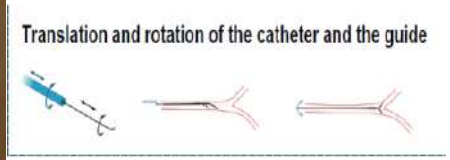
BASE INSTALLÉE DE ROBOTS au niveau mondial

(source : rapports financiers des sociétés)



1. Deux plateformes robotiques actuellement disponibles sur le marché européen

CorPath 200 et **CorPath GRX**
Corindus/Siemens Healthineers
US/Germany



R-One
Robocath
Rouen, Normandie, France

2. Car nous sommes exposés à des risques !

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

Andreassi et al. JACC Cardiovasc Intv 2015

2. Car les autres alternatives sont insuffisantes ou peu adaptées à nos pratiques

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

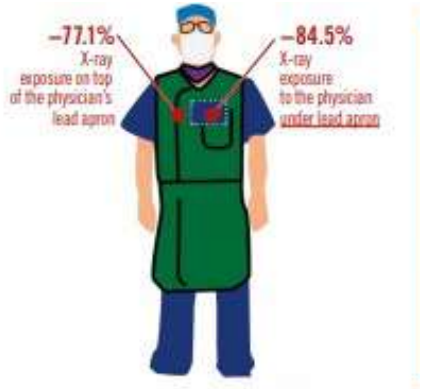
> **Zero Gravity launched in 2010[4] by CFI Medical & Biotronik** is a suspended body shield that provides following improvements:
- increased radiation protection (protects all areas except hands)
- increased comfort (suspended apron)

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)

3. Pourquoi intégrer la robotique vasculaire dans ma pratique quotidienne ?

1. Diminuer drastiquement mon exposition aux rayons X



5. Optimiser la procédure

- Point fixe permanent
- Avance millimétrique
- Torque robotique

4. Standardiser la procédure

- Courbe d'apprentissage rapide

2. Réduire les troubles musculo-squelletiques

½ opérateur

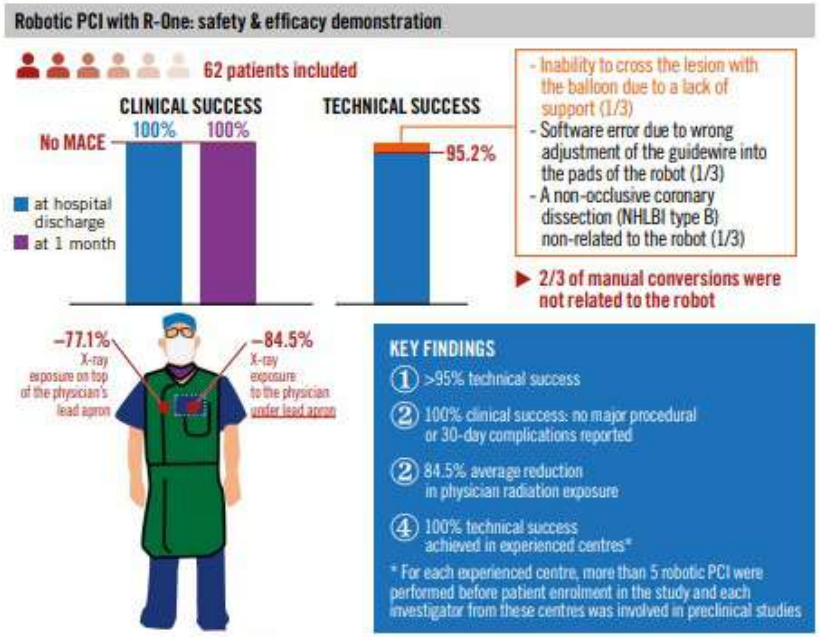
3. Améliorer l'ergonomie de travail

- Proximité visuelle des écrans
- Position assise

4. Pour quels résultats cliniques ?

EuroIntervention

CENTRAL **ILLUSTRATION** Safety and efficacy of R-One Robotic System for PCI in patients with a de novo coronary artery stenosis.



MACE: major adverse coronary events; NHLBI: National Heart, Lung, and Blood Institute; PCI: percutaneous coronary intervention

Durand E, et al: the R-EVOLUTION study, EuroIntervention 2023, 10.4244/EIJ-D-22-00642

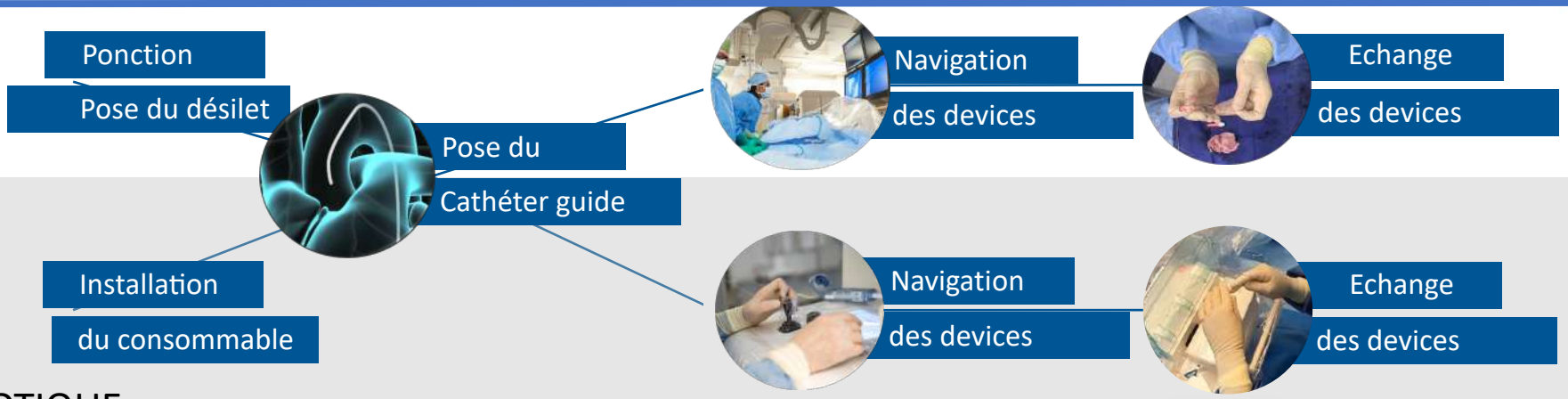
4. Pour quels résultats cliniques ?

	Beyar et al[29]	PRECISE[21]	CORA-PCI[22]	Smitson et al[19]	PRECISION Registry*	R-EVOLUTION
System used	**RNS**	**CorPath 200**	**CorPath 200**	**CorPath GRX**	**CorPath GRX**	**R-One**
Number of sites, n	1	9	n/r	1	20	6
Patients, n	18	164	108	40	980	62
Complex lesions, %	n/r	31.7	78.3	77.8	68.8	25.0
Technical success, %	83.3	98.8	91.7	90.0	86.5	95.2
Clinical success, %	100	97.6	99.1	97.5	97.8	100
MACE, % (follow-up)	0 (in-hospital)	0 (30 days)	0.9 (in-hospital)	n/r	0 (in-hospital)	0 (30 days)
Total procedure time, min	44	n/r	44.5	40.2	54.3	39.9
Total robotic procedure time, min	n/r	24.4	n/r	n/r	n/r	19.9
Mean fluoroscopy time, min	8.8	11.1	18.2	17.4	17.8	10.3
Mean contrast injection volume, mL	n/r	144.2	183.4	171	118.2	118.3
Mean patient radiation exposure, mGy	n/r	1,5	n/r	n/r	n/r	540.3
Mean reduction in operator radiation exposure with lead protection, %	n/r	n/r	n/r	n/r	n/r	84.5
Median reduction in operator radiation exposure, %	n/r	95.2	n/r	n/r	n/r	100 (under lead) 86.07 (on lead)

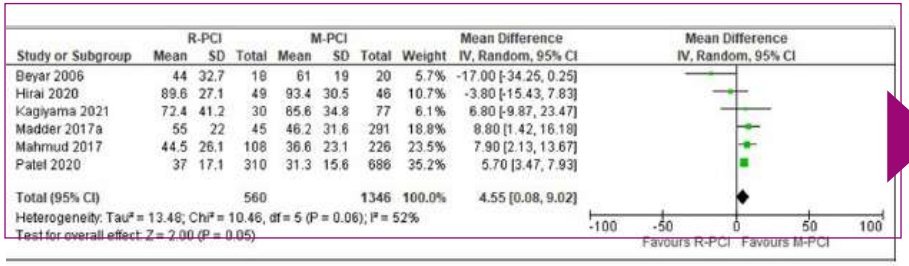
*(Medranda GA, Waksman R. Safety and Efficacy of the Second-Generation Robotic Assisted Systems for PCI. Society for Cardiovascular Angiography and Interventions. 2 July 2021; https://scai.org/safety-and-efficacy-second-generation-robotic-assisted-systems-pci-coverage-late-breaking-science. [Last accessed 7 Dec 2022]). MACE: major adverse cardiac event; mGy: milligray; n/r: not reported

Durand E, et al: the R-EVOLUTION study, EuroIntervention 2023, 10.4244/EIJ-D-22-00642

5. Idée reçue n°1: *une intervention robotique prend plus de temps qu'une intervention manuelle!*



ROBOTIQUE



Study or Subgroup	R-PCI Mean	SD	Total	M-PCI Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Beyar 2006	44	32.7	18	61	19	20	5.7%	-17.00 [-34.25, 0.25]
Hirai 2020	89.6	27.1	49	93.4	30.5	46	10.7%	-3.80 [-15.43, 7.83]
Kagiyama 2021	72.4	41.2	30	65.6	34.8	77	6.1%	6.80 [-9.87, 23.47]
Madder 2017a	55	22	45	46.2	31.6	291	18.8%	8.80 [1.42, 16.18]
Mahmud 2017	44.5	26.1	108	36.6	23.1	226	23.5%	7.90 [2.13, 13.67]
Patel 2020	37	17.1	310	31.3	15.6	686	35.2%	5.70 [3.47, 7.93]
Total (95% CI)			560			1346	100.0%	4.55 [0.08, 9.02]

Heterogeneity: Tau² = 13.46; Chi² = 10.46, df = 5 (P = 0.06); I² = 52%
Test for overall effect: Z = 2.00 (P = 0.05)

Mean Difference IV, Random, 95% CI
-100 -50 0 50 100
Favours R-PCI Favours M-PCI

Pendant la procédure

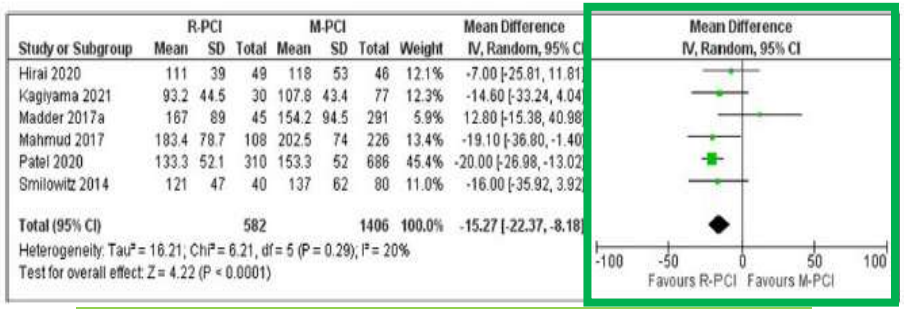
Manuel **[37 – 90 min][1]**

Robotique **[31 – 93 min][1]**

Pas de différence significative

1 Jaffar-Karballai M, et al. J Cardiol. 2022 Feb 11:S0914-5087(22)00023-5. doi: 10.1016/j.jjcc.2022.02.002. Epub ahead of print. PMID: 35165012.

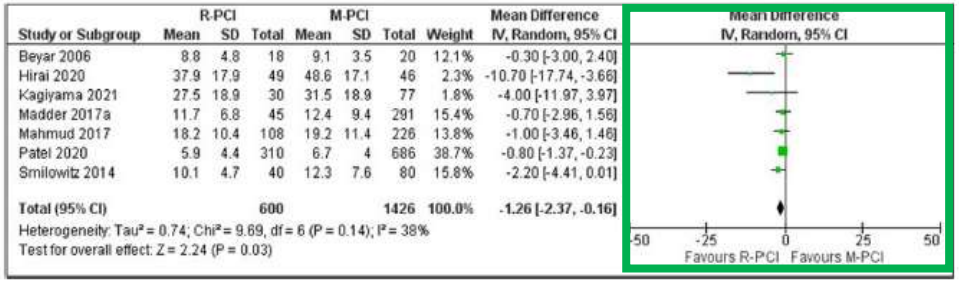
5. Idée reçue n°2 : *il n'y a pas de bénéfice pour le patient !*



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)

Diminution du volume de contraste



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)

Diminution de la durée de scopie

Diminution de l'exposition aux Rx

Characteristics	T-PCI (n=280)	R-PCI (n=280)	*P* Value
AK, mGy	1110 (699–1498)	884 (537–1398)	0.002
Dose-area product, cGycm²	5746 (3751–7833)	4734 (2695–7746)	0.003

Jaffar-Karballai et al. J Cardiol 2022

5. Idée reçue n°3 : je ne peux pas traiter toutes les lésions

Table 6. Results comparison with similar devices.

	Beyar et al[29]	PRECISE[21]	CORA-PCI[22]	Smitson et al[19]	PRECISION Registry*	R-EVOLUTION
System used	**RNS**	**CorPath 200**	**CorPath 200**	**CorPath GRX**	**CorPath GRX**	**R-One**
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Complex lesions, %	n/r	31.7	78.3	77.8	68.8	25.0
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Clinical success, %	100	97.6	99.1	97.5	97.8	100
MACE, % (follow-up)	0 (in-hospital)	0 (30 days)	0.9 (in-hospital)	n/r	0 (in-hospital)	0 (30 days)
Total procedure time, min	44	n/r	44.5	40.2	54.3	39.9
Total robotic procedure time, min	n/r	24.4	n/r	n/r	n/r	19.9
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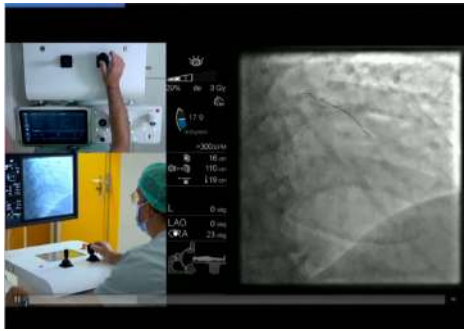
Mean contrast injection volume, mL	n/r	144.2	183.4	171	118.2	118.3
Mean patient radiation exposure, mGy	n/r	1,5	n/r	n/r	n/r	540.3
Mean reduction in operator radiation exposure with lead protection, %	n/r	n/r	n/r	n/r	n/r	84.5
Median reduction in operator radiation exposure, %						100 (under

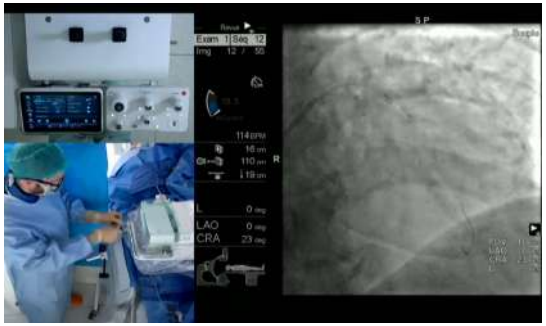
Hirai et al. 2020	Retrospective	CorPath GRX	95	Procedure time Cockpit time	46 Manual CTO-PCI 49 Robotic CTO-PCI	No difference in procedure time or MACE Higher cockpit time in robotic PCI	

5. Idée reçue n°4 : c'est l'opérateur secondaire/l'infirmier qui est désormais plus exposé

Exemple d'un cas enregistré en avril 2022
> Mesure de doses sur les deux opérateurs (celui au robot et celui à l'unité de commande)

- Dose mesurée à l'unité de commande située en control room : **0 µSv**
- Dose mesurée au robot par l'opérateur en charge du chargement/déchargement des devices, inflation et injection de contraste) :
  - Sous le tablier plombé : **0,27 µSv**
  - Sur le tablier plombé : **0,47 µSv**





Successful introduction of robotic-assisted percutaneous coronary intervention system into Japanese clinical practice: a first-year survey at single center

Kotaro Kagiyama[1] · Yoshiaki Mitsutake[1] · Takafumi Ueno[1,2] · Shinji Sakai[3] · Takuya Nakamura[4] · Kazunori Yamaji[1] · Takashi Ishimatsu[1] · Masahiro Sasaki[1] · Hidetoshi Chibana[1] · Naoki Itaya[1] · Ken-ichiro Sasaki[1] · Yoshihiro Fukumoto[1]

	R-PCI ($p=30$)	M-PCI ($p=77$)	p value
Clinical success* rate	93.3% (28)	92.2% (71)	0.97
Residual stenosis < 30%	93.3% (28)	92.2% (71)	0.97
In hospital MACE†	0%	0%	1.0
Robotic technical success‡ rate	90.0% (27)		
Completion robotically	83.3% (25)	–	–
Partial manual assistance	6.7% (2)		
Manual conversion	10.0% (3)		
Procedure time (min)	72.4 ± 41.2	65.6 ± 34.8	0.40
Fluoroscopy time (min)	27.5 ± 18.9	31.5 ± 18.9	0.33
Contrast medium (ml)	93.2 ± 44.5	107.8 ± 43.4	0.13
Radiation exposure			
Dose area product (Gycm^2)	77.6 ± 49.6	104.8 ± 54.4	0.02
To operator (µSV)	0 (0–1.3)	21.5 (12.0–37.5)	< 0.0001
To assistant (µSV)	10.5 (8.8–20.3)	9.0 (4.0–15.0)	0.14

Pas de différence significative
Manuel vs Robotique
pour le second opérateur

6. Limites actuelles et prochains développements

Limites actuelles

- Impossibilité d'utiliser certains dispositifs (**OTW,** tels que : microcathéter, Rotablator), incompatibilité imagerie endovasculaire
- Impossibilité de mobiliser **simultanément** plusieurs guides et/ou ballons/stents
- **Perte du feed-back tactile**
- **Pas d'études randomisées** « manuel vs robotique »

Prochains développements

- **Registre** observatoire pour tous les centres impliqués dans un programme robotique
- **Intervention depuis la salle de contrôle**
- **Prochaine génération robotique**:
  - Repositionnement robotisé du cathéter guide
  - Management de plusieurs devices simultanément (rapid-exchange & over-the-wire)
  - Intégration complète dans le cathlab
- **Interventions à grande distance** (neuro ++ et pays manquant d'infrastructures en cardio) et **teleproctoring**
- **Digitalisation du cathlab** : collecte des données pour intégrations de mouvements semi-autonomes et autonomes à terme

6. En conclusion

Opérateurs

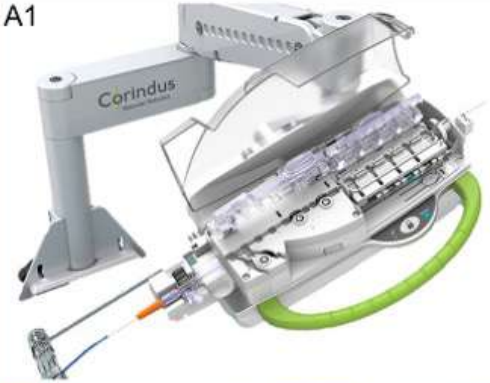
- **Position ergonomique** (meilleure visualisation, prévention des TMS)
- **Protection totale des Rx**
- **Courbe d'apprentissage rapide** (simplicité/sécurité)
- **Guide verrouillé**
- **Conversion manuelle rapide** et intuitive (R-one)

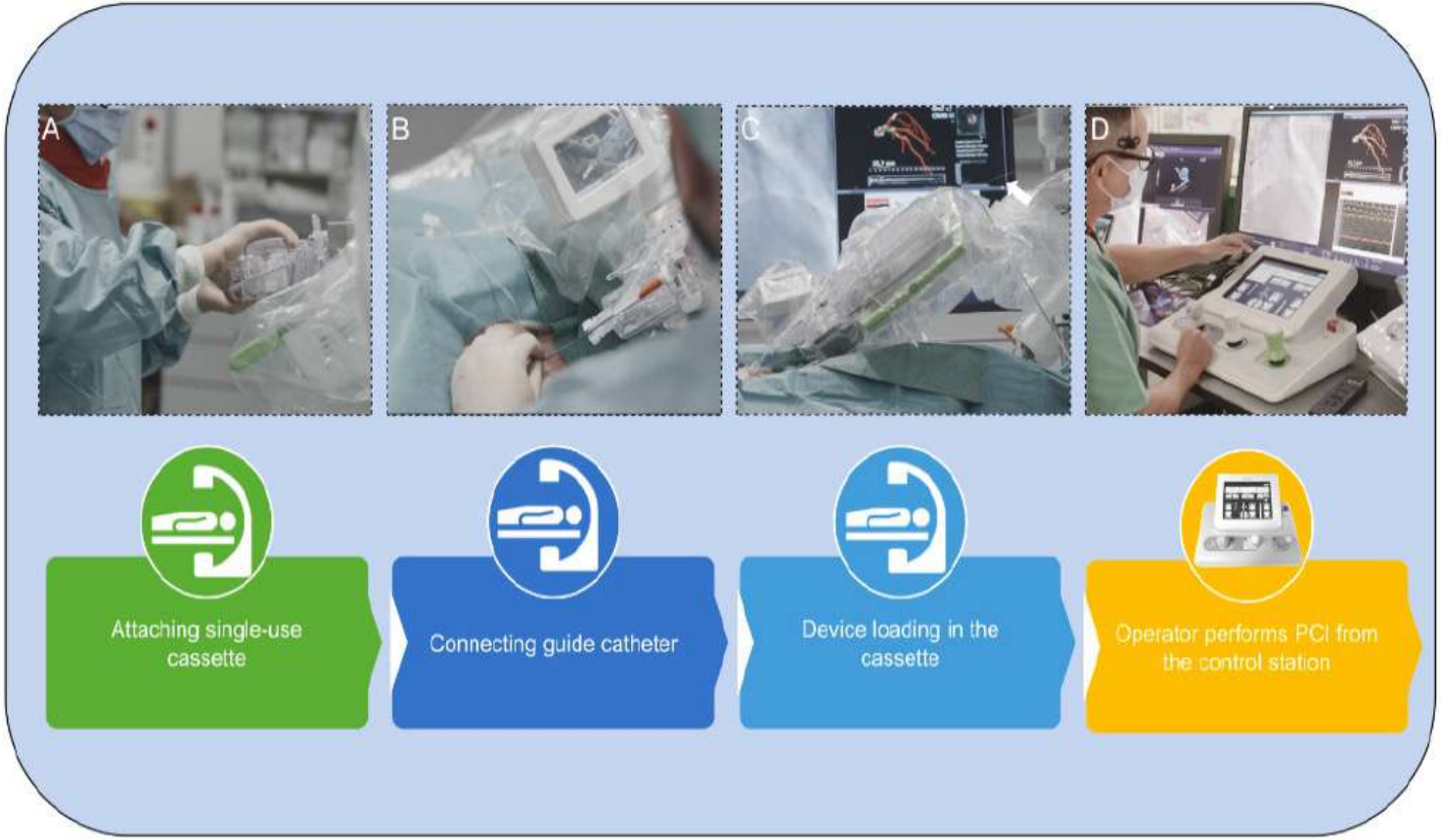
Patients

- Précision (manipulation guide, positionnement du stent)
- Diminution de l'exposition aux Rx
- Diminution du contraste
- Moins de fatigue pour l'opérateur/meilleur résultat ?

Centres

- Innovation
- Attractivité (opérateur/patient)
- Coopération Médecin/2nd opérateur: IDE
- Programmes de formation

Corindus CorPath 200	Corindus CorPath GRX	R-One
A1 	B1 	C1 
A2 	B2 	C2 


A
B
C
D
Attaching single-use cassette
Connecting guide catheter
Device loading in the cassette
Operator performs PCI from the control station

Study	Study Design	R-PCI system	Patients	Primary Endpoints	Groups	Technical success	Clinical success
Beyar, et al. 2006	Pilot Clinical Study	Remote Navigation System (RNS)	18	To evaluate safety and feasibility of a novel RNS		94% Guide wire navigation 83% Overall procedure	100%
Granada, et al. 2011	Single-arm, open-label, prospective	CorePath 200™	8	Device clinical success (< 30% residual stenosis) without in-hospital MACE		97.90% The robotic-system completed 47 of 48 planned steps	100%
PRECISE 2013	Prospective, single-arm, multicenter, open-label, non-randomized study	CorePath 200™	164	Clinical procedural success device technical success		98.80% Conversion to M-PCI (n = 2)	97.9% Periprocedural MI (n = 4)
PRECISION Registry	Registry	CorePath 200™	273, 344 lesions			93.70%	85.70%
CORA-PCI-2017	Non-randomized, single-center, comparison study	CorePath 200™	315	Clinical success (successful PCI without MACE)	108 R-PCI, 226 M-PCI	91.7% R-PCI Manual assistance (11.1%) Manual conversion (7.4%)	91.1% R-PCI 91.1% M-PCI
Smitson et al. 2018	vProspective, single-arm, multicenter, open-label, non-randomized study	CorPath GRX	40	Clinical procedural success (<30% residual stenosis without in-hospital MACE) Device technical success (robotic procedural success without the need for unplanned manual conversion)		90% Unable to advance overlapping stent (n = 1) Unable to cross lesion with guide wire (n = 1) Unable to cross lesion with balloon (n = 1)	97.50%
Hirai et al. 2020	Retrospective	CorPath GRX	95	Procedure time Cockpit time	46 Manual CTO-PCI 49 Robotic CTO-PCI	No difference in procedure time or MACE Higher cockpit time in robotic PCI	