

**R-EVOLUTION EUROPEAN MULTICENTER STUDY  
TO EVALUATE THE SAFETY & EFFICACY  
OF THE R-ONE™ SYSTEM  
IN PERCUTANEOUS CORONARY INTERVENTIONS**

Eric Durand, PhD, on behalf of all the investigators of the R-Evolution study

STUDY

DESIGN

- **Design:** prospective, multicenter, single-arm
- **Population:** 62 patients (64 lesions)
- **Centers:** 6 (the University Hospitals in Rouen and Caen with Prof. Durand and Prof. Sabatier, the Clinique Pasteur in Toulouse with Dr. Fajadet, all based in France; the ZNA Middelheim hospital in Antwerp, Belgium, with Prof. Verheye; the Maasstad clinic in Rotterdam, Netherlands, with Prof. Smits and Dr. Van Der Ent; and the National Interventional Cardiac Surgery Institute in Luxembourg with Dr. Pereira and Dr. Muller)
- **Indication:** de novo, up to 2 lesions in a single procedure (1 lesion per vessel)
- **Exclusion criteria:** length > 38mm, diameter > 4.00mm, severe calcification and tortuosity, bifurcations, ostial lesions, restenosis, LM, SVGs
- **Follow-up:** 1 month
- **Primary endpoints:**
  - **Clinical Success:** absence of major complication at 30 days follow-up
  - **Technical Success:** robotic PCI without total manual conversion

CLINICAL  
& ANGIO

CHARACTERISTICS

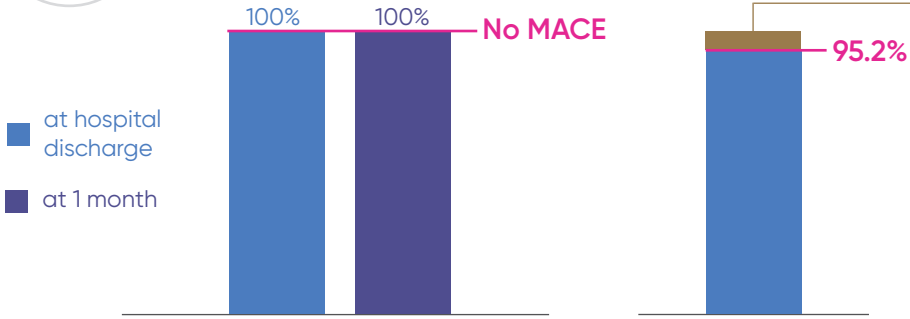
Variables	Overall population (N=62)
Age, years	65.4 ± 10.1
Male, N (%)	50 (80.6)
BMI, Kg/m <sup>2</sup>	27.2 ± 4.7
Clinical presentation, N (%)	
Silent ischemia	23 (37.1)
Stable angina	26 (41.9)
Unstable angina	6 (9.7)
NSTEMI	7 (11.3)

Variables	Overall population (N=62)
Radial artery (left or right), N (%)	60 (96.8)
Lesion location, N (%)	
LAD	22 (34.4)
LCX	21 (32.8)
RCA	17 (26.5)
B2/C lesions, N (%)	16 (25.0)
Pre-dilatation, N (%)	38 (59.4)
Stent per lesion	1.05 ± 0.28
Stent diameter, mm	3.0 ± 0.4
Stent length, mm	19.5 ± 6.5
Post-dilatation, N (%)	24 (37.5)

**STUDY RESULTS**

**CLINICAL SUCCESS**

**TECHNICAL SUCCESS**



No MACE

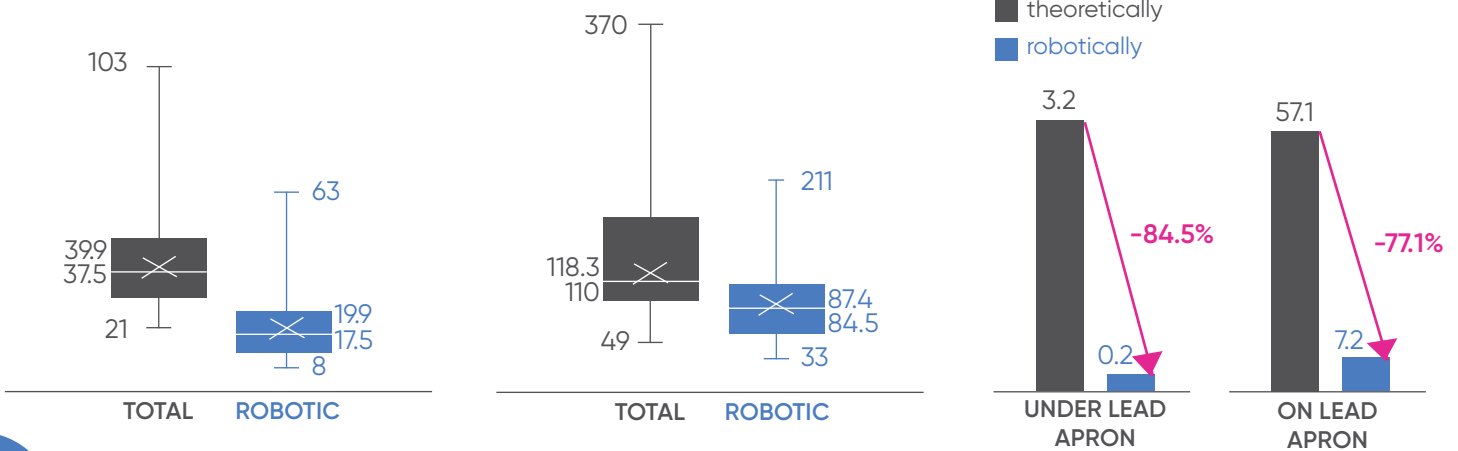
- Inability to cross the lesion with the balloon due to a lack of support (1/3)
- Software error due to wrong adjustment of the guidewire into the pads of the robot (2/3)
- a non-occlusive coronary dissection (NHLBI type B) non-related to the robot (3/3)

▷ 2/3 of manual conversions were not related to the robot

**PROCEDURE DURATION (min)**

**CONTRAST VOLUME (mL)**

**RADIATION EXPOSURE (µSv)**



**KEY FINDINGS**

- 1 >95% technical success
- 2 100% clinical success: no major intra-procedural and 30-day complications reported
- 3 84.5% average reduction in physician radiation exposure
- 4 100% technical success achieved in experienced centers\*

\* For each experienced center, more than 5 robotic PCI were performed before patient enrollment in the study and each investigator from these centers were involved in preclinical studies

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BSI, CE n°60387  
The R-One robotic platform is a Class IIb medical device.  
The R-One consumable kit is a Class I medical device.  
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