

The NAVIGATE study summary

An evaluation of the CorPath® GRX technIQ™ Automated Movements in PCI



Lead investigator

Professor Dariusz Dudek,
Interventional Cardiologist

Hospital

Institute of Cardiology
Jagiellonian University Medical College
Krakow, Poland



SIEMENS
Healthineers

Purpose:

The NAVIGATE study was conducted to investigate the impact of technIQ Smart Procedural Automation in robotic-assisted PCI procedural characteristics including:

- Total procedure time
- Dose area product
- Fluoroscopy
- Contrast volume
- Air kerma¹

technIQ Smart Procedural Automation is a set of automated robotic movements designed for the CorPath GRX System. The software includes 5 automated movements:

1. Rotate on Retract (RoR)
2. Spin
3. Wiggle
4. Dotter
5. Constant Speed

Materials and methods:

- Randomized, open-label, single-center study
- Patient population: 50 patients with coronary artery disease; randomized with technIQ On and technIQ Off

technIQ status	Patients enrolled	Patients treated with r-PCI	Notes
technIQ Off	25	21	<ul style="list-style-type: none">• Four patients were treated manually due to inability to cross the lesion(s) robotically
technIQ On	25	19	<ul style="list-style-type: none">• One patient was treated manually due to power failure of the system• Five patients were treated manually due to inability to cross the lesion(s) robotically
Total	50	40	

- The baseline demographics and lesion characteristics were similar between the two groups

Baseline demographics	technIQ Off	technIQ On	Lesion characteristics	technIQ Off	technIQ On
Number of patients	N=21	N=19	AHA/ACC classification severity		
Age (Mean ± SD)	66.5 ± 7.8	71.0 ± 7.1	• A/B1	11	13
Sex			• B2/C	11	9
Male	57.1%	84.2%	Calcification severity		
Female	42.9%	15.8%	• None/mild	17	18
BMI	29.1	27.5	• Moderate	4	3
Hypertension	93.3%	84.2%	• Severe	1	1
Coronary artery disease	86.7%	89.5%	Pre-procedure stenosis %	76.8 ± 11.8	79.6 ± 10.1
Diabetes Mellitus	56.7%	68.4%	Post-procedure stenosis %	1.3 ± 4.2	1.8 ± 6.6

Materials and methods (continued)

- Vessel assessments were used to evaluate the vessel's anatomical characteristics (angulation, tortuosity, branches before lesion, and visible calcifications) to determine correlation between wiring time and vessel complexity.

Vessel characteristics



Lesion characteristics



Click on the [+] buttons to view the lesion and vessel scoring systems

Primary outcome measures

Clinical success:

Less than **30%** residual stenosis post PCI in the lesion(s) treated with robotically without in-hospital major adverse coronary events.

Technical success:

Defined as successful completion of the robotic-assisted PCI absent unplanned unplanned conversion to manual for guidewire or balloon/stent catheter inability to navigate vessel conversion to manual.

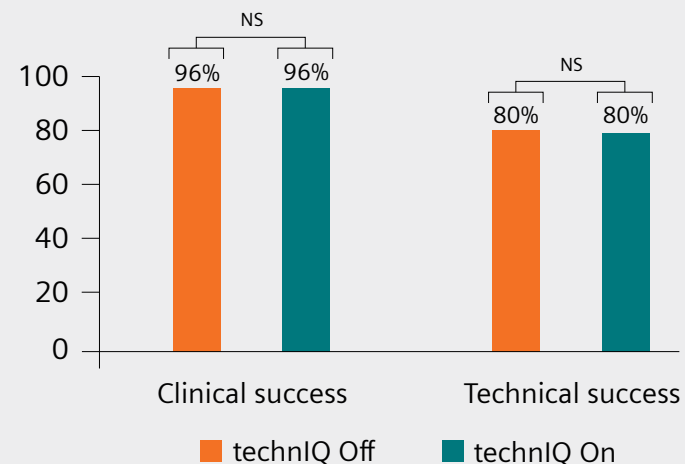
Key findings

Clinical success:

96% of patients in each group were treated successfully with no statistical significance between the groups.

Technical success:

80% of patients in each group were treated successfully without unplanned manual conversion with no statistical significance between the groups.



Key findings (continued)

Vessel and lesion assessment versus wire crossing time:

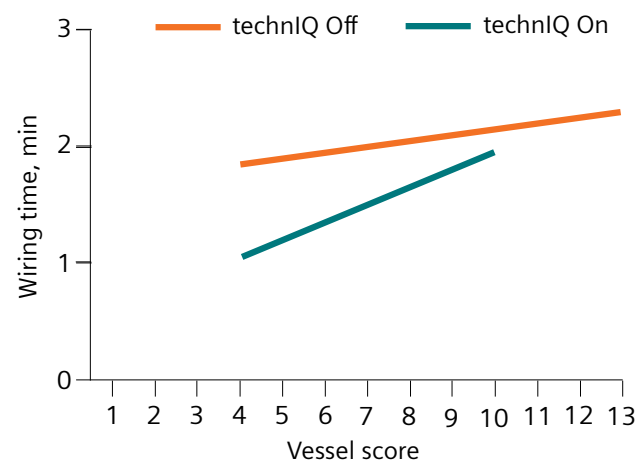


Figure 1. Shows the relationship between vessel characteristic score and wire crossing time. There is a correlation between vessel complexity and wiring time (more complicated vessels resulted in longer wiring time). The use of technIQ resulted in reduced wiring time.

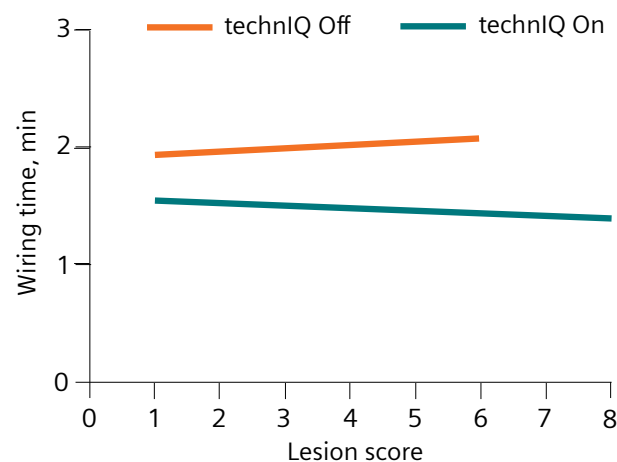


Figure 2. Shows the relationship between lesion characteristic score and wire crossing time. Lesion complexity had less of an impact on wiring time. The use of technIQ resulted in reduced wiring time.

technIQ Off versus technIQ On procedural characteristics:

Procedure time (minutes)

technIQ Off technIQ On

60.5

45.0

$p = 0.003$

Fluoroscopy time (minutes)

technIQ Off technIQ On

14.85

10.3

$p = 0.003$

Air kerma (mGy)

technIQ Off technIQ On

559.5

445.0

$p = 0.004$

Contrast volume (ml)

technIQ Off technIQ On

150

120

$p = NS$

Dose area product ($\mu\text{Gy}\cdot\text{m}^2$)

technIQ Off technIQ On

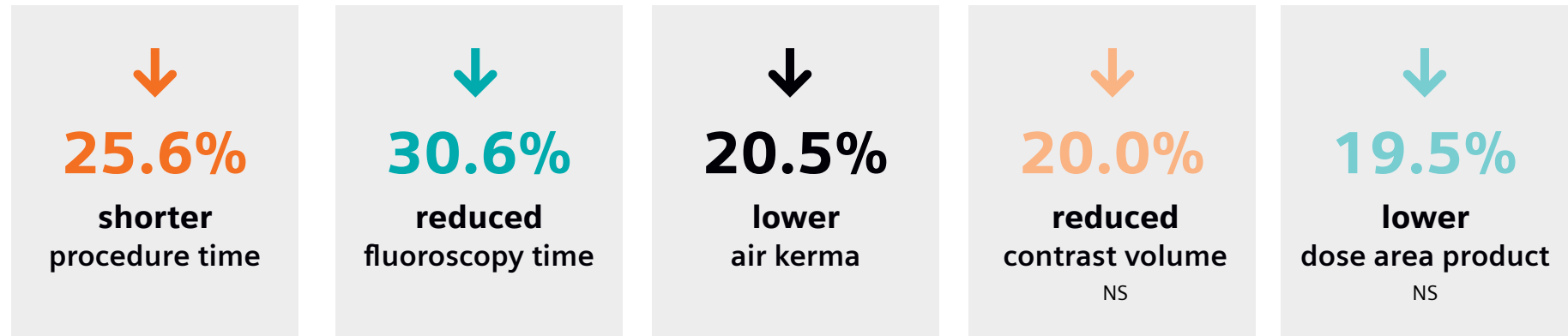
3081

2479

$p = NS$

Conclusion

- 1 The NAVIGATE study demonstrated that technIQ Smart Procedural Automation resulted in more efficient robotic-assisted PCI, with significant reductions in procedure time, fluoroscopy time, and air kerma.



- 2 Vessel complexity had a greater impact on wiring time compared to lesion complexity, as shown in Figures 1 and 2, demonstrating a correlation between wire crossing time and vessel score. Overall, the NAVIGATE study resulted in reduced wiring time with the use of procedural automation during robotic-assisted PCI using vessel and lesion scoring assessments.



The CorPath GRX System is intended for use in the remote delivery and manipulation of guidewires and rapid exchange catheters, and remote manipulation of guide catheters during percutaneous coronary and vascular procedures.

Caution: Federal law restricts this device to sale by or on the order of a physician.



Siemens Healthineers Headquarters

Siemens Healthcare GmbH

Henkestr. 127

91052 Erlangen, Germany

Phone: +49 9131 84-0

siemens-healthineers.com