Robotics Will Have a Key Role in Future Vascular Procedures

A New Robotic Device (From Sentante) To Assist With Endovascular Treatments: It Can Accommodate 3 Devices At Once at a Great Distance

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Disclosure Related to Robotics

- Consulting for Sentante

Original Premise: The Promise of Tele Surgery

Stimuli of Robotics
- First pushed by NASA
- Worldwide physician shortage
- Has not come to fruition

Reasons Tele Delayed
- Worry about signal stability
- Internet security
- Medicolegal issues complex
- Consent complex
- Expense to outlying hospital
- Sheath Insertion and removal
- Post procedure recovery needs

What Can Robotics Potentially Offer: Percutaneous Treatment

- Standardization of procedures
- Significantly less environmental risk to healthcare team
  - Radiation
  - Orthopedics
  - Hearing protection
- Less procedural error with less procedural fatigue?
- Incorporation of AI?

Early Endovascular robots

Overview of existing systems

Indications for use:
- Electrophysiology
- Coronary
- Peripheral
- Neuro

STEREOTAXIS USA, EU
Corindus Vascular Robotics USA, EU
Corindus Vascular Robotics USA, EU
Robocath EU
Magellan Robotic System EU
LN ROBOTICS LIBERTAS+NOVA Korea
none approved, many in development
basecamp vascular nanoflex XCath

Mechanism of action specifics:
- Control of dedicated steerable catheters, guidewires
- Control of off of shelf **Rx** based devices

MORAY MEDICAL STEREOTAXIS Magellan Robotic System
Corindus Vascular Robotics Robocath LN ROBOTICS LIBERTAS+NOVA

Endovascular robots

Overview of Historic Main Systems

Magellan:
Robotic assisted procedures
Withdrawn from the market in 2016

CorPath:
Robotic assisted procedures
Withdrawn from the market in 2023

Robocath:
Robotic assisted procedures
CorPath Me-too approach
CE in 2019

LN Robotics:
Robotic assisted procedures
Certified for Korea market in 2023

FSI

Robotic Assisted Surgery Landscape Review

2024 Report

April 2024

FDA clearance/ approval	Stereotaxis
OUS regulatory approval	LN Robotics, Robocath
US clinical trials	
OUS clinical trials	Robocath, sentante
In-development	Siemens Healthineers, Capstan, Catheter Precision, sentante, nanoflex, EndoNovo, telos, microbot, Artedrone, Xcath, Robocath, Laza, M.U.R.A.Y.

Historic workflow of robotic assisted procedures (Not Optimized)

Start of the procedure:
Guiding catheter is placed to the ostium of the target vessel **manually**

Middle of the procedure:
0.014" wire is manipulated through the lesion robotically, Rx stents placed robotically

End of the procedure:
All instruments are retracted **manually**

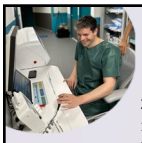
Why Early Endo Robotic Attempts Not Optimized

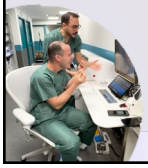
Surgery ➡ Robotic
- Smaller incision
- Less blood loss
- Faster procedure
- More precise

Endo ➡ Robotic
- Larger sheath size
- Already minimal blood loss
- Procedure time lengthened
- Much of procedure still not robotic
- Precision less of an issue
- No haptic feedback
- Increased cost due to robot and disposables

The Next Generation of Robot Optimizing with Sentante

- **3 or more concurrent use**
- **Acceptable size**
- **Using traditional devices**
- **Multiple area use ie PCI and PVI or PVI, PCI and Neuro**
- **Haptic Feedback**
- **Ease of use**
- **Concurrent remote inflation or aspiration or fluid installation**





Pre-clinical testing

sentante

24 Cadaver procedures
16 Animal (porcine) procedures
36 GLP Animal (porcine) procedures
76 procedures in Total:
- 38 diagnostic procedures
- 38 treatment procedures:
  - Iliac and BTK arteries stenting and PTA
  - Renal artery stenting and embolization
  - Visceral arteries PTA
  - Vertebral artery stenting

Results:
- 100% technical success
- 0% of safety issues
- NO X-Ray radiation to all medical personnel
- Positive User feedback

EU Clinical study

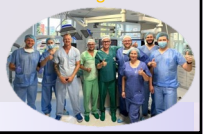
sentante

10 Patients
21 Peripheral vascular procedures:
- 10 diagnostic procedures:
  - Aortic arch
  - Renal arteries
  - Iliac and femoral region
  - Below the knee
- 11 treatment procedures:
  - PTA
  - Balloon expandable stents
  - Covered stents
  - Anplatzer vascular plug

Different diseases and conditions:
- Peripheral arterial disease
- Aneurysmal disease
- Dissection
- Stent fracture

Results:
- 100% technical success
- 0% of safety issues
- NO X-Ray radiation to all medical personnel

Excellent feedback from investigators



Summary

- Robotics appear to be making headway by using standard equipment
- Ease of use and Haptic Feedback occurring with Sentante
- Procedural training may be more standardized with robotics
- Jury still out on remote robotic use but technology will be there
- Clinical Trials are ongoing