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Article

# Further increase in the possible applications using AI with ROSES, our system for endovascular treatment

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**Abstract:** ROSES (Robotic System for Endovascular Surgery) continuously measures the resistance encountered by a catheter during advancement without requiring additional specialized components. The system consists of up to six robotic actuators arranged linearly on slides that move along an inclined rail toward the patient. The final slide accommodates the sixth actuator, which houses four stepper motors, allowing for adjustments in the relative positions of the actuators. The proximal actuator is affixed to the last slide using side bars. A force transducer, connected to the motorized slide by a wire, measures the gravitational component of any object on the rail, which remains constant as the actuators move. However, if an external obstruction hinders catheter or guidewire progression, the force changes, triggering an alert. The system also facilitates the introduction of the first catheter, even if pre-curved, enabling complete separation between the surgeon and the patient throughout the entire procedure. ROSES employs compact, purely mechanical, disposable components compatible with commercially available catheters and guidewires, making it suitable for a wide range of interventions, including cerebral arterial procedures, aneurysm treatment, ischemic interventions, angioplasty, Transcatheter Aortic Valve Implantation (TAVI), and various lower and upper limb surgeries. Future enhancements include AI-assisted brain endovascular treatments and the integration of animated catheters capable of shape adaptation via console control. By recording console inputs, resistance forces, device penetration lengths, and X-ray images, ROSES effectively functions as the "black box" of endovascular surgeries. The system is protected by multiple pending international patent applications.

**Keywords:** robotic-assisted minimally invasive surgery; endovascular black box; elimination of ionizing radiation for surgeons; freedom for neuro-radiologists from X-ray

## 1. Introduction

Minimally invasive surgeries, including laparoscopic, orthopedic, and spinal procedures [1–5], offer significant advantages such as reduced surgical risks, faster recovery times, and lower overall costs. While robotic systems are widely employed

in various fields of minimally invasive surgery [6–10], their adoption in endovascular procedures remains limited. This is primarily due to challenges such as high costs and the scarcity of robots, which are often designed for highly specific applications.

For example, the CorPath system by Corindus [11–15] and Robocath [16] are primarily intended for angioplasty, while the Magellan system by Hansen Medical [17–20] focuses on endovascular interventions. A recently proposed biomimetic system [21], not yet available on the market, attempts to replicate the movement of a surgeon's arms and hands during procedures. However, in practice, it appears considerably more cumbersome than our system.

Advancements in fluoroscopic imaging have significantly reduced radiation exposure while improving image quality. In particular some authors [22–25] simply talk about occupational hazard, others [26–29] report on damages of the operators, while Luani et al. [30] preferred to use catheter visualization using intracardiac echocardiography, in order to bypass the problem. Protective lead aprons offer extensive coverage for surgeons but leave the hands exposed, and their weight can lead to long-term spinal issues [31–33].

Surgeons often believe that manually manipulating catheters yields better outcomes. However, they overlook the advantages of robotic systems, such as quantitative force measurement and precise recording of catheter advancement—parameters that are difficult to assess manually. Our system even enables the measurement of stenosis length before selecting the appropriate stent. As a result, robotic adoption remains limited, a challenge underscored by Fichtinger et al. [34] in a key publication.

A study by Haidegger [35] points out that nearly all existing robotic systems function in a master-slave configuration and lack autonomous capabilities. While this is generally true, it is important to recognize that even a highly precise robotic "slave" can provide data that a human operator cannot infer through manual dexterity alone—at least, not with precision. Moreover, with AI integration, our system will be capable of performing limited automated tasks, gradually transitioning into a semi-autonomous mode.

For procedures involving the brain, such as thrombectomy or aneurysm treatment, ionizing radiation exposure increases significantly. Without a system that ensures complete physical separation between the surgeon and the patient, radiation exposure becomes unmanageable.

A recent study [36] analyzing existing robotic systems concluded that none met all the criteria for an "ideal" endovascular robotic platform. However, this study did not include our system, as its first major publication appeared in 2022—after their review had concluded in 2021. We plan to compare our system's features against the benchmarks outlined in their study to highlight its advantages.

Additionally, while CorPath and Robocath utilize large disposable components that house both the catheter and guidewire motors, as well as force sensors when necessary, ROSES takes a different approach. Our disposables are compact, purely mechanical devices, while the motors remain housed in the robotic actuators. This design also incorporates a single fixed-position force sensor, which collects all necessary data while minimizing complexity and cost.

Our system has been detailed in six prior publications [37–41], but this article

focuses on recent simplifications and additions that, when combined with previous innovations, make ROSES a truly revolutionary advancement in endovascular surgery. Its key advantages include:

(1) Versatility—A single system capable of handling a wide range of interventions, reducing acquisition costs for hospitals.
(2) Complete Physical Separation—Surgeons remain entirely removed from the patient throughout the procedure, eliminating direct radiation exposure.
(3) Comprehensive Surgical Record—The system functions as the "black box" of endovascular surgery, storing procedural data, forces encountered, penetration depths, and fluoroscopic images.

The following sections will detail the individual components of ROSES, outlining the key elements that drive this breakthrough in robotic endovascular surgery. Notably, ROSES is protected by multiple pending international patent applications [42–44], discouraging unauthorized replication.

## 2. The robotic actuators

The core mechanism of the robotic actuators (RA) is based on a gear train system, which consists of a primary gear and a secondary rotating disk firmly attached to it. Within this rotating frame, one or two hollow gears with internal teeth are positioned, separated by ball bearings to ensure proper alignment. Planetary gears, engaging with the hollow gears, are mounted on shafts extending from either the primary gear or the corresponding rotating disk. These shafts are further equipped with bevel gears or faceted shafts to transmit motion.

To maintain stability, the gear train is supported by three additional shafts, positioned at 120° intervals, each holding external idle gears that contribute to overall system balance. Each robotic actuator is driven by an external motor, which transmits motion through a combination of bevel and spur gears. When rotation of the primary gear is required, all gears must rotate at the same speed to maintain their position, unless also advancement or retrieval is also required, in which case the controlling system sends separate commands to the three gears, summing or subtracting the required rotation from the primary gear rotation, ensuring precise and controlled movement.

Building upon this fundamental design, different RA models were developed, featuring two, three, four, five, or six motors. In the RA5 and RA6 models, two gear trains are stacked together, providing increased degrees of control. The external shafts emerging from the system interface with disposable components, which are inserted into a central sterile passage with a 36 mm diameter.

One specialized actuator, the RA2, features a compact two-motor configuration, with the disposable element positioned inside the gear train to save space. This actuator serves as the proximal RA, indicated as S1 (Slave 1), facilitating initial catheter introduction from a remote workstation. While previous publications have illustrated the internal gearing system, **Figure 1** provides a sectional view of RA2, showing the transmission of motion to the lower friction wheel.

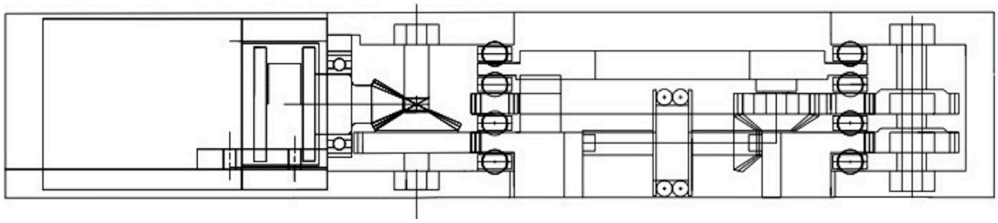

**Figure 1.** Section of RA2 showing the gear transmission to the lower friction wheel.

In **Figure 2**, the design of the RA2 disposable component is depicted, illustrating the guiding system for the first catheter. The tubing directs the catheter from the friction wheels to the entrance into the patient's arteries. Notably, the final portion of this tubing, located outside the disposable, is flexible, ensuring smooth catheter introduction. This innovative design enables the remote insertion of the first catheter, significantly reducing radiation exposure for the surgeon.

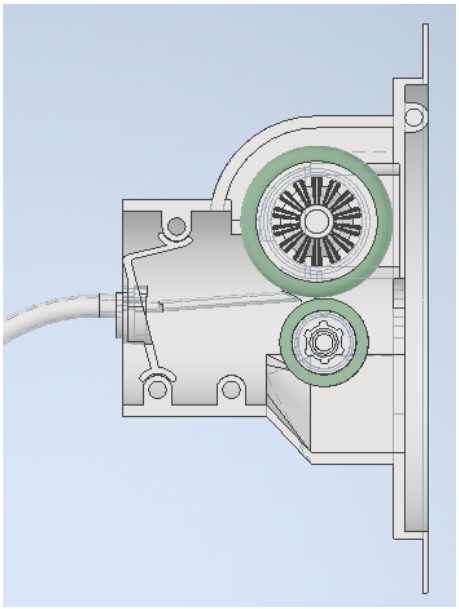

**Figure 2.** Image of the RA2 disposable, showing the tubing guiding the first catheter from the friction wheels to the entrance into the patient arteries, where the final.

All aspects of this system are protected by multiple patent applications, including a Patent Cooperation Treaty (PCT) filing covering international jurisdictions [43].

## 3. The force-measuring system coupled to the Robotic Cart

The Robotic Cart (RC) is designed to support and guide the robotic actuators (RA) while integrating a force-measuring system that continuously monitors resistance during catheter advancement. The structure consists of an inclined bar topped by a rail, along which up to six sliding platforms (each supporting a robotic actuator) can move.

The last slide of the system also houses the motors responsible for moving the intermediate RAs (S) via belt-driven mechanisms, while the first S1 is fixed to the motorized platform using a lateral support bar.

To measure force variations during catheter insertion, a counterweight-based system is integrated. The motorized slide is connected to two wires:

- One wire is attached to a counterweight, which neutralizes most of the gravitational (g) component of the elements positioned on the rail.
- The second wire is linked to a force transducer, which measures the residual gravitational force and any additional resistance encountered by the catheter.

Since the bar is slightly inclined toward the patient, the gravitational force exerted by any object placed on the rail remains constant. However, if the catheter or guidewire encounters external resistance (e.g., vessel stenosis or obstruction), the measured force changes, triggering an alert. This ensures that the system detects and quantifies the forces exerted by the patient's vasculature against catheter penetration. The counterweight system is particularly crucial since these forces are small and would otherwise be difficult to measure accurately, as shown in **Figure 3,** which illustrates the Robotic Cart after the introduction of the first catheter, demonstrating its readiness for brain surgery applications (such as aneurysm treatment).

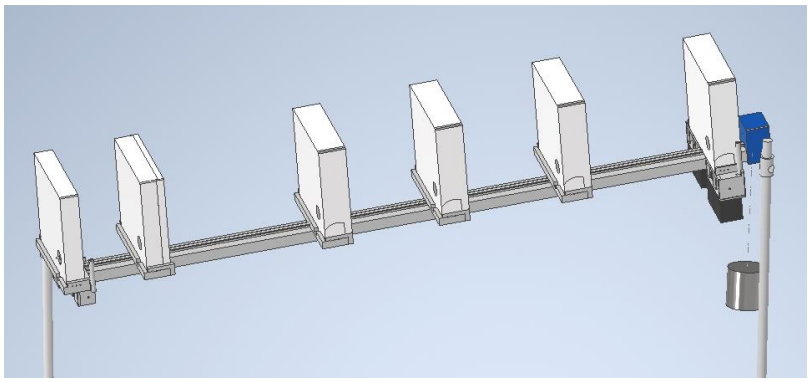

**Figure 3.** The Robotic Cart after the introduction of the first catheter, ready for any brain surgery (as we will show for aneurysm procedures, three RA will be sufficient).

In particular, about the system configuration and functionality, notice that:

- Typically, three to four RAs are sufficient for these procedures, although the system can accommodate up to six RAs when required. For clarity it is better to quote the different actuators as S1 (Slave 1), S2 etc., thus referring to the position on the rail, rather than to the number of motors hosted in it.
- In the image, S2 is positioned close to S1, indicating that the first catheter has been fully inserted into the patient, and the system is now prepared for the next phase of the surgery.

Further operational details and software control mechanisms will be discussed in later sections. The Robotic Cart and force measurement system are protected by an Italian patent and a pending European patent application [44].

## 4. The new disposables for catheters and guidewires

The development of disposables for robotic-assisted endovascular procedures has evolved significantly over time. The initial design for ROSES was derived from an earlier project, ROSINA (Robotic System for Intubation) [45], which was developed during the COVID-19 pandemic. While the ROSINA project was ultimately discontinued due to its late implementation—by which time protective anti-COVID

suits were already performing well—this research laid the groundwork for the current disposable designs used in ROSES.

Previously, robotic actuators were designed with a sterile passage diameter of only 7 mm, which was sufficient for standard angioplasty procedures but posed limitations in handling larger catheters. For example, procedures like Transcatheter Aortic Valve Implantation (TAVI), requested by Professor Massetti, require removing the initial catheter while keeping the guidewire in place. This necessitated a larger sterile passage to accommodate the hemostatic valve and facilitate guidewire retention.

To address these limitations, first we changed the number of teeth of the main gear train, passing from the 7 mm to a 36 mm passage, plus we developed a new modular disposable system, segmented into three main components:

(1) A tube-like structure that separates the disposable from the internal gears.
(2) An upper section containing the friction wheels that interact with the catheter or guidewire.
(3) A lower section, which can be disposed of separately, allowing for easier removal without disturbing other elements within the sterile passage.

This redesign resulted in a stronger, more compact disposable, with bevel gear teeth engineered to prevent lateral deformation and eliminate gear slippage—a common issue in earlier prototypes.

The primary distinction between disposables for guidewires and catheters lies in the position of the bevel gear:

- For catheters, the bevel gear is positioned on the left side.
- For guidewires, it is placed on the right side.

During further testing, we realized that the disposables designed for ROSINA (**Figure 4**) included unnecessary appendages that complicated production. Through refinements, we discovered that using a pair of silicon rings on the lower friction wheel allowed for stronger contact between the catheter and the friction mechanism at three distinct points (**Figure 5**). By modifying the counter-friction wheel shape, we ensured firm engagement for both catheters and guidewires.

**Figure 4.** The ROSINA disposables present unnecessary appendices.

These findings enabled us to simplify the disposable design for angioplasty and other procedures, making it more efficient and cost-effective than those presented in previous studies.

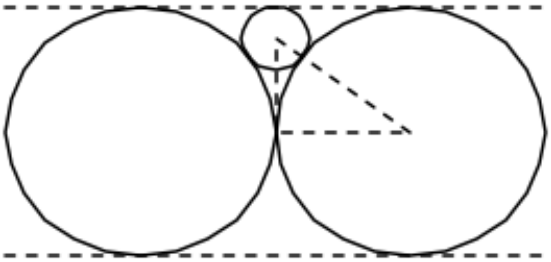

**Figure 5.** The working scheme of the new friction wheels.

Additionally, certain fixation components—such as the L-shaped element on the cover and the two round arms with small locking teeth—were found to be redundant. These parts were originally intended to secure the disposable to the tube separating the mechanisms from the catheters. However, we observed that the same key used to lock the disposable to the exit gear of the rotating system was sufficient to hold everything in place. This simplification significantly reduced manufacturing complexity.

**Figure 6** compares the previous disposable design (DEA: Disposable Element for Angioplasty) with the new simplified version (DEAS: Disposable Element for Angioplasty Simplified).

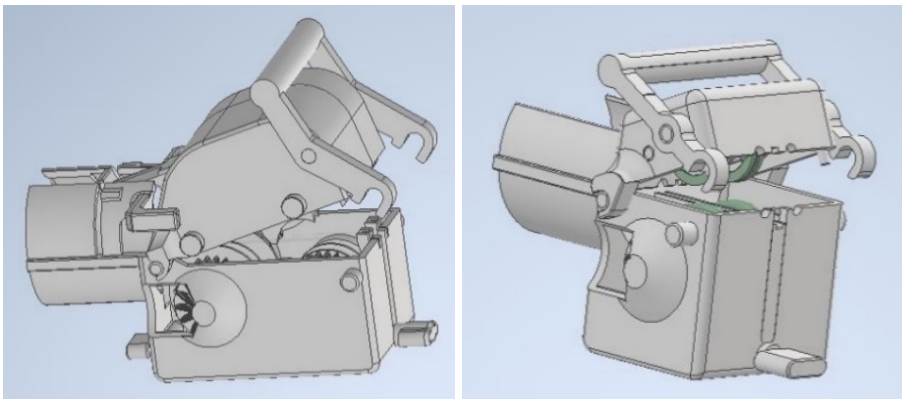

**Figure 6.** The comparison between old and new disposables for angioplasty.

To further improve versatility, we designed a new spring-loaded upper counterwheel, allowing a single disposable unit to accommodate catheters of varying sizes. This was achieved by:

(1) Mounting the upper counterwheel on a movable frame, which is pushed by torsional springs to maintain firm contact with the catheter.
(2) Keeping the lower section of the disposable unchanged, except for cases involving extra-large catheters (e.g., TAVI).

This approach proved particularly beneficial for neurovascular procedures, where microcatheters of varying diameters are used. **Figure 7** illustrates the new spring-loaded cover (left) and the frame supporting the counterwheel (right). The upper element of the disposable now self-adjusts to different catheter sizes while maintaining secure contact.

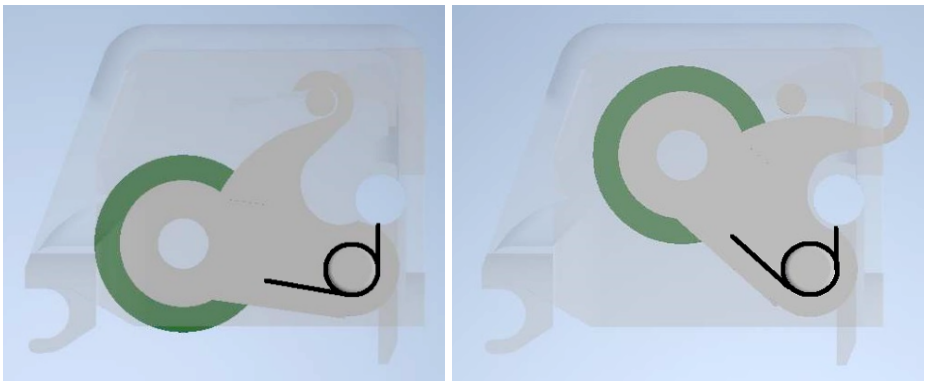

**Figure 7.** The new spring-loaded cover for standard and big catheters and the relative frame holding the counterwheel.

## 5. The special rotating hemostasis valve

To secure the valve (**Figure 8**) position, two different supports are utilized (**Figure 9**), with the relative securing cap. The first support is fixed for a configuration with only three motors, typically requiring manual insertion of the first catheter. The second support is attached to the rotating frame of a second gear train, using a combination of RA4 or RA5 in the second position (S2) and RA2 in the proximal position (S1). This configuration allows for remote control of the first catheter's introduction from a console. In both cases, a cap is used to fix the final component of the hemostasis valve.

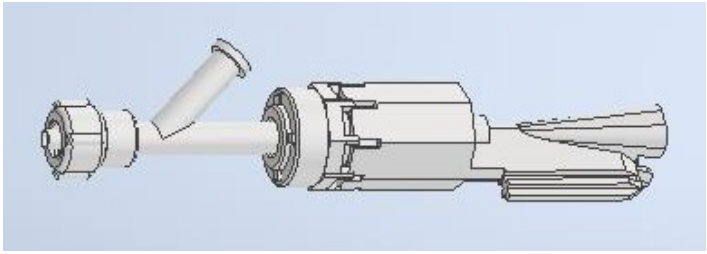

**Figure 8.** The rotating hemostasis valve.

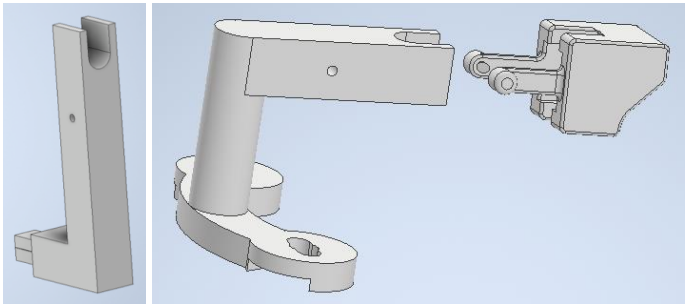

**Figure 9.** The fixed and rotating support for the hemostasis valve and its closing cap (common for both).

## 6. The disposable for brain endovascular treatments

Endovascular procedures within the brain require extreme precision due to the delicate structure of intracranial vessels. To accommodate these specific needs, we developed two new disposable designs for cerebral endovascular interventions. These designs improve the handling of microcatheters and introduce controlled tip curvature, a key feature for navigating complex vascular anatomy.

### 6.1. Disposable for variable-geometry microcatheters

The first disposable is optimized for microcatheters with variable diameters. Its design is based on a standard lower angioplasty component combined with a specialized upper section that adapts to the catheter's size. The upper section features:

- A fixed counterwheel on the guidewire side, ensuring stability.
- A spring-loaded frame on the catheter side, allowing automatic adjustment to different microcatheter diameters.

This adaptation enhances grip and control while ensuring smooth catheter advancement. **Figure 10** shows a bottom view of the cover, highlighting the spring-loaded frame that adjusts dynamically based on the catheter's diameter.

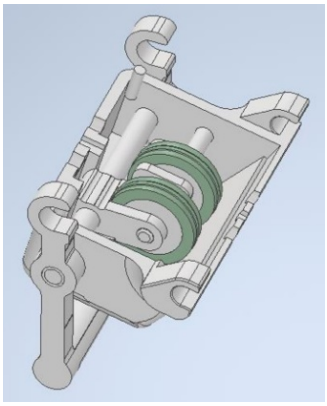

**Figure 10.** The cover for micro-catheters presents a frame pushed by springs on the catheter side.

### 6.2. Disposable for the curvature-controlled microcatheter

The second disposable is designed for a curvature-controlled microcatheter, which is particularly useful for procedures requiring precise catheter navigation. This microcatheter features:

- Two lumens: one for the guidewire and another for a nylon wire that controls tip curvature.
- A pre-shaped distal section with a series of wedge-shaped cuts, allowing controlled bending.

A micro drum mechanism (**Figure 11**) is integrated into the robotic actuator to pull and release the nylon wire, modifying the catheter tip's shape in real time. This enables finer control when navigating complex arterial structures.

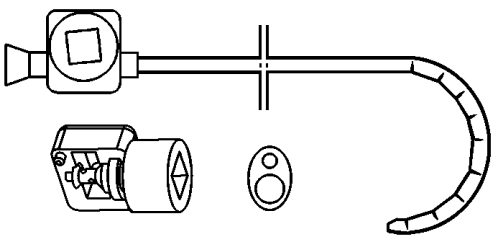

**Figure 11.** Scheme representing the catheter with controlled tip curvature for the brain, showing also the catheter section and micro drum that pulls and releases the nylon wire inside its holding frame.

### 6.3. Robotic integration and operation

To ensure seamless robotic operation:

- The curvature-controlled microcatheter is mounted on the third robotic actuator (S3), which features five motors—two of which are dedicated to catheter rotation and tip curvature control.
- During insertion, S3 moves in sync with the internal gearing of S2, with motion controlled by the last slave via belts, ensuring smooth catheter progression.
- When reaching the target site, the tip's orientation is adjusted by precisely controlling the micro drum mechanism (**Figure 12**).

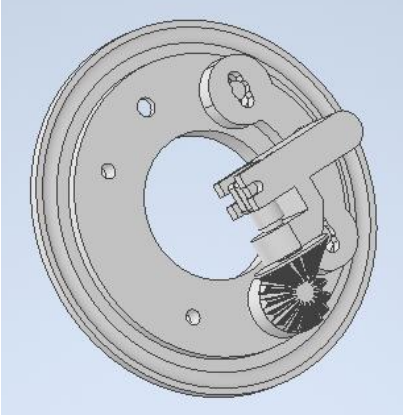

**Figure 12.** The mechanism that commands tip curvature.

Since catheter curvature adjustments are commanded remotely, the system significantly enhances procedural accuracy and safety, eliminating the need for direct manual intervention.

Note that key advantages of these disposables are:

- Precise Catheter Control: The spring-loaded frame ensures optimal grip for microcatheters of varying sizes.
- Enhanced Navigation: The curvature-controlled microcatheter allows real-time tip adjustments, improving vessel access.
- Seamless Robotic Operation: Designed for full integration with ROSES, ensuring precise movement and automated adjustments.

These innovations mark a major step forward in robotic-assisted neurovascular interventions, making complex procedures safer, more efficient, and more precise.

## 7. The new sterile cover for the cart and the robotic actuators

Sterility is a critical requirement in robotic-assisted endovascular surgery. While the disposables used within the robotic actuators (RAs) ensure a sterile passage for catheters and guidewires, the external surfaces of the RA units and the space between the bar and rail remain exposed. This poses a potential contamination risk if a catheter or guidewire inadvertently touches these areas.

To address this issue, we developed a new sterile covering system, designed to:

- Fully enclose the robotic actuators.

- Cover the space between the bar and the rail, ensuring a sterile environment.
- Allow free movement of the RA units along the rail while remaining covered.

## 7.1. Covering system design

The system consists of:

- Four vertical bars: Two positioned on either side of S1 and two near the motorized platform that moves the intermediate actuators.
- Tensioned nylon wires: These run at the height of the RA gear train axis, providing structural support for the covering material.
- Special sterile plastic envelopes: Each RA is encased in a sterile cover featuring side openings for the gear train, which are sealed using flexible sterile rings to maintain sterility even when the actuators rotate.

Additionally, a sterile pleated plastic strip is welded to the envelopes, spanning between adjacent RAs. This strip ensures that as actuators move along the rail, the covering system expands and contracts accordingly, maintaining a continuous sterile barrier.

## 7.2. Application and practical benefits

- The covering system is designed to be pre-assembled in a compressed form.
- Upon installation, the nylon wire loop is opened and secured at both ends, automatically deploying the sterile cover across the Robotic Cart.
- Once installed, the cover allows full system mobility while ensuring that all surfaces remain protected.

**Figure 13** illustrates the covering system in action, showing the sterile barrier in place when the system is configured with three actuators for aneurysm repair.

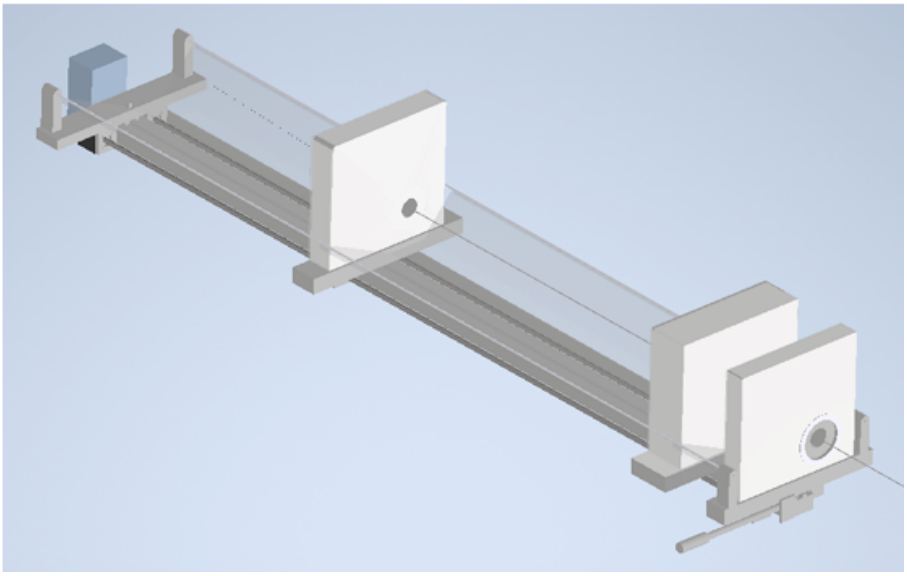

**Figure 13.** The sterile cover is installed on the system in the case of the presence of only three actuators, as in the case of an aneurysm repair.

### 7.3. Patent protection and automation

This innovative covering system is protected by a PCT application [43]. Given the complexity of manufacturing the pleated sterile cover, a robotic assembly process is currently under development to streamline production. Without automation, manual fabrication costs would be prohibitively high.

Summarizing, key advantages of the sterile cover are:

- Maintains a Sterile Environment: Covers all exposed areas, eliminating contamination risks.
- Enables Full Actuator Mobility: The system expands and contracts without restricting movement.
- Simplifies Application: Pre-assembled design allows quick and easy installation.
- Patent-Protected and Scalable: Ensures long-term feasibility and automation.

By implementing this covering system, the ROSES platform achieves complete sterility, ensuring maximum safety and compliance in robotic-assisted endovascular surgery.

## 8. Description of the introduction and removal of the catheter for brain surgery of an aneurysm

Endovascular treatment of intracranial aneurysms requires precise catheter navigation through the arterial system, typically accessed via the right femoral artery using the Seldinger technique [46]. The ROSES system enables a fully robotic approach, ensuring complete physical separation between the surgeon and the patient while maintaining precise control over catheter and guidewire movement.

### 8.1. Initial setup and catheter introduction

Before starting the procedure, the system must be configured as follows:

(1) Preparation of the First Catheter
- The first catheter is fixed to the hemostasis valve and inserted into S1 without being locked, advancing it and passing through its guiding disposables to reach the introductory catheter.
- The final portion of this guiding disposable consists of a simple, flexible tube, allowing smooth catheter introduction (**Figure 2**).

(2) Securing the Guide Catheter in S2
- The guide catheter, already attached to the hemostatic valve, is locked in S2, adjusting its position to ensure a straight, unobstructed path for the catheter.

(3) Insertion of the Guidewire into S2
- If a movable-core guidewire is used, its lower disposable component is attached to the S2 support tube (**Figure 4**).
- The upper disposable component is locked in place, ensuring the guidewire is correctly positioned between the friction wheels.

(4) Transition to Remote Control
- These preparatory steps, performed under ultrasound guidance, do not

require fluoroscopy, minimizing radiation exposure for the surgeon.

- The surgeon then moves to the control room, where catheter advancement is fully robotic using joysticks.
- The catheter is guided through the carotid artery toward the intracranial region, with S2 being moved in sync with S1 commanded catheter advancement at the same speed, by the rotaton of the motors placed under the last actuator (SN) via toothed belts.

## 8.2. Guidewire removal and 3D imaging

- Once the guide catheter reaches its target position, the system automatically retracts the guidewire, stopping just before it exits the disposable.
- A contrast agent is injected, and a 3D angiographic scan is performed to reconstruct the intracranial arterial circle.
- The angiographic model is then processed and transferred to the ROSES workstation, which replaces the console used in previous angioplasty trials [43].

At this point, the surgeon briefly re-enters the operating room to remove the guidewire and replace the S2 disposable component with the standard disposable with a spring-loaded microcatheter cover (**Figure 10**).

## 8.3. Introduction of the microcatheter and automated guidance

With the 3D arterial model now available, the microcatheter is introduced:

(1) The S3 actuator, equipped with a second hemostatic valve on which the microcatheter is fixed, is positioned at a certain distance from S2, to insert the microcatheter in the S2 disposable.
(2) The surgeon selects microcatheter mode from the workstation and advances the catheter using joystick controls.
(3) S3 moves in sync with the catheter advancement commanded by S2 disposable via toothed belts moved by the last actuator, ensuring smooth progression through the cerebral arteries.

At this stage, AI-assisted guidance, Martelli et al. [47], can be employed, as explained in the patent application [43]:

- The angiographic software, with the help of new software developed by us with the help of AI, locates the centerline of the vessel lumen, calculating the optimal catheter trajectory.
- The system determines the stent length required to bypass the aneurysm and calculates the entry and exit points.
- AI then determines the starting position and orientation of the microcatheter inside the carotid artery to optimize navigation.

**Figure 14** shows how AI intervention transforms the original angiographic image, providing a precise navigation path for catheter insertion.

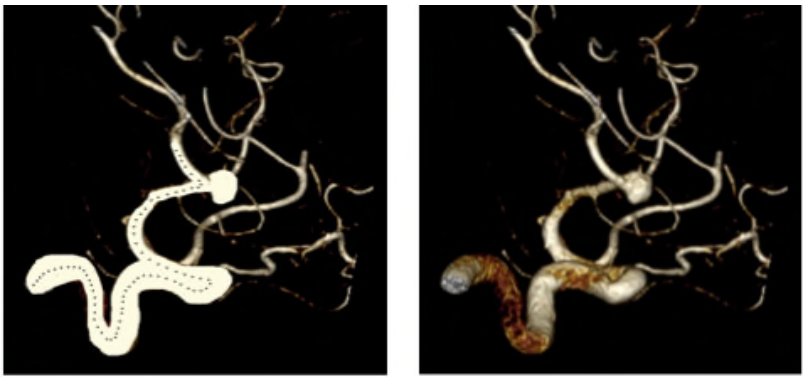

**Figure 14.** Illustration of how with the help of AI the original image is transformed in a sequence of points of known coordinates in the angiographic frame of reference.

## 8.4. Automated placement of the stent or coils

Once the microcatheter reaches the target site, the guidewire is removed, and the stent is introduced:

- The stent is advanced through the microcatheter to its final position.
- The microcatheter is retrieved, allowing the stent to expand and secure the vessel.
- If the procedure involves Guglielmi coils [48] for aneurysm occlusion, the microcatheter is reinserted, and the system automatically searches for openings in the stent mesh to deliver the coils into the aneurysm.

After deployment, all catheters and guidewires are retrieved, completing the procedure.

## 8.5. Alternative approach using the animated catheter

If an animated catheter (equipped with controlled tip curvature) is used instead of a microcatheter, the procedure remains the same. However:

- The animated catheter is preloaded with the stent at its tail.
- A fluoroscopically guided internal lumen within the catheter prevents blood leakage.
- The curvature control mechanism is used to navigate tortuous vessels, minimizing the need for manual guidewire manipulation.

This is illustrated in **Figure 15**, which illustrates the various steps of this procedure.

Substantially, key advantages of the ROSES approach are:

- Complete Radiation Protection: All fluoroscopic steps are performed remotely, eliminating radiation exposure for the surgeon.
- AI-Assisted Navigation: Automated vessel centerline tracking enhances catheter guidance.
- High-Precision Stent Deployment: The system accurately measures stenosis length and catheter positioning.
- Flexible for Different Devices: Works with standard microcatheters or animated catheters for advanced maneuverability.

With these innovations, ROSES represents a major advancement in robotic-assisted neurovascular interventions, setting a new standard for safety, precision, and efficiency.

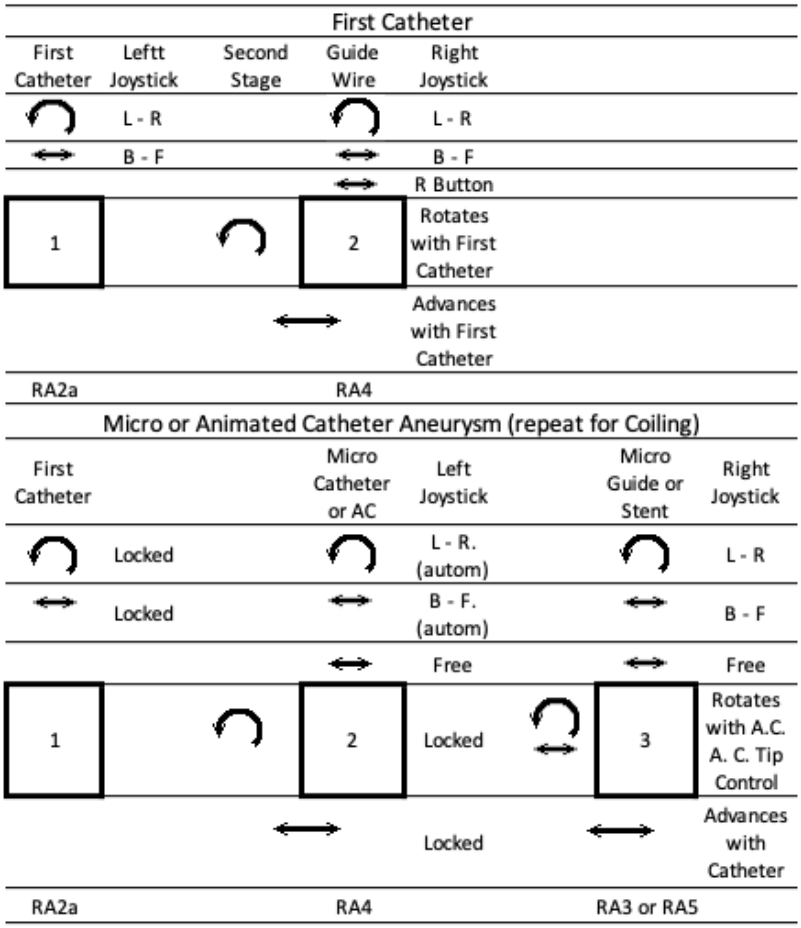


**Figure 15.** Illustrating the working system, showing how robotic actuators interact with catheters and guidewires during navigation.

## 9. The hardware configuration and relative software

The ROSES system integrates a workstation-based console, joystick controllers, and a network of microcontrollers, ensuring precise real-time control over catheter and guidewire movements. The hardware configuration supports a minimum of 11 degrees of freedom (DOF) and a maximum of 26 DOF, depending on the number and types of robotic actuators (RAs) used.

### 9.1. The console: Workstation-based control system

A significant advancement in the current version of ROSES is the transition from a traditional console to a high-performance workstation. This upgrade allows for:

- Real-time data processing from the force sensor, catheter penetration tracking, and fluoroscopic images.
- Seamless AI integration, enabling automated catheter navigation based on angiographic data.
- Enhanced user interface, providing the surgeon with precise control and real-time feedback.

The workstation is equipped with:

- Two 4-DOF joysticks, each controlling specific catheter and guidewire movements.
- A touchscreen interface, featuring four customizable cursors that adjust the relationship between joystick motion and catheter movement speed.
- Graphical overlays, allowing the visualization of angiographic reconstructions and force measurements.

## 9.2. Microcontroller-based motion control

Each robotic actuator (RA) is equipped with a dedicated microcontroller, ensuring smooth and synchronized motion. The system utilizes two types of interface boards:

(1) Motor Control Boards
- Each board controls three or four motors, allowing precise advancement, rotation, and position control after initial calibration.
- Used in RA4, RA5, and RA6, which require stacked gear trains for multiple movement axes.

(2) Force Sensor Interface Board
- Continuously monitors resistance encountered by the catheter or guidewire.
- Provides real-time alerts if excessive force is detected, preventing vessel damage.

All microcontrollers are labeled based on their corresponding RA type and communicate via advanced standard protocols, ensuring rapid data transmission and precise coordination.

## 9.3. Joystick-based motion control

Each 4-DOF joystick provides the following control capabilities:

- Forward and backward movement → Catheter/guidewire advancement.
- Left and right movement → Catheter/guidewire rotation.
- Additional controls → Functions vary depending on the procedure (e.g., tip curvature adjustment for animated catheters).

Additionally, four cursors on the touchscreen allow real-time adjustments to:

- Speed scaling between joystick motion and catheter movement.
- Sensitivity settings, optimizing control for different anatomical regions.

## 9.4. Software and AI integration

The ROSES software was designed to:

- Issue precise motor commands, ensuring smooth catheter advancement and retrieval.
- Interpret force sensor data, adjusting catheter movements to prevent excessive pressure on vessel walls.
- Process fluoroscopic images and angiographic reconstructions, enabling AI-

assisted guidance.

AI-powered automation is a major feature of the latest software version, allowing:

- Automatic trajectory planning, based on real-time vessel centerline analysis.
- Automated catheter adjustments, ensuring optimal tip orientation and positioning.
- Stenosis length measurement, facilitating accurate stent selection.

By integrating hardware, real-time software processing, and AI-driven guidance, ROSES achieves an unprecedented level of precision and safety in robotic-assisted endovascular surgery.

Key advantages of the ROSES Hardware & Software System are then:

- High-Precision Control: The combination of joysticks, AI, and force feedback ensures superior catheter manipulation.
- Real-Time Data Processing: The workstation console records and analyzes every movement and force measurement.
- Seamless AI Integration: The system assists surgeons in trajectory planning and vessel navigation.
- Advanced Safety Features: The force sensor interface provides alerts to prevent vessel damage.

The next-generation ROSES system represents a significant technological leap, combining robotics, AI, and real-time imaging for the safest and most precise endovascular interventions to date.

## 10. Discussion

The ROSES system represents a major breakthrough in robotic-assisted endovascular surgery, offering a fully automated, remotely controlled approach that ensures complete physical separation between the surgeon and the patient. This separation is crucial for:

- Eliminating direct radiation exposure for medical staff.
- Improving procedural precision through robotic control and force feedback.
- Enhancing patient safety by reducing procedural variability and minimizing manual catheter manipulation.

ROSES is the only robotic system capable of fully guiding the introduction of the first catheter and seamlessly transitioning to various endovascular interventions. Its versatile design allows easy selection of the appropriate programs and disposables, making it adaptable to a wide range of procedures.

### 10.1. Unique capabilities of ROSES compared to existing systems

Unlike current robotic systems, which are often limited to specific applications, ROSES offers:

(1) Multi-Purpose Functionality

- Can be used for angioplasty, aneurysm treatment, ischemic interventions,

TAVI, and limb surgeries.

- Compatible with commercially available catheters and guidewires, avoiding the need for proprietary special disposables.

(2) AI-Assisted Navigation

- AI can analyze angiographic images, determine optimal catheter trajectories, and assist in stenosis length measurement.
- Reduces the reliance on manual dexterity, enabling precise and consistent outcomes.

(3) Advanced Force Measurement and Feedback

- The integrated force sensor continuously measures catheter resistance, providing real-time alerts to prevent vessel damage.
- Surgeons gain quantitative force data, a critical advantage over manual catheter manipulation, which relies on subjective tactile feedback.

(4) Sterility and Radiation Protection

- The new sterile covering system ensures full sterility of the Robotic Cart and actuators.
- Eliminates the need for heavy lead aprons, reducing the risk of spinal injuries among interventional radiologists.

(5) Integration of an Endovascular "Black Box"

- The system records all procedural parameters, including penetration depth, force exerted, and X-ray images.
- Creates a comprehensive surgical log, improving post-procedure analysis and training.

## 10.2. Addressing challenges in robotic endovascular surgery

Several challenges have historically limited the adoption of robotics in endovascular procedures. ROSES directly addresses these concerns, practically finding solutions for every problem, as listed in **Table 1**:

**Table 1.** Problems solved with the introduction of ROSES.

| Challenge | How ROSES solves it |
|---|---|
| High cost of robotic systems | ROSES operates with standard catheters and uses mechanical disposables, making it more cost-effective. |
| Limited versatility | Unlike other robotic systems, ROSES is multipurpose, reducing acquisition costs for hospitals. |
| Lack of force feedback | The integrated force sensor provides quantitative force data, enhancing procedural safety. |
| Sterility concerns | The novel sterile cover system ensures that all moving components remain sterile. |
| Radiation exposure for surgeons | ROSES enables full remote operation, eliminating the need for lead aprons and reducing long-term health risks. |

A recent review [37] concluded that no single robotic system meets all the criteria for an ideal endovascular surgery platform. However, this study did not include ROSES, as our first major publication appeared in 2022, while their review ended in 2021. A direct comparison between ROSES and the benchmark criteria outlined in that study is currently being prepared.

### 10.3. Future developments and research directions

The next steps in the development of ROSES include:

- Expanding AI Capabilities
  - Further refining AI-assisted catheter navigation, allowing the system to perform semi-automatic maneuvers.
  - Developing AI-based predictive algorithms for procedural planning.
- Remote-Controlled Injection and Balloon Inflation
  - Exploring existing automated contrast injection systems to enable fully robotic angioplasty procedures.
  - Developing robotic control of balloon inflation and stent deployment.
- Clinical Trials and Certification
  - Preparing documentation for initial regulatory approval.
  - Collaborating with hospitals to begin simulated procedures using 3D-printed vascular models.
  - Launching multi-center patient trials across Italy, Europe, and North America.

By integrating robotics, AI, and real-time imaging, ROSES is positioned to redefine the field of endovascular surgery, making procedures safer, more precise, and more efficient.

Key advantages of the ROSES System:

- The only system enabling full robotic catheter insertion and remote control.
- AI-powered navigation enhances precision and procedural safety.
- Integrated force feedback prevents vessel damage and improves stent placement accuracy.
- Multi-purpose system reduces costs and improves hospital efficiency.
- First system to incorporate an endovascular “black box” for data recording and analysis.

ROSES represents a major step forward in robotic-assisted endovascular interventions, bridging the gap between human expertise and AI-driven automation.

## 11. Conclusion

The ROSES system represents a significant advancement in robotic-assisted endovascular surgery, combining precision robotics, AI-assisted navigation, and force feedback to improve surgical accuracy and safety. Unlike existing robotic platforms, ROSES enables full remote catheterization, eliminating radiation exposure for surgeons while maintaining complete procedural control.

The system’s key innovations include:

- A fully robotic catheter insertion process, allowing complete physical separation between the surgeon and the patient.
- AI-assisted trajectory planning, improving catheter navigation and stent placement accuracy.
- Integrated force measurement, providing real-time resistance data to prevent

vessel damage.

- A novel sterile covering system, ensuring full aseptic conditions without restricting actuator mobility.
- An endovascular "black box", recording penetration depth, force data, and fluoroscopic images for enhanced procedural analysis.

## 11.1. Path to clinical implementation

The next phase of development focuses on:

- Regulatory Approval: Preparing the necessary documentation for initial medical device registration.
- Clinical Simulations: Testing the system with 3D-printed vascular models based on CT scan data.
- Multi-Center Patient Trials: Initiating studies in hospitals across Italy, Europe, and North America.
- Expanding AI Capabilities: Further developing predictive algorithms for automated catheter guidance.

Additionally, future research will explore:

- Remote-controlled contrast injection and balloon inflation, enabling fully robotic angioplasty procedures.
- Adaptation for new interventions, including robotic-assisted ablation therapies.

## 11.2. Final outlook

By integrating robotics, AI, and real-time imaging, ROSES is set to redefine the future of endovascular surgery, offering:

- Enhanced procedural accuracy, reducing human error.
- Greater surgeon safety, eliminating exposure to ionizing radiation.
- Increased hospital efficiency, as a single system can handle multiple intervention types.

With its pending international patents, ongoing clinical validations, and future AI advancements, ROSES is poised to become the next-generation standard in robotic endovascular intervention.

**Author contributions:** Conceptualization, practically the electromechanical components were designed by GD, PFG, GL, and SL, while all suggestions on what was desiderable came from the doctors: SDR, ODB, CI, GL, MM, US, ET, GT, and YT; methodology, GD, PFG, GL, and SDR; software, GL, GD; validation, GD, SDR, PFG, CI, and GL; formal analysis, GD; investigation, GD, SDR, PFG, CI, and GL; resources, GD and CI; data curation, GD, SDR, PFG, CI, and GL; writing—original draft preparation, GD; writing—review and editing, GD and SDR; visualization, GD, ODB, and SL; supervision, GD, SDR and CI; project administration, GD; funding acquisition, GD and CI. All authors have read and agreed to the published version of the manuscript.

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**Institutional Review Board Statement:** In the present article is described a robotic system that in the present configuration was never tested. However the base of this was instead tested also on humans as described in "First-in-human robotic percutaneous coronary intervention by the ROSES robotic system: A case report" and the study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of Regione Calabria (protocol 13 and date of approval January the 18th 2018).

**Informed Consent Statement:** So far no informed consent had to be obtained, and the first patients to undergo experimentation of this system will be an in-vitro patient described in the last PCTIB2025059270 application by Danieli.

**Data Availability Statement:** There are no patient data available at the moment.

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