ISSN 2564-3207

ORIGINAL ARTICLE

ROSES: The most Complete System for Endovascular Surgery

Guido Danieli[1,2*], Salvatore De Rosa[3], Pasquale F. Greco[2], Ciro Indolfi[3], Gabriele Larocca[2], Massimo Massetti[4], Giovanni Tinelli[4], and Yamume Tshomba[4]

Danieli G, Rosa SD, Greco PF, et al. ROSES: The most Complete System for Endovascular Surgery. Int J Endovasc Treat Innov Tech. 2024;5(1):17-31.

Abstract

ROSES, an innovative Robotic System for Endovascular Surgery, features a unique mechanism that continuously measures the resistance encountered by catheters and guide wires as they advance within the body. This feature operates seamlessly without the need for additional specialized components. The system is comprised of a series of robotic actuators (up to three) arranged linearly on slides running along a rail, inclined toward the patient. Another slide, housing a pair of step motors, facilitates the adjustment of relative positions between the actuators, with the proximal actuator affixed to the motor slide by a lateral bar. A force transducer, linked to the motor slide via a wire, is responsive to the gravitational component of any object on the rail. Importantly, this force remains constant even as the actuators move. However, the force dynamically changes if an external obstruction hinders the progress of catheters and guide wires, serving as an alert to the attending physician. The system, uniquely, is also capable of guiding the introduction of the first catheter, even if it is pre-curved. This capability facilitates the complete separation of the doctor from the patient throughout the entire surgical procedure. The system employs compact, purely mechanical disposables designed for a wide range of interventions utilizing commercially available catheters and guide wires, including angioplasty, brain and carotid surgery (for aneurysms or thrombi), TAVI, and various lower and upper limb procedures. Future developments include the incorporation of animated catheters capable of altering their shape configuration under console control. As the system also records the penetration length of each device and transmits this data to a workstation along with X-ray images, it effectively becomes the “black box” of endovascular surgeries. This functionality allows for a complete separation between physicians and patients throughout the entire surgical procedure. The system is safeguarded by multiple pending international patent applications.

Key Words: *Robotic assisted least invasive surgery; Black box of endovascular; Elimination of ionized radiations for operators*

[1]*DIMEG – Calabria University, Rende, Italy*

[2]*Calabrian High Tech – CHT S.R.L. Rende, Italy*

[3]*Magna Graecia University, Germaneto, Italy*

[4]*Gemelli Policlinic, Sacred Heart University, Rome, Italy*

[*]*Corresponding author: Guido Danieli, Professor, Calabria University, DIMEG, Ponte Bucci Cubo 46C, 87036 Rende (CS), Italy, E-mail: danieli@unical.it*

Received: February 05, 2024, Accepted: March 27, 2024, Published: April 10, 2024

Introduction

Minimally invasive surgeries, such as laparoscopy, orthopedic, or spine procedures [1-5], can significantly benefit patients by reducing the risks associated with surgery, accelerating their recovery, and consequently lowering overall costs. Robots play a significant role in almost every sector within this field [6-10], but surprisingly, they are seldom utilized in endovascular surgery. This can be attributed to a series of challenges, including high costs, and a limited availability of robots, which are often designed for specific applications. For example, the CorPath system by Corindus [11-16] and Robocath [17] is primarily intended for angioplasty, and the Magellan system by Hansen Medical [18-21] is designed for endovascular surgery. A novel biomimetic system [22] was recently presented, not yet present on the market, that reproduces the motion of the arms and hands of the doctors during the surgery, but, honestly, it seems much more cumbersome than our system. On the other hand, the advancements in fluoroscopic systems, which have significantly reduced radiation exposure while also enhancing image quality, have partially mitigated the risks of ionization, though these risks remain a concern [23-31]. Furthermore, the specialized aprons provide extensive coverage for the doctor's body, with the exception of their hands, yet these aprons are quite heavy and can lead to spine problems [32-34].

Conversely, doctors often believe that manually manipulating catheters can achieve better results. They overlook the fact that robotic systems like ours provide quantitative force measurements and can accurately record the extent of catheter advancement—an aspect they may not be able to assess. This capability even enables them to measure stenosis length before selecting the appropriate stent. As a result, their adoption remains relatively limited, as highlighted by Fichtinger et al. in a compelling paper [35].

Another reference [36] observes that nearly all of these robotic systems fall into the master-slave category and lack the capability to function autonomously. While this observation is accurate, it's worth noting that even a highly skilled slave can provide information that the operator cannot deduce solely through manual dexterity, unless it's done in a rough approximation. Our system is already equipped to deliver such information. Furthermore, the notion of operating within the brain to remove thrombi or address aneurysms undoubtedly necessitates increased ionizing radiation, which becomes unmanageable without the implementation of a system that maintains a physical separation between doctors and patients.

Additionally, CorPath and Robocath utilize disposables that are notably large in size and house both the motors for controlling catheter and guide wire movements, as well as the force sensor, if necessary. In contrast, ROSES disposables are straightforward mechanical devices, with the motors housed within the robotic actuator, and a single fixed-position force sensor that collects all the necessary data.

While our system has been discussed in five previous articles [37-42], this one is primarily dedicated to summarizing the compelling reasons why ROSES represents a revolutionary advancement in the field. It commences with its readiness for a wide range of interventions using a single system, consequently reducing acquisition costs for those seeking comprehensive preparedness. It proceeds with the capacity to maintain a physical separation between doctors and patients throughout the entire process and culminates with its potential to serve as a central component of a comprehensive record for all endovascular surgeries. The following sections will detail the components of ROSES, highlighting the fundamental aspects that drive this revolutionary advancement. It's important to note that ROSES is safeguarded

by a series of international applications on its path to becoming patented [43-46], which significantly deter any attempts at replication without potential infringement.

The Robotic Actuators

The foundation of the robotic actuators consists of a gear train, which comprises a primary gear. This primary gear, combined with a second disk firmly affixed to it, forms a rotating frame. Within this frame, one or two hollow gears featuring internal toothing, are interposed, and they are separated by ball bearings to maintain proper alignment. Planetary gears, engaging with the internal toothing of the hollow gears, are affixed to shafts emerging from either the main gear or the corresponding rotating disk. These shafts are further equipped with bevel gears or faceted shafts to transmit motion. The gear train is additionally stabilized by three shafts positioned at 120° intervals, each holding external idle gears to contribute to system stability. An external motor, assigned to each gear within the train, facilitates the necessary motion transmission through a combination of bevel and spur gears. It's evident that when the main gear rotates, in order to maintain the position of the secondary shafts, all gears must rotate at the same speed. Building upon this foundation, robotic actuators (RA) were generated with two, three, five, and six motors by stacking two gear trains for RA5 and RA6. The shafts coming out of the system are then used to drive the disposables, which are inserted into the central sterile passage, 36 mm wide. In one case, a special two-motor RA presents the disposable inside the gear train to save space, and this is used as a proximal RA, called RA2. Figure 1 shows the internal arrangement of a robotic actuator with three motors seen from the top, with the final disk eliminated in order to show the internal mechanisms of the first gear train. On the side, the version with 5 motors in construction obtained simply widening the base plate. Figure 2 represents a transversal section of the gear train of the 5 motors RA, evidencing the presence of the two superimposed gear trains and how the motion to the various gears is transmitted from the motors. Notice, however, that no motors are posed in opposition with respect to the gear train, so the motor representation is not a true section, since the real motor's positions are represented in Figure 1. In any event, the motor's portions on the two sides show how the transmission to the train is organized. All this is protected by various patent applications, quoting a PCT for all other applications [43].

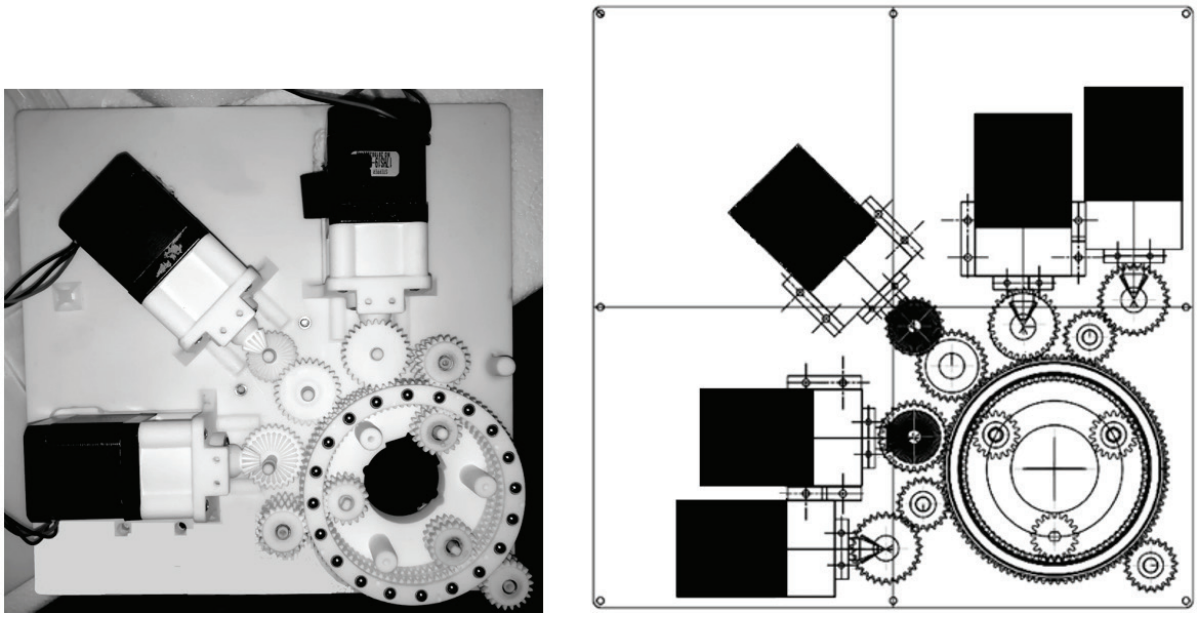

Figure 1) *View from the top of the bases of the RA3 and of RA5.*

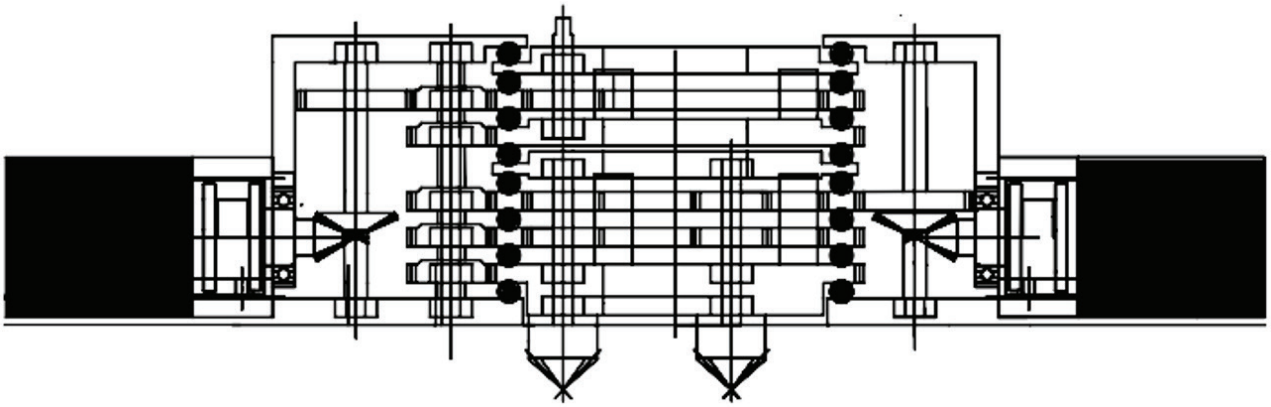

Figure 2) *Section of RA5 shows the two superimposed gear trains and the power inputs on both sides, only for two of the five motors.*

The Force Measuring System Coupled to the Robotic Cart

The Robotic Cart (RC) with an integrated force measuring system consists of a bar inclined towards the patient, which is topped by a rail. Three or four slides are mounted on this rail, with each slide accommodating a Robotic Actuator (RA) for the first two or three slides. The last slide houses the motors responsible for moving the second or third RA via belts, while the first RA is fixed to the motors by a lateral bar. The slide supporting the motors is connected by a wire to the force measuring system, which, due to the slight inclination of the bar towards the patient, detects the gravitational (g) component of any object placed on the rail. As a result, if there is any movement within an RA or between different RAs, the gravitational component remains constant. However, the force measured can change only if there is resistance to the advancement of any element exiting the system, indicating that the system senses the forces exerted by the patient's body against catheter penetration. Figure 3 provides a visual representation of this system. Note that three RA are aligned on the rail, allowing both to guide the first catheter introduction and then brain and carotid surgery, plus angioplasty, as will be clarified later. In fact, in this picture, RA5 is represented very close to RA2, which implies the fact that the introduction of the first catheter ended, reaching the point from which the real surgery has to start, and the first catheter is now inside the patient.

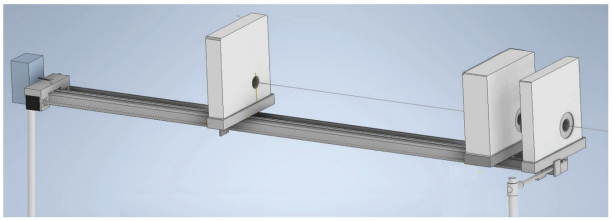

Figure 3) *Tre robotic cart after the introduction of the first catheter, ready for brain surgery.*

Further details on its functioning will be discussed in the context of the programs. This innovative system is protected by an Italian patent and a European patent application [45,46].

The Disposable for Standard Catheters and Guide Wires

The initial disposable design for the new RA was actually intended for the development of ROSINA (Robotic System for IntubAtion) [47]. This project was undertaken during the COVID-19 pandemic to maintain a safe separation between doctors and patients during intubation procedures. However, it was implemented somewhat late, as the protective anti-COVID suits were already performing well. Nevertheless, this effort was valuable as it laid the groundwork for the development of all subsequent disposables. It's important to note

that up to that point, the Ras were featuring a sterile passage with a diameter of only 7 mm. The disposables used for angioplasty were considerably thinner and more flexible. This posed a challenge as if the torque applied to the disposable exceeded a certain threshold, it would result in the gears slipping with disruptive noise. Furthermore, it was recognized that to facilitate the future positioning of a catheter for Transcatheter Aortic Valve Implantation (TAVI), a request made by Professor Massetti, it was essential to remove the initial catheter while retaining the guide wire in place. For this purpose, the passage through the RA had to be kept sterile. The only viable solution was to segment the disposable into three components: a tube-like structure separating the disposable from the internal gears, along with upper and lower sections that could be disposed of separately. This design allowed for the removal of the disposable without the necessity of extracting what was already situated within the RA passage. As a result, a considerably sturdier disposable of the same length as the previous one was developed, but wider, with bevel gears teeth designed to eliminate lateral deformation and prevent teeth slipping. The key distinction between disposables for guide wires and catheters lies in the position of the bevel gear (on the left for catheters, on the right for guide wires) and the design of the friction wheels. Figure 4 illustrates an image of the disposable for larger catheters, featuring a screw at the top for pressure control. For normal-size catheters, ranging from 4 to 10 French, two springs enable automatic adjustment. Figure 5 shows the new upper element (cover, left) holding the rotating frame (right) pushed by springs and limited in excursion by a bar placed in the highest hole in the cover.

Figure 4) *The first edition of a disposable for big catheters, from which all the others derive.*

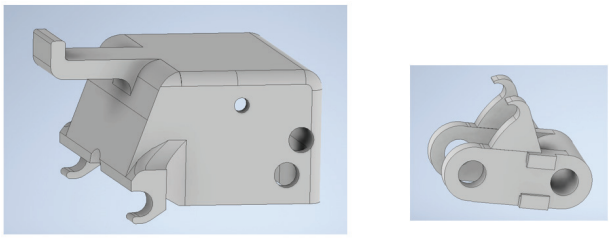

Figure 5) *The new spring-loaded cover for standard catheters and the relative frame holding the counterwheel.*

The Disposable for Angioplasty

In this configuration, bevel gears are located on both sides, and the design of the disposable component differs on each side. On the left side, four friction wheels are present, with the lower ones rotating in unison due to an idle gear that meshes with two spur gears positioned between the bevel gear and the friction wheel on the motorized shaft. These spur gears are aligned laterally with each other but not with the friction wheel. These are both surmounted by two small friction wheels that can freely rotate. On the wire side, there is an identical friction wheel as on the catheter side, which is motorized. Additionally, two more friction wheels are positioned to make contact with a larger radius friction wheel on the cover. This arrangement forces the wire to follow a double curvature, allowing torque to be transmitted to the thin wire used as a guide wire in angioplasty. Figure 6 provides a visual representation of the disposable CAD model, with the side wall being transparent to show the internal mechanisms.

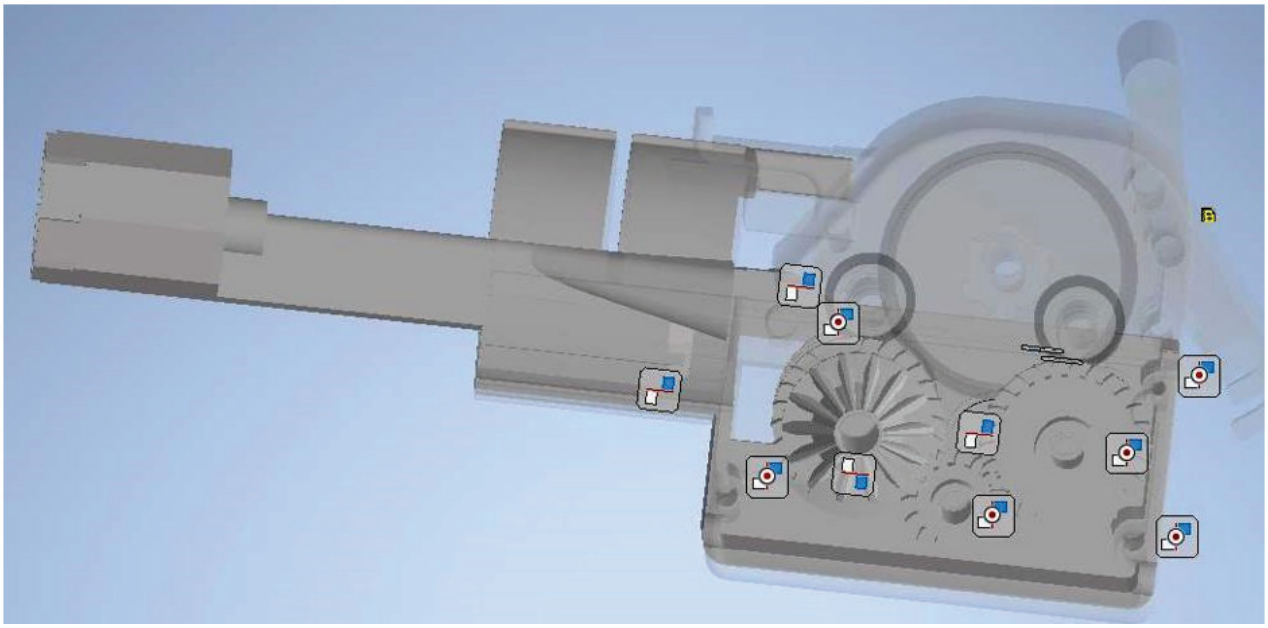

Figure 6) *The angioplasty disposable.*

The Special Rotating Hemostasis Valve

While discussing the matter with Prof. De Rosa, we identified an issue in our previous model of the angioplasty disposable. Occasionally, problems with the guide wire rotation were encountered which appeared slow and hindered in its ability to turn around its axis. To address this issue, a solution was needed.

In the already-tested original system, both the catheter and guide wire were positioned on the same disposable, and they entered the hemostasis valve at the end of the disposable. However, in angioplasty, the guide wire is only internal to the catheter for a short distance near the catheter tip. As a result, in the first system, after entering the valve, once the catheter is advanced, the catheter and guide wire almost always have separate access points into the valve. The problem arose when we rotated the disposable while the valve remained fixed. This motion caused the guide wire to wrap around the catheter in the short region between the friction wheels and the valve. To overcome this issue, the idea came of using a valve that could rotate along with the disposable, as depicted in Figure 7. It's important to note that there is a significant change compared to previously published work. This valve, whose inner portion is similar to what is produced by other manufacturers, can now be adjusted to control the friction opposing the advancement of guides and catheters. This adjustment is achieved by rotating an element that moves closer to the fixed tube inside the valve, engaging with an inner threaded portion covering the silicon valve.

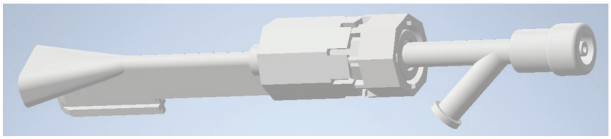

Figure 7) *The new rotating hemostasis valve.*

To prevent unintended adjustments during disposable rotation, a locking slider has been introduced in the valve.

To secure this setup, two different supports are utilized (Figure 8). The first support is fixed for a configuration with only three motors, typically requiring manual insertion of the first catheter (RA). The second support is attached to the rotating frame of a second gear train, using a combination of RA5 in the distal position and RA2 in the proximal position. This configuration allows for remote control of the first catheter's

introduction from a console. In both cases, a cap is used to seal the final component of the hemostasis valve. Figure 6 displays the two valve supports and the corresponding cap in the rotating configuration.

only the initial portion, to keep the guidewire controlled in position until the catheter is inserted. The majority of catheters for the brain and carotid have the guidewire inside a lumen for their entire length. However, when using stent catheters similar to angioplasty, where

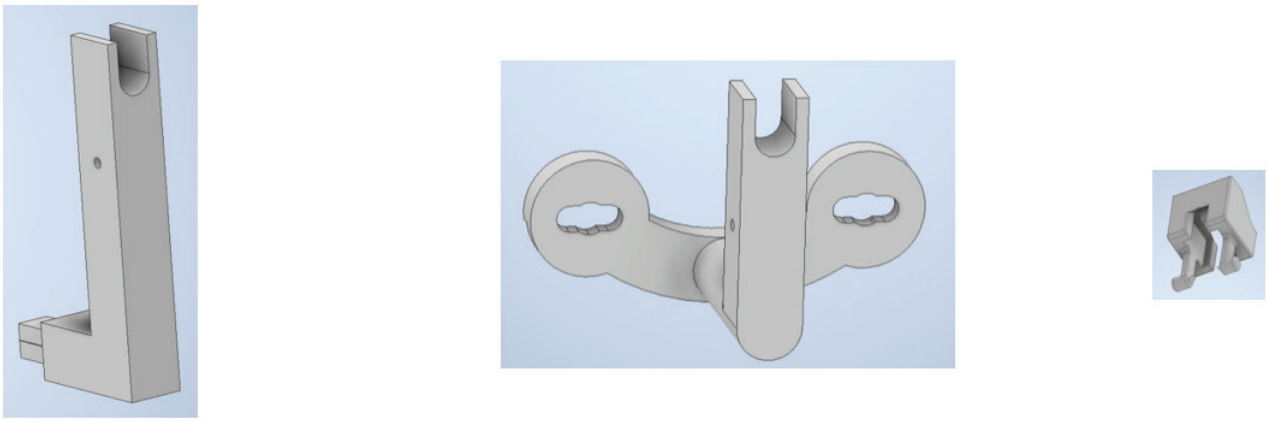

Figure 8) *The fixed and rotating support for the hemostasis valve and its closing cap.*

The Disposables for the Brain and Carotid

These disposables are derived from angioplasty disposables [46] and come in three types, two of which are simpler and designed for catheters and guidewires of very small dimensions. They are intended to be positioned in the second and third RA, as shown in Figure 3. It's important to note that ROSES is the only system that manages the first catheter plus two other instruments, as the third RA is almost always dedicated to guidewires for the brain and carotid. The two simpler disposables are modifications of the angioplasty disposables, created by eliminating the portion dedicated to guidewires for the catheter, and vice versa for the guidewire. In the latter case, it is necessary to add a portion of the hemostasis valve without the valve itself, the guidewire is internal to the catheter only near the tip, it is necessary, for instance, after positioning the stent in correspondence to an aneurysm, to position a second catheter either to introduce the filling guidewires or to suction blood if the aneurysm is ruptured. In this case, since the disposable is already occupied by the stent catheter, but the guide keeps it in position, it is possible to displace the catheter by opening the catheter side of the special disposable. This allows for the catheter side to be opened without affecting the guidewire side. The stent catheter can be positioned in the cavity between the two sides of the disposable, and the new catheter can be placed to bring it to the region of interest, working with the guidewire driven by the third RA. Figure 9 illustrates these three new disposables, with the third one showing the half-cover open.

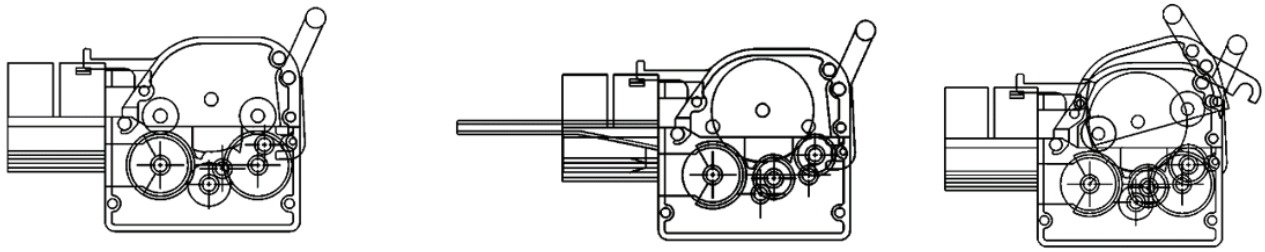

Figure 9) *The three disposables for the brain and carotid, for catheters, guide wires, and stents angioplasty-like.*

The Disposables for Guide Wires with a Movable Core

At the outset, registration challenges with the animated catheters will be encountered. Catheters require a more extended approval process compared to electromechanical devices that don't contact the human body. To address this, we decided to develop disposables for guide wires, which come in two types: one with a movable core allowing free movement inside the wire and another with the core fixed at the tip. Both of these disposables utilize bevel gears exiting from the main gear of the RA (robotic actuator). This setup requires the use of joysticks with three analog controls. Specifically, the three joy-stick controls are dedicated to controlling the three motors within the first gear train. For the first type, a pair of friction wheels on the right side was placed, which is always dedicated to the advancement retraction of the guide wire, while on the left, a large external wheel is used around which the core can be wrapped. This large external wheel is enclosed by a cover that defines a toroidal passage where the core is housed. The large wheel, responsible for guiding the core, must not interfere with the bevel gear transmitting motion to it. To achieve this, the guide wire initially passes on the right side, and its tail is introduced into a small hole aligned with the toroidal cavity. The large wheel features a brief empty sector with an inclined hole containing a threaded insert to secure the tip of the wire's tail. To facilitate the insertion of the wire tip into this cavity, a small mechanism, kept in place by a spring (not shown in the image), is used to bend the tip precisely. Finally, another threaded insert is employed to secure the wire's body. In the case of the core fixed at the tip, there is no external wheel. Instead, a rack is utilized, moved by two gears with an idle gear in between. This arrangement is depicted in Figure 10.

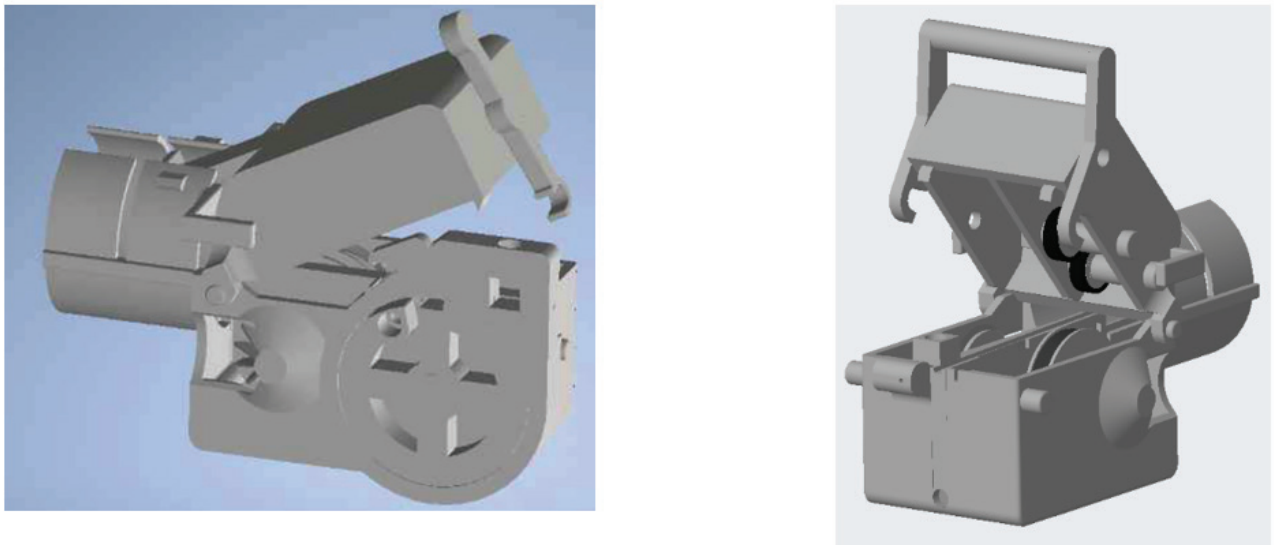

Figure 10) *The CAD model of the guide wire with a movable core (left) and fixed to the tip (right).*

The Device to Control the Motion of the Animated Catheters

Before delving into the device's description, let's introduce the new five-lumen catheter (Figures 11 and 12). It comprises four very small lumens, approximately 1.5 French in size, paired on opposite sides relative to the larger central lumen. On one side, near the tip, two different series of wedge-shaped cuts are made, corresponding to one of the pairs of small lumens. In a different location, wedge-shaped cuts are present on both sides, enabling the catheter to bend in two directions.

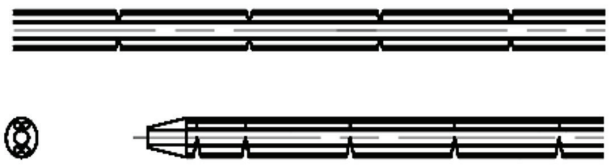

Figure 11) *Cross section, tip, and central portion configuration of possible cuts.*

Figure 12) *Examples of possible shapes assumed by the animated catheter.*

Before describing the control mechanism for this catheter, it's essential to note that this mechanism necessitates the use of a robotic arm (RA) with six motors. This setup requires two complete gear trains, each comprising three gears. The first set of three gears controls the disposables, the second set ensures rotation as directed by the operator, while catheter advancement is achieved using the two motors in the proximal RA with an internal disposable, synchronized with the advancement of the RA6 driven by the Robotic Cart (RC). As a result, two shafts with faceted ends extend from the rotating frame of the second gear train of RA6. Figure 13 shows the scheme of the six motors RA, in which the sixth motor is positioned on top of the central one, using the same transmission scheme used for the lower motor, just flipped around, obviously dividing the relative shafts to be completely independent. Thus, the thickness of the RA is increased just by the addition of a hollow gear and relative plastic ball bearing.

These shafts are connected to two longer shafts, which transmit commands to the catheter connector. The catheter connector houses two small drums on which the wires inside the small lumens are wound, maintaining minimal slack between the two cables to accommodate changes in the catheter's configuration. Finally, the rotation is transferred to the drums via two pairs of bevel gears, which are not shown in Figure 14 and are limited showing the basic structure of the support that substitutes, in this case, the one presented in Figure 7.

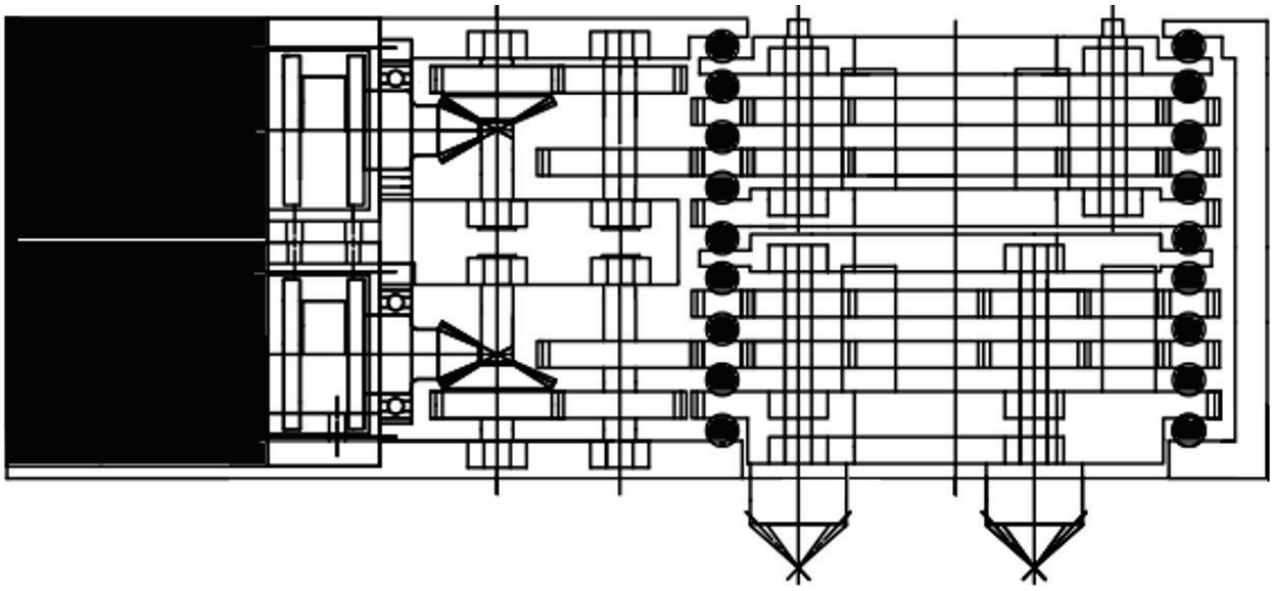

Figure 13) *The internal gearing configuration of RA6.*

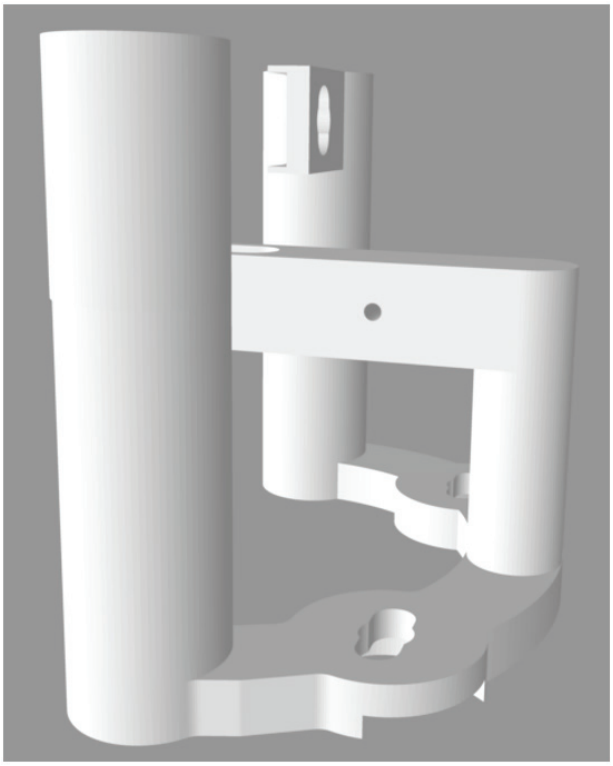

Figure 14) *The controlling mechanism of the two degrees of freedom animated catheter.*

The Hardware Configuration and Relative Software

The hardware configuration is straightforward, primarily utilizing off-the-shelf microcontroller boards. These have been supplemented with specially designed interface boards of only three types. One is for the console, and each group of three motors (e.g., RA5 and RA6 have two of these boards), each equipped with its microcontroller. A third board controls the two available motors on the robotic cart (RC) while continuously monitoring the output from the force sensor. Each microcontroller is named to indicate the type of RA on which it's installed, and they all communicate via cables using advanced standard protocols. As can be clear from the number of motors quoted, the system has 12 Degrees of Freedom (DOF), but as it is obvious, not all of them have to work together. In the meantime, the Console has only two joysticks, of which the one on the left usually controls catheter motion, while the one on the right is usually dedicated to guide wires. Each joystick bears three or four linear controls, the back and forth being dedicated to advancement, and the transversal motion to rotation, while the other two are dedicated to different tasks depending on the program. Four turning buttons are dedicated to controlling the relation between the joystick's actual motion and the speed of motion or rotation of catheters and guidewires.

The software poses the primary challenge as it must issue precise commands to each motor, accounting for the potential rotation of the entire gear train, but it also requires different programs depending on the specific task at hand.

To understand how the system works, let's start by describing some of the possible tasks controlled by our system. For each task, it is necessary to select the correct program first.

For example, when introducing the first catheter, which can be also pre-curved, the left joystick commands the catheter's advancement and rotation. Rotations are transmitted to RA2 and to the second train of RA5, while advancements are directed to RA2 and to a motor of the robotic cart (RC). With the right joystick, the guidewire rotation and advancement commands are issued to the first gear train of RA5. The motion of the core is controlled by rotating the button on the top of the right joystick, actuating the motor responsible for catheter advancement in angioplasty, again on the first gear train of RA5. Once the desired position is reached, RA2, RC, and the second stage of RA5 are halted. At this point, the left joystick commands the advancement of the catheter on the first train of RA5, and if the angioplasty option has been chosen, the right joystick commands the advancement of the guide wire along with the rotation of the entire disposable, which includes the hemostasis valve.

A different solution in case the desired task is to position a TAVI using our two degrees of animation catheter, which is mounted on RA6 with the previously described device. We also

use a standard guide wire mounted on a suitable disposable, which can be adapted if additional maneuvers are required to make it rigid (the disposable for the movable core can accomplish this if necessary). In this case, the joysticks are equipped with four linear controls each. The software commands the following actions:

- Advancement of the catheter is controlled on RA2 and RC
- Rotation is handled by RA2 and the second stage of RA6
- Shape control is managed by the second stage of RA6, using the two extra linear commands on the left joystick

Once the desired position is reached and the guide wire is in place, the robotic cart (RC) retracts the catheter by pulling back the RA6, while the motor of the first train of RA6 advances the guide wire to ensure it remains in position.

After removing the catheter from the patient, the guide wire is secured with a clamp in front of RA2. Subsequently, the guide wire disposable and the mechanism for controlling the animated catheter are removed. The catheter is detached from the bevel gears at the connector, allowing everything to pass through the sterile hole of RA6.

Next, the TAVI catheter is inserted into the tail of the guide wire and advanced into the patient using RA2, changing the upper component if necessary to substitute the spring-loaded upper friction wheel with one controlled manually turning a screw like the one shown in Figure 4. Once the TAVI catheter reaches the correct position, the TAVI can be activated, and both the TAVI catheter and guide wire are removed when their tasks are complete.

The last important example is the surgery on the brain and carotid. In this case, first, one has to bring the initial catheter at the point from which the brain surgery starts. Then, again, the position of RA2 and the second stage of RA5 or RA6 are blocked, and one should install on the intermediate actuator (RA5 or RA6) either the disposable for the brain presented in the third position of Figure 9 if one wants to use a stent catheter similar to the angioplasty ones, or the disposable for brain catheters, first position in Figure 9, while the disposable for the wire is to be installed in the third RA, usually a RA3. However, before going any further, one must introduce the guidewire into the hemostasis valve using an appropriate long needle, pushing the entrance cone of the valve to introduce the wire. Then one can position the catheter on the guidewire, pushing again the entrance cone of the valve to pass the valve. At this point one must close the disposable of the catheter, and, acting on the box that controls the last two motors, can push back the RA3 so that the catheter is in correspondence with the exit of the small tube of the disposable for guidewires (drawing in the middle of Figure 9). From this point, the left joystick will command the catheters on the intermediate RA, while the right joystick will command the guide wire on the most distal RA, commanding also the approach between the two as the catheter advances. Note that now it is possible to add new catheters and guidewires, by simply moving the ones present in the central channel of these disposables, using again the long needle to introduce the guidewire into the valve.

Finally, a very important note. The sterility of the system is ensured by the sterility of all disposables, including the internal tubes that separate the mechanisms, and by two disks that cover both sides, leaving a small ring in which the sterile transparent plastic covers placed on the various RA enter, ensuring that these covers will not be trapped when the gear train rotates. Moreover, a system of light plastic covers held laterally by wires and fixed on both sides to the RA covers will cover the rail and the bar, so that

the upper part will be all sterile.

Discussion

It's important to highlight that the ROSES system is the sole solution capable of maintaining a complete separation between the patient and the doctor throughout the entire medical procedure. This includes guiding the initial catheter and seamlessly transitioning to various endovascular procedures. The system's versatility enables easy selection of the appropriate program and disposables, making it a valuable asset.

Moreover, ROSES is the only system that allows for the performance of a wide range of endovascular surgeries under the guidance of expert doctors. This not only enhances the efficiency of medical facilities but also leads to cost savings in equipment acquisition. Looking ahead, the integration of AI holds promise for further improvements.

Additionally, ROSES offers the capability to record penetration lengths and forces encountered at every stage of the procedure. By adding a workstation to record real-time data from the console and images, the first 'black box' for endovascular surgeries will have birth. This significant feature greatly enhances safety.

Conclusion

Currently in the process of preparation of all device documentation for the initial registration phase in undergoing. Soon, it will be possible to start collaborating with medical professionals to simulate surgeries using models of human vessels. These models include 3D-printed replicas derived from CAT scan data on transparent plastic.

Once the necessary permissions are obtained, patient trials will start in multiple hospitals, spanning Italy, Europe, and, hopefully, the USA and Canada. Being aware of the need to explore systems for remote control of radio-opaque liquid injection and balloon inflation, first existing options will be considered or remote control solutions develop as needed.

Furthermore, we are ready to design new disposables for additional procedures, such as ablation. Our system's capabilities now extend to intracranial applications, enabling the introduction of catheters and guide wires into the skull, a feat only achievable through complete remote control.

Funding

The research described in this manuscript received funding from the Italian Government between 2015 and 2017 under grant number PON02_PON03PE_00009-4, titled 'Optima Cardiopaths,' with a total funding of €100,000. Additionally, private funding was provided by Professor Guido Danieli, who served as a full professor at Calabria University until his retirement in 2016 due to age limits and continued to support the project up to the present time.

Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Region Calabria (protocol 13 of 18/01/2018).

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Acknowledgment

We extend our gratitude to the Cardiology Unit at Magna Graecia University, Italy, for their valuable support before and during the clinical trials of ROSA. We also appreciate the assistance of Calabrian High Tech personnel and the clever suggestions by Gemelli Professors.

References

1. Spirtos NM, Schlaerth JB, Gross GM, et al. Cost and quality-of-life analyses of surgery for early endometrial cancer: laparotomy versus laparoscopy. Am J Obstet Gynecol. 1996;174:1795-800.
2. Gadacz TR, Talamini MA. Traditional versus laparoscopic cholecystectomy. Am J Surg. 1991;161:336-8.
3. Santos BF, Enter D, Soper NJ, et al. Single-incision laparoscopic surgery (SILS™) versus standard laparoscopic surgery: a comparison of performance using a surgical simulator. Surg Endosc. 2011;25:483-90.
4. van Dijk CN, van Bergen CJ. Advancements in ankle arthroscopy. J Am Acad Orthop Surg. 2008;16:635-46.
5. Sekiya I, Kobayashi M, Okamoto H, et al. Progress and role of finger joint arthroscopy. Hand Clin. 2017;33:819-29.
6. Sung GT, Gill IS. Robotic laparoscopic surgery: a comparison of the da Vinci and Zeus systems. Urology. 2001;58:893-8.
7. Babbar P, Hemal AK. Robot-assisted urologic surgery in 2010 - advancements and future outlook. Urol Ann. 2011;3:1-7.
8. Zheng G, Nolte LP. Computer-assisted orthopedic surgery: current state and future perspective. Front Surg. 2015;2:66.
9. Lopomo NF. Computer-assisted orthopedic surgery. In: Innocenti B, Galbusera F (eds), Human Orthopaedic Biomechanics. Academic Press, Cambridge, Massachusetts, USA. 2022;pp.533-54.
10. Rasouli JJ, Shao J, Neifert S, et al. Artificial intelligence and robotics in spine surgery. Global Spine J. 2021;11:556-64.
11. Beyar R, Gruberg L, Deleanu D, et al. Remote-control percutaneous coronary interventions: concept, validation, and first-in-humans pilot clinical trial. J Am Coll Cardiol. 2006;47:296-300.
12. Carrozza JP. Robotic-assisted percutaneous coronary intervention—filling an unmet need. J Cardiovasc Transl Res. 2012;5:62-6.
13. Britz GW, Panesar SS, Falb P, et al. Neuroendovascular-specific engineering modifications to the CorPath GRX Robotic System. J Neurosurg. 2019;133:1830-6.
14. Smitson CC, Ang L, Pourdjabbar A, et al. Safety and feasibility of a novel, second-generation robotic-assisted system for percutaneous coronary intervention: first-in-human report. J Interv Cardiol. 2018;30:152-6.
15. El Naamani K, Abbas R, Sioutas GS, et al. Endovascular robotic interventions. Neurosurg Clin N Am. 2022;33:225-31.
16. Beyar R. Transmission for a remote catheterization system. European Patent EP1755727B1, 2012.
17. https://www.robocath.com
18. Riga CV, Bicknell CD, Rolls A, et al. Robot-assisted fenestrated endovascular aneurysm repair (FEVAR) using the magellan system. J Vasc Interv Radiol. 2013;24:191-6.
19. Mazomenos EB, Chang PL, Rippel RA, et al. Catheter manipulation analysis for objective performance and technical skills assessment in transcatheter aortic valve implantation. Int J Comput Assist Radiol Surg. 2016;11:1121-31.
20. Perera AH, Riga CV, Monzon L, et al. Robotic arch catheter placement reduces cerebral embolization during thoracic endovascular aortic repair (TEVAR). Eur J Vasc Endovasc Surg. 2017;53:362-9.
21. Jones B, Riga C, Bicknell C, et al. Robot-assisted carotid artery stenting: a safety and feasibility study. Cardiovasc Intervent Radiol. 2021;44:795-800.
22. Song C, Xia S, Zhang H, et al. Novel endovascular interventional surgical robotic system based on biomimetic manipulation. Micromachines. 2022;13:1587.
23. El-Sayed T, Patel AS, Cho JS, et al. Radiation-induced DNA damage in operators performing endovascular aortic repair. Circulation. 2017;136:2406-16.

24. Aventin DL, Gil I, Gonzalez DML, et al. Chronic scalp ulceration as a late complication of fluoroscopically guided cerebral aneurysm embolization. Dermatology. 2012;224:198-203.

25. Luani B, Zrenner B, Basho M, et al. Zero-fluoroscopy cryothermal ablation of atrioventricular nodal re-entry tachycardia guided by endovascular and endocardial catheter visualization using intracardiac echocardiography (Ice&ICE Trial). J Cardiovasc Electrophysiol. 2018;29:160-6.

26. Li J, Leon DH, Ebato B, et al. Endovascular irradiation impairs vascular functional responses in noninjured pig coronary arteries. Cardiovasc Radiat Med. 2002;3:152-62.

27. Gerber TC, Carr JJ, Arai AE, et al. Ionizing radiation in cardiac imaging: a science advisory from the American Heart Association Committee on cardiac imaging of the Council on Clinical Cardiology and Committee on cardiovascular imaging and intervention of the Council on Cardiovascular Radiology and Intervention. Circulation. 2009;119:1056-65.

28. Picano E, Vano E. Radiation exposure as an occupational hazard. EuroIntervention. 2012;8:649-53.

29. Picano E, Andreassi MG, Piccaluga E, et al. Occupational risks of chronic low dose radiation exposure in cardiac catheterisation laboratory: the Italian Healthy Cath Lab study. EMJ Int Cardiol. 2013;1:50-8.

30. Klein LW, Miller DL, Balter S, et al. Occupational health hazards in the interventional laboratory: time for a safer environment. Radiology. 2009;250:538-44.

31. Roguin A, Goldstein J, Bar O, et al. Brain and neck tumors among physicians performing interventional procedures. Am J Card. 2013;111:1368-72.

32. Monaco MG, Carta A, Tamhid T, et al. Anti-X apron wearing and musculoskeletal problems among healthcare workers: a systematic scoping review. Int J Environ Res Public Health. 2020;17:5877.

33. Dixon RG, Khiatani V, Statler JD, et al. Society of interventional radiology: occupational back and neck pain and the interventional radiologist. J Vasc Interv Radiol. 2017;28:195-9.

34. Benjamin JL, Meisinger QC. Ergonomics in the development and prevention of musculoskeletal injury in interventional radiologists. Tech Vasc Interv Radiol. 2018;21:16-20.

35. Fichtinger G, Troccaz J, Haidegger T. Image-guided interventional robotics: Lost in translation? Proc IEEE. 2022;110:932-50.

36. Haidegger T. Autonomy for surgical robots: concepts and paradigms. IEEE Trans Med Robot Bionics. 2019;1:65-76.

37. Greco PF, Larocca G, Perrelli M, et al. ROSA – Robotic System for Angioplasty. In: Carbone G, Ceccarelli M, Pisla D (eds), New Trends in Medical and Service Robotics. Mechanisms and Machine Science, Springer, Cham 2019.

38. Danieli G, De Rosa S, Greco PF, et al. Extending ROSA to the entire endovascular field. Int J Latest Eng Manag Res. 2020;5:10-8.

39. Danieli G, Greco PF, Larocca G, et al. Development of disposables and accessories for ROSES and their *in vitro* experimentation. Appl Mech. 2022;3:956-73.

40. Danieli G, Tinelli G, De Rosa S, et al. Presenting a new version of the Robotic System for Angioplasty. Med Res Arch. 2023;11:1-13.

41. Danieli G, De Rosa S, Greco PF, et al. ROSES, the only robotic system for any endovascular surgery, including the control of an animated catheter characterized by the presence of two controlled curvatures. Int J Endovas Treat Innov Techn. 2023;4:1-10.

42. Indolfi C, Polimeni A, De Rosa S, et al. First-in-human robotic percutaneous coronary intervention by the ROSES robotic system: a case report. Eur Heart J Case Rep. 2023;7:506.

43. Danieli G, De Rosa S, Carbone G, et al. New components disposable and multi-use re-sterilizable for the robotic system for endovascular surgery. PCT/IB2023/056635. 2023.

44. Danieli G, De Rosa S, Greco PF, et al. Evolution of ROSE system for endovascular Surgery. PCT/IT2021/000042. 2021.

45. Danieli G, Greco PF, Larocca G. Endovascular surgery robot equipped with an opto-haptic system to measure and represent the forces opposing the advancement of a catheter or a guide within the endovascular system. Italian Patent application 102019000006657. 2021.

46. Danieli G. Opto-haptic system to measure and represent forces opposing catheter or guide wire penetration into the vascular system for robots for endovascular surgery. PCT/IT2020/050109. 2022.

47. Danieli G, Gallo R, Greco PF, et al. Development of ROSINA (Robotic System for INtubAtion). Int J Biotech Trends Technol. 2021;11:1-7.

48. Danieli G. New disposables for brain and carotid interventions using the Robotic system for endovascular surgery. Italian Patent Application 102023000026775. 2023.