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RESEARCH ARTICLE

Presenting a New Version of the RObotic System for Angioplasty

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Abstract

This paper describes the new version of RObotic System for Angioplasty (ROSA), which was developed from a simplified version of the RObotic System for Endovascular Surgery (ROSES). ROSES itself arose from the original ROSA device and has been tested for clinical use on patients.

The new version of ROSA offers several advantages over the previous versions. First, it allows the measurement of forces used to track catheters during the endovascular procedure. This process only requires standard mechanical disposables, since the measuring system is embedded in a special cart that controls the movement of various robotic actuators. Second, it uses a new hemostasis valve that rotates with the angioplasty disposable, making it easier to guide rotations. Finally, it offers the possibility of positioning the initial catheter using a system that includes two robotic actuators found on the cart. The first of these is simpler and has an internal disposable, whereas the second is new and contains two gear trains, which control five independent parameters (two rotations and three advancements). This makes it possible to control advancement and rotation of the initial catheter, while straightening its curvature using a movable core guidewire. Once the first catheter is correctly positioned, it is possible to perform all procedures without changing the position of the guiding catheter by replacing the disposable for the 0.035" guidewire with movable core with the disposable for angioplasty, which drives both the angioplasty balloons or stents and the 0.016" wire, which instead needs to turn on its axis in order to ease penetration of the small guide wire which has to penetrate the winding path of the coronaries. And this is allowed by the presence of the two independent gear trains of the recent robotic actuator, which can block rotations of the gear train on which the initial catheter is positioned, while allowing all rotations needed for the angioplasty disposable. However, in the near future it will also be possible to change the position of the guiding catheter using a special 6 French catheter with controlled tip curvature, for example, to perform an additional angioplasty on a different coronary artery, should this be required.

Introduction

At present, the use of robotic systems such as CorPath (developed by Corindus). 1,2,3,4,5,6, or French Robocath. 7 and Magellan (developed by Hansen Medical). 8,9,10,11 for endovascular surgery, is not widely adopted. Besides the cost element, there is a general reluctance to use new tools that substantially alter standard protocols. This is especially true if the novel approach only applies to a specific application. Despite evidence that these new robotic technologies dramatically reduce operator exposure to ionizing radiation. 12,13,14,15,16,17,18, there is reluctance to embrace it in the clinic. Moreover, although the aprons conventionally used to shield operators from X-rays offer a good level of protection, their heavy weight still poses a health risk, especially for high-volume operators, who frequently suffer from spinal problems. 19,20,21. In addition, even during X-ray apron use, multiple body parts remain exposed. Hands in particular are vulnerable as they are positioned closely to the X-ray source.

In order to compensate this lack of interest for robots applied to endovascular treatments, our system offer information that are not easily available to a manual operator, such as the quantification of the forces opposed by the body to penetration without special tools and length of penetration of the various tools used. And this is exactly what the newly developed RObotic System for Angioplasty (ROSA), has to offer as standard information.

The CorPath system offers a way to measure forces that resist the advancement of guidewires and catheters. However, the system requires a specific and more costly disposable, which is why it is seldom used. Moreover, additional information, such as the length of catheter penetration and the length of a particular vessel segment or stenosis are not provided by the currently licensed products. With the new ROSA, these parameters are registered, shown on the console, and in the following transmitted to a central unit, which records (including images) and tracks the entire procedure. Such information may be used intraoperatively, for instance to establish the length of a stenosis, allowing the operator to select a stent of appropriate length. Moreover, the new ROSA system is designed for application in a broad range of procedures, making it a very useful tool in a catheterization laboratory, while avoiding the need to acquire multiple robotic endovascular surgical instruments. These advantages have been described in various patent applications filed by our research group. 22,23,24,25,26.

The original version of ROSA was first presented at the IFTOMM (International Federation for the Promotion of Mechanisms and Machine Science) Congress in Cassino, Italy in 2018. 27. Since then, the system has been updated several times and has been tested on patients undergoing angioplasty at the Magna Graecia University of Catanzaro, Italy, using the original robotic actuator with a narrow passage for catheters and guidewires, of which the Fig. 1 shows the three-gear train even if in the present big passage edition, which differs only in the number of teeth of the gears.

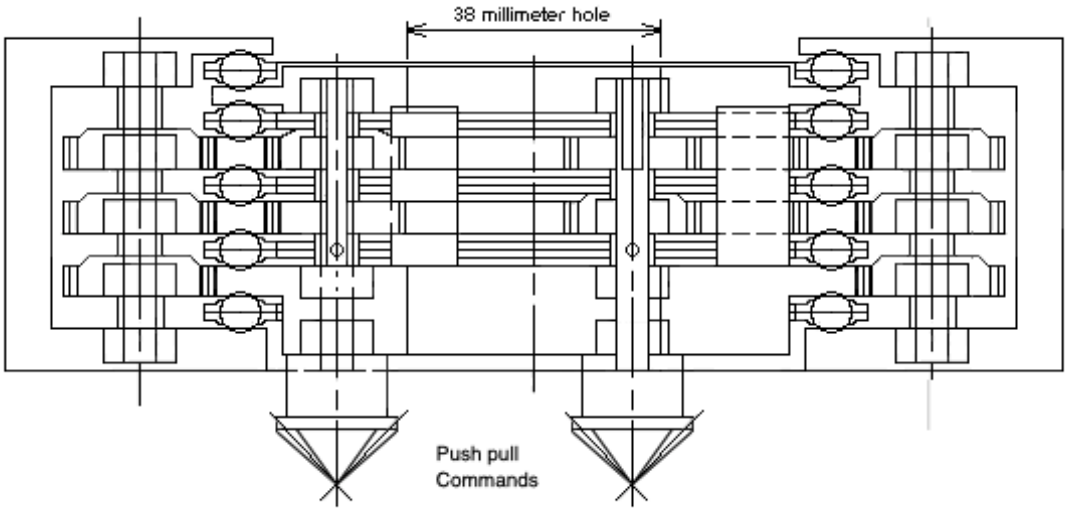

Fig. 1. Schematic representation of the internal gear train.

At the base of this actuator is a gear train composed of three large gears and a fourth untoothed disk, which is fixed internally to the first gear to frame the rotating mechanism. The second and third gears are hollow, with internal teeth that mesh with smaller gears. These smaller gears are

fixed to shafts and kept in position by the frame. The front gear terminates with two bevel gears. The gear train is stabilized by three shafts (only two of these shafts are shown in the two- dimensional Fig. 1), which are positioned at 120° and each hold an idle gear corresponding to each of the large gears. A ball bearing is also incorporated for stability. The three large gears are operated independently via gears moved by step motors, which are not shown in Fig. 1.

This system is able to control three parameters, although they are influenced by the rotation of the main gear. However, adding or subtracting the desired rotation of the internal shafts to/from the rotation of the main gear controls these parameters. This means that for angioplasty, it is possible to control global rotation together with two independent advancements. However, a disposable was required as an interface between the actuator and catheters/guidewires.

Various editions of this disposable have been developed. The latest uses gear to rotate two pairs of friction wheels at the same speed. In this setup, the lower friction wheel meshes with an intermediate idle gear to direct the movement of both the catheter and guidewire. While the catheter path is linear (blue line), the wires are forced along a curved path (red + dashed black lines), which forces their rotation (Fig. 2 and 3).

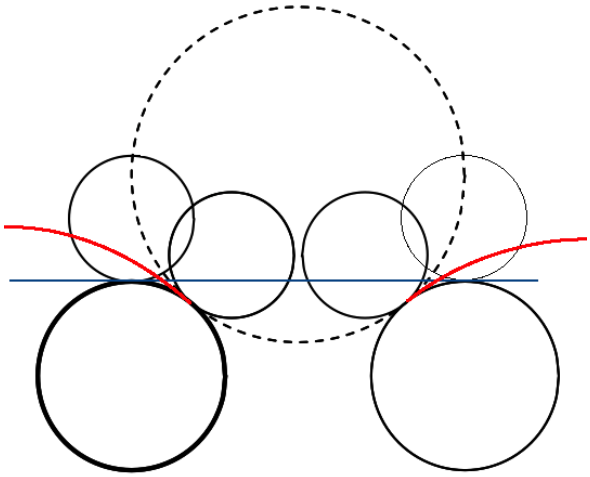

Fig. 2. Schematic representation of the catheters and guidewire paths inside the disposable.

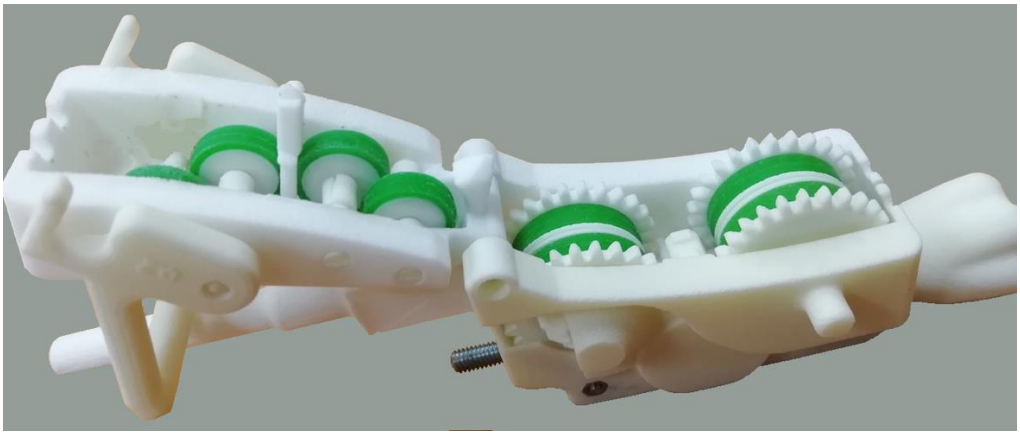

Fig. 3. The latest version of the angioplasty disposable (in open position) before its dimensions were altered in the new ROSA.

Methods

During the design of the Robotic System for Endovascular Surgery (ROSES) to broaden the application of ROSA in the field of endovascular surgery, it became clear that the dimensions of the passage hole needed be changed (as suggested by Professor Massetti, Head of Gemelli Institute Department of Cardiovascular Sciences. 28) to guide catheter insertion during transcatheter aortic valve implantation (TAVI). Thus, the mechanism inside the robotic actuator was redesigned by simply changing the number of teeth in the gear train that controls the rotation and the two distinct advancements; one for the guidewire and the second for the catheter. This changed the passage diameter from 7 to 36 mm, which enabled the insertion of larger catheters and hemostasis valves, as is sometimes necessary. Consequently, the disposable had to be adapted to the new passage dimensions.

In parallel, we were also working with Professor Tshomba, Head of Gemelli Institute Complex Unit of Vascular Surgery. 29, on developing a system that could move the catheter and guidewires independently. To achieve this, at least two robotic actuators had to be positioned in series. In addition, their relative positions had to be controlled. Thus, a special cart was designed.

Professor Tshomba. 30 also requested that our robot controlled the tip curvature of the catheter, as

is possible using the Magellan instrument, 9. To achieve this, a new catheter was designed, in which a wire inside a second smaller lumen, fixed at the catheter tip, could be pulled to induce curvature. The first design of the catheter, which is yet to be built, is presented in Fig. 4.

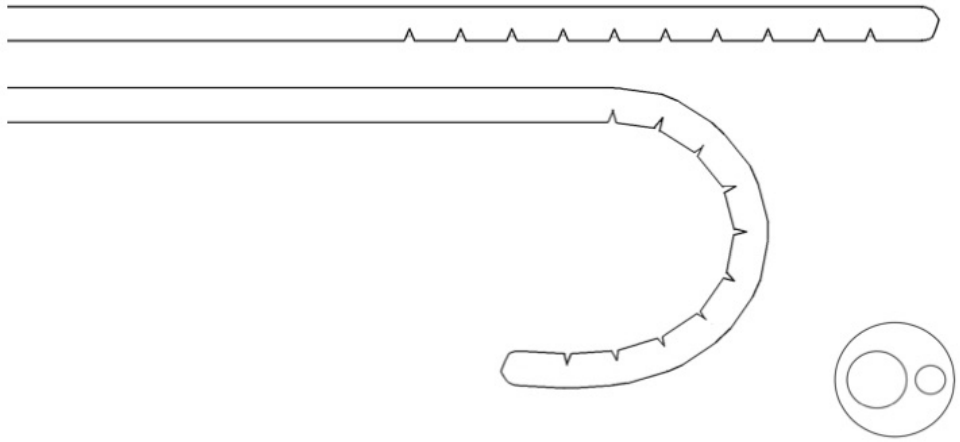

Fig. 4. Schematic representation of the catheter with a tip-controlled curvature.

However, it was unclear how the wire could be pulled inside the catheter while introducing the catheter into the patient's body. Luckily, the cart, which could accommodate two actuators in series and control their relative positions, was already under development. Subsequently, a double robotic actuator (called RA5), which was able to control two different rotations and up to four translations, was developed. Typically, three translations are deemed sufficient; two associated with the main rotation and the third associated with the secondary rotation.

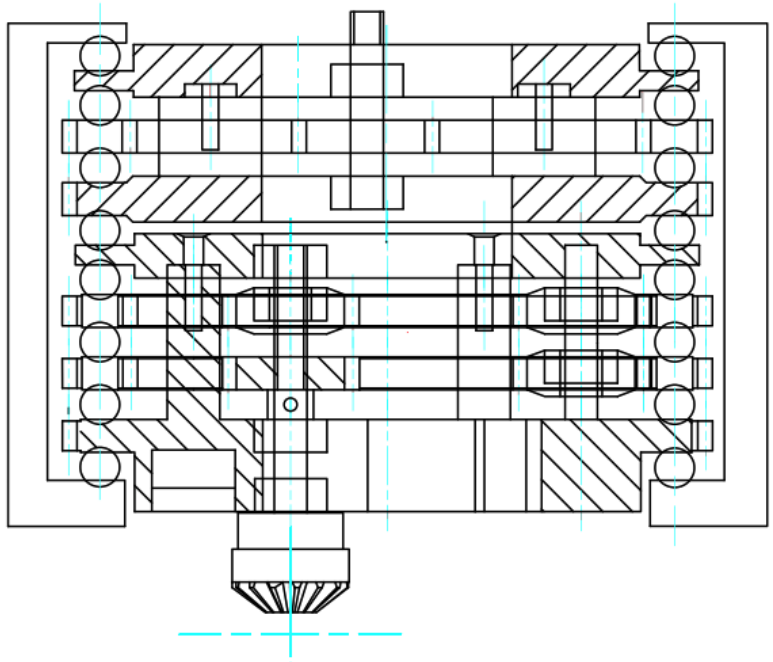

Fig. 5. Schematic representation of a section of RA5, showing the internal structure of the double gear train.

This was achieved by placing a second gear train in front of the main one. This second gear train wound the wire around a small drum, while a guidewire with a movable core (the advancement and core position of which were controlled by the main gear train) straightened the catheter while releasing the inner cable. A second robotic actuator, placed in front of RA5, inserted the catheter into the patient using advancement and rotation. This required that the first robotic actuator and the front portion of RA5 rotated at the same speed while RA5 approached the proximal robotic actuator near the patient at the speed of catheter advancement. Fig. 5 shows a cross section of RA5,

with its five independent motors, while Fig. 6 shows the positions of the five motors on the base plate.

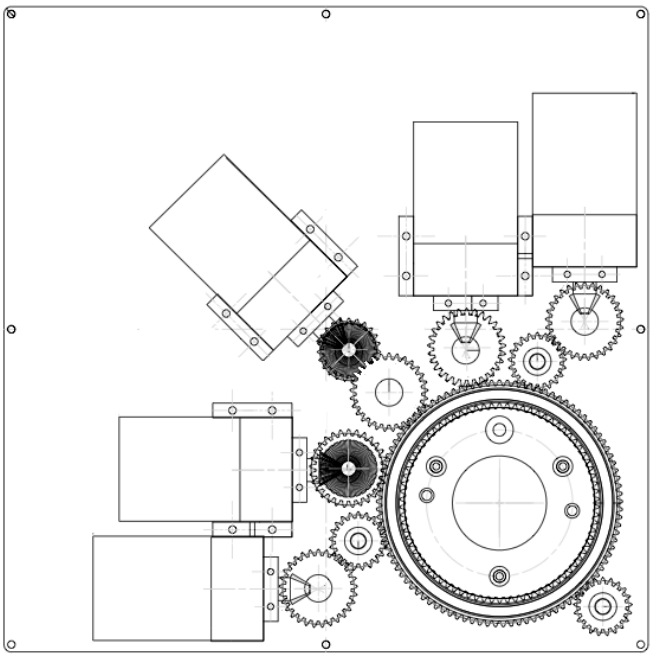

Fig. 6. Schematic representation of the RA5 base, showing the five motors and reducers, as well as the relative transmission gears.

In addition to directing the curvature of straight catheters, this system also works with pre-curved catheters. In this instance, the movable core guidewire is fixed with a suitable disposable on the main gear train, enabling the advancement of the pre-curved catheter by straightening its tip when needed.

The cart is assembled from a stainless-steel beam, which is suspended on two tripods and slightly inclined toward the patient. A rail is positioned on top of the beam, along which various robotic actuators move, each on a separate slide. A step motor, fixed to the proximal actuator by a lateral bar, is mounted on a third or fourth slide, depending on the number of actuators needed. This motor, controls the relative position between the two actuators via a worm gear. Finally, the motor is hooked up to a force sensor, which is subject to a constant g component of the various objects placed on the rail. Since anything that moves in this system does not change its weight, this system can only be perturbed by the patient's body reacting to catheter penetration, which reduces the force measured by the sensor. 31. The idea for this system actually came about while reviewing a Chinese paper. 32, discussing the challenges of measuring forces associated with the body's resistance to catheter advancement. A technical solution to this problem was found and a patent application was subsequently issued. When the examiner studied the application, he also quoted a Chinese patent with a similar working principle; however, this patent was filed after our application. A recent paper. 33 had already described the features of an earlier version of ROSA. Here, we describe the most recent advancements, including the expanded application for endovascular interventions, and the relative computer-aided design models, which are ready to implement.

Of note, RA5 (the double actuator) also enables the introduction of a pre-curved catheter, separating the operator from the patient, by simply fixing the hemostasis valve to the secondary gear train of the double robotic actuator, while straightening the curved parts with the movable core guidewire. Then, once the initial catheter is positioned, a change in the program maintains the catheter in that position. Thus, replacing the disposable used for guidewires with a movable core with one used for angioplasty, allows the surgery to proceed.

As briefly introduced above, some new angioplasty-specific features were developed working on a parallel project. In fact, some of these improvements originate from the design of the RObotic System for INtubAtion (ROSINA). 34, which was developed during the COVID-19 pandemic to distance physicians from patients during intubation. However, ROSINA development was delayed and

the problem was instead solved by providing operators with more suitable personal protective equipment. The robotic actuator used in ROSINA was actually derived from the one used in ROSA, increasing the number of teeth of the gears; this was later adopted as the standard robotic actuator in ROSES. During the development of ROSINA, a new system of connection between the robotic actuator and the new disposable was created, as well as a new disposable which sits inside the robotic actuator, reducing the length necessary for catheter advancement to less that 5 cm. This new system was then adopted as the standard proximal robotic actuator for ROSES (also called RA2), since it can only push and rotate a catheter.

In actuality, all systems can be installed on the cart and it is the software that recognizes the various robotic actuators and suggests changes if the configuration mounted on the cart if unsuitable for the task. Thus, to initiate the process, the user must first select the appropriate configuration by communicating with the console.

Let us next examine the features of the disposable for large catheters, since it serves as the basis for the design of every other disposable (Fig. 7). This new disposable is composed of three separate elements, which become a single unit only after assembly. By contrast, old disposable versions (Fig. 3) consisted of only two components joined by a hinge, holding also the duct that separates the catheters and guide wires from the internal robotic actuator mechanisms. The new disposable design offers a big advantage: the separation of the upper and lower components from the duct allows for their removal without disturbing what is inside, which is crucial for certain endovascular procedures, leaving the duct still sterile. For instance, in TAVI, the catheter and guidewire must be navigated to reach the valve. At this point, it becomes necessary to eliminate the catheter and hemostasis valve, leaving in place the guidewire on which the TAVI catheter is to be mounted (starting from the guidewire tail).

To achieve a secure connection between the disposables and the robotic actuator, which is necessary to transmit the required torque, the lower components have two small teeth which penetrate into the sterile tube, while the upper component has two small arms which grip the two pins of the lower component. In addition, there is a relatively large tooth which penetrates into the sterile tube in the upper zone, while two teeth lock it in position with respect to the lower component. Finally, a key locks the lower and upper components, as well as the tube, to the robotic actuator structure. On top of the upper component of the disposable there is a screw which can be used to adjust the catheter dimension from 6 to 30 French.

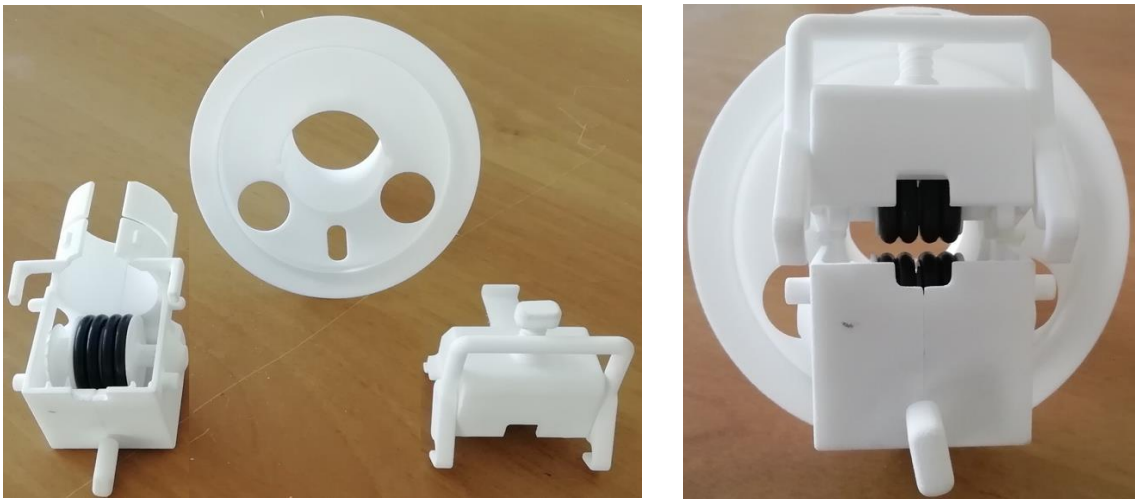

Fig. 7. Photographs showing the three disposables used for large catheters, assembled (right) and disassembled (left).

The new disposable for angioplasty, which also contains a portion for the catheter and a second portion for the small guidewire, uses friction wheels (previously described during catheter insertion) which forced an increase of the length of the body with respect to that of the disposable shown in Fig. 7. It also hosts the two friction wheels and the three gears found in the earlier model of the disposable, which are used for the small passage robotic actuator. The portion dedicated to the guidewire has undergone considerable changes, as it now accommodates a system which accurately controls the curvature of the guidewire. This is achieved by introducing a large friction wheel into the upper component, which comes into contact with three friction wheels on the lower component. In addition, it is centered by special protrusions, which guide the wire to the middle of the large upper wheel. A

central channel is present between the catheter and wire command region, which can accommodate an extra guidewire and catheter, in the case of a coronary bifurcation near a stenosis. This enables the placement of a second wire in the bifurcation before the stent balloon is inflated, making it possible to place a second stent to reopen the closure.

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There is another important difference between the first edition of ROSA and the present one. In the original ROSA design, the catheter and guidewire had to pass through the hemostasis valve. However, when it was necessary to rotate the guidewire, its rotation had to be limited to half a turn on either side; otherwise, the wire would wrap itself around the catheter, which would limit its ability to turn on its axis. To overcome this, a valve was placed on the tip of the disposable, dividing the system into two parts by a waterproof joint that enabled rotation between the two components. In this way, the connection for radiopaque liquid stayed fixed while the valve rotated. However, in cases when an initial catheter has to turn about its axis during introduction, to follow the inner vases geometry, the connection with the radiopaque liquid has to follow the rotation of the catheter.

In situations where the first catheter (with its pre-curved configuration) needs to be straightened by the guidewire with a movable core, it is necessary to use the same hemostasis valve for both the angioplasty and the guidewire with movable core disposables. Consequently, the disposables and the rotating hemostasis valve have been divided into two components (Figs. 8 and 9).

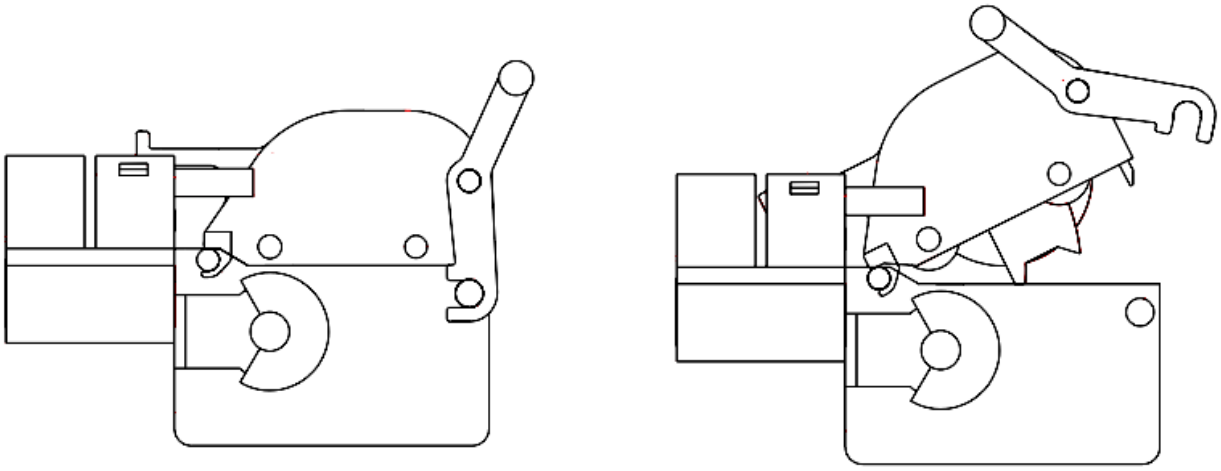

Fig. 8. Schematic representation of the open (right) and closed (left) positions of the disposable used for angioplasty.

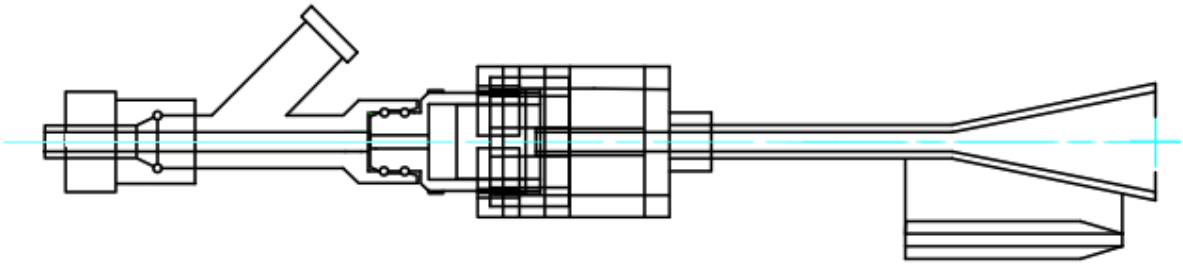

Fig. 9. Schematic representation of the special hemostasis valve used for angioplasty and the movable core wires.

Of note, the lower portion of the hemostasis valve on right side does not reach the cone designed to guide catheters and guidewires to the hemostasis valve. It is instead tapered to ease the entry of disposables when a system change is needed. Moreover, a rotating support was designed to lock the valve into position during initial catheter introduction. This support turns to accommodate the internal shape of the endovascular system.

Before proceeding any further we should now describe the disposable for movable core valves, which is shown in Fig. 10.

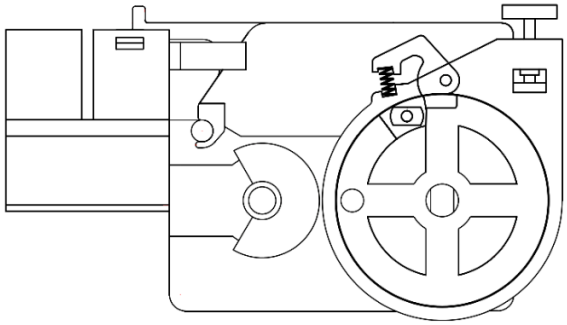

Fig. 10. Schematic representation of the disposable for movable core wires.

Essentially, the right side of the device contains two friction wheels, which are commanded by the bevel gear, exiting from the robotic actuator, to advance/retrieve the wire. Meanwhile, the left side, which is also commanded by the bevel gear and which in angioplasty commands advancement of the catheter, is dedicated to the motion of the movable core. The first, internal bevel gear in the disposable moves a chain of three, parallel-axis spur gears. The last of these gears moves a large, external wheel, which moves inside an external round frame. The external wheel and the frame have a central, circular cavity to hold the movable core, which passes through the friction wheels of the right side and turns 180°. It then enters a hole in the frame, which is aligned with the circular cavity, until it reaches the top portion of the large external wheel; as this portion of the wheel is empty, its contents are visible. The principle described is depicted in Fig. 11.

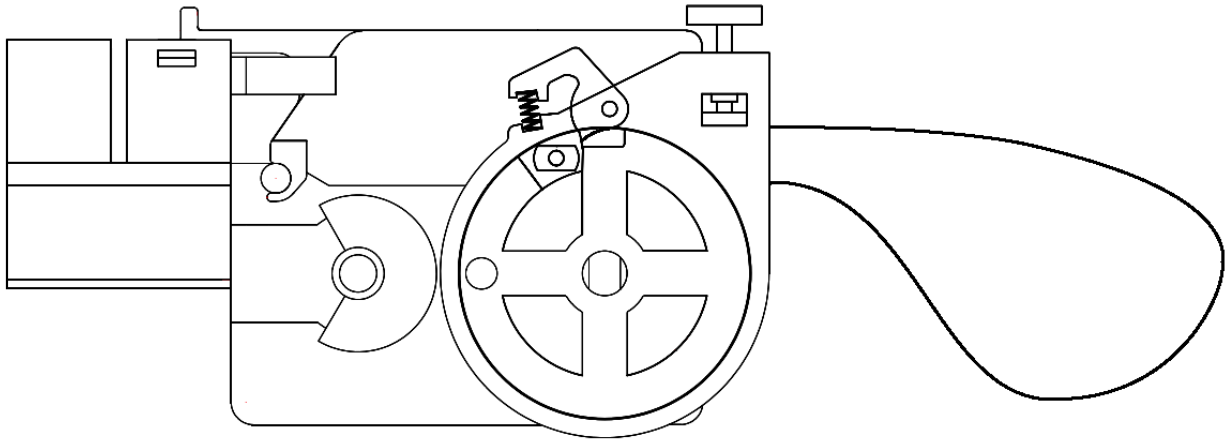

Fig. 11. Schematic representation showing that a single disposable may move the inner core of a guidewire.

Pushing the small lever on top of the external frame forces the tip of the guidewire tail inside the cavity of the large wheel (visible in Fig. 12); this motion is blocked by the lateral screw. Then, the external body of the wire can be locked in position with a screw and the internal wire can be wrapped around

the external wheel and moved back and forth according to how the catheter should advance.

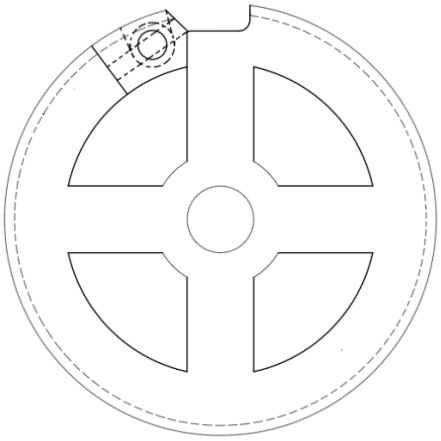

Fig. 12. Schematic representation of the external wheel used to move the guidewire core; the internal portion is shown using dashed lines.

It is also possible to have a version of the system that does not measure force and is unable to guide initial catheter insertion, by using an RA3, a shorter rotating hemostasis valve, and a fixed support. However, altering the system is this way is not recommended, even if it will reduce costs. Instead, the ROSA configuration previously described can also be used for TAVI or any other type of endovascular surgery; hence, acquiring the new ROSA represents a worthy investment.

After discussing the rationale for designing the rotating valve for angioplasty, the new version of the device controlling the special catheter tip curvature can now be introduced. The device is mounted on the disk that closes the second gear train of RA5, 26 (Fig. 13). On the left side of the device is a column with a shaft, which is moved by a hollow gear of the second gear train. The shaft is topped by a bevel gear, which mashes with a second bevel gear, which then transmits motion to a very small drum within a special connector mounted on the Luer lock. This connector closes the rotating hemostasis valve and is kept coaxial to the double gear train by a small column placed on a portion of a ring that surrounds the central passage. The column has a protrusion (see the lower image in Fig. 13) and a special cap to securely position it vertically. Despite its complex appearance, this device is only 7 cm long.

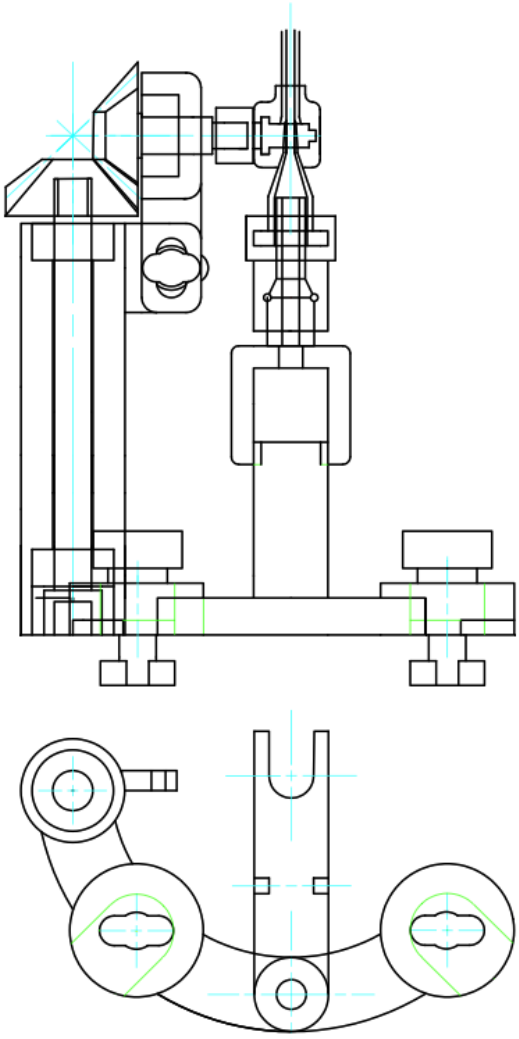

Fig. 13. The new mechanism that controls tip curvature

Finally, Fig. 14 shows the design of the new cart, which is a robot in itself. Its function is to move the various robotic actuators, each sitting on a slide running along a single rail. This rail is fixed to a stainless-steel bar, which is slightly inclined toward the patient. The proximal RA2 is kept at a fixed distance from the motors by a lateral bar. The motor itself is fixed to the first slide on the rail, while the second and possibly third robotic actuators are each moved by a worm gear. Finally, the motor support is fixed in position by a wire, which connects to a force transducer housed in a box fixed to the end of the bar. The transducer measures the g component of the weight of the equipment minus any force exerted by the body to resist insertion.

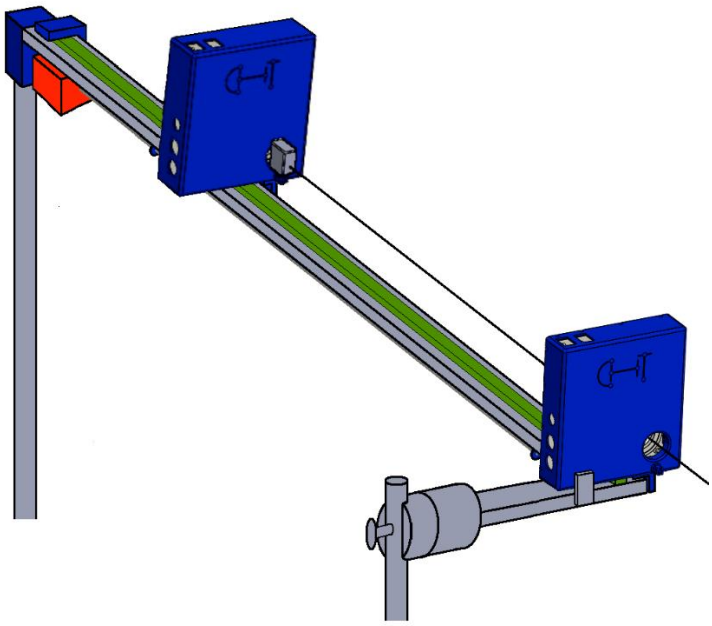

Fig. 14. Schematic representation of the fully assembled cart, showing the two robotic actuators (blue) mounted on slides, the inclined bar with a relative rail, the step motors (red) commanding the motion of the distal robotic actuator (only one in this case), and the box containing the sensor (also blue).

Results

Among the various characteristics of this system lies the possibility of measuring distances covered by guidewire and catheter advancement. By determining the transmission ratio between the gears of the robotic actuator and the diameter of the friction wheels, as well as by counting the number of steps taken by the motors, the distance of catheter or guidewire advancement can be calculated. Hence, a program was developed to convert the number of motor steps into length, which could then be displayed on the console screen. An icon representing a measuring tape was therefore added to the console screen; it could be activated (colored icon) and inactivated (white icon) by pressing the touchscreen of the console. To demonstrate this feature, we used transparent tubing and marked it with two lines to simulate the beginning and end of a stenosis, while measuring length using an electronic vernier. When measuring the length of a stenosis to decide on the length of stent to be used with a guidewire, which is characterized by very soft and curved tip, the operator should always pull and never push the wire. Thus, the wire should be advanced well above the starting point of the measurement and then be moved by slowly pulling it until it reaches the distal point to start the measurement. The measuring tape icon should be pressed while pulling the wire until it reaches the second mark. We repeating this procedure eight times (four times with straight tubing and four times with curved tubing) and found that it had an average error of less than 3% over a distance of 41 mm. Fig. 15 shows photographs representative of one of the eight experiments. Although these experiments were performed using the original version of the robotic actuator, we are confident that the new system will work in exactly the same way.

Fig. 15. Sequence of photographs showing how catheter/guidewire advancement was measured using curved tubing. 1. The wire stopped at the first mark on the tube. 2. The measuring tape icon was pressed once (changing its appearance from "white" to "in color") to initiate length measurement. 3. The wire in its final position in the tube, having travelled 41.5 mm. 4. The entire console touchscreen display.

Plans to redesign ROSA were put on hold due to a long funding crisis caused by the COVID-19 pandemic. Thus, we can only show the image of the RA3 (Fig. 16) at present. However, we are in a process of negotiation to continue this work with an Italian firm or with other foreign firms. Meanwhile, thank to another research, we are starting the production of the first complete system. This enormous delay is a consequence of the insufficient emphasis placed on technology innovation in Italy. Really, we would love an Italian solution to finally bring these products to market, but it all depends on the agreement that can be reached.

Fig. 16. The first working prototype of RA3, with a 36-mm passage.

Discussion

The new ROSA system described in this paper contains a stainless-steel bar, which is longer than the longest catheter to be used. However, since this bar sits on a couple of tripods, it can be easily removed and relocated to another surgical room for use in a different procedure if needed. Thus, the size of the bar is not a significant hinderance, especially as its width is not an issue (50 cm near the patient and 30 cm away from the patient). A single cable connects the cart to the console. Moreover, the console requires one power cable and one cable to connect it to the robots.

As described earlier, this system could be called either ROSA or ROSES, even if a ROSA system exist already in the market as Stryker knee system, so that to avoid confusion the final brand name will be the second. But what is important is that this system is potentially suitable for all types of transcatheter endovascular surgery. Its next application, currently under development, is in carotid and brain endovascular interventions. For this purpose, we will add a third RA3 between the RA5 and the measuring unit, which also controls robotic actuator motion on the cart. This is because, unlike in angioplasty, the guidewires in these applications must be positioned inside the catheter for the entire length of insertion. Moreover, the front portions of RA5 and RA2 will direct the initial catheter into the correct position, owing to the unique properties of catheters with a controlled tip curvature.

Conclusions

Although the new version of ROSA will have to undergo clinical testing in a catheterization laboratory, we anticipate that any modifications made will not substantially impact its clinical performance. Moreover, this system offers clear advantages over other systems currently on the market; we are also not aware of any similar developments in available systems which can match the performance of the new ROSA.

Conflicts of Interest Statement

The only potential conflict of interest lies in the fact that Calabrian High Tech, founded by Professor Guido Danieli in 2002, received loans from its founder to conduct the research described in this manuscript between 2017 and 2023.

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References

1. Beyar R, Gruberg L, Deleanu D, Roguin A, Almagor Y, Cohen S, Kumar G, Wenderow T. Remote-Control Percutaneous Coronary Interventions: Concept, Validation, and First-In-Humans Pilot Clinical Trial. J. Am. Coll. Cardiol. 2006, 47, 296–300.
2. Carrozza JP. Robotic-assisted percutaneous coronary intervention—Filling an unmet need. J. Cardiovasc. Transl. Res. 2011, 5, 62–66.
3. Britz GW, Panesar SS, Falb P, Tomas J, Desai V, Lumsden A. Neuroendovascular-specific engineering modifications to the CorPath GRX Robotic System. J. Neurosurg. 2019, 133, 1830–1836.
4. Smitson CC, Ang L, Pourdjabbar A, Reeves R, Patel M, Mahmud E. Safety and feasibility of a novel, second-generation robotic-assisted system for percutaneous coronary intervention: First-in-human report. J. Invasive Cardiol. 2018, 30, 152–156.
5. El Naamani K, Abbas R, Sioutas GS, Tjoumakaris SI, Gooch MR, Herial NA, Rosenwasser RH, Jabbour PM. Endovascular Robotic Interventions. Neurosurg. Clin. 2022, 33, 225–231.
6. Beyar R. Transmission for a Remote Catheterization System. European Patent EP1755727B1, 11 January 2012.
7. Durand E. Evolution European Multicenter Study to Evaluate the Safety & Efficacy of the R-Onetm System in Percutaneous Coronary Interventions, Available online: https://www.robocath.com (accessed on 11 Marc 2023)
8. Riga CV, Bicknell CD, Rolls A, Cheshire NJ, Hamady MS. Robot-assisted fenestrated endovascular aneurysm repair (FEVAR) using the Magellan system, J Vasc Interv Radiol. 2013 Feb;24(2):191-6.
9. Mazomenos EB, Chang PL, Rippel RA, Rolls A, Hawkes DJ, Bicknell CD, Desjardins A, Riga CV, Stoyanov D. Catheter manipulation analysis for objective performance and technical skills assessment in transcatheter aortic valve implantation, Int J Comput Assist Radiol Surg. 2016; 11: 1121-1131.
10. Perera AH, Riga CV, Monzon L, Gibbs RG, Bicknell CD, Hamady M. Robotic Arch Catheter Placement Reduces Cerebral Embolization During Thoracic Endovascular Aortic Repair (TEVAR), Eur J Vasc Endovasc Surg. 2017 Mar; 53(3): 362-369.
11. Jones B, Riga C, Bicknell C, Hamady M. Robot-Assisted Carotid Artery Stenting: A Safety and Feasibility Study, Cardiovasc Intervent Radiol, 2021 May; 44(5): 795-800.
12. El-Sayed T, Patel AS, Cho JS, Kelly JA, Ludwinski FE, Saha P, Lyons OT, Smith A, Modarai B. Radiation-Induced DNA Damage in Operators Performing Endovascular Aortic Repair. Circulation. 2017 Dec 19; 136 (25): 2406-2416.
13. Lopez Aventìn D, Gil I, Lopez Gonzalez DM, Pujol RM. Chronic scalp ulceration as a late complication of fluoroscopically guided cerebral aneurysm embolization. Dermatology. 2012;224(3):198-203.
14. Luani B, Zrenner B, Basho M, Genz C, Rauwolf T, Tanev I, Schmeisser A, Braun-Dullaeus RC. 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 Jan; 29(1): 160-166.
15. Li J, De Leon H, Ebato B, Cui J, Todd J, Chronos NA, Robinson KA. Endovascular irradiation impairs vascular functional responses in noninjured pig coronary arteries. Cardiovasc Radiat Med. 2002 Jul-Dec;3(3-4):152-162.
16. 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.
17. Picano E, Vano E. Radiation exposure as an occupational hazard. EuroIntervention. 2012; 8: 649- 53.
18. 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.
19. Monaco MGL, Carta A, Tamhid T, Porru S. Anti-X Apron Wearing and Musculoskeletal Problems Among Healthcare Workers: A Systematic Scoping Review. Int J Environ Res Public Health. 2020 Aug 13;17(16):5877. doi: 10.3390/ijerph17165877. PMID: 32823627; PMCID: PMC7459898.
20. Dixon RG, Khiatani V, Statler JD, Walser EM, Midia M, Miller DL, Bartal G, Collins JD, Gross KA, Stecker MS, et al. Society of Interventional Radiology: Occupational Back and Neck Pain and the Interventional Radiologist. Standards of Practice. J. Vasc. Interv. Radiol. 2017; 28:195–199. doi: 10.1016/j.jvir.2016.10.017
21. Benjamin JL, Meisinger QC. Ergonomics in the Development and Prevention of Musculoskeletal

Injury in Interventional Radiologists. Tech. Vasc. Interv. Radiol. 2018; 21:16–20. doi: 10.1053/j.tvir.2017.12.004.

22. Danieli G, Indolfi C, De Rosa S, Battaglia D, De Gaetano G, Fragomeni G., Greco P.F., Larocca G, Perrelli M. Robotic System for Angioplasty and Endoluminal Surgery. PCT/ IT2018/ 050209 printed 91.07.2021, nazionalized USA US20210196412, 17/04/2020, Europe EP18807725.9, 25.05.2020, India E- 1/23927/2020-DEL, 26/05/2020
23. 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. Italian Patent PCTIT2020050109, 14 March 2022.
24. Danieli G, De Rosa S, Greco PF, Indolfi C, Larocca G, Massetti M, Tinelli G, Tshomba Y, Evolution of ROSES System for Endovascular Surgery. PCT/IT2021/000042, august 31st 2021
25. Danieli G, De Rosa S. New Disposable Components for ROSES Robotic System for Endovascular Surgery. Italian Patent Application 102022000013684, 28 June 2022
26. Danieli G. Small modifications and complementary elements for the disposables of the Robotic System for Endovascular Surgery. Italian Patent Application 1020230000, April 3rd 2023
27. Greco PF, Larocca G, Perrelli M, Danieli G, De Rosa S, Indolfi C ROSA – RObotic System for Angioplasty Mechanisms and Machine Science 2019, 65, pp. 72-81
28. Danieli G, Greco PF, Massetti M, Tinelli G e Tshomba Y, New version of the Robotic Actuator (RA) "Big Mouth" of ROSES (RObotic System for Endovascular Surgery) for TAVI and related disposables. Italian patent application 102020000020746, presented 01/09/2020
29. Tshomba Y, Tinelli G, Mammolito F, Larocca G, La Greca G, Greco PF, Danieli G. Trolley for support and movement of ROSES Robot Actuators in angioplasty and endovascular surgery which allows the measurement of the forces opposed by the body to the advancement of the catheters. Italian patent application 102020000020734, presented 01/09/2020
30. Tshomba Y, Tinelli G, Larocca G, Greco PF, Danieli G. Catheter with curved tip controllable from the Console of the ROSES robot for angioplasty and endovascular surgery, and relative disposable, Italian patent application 102020000020740, presented 01/09/2020
31. 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 guidewire within the endovascular system. Italian patent application 102019000006657, presented 08/05/2019, granted 13/04/2021
32. Yang, C., Guo, S., Bao, X. et al. A vascular interventional surgical robot based on surgeon's operating skills. Med Biol Eng Comput 57, 1999–2010 (2019). https://doi.org/10.1007/s11517-019-02016-8
33. Danieli G, Greco PF, Larocca G, De Rosa S, Indolfi C, Polimeni A, Massetti M, Tinelli G, Tshomba Y, Venturini L. Development of disposables and accessories for ROSES and their in vitro experimentation. Appl. Mech. 2022, 3, 956–973. https://doi.org/10.3390/applmech3030054
34. Danieli G, Gallo R, Greco PF, Larocca G, Maiarota F and Sorbello M. Development of ROSINA (Robotic System for INtubAtion). IJBTT-2021, Volume 11, Issue 3