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# Extending ROSA to the entire Endovascular Field

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**Abstract:** Starting at the end of 2013 our research group, with the help of Prof. Indolfi and his team of Magna Graecia University, began working on the problem of separating doctors from patients during angioplasty. We knew from the beginning that a robot, CorPath by Corindus, was already on the market and we started on a totally different technology where the only point in common was the field of application, obtaining ROSA (RObotic System for Angioplasty), that started patient trials in January 2019. But studying the problem we understood, with the help of Prof. Tshomba of Gemelli Institute and his team, that an evolution of this system was possible to cover the entire field of Endovascular Surgery. The article, starting from a brief description of the 2019 robot illustrates the innovations that transformed this into the most complete system for all kinds of endovascular surgery, assuming the new name of ROSES (RObotic System for Endovascular Surgery).

**Keywords:** Ionized Radiations Guided Surgeries, Robot Assisted Angioplasty, Robot Assisted Brain Thrombus Removal, Robot Assisted Endovascular Surgery, Robot Assisted Transcatheter Aortic Valve Implant

## I. INTRODUCTION

The fact that ionized radiations are negative [1-5] for the human body is a well known fact, but in particular while the patients are subject to these, and often in live savers interventions, the doctors that perform these interventions are subject to these on a daily base. Moreover, just recently also retrieval of thrombus causing stroke and cerebral aneurisms are entering in the picture, where the X ray necessary to penetrate the skull are definitely stronger that those needed for other body regions. Thus the importance of robots to separate patients and operators is now highly grown.

As already mentioned, the first firm to reach the market for angioplasty was Corindus [6-13] with a system that works separately but in parallel using a big disposable on catheter and 0,014” guide wires, and needs to position first manually the initial catheter. Our system instead [14] drives catheters and guide wires with the same small disposable transmitting the same rotation to catheter and guide-wire, but moving them independently as far as advancement is concerned. In fact we developed a Robotic Actuator (RA in short) characterized by the possibility of controlling three parameters. The base of this RA characteristics is supplied by the mechanical heart of the system, composed by a kind of three main gears planetary train that rotates kept aligned by external idle gears in fixed position and with internal planets that mesh with rings belonging to the second and third central gear, that allow transmitting to a couple of bevel gears exiting from the front gear, rotation that depend on the relative rotations between the first gear, that acts as a rotating frame, and the second and third hollow gear. Three external motors transmitting rotations the three gear train, allow controlling three parameters independently, a common rotation and two independent rotations that may be cause advancement through friction wheels. The center of this gear system is hollow, and may allow the passage of catheters and guide wires in a sterile environment.

The Console, characterized by the presence of two three degrees of control joysticks, in angioplasty applications controls, with the left joystick catheter advancement, while with the right joystick guide wire advancement and rotation. But it is clear that the Console may control in the same time two RA placed in series, one dedicated to catheters, the second to guide-wires. In this case however a third component is also needed, a cart allowing the vary the relative position between the RA [15], which can also be controlled by the Console, selecting the appropriate program.

At this point the system may seem more like Magellan of Hansen Medical [16-19], but with big differences. First it may allow passage of catheters of any dimension simply modifying the number of teeth of the gears that compose the mechanical heart of the system, in fact we just increased the diameter of the central passage inside the RA from 7 to 36 mm in diameter [20], also thanks to the fact that we use 3D printers for producing our robots, and similarly we developed, starting from the disposable originally studied for angioplasty, disposables for any kind of catheters. Next, the new disposables are made in two separate elements, that can be removed separately leaving the central passage, covered by a sterile cover, fully free with its 36 mm of diameter. Moreover, the system is equipped with the only system [21] that allows measuring the force opposes by the body to catheter advancement without the need of using expensive special catheters, as will be illustrated in the following, and a system to control tip curvature of the catheter suitable for our system was also devised and the patent applied for [22]. Last but not least, the system may still be employed for angioplasty, either guiding the introduction of the first catheter with the tip controlled curvature catheter or introducing a conventional catheter manually, while thanks to the increased dimensions of the RA, a second special RA is no longer needed to guide a second guide wire in a coronary branch in case a stenosis may be too close to it, so that positioning a stent or inflating a balloon the branch may be closed, while positioning a second guide wire into the branch before inflating the balloon, the branch may be then reopened.In fact it is enough to open the top cover positioning the first catheter and guide wire in a central grove of the disposable, to position the new guide wire to be brought into the branch, then inflate the balloon and decide if the second balloon is needed.

## II. DESCRIPTION OF THE NEW FEATURES

Let's first observe that there are two important variations with respect to the first article presented on this topic at MESROB [23] in July 2018, that are the new Console which incorporates a screen touch, Fig. 1, which allows changing the programs and also measuring the length of a stenosis, and the new disposable for angioplasty, that opens the top in order to facilitate visual control, and presents four friction wheels on the upper and lower component, of which the lower ones for both the catheter and the guide wire are coupled via gears meshing with an idle gear in order to increase the push on the catheters.


Figure 1 - The new Console of ROSES

Figure 2 - The 2019 disposable for angioplasty

Moreover, the upper friction wheels on the guide side are positioned to force a curvature of the guide in order to improve torsion transmission, Fig. 2.

But the first recent modification has been performed on the RA, previously called Slave, increasing the number of teeth of both the external teeth and those of the rings, controlling also that no interference between involutes may occur. Fig. 3 shows the comparison between the internal gearing in the previous and actual edition of the RA, where it is clear the big difference between the passage diameters, passed from 9 to 38 mm, with a 2-millimeterfurther reduction in diameter due to the sterile protection to separate the internal mechanisms from the sterile products.

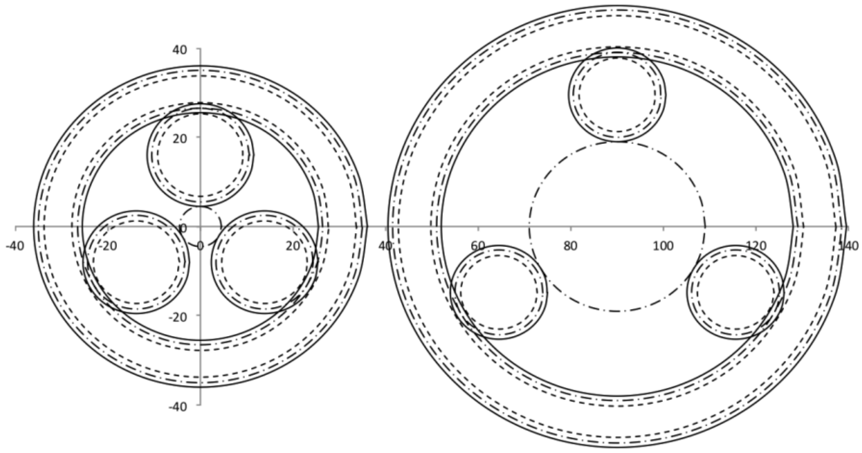


Figure 3 - Comparison between the internal gearing in the old and new RA

The next image presents the duct designed to separate all other disposable products from the internal mechanisms, and to allow the unique positioning of the upper and lower component of the push pull disposables but also to guarantee the possibility of separating the central gear and relative disposables from the light sterile cover of the RA avoiding the risk of dragging it when turning.

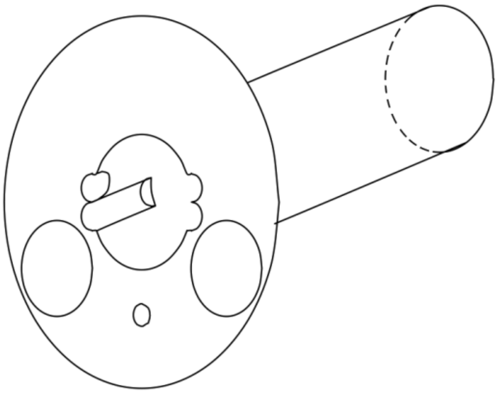

Figure 4 - The disposable duct to separate the sterile components from the internal mechanisms

In particular note the four groves, two linear for fixing the lower component of the push pull disposable, while the upper ones assume a spherical shape in order to act as the hinges for the upper component. Fig. 5 shows the new upper push pull component presenting four friction wheels as before, but also the hemispherical shape of the connecting hinge, two teeth on the opposite side to direct the upper and lower components in the correct position, and a double hook to lock them.

The lower component is presented in the following Fig. 6 together with the upper one in order to show a corresponding image of Fig. 2. The mechanism is identical, only the dimensions of the shell are different, with the advantage of the possibility of separating the two components, and the advantage of a central grove where it is possible to place catheter and guide wire in the case of a stenosis close to a branch, as mentioned before.

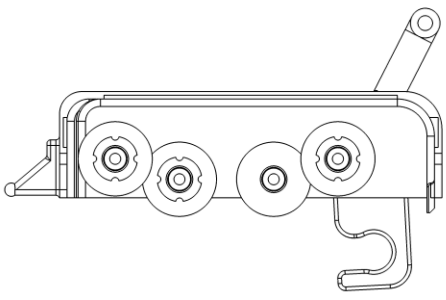

Figure 5 - The upper push pull component

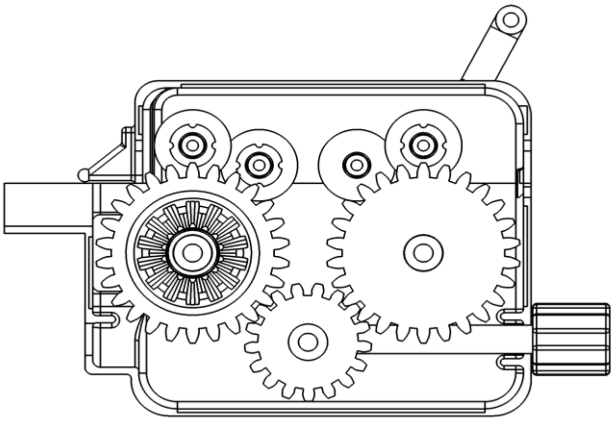

Figure 6 – Assembly of the new push pull disposable for angioplasty

Also in this case the two small friction wheels used on the right sideare dedicated to the 0,014" guide wire to allow a better transmission of axial rotations to this by forcing its curvature.

Naturally for catheters and guide wires of different dimensions, a similar push pull disposable has been designed, which however are limited either to catheters or guide wires. In the case of catheters, however, while the friction wheels for angioplasty are flat, just covered by a silicon ring, these are no longer flat, always covered by silicon, but present groves on both sides, whose depth is a function of the catheter French, in order to increase the push while avoiding smashing the catheters. Fig. 7 presents on the left the cross section of a disposable for catheters, on the right for guides. Note that the motion is transmitted on the left for catheters, and on the right for guides.

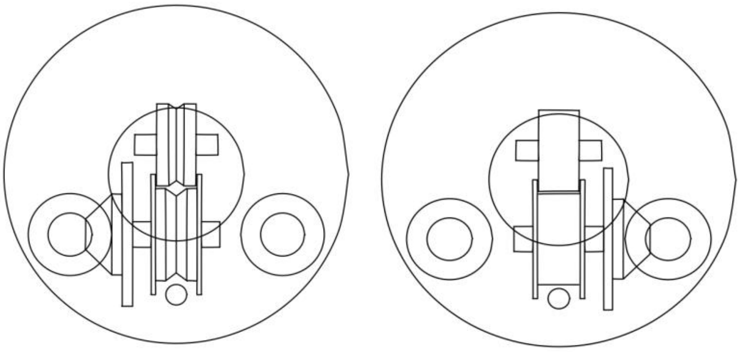

Figure 7 - Cross section of the disposables for catheters (left) and guide wires (right)

In the case of wires, since some of them have movable core, two special disposables have been designed, even if not yet developed for the new RA, but very soon will be also available, that use the third parameter (the catheter advancement command) to move the core with respect to the guide wire. And since there are movable cores welded on the tip, to straighten the initial curve, and free to move, we designed and applied patents for two different push pull disposables, one with a very limited range of motion, connecting the core to a rack, the second with a much wider one [24], in which the core is connected to a wheel, while in both cases the body of the guide wire is clamped on the body of the disposable, and the wire passes through the disposable and returns to it through a loop. Fig. 8 and 9 show the pictures of the two disposables.

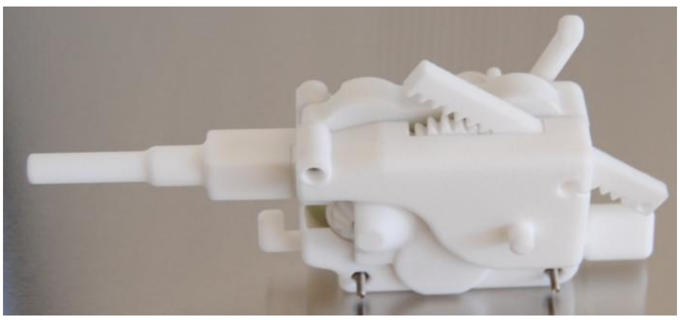

Figure 8 - Disposable for guide wire with movable core welded at the tip

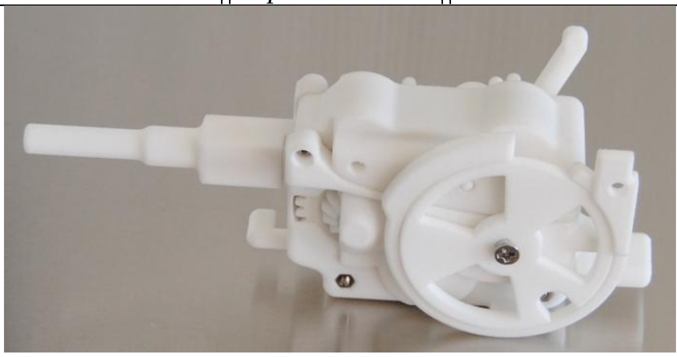

Figure 9 - Disposable for guide wire with movable core

However what seems even more important is to have a catheter with controllable tip curvature. Now to make such a catheter is not so difficult, it is enough to take a two lumen catheter, of which of about 3 French, to allow easy passage of a 0,035" guide wire, and a smaller one, about 1,5 French in which a nylon wire has to pass, then make a series of parallel wedge shaped cuts near the tip, and in correspondence of the small lumen, then pass the wire in the small lumen, make a knot near the tip, then heating small glass conical tubes deform the tip while welding the knot and the thermo plastic material of the catheter. On the other end of the catheter put a connector that you glue to a small housing containing a very small drum and the job is done. Fig. 10 shows the tubing on the left while on the right shows the connector with the drum housing and the wire wrapped around. But the problem was how to actuate the tip, while the catheter in entering the patient's body?

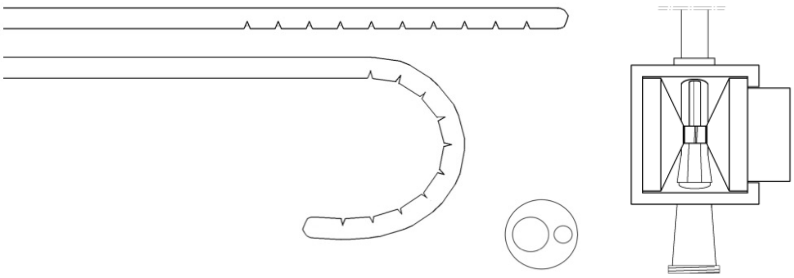

Figure 10 - Catheter tip configuration, catheter cross section and commercial catheter connector glued into the drum housing

As already mentioned, we understood that during the catheter penetration guided by a RA closer to the patient, it was a good idea to move also the RA holding the guide wire, so that, is the catheter advances with the same speed of the RA holding the guide, the two will enter at the same speed and actin on the second RA will simply change the relative position, which may be very useful. On the other hand, we said that each RA may control three different parameters. Now either we use a guide wire with movable core, or a catheter with controllable tip curvature and a guide wire with straight soft tip. Moreover if the guide wire is straight, there is no need to turn it in a different manner from the catheter. At this point we may add a further disposable that will rotate the drum pulling the cable, and this disposable will be sitting on the second RA, but in front of it, while behind there is the disposable for changing the relative position between guide wire and catheter. The only other condition we have to impose is that whatever rotation will be required to the catheter will be reproduced on the second RA, since obviously the had and the tail of the catheter need turning at the same speed. And to use the third degree of freedom of the second RA to pull the wire that controls tip curvature, we simply have to let the shaft of the bevel gear of the catheter to exit also from the rear of the central planetary train. Then with a spindle we can connect and disconnect a gear train that will transmit motion to the drum controlling tip catheter curvature. Clearly this requires a bit of software development, but in reality it will be relatively easy, since we already learnt to control two RA independently with the Console. Fig. 11 shows a section of the central gearing that shows the shaft dedicated to the catheter exiting from the back of it. The following Fig. 12 shows a first trial design of the disposable that commands tip rotation.

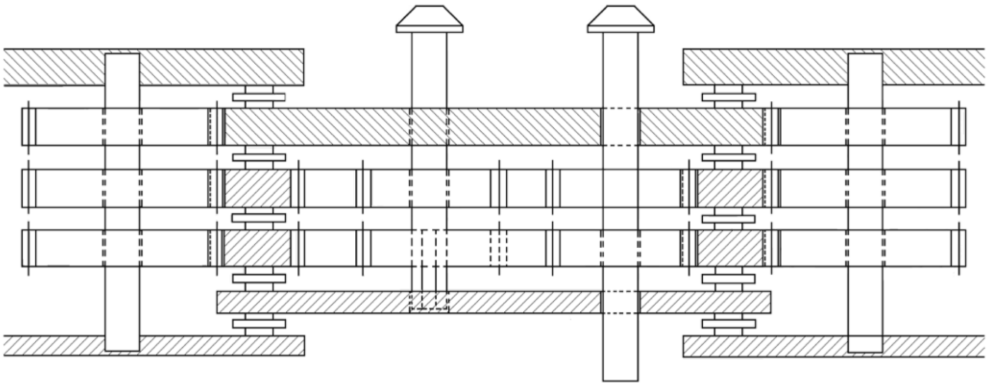

Figure 11 - Transverse section of the central gearing showing the shaft exiting from behind to command tip rotation

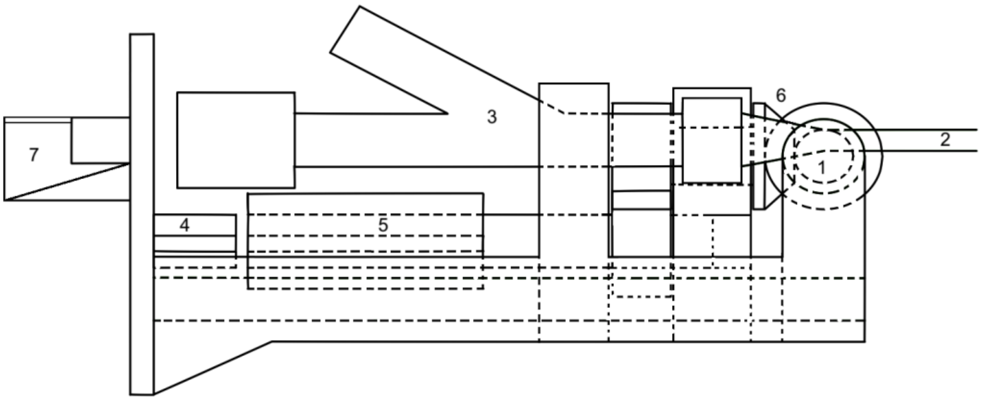


Figure 12 - First side view of the disposable to command tip curvature variation

In particular 1 is the drum, 2 the catheter and its connector in one piece with the drum housing, 3 the hemostasis valve, supported by the disposable, which in reality could be easily resterilized and reused for a number of times, 4 the shaft exiting from the gearing of figure 11, 5 the spindle to connect disconnect the curvature control system, 6 the gears (two bevel, visible, two spur, not visible), and 7 a support to help centering the hemostasis valve with the guide wire.

Before entering the discussion on the various problems and their solution via software, let us show first the principle under which it is possible to measure the forces opposed by the body to catheter penetration which is one of the fundamental elements of the cart containing and moving the RA.

With reference to Fig. 13, note that if you suspend to a force sensor a slide inclined by an angle containing a system that sends something like a catheter in steady conditions to penetrate a vessel, you con only measure the gravity component of the weight that is suspended un the slide. And this does not take minimally into account whatever happens inside your system, whose internal frictions may contribute to the power needed, but has no effect on the force measured by the sensor. However if something opposes the penetration into the vessels, you will note a decrease of the measured force. This is what is to be continuously recorded, particularly when this force decreases too rapidly.

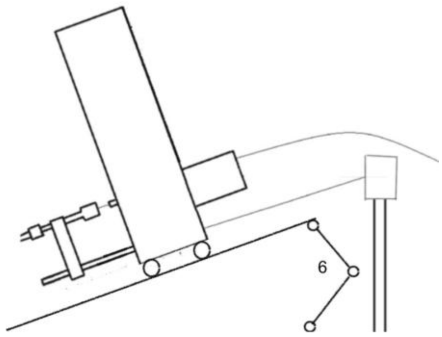


Figure 13 - Working principle of the force measurement

Using this principle, the cart for ROSES has been designed. First of all, a six degrees of freedom support composed by a vertical slide, either with manual or electronic control using a worm gear, followed by 5 degrees of rotation, three having vertical parallel axes, then by an horizontal axis and finally by a last hinge perpendicular to the last one, allows setting the system in any position, for maximum comfort of patients and doctors. Each joint is lockable by hand or using an electronic system normally closed, the first three in the mean time pushing a button, the last two with two independent buttons. Beware that fourth hinge is particularly relevant, because is connected with the maximum force that can act on the slide, and hence will be mechanically limited. To this last joint is connected the force sensor (8) through a bar running below the slide. The slide in mounted on very short side rails provided with stroke limiters, while on the upper face of the slide may move the posterior RA driven by a worm gear whose rotation is controlled by a stem motor. Clearly the possible robotic arm control is completely independent from the ROSES control system, while all components, the two RA, the motor moving the posterior RA, and the force sensor are all connected in a serial bus and controlled by the Console.

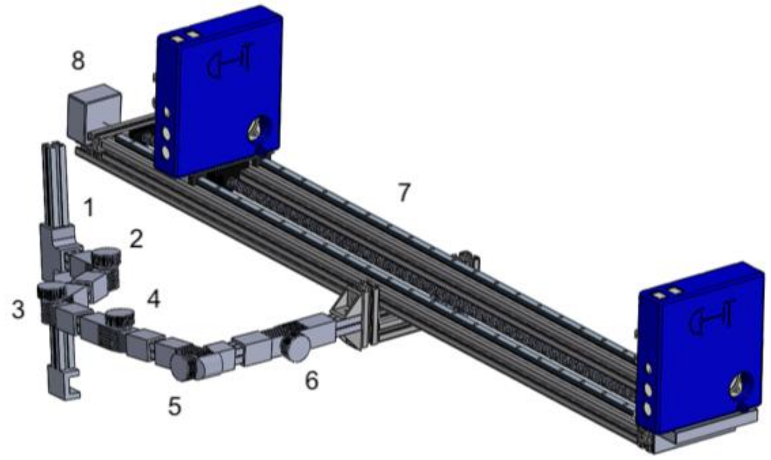


Figure 14 - ROSES cart

## III. DISCUSSION ON THE SYSTEM

As can be seen the system is now complete, but is certainly interesting to describe how the system may be used for the various applications. Clearly for angioplasty it can be used as other systems, both introducing manually the first catheter or using it on the second RA, using the tip controlled curvature catheter to reach the initial position, noting that in this case it is possible also change the coronary to explore, it is enough to reconnect the spindle using the 0,014" guide wire to reach the new coronary, then detaching it once reached the position, to work with catheters and guide wires as in normal angioplasty, keeping in mind that the doctor can take all the necessary time if it is a question of life and death for the patient. The only thing to observe is that while using the first catheter introduced manually the disposable may be used with the full length of the probe, using the catheter controlled tip curvature one has to eliminate the last portion of it not to enter in conflict with the protrusion of its disposable, made to allow centering the hemostasis valve with the guide wire. But this is not the problem since the disposable does non reaches the correct position if one forgets to eliminate it.Similar considerations might be applied for intracranial interventions, but this might be just a guess.

Instead usually for endovascular surgery it is usually necessary to bring first in position the guide wire using the controlled tip curvature catheter. And this, should not a big problem, since even if the curvature allowed is in one direction only with respect to the catheter, obviously one may rotate the catheter (and the guide, in this case) as many times as necessary, so that any body district may be reached. More difficult is to eliminate the catheter to leave the guide wire, that must be pretty long, at least 3 meters if one uses a 1,5 meters catheter that will be available. In fact it is first necessary to eliminate the catheter selecting the appropriate program, that will take care of advancing the guide wire exactly of the same amount of which the catheter is extracted, in order to keep the position needed for the intervention. Once the full catheter is extracted, it's necessary to clamp the guide wire in front of the proximal RA. Then it is advisable to extract the push pull components of the catheter, that will have to be replaced with the ones of the catheter to be introduced, usually of greater dimension in French. Similarly also the push pull components of the wire, that however afterward will have to be repositioned. At this point we first have to disengage the hemostatic valve from the tip controller disposable, which can be eliminated just lowering it since it is open on the upper portion. Then disconnecting the catheter from the hemostasis valve, each can be passed through the hole of the RA, which is just wide enough to pass the valve, while the catheter is much smaller, even with its drum. Once this is done, the new catheter may be introduced from the tail of the guide wire, then the disposables may be positioned, and once the disposable for the guide wire is repositioned and locked, the clamp in front of the first RA may be removed. And with this system there is practically on the dimensions of the catheter, so that, with the suitable disposable, even the TAVI catheters can be positioned.

## IV. CONCLUSION

The paper describes the present evolution of ROSES, a system designed for all kinds of endovascular interventions. Now we have to start new clinical trials, since the system undoubtedly is different from the original, mainly for the addition of new elements such as the cart, the force measuring system and the tip controlled curvature catheter, while the fundamental part of it, such as the Console, remained identical, while the RA and similarly the push pull disposable just were subject to dimensional modifications. We are at this point pretty confident of being in future able to develop any possibly requested disposable, also thanks to the use of 3D printing and the experience gained on this field.

## V. ACKNOWLEDGEMENTS

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## REFERENCES

[1] 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. 2019; Dec 19; 136 (25): 2406-2416

[2] LópezAventín D, Gil I, López González DM, Pujol RM. Chronic scalp ulceration as a late complication of fluoroscopically guided cerebral aneurysm embolization. Dermatology. 2012; 224(3):198-203

[3] 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

[4] 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):152-62

[5] 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

[6] Togni M, Balmer F, Pfiffner D et al. Percutaneous coronary intervention in Europe 1992-2001. Eur Heart J. 2004;25:1208-13

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

[8] 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

[9] Walters D, Omran J, Patel M, Reeves R, Ang L, Mahmud E. Robotic-Assisted Percutaneous Coronary Intervention: Concept, Data, and Clinical Application. Interv Cardiol Clin. 2019 Apr;8(2):149-159

[10] Beyar R. Transmission For A Remote Catheterization System. European Patent EP1755727B1, granted January the 11th 2012.

[11] Guerrera S. Catheter System Cassette. US Patent USD671640, granted November 26th 2012.

[12] Beyar R. User interface for remote control catheterization. US Patent US8257302, granted September 4th 2012

[13] Meglan DA. User interface for remote control catheterization. US Patent US 6096004, granted August 1st 2000

[14] Danieli G, Indolfi C, De Rosa S, Battaglia D, De Gaetano G, Fragomeni G, Greco PF, Larocca G, Perrelli M. Robotic System for Angioplasty and Endoluminar Surgery. PCT/ IT2018/050209 deposited 26.10.2018, US extension US16756965, 17/04/2020, Europe EP18807725.9, 25/05/2020, India E-1/23927/2020-DEL, 26/05/2020

[15] Tshomba Y, Tinelli G, Mammolito F, Larocca G, La Greca G, Greco PF, Danieli G. Cart holding and moving Robotic Actuators of ROSES for Angioplasty and Endovascular Surgery while measuring forces opposed by the body to penetration of catheters and guide wires. Italian Patent Application 102020000020734 deposited September 1st 2020

[16] Wolujewicz M. Robotic-Assisted Endovascular Pulmonary Artery Foreign Body Retrieval: A Case Report. Endovascular Surgery, 2016 Apr;50(3):168-70
[17] Alvarez JB, Macnamara F, Miller T, Reis G, Romo E, Sewell CM, Stahler GJ, Tanner NA, Walker SP, Weiss AM, Yu AL. Robotically Controlled Steerable Catheters. EP2615992A2, granted July 24th 2013
[18] Adams DT, Martin KM, Moll FH, Moore DF, Niemeyer GD, Stahler GJ, Wallace DT, Younge RG, Zinn MR. Instrument driver for robotic catheter system. US Patent US2006084945A1, granted November 31st 2011
[19] Adams DT, Martin KM, Moll FH, Moore DF, Niemeyer GD, Stahler GJ, Wallace DT, Younge RG, Zinn MR. Robotic Catheter System. US Patent US2017215978A1, presently under examination
[20] Danieli G, Greco PF, Massetti M, Tinelli G and Tshomba Y. New version of the Robotic Actuator “Big mouth” of ROSES (RObotic System for Endovascular Surgery) for TAVI and relative disposables. Italian Patent Application 102020000020746 deposited September 1st 2020
[21] 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/IT2020050109, deposited July 7th 2020
[22] Tshomba Y, Tinelli G, Larocca G, Greco PF and Danieli G. Curved tip catheter controllable by the ROSES robot console for angioplasty and endovascular surgery, and relative disposable. Italian Patent Application 1020200000207340 deposited September 1st 2020
[23] Greco PF, Larocca G, Perrelli M, Danieli G, De Rosa S, Indolfi C. ROSA RObotic System for Angioplasty. Proceedings of the MESROB 2018 July 4-6, 2018, Cassino, Italy, paper 39, pp. 72-81
[24] Danieli G., Greco P.F., Larocca G., De Rosa S., Indolfi C., Thsomba Y. E Venturini L., "New disposables for endovascular surgery applications with ROSES (RObotic System for Endovascular Surgery)", Italian Patent Application 102019000020474, presentedNovember 6th 2019