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Development of ROSINA (Robotic System for Intubation)

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Abstract *- The paper describes the development of a new robotic system for guiding the intubation using a laryngoscope, separating the patient from the doctor, and allowing to fully control the introduction using a small console with two joysticks. The basic mechanism derives from our ROSES, robotic system for endovascular surgery, presently going through clinical tests in the field of angioplasty, and consisting in a particular planetary train that allows controlling three parameters, advancement, rotation of the laryngoscope, and possibly curvature of its tip. In the final edition, however, the third parameter control was suppressed substituted by a motor positioned on the clamp that holds the laryngoscope. The system includes a stand holding the robotic actuator placed above the patient's mouth, the clamp to grasp the laryngoscope suspended to a wire, whose weight is counterbalanced. On the opposite side of the actuator is placed the small console. A brake allows blocking the wire that joins the clamp with the counterweight. Clinical trials on this system are also about to start since we are waiting for the permission of the ethical committee.*

Keywords — *guiding a laryngoscope in the upper airways, risk reduction in patient intubation, robotic system for intubation, separating the doctor from the patient during intubation.*

I. INTRODUCTION

It is described in the literature [1-3] how the introduction of endotracheal cannulas with standard techniques can become difficult due to the anatomical irregularities of the patient's first airways and endanger the patient's life. Furthermore, we live in a time when the standard approach to the patient's airways, by providing for the use of the laryngoscope, forces the Anesthesiologist to a kind of close combat with the patient, which is very, very dangerous due to the high risk of contagion from COVID 19.

Calabrian High Tech had developed a piece of equipment called ROSES, (RObotic System for Endovascular Surgery) [4], initially designed for angioplasty, but presently in extension to the full field of endovascular surgery, including TAVI (Transcatheter Aortic Valve Implant) [5] and lower limb vascular intervention [6].

Since, however, the endotracheal cannulas obviously have very different dimensions from angioplasty catheters, it was necessary to build a Robotic Actuator with different internal gears in order to allow the passage of the cannulas, once the fiberscope has reached the correct position, but otherwise, the system is absolutely identical.

This system consists of a particular planetary train that allows controlling three parameters, used in angioplasty through a suitable disposable to rotate guide-wire and catheter simultaneously while advancing them separately. The original actuator had a small hole to pass the catheters, and the disposable was made of two components hinged together. And to transform it into the present actuator, we had simply to increase the number of teeth of the gears constituting the planetary and divide the disposable into two separate components in order to apply it to the guide of the fiberscope, allowing then the passage of the endotracheal cannula. Both these modifications were also needed for installing the TAVI since, in this case, it is necessary first to push a first catheter coupled with a standard guidewire, then, once the guidewire reached the valve to be replaced, one needs to extract the catheter leaving the guidewire in place, and this requires to extract also the hemostatic valve, that must pass through the robotic actuator. Thus a big passage was required, and the disposable was removed without dislocating whatever was inserted in it (the fiberscope for ROSINA, catheters, and guidewires for TAVI).

At the same time, we had to build mobile support to hold the ROSES Actuator near the patient's mouth, also keeping the fiberscope on this, aligned with the Robotic Actuator entrance, free to rotate on its axis and suspended with a nylon cable, which, passing on two pulleys, should completely counterbalance the weight of the fiberscope with a suitable counterweight.

While initially, we thought to use a flexible transmission to actuate the fiberscope tip adding a special clamp designed to grasp any fiberscope in order to transmit the motion to the tip, we soon realized that a simpler solution was to mount a third motor of the clamp, in this case reducing the number of control parameters in the robotic actuator placed above the patient's mouth. The resulting device completely separates the patient and operator, greatly facilitating the process of introducing the fiberscope. This is certainly useful in this period of ever-changing pandemic viruses but will be useful in every case of difficult intubation.

II. DESCRIPTION OF THE DEVICE

Before describing the actual version of the ROSINA Robotic Actuator, let's start with a minimum of history of its development to reach the actual version.

Everything that is shown here has been enclosed in four Italian patent applications [7- 10]. To start the description, let's first show the internal gearing of the original robotic actuator, composed of three bigger gears of which the first, together with a fourth non toothed wheel, connected to the first via internal rods integral to it, also act as gear train to support an internal planet meshing with the toothing internal to the second and third hollow gears. Figure 1 shows this gearing system deprived of the front gear and seen from the axial direction to allow to understand how it is possible to independently control the three axes that make up the control system, also showing the position of the motor. Obviously, it is clear that by acting only on the hollow gears, connected in the present case respectively to the advancement of the fiberscope and in the initial configuration to the tip's flexion of the same, the rotation of the axes connected to the internal planets is obtained, while if the first gear is rotated, which also produces the rotation of its axis on the fiberscope, also rotates the axes of the planets. Thus, if one wants to ensure that the relative position of these with respect to the first wheel does not vary, and therefore the position of what it controls remains unchanged (advancement and bending of the tip), it is necessary to rotate all three wheels at the same speed. From this, it is also understood that, on the other hand, if one wishes to vary the two output parameters while the main wheel rotates, one must add or subtract the movement required from that of the main gear.

Having clarified how the system is made to allow separate control of three parameters on a rotating disk, let us show in Figure 2 the difference between the original ROSES gears dimensions and those of the new gearing system designed for TAVI and ROSINA. The principle is identical, but the dimension of the internal passage through the gears is enormously different. Note also that the CAD model picture of Figure 1 is relative to an intermediate version presenting a first increase of the central hole dimensions.

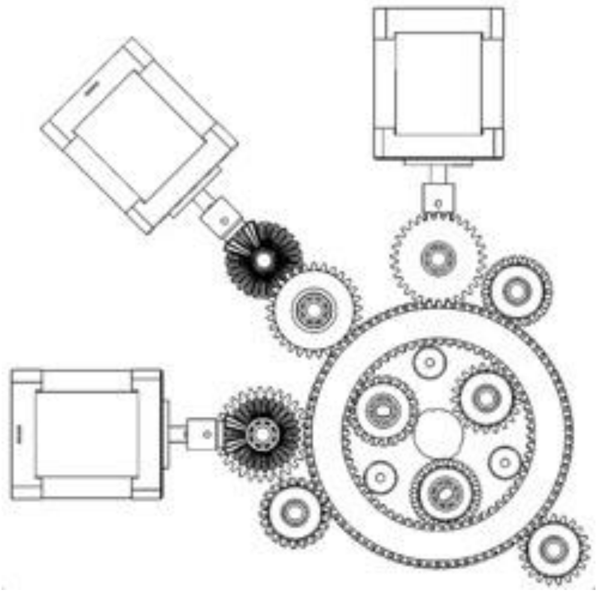

Fig. 1 The internal gearing of the Robotic Actuator and the motor's position

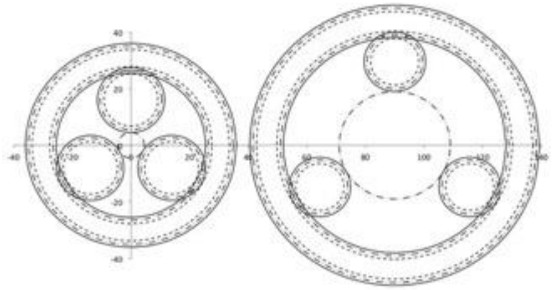

Fig. 2 Comparison between the old and new gearing and central passage dimensions.

Figure 3 shows the comparison between the new Robotic actuator just built in a three motors version and the previous version. In fact, for simplicity, we used the same chassis holding three motors since there are two bevel gears coming out of the front gear. In fact, the version with only two motors inside the Robotic Actuator will be built only after the first trial with the dummy. Note that being the passage is rather big, now it is possible to see the system's internal gearing. Note also that the overall dimensions of the RA are almost unchanged.

Fig. 3 Comparison between the old and new RA with three motors

Naturally, also the various sterilizable interface components between the RA and the fiberscope were completely redesigned. Figure 4 shows the set of the last version of the three reusable components of which the first separates the thrust components in contact with the fiberscope from the internal mechanisms, also separating both the cannula of the fiberscope and the endotracheal cannula after extraction of both upper (left) and lower (right) component to push the cannula sliding over the fiberscope into the patient’s throat. This system also allows the univocal installation of the two sterilizable thrust components thanks to the particular shape of the teeth that grasp the component that separates the reusable elements from the RA, while the small key at the bottom of the lower component secures the system to the RA allowing full transmission of the motors torque without any slip between gears.

Fig. 4 The three reusable elements used to protect sterility and push the fiberscope

Next, moving on to figure 5, we note on the left the three components assembled but open. As can be seen, the two thrust components are linked together via two small arms that surround two lateral knobs fixed on the lower component, while internal teething allows centering the two when the double leverage is closed. Note that the friction wheels are made by four O rings placed in parallel, and the lower ones are driven by the 14-tooth bevel gear, while the two semicircular protuberances guide the correct alignment of this element which the protecting tube to keep it aligned. Note also the presence of a screw that allows regulating the pressure between friction wheels without exaggerating in order not to damage the fiberscopes while allowing to accept fiberscopes of diameters between 4 to 6 mm. The upper component is inclined during this phase of introduction so that once closed on the lower component, a tooth penetrates the tube, further ensuring the strength of the component assembly. Figure 6 shows the simple instrument to push the cannula through the RA after eliminating the upper push element.

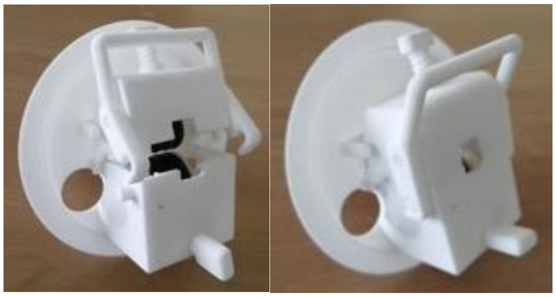

Fig. 5 The two reusable lower and upper thrust components

Fig. 6 The simple instrument to push the cannula through the RA at the end of the process

Let's now examine the clamp for gripping the fiberscope, shown in Figure 7. We note first of all that in this case, we are referring first to the clamp equipped with a motor, while the decision was taken not even to try the solution with the flexible transmission since this would have been undoubtedly heavier and bulkier than a simple servomotor and its actuation cable, also because the number of complete rotations about its axis of the fiberscope would have been zero for guiding the cannula, very few for lungs examination. In this case, one of the motors inside the RA can be eliminated, and consequently the relative gears, making everything much easier. Lighter and shorter. It is a real clamp, although of a very particular shape, which tightens the fiberscope in the direction parallel to that of the axis of the control lever of the tip of the fiberscope, equipped with two adjustment screws and suitably shaped thrust elements to distribute the thrust on the surface of the fiberscope itself. On the opposite side, we note instead that the motor is connected to a shaft which drives the tip of the fiberscope through an L-shaped element inserted in a direction perpendicular to the axis of the shaft in a wheel concentric to it but which, thanks to a weakly forced coupling (uncertain) whose exact position can be adjusted manually if necessary, grips the control lever of the fiberscope laterally. This lever, usually with a thickness of between 6 and 12 mm, is fixed to the L-shaped element thanks to the conical shape of the two protrusions that protrude from it. Finally, four cables start from the ends and middle of the clamp itself and are connected at the top to a cable that does not oppose a great resistance to axial rotation.

Fig. 7 The clamp to grasp the fiberscope suspending it on the vertical of the RA

Note that, in order to tighten the fiberscope is necessary to turn two opposite knobs, which requires some time, during which the fiberscope has to be held in position by someone, which delays the operation. And on this point, we will return later.

At this point, we were ready to build the complete ROSINA system, in the version with the motor actuating the fiberscope's tip mounted on the clamp, ready to host the various fiberscopes. As can be seen, a vertical bar starting from a wheeled tripod holds midway on one side the RA, on the opposite the small console, while a horizontal bar at the top holds two pulleys, one on the vertical of the RA passage hole, the second, on the opposite side, holds the counterweight suspended to a pulley while the wire if then fixed to the horizontal bar, in order to limit the counterweight excursion. Note also the presence of an electronic brake whose movable part was fixed to the pulley on which the wire was making one complete turn around it before reaching the counterweight, but this, even when the brake was unlocked, generated too much friction. In fact, in the final version, which will be shown at the end, the brake has been moved to a different position so that the wire passes undisturbed when the brake is inactive but is blocked when needed, which occurs once the fiberscope reaches the trachea, in order to avoid unwanted extractions of the fiberscope due to the counterweight, once the upper push element is extracted to allow passage on the cannula. This is shown in Figure 8.

Fig. 8 The complete system built in the version with the motor mounted on the clamp

But as soon as our Doctors saw the system with the upper and lower disposables mounted on it said that they were afraid that the length of the fiberscope needed to command its advancement, about 12 cm, was probably too long, and this forced the other members of the team to "engineer" a solution.

Luckily now, the internal hole of our RA was big, even if initially designed only to host the passage of hemostasis valves, but, having to find a solution, the first idea was to bring inside the big gear train the bevel gear that was outside to command the friction wheel. First, a bevel gear of 19 teeth (number of teeth equal to that of the spur gear meshing with the internal toothing of the hollow gear) that was designed to mash with a 14 teeth bevel in order to limit in height the position of the perpendicular axis made to host the internal friction wheels. Then we realized that the same friction wheels used for the external lower thrust element could fit internally if only we would modify the shape of the first (mother) gear of the main RA gear train.

Since now we only need one hollow gear, we also decided to suppress any other internal gear, but for the one that had to be topped by the 19 teeth bevel gear, positioning instead shafts that will barely be tangent to the internal t.eeth of our hollow gear, in order to help to keep the alignment between the various gears, that are in any event guaranteed both by the three external gears placed at 120° degrees and by the homemade ball bearing that separates the various gears of the main gear train. Figure 9 shows on the left the hollow gear meshing with the internal toothing of the second gear, on the right the superposition of the first gear highly modified, and the position of the shaft holding the lower friction wheel and driven by the 14 teeth bevel gear driven by the 19 teeth one.

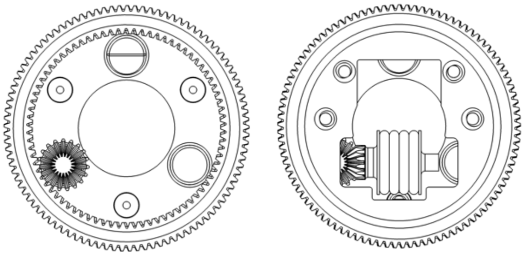

Fig. 9 The new internal gearing of this system, on the, left the meshing between the 19 teeth spur gear and the hollow gear, on the right, the addition of the deeply modified first gear and the position of the internal friction wheels

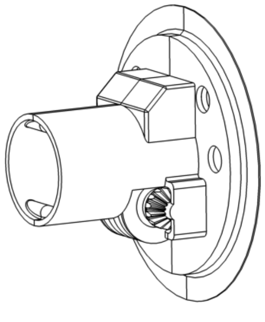

Fig. 10 The lower thrust component that incorporates the element to keep the field sterile

At this point, given the limited space, we deduced that we had to join the disposable element to separate the thrust components from the internal mechanisms, with the lower thrust components obtaining what is depicted in figure 10.

Now we only need to position the upper thrust element in the approximately rectangular space above the lower friction wheels. Naturally, also, in this case, we use a screw to push the two pairs of friction wheels against the fiberscope cannula, as shown in section in figure 11.

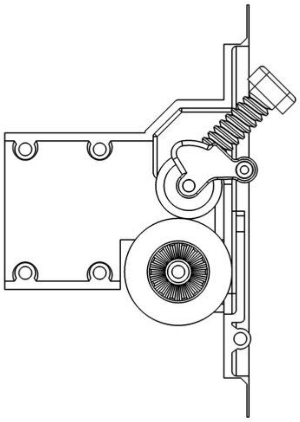

Fig. 11 Section of the two thrust elements to show how they work

If there is any doubt about the possibility of passing the cannula, once the upper thrust element is eliminated, the following picture should eliminate it.

Fig. 12 Picture of the lower thrust element installed in ROSINA letting the connector of a cannula pass without problems

Thus we were able to pass from the need of 12 cm to push the fiberscope to 6, and we will still reduce to 5 with the new version of the RA designed only for ROSINA, but the novelties did not end yet. As I previously noticed that to lock and then free the fiberscope from the clamp was difficult, then we developed a system of double ratchets that would lock and unlock the fiberscope in a matter of seconds, even if this is still to be slightly improved, and is shown in the next picture, where the arrows indicate the buttons to be pushed to release the two ratchets that will free the two elements positioned where before were the screws, loaded by springs that will, when the ratchets are released, pop them out freeling the fiberscope. Moreover, since we found that friction inside the lever that commands motion of the fiberscope tip was not sufficient to keep it in position when activated, we built a system controlled by a screw to block the lever in the right position. This is also visible in the next figure.

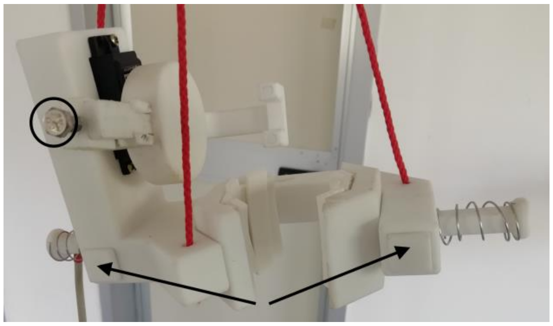

Fig. 13 The new clamp with ratchets, the arrows indicate the buttons to be pressed to release the ratchets, while the circle indicate the screw to set the proper position for the lever that guides the tip motion

The next figures 14 and 15 show the actual RA of ROSINA closed and the final shape of ROSINA RA, where the circles represent the pitch curves of the various gears external to the main gear train, the bigger rectangles the motor + reducer position, and the two smaller rectangles the two bars entering the RA bringing all electrical connections.

Fig. 14 The ROSINA RA showing the two thrust units assembled

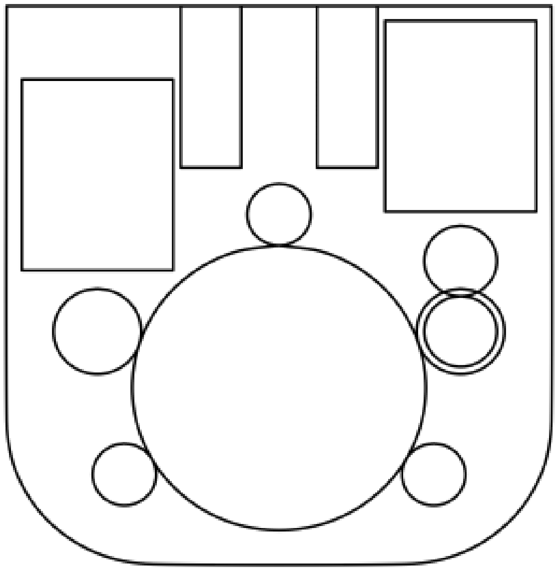

Fig. 15 The final shape of the ROSINA RA

Fig. 16 Shows a frame of ROSINA presentation o the National TV broadcast with Dr. Maiarota and Gallo

III. CONCLUSIONS

Very little final adjustments are still needed, but we can really start the process of certifications very soon, and we expect that given the actual continuous insurgence of new versions of the virus, both the Italian Government and the CEE should exit initial orders for a good number of ROSINA for all COVID centers.

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