

# A miniaturized robotic platform for natural orifice transluminal endoscopic surgery: in vivo validation

Selene Tognarelli · Marco Salerno · Giuseppe Tortora ·  
Claudio Quaglia · Paolo Dario · Marc Oliver Schurr ·  
Arianna Menciassi

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## Abstract

**Background** Natural orifice transluminal endoscopic surgery (NOTES) involves accessing the abdominal cavity via one of the body natural orifices for enabling minimally invasive surgical procedures. However, the constraints imposed by the access modality and the limited available technology make NOTES very challenging for surgeons. Tools redesign and introduction of novel surgical instruments are imperative in order to make NOTES operative in a real surgical scenario, reproducible and reliable. Robotic technology has major potential to overcome current limitations.

**Methods** The robotic platform described here consists of a magnetic anchoring frame equipped with dedicated docking/undocking mechanisms to house up to three modular robots for surgical interventions. The magnetic anchoring frame guarantees the required stability for surgical tasks execution, whilst dedicated modular robots provide the platform with adequate vision, stability and manipulation capabilities.

**Results** Platform potentialities were demonstrated in a porcine model. Assessment was organized into two consecutive experimental steps, with a hybrid testing modality. First, platform deployment, anchoring and assembly

through transoral–transgastric access were demonstrated in order to assess protocol feasibility and guarantee the safe achievement of the following experimental session. Second, transabdominal deployment, anchoring, assembly and robotic module actuation were carried out.

**Conclusions** This study has demonstrated the feasibility of inserting an endoluminal robotic platform composed of an anchoring frame and modular robotic units into a porcine model through a natural orifice. Once inserted into the peritoneal cavity, the platform provides proper visualization from multiple orientations. For the first time, a platform with interchangeable modules has been deployed and its components have been connected, demonstrating in vivo the feasibility of intra-abdominal assembly. Furthermore, increased dexterity employing different robotic units will enhance future system capabilities.

**Keywords** Laparoscopic surgery · Miniature robots · NOTES · Modular platform

Like laparoscopy had great impact on the surgical treatment in the past 30 years, natural orifice transluminal endoscopic surgery (NOTES) has enormous potential to create a paradigm shift in modern surgery [1]. Nevertheless, being an emerging surgical procedure, it requires preclinical and clinical assessment and depends largely on the development of appropriate surgical tools. By gaining access to the abdominal cavity via one of the bodies' natural orifices (e.g., mouth, anus, or vagina), thus completely eliminating abdominal wall trauma and reducing postoperative pain, NOTES is appealing from the patient's perspective. However, the constraints imposed by the access mode and by the limited available technologies make NOTES very challenging for surgeons. Redesign of the

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S. Tognarelli (✉) · M. Salerno · G. Tortora · C. Quaglia ·  
P. Dario · A. Menciassi  
The BioRobotics Institute, Scuola Superiore Sant'Anna,  
V.le R. Piaggio 34, Pontedera, Pisa, Italy  
e-mail: s.tognarelli@sssup.it

M. O. Schurr  
IHCI-Institute, Steinbeis University Berlin, Tuebingen, Germany

instruments is imperative in order to make this emerging operative modality safer and more reliable [2].

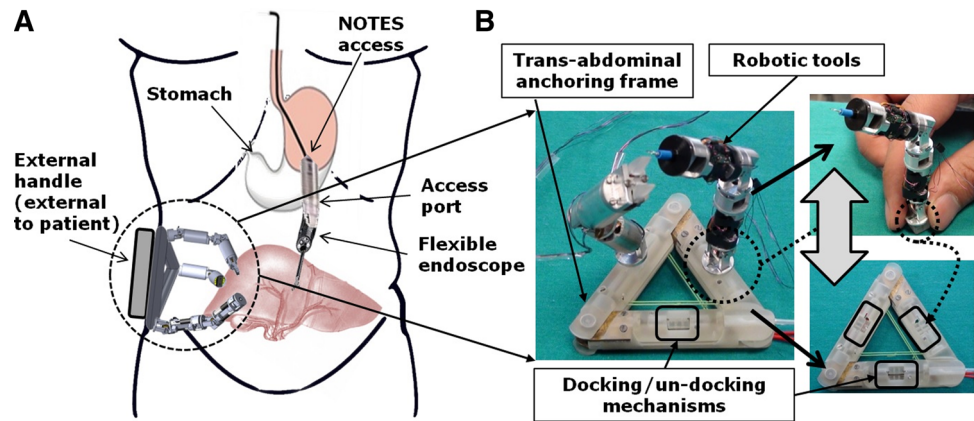
Nowadays, the most promising research investigations concern: (1) flexible instruments based on improvement of current endoscopic platforms and (2) robotic platforms based on micromechatronics technologies. Flexible endoscopes are the main tools used in interventional gastroenterology; however, conventional endoscopes are inadequate for performing complex transluminal surgical procedures. Emerging devices, including specialized endoscopes (e.g., Transport and Cobra systems, R-Scope, NeoGuide Endoscopy System and Anubiscope system [3–6]), flexible platforms (e.g., Incisionless Operating Platform—IOP [7] or the EndoSamurai system [8]), and master–slave flexible systems (e.g., Via-Cath endoluminal system [9] and Master and Slave Transluminal Endoscopic Robot—MASTER [10]) are being developed and advanced research in this field is widely encouraged [11]. Despite that, important deficiencies still exist due to the intrinsic features of the access system: flexibility of the devices makes tissue retraction difficult to be performed, the end effectors are generally small and weak, and instrument triangulation is still inadequate. Furthermore, most of these emerging devices have to be extracted to exchange tools and then re-deployed for completing the surgical procedure. Finally, the complexity of the devices does not allow for a smooth and controlled movement of the tip, making simple surgical maneuvers very challenging [12].

On the other hand, robotic technology allows for more reliable instruments, enabling procedures that cannot be done by conventional minimally invasive techniques. In order to provide potential solutions to the NOTES approach, novel concepts of miniature/modular robots are being developed [2, 13–15]. A promising research strategy in the development of transluminal instrumentation is to use robotic systems completely inserted into the peritoneal cavity [16, 17]. For example, several authors have been investigating the use of magnetic anchoring systems in order to provide such insertable devices with mobile ability [18–20]. Comparing with flexible endoscopes, the robotic approach facilitates NOTES operations by allowing the use of multiple surgical instruments, and also improving ergonomics, triangulation and visualization, because the camera can be freely navigated around the abdomen without colliding with the surgical instruments. Nevertheless, the complexity of the setup, the limited platform stability, the necessity of versatile and robust operation tools and articulated instruments and, finally, the use of wires for power and image transmission are technical challenges that still need to be addressed for their seamless integration within the operative room. Moreover, these miniature robots are effectively in the *in vivo* animal evaluation stage, and they are not mature enough for clinical use.

In this framework, recent research of the authors has been directed to the development of reconfigurable modular robotic platforms for endoluminal surgery [14]. In [21], we proposed an innovative magnetic platform for transgastric NOTES procedures composed of a transabdominal magnetic frame for robotic module anchoring and dedicated miniaturized robotic tools. As already demonstrated in the literature [17], the magnetic coupling between an internal frame and a dedicated external handle assures the stability of the platform for anchoring it within abdominal cavity. In this platform, as an additional design feature, the transabdominal magnetic frame was equipped with a dedicated active docking mechanism for the anchoring of the robotic tools. By attaching the robot to the magnetic frame with an active mechanism, and attaching the complete platform to the abdomen with permanent magnets, the stabilization of the robots is increased compared to the designs described in the literature. Magnetic robots reported in the literature are directly attached to the abdominal wall through permanent magnets, and relative motion of the devices, due to the surrounding soft tissues, is frequent during surgical tasks. Additionally, the proposed platform was conceived according to a modular approach for increasing both flexibility and versatility of the system. Depending on the surgical task to be addressed, different robotic tools can be inserted into the abdominal cavity through the mouth, assembled and synergically configured according to different surgical scenarios. The modular design simplifies the structure of each individual robot and miniaturizes the size to enable their passage through the human esophagus. Moreover, all robotics modules are conceived to keep the access port almost free during the surgical procedure for the insertion of additional robotic tools and/or the traditional flexible endoscope, which is used as an assisting tool to improve procedure safety and controllability.

The aim of our current work was the *in vivo* validation of the miniaturized platform for NOTES procedures, i.e., the transabdominal magnetic frame, the camera robot and dedicated docking mechanism. The technical description of single components of the system was already presented in previous works by the same authors, as reported in [22, 24]. We report here the first *in vivo* test of the complete robotic NOTES platform in order to highlight the potential of the system for a future clinical application. The promising results represent demonstration of practical surgical feasibility, paving the way for a new design concept for NOTES robotic devices. In order to assess the feasibility of the overall platform and the validation of the proposed approach, a camera robot was used in the animal laboratory. It is worth mentioning that due to the modular property of the devices, the deployment and the anchoring of any robotic module (with same diameter and docking mechanism) can be achieved similarly (Fig. 1).

**Fig. 1** **A** Overview of the paper concept; **B** assembled NOTES platform composed of a transabdominal magnetic frame for robotic module anchoring and dedicated miniaturized surgical robots; a further docking slot is devoted to camera robot docking

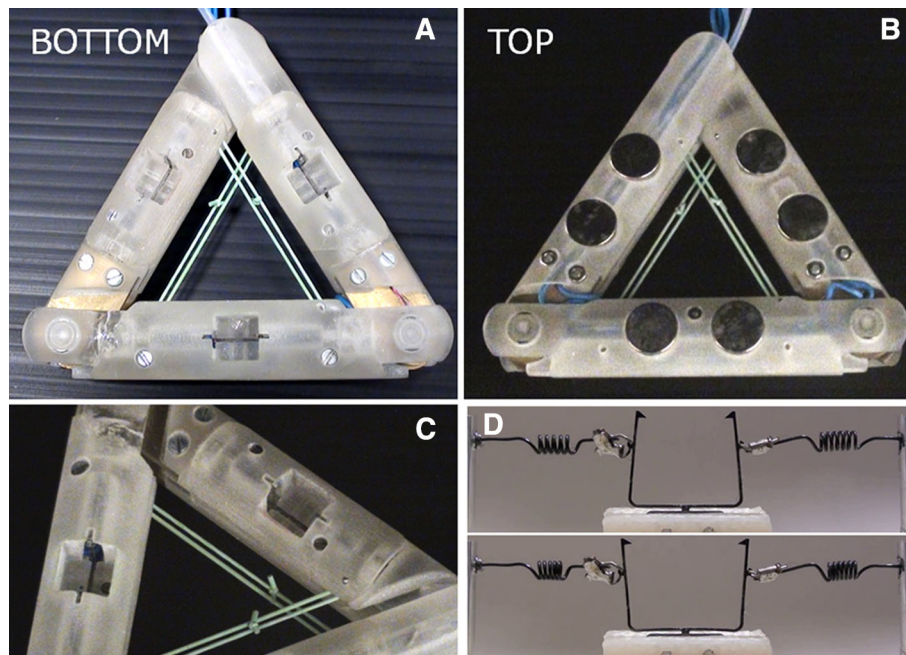


## Materials and methods

In the anterograde transoral/transesophageal/transgastric approach, the deployment of a set of miniaturized robotic devices capable of performing dedicated tasks will overcome typical drawbacks of robotic surgery, both in terms of dexterity, number of degrees of freedom (DoFs) and triangulation. Based on this consideration, in the NOTES platform proposed by the authors in [20], a triangle-shaped device magnetically anchored to the abdominal wall by means of an external magnetic handheld structure was used as a stable base for miniaturized surgical robots to be docked or un-docked during the procedures [22]. This system improves the stability of the overall platform with respect to other magnetic-anchored systems described in the literature because it maximizes the magnetic material volume and holds the relative position references between the robots. Taking into account the intrinsic limitations of the magnetic anchoring strategy, the frame design was carried out as a trade-off between the maximization of the magnetic volume and the fulfillment of the anatomical constraints (the maximum diameter of the frame during deployment should be no larger than 14 mm). The final prototype of the transabdominal anchoring frame has a diameter of 14 mm, a total length of 186 mm in extended configuration and a total weight of 48 g (Fig. 2A). The miniaturization requirements and the presence of magnets led to the use of a shape memory alloy (SMA) as frame actuators: two active springs coupled with two elastic bands used as actuator bias elements have been designed and integrated in the final prototype. The angular actuator reaches the 120° actuation range, needed for configuration change, by using the SMA martensitic and austenitic temperature driven phase shift. The elastic bands are used both as bias element for restoring the triangular close configuration and as a safety countermeasure in the event of device malfunctioning. Within the abdominal cavity, they can be cut using a traditional flexible endoscope thus

allowing the safe extraction of the device in a flexible straight position. Finally, for magnetic coupling with the external handle, the frame embeds six cylindrical magnets placed on the upper part of the system (Fig. 2B). In the current configuration, the magnetic system can sustain up to 500 g considering an abdominal wall thickness of 25 mm. On the bottom part of the magnetic frame, three dedicated docking/undocking mechanisms were integrated to connect and house the modular surgical units (Fig. 2C). From the first attempt to use a very simple magnetic docking mechanism [23], authors moved to an active SMA docking system composed of two linear helicoidal SMA spring actuators interfaced with a passive steel element that plays both the role of bias element of the mechanism and docking system for the robotic units (Fig. 2D). This mechanism provides for a docking force up to 10 N.

Finally, with the aim to provide versatile and robust operation tools, miniaturized modular robotic units were designed to fit the dimensional requirements of an esophageal access (Fig. 1B). The concept of basic modules which can be assembled together led to share a basic design, but provided with different functions depending on the assembly procedure. Internal miniature actuators (SBL04 by Namiki, Akita, Japan, reduction ratio 1:337) were employed for each basic robotic unit to provide them with two DoFs in a compact design featuring 35 mm in length and 12 mm in diameter [24]. The operative modular robots mainly consist of some basic operation tools, such as a camera robot, a manipulator and a cautery device (Fig. 3). The modular design of the robots allows equipping the robotic platform with different end effectors such as scissors, needle driver and dissector by simply changing the distal module, but keeping the same actuation method. Versatile and robust operation tools broaden the range of the surgical operations and avoid the use of the flexible endoscope as NOTES assistant. Although different robotic modules have been developed so far, the in vivo platform delivery and docking have been demonstrated by using



**Fig. 2** Final prototype of the transabdominal anchoring frame in closed configuration: **(A)** bottom side with docking/un-docking mechanisms; **(B)** top side with six cylindrical magnets used for the magnetic anchoring; **(C)** docking/undocking mechanisms integrated in the frame for the modular surgical units housing; **(D)** mechanical

details of the docking/undocking mechanism: The austenitic phase of the helical springs is used to open the bias element, thus allowing the robotic modules insertion/extraction; the elasticity of the bias element is used for restoring the deformed shape and thus for guaranteeing the closure of the docking mechanism and the anchoring of the module

only the camera robot because it is more stable and robust with respect to other robotic modules as reported in [24]. Other modules are still subject to electrical or mechanical shortcomings that can be managed in bench testing, but could prevent their intra-abdominal use in *in vivo* experiments. In any case, the camera robot has the same dimensions and similar weight of the other modules, which will allow the same deployment and assembly procedure for all the modules that have been successfully demonstrated on bench [24]. In particular, the camera robot includes a basic two-DoF module, a passive support for the stereoscopic camera (UXGA, 30 fps, by ST Microelectronics, Milano, Italy) and a light emission diode-illumination system (LEDs, NESW007BT, Nichia, Tokyo, Japan).

The single modules of the modular platform were already described in detail and tested on-bench in separate test sessions (both *in vivo* and *ex vivo*) as reported in [22, 24], and the transgastric deployment and anchoring procedure of the whole system were previously validated in *in vitro* conditions by using a commercially available gastro-bulboscopy human phantom (OGI phantom, CLA medical training phantom, CLA Coburger Lehrmittel Anstalt, Germany). The typical insertion time for the platform including the docking of the camera robot takes about 4–5 min (see the attached video for details).

However, in order to confirm the performances of the platform also in an anatomical scenario, two additional tests were performed in a porcine model:

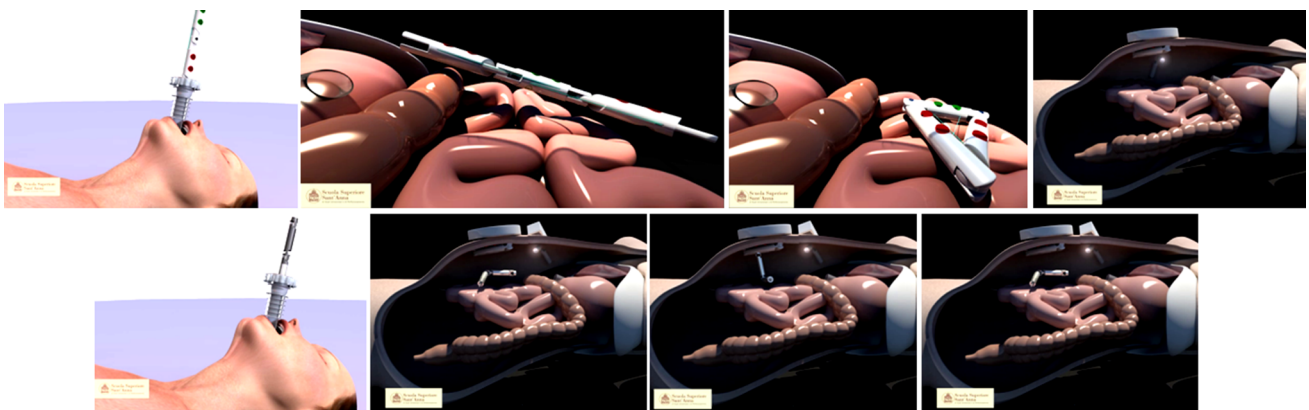
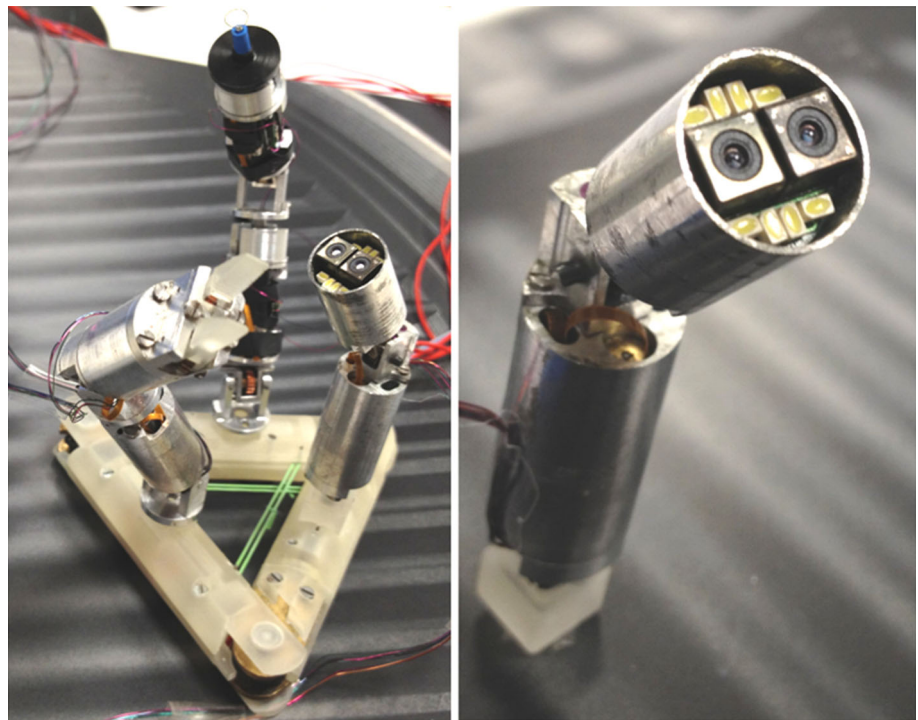
- (1) *in vivo* transgastric NOTES deployment and anchoring procedure;
- (2) *in vivo* transabdominal assembly procedure and platform capabilities validation.

The two *in vivo* tests were performed in the domestic pig model ( $n = 2$ , female, approx. 60 kg) and were carried out in accordance with German animal protection law provisions, approved by the regional government authority. The animals were euthanized after the experiment, as according to the study protocol.

## Results

The complete surgical test procedure is schematically reported in Fig. 4. It involves the following steps: (a) placement of the endoscopic overtube in the porcine esophagus for reaching the abdominal cavity, and then transgastric access is created by inserting the gastroscope into the access port (i.e., NOTES procedure); (b) SMA actuation and frame opening phase for deployment; (c) deployment of the frame in the abdominal cavity by using a flexible endoscope

**Fig. 3** Assembled prototypes of the modular robotic units anchored on a magnetic frame mock-up by exploiting the docking/undocking mechanism of Fig. 2C. Detail of the camera robot on the right

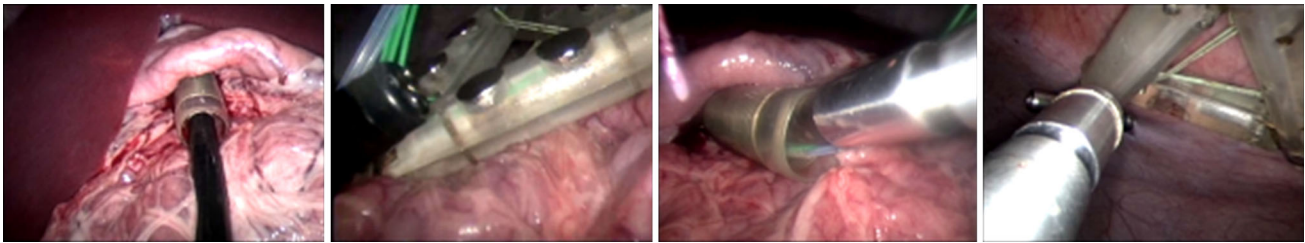


**Fig. 4** Schematic representation of the test protocol: frame insertion, frame anchoring, docking and undocking procedure of the surgical robotic unit

(STORZ, 13803 PKS, Head V2.4, Germany), both for manipulation purposes and real-time video streaming to the surgeon; (d) SMA spring cooling process for returning to the closed triangular-shaped configuration; (e) frame stabilization and anchoring by means of the external handheld magnetic module; (f) deployment of the robotic unit through the endoscopic overtube up to reach the abdominal cavity; (g) docking of the robotic unit on the magnetic frame; (h) stability check; (i) undocking of the robotic unit from the anchoring frame and retraction through the overtube; (l) re-opening procedure of the magnetic frame by supplying current to the SMA actuators and frame retraction through the phantom esophagus. An additional laparoscope, which is

not needed for practical purposes, was used for observing and recording the procedure.

Firstly, transgastric system deployment, anchoring and assembly procedures were tested. Owing to porcine anatomy, an access port at least 800 mm in length is needed to reach the abdominal cavity. A custom port, obtained by connecting a PMMA (polymethylmethacrylate) tube 18 mm in internal diameter and 300 mm in length with a Guardus Overtube commercial access port (US Endoscopy, Mentor, USA) having an internal diameter of 17 mm and total length of 500 mm, was used for reaching the porcine abdomen through the gastric cavity (Fig. 5 on the left). Then, the deployment/anchoring procedure was successfully performed



**Fig. 5** NOTES procedure under the supplemental laparoscopic view for observational purposes: On the left, the abdominal cavity was reached through the gastric cavity; deployment of the frame and of the

robotic module is reported in the middle images; finally, assembly task is illustrated on the right

demonstrating device suitability for NOTES procedures: Frame configuration change, deployment of the platform modules (e.g., magnetic frame and a simple mock-up of the robotic module) into the abdominal cavity through the gastric wall, anchoring tasks, and system retraction were efficiently achieved (Fig. 5).

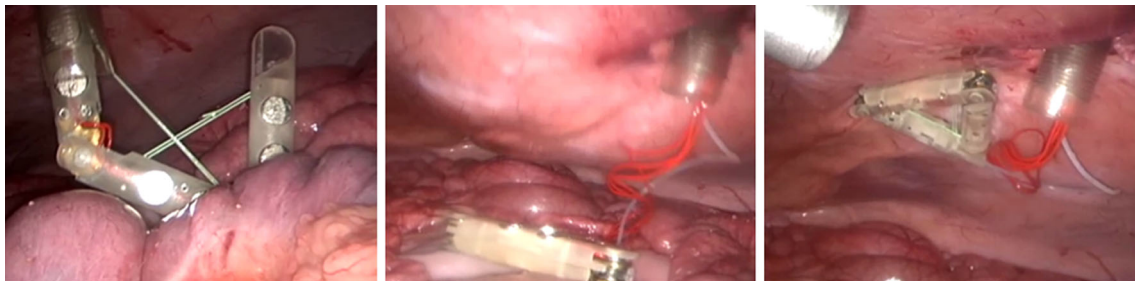
Due to the anatomical conditions in the porcine model, the insertion of the overtube to reach out of the gastric cavity into the abdominal cavity was a relatively time-consuming maneuver. After the overtube is inserted, the insertion of the robotic platform modules takes only short time, <1 min for each module, with the exception of the anchoring frame that requires more time (several minutes).

A transabdominal *in vivo* test was then performed in order to further assess the effectiveness of each mechanism and to validate the stability of the proposed strategy during a real operating task. Starting from the successful results achieved within the transgastric deployment and anchoring

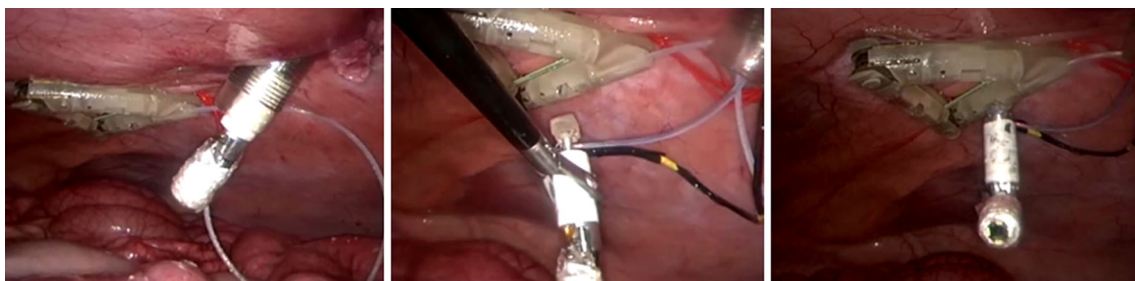
procedure, the prototype of the camera robot was used for a complete assessment. A small incision was performed on the porcine abdomen, and a traditional trocar (15 mm) was inserted. After trocar insertion, deployment and magnetic anchoring procedures of the magnetic frame prototype were successfully tested, confirming the results observed during the first animal laboratory study (Fig. 6).

Afterward, the camera robot was introduced into the abdominal cavity and successfully anchored on the magnetic frame by using a traditional endoscopic tool (i.e., endoscopic grasper) as shown in Fig. 7. By exploiting the animal experience, the SMA-based docking/undocking mechanism was found to be reliable, intuitive and easy to operate (Fig. 8).

At the end of the assembly procedure, the stability of the entire platform (magnetic frame and camera robot) was tested by making use of both the active DoF of the camera robot and the passive DoF of the magnetic frame by



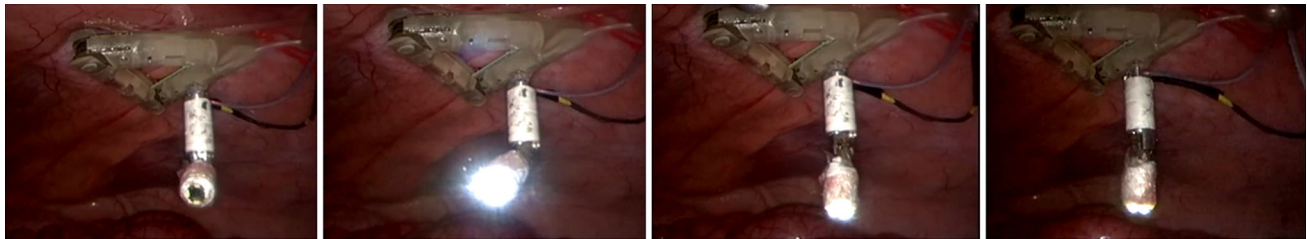
**Fig. 6** Deployment and anchoring procedure of the magnetic frame during the transabdominal *in vivo* test session



**Fig. 7** Deployment and docking procedure of the camera robot during the transabdominal *in vivo* test session



**Fig. 8** Docking/undocking procedure: From left to right, the robotic module is moved close to the magnetic frame, the docking/undocking mechanism is opened, and the camera robot is anchored to the frame



**Fig. 9** Vision tasks and stability check by exploiting the internal and external module DoFs

exploiting the external handle. The camera robot was activated by the surgeon using designated control buttons (Fig. 9). Finally, the camera module un-docking procedure, re-opening of the magnetic frame and modules (i.e., magnetic frame and robotic module) extraction were carried out. The average time for completing the assembly/disassembly procedure of the whole modular platform was 16 min. With continued practice, this time can be considerably reduced.

## Discussion

For the first time, the *in vivo* validation of a modular robotic platform for NOTES procedures was carried out within two animal tests, and the technical potential of such a platform solution was successfully demonstrated in the *in vivo* porcine model.

The animal investigation demonstrates the feasibility of inserting an endoluminal robotic platform into the abdominal cavity through natural orifices, with the final aim of setting up a complete miniaturized “surgical room” in the patient’s abdomen by passing through the mouth, esophagus and stomach wall (Fig. 5). The delivery and docking of the camera robot successfully demonstrate the feasibility of the approach. Any other robotic module can be inserted in the same way, being equivalent to the camera robot in terms of external diameter and weight. Once inserted into the peritoneal cavity, the platform provides visualization and dexterous capabilities from multiple orientations, secured by the magnetic link established by the

external components (see the companion videos for details). The platform stability represents one of the most important features for miniaturized robotic platform during NOTES procedure: As in this paper, most operative miniature robots described in the literature are anchored on the abdominal wall by magnetic coupling. However, the magnetic attraction force drastically drops with respect to the distance between the internal magnetic joint and the external handle, resulting in unstable platform in humans with thicker abdominal walls. Platform stability investigations were carried out by the authors during the validation test sessions, and good results were achieved by exploiting a custom design of the anchoring frame properly studied and deeply described in [22]. As investigated in the literature, magnetic coupling was analyzed to assure anchoring of the magnetic frame to the abdominal wall; additionally, a stable docking/undocking mechanism for the anchoring of the miniature robots on the magnetic frame was integrated in each frame side. These design solutions guarantee a robust and safe assembly of the modular platform: all the robotic units can be delivered transgastrically and assembled on the docking areas of the magnetic anchoring frame, thus allowing surgical tasks in the specific operative region. Depending on the surgical task to be addressed, other robotic units with different end effectors can be re-assembled on the NOTES platform during the operation by simply exploiting the docking and undocking mechanisms of the anchoring frame.

By considering the robotic units of the NOTES platform, multiple DoFs allow to actuate the end effector of the

robotic modules providing an extended workspace and higher dexterity, when compared to the operative miniature robots for NOTES already presented in the literature [19], which show basic tools directly attached to magnetic joints. The proposed design maintains a simple mechanical structure and compact size, but improves the system working space and thus the performance of the platform.

Future work includes performing basic surgical procedures after assembling of the whole platform *in vivo*, as soon as the reliability of the robotic modules in terms of possible failures during surgical procedures is assessed.

Finally, the current version of the validated platform is tethered to the external power and control system. Taking into account all the complications related to the presence of wires in the operational theater during a surgical procedure, an optimized version of the platform exploiting a wireless control will be analyzed, thus reducing the overall number of wires and possible conflicts between modules, as introduced in [24].

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