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Total Mesorectal Excision Using the STIFF-FLOP Soft and Flexible Robotic Arm in Cadaver Models

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Abstract

In this chapter, we discuss the perspectives related to the use of a soft and flexible robotic camera during a series of rectal resections with total mesorectal excision (TME) that were performed in two human cadaver models. The robotic prototype comprised two modules that are 60 mm long and 14.3 mm large. The robot is connected to a rigid shaft that is in turn attached to an anthropomorphic robotic arm with six degrees of freedom. Briefly, three standard laparoscopic tools were employed to perform the surgical procedure. After the splenic flexure mobilization and the inferior mesenteric vessel division, the mesorectum was entirely *en bloc* excised. Neither intra-operative adverse effects nor technical issues were recorded. This preliminary experience shows that the STIFF-FLOP soft and flexible robotic optic arm is an effective tool that is characterized by a better vision of the surgical field than the standard laparoscopic rigid camera. The implementation of new soft and flexible robotic systems may help surgeons overcome the technical issues that are encountered during challenging minimally invasive surgical procedures performed using the standard rigid camera.

19.1 Introduction

While the laparoscopic approach to colon cancer has been widely adopted worldwide, with significantly better short-term outcomes than open surgery and similar oncologic outcomes [1–4], the current evidence about the role of laparoscopic resection for rectal cancer is controversial.

The introduction and rapid implementation of routine total mesorectal excision (TME) during resection of the mid and low rectum for cancer has led to a significant decrease in local recurrence rates [5] with subsequent improvement of long-term survival [6]. However, the open approach still represents the standard of care for the elective surgical treatment of rectal cancer, based on controversial results of recently published randomized controlled clinical trials. While the COLOR II trial showed that the minimally invasive approach is not inferior to the open approach, reporting similar short-term oncologic outcomes including resection margins and completeness of the mesorectal excision [7], and no significant differences in local recurrence rates and disease-free and overall survival at 3 years [8] between the two approaches, both the ACOSOG [9] and the ALaCaRT [10] randomized controlled trials (RCTs) failed to prove the non-inferiority of the minimally invasive approach regarding the pathology results, including completeness of TME and clearance of both radial and distal resection margin in stage 2 and 3 rectal cancer patients.

The current evidence from RCTs and prospective comparative studies [11, 12] shows that the laparoscopic approach to selected patients with both high and mid/lower resectable rectal cancer rectal resection has clinically measurable short-term benefits over the open approach, resulting in a significant decrease of 30-day mortality and faster recovery. In particular, the minimally invasive approach is associated with significantly lower incidence of overall surgical and medical postoperative complications. Based on these high-quality data, it can be stated that minimally invasive rectal surgery is safe with better short-term outcomes than open surgery. In addition, the laparoscopic approach does not jeopardize long-term survival as demonstrated by several RCTs and non-RCTs [13].

However, laparoscopic surgery for mid and lower rectal cancer is a complex and technically challenging procedure that requires a steep learning curve. It has been advocated that the use of robotic technologies might help reduce the technical difficulties encountered during the procedure and might shorten the learning curve. Standard robotic platforms, including the

Da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA, United States – www.intuitivesurgical.com), have been developed aiming at increasing the dexterity and improving the ergonomics of the surgeon. However, they are very expensive and their potential benefits in the surgical treatment of rectal cancer are not proved [14]. For instance, the RCT that compared RObotic and LAparoscopic Resection for Rectal Cancer (ROLARR) failed to demonstrate statistically significant differences in terms of rate of conversion to open surgery, intraoperative complications, early post-operative morbidity, and in the rate of positive radial margins after laparoscopic or robotic surgery [15]. Based on this evidence, the robotic technology currently available on the market that uses rigid instruments does not facilitate the procedure and does not further improve the outcomes achieved after standard laparoscopic surgery. As a consequence, the research has recently focused on the development of novel flexible devices for minimally invasive surgery [16–18]. In particular, soft and stiffness-controllable robotic technology has proved to be effectively used in different body districts, including heart, throat [19–21], brain [22, 23], and abdominal organs, through a single-port access [24, 25]. Following the experience with flexible endoscopes with enhanced features that have been used to guide tools into intra-abdominal organs through natural orifices [26, 27], highly articulated and actively guided surgical instruments have been conceived to reach the surgical site with very limited interaction with the surrounding structures [28]. The ideal tool to achieve this goal should be soft, with the ability to become stiff when considerable forces are needed for tissue or organ retraction or to accomplish surgical tasks with the end-effector [29, 30]. In 2011, these concepts and the close observation of the tentacles of the octopus led to the conception of a novel robotic platform. The project, which was funded by the European Commission within the Seventh Framework Program, started in January 2012. During the following 4 years, a robotic arm including a camera that was able to pass through a standard, commercially available 15-mm trocar was designed. This chapter aims at showing the feasibility of laparoscopic TME under the vision provided by a soft and flexible robotic camera in human cadavers.

19.2 Methods

Building up the prototype model included assembling the flexible modules and adding detecting abilities, force feedback, route control, and in addition, a user interface (UI) and complex software to empower real-time dialog of all the components. Initially, large-scale prototyped models were produced with the specific aim to verify the idea on benchtop models. A 24-mm-diameter prototype of the STIFF-FLOP arm was made, comprising various soft, pneumatically incited three-chamber sections [31]. Extra chambers were incorporated inside the sections in order to permit their hardening, utilizing an approach based on the granular jamming principle (Figure 19.1). Models with two or three sections were manufactured and some human stomach phantom models were used in order to test the framework [32]

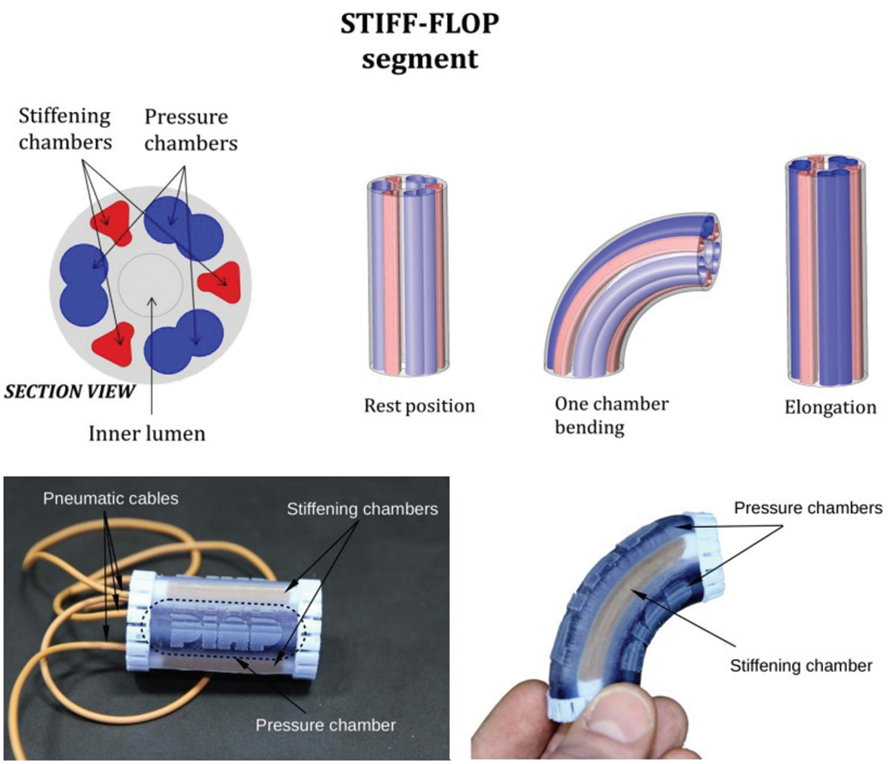

Figure 19.1 Computer model design of one STIFF-FLOP arm segment. From the left: section view of the segment showing the arrangement of the chambers (pneumatic and stiffening); segment in the rest position (no pressure is supplied to the chambers); bending of the segment due to the pressurization of one pneumatic chamber (in dark blue); elongation of the segment due to the simultaneous pressurization of all the chambers. The stiffening mechanism can be activated by controlling the level of vacuum in all the stiffening chambers (in red), once the desired position of the segment is reached.

Figure 19.2 Six degrees of freedom (DoF) haptic input device, based on a Delta robot design.

(Figures 19.2 and 19.3). The STIFF-FLOP sections were activated utilizing pressure controllers, which were managed by a RoNeX-board (Shadow Robotics, London, United Kingdom). The stiffening of the three-chamber sections was controlled through valves commanded by a RoNeX-boar. When the valves were open, a vacuum is applied to the granules contained in the three chambers, which thus transform the flexible segment of the STIFF-FLOP arm into a stiff segment. Sensors were installed in the STIFF-FLOP modules to quantify interaction forces (between the robot and its environment) and the robot's setup. In this specific scenario, each section was embedded with a three-pivot force/torque (F/T) sensor and a three-degrees-of-freedom bending sensor. To increase the pose route, a laparoscopic camera, two outer sensors, and an NDI Aurora magnetic tracker (NDI International Headquarters, Waterloo, ON, Canada) were used. In order to achieve this purpose, various markers were appended at different areas along the STIFF-FLOP arm. A Schunk mechanical arm (Schunk GmbH and Co. KG,

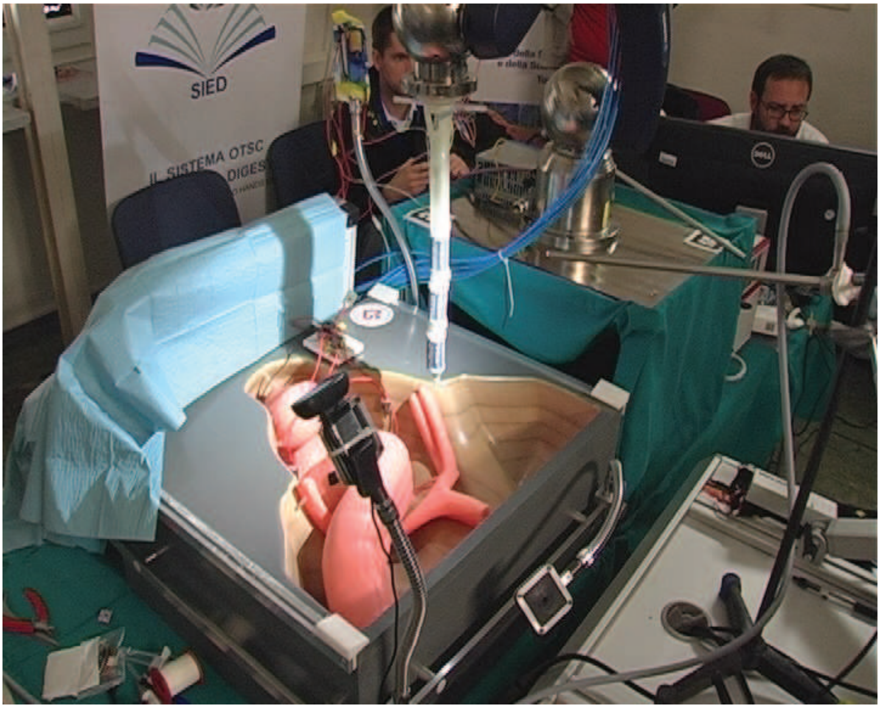

Figure 19.3 Three-segments STIFF-FLOP arm with embedded sensors, connected to the SCHUNK robot during invitro Tests done at UNITO

Hamburg, Germany) was then linked at the base of the STIFF-FLOP robotic arm, out of the body of the patient, to allow the STIFF-FLOP arm to move in and out through a trocar cannula and to position and orientate the base of the STIFF-FLOP arm as required. Contribution from the magnetic sensors guaranteed that the pivot point of the trocar and the mechanical arm were always linked. This approach guaranteed that the STIFF-FLOP arm was constantly embedded along the central longitudinal axis of the trocar cannula, allowing the pitch and yaw on the trocar access point. Control and route strategies were created to process the inverse kinematics for the extended kinematic chain of the robotic arm and the STIFF-FLOP arm continuously and in real time, thanks to the contributions from different sensors. Due to this real-time control, the operator could control the position of the tip of the STIFF-FLOP arm in the working space without the need to control the movements of each arm segment. A recently created UI, derived from a Delta robot [33], was used for moving and positioning the tip of the STIFF-FLOP arm inside the body (Figure 19.2). In the screens of the platform, the operator could see the visual feedback derived from the camera with the addition of a real-time 3D simulation demonstrating the 3D positioning of all STIFF-FLOP modules. The inputs acquired from the F/T sensors were sent back to the UI, giving to the surgeon real-time force feedback, opposing the physician's hand movements when the robot was in contact with an anatomic structure of the patient. The tip effectors of these models were outfitted with various surgical laparoscopic instruments, such as a gripper and a monopolar hook. Successful utilization of these devices in realistic situations was proven.

A thinner STIFF-FLOP model able to pass through a standard 15-mm trocar was created for *ex vivo* human setting tests. This STIFF-FLOP model has thin pneumatically activated sections, a camera that is positioned at the distal tip of the last segment, and a positioning device. The consortium effectively figured out how to downscale the entire soft robot framework to 14.3 mm diameter, equipped for being embedded into the human body through a standard trocar cannula. Downsizing the STIFF-FLOP model constrained us to renounce the detecting capacities aside from the camera; for this reason, the control of the tip of the soft robot was conceivable by independently moving the two robots' segments with the two joystick inputs. This controlling system permits each soft-robotic module to elongate along the central longitudinal axis and also to bend in any direction.

The soft robot has a 4-mm free lumen along the center of its long axis, which permits the electrical wires the passage that is required for the laparoscopic visual module situated at the tip of the robotic arm. The MD-T1003L-65 optics (Misumi, New Taipei City, Taiwan) is 12 mm long and 3.8 mm in diameter; the optics are incorporated with a light framework (four LEDs) and are connected to a computer station by a USB connector. The STIFF-FLOP camera robotic module was appended to an unbending shaft 10 mm in diameter, which was linked to the surgical table with an articulated arm with three ball-shaped joints (KLS Martin GmbH and Co. KG, Freiburg, Germany). This arm could be physically moved and adjusted in order to have the correct positioning of the robot base during the intervention. The primary goal of the test was to prove that the STIFF-FLOP robotic framework was adequate to achieve a laparoscopic TME in a human model and to assess if flexibility, softness, and dexterity of the STIFF-FLOP visual module may represent an advantage when compared to standard unbending laparoscopic tools.

19.3 Operative Technique

The feasibility and effectiveness of the 14-mm robotic STIFF-FLOP camera during a laparoscopic TME on a human cadaver model were tested at the Institute for Medical Science and Technology (IMSaT), Dundee, Scotland. The robotic system, including the software and the robotic STIFF-FLOP camera, was installed by the engineers. The robot-assisted laparoscopic TMEs were performed on two cadavers that were embalmed following the Thiel method. According to this technique, salt compounds mixed to very low quantities of volatile formaldehyde and formalin are used to fix tissues, guaranteeing excellent antimicrobial properties, keeping a life-like flexibility of the different segments of the cadaver, and preserving the natural color of muscles, viscera, and vessels, with no detectable odor.

The suitability of the two human cadaver models had been tested by surgeons in a previous lab session. After positioning and safely securing each cadaver to a dedicated operating table, the entire instrumentation was checked. Then, a 10-mm trocar was placed trans-umbilically to get access to a 30° camera and to create a stable pneumoperitoneum. The intra-abdominal organs and the abdominal wall compliance to the pneumoperitoneum were assessed. The following step included the placement of three 5-mm trocars in the right flank, right iliac fossa, and left flank. Then, the surgeon carefully checked the thickness of both bowel and mesocolon. Lastly, the surgeon mobilized the left colon from the abdominal wall and checked the feasibility of mesenteric vessel dissection.

The surgical team included three surgeons. Before starting the laparoscopic TME, the cadaver was placed on and secured to the operating table, and all operative tools were checked. Four trocars were used: one 15-mm trocar was positioned on the midline about 2 cm above the umbilicus, and the other three 5/12-mm trocars were positioned in the right flank, left flank, and right iliac fossa, respectively. The consistence of bowel and mesocolic fatty tissue was then checked under the vision of a standard 10-mm 30° laparoscopic camera positioned through the median trocar. Then, a fifth 10-mm trocar was inserted in the left upper quadrant, posterior to the median trocar, aiming at achieving an overview by a standard 10-mm 30° laparoscopic camera and introducing under direct vision the flexible STIFF-FLOP camera (Figure 19.4). The entire laparoscopic TME was followed on two screens: one monitor was connected to the standard laparoscopic camera and the second to the STIFF-FLOP optic. The surgical procedure was entirely

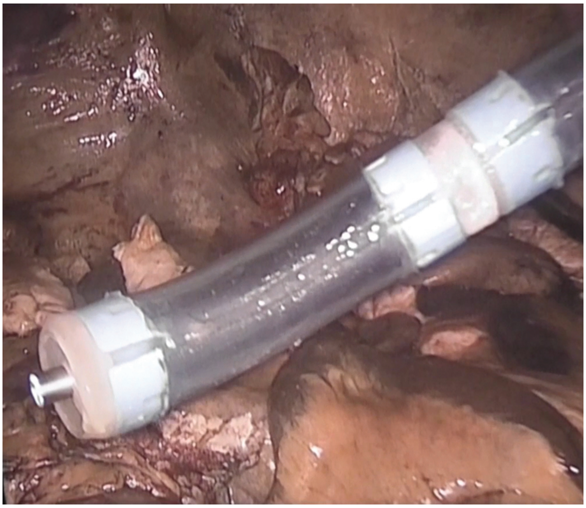

Figure 19.4 Flexible STIFF FLOP camera during cadaver tests.

recorded at a standard 24-frame per second rate for subsequent review and critical analysis.

During the first step of the surgical procedure, the medial dissection of the sigmoid mesocolon was performed using standard laparoscopic tools. Then, the inferior mesenteric vessels were identified, dissected, clipped, and divided. The STIPP-FLOP camera helps the surgeon to clearly recognize the inferior mesenteric vessels and the autonomic nerves that were successfully spared. The operation continued with the identification of the iliac vessels and both ureters, and with the posterior dissection of the mesorectum in the presacral avascular plane down to the pelvic floor. Afterwards, the surgeon completed the mesorectal excision laterally on both right and left rectal sides. Lastly, the anterior dissection of the mesorectum was completed after identifying the Denonvillers' fascia and preserving the seminal vesicles and the lateral pelvic nerves. At the end of the procedure, the rectum was circumferentially mobilized and prepared for transection. The quality of the dissection was evaluated by assessing the integrity of the mesorectal fascia.

19.4 Results

A team including three surgeons performed both laparoscopic TME procedures. One of the three surgeons used a dedicated joystick to orient the STIFF-FLOP camera by means of an X-BOX controller for each robotic module, thus allowing bending movements in the two axes and translation. The elongation and retraction of the system were both assisted by an engineer. One surgeon performed the operation, while the third surgeon drove the standard 30∘ laparoscopic camera. The STIFF-FLOP camera was controlled only by the visual feedback provided by the camera, without the help of any other sensor.

As the first step of the laparoscopic TME, the sigmoid mesocolon was medially dissected, and both inferior mesenteric artery and vein identified and divided under the direct view given by the STIFF-FLOP camera. The STIFF-FLOP camera also clearly showed the autonomic nerves, avoiding the risk of nerve injuries. After the completion of the sigmoid mesocolon dissection, the surgeon moved toward the pelvis to perform the mesorectal excision under the direct vision provided by the STIFF-FLOP camera. The mesorectal dissection was first started in the posterior avascular plane: the enhanced and stable view provided by the STIFF-FLOP camera and its flexibility facilitated this surgical step by allowing the surgeon to follow the sacral curve very closely and perform the dissection precisely. After reaching the pelvic floor posteriorly, the surgeon completed the mesorectal excision laterally and anteriorly. Also, this step of the laparoscopic TME was not difficult to carry out thanks to the magnification of the view of the surgical field that was achieved by using the flexible STIFF-FLOP camera. At the end of the operation, the mesorectal excision was complete and the mesorectal fascia was intact. The overall operative time was 165 min for the first case and 145 min for the second case. There were no intra-operative adverse events. From a technical point of view, no problems were encountered. At the beginning of each procedure, the STIFF-FLOP robotic arm was inserted in the abdomen through a 15-mm trocar without any difficulties; the surgeons did not report any movement limitation during the navigation forward, backward, and laterally. The cleaning of the STIFF-FLOP camera was required only twice during each operation and was performed by taking out the arm from the abdomen as is usually done with the standard rigid laparoscopic camera. Only a few minutes of training were necessary to achieve the adequate ability to manipulate the dual-joystick input device. Intra-abdominal navigation was facilitated by a double check looking at the screen connected to the standard laparoscopic camera.

The three surgeons performed the same surgical tasks on two human cadavers showing the friendly use and robustness of this robotic camera for several hours.

19.5 Discussion

The minimally invasive approach to extra-peritoneal rectal cancer is safe and feasible, even though it is technically demanding. Despite the obvious advantages from the patient's perspective [10, 11], the laparoscopic approach has not gained wide acceptance and to date it is not routinely adopted. The use of robots was conceived to improve the surgical outcomes in rectal cancer patients. However, the currently available literature does not show clear benefits from the robotic technology over the standard laparoscopy, in terms of both ergonomics of the surgeon and outcomes of the patient [13]. Major efforts have been made to improve surgical training for both laparoscopic and robot-assisted surgery. We feel that the implementation of the new idea of flexible robotic arms on top of the existing robotic technology may be key to reducing the "human" factor that has a major impact on the outcomes of surgical procedures performed using current "rigid" technology.

For these reasons, in 2011, we conceived a new soft and flexible robot that was characterized by the ability to easily reach narrow spaces, including the pelvis. During this 4-year project, we were able to develop a modular technology, made of soft and flexible modules, able to bend under pneumatic swelling of dedicated chambers, and also to become stiff when required using the granular jamming technology of committed chambers incorporated in the STIFF-FLOP arm prototypes. The UI that controls all the movements consist of two separate joysticks derived from a modified Delta robot. The STIFF-FLOP arm is designed in order to permit unconstrained and free independent movements of every module in any direction, bending from the major axis of the module, accomplishing an extensive variety of movements and a large workspace. Moreover, lengthening can also be accomplished. The UI controller leaves the operator the control in real time of the spatial position of the end-effector tip. It assures the positioning of the system by setting the correct spatial coordinates of where the tip of the arm should move to and its orientation. In the meantime, in order to get the desired spatial position and orientation of the arm, the arm will move, like an octopus tentacle, driven from a software algorithm that will compare in real time the required position, given from the UI, and the real position and automatically route the arm in the best way to reach the target position and orientation. This routing is made possible by the several sensors set along the arm, which permit a fine control of the position of every module, and additionally, thanks also to the force sensors that are able, in conjunction with the visual output, to give a haptic feedback to the operator through the UI input device. These unique characteristics make this new robotic platform extremely innovative compared to the currently available flexible surgical tools. Indeed, the flexibility of both robotic and laparoscopic tools is restricted to the tip of the device, which keeps a rigid stem that does not allow following the curved surfaces inside the human body. The presence of a modular, stiff, but, at the same time, soft and flexible arm when necessary, might allow easy reach of any target inside the abdomen or the chest.

Theoretically, these characteristics should exceed the majority of the drawbacks of the currently available surgical robots, which are limited by a rigid architecture. With a specific end-goal of being able to insert the arm into a standard trocar for the human cadaver study, we decided to cut off the detecting abilities in order to be able to scale-down the arm and be able to test the soft and flexible arm concept in a first sensorless fashion. For testing, the miniaturized STIFF-FLOP robot was connected to a rigid shaft in turn attached to the operative table by means of an anthropomorphic arm. A double joystick was used to control the entire system. We tested this robotic tool on two human cadavers, aiming at assessing and demonstrating the feasibility, effectiveness, and adequacy of its geometry and function.

We were able to complete a TME procedure with the help of the STIFF-FLOP camera in two consecutive human cadavers by using standard laparoscopic rigid instruments. The operative time for both TMEs was shorter than 180 min and neither complications nor technical issues were experienced. We appreciated the ability of the STIFF-FLOP arm to enter the pelvis getting very close to the sacral bone and the lateral walls of the rectum, thus allowing a very precise mesorectal excision that is otherwise very difficult during a laparoscopic TME. The ability to provide a magnified and close view of this low and very limited surgical field has demonstrated the correct concept and geometry of the robotic tool.

We have shown that a TME procedure performed under the direct vision of a soft and flexible camera is feasible and safe in human cadaver models. However, further cadaver test and possibly clinical studies are needed to confirm these preliminary findings and studies comparing the STIFF-FLOP camera with the last version of 3D high-definition cameras with flexible tip are awaited to better define the possible impact of this robotic technology in the clinical practice.

The STIFF-FLOP technology has some strengths and weaknesses. Strengths include the magnified vision of the surgical field with good image quality and the steady control of the camera movements by using the dedicated joystick. Weaknesses include the reduced intuitiveness of the control of the device, which might be improved by adopting the inverse kinematics-based approach that was used in the large STIFF-FLOP arm prototype. The insertion of sensors in the prototype used during the TME procedures and the use of computing inverse kinematics in real time will permit the employment of the modified Delta robot to control both orientation and position of the robotic system. Consequently, the navigation of the robotic camera will improve and become more user friendly. During the project period, we have also developed a new robotic prototype with an embedded gripper on the tip and a monopolar coagulator that will let us shortly attempt a complete laparoscopic procedure by means of soft and flexible robotic tools.

19.6 Conclusions

This chapter reports the first two cases of laparoscopic surgical procedures performed with the assistance of a flexible and soft robot. Based on this preliminary experience, we feel that the optimized vision of the surgical field along with the flexibility of the robotic camera might significantly help the surgeon to perform a technically demanding surgical procedure, such as laparoscopic TME, in a very precise way. However, further cadaver tests are required to prove the safety of this very promising technology before suggesting clinical trials.

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