ORIGINAL ARTICLE

Total Mesorectal Excision using a soft and flexible robotic arm: a feasibility study in cadaver models.

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Abstract

Background

Sponsored by the European Commission the FP7, Stiff-Flop project aimed at developing a STIFFness controllable Flexible and Learn-able Manipulator for surgical operations, in order to overcome the current limitations of rigid robotic technology. Herein, we describe the first cadaveric series of Total Mesorectal Excision (TME) using a soft and flexible robotic arm for optic vision in a cadaver model.

Methods

TME assisted by the Stiff-Flop robotic optic was successfully performed in 2 embalmed male human cadavers. The soft and flexible optic prototype consisted of 2 modules, each measuring 8 cm in length and 14 mm in maximum outer diameter. This was attached to a rigid shaft connected to a dexterity robot with 3 ball-shaped joints. The system was controlled by means of a double joystick. The Cadavers (BMI 25 and 28 kg/m2) were prepared according to the Thiel embalming method, which allows a lifelike texture and colour of structures with flexibility of the peritoneal membrane and internal viscera. The procedure was performed using three standard laparoscopic instruments for traction and dissection, with the aid of a 30° rigid optic in the rear for documentation.

Results

Following mobilization of the left colonic flexure and division of the inferior mesenteric vessels, TME was completed down to the pelvic floor. The Stiff-Flop robotic optic arm seemed to acquire superior angles of vision of the surgical field in the pelvis for both cases, resulting in an intact mesorectum in both cases. Completion times of the procedures were 165 and 145 minutes respectively. No intraoperative complications were recorded. No technical failures were registered.

Conclusions

The Stiff-Flop soft and flexible robotic optic arm proved effective in assisting a laparoscopic TME in human cadavers. The field of vision was superior to the standard laparoscopic vision during the TME dissection, especially low in the pelvis. The introduction of novel technology for optics and instrumentation such as soft and flexible robotic devices may aid in overcoming the technical challenges of difficult laparoscopic procedures.

Introduction

Although laparoscopic resection of colon cancer is recently gaining acceptance [1-4], the role of laparoscopy in the treatment of rectal cancer is still controversial. Excellence of surgical technique is of particular relevance in the treatment of rectal cancer. Routine excision of the intact mesorectum during resection of cancers of the middle and lower rectum has resulted in a consistent reduction of local recurrences [5] and in an increase of long-term survival rates [6]. At present, however, open surgery is considered the treatment of choice for elective rectal resection for malignant diseases.

Good-quality RCTs comparing short-term outcome of laparoscopic TME are necessary. Nevertheless, we recently published a systematic review and meta-analysis [7] of available data, which proves that on the basis of evidence of both randomized and prospective matched series, laparoscopic rectal resection appears to have clinically measurable short-term advantages in selected patients with primary resectable rectal cancer. The main finding of the cited meta-analysis was a significant reduction of mortality in the laparoscopic group as compared to the open surgery group. Furthermore, the overall incidence of postoperative complications was also significantly lower in the laparoscopic group, with a RR of 0.81. The analysis of all included studies showed a clear advantage for laparoscopy in the specific analysis of both surgical and medical complications. Therefore, it can be concluded that although technically demanding, laparoscopic rectal resection is safe and results in faster recovery. This conclusion remains accurate when the analysis is restricted to only extra-peritoneal lesions or mid-low rectal cancers [8], which entails TME with or without colo-anal anastomosis or abdomino-perineal resection with anal amputation, both approaches being even more technically challenging.

Nor laparoscopy impairs the oncologic results of surgery as we demonstrated in a further systematic review and meta-analysis [9]. Based on the evidence from the RCTs and non-RCTs examined in this systematic review, the short-term benefit and oncological adequacy of laparoscopic rectal resection appears to be equal to open surgery, with some evidence potentially pointing to comparable long-term outcomes and oncological adequacy in selected patients with primary resectable rectal cancer.

Regardless of these studies, minimally invasive surgery for rectal cancer fails to affirm its superiority in routine use due to the technical challenges that force long training, stressful procedures and careful patient selection. It has been advocated that robotic technology might be of some help in reducing challenges, and the learning curve. Short-term outcomes of the randomized controlled trial comparing RObotic and LAparoscopic Resection for Rectal Cancer (ROLARR) demonstrated no significant differences between the laparoscopic and robotic group in the conversion rates to open surgery, in intraoperative and postoperative complications, and in the rate of positive circumferential margins [10]. The results of this large randomized controlled trial suggest that the use of the current robotic technology does not help to improve the outcomes observed after conventional laparoscopic surgery.

In 2011 based on these assumptions, and taking inspiration from nature, we conceived the notion to consistently change the design of a robotic surgical instrument, taking into consideration the importance of generating a soft and flexible device, which when circumstances dictate has the necessary stiffness. Our inspiration came from the tentacles of an octopus. The project was funded by the European Commission within the Seventh Framework Programme and started on January 1st 2012.

As this project has evolved over the last four years, we developed a robotic arm containing an optical camera, with a reasonable dimension, able to be inserted through a standard 15 mm trocar to facilitate testing on a human model. To date, abdominal surgery with the aid of soft flexible robotic devices has not been described in the literature. The aim of this study is to demonstrate the feasibility of laparoscopic TME with the aid of soft flexible robotic optics in a cadaveric model.

Methods

Developing the prototype included manufacturing the flexible modules and incorporation of sensing capabilities, force feedback, navigation control, as well as user interface and advanced algorithms to enable integration of all of the above. At first, large-scale prototypes were developed in order to test the concept on bench top models. A set of STIFF-FLOP arm prototypes with a diameter size of 24 mm were manufactured, consisting of multiple soft, pneumatically actuated 3-chamber segments. Additional chambers are integrated within the segments to allow their stiffening, employing an approach based on the concept of granular jamming (Figure 1). Prototypes with two and three segments, respectively, were created and several large-scale human abdominal cavity models were manufactured for testing the system (Figures 2 and 3). The STIFF-FLOP segments are actuated using pressure regulators which are controlled by RoNeX boards (product developed during the first year of the STIFF-FLOP project to facilitate hardware integration). In a similar fashion, the stiffening chambers are interfaced via valves also controlled by RoNeX boards, applying a vacuum to the granules in the chambers which in turn generate a stiffening behaviour for the STIFF-FLOP arm.

Sensors are embedded in the STIFF-FLOP modules to measure interaction forces and the robot's configuration. In this context, each segment is equipped with a three-axis Force/Torque (F/T) sensor and a three-DoF bending sensor. To augment the pose tracking, two external sensors, a laparoscopic camera and a NDI Aurora magnetic tracker (NDI International Headquarters, Waterloo, Ontario, Canada), are employed. To this end, sets of markers are attached at various locations along the STIFF-FLOP arm. A commercial robotic arm (Schunk GmbH & Co. KG, Hamburg, Germany) is attached to the base of the stiff flop arm, outside of the abdomen, to move the stiff flop arm in and out through the trocar. Input from the magnetic trackers ensures that the pivot point of the trocar and the robotic arm are identical. This approach assures that the STIFF-FLOP arm is always advanced along the central axis of the trocar port, pitching and yawing about the trocar insertion point. Advanced control and navigation techniques have been developed and are integrated which computes the inverse kinematics for the extended kinematic chain of the Schunk arm and the STIFF-FLOP arm in real time, based on the inputs from the various sensors. This allows the surgeon to control the tip of the extended robot arm in tool space without the need to control the proximal part of the arm.

A newly developed user interface, based on a Delta robot design [11], is used to move and position the tip of the STIFF-FLOP arm inside the abdomen (Figure 4). In addition to the standard visual feedback from a laparoscopic camera, a real time 3D visualizer showing 3D views of the STIFF-FLOP modules is also available. Signals obtained from the force/torque sensors are fed back to the user interface console providing the operator with force feedback, effectively resisting the operator’s motion when the robot is in physical contact with the environment. The end effector of these prototypes was equipped with different tools, including a monopolar hook and a gripper. Successful usage of these tools in realistic environments was demonstrated.

Once functionality was proven in the ex-vivo setting, a thinner prototype capable of passing through a standard 15 mm trocar cannula was developed for experiments in human cadavers. This fully integrated prototype consists of miniature pneumatically actuated segments, a positioning device, and a camera at the tip. The consortium successfully managed to scale down the overall system dimensions to a 14.3 mm diameter soft robot, capable of being inserted into the human body via a commercially available trocar port. Scaling down the dimensions of the prototype compelled us to forgo some of the sensing capabilities, so that controlling the tip of the optics was possible by moving separately the two modules with the two separate joysticks. This included translation and bending movements in each of the 3 axis for a total of 6 degrees of freedom (DoF). Therefore, the main objective of the test was to validate that the architecture of the system was compatible with human anatomy for laparoscopic TME and to determine if the softness and flexibility of the optics could represent a potential improvement compared to standard rigid laparoscopic instrumentation.

Operative Technique

A one-day session on human cadavers took place at the Institute for Medical Science and Technology (IMSaT) of Dundee, Scotland. The aim of this session was to prove the feasibility of the use of the 14 mm STIFF-FLOP camera while performing a minimally invasive laparoscopic TME. The team of engineers installed the entire system, including the software and the STIFF-FLOP camera that was secured to the operative table by a Martin arm. The surgical team (AA, YM, MEA) used two human cadavers previously selected.

The study was performed on two cadavers prepared according to the method described by Thiel, at the Centre for Anatomy and Human Identification, University of Dundee. Briefly, the Thiel embalming method for cadaver preservation is a technique, which relies on a mixture of salt compounds and very low amounts of volatile formaldehyde and formalin which effect fixation of tissue with a number of unique properties. Cadavers preserved with this method have no detectable odour and demonstrate a lifelike flexibility of body parts, excellent colour preservation of muscle, viscera, and vasculature, and superior antimicrobial preservation properties. Due to this preservation of lifelike qualities, soft-embalmed cadavers are excellent models for training in surgical, diagnostic and interventional procedures as well as a model for research and development of new surgical devices. In our experiment, the BMI for the cadavers were 25 and 28 kg/m2 respectively.

Prior to starting the session, each cadaver was positioned and safely secured to a mobile operating table, and the all instrumentation was thoroughly checked. For the duration of surgery, the cadavers were strapped to a Maquet surgical table (Maquet Holding B.V. & Co. KG, Rastatt Germany) and draped in standard surgery gowns in preparation for the surgical intervention. At the beginning of the each test, 4 trocars were inserted: one 15-mm trocar on the median line about 2 cm above the umbilicus, through which the flexible STIFF-FLOP camera was inserted, the other three 5/12 mm trocars in the left flank, right flank and right iliac regions respectively. At that point, the consistence of both bowel and meso-colic fatty tissue was carefully checked. An additional 10 mm trocar was placed in the left upper quadrant, posterior to the STIFF-FLOP camera, to obtain an overview vision by means of a standard rigid 30° laparoscopic 10-mm camera (Figure 5). Two monitors were used to follow the procedure: one was connected to the rigid standard laparoscopic camera, while the other was connected to the flexible STIFF-FLOP camera. The gross anatomy of the abdominal cavity and the compliance of the abdominal wall to the CO_2 insufflation were evaluated.

The dissection was then initiated, using sharp scissor dissection and standard laparoscopic instruments. The dissection was carried out proximally in an infra-mesocolic dissection plane identifying the avascular plane caudal and cranial to the inferior mesenteric artery. The inferior mesenteric artery (IMA) was then divided using standard titanium clips and scissors. Then the posterior mesorectal was identified and dissection was continued in the pre-sacral avascular space to the level of the pelvic floor. The left and right iliac vessels and ureters were identified at this point. The lateral dissection plane was then thinned out with anterior blunt traction and dissection. The anterior dissection was then performed with sharp dissection posterior to Denonviliers fascia. The seminal vesicles and the right and left ureters were identified and spared from injury. The anterior dissection plane was continued laterally, further thinning out the remaining lateral stalks, taking care to preserve the lateral pelvic nerve bundles. The lateral stalks were divided, moving the optics from one side to the other, over the rectum keeping the surgical field in the optimal line of vision. The circumferential mobilization of the rectum was then completed. The integrity of the specimen, with particular attention to the mesorectal fascia, was evaluated laparoscopically.

Results

Both cadavers were operated on the same day by three surgeons, while one manipulated the STIFF-FLOP camera through a controller independently moving each of the two modules by means of a dedicated joystick. One surgeon performed the TME and one was in charge of documentation using the standard laparoscope.

The first step of the procedure included the medial dissection of the mesocolon of the sigmoid and descending colon, and the identification and division of the vessels (Figure 6). The use of the STIFF-FLOP camera allowed the surgeon to clearly visualize the inferior mesenteric vessels and the autonomic nerves that were subsequently spared from injury. After the completion of the vessel division, the sigmoid mesocolon was completely dissected. Then, the instruments were moved down to the pelvis to start the TME under direct visualization of the STIFF-FLOP camera. The surgeons performed first the posterior dissection of the mesorectum down to the pelvic floor. The ability to smoothly follow the sacral curve due to the flexibility of the manipulator and the magnified vision provided by the STIFF-FLOP camera, allowed the surgeons to perform a very precise dissection of the posterior part of the mesorectum (Figure 7). The mesorectal excision was then completed laterally on both right and left sides of the rectum as well as anteriorly (Figure 8). This step of the procedure was performed quite easily due to the flexibility of the modules that allowed the surgeons to achieve a magnified vision of the mesorectum and adjacent structures. The same procedure was performed on both human cadavers, demonstrating the ease of use of the system.

A complete TME dissection was completed in both cadavers resecting the mesorectal fascia down to the pelvic floor. The STIFF-FLOP robotic optics assured a sufficient visualization of the surgical field in both cases, so that an intact mesorectum was obtained at completion of both cases. The STIFF-FLOP robotic arm was inserted with no hesitation, through a standard 15 mm trocar and without limitation of movement in and out. The camera was cleaned approximately twice for each procedure in the standard approach i.e. taking the arm out for cleaning. Manipulation of the double joystick was achieved easily following a few minutes of practice and understanding of the movements seen first with the laparoscopic camera. Following this minimal training, manipulation was achieved without difficulty. Completion time of the procedure were 165 and 145 minutes respectively. No intraoperative complications were recorded. No technical failures were registered.

Discussion

Laparoscopic low anterior resection with TME is a feasible approach for the surgical management of rectal cancer, however it is technically challenging. Despite the evident benefits for the patient's outcome [7,8], this technique has not been generally adopted and has a limited routine application. Robotic technology, thus far has failed to deliver significant benefits in gaining better outcomes as compared to standard laparoscopy, both in terms of technical challenges for the operator and of clinical benefits for the patient [10]. Current attention is on improving training, both for standard laparoscopy and for robotics. We believe that adding the new concept of flexible robotic arms on top of the existing robotic technology, may be the impetus needed to reduce the "human" factor which influences the end results.

For this reason in 2011, we envisioned a soft and flexible robot whose characteristics should theoretically allow better flexibility in narrow spaces, such as the pelvis. The project has lasted four years, thus far, and allowed us to develop a modular technology, made of soft, flexible segments, both characterised by the capability to bend under gas inflation of dedicated chambers, as well as to become rigid due to granular jamming of dedicated chambers. All movements are piloted by means of a modified Delta robot, with a specific handle design. The STIFF-FLOP arm is designed to allow unconstrained movement of each module, if not for the fixation to the previous one, so that any spatial achievement, in the range that elongation and deflection of the modules allow, results possible. The Delta robot control allows for determination of the exact spatial coordinates the operator aims the tip of the instrument and the orientation of the tip as well, while, similar to the octopus tentacle, the shape of the arm is self-adjusted via software. This adjustment is available due to several sensors placed along the arm, which allow a fine control of the position of each module, as well as other force sensors that provide haptic feedback to the operator through the handle.

In principle, these characteristics should overcome the current limitations of the available surgical robots, which are constrained by a rigid architecture. In order to downsize the robotic arm to a standard trocar size for the cadaver study, we decided to forgo the sensing capabilities for the time being and test the concept of the soft flexible arm without the entire system capabilities. For testing, STIFF-FLOP was attached to the Schunk robot by means of a rigid shaft, and was also controlled by means of the same man machine interface. The system was tested on human cadavers to prove appropriateness of the geometry and function.

With the STIFF-FLOP arm equipped with frontal optics a TME was completed in two consecutive cases by means of standard laparoscopic instruments. In both cases the procedure lasted less than 3 hours, and neither intraoperative complications nor technical failures were registered. In particular, the capability of the STIFF-FLOP arm to enter the pelvis sliding either along the sacral bone, or getting across the rectum was appreciated, both of which are in general critical steps during a TME procedure. This unique ability allowed for close-up visualization of the surgical field by the surgeon when operating, which was more than sufficient to prove the concept and the correct geometry of the device.

The feasibility and safety of TME under soft flexible robotic optics control, has now been demonstrated in human cadavers. Compared to current minimally invasive abdominal approaches (including robotic surgery), the authors have observed improved low pelvic visualization, particularly during the posterior and left lateral dissection for TME. However, definitive conclusions for or against improved visualization are limited to this cadaveric series and will need further evaluation in a clinical setting.

The strengths and the weaknesses of the optics were discussed between the two tests and at the end of the whole session. Pros of the robotic system included good image quality and stable control of the movements of the camera using the joystick. Technical aspects requiring improvement are strictly related to device control, which needs to be more intuitive rather than using two separate joysticks. Embedding miniature sensors in this prototype, will allow the use of the modified Delta robot to control the positioning of the system, which in turn should resolve this issue. At the same time, a prototype equipped with a gripper at the tip as well as a prototype equipped with a monopolar coagulator have been developed. This would allow testing the possibility of a complete soft flexible robotic procedure, which will be attempted shortly.

Conclusions

This is the first report of a laparoscopic abdominal procedure performed with the aid of soft flexible robotic technology. The results of this session suggest that the properties of the STIFF-FLOP manipulator allows performing a technically challenging procedure like a laparoscopic TME with a high level of precision and accuracy due to the optimization of the view of the surgical field. The safety and oncologic outcomes of TME using the current platform need to be further investigated in the setting of carefully conducted human cadaver tests first followed by clinical trials.

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Footnotes

The authors have no conflict of interests to declare.

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Captions to figures

Figure 1 Computer model design of the module showing an inflated balloon resulting in deflection.

Figure 2 Two-segments STIFF-FLOP arm with embedded sensors, connected to the SCHUNK robot, equipped with IR markers, and relative AURORA tracking system.

Figure 3 Three-segments STIFF-FLOP arm with embedded sensors, connected to the SCHUNK robot.

Figure 4 Six degrees of freedom (DoF) haptic input device, based on a Delta robot design.

Figure 5 Overview vision by means of a standard rigid 30° laparoscopic 10-mm camera

Figure 6 Identification and division of the inferior mesenteric vessels.

Figure 7 The ability to smoothly follow the sacral curve due to the flexibility of the manipulator and the magnified vision provided by the STIFF-FLOP camera, allowed the surgeons to perform a very precise dissection of the posterior part of the mesorectum.

Figure 8 The mesorectal excision was then completed laterally on the right side (a) and the left side (b) of the rectum as well as anteriorly (c).