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Doctoral Dissertation
Doctoral Program in Bioengineering and Medical-Surgical Sciences (30th Cycle)

Development and applicability of a soft and flexible robotic arm in digestive surgery

By

Simone Arolfo

Supervisor(s):

Prof. Mario Morino, Supervisor
Prof. Alberto Arezzo, Co-Supervisor

Doctoral Examination Committee:

Politecnico di Torino 2017

Declaration

I hereby declare that, the contents and organization of this dissertation constitute my own original work and does not compromise in any way the rights of third parties, including those relating to the security of personal data.

Simone Arolfo

2017

* This dissertation is presented in partial fulfillment of the requirements for **Ph.D. degree** in the Graduate School of Politecnico di Torino (ScuDo)

Abstract

Introduction

The oncologic adequacy of laparoscopy in digestive surgery is still controversial, especially in some technically demanding operations like Total Mesorectal Excision (TME). Even if standard robotic platforms, i.e. the da Vinci Surgical System, can improve dexterity and manouvability of surgical instruments, there is no evidence supporting its use in digestive and rectal cancer surgery. The only multi-centre prospective RCT (ROLARR trial) suggests that robotic TME has no advantages compared to laparoscopic TME in terms of clinical and oncologic outcomes. A possible explanation of this lack of real advantages is that the articulation is possible only on the tip of the instrument. The opportunity to have a robotic platform with modular flexibility on the whole length of the arm could overcome technical limitations, improving results and allowing standardization and diffusion of the procedures.

Methods

The 7FP STIFF FLOP project was financed by the European Commission in order to develop a STIFFness controllable Flexible and Learn-able manipulator for surgical operations. Engineers were inspired by the tentacles of an octopus. A prototype was realized, consisting of multiple soft, pneumatically actuated three-chamber segments. Additional chambers are integrated within the segments to allow their stiffening, employing an approach based on the concept of granular

jamming. The STIFF-FLOP segments are actuated using pressure regulators and the stiffening chambers are interfaced via valves, applying a vacuum to the granules in the chambers. Sensors are embedded in the STIFF-FLOP modules to measure interaction forces (between the robot and its environment) and the robot's configuration. A newly developed user interface, based on a Delta robot design, is used to move and position the tip of the STIFF-FLOP arm inside the abdomen. Signals obtained from sensors are fed back to the user interface console providing the operator with force feedback. The entire soft robot is equipped with a 4 mm in diameter centre-free lumen, which allows the passage of the electrical wires needed for the laparoscopic miniaturized optic system positioned at the tip of the robot.

Phantom test

The prototype was tested in order to assess learnability and satisfaction of the operators. The test was designed as a spatial motion task, consisting of movements between predefined target points clockwise and counter clockwise in a 3D phantom of the abdominal cavity. The participants were asked to conclude the task for the first time with the STIFF-FLOP prototype (SF1), then to repeat the task using conventional laparoscopic instrumentation (LAP) and finally to perform the task once more with the STIFF-FLOP arm (SF2). Surface EMG signals from the forearm muscles were recorded during the test.

Results

SF1 took a longer time than the other tasks, i.e. 36.4% more than LAP ($p=0.0071$). However, from SF1 to SF2 there was a 32.1% time reduction ($p=0.0232$). EMG amplitude analysis showed a higher overall average muscle activity during LAP. Moving from LAP to SF2 there was a 25.9% reduction in average muscle activity ($p=0.0128$).

Cadaver test

The main objective of the test was to validate the compatibility of the system with human anatomy for laparoscopic TME and to determine whether the soft robot could represent a potential improvement compared to standard rigid laparoscopic instrumentation. The study was performed on two cadavers prepared according to the method described by Thiel.

Results

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. The ability to smoothly follow the sacral curve due to the flexibility of the manipulator allowed the surgeons to perform a very precise dissection of the posterior part of the mesorectum. The same procedure was performed on both human cadavers, demonstrating the ease of use of the system. Completion times of the procedure were 165 and 145 min, respectively. No intraoperative complications were recorded. No technical failures were registered.

Conclusion

The STIFF FLOP flexible robotic arm is an intuitive technology that can be easily learned. The prolonged use of the STIFF FLOP manipulator is more comfortable than standard laparoscopic instrumentation and can be used for a long time without exhaustion. The system is compatible with human anatomy and allows to perform a standard surgical abdominal operation. The STIFF FLOP arm seems to improve visualization of the operatory field especially in narrow spaces like the pelvis.

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Chapter 1

History and State of the Art of Robotic Surgery

1.1 History

Robotic surgery represents a technological phenomenon. The diffusion of surgical robotic platforms increased during the last 10 years, between consensus and criticism among surgeons. The term robotic surgery, even if currently used, is actually not correct and should be replaced by "telepresence surgery". In this type of surgery the surgeon is physically separated from the patient. He can't see the patient under direct vision, but only through an artificial image generated by a stereoscopic camera introduced in patient's abdomen or thorax [1]. The concept of telepresence surgery was developed for the first time for military purposes, to minimize combat deaths [2]. On the battlefield, 90% of all deaths occur before the soldier reaches a medical facility [3, 4], so US Army tried to produce a platform allowing surgeons to immediately operate wounded soldier from a remote secure

location [5]. The first prototype was designed for open surgery: 2 cameras were placed above the patient in the operating room projecting an image to the surgeon, who could operate through a console connected to a 2 arms telerobot reproducing his movements [6]. Once the feasibility of telemanipulation was shown, the potential of surgical robotic arms with degrees of freedom similar to human hands and easily manipulated by an intuitive console was thought as a possible technical solution to the limitations of conventional laparoscopy. Rigid laparoscopic instruments offer only four of the six degrees of freedom required for the free handling of objects in space. At the beginning of the 1990s Buess and coworkers designed and developed a master-slave manipulator system called ARTEMIS (Advanced Robotic Telemanipulator for Minimally Invasive Surgery) for laparoscopic surgery as a prototype. The system consisted of two robotic arms holding two steerable laparoscopic instruments. These two work units were controlled from a console equipped with two master arms operated by the surgeon. The placement of ligatures and sutures and the handling of catheters were possible in phantom models and the surgical practicability of the system was demonstrated in animal experiments [7-9]. The development of the system was abandoned for lack of investments as it was not clear at that stage of development, the real worth of such an effort.

In 1989, Yulun Wang founded his own company with funding from the U.S. government and private industry. Computer Motion Inc.[®] launched AESOP[®] (Automated Endoscopic System for Optimal Positioning) [10], a robotic telescope

manipulator, and the robotic surgical system ZEUS[®] [11]. Food and Drug Administration (FDA) approved for use AESOP in 1994 and ZEUS in 2001 to assist in the control of blunt dissectors, retractors, graspers, and stabilizers during laparoscopic and thoracoscopic surgery. ZEUS had three robotic arms mounted on the operating table. One robotic arm called AESOP was a voice-activated robot used to hold the endoscope; the other two arms of ZEUS were the extension of the left and right arms of the surgeon. Surgeons sat at a console and wore special glasses that created a three-dimensional image. After FDA approval the possibilities of remote telepresence surgery were tested by J. Marescaux, who performed a transatlantic cholecystectomy using ZEUS surgical System [12-14].

Intuitive Surgical Inc.[®] developed a telepresence surgery device suitable for minimally invasive surgery: the da Vinci System, that was tested for the first time in humans in 1997. FDA approved the da Vinci in July of 2000, requiring surgeons perform telerobotic operations within the same operating room as the patient.

Competition between Intuitive Surgical Inc. and Computer Motion Inc. began to increase, as the market became ready to adopt surgical robotic technology. After several legal proceedings for patent infringement from both sides, in March 2003 the two companies announced that they were merging into one company combining their strengths in operative surgical robotics, telesurgery, and operating room integration, to better serve hospitals, doctors and patients. The ZEUS

Robotic Surgical System was then discontinued and the da Vinci System remained the only surgical platform available on the market. The system includes three main features: a console/slave system providing intuitive control of seven degrees of freedom laparoscopic instruments, a stereoscopic vision system and a system architecture composed of redundant sensors to warrant maximum safety in operations. To facilitate telepresence surgery, the computer console purposely isolates the surgeon from his environment. As the surgeon inserts his head into the viewing area he descends into the virtual 3D operative field and, whenever he removes his eyes from the binoculars, an infrared beam deactivates the robotic tower. The surgeon's fingers are inserted into freely moving rings that convert the 3D motions of the surgeon's hands into electrical signals. The computer translates these electrical signals into computer commands directing the robotic instruments to perform identical 3D movements. Robotic tower positioning and robotic instruments changing require the presence of an assistant surgeon at the operatory table. Several technological improvements have been developed during the last 15 years. The da Vinci Si introduced 3D HD vision and an integrated fourth arm. The da Vinci Si was launched in April 2009 and introduced several enabling features, including enhanced high-definition 3D vision and dual-console capability to support training and collaboration during minimally invasive surgery. The fourth generation of Intuitive robots is the da Vinci Xi. It combines the functionality of the previous system with the flexibility of a mobile platform. The surgical cart can be placed at any position around the patient allowing for four-quadrant access and

redesigned thinner arms offer greater range of motion. The scope can be placed on any of the four arms, allowing more flexibility in surgical site identification. With these improvements docking is faster and conflict among arms significantly reduced.



Figure 1 The da Vinci Xi surgical system

The main drawbacks to this technology are the steep learning curve, shorter for experienced laparoscopic surgeons, and the high cost of the device. One of the greatest technical problem is the loss of tactile, or haptic, sensation (ability to “feel” the tissue). In laparoscopic surgery surgeons handle tissues with lap instrumentation directly feeling intrinsic resistance or pathologic features. Besides technological improvements, lack of precise tactile feedback remains a critical issue concerning this kind of technology.

1.2 State of the Art in Digestive Surgery

Laparoscopic surgery represents a revolution for surgeons and patients. Several trials clearly showed feasibility and safety of the technique and short term functional and oncologic results are comparable to open surgery for the majority of abdominal cancers. Post-operative course is dramatically shortened and cosmetic results significantly better. Laparoscopic surgery requires high technical skills and learning curves are very long. After 25 years of laparoscopic and 15 years of robotic surgery the question is: does robotic surgery represent a revolution for surgeons and patients? Concerning general surgery the answer is: may be for surgeons, probably not for patients. Surgical stress, post-operative course, functional and oncologic outcomes and cosmetic results are comparable. Unfortunately evidence from literature is quite weak, so it is very difficult to precisely establish the real impact of robotic surgery on public health, besides its high costs.

1.2.1 Minimally Invasive Esophagectomy

Robot assisted minimally invasive esophagectomy (RAMIE) has been reported to be safe and feasible with good short term oncologic results by several groups [15], but randomized controlled trials are still lacking. In large reported series, it seems that some complications occur more often after RAMIE than after Minimally Invasive Esophagectomy (MIE) or open surgery [16], but the level of evidence is very low and this moment no conclusion can be drawn. Pulmonary complications could be reduced by shortening operating time, which is actually

quite long compared to operating times of the teams very experienced in MIE [17]. The main technical advantage advocated by experts is the possibility to perform an accurate lymphadenectomy of the upper mediastinum, that is very uncomfortable both in MIE and open surgery [18].

1.2.2 Minimally invasive antireflux surgery

Since 2001, several papers have been published on robot assisted hiatal hernia repair and antireflux surgery, including 5 RCTs [19-23]. General consensus among all publications is that there is no advantage in using the da Vinci robot in primary hiatal hernia and antireflux surgery. Operating time and costs are significantly higher with no differences in post-operative outcome, complication rate, conversion rate, quality of life, duration of hospital stay or post-operative morbidity. In experts' opinion robotic technology might only be beneficial for large and giant hiatal hernia repair and in redo antireflux surgery, but further studies are needed to show it [24].

1.2.3 Minimally invasive radical gastrectomy

Robotic gastrectomy for cancer is considered to have little benefit compared with laparoscopic surgery, at least for the current indications of minimally invasive surgery for gastric cancer. It represents a safe and feasible alternative to laparoscopic surgery, but the real benefits remain unclear and should be investigated using well-designed prospective studies before the indications for robotic surgery for the treatment of gastric cancer are expanded [25].

Concerning robot assisted bariatric surgery, literature is controversial with a low level of evidence. No conclusions can be drawn about the real advantages of robotic platform both in sleeve gastrectomies and gastric bypass. Despite the lack of data there has been a steady increase in the number of surgeons using robot to perform weight loss surgical procedures [26], and it's hopeful that more high quality papers will be published to better define the correct indications.

1.2.4 Minimally invasive hepatic and pancreatic surgery

There are no prospective studies investigating the impact of robotic surgery in hepatic resections. Therefore, it is difficult to draw any definitive conclusions at this time with regard to overall efficacy and benefits in both immediate (length of stay, postoperative pain, morbidity, mortality, and cost-effectiveness) and long-term (quality of life, oncologic recurrence) patient outcomes [27]. Existing data are promising and warrant further investigation, especially for major hepatectomies.

Laparoscopic surgery has been relatively slow to be adopted in pancreatic surgery. This is mainly true for pancreatoduodenectomy (PD), an operation requiring high surgical skills both in dissection and reconstruction steps. On the other side, laparoscopic distal pancreatectomy (DP) gained large consensus and is currently performed by several pancreatic surgeons. Robotic surgery may assist the surgeon in overcoming many of the obstacles to the widespread application of laparoscopic pancreatic surgery. Only few series of robot assisted PD and DP

from high volume centres have been published with encouraging results [28], but high quality prospective data are not available.

1.2.5 Minimally invasive colo-rectal surgery

Robotic colon resections can be performed safely, with good short-term post-operative outcomes [29]. There is only a randomized study comparing laparoscopic and robotic right hemicolectomy [30]. Estimated blood loss, conversion rate, length of stay, surgical complications, postoperative pain, resection margins and lymph node clearance were similar. However, the robotic group was associated with a significantly longer operative time, and an approximately 16% higher total hospital cost. A meta-analysis including this study and 6 retrospective series showed reduced estimated blood loss, reduced postoperative complications, longer operative time and a significantly faster recovery of bowel function in the robotic group. There were no differences in the length of hospital stay, conversion rate to open surgery, anastomotic leak or bleeding [31]. Robotic left colectomy and sigmoid resections have been only investigated by retrospective studies [32-36], showing good short-term results with a low level of evidence. In conclusion there is no evidence that robot assisted colon resections present significant advantages compared to laparoscopic technique.

The situation is relatively similar for rectal surgery. Even if many surgeons consider robotic platform a very useful tool in rectal cancer surgery, there is no

evidence in literature confirming this suggestion. A pilot RCT including only 36 patients concluded that meso-rectal excision was performed safely and effectively using the da Vinci Surgical System and the perioperative outcomes were acceptable [37], but it was underpowered. Two meta-analyses revealed a significant difference in favour of laparoscopic procedures regarding costs and operating time and in favour of robotic surgery concerning morbidity rate, although no benefits were documented when analysing exclusively randomized trials [38]. Furthermore robotic surgery had lower conversion rate to open surgery, a shorter time to first flatus and better recovery in voiding and sexual function [39]. Case series, comparative and multi-centre studies have revealed that implementation of robotic technology is feasible, effective and safe for rectal cancer [40]. However, the only multi-centre prospective RCT (ROLARR trial) [41] comparing robotic and laparoscopic rectal resections failed to demonstrate the superiority of robotic approach. The study compared robotic and laparoscopic rectal anterior resections and abdomino-perineal excision for cancer and enrolled 466 patients. The primary outcome was conversion to open laparotomy. Secondary end points included intraoperative and postoperative complications, circumferential resection margin positivity (CRM+) and other pathological outcomes, quality of life (36-Item Short Form Survey and 20-item Multidimensional Fatigue Inventory), bladder and sexual dysfunction (International Prostate Symptom Score, International Index of Erectile Function, and Female Sexual Function Index) and oncological outcomes. Conversion rate

was 12.2% in lap group and 8.1% in robotic group, showing no significant differences. No statistically significant differences were found in all tested outcomes. Authors conclude that robotic-assisted laparoscopic surgery, when performed by surgeons with varying experience with robotic surgery, does not confer an advantage in rectal cancer resection. There are three others RCTs comparing laparoscopic and robotic rectal resections registered on clinicaltrial.gov and coordinated by three Asian University Centres [42, 43, 44]. Data will be available in 2018 and 2019.

1.2.6 Minimally invasive hernia repair

There is a moderate interest and diffuse scepticism among surgeons in robotic inguinal hernia repair by trans-abdominal approach. Currently in the published literature the vast majority of experience in robotic inguinal hernia repair has been done by urologists, who have dealt with this clinical entity while performing robotic assisted radical prostatectomy. They have done this without reporting an increase in morbidity rates when compared to robotically assisted radical prostatectomy alone [45]. There still does not exist a reported case series of robotic inguinal hernia repair from a general surgery standpoint [46].

1.3 In Closing

The concept of tele-presence surgery has been developed and moved to minimally invasive surgery, in order to overcome technical limitations of conventional laparoscopy. The only robotic platform for surgery commercially

available today is the da Vinci system, that widely spread in the US, Europe and Asia despite the extremely high costs. Even if robot assisted surgery represents a fascinating technology, after 15 years of practice a scientific validation is mandatory. As explained above, at least for digestive surgery procedures, literature is scarce and with a very low level of evidence. Nowadays, the only conclusion the surgical community can draw is that the da Vinci robot is very expensive, but adds no benefit to conventional laparoscopy. For general surgeons skilled in laparoscopic techniques, robotic procedures are considered time consuming, with short term outcome comparable to laparoscopic operations as shown by the few RCTs published. The marketing strategies of Intuitive have a huge impact on media, so that patients are attracted by this technology and search for "robotic" hospitals and surgeons. It is difficult to predict if National Health Systems could sustain the costs of robotic surgery, especially considering the real advantages provided by the da Vinci. At the same time there is no discussion that the future of surgery is in large areas of interest linked to the development of specific robotic systems to aid the surgical action. Flexible robotic arms or miniaturized robotic platforms represent ongoing challenges in the development of new systems and will probably enhance the advantages of robotic technology in the surgical field. More than on robots to facilitating current surgical indications, we should concentrate on robots allowing organ sparing surgery performed in a minimally invasive way. In order to achieve this, miniaturization, flexibility and sensing are the three challenges we have to face.

Chapter 2

A new Surgical Soft Robotic arm

2.1 Nature inspired concept

The lack of evidence of a real benefit in using a "stiff" robotic technology, pushed to find a different solution, taking inspiration from nature. The project, called STIFF-FLOP (STIFFness controllable Flexible and Learn-able Manipulator for surgical OPERations), was funded by the European Commission within the Seventh Framework Programme. The concept of a soft and flexible robotic arm was inspired by the octopus. This strange animal has no rigid structures in his body and the softness of its tentacles allow to squeeze and pass through narrow holes. At the same time tentacles can elongate, bend and stiffen, by means of a complex neuro-muscular network. The possibility to include all these features in a robotic arm could really



Figure 2 The STIFF-FLOP logo

improve surgical performances, but requires the development of new hardware and software concepts, materials, sensors, actuators and control schemes.

2.2 Actuation

The new surgical arm should include the following characteristics: it should be thin, flexible, have multiple degrees of freedom, with the possibility of elongating for reaching all areas of the surgical field and the capability to stiffen on demand. A modular structure is proposed: each module is able to provide all the functionalities in terms of movements and stiffening capabilities. Multiple modules can be combined in order to realize complex behavior: this would allow to hold, for example, an organ with the proximal module and to use the distal one to perform a delicate surgical task. The technical solution chosen to realize the robotic arm is based on the physical phenomenon of granular jamming. It consists in a sort of phase change of the granular matter when an external stimulus occurs: temperature, shear stress, or an increase of the density of the system (i.e., compacting the granules) [47]. In robotic applications, a flexible membrane containing granular matter is vacuumed to increase granular density and induce jamming. The vacuum level modifies the density, so that the particles can behave like a liquid or a solid. A stiffening mechanism based on granular jamming was selected because it can be easily integrated in soft membrane built modules and undergo shape modifications. Furthermore, granular jamming-based stiffening mechanisms provide variable stiffness range, fast activation, easy fabrication, and typically limited production costs. Due to these characteristics, granular jamming

has been integrated into medical and robotic devices such as grippers [48], manipulators [49], locomotion robots [50], variable stiffness endoscopes [51], and variable stiffness joints [52]. The combination of pneumatic actuation for obtaining bending and elongation and granular jamming for varying the stiffness represents the final solution adopted. The flexibility of fluidic chambers enables the possibility to bend the manipulator in each direction, while the granular jamming-based mechanism allows the transition from completely floppy and highly squeezable to stiff structures, which are able to produce relatively high forces [53].

The prototype of module consists in an elastomeric cylinder containing three fluidic chambers equally spaced in a radial arrangement. In order to limit the radial expansion of the chamber when inflated, the cylinder is surrounded by a crimped sheath, allowing an effective and controllable motion of the actuator. When the pressure changes in the chambers, the actuator is able to perform different movements. If only one or two chambers are actuated, the result is a bending. When all the three chambers are actuated at the same time, the result is a pure elongation of the module (Figure 3). The 3 stiffening chambers are composed of a latex membrane filled with coffee powder and are inserted between the fluidic chambers. Coffee powder was used since it has been demonstrated in previous studies to perform well as a granular material [54]. Jamming is induced by increasing density in the flexible membrane because of the applied vacuum.

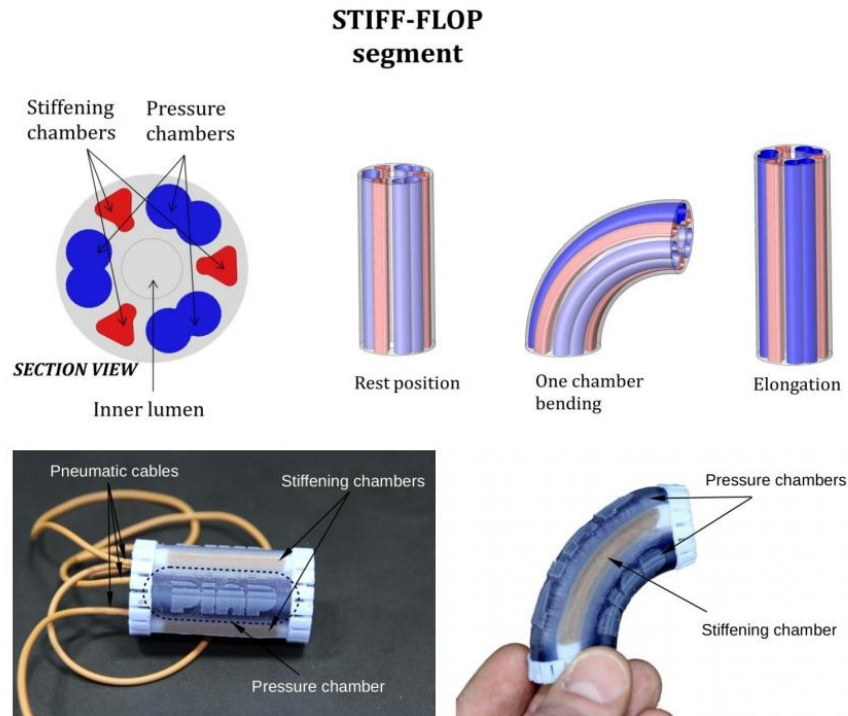


Figure 3 STIFF-FLOP segment design

By controlling the vacuum level, the stiffness can be tuned. A modular architecture has been pursued, in order to obtain the higher flexibility and versatility.

In the initial prototype every segment had a diameter of 24 mm. Prototypes with two and three segments, respectively, were created and several large-scale human abdominal cavity models were manufactured for testing the system (Figure 4). The final model was a realistic representation of the abdomen whose proportions were derived by multiple CT scan reconstructions (Figure 4C).

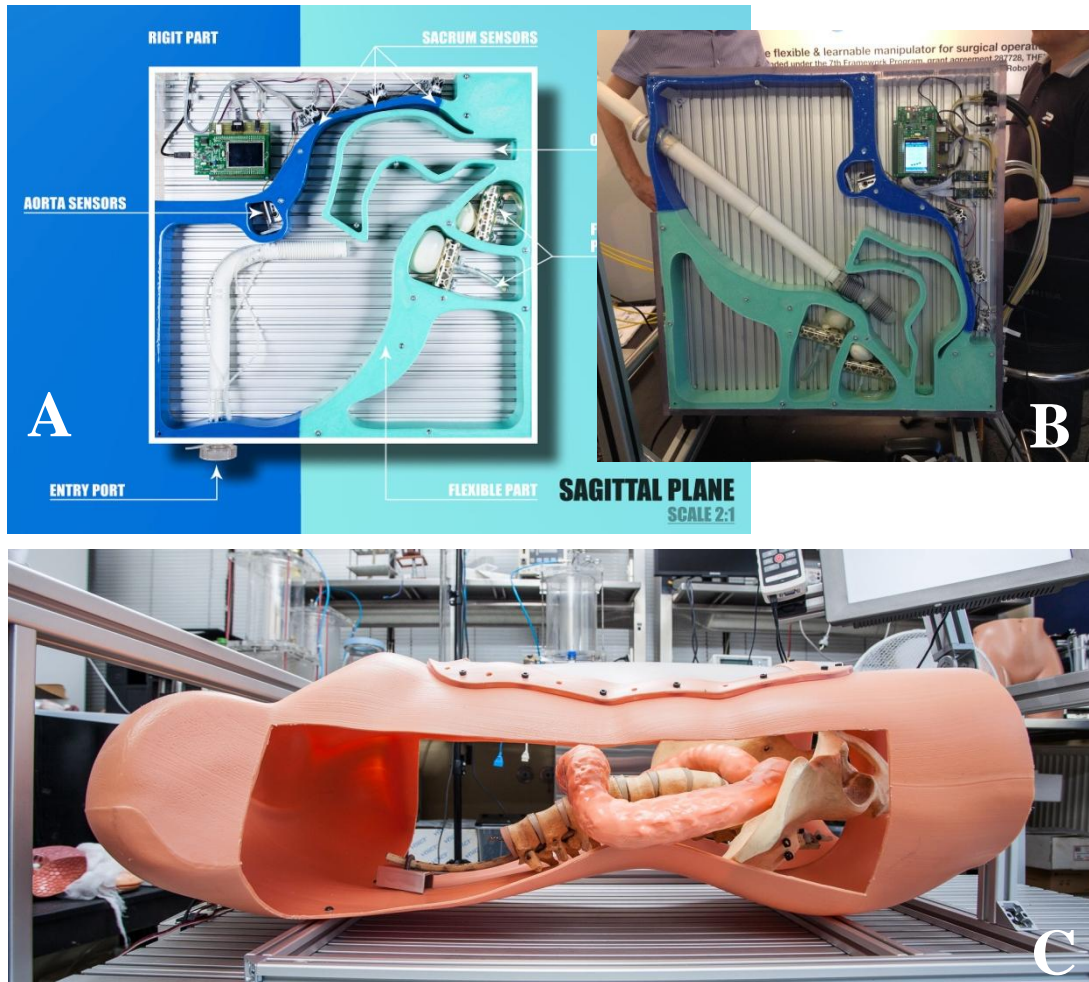


Figure 4 2:1 scale human abdomen models. A: project of a 2D model with sensors embedded for preliminary tests. B: Setting of the manufactured model for tests. C: 3D human abdomen model with realistic representation of bones and viscera derived from a CT reconstruction

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 (see Chapter 4).

2.3 Sensors

The use of a soft robotic manipulator for surgical purposes implies safety issues. When the arm is introduced through narrow spaces, it will inevitably contact with the internal organs. Thus a sensor which can measure the interaction forces between the robot and the organs is mandatory for improving the safety of steering a flexible robot. Usually multi axial force sensors are made of metal components and employ strain gauges driven by electrical circuitry. These sensors make the robotic arm vulnerable to magnetic or electrical fields, routinely employed during laparoscopic operation (coagulation streams). Furthermore this class of sensors does not allow the passing through of cables and tubes needed for a fully-functional surgical device. To overcome the lack of body contact sensing, a new sensor was developed, able to provide the contact location along the sensor outer surface and the direction and magnitude of the normal contact force [55]. This new sensor is based on a fibre optic sensing approach [56-59], which is safe and easily compatible with intra-operative imaging systems. A ring-shaped multi-axis force sensor (Figure 4) has been designed and implemented allowing the passage of cables and pipes for pneumatic actuation from the base to the tip of the robotic arm.

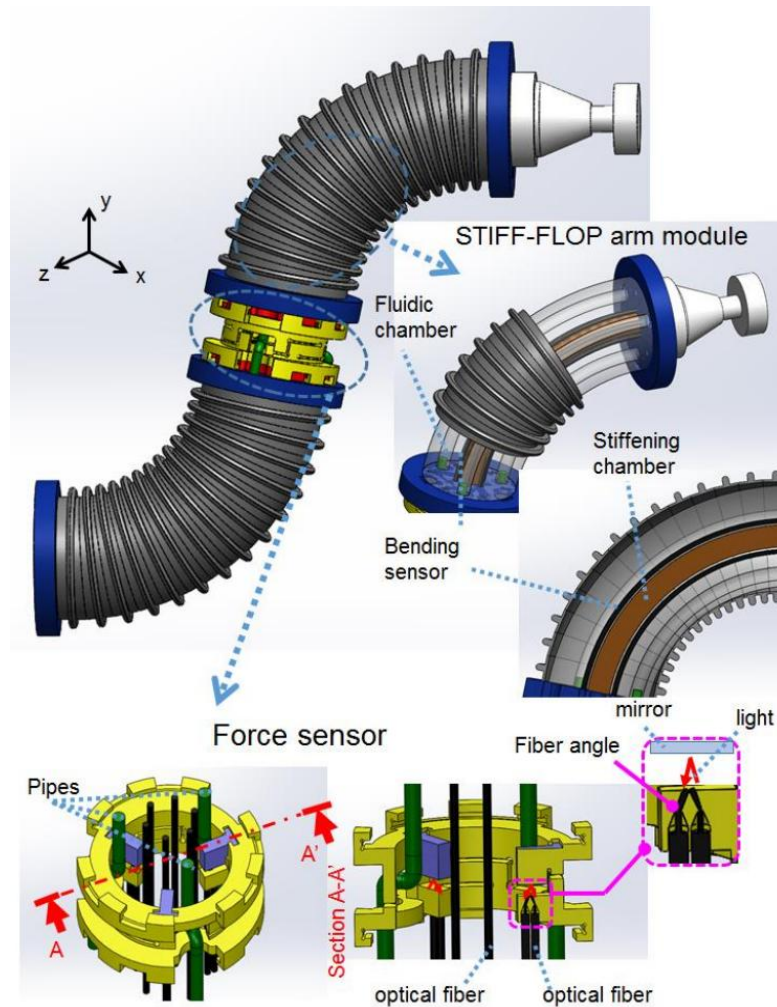


Figure 5 STIFF-FLOP arm with integrated sensors [55]

Sensors were embedded in the STIFF-FLOP modules to measure interaction forces (between the robot and its environment) and the robot's configuration. In each segment of the arm a three-axis force/torque (F/T) sensor and a three degrees of freedom bending sensor were integrated.

2.4 Control

A newly developed user interface, based on a Delta robot design [60-61], is used to move and position the tip of the STIFF-FLOP arm (Fig. 5). The visual feedback is warranted by a standard laparoscopic camera. Signals obtained from the F/T 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.



Figure 6 Input device, based on a delta robot design

Chapter 3

Phantom tests

Part of the work described in this chapter has been also previously published in:

Shafti A, Andorno F, Marchese N, Arolfo S, Aydin A, Elhage O, Noh Y, Wurdemann HA, Arezzo A, Dasgupta P, Althoefer K. Comfort and learnability assessment of a new soft robotic manipulator for minimally invasive surgery. Conf Proc IEEE Eng Med Biol Soc. 2015: 4861-4

3.1 Surgeon's perspective: need of objective tests

The development process of the prototype described in the previous chapter is fascinating from a purely scientific point of view, but the aim of the project is to realize a useful tool able to improve surgical performances in minimally invasive surgery. Since the first prototype of 24 mm in diameter was available, ex vivo tests sessions performed by expert and novice surgeons were organized, in order

to assess learnability and satisfaction. The purpose was to test how easy it was for participants to use STIFF-FLOP the first time they encountered it and how comfortable did they find its use. This kind of test is purely qualitative and extremely influenced by the experience and the background of surgeons. Its only utility is to give an initial and generic approval rating among surgeons, but the lack of measurable outcomes makes it useless for scientific purposes. Usually, studies investigating comfort and ergonomics in surgical activities are built on video monitoring and questionnaires. One of the most used index is the Borg scale. The Borg RPE scale is a scale for ratings of perceived exertion (RPE). It is a tool for estimating exertion, breathlessness and fatigue during physical work [62]. Even this method is subjective, while comfort and efforts involved in a task should be assessed objectively, in order to provide referable and trusted results. That is why in our study, aside from timing, video monitoring and questionnaires, we relied mainly on our purpose-built electromyography (EMG) acquisition system to record muscle activity from participants. EMG refers to the collective electric signal from muscles, which is controlled by the nervous system and produced during muscle contraction. The signal represents the anatomical and physiological properties of muscles; in fact, an EMG signal is the electrical activity of a muscle's motor units [63]. Changes in EMG signals reflect muscle activity during surgical tasks and represent an objective measure of fatigue. Thus it can be used to assess the comfort of the new soft robotic arm prototype.

3.2 Methods

The aim of the tests was to assess the arm prototype built with 2 segments of 24 mm in diameter for learnability and satisfaction. A spatial motion test consisting of movements between predefined target points was designed. A 3D phantom of the abdominal cavity, whose proportions were derived by multiple CT scan reconstructions, was specifically designed and created (Figure 4C). The phantom was scaled 2:1 because the prototype tested was larger than the final laparoscopic size. Figures 7 and 8 show the test set up. Three points were marked in the phantom, the first one on the right iliac wing (A), the second one on the sacral promontory (B) and the third one on the distal part of the sacral concavity (C). Points A, B and C were located in a circular (diameter \approx 20cm) pattern, at 120 degree intervals.

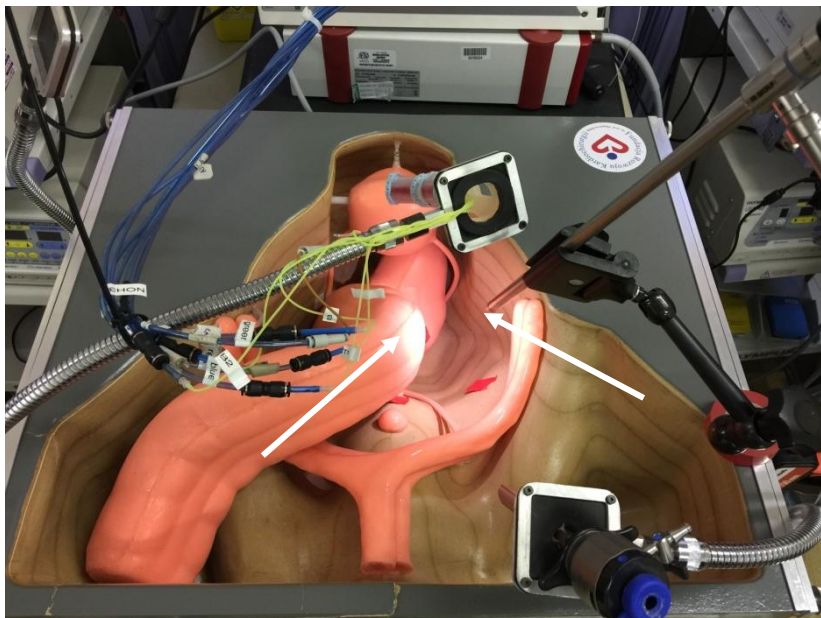


Figure 7 Test setting; view of the abdomen model. Arrows indicates marked points for the task

A standard 0 degrees laparoscopic camera pointed on the pelvis was secured to the phantom with a Martin arm and connected to a standard laparoscopic tower. A 5 mm trocar was secured to the phantom by means of a second Martin arm allowing a pivotal point mimicking a real laparoscopic operation. The trocar was used to introduce a standard laparoscopic grasper to perform the laparoscopic tasks. The STIFF-FLOP arm was secured as well to the phantom and introduced in the pelvis. Once the setup was completed the phantom was covered so that participants could only see the image of what they were doing on the monitor, like in a real minimally invasive operation.

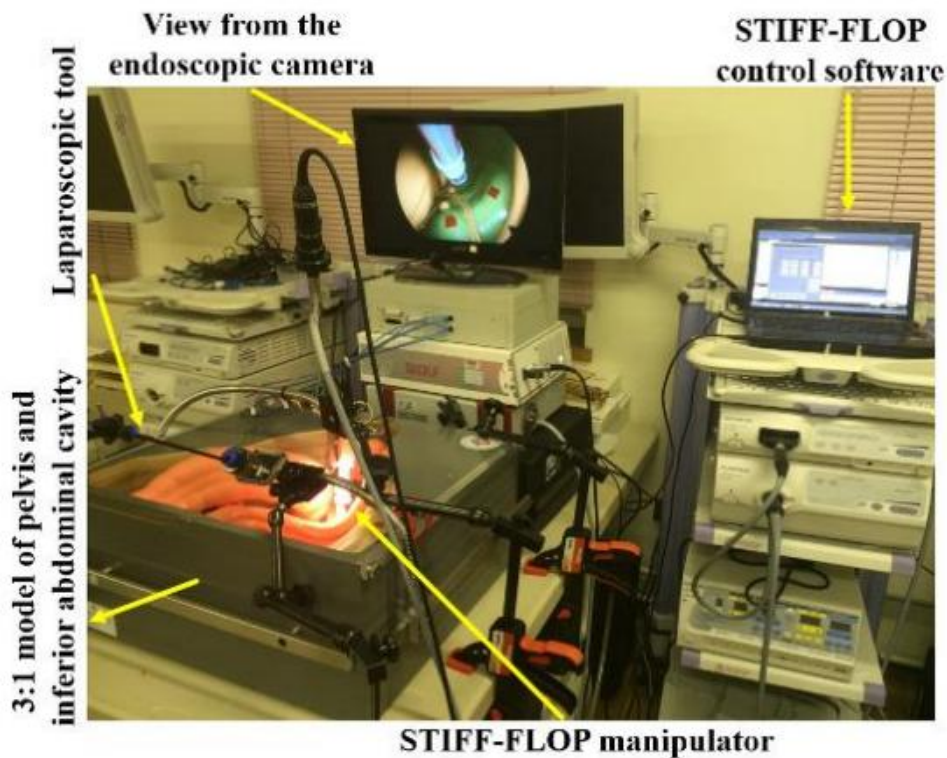


Figure 8 Test set-up

Every participant executed the first task with the STIFF-FLOP prototype, starting from the marked area to their right (point A) and moving on to the next points in a clockwise direction (points B and C consecutively). At each point, the participants had to press a button on the controller 2 times. They were then asked to repeat the task in a counter clockwise direction (A to C to B). The same task was then repeated using a conventional laparoscopic tool (grasper). The participants would move the tool to the same marked areas and in the same directions as before. At each marked area they now had to open and close the laparoscopic grasper 2 times, to mimic the button-press action on the controller. Once the laparoscopic task was finished, the participants were asked to perform the STIFF-FLOP task once more. Number of trials per participants is limited to this as the study involves learnability and how fast the user can adapt to the new tool during the first encounter. Time spent on each task was recorded. The camera view for each participant was recorded for the duration of all tasks. Surface EMG signals from the flexor and extensor muscle groups in the forearm were recorded during the test.

At the beginning of the study, participants were asked to perform 3 sets of maximum contractions on these muscles in a static position. This provides a measure of their maximum voluntary contraction (MVC) which can be used for normalisation during signal processing. Normalisation of the EMG signal to each participant's MVC will allow a fair comparison between different participants of different ages, muscle sizes and skin types.

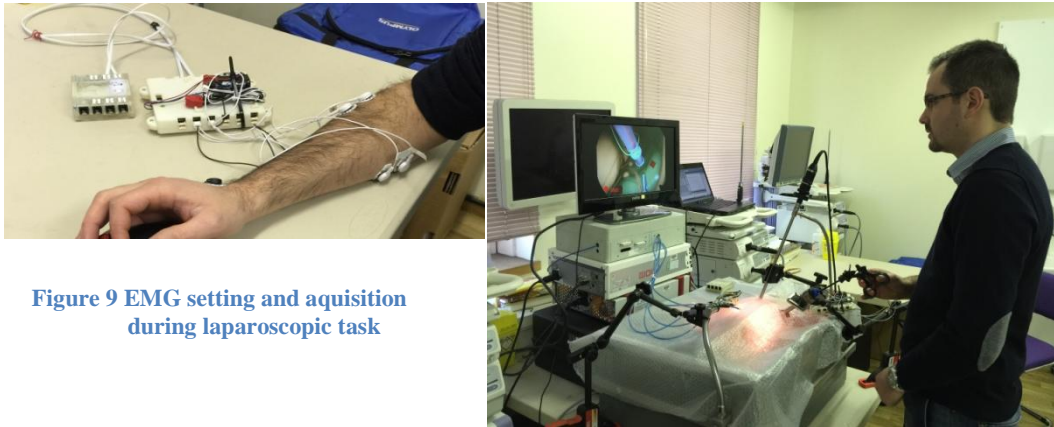


Figure 9 EMG setting and acquisition during laparoscopic task

EMG signals and elapsed time were recorded concurrently when the participants performed the tasks: MVC, 1st STIFF-FLOP trial (SF1), Laparoscopic trial (LAP) and the 2nd STIFF-FLOP trial (SF2). Figure 10 shows the custom built surface EMG acquisition system being used during the laparoscopic tasks.

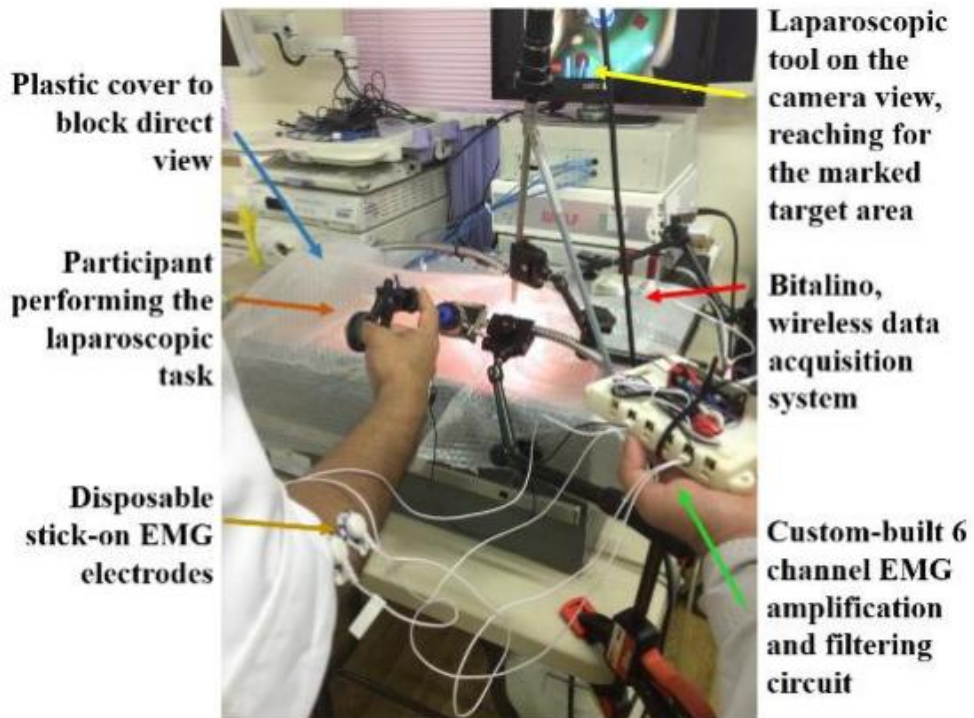


Figure 10 EMG acquisition during the test

The participants finally filled a questionnaire about their experience. This involved statements regarding ease of use, exhaustion during use and ergonomity to be rated from 1 to 5, with 1 meaning “strongly disagree” to 5 meaning “strongly agree”. These are to provide a subjective assessment of the system to use alongside the objective results from the EMG measurements.

STIFF-FLOP TEST FEEDBACK

ID: _____

Please, tell us about your experience with the manipulator utilized in the exercises we asked you to perform, by completing this brief survey.

Think about the manipulator use, rate how much you agree or disagree with the following sentences

(1: strongly disagree; 5: strongly agree)

STIFF-FLOP test feedback	1	2	3	4	5
1. The STIFF-FLOP manipulator was easy to use					
2. The weight of the STIFF-FLOP manipulator is adequate to its clinical use					
3. While using the STIFF-FLOP manipulator I felt mentally tired					
4. While using the STIFF-FLOP manipulator I felt physically tired					
5. The robotic interface is intuitive					
6. The robotic interface is ergonomic					

Laparoscopic test feedback	1	2	3	4	5
1. The laparoscopic instrumentation was easy to use					
2. The weight of the laparoscopic instrumentation is adequate to its clinical use					
3. While using the laparoscopic instrumentation I felt mentally tired					
4. While using the laparoscopic instrumentation I felt physically tired					
5. The laparoscopic interface is intuitive					
6. The laparoscopic instrumentation is ergonomic					

Thank you for completing the survey

Figure 11 Questionnaire

The tests were performed at the Sherman Education Centre, Guy’s Hospital, London. Ethical approval was previously obtained for these tests (reference number BDM/13/14-123).

EMG signal acquisition was achieved by means of a 6 channel circuit specifically designed and built for this study. After a series of specific filters, the signal was passed on to the analogue input ports of a Bitalino microcontroller system, which sampled the signal at 1 kHz and transmitted it wirelessly using Bluetooth to a nearby computer. The computer was then able to display the signal and record it in real-time. Recommendations from SENIAM (Surface ElectroMyoGraphy for the Non-Invasive Assessment of Muscles – SENIAM.org) were used during system design and use. The signal recorded on the computer was a raw EMG signal. During the MVC task, the maximum absolute value of the raw EMG signal was identified and used to normalise the signal. The signal is then high-pass filtered using a 4th order Butterworth filter with a cut-off frequency of 20Hz to remove any remaining effect of the participant's arm movement and other artefacts. In order to acquire a linear signal envelope, the sliding root mean square method was used. Root mean square (rms) is defined as the square root of the mean of the squares of a sampled signal and is a measure of the signal's power. The sliding rms is done by selecting a small window of the signal and calculating the rms value for it. The window is then advanced slightly forward and the rms is calculated again. Employing an appropriate window length will result in a time varying rms for the signal, which can be used as a linear envelope. A 200 msec window was used for this procedure. Apart from the amplitude analysis, a frequency domain analysis was also performed on the signals. The median frequency (MF) of the signal spectrum was defined as the point in the frequency

spectrum that divides it into two parts of equal power. If the MF is obtained as a function of time it will effectively describe the shift in EMG frequency throughout a certain task. A time varying MF can be obtained by calculating the MF for smaller sliding windows of the signal. To compare different participants we looked at the variation of their muscles' MF while they were performing the prescribed tasks. During an isometric contraction, a decrease in the median frequency would represent fatigue. For our experiments, we were particularly interested to extract the firing rate from the recorded signals. When comparing two participants, the one with less variation in their firing rate, was assumed to move the tool in a more steady and more controlled manner. The coefficient of variation (CV) was used to assess this. The CV is defined as the ratio of the standard deviation to the average of the data and it is used as a measure of dispersion. All variables were analyzed using the t-test; all reported p-values were two-sided, at the conventional 5% significance level.

3.2 Results

A total of 25 participants were tested consisting of 8 experts and 17 novices. Experts were defined as those with combined number of laparoscopic and endoscopic procedures of at least 500. The rest of participants were categorised as novices. The first variable analyzed was time spent to conclude a task. SF1 took in average a longer time than the other tasks, i.e. 36.4% more than LAP ($p=0.0071$). However, from SF1 to SF2 there was in average a 32.1% reduction of

time spent by participants ($p=0.0232$). Results follow the same pattern when looked at for novices and experts specifically, but times were generally longer for experts (Figure 12).

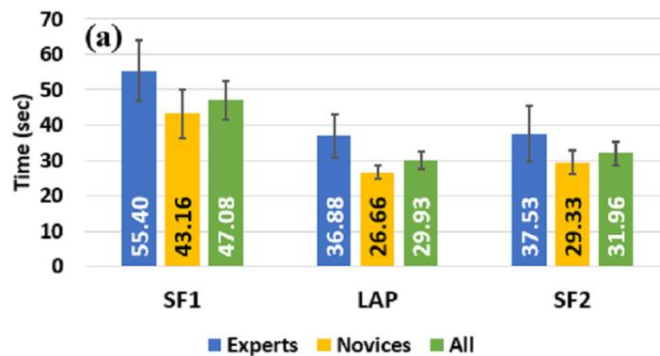


Figure 12 Mean time spent on different tasks with standard deviation

EMG amplitude analysis showed a higher overall average muscle activity during LAP. Moving from LAP to SF2 there was a 25.9% reduction in average muscle activity ($p=0.0128$). Results follow a similar trend in experts and novices, as showed in Figure 13. The EMG recording for one expert participant was corrupted and therefore 24 participants were included in the analysis for EMG results. Experts tended to perform directed procedures at lower paces to retain precision. This could explain differences in timing and muscle activity of the two groups.

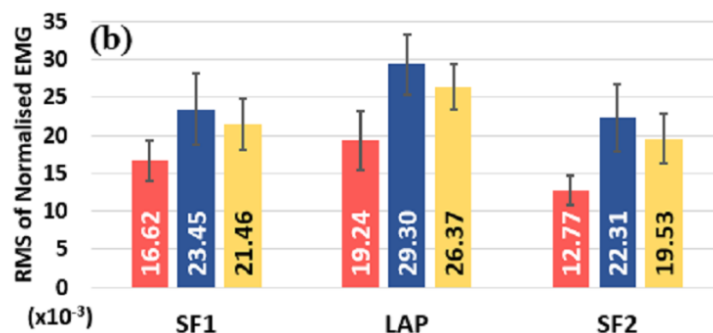


Figure 13 Average root mean square (RMS) EMG levels for the flexor muscle group during different tasks with standard deviation

In case of frequency analysis for EMG, changes in median frequency were considered. CV was calculated for all participants and tasks as described above. Figure 14 shows the comparison for an average CV in median frequency for the flexor muscle. Results show small differences in average CV percentage, with it being slightly higher for all types of participants when working with the laparoscopic device.

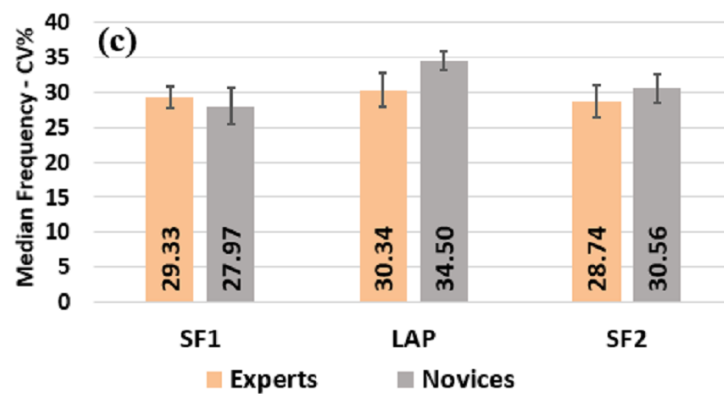


Figure 14 EMG median frequency coefficient of variation (CV) of flexor muscle group for different tasks with range

However the differences were about 5% in the case of novices and about 2% for experts. This makes the result less significant and is possibly more of a representation of the expert participants' skills in keeping steady force levels rather than a result of the device used. The answers to the questionnaires, in particular questions most concerned with comfort and ergonomics are summarized in figure 15. Answers show that subjectively, most participants found no mental or physical exhaustion in using the new STIFF-FLOP manipulator. However, 40% of participants found it not so easy to use in its current state.

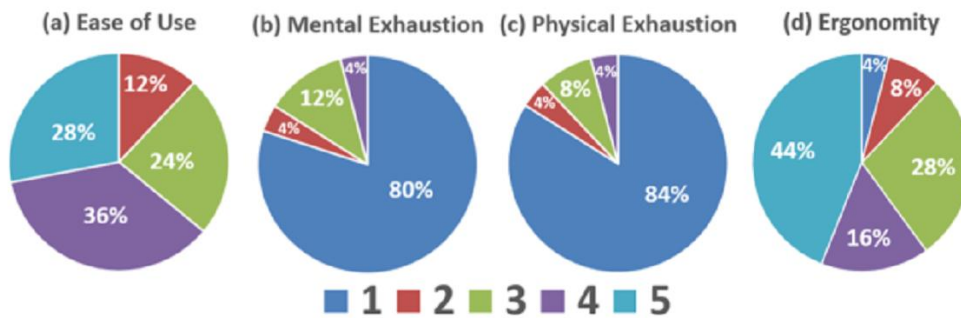


Figure 15 Questionnaire results

3.3 Final considerations

Results showed how the new manipulator requires less fatigue in performing very simple surgical tasks compared with a laparoscopic tool. Furthermore, the new robotic arm took 32.1% less time to operate during the second attempt, showing its learnability. Despite these encouraging findings, questionnaire suggested that many participants had issues with ease of use of the new manipulator. It must be noted, however, that this test involved a limited prototype of STIFF-FLOP only capable of general spatial motion: a very easy task to be performed with a laparoscopic tool. Furthermore the 2:1 scaling of the phantom organ benefited the laparoscopic tool. Newer STIFF-FLOP prototypes are able to perform complex tasks involving bending around organs and reaching different areas with control which would be far more difficult to do with a conventional laparoscopic tool. Future experiments, described in the next Chapter, tested a thinner prototypes in a 1:1 scale environment, providing a far higher margin of improvement in experience with the STIFF-FLOP arm.

Chapter 4

Cadaver tests

Part of the work described in this chapter has been also previously published in:

Arezzo A, Mintz Y, Allaix ME, **Arolfo S**, Bonino M, Gerboni G, Brancadoro M, Cianchetti M, Menciassi A, Wurdemann H, Noh Y, Althoefer K, Frasc J, Glowka J, Nawrat Z, Cassidy G, Walker R, Morino M. Total mesorectal excision using a soft and flexible robotic arm: a feasibility study in cadaver models. *Surg Endosc.* 2016; 31(1):264-273

4.1 Rationale and Methods

The encouraging results on ex vivo tests described in the previous chapter pushed engineers to miniaturize the robotic arm prototype, in order to test its performance in a setting more similar to a real surgical situation. We didn't choose

any animal models because the main goal of the test was to assess the capability to move in human narrow spaces (e.g. the pelvis) in order to perform one of the most challenging laparoscopic operation: Total Mesorectal Excision (TME). The animal showing an abdominal anatomy most similar to the human being is the pig. Unfortunately the pelvis of the pig is not so narrow and the anatomy of the rectum is slight different especially in vascularization. To obtain valuable data, the only possible model was represented by the human body, but of course no prototypes at this stage of development can be tested in a real surgical setting. At this phase of the experiments the cadaver represented the ideal model, so a 1-day session on human cadavers took place at the Institute for Medical Science and Technology (IMSaT), Dundee, Scotland. The aim of this session was to prove the feasibility of the use of the STIFF-FLOP camera robot whilst performing a minimally invasive laparoscopic TME.

4.1.1 Setting

The team of engineers installed the entire system, including the software and the STIFF-FLOP camera robot. The user interface, very smart and intuitive, was used to move and position the tip of the STIFF-FLOP arm inside the abdomen. In addition to the standard visual feedback from a laparoscopic camera, a real-time 3D visualizer showing 3D views of the STIFF-FLOP modules was also available. Sensors embedded in the robotic arm warranted haptic feedback to the operator, thus facilitating all the tasks to be performed. The target of miniaturization was a

diameter of 15 mm, capable of passing through a standard 15-mm trocar cannula. This fully integrated thinner prototype consisted 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, able to be inserted into the human body via a commercially available trocar port (Figure

16). The entire soft robot was equipped with a 4 mm in diameter centre-free lumen, which allowed the passage of the electrical wires needed for the laparoscopic miniaturized optical system positioned at the tip of the robot. The employed MD-T1003L-65

optics [Misumi New Taipei

City, Taiwan (R.O.C.)] measured 3.8 mm in diameter and 12 mm in length; the optics was integrated with an illumination system (four LEDs) and was connected via USB to a computer system. The STIFF-FLOP camera robot was attached to a rigid hollow shaft (10 mm of diameter), which was secured to the operative table by means of an anthropomorphic arm with three ballshaped joints (KLS Martin GmbH & Co. KG,



Figure 16 The thinner prototype (14.3 mm in diameter) compared to standard laparoscopic instruments

Freiburg, Germany). This arm could be manually adjusted during the operation for a proper positioning of the base of the STIFF-FLOP robot. 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 whether the softness, flexibility, and dexterity of the soft robot-based optics could represent a potential improvement compared to standard rigid laparoscopic instrumentation.

4.1.2 Operative Technique

The surgical team (AA, YM, MEA) used two human cadavers previously selected. The study was performed on two cadavers made available at the Centre for Anatomy and Human Identification, University of Dundee, and prepared according to the method described by Thiel [64]. 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 [65-66]. 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 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 (Figure 17).

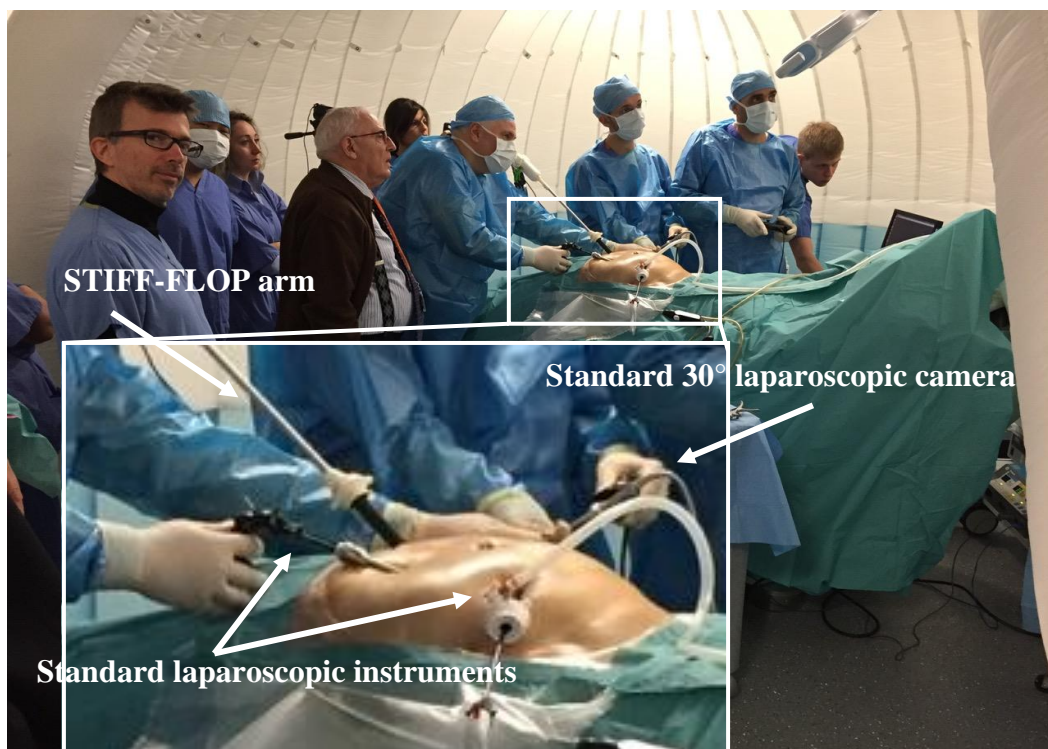


Figure 17 The beginning of the test after complete setting

At the beginning of each test, four 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, and 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 mesocolic 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 degrees laparoscopic 10-mm camera (Figure 18). Two monitors were used to follow the procedure: one was connected to the rigid standard laparoscopic camera, while the other one was connected to the flexible STIFF-FLOP camera. The gross anatomy of the abdominal cavity and the compliance of the abdominal wall to the CO₂ insufflation were evaluated. Camera images were recorded at a standard rate of 24 frames per second for subsequent analysis.



**Figure 18 Overview of the embalmed abdomed using a 30° laparoscopic camera.
The STIFF-FLOP arm was introduced and placed under direct vision**

The surgical operation 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 (Figure 19).

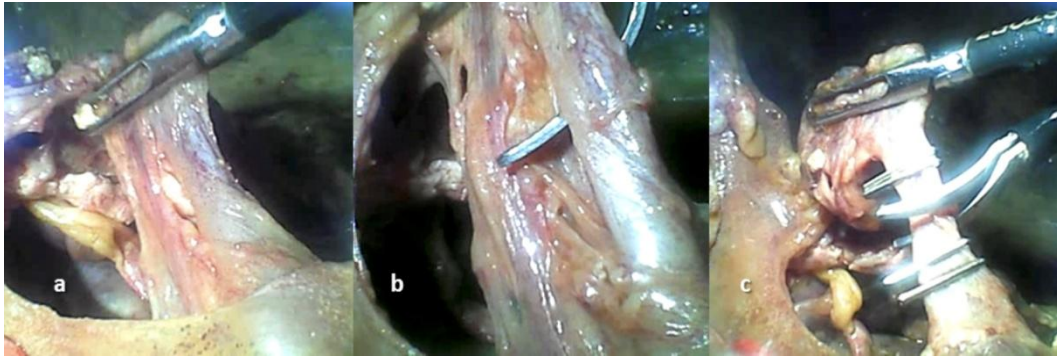


Figure 19 Identification (a), dissection (b) and division (c) of the inferior mesenteric artery. Images are provided by the camera on the tip of the STIFF-FLOP arm

Then the posterior mesorectum was identified and dissection was continued in the presacral avascular space to the level of the pelvic floor (Figure 20).

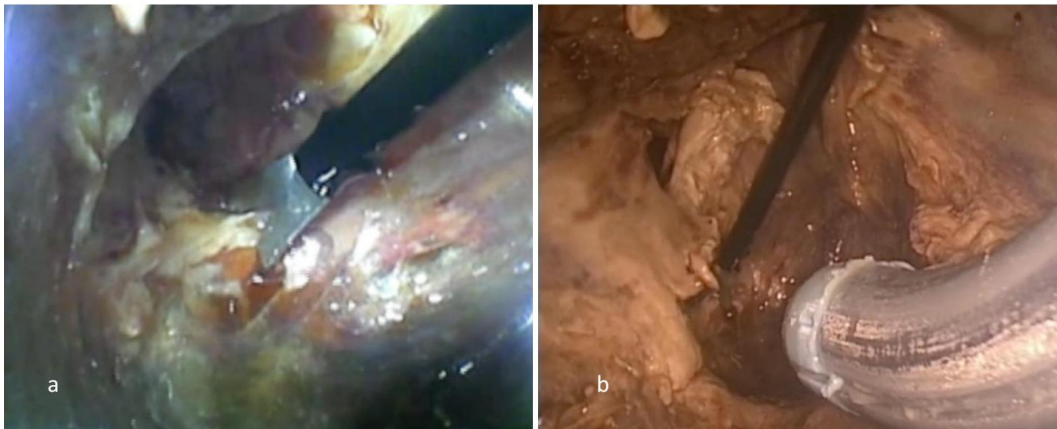


Figure 20 Dissection of the posterior side of the mesorectum. STIFF-FLOP view (a) and Laparoscopic view (b)

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 Denonvilliers' 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.

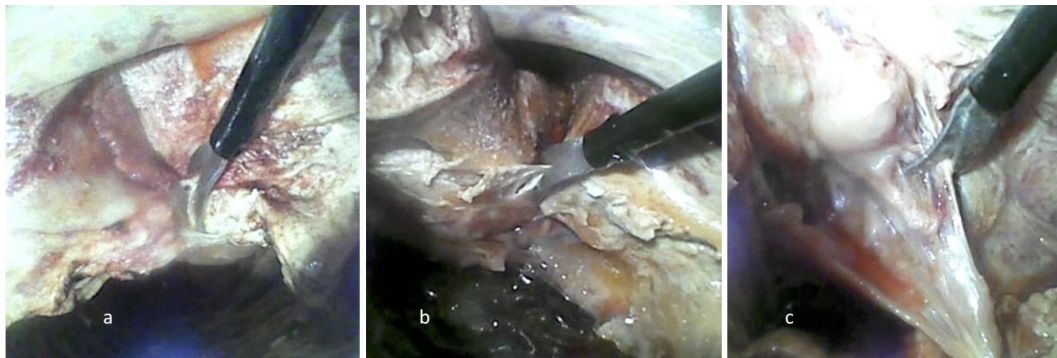


Figure 21Right (a), left (b) and anterior (c) dissection of the mesorectum. STIFF-FLOP view.

The circumferential mobilization of the rectum was then completed. The integrity of the specimen and the mesorectal fascia was evaluated laparoscopically.

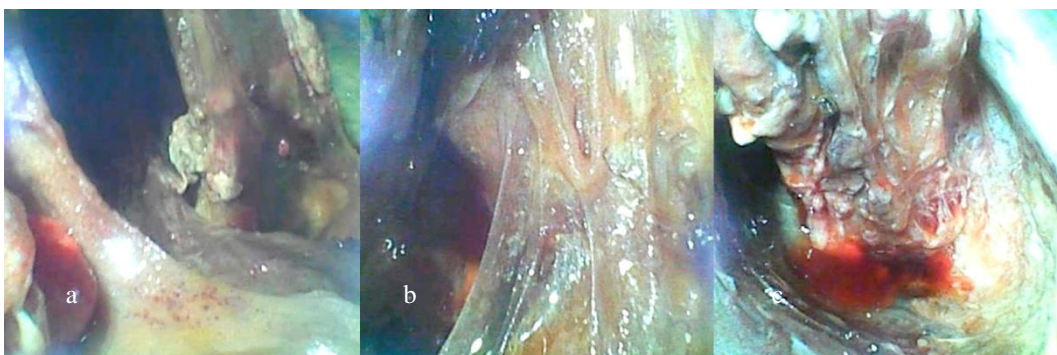


Figure 22 Completion of TME (a,b) and final aspect of the dissection

4.2 Results

Both cadavers were operated on the same day by a team of three surgeons. While one surgeon manipulated the STIFF-FLOP camera, the second surgeon performed the TME and the third surgeon 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 19). 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 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 (Figures 20, 22). The mesorectal excision was then completed laterally on both right and left sides of the rectum as well as anteriorly (Fig.21). 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 as well as its robustness of operation over many hours. 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 perceivable difficulty, 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. the arm was taken out for cleaning. Manipulation of the input device was achieved easily following a few minutes of practice and understanding of the movements, using the images from the laparoscopic camera as a navigational aid. Following this minimal training, control of the STIFF-FLOP camera was achieved without difficulty. Completion times of the procedure were 165 and 145 min, respectively. Neither intraoperative complications nor technical failures occurred.

4.2 Final Considerations

The thinner prototype of the STIFF-FLOP arm allowed to perform an exciting test session on embalmed human cadavers, definitely confirming how surgery is not only feasible but also facilitated by this new technology. The wide range of movements of the flexible robotic arm and its possibility to stiffen and maintain a desired position granted an optimal visualization of the pelvis during the entire operation, overcoming the limitations of rigid laparoscopic instruments. The

importance of this test is mainly due to the demonstration that the potential of this technology is unlimited. Surgeons who performed the operation were amazed by the improved vision of the deep, narrow pelvis provided by the camera embedded on the STIFF-FLOP arm. Of course both surgeons and engineers are already thinking about the possibility to integrate 3 or 4 soft robotic arms in order to extend the range of movements and the flexibility to the operative arms. Enormous technical improvements are needed to reach this goal, especially regarding miniaturization of components, development of sensors and software for integration and control.

Chapter 5

Conclusions and future perspectives

3.1 The paradigm shift in surgical robots development

The STIFF-FLOP project has been an ambitious project that for the first time tried to introduce a new concept of robot in the surgical scenario. The idea of robotic surgery or telepresence surgery, as explained in the first chapter, is quite old and was born for completely different purposes. The vision of common people and many surgeons and engineers is a robot mimicking human movements in performing an operation. But researchers should not forget that the real goal is to realize a complex machine able to facilitate surgical tasks maintaining or improving oncologic results and minimizing surgical trauma for patients. If we focus carefully on this goal, probably we have to change our way of thinking. More than a robot created in image and likeness of surgeons, we should focus on robots able to do what a surgeon will never can do. To make an example,

engineers who created the widely used cleaning robots, did not think about an antropomorphic robot able to use the vacuum cleaner like an housewife, but designed a disc shaped vacuum cleaner capable of self moving due to the sensors embedded and the complex control software. Compared to an antropomorphic robot it's small, able to pass under beds and furnishings and over carpets, saves energy and has very good cleaning performances. In one word, it's smart. It is not perfect and will never clean like a woman, but no robot able to completely satisfy housewife's expectations will ever be created. The da Vinci surgical system could be compared to an antropomorphic cleaning robot with arms with many degree of freedom controlled by a master-slave console able to reach the most uncomfortable corners in the house. It is not smart. That's why nowadays engineers and surgeons should change their perspectives on "robotic" surgery. The new frontiers of the research should focus on the introduction of smart robotic solutions.

3.1.1 Strengths of the STIFF-FLOP project

The STIFF-FLOP project tried to open a track on this direction. The Consortium was composed by engineers and clinical partners, in order to modulate the technical choices on clinical demand. This collaboration is extremely important because accelerates the development of prototypes really usable and useful in a real surgical situation. The other important task of the project was dissemination of the concept among surgeons. Usually surgeons are

not so happy when a revolutionary technology is proposed, because they are used to perform an operation in a certain way with good results and so they ask: "Why should I change?". This is mainly true for something they have never seen before, like a soft and flexible arm. Dissemination of the idea, information about the progresses in development and feedback from surgeons help to introduce a new technology in the medical community from the beginning, drastically reducing scepticism and rejection.

3.1.2 Drawbacks of the STIFF-FLOP project

At the beginning of the project all members were enthusiast and confident of realizing, within 3 years, a 3 arm integrated prototype and testing it in real surgical scenarios. Unfortunately only a prototype with 1 arm was tested on cadavers, as described in Chapter 4. Miniaturization of the components created many technical problems, especially in sensors embedding and control. Despite the results of the test have been encouraging, the impact of the technology on surgical community at this stage of development has been very poor.

3.2 New robots for medical applications

Even if the da Vinci surgical system represented an undoubted technological innovation, the time is now ripe to go further and looking for new ideas in robotic technology. Science Robotics published in July 2 interesting papers presenting new incredible robots. The first one is from Stanford and describes a new type of

soft pneumatic robots [67]. They have been inspired by nature: certain cells like fungal hyphae, developing neurons and trailing plants, navigate their environment not through locomotion but through growth. This type of navigation is characterized by extension from the tip of the body, length change of hundreds of percent, and active control of growth direction. This new class of robots mimics this behaviour, growing in length from the tip by means of pressurization of an inverted thin walled vessel. While growing, they actively control direction using onboard sensing of environmental stimuli, with a peak lengthening rate comparable to locomotion. These robots are capable to lengthen through constrained environments by exploiting passive deformations and form three-dimensional structures. The potential of such a technology is huge. It could represent, for example, a revolution in flexible endoscopy. These robots could navigate the lumen of the viscera without pain and with theoretically no limits. Scaling down the components, robots could navigate blood stream, biliary tract, urinary tract and so on.

The second paper comes from Harvard and demonstrates a battery-free wireless folding method for dynamic multi-joint structures, achieving addressable folding motions without the use of batteries, but using only basic passive electronic components on the device [68]. The method is based on electromagnetic power transmission and resonance selectivity for actuation of resistive shape memory alloy actuators without the need for physical connection or line of sight. This technology has been inspired by Japanese origami and allows

to switch a robot from a folded to an unfolded shape. It could allow to introduce the folded robot into the human body from a small incision, then to unfold it to make the required task guided by the operator by means of an external master-slave console.

A group from the Massachusetts Institute of Technology published on Nature a paper presenting new hydrogel robots inspired to sea animals such as leptocephali [69]. Tissues and organs of these fascinating creatures are composed of active transparent hydrogels giving to them the capability to achieve agile motions and natural camouflage in water. Hydraulic actuations of hydrogels can give soft actuators and robots that are high-speed, high-force, anti-fatigue and optically and sonically camouflaged in water. These robots are able to swim, kick rubber-balls and even catch a live fish in water. The researchers declared they are focusing on the potential benefits of handling soft tissues and organs in biomedical situations: during surgery or helping organs do their job by replicating them.

These are only some examples of potentially disruptive technologies, showing how researchers are exploring new frontiers of robotics. The paradigm of an antropomorphic mechanically actuated huge metallic robot is shifting to new shapes, materials and functions. The medical community should pay attention to these research fields, helping engineers to select a technology really able to overcome the technical limits of modern surgery. Only a constant collaboration will allow to realize smart robots for medical purposes, setting the term "robotic surgery" free from the current stereotype.

References

1. Ballantyne GH, Moll F. The da Vinci telerobotic surgical system: the virtual operative field and telepresence surgery. *Surg Clin North Am.* 2003; 83(6):1293-304
2. Satava RM. Virtual reality, telesurgery, and the new world order of medicine. *J Image Guid Surg* 1995; 1:12–16
3. Bellamy RF, Manings PA, Vayer JS. Epidemiology of trauma: military experience. *Ann Emerg Med* 1986; 15:1384–1388
4. Bellamy RF. The causes of death in conventional land warfare: implications for combat casualty care research. *Mil Med* 1984; 149:55–63
5. Satava RM. Virtual reality and telepresence for military medicine. *Ann Acad Med Singapore* 1997; 26:118–120
6. Satava RM, Jones SB. Preparing surgeons for the 21st Century. *Surg Clin N Amer* 2000; 80:1353–1365
7. Schurr MO, Arezzo A, Buess GF. Robotics and systems technology for advanced endoscopic procedures: experiences in general surgery. *Eur J Cardiothorac Surg.* 1999; 16 Suppl 2:S97-105

8. Schurr MO, Buess G, Neisius B, Voges U. Robotics and telemanipulation technologies for endoscopic surgery. A review of the ARTEMIS project. Advanced Robotic Telemanipulator for Minimally Invasive Surgery. *Surg Endosc.* 2000; 14(4):375-81
9. Arezzo A, Testa T, Schurr MO, Buess GF, De Gregori M. Tecnologia robotica e dei sistemi per procedure endoscopiche avanzate. *Ann Ital Chir* 2001; 72:467-472
10. Unger SW, Unger HM, Bass RT. AESOP robotic arm. *Surg Endosc* 1994; 8(9):1131.
11. Marescaux J, Rubino F. The ZEUS robotic system: experimental and clinical applications. *Surg Clin North Am.* 2003; 83(6):1305-15
12. Marescaux J, Leroy J, Gagner M, Rubino F, Mutter D, Vix M, et al. Transatlantic robot-assisted telesurgery. *Nature* 2001; 413(6854):379–380
13. Larkin M. Transatlantic, robot-assisted telesurgery deemed a success. *Lancet.* 2001; 358(9287):1074.
14. Marescaux J, Leroy J, Rubino F, Smith M, Vix M, Simone M, et al. Transcontinental robot-assisted remote telesurgery: feasibility and potential applications. *Ann Surg* 2002; 235(4):487–492
15. Ruurda JP, van der Sluis PC, van der Horst S, van Hillegersberg R. Robot-assisted minimally invasive esophagectomy for esophageal cancer: A systematic review. *J Surg Oncol.* 2015; 112(3):257-65

16. Luketich JD, Pennathur A, Awais O, et al. Outcomes after minimally invasive esophagectomy: Review of over 1000 patients. *Ann Surg* 2012; 256:95–103
17. Biere SS, van Berge Henegouwen MI, Maas KW, et al.: Minimally invasive versus open oesophagectomy for patients with oesophageal cancer: A multicentre, open-label, randomised controlled trial. *Lancet* 2012; 379:1887–1892
18. Kim DJ, Park SY, Lee S, et al.: Feasibility of a robot-assisted thoracoscopic lymphadenectomy along the recurrent laryngeal nerves in radical esophagectomy for esophageal squamous carcinoma. *Surg Endosc* 2014; 28:1866–1873
19. Draaisma WA, Ruurda JP, Scheffer RC, et al.: Randomized clinical trial of standard laparoscopic versus robot-assisted laparoscopic Nissen fundoplication for gastro-oesophageal reflux disease. *Br J Surg* 2006; 93:1351–1359
20. Nakadi IE, Melot C, Closset J, et al.: Evaluation of da Vinci Nissen fundoplication clinical results and cost minimization. *World J Surg* 2006; 30:1050–1054
21. Cadiere GB, Himpens J, Vertruyen M, et al.: Evaluation of telesurgical (robotic) NISSEN fundoplication. *Surg Endosc* 2001; 15:918–923
22. Muller-Stich BP, Reiter MA, Mehrabi A, et al.: No relevant difference in quality of life and functional outcome at 12 months' follow-up-a randomised

- controlled trial comparing robot-assisted versus conventional laparoscopic Nissen fundoplication. *Langenbecks Arch Surg* 2009; 394:441–446
23. Morino M, Pellegrino L, Giaccone C, et al.: Randomized clinical trial of robot-assisted versus laparoscopic Nissen fundoplication. *Br J Surg* 2006; 93:553–558
24. Tolboom RC, Broeders IA, Draaisma WA. Robot-assisted laparoscopic hiatal hernia and antireflux surgery. *J Surg Oncol.* 2015; 112(3):266-70
25. Son T, Hyung WJ. Robotic gastrectomy for gastric cancer. *J Surg Oncol.* 2015; 112(3):271-8
26. Alibhai MH, Shah SK, Walker PA, Wilson EB. A review of the role of robotics in bariatric surgery. *J Surg Oncol.* 2015; 112(3):279-83
27. Ocuin LM, Tsung A. Robotic liver resection for malignancy: Current status, oncologic outcomes, comparison to laparoscopy, and future applications. *J Surg Oncol.* 2015; 112(3):295-301
28. Stafford AT, Walsh RM. Robotic surgery of the pancreas: The current state of the art. *J Surg Oncol.* 2015; 112(3):289-94
29. Pappou EP, Weiser MR. Robotic colonic resection. *J Surg Oncol.* 2015 Sep; 112(3):315-20
30. Park JS, Choi GS, Park SY, et al.: Randomized clinical trial of robot-assisted versus standard laparoscopic right colectomy. *Br J Surg* 2012; 99:1219–1226
31. Xu H, Li J, Sun Y, et al.: Robotic versus laparoscopic right colectomy: A meta-analysis. *World J Surg Oncol* 2014; 12:274

32. Rawlings AL, Woodland JH, Vegunta RK, et al.: Robotic versus laparoscopic colectomy. *Surg Endosc* 2007; 21:1701–1708
33. Casillas MA, Jr., Leichtle SW, Wahl WL, et al.: Improved perioperative and short-term outcomes of robotic versus conventional laparoscopic colorectal operations. *Am J Surg* 2014; 208:33–40
34. Woeste G, Bechstein WO, Wullstein C: Does telerobotic assistance improve laparoscopic colorectal surgery? *Int J Colorectal Dis* 2005; 20:253–257
35. Shin JY: Comparison of short-term surgical outcomes between a robotic colectomy and a laparoscopic colectomy during early experience. *J Korean Soc Coloproctol* 2012; 28:19–26
36. Spinoglio G, Summa M, Priora F, et al.: Robotic colorectal surgery: first 50 cases experience. *Dis Colon Rectum* 2008; 51:1627–1632
37. Baik S, Ko Y, Kang C, et al.: Robotic tumor-specific mesorectal excision of rectal cancer: Short-term outcome of a pilot randomized trial. *Surg Endosc* 2008; 22:1601–1608
38. Lorenzon L, Bini F, Balducci G, Ferri M, Salvi PF, Marinozzi F. Laparoscopic versus robotic-assisted colectomy and rectal resection: a systematic review and meta-analysis. *Int J Colorectal Dis*. 2015 Sep 26. [Epub ahead of print]
39. Lee SH, Lim S, Kim JH, Lee KY. Robotic versus conventional laparoscopic surgery for rectal cancer: systematic review and meta-analysis. *Ann Surg Treat Res*. 2015; 89(4):190-201

40. Rencuzogullari A, Gorgun E. Robotic rectal surgery. *J Surg Oncol.* 2015; 112(3):326-31.
41. Jayne D, Pigazzi A, Marshall H, Croft J, Corrigan N, Copeland J, Quirke P, West N, Rautio T, Thomassen N, Tilney H, Gudgeon M, Bianchi PP, Edlin R, Hulme C, Brown J. Effect of Robotic-Assisted vs Conventional Laparoscopic Surgery on Risk of Conversion to Open Laparotomy Among Patients Undergoing Resection for Rectal Cancer: The ROLARR Randomized Clinical Trial. *JAMA* 2017; 318(16):1569-1580
42. Choi GS. A Trial to Assess Robot-assisted Surgery and Laparoscopy-assisted Surgery in Patients with Mid or Low Rectal Cancer (COLRAR). ClinicalTrials.gov identifier: NCT01423214. Secondary A Trial to Assess Robot-assisted Surgery and Laparoscopy-assisted Surgery in Patients with Mid or Low Rectal Cancer (COLRAR). ClinicalTrials.gov identifier: NCT01423214. <http://clinicaltrials.gov/ct2/show/NCT01423214>.
43. Park JW. Clinical Assessment of Laparoscopic and Robotic Surgery for Rectal Cancer Randomized Phase II Trial. <http://clinicaltrials.gov/ct2/show/>
44. NCT01591798.
45. Xu J. A Multicentre, Prospective, Randomised, Controlled, Unblinded, Parallel-group Trial of Robotic-assisted Versus Laparoscopic Versus Open Abdominoperineal Resection for the Curative Treatment of Low Rectal Cancer. ClinicalTrials.gov identifier: NCT01985698. Available from: <http://clinicaltrials.gov/ct2/show/NCT01985698>

46. Lee DK, Montgomery DP, Porter JR: Concurrent transperitoneal repair for incidentally detected inguinal hernias during robotically assisted radical prostatectomy. *Urology* 2013; 82:1320–1322
47. Escobar Dominguez JE, Gonzalez A, Donkor C. Robotic inguinal hernia repair. *J Surg Oncol.* 2015; 112(3):310-4
48. Liu AJ, Nagel SR. Jamming is not just cool anymore. *Nature* 1998;396:21–22.
49. Brown E, Rodenberg N, Amend J, Mozeika A, Steltz E, Zakin MR, Lipson H, Jaeger HM. Universal robotic gripper based on the jamming of granular material. *Proc Natl Acad Sci USA* 2010;107:18809–18814.
50. Cheng NG, Lobovsky MB, Keating SJ, Setapen AM, Gero KI, Hosoi AE, Lagnemma KD. Design and analysis of a robust, low-cost, highly articulated manipulator enabled by jamming of granular media. 2012 IEEE International Conference on Robotics and Automation (ICRA), 2012, pp. 4328–4333.
51. Steltz E, Mozeika A, Rembisz J, Corson N, Jaeger H. Jamming as an enabling technology for soft robotics. *SPIE* 2010;7642:63.
52. Loeve A, van de Ven OS, Vogel JG, Breedveld P, Dankelman J. Vacuum packed particles as flexible endoscope guides with controllable rigidity. *Granular Matter* 2010; 12:543–554.
53. Jiang A, Ataollahi A, Althoefer K, Dasgupta P, Nanayakkara T. A variable stiffness joint by granular jamming. *Proceedings of the ASME* 2012

International Design Engineering Technical Conferences & Computers and Information in Engineering Conference IDETC/CIE, 2012

54. Cianchetti M, Ranzani T, Gerboni G, Nanayakkara T, Althoefer K, Dasgupta P, Menciassi A. Soft robotics technologies to address shortcomings in today's minimally invasive surgery: the STIFF-FLOP approach. *Soft Robotics Journal* 2014; 1(2):122-131
55. Brown E, Rodenberg N, Amend J, Mozeika A, Steltz E, Zakin MR, Lipson H, Jaeger HM. Universal robotic gripper based on the jamming of granular material. *Proc Natl Acad Sci USA* 2010;107:18809–18814.
56. Noh Y, Sareh S, Back J, Wurdemann HA, Ranzani T, Secco EL, Faragasso A, Liu H, Althoefer K. A three-axial body force sensor for flexible manipulators. *IEEE International Conference on Robotics and Automation (ICRA)*, Hong Kong, 2014.
57. Polygerinos P, Puangmali P, Schaeffter T, Razavi R, Seneviratne LD. Novel miniature MRI-compatible fiber-optic force sensor for cardiac catheterization procedures. *IEEE International Conference on Robotics and Automation (ICRA 2010)*: 2598 – 2603
58. Puangmali P, Liu H, Seneviratne LD, Dasgupta P, Althoefer K. Miniature 3-axis distal force sensor for minimally invasive surgical palpation. *Mechatronics, IEEE/ASME Transactions on* 17 (4), 646-656

-
59. Polygerinos P, Zbyszewski D, Schaeffter T, Razavi R, Seneviratne LD, Althoefer K. MRI-compatible fiber-optic force sensors for catheterization procedures. *IEEE Sensors Journal* 2010: 1598-1608
 60. Liu H, Li J, Song X, Seneviratne LD, Althoefer K. Rolling indentation probe for tissue abnormality identification during minimally invasive surgery. *IEEE Transactions on Robotics* 2011;27(3):450-460
 61. Clavel R. Conception d'un robot parallèle rapide à 4 degrés de liberté. Thèse de doctorat, Ecole polytechnique de Lausanne, 1991
 62. Miller K, Clavel R. The lagrange-based model of delta-4 robot dynamics. *Robotersysteme* 1992;8:49–54
 63. Borg, G. Borg's perceived exertion and pain scales. 1998 Champaign, IL: Human Kinetics
 64. Chowdhury RH, Reaz MBI, Bin Mohd Ali MA, Bakar AAA, Chellappan K, Chang TG. Surface Electromyography Signal Processing and Classification Techniques. *Sensors* 2013;13:12431-12466
 65. Thiel W. The preservation of the whole corpse with natural color. *Ann Anat.* 1992;174(3):185-95
 66. Healy SE, Rai BP, Biyani CS, Eisma R, Soames RW, Nabi G. Thiel embalming method for cadaver preservation: a review of new training model for urologic skills training. *Urology* 2015; 85(3):499-504

67. Hayashi S, Naito M, Kawata S, Qu N, Hatayama N, Hirai S, Itoh M. History and future of human cadaver preservation for surgical training: from formalin to saturated salt solution method. *Anat Sci Int.* 2016;91(1):1-7
68. Hawkes EW, Blumenschein LH, Greer JD, Okamura AM. A soft robot that navigates its environment through growth. *Science Robotics* 2017;2(8), eaan3028
69. Boyvat M, Koh JS, Wood RJ. Addressable wireless actuation for multijoint folding robots and devices. *Science Robotics* 2017;2(8):eaan1544
70. Yuk H, Lin S, MA C, Takaffoli M, Fang NX, Zhao X. Hydraulic hydrogel actuators and robots optically and sonically camouflaged in water. *Nature Communications* 8 Article number: 14230 (2017)