Soft Robots in Surgery

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Abstract Minimally Invasive Surgery (MIS) represents the gold standard in the majority of abdominal operations, although some fundamental limitations are still present and are far to be really addressed despite emerging robotic solutions. Flexible endoscopes can exploit their high flexibility to reach the surgical target while being inserted remotely or by a natural orifice. However endoscopes may lack stability that rigid tools normally provide. Novel surgical instrumentation is being developed in order to provide higher dexterity and flexibility to the surgeon, but unlike traditional surgical manipulators, here we report the approach followed in the development of the STIFF-FLOP manipulator. The main idea is based on the exploitation of soft materials to be intrinsically flexible and safe while combining different fluidic actuation technologies to enable high dexterity and selective stiffness variability. In this chapter, the functional evolution of the robot is reported highlighting advantages and drawbacks that steered the development of a manipulator which in the end demonstrated to be effective in overcoming mobility limitations experienced with standard rigid tools.

1 Flexibility and Dexterity in Surgical Robotics

In the second half of the 20th century, Minimally Invasive Surgery (MIS) started replacing traditional open surgery laying the foundations of a real revolution in operative medicine. The main shortcomings of open surgery (e.g., patient discomfort and pain, costs associated with the procedures, complications, hospitalization duration and cosmetic effects) pushed the advancements of minimally invasive surgical techniques [1]: in particular, the reduction of intervention trauma represents the key feature of MIS [2]. Although the advantages of MIS for the patients are undeniable, from surgeons' point of view additional technical hitches and difficulties are introduced due to the minimal access. The use of instrumentation

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suitable for MIS often results in limiting the surgeon's capabilities of maneuverability and dexterity, and his/her visibility of anatomical structures via the monodimensional endoscope.

Exploiting the strengths of robotics, in terms of accuracy, teleoperation, integration of multiple sensing sources, holds the potential to again revolutionize the MIS scenario [3].

On the other hand, a target which seems still difficult to achieve even if with the integration of the most advanced robotics technologies, is the possibility to operate in robotic MIS with the same flexibility and dexterity typical of the human hands: differently from any robotic surgical tool, the human hands (under the human control) can manipulate, palpate, dislocate organs with an excellent dexterity and adaptability to different tissue conditions. Reaching the same level of flexibility and dexterity is a challenge for the academia and the industrial community. The authors have identified in the state of the art three different trends for enhancing dexterity and flexibility in MIS:

- Reconfiguration of "bricks" in MIS and laparoscopic surgery (i.e. minimally invasive techniques in the abdomen).
- Deployable structures for MIS with an "origami" architecture.
- "Soft" exploration of the internal organs, both in an endoluminal fashion (e.g. through the gastrointestinal tract) and in the abdominal cavity in MIS.

As regards the possibility to increase flexibility and dexterity by reconfiguration, some seminal proposals to build up a reconfigurable robot to be used in heart surgery appeared in Japan in the 80 s. Taking inspiration from swarm robotics, from rescue and field robotics, and from the possibility to generate an advanced robotic device starting from simple bricks with minimal functions and docking capabilities, the Paolo Dario team proposed different concepts and prototypes for gastrointestinal applications and abdominal surgery [4, 5]. The idea is to set up—by magnetic docking or dedicated mechanisms—a large internal robot with the ability to achieve different configurations and different manipulation abilities. The robot should be composed by thin and slim pieces to be swallowed or to be introduced by surgical access ports (no more than 15 mm in diameter). All modules are provided with a couple of miniature motors which can be used for pitch and roll of end-tools or for executing real tasks (e.g. taking a bioptic sample).

The problem of reaching the wall of the abdominal cavity or exploring the wall of large diameter organs (such as the stomach) is extremely challenging from the kinematic viewpoint, especially when all tools that can be introduced have a limited diameter. In this scenario, origami architectures represent a valid opportunity for achieving a large operating workspace by starting from tiny (and lightweight) structures. Few examples have been proposed for surgical applications, but the potential of adding origami-enabled degrees of freedom into traditional surgical tools has been already demonstrated [6, 7].

A third kind of approach (connected to the second one in terms of materials exploitation) makes use of soft matter to build devices and tools with high compliance

and dexterity. Soft robots are often based on continuous structures and this high degree of mobility can be used to enrich the motion capability. Soft robots are also intrinsically safe (due to their passive compliance) but can count on technologies which are able to vary their stiffness and allow to generate relatively high forces. This chapter is aiming at reporting the main results obtained with this last approach in the STIFF-FLOP manipulator. The historical development led by failures and achievements will underline the limitations and the advantages of such an approach.

2 A New Paradigm in Endoluminal and Endocavitary Surgery

By combining the different needs in minimally invasive and endoluminal surgery, ranging from improving flexibility, enhancing dexterity and—last but not least—preserving the maximum safety, soft-bodied robots emerge as the elective choice. In comparison with highly articulated—yet rigid—robots, soft-bodied robots can adapt passively to external environments and can be collapsed to enter small access ports.

The development of a soft bodied system is usually a very difficult and long process. Mechatronic devices usually follow an integrated design, so that each component (sensors, actuators, mechanisms, electronics and power supply) are studied from the very beginning for being integrated in a single system. This entails a design which takes into consideration functionalities together with the interface among the parts. In the area of Soft Robotics, a platform based on soft and compliant materials cannot follow a "simple" integrated approach. The new paradigm for soft mechatronics is to consider and design a single all-in-one system. Each part affects all the others, from an active but also from a passive point of view: a soft actuation system supported by a flexible structure loses its main characteristic if a bulky rigid sensor is necessary on board. This approach can show all its potentiality only if all the components are contextually taken into consideration as fused together, going even beyond the biomechatronic approach in terms of integrated design.

This is the reason why in this discipline the development of simplified mockups has a central role. The basic functionalities (and flaws) of a chosen combination of technologies are easily highlighted by simplified platforms. Of course they have to embed all the parts, but they can be inserted one by one, allowing the assessment of the single contributions in terms of overall functionality.

This approach has been followed in the design of the STIFF-FLOP manipulator, where two different actuation technologies, the support and the power supply have been contextually taken into consideration in a series of prototypes (conventionally divided into three generations—Fig. 1).



Fig. 1 The evolution of the STIFF-FLOP manipulator: the first (a), the second (b) and the third (c) generation

3 STIFF-FLOP Manipulator Evolution

The STIFF-FLOP manipulator has been conceived to present the following functionalities:

- ability to pass through standard MIS access ports (trocar);
- a flexible, but articulated and functional length of 100-300 mm;
- 30 % of elongation capability;
- 1-20 N of force at the tip and in other relevant points along the arm;
- controllable stiffness.

A modular architecture was adopted from the very beginning: each module showing high dexterity and stiffness tunability. The embedded technologies were thus selected among several possibilities which also met the soft requirements [8]. For the actuation system a combination of fluidic technologies has been selected. Flexible fluidic actuators (FFA) for enabling omnidirectional bending and elongation, while granular jamming (GJ) based chambers to include variable stiffness capability. Being based on fluidics, the power supply was decided to be maintained externally placed. This eased the development, but tubing had to be carefully taken into consideration anyway. In particular dimensions and flexibility of the tubes used for inflation represented a potential threat limiting the system flexibility. Soft structural material (silicone Ecoflex[™] 0050, 0030—Smooth-on Inc.) has been used to support, embed and drive the actuation system.

3.1 First Generation: Converging into Working Modules

FFAs are known to be very simple but effective soft actuators. They can exploit the vast knowledge already available in driving fluidic systems and they are very versatile. They can be shaped in the most convenient manner, enabling different morphing possibilities. Being based on the inflation of elastomeric chambers, this kind of actuator often requires a restraining system to limit and lead deformations along preferential directions. In literature different approaches have been used like patterning [9], folded paper [10], wrapped-around threads [11] or high elastic modulus materials [12]. In our first generation of the STIFF-FLOP manipulator an approach derived from the McKibben actuators have been preferred. McKibben actuators are a special class of FFA that are based on a braided sheath which contains the internal balloon inflation. The braided sheath guides the actuator deformation and in particular the braiding angle. This also leads to the main limit of such actuators: the braiding angle is physically constrained to range between 54.7° to almost 90° that translates in an elongation capability which rarely exceeds 50 %. In order to exploit the same principle, but with an enhanced elongation the braided sleeve has been modified through a peculiar thermo-mechanical treatment [13]. As a result it shows circumferential folds which still have a containment effect, but increased elongation capabilities since the folds are first flattened and then the braiding angle starts to change (Fig. 1a).

The internal arrangement of the actuation components are showed in Table 1—first column. The FFA have a semicircular section to optimize space allocation and

Generation	I	П	ш
	1		
External diameter	35 mm	25 mm	14.7 mm
Module length	50 mm	50 mm	55 mm
FFA shape	Half cylinder	Cylinder	Cylinder
Containment method	External with braided sheath	Internal with helicoidal threads	Internal with helicoidal threads
Tubing	Through the silicone body	Inside the inner channel	Inside the inner channel
GJ position	Inside the inner channel	Between FFAN	N/A
Free space in the inner channel	Not usable	Lodging tubes	Lodging tubes
Cross section sketch			8

 Table 1 Different design approaches used in the three development generations of the STIFF-FLOP manipulator



Fig. 2 Different solutions for tubes arrangement: chambers and tubes aligned (a), tubes aligned and chambers rotated (b), tubes rotated and chambers aligned (c)

they are arranged longitudinally at 120° to enable omnidirectional bending while the granular jamming is hosted in a cylindrical central channel. The length of a single module was set to 50 mm, but several versions of 2- and 3-module manipulator have been developed too, reaching a final length of 135 and 190 mm respectively (additional space is requested to create a flexible silicone-based joint between the modules).

The development of multi-module manipulators required to cope with a very important issue: how to arrange the tubes so that inflation and/deflation can reach all the chambers (including the GJ system)? Several possibilities have been evaluated and while for the GJ system an in-series solution has been adopted (the three modules stiffened all together) for the FFA different solutions have been evaluated:

- In a first possible solution the chambers of the modules are aligned (Fig. 2a). Nine tubes, three for each chamber, pass through the first module. Focusing on a single chamber, one tube stops at the base of the chamber for its actuation, while the other two pass into the same chamber up to the second module, in correspondence of the aligned chamber. One tube stops at the base of the chamber, while the last one pass into the chamber and stops at the next chamber of the third module. Features of this solution:
 - The chambers are aligned: the trajectory of the manipulator is more intuitive;
 - There is more free space: it can be used for the integration of the sensory system or it can allow for a further reduction of the module diameter;
 - The chambers are perforated in bottom and top area: there can be more leakages, but solutions to reduce leakages are under testing;

- The chambers in the first module have an effective volume smaller than in the second and in the third modules. This could produce different performance among modules.
- A second solution is based on an axial-symmetric design for the disposition of the chambers and the corresponding tubes (Fig. 2b). The chambers and the respective tubes are placed at 40°. Nine tubes are located in the first module: three actuate the chambers while the others six pass through the module, externally respect to the chambers and each one in a dedicated duct, up to the second module where the location of the tubes is the same. Features of this solution:
 - The chambers are perforated only at the base where the supply tube is located: the leakages are reduced;
 - There is a little free space: low possibility to insert other components in the same structure or to reduce the dimensions;
 - The chambers are not aligned: the inflation of the chambers respect to the trajectory of the manipulator is less intuitive, especially on bench tests during the first evaluations of the manipulator performances;
 - The ducts of the tubes are very close to the chambers: the chambers could break during their activation or in the fabrication process.
- In the third solution the chambers of the modules are aligned (Fig. 2c). Nine tubes are placed in the first module: three actuate the chambers while the others six pass through the module, externally respect to the chambers and in a single duct, up to the second module and so on to the third module. Features of this solution:
 - The chambers are aligned: the trajectory of the manipulator is more intuitive;
 - The chambers are perforated only at the base: the leakages are reduced;
 - There is free space: it can be used for the integration of the sensory system or it can allow the reduction of the module diameter;
 - Not straightforward fabrication process especially in correspondence of the junctions between two modules.

3.2 Second Generation: Optimizing Spaces

After functionality tests carried out to assess the performance of the manipulators composed of first generation modules it was quite clear that despite the promising results from a mechanical point of view there were issue related to the inflation of the chambers: the external braided sheath limits the radial deformation directed outwards, but chambers tend to extend also inwards. In principle thus does not represent a problem until the GJ system is not deformed too much, but there is an issue related to the actuation system: when inflated singularly the chambers are very much precise and with high repeatability, but when two or more chambers are

combined to generate intermediate plane bending and/or elongation the interference between the chambers makes not univocal the relation between chamber activation and tip position. The motion becomes sensible to the order of chamber inflation and the amount of pressure used. Moreover the use of the external braided sheath poses limit also from the scalability point of view. Theoretically the structure would work at any scale, but the manufacturing becomes prohibitive.

To overcome this issue a new method for confining the chambers' expansion has been introduced [14]. A chamber with a thread helicoidally wrapped directly around it has minor shape possibilities, but represents a much more compact solution (Fig. 1b). In this way each chamber is singularly limited to extend only and any other interference is avoided. While this solution allowed the removal of the external braided sheath, on the other side it imposes strong limits in the chamber's shape. In the first generation the half-circle cross section was used to optimize the exploitation of the internal space, but with the new approach the circular cross section is the only possibility (any other shape will tend to a circle under pressurization, implying a lateral deformation).

A general reconfiguration of the actuation system has thus been implemented. The necessity of using cylindrical chambers reduced the diameter of the internal channel leading to the choice of moving the variable stiffness system to a more external position. This implies a more efficient stiffening (the area moment of inertia of the system varies much more if the GJ is placed at higher distance from the center) without increasing the number of tubes. In fact, the three GJ chambers were locally connected, so that one single tube is sufficient to create vacuum in all the 3 chambers. Moreover leaving the central channel free, this can be used to lodge fluidic tubes or flexible instruments and tools. This solution is showed in Table 1—central column.

3.3 Third Generation: Going Thin

The diameter of the first two generations of the STIFF-FLOP manipulator was almost suitable for single access (single-port laparoscopy) or for natural orifice translumenal endoscopic surgery (NOTES), but not compatible with standard trocar ports usually used in MIS. This pushed a further development of the device in reducing its overall diameter (Fig. 1c). The third generation is still under study for further improvements but gaining on the experience deriving from the previous extensive use of the fluidics technologies, some thinner manipulators have been already manufactured and tested.

In particular a 2-module manipulator has been proposed with the specific aim of being used as a soft vision tool thus equipped with a miniaturized camera. The arrangement of the fluidic chambers resembles the previous version, but a substantial modification has been introduced from the actuation view point. For its specific task the variable stiffness capability has been neglected since very limited interaction with the surrounding environment is expected. Without the GJ system, the FFA chambers have been doubled, so that the effectiveness of the bending motion has been enhanced. 6 chambers (coupled in pairs) have been embedded in each module and the central channel is used to lodge tubes and electric connections necessary for the camera.

4 Main Achievements and Results

The first generation of the STIFF-FLOP manipulator was quite handcrafted and this was visible from an esthetic (due to a mostly manual fabrication) and a functional point of view (asymmetries), but already demonstrated to meet the basic functionalities listed in Sect. 3. The single module have been fully and accurately characterized [13, 15] and the results proved that this approach represents a breakthrough in surgery. Elongation, omnidirectional bending and variable stiffness were combined in a compact system completely made of soft materials. Moreover the two-module version paved the way to a new surgical scenario: it is possible to exploit the modular structure of the manipulator to carry out different tasks with different sections of the manipulator. For example, while the proximal module (at the base) is retracting and stabilizing an organ/tissue, the distal module (at the tip) can freely interact with other targets by bending and elongating independently from the first module.

The second generation of the STIFF-FLOP manipulator is characterized by a much more reliable and accurate manufacturing process which led to improved performances in a more compact size. The new restraining approach allowed to reduce the overall dimensions without affecting the overall strategy too much. But the most important result achieved with this version is the possibility to maximize the modularity of the system. The new method, indeed, leaves free the inner channel (previously occupied by the GJ system) and allows lodging tools and/or let tubes pass through the modules without hindering motions.

The third generation of the STIFF-FLOP manipulator was aimed at achieving dimensions more compatible with MIS constraints. Despite the first two versions of the manipulator were squeezable and resilient to high deformations, they suffered from limitations in dealing with standard trocar ports. This thinner version has been also tested with human cadavers. A surgeon used the manipulator equipped with a miniaturized camera as a vision tool to perform a Total Mesorectal Excision (TME). Its high dexterity and mobility demonstrated to acquire superior angles of vision of the surgical field (respect to the standard laparoscopic vision) while neither intraoperative complications nor technical failures were registered during the two hours of continuous work necessary for the procedure [16].

Recently the manipulator has been also integrated in the daVinci surgical robot and has been invited as finalist to the 2016 Surgical Robot Challenge (event connected to the Hamlyn Symposium of the UK Robotics Week) demonstrating the possibility to be completely functional as a MIS tool. The integration was full since the surgeon was enabled to intuitively control the STIFF-FLOP motion directly from the master console of the daVinci robot.

5 Conclusions

The development of the STIFF-FLOP manipulator highlighted the possibility to exploit technologies based on soft materials in the surgical field, but also it underlined that the exploiting soft mechatronics technologies still present many threats. Manufacturing techniques, for example, are still far from being suitable. There exist many possibilities (like multi-step molding processes), but several fabrication phases are still manual. This usually undermines the robustness and the repeatability of the system or at least introduces structural weaknesses. Also the very recent and promising 3D printing techniques are not able to fully satisfy soft robotics requirements. The printed materials are usually soft enough, but the low tensile strength limits the elongation at break to unsuitable values.

Another limit which should be seriously taken into consideration in the development of soft robots based on FFAs regards tubing. The integration of a pressurized fluid source is currently not compatible with size and mechanical properties of commercially available pumps, thus lodging tubes inside the robot is mandatory to use an external pump. But while the dimension of the chambers is not constrained, tubes have to guarantee structural stability thus their diameter is hard to be reduced as well as it is difficult to decrease the hardness of the material they are made of. This is especially difficult in two cases: if pressure drops become too high and if the tubes are used to create vacuum in the chambers. Moreover the connection of the tubes to the chambers represents a discontinuity point which needs to be curated to guarantee reliability.

Despite this, the experience of the STIFF-FLOP manipulator demonstrates that the introduction of novel technologies for tools and instrumentation such as soft and flexible robotic devices may aid in overcoming the technical challenges of difficult laparoscopic procedures based on standard, rigid instruments. Soft robotics represents a design methodology with the potential to change the perspective of traditional robotics and traditional application scenarios. On the other hand, it can be challenging to radically substitute existing robotic devices with soft robot architectures. The experience of the authors in developing the STIFF-FLOP manipulator can be a paradigmatic example of a successful methodology aimed to a concrete take up of soft robotic technologies. First of all, the soft robotic architecture should be tuned in a pragmatic way in order to obtain first early prototypes which immediately demonstrate the possible advantages of the soft robotic technologies. Only in this way users can provide useful hints for further improvements. As a second step, the soft robotic technologies must be completely dominated for integrating the most adequate solutions for the targeted applications, by trying to merge traditional functionalities with more advanced functionalities, specifically enabled by soft technologies. Finally, the users and the soft robotics engineers should test their results in the field, for an objective benchmarking on well-known and familiar applications. For doing this, it is crucial to identify the soft features that could be relaxed and the soft features to be maintained for an effective translation into the selected application scenario.

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