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TECHNICAL ADVANCES

Assessment of a flexible robotic system for endoluminal applications and transanal total mesorectal excision (taTME): Could this be the solution we have been searching for?

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Introduction

Experimentation with robotic transanal surgery (RTS) began in 2011 [1] as a natural evolution of transanal minimally invasive surgery (TAMIS) [2]. Using first-, second-, and eventually third-generation multi-arm Da Vinci *S*, *Si*, and *Xi* master–slave robotic systems (Intuitive Surgical Systems, Sunnyvale, CA, USA), RTS has evolved from endoluminal applications [3] (most notably for local excision of rectal neoplasia) to subsequent use as a platform for transanal total mesorectal excision (taTME), with the first such case reported in 2013 [4]. To date, several feasibility studies and pilot investigations with RTS have been described for local excision and taTME [5–19], leading some surgeons to believe that transanal approaches could represent a "sweet spot" for robotics in colorectal surgery [20] and a solution to its Achilles' heel [21, 22]. While RTS can achieve extreme operative precision, the principle shortcoming of the approach has been that straight instruments and the multiple, bulky Da Vinci arms limit the ability to dock the robotic cart transanally and access the anorectum and pelvis in this manner; this in turn translates into limited proximal reach.

The Da Vinci platform evolution to *Xi* has considerably enhanced the profile of the robotic arms and provides an extended arm span. These features enable transanal cart docking, but this is at a trade-off with *Si,* because the *Xi* does not [currently] have 5-mm instruments, which makes the transanal operation more challenging. Fortunately, a new wave of robotic platforms specifically designed for single port and natural orifice surgery lie on the immediate horizon [23]. The main advantage of these systems is the addition of flexible effector arms and/or cameras which can be manipulated in part, or completely, by a master–slave, computer assisted system [24]. Such systems could change our approach to complex surgical problems unique to the field of colorectal surgery, but they first require careful assessment and vetting.

On May 4, 2017, the United States Food and Drug Administration (FDA) provided Section 510(k) approval of the Flex® Robotic System and Flex® Colorectal (CR) Drive (MedRobotics, Corp. Raynham, MA, USA) a semi-robotic apparatus for colorectal surgery specifically indicated for transanal endoluminal applications, as well as more radical resection (i.e., taTME). This system has already been utilized by European surgeons for transoral surgery with feasibility determined in both preclinical and clinical studies [25–28]. For colorectal surgery, assessment and evaluation of the Flex® Robotic System has begun by leading experts, and during the proceedings of the American Society of Colon and Rectal Surgeons and Tripartite Meeting (Seattle, WA, USA, June 10–14, 2017) V. Obias, P. Sylla, and A. Pigazzi presented their initial assessment of this system for transanal access in a preclinical setting. Here, this flexible robotic system is described and its use for local excision and taTME in a cadaveric model is illustrated with a video supplement.

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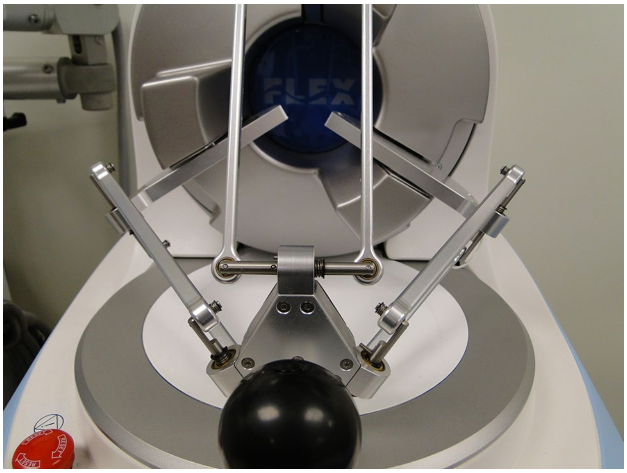

Fig. 1 Master control for the Flex® Robotic Scope is a control knob that can be manipulated in three-dimensional space. Movement of this bedside, surgeon-operated device represents an exact translation of the Flex® Scope's excursion

Fig. 2 Flex® Robotic Base (draped) is shown. This accommodates the Flex® Robotic Colorectal Drive, which has recently received Federal Drug Administration 510(k) clearance in the USA

Flex® Robot design and instrumentation

The system consists of two main units, (a) a robotic control console or Flex® Cart (Fig. 1) and (b) the Flex® Base (Fig. 2) and Flex® Scope (Fig. 3). The 28-mm dia. Flex® Scope CR Drive is controlled directly by the surgeon (who is stationed at the patient's bedside, and not at a remote surgeon console). The disposable, single-use Flex® Scope CR Drive is fitted onto to the Flex® Base prior to use and transanal docking. Essentially, a surgeon-operated control knob (Fig. 1) can be used to remotely translate the scope in three-dimensional space. Movements of the control knob represent an absolute measurement of the Flex® Scope's excursion (as demonstrated in the online video supplement). The surgeon thus operates at the bedside by using flexible, pistol-grip laparoscopic style instruments (Fig. 4). These non-robotic

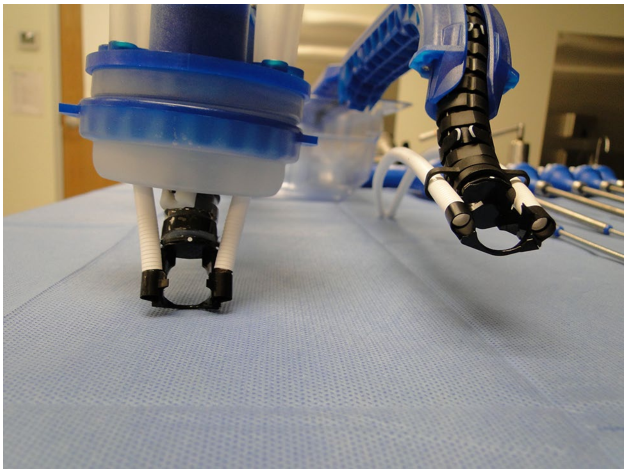

Fig. 3 Working ends of the two versions of the Flex® Robot are shown. (right) The scope used by otolaryngologists, (left) is the same as the adaption of the scope for colorectal surgery, which is termed the Flex® Scope CR Drive. Note that a disposable cap, which is assembled with the robotic system, is used to provide an airtight seal when mated with the reusable access channel. While the camera itself is reusable, all other components are disposable and are intended for single use only. Note the two white tubes or channels that are at the 3 and 9 o'clock position. These accommodate 3.5-mm flexible instruments used to perform surgery and triangulate with the 0° camera lens

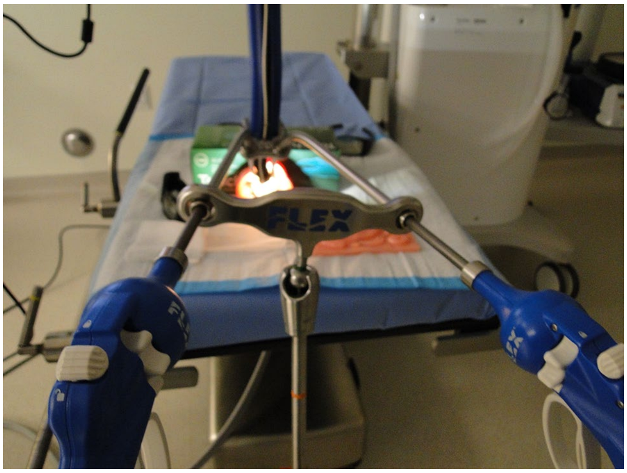

Fig. 4 Flex Robot System with Colorectal Drive is docked transanally. In this configuration, the Flex Robot is at the 12 o'clock position, and an 8 mm AirSeal trocar is positioned at 6 o'clock and is connected to a high-flow insufflator for stable pneumatics. At the 3 and 9 o'clock position are metal tubes through which the flexible instruments are delivered (within the access channel these tubes become flexible). The entire system is secured to the operating table rail by mounts so as to provide platform stability

instruments are delivered to the end of the flexible robot where they can be positioned so as to produce working angles that are delivered away from the otherwise very narrow scope axis, thereby permitting triangulation. The system accommodates various wristed 3.5-mm instruments, such as needle drivers, hook, and needle point monopolar cautery, and various graspers. It is possible to exchange right and left hand instruments through the bedrail-mounted apparatus when required. A reusable HD camera with light-emitting diodes allows for clear illumination and definition of the operative field which is displayed on an HD monitor in a similar fashion to laparoscopy. An operational prototype 3D camera has been developed, but is not yet approved for use the Flex® Robotic System at the time of this writing; it is expected to be available by 2018.

The system is designed to be operated by a single surgeon. With such a design, operation of the snake-like flexible robotic camera cannot be performed while simultaneously operating the wristed flexible instruments. Thus, the surgeon first establishes a field of view and then operates using the flexible instruments to perform the dissection. There are only two flexible 3.5-mm instruments which can be used (currently), which are introduced at the 3 and 9 o'clock position relative to the scope axis (Fig. 4). A flexible instruments channel through a bedrail-mounted bracket that mates with the Flex® Scope CR Drive, which itself is docked transanally with a reusable transanal endoscopic microsurgery (TEM)-like metal access channel that is also bedrail-mounted (Fig. 5). In addition, the Flex® Scope CR Drive has suction, irrigation, and lens cleaning capability, but this must be performed by manual introduction of saline. Finally, a valveless trocar system (AirSeal, ConMed, Inc, Utica, NY, USA) can be adapted to the system as well to establish a stable pneumorectum (Fig. 6).

Local excision

This flexible robotic system is particularly well suited for local excision of rectal, and potentially sigmoid, neoplasia. The maximum scope excursion (i.e., reach beyond the anal verge) is currently 17 cm. Thus, the entire rectum is accessible. Comparatively, straight (or articulated) instruments utilized by TEM, TAMIS, and other advanced platforms provide a reach of about 15 cm from the anal verge.

To perform local excision of a neoplasm, the surgeon or operating room personnel selects the Flex® Robot CR Drive and attaches it to the flexible robotic Flex® Base. It is docked transanally using a rigid platform designed to rendezvous with the Flex® Robot CR Drive creating an airtight seal. This is then secured to the operating table with a rail mount (similar to TEM). Next, the surgeon uses the control console to navigate and advance the scope to the operative target, and this technique is not at all the same as advancement with the scope during colonoscopy. It can require 5–10 min to precisely deliver the Flex® Robot to the correct position, depending on the level of the target lesion. Once the operative field has been defined, the surgeon no longer uses the control knob to adjust the scope's position and relies on the flexible instruments to complete the excision at the beside; the scope position remains fixed during this time (Fig. 7a).

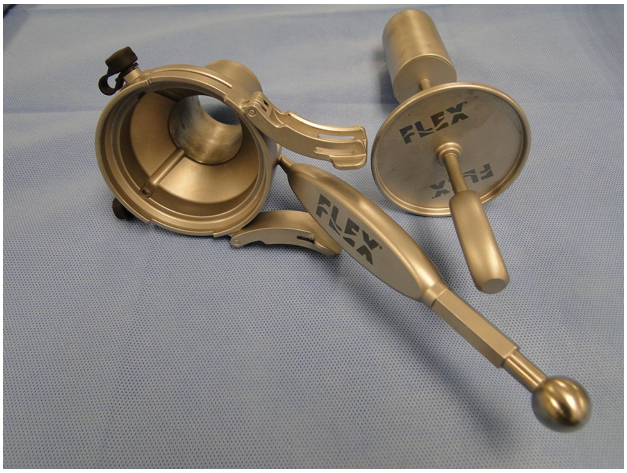

Fig. 5 The single-use Flex® Robot Colorectal Drive is mated to this specially designed and reusable access channel. Thus, some aspects of the apparatus are disposable, while others are reusable

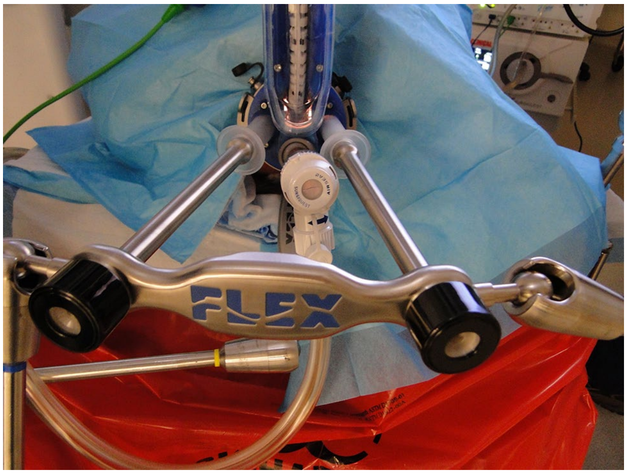

Fig. 6 Two 3.5-mm dia. flexible effector arms are shown. These course along the 3 and 9 o'clock position of the snake-like robot, which has an excursion of 17 cm. While the Flex® Robot motion is based on master–slave control, the actual operation is carried out with pistol-grip-style instruments, similar to techniques used in traditional laparoscopy. With this current design, a bedrail mount is necessary to provide stability

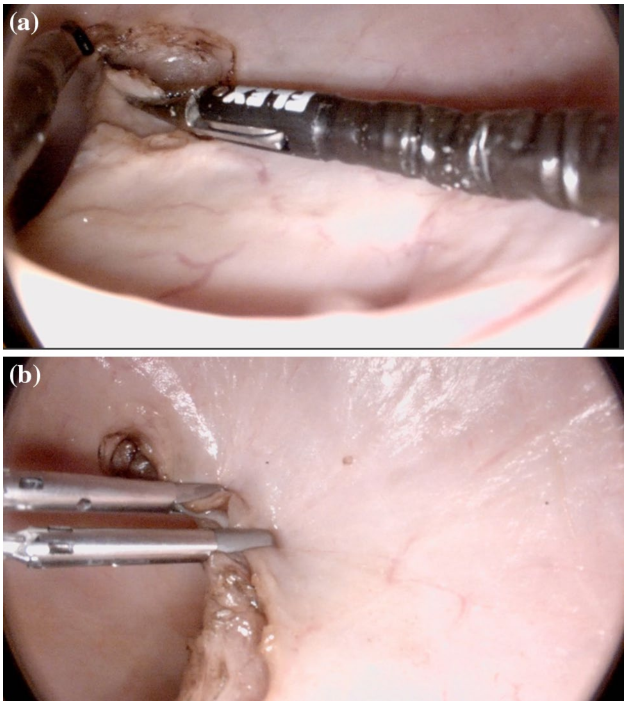

Fig. 7 **a** Local excision in a cadaveric model using the Flex® Robotic System with Colorectal Drive. In this example a flexible 3.5-mm hook cautery and flexible 3.5-mm Maryland grasper are used to perform a full thickness dissection. **b** Endoscopic clips are used to reapproximate the bowel wall, a technique used by advanced endoscopists, and one which can be adapted to the flexible robotic system. This approach could obviate the need for more complex closure methods, such as endoluminal suturing

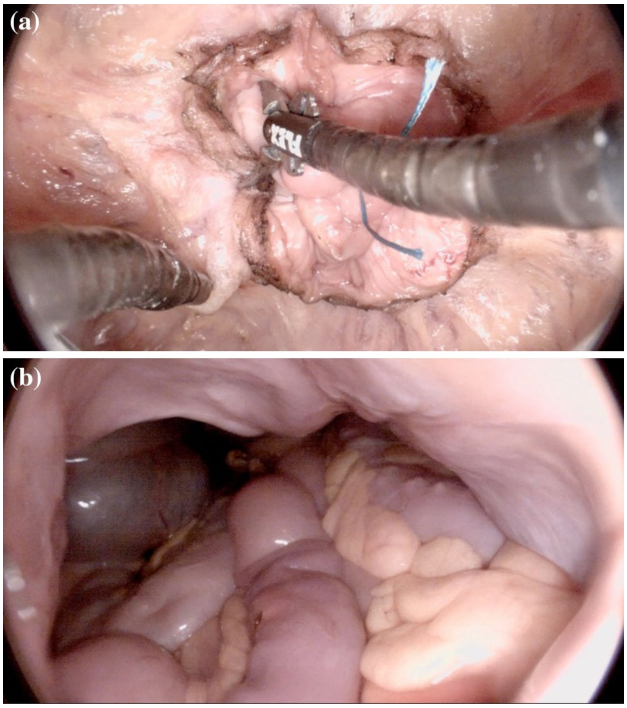

Fig. 8 **a** taTME dissection using the Flex Robotic System as demonstrated in a cadaveric model. **b** Anterior entry into the peritoneal cavity. One advantage of a flexible system is that it can allow for a higher reach, and the ability to access structures above the level of the sacral promontory, potentially increasing the scope of what can be realistically accomplished via transanal access

Suture closure with 3.5-mm flexible needle drivers is possible, but instrumentation for delivery of the needle and suture to proximal targets and retrieval of the same needle has yet to be developed, limiting somewhat the ability to reapproximate defects after local excision. However, it is possible to accomplish this goal with techniques used in colonoscopy. For example, it is possible to utilize endoscopic vascular clips to reapproximate the rectal wall (Fig. 7b), as demonstrated in the video supplement.

Transanal total mesorectal excision (taTME)

With the same system setup and instruments used to perform local excision, the flexible robotic system can also be used to perform more advanced resections, in particular taTME (Fig. 8a, b). While flexible instruments offer improved access to the subperitoneal pelvis, because taTME is (when compared to local excision) performed in a broader field, the surgeon must readjust the scope position frequently during this operation, which limits the overall speed as this is significantly more time intensive. However, one advantage when compared to TAMIS for taTME, is that the surgeon is the sole operator, and an assistant is not necessary to manage the scope as it remains in a fixed position until repositioned by the operator.

Flexible 3.5-mm instruments (which are, comparatively, less than ½ the size of current, Da Vinci effector arms) result in minimal restriction of the field of view, and they allow surgeons a range of motion that is improved over straight laparoscopic instruments, as are commonly used for taTME with standard TAMIS techniques. Furthermore, the system design prevents instrument collision and clashing. Although these end effectors are not yet roboticized, their use is instinctive, with a learning curve that is probably shallow.

One of the most encouraging aspect of the Flex® Robotic System for taTME is that it can allow for more proximal reach, and the ability to manipulate the Flex® Scope allows the surgeon to navigate beyond barriers, such as those posed by the sacral promontory (Fig. 8b). This allows surgeons potential access to areas not otherwise approachable and thus could result in newfound applications via the transanal route.

Discussion

The purpose of robotics in surgery has altogether changed. The original aim was 'tele-presence' surgery [29, 30], that is, to use master–slave technology to perform remote operations (an example is battlefield surgery) as robotics can provides surgeons access to patients in hazardous or remote locales. In no way, at that time, was the objective to develop a technology that provided higher-quality surgery that challenges open or laparoscopic techniques. In a similar fashion, TEM was originally designed for higher reach [31], not better resection quality, and taTME was developed as a solution to the difficult android pelvis [32], not specifically as a method to more completely excise the Heald envelope with improved oncologic metrics [33].

Throughout the past 17 years, the objective of robotic surgery has quietly shifted from tele-surgery, to optimization of field access in anatomically constrained regions with platforms capable of improvement of the 'composite' operative environment, such as with refined ergonomics, tremor cancelation, 3D high-definition optics, and true-wristed instruments that are intuitive and simple to operate. Thus, our quest is toward surgical precision [34] and, now, something else: an increasingly centered focus on the ability to access anatomic areas which have been heretofore impossible to approach. Interestingly, despite 30 years of advancements and innovation in transanal surgery (such as TEM and TAMIS,), we have not been able to routinely cross the 15-cm barrier in endoluminal surgery (except when using fiberoptic colonoscopes which are only suitable for rudimentary procedures due to inherent design limitations).

The flexible robotic system described here is designed with the specific goal of accessing remote anatomic fields. Already shown to be efficacious for transoral surgery, the Flex® Robot CR will likely deliver similar results. Perhaps one important aspect of this system is that the roboticized Flex® Scope can be translated into the lumen of the colon in a controlled and stabilized manner that drastically differs from colonoscopic advancement and manipulation. This is because the surgeon is able to 'drive' the Flex® Scope through the lumen, which is not possible in colonoscopy, whereby the scope is forcibly pushed through the lumen. For this reason, common technical challenges of colonoscopy, such as looping, parallax motion, and lack of anterior–posterior orientation, are overcome by this snake-like flexible robotic system.

The system described herein is a radical departure from Da Vinci Surgical Systems and represents an entirely different method to operate within the bowel lumen. While currently there is a limitation of 17 cm of scope excursion, this can likely be expanded such that the entire large bowel is accessible, thereby creating a method to manage the excision of lesions in all large bowel segments. Theoretically, this could someday replace the technique of endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) as it provides a more stable platform compared to dual channel colonoscopes.

The flexible effector arms measure only 3.5 mm, but are not robotic assisted, which is a limitation of the current technology and many surgeons would (rightly) consider this system to be semi-robotic only. As there is a limit to flexible effector arm length, to gain further reach, future renditions of this platform may include roboticized end effectors. Other limitations include suturing at ranges beyond 15 cm, where needle delivery, retrieval, and the process of suturing itself is encumbered by the Flex® Robot's convolution throughout the sigmoidal bends. Borrowing techniques from advanced endoscopy, (such as the use of deployable metal clips to reapproximate the defect after local excision), is an important type of adaption that appears to work well with the Flex® Robot. Despite some other limitations, the platform was found to be feasible for both local excision and taTME in a cadaveric model, and this new, field-specific technology appears to represent the next chapter in colorectal robotics.

Conclusions

The Flex® Robotic System was shown to be feasible in the preclinical setting for local excision and taTME. Flexible robotic systems specifically address problems in colorectal surgery by the nature of their design. As advancements in this direction continue, laparoscopy and next-generation robots will become increasingly divergent, as flexible robots have the potential to perform operative tasks not otherwise possible with conventional methods.

Compliance with ethical standards

Conflicts of interest S Atallah is a paid consultant for ConMed, Inc, Applied Medical, Inc, THD, America, and has an ongoing consultant relationship with Medicaroid Robotics and MedRobotics, Inc. This research was supported by MedRobotics, division of Colorectal Surgery, Research and Development.

Ethical approval This research was performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was not applicable as the work represented herein did not involve human subjects. Cadaveric research was conducted in accordance with the standards set forth by ethics and hospital regulations.

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