MULTIMEDIA ARTICLE

Direct target NOTES: prospective applications for next generation robotic platforms

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Abstract

Background A new era in surgical robotics has centered on alternative access to anatomic targets and next generation designs include flexible, single-port systems which follow circuitous rather than straight pathways. Such systems maintain a small footprint and could be utilized for specialized operations based on direct organ target natural orifice transluminal endoscopic surgery (NOTES), of which transanal total mesorectal excision (taTME) is an important derivative.

Methods During two sessions, four direct target NOTES operations were conducted on a cadaveric model using a flexible robotic system to demonstrate proof-of-concept of the application of a next generation robotic system to specific types of NOTES operations, all of which required removal of a direct target organ through natural orifice access. These four operations were (a) robotic taTME, (b) robotic transvaginal hysterectomy in conjunction with (c) robotic transvaginal salpingooophorectomy, and in an ex vivo model, (d) trans-cecal appendectomy.

Results Feasibility was demonstrated in all cases using the Flex® Robotic System with Colorectal Drive. During taTME, the platform excursion was 17 cm along a non-linear path; operative time was 57 min for the transanal portion of the dissection. Robotic transvaginal hysterectomy was successfully completed in 78 min with transvaginal extraction of the uterus, although laparoscopic assistance was required. Robotic transvaginal unilateral salpingo-oophorectomy with transvaginal extraction of the ovary and fallopian tube was performed without laparoscopic assistance in 13.5 min. In an ex vivo model, a robotic trans-cecal appendectomy was also successfully performed for the purpose of demonstrating proof-of-concept only; this was completed in 24 min.

Conclusions A flexible robotic system has the potential to access anatomy along circuitous paths, making it a suitable platform for direct target NOTES. The conceptual operations posed could be considered suitable for next generation robotics once the technology is optimized, and after further preclinical validation.

Keywords Minimally Invasive Surgical Procedures · Surgical Procedures, Robotic · Natural Orifice Endoscopic Surgery · Hysterectomy, Vaginal · TaTME · Appendectomy

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Introduction

Natural orifice transluminal surgery (NOTES) was a disruptive technology developed predominantly in the mid 2000s $[1-3]$ $[1-3]$ $[1-3]$. It provided gastrointestinal operators with access options which spared the abdominal wall from trauma and the inherent risk posed by such routes of access. Hence, the impetus behind the development of NOTES was to eliminate (or at least minimize) the incidence of surgical site infections, post-surgical pain, incisional hernias, and scarring. This ultimately redefined the boundaries of surgery. While NOTES was initially developed by endoscopists [\[1](#page-7-0)], it soon became a collaborative consortium which included industry

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engineers, minimally invasive surgeons, and advanced interventional gastrointerologists [\[4](#page-7-2), [5](#page-7-3)].

Importantly, NOTES represents a heterogeneous spectrum of operations, with distinct differences in access points, instrumentation, and type of surgery [[6\]](#page-7-4). One critical distinction for NOTES is whether the operation is an approach for direct versus indirect target organs (Table [1](#page-1-0)). In direct target organ NOTES, the viscerotomy created is a component of the planned operation and not created in the so-called 'bystander' organ. Bystander organ viscerotomy provides body cavity access, but is used only as a means of obtaining this access to distant (or indirect) target organs. A classic example of indirect target NOTES would be transgastric appendectomy or transgastric cholecystectomy [[7,](#page-7-5) [8](#page-7-6)]; both of which ultimately utilize a per-oral route of specimen retrieval.

A limitation of NOTES, which has principally been endoscope based, is the inability to realize proper working angles of effector instruments. This is because conventional scope-transmitted instruments do not triangulate and instead the operator must perform an arduous procedure working along the narrow scope axis. Conventional scope design is also limited because, although quite flexible, its position and somewhat pliable shape passively conforms to gravity and the lumen through which it is being navigated.

In 2017, a flexible robotic system (Flex® Robotic Systems, Medrobotics, Raynham, MA, USA) became approved for colorectal use by the Food and Drug Administration in the United States. This system represents a chimera of techniques, uniquely blending aspects of laparoscopy, robotics, and colonoscopy. Already used in Europe by otolaryngologists for per-oral surgery [\[9](#page-7-7)], it has been shown to be a feasible platform for local excision of rectal and rectosigmoid lesions and for transanal total mesorectal excision (taTME) [\[10](#page-7-8)]. Currently, this is being further evaluated in an ongoing multi-center trial in the United States. Compared to conventional scopes, the Flex® Robotic System allows for triangulation and purposeful steering of the instrument head along non-linear, circuitous lumens and anatomical pathways to access targets of interest—making it a particularly appropriate platform for direct organ target NOTES.

Here, this next generation flexible robotic system is used to perform four separate direct target organ NOTES operations. In cadaveric and ex vivo models, the approach to Flex® Robotic taTME is demonstrated. In addition, the first robotic transvaginal hysterectomy, including transvaginal robotic salpingo-oophorectomy, and first robotic natural orifice trans-cecal appendectomy are described. These four NOTES-derived operations are each detailed in the supplemental video content.

Study design

A cadaveric model was used to assess the feasibility of four direct target NOTES operations. Certain portions of the experimentation were performed ex vivo, and will be described separately (in particular, NOTES robotic transcecal appendectomy). Experimentation was conducted in two, full day sessions by a single surgeon at a specialized laboratory equipped with laparoscopic equipment, a valveless trocar and insufflation system, and a flexible robotic system. The Flex® Robotic System and specifically the Flex® Colorectal (CR) Drive were utilized for all experimental constructs. Some operations were performed with laparoscopic assistance. The valveless trocar system (8 mm trocar and AirSEAL® Insufflation Device, ConMed, Inc., Utica, NY, USA) was adapted to the flexible robotic platform. The objective was to demonstrate feasibility, and in most cases, simply proof-of-concept. Thus, the experimentation described below represents off-label use of the Flex® Robotic System, except when the application of taTME is illustrated.

Robotic transanal total mesorectal excision (taTME)

A fresh female cadaver was used to perform robotic taTME utilizing the methods and techniques described previously [[10\]](#page-7-8). After application of a distal purse-string, the Flex® Robotic System was docked transanally and the Flex® CR

Table 1 Direct versus indirect target organ NOTES

Direct target NOTES	Indirect target NOTES
The anatomical target organ is juxtaposed to the viscerotomy	The anatomical target organ is at a distance from the viscerotomy
Viscerotomy is part of planned operation	Viscerotomy of 'bystander' organ is necessary
Accepted technique	Technique controversial, especially with viscerotomy in alimentary tract
Was initially described with rigid instruments (with some exceptions)	Was initially described with flexible instruments
Examples: taTME, VAMIS, trans-cecal appendectomy, POEM, PEG	Examples: transgastric appendectomy, transvaginal cholecystectomy

POEM peroral endoscopic myotomy, *PEG* peroral endoscopic gastrostomy, *taTME* transanal total mesorectal excision, *VAMIS* vaginal access minimally invasive surgery, *NOTES* natural orifice transluminal endoscopic surgery

Drive module connected. Using the flexible robotic control console, and upon insufflation of $CO₂$ using a valveless 8 mm trocar (AirSEAL, ConMed, Inc.) the drive head was navigated to the target anatomy—in this case, the rectal wall—just distal to the purse-string which had been applied under direct vision with a hand-held anorectal retractor.

Dissection proceeded in hemispheric operative fields, and the rectotomy was created to enter the TME plane. In this example, the posterior hemispheric dissection was established first, extending from the 3 O'clock to 9 O'clock position of the rectum with the cadaveric torso positioned dorsally. Using this system, it was preferred to work as much as possible in one section before repositioning the robot for the next. Thus, as the potential space of the extraperitoneal pelvis became actualized, surgery was focused in specific zones or hemispheres, since dissecting circumferentially required multiple changes of the field of view, which in turn would have required manipulation of the Flex® Robot camera head that can be time intensive. This is because camera head and conjoined operator effector arm movement are computer controlled and thus are not subject to the otherwise rapid free-play and manipulation of hand-held, conventional cameras and scopes. This allows for precise surgery with the advantage of higher reach along non-linear pathways during $taTME$ (Fig. [1\)](#page-2-0).

The trade-off changes the methodology of taTME dissection, as working in specific zones should be continued until completion. This was the technical approach utilized in the taTME performed, which was successfully completed in 57 min, from flexible robotic cart docking to peritoneal entry.

Because the rectotomy created is part of the planned operation, taTME (robotic or otherwise) is an example of direct organ target NOTES, even though the standard technique

Fig. 1 Flexible robotic taTME is demonstrated. With the surgeon at the bedside, the robotic head is navigated precisely to the anatomical target and the flexible, hand-held retractor and hook monopolar cautery are used to perform the dissection, here proceeding posteriorly along the embryonic fusion plane between the endopelvic fascia and the mesorectal envelope. The 'angel hair' of this avascular plane can be seen clearly as it is pneumatically dissected

is performed using hybrid NOTES with laparoscopic assistance in most, but not all cases to date $[11-18]$ $[11-18]$ $[11-18]$.

Robotic transvaginal hysterectomy and salpingo‑oophorectomy

Transvaginal hysterectomy with or without salpingo-oopho-rectomy is one of the original natural orifice operations [[19](#page-7-11)]. The technique of using a transanal minimally invasive surgery (TAMIS) [\[20](#page-7-12)] platform transvaginally for the purpose of hysterectomy has been described previously in a cadaveric model [[21,](#page-7-13) [22](#page-7-14)], and subsequently demonstrated feasible in a clinical setting [[23–](#page-7-15)[25](#page-7-16)]. This new approach to hysterectomy has been termed vaginal access minimally invasive surgery (VAMIS). In this experiment, robotic VAMIS was performed using a flexible robotic platform for the first time. In the initial portion of this cadaveric experiment, the robotic VAMIS hysterectomy is performed, and then, though the same natural orifice (i.e, the vaginal vault), a robotic VAMIS right salpingo-oophorectomy was also performed.

The first step was to dock the Flex® Robotic System utilizing the $Flex^{\omega}$ Colorectal (CR) Drive utilizing its reusable access channel (positioned transvaginally). An adequate seal was obtained using the native device. An 8-mm valveless trocar system was used and the vaginal vault was insufflated with the pressure set to 15 mmHg. The robotic system camera and working head was then navigated to the target anatomy, the cervix. The cervical os was grasped with a 3.5-mm flexible, hand-operated effector arm, and used to manipulate the position of the cervix, similar to a joystick. This allows for adequate and precise tension-counter tension tissue apposition during surgical dissection. Using monopolar electrocautery configured to a spatulated 3.5-mm flexible effector arm, a circumferential colpotomy was performed thereby entering the peritoneal cavity. This was conducted by addressing the dorsal aspect (posterior dissection) and by subsequently entering the peritoneal cavity along the pouch of Douglas, before progressing to the ventral (anterior) colpotomy and dissection. Upon entering the peritoneal cavity anteriorly and posteriorly, the uterovaginal fascia, cardinal ligament, parametrium, and broad ligament were divided in stepwise fashion with cautery (Fig. [2](#page-3-0)). Transection of the isthmus of the fallopian tubes (juxtaposed to the uterine fundus) was also performed via the transvaginal robotic route. While the robotic transvaginal hysterectomy was completely performed from the vaginal approach, there was laparoscopic assistance. Specifically, via two laparoscopic 5- mm ports, a 5-mm camera lens and a single 5-mm grasper were used to (a) clear small bowel from the pelvis, and (b) retract the uterine fundus to assist with NOTES robotic transvaginal exposure and dissection. Upon completion, the uterus was removed, intact, and delivered transvaginally. Operative time from docking the robot until

Fig. 2 Flexible robotic VAMIS hysterectomy is performed by docking the system transvaginally, using the CR Drive. Here the flexible 3.5-mm grasper and cautery are used to perform dissection along the left broad ligament of the uterus. The operation required laparoscopic assistance, principally for uterine retraction

Fig. 3 The right adnexa, including ovary and fallopian tube were dissected using the flexible robotic system which had been docked transvaginally. The adnexa was successfully dissected and the specimen retrieved vaginally after completion of the VAMIS hysterectomy

specimen retrieval was 78 min. The vaginal cuff can typically be closed with conventional methods under direct vision transvaginally as this is easily accessible; this was not performed in this robotic VAMIS cadaveric model as the objective was only to demonstrate feasibility. After robotic VAMIS hysterectomy, the robotic cart was re-docked transvaginally and the right adnexa, including the right fallopian tube and ovary, were excised as well through robotic transvaginal access **(**Fig. [3](#page-3-1)). Robotic transvaginal salpingo-oophorectomy was completed in 13.5 min. The procedures are demonstrated in in the supplemental video content.

Robotic trans‑cecal appendectomy

The current flexible robotic platform, through transanal access, has a limited reach of 17 cm. However, in this hypothetical construct and by experiment design, this limitation was effectively bypassed so that trans-cecal appendectomy could be attempted.

To test feasibility and to circumvent the limited reach of the current flexible robotic platform, this experiment was constructed in an ex vivo cadaveric model and was designed to demonstrate proof-of-concept only. Here, a cadaveric laparotomy and a right hemicolectomy were performed. Next, the entire ascending colon, terminal ileum, and appendix were explanted from the fresh, female cadaver. The lumen of the ileocolic bowel was then prepped and irrigated with saline solution. Next, the Flex® Robotic System utilizing the Flex® Colorectal (CR) Drive was adapted and secured to the ascending colon ex vivo. A valveless 8-mm trocar was utilized to provide pneumocolon and the terminal ileum was sutured closed to prevent leakage of CO_2 gas. The access channel of the Flex[®] Colorectal (CR) Drive was secured to the ascending colon with zip-ties and insufflation was adequately maintained in this model, thus placing the robotic platform within a 17-cm range from the cecum. Next, the flexible robotic camera was navigated to the target: the appendiceal orifice. This was easily identified. Next, the orifice was gasped and monopolar electorcautery was used to circumscribe the target anatomy. A full-thickness division of the cecal wall around the orifice was performed, thereby completely dismounting the appendix. Despite the cecotomy, pneumocolon remained stable and no billowing was observed. Next, the meso-appendix was isolated and divided using the robotic platform (Fig. [4](#page-4-0)). After complete division, the appendix was then delivered into the lumen of the colon. Conceptually, this could have been removed transanally, similar to how large colonic polyps are retrieved. The defect itself could have been closed using the robotic platform with suture or clips as described previously [\[10](#page-7-8)]. Operative time was 24 min.

Discussion

Robotic platforms in surgery are rapidly evolving to meet the demands of a new era $[10, 26]$ $[10, 26]$ $[10, 26]$ $[10, 26]$. Remodeled by the potential to access the abdominal and pelvic cavity via natural orifice modes, next generation-reduced footprint medical robots will provide surgeons with access options not previously imagined. An important rethink in robotic design has been the evolution to include flexible arm

Fig. 4 In an ex vivo conceptual model, the Flex® Robotic System utilizing the Flex® Colorectal (CR) Drive has been adapted to function in the ascending colon and cecum. A seal was created between the divided right colon and the access channel of the CR Drive, and the lumen was insufflated with $CO₂$ gas. The system was then used to target the appendiceal orifice, creating a circumferential colotomy around it, effectively dismounting the appendix from the cecum. Division of the mesentery (shown) using the flexible system allows for appendectomy and endoluminal specimen capture

systems which achieve operative access through a single port rather than conventional, multi-trocar, transabdominal routes that are the mainstay of current medical robotics, and which had essentially been designed to imitate laparoscopic instrumentation and access techniques.

Thus, the addition of flexible elbows to robotic or handoperated effector arms, with controlled supination and pronation, together with single-port configuration, represent important steps forward in instrument design. By providing triangulation, a distinct limitation of existing two-channel colonoscopes used by today's interventional endoscopists, surgeon dexterity and operative field control are significantly improved. Together, these innovations pave a pathway suitable for NOTES.

Here, the potential advantages and prospective applications of flexible robotic NOTES are demonstrated in four vastly different applications which conserve a fundamental surgical principle that obviates the need for bystander organ viscerotomy. Perhaps the most provocative of the four examples of robotic direct target NOTES described is the concept of trans-cecal appendectomy as an alternative to other NOTES approaches previously reported [[7,](#page-7-5) [8](#page-7-6), [27](#page-7-18)]. In a simple *ex vivo* model, it was demonstrated that, if robotic system limitations of reach and function were overcome, it would be possible to excise the appendix, deliver it into the colon, and ultimately retrieve it transanally.

Valid concerns for direct target organ NOTES (robotic assisted or otherwise) along the alimentary tract include fecal spillage and the potential for bacterial seeding and sepsis which is a non-zero risk, as demonstrated from clinical data on taTME [[28](#page-7-19)]. However, extrapolating from data on the safety of peritoneal entry with full-thickness excision of lesions using transanal endoscopic microsurgery (TEM) [[29,](#page-8-0) [30\]](#page-8-1) and laparoscopic or robotic (purposeful) enterotomy used to perform colonic intracorporeal anastomosis [[31,](#page-8-2) [32\]](#page-8-3), adverse outcome from spillage are infrequent as long as there is adequate control of the operative field, with adequate bowel preparation. Thus, trans-cecal appendectomy via targeting the appendiceal orifice may not impose new risks, assuming the closure is durable.

Clearly, should such a technique come to fruition, it should be considered only for carefully selected patients. For example, it could be an alternative for patients with poor performance status for whom general anesthetic risks are prohibitive, or for patients whose abdominal wall poses particular access risk (such as extensive burns, eschar, or contractures). Robotic NOTES trans-cecal appendectomy could also be a technique suitable for those harboring benign appendiceal neoplasia (versus acute appendicitis).

Importantly, this allows one to consider transposing the concept of trans-cecal appendectomy to other targets within, or juxtaposed to, the alimentary tract. For example, in the colon the concept could be applied to the excision of pre-malignant neoplasia, and even proximal T1 cancers in patients who are too infirm to undergo radical resection, or who decline to have standard of care treatment for various reasons. Indeed, this exact concept has already been used by interventional gastroenterologists performing full-thickness endoluminal excisions of colonic neoplasia, whereby unique over-the-scope suturing devices such as OverStitch™ (Apollo Endosurgery, Inc.) and specialized endoscopically deployed clips, (OTSC® System, Ovesco Endoscopy AG) are used to reapproximate bowel wall defects after excision. With the advent of this scope technology, interventional gastroenterologists have gradually advanced from endoscopic mucosal resection (EMR), to endoscopic submucosal dissection (ESD), and now to full-thickness resections using what are often termed full-thickness resection devices (FTRD) [[33](#page-8-4)[–36\]](#page-8-5). In the United States, this is restricted to a few, highly specialized centers with technical expertise in this field [[37](#page-8-6), [38](#page-8-7)].

As flexible robotic systems undergo a refinement in system design that allow for controlled flexibility and more proximal reach, it is conceivable that local excision of neoplasia may be more frequently performed by surgeons (rather than non-surgeons) for lesions beyond the confines of the rectum proper. In essence, this could shift the endoscopicbased practice of ESD and FTR from the field of gastroenterology to surgery as newer robotic technology will supplant existing, more rudimentary endoscopes which had in principle only been designed to view the lumen and biopsy retrievable polyps.

Clear Smoke evacuation and TAMIS mode insufflation (Stryker, Inc.), *AirSEAL® iFS* valveless trocar system and smoke evacuation system (ConMed, Inc.), *ISB* Insufflation Stabilization Bag Clear Smoke evacuation and TAMIS mode insufflation (Stryker, Inc.), AirSEAL® iFS valveless trocar system and smoke evacuation system (ConMed, Inc.), ISB Insufflation Stabilization Bag (Applied Medical, Inc.), SILSTM Port Single Incision Laparoscopic Surgery (TAMIS port, Covidien-Medronic) (Applied Medical, Inc.), *SILS™ Port* Single Incision Laparoscopic Surgery (TAMIS port, Covidien-Medtronic)

this, non-robotic VAMIS for hysterectomy, was described and presented in 2014, and reported at the 43rd Annual Global Congress on Minimally Invasive Gynecologic Surgery in Vancouver, British Columbia [[21](#page-7-13)]. Preclinical, cadaveric work was subsequently published [[22](#page-7-14)]. While the flexible robotic system was demonstrated to be feasible for VAMIS hysterectomy, there were important limitations of the technique which may prevent translation into a clinical context. This was found to be related to two limitations of the current system design. First, robotic VAMIS hysterectomy required laparoscopic assistance. Although minimal, it should be recognized that with only two working arms using the flexible robotic system, retraction can be limited and thus control of the surgical field can pose a challenge to the surgeon, for example, manipulation of the uterine fundus required traction provided by a 5-mm laparoscopic grasper. Second, successful management of arterial vessels with cautery alone is unlikely and the addition of a flexible robotic vessel

Successfully demonstrated herein was direct target robotic VAMIS hysterectomy, which, to the best of our knowledge, represents the first report of its kind. Prior to

ful transvaginal salpingo-oophorectomy. Further assessment of the flexible robotic platform for taTME was also successfully demonstrated. In the near future, colorectal surgeons will have multiple platform options for taTME, including TAMIS [[39\]](#page-8-11), TEM/transanal endoscopic operation(TEO) [[40,](#page-8-12) [41\]](#page-8-13), da Vinci Multi-Arm (*Si* and *Xi*) [\[42–](#page-8-9)[45](#page-8-14)], da Vinci *SP* [\[46\]](#page-8-10), and the Flex® Robotic System [[10\]](#page-7-8). Furthermore, there will most likely be a multitude of newer options on the immediate horizon [[47\]](#page-8-15). Each of the current (robotic and non-robotic) platforms applied to taTME and transanal surgery have differentiating characteristics, and each has unique advantages and disadvantages, as delineated in Table [2.](#page-5-0)

sealer or clip applier represents an important requirement before safely transitioning to clinical trials. Otherwise, from a conceptual standpoint, transvaginal, direct target robotic NOTES hysterectomy allows for excellent exposure and precision. Improved reach and the ability to direct the robotic head in curvilinear paths contributed to the ability to address the adnexa, allowing for success-

The original goal of robotics has shifted dramatically through the first two decades of the millennium. Medical robots were initially designed for telepresence surgery [[48](#page-8-16), [49\]](#page-8-17), but then became a platform purported to rival laparoscopy [[50,](#page-8-18) [51\]](#page-8-19). More recently, medical robotics have evolved into a platform which allows surgeons to access anatomical targets in a method not otherwise possible, thereby unlocking new pathways to reach anatomical targets [\[10\]](#page-7-8).

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Conclusions

A flexible robotic system has the potential to access anatomy along circuitous paths, making it a suitable platform for direct target NOTES. With future innovation and technological advancement, the conceptual operations posed herein could be applied clinically, providing select patients with treatment options not previously imagined.

Compliance with ethical standards

Conflict 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. The other authors declare that they have no conflict of interest.

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 scientific laboratory regulations.

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