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NEW TECHNOLOGY REPORT

Clinical Experience of a Smart Articulating Digital Device For Transanal Minimally Invasive Surgery

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KEY WORDS: HandX; Minimally invasive surgery; Rectal cancer; Robotic-assisted surgery; Significant rectal polyps;Transanal minimally invasive surgery (TAMIS).

ABSTRACT

BACKGROUND: The constrained access associated with transanal minimally invasive surgery has led surgeons to deploy robotic-assisted platforms to offset inherent maneuverability limitations and, perhaps, skills deficits.

IMPACT OF INNOVATION: A handheld, powered 5-mm lightweighted laparoendoscopic electromechanical digital device (HandX™, HumanXtensions, Israel) with hardware and software components that convert surgical hand movements precisely to the instrument's articulating tip enabled robotic transanal minimally invasive surgery with its full roticulation for hook diathermy and suturing.

TECHNOLOGY MATERIALS AND METHODS: After bench and biomedical model training, HandX™ was used in 3 transanal minimally invasive surgery procedures (2 male and 1 female patient, mean age 66.3 years). The rectal lesions averaged 30 mm in maximum dimension and were located posteriorly (n = 2) and laterally (n = 1) a mean of 3 cm from the anal verge. Standard transanal minimally invasive surgery setup and instrumentation (Gelport Path, Applied Medical with Airseal, Conmed) were used adding the HandX™ device for circumferential lesion marking and haemostatic full-thickness excision as well as defect suturing where appropriate.

PRELIMINARY RESULTS: All procedures completed without undue prolongation (operating times <1 hour) despite nuisance hemorrhoidal bleeding in one. All lesions were fully excised with 2 proving to be T1 cancers and 1 tubullovillous adenoma with high-grade dysplasia. All patients were discharged within 48 hours postoperatively (one suffered secondary hemorrhage on postoperative day 5).

CONCLUSIONS AND FUTURE DIRECTIONS: HandX™ capably facilitated endoscopic robot-like instrument movement for transanal minimally invasive surgery without disrupting workflows. With time dedicated to instrument understanding and training, HandX™ increased dexterity with small operating room footprint may be offering greater cost-effectiveness than other platforms.

INTRODUCTION

Transanal minimally invasive surgery (TAMIS) offers a natural orifice, intraluminal approach for the excision of rectal neoplasia, providing a cure for benign and selected malignant lesions.1,2 It utilizes a widely available transanal platform (Gelport Path, Applied Medical) that provides for *laparoscopy within the rectum* via a gas-insufflated pneumorectum. In this way, the cooperative efforts of two surgeons working between the lower limbs of the anesthetized patient, positioned in lithotomy, using standard laparoscopic instrumentation (usually a 5- or 10-mm 30-degree laparoscope along with a tissue graspers and hook cautery) perform lesion excision and, when appropriate, suture closure of the resulting defect. The approach has however intrinsic maneuverability limitations with its enforced clustering of working instruments in a small volume targeted at the rectal wall. The inherent constraint associated with transanal access has undermined uptake generally meaning many potentially suitable patients still undergo flexible endoscopic and even laparoscopic resection.

The potential advantages of TAMIS (i.e., lower morbidity and rectal preservation versus laparoscopic resection and greater completeness of specimens versus endoscopic submucosal dissection3) have encouraged some surgical groups to deploy incumbent robotic-assisted surgical platforms4 to offset their difficulties in performing the technique. Indeed new procedure specific platforms are in development (e.g., Flex Robotics System, Medrobotics, Da Vinci SP, Intuitive).5 While feasible, efforts to deploy robotic-assistance are presently limited by the high cost and relative unavailability of such platforms as well as their incompatibility with existing TAMIS workflows and generally limited added value for other general or colorectal surgical needs within the surgical department.

Advanced endolaparoscopic instrumentation is now available that enables roticulated end-instrument movement to provide greater dexterity and precision during operations. While such capability can be achieved with pure mechanical engineering,6 the size of the gimbal configuration currently precludes such instrument use for TAMIS. The new clinically available handheld, powered 5-mm lightweight, laparoendoscopic electromechanical smart articulating digital device (HandX™, Human Xtensions, Israel) seems more applicable to TAMIS now without workflow modification. The device includes both hardware and software components that convert the surgeons hand movements precisely to the instrument-articulating tip, allowing enhanced degrees of freedom and full articulation-roticulation for hook diathermy and suturing. Building on our prior training and clinical experience,7 we present here our initial clinical experience of this device's application to TAMIS.

METHODS

After dedicated training on the smart device and a limited laparoscopic clinical series with graded levels of operative complexity,7 three TAMIS procedures were scheduled. As a CE-marked, commercially available device being used as per its licensed indication in standard operations, institutional review board (IRB) approval was not required for device use per se but patient data processing, analysis, storage with participant consent was performed under IRB approval (reference: 1/378/2092). Training was of 3-hour duration for 2 surgeons each and included both standard laparoscopic box simulators (including both peg transfer and suture skills) and a boutique biomedical TAMIS model with a silicon insert and bovine intestine (Fig. 1). Thereafter, 3 patients were planned for TAMIS, including the smart device within an otherwise standard TAMIS setup (including lithotomy patient position and Airseal insufflator

system, Conmed). A company representative provided initial training for both surgeons and nurses and was in attendance during each operative case to facilitate instrument setup.

RESULTS

The smart device was effectively used for all cautery, including marking and tissue dissection, and suturing in this series (Fig. 2). The first patient was an 80-year-old, frail woman with comorbidity and aversion to stoma and blood transfusion. Her rectal lesion was 29 mm in maximum dimension (after formalin fixation) and was located posteriorly in the rectum, 4 cm from the anus. The second patient was a 68-year-old man who had a 30-mm rectal lesion posteriorly, 2 cm above the sphincter on a background of chronic ulcerative colitis. The third patient was a 47-year-old man with a 30 mm lesion of the left side of the rectum between 3 and 5 o'clock, 25 mm from the sphincter. Each TAMIS procedure was completed without undue operative prolongation (operating times <1 hour in each case) including defect closure in one patient (in the others, the defect was left open due to the position of the defect). The third case was temporarily interrupted to allow direct pressure control nuisance hemorrhoidal bleeding. All lesions were fully excised macro- and microscopically. All patients were discharged within 48 hours postoperatively. One patient required readmission on postoperative day 5 for secondary hemorrhage that stopped spontaneously and did not require red cell transfusion. Pathology proved one lesion to be a tubulovillous adenoma while the other two were T1 cancers. One patient with cancer proceeded to abdominoperineal resection because of pathological adverse factors (venous and perineural invasion in the specimen), while the other two are fully disease free after more than one year of follow-up.

DISCUSSION

TAMIS evolved from its forebearer transanal endoscopic microsurgery/operation, which had proved transanal access an effective method to address rectal neoplasia. With increased uptake of laparoscopic operating and availability of equipment and skillsets along with the nudge given by the developmental effort associated with both natural orifice translumenal surgery (NOTES) and single port laparoscopic surgery, TAMIS has become a defined and accepted albeit still somewhat niche entity. The development of dedicated disposable access devices along with smart insufflation systems has enabled surgical groups to offer this procedure using devices (i.e., cameras and working tools) already in standard use for laparoscopic operations in their departments. However, despite this and established training pathways, TAMIS remains a relatively restricted procedure due in part to the inherent difficulties related to the constrained access (both on the patient exterior due to the lithotomy position and internally within the rectum) which require specific skillsets to overcome. These limitations have meant surgical groups are exploring and indeed celebrating robotic platform feasibility8,9 although of course such platforms are themselves limited in availability and, when utilized transanally impose new operative workflows without synergy with other laparoscopic or robotic-assisted approaches within the same department.

In this report, we describe successful deployment of a new smart articulated instrument in a small series of patients which required some pretraining to accommodate. This device comprises two main parts: a hand piece (the capital component, including control interface) and Instrument (a single-use, disposable, detachable, sterile component packed in blister packaging). Additional disposables are single use finger pads, arc and cables and a standard sterile drape for the hand piece. The device weighs 0.665 kg (other dimensions are shown in Supplementary Fig. 1 at

http://links.lww.com/DCR/C242) and can be used single handedly. The in-line handle and the degree of tip articulation help avoid the need for much supination and pronation of the working dominant hand during TAMIS and so less collisions with the camera/other instruments arise. While operative times and outcomes were like those commonly achieved in our department, the advance here is that the instrumentation may allow improved dexterity and precision enabling and/or encouraging others adopt the technique. Furthermore, any investment in this technology has immediate applications across the general laparoscopic portfolio including other colorectal operations including rectopexy and of course upper gastrointestinal, bariatric and hepatobiliary surgery.

Appealingly, the robotic system enables a choice of setting between “laparo” and “robo” styles, the former maintains the hand:tip movement ratio of laparoscopic surgery where a hand movement to the left moves the instrument tip to the right while the latter means hand movement left translates to instrument tip movement left. The latter may be especially helpful during TAMIS where radial/ulnar deviation limitations can impact procedure ergonomics especially with forearm rotation. The system too is planned to evolve to a common hand unit which will allow differing end effectors to be mounted rather than the current set-up which needs a different hand piece for each instrument type. In addition, an expanded number of instruments is in development (alongside today’s availability of grasper, hook cautery, spatula and a needle holder) along with smart instrument data analytics. Cost comparison of the smart handheld device versus a DaVinci robotic platform has been performed previously, and on a per procedure basis, the smaller smart device was considerably more cost effective then the Da Vinci robotic platform10 (capital costs are also less with the smart system but were excluded from this cost analysis as the companies have different strategies according to institution and jurisdiction).

Clearly, the lesions and patients detailed here could have been ably treated by standard TAMIS with conventional instrumentation by any skilled surgical team. Therefore, perhaps the real value of the smart digital device will become even more apparent with more advanced confined access techniques such as transanal total mesorectal excision (TME) or indeed potentially even standard minimal access TME (but probably not TEO/TEM) where robotic platforms are increasingly being utilized. Nonetheless this report provides baseline evidence (and indeed an “entry level” use case) of the usefulness of this device and provides a video for practitioners to make a better informed decision regarding its possible value to their practices.

Alongside the greater availability of access platforms for TAMIS, there is now so also smart instrumentation available to offset maneuverability limitations. The one remaining aspect undermining broader uptake of this access relates to lesion and patient selection in that there is considerable inaccuracy in pre-TAMIS lesion characterization. There are, however, evolving innovative methods for such characterization via high resolution and multispectral imaging that may soon solve this also.11

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FIGURE LEGEND

1. Photograph of bench training with the smart articulating digital device (HandX™) in a TAMIS model to ensure understanding and dexterity of instrument use prior to clinical use.

2. Photographs showing (a) the smart digital device (HandX™) just prior to use in a TAMIS case showing tip flexion and the smart handpiece within sterile drape (b) roticulated circumferential cautery marking around rectal lesion (Case Two) (c) roticulated lesion dissection (d) roticulated needle mounting.

Video: Edited footage from each case in this series showing the smart digital device (HandX™) in use for TAMIS procedures for rectal neoplasia including circumferential cautery, lesion dissection and defect suture closure.

Figure 1

Figure 2