Twenty First Century Technological Toolbox Innovation for Transanal Minimally Invasive Surgery (TAMIS)

ALICE MOYNIHAN, MB, BCH, BAO, MRCS[1]
SPECIAL LECTURER

PATRICK BOLAND, MB, BCH, BAO, MRCS[1]
RESEARCH FELLOW

RONAN A CAHILL, MD, FRCS [1,2]
PROFESSOR

[1] CENTRE FOR PRECISION SURGERY, UCD, DUBLIN, IRELAND
[2]DEPARTMENT OF SURGERY, MATER MISERICORDIAE UNIVERSITY HOSPITAL, DUBLIN, IRELAND

ABSTRACT

Transanal minimally invasive surgery (TAMIS) is an effective procedure that plays an important role in the care of patients with significant rectal neoplasia and polyps including early-stage cancers. However, it is perhaps underutilised and under threat from both advanced flexible endoscopic procedures and proceduralists (who often act as gatekeepers for referral to colorectal surgeons), as well as from robotic surgery proponents. TAMIS advocates can learn and adopt practice insights from both these fields and incorporate available technological innovations building on the huge accomplishments already delivered in this area. Evolved practice through technology has the potential to offset current limitations regarding technical constraints and indeed patient selection (via artificial intelligence methods). Potential target areas for advances are considered in this review from different perspectives: (1) Access (2) Insufflation (3) Visualisation (4) Disease Characterization in situ, and (5) Tissue Handling and Suturing. While a bundle approach may be most useful, the advances for each component are potentially useful in their own right and could be applied without depending on the other practices detailed so that more accurate (and perhaps even numerically more) TAMIS procedures can be performed globally to improve patient care.

INTRODUCTION

Transanal minimally invasive surgery emerged in 2010 [1] as a next step for the surgical treatment of rectal neoplasia from the technical and technological achievements associated with Single Port Laparoscopic Surgery and indeed Natural Orifice Transluminal Endoscopic Surgery NOTES.[2,3] Since then, it has been used as an access modality for both partial and full thickness local rectal excision for significant polyps and earliest-stage cancer and has been further developed with respect to both concept and practice to provide Transanal Total Mesorectal Excision (initially termed TAMIS-TME[4] and now more commonly called TaTME).[5,6] Its advantages in the former application mean it still can play a valuable role in patient care alongside advances in flexible endoscopic techniques and technology (specifically endoscopic submucosal dissection (ESD) methods) as it provides for full-thickness excision of intact specimens enabling local cure and pathological examination of suitable neoplastic lesions in selected patients. Despite some controversy,[7] TaTME using TAMIS concepts and devices can also play a distinct role for practitioners versus standard and robotic-assisted laparoscopic access methods for TME[8,9]

However, TAMIS in general remains confined to a relatively limited number of patients and practitioners, at least compared to conventional and robotic-assisted laparoscopic surgery. While an estimated 10,000 patients a year in both Europe and the US could potentially benefit from this access approach, the published experiences are only a small fraction of this, with top-performing centres often performing in the range of 20-30 cases per year.[10,11] While the equipment required has been widely accessible to surgeons and surgical departments for some time, it remains a technically demanding operation with uncertainties regarding optimum patient selection based on presently imperfect staging pre-excision. Although new robotic platforms are being developed and promoted to offset the confined-access operating issues,[12,13] such innovation often requires considerable capital expenditure and new theatre workflows and even then can still be undermined by patient-selection issues.[14] However, the technological capabilities of these systems indicate avenues for potential exploitation within TAMIS. After the initial phase of innovations in technique and technology as TAMIS was developed, the methods and devices now most often used have tended to become standardised, despite advances in surgical operating instrumentation more generally. While the desire for standardisation with respect to the approach and a stable clinical field is understandable and very appropriate, especially for training courses and early adopters, there is now an opportunity for evolved instrumentation and operation that could facilitate numerically more and more accurate TAMIS interventions building on current achievements to date. Potential target areas for advancement can be considered under the following headings: (1) Access (2) Insufflation (3) Visualisation (4) Disease characterization in situ, and (5) Tissue Handling and Suturing. This review spotlights some persisting limitations to practice under these headings and some potential emerging technologies that could perhaps offset some of the challenges that limit TAMIS practice globally.

Current State of the Art

While early experiences used single-port access devices[1] and even custom-made devices,[15] more recently the most commonly used commercially available access system for TAMIS is the GelPOINTPath Transanal Access Platform (Applied Medical, Rancho Santa Margarita, CA) (Fig. 1),[16] a device specifically adapted from a pre-existing laparoscopic access device. This, along with the general use of standard laparoscopic instruments (most often a cautery hook and graspers with episodic suction/irrigation and often suture holders in cases where the defect is being closed by suture) and insufflation differentiate this modality from Transanal Endoscopic Microsurgery (TEM) and Transanal Endoscopic Operation (TEO) which have dedicated systems and surgical kits for end-to-end performance of the operation.[17] While some individual experiences have proposed that curved rigid instrumentation could have a role in TAMIS operations,[18] more recently, the focus on technical and technology aspects has tended to a consideration of large general surgery robotic-assisted laparoscopic systems,[14,19] and indeed other novel robotic systems more focused on endoluminal rectal operations are in development.[20] The need for effective rectal distension to enable intraluminal working space (i.e., a ‘pneumorectum’) means that effective carbon dioxide (CO_2) insufflation is important, along with inclusion of a reservoir device with the access device markedly promoting the stability of such distension, and high-powered, smart insufflation[21] has also been endorsed for TAMIS by many experts and even professional bodies, and a commercial system (AirSeal, Conmed, Utica, NY) has become the most commonly cited insufflator for this indication.[22,23] Patient selection for TAMIS most often follows an initial colonoscopic identification of neoplastic disease in a symptomatic and screening-identified individual with the precise means of endoscopist evaluation depending on the practitioner’s experience and expertise (including with the use of spectral light interrogation when available)

Figure 1. The GelPOINTPath Transanal Access Platform, which is commonly used for TAMIS procedures for patients with significant rectal neoplasia. (Applied Medical, Rancho Santa Margarita, CA) Image taken from company website.

with or without biopsy and sometimes preoperative imaging in the form of endorectal ultrasound or magnetic resonance imaging)[24] and thereafter discussion at a multidisciplinary meeting.[25] Some patients may have an attempt at ESD at that or subsequent endoscopy that proved incomplete either during the procedure (due to difficulties in the submucosal plane completion) or afterwards (due to pathological identification of cancer or positive margins for a benign lesion) that leads to a recommendation for TAMIS while others may not undergo any attempt at endoscopic biopsy or resection due to concerns regarding macroscopic features. This workup can be variable and subject to individual centre and practitioner expertise and experience[3] and each assessment method is imperfect when it comes to profiling significant (>2cm in diameter) rectal polyps including endoscopist visual assessment (50-70% accurate), endoscopic biopsy (80% accurate at best) and pre-excision radiological staging (c. 50% accurate) which means that some now recommend avoiding biopsy and excision prior to TAMIS (which then becomes in effect a 'big biopsy') with progress to 'completion' radical surgery for patients who are then proven to have cancer with anything other than the most favourable features.[26,27]

TARGET AREAS FOR TECHNOLOGICAL INNOVATION

(1) Access

The current access method consists of a sterile deformable access tube that is placed transanally and capped on its exterior with a gel access that houses Luer lock connectors in its rim and short valved trocars that are inserted into the gel on set-up (Fig. 1). CO_2 gas to achieve pneumorectum for the purposes of creating working space, can be insufflated into the rectum via the tapped connectors and the intra rectal pathology is then addressed by standard laparoscopic instruments. The inclusion of a laparoscopic camera means that, in general, two working instruments are used at any one time and the primary surgeon and surgical assistant sit between the legs of the anaesthesied patient positioned in lithotomy. The access device comes packaged in a set and although the cylindrical access tube comes in three different sizes, each is packaged along with the gel access and trocar insert as a kit rather than being supplied separately. Therefore, changing to a different insert in the event of a poor fit means opening a new set, wasting the unused components of the previous set. The exact sizing of an inset to a patient is not by any means an ideal science and is usually done based on surgeon judgment. Alongside lesion height and position as well as anal canal length, the distance between ischial spines of the patient's pelvis is an important consideration and naturally male and female pelvis configurations differ. While studies have indicated that TEM procedures have no short- or long-term impact on sphincter function,[28-31] poor insert fit may induce damage and can at least impair the efficient commencement and performance of the procedure. While the move of the access device away from a 'one size fits all approach' in the technique's earliest days is welcome, a softer, in some way mouldable access to fit the patient and respect anal canal and sphincter physiology could likely offer a gentler and more consistent operative initiation and flow.

(2) Insufflation

Early experiences with TAMIS suffered from instability of the degree of rectal distension due to the fact that the colorectum is not a closed circuit. Insufflated gas can leak up the colon and indeed has been shown to escape around the GelPOINT access device.[31] While this has been helped markedly by inclusion of a reservoir device and AirSeal insufflation as discussed above, deployment of this insufflator often entails an additional valveless trocar from the same manufacturers that has a different length than the TAMIS access trocars and requires additional dedicated tubing. While this does provide often excellent rectal distension, due to the rapid pressure-sensing and gas flow-compensation, which also aids with effective smoke evacuation, the system has drawbacks. It can be considered noisy but more significantly the valveless trocar is associated with the leakage of gas and intraluminal particles out of the valveless port and into the surgical breathing zone.[32] Also, with the valveless trocar, intracorporeal suctioning often results in nonsterile room-air entrainment, which significantly impacts the gas composition of the pneumorectum. These phenomena have been demonstrated by independent investigators[33-35] and are now considered to be 'features' in the device documentation. The effluvium chimney effect is particularly problematic when the system is deployed for TAMIS as the inline horizontal line of the device then makes the

Figure 2. Photographs showing the set-up and use of a novel smart insufflation for endolaparoscopy surgery (EVA15 device; Palliare, Ireland) during TAMIS.

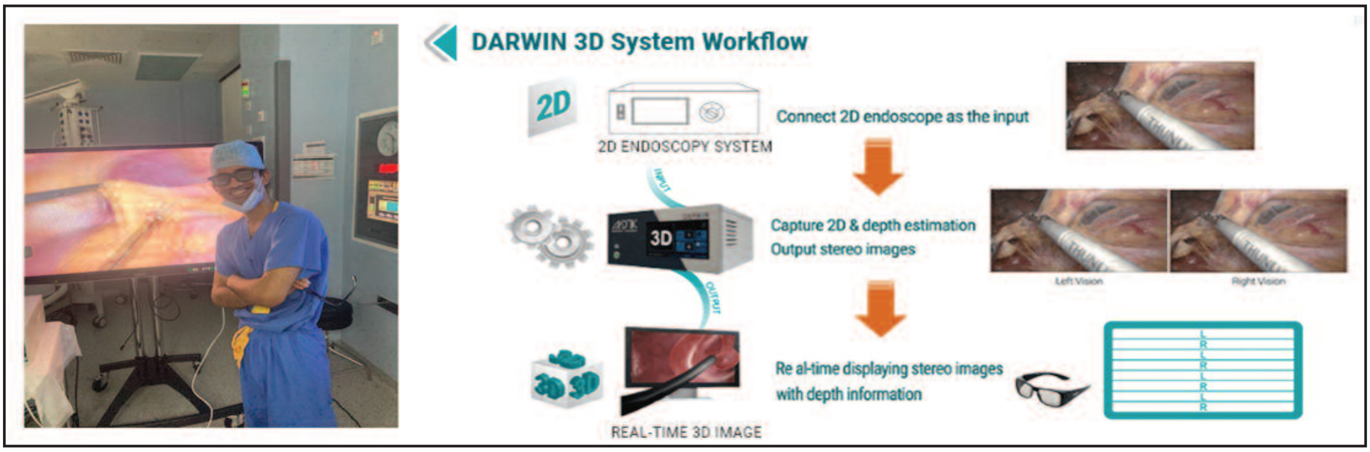

Figure 3. Photograph and schematic showing use and design of the Darwin 2d to 3d endolaparoscopic conversion imaging system for surgery (Medicaltek, Taiwan)

port subject to fluid-filling and nebulisation (in contrast to its vertical position above and usually away from the target operative site during laparoscopy). On a practical basis too, the AirSeal tubing is unfiltered between the trocar and insufflator, meaning that any fluid ingress tends to require shutting down the system to protect it (and thus other patients) from intrinsic system contamination. Aside from the risks of contamination and indeed combustion associated with endoscopic operation in the presence of non medical-grade room air, patients undergoing TaTME can suffer gas embolism.[36] It seems that pelvic sidewall venous injury during this procedure with the associated high-powered suctioning while the bleeding is managed can provoke gas embolism perhaps due to the change in the gas composition.[37] While reports of embolism have typically labelled this phenomenon CO_2 embolism (based on the assumption that intraprocedurally CO_2 has been insufflated, although this gas is water-soluble) the known changes in gas composition may suggest that air embolism may be occurring instead.

Recently, a new high-powered insufflator (EVA 15, Palliare, Dangan, Galway, Ireland[38]) has been launched that connects with ULPA filtered tubing to the TAMIS access device rim Luer lock connectors and, along with one extra standard port, or indeed more simply (to allow a low profile) a cut intravenous connector tubing which thereby provides for gas insufflation, continuous pressure sensing and foot pedal-activated smoke evacuation (Fig. 2)[39] (another available adaptor enables direct connection of this insufflator to standard flexible endoscopic systems to allow for the first time pressure-monitored flexible endoscopic working).The ability to connect with valved trocars potentially reduces the gas leak and entrainment issues discussed above while rapid sensing means that insufflation can be capable throughout TAMIS procedures even in the presence of high-powered suctioning.

(3) Visualisation

3D visualisation is an often-claimed advantage of Da Vinci Robotic operating systems (Intuitive Surgical, Sunnyvale, CA) alongside immersive binocular vision that is proposed to translate to value when this system is deployed transanally. Although its use has not become widespread in laparoscopic surgery more generally, various medical imaging companies now offer 3D laparoscopic systems for this modality. In general, such contemporary systems contain separate lenses at the tip of a dual-channel laparoscope providing separate images with differing perspectives that need to be presented to each eye of the surgeon individually to simulate binocular disparity.[40] Most of these systems require an active shuttering screen and user-worn polarised glasses to perceive the image in 3D (Fig. 3).[41] As laparoscopic surgery has become more complex, potential advantages of 3D imaging have been proposed including improved optical resolution and depth perception, as has been evidenced via subjective feedback in clinical trials.[42,43] Similarly, user reports have suggested a decreased cognitive burden with 3D setups,[44,45] and the European Association of Endoscopic Surgeons has even suggested that the use of 3D imaging can reduce operating times and potentially complication rates, in particular when laparoscopic suturing is employed.[46-48] Furthermore, in simulated settings, trainees have been shown to perform significantly faster and with fewer errors when using 3D. Together for these reasons, 3D viewing could provide particular benefit to TAMIS practitioners. Correct depth perception may improve visual judgement regarding marginal assessment and help suturing of the defect (which can also be particularly challenging, especially for surgeons who do not routinely perform this step during laparoscopy but also even for those are adept at intracorporeal suturing as TAMIS presents a new layer of complexities for this task due to the reduced space.[22] The enhancement of suturing skills and reduced operating times associated with 3D imaging would seem to likely transfer to TAMIS, although this has not been formally evaluated.

Moving to 3D imaging has previously required an update of the entire in-theatre imaging set up, including the camera, stack and monitor. Recently, the DARWIN 3D Endoscopic system (MedicalTek Co., LTD, Taiwan) has been introduced to the market (Fig. 3).[49] This CE-approved system works as an add-on to any existing, standard 2D laparoscopic system, converting its 2D imagery to 3D in real-time via an additional output cable connecting via the systems converter which outputs onto a standard 3D monitor. Again, this requires polarising glasses to view but as the device works in addition to the already installed 2D system, the surgeon can operate in 3D while others can view 2D images on the standard theatre monitors, negating the need to update an entire theatre inventory. Converting the 2D image to 3D means that the system works with standard single-channel cameras (conventional 3D systems requiring dual-channel cameras are presently limited to 10mm diameter cameras) and so the DARWIN system can work with 5mm or thinner cameras. Reducing the camera size to such a degree has been shown to confer benefits from single surgeons in cases of single-port laparoscopy and NOTES and would seem to be of value in TAMIS. Interestingly, the device can also "piggyback" on near-infrared endolaparoscopic systems, displaying fluorescence imagery in 3D following indocyanine green dye (ICG) administration.

(4) In Situ Disease Characterization

TAMIS as 'big biopsy' discussed above refers to the practical consideration that rectal neoplasia at present may only be fully and correctly understood after complete excision of the tumour. This is because visual (including narrow band imaging) assessment is imperfect, and biopsy may miss areas of invasive pathology among a mostly benign neoplastic lesion.[50,51] Furthermore, biopsy may induce submucosal fibrosis complicating any subsequent wall-preserving excisions. Similarly, the differentiation between T1 and T2 cancers is suboptimal with MRI tending to over-stage these lesions.[52] This means that decisions regarding the most appropriate initial surgical pathway must often be made in the absence of a definitive diagnosis. While TAMIS is considered to be suitable for T1 tumours and benign lesions, patients who are found to have more advanced cancers upon excision will require completion surgery in the form of radical resection to achieve the optimum oncologic response. While clinical series have shown no oncological compromise following radical resection in patients who have previously undergone TAMIS,[53] technical aspects of the subsequent operation can be challenging. In particular, planar dissection and clearance may be harder to achieve, especially in anterior lesions, and low lesions may require ultralow radical resection. This is particularly the case for excisions in which the defect was not closed, as TAMIS excision involves an extra margin around and below the lesion and higher rates of abdominoperineal resection after initial TAMIS have been reported.[54] Technical challenges such as these aside, the patient must undergo an extra procedure and will require additional counselling for this and the diagnostic uncertainty.

Accurate in situ digital lesion characterisation would enable better personalised care, potentially from the time of the first endoscopic encounter, and has been a 'holy grail' of colonoscopy for some time. Recent work has moved away from surface-only characterisation with promising research that uses ICG and fluorescence examination to determine differential perfusion patterns between the area of abnormality and normal adjacent mucosa and indeed between different intra-lesional regions (Fig. 4).[54,55] The underlying concept is that angiogenesis and other vascular anomalies are early and consistent features of malignant transformation within tissues which can be identified through the delivery and observed distribution characteristics of plasma-bound compounds, such as ICG. Both intravascular flow as well as interstitial diffusion may be impacted, the latter due to enhanced permeability and retention characteristics of cancerous tissues. This work has shown significant differences in dye signalling patterns between both benign and malignant lesions and normal tissues, as well as between benign and malignant lesions[56] and is currently undergoing validation in a multicentre prospective clinical study using artificial intelligence (AI) methods including computer vision and machine learning to make the foundational discoveries usable.[57] While initial indicators are that the method can be performed with higher accuracy than endoscopic incisional biopsy, actually matching the accuracy of biopsy in a non-invasive, immediate way would represent significant added value for TAMIS and endoscopy more generally, especially if the method (currently confined to rigid laparoscopic optical systems) could be extended proximally beyond the rectum with the flexible endoscopy paradigm. If proven to be accurate, this method of machine learning tissue classification could be further

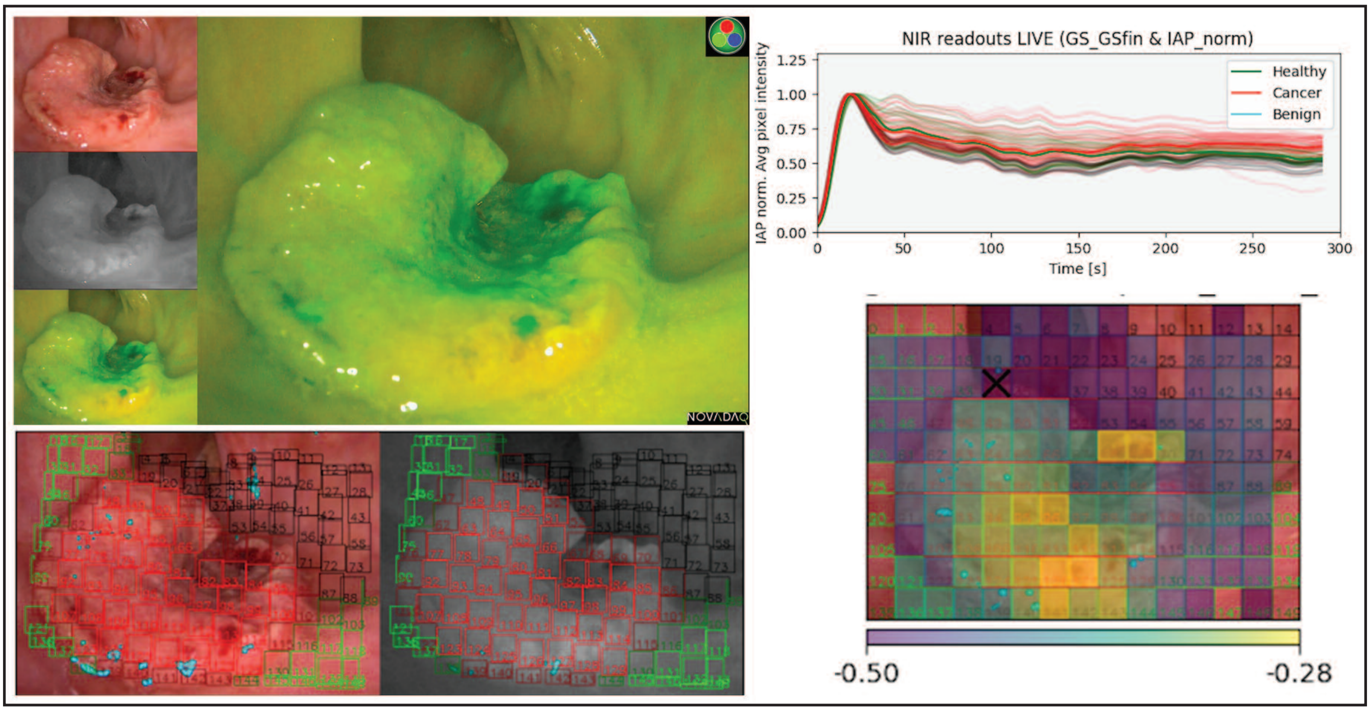

Figure 4. Endoscopic imagery and graphs related to near-infrared perfusion analysis of rectal cancer. Using computer vision, the live image is split into grid regions with perfusion quantification from fluorescence intensity time-series generated from each region allowing immediate comparative analysis between areas in the tumor and the surrounding normal tissue to discriminate between neoplasia and invasive malignancy using AI methods.

adopted to assess lesion boundaries (currently TAMIS resection results in positive margins in 20% of cases,[10,58] with these patients ultimately requiring further surgery in the form of repeated TAMIS or in cases of cancer, often radical resection). While incorporating AI into the operating room raises legal and ethical debates that must also be considered, this method relies on interpretable methods which have the advantage that it is possible to recall and display the reasons why a decision was made (so avoiding some of the complexity surrounding the use of uninterpretable or "black-box" AI algorithms). In addition, the use of biophysical methods requires smaller data sets for reliable performance which is an advantage given the lack of pre-existing rectal cancer imagery. Optimal application of any such technology requires ensuring consistently high-quality video output. Excessive camera movement, peristalsis or a sudden loss of pneumorectum (including suctioning to clean the field of blood, mucus or stool) will disturb the visual processing required to capture perfusion patterns of each area and therefore threaten the accuracy of this or indeed any image-based decision support tool such as that described above. Therefore any such system will also rely on the other topics discussed in this review.

(5) Tissue handling and suturing

Accurate, dexterous instrument tip maneuvering is a core tenet of TAMIS. While some of the base skillset is shared with single-port laparoscopy, in general, most surgeons performing TAMIS use standard multiport laparoscopy or indeed robotic-assisted surgery where the instrument choreography differs. Articulating instrument tip action is, again, an oft-stated advantage of robotic operating platforms and such capability has recently manifest in handheld laparoscopic instrumentation[59] including via the innovative technology of HandX (Human Factors[60]). This device with small OR footprint provides the trained surgeon with the capability for laparoscopic instrument tip articulation during TAMIS (as well as other endolaparoscopic operations). It works via standard 5mm trocars and in the confined surgical team position associated with TAMIS (different to mechanical only systems whose gimbal prevents working between the patient's lower limbs unfortunately) and so equips the non-robotic interventionalist with robotic-like dexterity[61] after training.[62] In TAMIS, this offers improved precision in dissection and defect suturing

DISCUSSION

TAMIS is an effective procedure that plays an important role in the care of patients with significant rectal neoplasia, both benign and malignant. However, it is under threat from both advanced flexible endoscopic procedures and proceduralists (who often act as gatekeepers for referral to colorectal surgeons) and indeed from robotic surgery proponents. However, TAMIS advocates can learn and adopt practice insights from both these fields and look to incorporate now available technological innovation to provide better TAMIS care on a more widespread basis. While initially there was concern that the relatively cheaper and more acceptable TAMIS kits could undermine the position of TEO and TEM as high-quality surgical interventions, the roll-out of TAMIS seems to have been limited more by the inherent technical challenge of performing the procedure along with difficulties in patient selection due to uncertainties regarding lesion nature. The 'Targets for Innovation' detailed here aim to inform, inspire and educate stakeholders in surgery as to some newer concepts and technologies that could augment TAMIS and potentially other minimally invasive practices. While a bundle

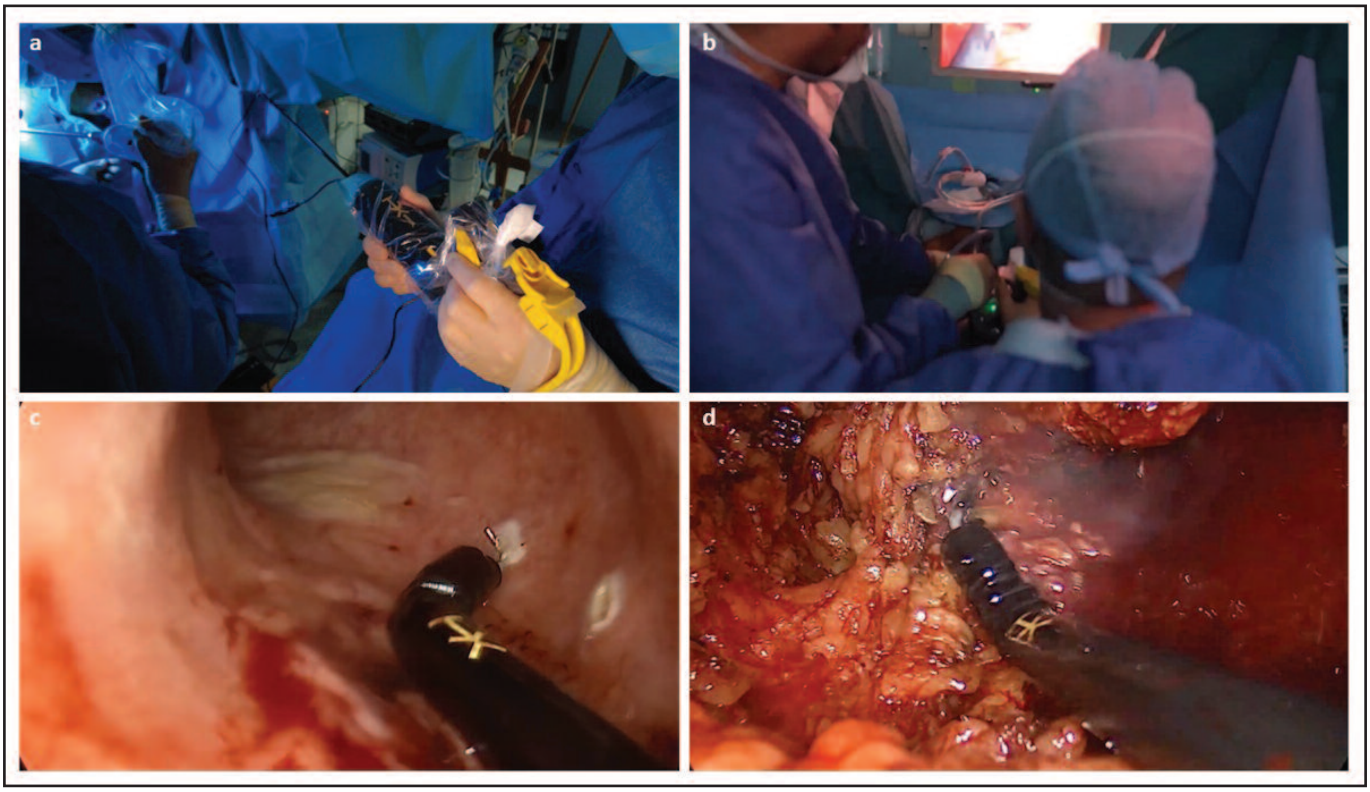

Figure 5. Intraoperative photographs showing use of the handheld smart tip articulating surgical instruments, the Hand x device (Human Xtensions, Netanya, Israel), during TAMIS.

approach may prove most useful, each component advance is potentially useful in its own right and could be applied without dependency on the other practices detailed. There are other potentially useful means to advance TAMIS and the framework approach used here may allow the value of future innovations to be contextualised within current clinical practice. STI

AUTHORS' DISCLOSURES

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