DEVELOPMENT AND EVALUATION OF A VIRTUAL KNOWLEDGE ASSESSMENT TOOL FOR TRANSANAL TOTAL MESORECTAL EXCISION

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ABSTRACT (ENGLISH)

Importance: Surgical performance and clinical outcomes vary widely amongst surgeons for complex procedures. Transanal Total Mesorectal Excision (TATME) is novel, difficult to learn and can result in serious complications. Current training paradigms for assessing performance and competency may be insufficient.

Objective: To develop and provide preliminary validity evidence for a TATME virtual assessment tool (TATME-VAT) to assess the cognitive skills necessary to safely complete TATME dissection.

Design: TATME-VAT was administered to participants via an interactive online platform between 11/2019-05/2020. Participants also completed a demographic questionnaire.

Setting: Participants from North America, Europe, Japan and China were recruited via email or in-person invitation.

Participants: Expert (30 or more TATMEs in independent practice and who were nominated by their peers; n=20), experienced surgeons (surgeons with a significant rectal cancer practice with less than 30 TATME cases; n=18), and novices (general surgery residents; n=28).

Interventions: TATME-VAT is a 24-item web-based assessment evaluating advanced cognitive skills, designed according to a blueprint from consensus guidelines. Eight items were multiple choice questions. Sixteen items required subjects to make annotations on still frames of TATME videos (visual concordance test), and annotation scores were calculated using a validated algorithm derived from experts’ responses.

Main outcome measure: Mean annotation (range 0-100), multiple choice (range 0-100), and overall scores (sum of annotation and multiple-choice scores, normalized to μ=50 and
Scores were compared between the three groups. Subgroup analyses were performed according to case volumes and recent complications.

**Results:** There were significant differences between the expert, experienced, and novice groups for the annotation ($p<0.001$), multiple-choice ($p<0.001$), and overall scores ($p<0.001$). In particular, the annotation ($p=0.439$) and overall ($p=0.152$) scores were similar between the experienced and novice groups. Annotation scores were higher in participants with 51 or more vs. 30-50 vs. less than 30 cases. Scores were also lower in users with a self-reported recent complication vs. those without.

**Conclusions and relevance:** This study describes the development of an interactive video-based virtual assessment tool for TATME dissection and provides initial validity evidence for its use. Future studies can employ this methodology to develop more robust metrics for the quality and safety of operative performance.
RÉSUMÉ (ABSTRACT IN FRENCH)

Introduction: Les performances chirurgicales et les résultats cliniques varient considérablement d’un chirurgien à l’autre pour des procédures complexes. TATME est nouveau, difficile à apprendre et peut entraîner de graves complications. Les paradigmes de formation actuels pour évaluer les performances et les compétences peuvent être insuffisants.

Objectif: Développer et fournir des preuves de validité préliminaires pour un outil d’évaluation virtuelle TATME (TATME-VAT) pour évaluer les compétences cognitives nécessaires pour terminer en toute sécurité la dissection TATME.

Conception: TATME-VAT a été administré aux participants via une plateforme en ligne interactive entre Novembre 2019 et Mai 2020. Les participants ont également rempli un questionnaire démographique.

Cadre: Les participants d’Amérique du Nord, d’Europe, du Japon et de Chine ont été recrutés par e-mail ou sur invitation en personne.

Participants: Experts (30 TATME ou plus en pratique indépendante et qui ont été nommés par leurs pairs; n = 20), chirurgiens expérimentés (chirurgiens ayant une pratique significative de cancer rectal avec moins de 30 cas TATME; n = 18), et novices (général résidents en chirurgie; n = 28).

Interventions: TATME-VAT est une évaluation en ligne de 24 éléments évaluant les compétences cognitives avancées, conçue selon un plan issu de lignes directrices consensuelles. Huit items étaient des questions à choix multiples. Seize éléments exigeaient
que les sujets fassent des annotations sur des images fixes de vidéos TATME (test de concordance visuelle), et les scores d’annotation ont été calculés à l’aide d’un algorithme validé dérivé des réponses d’experts.

**Mesure du résultat principal:** annotation moyenne (intervalle de 0 à 100), choix multiple (intervalle de 0 à 100) et scores globaux (somme des scores d’annotation et à choix multiple, normalisés à $\mu=50$ et $\sigma = 10$). Les scores ont été comparés entre les trois groupes. Des analyses de sous-groupes ont été effectuées en fonction des volumes de cas et des complications récentes.

**Résultats:** Il y avait des différences significatives entre les groupes experts, expérimentés et novices pour l’annotation ($p <0,001$), les choix multiples ($p <0,001$) et les scores globaux ($p <0,001$). En particulier, les notes d’annotation ($p = 0,439$) et globale ($p = 0,152$) étaient similaires entre les groupes expérimentés et novices. Les scores d’annotation étaient plus élevés chez les participants avec 51 ou plus vs 30-50 vs moins de 30 cas. Les scores étaient également inférieurs chez les utilisateurs ayant une complication récente autodéclarée par rapport à ceux qui n’en avaient pas.

**Conclusions et pertinence:** Cette étude décrit le développement d’un outil d’évaluation virtuelle interactif basé sur la vidéo pour la dissection TATME et fournit des preuves de validité initiale pour son utilisation. Des études futures peuvent utiliser cette méthodologie pour développer des mesures plus robustes pour la qualité et la sécurité des performances opérationnelles.
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CONTRIBUTION OF AUTHORS

Dr. Carmen Mueller (supervisor)

- Contributed to study conception and design.
- Reviewed and provided feedback about the TATME-VAT scenarios before recruiting participants.
- Assisted with data analysis and interpretation.
- Reviewed, and edited manuscript.

Dr. Lawrence Lee

- Performed the surgeries from which TATME-VAT scenarios were generated.
- Contributed to study conception and design.
- Reviewed and provided feedback about the TATME-VAT scenarios before recruiting participants.
- Helped with data acquisition and recruited expert participants.
- Assisted with statistical analysis.
- Reviewed, and edited manuscript.

Dr. Amin Madani

- Contributed to study conception and design.
- Reviewed and provided feedback about the TATME-VAT scenarios before recruiting participants.
- Reviewed and edited manuscript.
**Dr. Johnny Chau**

- Helped in development of TATME-VAT scenarios by identifying clear surgical videos and reviewing multiple choice questions.

**Dr. John Monson**

- Reviewed and provided feedback about the TATME-VAT scenarios before recruiting participants.

**Ms. Pepa Kaneva**

- Helped with ethics approval.
- Assisted with statistical analysis.
INTRODUCTION

The management of patients with rectal cancer is complex, requiring multi-disciplinary collaboration between radiology, medical and radiation oncology, and surgery, but high-quality surgery remains the cornerstone of rectal cancer care. However, tumors in the lower third of the rectum pose significant technical challenges given the anatomic restrictions of the bony pelvis and the thin mesorectum at this level.\textsuperscript{1,2} Laparoscopic or robotic total mesorectal excision (TME) were initially advocated to improve the quality of surgical resection with better optics and more accurate dissection along the TME planes, but randomized trials have failed to consistently demonstrate improvements in surgical TME quality.\textsuperscript{3-5} Transanal total mesorectal excision (TATME) was first described in 2010\textsuperscript{6} and has recently gained popularity as a new technique to approach the surgically challenging low rectal cancers.\textsuperscript{7} This technique approaches the dissection from the bottom-up and avoids the anatomic restrictions that can significantly hinder transabdominal TME.\textsuperscript{8} Initial data regarding TATME dissection resection quality from an international registry were favorable.\textsuperscript{9} However, more recent data have shown a high incidence of multifocal local recurrences\textsuperscript{10}, leading to a moratorium on TATME in certain countries and a pause on TATME teaching pathways\textsuperscript{11-13}.

It is clear that TATME is technically challenging, as approaching the planes of dissection from the bottom-up can be disorienting, even for expert rectal cancer surgeons.\textsuperscript{8,14} Poor quality TME is associated with worse oncologic outcomes\textsuperscript{15} and TATME can also introduce new complications, such as urethral injuries, that were hitherto rare or non-existent.\textsuperscript{16} The current training paradigm for TATME of structured training courses, hands-on practice on human cadaveric models, and expert mentoring for the early learning
experience\textsuperscript{17,18} may be insufficient and may lend a false sense of competence. There was an alarming incidence of poor quality resection and high complication rates, especially urethral injuries, in the initial cases after course completion.\textsuperscript{16} Achieving competence in surgical procedures is a complex process requiring simultaneous development of a variety of technical and non-technical skills.\textsuperscript{19} It is unreasonable to expect surgeons who are learning TATME to achieve proficiency and implement this new approach after undergoing only a short-term curriculum without assessment of their understanding of operative planes that are specific to TATME.\textsuperscript{20}

Currently, there is no formalized tool that assesses proficiency in TATME before operating on patients. The objective of this project is to develop and evaluate a virtual assessment tool for the knowledge and decision-making necessary to perform TATME dissection. The tool will assess the surgeon’s higher-order cognitive processes, such as decision-making, situational awareness and pattern recognition, that are critical to perform complex tasks successfully. A virtual, video-based platform is ideal for this function, as planes of surgery and complex intra-operative decision-making can be tested in a secure, ubiquitously accessible, easily adaptable, interactive, and cost-effective manner.\textsuperscript{21-23} This TATME- Virtual Assessment Tool (TATME-VAT) aims to assess the user’s thought process and his ability to make important judgements based on real visual data from the operating room.\textsuperscript{24} We hypothesize that the TATME-VAT will be able to differentiate between expert TATME surgeons and non-expert surgeons.
THESIS OBJECTIVES

1. To develop a TATME virtual assessment tool (TATME-VAT) of the knowledge and decision-making of TATME dissection.

2. To evaluate and gather validity evidence for the use of TATME-VAT in the context of assessing TATME dissection proficiency.
LITERATURE REVIEW

Epidemiology

Colorectal cancer is the third leading cause of cancer mortality and the fourth most common cancer in the world. It accounted for approximately two million new cases and one million deaths in 2018 worldwide. Rectal cancer was estimated to be responsible for 704,000 of these cases and 310,000 of these deaths. The cumulative risk, at age 0 to 74 years, of dying from rectal cancer is 0.46% among men and 0.26% among women.

In Canada, there is a declining trend in incidence of colorectal cancer mainly due to increased cancer screening, and a decrease in death rates, which is driven by improved standard of care. According to the Canadian Cancer Society, 12% of new cancer cases and cancer deaths in Canada in 2020 were caused by colorectal cancer. In 2020, 26,900 Canadians were diagnosed with colorectal cancer and 9,700 died from it. It is currently estimated that 1 in 14 Canadian men and 1 in 18 women will develop this cancer during their lifetime, and 1 in 32 Canadian men and 1 in 37 women will die from it. So, in spite of the decrease in incidence, colorectal cancer remains a significant health problem that may affect many Canadians’ lives today.

Pathophysiology

The accumulation of somatic or germline mutations is usually responsible for the transformation of normal colorectal epithelium to adenomas and ultimately invasive carcinomas. Colorectal cancer often arises from polyps that acquire dysplastic changes over 10-15 years before developing invasive carcinomas. These polyps are most frequently
adenomatous, although evidence suggests that hamartomatous and serrated polyps could also evolve into colorectal cancer.\textsuperscript{32,33}

Mismatch repair, chromosomal instability and hypermethylation are the three main molecular pathways that lead to colorectal cancer.\textsuperscript{34,35} Lynch syndrome is a prime example on deficient mismatch repair genes, namely MLH1 or MSH2.\textsuperscript{36} This deficiency leads to microsatellite instability due to the rapid accumulation of errors within the genome.\textsuperscript{37} The tumor suppressor adenomatous polyposis coli (APC) gene mutations in familial adenomatous polyposis (FAP) demonstrates chromosomal instability. In this pathway, the mutations disturb the normally balanced oncogene and tumor suppressor equilibrium.\textsuperscript{38} CpG hypermethylation of DNA could activate the expression of BRAF or silence that of MLH1.\textsuperscript{39,40}

Some other pathways have been implicated in colorectal cancer tumorigenesis. These include sporadic somatic mutations of RAS, SRC or MYC genes and bi-allelic loss of tumor suppressor genes (APC 5q21, TP53 17p or DCC/SMAD2-4 18q).\textsuperscript{41-44} Cyclooxygenase-2 (COX-2) and peroxisome proliferator-activating receptor (PPAR) genes are also suspected to be involved in colorectal cancer and are being investigated for potential chemo-protection.\textsuperscript{45-47}

\textbf{Diagnosis}

80% of colorectal cancer cases are diagnosed by colonoscopy following suspicious signs and symptoms. The most common triggers warranting a diagnostic colonoscopy are blood per rectum (37%), abdominal pain (34%) and anemia (23%). 11% of colorectal cancer patients are diagnosed with asymptomatic screening tests and 7% are found incidentally at
an acute abdomen emergent admission. Symptomatic patients typically have larger and more advanced tumors.\textsuperscript{48}

A complete diagnostic colonoscopy with multiple biopsies is required for all suspected colorectal cancer patients for pathological evaluation. Rigid sigmoidoscopy is used to measure the distal extension of rectal tumors from the anal verge and classify lesions into low (< 5 cm), middle (< 10 cm) and high (< 15 cm).\textsuperscript{49} Patients should undergo baseline CT scan of the chest, abdomen and pelvis with intravenous and oral contrast for staging purposes. Suspicious metastatic sites should be biopsied to confirm the diagnosis.

**Management**

The tumor, node, metastasis (TNM) staging system is recommended by the American Joint Committee on Cancer for staging of colorectal cancer as seen in figure 1.\textsuperscript{50} Accurate staging using this system will determine the most appropriate management plan.

Endoscopic resection can be offered to patients with a favorable-risk and early-stage polyp that can be completely excised. It is indicated for T0-1, less than 3 cm diameter, mobile tumors that exhibit feasible resection margins on transrectal ultrasound and no distant metastasis on radiographic imaging. These patients usually agree to close surveillance and understand that they might need future surgical resection if high-risk features were detected during or after the endoscopic resection.\textsuperscript{51} High-risk features include invasion of muscularis propria (T2), poor histological grade and lymphovascular or perineural invasion.

Neoadjuvant therapy is indicated for locally advanced resectable rectal cancer (cT3-4N0-2M0) and some low-lying lesions. Adjuvant therapy is strongly recommended for all T3
and nodal involvement cases on pathology. Palliative systemic chemotherapy is offered to patients with unresectable locally advanced disease or those who have high metastatic burden. Oligo-metastatic lung and liver disease colorectal patients can benefit from surgery with peri-chemotherapy.

The primary aim of surgical resection in rectal cancer patients is the complete resection of the tumor with elimination of lymphovascular spread. This is achieved by a minimum negative proximal margin of 5 cm, a distal of 2 cm and a radial greater than 1 mm. The surgical technique used depends on the feasibility of achieving the desired distal margin without affecting the anal sphincter. The two main surgeries used are the sphincter-sparing low anterior resection (LAR) and the non-sparing abdominal perineal resection (APR). Both surgeries require total mesorectal excision to ensure margin and lymph node retrieval. These surgeries are performed transabdominally, either open or laparoscopically. Some centers offer robotic surgeries, but these do not confer additional advantage to the patient over non-robotic modalities except for a lower conversion rate to open compared to laparoscopic procedures. Transanal total mesorectal excision (TATME) remains a controversial alternative approach that was associated with multifocal local recurrence linked to suboptimal execution rather than the technique itself.

Transanal total mesorectal excision (TATME)

Transanal total mesorectal excision (TATME) offers a solution to the difficult visualization of the pelvic anatomy from an abdominal approach by providing access transanally and direct visualization from below. The first clinical case of TATME was described in 2010 as an alternative approach for mid to low rectal cancers. TATME involves dissecting the distal part of the rectum and mesorectum under direct vision via a transanal approach.
TATME builds on prerequisite skills derived from laparoscopy and minimally invasive transanal resection. The bottoms up approach of TATME offers several advantages including being able to select the exact distal resection margin, obviating the need for laparoscopic stapling in a narrow pelvis, and better visualization of the lower pelvis thereby potentially improving the oncologic quality of the surgery.\textsuperscript{57}

TATME is technically challenging because it requires learning planes of dissection from a different point of view, and the anatomical landmarks can be disorienting for the surgeon. The literature has shown significant variability in the visualized planes of dissection, even among consultant staff.\textsuperscript{14} This creates a potential for serious injuries unique to TATME. These include urethral injuries, entry through the posterior wall of the vagina, neurovascular bundle of Walsh injuries, prostate injuries and pre-sacral plexus injuries.\textsuperscript{58}

The published results from an international registry of the first 720 TATME cases show that TATME appears to be an oncologically safe and effective technique for mesorectal dissection with good short-term outcomes and good specimen quality. A good quality of the TME specimen (intact mesorectum) was obtained in 85\% of cases, a low positive distal resection margin was found in 0.3\% of cases, and a low positive circumferential resection margin was found in 2.4\% of cases.\textsuperscript{9} The safety of TATME, however, is still debatable because some studies have shown that rates of multifocal local recurrence can be as high as 10\%.\textsuperscript{10,11} On the other hand, an extensive study comprising 767 patients who underwent TATME and were followed up for two years reported a local recurrence rate of 3\%, which is similar to that observed after TME using other surgical techniques.\textsuperscript{59}
**TATME training and its learning curve**

This discrepancy in the outcomes of TATME brings up the question of whether worse outcomes are observed due to the technique itself or the suboptimal execution of it. The literature suggests that experienced laparoscopic colorectal surgeons need to perform at least 30 TATME cases to overcome the learning curve. Studies show that a surgeon’s TATME case volume directly affects his surgical outcomes, including less conversion rates, less complications and more complete TMEs.

Achieving competence in surgical procedures is a complex process requiring simultaneous development of a variety of technical and non-technical skills. Operative performance and proficiency include psychomotor skills, declarative knowledge, interpersonal skills, personal resourcefulness and advanced cognitive processes. Regardless of the specific task, or parts of a task, being learned, progress through the continuum from novice to expert can be aided by scaffolding – guided instruction causing the internalization of new skills until they are routine and require a limited cognitive load on the individual, allowing for advancement to the next level of skill acquisition.

Besides formalized fellowship training, colorectal surgeons can learn to perform TATME through courses that offer live observation, hands-on human cadaveric experience and proctorship. However, it is unclear whether the current training paradigm of structured didactic teaching with hands-on cadaveric training can achieve that goal for TATME within a two-day course. Participants may lack the prerequisite technical skill and knowledge of the anatomic planes necessary to safely introduce TATME. The steep learning curve of TATME makes many surgeons feel uncomfortable performing the
procedure independently after these courses.66 Many of those who adopt the technique into their practice and start operating on patients have high complication rates in their initial cases.62,69 These surgeons have not gone through a formal credentialing process and their performance has not been measured by a valid assessment tool.
METHODOLOGY

Ethics approval for this project was obtained by the McGill University Faculty of Medicine institutional review board under IRB (Appendix A) study number A09-E66-18B.

Participants

This was a multi-center, international study, with participants recruited from North America, Europe, Japan and China. Participants were grouped based on prior experience. All identified TATME surgeons were invited to make a submission using the TATME-VAT. Those who have performed 30 or more TATMEs as primary surgeons were considered experts.\textsuperscript{17,63} A systematic review has shown that the learning curve for TATME is consistently reported to be at least 30 to 40 cases, regardless of the proficiency outcome used.\textsuperscript{62,63,70} Consensus guidelines have recommended that TATME proctors should have performed at least 20 to 30 cases.\textsuperscript{17,71} Other studies suggest that the number of cases required to gain proficiency using surgical resection quality outcomes may be even higher.\textsuperscript{70} Experienced surgeons included colorectal surgeons and colorectal fellows who have performed less than 30 TATME cases. Novice surgeons were defined as general surgery residents (PGY 1-5) with no prior TATME experience.

All participants were contacted for participation via email or in-person. Participants who provided online consent (Appendix B) were asked to complete the TATME-VAT and a pre- and post-test surveys (Appendices C and D) to collect information about the participants’ previous experience and to get feedback about the tool itself. They were also asked to indicate their confidence level for each item answered on a 0-10 scale. Participants were not given any curricular modules before the assessment. They all received a unique username and password and completed the assessment remotely on a personal computer,
tablet or mobile device. Scores were automatically calculated by the software and investigators were blinded. Submissions were made between November 2019 and May 2020. Participants who made an initial submission were invited to re-submit their answers 10-12 weeks after initial submission for test-retest reliability measurement.

**Development of the Transanal Total Mesorectal Excision – Virtual Assessment Tool**

An online, password-protected, HTML-5 based e-learning platform ([www.thinklikeasurgeon.ca](http://www.thinklikeasurgeon.ca)) was developed to provide users with remote access to the content of the tool. Video scenarios of the important TATME steps were developed from the principal investigator’s video library. Multiple Delphi consensuses of TATME experts were used to create a blueprint of the most important technical steps of the transanal portion of TATME dissection (Table 1). The steps included are also consistent with the Delphi consensus results published by the COLOR III trial in November of 2019. A colorectal fellow with TATME training helped identify clear operative videos. The content was then reviewed by four independent surgeons: two TATME experts and two surgeons with formalized training in surgical education. Scenarios were then added, removed or modified according to their feedback.

For each item in the assessment, videos are stopped at predefined time points to highlight one of the key technical steps of TATME. The user is then presented with a still frame and asked to answer one of two question types: annotation questions or multiple-choice questions (MCQs). Each question type is used to assess proficiency of TATME dissection on different cognitive levels.
The Visual Concordance Test

In the annotation questions, the user is prompted to draw an annotation on the still frame image tracing the plane where they propose to proceed with the dissection. Once an answer is drawn on the surgical field and submitted, an accuracy score is calculated by comparing these annotations to annotations made by experts using the Visual Concordance Test (VCT).

It is difficult to define a “correct” answer for the annotation questions in TATME-VAT because even experts would seldom select the same set of pixels on the same static image. To solve this, a panel of experts makes annotations on the same frames and the distribution of their annotations is used to create weighted zones and topographical maps on Cartesian coordinates for each item (based on how many experts select each pixel). On manual review, outlier annotations that did not have common pixels with any of the other experts’ annotations were excluded from the final VCT scoring maps. Annotations made in a plane different than the intended plane were also excluded. The VCT then generates accuracy scores for subsequent users based on an algorithm comparing their annotations to these heat maps (Figure 2). The annotation score thus represents the percentage of agreement between the participant’s proposed response and the aggregate expert responses.

This methodology allows users to describe their thought processes in relation to a graphical illustration by carrying out tasks that highlight their anatomical knowledge in a surgical field. It assesses cognitive skills, such as pattern recognition and situational awareness, in a way that simulates real-life surgical decision making. The VCT has already been validated in the context of laparoscopic cholecystectomy and thyroidectomy.
**TATME-VAT scoring**

The MCQ score was calculated as the percentage of correct answers with all questions given equal weight. To combine the annotation and MCQ portions of the TATME-VAT, the standardized z-score was used to re-scale each item individually, with a mean of 50 and standard deviation of 10. The final score (VCT + MCQ) for each participant was then calculated as the mean of their standardized item scores.

**Data Collection**

The TATME-VAT test was administered between November 2019 – May 2020. All participants completed a demographic questionnaire regarding their training, TATME experience, outcomes and current practice setting. The TATME-VAT tool was accessed by unique login for each user and completed privately. Scores were calculated by automated computer algorithm and tabulated anonymously. After completion of the test, participants completed a feedback questionnaire regarding the tool’s usefulness and clarity. After 10-12 weeks, all participants were invited to take the test again for assessment of test-retest reliability.

**Statistical analysis**

Internal structure reliability was assessed using Cronbach’s alpha, inter-item correlations and total-item correlations. Item difficulty and discrimination indices were calculated for MCQs. Test-retest reliability was calculated using intraclass correlation. After internal validation, the mean scores, standard deviations and coefficient of variations were calculated for each portion of the test (annotation and MCQ) and for the combined TATME-VAT score. Continuous variables were compared using Student’s t-test or two-tailed ANOVA. Subgroup analyses were performed according to self-reported experience and proficiency,
represented by TATME case volumes and recent TATME complications (defined as a complication within the past 10 cases) respectively. Proficiency cut-offs for the total TATME-VAT score were generated using receiver operating curves to maximize sensitivity and specificity. Using an $\alpha$ of 0.05, a power of 80%, and a medium effect size of 0.5, more than 14 participants were required in each of the three subgroups to evaluate the TATME-VAT. Statistical significance was defined as $p<0.05$. 
RESULTS

The original TATME-VAT test contained 29 scenarios: 18 annotation questions (Appendix E) and 11 MCQs (Appendix F), of which 24 were kept for final analysis (16 annotation questions and 8 MCQs) after internal validation. Two annotation questions were eliminated because novice participants scored as high as experts on them. They also had Spearman correlation coefficients of 0.023 and -0.039 compared to the total annotation score. One MCQ was excluded because it had a correlation coefficient of 0.021 when compared to the total MCQ score. The other two eliminated MCQs were too easy, with difficulty indices of 0.89 and 0.8, and one had a discrimination index of 0.13. There was no redundancy between any of the TATME-VAT items, as all inter-item correlations were less than 0.9.

A total of 66 subjects completed the TATME-VAT, including 20 expert, 18 experienced and 28 novice surgeons (Table 2). Experts reported higher annual proctectomy volume and were more likely to perform proctectomies by minimally invasive approaches other than TATME. There were no differences in age or years in practice between the expert and experienced groups. The overall response rate for the TATME-VAT was 66 out of 180 total invited participants (36.7%), with the expert response rate being 20 out of 55 (36.4%). Experts agreed that at least 32 TATMEs were needed to overcome the learning curve for this procedure, which further justifies our definition of expert TATME surgeons.

The maximal percentage agreement between experts for the scoring maps in the TATME-VAT’s annotation scenarios ranged from 56% to 96% (Table 3). Internal consistency of the TATME-VAT was high, with Cronbach’s $\alpha = 0.84$ for the standardized combined score, 0.79 for the annotation questions, and 0.59 for the MCQs.
There was a significant difference in the mean annotation score by group (Figure 3A). Experts scored an average of 46.4, compared to 34.9 for experienced and 33.3 for novice surgeons. After correcting for mean differences, experts’ and experienced surgeons’ responses exhibited less variability (coefficient of variation 17.3% and 18.8% compared to 20.9% for novices). The annotation score was able to differentiate between experts and either of the other two groups, but there was no difference between experienced and novices. Surgeons in the experienced group that had already performed a TATME received a higher mean annotation score compared to those with no TATME experience: 41.4 (SD 8.0) vs. 34.8 (SD 7.6), \( p = 0.047 \), but still lower than experts (\( p = 0.005 \)). Experienced surgeons without TATME experience scored similarly to the novice group (\( p = 0.496 \)). Mean annotation scores were also higher among experts that had performed 51 or more cases versus those that performed between 31 to 50 cases: 53.6 (SD 5.5) vs. 43.0 (SD 9.3), \( p = 0.005 \). The correlation coefficient with self-reported TATME experience was 0.73 (Figure 4) versus -0.14 for total years in surgical practice (Figure 5).

The MCQ portion of the test was able to differentiate between all groups (Figure 3B). Experts scored higher than either group (86.3% vs. 67.4% and 50.4%), and the experienced group scored higher than novices. Correlation between the annotation and MCQ scores was \( r = 0.58 \) (95% CI 0.39-0.72). In the combined final TATME-VAT score, experts scored significantly higher than either of the two other sub-groups (54.7 vs. 49.1 and 47.2; Figure 3C). There was no significant difference between experienced and novice scores.

A total of 20 of the 31 participants who had ever performed a TATME independently (65%) reported a major complication specific to TATME during their case history. There were 7 users that reported a recent TATME complication within the past 10 cases (Table 2). Users with recent complications had lower mean annotation (36.1 (SD 8.9) vs. 50.9 (SD 6.6),
MCQ (67.8 (SD 21.4) vs. 86.4 (SD 11.6), \( p=0.005 \)), and total (48.2 (SD 3.1) vs. 54.6 (SD 3.0), \( p<0.001 \)) scores compared to those without recent complications. There was a strong inverse correlation (\( r=-0.69 \)) between the occurrence of recent complications and the total TATME-VAT score (Figure 6). Participants with a higher self-reported level of confidence during the test also scored better (\( r=0.61 \)) than those who were uncertain of their responses (Figure 7).

A total of 22 users (experienced \( n=6 \), expert \( n=16 \)) completed a second TATME-VAT 10-12 weeks after their initial submission. Test-retest correlation coefficients were 0.92 for annotation questions and 0.75 for MCQs, with an intraclass correlation coefficient of 0.918 for the total score. Submissions were compared using a paired t-test with no significant difference between initial and retest scores (\( p=0.289 \)). None of these users had a significant increase in their TATME case volume between the two submissions.

The generated receiver operating curve based on the combined TATME-VAT score had an area under the curve of 0.92 (Figure 8). A cut-off point of 51.45 was chosen to maximize overall specificity (86.96%) and sensitivity (95%). This cut-off score was able to accurately differentiate experts from both experienced and novice surgeons separately with specificities of 77.78% and 92.86%, respectively. Four experienced surgeons (22.22%) and two novices (7.14%) scored higher than the cut-off, while only one expert (5%) scored below it.

All participants agreed or strongly agreed with the statement that the tool was easy to use and understand (Figure 9). None of the users reported problems navigating the tool. Participants reported high satisfaction (strongly agree or agree) to all of the six questions in the post-test survey. Over 95% of participants felt that the TATME-VAT could be helpful in
learning TATME, and 78% of participants felt that this tool should be incorporated into TATME credentialing programs. There were no differences in the response categories between expert, experienced, and novice participants.
DISCUSSION

TATME is an important procedure that can substantially improve the quality of surgical care delivered to patients with rectal cancer. However, it is essential that the adoption and implementation of the procedure do not mirror past mistakes, such as was the case during the early experience of laparoscopic cholecystectomy which saw an increase in bile duct injuries. Recent TATME data have suggested a high rate of local recurrences, especially in the early phases of implementation. These results have led to a moratorium against TATME in Norway\textsuperscript{11,13}, and a recommendation by the Association of Coloproctology of Great Britain and Ireland to suspend their training program.\textsuperscript{12} It is hypothesized by many that the reason for this may be related to the technical execution of TATME, rather than TATME itself.\textsuperscript{10} Indeed, local recurrences appear to be higher in the early phases of implementation.\textsuperscript{10} Others have also found that technical complications, such as wrong surgical plane, urethral injuries and anastomotic leak, were higher in the early adoption period,\textsuperscript{69,80,81} regardless of completion of a training course.\textsuperscript{16,69} Many of these training courses (in particular the national training pathways in the Netherlands and the United Kingdom) require that surgeons who wish to enrol into the TATME training program be experienced with minimally invasive proctectomy and transanal endoscopic surgery with adequate annual rectal cancer volumes. These data suggest that the current training pathways may not be sufficient, or that a more objective assessment of the understanding of the TATME planes of dissection is required before the procedure is carried out in patients.

In response, we have developed a virtual, computer-analyzed test to objectively assess knowledge of critical anatomy and dissection planes necessary to perform TATME with high correlation of scores to both experience level and incidence of adverse intra-
operative events. This tool has the advantages of being easily accessible, can be administered without proctoring, is scored automatically without risk of introducing human-rater biases (halo effect and leniency bias, and requires no costly cadaver, simulator or live patient resources. In addition, VCT performance has previously been shown to also correlate with live performance for laparoscopic cholecystectomy\textsuperscript{78} and thyroidectomy\textsuperscript{77}, meaning this assessment tool may have important applications in evaluating the knowledge and decision-making necessary to perform a variety of procedures.

This study aimed to provide evidence for all sources of validity defined by the most contemporary unitary frameworks for assessment in surgical education.\textsuperscript{82-85} Table 4 delineates these frameworks and summarizes the validity evidence provided for the use of TATME-VAT in assessing TATME dissection proficiency. The annotation questions in this tool require users to draw where they would proceed with the next step in the dissection, essentially simulating surgical decision-making in a low-risk environment. We furthermore used visual concordance mapping to generate expert-consensus scoring zones against which to compare users’ annotation responses. This has the advantage of not having a single ‘correct’ answer in regard to the plane of dissection, but rather a range with diminishing points awarded the more a response deviates from the areas of high expert agreement. Furthermore, our tool was able to differentiate between TATME experts and experienced rectal cancer surgeons without a high volume of TATME experience. Interestingly, experienced rectal cancer surgeons scored similarly to novices in the annotation questions, suggesting prior rectal cancer surgery experience itself does not necessarily convey expertise in the planes of dissection specific to TATME. Further demonstration of the validity of the TATME-VAT is our finding that surgeons (regardless of expertise) who had had a recent TATME-specific intraoperative complication scored lower than those without.
Another interesting finding of this study is the high variability between expert annotations for the 16 annotation scenarios. Our definition of expert proficiency was based on case volume, which had been previously shown to require at least 30 to 51 cases to overcome the learning curve.\textsuperscript{62,63,70,86} We also asked identified experts to peer nominate other surgeons who they considered to be experts. However, our results also did show that there was a clear difference in annotation scores based on experience, even amongst experts. These data suggest that expert proficiency may not be attained until a significant case volume has been achieved. These results should be validated with a larger group of experts to rule out any potential response or volunteer biases. We also did not have an objective method to determine the difficulty of the case, which was defined instead through consensus during the scenario creation. The anterior and anterolateral plane scenarios had the lowest agreement between experts, which suggests that there is no clear ‘right’ answer, or that our definition of ‘expert’ in this study is lacking. However, there may be missing clinical information in the scenarios that may affect the experts’ annotation planes, especially for the anterior plane (for example if the tumour is located anteriorly then the proposed dissection plane may incorporate Waldeyer’s fascia vs. preserving this fascial plane for posterior tumours).

The results of this study need to be interpreted in view of other limitations. We could not develop scenarios for all of the important TATME steps, such as the purse-string and anastomosis creation. These steps were largely un-recorded, performed ‘open’, or were difficult to translate into VCT scenarios. Certain of these steps are crucial to TATME and are often the most difficult and associated with the most complications. Furthermore, the VCT does not assess many technical skills, such as providing the optimal retraction. In these VCT scenarios, the optimal tension and exposure to expose dissection planes were already
provided and we could not assess whether the user has the capability to replicate this in a real case, or if the user would have exposed the planes differently than provided in the scenario. Additional assessments are required to evaluate these skills that collectively comprise the myriad of technical skills necessary to perform TATME safely. We were also unable to assess the TATME-VAT performance with other proficiency measures, such as TME quality and oncologic outcomes. It would be interesting to for future studies to determine if TATME-VAT performance correlated with technical ability and oncologic outcomes, especially since there are emerging data to suggest the strong link between these two variables in colorectal cancer surgery.\textsuperscript{87,88} Adaptive testing and scoring should also be applied, as currently the scores are calculated as an average, instead of differential weighting based on scenario difficulty.\textsuperscript{89} Modern psychometric testing methods such as item-response theory or Rasch modeling may be used in this effect with a larger number of responses than was achieved in this study. Finally, additional assessment methods for the cognitive and technical elements that do not lend themselves to the VCT should be developed in order to fully evaluate TATME proficiency.
CONCLUSION

In summary, this study describes the development of a video-based virtual assessment tool for TATME dissection and provides initial validity evidence for its use. We demonstrate that this assessment tool can differentiate between expertise levels, as well as complication occurrence. While additional validity evidence is still required, the TATME-VAT may have promise as a summative assessment tool for any potential credentialing process.
REFERENCES


Table 1 – Operative steps included in TATME-VAT

<table>
<thead>
<tr>
<th>Operative step</th>
<th>Still frame image example</th>
<th>Scoring zone example</th>
<th>Critical task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rectal purse-string</td>
<td></td>
<td></td>
<td>Avoid positive distal margins</td>
</tr>
<tr>
<td>Marking the proctotomy line</td>
<td></td>
<td></td>
<td>Avoid entry into the rectal tube</td>
</tr>
<tr>
<td>Posterior plane</td>
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<td></td>
<td>Avoid presacral plexus, anococygeal ligament and fibrous band</td>
</tr>
<tr>
<td>Anterior plane</td>
<td></td>
<td></td>
<td>Males: avoid prostate, urethra and NVW</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Females: avoid posterior vaginal wall</td>
</tr>
<tr>
<td>Lateral plane</td>
<td></td>
<td></td>
<td>Avoid autonomic nerves and entry into pelvic sidewalls</td>
</tr>
<tr>
<td>Table 2 – Participant characteristics</td>
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<td></td>
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<tr>
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<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Expert (n=20)</strong></td>
<td><strong>Experienced (n=18)</strong></td>
<td><strong>Novice (n=28)</strong></td>
<td><strong>p</strong>*</td>
</tr>
<tr>
<td>---------------------</td>
<td>------------------------</td>
<td>-------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Median age, years [IQR]</td>
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<td>45 [36-63]</td>
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<td>3 (11%)</td>
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<td>15 (54%)</td>
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<td>0 (0%)</td>
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<td>31+</td>
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<td>9 (50%)</td>
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<td>17 (85%)</td>
<td>13 (72%)</td>
<td>11 (36%)</td>
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<td>11-30</td>
<td>2 (10%)</td>
<td>4 (22%)</td>
<td>1 (4%)</td>
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<td>0 (0%)</td>
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<td>15 (54%)</td>
</tr>
<tr>
<td>1-10</td>
<td>3 (15%)</td>
<td>3 (17%)</td>
<td>10 (36%)</td>
</tr>
<tr>
<td>11-30</td>
<td>9 (45%)</td>
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<td>3 (11%)</td>
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<td>31+</td>
<td>8 (40%)</td>
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<td>0 (0%)</td>
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<td>Annual robotic proctectomy volume</td>
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<td>16 (89%)</td>
<td>27 (96%)</td>
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<td>1-10</td>
<td>6 (30%)</td>
<td>2 (11%)</td>
<td>1 (4%)</td>
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<tr>
<td>11-29</td>
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<td>30+</td>
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<td>1-14</td>
<td>15-24</td>
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<td>Performance of any MIS intracorporeal GI anastomosis</td>
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<td>Total TATME experience</td>
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<td>&lt;0.001†</td>
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<td>Recent TATME complications‡</td>
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<td>5 (38%)</td>
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<td>Urethral injury</td>
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<td>Prostate injury</td>
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<td>2</td>
<td>–</td>
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<td>Neurovascular bundle of Walsh injury</td>
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<tr>
<td>Inadvertent injury of posterior vaginal wall</td>
<td>–</td>
<td>2</td>
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<tr>
<td>Failure of pursestring</td>
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<td>–</td>
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<tr>
<td>Other</td>
<td>–</td>
<td>1</td>
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</table>

MIS, minimally invasive surgery; TES, transanal endoscopic surgery; GI, gastrointestinal

*p-value comparing all three groups
†p-value comparing expert vs. experienced
‡Defined as complications within the last 10 cases; expert n=20, experienced n=11
Table 3 – Breakdown of the annotation questions

<table>
<thead>
<tr>
<th>Question</th>
<th>Operative step</th>
<th>Rated difficulty</th>
<th>Expert agreement</th>
<th>Expert score*</th>
<th>Experienced score*</th>
<th>Novice score*</th>
<th>p†</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Anterior dissection</td>
<td>Easy</td>
<td>56%</td>
<td>29.6 (15.3)</td>
<td>21.5 (12.3)</td>
<td>22.9 (11.1)</td>
<td>0.109</td>
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<tr>
<td>2</td>
<td>Anterior dissection</td>
<td>Difficult</td>
<td>56%</td>
<td>40.0 (12.2)</td>
<td>38.4 (10.5)</td>
<td>35.4 (9.1)</td>
<td>0.299</td>
</tr>
<tr>
<td>3</td>
<td>Anterolateral (Left) dissection</td>
<td>Easy</td>
<td>63%</td>
<td>37.3 (23.1)</td>
<td>24.9 (13.1)</td>
<td>19.6 (16.3)</td>
<td>0.005</td>
</tr>
<tr>
<td>4</td>
<td>Lateral (Left) dissection</td>
<td>Easy</td>
<td>63%</td>
<td>33.0 (14.9)</td>
<td>24.3 (14.4)</td>
<td>16.6 (11.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>5</td>
<td>Lateral (Right) dissection</td>
<td>Moderate</td>
<td>68%</td>
<td>30.1 (15.1)</td>
<td>25.6 (18.1)</td>
<td>25.4 (13.5)</td>
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</tr>
<tr>
<td>6</td>
<td>Posterior dissection</td>
<td>Moderate</td>
<td>71%</td>
<td>41.6 (13.9)</td>
<td>31.0 (18.7)</td>
<td>30.6 (22.4)</td>
<td>0.156</td>
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<tr>
<td>7</td>
<td>Proctotomy</td>
<td>Easy</td>
<td>79%</td>
<td>48.2 (13.9)</td>
<td>26.7 (12.4)</td>
<td>28.6 (15.5)</td>
<td>&lt;0.001</td>
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<tr>
<td>8</td>
<td>Anterolateral (Left) dissection</td>
<td>Moderate</td>
<td>87%</td>
<td>54.5 (19.9)</td>
<td>46.5 (22.1)</td>
<td>40.6 (24.4)</td>
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<td>9</td>
<td>Posterior dissection</td>
<td>Easy</td>
<td>85%</td>
<td>46.4 (15.0)</td>
<td>31.6 (21.5)</td>
<td>26.2 (15.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>10</td>
<td>Anterolateral (Right) dissection</td>
<td>Difficult</td>
<td>78%</td>
<td>36.0 (11.5)</td>
<td>33.6 (12.9)</td>
<td>29.9 (16.3)</td>
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<tr>
<td>11</td>
<td>Anterolateral (Left) dissection</td>
<td>Moderate</td>
<td>78%</td>
<td>38.5 (19.0)</td>
<td>35.0 (18.7)</td>
<td>27.3 (19.6)</td>
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<td>12</td>
<td>Anterolateral (Left) dissection</td>
<td>Moderate</td>
<td>68%</td>
<td>42.2 (11.9)</td>
<td>22.7 (14.1)</td>
<td>17.6 (15.1)</td>
<td>&lt;0.001</td>
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<tr>
<td>13</td>
<td>Posterior dissection</td>
<td>Easy</td>
<td>96%</td>
<td>74.6 (15.4)</td>
<td>62.7 (20.3)</td>
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<td>14</td>
<td>Proctotomy</td>
<td>Easy</td>
<td>83%</td>
<td>61.6 (13.6)</td>
<td>42.0 (15.7)</td>
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<td>15</td>
<td>Purse-string placement</td>
<td>Moderate</td>
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<td>46.7 (21.9)</td>
<td>49.2 (20.3)</td>
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<tr>
<td>16</td>
<td>Proctotomy</td>
<td>Easy</td>
<td>86%</td>
<td>68.3 (14.7)</td>
<td>45.4 (23.3)</td>
<td>52.6 (26.4)</td>
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*reported as mean (SD)
†p-value comparing expert, experienced, and novice scores
<table>
<thead>
<tr>
<th>Evidence Source</th>
<th>Definition*</th>
<th>Examples from TATME-VAT</th>
</tr>
</thead>
</table>
| Content         | The “relationship between a test’s content and the construct it is intended to measure.” | - Test blueprint based on expert Delphi consensus
- Scenarios developed from real TATME videos
- Content reviewed independently by 2 expert TATME surgeons and 2 surgeons with formalized training in surgical education |
| Response process| Analyses of responses of individual respondents or observers. Differences in response process may reveal sources of variance irrelevant to the construct being measured. It includes instrument security, scoring and reporting of results. | - All users agreed that TATME-VAT was easy to use, understand and navigate
- Scores generated automatically, eliminating rater biases
- Acceptable response rate (no non-response bias)
- Strong positive correlation between sub-scores and standardization of items allowed for accurate score combination |
| Internal structure | Degree to which individual items within an instrument fit the underlying constructs. It is often reported by measures on internal consistency reliability and factor analysis. | - Inter-item and total-item correlations for all questions (annotation + MCQs)
- Item difficulty and discrimination indices for MCQs
- Elimination of 5 items (due to low total-item correlation or if item is too easy)
- Cronbach alpha = 0.84
- Test-retest reliability (ICC = 0.92)
- No redundancy between items (inter-item correlations <0.9) |
| Relation to other variables | Relationship between scores and other variables relevant to the construct being measured. Relationships may be positive or negative depending on the constructs being measured. | - Positive correlation with TATME cases performed
- No correlation with years in practice
- Negative correlation with recent complications
- Positive correlation with confidence level (negative correlation with guessing) |
| Consequences | Assessments are intended to have some desired effect or may have unintended effects. | - 95% sensitivity and 87% specificity
- Should be used as an adjunct to other assessment tools (not a stand-alone summative or high-stakes assessment)
- High negative predictive value (97.6)
- Can be used as a formative assessment tool to track trainee progress
- Can be used to evaluate the outcomes of TATME courses |

* Reference:
Figure 1 – Colon and rectal cancer staging*

* Reference:
Figure 2 – Annotation question scoring example. A) The user draws their annotation on still frame. B) The tool converts the line drawn by the user into pixels. C) Pixels are assigned a percentage based on where they fall on the expert scoring zones. The final score for each annotation question is the average score for these pixels.
**Figure 3** – Comparison of TATME-VAT scores between experts, experienced, and novices for A) annotation questions, B) multiple choice questions, and C) combined standardized scores.
Figure 4 – Correlation between the participant’s TATME experience and the TATME-VAT total score [correlation coefficient (r) = 0.73]
**Figure 5** – Correlation between the participant’s years in surgical practice and the TATME-VAT total score [correlation coefficient ($r$) = -0.14]
Figure 6 – Correlation between the presence of recent complications and the TATME-VAT total score [correlation coefficient ($r$) = -0.69]
Figure 7 – Correlation between the participant’s confidence level and the TATME-VAT total score [correlation coefficient (r) = 0.61]
Figure 8 – Receiver operating curve for TATME-VAT

* Cut-off point for pass/fail (expert or non-expert) of TATME-VAT

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Expert</th>
<th>Non-expert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert</td>
<td>19</td>
<td>1</td>
</tr>
<tr>
<td>Experienced</td>
<td>4</td>
<td>14</td>
</tr>
<tr>
<td>Novice</td>
<td>2</td>
<td>26</td>
</tr>
</tbody>
</table>

Specificity = 86.96%
Sensitivity = 95%
Figure 9 – Feedback scores for the TATME-VAT

- I was easily oriented to the surgical field in the TATME-VAT videos
- TATME-VAT assessed the most critical dissections steps
- TATME-VAT was simple to use and understand
- TATME-VAT is an effective adjunct to formalized official assessment
- TATME-VAT could facilitate learning of intra-operative decision-making
- TATME-VAT should be incorporated into credentialing programs

Percent of respondents

Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree
January 10, 2019

Dr. Lawrence Lee
Department of Surgery
1650 Cedar Avenue – Room E19-125
Montreal, Quebec

RE: IRB Study Number A01-E04-19A

Development of a web-based tool to assess decision-making for trans-anal total mesorectal excision

Dear Dr. Lee,

Thank you for submitting, on behalf of Dr. Hamzeh Naghawi, the above study for IRB review.

As this study involves no more than minimal risk, and in accordance with Articles 2.9 and 6.12 of the 2nd Edition of the Canadian Tri-Council Policy Statement of Ethical Conduct for Research Involving Humans (TCPS 2) and U.S. Title 45 CFR 46, Section 110 (b), paragraph (1), we are pleased to inform you that ethics approval for the study, study instruments and consent forms (December 18, 2018) is provided via an expedited review provided by the IRB Co-Chair on January 10, 2019. The ethics certificate is valid until January 2020. The study proposal will be presented for corroborative approval at the next scheduled meeting of the Institutional Review Board, and a certification document will be issued to you at that time.

A review of all research involving human subjects is required on an annual basis in accord with the date of initial approval. The annual review should be submitted at least one month before January 2020. Please inform the IRB promptly of any modifications that may occur to the study over the next twelve months.

Sincerely,

Carolyn Ellis, PhD
Co-Chair
Institutional Review Board

cc: Dr. Hamzeh Naghawi
A01-E04-19A
January 14, 2020

Dr. Lawrence Lee
Department of Surgery
1650 Cedar Avenue – Room E19-125
Montreal, Quebec

RE: IRB Study Number A01-E04-19A

 Development of a web-based tool to assess decision-making for trans-anal total mesorectal excision

Dear Dr. Lee,

Thank you for submitting an application for Continuing Ethics Review for the above-referenced study. The study progress report was reviewed and Full Board re-approval was provided on January 13, 2020. The ethics certification renewal is valid from January 9, 2020 to January 8, 2021.

The Investigator is reminded of the requirement to report all IRB approved protocol and consent form modifications to the Research Ethics Offices (REOs) for the participating hospital sites. Please contact the individual hospital REOs for instructions on how to proceed. Research funds may be withheld and / or the study’s data may be revoked for failing to comply with this requirement.

Should any modification or unanticipated development occur prior to the next review, please notify the IRB promptly. Regulation does not permit the implementation of study modifications prior to IRB review and approval.

Regards,

Roberta Palmour, PhD
Chair
Institutional Review Board

cc: Dr. Hamzeh Naghawi
Pepa Kaneva
A01-E04-19A
January 12, 2021

Dr. Lawrence Lee
Department of Surgery
1650 Cedar Avenue – Room E19-125
Montreal, Quebec

RE: IRB Study Number A01-E04-19A

Development of a web-based tool to assess decision-making for trans-anal total mesorectal excision

Dear Dr. Lee,

Thank you for submitting an application for Continuing Ethics Review for the above-referenced study.

The study progress report was reviewed and full Board re-approval was provided on January 11, 2021. The ethics certification renewal is valid from January 8, 2021 to January 7, 2022.

The Investigator is reminded of the requirement to report all IRB approved protocol and consent form modifications to the Research Ethics Offices (REOs) for the participating hospital sites. Please contact the individual hospital REOs for instructions on how to proceed. Research funds may be withheld and / or the study’s data may be revoked for failing to comply with this requirement.

Should any modification or unanticipated development occur prior to the next review, please notify the IRB promptly. Regulation does not permit the implementation of study modifications prior to IRB review and approval.

Regards,

Roberta M. Palmour, PhD
Chair
Institutional Review Board

cc: Dr. Hamzeh Naghawi
    Pepa Kaneva
    A01-E04-19A
Appendix B – Consent Form

Consent Form for Educational research

Title: Development of a Web-Based Tool to Assess Decision-Making for Trans-Anal Total Mesorectal Excision

Investigators: Lawrence Lee MD, Hamzeh Naghawi MD, Johnny Chau MD, Carmen L Mueller MD

Institution: Steinberg-Brernstein Center for Minimally Invasive surgery, Montreal General Hospital

Background

Total mesorectal excision (TME) is now the standard of care for rectal cancer. The pelvic anatomy combined with the limitations of long straight instruments can make minimally invasive TME challenging, even in the most experienced of hands, especially in the narrow male pelvis. Transanal total mesorectal excision (TATME) offers a solution to the difficult visualization of the pelvic anatomy from an abdominal approach by providing access transanally and direct visualization from below. As with the debut of any innovation, there are concerns with the safe introduction of TATME in clinical practice. Critical dissection points need to be identified and an objective measure of proficiency to approach these points should be developed. The use of a visual concordance test (VCT) model has been previously applied in the context of teaching curriculums for laparoscopic cholecystectomy and thyroidectomy and has been shown to objectively assess decision-making. The same principle can be applied to the development of a TATME curriculum that will eventually help trainees hone the skills required for performing the procedure.

Purpose

1. To develop an e-learning, web-accessible platform that uses the visual concordance test (VCT) to assess intra-operative decision-making for the critical dissection steps of TATME.

2. To test the psychometric properties of the VCT as a measure of accuracy for critical decision points in TATME dissection.
Design

You will be asked to complete a questionnaire providing basic demographic information (for example: PGY level or years in practice) and information about your rectal cancer surgery experience and simulator training. You will be shown a series of videos of different critical points for a TATME procedure, and asked to identify the proper plane of dissection by drawing annotations on the still surgical field. After you complete the test, we will ask you to complete a short questionnaire about the newly developed platform. The duration of the test and the questionnaires will take approximately 15-20 minutes.

Confidentiality

All data obtained will be coded and kept confidential. All reporting of results will be anonymous. The file linking the ID number of participants and their experience will be password protected with only principal investigators having access to it. There are no paper documentations of participants’ results – all data is electronic. The study investigator will use the study information collected about you for research purposes, only to reach the study goals as they are explained in this Information and Consent Document. The participation in this study provides no additional risk to the participants and requires no additional resources of the institution. The results of the evaluations will be kept confidential. The evaluation of trainees will not be made available to the Program Director and will not be used for the purposes of promotion and formal evaluation. Data will be kept on a password protected computer and the data will be stored at the Steinberg-Bernstein Centre for Minimally Invasive surgery, Montreal General Hospital (Montreal, QC) and will be made available only to the investigators in this study. The data will be kept for 7 years after the study completion and then discarded.

Risk and Benefits

There are no risks associated with this study. You are not expected to directly benefit from participating in this study; however, your participation in this study may help in developing novel assessment tools to train residents and improve the quality of their training.
Questions and contact information

If you have any questions regarding the study, you may contact the study coordinator: Dr. Hamzeh Naghawi 514-934-8044, E19-125 Montreal General Hospital, hamzeh.naghawi@mail.mcgill.ca or either principal investigator: Dr. Carmen Mueller, 514-934-1934 x 44327; carmen.mueller@mcgill.ca or Dr. Lawrence Lee, 514-934-1934 ext. 44365; larry.lee@mcgill.ca. For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the McGill University ethics office at 514-398-8302.

Voluntary participation and/or withdrawal

Your participation in the study is voluntary. Refusal to participate or withdrawal from the study at any time will not involve any penalty or prejudice. We may use the data collected prior to your withdrawal unless you advise us that you would like all your previous data to be destroyed or not to be used.

Consent

I am aware that participation is voluntary and that refusal to participate or withdrawal from the study at any time will not involve any penalty or prejudice. I have read the above information and have had the opportunity to have all of my questions answered to my satisfaction. I agree to participate in this study, and I am aware that by checking this box I do not give up any of my legal rights.

Date:___/___/___
## Basic Demographics

<table>
<thead>
<tr>
<th>Study ID number</th>
<th>Age</th>
<th>Gender</th>
<th>Training level</th>
<th>Fellowship (check all that apply)</th>
<th>What is the focus of your clinical practice (check all that apply)</th>
<th>Practice Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>Staff – years in practice</td>
<td>Colorectal</td>
<td>Colorectal</td>
<td>Academic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Female</td>
<td>Fellow – PGY</td>
<td>MIS</td>
<td>MIS (hernia/upper GI/bariatrics)</td>
<td>Community (teaching)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other</td>
<td>Resident – PGY</td>
<td>Surgical Oncology</td>
<td>Surgical Oncology</td>
<td>Community (non-teaching)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Other (specify)</td>
<td>Other (specify)</td>
<td>Other (specify)</td>
<td>Private practice</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Other (specify)</td>
</tr>
</tbody>
</table>

## Previous Experience

1. **Percentage of minimally invasive cases performed in your practice**
   - □ <25%
   - □ 25-50%
   - □ 50-75%
   - □ >75%

2. **Number of rectal cancer resections per year (any approach)**
   - □ None
   - □ 1 to 10
   - □ 11 to 30
   - □ 31 or more

3. **Number of open rectal resections in the past year**
   - □ None
   - □ 1 to 10
   - □ 11 to 30
   - □ 31 or more

4. **Number of laparoscopic rectal resections in the past year**
   - □ None
   - □ 1 to 10
   - □ 11 to 30
   - □ 31 or more

5. **Number of robotic rectal resections in the past year**
   - □ None
   - □ 1 to 10
   - □ 11 to 30
   - □ 31 or more

6. **Total number of local excisions performed via TAMIS or TEMS (overall experience)**
   - □ None
   - □ 1 to 14
   - □ 15 to 24
   - □ 25 or more

7. **Do you perform any laparoscopic intracorporeal GI anastomoses in your practice?**
   - □ No
   - □ Yes

8. **Total number of TATME already performed (overall experience)**
   - □ None
   - □ 1 to 5
   - □ 6 to 10
   - □ 11 to 20
   - □ 21 to 30
   - □ 31 to 50
   - □ 51 or more
<table>
<thead>
<tr>
<th>If you perform TATME in your practice, how did you learn to perform this operation?</th>
<th>☐ Self-taught.  ☐ Watching videos and online material.  ☐ TATME hands-on course, # of courses ______  ☐ Official training/ fellowship.  ☐ Other (specify) ____________________________  ☐ Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>What do you think are challenges surgeons face in achieving proficiency in TATME? (Check all that apply)</td>
<td>☐ Difficulty of the procedure  ☐ Lack of access to formalized training  ☐ Increased OR time requirements  ☐ Fear of complications  ☐ Inadequate case volume to allow skill advancement  ☐ Need for specialized equipment  ☐ Lack of a valid assessment tool to establish proficiency  ☐ Lack of availability of qualified proctors/mentors  ☐ Unique approach that is difficult to generalize from other surgical approaches/techniques  ☐ Other (specify) ____________________________</td>
</tr>
<tr>
<td>How many procedures do you think a trained colorectal surgeon should do to overcome the learning curve for TATME?</td>
<td>______</td>
</tr>
<tr>
<td>Do you think TATME should be credentialed?</td>
<td>☐ Yes  ☐ No</td>
</tr>
</tbody>
</table>
### Appendix D – Participant post-test questionnaire

**TATME-VAT PARTICIPANT POST-TEST QUESTIONNAIRE**

<table>
<thead>
<tr>
<th>Study ID number</th>
</tr>
</thead>
</table>

1. **The videos in the TATME Visual Concordance Test (VCT) allowed me to become easily oriented to the surgical field and relevant anatomy.**

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree or disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
</table>

2. **I think the TATME Visual Concordance Test assessed the most important critical points of developing the trans-anal dissection plane.**

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree or disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
</table>

3. **I found the VCT tool simple to use and understand.**

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree or disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
</table>

4. **The VCT is an effective adjunct to formalized official assessment by an expert proctor.**

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree or disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
</table>

5. **The VCT could be used to facilitate LEARNING of intra-operative decision-making for TATME.**

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree or disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
</table>

6. **This platform should be incorporated into credentialing programs for TATME.**

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree or disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
</table>

7. **Were there any limitations to the TATME Visual Concordance Test?**

8. **Other comments?**
9. Which of the following complications have you encountered in your own TATME cases as a primary surgeon?

<table>
<thead>
<tr>
<th>Complication</th>
<th>How many times?</th>
<th>When did it last occur?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Urethral injury</td>
<td>__________</td>
<td>□ First 10 cases</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ 10&lt;sup&gt;th&lt;/sup&gt; – 30&lt;sup&gt;th&lt;/sup&gt; case</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ After 30&lt;sup&gt;th&lt;/sup&gt; case</td>
</tr>
<tr>
<td>☐ Entry through the posterior wall of vagina</td>
<td>__________</td>
<td>□ First 10 cases</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ 10&lt;sup&gt;th&lt;/sup&gt; – 30&lt;sup&gt;th&lt;/sup&gt; case</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ After 30&lt;sup&gt;th&lt;/sup&gt; case</td>
</tr>
<tr>
<td>☐ Neurovascular bundle of Walsh injury</td>
<td>__________</td>
<td>□ First 10 cases</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ 10&lt;sup&gt;th&lt;/sup&gt; – 30&lt;sup&gt;th&lt;/sup&gt; case</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ After 30&lt;sup&gt;th&lt;/sup&gt; case</td>
</tr>
<tr>
<td>☐ Prostate Injury</td>
<td>__________</td>
<td>□ First 10 cases</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ 10&lt;sup&gt;th&lt;/sup&gt; – 30&lt;sup&gt;th&lt;/sup&gt; case</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ After 30&lt;sup&gt;th&lt;/sup&gt; case</td>
</tr>
<tr>
<td>☐ Pre-sacral plexus injury</td>
<td>__________</td>
<td>□ First 10 cases</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ 10&lt;sup&gt;th&lt;/sup&gt; – 30&lt;sup&gt;th&lt;/sup&gt; case</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ After 30&lt;sup&gt;th&lt;/sup&gt; case</td>
</tr>
<tr>
<td>☐ Other (specify)</td>
<td>__________</td>
<td>□ First 10 cases</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ 10&lt;sup&gt;th&lt;/sup&gt; – 30&lt;sup&gt;th&lt;/sup&gt; case</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ After 30&lt;sup&gt;th&lt;/sup&gt; case</td>
</tr>
</tbody>
</table>
### Appendix E – List of annotation questions

<table>
<thead>
<tr>
<th>Still Frame</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.jpg" alt="Still Frame 1" /></td>
<td>Draw a line tracing the plane where you would propose to proceed with the dissection</td>
</tr>
<tr>
<td><img src="image2.jpg" alt="Still Frame 2" /></td>
<td>Draw a line tracing the plane where you would propose to proceed with the dissection</td>
</tr>
<tr>
<td><img src="image3.jpg" alt="Still Frame 3" /></td>
<td>Draw a line tracing the plane where you would propose to proceed with the dissection</td>
</tr>
<tr>
<td><img src="image4.jpg" alt="Still Frame 4" /></td>
<td>Draw a line tracing the plane where you would propose to proceed with the dissection</td>
</tr>
<tr>
<td>5</td>
<td>Draw a line tracing the plane where you would propose to proceed with the dissection</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>6</td>
<td>Draw a line tracing the plane where you would propose to proceed with the dissection</td>
</tr>
<tr>
<td>7</td>
<td>Draw a line tracing the plane where you would propose to proceed with the dissection</td>
</tr>
<tr>
<td>8</td>
<td>Draw a line tracing the plane where you would propose to proceed with the dissection</td>
</tr>
<tr>
<td>9</td>
<td>On this still frame, draw a line marking the proposed line of proctotomy</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>10</td>
<td>Draw a line tracing the plane where you would propose to proceed with the dissection</td>
</tr>
<tr>
<td>11</td>
<td>Draw a line tracing the plane where you would propose to proceed with the dissection</td>
</tr>
<tr>
<td>12</td>
<td>Draw a line tracing the plane where you would propose to proceed with the dissection</td>
</tr>
<tr>
<td>13</td>
<td>Draw a line tracing the plane where you would propose to proceed with the dissection</td>
</tr>
<tr>
<td>14</td>
<td>Draw a line tracing the plane where you would propose to proceed with the dissection</td>
</tr>
<tr>
<td>15</td>
<td>Draw a line tracing the plane where you would propose to proceed with the dissection</td>
</tr>
<tr>
<td>16</td>
<td>On this still frame, draw a line marking the proposed line of proctotomy</td>
</tr>
<tr>
<td>17</td>
<td>Draw a line where you would place the rectal purse-string</td>
</tr>
<tr>
<td>----</td>
<td>---------------------------------------------------------</td>
</tr>
<tr>
<td>18</td>
<td>On this still frame, draw a line marking the proposed line of proctotomy</td>
</tr>
</tbody>
</table>

Questions 6 and 8 (highlighted in grey) were excluded from the final TATME-VAT
### Appendix F – List of multiple-choice questions

<table>
<thead>
<tr>
<th>Still Frame</th>
<th>MCQ</th>
</tr>
</thead>
</table>
| ![Image](image1.png) | **1**

If the surgeon makes an incorrect deep dissection in this plane, all the following structures would be prone to injury EXCEPT:

A) Presacral plexus  
B) Prostate  
C) Neurovascular bundle of Walsh  
D) Urethra

| ![Image](image2.png) | **2**

This video shows part of an intersphincteric dissection. Which of the following structures is most likely to be injured if the surgeon incorrectly makes a deep dissection anteriorly?

A) Prostatic urethra  
B) Ureter  
C) Bladder

| ![Image](image3.png) | **3**

The surgeon was dissecting in the wrong left anterolateral TME plane, evident by injuring the structure shown in the video. Identify the encircled structure.

A) Neurovascular bundle of Walsh  
B) Seminal vesicle  
C) Part of the prostate  
D) Presacral plexus

| ![Image](image4.png) | **4**

If the surgeon makes an incorrect deep dissection in this plane, which of the following would be most prone to injury?

A) Pelvic floor nerves  
B) Seminal Vesicles  
C) Neurovascular bundle of Walsh  
D) Ureter
<table>
<thead>
<tr>
<th></th>
<th>If the surgeon makes an incorrect deep dissection in the encircled location, which of the following structures would be most likely to be injured?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Endopelvic fascia</td>
</tr>
<tr>
<td>B</td>
<td>Presacral plexus</td>
</tr>
<tr>
<td>C</td>
<td>Obturator canal</td>
</tr>
<tr>
<td>D</td>
<td>Neurovascular bundle of Walsh</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>The surgeon’s dissection in the right lateral/ anterolateral plane uncovered the encircled space. Identify this structure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Obturator Canal/ Fossa</td>
</tr>
<tr>
<td>B</td>
<td>Neurovascular bundle of Walsh</td>
</tr>
<tr>
<td>C</td>
<td>Seminal vesicle</td>
</tr>
<tr>
<td>D</td>
<td>Rectal wall</td>
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</table>

<table>
<thead>
<tr>
<th></th>
<th>In a correct left anterolateral TME dissection plane, the encircled structure should not be injured. Identify this structure.</th>
</tr>
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<tbody>
<tr>
<td>A</td>
<td>Neurovascular bundle of Walsh</td>
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<td>B</td>
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<tr>
<td>C</td>
<td>Part of the prostate</td>
</tr>
<tr>
<td>D</td>
<td>Presacral plexus</td>
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<tr>
<td>Question</td>
<td>Image</td>
</tr>
<tr>
<td>----------</td>
<td>-------</td>
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</table>
| 9        | ![Image](image1.jpg) | If the surgeon makes an incorrect deep dissection in this location, which structure is most likely to be injured?  
A) Presacral plexus  
B) Superior rectal vessels  
C) Anococcygeal ligament  
D) External iliac arteries |
| 10       | ![Image](image2.jpg) | Which of the following is a necessary feature of an ideally placed purse-string?  
A) Bites should be taken in a circumferential manner to ensure airtight seal  
B) Bites should be taken directly next to the tumor in order to make it possible to preserve the rectal stump length  
C) Bites should be taken far apart to minimize tumor manipulation  
D) The purse-string should be made loose to be able to visualize the tumor at any point during the operation |
| 11       | ![Image](image3.jpg) | Placing the proctotomy line at a correct distance from the purse-string is essential for all the following reasons EXCEPT:  
A) To avoid positive distal margins  
B) To avoid entry into the rectal tube  
C) To avoid undoing of the purse-string  
D) To leave adequate distal rectal cuff |

Note: Questions 5, 9 and 10 (highlighted in grey) were excluded from the final TATME-VAT
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ANOVA</td>
<td>Analysis of variance</td>
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<tr>
<td>APC</td>
<td>Adenomatous polyposis coli</td>
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<tr>
<td>APR</td>
<td>Abdominoperineal resection</td>
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<td>CI</td>
<td>Confidence interval</td>
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<td>Cyclooxygenase-2</td>
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<td>Deoxyribonucleic acid</td>
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<td>FAP</td>
<td>Familial adenomatous polyposis</td>
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<tr>
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<td>GastroIntestinal</td>
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<td>Interquartile range</td>
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<td>MCQ</td>
<td>Multiple-choice question</td>
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<td>PPAR</td>
<td>Peroxisome proliferator-activating receptor</td>
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<tr>
<td>SD</td>
<td>Standard deviation</td>
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<td>TATME</td>
<td>Transanal total mesorectal excision</td>
</tr>
<tr>
<td>TATME-VAT</td>
<td>Transanal total mesorectal excision – virtual assessment tool</td>
</tr>
<tr>
<td>TES</td>
<td>Transanal endoscopic surgery</td>
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<td>TME</td>
<td>Total mesorectal excision</td>
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<tr>
<td>TNM staging</td>
<td>Tumor, node, metastasis staging</td>
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<tr>
<td>VCT</td>
<td>Visual concordance test</td>
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