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## Introduction of new techniques and technologies in surgery: Where is transanal total mesorectal excision today?

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### Abstract

The introduction of new surgical techniques and technologies has traditionally been unregulated. In many settings surgeons frequently adopt novel procedures without following a structured program of implementation or supervision. The appearance of innovative technology played a pivotal role in the advancement of new surgical techniques during the industrial revolution. Innovation has been an essential component of surgical development, which led to contemporary surgical techniques such as minimally invasive surgery. Different initiatives have been developed to guide the safe introduction of new surgical techniques and other procedures. Those include comprehensive concepts such as the Idea, Development, Exploration, Assessment, Long-term study framework, which could be particularly relevant when reflecting on the novel transanal total mesorectal excision (taTME), introduced a decade ago. This relatively novel and complex procedure promised to overcome some of the major limitations of traditional surgical approaches for rectal cancer. According to the Idea, Development, Exploration, Assessment, Long-term study framework, taTME is in the phase of exploration, where there is an existing and increasing number of reports being published as the experience grows. The current management of rectal cancer is in a state of radical evolution, with multiple options that were not previously available. TaTME is only one technique amongst many which could be part of a rectal cancer surgeon's armamentarium; however, it requires further rigorous study and evaluation.

**Key words:** Rectal cancer; New technology; Safety; Innovation; Transanal surgery

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**Core tip:** The introduction of new surgical techniques and technologies has traditionally

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been unregulated. In many settings surgeons frequently adopt novel procedures without following a structured program of implementation or supervision. According to the Idea, Development, Exploration, Assessment, Long-term study framework, transanal total mesorectal excision (taTME) is in the phase of exploration, where there is an existing and increasing number of reports being published as the experience grows. In addition, there are prospective collaborative studies including registries, audits and databases. This experience leads into the phase of assessment, at this point randomized controlled trials such as the Multicenter Phase II Study of Transanal TME (UStaTME trial), the Transanal vs Laparoscopic TME (COLORIII trial), French Research Group of Rectal Cancer Surgery and others are actively recruiting patients

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## INTRODUCTION

### History

The introduction of new surgical techniques and technologies has traditionally been unregulated. Historically, surgeons either elected or needed to adopt novel procedures without following a structured program of implementation or supervision. Surgery was consistently unsuccessful with common occurrence of fatal outcomes. Surgeons and their interventions were considered part of a barbaric craft, even regarded as inferior when compared to their medical counterparts. Consequently, surgery was left as a last resort, with many preferring death over the pain and suffering of surgery<sup>[1]</sup>. Nonetheless, over the last two centuries surgery has become much more effective, safer and significantly less invasive. The rise of modern surgery and its continuous innovation have been enabled by the development of three specific interventions: The implementation of asepsis and antisepsis; bleeding control and transfusion techniques; and pain suppression by the successful introduction of anesthetic drugs<sup>[2]</sup>.

### Evolution

Surgeons were able to transform their trade into a science-based profession, going from the traditional barber-surgeon to the college-trained surgeon<sup>[3]</sup>. During this period of evolution, the perception of the surgeon, transitioned to be a respected figure with implicit autonomy and even at times with unquestionable authority. A pyramidal model of learning and training flourished and strongly relied upon the notion of “see one, do one, teach one”, with experience gained by constantly being present in the operating room<sup>[4]</sup>. The practice of anatomical dissection as a teaching tool at European universities had a positive impact on the development of surgery<sup>[5]</sup> along with the evolution of the trade into a formal discipline came the development of emerging technology. The appearance of innovative technology played a pivotal role in the advancement of new surgical techniques during the industrial revolution<sup>[6]</sup>. Innovation has been an essential component of surgical growth, being conducive to the development of contemporary surgical techniques such as minimally invasive surgery. There have been many factors influencing these advancements<sup>[7]</sup>.

## ARGUMENTS

The cognitive aspects of education have also evolved, surgeons understood long ago that in order to achieve surgical competency, there must be an effective translation of cognitive knowledge to technical skills<sup>[8]</sup>. Several recent publications have focused on the safe introduction of new techniques and technologies in surgery<sup>[7,9,10]</sup>. The Idea, Development, Exploration, Assessment, Long-term study (IDEAL) framework, introduced by Pennell *et al*<sup>[9]</sup>, is a comprehensive concept developed to guide the safe introduction of new surgical techniques and procedures. Unlike the introduction of new pharmaceuticals compounds, new surgical techniques often lack significant regulation, leading to a deficiency in high quality evidence supporting the new

approach. This issue, combined with the increasing complexity of procedures, have resulted in concerns of poor outcomes and questionable oversight<sup>[10]</sup>. Similar to the IDEAL and other initiatives; the Medical Research Council (MRC) framework distinguishes five stages of investigation in the evaluation of a novel intervention, from theory, modeling, exploratory trial, definitive randomized controlled trial (RCT) and long-term implementation. The distinctive point in the Medical Research Council model is that it sets the objectives at each stage to be completed before progressing into the next one, as a continuum of increasing evidence<sup>[11]</sup>. A useful and perhaps less well-known instrument is the Macquarie surgical innovation identification tool. It provides simple steps to identify whether a new procedure is innovative<sup>[12]</sup>. The tool is a practical and likely underutilized, however it could be of great benefit since evidence indicates the majority of chairs of academic surgical departments in the United States are unaware of what constitutes surgical innovation. Furthermore, it is unclear whether surgical departments provide any education on the appropriate development and implementation of surgical innovation<sup>[13]</sup>.

The situations discussed above are particularly relevant when reflecting on the novel transanal total mesorectal excision (taTME) technique, introduced by Sylla *et al*<sup>[14]</sup> a decade ago. TaTME is a complex and technically demanding procedure that has been regarded as a promise to overcome some of the major limitation conventional surgical approaches for rectal cancer commonly encounter<sup>[15]</sup>. The challenges for those approaches gravitate around poor visualization of critical structures, which is particularly evident in males, obese patients and those with mid to distal rectal pathology. For the most part, surgeons adopting taTME have focused on trying to rapidly acquire the technical skills, this carries many challenges on its own. As previously stated, the process of implementation into clinical practice has been largely unregulated, disorganized and unsupervised. This has resulted into low levels of proficiency at several centers leading to devastating complications and ultimately poor long-term surgeon uptake<sup>[16]</sup>. In addition, the recent issuing of a regional moratorium on the procedure in Norway due to concerns of early and multifocal patterns of local recurrence<sup>[17]</sup> has served as a wake-up call for rectal cancer surgeons across the globe. The moratorium has led the surgical community to recognize the lack of oversight and comprehensive assessment required for the safe adoption of taTME, with this scenario likely being applicable to any new surgical technique or technology. According to the IDEAL framework, taTME is perhaps departing from the phase of exploration, in which there is an existing and increasing number of reports being published as the experience grows. Prospective collaborative studies including registries, audits and databases exist and continue to be produced. Based on the sequence, progression would lead to the next phase, reliable evidence- assessment through RCTs, for that purpose the UStaTME trial, COLOR 3 trial, GRECCAR 11 and others that are actively enrolling patients<sup>[18-20]</sup>.

Valid concerns regarding taTME exist<sup>[21]</sup>, mainly related to poor oversight and concerning oncologic outcomes as they were reported by the Norwegians on 110 patients from 4 hospitals with a local recurrence rate (LR) of 9.5% after a median follow up of 11 mo<sup>[17]</sup>. Further concerns are related to the associated incidence of potentially devastating and otherwise infrequent complications, including urethral and neurovascular injuries<sup>[22-24]</sup>. Urethral injuries remain sporadic and are almost an exclusive complication from abdominoperineal resection. Nevertheless, they have been reported on a few taTME cases, with an incidence of 0.8% according to the international registry<sup>[24]</sup>.

We have discussed the negative arguments against taTME, conversely, we considered appropriate to present the prospective possibilities the technique may offer to the management of patients with rectal cancer. In a recent editorial, Atallah *et al*<sup>[25]</sup> highlighted and contrasted the concerning results from the Norwegian moratorium with a recent publication<sup>[26]</sup> from two institutions in the Netherlands. The latter study showed reassuring long-term oncologic outcomes, including a LR of 3.8 % on 159 patients after a median FU of 52 mo. The authors went to suggest that such a discrepancy in the oncological results between the two publications may be related to the lack of centralization of the technique in Norway; however, details regarding the Norwegian experience remain largely undisclosed<sup>[25]</sup>. Centers in many other countries have recently published encouraging acceptable long-term results. On a multicentric study, including 767 patients, the authors reported a LR of 3.1% after a median FU in excess of 25 mo<sup>[27]</sup>. Perdawood *et al*<sup>[28]</sup> reported 3.5 % LR on 200 patients from one institution in Denmark, with a mean FU of 29 mo, Caycedo-Marulanda *et al*<sup>[29]</sup> reported on 100 patients operated at a single institution in Canada, with a mean FU of 25.5 mo and a 2% LR. These studies reported unifocal patterns of recurrence, except in 2 of 7 patients from the Danish experience who went to develop a multifocal presentation. Outcomes from these studies are reassuring and in keeping with the accepted standards<sup>[30-32]</sup>.

TaTME offers potential for integration with robotic surgery as further expansion of the technique. A pilot study by Gómez Ruiz *et al*<sup>[33]</sup> has already demonstrated feasibility. There is a matched cohort trial for mid to low rectal cancer registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) set to prospectively compare robotic *vs* taTME surgery<sup>[34]</sup>. To our knowledge the study is not actively recruiting yet.

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## REFLEXION

On an eloquent manuscript on adoption of new surgical technology published in 2006<sup>[35]</sup>, the author concluded that “technology that is easy to use and is applicable to large number of patients is most likely to be adopted without evidence”. Paradoxically, taTME is beyond difficult from the technical standpoint, but it could be definitively applicable to a large number of patients. Nevertheless, a multitude of surgeons have attempted to implement it without definitive evidence. As outlined by Buie<sup>[36]</sup>, it is important that we do not fall into the paradox of Buxton’s law “it is always too early (for rigorous evaluation) until suddenly it’s too late.” The challenge is to determine the appropriate time to shift from an exploratory to an investigative study. The importance of timing is reflected in the author’s statement: “If performed too early the definitive technique may not be established and the results may reflect a point on the learning curve, if the investigative study is too late and the intervention is widely available, equipoise is lost and recruitment difficult”. With this in mind, we consider it is advisable to await for the results of the RCTs as those most likely will provide the surgical community with the required evidence to either permanently support or reject taTME.

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## CONCLUSION

Based on what we know today and the available evidence, we favor prudence when considering adopting the technique, taTME should neither be performed casually nor at centers with limited expertise; rather a cautious and supervised pathway must be followed. The current management of rectal cancer is in a state of radical evolution with multiple options that were not previously available. TaTME is only one technique amongst many which could be part of the rectal cancer surgery armamentarium, however, it requires further and rigorous evaluation.

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