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Special Article

Innovations and New Technologies in Gastrointestinal Surgery

Innovaciones y nuevas tecnologías en cirugía gastrointestinal

Inovações e novas tecnologias em cirurgia gastrointestinal

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ABSTRACT

Introduction. Innovations in surgery have advanced significantly in the last decade. The new technologies in minimally invasive surgery, including robotics, advanced endoscopy, and the progress in artificial intelligence and machine learning are impacting gastrointestinal surgery and medicine. These technologies have been available since 1956, and in the early 1970's, they were implemented for first time with the Mycin system, which was developed to detect infectious diseases in blood. **Objective.** To describe the experiences of new technology innovations in surgery, in terms of novel interventions, development of devices, and the process of adopting these technologies in the clinical practice. **Methodology.** Personal reflections about the process of adopting new technologies in surgery and its future implications, documented from my perspective as an academic surgeon. **Results and discussion.** This article summarizes the most relevant advances in the field of gastrointestinal surgery during the last decade. **Conclusions.** Adopting a culture of innovation in surgery involves knowledge of the process, technical resources available to support initiatives, access to mentors or tutors, and support services.

Keywords:
Creativity; Minimally Invasive Surgical Procedures; Robotic Surgical Procedures; Endoscopy; Artificial Intelligence; Simulation Training.

RESUMEN

Introducción. Las innovaciones en cirugía han avanzado significativamente en la última década. Las nuevas tecnologías en cirugía mínimamente invasiva, incluida la robótica, la endoscopia avanzada, el progreso en inteligencia artificial y el aprendizaje automático están impactando en la medicina y la cirugía gastrointestinal. Estas tecnologías existen desde 1956, y en la década de 1970 se implementó por primera vez en el sector salud con el denominado Mycin, un sistema orientado a la detección de enfermedades infecciosas en la sangre. **Objetivo.** Describir las experiencias de nuevas innovaciones tecnológicas en cirugía, en términos de intervenciones novedosas, el desarrollo de dispositivos, la incorporación de las innovaciones en la práctica clínica y las implicaciones hacia el futuro. **Metodología.** A partir de la experiencia como cirujano académico al incorporar las nuevas tecnologías en cirugía, se documentan las reflexiones sobre el proceso de adaptación de nuevas tecnologías en cirugía y su implicación en el futuro. **Resultados y discusión.** Este articulo resume los avances más relevantes en el campo de la cirugía gastrointestinal en la última década. **Conclusiones.** La adopción de una cultura de innovación en cirugía implica conocimiento del proceso, recursos técnicos disponibles para respaldar las iniciativas, acceso a mentores o tutores y servicios de apoyo.

Palabras clave:
Creatividad; Procedimientos Quirúrgicos Mínimamente Invasivos; Procedimientos Quirúrgicos Robotizados; Endoscopía; Inteligencia Artificial; Entrenamiento Simulado.

RESUMO

Introdução. As inovações em cirurgia avançaram significativamente na última década. Novas tecnologias em cirurgia minimamente invasiva, incluindo robótica, endoscopia avançada, avanços em inteligência artificial e aprendizagem automatizado, estão impactando a medicina e a cirurgia gastrointestinal. Essas tecnologias existem desde 1956 e, na década de 1970, foram implementadas pela primeira vez no setor da saúde com o chamado Mycin, um sistema destinado a detectar doenças infecciosas no sangue. **Objetivo.** Descrever as experiências de novas inovações tecnológicas em cirurgia, em termos de novas intervenções, desenvolvimento de dispositivos e o processo de incorporação dessas tecnologias na prática clínica. **Metodologia.** A partir da experiência como cirurgião académico na incorporação de novas tecnologias em cirurgia, documentam-se as reflexões sobre o processo de adaptação de novas tecnologias em cirurgia e as suas implicações no futuro. **Resultados y Discussão.** Este artigo resume os avanços mais relevantes no campo da cirurgia gastrointestinal na última década. **Conclusões.** A adoção de uma cultura de inovação em cirurgia implica conhecimento do processo, recursos técnicos disponíveis para apoiar as iniciativas, acesso a mentores ou tutores e serviços de apoio.

Palavras-chave:
Criatividade; Procedimentos Cirúrgicos Minimamente Invasivos; Procedimentos Cirúrgicos Robóticos; Endoscopia; Inteligência Artificial; Treinamento por Simulação.

Introduction

The new technologies in minimally invasive surgery, including robotics, advanced endoscopy, and the progress in artificial intelligence and machine learning are impacting gastrointestinal surgery and medicine. These technologies have been available since 1956, and in the early 1970's they were implemented for first time with the Mycin system, which was developed to detect infectious diseases in blood. Innovation has produced continuous advancements in surgery (1).

Surgeons have relied on problem-solving skills and improvisation to deliver optimal care in the operating room and in non-surgical patient management. The last several decades, however, have ushered in significant changes in technologies that provide more effective and less invasive treatments of gastrointestinal diseases (2). The rate of this change has accelerated in the last several years and will continue to do so in step with advanced technologies. Innovative gastrointestinal therapies are an exciting area of immediate application and offer immense opportunities for the future (1). As such, the objective of this manuscript is to describe the experiences of new technology innovations in surgery, in terms of novel interventions, development of devices, and the process of adopting these technologies in the clinical practice.

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What is known

- The progress in artificial intelligence and machine learning is impacting gastrointestinal surgery and medicine in general.
- In recent decades there have been major changes in the technologies and treatments for gastrointestinal diseases, making them more effective and less invasive.
- The pace of change has been accelerating in recent years and will continue to do so at an even faster rate, presenting new opportunities for the future.

Methodology

Personal reflections about the process of adopting new technologies in surgery and its future implications, documented from my perspective as an academic surgeon.

Results and discussion

This article summarizes the most relevant advances in the field of gastrointestinal surgery during the last decade. This article will:

1) Define innovation domains and provide specific surgery examples; 2) explore the process of invention disclosure; 3) describe the development of devices, products, and programs for patient care, and as a practical matter, 4) discuss ways in which innovations can be incorporated into the complex roles and responsibilities of the modern General Surgery Department.

1. Types of Healthcare Innovations

Innovation in medicine can broadly be separated into the categories of products, pharmaceuticals, processes, and programs. Product innovation often refers to the development of new devices and modifications of existing ones, and includes advancements in manufacturing processes. This may also include innovation in modes of practice and care delivery. This distinction is important because it is dissimilar to innovation in pharmaceuticals, which largely relies on basic research, large and well-funded organizations, and the incorporation of fundamental changes. Instead, medical device development often focuses on a clinical problem to which engineering solutions may be applied, and therefore can be more readily approached by small groups or individuals. The changes may be incremental and often do not rely on long-term basic science.

The reasons to innovate in surgery are diverse. Fundamentally, change should lead to improvements in patient care and outcomes, but it also involves aspects such as the educational process, industry experience, and financial incentives. Innovation in surgery can occur at different levels of complexity and scope, and may include simple developments or modifications of tools, such as the development of a new grasping clamp. Innovation can occur on a more wide-reaching level with revolutionary changes, such as the development of laparoscopic surgery, which has fundamentally changed the way gastrointestinal surgery is performed. Change may also occur on a broader, more impactful level by revolutionizing technology or science, such as general anesthesia and pulse oximetry for cardiopulmonary sedation (1).

2. Disease Treatments Innovations

Obesity is becoming an epidemic: 2/3 of Americans are overweight and 1/3 of Americans are obese. Obesity in the United States remains the second leading cause of preventable death and the rates of severe obesity have rapidly increased over the last 30 years. Obesity requires multi-modal treatments, over long durations, and by many different caregivers and medical teams. One of the first, and most important, articles describing the surgical treatment of obesity and diabetes was published under the provocative title "Who would have thought it? An operation proves to be the most effective therapy for adult-onset diabetes." In this 1995 article, Pories et al. describe a 14-year experience of treating patients with obesity with gastric bypass, demonstrating excellent outcomes not only for weight loss, but specifically for diabetes (2). The widely followed results heralded a new era of intervention for diabetes management. Since then, multiple articles have been published showing the efficacy and safety of metabolic and bariatric surgery for obesity treatment and weight-related conditions, including not only diabetes but also hypertension, hypercholesterolemia, atherosclerotic heart disease, gastroesophageal reflux disease, degenerative joint disease, stress urinary incontinence, venous stasis disease, and many others (Figure 1). In 2012, Schauer et al. published a randomized, prospective study comparing bariatric surgery versus intensive medical therapy for diabetes. It showed that metabolic and bariatric surgery is more effective than medical therapy alone, both in the short and long term (3). This landmark article has prompted similar high-quality studies. A 2015 study reviewed a group of American veterans over 10 years (4). All-cause mortality decreased in patients with obesity who underwent surgery for obesity, compared to those who did not undergo intervention, by 23.9% to 13.8% respectively. In part due to Pories' provocative article, the overall body of research, medical society and quality assurance programs that maintain high safety standards, a new field of

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bariatric and metabolic surgery with a plethora of bariatric procedures are now used to treat patients worldwide for obesity and weight-related medical problems (2).

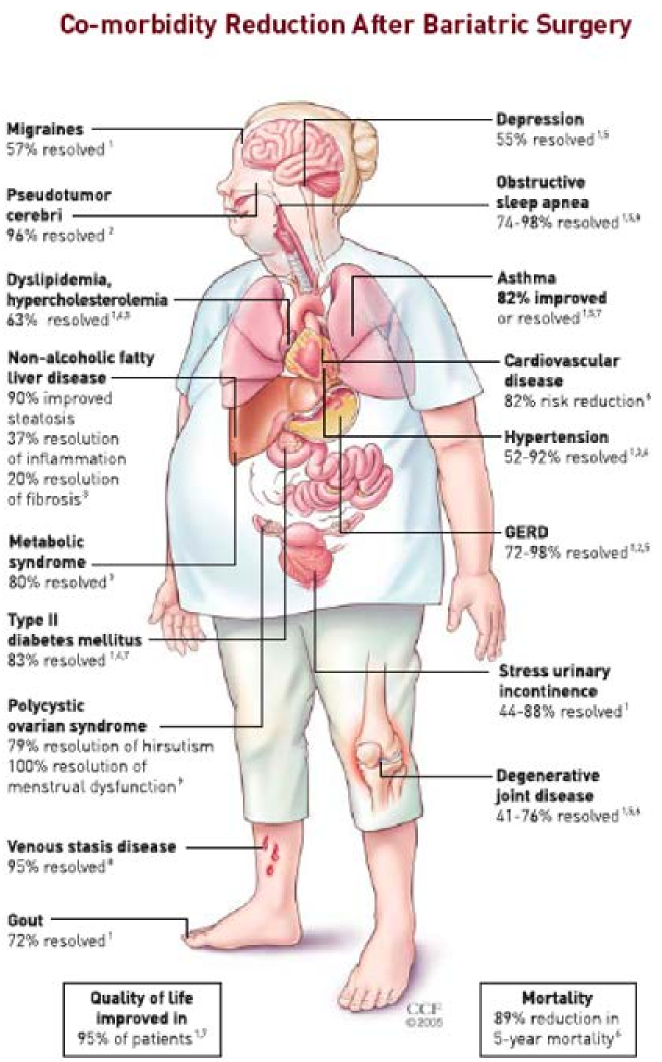
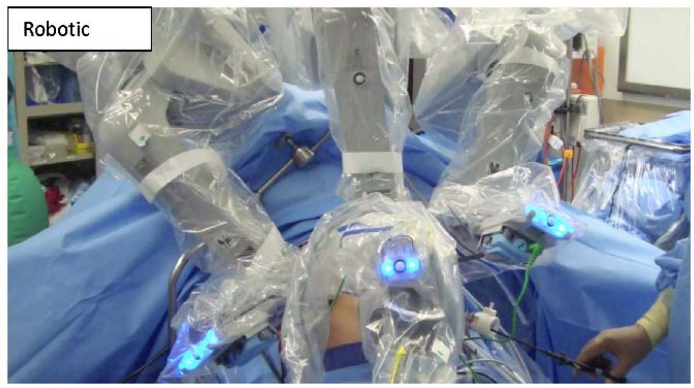


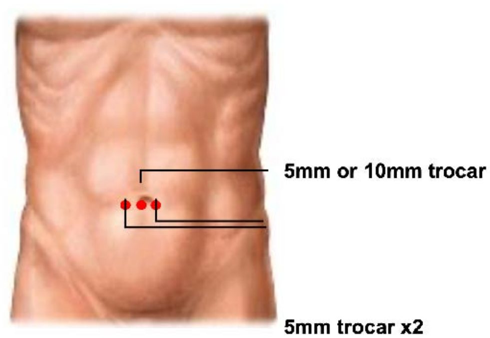
Figure 1. Metabolic Diseases Associated with Obesity, including Improvement after Bariatric Surgery.
Source: elaborated by the author

3. Device Development Innovations

Tool development and refinement are central to surgical innovation and healthcare in general. One of the most significant contributions in the past decades has been the application of robotics to minimally invasive surgery. Although there are multiple types of robotic devices, the most commonly used commercial device in gastrointestinal surgery is the da Vinci system™, first introduced in 1999 (Figure 2). Robotic assisted-surgery increased the number of minimally invasive procedures that may not have otherwise been achieved, particularly in the fields of urology and gynecology, but also in sub-specialties of general surgery. Originally, adoption was driven by the device's technical advantages for conducting surgery. But over the last two decades, the operating system has improved with multiple iterations that affords the robot not only technical advantages, but also the ability to provide efficiency of movement, data, surgery simulation, advanced vision overlays to identify critical structures, and an ecosystem of interactive applications in integrated robotic networks for sharing and learning. Although the surgical market has been dominated by a single manufacturer, there are multiple new platforms of varying sizes and complexities that will further increase adoption of robotics in gastrointestinal surgery in the near-future.



A. Placement of trocars on the abdominal wall



B. Intraoperative view of trocars for cholecystectomy

Figure 2. Robotic Surgery Platform (Intuitive Surgical, Sunnyvale, CA)
Source: elaborated by the author

Innovation, however, is not always a straight-line forward progression. Laparoscopic surgery has been widely adopted for many general surgical procedures because it offers decreased patient pain, faster recovery, and fewer complications. However, other innovative devices and techniques have not resulted in improved patient outcomes or widespread adoption. Some examples include natural orifice transluminal endoscopic surgery (NOTES™) and single incision laparoscopic surgery (Figure 3). NOTES™ is a technique that involves using a flexible endoscope to perform intraperitoneal operations by trans-gastric, transrectal, or transvaginal access, without producing any visible external scars. The first reported operation was performed by Reddy and Rao in 2004, and involved an endoscopic, trans-gastric approach to appendectomy (5). This technique was received with great enthusiasm, but turned out to be technically challenging. Another hurdle included the potential of leakage from the access site in the stomach, which implied that the NOTES™ technique was not widely adopted for common surgical procedures. Despite NOTES™ not being commonly practiced, there remained keen interest in decreasing the morbidity of laparoscopy. Single incision laparoscopic surgery was designed to fill this perceived need. This technique involved a trans-abdominal approach similar to standard laparoscopy, but through a single incision at the umbilicus. This device and technique innovation was expected to produce less pain and smaller scars. In the realm of general surgery, single incision laparoscopy has been applied to gallbladder removal, one of the most common general surgical procedures performed worldwide. The first laparoscopic cholecystectomy was performed in 1987, and in the 1990's the first single incision laparoscopic cholecystectomy was reported as a potentially less invasive technique. This technique has multiple applications in general surgery, urology, gynecology and thoracic surgery, and it was adopted at the Cleveland Clinic. However, it has been found that this technique increases operating times, involves a steep learning curve, and gives rise to specific new and unique complications associated with this type of access (6). In a study performed at the Cleveland Clinic that compared patients who underwent standard laparoscopic surgery with multiple site access versus single site surgery, a postoperative review showed that less than 50% of the patients remembered which technique they underwent, and two thirds of the patients would have preferred to eliminate the umbilical access site used for both the standard and single incision laparoscopy groups (7).

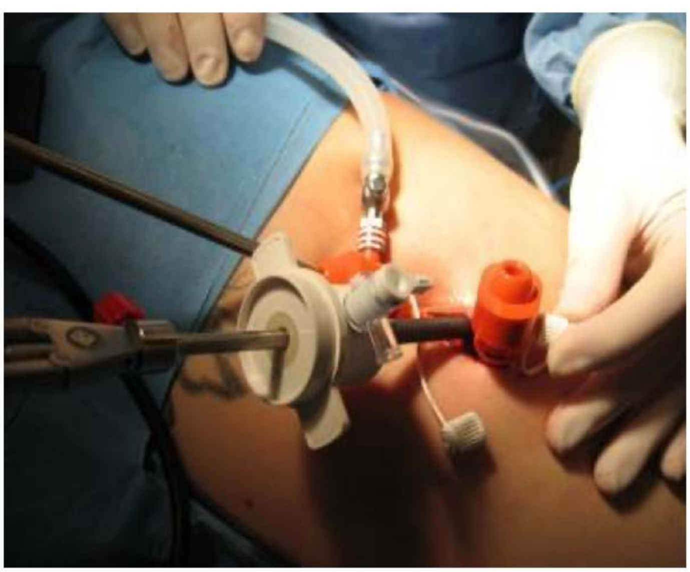


Figure 3. Single Incision Laparoscopic Surgery
Source: elaborated by the author

The overall results were disappointing. With unclear advantages aside from cosmesis, the shortcomings of single port surgery are well documented, and include a longer learning curve, overall poor ergonomics, and increased collisions of the instruments due to the small working space. Some of these, however, are largely engineering challenges that might be overcome through the application of robotics. In the early 2000's, the use of robotics, specifically in the field of urology, opened the door for the adoption of less invasive approaches to surgery, and at the time single incision laparoscopy seemed to be an excellent application for robotics. After development and training, the first human surgery with a novel single port robotic system was performed at the Cleveland Clinic in Ohio by the minimally invasive surgery group (8). This was a series of laparoscopic cholecystectomy performed with a single port robotic platform designed specifically for this type of surgery (Figure 4). In this study, we demonstrated feasibility and safety, with no conversion to open procedures and no major complications. However, the operating times were longer, and this modified technique involved a different learning curve. Since then, further improvements have been made both in the device and the technology. Based on this and other experiences, the single port robotic assisted system known as the SPTM surgical system has gained widespread interest and adoption in urology, with a simplified set-up and better usability (9).

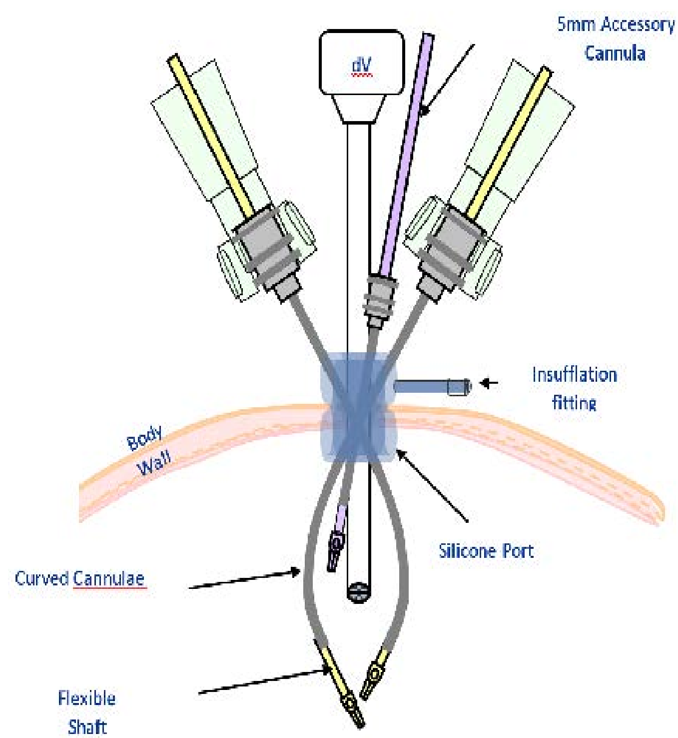


Figure 4. Schematic of Single-Site Robotic Surgery platform
Source: elaborated by the author

Innovation in the field of gastrointestinal diseases is occurring with the development of devices to support procedural innovation, such as advanced flexible endoscopy. Endoscopy, performed either transorally or transanally, is a well-established tool for the diagnosis and treatment of a large number of conditions. When compared to surgery, endoscopy probably offers decreased morbidity because it eliminates the need for transabdominal or transthoracic access. However, the disadvantages of these techniques include the need for substantial training and relatively limited tools to perform these procedures. Endoscopic techniques have largely replaced surgical intervention for many gastrointestinal diseases, including treatment of common bile duct stones, polyp removal, and management of Barrett's esophagus. New device technologies including advanced endoscopy platforms, better instrumentation, and effective suture devices have fundamentally disrupted the way in which surgical operations are and will be performed in the future.

A current example of endoscopic therapy displacing surgical intervention is the modern treatment for achalasia. Initially described in 1913 as a thoracic anterior and posterior surgical cardiomyotomy, the procedure underwent modifications, until 1991 when Cuschieri initially described a thoracoscopic myotomy and then in 1992, laparoscopic myotomy. Laparoscopic outcomes for Heller myotomy for achalasia demonstrate durable and consistent success for treatment of achalasia and is considered the standard by which other treatments are evaluated (10). Somewhat based on the work accomplished through NOTES™, endoscopic approaches to the treatment for achalasia continued to evolve. Initial techniques were somewhat rudimentary, involving full-thickness incisions, including the mucosa in experimental models. The first report in 17 patients undergoing endoscopic peroral endoscopic myotomy (POEM) was published by Haruhiro et al. with successful outcomes and no abdominal incisions (11). This landmark work created a novel third space endoscopic procedure for treatment of achalasia, which has since demonstrated excellent efficacy, safety, and durability with long-term data accruing. The POEM procedure has largely replaced the standard laparoscopic Heller myotomy at many institutions. With this clinical success, this third space endoscopy technique has also been applied to other areas of the gastrointestinal tract for treatment of motility disorders.

A similar third space technique has been applied to gastroparesis treatment. Gastroparesis is a vexing and challenging disease process that has a high rate of medical failure. Palliative treatments include feeding jejunostomy and decompressive gastrostomy. Other treatments include gastric electrical stimulation and Roux-en-Y reconstruction with and without gastrectomy. After demonstrating that laparoscopic pyloroplasty is successful for the treatment of gastroparesis, Dr. Shlomovitz et al. subsequently published similar results with an endoscopic technique (12). Per oral pyloromyotomy, an endoscopic third space technique similar to POEM, showed safety and efficacy with early human experience. Since then, multiple studies have confirmed this finding, including one of the largest series in the current literature by Rodriguez et al. and this technique has been widely adopted (13).

The evolution of minimally invasive surgery has progressed from open surgery to laparoscopy because of the clear benefits of faster recovery, less pain, and fewer complications, but this advancement would not have been possible without device development. Similarly, endoscopic procedures and correlating device innovation for gastrointestinal diseases have supplanted some surgical procedures and likely will continue to do so.

4. Healthcare Delivery and Quality Innovation

Outside of techniques and devices, innovation can also be seen in other aspects of care delivery. A specific area in which this has been successful has been the organization of care. Traditionally at academic medical centers, clinical divisions are determined along a medical and surgical divide. This delineation reflects training paradigms and practice patterns, but it may not be an efficient way to deliver care to a patient. Some healthcare organizations have reorganized divisions into patient-oriented institutes which are based on disease processes instead of the medical professionals' training. This allows for physicians from medical and surgical and their accompanying allied health teams to function as a single unit to treat patients in a multi-disciplinary fashion. An example of this structure is the Cleveland Clinic Comprehensive Esophageal Center. This group includes specialists from gastroenterology, thoracic surgery, general surgery, nutrition support, pain management, psychology, radiation oncology, medical oncology, and regional practices outside of the main campus to care for patients with esophageal disease. In addition to clinical care, research, and training, one of the important results of this reorganization is the development of best care pathways for esophageal disease across divisions. These pathways have allowed for standardization of care for both common and complex diseases across a wide practice footprint and the promotion of innovative practices.

Program innovation will likely impact our practices in the next 5-10 years due to immense data acquisition and processing. Digital surgery is a relatively new concept that offers significant opportunities to analyze performance and to compare outcomes. Procedural video is a rich data source commonly used for education and training, including

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postoperative debriefing and coaching. More recently it has been applied in advanced-level conferences such as morbidity and mortality meetings. Data acquired can result in quality improvements and may align consistency of practice. However, video analytics can be time-consuming and cumbersome to collect and process. Programs are utilizing artificial intelligence algorithms to evaluate and segment data to allow for practical review and real-time use. Video review and expert feedback can accelerate surgical learning curves. In a statewide surgical coaching program, the Michigan Bariatric Surgery Collaborative demonstrated the perceived value of such a program, resulting in practice changes and decreased overall operating times, but without correspondent improvement in patient outcomes (14). Privacy-protected, cloud-based, and universal image capture can be facilitated and may make such reviews and quality improvement programs more easily implementable.

5. Innovation Pathways

Pathways for creation and innovation can be unclear and complicated. Organizational structure, receptivity, and available resources further mar or promote progress. A system that creates innovation thrives in a rich culture where all parties participate and celebrate novel ideas and allow for the possibility of failure. The goal of innovation is focused on improved patient care. The innovation journey for device development is often long and resource-intensive. It starts with the identification of the problem, progresses to concept design and description, incorporates disclosure, and moves on to a highly variable process of intellectual property protection testing, prototyping, identifying a business partner to move the process forward, validation, regulatory pathways, and then ultimately market entrance.

Given these hurdles and protracted timeline, what eventually brings about innovation? Often the user is the inventor, and this occurs in a clinical or academic setting. If that invention gets far enough along this path, the manufacturer is often supportive. Unfortunately, there are infrequent conversions to development and there are both real and perceived hurdles including overall value, developing relationships, and intellectual property ownership.

The innovation process can be informal, but this creates inefficiencies that hamper conversion to an actionable idea or product. Structured innovation is likely to result in more effective generation of ideas. This involves team brainstorming, diversity, and the ability to develop a problem statement including an overall objective. In these sessions, the principles of nonjudgment and inclusion are crucial. The space and time to participate in these activities may not fit into clinical, research, and education practices. Typical clinical department metrics may not reflect this work, as it is hard to measure success in a process that can take time (usually years) and persistence. The current healthcare environment often requires us to do more with less, and this is often at odds with the need to perform tangible clinical work.

In the modern healthcare system, innovation likely needs to be a multipronged program that is embedded in the culture of the organization with easy access to caregivers. At the Cleveland Clinic Digestive Disease and Surgery Institute, the Innovation and Technology program is based on 5 areas. 1) Intellectual property development and invention disclosure ultimately occur through a distinct entity, Cleveland Clinic Innovations, which has the expertise and specific resources in these areas. Additionally, we work closely with industry colleagues on existing and new ideas that will be impactful in the field of gastrointestinal diseases. 2) Digital surgery and ultimately artificial intelligence applications can improve the consistency of surgery and endoscopy that will likely impact all of our practices in the next 5 to 10 years. 3) Telehealth access and new developments in information technology are giving us new and creative ways to interact with other patients. These programs allow forms of access that are more acceptable to patients, efficient, and cost effective. 4) Education and research need to continue to innovate and to ensure that the next generation of trainees fully maximizes these opportunities and that research outcomes are consistent with the evolving metrics of innovation. 5) And increasingly, global connectivity allows for diverse groups from far-flung geographic regions to synergistically participate in innovation, research, and education that was not previously available without current technologies.

What does the article contribute?

- The reasons to innovate in surgery are diverse. Fundamentally, change should lead to improvements in patient care and outcomes, but it also involves aspects such as the educational process, industry experience, and financial incentives.
- Given the research and advances reported by different authors, we have data describing mortality rates from patients who underwent bariatric surgery. It decreases, compared to those who did not undergo bariatric surgery, by 23.9%. Due to the current evidence in bariatric and metabolic surgery, it is possible to successfully treat patients with obesity and weight-related conditions.

- One of the most significant contributions in the development of tools is the application of robotics to minimally invasive surgery. As an example of this process, the da Vinci surgical systemTM is actively used in gastrointestinal surgery. This platform increases the number of minimally invasive procedures that would otherwise not have been achieved.

Conclusions

Surgeons and proceduralists often rely on innovation, as this skill is required in the course of operations for immediate problem solving and to find new solutions for tactical scenarios in the operating room. The physician innovator faces unique challenges in the healthcare space including lack of time, trained innovation personnel with technical development expertise, and standardized evaluation metrics. Additionally, modern healthcare department goals can be at odds with innovation, due to its long lag times to demonstrate goods and high non-delivery rates. However, to build a culture of innovation and continuous improvement, organizations need to lower or remove these barriers. Ideally, a culture of innovation can be created when there is knowledge of the process and technical resources available to support it, as well as access to mentors and support services. Ultimately, there should be a focus on value-based solutions with collaborative input with diverse team members, to improve patient care.

Conflicts of interest

The author declares no conflicts of interest

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Ethical responsibilities

Protection of people: the present study is considered a research without risk given its nature.

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