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FRONTIER

- 7210** Frontiers in antibiotic alternatives for *Clostridioides difficile* infection
Phanchana M, Harnvoravongchai P, Wongkuna S, Phetruen T, Phothichaisri W, Panturat S, Pipatthana M, Charoensutthivarakul S, Chankhamhaengdech S, Janvilisri T

OPINION REVIEW

- 7233** Serologic diagnosis of celiac disease: May it be suitable for adults?
Losurdo G, Di Leo M, Santamato E, Arena M, Rendina M, Luigiano C, Ierardi E, Di Leo A
- 7240** Digital surgery for gastroenterological diseases
Hardy NP, Cahill RA

REVIEW

- 7247** Gossip in the gut: Quorum sensing, a new player in the host-microbiota interactions
Coquant G, Aguanno D, Pham S, Grellier N, Thenet S, Carrière V, Grill JP, Seksik P
- 7271** Hepatitis B virus/hepatitis D virus epidemiology: Changes over time and possible future influence of the SARS-CoV-2 pandemic
Sagnelli C, Pisaturo M, Curatolo C, Codella AV, Coppola N, Sagnelli E

MINIREVIEWS

- 7285** Hemostasis testing in patients with liver dysfunction: Advantages and caveats
Nguyen G, Lejeune M, Crichi B, Frere C
- 7299** Colonoscopy-related colonic ischemia
Sadalla S, Lisotti A, Fuccio L, Fusaroli P

ORIGINAL ARTICLE

Basic Study

- 7311** *Fusobacterium nucleatum* colonization is associated with decreased survival of *helicobacter pylori*-positive gastric cancer patients
Hsieh YY, Tung SY, Pan HY, Chang TS, Wei KL, Chen WM, Deng YF, Lu CK, Lai YH, Wu CS, Li C
- 7324** Detailing the ultrastructure's increase of prion protein in pancreatic adenocarcinoma
Bianchini M, Giambelluca MA, Scavuzzo MC, Di Franco G, Guadagni S, Palmeri M, Furbetta N, Gianardi D, Funel N, Ricci C, Gaeta R, Pollina LE, Falcone A, Vivaldi C, Di Candio G, Biagioni F, Busceti CL, Morelli L, Fornai F
- 7340** Gut microbiome composition can predict the response to nivolumab in advanced hepatocellular carcinoma patients
Chung MW, Kim MJ, Won EJ, Lee YJ, Yun YW, Cho SB, Joo YE, Hwang JE, Bae WK, Chung IJ, Shin MG, Shin JH

Retrospective Cohort Study

- 7350** Presentation, patterns and predictive value of baseline liver tests on outcomes in COVID-19 patients without chronic liver disease

Bernstein D, Roth N, Kim A, Epstein M, Hirschwerk D, Kvasnovsky CL, Satapathy SK

- 7362** Survival and outcomes for co-infection of chronic hepatitis C with and without cirrhosis and COVID-19: A multicenter retrospective study

Afify S, Eysa B, Hamid FA, Abo-Elazm OM, Edris MA, Maher R, Abdelhalim A, Abdel Ghaffar MM, Omran DA, Shousha HI

Retrospective Study

- 7376** Endoscopic ultrasound features of autoimmune pancreatitis: The typical findings and chronic pancreatitis changes

Zhang SY, Feng YL, Zou L, Wu X, Guo T, Jiang QW, Wang Q, Lai YM, Tang SJ, Yang AM

Observational Study

- 7387** Long-term clinical outcomes of lipiodol marking using standard gastroscopy for image-guided radiotherapy of upper gastrointestinal cancers

Be KH, Khor R, Lim Joon D, Starvaggi B, Chao M, Ng SP, Ng M, Zorron Cheng Tao Pu L, Efthymiou M, Vaughan R, Chandran S

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Digital surgery for gastroenterological diseases

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Abstract

Advances in machine learning, computer vision and artificial intelligence methods, in combination with those in processing and cloud computing capability, portend the advent of true decision support during interventions in real-time and soon perhaps in automated surgical steps. Such capability, deployed alongside technology intraoperatively, is termed digital surgery and can be delivered without the need for high-end capital robotic investment. An area close to clinical usefulness right now harnesses advances in near infrared endolaparoscopy and fluorescence guidance for tissue characterisation through the use of biophysics-inspired algorithms. This represents a potential synergistic methodology for the deep learning methods currently advancing in ophthalmology, radiology, and recently gastroenterology *via* colonoscopy. As databanks of more general surgical videos are created, greater analytic insights can be derived across the operative spectrum of gastroenterological disease and operations (including instrumentation and operative step sequencing and recognition, followed over time by surgeon and instrument performance assessment) and linked to value-based outcomes. However, issues of legality, ethics and even morality need consideration, as do the limiting effects of monopolies, cartels and isolated data silos. Furthermore, the role of the surgeon, surgical societies and healthcare institutions in this evolving field needs active deliberation, as the default risks relegation to bystander or passive recipient. This editorial provides insight into this accelerating field by illuminating the near-future and next decade evolutionary steps towards widespread clinical integration for patient and societal benefit.

Key Words: Digital surgery; Artificial intelligence; Gastrointestinal disease; Biophysics; Deep learning; Fluorescence-guided surgery

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Core Tip: Here, we introduce the concept of digital surgery and why it is important for everyone involved in the area of gastroenterological disease management. The current state and near-future of the art in this area are discussed, including the use of artificial intelligence methods to provide intraoperative real-time augmented decision making. Moral, ethical and legal challenges pertinent to digital surgery are explored, including the concerns relating to big data in health care and the transitioning role of industry in surgical development, as well as the implications such profound and imminent changes may have on the role of the clinician.

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INTRODUCTION

Since the mid-20th century, our analog electromechanical world has increasingly transitioned to a digital and even automated one, leading to our current epoch being named the “Digital Age” or “Information Age”. While many sectors have been rapid converts to this new order (notably retail and finance), adoption in the healthcare domain has been slower. In particular, in surgery, the focus has been on incremental iterations of existing technologies (such as upgraded displays and tweaked surgical instruments) over radical reformatting of existing methods. The reasons behind this are multifactorial, including a natural and understandable professional conservatism regarding clinical care, along with privacy concerns (patient and practitioner), ethical, moral and liability uncertainties, as well as a potential reluctance on behalf of system developers to involve themselves in intraprocedural decision making (preferring instead to leave this responsibility firmly in the hands of the human operator, for now at least). However, the evolution of surgical practice has plateaued.

Even the most sophisticated of new surgical machinery in general surgery, such as present-day robotic platforms, depend fully on the practitioner for their value and have led only to marginal benefit over the past 20 years. This is partly because of inequity in access but mostly because the fundamental distinguishing characteristic of best operative care relates to the intraoperative decision-making rather than dexterity of the practitioner. The new great hope is that the digitalisation of surgery, including the integration of artificial intelligence (AI) to the surgical workflow, will lead to better outcomes broadly; although, how exactly this will happen remains the challenge. Specifically, “digital surgery” exploits real-time analytics with technology during operations, and this editorial provides perspectives of its impact now and in the near future to all those looking after patients with digestive diseases.

AI DECISION-PROMPTING IN GASTROENTEROLOGY

This month’s landmark publication of the European Commission’s “Laying Down Harmonised Rules on Artificial Intelligence” attempts to shape the future of AI’s incorporation across society[1]. In this document, the enormity of the socioeconomic potential of AI is stressed, and it emphasizes that the same elements that drive benefits will bring about new risks of potential great consequence. Also this month, the first commercial AI system for endoscopy, “GI Genius” by Medtronic (Dublin, Ireland), has been approved for clinical use by the United States Food and Drug Administration (FDA)[2]. This system and others like it (e.g., Olympus ENDO-AID) act as a “second pair of eyes”, constantly watching the screen and alerting the user to any potential anomaly by highlighting the detected area and leaving the human to decide on its importance[3]. Unlike the endoscopist, the computer aid does not have a single point of focus on the screen and so provides accurate full field of view observation at all times, a digital safety net. While impressive results are reported regarding increased polyp detection rates by this combination (14% absolute increase in adenoma detection rate over standard endoscopy), intra-procedural polyp characterisation remains

unsupported. Detailed descriptions of AI advances in endoscopic systems have been covered elsewhere[4-6].

When assessing such applications, the FDA stratifies the risk associated with the AI tool by the device's intended use[7]. Technologies designed to treat and diagnose or to drive clinical management receive higher risk ratings than those that aim to inform clinical management. Furthermore, to date, the FDA has only approved AI or machine learning systems that are "locked" prior to marketing. In locked systems, the algorithms used must provide the same output each time the same input is provided (*i.e.*, these systems cannot "learn" or adapt as they accrue more data, which really should be their hallmark). However, it is understandable that these early models should function within the safety of a locked domain while the appropriate regulatory and surveillance frameworks for unlocked AI are put in place. Such oversight would need to ensure that the performance and effectiveness of an unlocked system in clinical use was maintained as it evolved through learning over time. Furthermore, locking helps to ensure that the functionality of a device can be understood by clinicians and its abilities not overstated.

As more advanced systems come online, however, it is likely such "unlocked" systems will become approved for use. Therefore, the endoscopic support systems currently approved for use only represent a first pass at clinical entry, allowing sequential iterations to evolve serially with increasing degrees of data recording, analytics and self-learning, and therefore automatism.

AI IN SURGERY

While other areas of surgical practice, such as orthopedics, neurosurgery and maxillo-facial surgery, have embraced surgical preplanning through computer-generated models and intraoperative navigational aids, the incorporation of AI methods for gastrointestinal surgery is only in its infancy[8-10]. The lack of fixed, easily identifiable landmarks and the tendency for the operator to completely shift the anatomical field intraoperatively (from the preoperatively recorded imagery) has proven difficult to accommodate in the same way as is possible with interventions in osseous lattices. Furthermore, the most valuable asset in the advancement of AI methods has been the rapid ability to accumulate, store, annotate and distribute data streams. As a result, it has been most applicable to nonsurgical uses, where enormous pre-existing archives of categorised images exist (with data points in the millions), such as breast mammography and retinal screening[11,12]. For similar impact in surgery, computer methods need integration with surgical video, which is inherently more complex and, for this reason, harder to extract meaningful datapoints from.

Indeed, the necessary technology is only now proving sufficiently capable for such analysis to be envisaged, and the main rush right now relates to the accumulation of videos for future exploitation. The major companies are, therefore, looking at placing systems alongside their core imaging technology that allow uploading of material at the operator's discretion rather than automatically. This is because, with some exceptions, the prevailing business model has been to sell imaging systems with the imagery belonging fully to the purchaser. With the current realisation that such data have real value on an aggregated basis, it is likely that the next full-service subscription models will include data sharing as a contractual clause. Therefore, the technical obstacles of video set-up, storage and distribution have already diminished in this era of big data, leaving then annotation, curation and linking to metadata to be addressed.

IMAGE-GUIDED SURGERY

Surgical video contains more information than still images do, which means greater value but also complexity. Superimposition of more easily interpreted signals to these videos greatly enables data extraction. One such method successfully used in this manner utilizes near infrared imaging and indocyanine green, a fluorescent dye, to disclose information regarding the perfusion status of tissues in surgical videos and, hence, characterise their nature[13-15]. Indocyanine green binds to albumin within the vasculature, and real-time tracking of fluorescence intensity as it circulates can be used to create perfusion signatures of tissues. Alongside prediction of healing-nonhealing risk, this technique has been successfully piloted for the interrogation and classification of neoplasia of the colorectum using computer vision and AI with high levels

of accuracy intraoperatively based on biophysics-inspired principles (*i.e.*, perfusion within malignant tissue is fundamentally altered when compared to adjacent healthy regions in the same field of view[16]) (Figure 1).

BEYOND FLUORESCENCE

Accurate computerised identification and labelling of structures at operation, through fluorescence or otherwise, could soon lead to better, safer surgery. Automated localisation with operator-prompting for important structures, such as the inferior mesenteric artery, ureter or neurological bundles, during left-sided colonic surgery would assist experienced surgeons in difficult cases or normalise for experience in those at the beginning of their career or with low volume practices. Deep learning models have even been demonstrated to accurately identify when the critical view of safety has been demonstrated during laparoscopic cholecystectomies[17]. Once a tissue can be accurately characterised, the next logical progression from on-screen display is the integration of such data into smart instruments to guide operative steps. This may be by way of haptic or auditory feedback or even automatic shutoff in the case of destructive instruments, such as diathermy encountering structures that require safeguarding (this already exists with some orthopaedic instrumentation).

More rudimentary systems of instrument tracking and operative step identification are already available that allow retrospective auditing of performed operations and instrument efficiency[18,19]. Parsing of operations into component steps linked with metadata including operative costs and standard (*e.g.* hospital stay and complications requiring intervention) as well as evolved patient metrics (*e.g.*, patient-reported outcome measures) could greatly facilitate our move toward value-based health care. Early-stage iterations are now emerging, with automated operative phase identification in peroral endoscopic myotomy recently being described with the hope that further technological refinement may facilitate intraoperative decision support[20].

SURGICAL VIDEO DATA BANKS AT SCALE

Collation of surgical outcomes and surgical performance, either by the individuals wishing to gain insight into their own practice or as part of professional regulatory oversight, still presents potential controversies. The centralised deposition of surgical video followed by anonymised analysis of technique and outcomes, likely by other specialty practitioners initially and followed by AI when permissible, would provide a means for impartial appraisal and maintenance of standards (both of practitioners and indeed surgical instruments). However, there are risks to use of the data to promote commercial interests rather than the public good (this also applies to practitioners and/or institutions); as such, great transparency is needed and trust-boards should be considered. In addition, practitioners have privacy rights, as do patients, and the special status of the doctor-patient relationship prevents exploitation of this privilege, which is an important consideration alongside legality alone (*e.g.*, respect of frameworks such as General Data Protection Regulation). Furthermore, aggregation of surgical video in siloed collections, however individually large, risks lack of proper representation. Closed datasets also limit progress if others with relevant interest are excluded (frustrating the principle of reusability as a findability, accessibility, interoperability, and reusability principle), which may precipitate monopolistic practices.

AI PITFALLS AND CONCERNS

The relatively delayed adoption of AI within surgery permits a glimpse into potential pitfalls by observing the experience of other sectors. In October 2020, the United States House Antitrust Subcommittee Report on Competition in the Digital Market noted that, in many digital domains, few dominant corporations held singular control of channels of mass distribution in a fashion that allowed them to maintain power and absorb or remove competitors with ease[21]. This is a real concern, considering the enormous financial incentives associated with success in healthcare provision. Potential safeguards include an open/shared data repository (with appropriate regulatory compliance) upon which clinicians, academics and companies could work, as well as the standardisation of policies for the acquisition and storage of digital data,

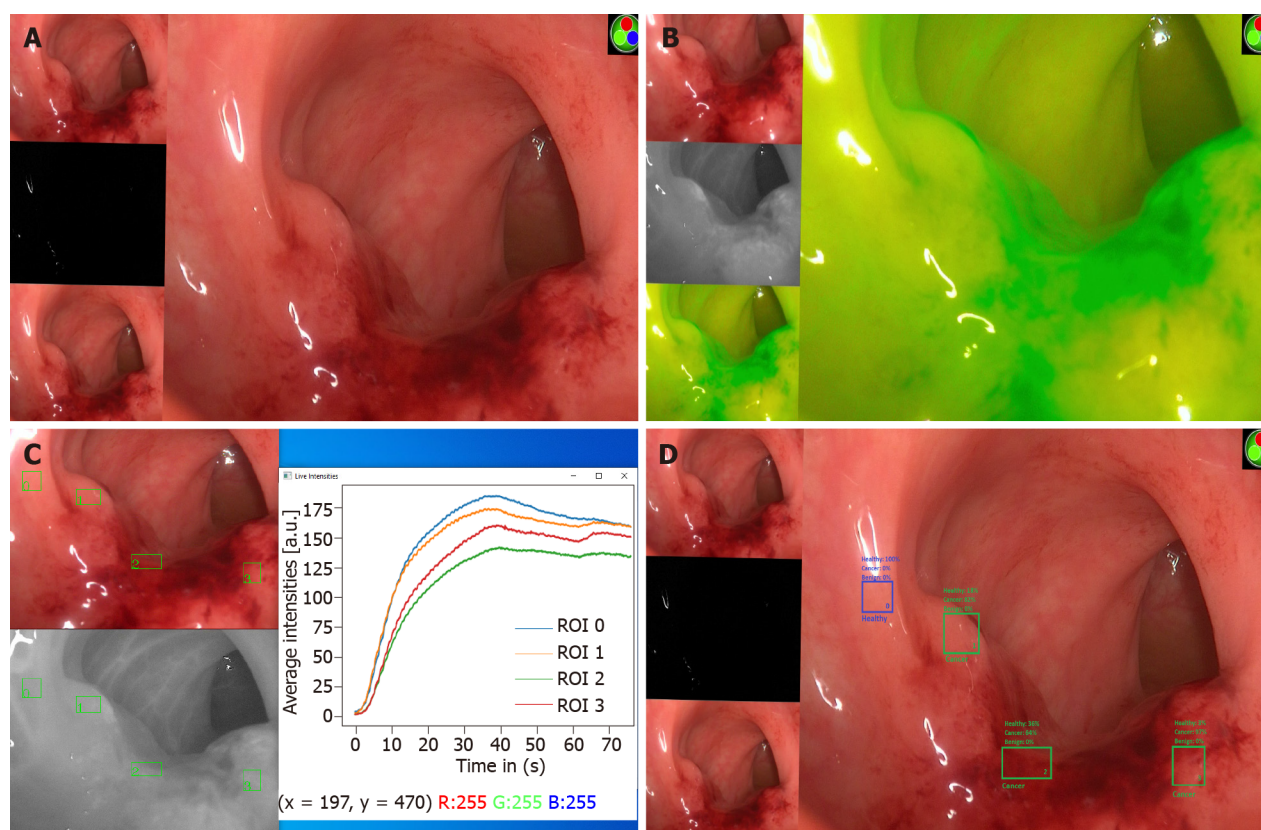


Figure 1 Digital surgery in action—real-time discrimination of tissue nature using fluorescence imaging and artificial intelligence. A: Transanal imaging of a rectal lesion using a Pinpoint (Novadaq, Mississauga, Canada; Stryker, Kalamazoo, MI, United States) near infrared imaging system; B: Following intravenous administration of indocyanine green (ICG) (0.25 mg/kg), fluorescence is observed within the lesion and surrounding tissue; C: In tandem with the ICG administration, regions of interest within healthy and unhealthy tissue (regions 0–3) are chosen by the surgeon for real-time assessment. Image tracking is performed using the visible light mode and light intensity readings extracted from the corresponding regions within the infrared spectrum video for each of these regions over time; D: Intensity profiles are subsequently fitted to biophysics-inspired artificial intelligence models of fluid movement in tissue to predict tissue nature with a binary outcome (healthy vs cancer) and a probability score (%).

to ensure universal accessibility. Additionally, the history of AI is replete with “boom and bust” cycles, and it is possible that its promised integration into surgery could prove another false dawn, especially with regard to more complex unsupervised machine learning and deep learning methods[22]. This may be a result of the complexity required to fine tune these systems to achieve acceptable results for use in humans. Controversies surrounding explainability (describing the settings used in the machine), interpretability (the degree to which a human can understand the decision) and bias within data training sets, as well as possible societal rejection of this form of technology in healthcare (akin to the criticisms of AI-based facial recognition software and recidivism predictors or any perception of data harvesting for surveillance capitalism), are other concerns.

CONCLUSION

Nevertheless, the formative years of digital surgery have begun. As a consequence, the landscape of surgical practice as it currently stands is likely to undergo rapid and most probably frequent evolutions. Such changes will have far reaching implications on the role of professional bodies, societies and institutions and, most fundamentally, clinicians. Moore’s law cautions that the limits of such changes will be neither technological nor computational. The role of implementation of digital surgery remains, for now, with the clinician in their duty as patient caregiver. Whether this role will, in time, increasingly become one of the clinician as early enabler and later bystander or clinician as co-developer and collaborator remains yet to be determined. For the latter, co-ordinated, purposeful cross-collegiate action is needed urgently.

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