

# AI Endoscopy for Dysplasia in the Stomach and Colon



COLUMBIA UNIVERSITY  
MEDICAL CENTER

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# Faculty Disclosures

## Financial/industry relationships within the past 36 months:

Value Analytics: Consulting Fees

Exact Sciences: Consulting Fees

Vivante Health: Advisory Board

Cambridge Biomedical and Economic Consulting Group: Founder

**None directly relevant to this presentation.**

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Gastric Cancer Screening and Prevention: U01CA265729





# Presentation Outline

## 1. Background

- I. Key questions regarding AI in Endoscopy
- II. CAD
  - I. Computer-Aided Diagnosis (CADx)
  - II. Computer-assisted polyp detection (CAdE)

## 2. Colorectal Real-time CAdE

1. Clinical Evidence
2. FDA Approved Platforms

## 3. Gastric Real-Time CAdE

## 4. Conclusions and Future



What's the question about AI Endoscopy that you really want to know the answer to?

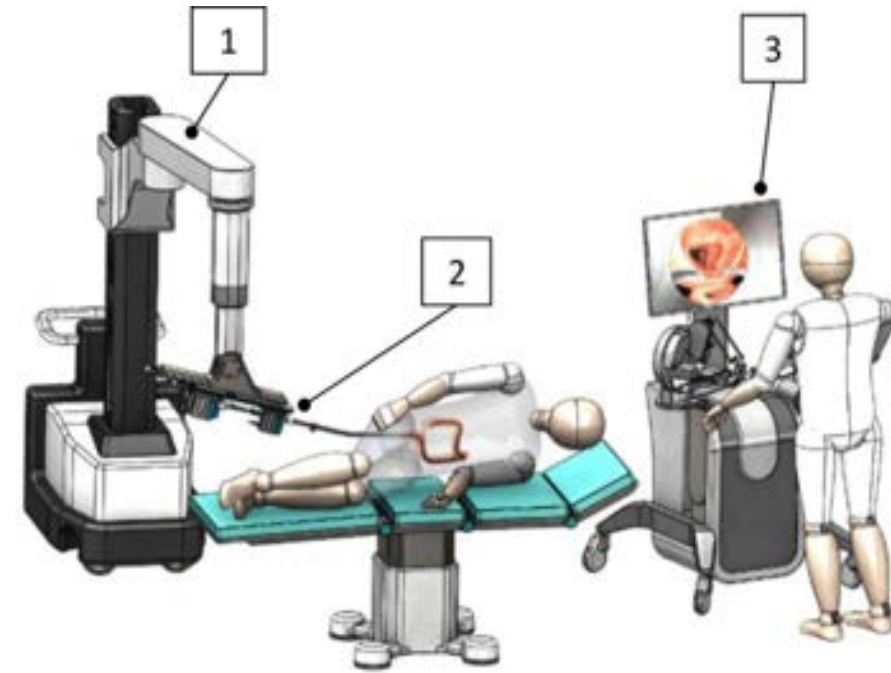
When will computers be able to do endoscopy?  
...and take my job



# When will computers be able to do endoscopy?

## ChatGPT 4.0 Transcript

- User: How long before computers can do endoscopy?
- *ChatGPT: Currently, AI and robotic technologies are advancing rapidly and have started to play significant roles in assisting with endoscopic procedures. However, the complete automation of endoscopy, where computers perform the procedure with minimal or no human oversight, involves several challenges and considerations.*



University of Stuttgart



# When will computers be able to do endoscopy?

## Challenges to Autonomous Endoscopy

- **Technical Complexity**

- ...requires not only navigating the endoscope through delicate and varied anatomy but also making real-time decisions based on visual and sometimes tactile feedback.

- **Safety and Efficacy**

- An autonomous system would need to handle unexpected situations, anatomical variations, and complications with the same or better proficiency than a skilled physician.

- **Ethical and Legal Considerations**

- Legal frameworks currently do not account for fully autonomous medical procedures performed by AI or robots.

- **Regulatory Approval**

- Gaining regulatory approval for fully autonomous endoscopic systems would require extensive evidence of safety and efficacy, likely involving prolonged and rigorous clinical trials.



# When will computers be able to do endoscopy?

## ChatGPT

### Long-term Prospects:

- Predicting a timeline for when computers might independently perform endoscopy is challenging due to the rapid pace of technological change and the significant hurdles that remain.
- It could be several decades before we see systems capable of fully autonomous endoscopy, depending on advancements in AI, robotics, sensor technology, and changes in regulatory and ethical standards.



# When will computers be able to do endoscopy?

**User: Give me an estimate even if difficult with a range**

## ChatGPT

- **Short-term (Next 5-10 Years)**

- **AI and Robotics Integration:** Continued integration of AI and robotic assistance in endoscopic procedures, with AI focusing on image analysis and lesion detection, and robotics enhancing precision and control.
- **Semi-autonomous Functions:** Development and deployment of semi-autonomous functions, such as automated navigation to areas of interest within the gastrointestinal tract, under the supervision of a physician.





# When will computers be able to do endoscopy?

## ChatGPT

- **Medium-term (10-20 Years)**

- **Advanced AI Capabilities:** Significant improvements in AI capabilities, allowing for more complex procedural tasks, including real-time decision-making based on visual cues and patient data.
- **Robotic Autonomy:** Incremental steps towards partial autonomy in endoscopy, where robotic systems can perform certain predefined tasks with minimal human intervention, such as biopsy of identified lesions.

- **Long-term (20-30+ Years)**

- **Full Autonomy Possibility:** This would require breakthroughs in AI, machine learning, robotics, and sensor technology, as well as comprehensive solutions to ethical, legal, and regulatory challenges.
- **Widespread Clinical Trials and Regulatory Approval:** Extensive clinical trials to prove the safety and efficacy of autonomous systems, followed by a lengthy process of regulatory review and approval.



# AI in Endoscopy

**CADx**- Computer Aided Diagnosis

**CADe**- Computer Aided Detection

## FDA Definitions:

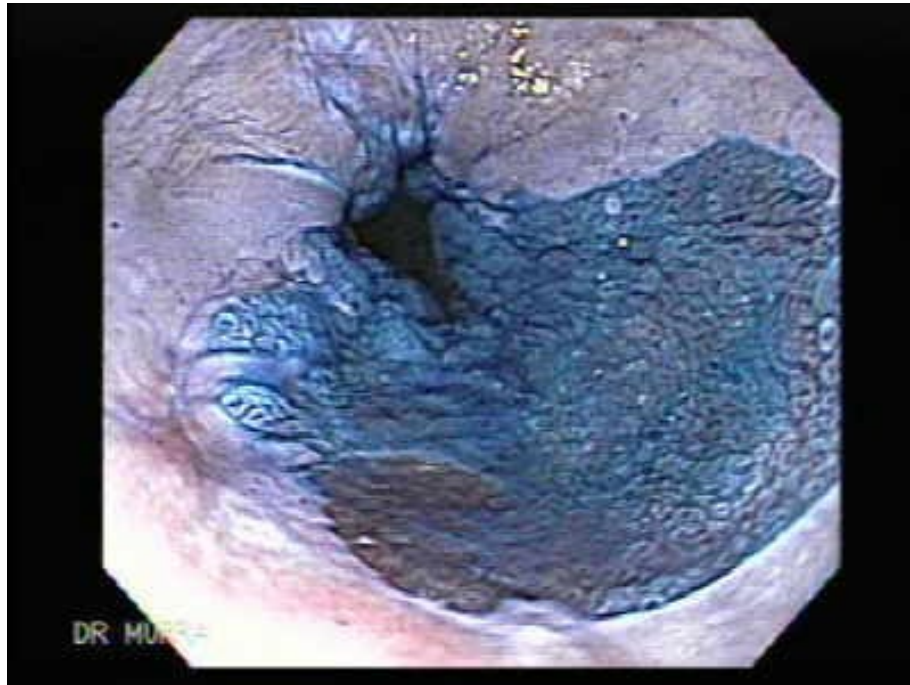
- **CADx** device is “intended to provide information beyond identifying abnormalities, such as an assessment of disease.”
  - Gastric Example CADx- real time optical biopsy of mucosa to determine if dysplasia
- **CADe** device is “intended to identify, mark, highlight or otherwise direct attention to portions of an image that may reveal abnormalities during interpretation of images by the clinician.”
  - Colon Example CADe- real time polyp detection to decrease the rate of missed polyps

When is AI most useful for endoscopy?  
*Clinical circumstances when we need to “see” better.*

- I. Methods to improve endoscopic diagnosis (CADx)
- II. Best clinical scenarios: Chromoendoscopy and Optical Biopsy
  - I. BE Dysplasia
  - II. Gastric Dysplasia
  - III. DALM IBD

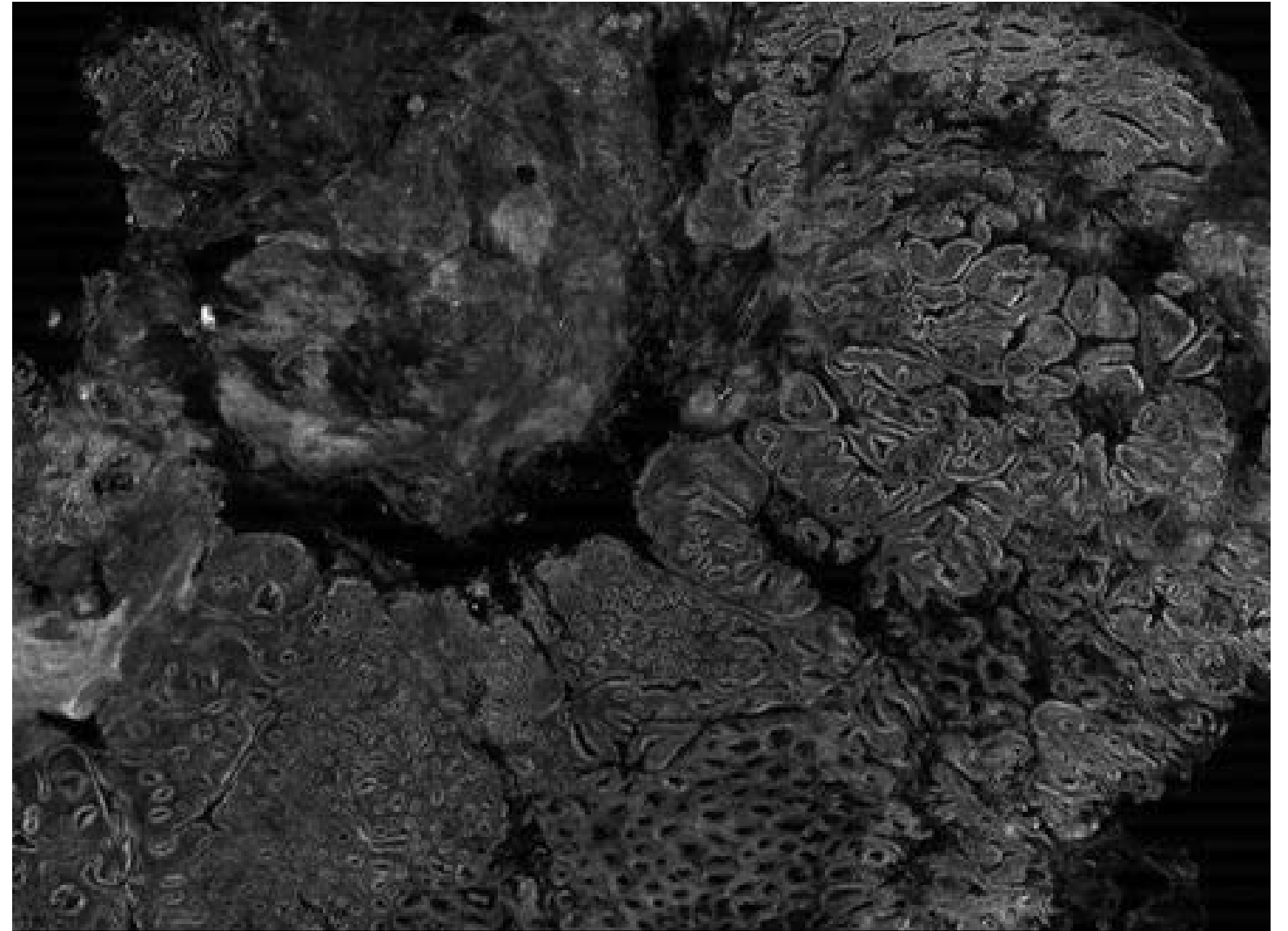
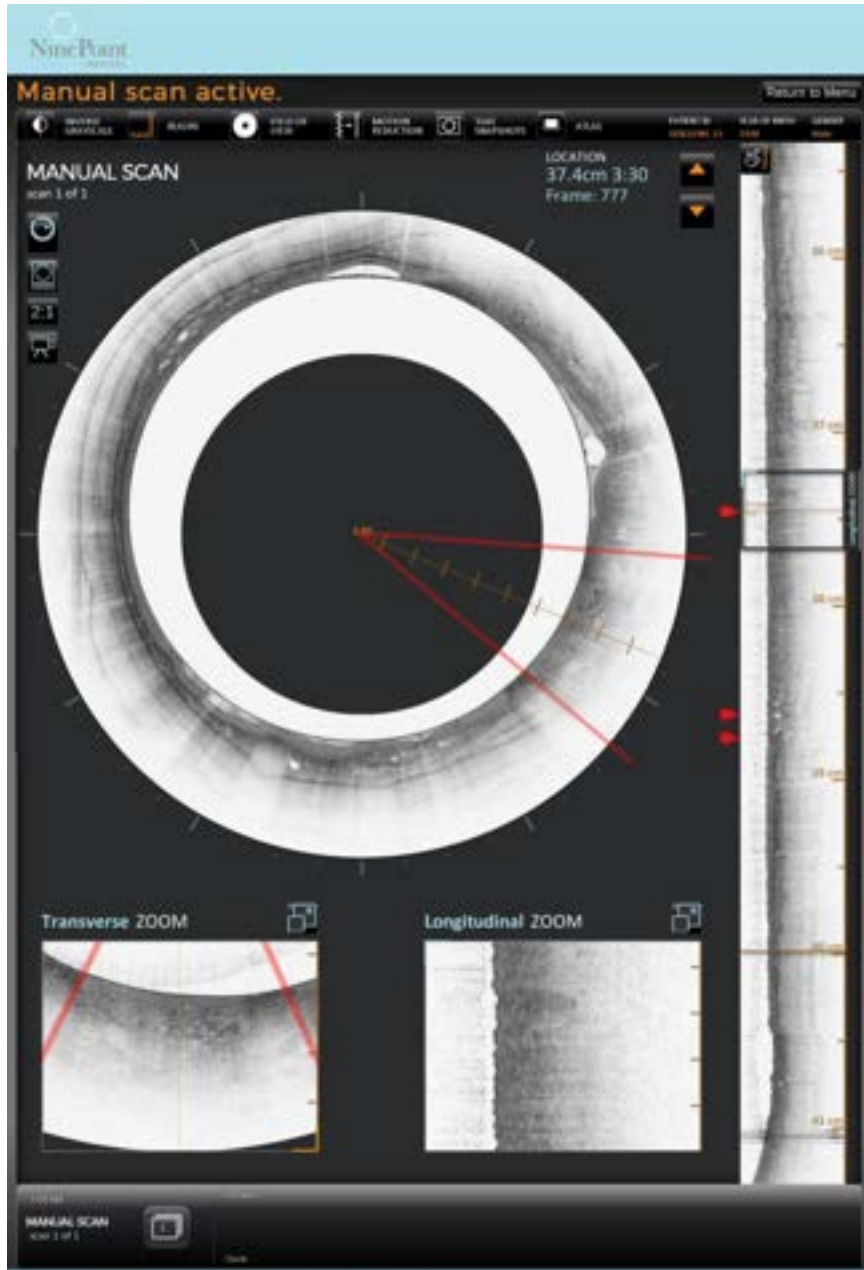
When is AI most useful for endoscopy?  
*Clinical circumstances when we need to “see” better.*

I. Chromoendoscopy, Barrett’s Esophagus



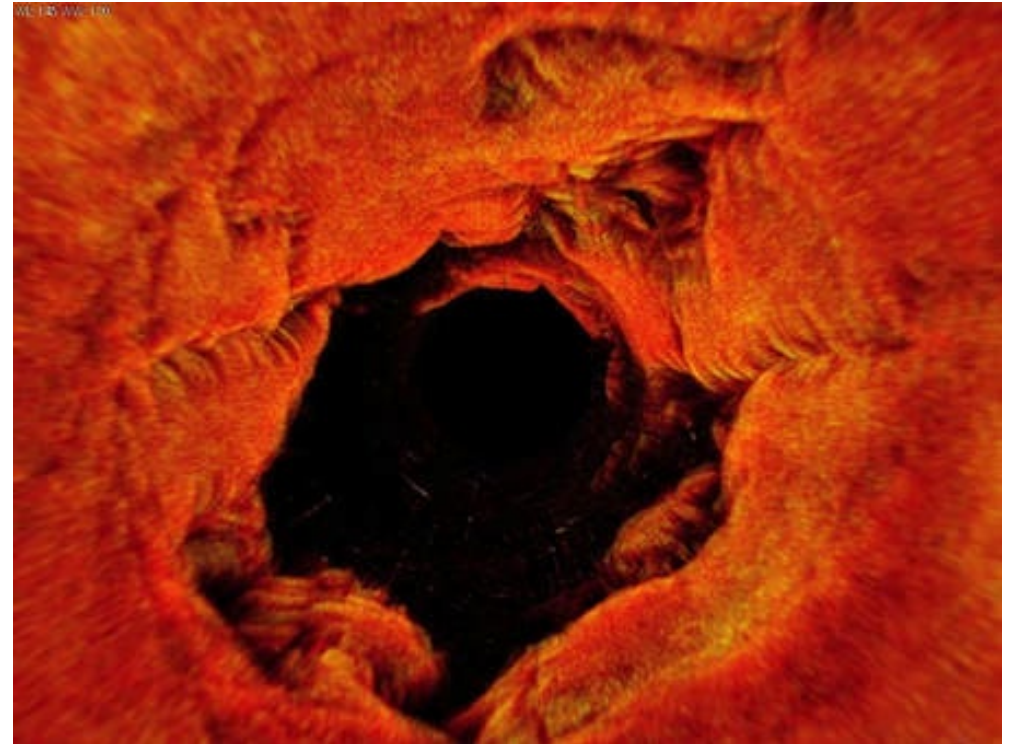


# Barrett's Esophagus



# *Gastric Dysplasia*

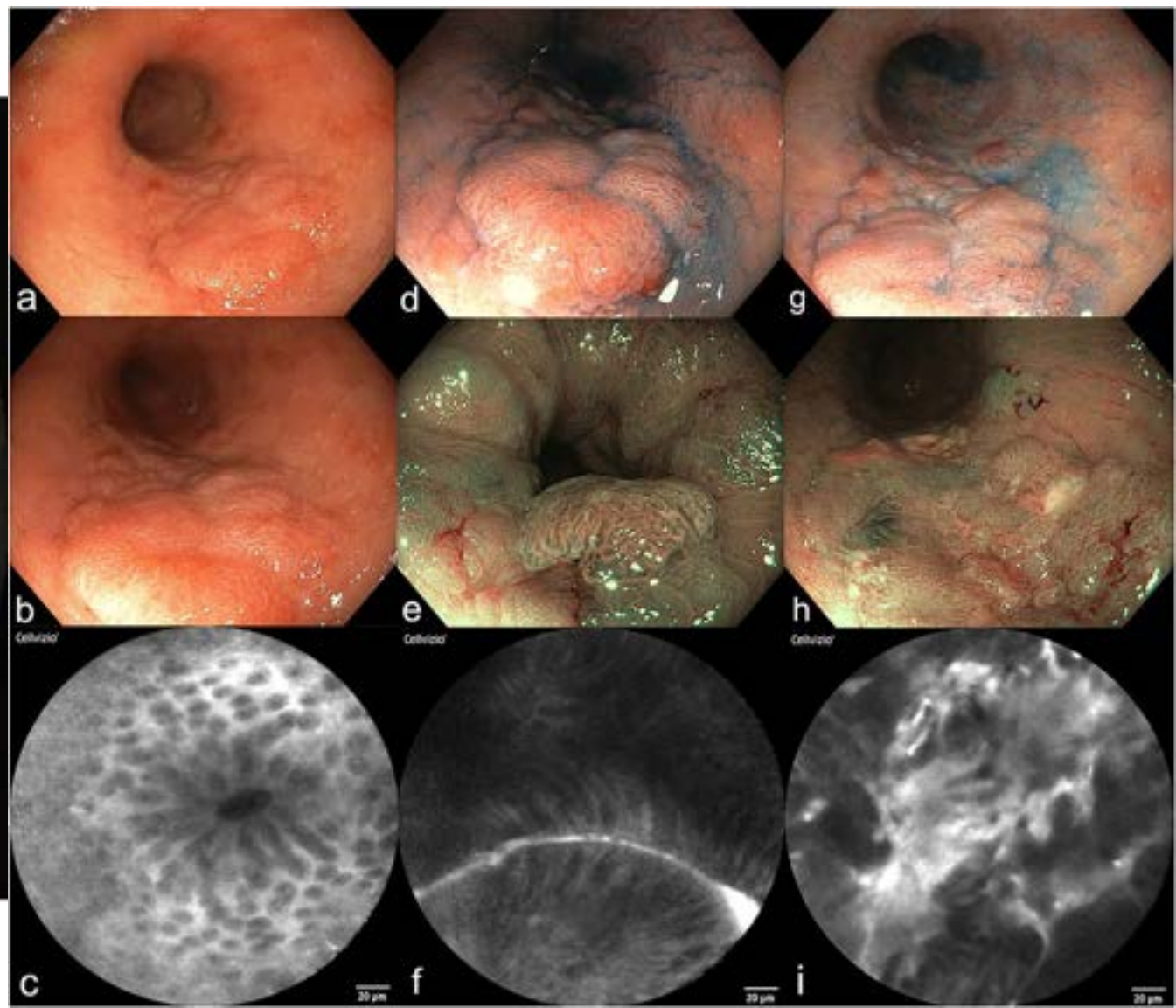
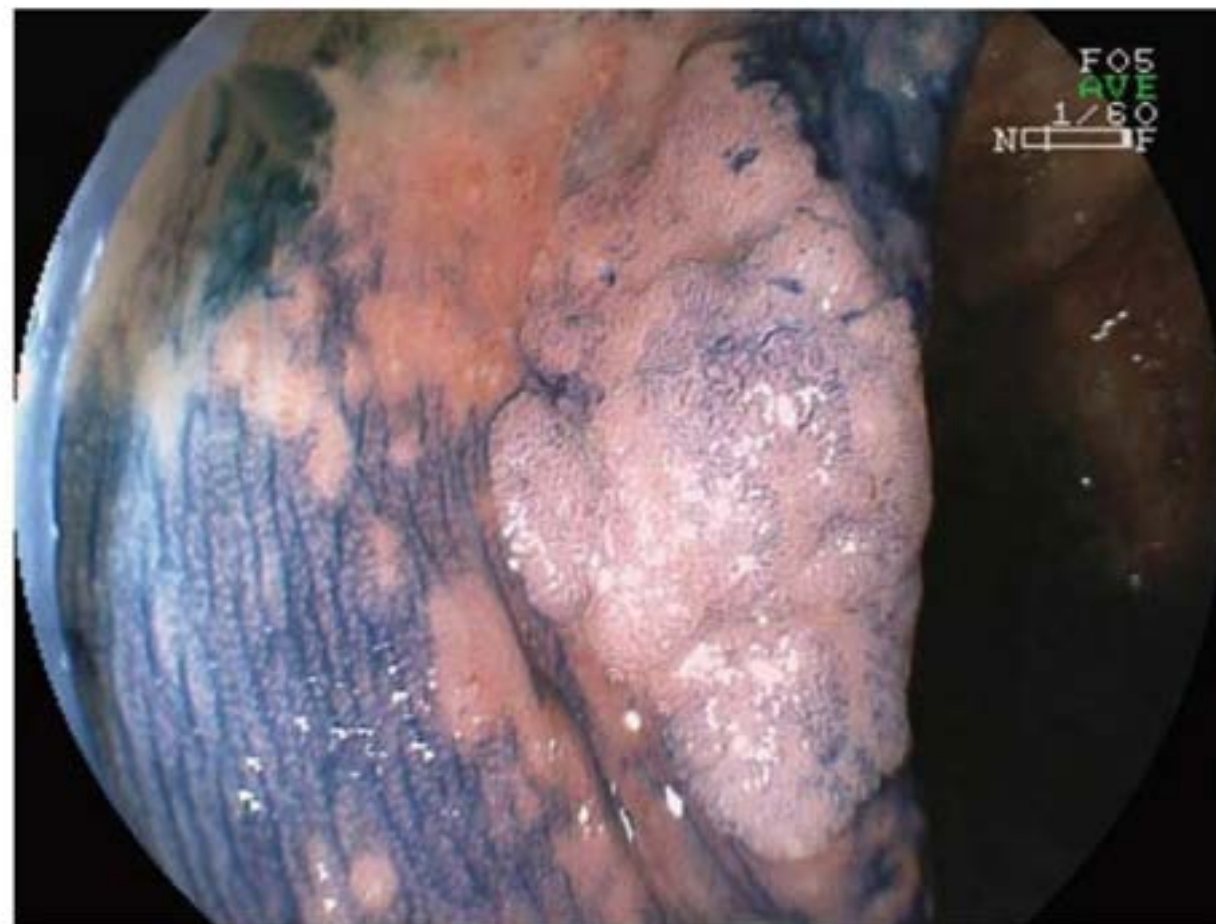
Tethered OCT Capsule  
Gary Tearney, MGH





# When is AI most useful for endoscopy?

## *Dysplasia in IBD*



# AI in Real Time Colonoscopy for Polyp Detection





# What are areas in polyp detection that can be improved?

## 1. Variation in Adenoma Detection Rates (ADR) amongst endoscopists

1. Estimated 7-28% polyp miss rate

## 2. Flat Polyps

1. **Challenge:** Their lack of a prominent structure means they can easily blend into the surrounding mucosa, especially in areas with folds or bends in the colon.

## 3. Sessile Serrated Polyps/Adenomas (SSPs/SSAs)

1. **Challenge:** These polyps are not only difficult to detect due to their appearance and consistency but are also challenging to differentiate from hyperplastic polyps, which are typically benign. However, SSPs/SSAs have a higher risk of progression to colorectal cancer.

## 4. Polyps in Difficult-to-Access Locations

1. **Challenge:** Behind folds, within flexures (e.g., the hepatic or splenic flexure), or near the ileocecal valve.

## 5. Poor prep?

# Clinical Evidence I

## **AI polyp detection compared to conventional colonoscopy**

- Systematic review and meta-analysis of 5 randomized trials that included 4354 patients
- Computer-aided detection (CAdE) system had higher pooled ADRs as compared with conventional colonoscopy.
- CAdE resulted in higher adenoma per colonoscopy regardless of size and polyp location, polyp type (adenoma, sessile serrated, *advanced adenoma*\*)
- Range of RR: 1.35-1.70-fold improvement in ADR

Conclusion: Computer-aided diagnosis can improve ADRs compared to standard colonoscopy.

Gastrointest Endosc. 2021;93(1):77.

# Clinical Evidence II, *tougher comparator*

## AI polyp detection compared to Enhanced Colonoscopy

- A systematic review and network meta-analysis (NM) of randomized controlled trials that AI compared with other endoscopic interventions aimed at increasing ADR
  - including distal attachment devices, dye-based/virtual chromoendoscopy, water-based techniques, and balloon-assisted devices.
- 94 randomized controlled trials with 61,172 patients and 20 discrete study interventions
- Network meta-analysis demonstrated significantly improved ADR for AI compared to:
  - Autofluorescence imaging, dye-based chromoendoscopy
  - Endocap, Endocuff, Endocuff vision, EndoRing
  - Flexible spectral imaging color enhancement, full-spectrum endoscopy, high definition, linked color imaging, narrow band imaging
  - Water exchange, and water immersion
- ADRs for AI were significantly higher RR Range from 1.19-1.41-fold improvement



# FDA-Approved AI Platforms in Colonoscopy

## **1. Medtronic, GI Genius**

FDA De Novo Approval April 2021

## **2. Wision AI, EndoScreener**

FDA 510(k) Approval in November 2021

## **3. Iterative Health, SKOUT**

FDA 510(k) Approval in September 2022

## **\*Magentiq-Colo Software**

Marketing Approval July 2023



Without GI Genius™  
intelligent endoscopy module



With GI Genius™  
intelligent endoscopy module



**Medtronic**

# Gastric Dysplasia Detection and Surveillance

- Challenges
  - Large Surface Area and Folds, gastric fluids and need for distention
  - Hereditary Diffuse Gastric Cancer

# AI Upper Endoscopy Studies for Gastric Cancer and Dysplasia

Table. Clinical Studies of AI in upper GI endoscopy.

Authors, Year	Study Groups	Endoscopy, AI Technology	Findings
Niikura R, et al., 2022	500 patients (249 were allocated to the AI diagnosis group and 251 to the expert endoscopist diagnosis group)	White light endoscopy, SKOUT; Iterative Scopes, Cambridge, MA	The per-image rate of gastric cancer diagnosis was higher in the AI group (99.87%, 747/748 images) than in the expert endoscopist group (88.17%, 693/786 images)
Lianlian, W et al., 2021	1812 patients (907 were allocated to the AI diagnosis group and 905 to the routine-first group, endoscopy group)	White light endoscopy, ENDOANGEL-LD system	The use of an AI system during upper gastrointestinal endoscopy significantly reduced the gastric neoplasm miss rate.
Zhang, X et al., 2019	215 patients	SSD for Gastric Polyps (SSD-GPNet)	SSD-GPNet improves polyp detection recalls over 10%
Kanesaka, T et al., 2018	147 patients (127 patients with EGC and 20 non-EGC participants)	Magnifying narrow-band imaging (M-NBI), computer-aided diagnostics (CADx)	96.3% EGC detection accuracy based on irregular microvessel imaging
Kahn, A et al., 2022	67 patients underwent virtual chromoendoscopy (VLE)-IRIS, 66 in the IRIS-VLE group	High-definition white light (HDWLE) and narrow-band imaging (NBI), intelligent real-time image segmentation (IRIS)	100% of dysplastic areas were identified when applying IRIS and 76.9% with VLE as the first interpretation modality ( $p = 0.06$ )

# ENDOANGEL-LD RCT for gastric neoplasia miss rate

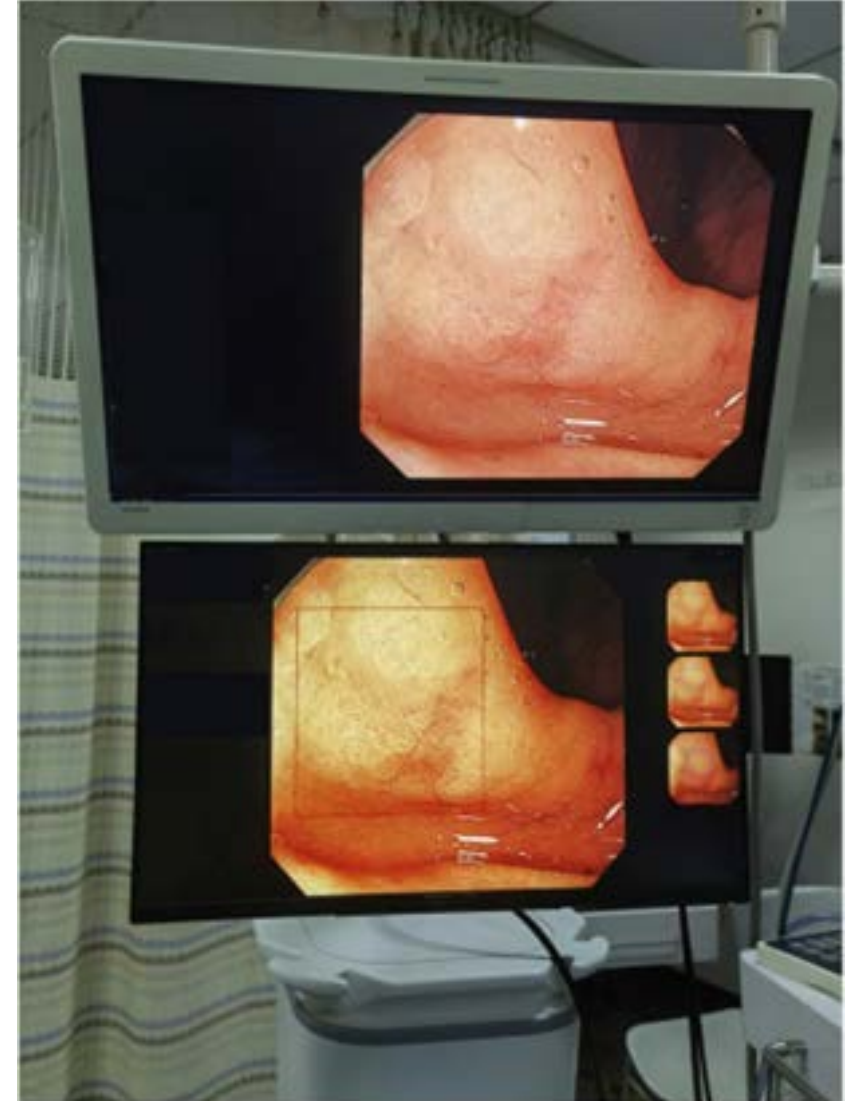
*Effect of a deep learning-based system on the miss rate of gastric neoplasms during upper gastrointestinal endoscopy: a single-centre, tandem, randomised controlled trial.*

*Lancet Gastroenterol Hepatol 2021; 6: 700–08.*

## **Background:**

AI system designed to detect focal lesions and diagnose gastric neoplasms on reducing the miss rate of gastric neoplasms in clinical practice.

<https://www.youtube.com/watch?v=H1F2SG0IXUA>





# ENDOANGEL-LD RCT for gastric neoplasia miss rate

## Methods:

- Single-centre, randomised controlled, tandem trial, Renmin Hospital of Wuhan University, China.
- Consecutive patients undergoing routine upper gastrointestinal endoscopy for screening, surveillance, or symptoms.
- Randomized to Tandem AI followed by WLE **OR** vice Order → Targeted biopsies of all detected lesions after 2nd examination.
- Primary endpoint: Miss rate of gastric neoplasia

## Results:

- 907 AI-first group and 905 to the routine-first group, July-Dec 2020
- The gastric neoplasm miss rate was significantly lower in the AI-first group than in the Routine first group
- Routine first group **6.1%** vs **27.3%**; relative risk **0.224**, 95% CI 0.068-0.744; **p=0.015**).

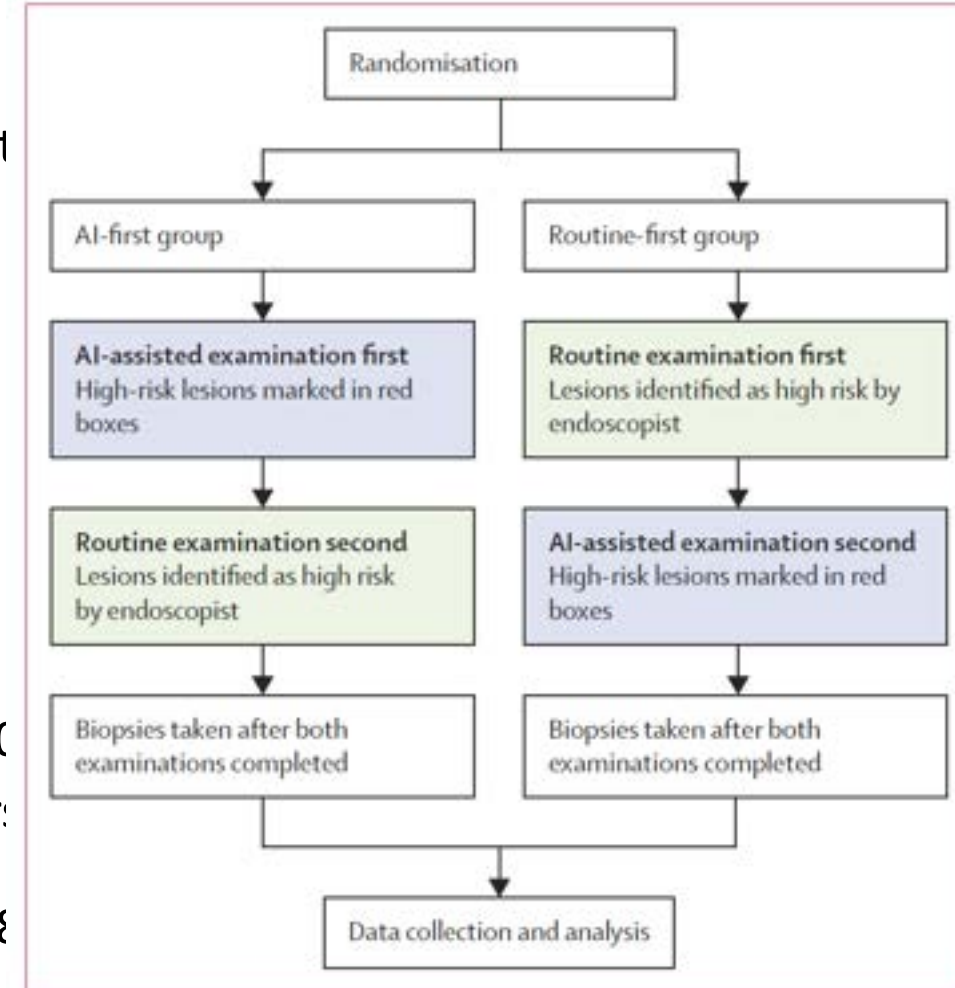


Figure 1: Trial design  
AI=artificial intelligence.

# NAVICAM Magnetically Controlled Capsule Endoscopy

- The ingestible NaviCam® capsule is a pill-sized video camera that the patient swallows with water before starting the examination.
- Inside the capsule is a tiny camera that has its own light source; it takes pictures of the patient's stomach while its movement is controlled by the physician.
- **GastroScan:** *"Autopilot"*- predetermined sequence of device motion instructions allowing for sequential execution with minimal or no user intervention complete visualization of the stomach seamless.





# Conclusions: Current State of AI in Endoscopy

- AI for Polyp Detection
  - Good clinical evidence that it improves polyp detection
  - 3 FDA approved platforms, more to come
- AI for Gastric Dysplasia
  - Less data, RCT in China

# Future

- AI Colonoscopy Implementation
  - Cost Reduction with competition?
- AI EGD Implementation
  - High risk areas for gastric and esophageal cancer
  - High risk patients like those with CDH1/Hereditary Diffuse Gastric Cancer may be the best place to start
- Endoscopic biopsy and eradication (e.g. polypectomy and ESD) will still be needed for AI positives until fully automated endoscopic robotic technology becomes available
  - Our jobs are safe for a while...





# Questions

