*Case Report*

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# Case Study: First Ever Visualization of Esophagogastric Junction Following Endoscopic Fundoplication in an Awake Patient Using Magnetically Controlled Capsule Endoscopy

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## Abstract

**Background:** Endoscopic retroflexion evaluates the gastroesophageal junction (GEJ) which is traversed by the gastroscope in a sedated patient. Magnetically Controlled Capsule Endoscopy (MCCE) examines the GEJ in a collapsed natural state in awake patients. This report is the first-ever visualization of endoscopic fundoplication status post transoral incisionless fundoplication (TIF) without gastroscope or sedation.

**Case Description:** This patient is a 69-year-old female with recurrent antral gastritis. She underwent laparoscopic hiatal hernia repair and concomitant TIF (cTIF) in 2019. She tolerated swallowing the MCCE capsule well. As we guided the MCCE to evaluate the cardia, we observed the first visualization of a collapsed postoperative TIF valve. She had no adverse events and was discharged 30 minutes post-procedure.

**Discussion:** MCCE has the advantage of avoiding sedation and its risks. There is no need to stop critical medications, including anticoagulants. MCCE has a short duration, enabling the physician to show high-resolution images and discuss the plan with an awake patient who can drive after the procedure. The use of MCCE in evaluating the reconstructed postoperative valve is promising. It enables visualization of the valve in its natural position, can measure the length of the valve, and has the potential to perform dynamic evaluation of the GEJ in an awake patient.

**Conclusion:** The Magnetically Controlled Capsule Endoscopy system evaluates the original and reconstructed gastroesophageal valve in its natural status without sedation. It can potentially enhance the understanding of GERD and its surgical treatment.

## Keywords

magnetically controlled capsule endoscopy, Navicam, esophagogastroduodenoscopy, transoral incisionless fundoplication

## Background

Esophagogastroduodenoscopy (EGD) is an essential diagnostic tool for gastroesophageal reflux disease (GERD).[1] Retroflexion enables the endoscopist to evaluate the gastroesophageal junction (GEJ). However, this examination is unnatural and suboptimal. It does not show the normally collapsed GEJ; instead, it features the junction traversed by the gastroscope in a sedated patient. The same drawbacks apply to evaluating post-antireflux valves. There is a need for technology that allows studying the morphology of the normal GEJ in an awake patient. The information gained can guide the creation of the optimal anti-reflux surgery. Magnetically Controlled Capsule Endoscopy (MCCE) fills this void by examining the GEJ in a collapsed state without sedation. This report is the first-ever visualization of endoscopic fundoplication status post transoral incisionless fundoplication (TIF).

## Introduction to MCCE

Magnetically Controlled Capsule Endoscopy (MCCE), also known as Navicam system, is manufactured by Anx

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**Figure 1.** Navicam capsule.

Robotica (Plano, Texas). It was FDA-cleared on May 4, 2021, for visualization of the stomach for adults greater than 22 years of age and a BMI < 38.0. Recently, the FDA-cleared extending the age limit (≥6 years of age) and BMI (≤65.0 and waist circumference ≤77.0 inches) in clinics and hospitals, including Emergency Room settings.

MCCE system consists of a capsule (27 × 11.8 mm) containing 4 lights, a camera collecting images at 2 frames/second, and a magnet (Figure 1). It also includes a data recorder with sensors and a mechanical robot via a C-arm, generating a magnetic field of up to 200 mT (Figure 2). Using the robotic magnetic control system, the capsule rotates in 5 degrees of freedom, 2-rotational and 3-translational, with controlled migration from the cardia to the pylorus. Two applications are available for capsule control: manual manipulation and software directed. The MCCE is performed at the surgeon's medical center without anesthesia or a companion driver. Patients complete the MCCE pre-test protocol by withholding food post 8 p.m. the day before the procedure. On procedural day, the MCCE preparation includes 70 mg of Simethicone diluted in 100 ml of water; following a 10-minute latency period, 2 additional water volumes are ingested, 100 and ≥500 ml, before MCCE administration. Total water consumption is about 1200 ml of water. The data recorder vest is positioned to cover the chest region and abdominal cavity. The MCCE capsule is ingested in the left lateral decubitus position with a small volume of water, 20 ml. Images are transmitted wirelessly through the sensors in the data recorder vest. The surgeon traverses each region by magnetically controlling the capsule orientation and location. During the MCCE, the patient is placed in 3 positions: left and right lateral decubitus and supine.

## Case Description

This patient is a 69-year-old female with a past medical history of hypothyroidism and hypertension. She had recurrent antral gastritis. She elected to proceed with MCCE instead of a repeat EGD to avoid sedation and the need for a companion driver. She underwent laparoscopic hiatal hernia repair and concomitant TIF (cTIF) in 2019.

The patient required no preoperative laboratory testing and maintained her medications. She tolerated swallowing the capsule and followed the above protocol. There was an improvement in antral gastritis, which did not completely resolve. As we guided the MCCE to evaluate the cardia, we observed the first visualization of a collapsed postoperative TIF valve (Supplemental Video 1). She had no adverse events and was discharged 30 minutes post-procedure. The comparison of the endoscopic and MCCE findings is highlighted in Figure 3.

## Discussion

This is the first-ever reported visualization of the TIF valve using the innovative MCCE technology. Unlike traditional capsule endoscopy, which is governed by gravity and peristalsis, MCCE can scan the stomach and be directed intentionally using the console. Different types of MCCE, including Navicam, have been shown to be safe with an overall sensitivity of 87% (95% confidence interval [CI], 84%-89%) in detecting gastric lesions.[2]

Controlling the Navicam capsule requires training for providers to manually navigate the capsule in the stomach using joysticks to manage orientation and magnet positioning. The training differs from provider to provider relative to previous endoscopy experience and comprehension of equipment. In our early experience, the physician performed manual navigational control of the capsule, and the learning curve consisted of five proctored procedures.

Two new additional features make MCCE even more appealing. The first is GastroScan, an artificial intelligence scanning of the stomach using proprietary software. Gastroscan entails a systematically predetermined sequence imaging of all sections of the stomach, from the cardia to the pylorus, with minimal or no user intervention.

The second improvement is the detachable tether, which is mounted on the capsule. It allows the capsule to be retracted into the distal esophagus or the GEJ and offers the potential to examine these areas closely. The tether is easily released after the capsule has again entered the stomach for the remainder of the examination.

MCCE has the advantage of avoiding sedation and its risks. It requires no preoperative laboratory testing, and there is no need to stop critical medications, including anticoagulants. MCCE has a short duration, enabling the physician to show high-resolution images and discuss the plan with an awake patient who is able to drive after the procedure.

MCCE has the same contraindications as conventional capsule endoscopy, such as inability to swallow or swallowing disorders, higher incidence of bowel stenosis such as Crohn's disease, or history of bowel obstruction.

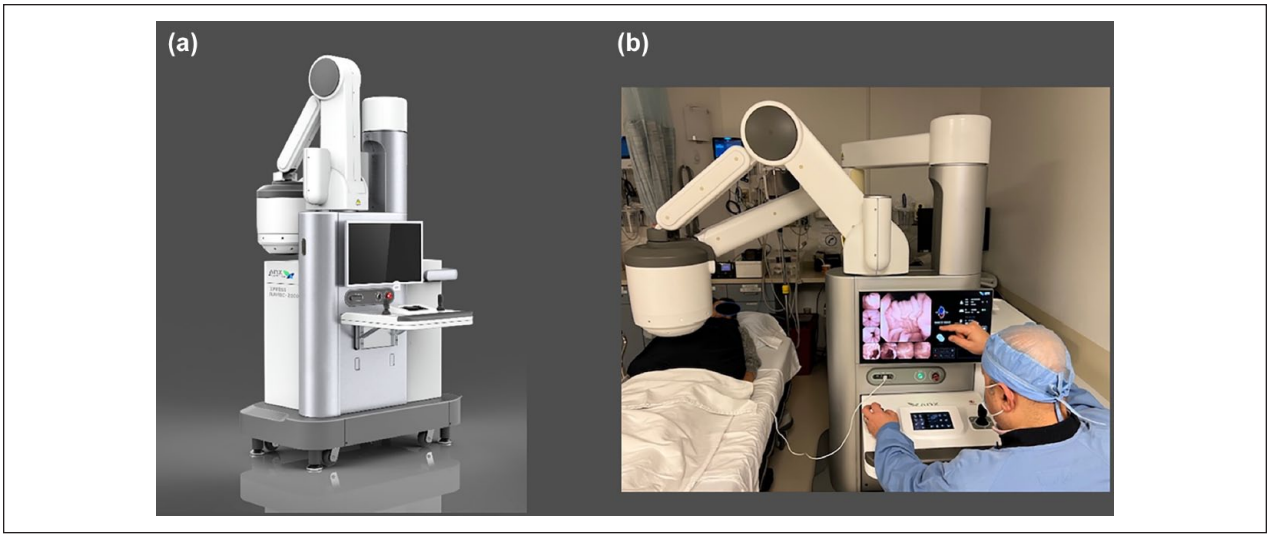


**Figure 2.** Magnetically controlled capsule endoscopy, folded (a) and in use (b).

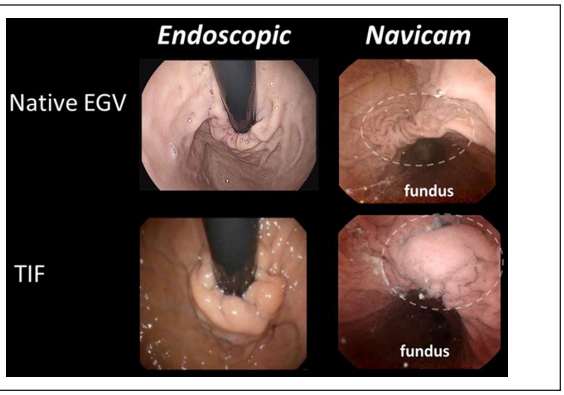


**Figure 3.** MCCE and endoscopic views of normal and post TIF esophagogastric valve (EGV).

The use of MCCE in evaluating the reconstructed postoperative valve is promising. It enables visualization of the valve in its natural position, can measure the length of the valve, and has the potential to perform dynamic evaluation of the GEJ in an awake patient.

## Conclusion

The Magnetically Controlled Capsule Endoscopy system provides opportunities to evaluate the original and reconstructed gastroesophageal valve. MCCE has the potential to offer new insights about gastroesophageal reflux disease as it overcomes the shortcomings of endoscopy, such as sedation and traversing the gastroesophageal junction.

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### Author Contributions

M.F.: writing the manuscript and editing images and video. D.L.: writing and editing the manuscript.

### Declaration of Conflicting Interest

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr. Fanous has no conflict of interest or financial ties to disclose. Mr. Lorenson was a consultant for EndoGastric Solutions.

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### Ethical Approval

Dr. Fanous and Mr. Lorenson consciously assure that the following is fulfilled: (1) This material is the authors' own original work, which has not been previously published elsewhere. (2) The paper is not currently being considered for publication elsewhere. (3) The paper reflects the authors' research and analysis in a truthful and complete manner. (4) The paper properly credits the meaningful contributions of co-authors.

### Patient Consent

Obtained.

### The Use of Artificial Intelligence Software

Dr. Fanous and Mr. Lorenson declare that they have not used generative artificial intelligence to write this manuscript or create images.

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## Supplemental Material

Supplemental material for this article is available online.

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