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Development of colonic stent simulator using three-dimensional printing technique: a simulator development study in Korea

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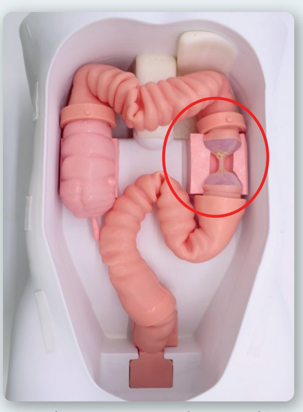
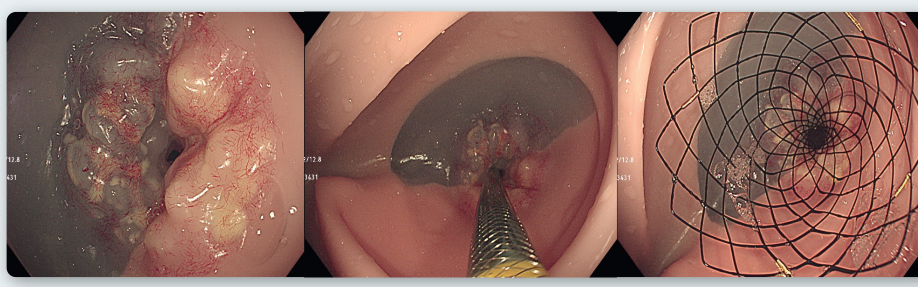
Development of colonic stent simulator using three-dimensional printing technique: a simulator development study in Korea



Colonic stent simulator with interchangeable modules



Stent insertion procedures using this colonic stent simulator

- This simulator were manufactured using silicone molding techniques in conjunction with 3D printing.
- Training for colonoscopy insertion, cecum intubation, loop reduction, and stenting within stenotic areas.
- Interchangeable stenotic modules for four sites (rectum, sigmoid colon, descending colon, and ascending colon).
- Reusable metallic stent that can be deployed repeatedly.

This innovative simulator offers secure colonic stenting practice across various locations, potentially enhancing clinical outcomes by improving operator proficiency during actual procedures.

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Background/Aims: Colonic stenting plays a vital role in the management of acute malignant colonic obstruction. The increasing use of self-expandable metal stents (SEMS) and the diverse challenges posed by colonic obstruction at various locations underscore the importance of effective training for colonic stent placement.
Methods: All the components of the simulator were manufactured using silicone molding techniques in conjunction with three-dimensional (3D) printing. 3D images sourced from computed tomography scans and colonoscopy images were converted into a stereolithography format. Acrylonitrile butadiene styrene copolymers have been used in fused deposition modeling to produce moldings.
Results: The simulator replicated the large intestine from the rectum to the cecum, mimicking the texture and shape of the human colon. It enables training for colonoscopy insertion, cecum intubation, loop reduction, and stenting within stenotic areas. Interchangeable stenotic modules for four sites (rectum, sigmoid colon, descending colon, and ascending colon) were easily assembled for training. These modules integrate tumor contours and blood vessel structures with a translucent center, allowing real-time visualization during stenting. Successful and repeatable demonstrations of stent insertion and expansion using the reusable SEMS were consistently achieved.
Conclusions: This innovative simulator offers a secure colonic stenting practice across various locations, potentially enhancing clinical outcomes by improving operator proficiency during actual procedures.

Keywords: Colonoscopy; Intestinal obstruction; Self-expandable metallic stents; Simulation training

INTRODUCTION

Colon cancer ranks among the most prevalent cancer types globally, with the third highest incidence rate and the second highest mortality rate among all cancers.[1] Despite the implementation of colorectal cancer screening programs aimed at detecting early stage cases, a considerable number of patients still present with advanced stages of the disease, leading to large bowel obstruction, which occurs in 7% to 29% of patients with colorectal cancer.[2-4] Since its introduction in the early 1990s,[5] colonic stenting with self-expandable metal stents (SEMS) has been widely applied in managing malignant colorectal obstruction. Colonic stenting is a minimally invasive procedure that can serve as an alternative to emergency surgery, thereby reducing the need for permanent colostomy and lowering the morbidity and mortality associated with emergency surgical interventions.[6-9] It has various applications, including providing immediate relief from obstruction, serving as a bridge therapy for elective surgery, and offering palliative rescue treatment for non-operable colorectal cancers.

Although colonic stenting is generally considered a safe procedure with high rates of technical and clinical success,[6,10,11] unfavorable outcomes such as perforation, rectal bleeding, incomplete decompression, and stent migration can still occur.[12] These outcomes may be influenced by both tumor characteristics and endoscopist expertise. Proximal lesion locations and acute angular lesions have been associated with less favorable outcomes following colonic stenting.[13,14] Additionally, the experience level of the endoscopist plays a crucial role, as inexperienced practitioners tend to have higher rates of technical failure and complications than experienced practitioners.[14,15] Therefore, ensuring successful colonic stenting requires adequate training and experience gained through repeated procedures across various tumor locations.

Historically, the apprenticeship-based training method (ABTM) has been the primary approach for training endoscopy practices. However, this approach has several drawbacks, including difficulties in maintaining standardized training, potential concerns about patient complaints, and inefficiencies in terms of time and effectiveness.[16,17] To address these issues, a new methodology of simulator-based training has been introduced.[18] Although several mechanical colonoscopy models have been developed and commercialized,[19] to the best of our knowledge, system that can effectively train stent deployment procedures is currently not available.

Therefore, this study aimed to develop a colonic stent simulator using three-dimensional (3D) printing technique, incorporates four interchangeable stenotic modules at various colonic locations.

METHODS

3D modeling and fabrication of colonic stent simulator

To produce a colonic stent simulator, digital imaging and communications in medicine images derived from computed tomography (CT) scans of both actual patients with colon cancer and normal individuals were used as the source for 3D modeling, along with electronic health data retrieved from Yeouido

St. Mary's Hospital. All methods were performed in accordance with the ethical principles of the Declaration of Helsinki and the current scientific guidelines.

3D models of each colorectal segment were generated using MEDIP PRO v2.0.0 (Medical IP Co., Ltd.) (Fig. 1A, B). Two-dimensional images were stacked using the software, yielding a threshold segmentation module with tools for selecting pixels within a defined range of Hounsfield units representing the anatomical structures of interest. Segmented 3D images from CT scans and colonoscopies were converted into stereolithography format, featuring a triangular surface mesh structure. The resulting moldings were 3D printed using acrylonitrile butadiene styrene copolymers via the fused deposition modeling method employing an FDM-type 3D printer (Fig. 1C–E). Colonic segments with a wall thickness of 2 mm were then modeled with an outside offset function using a Meshmixer (Autodesk Inc.).

To ensure the durability and practicality of the simulator, the components were categorized as fixed or movable with variations in wall thickness and silicone smoothness. Soft material was applied to the anus, rectum, sigmoid colon, and transverse colon, whereas harder silicone was applied to the descending and ascending colons.

Reusable metallic colon stent

For educational purposes, developing repeatedly deployed stents is crucial. The deployed stent can be reinserted into the catheter using a funnel-shaped reconstruction device (M. I. Tech Co., Ltd.), making it reusable (Fig. 2).

Ethical statements

This study was approved by the Institutional Review Board (IRB) of Yeouido St. Mary's Hospital (approval number: SC22ZISI0104).

RESULTS

In simulator development, a stent simulator model that closely mimics the intricacies of actual human anatomy is important. The model consisted of fixed segments, including the rectum, descending colon, and ascending colon, along with movable segments, such as the sigmoid colon and transverse colon. Specifically, the sigmoid colon, which is known to receive significant pressure from looping during colonoscope insertion, was designed to be slightly thicker (3 mm) than the other segments (2 mm). Through repeated testing, natural alpha loop formation was observed in the sigmoid colon when the colonoscope

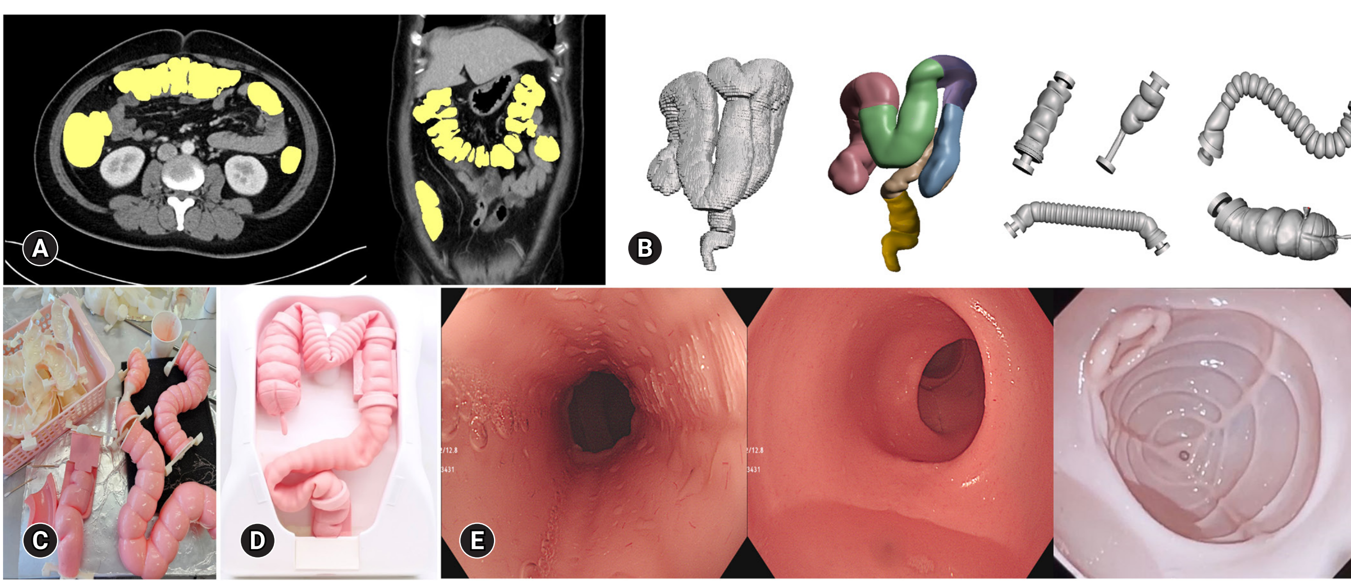

Fig. 1. Three-dimensional (3D) modeling and fabrication of a colonic stent simulator. (A) Automated segmentation of the colon from contrast-enhanced computed tomography. (B) 3D images of an artificial whole colon and its individual segments generated using modeling software. (C) A silicone-based colon model and malignant stenotic module were produced through 3D printing. (D) All colon parts were assembled in the body case. (E) Intraluminal view of 3D-printed model.

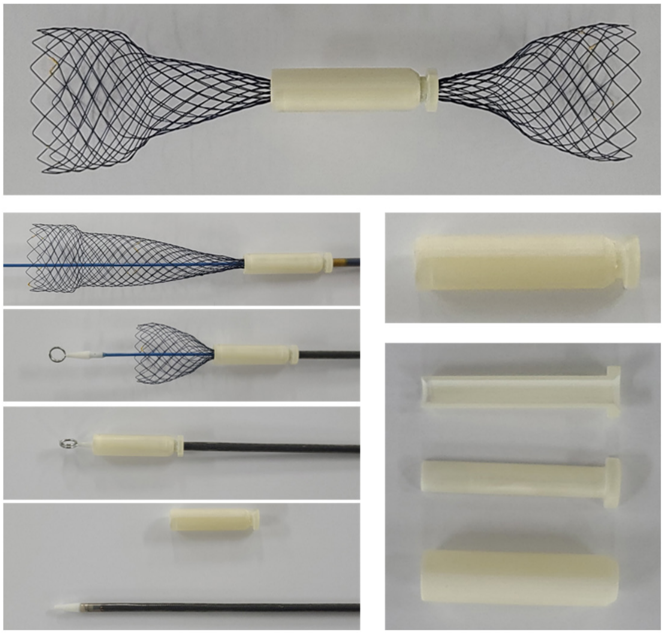

Fig. 2. Reusable self-expandable metal stent using a funnel-shaped reconstruction device.

entered the sigmoid-descending junction. Subsequently, the colonoscope was straightened during unlooping as it entered the descending colon, thereby closely mimicking the process of actual colonoscope insertion via right-turn shortening. This comprehensive design serves the dual purpose of facilitating the practice of general diagnostic colonoscopy and refining skills for stent insertion.

To enhance the versatility of our simulator, interchangeable stenotic modules were developed for four distinct regions: the rectum, sigmoid colon, descending colon, and ascending colon (Fig. 3). This allows trainees to engage in detailed and specialized training considering variations in the tortuosity and redundancy of each colon section, which can significantly affect stent deployment techniques.

All stenotic modules featured a standardized stenosis 3 mm in diameter, incorporating realistic tumor contours and blood vessel structures (Fig. 4A). The inclusion of these anatomical details closely describes the endoscopic perspective and pro-

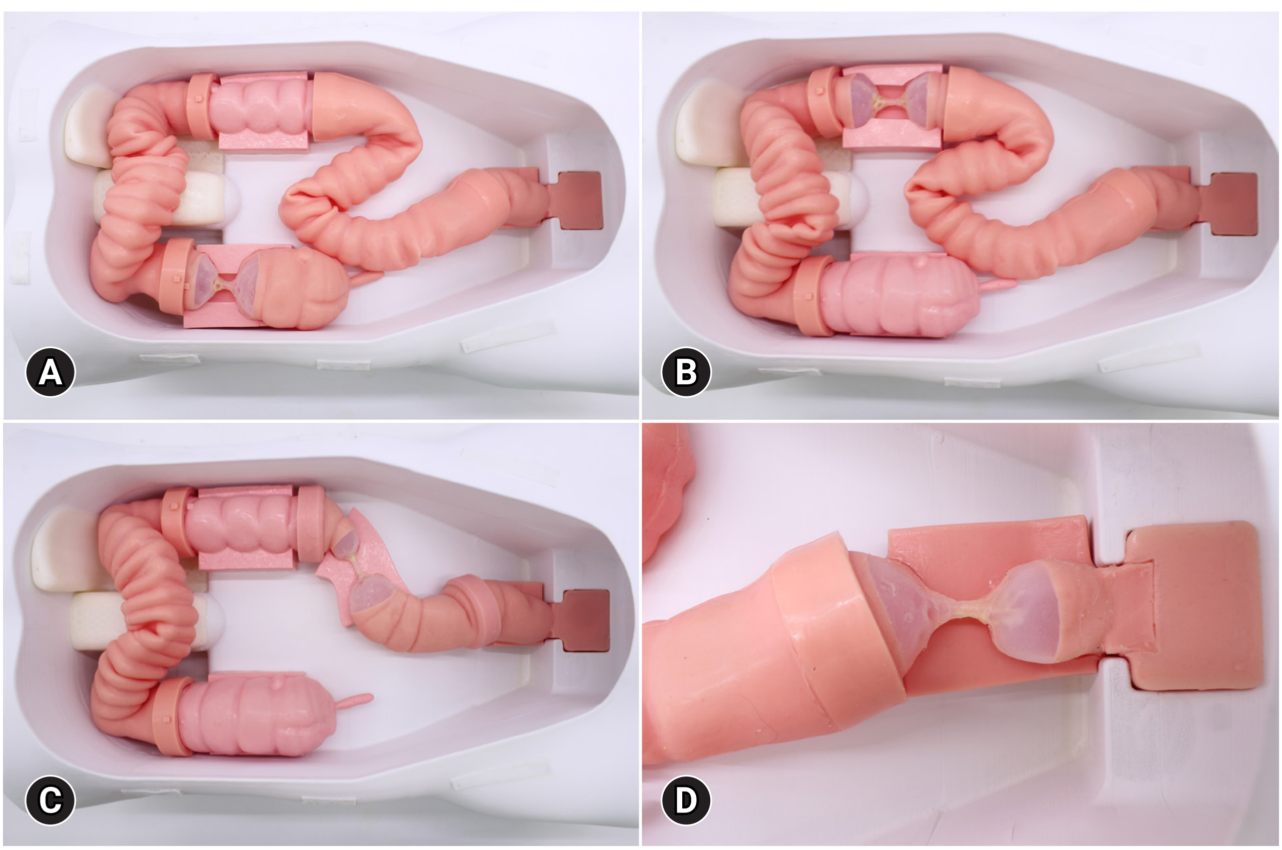

Fig. 3. Interchangeable colonic stenotic modules. (A) Ascending colon stenosis. (B) Descending colon stenosis. (C) Sigmoid colon stenosis. (D) Rectum stenosis.

vides a life-like simulation of tumor observation. To ensure accurate stent placement, extension beyond the stenosis by at least 1.5 to 2 cm on each side is recommended.

The translucent center of the stenotic module plays a pivotal role in allowing real-time visualization during stenting. Through the transparent center, confirming that the middle part of the stent is located in the center of the stenosis without fluoroscopic guidance is possible (Fig. 4B). This feature is important because it enables preceptors to observe and guide the trainee, ensuring proper expansion of the stent at the right moment. Recognizing the critical importance of accuracy in stent deployment to avoid perforation and migration, the ability to provide real-time guidance significantly contributes to the effectiveness of the training experience.

Throughout the testing and training sessions, we consistently achieved successful and repeatable demonstrations of stent insertion and expansion within the simulator (Fig. 5, Supplementary Video 1). Feedback and evaluations regarding texture similarity and effectiveness compared to a real colonoscope insertion were gathered from gastroenterology fellows with at least six months of training and independent performance of diagnostic colonoscopy. Additionally, a group of experienced gastroenterologists who attended the hands-on course of the Korean Society of Gastrointestinal Endoscopy Days 2023 provided their assessments about stent deployment.

DISCUSSION

Although the use of stents for malignant colonic obstruction is increasingly replacing emergency surgery, training in colonic stenting has not significantly evolved. Currently, endoscopic stenting training relies on traditional ABTM because of a lack of effective training models. However, this approach has limited educational effectiveness because accessing enough cases for training is challenging. In addition, patients' conditions are often critical. Moreover, the nature of stenosis varies widely

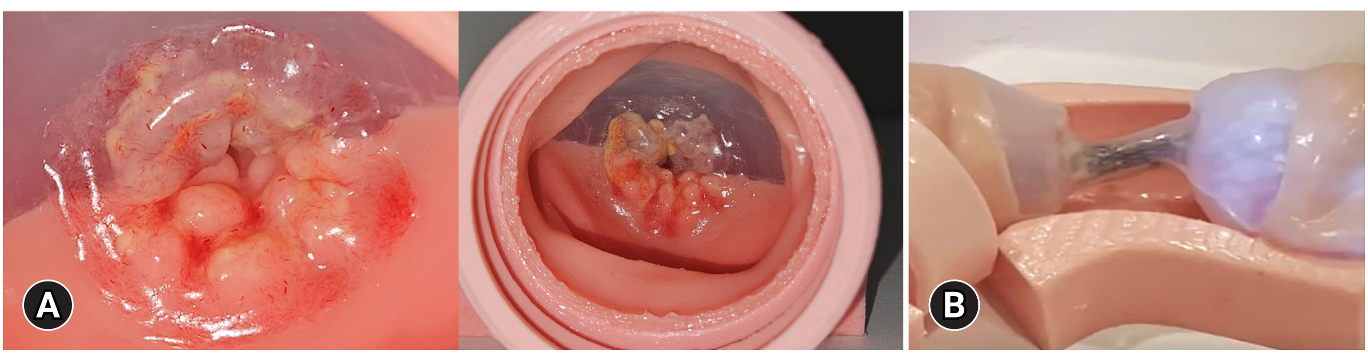

Fig. 4. Details of the colonic stenotic module. (A) The internal form of stenosis incorporates tumor contour and surface blood vessel structure, making it appear realistic. (B) The center of the stenosis module is made of a translucent material, allowing for visual observation during stent insertion.

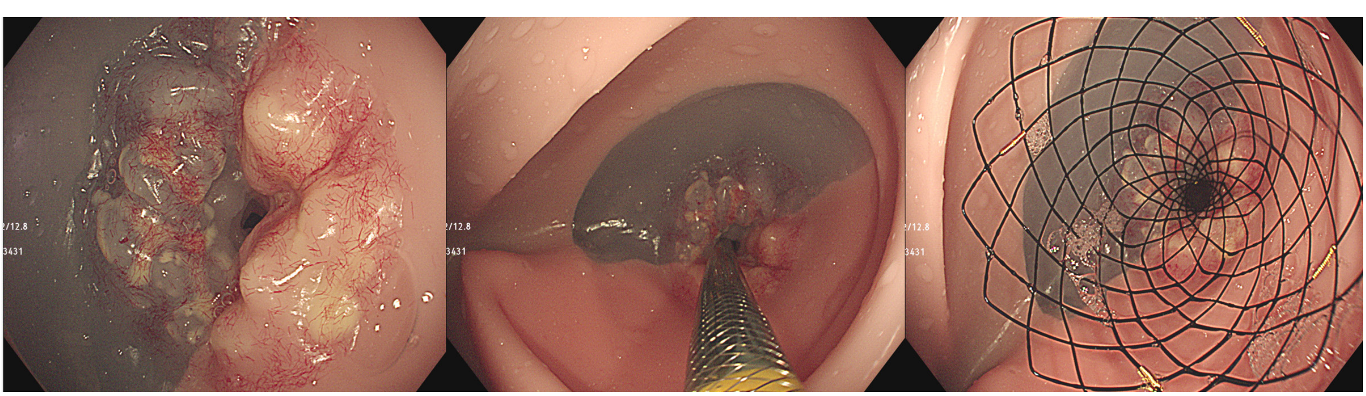

Fig. 5. Stent insertion procedures using our colonic stent simulator.

among individuals.

Education using simulators is widely used for various medical procedures, including stent insertion. Simulators for endovascular stent training in vascular diseases, such as aortic dissection and coronary artery stenosis, have been developed and employed.[20-22] Gastrointestinal endoscopy is an area where simulator-based education is actively pursued.[19] In the case of colonoscopy, various models have been developed for training purposes, allowing practice not only for basic cecal intubation, but also for polyp detection and removal. Although gastrointestinal stricture is a common condition requiring multiple endoscopic interventions, an effective educational model has not yet been developed.

An excellent endoscopy simulator should be semipermanent. This should enable repeated practice of endoscopy scenarios that mimic actual patient conditions. We aimed to develop a model that would allow the practice of basic colonoscopy insertion and stent placement for colonic stenosis. To achieve a life-like representation of colonic malignant tumor-induced stenosis, we utilized 3D modeling data derived from human CT scans and endoscopic images.

An important aspect of the development process is the creation of a simulator that does not rely on fluoroscopy. This decision was made to avoid radiation exposure and reduce associated costs and resource requirements. To ensure proper positioning of the stent within the stenosis without fluoroscopy, the central portion of the module was made of a semi-transparent material, allowing visual confirmation of the position of the stent. Another important aspect of the development process is the development of a SEMS that can be reused. Typically, a SEMS cannot be reused because, once fully deployed, returning it to its original compressed form is difficult. However, reusable SEMS are essential for educational purposes. This was achieved by designing a simple device that allowed a fully deployed SEMS to be manually inserted back into the catheter, ensuring durability during repeated training sessions. To facilitate training on stenosis in various locations, a model was designed to allow the interchangeable use of both normal and stenotic colons. Trainees can select the desired location from four modules spanning the rectum to the ascending colon, enabling comprehensive practice sessions.

Repeated stent placement training using this simulator is expected to enhance operator proficiency. Previous studies have demonstrated a distinct learning curve among individual endoscopists for positioning colonic stents, with the success rate increasing and procedure time decreasing over time.[23-27] Improved technical success and reduced stent usage were observed after a minimum of 20 procedures.[24,25] Furthermore, data strongly suggest that procedures performed by less experienced endoscopists are associated with higher complication rates, especially concerning procedure-related perforations.[6,14,15]

The successful deployment of stents in cases of proximal colon obstruction presents greater challenges, highlighting the critical importance of reaching the obstruction site without forming a loop.[13] Additionally, sites with acute angles, such as the hepatic flexure, present formidable hurdles in stent installation, often resulting in suboptimal outcomes. These findings underscore the significant impact of training and experience on stenting outcomes and emphasize the potential for enhancement using dedicated training modules. Traditionally, stent insertion predominantly targets left colorectal cancer, with limited reports documenting cases of right-sided cancer. However, current trends reflect a shift towards utilizing stent insertion as a bridge to emergency surgery for proximal lesions. Several studies have reported the efficacy and safety of successful stent placement in right-sided colon cancer.[28-30] The development of this simulator with interchangeable stenotic modules tailored to different regions holds promise for alignment with contemporary practices.

This study had some limitations. Owing to the inherent properties of silicone, its surface tension exceeds that of the human colonic mucosa. For this reason, the increased friction between the model's surface and the endoscope caused strong resistance when inserting the endoscope. By using a sufficient lubricant such as glycerin to reduce friction, a sensation similar to that of a colonoscopy performed on a real person was achieved. As the semi-transparent area is located only in the central part of the stenotic module, the overall stent position or guidewire movement in detail, similar to fluoroscopy, is difficult to observe. In addition, because the angulation points of the large intestine, such as the hepatic or splenic flexures, are the connecting points of each part of the large intestine model, this model did not create a stenosis module at the exact angulation location. Instead, it was designed to allow basic colonoscope insertion into a normal colon or to select and practice strictures in various other locations.

In summary, we developed a simulator utilizing 3D printing technology that enables stent placement for colonic obstruction across different locations. This simulator allows for repeated training using reusable SEMS, which can be performed without fluoroscopy. A validation study of this stent simulator will help evaluate its utility in real-life procedures and assess its learning curve.

Supplementary Material

Supplementary Video 1. Implementation of colonic stenting procedures using the simulator.

Supplementary materials related to this article can be found online at https://doi.org/ce.2024.110.

Conflicts of Interest

The authors have no potential conflicts of interest.

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Author Contributions

Conceptualization: HG, SL, HHL; Investigation: SL, SK, HHL; Methodology: HG, SL, SK, KSK, YRS; Resources: SK, HLJ, DWC, KSK; Supervision: DYC, BIL, JIK; Writing–original draft: HG, SL, HHL; Writing–review & editing: all authors.

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