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Development of an ESD (endoscopic submucosal dissection) simulator model for early-stage gastrointestinal neoplasms Results of the third “Medical Rising STAR” industry-academia collaboration project

[Key Points of the Presentation]

- We have developed a dry simulator that allows comprehensive training in ESD (endoscopic submucosal dissection)^{Note 1)} that was developed in Japan as a highly complex, minimally invasive endoscopic treatment for early gastrointestinal neoplasms^{Note 2)}.
- Using a soft proprietary material, we have created a multilayer ESD sheet that resembles the mucosa, submucosa, muscle layer, and blood vessels of the human digestive tract, which can be treated with electrocautery. When used together with a gastrointestinal tract lumen model that can respond to changes in the air volume, it is possible to reproduce realistic procedures.
- Bleeding during the procedure can be reproduced, and it is also possible to perform hemostasis. If the muscle layer is accidentally damaged, the fat layer outside the wall becomes visible, allowing the visual simulation of perforation. Therefore, it is expected to reduce risky procedures and contribute to safer medical care.

[Outline]

While ESD allows a highly curative and minimally invasive treatment for early gastrointestinal cancer, it carries a high risk of complications such as perforation and bleeding. Medical doctors performing this delicate procedure need advanced training before carrying it out on patients. Yet, training environments where beginners can practice safely are lacking.

Based on the results of joint research conducted by the research group of Associate Professor Takeshi Kanno and Professor Atsushi Masamune of the Division of Gastroenterology, Tohoku University Graduate School of Medicine, Denka Company Limited (Head Office: Chuo-ku, Tokyo; President: Ikuo Ishida), and U-A Corporation (Ohta-ku, Tokyo; President: Hiroshi Inanaga), we have developed a simulator (Figure 1). The research was conducted under the third initiative of the “Medical Rising STAR”^{Note 3)} project.

Using an actual endoscope and therapeutic tools, the simulator enables learners to study the comprehensive workflow of ESD, the core endoscopic treatment for early gastrointestinal neoplasms, including local injection, mucosal incision, submucosal dissection, bleeding control, and removal of the lesion, while also experiencing the complication of perforation caused by inadvertent injury to the muscle layer.

The study results were published online in *Endoscopy*, a journal of clinical medicine, on January 8, 2026. We are also preparing to market this model.

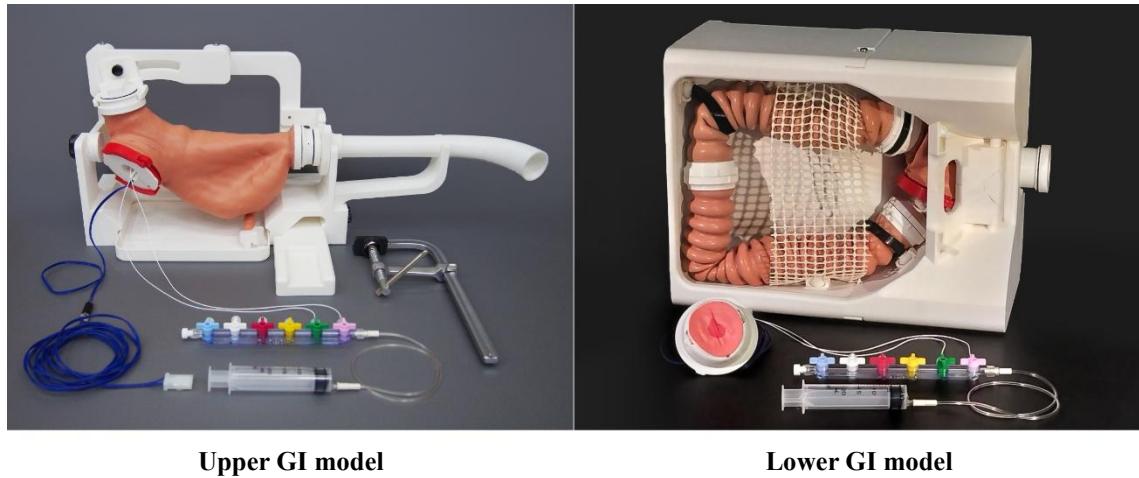


Figure 1. Appearance of the Simulator (Left: Upper GI Model; Right: Lower GI Model)

[Detailed Explanation]

Background of the research

It is known that cancers of the digestive tract, including esophageal, gastric, and colorectal cancers, are often curable with endoscopic treatment by removing the surface mucosal layer when detected at a very early stage through screening. Since it is less invasive than surgical treatment, such as thoracotomy or laparotomy, endoscopic resection has become the standard treatment in Japan, with further adoption overseas as well as its application to pharyngeal tumors also anticipated.

ESD originated in Japan. It enables the radical resection of larger tumors and involves precise and safe dissection between tissue membranes that are only a few millimeters thick (Figure 2). Although it is an endoscopic procedure, it carries a high risk of complications such as perforation and bleeding, and therefore requires a high level of technical skill. There is an urgent need to establish a training environment that allows beginners to learn the procedure safely, and this is also the reason why its adoption overseas has been slow.

Training has traditionally been conducted in real-time treatment settings involving actual patients. Training has also been performed using animal models (e.g., porcine stomach), but there are ethical, hygienic, and cost-related issues. Beginners should refrain from highly complex procedures directly on patients in actual clinical practice.

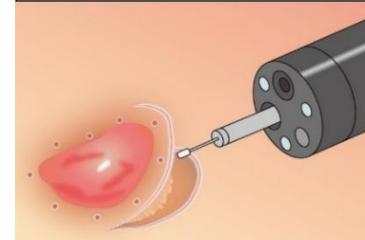
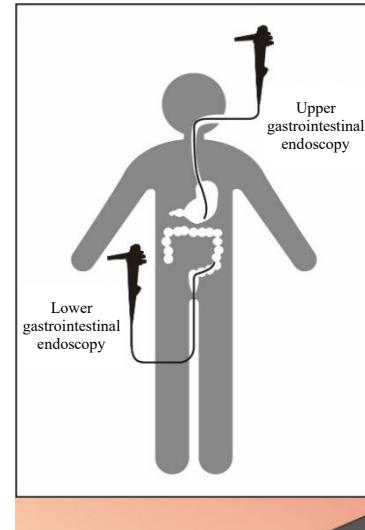


Figure 2. ESD involves dissecting and resecting beneath the mucosal layer where the tumor is located

This initiative

Associate Professor Takeshi Kanno, Dr. Yutaka Hatayama, and Professor Atsushi Masamune of the Division of Gastroenterology, Tohoku University Graduate School of Medicine, together with Yutaro Arata and other assistants from the Tohoku University Clinical Skills Laboratory, have developed an ESD sheet with a multilayer structure of mucosa, submucosa, and muscle similar to that of humans using special soft materials based on the results of the joint research project with Denka Company Limited (Head Office: Chuo-ku, Tokyo; President: Ikuo Ishida) and U-A Corporation (Ota-ku, Tokyo; President: Hiroshi Inanaga).

This model can reproduce the tactile sensation of dissecting the submucosal layer as well as bleeding that may occur during the procedure, allowing learners to practice using actual ESD knives (electrocautery) and hemostatic graspers.

By developing highly airtight, water-resistant, and flexible upper and lower GI models and combining them with ESD sheets that closely mimic the focal area, we have been able to reproduce endoscopic manipulation highly accurately. Validation by five expert physicians at Tohoku University Hospital demonstrated that lesions could be resected within a procedure time that is very close to that of actual clinical practice. The simulator is designed to allow beginners to learn how to safely secure the field of vision during layer dissection and to perform hemostasis without putting patients at risk. It is also expected to be useful for experienced practitioners to reproduce challenging cases and maintain their skills.

Since the ESD sheets contain artificial blood vessels, it is possible to practice multiple hemostatic procedures and the handling of occasional bleeding during dissection. Bleeding can be induced by an automatic bleeding device or manually, enabling learners to learn lesion resection while performing hemostasis. Perforation that may occur when the outermost muscle layer is excessively damaged during a procedure can also be simulated with this ESD sheet. The simulator is designed so that cancerous lesions (ESD sheets) can be placed at multiple sites, making it a useful model from the perspective of medical safety, given that the difficulty of ESD procedures varies depending on the lesion location and patient background.

Future development

This collaborative research, conducted under the “Medical Rising STAR” project to develop simulators for invasive endoscopic procedures, contributes to the advancement of patient safety and the improvement of endoscopic techniques by establishing learning methods that do not involve actual patients. We are also developing educational programs for inexperienced doctors using this simulator and are evaluating their effectiveness. We plan to expand our lineup to cover additional therapeutic and emergency endoscopic procedures in the future.

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[Industry–Academia Collaboration Initiatives]

This project is part of an initiative aimed to improve QOL in the healthcare field, based on the “Mission 2030” management plan of Denka Company Limited. Through our industry-academia collaboration with Tohoku University, we will contribute to the development of medical technologies in Japan and overseas by implementing cutting-edge research outcomes in the clinical practice. This project is also being advanced by U-A Corporation as part of its

efforts to develop medical models under the slogan “For The Next Frontiers.”

[Acknowledgment]

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[Description of Terms]

- Note 1. ESD (Endoscopic Submucosal Dissection): An advanced endoscopic therapeutic technique that involves endoscopically dissecting the submucosal layer to resect lesions that originate in the mucosal layer en bloc. It combines multiple techniques, such as local injection, mucosal incision, submucosal dissection, hemostasis, and advanced, precise endoscopic manipulation.
- Note 2. Early gastrointestinal neoplasm: Neoplasms that occur in the gastrointestinal tract from the mouth to the anus, such as esophageal, gastric, and colorectal cancers, which are at an early stage and are considered good candidates for endoscopic treatment.
- Note 3. Medical Rising STAR: The “STAR” in Medical Rising STAR stands for “Simulator Training model for Advanced high-Risk endoscopic therapy.” Medical Rising STAR is a registered trademark of Denka Company Limited.

[Publication Information]

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