

ISSN 0535-1405

No.524



INTERNATIONAL MEDICAL NEWS

**International Medical Society of Japan
Since 1925**

July 31, 2024

The 464th International Symposium on Therapy

**Industry-academia collaboration in the GI endoscopy.
The progress and challenge in Japan**

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Published by International Medical Society of Japan,

Chairman, Board of Directors: Kenichi Ishibashi, MD, PhD,

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Industry-academia collaboration in the GI endoscopy.

The progress and challenge in Japan

The 464th International Symposium on Therapy was held by the Zoom Webinar on May 23, 2024. Dr. Kazuki Sumiyama, Director of the International Medical Society of Japan (IMSJ), presided over the meeting.

Kazuki Sumiyama, MD, PhD
Director, IMSJ

Lecture I

Frontlines of Medical AI: Challenges of a University-Originated Startup

Yuki Shimahara, PhD
Founder, LPIXEL Inc.

The rapid development of AI technology since 2010s has expanded beyond the framework of traditional computer science and is paving the way to contribute widely to human culture and welfare. Naturally, the medical field has also attracted significant interest and has been influenced by AI. In the past decade, research and development for AI in the medical field has progressed. Especially since 2020, many AI have been approved as programmed medical devices, establishing AI as more than just a temporary trend and has now been used in real clinical situations. This presentation introduces the macro trends of politics and administration surrounding medical AI, and from a micro perspective, introduces the image diagnostic AI, EIRL, developed by the university-originated startup LPIXEL Inc., to provide a comprehensive understanding of the industry.

[1] Lung Nodule Detection AI "EIRL Chest Nodule"

This product detects nodules from chest X-rays and displays a rectangle around the lesion area (5 mm ~ 30 mm). After testing with 18 doctors, it was confirmed that the use of this product improved the reading sensitivity from 45.4% to 57.0%, maintaining its high specificity (Radiologists: 47.1% to 57.1%, Non-specialists: 43.8% to 56.9%).

[2] EIRL Colon Polyp*

This product assists in detecting colon polyp candidates from images obtained during colonoscopies, displaying an alert frame followed by a box around the four corners of the candidate area.

▼Performance Evaluation Results

In a retrospective performance evaluation test using positive videos (59) and negative videos (136) extracted from colonoscopy videos on Olympus Medical Systems endoscopy system, the results were as follows:

Sensitivity (based on lesion)

- Estimated value: 98.1%
- 95% CI: 94.6%- 99.6%

Specificity (frame-based)

- Estimated value: 95.0%
- 95%CI: 94.6%- 95.3%

Initially, only products from Olympus Medical Systems were targeted, but after a version upgrade, Fujifilm's endoscopy system was also included.

3

The products described above have undergone version upgrades following their market introduction, with some products utilizing the IDATEN system**. Quickly incorporating abundant feedback into product development and continuously upgrading is one of our company's strengths. In this presentation, we will introduce feedback from the field and discuss future expectations and challenges.

*This software was developed into a product based on the results of collaborative research conducted by The Jikei University School of Medicine and LPIXEL Inc., with the support of the AMED.

**The IDATEN system refers to a review system that allows improvements within the scope of the plan after obtaining approval for medical devices such as software medical devices utilizing AI, which are expected to have performance improvements after obtaining manufacturing and sales approval. PMDA pre-approves possible changes

related to performance improvements (software version upgrade plans, etc.).

Lecture II

Development of Flexible Endoscopic Devices: The Surgeon's Perspective

Kiyokazu Nakajima, MD, PhD

Professor,

Department of Next Generation Endoscopic Intervention,

Osaka University Graduate School of Medicine

For us surgeons, flexible endoscopy, or just "endoscopy" is near and far. Although we have opportunities to use them in our daily practice, we do not often perform surgery with them. Surprisingly, it is "endoscopists" who are able to dexterously perform surgeries with this long and floppy device. They are specialists in internal medicine, not surgery. I find this quite interesting, first of all.

We surgeons use laparoscope. It is rigid, and much shorter than endoscope. They may look similar, but they are completely different devices. Again, I find it interesting that the endoscope used by internists can perform a variety of surgeries, while the laparoscope used by surgeons is itself a just scope that can perform almost no surgery.

The endoscope used by endoscopist is inserted into the digestive tract (lumen) through the mouth or anus (natural orifice), without penetrating the body surface. Laparoscopes, handled by surgeons, on the other hand, are inserted into the abdominal cavity after making a hole on the body surface. Thus, endoscopy and laparoscopy have been simply divided into medical or surgical, without scalpel or with scalpel, luminal or abdominal. However, the boundary between the two has recently become a little blurred: endoscope enters the abdominal cavity (NOTES: Natural Orifice Transluminal Endoscopic Surgery), endoscope and laparoscope operate together (LECS: Laparoscopy Endoscopic Cooperative Surgery), and more! This is the area where "confusion" arises, but also where "innovation" can occur.

Confusion seems to be caused by stereotypes such as "endoscopy is like this" or "laparoscopy is like that." The stereotypes extend to the way the devices are used, how they are used, and even the way the users (medical doctors) think. In other words, the structural differences between endoscopes and laparoscopes, and the

differences between flexible instruments and surgical instruments, would induce differences in technique, and ultimately conflict between medicine and surgery.

On the other hand, innovation is produced by thinking with a flexible mind, free from stereotypes, such as “interpreting endoscopy from a surgeon’s point of view” or “looking at laparoscopy from an endoscopist’s point of view.” In fact, endoscopes are full of mysteries to surgeons. In this talk, I will start with what surgeons feel “strange” or “why?” about endoscopy. This presentation will introduce our efforts to create innovations through the collaboration between endoscopists and surgeons, and industry and academia. I hope this presentation will be of interest to those who are interested in creating innovation in the field of endoscopy.

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編集事務 早川 裕子、西山 敏夫

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発行日 2024年7月31日