Surgical safety management with AI in a large-scale

ophthalmic surgery center

Tsukazaki Hospital

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Take home message

- Surgical safety is a very promising field regarding the introduction of Deep Learning-based AI.
- Frontline staff need to overcome psychological barriers in the introduction of AI.
- AI detected medical errors 20 times more than previous reports.

Agenda

- Performance test of our AI safety system in experimental circumstances
- The introduction period (retrospective observational study)
- One year of implementation in the real-world setting (retrospective observational study)

Declaration of Interest

Topcon corporation [Japan]

Glory corporation [Japan]

Tomay corporation [Japan]

Clesco corporation [Japan]

Declaration of Helsinki

This study confirmed Declaration of Helsinki and approved by Ethics Committee of Tsukazaki Hospital.

Increasing number of cataract surgery

20million cases in the world and **1.5million** cases in Japan annually in 2015

Patients

R/L

IOL

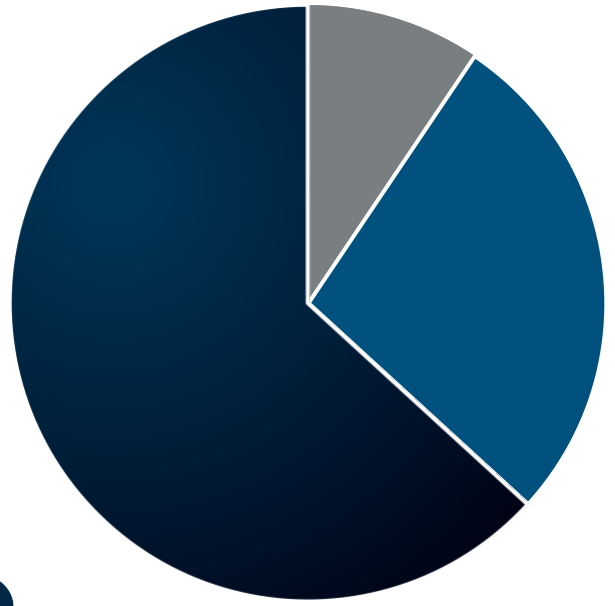
ID check

R/L check

IOL check

Surgical misidentification around the world

106 human errors, right/left errors, and IOL errors in the USA.
The frequency of occurrence is estimated to be at least **7/100,000**.



10%
Wrong Patient

29%
Wrong eye (R/L)

68%
Wrong equipment (IOL)

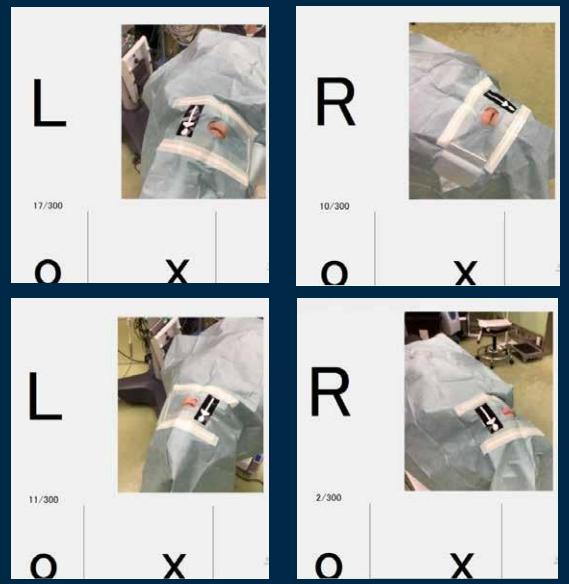
In any case, the goal should be to prevent all of these confusions.


NHK WORLD
JAPAN

Stress testing for authentication

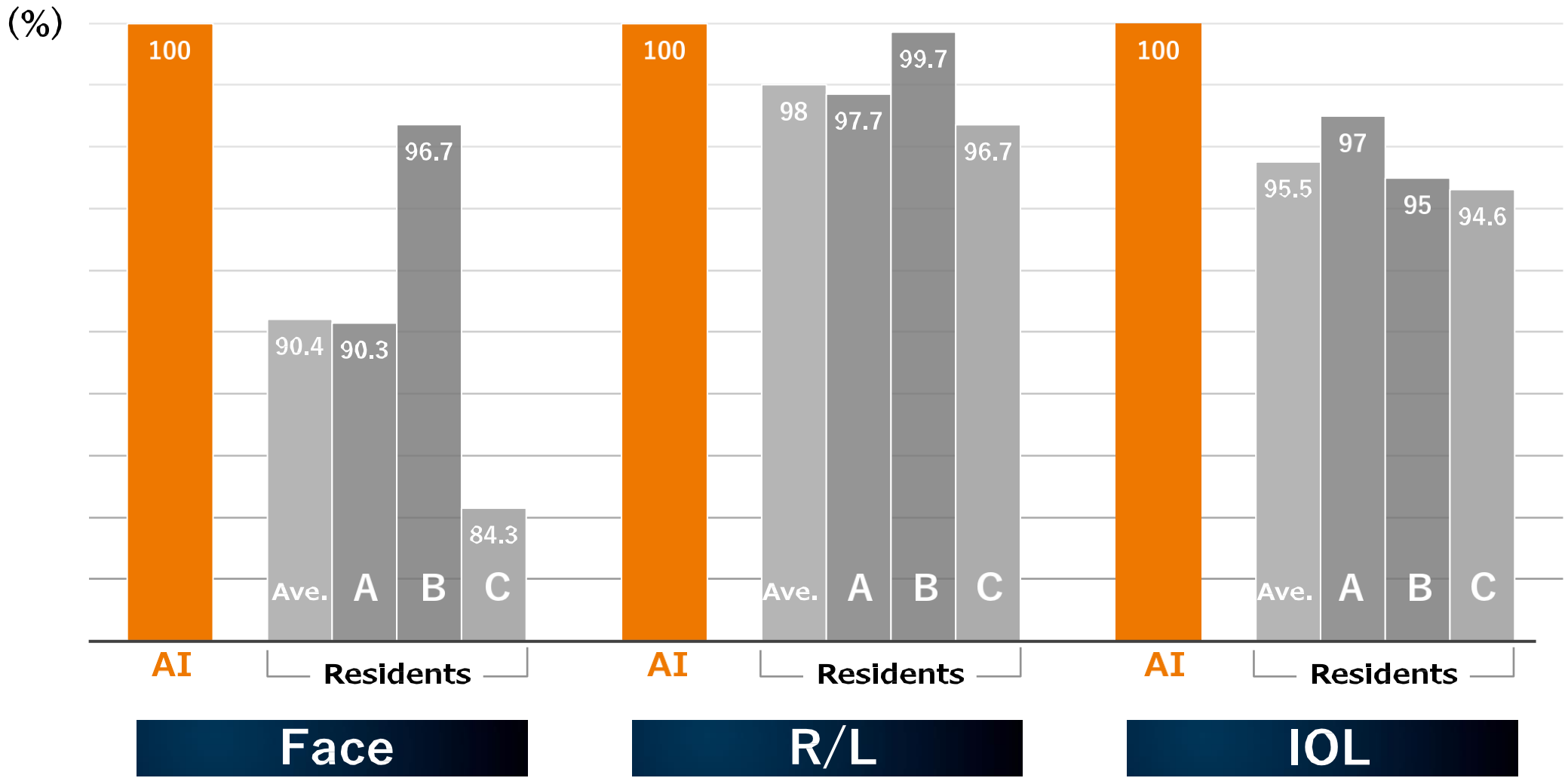
Face

R/L



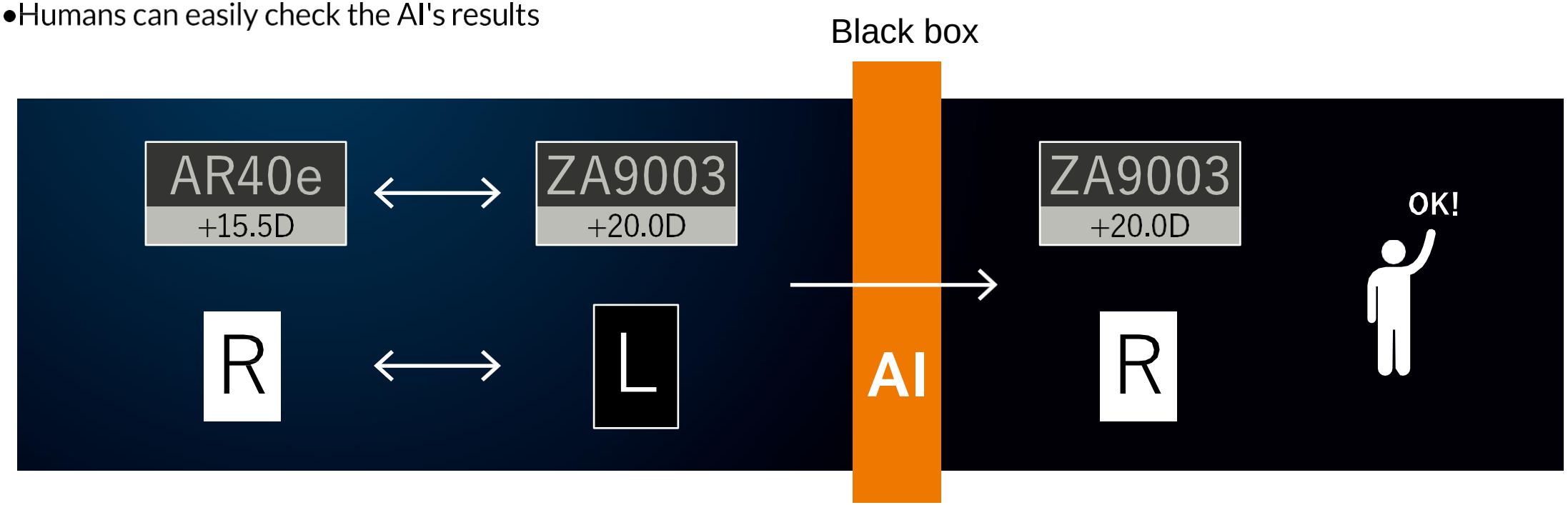
IOL

Comparison of Accuracy between AI and Residents

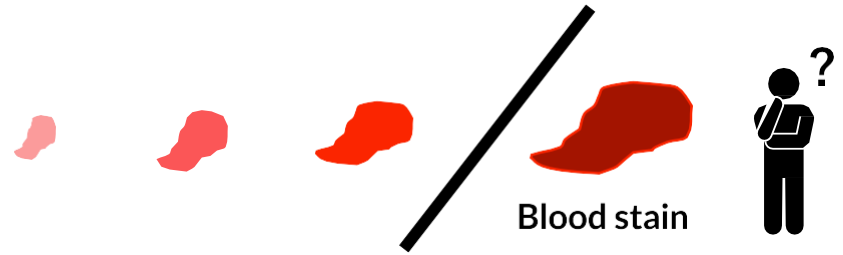


High performance with AI-based surgical safety management system

- The training dataset was high quality without any misleading images
- The tasks assigned to AI were clear and distinct, avoiding ambiguous questions
- Humans can easily check the AI's results

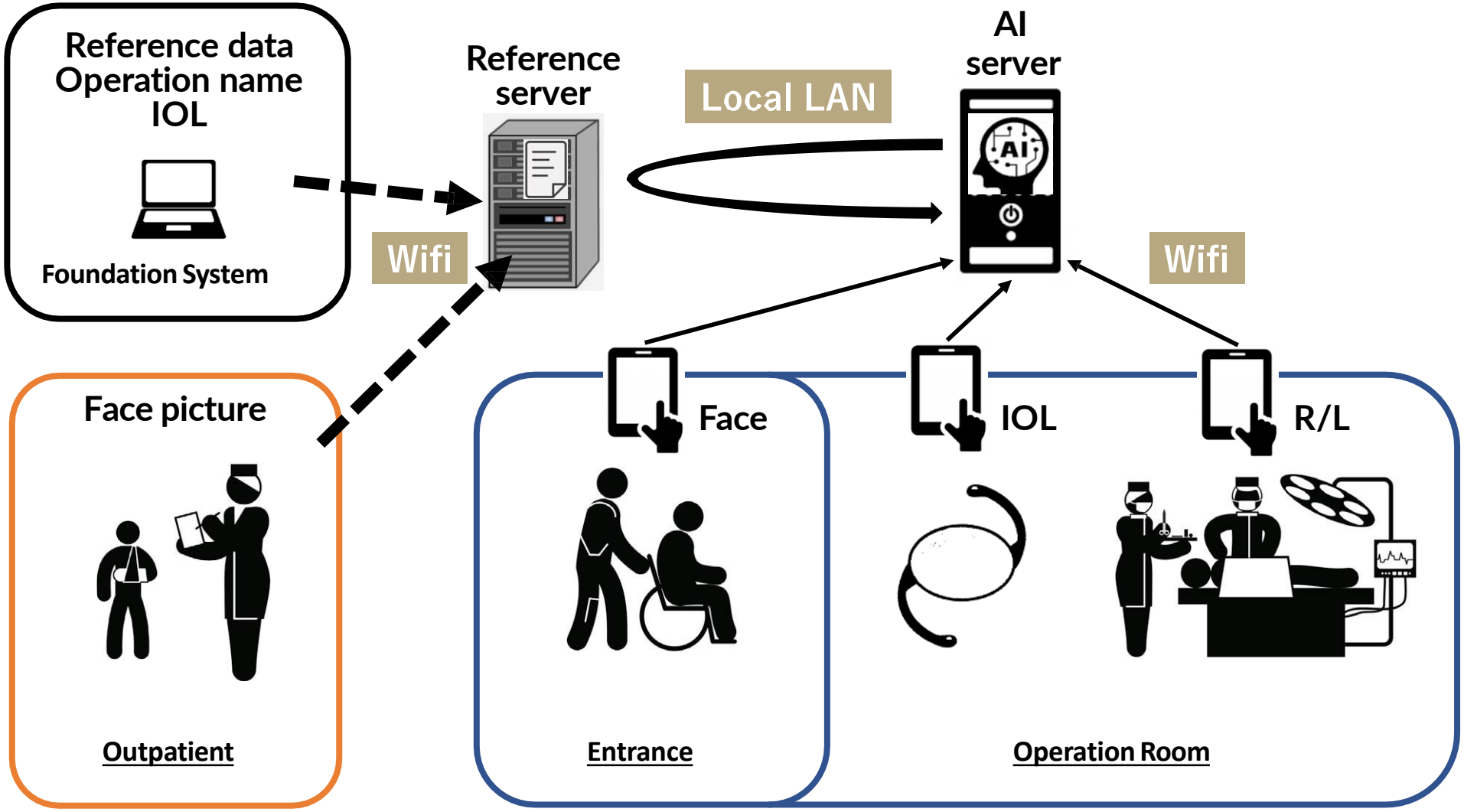


Application of Deep Learning AI

	Surgical Safety AI		Diagnostic AI
	 		
	Discrete	Dataset	Continuous
	Obvious	Borderline	Ambiguous
	×	Bias	○
	Simple	Interpretation	Complex
	Acceptable	Black box nature	Problematic
	Suitable		

Introduction period

System Flow Diagram



Introduction period

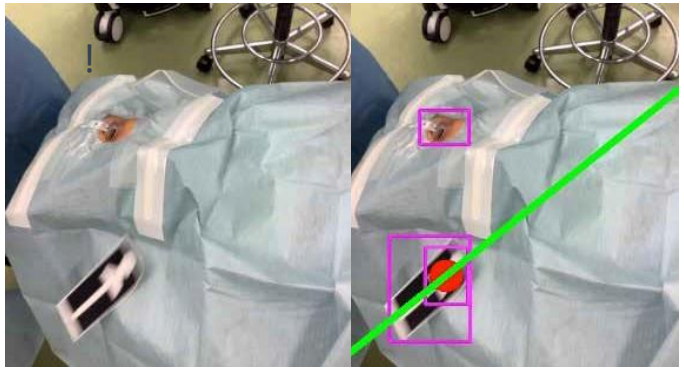
- The introduction period was from March 4, 2022, to June 18, 2022, and there were 1,940 cases involved.
- The authentication process was conducted as routine work by 15 outpatient nurses, 18 operating room nurses, 6 orthoptists, and 22 doctors.
- Meetings with relevant parties were scheduled monthly to check the status and provide feedback.
- The end points were the the authentication success rates by the AI system.

Typical image defects for authentication (IOL authentication).

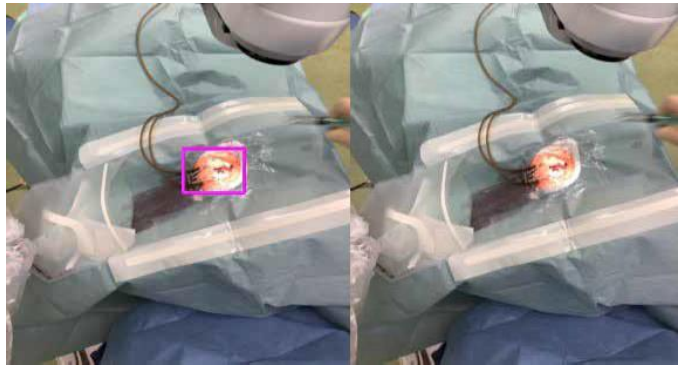
Extending beyond the screen

Out of focus

Typical image defects for authentication (Left-right authentication)

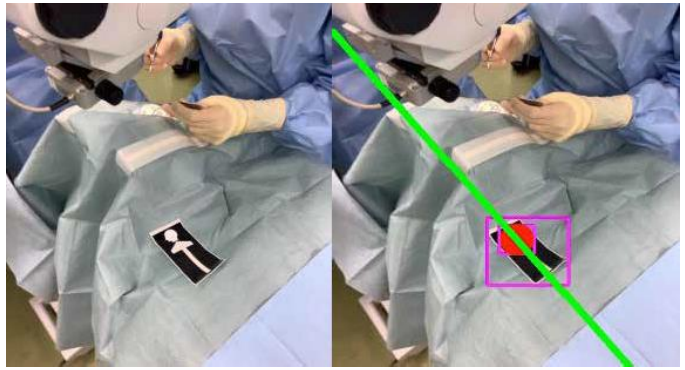


Position of the arrow sticker



The sticker is missing

Eye not detected



Position of the sticker & eye not detected

Two Cases of AI Deterrence in Intraocular Lens Mix-up

No.1

In the first authentication attempt, intraocular lenses prepared and photographed were for **a different surgeon and operating room.**

First preparation

YP2.2R	(20.5D)
NX-60	(21.0D)

AI Judge

AI Judge

Second preparation

XY1-SP	(18.0D)
X-70S	(17.0D)

No.2

In the first authentication attempt, intraocular lenses prepared and photographed were for the same surgeon and operating room, but for the subsequent surgery.

First preparation

YP2.2R	(18.5D)
X-70S	(17.5D)

AI Judge

AI Judge

Second preparation

YP2.2R	(17.5D)
X-70S	(17.0D)

Two Cases of Left-Right Discrepancy (AI system Not used)

Left eye Botox-injection

despite the timeout called by the nurse, invasive actions proceeded.

Right eye Eyelia-injection

In this case, the surgical drape was mistakenly placed over the opposite eye, and an injection attempt proceeded in this incorrect setting.

- **Post May 19, the policy has been updated to impose penalties for non-compliance.**

Obstacles to applying the AI system revealed during introduction period

- Presence of uncooperative doctors
- Lack of understanding of operations by implementers (surgical nurses/doctors)

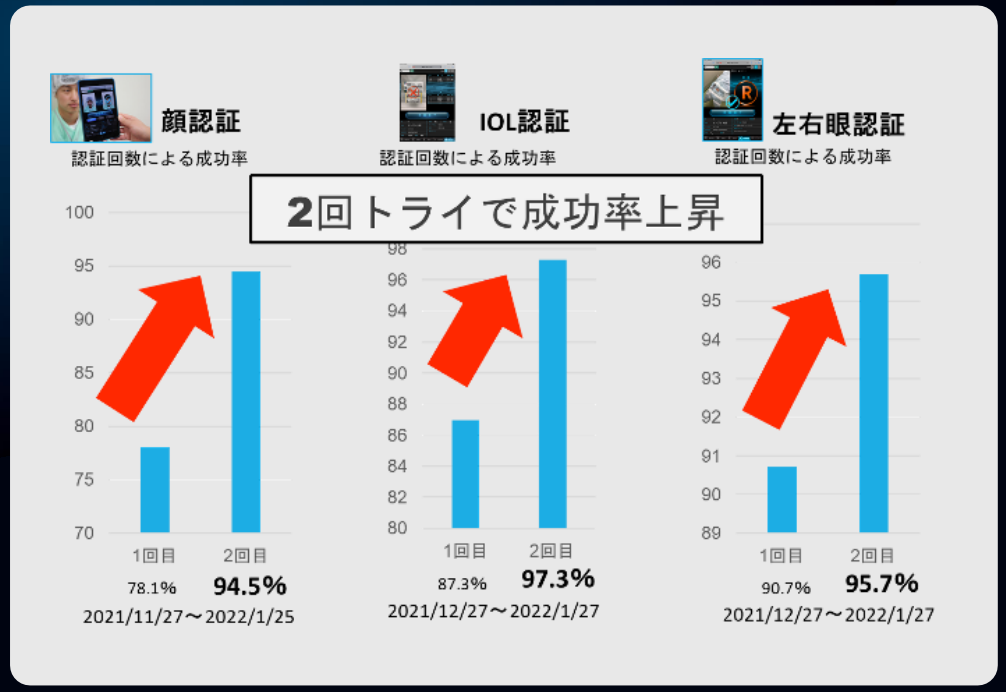
Identifying doctors resistant to the AI system

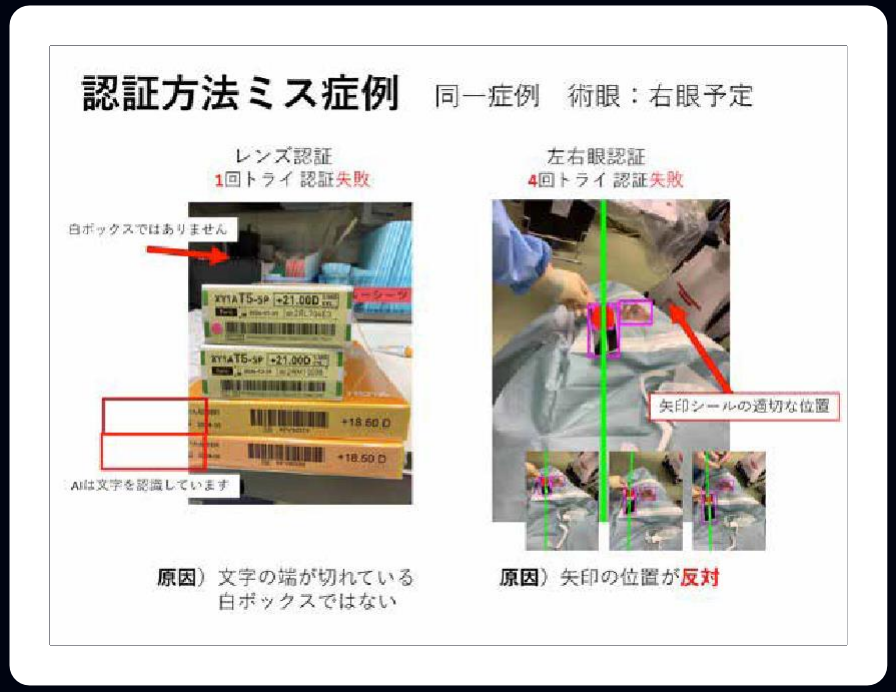
Cases without AI authentication (Initial phase of the introduction period)

Face authentication 7cases	Dr. B: 2 cases, Dr. E: 1 case, Dr. A: 1 case
Face authentication 56cases	Dr. A: 23 cases, Dr. D: 16 cases, Dr. C: 4cases
Face authentication 184cases	Dr. A: 32 cases, Dr. B: 31 cases, Dr. C: 23 cases

- There was a higher trend of non-implementation or failure rate with specific doctors.
- Orthoptists provided support in the operating room when the specific doctors were involved.

Information sharing and education for staff

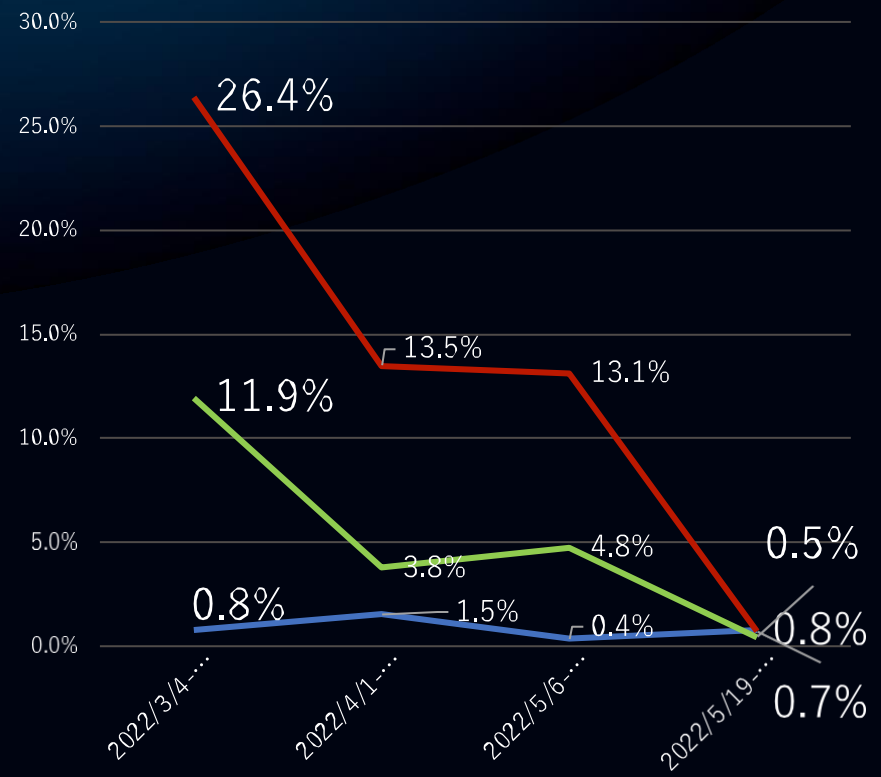




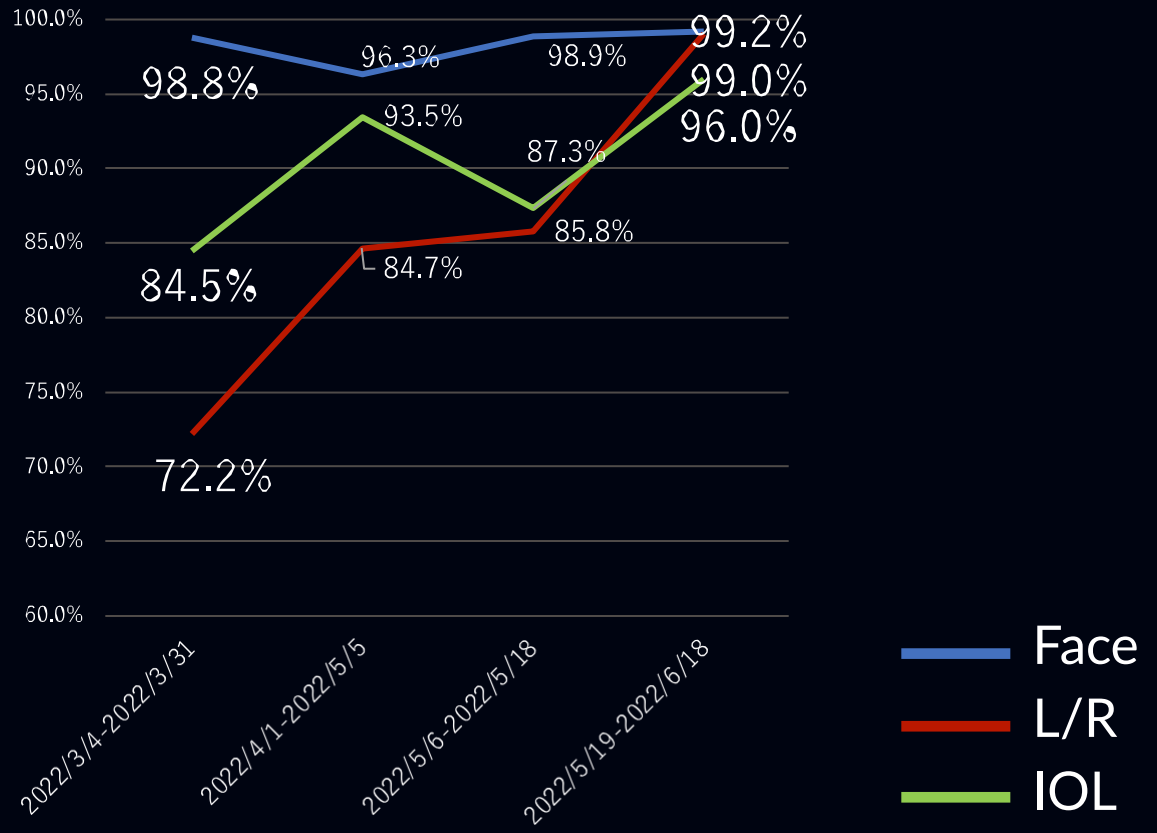
Regular analysis of implementation logs, prompt issue-addressing with on-site staff, and graphical sharing of key insights helped improve authentication success rates.

Improvement in the non-implementation rate and enhancement of the authentication success rate.

Trend in non-implementation rate



Trend in authentication success rate



Summary of the AI system outcomes during introduction period

- ✓ In the absence of AI implementation, 2 cases out of 1940 resulted in medical errors, accounting for a 0.103% error rate.
- ✓ With AI implementation, 2 cases out of 1066 (possible IOL authentications) were deterred, reflecting a 0.19% error deterrence rate.

Incidence rate: (2+2)/1940 = 0.21%

↕

Trans Am Ophthalmol Soc 2007

At least 0.0069% ~ Max0.069%

High likelihood of incomplete understanding of authentication errors

One year of implementation

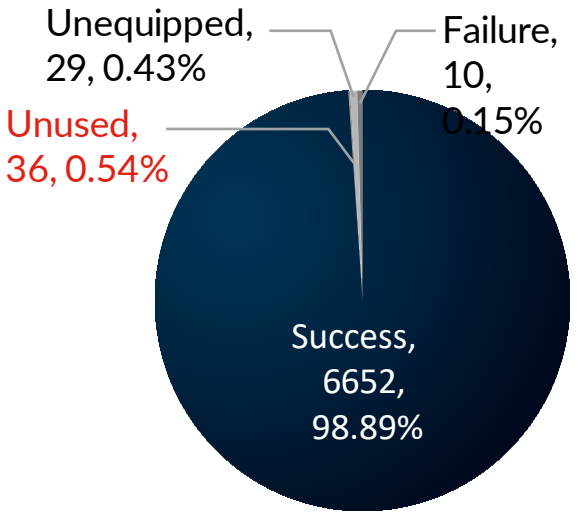
Social Implementation Verification

- Duration: May 19, 2022 to May 18, 2023
- The certification process was carried out as routine work, with 15 outpatient nurses, 18 operating room nurses, 6 orthoptists, and 22 doctors involved, depending on the situation.

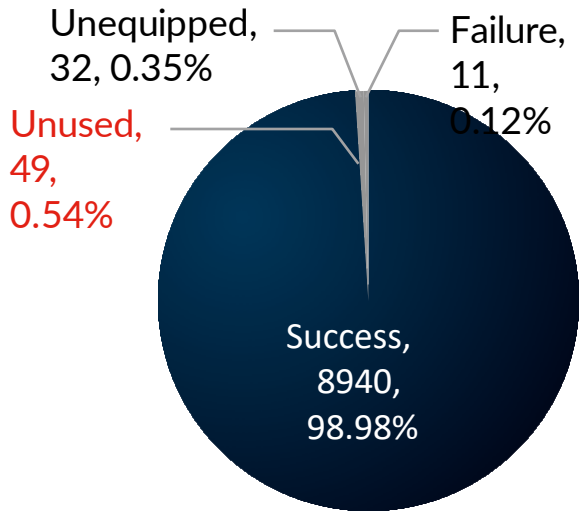
Over the year, these 61 medical staff managed the practical operation.

In a year, a total of 20,421 authentication were conducted across 9,021 cases.

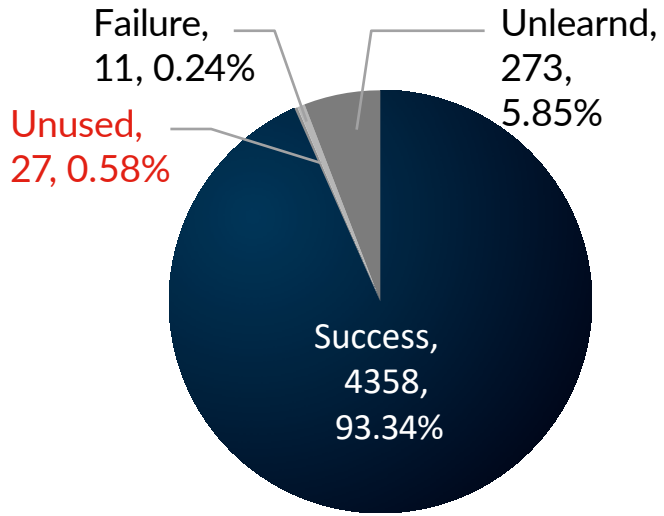
Face
Total 6727 cases



L/R
Total 9021 cases



IOL
Total 4673 cases



The implementation rates among authenticatable cases

99.5%

99.5%

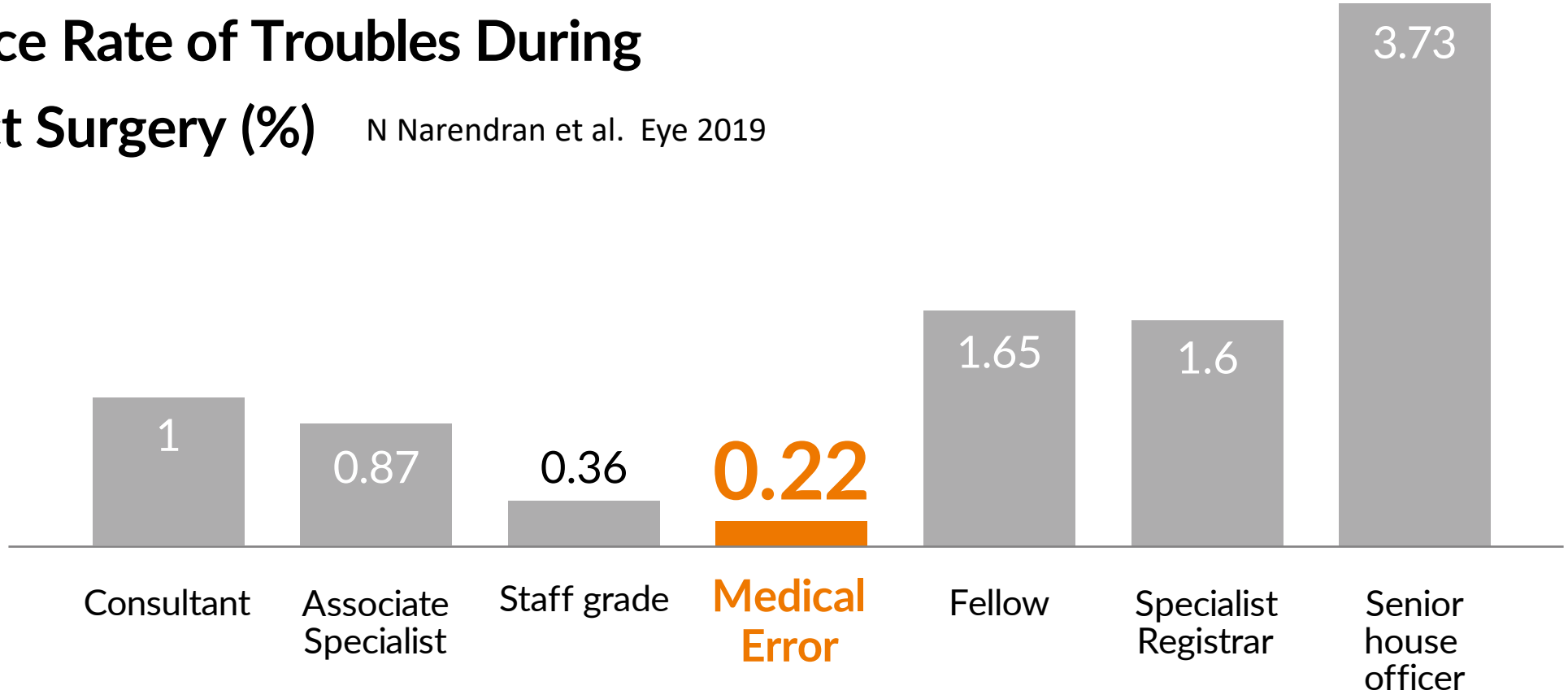
99.4%

Rates of errors detected by AI among 9021 cases

The incidence rate of 0.22% cannot be considered small

Incidence Rate of Troubles During Cataract Surgery (%)

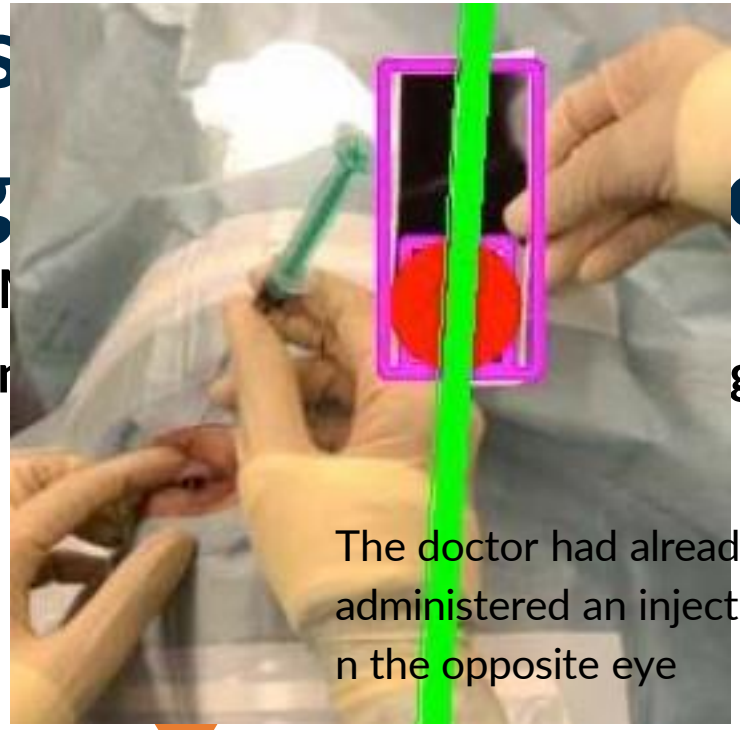
N Narendran et al. Eye 2019



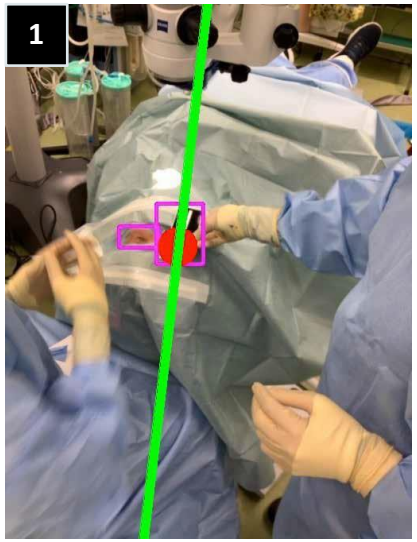
AI systems
everything
e making decisions.

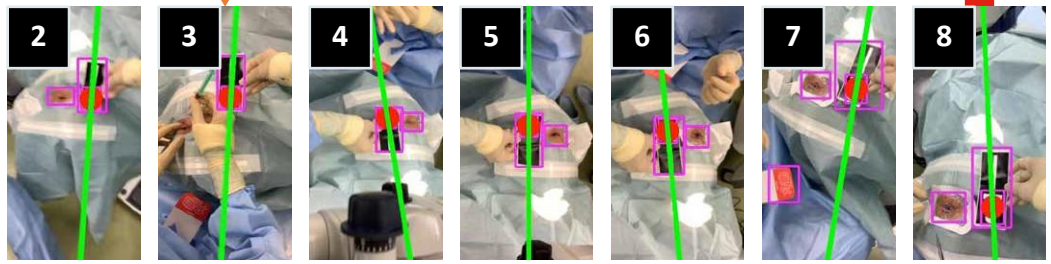
An ERM case,77y.o.M 5 Staffs (1 Dr and 4 Ns)

Finally, the AI auther gment agreed on the 10th try.



The doctor had already administered an injection n the opposite eye

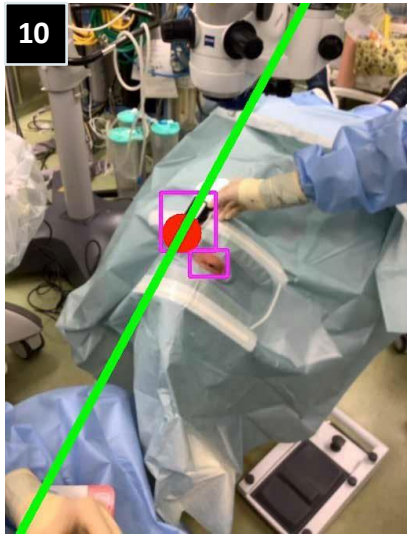




74 seconds

At this point, the clean cloth was corrected to the left and right.

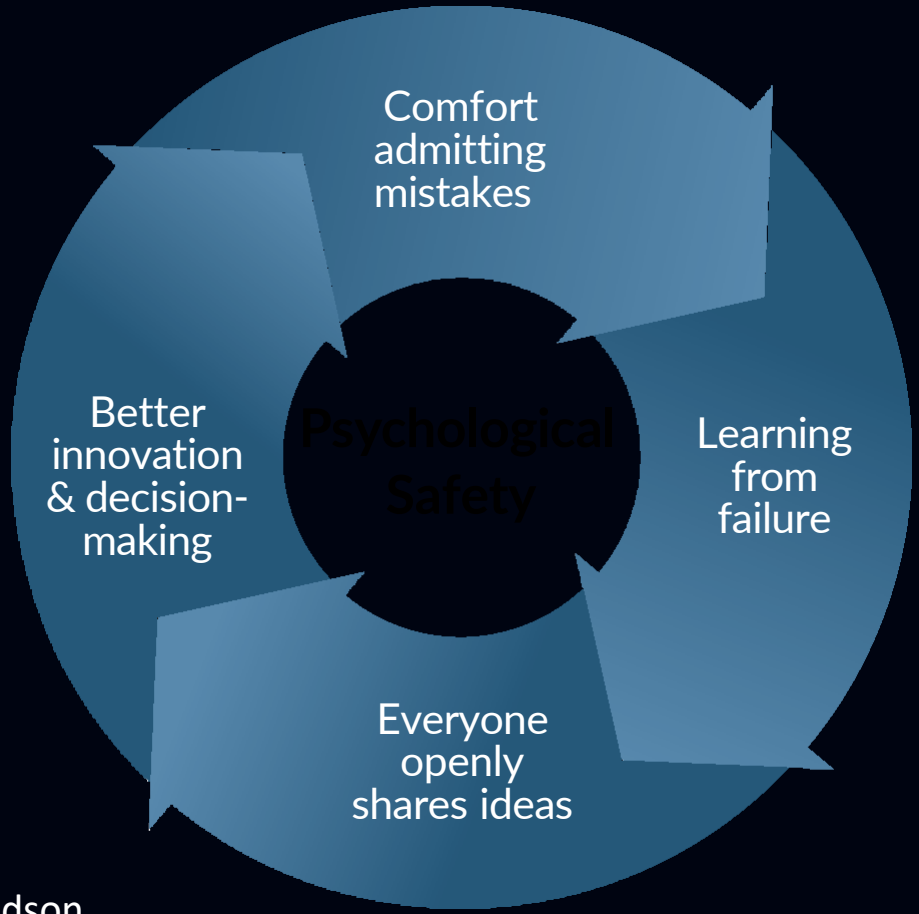
Poor quality of the authenticated photos



The nurse couldn't tell the doctor this error while AI continuously pointed out the error.

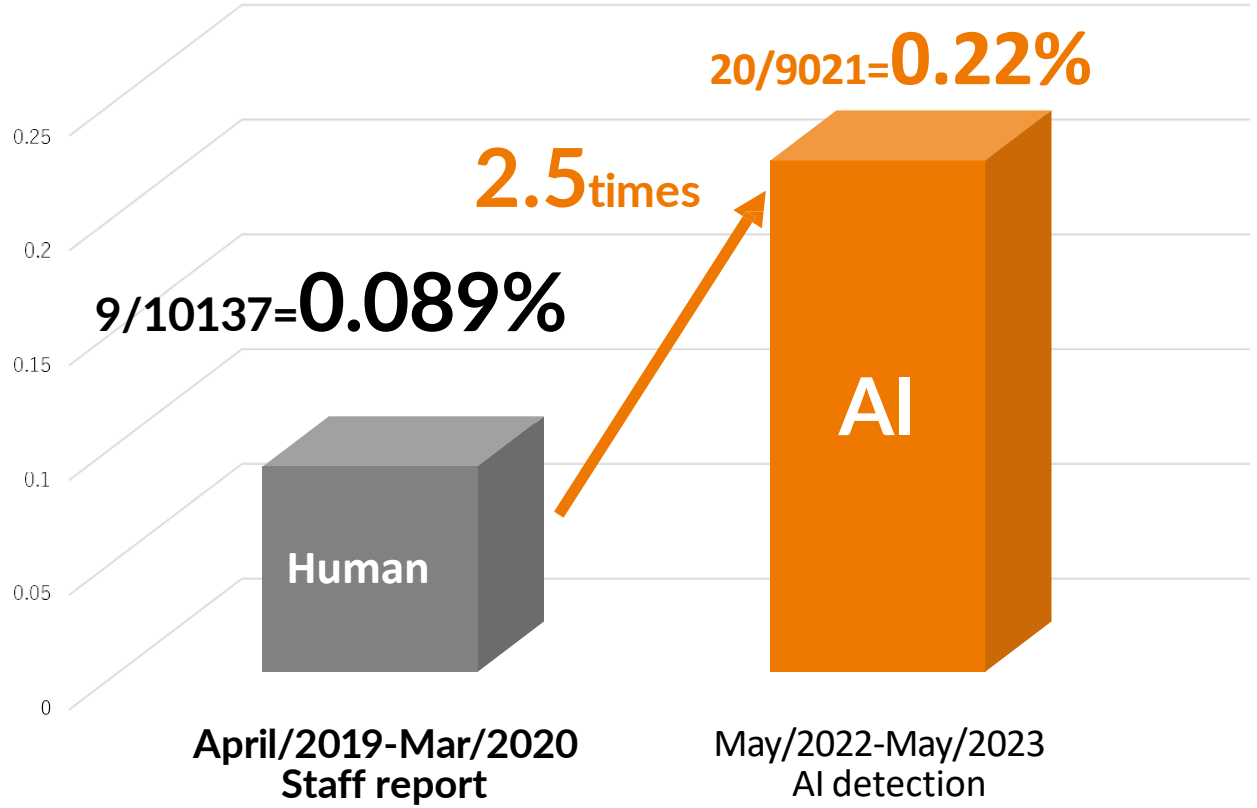
Psychological safety
(not blaming for mistakes)
is a major principle
of medical safety.

Under psychologically hazardous workplace conditions, the number of reported errors is suppressed.



Amy C Edmondson

Our AI detected more than double the errors of traditional reporting.



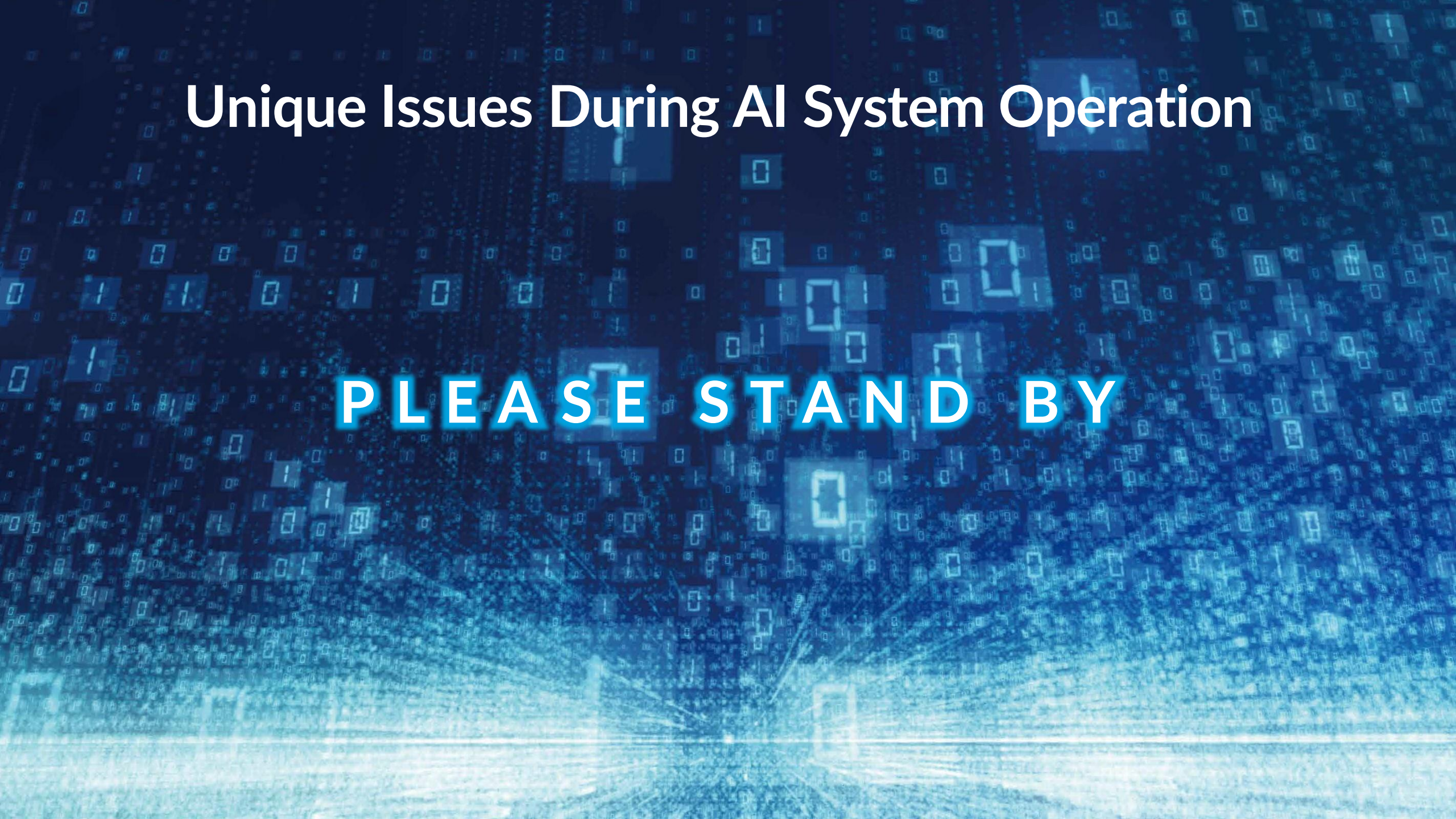
That's why the situation has not improved even after 16 years.

- In the United States, the number of deaths from medical errors is higher than that from traffic accidents (BMJ 1996).
- Medical errors are the third leading cause of death in the United States (BMJ 2012).

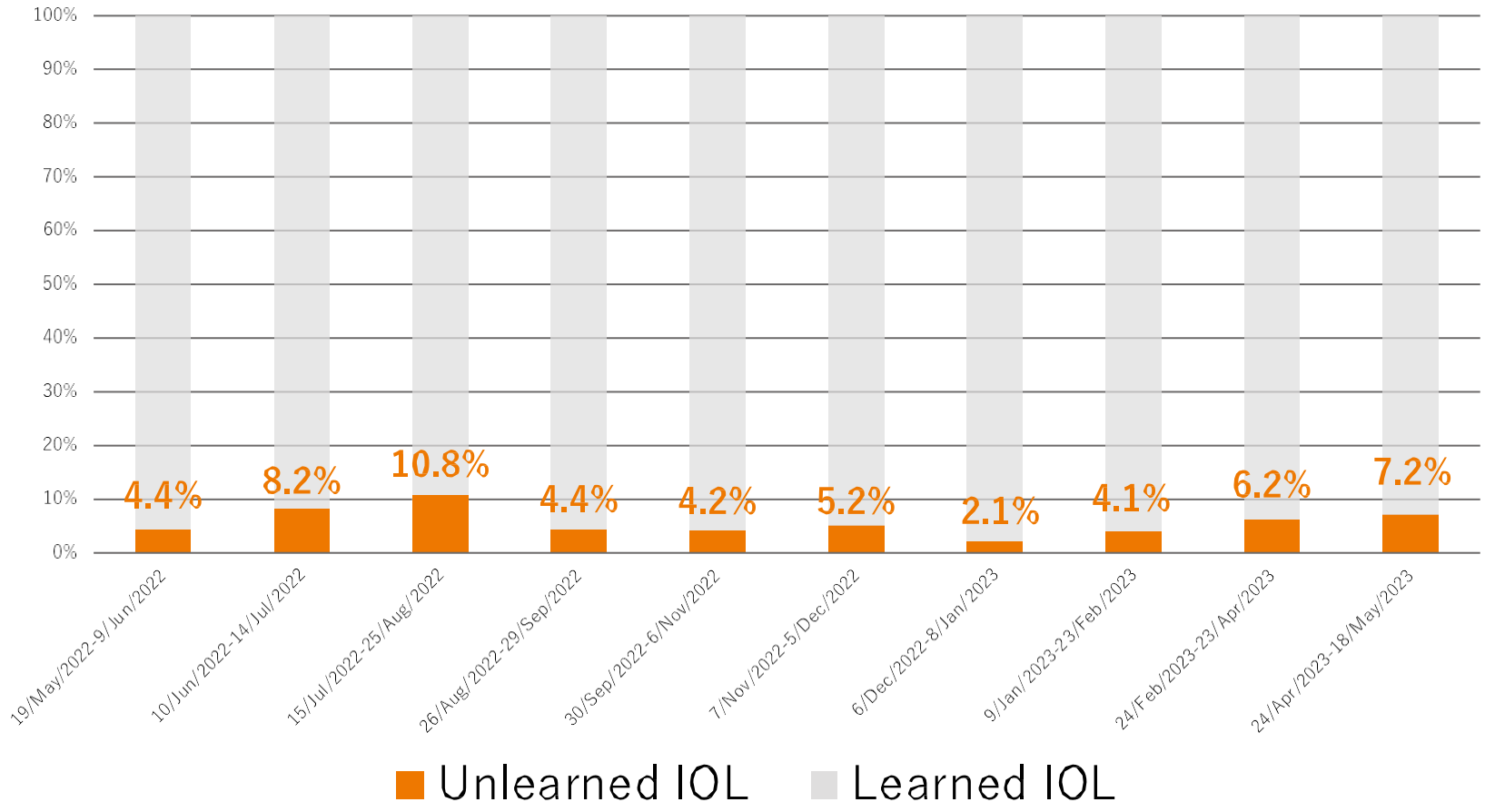
✓ The improvement cycle needs accurate reports, which are not being done at present.

✓ AI may provide perfect psychological safety, aiding humans.

Unique Issues During AI System Operation



On average, 5.8% of the IOLs used were unlearned.



In addition, partial network failures occurred over the course of 2 days, rendering 21 out of 20,421 certifications unimplementable.

0.1%

Five conclusions

- ✓ Deep Learning surpasses human performance in ensuring medical safety.
- ✓ On-site user comprehension was crucial during AI implementation.
- ✓ AI identified and corrected more errors than anticipated.
- ✓ In psychologically hazardous environments, some issues remained unresolved despite AI intervention.
- ✓ A distinct challenge in AI operation is the learning task.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Thank you