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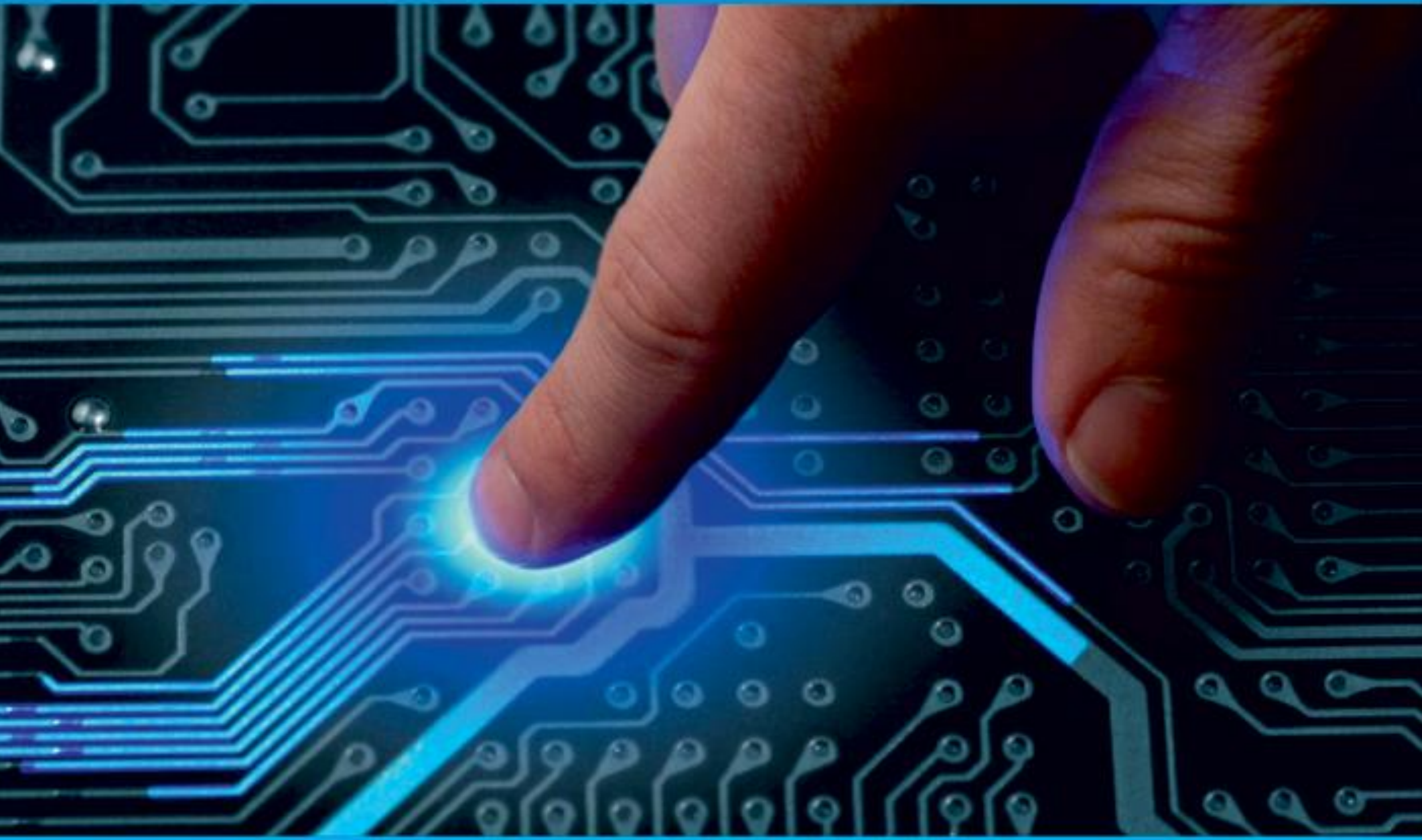

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Advancing Artificial Intelligence: Transforming the Future of Diabetic Retinopathy Diagnosis

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ABSTRACT: Diabetic retinopathy (DR) is a leading cause of blindness in adults, necessitating accurate and timely staging to prevent disease progression and vision loss. Traditional methods of DR staging rely on manual assessment by ophthalmologists, which can be subjective and prone to variability. In recent years, artificial intelligence (AI), particularly deep learning, has shown significant potential in enhancing the accuracy and efficiency of medical diagnoses. This study explores the application of deep learning algorithms to the staging of diabetic retinopathy, aiming to develop a robust and automated system for clinical use.

Purpose

Disease staging involves assessing the severity or progression of a disease, which is crucial for selecting appropriate treatments. In diabetic retinopathy, staging using a comprehensive retinal area is more desirable than using a limited one. We investigated whether deep learning artificial intelligence (AI) could be employed to grade diabetic retinopathy and assist in determining treatment and prognosis.

Methods

The retrospective study analyzed 9,939 posterior pole photographs of 2,740 patients with diabetes. Nonmydriatic 45° field color fundus photographs were taken of four fields in each eye annually at Jichi Medical University between May 2011 and June 2015. A modified fully randomly initialized Google Net deep learning neural network was trained on 95% of the photographs using manual modified Davis grading of three additional adjacent photographs. We graded 4,709 of the 9,939 posterior pole fundus photographs using real prognoses. It helps to analyze the posterior pole fundus.

Results

The PABAK to modified Davis grading was 0.64 (accuracy, 81%; correct answer in 402 of 496 photographs). The PABAK to real prognosis grading was 0.37 (accuracy, 96%).

Conclusions

We propose a novel AI-based disease staging system for grading diabetic retinopathy, utilizing retinal areas not typically visualized on fundoscopy. Additionally, we introduce another AI that directly suggests treatments and determines prognoses.

I. INTRODUCTION

Deep learning, a branch of the evolving field of machine learning, has advanced significantly in recent years. In 2012, a deep convolutional neural network, Alex Net, demonstrated increased accuracy in the classification of high-resolution images. In 2014 and 2015, similar models, including Google's Google Net and Microsoft's Reset, surpassed human accuracy in image recognition. Disease staging involves grading the severity or progression of illness to enhance treatment decisions and prognosis prediction. To ensure reproducibility, disease staging relies on clear, verbalizable observations. Additionally, skilled physicians gather insights from patients' non-verbalizable or unclear observations. However, disease staging is generally more accurate than these impressions due to human inconsistencies caused by factors such as exhaustion or fluctuating blood-sugar levels. This is not an issue with AI.

In our practice, we use the modified Davis staging (Table 1). Since diabetic retinopathy progresses from simple diabetic retinopathy (SDR) to pre-proliferative retinopathy (PPDR) to proliferative diabetic retinopathy (PDR), it is necessary to perform ocular pan retinal photocoagulation in cases of PDR (Fig 1A).

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Skilled physicians infer strongly negative impressions from some single SDR conventional photographs—when some features of PDR are predicted to be outside a 45˚ angle to the posterior pole, indicating poor prognosis—and weaker impressions from other SDR single conventional photographs—when no features of PDR are predicted to be outside the 45˚ angle.

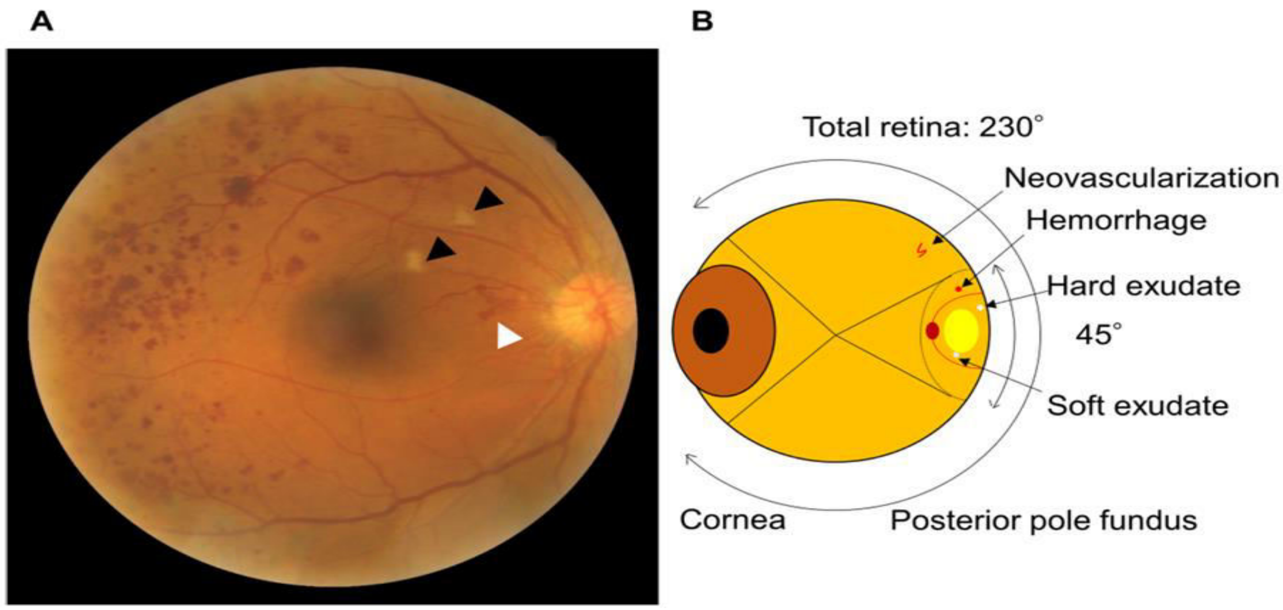

Fig 1. A fundusphotographandschemaofaneyeball

Here, we show an AI that grades diabetic retinopathy involving a retinal area that is not normally visible on fundus photography using non-verbalizable features that resemble impressions. The AI has greater accuracy than conventional staging and can suggest treatments and predict prognoses. Our proposed AI disease-staging system can recommend treatments or determine prognoses from both verbalizable and non-verbalizable observations. We believe that this staging sys tem will promote disease staging by helping to improve disease outcomes.

Methods
1. Study design
2. IRB approval

II. MATERIALS

The materials used in this study included color fundus photographs of four fields at 45 degrees, obtained using a fundus camera (AFC 230; NIDEK Co., Ltd., Aichi, Japan). These photographs were graded using the modified Davis grading system (Table 1). The dataset comprised 6,129 photographs of no diabetic retinopathy (NDR), 2,260 of simple diabetic retinopathy (SDR), 704 of pre-proliferative diabetic retinopathy (PPDR), and 846 of proliferative diabetic retinopathy (PDR). The grader was not informed that the grading would be used in this study. The original photographs had a resolution of 2,720 × 2,720 pixels. Due to variations in the number of images in each group, the accuracy (sensitivity) value of the predictions is not useful on its own. The accuracy value tends to be high and is only meaningful when comparing different AIs or graders. Similarly, the normal Fleiss' kappa value is of limited use due to these variations. Therefore, the prevalence- and bias-adjusted kappa (PABAK) was calculated as the main outcome measure instead.

Grading including unseen areas
We trained a modified Google Net deep convolutional neural network with 9,443 45 poste rior pole color fundus photographs using manual staging with three additional color photo graphs (AI1; Fig 2). We also trained the neural network with the same photographs using manual staging with only one original photograph (AI2; Fig 2). To maximize training sets, only 496 of the 9,939 photographs were randomly chosen (5%) for cross-validation three times from the eyes that were photographed only once.

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Grading using actual prognoses

Patients with SDR and higher staging were recommended for a second medical checkup. They underwent pan-fundus ophthalmoscopy. Patients with suspected PDR also underwent fluorescein angiography while those with PDR received pan retinal photocoagulate. Eyes with PDR and vitreous hemorrhage, fibro vascular proliferative membrane, or traction retinal detachment underwent vasectomy.

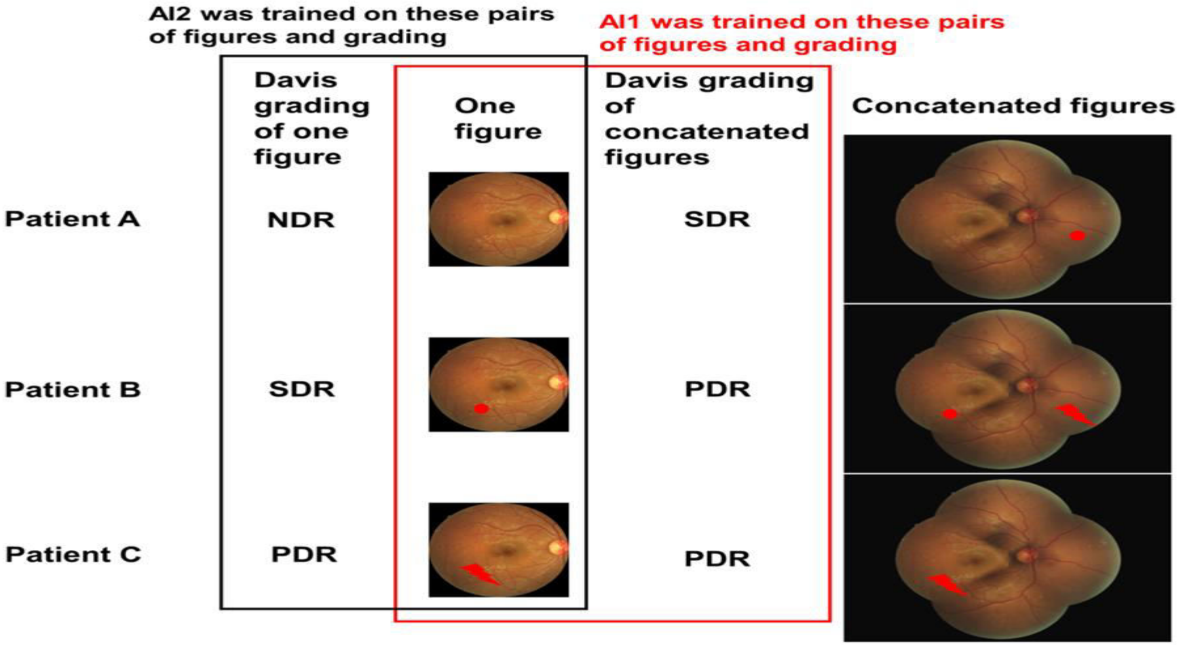

Fig 2. Two training methods and a three-patientmodel.

The remaining visual acuity represents visual prognosis within 0.2 logMAR after 6 months. Among the 4,709 photographs, 95% were used to train the neural network and 5% were used for validation; these photographs were randomly chosen from all grades at equal rates.

Table 2. Grading by actual prognosis.

Grading	Needed treatments	When	Prognosis	No. of 4709	NDR	SDR	PPDR	PDR
0	None	Next visit	All	4445	2479	1289	333	344
1	DME treatments			12	0	5	1	6
2	PRP		Improve	20	1	2	14	3
3			Stable	6	1	1	0	4
4			Worsen	0	0	0	0	0
5	Vitrectomy		Improve	2	0	0	0	2
6			Stable	4	0	0	0	4
7			Worsen	2	0	0	0	2
8	DME treatments	Current visit	All	16	0	0	7	9
9	PRP		Improve	108	0	0	40	68
10			Stable	31	0	1	5	25
11			Worsen	29	0	0	9	20
12	Vitrectomy		Improve	10	3	0	0	7
13			Stable	16	0	0	1	15
14			Worsen	8	0	0	0	8

DME, diabetic macular edema; PRP, panretinal photocoagulation.

III. RESULTS

Grading including unseen retinal areas

A representative fundus photograph was graded as SDR in one photograph (Fig 3A) but as PDR in four photographs (Fig 3B). We compared the visualization of the conv2/norm2 layer of Google Net trained with either one or four photographs. Neural networks trained on a single photograph visualized the image with higher frequency compared to those trained on four photographs (Fig 3C and 3D). The one-photograph-trained neural network could detect small retinal hemorrhages and hard exudates. In contrast, the four-photograph-trained neural networks suggested likelihood

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values of 28%, 26%, 23%, and 23% for NDR, SDR, PPDR, and PDR, respectively. The one-photograph-trained neural network suggested likelihood values of 1% for NDR and 99% for SDR. Thus, neural networks trained on four photographs are more useful than those trained on one photograph and can grade diabetic retinopathy involving retinal areas not visualized in a single photograph.

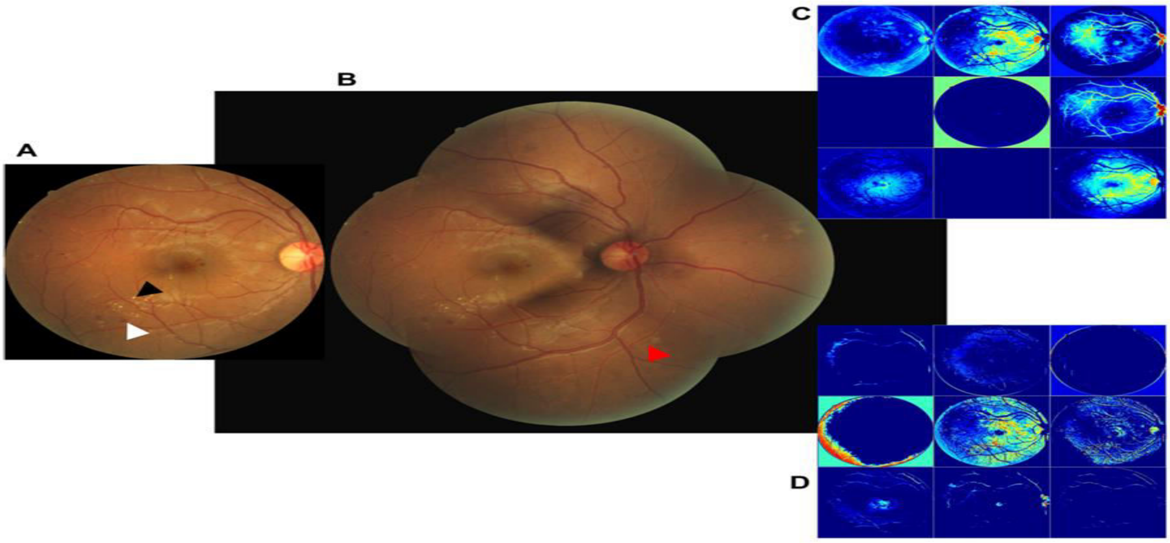

Fig3.TherepresentativefundusphotographwhichwasgradedasSDRinonephotographbutPDRinfourphotographs.

Grading using actual prognosis

Atotal of 4,709 posterior pole color fundus photographs were graded to 0±14. The grading cri teria were as follows: ªnot requiring treatmentº, ªrequiring treatment at the next visit.

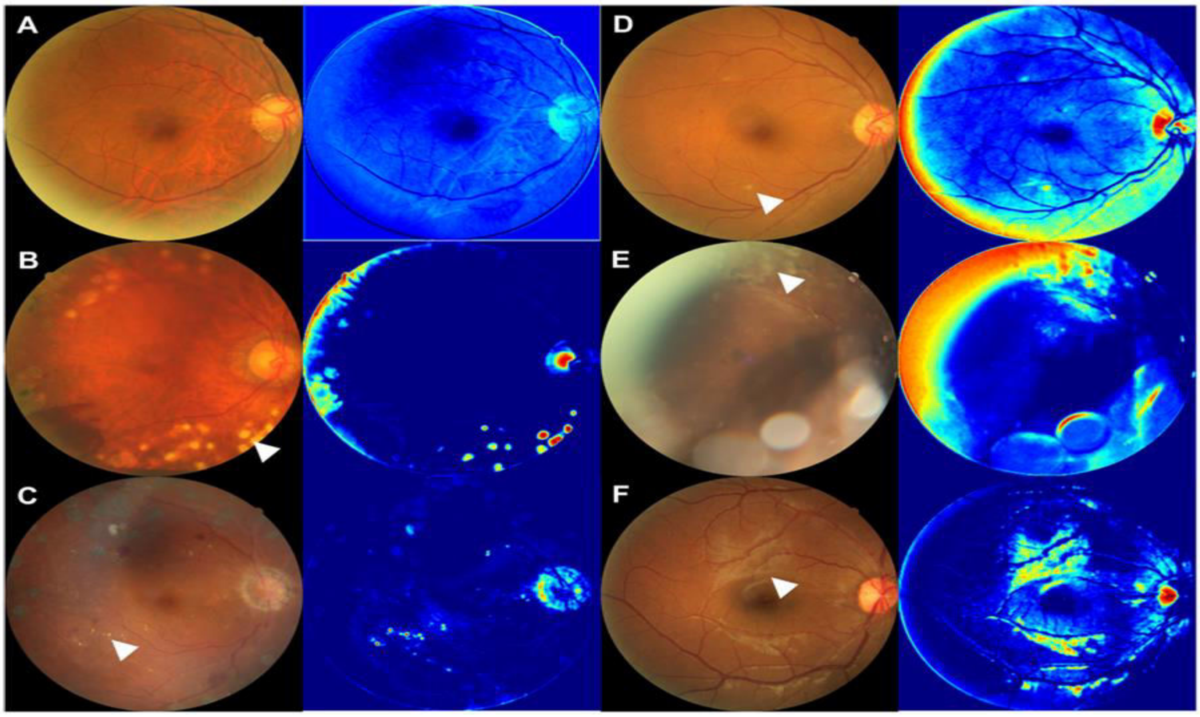

Fig 4. The images from the middle layer of the neural network.

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The modified Google Net was trained using 95% of the graded photographs. The PABAK of the trained neural network was 0.98 (mean accuracy, 96%) in the 224 photographs that were not used in the training phase. The PABAK of the traditional modified Davis staging was 0.98 (mean accuracy, 92%) in the same 224 photographs. The three retinal specialists (HT, YA, and YI) had PABAKvalues of 0.93 (mean accuracy, 93%), 0.92 (mean accuracy, 92%), and 0.93 (mean accuracy, 93%), respectively. The trained neural network was significantly more precise and consistent than the traditional grading (overall $P < 0.0001$): HT ($P = 0.018$), YA ($P = 0.0067$), and YI ($P = 0.034$) (two-sided paired t-test).

IV. DISCUSSION

The convolutional neural network Google Net was originally created for general image classification of 256 × 256 pixel images, but it has been found to be useful for classifying larger images, such as the 1,272 × 1,272 pixel images used in our first experiment. In our preliminary experiments, Alex Net did not achieve high accuracy, and Reset could not handle large images due to the 12 GB memory limitation of the graphical processing unit, restricting it to 256 × 256 pixel images and resulting in low accuracy (data not shown).

In our study, surface reflection of the retina was enhanced in 2 out of 20 PDR images (Fig 4F). Surface reflection has not previously been reported as a criterion for diabetic macular retinopathy (DMR). It is thought to be influenced by thickening of the internal limiting membrane, which has been reported in PDR but not used in grading. Although surface reflection is often seen in very young people, it is clear and not coarse. It is challenging to use reflection as a criterion for DMR because of the difficulty in distinguishing between clear and coarse reflections. Nonetheless, these findings suggest that deep learning might be a useful tool for detecting novel classification criteria.

In the second experiment, human judges found it difficult to grade images from 0 to 14 due to the lack of clear criteria. This lack of clear criteria is not a problem for machine learning. Most patients with PDR did not need treatment (Table 2) because the eyes that had previously undergone pan fundus photocoagulation were graded as having PDR.

V. CONCLUSION

We proposed a novel AI-based disease staging system that grades diabetic retinopathy using retinal areas not typically visualized on fundoscopy, along with another AI that directly suggests treatments and determines prognoses.

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