Diabetic retinopathy screening with artificial intelligence

A pivotal experience in the Italian Healthcare System

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Setting and venue

ASL TO 5 is a Local Health District of the
Turin Metropolitan Area with 310 315 residents.

ASL TO5 performed an integrated care pathway
dedicated to diabetic retinopathy.

The clinical pathway develops technological improvements,
like retinopathy screening with artificial intelligence.

The retinal images were acquired in a primary care setting
(District of Moncalieri) by trained nurses.

Methods

Diabetic patients were enrolled for a prospective observational study attending their annual visit. Participants were aged 18 years or older with a diagnosis of diabetes mellitus type 1 or 2.

All patients provided written informed consent. Retinal images were obtained with a true-color confocal, fully automated non-mydriatic fundus camera (iCare DRSplus® by Centervue Spa, Italy) without participants undergoing pupil dilatation.

Two photographic image fields were taken of each eye, one centered on the optic disc and the other one on the macula. Afterward the images were sent through a digital interface (iCare ILLUME by Icare Finland Oy, Finland), to the artificial intelligence (RetCAD™ by Thirona Retina BV, The Netherlands). Instantly iCare ILLUME provides a report available on a personal computer or even on a smartphone.

Data security and privacy met the highest standards.

An ophthalmologist graded the images. The evaluation was patient level: the eye with the most severe grading was the reference standard for DR, while the highest RetCAD score was the AI's DR grading. The classification by human grader and RetCAD™ were compared.

Images with insufficient quality for clinical evaluation, those displaying less than 50% of the fundus were deemed ungradable by a human grader.

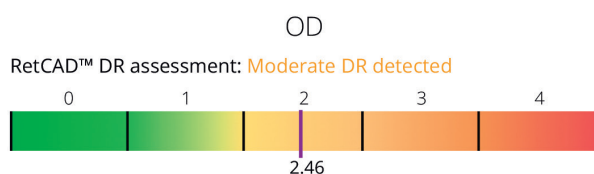# Diabetic retinopathy grading

RetCAD™

Patient information

Patient ID	mzpcVCqDqhyt
Patient Name	-
Accession No.	-

Examination date	4---0-2023
Processing date	03-04-2023

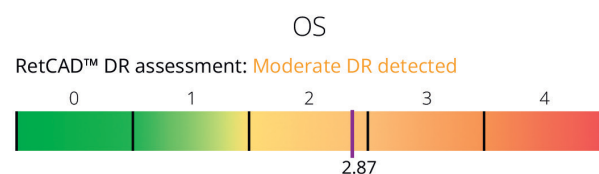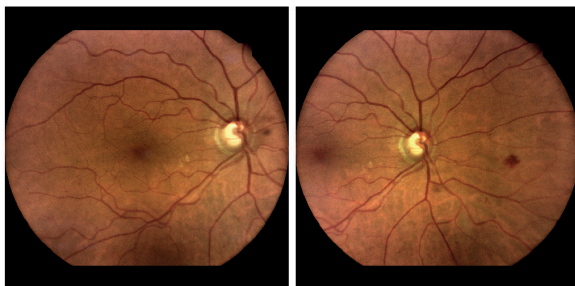## Patient recommendation

RetCAD™ outcome
More than mild DR detected.

Recommendation
Patient referral for follow-up testing is advised.

OD

RetCAD™ DR assessment: Moderate DR detected

0   1   2   3   4

2.46

Exam quality: good

OS

RetCAD™ DR assessment: Moderate DR detected

0   1   2   3   4

2.87

Exam quality: good
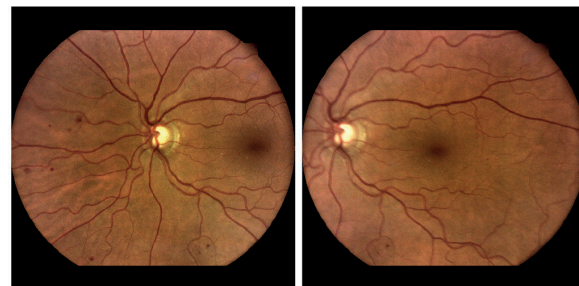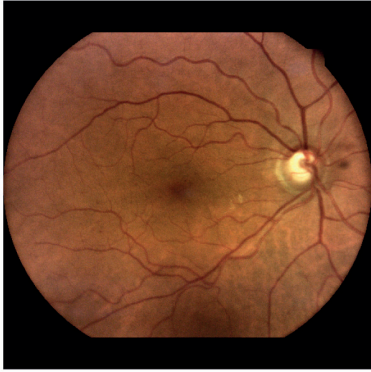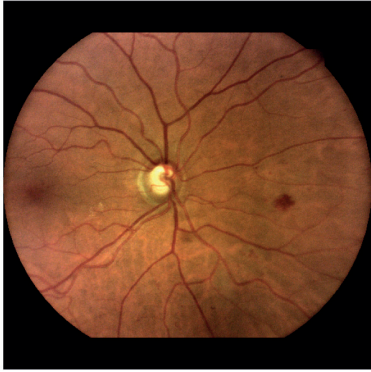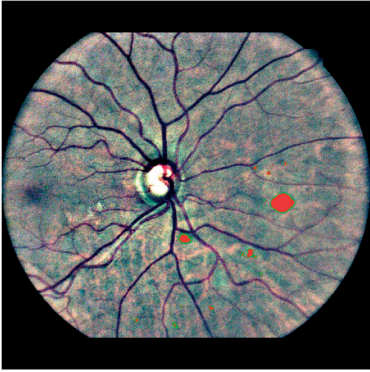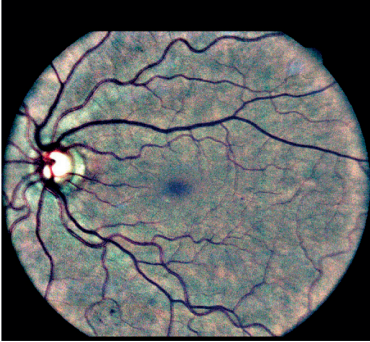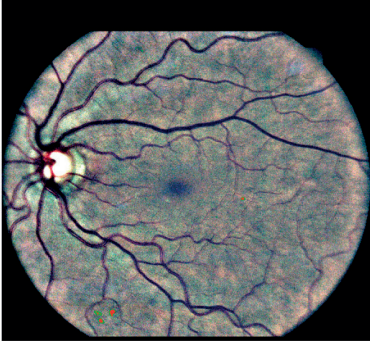
From the RetCAD report:
RetCAD score (patient level): the highest score of the
4 images is set to be the patient-level DR score.

UNGRADABLE: Images with low quality (≤ 25%) or missing macular/optic
nerve centered images.

If both images of a single eye are of poor quality, RetCAD doesn't provide
any score and the patient evaluated UNGRADABLE.

Detailed RetCAD™ analysis results

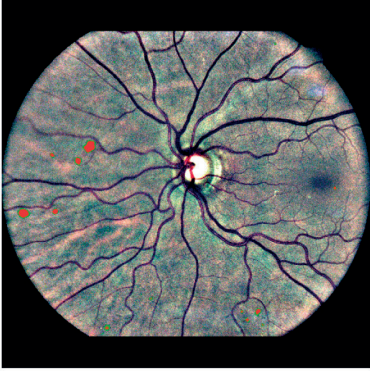| Original image	Bright lesions	Red lesions	Scores

OD

DR: 2.08
QA: 77.21

DR: 2.46
QA: 70.56

OS

DR: 2.87
QA: 74.35

DR: 2.23
QA: 84.94

Study population and used grading

In total, 2,004 images from 1,002 eyes of 507 patients were included in the study between October 2022 and March 2023.
Every eye was graded by a human expert using the ICDR scale.
Of these, 18 were deemed ungradable and excluded. 3 patients had both eyes ungradable and therefore excluded.
Additionally, 89 images obtained with DRSplus were omitted by RetCAD due to poor quality.

RetCAD provided a retinopathy grading according to the International Diabetic Retinopathy Severity Scale. When grading was more than mild retinopathy, patients were referable and sent for a complete exam by an ophthalmologist.

ICDR scale, used by the human expert and by RetCAD
R0: no retinopathy
R1: mild non proliferative retinopathy
R2: moderate non proliferative retinopathy
R3: severe non proliferative retinopathy
R4: proliferative retinopathy

RetCAD performance

Sensitivity and specificity rate
RetCAD automated retinal image analysis systems compared to human grader, on patient level.

RETINOPATHY GRADE (by manual grade)	RetCAD Sensitivity (95% confidence interval)	RetCAD Specificity (95% confidence interval)
Referable (≥ R2)	98,63%	90,33%
Referable (≥ R1)	90,97%	76,71%

Positive predictive value (PPV)
indicating the percentage of patients with referable retinopathy
(≥ R2) among those with a positive AI result was **95,03%**.

Negative predictive value (NPV)
indicating the percentage of patients without retinopathy among
those with a negative AI result was **99,82 %**.

Conclusion

RetCAD detected almost all patients with more than mild
retinopathy (sensitivity rate of 99%).

Positive predictive value (≥ R2) among those with a positive
AI result was 95,03%.

Negative predictive value (≥ R2) among those with a negative
AI result was 99,82 %, with a very low false negative rate
suggesting we don't miss any referable patient.

New knowledge and technologies such as, digital non mydriatic
cameras and artificial intelligence offer important support in diabetic
retinopathy screening. Among the main automated image assessment
systems, RetCAD through the digital interface iCare ILLUME
demonstrated an excellent sensitivity in detecting more than mild
retinopathy.

In addition, specificity was very accurate, with a low false positive rate.
This AI system can improve DR screening and monitoring in people
with diabetes by non-eye care professionals.

A.S.L. T05

Azienda Sanitaria Locale

di Chieri, Carmagnola, Moncalieri, e Nichelino