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Efficient Early Diagnosis of Diabetic Retinopathy using zero-dilation Scanning Laser Ophthalmoscopy

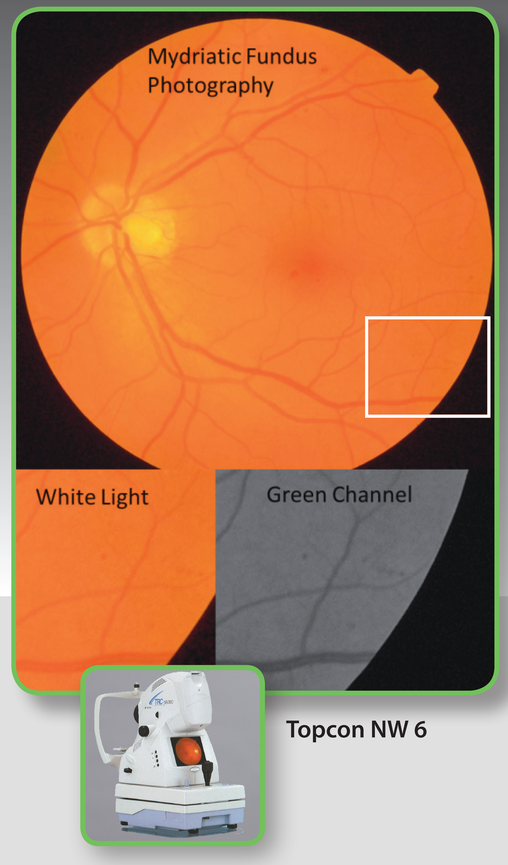
Purpose: The incidence of diabetic retinopathy (DR) is projected to escalate. To significantly reduce the risk of vision loss for these patients, regular DR screening to enable early intervention is the only way. New technology claims to make the DR screening process fast, patient-friendly, and accessible for everyone. And without mydriasis*. Can this be true? This pilot study compares one of the most typical fundus camera images (Topcon NW-6) against the performance of zero-dilation, cSLO based images (EasyScan**, i-Optics, Netherlands) in the diabetic population in Rotterdam.

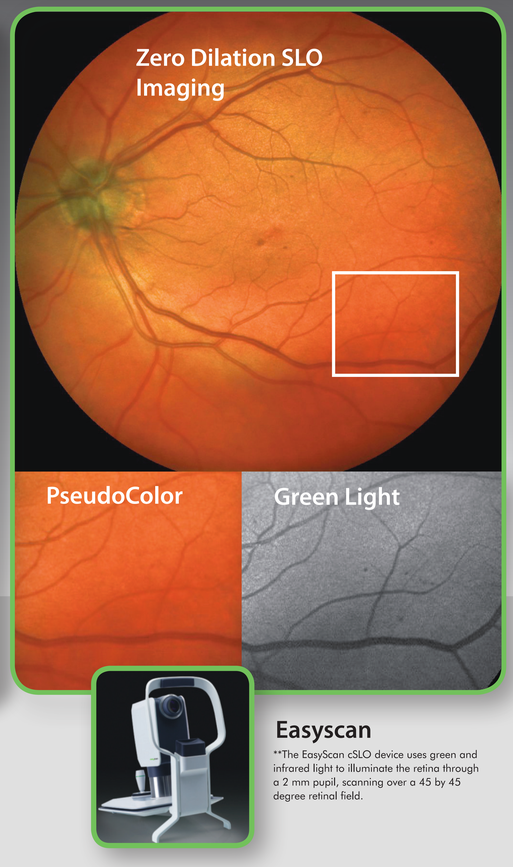
Methods: At a Rotterdam diabetes center 100 diabetic patients (age 60 +/-11 y) were recruited for cSLO imaging without mydriasis prior to their scheduled eye examinations with a fundus camera after mydriasis. Recorded were pupil diameter (calculated, figure 1), examination duration and referral rate. Two licensed graders assessed all 200 image sets independently, in a three-stage referral process, from both observer and device blinded to unblinded assessment (figure 4) until they agreed on referral for all patients. We analyzed both inter-observer agreement and agreements between the two instruments. (See table 1-3)

Results: 56% of the population had at least one pupil with diameter less than 3.3 mm and would therefore require mydriasis for traditional fundus camera imaging. Average image acquisition time was less than 3 minutes (figure 2 and 3). In the blinded assessment, both graders showed higher agreement based on the SLO images (Kappa = 0.79; [0.66-0.92] 95% CI) than based on the fundus images (Kappa = 0.65; [0.47-0.85]; 95% CI). Joint grader assessment of both image sets resulted in a significant agreement (Kappa = 0.85, [0.74-0.97] 95%CI) between both devices.

Conclusions: cSLO imaging provides an effective and efficient technology for early DR diagnosis without mydriasis.
- cSLO is 100% zero-dilation; all patients in this study were successfully imaged without mydriasis
- Time-effective; Mean acquisition time was below 3 minutes, and with elimination of dilation, shorter consultations can significantly reduce handling and cost for healthcare providers.
- Unambiguous referral; cSLO images led to a higher level of agreement between graders than with fundus.

We expect that it will enable higher patient throughput for early diagnosis and referral of DR, facilitating healthcare providers to cope with the increased global incidence of diabetes.





**Phase I: Blinded Inter-grader agreement

Grader II \ Grader I	Referral	Non referral	Total
Referral	16/27	3 / 6	19/ 33
Non referral	9 / 3	72/64	81/ 67
Total	25/30	75/70	100/100

FUNDUS: K = 0.65 (95% CI: 0.47–0.83); P = 0.14
cSLO: K = 0.79 (95% CI: 0.66–0.92); P = 0.51

**Phase II: Unblinded Inter-device agreement

Fundus \ cSLO	Referral	Non referral	Total
Referral	25	2	27
Non referral	4	69	73
Total	29	71	100

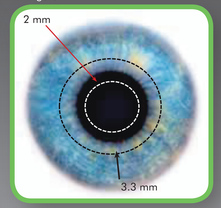
K = 0.85 (95% CI: 0.74–0.97); P = 0.69

**Phase III: Unblinded Comparison

Phase III \ Phase II	Referal	Non referal	Total
Referral	23/26	3 / 0	26/ 26
Non referral	1 / 2	72/73	74/ 74
Total	24/27	75/73	100/100

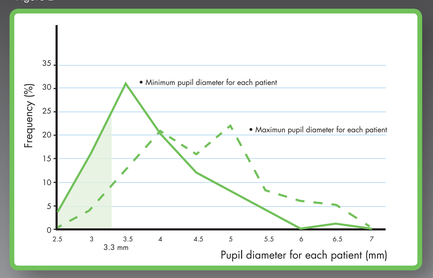
FUNDUS: K = 0.87 (95% CI: 0.76–0.98); P = 1.00
cSLO: K = 0.97 (95% CI: 0.92–1.00); P = 1.00

Figure 1



*With a traditional fundus camera, mydriasis is recommended when the pupil diameter is 3.3 mm or less. A confocal line scanning laser ophthalmoscope (cSLO) device eliminates this time-consuming, expensive and uncomfortable mydriasis, since it requires a pupil diameter of 2 mm.

Figure 2



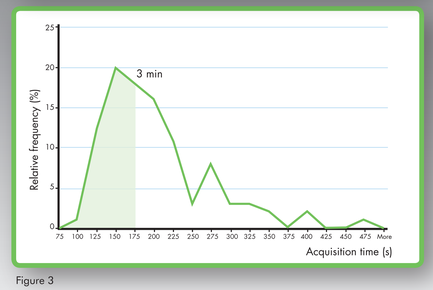


Figure 3

Kappa statistics were based on a three-stage referral of each patient's image set

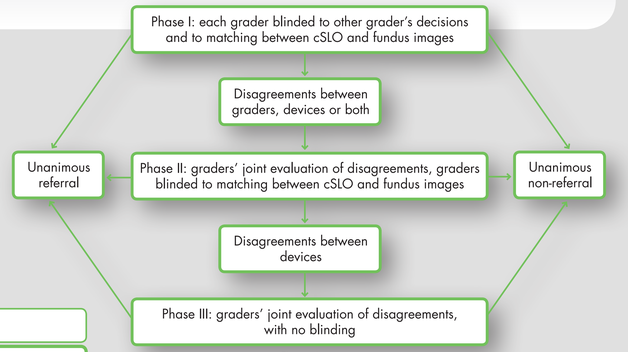


Figure 4

Dirk De Brouwere, i-Optics bv (E);
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Jose Martinez, i-Optics bv (F, C);
Michiel Mensink, i-Optics bv (I, P, S)