

Comparison of Nonmydriatic Optos® Fundus Imaging with Mydriatic Early Treatment Diabetic Retinopathy Study (ETDRS) 7-Standard Field Stereo Photography and Clinical Grading

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Purpose: To compare undilated Optos® P200MA images with dilated ETDRS 7-standard field 35-mm stereoscopic color 30° fundus photographs (ETDRS photos) and clinical examination for assessment of clinical level of diabetic retinopathy (DR) and diabetic macular edema (DME).

Methods: Subjects underwent nonmydriatic Optos® 100 and 200 degree imaging, dilated ETDRS photography and dilated fundoscopic examination by a masked retina specialist. Images were graded by two independent masked readers according to a strictly defined protocol. Each image was graded for presence and extent of specific diabetic lesions as well as for overall clinical DR severity. A third masked retina specialist adjudicated any discrepancies. Unweighted (K) and weighted (K_w) kappa statistics (linear scale) assessed agreement (almost perfect 0.81-1.0, substantial 0.61-0.80, moderate 0.41-0.60).

Results: Images from 206 eyes of 103 patients with type 1 or 2 diabetes were evaluated. By ETDRS photos there was no DR in 23 (12%) eyes, mild nonproliferative DR (NPDR) in 36 (18%), moderate NPDR in 72 (36%), severe or very severe NPDR in 17 (8%), and proliferative DR in 51 (26%). No DME was present in 107 eyes (64%), nonclinically significant DME in 39 (20%), CSME in 30 (15%) and 3 (1%) images were ungradable. Exact agreement of clinical DR grading between Optos 100 images (Optos Images) and ETDRS photos occurred in 74% with agreement within one level in 93% (K_w=0.81, K=0.67). Optos images exactly matched DR grading by clinical exam in 77% and were within one level in 97% (K_w=0.88, K=0.73). Clinical DR severity derived from lesion level gradings also had excellent agreement with ETDRS photos (K_w=0.81, K=0.69) and with clinical exam (K_w=0.79, K=0.65). Exact agreement with ETDRS photos for DME occurred in 84% and within one level in 96% (K_w=0.73, K=0.70). Exact agreement for DME was observed with clinical exam in 78% and within one level in 97% (K_w=0.67, K=0.58). Assessment of Optos 200 degree images did not increase agreement, but reduced the number of ungradable images from 9.3% to 3.7% for DR and from 11.1% to 9.0% for DME.

Conclusions: Undilated Optos images had excellent agreement with dilated ETDRS photos and dilated fundus examination in determining severity of DR and DME. If these results are confirmed in a broader diabetic population, Optos® imaging may be applicable to both research and clinical settings with the additional benefit of easier acquisition through an undilated pupil.