
The results of a clinical validation study comparing Optos ultra-widefield imaging to Early Treatment Diabetic Retinopathy Study (ETDRS) protocol fundus photography, the gold standard for assessing severity of diabetic retinopathy, was completed and published in the American Journal of Ophthalmology.

ETDRS protocol seven standard field 30-degree color fundus photography (ETDRS photos) has long been the imaging benchmark for assessing diabetic retinopathy severity. This study reports that the Optos’ ultra-widefield non-dilated optomap images compared favorably with dilated ETDRS photos and dilated retinal examination in determining clinical severity of diabetic retinopathy and diabetic macular edema.

“Nonmydriatic ultrawide field images compare favorably with dilated ETDRS photography and dilated fundus examination (by a retinal specialist) in determining DR and DME severity: however they are acquired more rapidly.”


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Building The Retina Company
This study validates Optos image quality for diabetic image assessment in the most stringent clinical study format.

optomap images had perfect agreement with the gold standard Early Treatment Diabetic Retinopathy Study (ETDRS) film for detecting diabetic retinopathy.

Non-mydriatic ultra-widefield images compared favorably with dilated fundus exam by a retinal specialist (MD) in determining diabetic retinopathy and diabetic macular edema severity.

- Sensitivity and specificity of ultra-widefield images for detecting and identifying diabetic retinopathy diagnosed on ETDRS photographs were 99% and 100%, respectively.

- optomap images were demonstrated to be “comparable with film, closely approximating or exceeding current standards for digital imaging with resolving power to detect most observable lesions.”

- “Exact diabetic retinopathy severity agreement between ultra widefield 100 imaging and ETDRS photography occurred in 84% with agreement within 1 level in 91%.” Demonstrating that Optos images are an effective tool for grading diabetic retinopathy.

- “Nonmydriatic ultra-widefield images exactly matched clinical examination results for diabetic retinopathy in 70% and were within 1 level in 93%.”

- The study shows 12-15% increase in exact agreement using Optos images compared to other published data on non-mydriatic cameras.
The presence of predominantly peripheral lesions were associated with an almost 5 fold risk in the progression of diabetic retinopathy (DR) over 4 years. A study published in Ophthalmology finds 40% of diabetic lesions located outside the area of ETDRS Gold Standard area. These lesions might result in a more severe grade of retinopathy in 10% of eyes.

The results of several clinical studies comparing optomap® ultra-widefield images have indicated that there is substantial agreement with Early Treatment Diabetic Retinopathy Study (ETDRS) 7-standard (ETDRS) film photographs and dilated fundus examination in determining diabetic retinopathy severity1-3. The peripheral lesions identified using ultra-widefield images in this cohort suggested a more severe assessment of diabetic retinopathy in 10% of eyes than was suggested by the lesions within the ETDRS fields. The presence of predominantly peripheral lesions were associated with the progression of diabetic retinopathy (DR) over 4 years, independent of baseline severity and A1C. 3

“The presence of DR lesions located predominantly in this peripheral area seemed to identify a subset of eyes at greatly increased risk of DR progression and onset of PDR...the rigorous evaluation of the peripheral retina may become an essential and routine component of accurately characterizing DR severity, and thus may prompt a revision of the ETDRS grading algorithms to best optimize the association of DR severity grade and clinical outcome.1 ”


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Peripheral Lesions Identified on Ultrawide Field Imaging Predict Increased Risk of Diabetic Retinopathy Progression over 4 Years.

Silva, Cavellerano, Haddad, Kwak, Dyer, Omar, Shikari, Aiello, Sun, Aiello
Ophthalmology - 2015

The results of a clinical study validates optomap images had substantial agreement with the gold standard Early Treatment Diabetic Retinopathy Study (ETDRS) film for the diagnosis and severity grading of diabetic retinopathy. In addition, the study identified that 40% of the lesions were in the area outside of ETDRS and that in 10% of patients these lesions suggested a more severe grade of retinopathy.

The presence of predominantly peripheral lesions were associated with the progression of diabetic retinopathy (DR) over 4 years, independent of baseline severity and A1C.

- Eyes with predominantly peripheral lesions (defined as outside of ETDRS 7 standard field) had a 4.7 fold increased risk of progression to proliferative diabetic retinopathy (PDR).
- Eyes with predominantly peripheral lesions had a 3.2 fold risk of 2 step progression in DR.
- There are ongoing longitudinal studies in this cohort to determine the clinical significance of these peripheral lesions.
- This paper suggests “Given that evaluation of these peripheral lesions may substantially alter risks of DR progression and onset of PDR, revision of the current ETDRS standard grading system may become necessary.”
- The patented ultra-widefield scanning laser technology from optos provides a photograph of the fundus that supports the detection, diagnosis, analysis, documentation and management of ocular pathology and systemic disease, especially those that first present in the periphery.