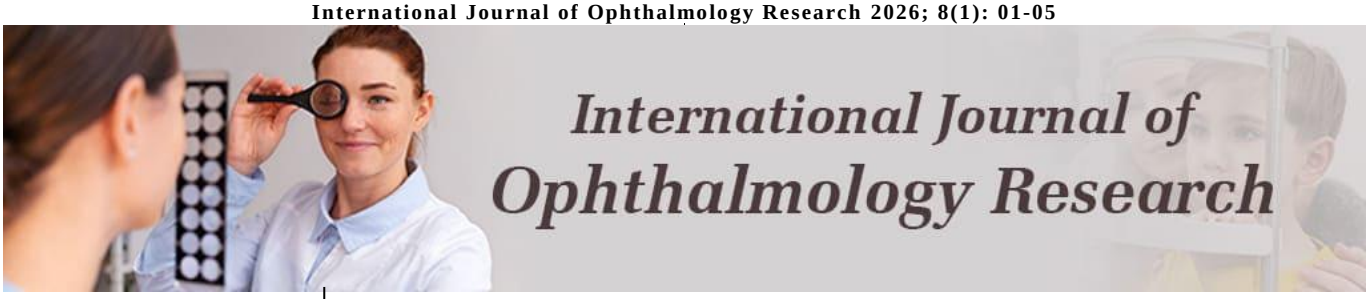

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May Barakat Ibrahim
Department of Ophthalmology, Tanta University Hospital, Tanta, Egypt

Magdy Salah Moussa
Department of Ophthalmology, Tanta University Hospital, Tanta, Egypt

Mohamed Hosny El-Bradey
Department of Ophthalmology, Tanta University Hospital, Tanta, Egypt

Mamdouh Mahmoud Kabil
Department of Ophthalmology, Tanta University Hospital, Tanta, Egypt

Corresponding Author:
May Barakat Ibrahim
Department of Ophthalmology, Tanta University Hospital, Tanta, Egypt

Diabetic retinopathy severity assessment using standard ETDRS fields and UWF color images: A comparative analysis

May Barakat Ibrahim, Magdy Salah Moussa, Mohamed Hosny El-Bradey and Mamdouh Mahmoud Kabil

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Abstract
Purpose: To assess the level of agreement between standard 7-field Early Treatment Diabetic Retinopathy Study (ETDRS) photography and ultra-widefield (UWF) color imaging in grading diabetic retinopathy (DR) severity.
Methods: This retrospective study analyzed UWF color images of patients with diabetic retinopathy imaged at Tanta University Hospital between January 2024 and January 2025. UWF images were acquired using the Optos California system. A standardized ETDRS 7-field (7F) mask was applied to UWF images to simulate conventional 7F grading, followed by grading of the full unmasked UWF images. DR severity was graded independently by expert graders using ETDRS Diabetic Retinopathy Severity Scale (DRSS) levels. Graders were masked to corresponding grades between protocols. Agreement between 7F and UWF DRSS levels was assessed using weighted kappa (κw) statistics.
Results: A total of 169 eyes from 94 subjects were included. Exact agreement between 7F-masked and UWF imaging was observed in 62 eyes (36.7%), while 139 eyes (82.2%) were within one DRSS step. Overall agreement between the two imaging protocols was moderate (weighted κw = 0.47). Additional peripheral retinal lesions were identified on unmasked UWF images in 123 eyes (72.8%). Among discrepant cases, 74.4% demonstrated lesions outside the 7F area, including predominantly peripheral lesions in 9.4% of eyes. Two eyes were reclassified from non-proliferative DR to proliferative DR due to peripheral neovascularization detected only on UWF imaging.
Conclusions: UWF imaging demonstrates moderate agreement with standard 7-field ETDRS photography for DR severity grading but frequently identifies additional peripheral lesions that can increase disease severity. These findings highlight the diagnostic advantage of UWF imaging and caution against interchangeable use of imaging modalities in clinical practice and multicenter trials.

Keywords: Astigmatism, cyclopegic, hyperopia, myopia, refractive error, visual impairment

Introduction
Diabetes mellitus (DM) is considered a global epidemic and one of the major health problems all over the world [1]. By 2035, Egypt is expected to have an over 96% increase in the diabetic population. Diabetes leads to a wide range of complication among them diabetic retinopathy (DR) [2].
DR is the leading cause of blindness among working age adults worldwide [3]. In 2013, it was estimated that 16% of Egyptian adults have type 2 diabetes and 2.6 million have diabetic retinopathy [4]. Projections for the next decade indicate that number of persons with diabetes will increase over the next twenty to thirty years by 35% creating a real challenge to the public health capacity to care for patients with diabetic retinopathy and persons at risk for its complication [5].
Film-based ETDRS 7-field imaging has served as the standard for evaluating the severity of DR and has been used in numerous DR clinical trials [6-11]. However, it is often associated with poor patient compliance [12].
Furthermore, UWF, covering more than 80% of the retinal surface [13, 14], facilitates the detection of extensive lesions located in the peripheral fields, which may influence the management of the disease [15, 16]. UWF may offer an efficient approach which can improve patient experience.

Limited studies have prospectively compared 7F with UWF imaging. Aiello *et al*. [17] compared the agreement between digital 7F and 7F-masked UWF. They demonstrated moderate agreement (κw = 0.51). Overall, they suggested that UWF imaging is comparable to 7F in quantifying DR severity and may be suitable for clinical trials [17].

As such, assessing the agreement between newer UWF modalities that are currently available and 7F is important for future clinical trials. The aim of the study is to assess the agreement between 7F and UWF in assessment of DR severity.

Patients and Methods

This was a retrospective analysis of UWF images of patients diagnosed with diabetic retinopathy at Tanta University hospital from January 2024 to January 2025. All participants signed a written informed consent prior to enrollment. The study received approval from the ethics committee/institutional review board (IRB) at Tanta university. The study adhered to the principles outlined in the Declaration of Helsinki and was performed in accordance with the Health Insurance Portability and Accountability Act.

Participants were required to be 18 years of age or older. Both type 1 and type 2 diabetes mellitus (DM) were included. Hemoglobin A1c levels of 10% or less. Subjects with clinically diagnosed diabetic retinopathy including both proliferative DR (PDR) and non-proliferative DR (NPDR). Exclusion criteria included previous focal or pan-retinal photocoagulation. Previous vitreoretinal surgery performed in the study eye at any time. Active intraocular or periocular inflammation or infection. Vitreous hemorrhage or any media opacities that could impede imaging. Other retinal vascular disorders that could interfere with study outcomes.

Ultra-wide field image acquisition: All participants underwent UWF color photographs using the Optos California device (Optos, Dunfermline, United Kingdom). All imaging was performed according to standard acquisition guidelines.

Diabetic retinopathy severity grading: UWF color images were imported as DICOM files and evaluated using the manufacturer (Optos plc) provided Optos Advance (OA) software. Expert UWF graders independently assessed UWF color images. 7 standard ETDRS fields mask overlay was applied over UWF color images using OA software to delineate the area encompassed by the 7F. Once the grading of these masked images was complete, the mask was removed to evaluate the full image, including the previously obscured UWF periphery.

The grading of masked and unmasked images was performed independently. Graders were masked to the assigned DRSS grades in corresponding masked images. The DR severity levels were aligned with ETDRS DRSS levels [18, 19] Cases with ungradable color images were excluded from analysis.

Statistical Analysis: Statistical analysis was performed using descriptive statistics to summarize patient demographic and clinical characteristics. Continuous variables are reported as means ± standard deviation, and categorical variables are presented as numbers and percentages. DRSS levels agreement between 7F images and UWF images was analyzed using weighted kappa [κw] statistics.[20] All statistical analyses were performed using SPSS software (IBM SPSS Statistics, Version 19.0, IBM Corp., Armonk, NY, USA). A p-value < 0.05 was considered statistically significant.

Results

188 eyes from 100 subjects had available UWF color images. A total of 19 images were ungradable resulting in 169 images (169 eyes from 94 subject) for analysis.

Comparison of imaging modalities in assessing DR severity

The distribution of diabetic retinopathy (DR) severity levels was assessed using both standard seven-field (7F) Early Treatment Diabetic Retinopathy Study (ETDRS) imaging and ultra-wide field (UWF) imaging protocols. Using UWF imaging, DR was absent in 0.6% of eyes, while micro-aneurysms only were identified in 1.8%. Mild non-proliferative diabetic retinopathy (NPDR) was observed in 21.9% of eyes, moderate NPDR in 21.3%, and moderately severe NPDR in 30.8%. Severe NPDR accounted for 13.6% of cases. Proliferative diabetic retinopathy (PDR) was less frequent, with mild PDR in 1.8%, moderate PDR in 4.1%, high-risk PDR in 3.6%, and very high-risk PDR in 0.6% of eyes.

In comparison, grading based on standard 7F ETDRS imaging showed absence of DR in 1.2% of eyes and micro-aneurysms only in 3.0%. Mild NPDR was more frequently classified using 7F imaging (39.1%), followed by moderate NPDR in 27.8% and moderately severe NPDR in 17.8% of eyes. Severe NPDR was identified in 5.3% of cases. PDR severity levels were infrequently detected with 7F imaging, including mild PDR in 1.2%, moderate PDR in 3.0%, high-risk PDR in 1.2%, and very high-risk PDR in 0.6% of eyes.

When comparing the assigned DRSS severity levels within the standard 7F to the UWF imaging protocol, 62 (36.7%) eyes matched exactly, and 139 (82.2%) were within one step, with moderate agreement between the 2 imaging protocols (κw = 46.7)

Lesions in retinal periphery on UWF

Among 107 eyes (63.3%) in the discrepant group between 7F and UWF, 80 eyes (74.4%) showed retinal abnormalities outside the 7F area, among them 10 eyes (9.4%) showed predominantly peripheral lesions, of which, two eyes had predominantly peripheral NVEs. Meanwhile, hemorrhage was detected in almost all cases (a representative example is illustrated in Figure 1.

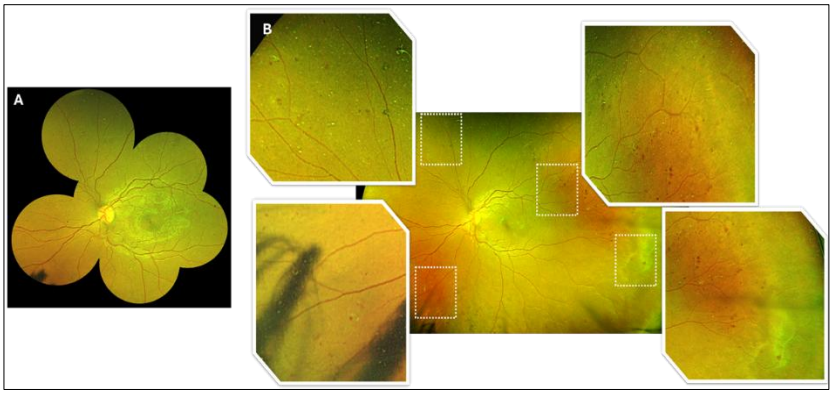

Fig 1: Peripheral Lesions Detected on Ultra-Wide field Imaging Resulting in Upstaging of Diabetic Retinopathy Severity

Montage color fundus photograph composed of the 7 standard ETDRS fields (A) demonstrating findings consistent with mild non-proliferative diabetic retinopathy (NPDR; DRSS level 35). Corresponding ultra-widefield (UWF) color fundus photograph of the left eye reveals widespread intraretinal hemorrhages and microaneurysms involving the posterior pole and predominantly extending into the peripheral retina across all four quadrants, with multiple areas suspicious for intraretinal microvascular abnormalities (IRMAs), resulting in upstaging to severe NPDR (DRSS level 53). Magnified insets highlight predominantly peripheral lesions (PPL), including clustered microaneurysms and hemorrhages in the superotemporal, superonasal, and inferotemporal quadrants. The inferonasal inset demonstrates peripheral hemorrhages with a vascular abnormality suspicious for IRMA versus early neovascularization elsewhere (NVE), not visualized within the standard 7-field ETDRS imaging area.

Discussion

Since the early 1990s, DRSS based on 7 field stereoscopic color fundus photographs have served as the gold standard for diabetic retinopathy staging [19]. However, the advent of UWF imaging has substantially expanded our knowledge of DR. UWF imaging has allowed visualization of various DR lesions out through the far retinal periphery [21-24]. In the current analysis, we evaluated the concordance in grading DR severity between UWF images and the standard 7 fields and observed a moderate agreement between both imaging protocols with exact agreement in only one third of cases. Additionally, more DR lesions were identified in UWF images in around 73% of eyes.

Multiple studies have compared the agreement between both imaging protocols [25-27]. Early study by Aiello *et al*. [28] demonstrated moderate to substantial agreement between UWF and 7-field imaging when assessing DR severity. They reported a weighted kappa value of 0.51 (95% CI, 0.44-0.58) for exact agreement between UWF and 7-field images, with 88% agreement within one step. Their agreement further improved to a weighted kappa of 0.77 (95% CI, 0.73-0.82) after open adjunction for discrepancies. They concluded that both modalities are comparable.

It is established that UWF imaging offers a substantial advantage over the traditional 7F protocol by capturing a significantly larger area of the retina. While the 7F imaging protocol documents approximately 35% of the retinal surface, UWF systems can visualize up to 90% of the retina in a single or a few images [29-32].

Given the need for diabetic retinopathy screening to be both efficient and sensitive in identifying patients at risk of vision-threatening complications, UWF imaging emerges as a powerful tool that balances diagnostic comprehensiveness with clinical practicality. Moreover, evaluating the level of agreement between UWF and 7F imaging is particularly important in the context of multicenter clinical trials, where variations in imaging protocols may exist. Understanding this agreement helps determine whether DR severity gradings derived from different modalities can be used interchangeably [5, 19, 26, 33, 34].

Our analysis demonstrated that while both grading protocols are comparable, they can't be exchangeable. Similarly, Domalpally *et al*. [27] demonstrated exact match in DRSS level in 48.8% and within one step in 84.9%, (Weighted κ = 0.59), indicating moderate agreement. They also noted that agreement was the lowest in early to moderate NPDR stages.

The recent results of the COCO study, (Comparison of Standard 7-Field, Clarus, and Optos Ultrawidefield Imaging Systems for Diabetic Retinopathy), further supports these findings [26]. They compared the standard 7 field with wide field imaging obtained by both Clarus and optos devices. They demonstrated moderate agreement with weighed kappa of 0.65 and o.58 respectively. Authors noted that most of the gradings were within 1 step of agreement (90.1% in Clarus and 85.9% in optos). We similarly detected 1 step of agreement in 82.2%.

In line with our findings, Aiello *et al*. [25] demonstrated exact agreement between 7F and UWF in 36.7% of cases. They also highlighted higher DR severity levels in UWF group. Likewise, our study revealed worse assigned DR severity levels using UWF in more than 58% of eyes. Interestingly, PPLs were identified in almost 10% of our cohort with 2 eyes (1%) demonstrating predominant peripheral NVEs that were reclassified to PDR using UWF imaging protocol. These findings, though appear to be statistically insignificant, have the utmost clinical relevance enabling early management and timely intervention.

Studies have established the presence of PPL as an indicator for DR progression and the need for intervention. Silva *et al*. reported that eyes with PPLs had a significantly greater likelihood of DR progression compared to those without PPL. In eyes that had NPDR at baseline, 34% of eyes with PPLs worsened by ≥2 DRSS steps over 4 years, versus only 11% of eyes without PPLs. Moreover, 25% of eyes with PPL progressed to PDR compared to just 6% of those without PPL over the same period.[35,36] Similarly, the DRCR.net protocol AA study noted higher cumulative rates

of vitrectomy, PRP, or anti-VEGF for DR in the PPL-positive groups (especially FA PPL) over 4 years. They concluded that PPL are independent risk factor for DR progression even after adjusting for DR stage and duration of diabetes [22, 37].

It needs to be mentioned that DR severity assessment is highly dependent on image quality regardless imaging modality. However, image quality can vary significantly under different circumstances with different equipment, quality control and acquisition protocols, or with variable levels of training and expertise of technicians acquiring these images. Future longitudinal studies are needed to quantify the impact of this variability on DR severity assessment using different imaging modalities [25].

Our study has several limitations that should be considered when interpreting the findings. First, the study design was retrospective in nature. Only a subset of participants with gradable UWF images were included, which may introduce selection bias. The availability and quality of UWF images varied across participants, further constraining the sample size and potentially limiting the generalizability of the results.

Collectively, our findings demonstrate moderate agreement between standard 7-field and UWF imaging for diabetic retinopathy severity grading using the ETDRS scale. While exact matches occur in roughly one-third to half of cases, most discrepancies are within one step. Importantly, UWF imaging reveals peripheral lesions, missed by the 7F protocol that can increase disease severity, including diagnosis to proliferative stages in a small but clinically significant proportion of eyes.

These findings highlight the diagnostic advantage of UWF in capturing the full extent of retinopathy and warrant caution against using different imaging modalities interchangeably in both clinical practice and multicentre research trials.

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