Optical Quality and Intraocular Scattering in the Diabetic Eye without Diabetic Retinopathy

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SIGNIFICANCE: This study suggests that despite having comparable best-corrected visual acuity and normal fundus appearance, objective measurements of optical quality showed that patients with diabetes but without overt retinopathy may have impaired visual function. Screening using the Optical Quality Analysis System might help identify those patients.

PURPOSE: Visual impairments are common in diabetes, but the status of the problem is unclear before the development of diabetic retinopathy. The aim of this pilot study was to investigate the optical quality and intraocular scattering in the diabetic eye without diabetic retinopathy.

METHODS: Twenty-seven patients with diabetes without diabetic retinopathy were enrolled. Twenty-seven age- and sex-matched healthy volunteers served as a control group. Optical quality parameters included modulation transfer function cutoff frequency, Strehl (two-dimensional) ratio, and Optical Quality Analysis System values at 100, 20, and 9 contrast levels. The objective scatter index was assessed using the Optical Quality Analysis System. Correlations were analyzed between the modulation transfer function cutoff, Strehl ratio, objective scatter index, and Optical Quality Analysis System value, and the age of the patient and the duration of diabetes mellitus.

RESULTS: The diabetic group exhibited lower modulation transfer function cutoff, Strehl ratio, and Optical Quality Analysis System values at 100, 20, and 9% contrast levels and higher objective scatter index than did the controls (all, $P < .01$). There were no associations between the optical quality parameters and age or the duration of diabetes mellitus in the diabetic participants (all, $P > .05$). Moderate associations were found between all parameters obtained from the Optical Quality Analysis System and age in the control group (all, $P < .01$).

CONCLUSIONS: This pilot study suggests that optical quality was reduced, and intraocular scattering increased in the diabetic eye without diabetic retinopathy compared with controls.

Optom Vis Sci 2019;96:248–255. doi:10.1097/OPX.0000000000001360

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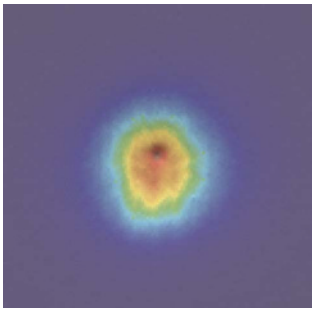

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The prevalence of diabetes mellitus has become an important public health problem in both developed and developing countries.[1] Diabetes mellitus is characterized by hyperglycemia, which, when uncontrolled, can result in retinopathy and vision loss.[2] The damage to the eye is such that diabetes mellitus is now considered to be a leading cause of vision loss and blindness in Western countries.[3,4] The prevalence of visual impairments secondary to diabetic retinopathy is increasing worldwide.[5,6] To prevent blindness, screening for retinopathy is considered an important part of diabetes care.[3] Without screening, the patients will consult only in the presence of severe visual impairment, but when visual acuity is not affected or only slightly affected, the patients often ignore the problems or neglect to seek care.[7]

In the eyes of healthy individuals, the retinal image quality depends on the perfect combination of each optical component. Any change in any optical component will lead to a blurred vision resulting from optical degradation. Previous studies indicate that diabetes mellitus affects almost all of the optical components of the eye, from the tear film to the retina, and include tear film instability, polymorphism of corneal epithelial and endothelial cells, central corneal thickening, corneal optical density increasing, lens thickening and increased convexity,[8–15] earlier vitreous degeneration,[16] retinopathy, higher-order aberrations,[17] and ocular scattering.[18,19] Some studies have suggested that visual function is also impaired in the early diabetic retinopathy stage and may include contrast sensitivity,[20–22] visual field sensitivity,[21,23] and color vision sensitivity.[9] Nevertheless, these visual functions were subjectively tested, and the actual retinal dysfunction may be greater than suggested. The effect of diabetes on the objective optical quality before the onset of retinopathy has not been reported to date.

With the development of new clinical instruments, the comprehensive and objective optical quality can be accurately detected. The Optical Quality Analysis System (Visiometrics, Terrassa, Spain) is based on the double-pass technique and has been widely used to evaluate the eye optical quality of patients undergoing refractive and cataract surgery.[24–26] The measurements achieved with the Optical Quality Analysis System show good repeatability and reproducibility.[27,28] The results from those studies suggest that this instrument can be used to assist the accurate evaluation of the optical quality in patients with diabetes mellitus without diabetic retinopathy.

Therefore, this pilot study was conducted to evaluate the optical quality and intraocular scattering in patients with diabetes mellitus but without diabetic retinopathy using the Optical Quality Analysis System. The results will provide evidence for the degree of visual impairment in patients with diabetes mellitus before overt retinopathy.

METHODS

Participants

All the procedures adhered to the tenets of the Declaration of Helsinki and were reviewed and approved by the institutional review boards of Shanxi Eye Hospital and the First Affiliated Hospital of Shanxi Medical University (Shanxi, China). Informed consent was obtained from each participant.

Participants were enrolled in the study between September 2016 and January 2017. The same examiner inspected both eyes of all participants. One eye of each participant was randomly chosen for statistical analysis by flipping a coin. Participants were classified into two groups: diabetic group and control group. Diabetic patients were recruited from the diabetes clinic of the First Affiliated Hospital of Shanxi Medical University. The controls were healthy volunteers selected from the hospital staff, relatives, and friends of the patients at the Shanxi Eye Hospital. The two groups were matched for age and sex. Diabetes mellitus was diagnosed according to the 2002 diagnostic criteria of the American Diabetes Association.[29]

The inclusion criteria were as follows: (1) eyes with a best-corrected distance visual acuity of 0.1 logMAR or better, (2) spherical refractive error from +3.00 to –3.00 diopters, (3) cylinder refractive error less than ±2.0 diopters with a normal fundus under ophthalmoscope, and (4) only normal age-related, nuclear sclerotic changes of the crystalline lens.

The exclusion criteria were as follows: (1) diagnosed as diabetic retinopathy; (2) any factor with a possible effect on ocular surface and visual function, including history of ocular trauma or surgery; (3) coexisting ocular disorders (e.g., uveitis, ocular hypertension or glaucoma, and corneal opacities); (4) pathology affecting ocular surface (e.g., contact lens wear, lid lesions, lacrimal dust obstruction, and pterygium); (5) disease of the immune system (e.g., Stevens-Johnson syndrome, Sjögren disease, thyroid eye disease, systemic lupus erythematosus, or any other connective tissue disorders); (6) significant cataract; or (7) treatment with medications that would influence visual functions such as ethambutol, amiodarone, hydroxychloroquine, corticosteroids, and vigabatrin.

Data Collection

Age and sex were collected when the participants were enrolled. Duration of diabetes mellitus was collected from the medical records. According to the protocol, all participants underwent a comprehensive ophthalmologic examination by two independent ophthalmologists, including anterior segment observation with slit-lamp, dilated fundus assessment, and noncontact intraocular pressure. The same optometrist conducted manifest subjective refractions. Refraction was performed on all patients following the principles of maximal plus to maximal visual acuity using an OU-400 system (Topcon, Tokyo, Japan).

The refractive diopter of participants was inputted in the system. After 5 minutes of adaptation in the dark room, the participants were asked to put their lower jaw on the lower jaw elevator and watch the test object. The distance of the optical probe was adjusted. When the pupil image appeared on the screen and the center of detection and pupil coincided, the process of autofocusing and automatic selection of the best focus was begun. The spherical equivalent was automatically corrected through the built-in lenses. When the participants had more than 0.75 diopter of astigmatism, the investigator had to correct the participants' astigmatism by means of a clean external lens and a subsequent test of light quality in the eye. An artificial 4-mm pupil diameter was used to measure optical quality. All subjects underwent three consecutive tests, and we used the average value. The following optical quality parameters were measured using the Optical Quality Analysis System: modulation transfer function cutoff frequency; Strehl (two-dimensional) ratio; Optical Quality Analysis System values at 100, 20, and 9% contrast levels; and objective scatter index. The participants were told to blink before data collection. All tests were performed by the same investigator. The test took 1 to 2 minutes.

The modulation transfer function cutoff frequency[30] is the frequency at which the modulation transfer function reaches a value of 0.01, that is, the threshold at which the eye can image an object in the retina with a significant 1% contrast. The higher the cutoff frequency value of modulation transfer function, the better the contrast sensitivity. It is normally assumed that a cutoff frequency of 30 cycles per degree in the contrast sensitivity function, which includes the contrast degradation imposed by the optics and posterior visual processing, corresponds to a decimal visual acuity of 1.0.

The Strehl ratio is often computed in the frequency domain as the ratio between the volume under the modulation transfer function curve of the measured eye and that of the aberration-free eye.[31] The Strehl ratio of unaffected people is approximately 30%. The higher the Strehl ratio value, the smaller the optical system aberration. It provides general information on the eye's optical quality. A value of 1 corresponds to a perfect optical system with no aberrations.

The three Optical Quality Analysis System values are normalized values of three spatial frequencies, which correspond to the modulation transfer function values for three contrast conditions commonly used in ophthalmic practice: 100, 20, and 9%.[32,33] These values reflect more specific information on the performance of the eye's optical system at different contrasts. Optical Quality Analysis System value at 100% contrast level is directly related to the modulation transfer function cutoff frequency (it is the modulation transfer function cutoff frequency divided by 30 cycles per degree) and therefore to the patient's visual acuity, although it is not affected by retinal and neural factors. Optical Quality Analysis System value at 20% contrast level and Optical Quality Analysis System value at 9% contrast level are computed in the same way from smaller frequencies that are linked to 0.05 and 0.1 modulation transfer function values, respectively, which maintain the proportion of contrasts of 20 and 9%. Therefore, they inform us about the shape of the modulation transfer function profile at lower frequencies than the modulation transfer function cutoff frequency. In addition, these two additional frequencies have been normalized so that the values obtained are comparable with standard decimal visual acuity values. Values higher than 1.0 are associated with high optical quality.

The objective scatter index is calculated as the ratio of the amount of light in the periphery and in the surroundings of the central peak of the Optical Quality Analysis System image. For the Optical Quality Analysis System, the central area selected is a circle with a radius of 1 minute of arc, whereas the peripheral zone is a ring set between 12 and 20 minutes of arc.[34] The higher the objective scatter index, the higher the level of intraocular scattering.

TABLE 1. Participant characteristics for the diabetic and control groups

Parameter	Diabetic group (n = 27)	Control group (n = 27)	*P*
Age (y), mean ± SD	56.4 ± 8.7	56.7 ± 8.4	.91*
Female, n (%)	14 (51.9)	14 (51.9)	.999†
Right eye, n (%)	15 (55.6)	14 (51.9)	.999†
Duration of DM (y), mean ± SD	8.2 ± 5.7	NA	NA
UCDVA (logMAR), mean ± SD	0.19 ± 0.20	0.10 ± 0.12	.06‡
CDVA (logMAR), mean ± SD	0.01 ± 0.04	0.00 ± 0.03	.27‡
Sphere (diopters), mean ± SD	0.61 ± 0.63	0.57 ± 0.51	.98‡
Cylinder (diopters), mean ± SD	0.65 ± 0.52	0.47 ± 0.43	.22‡
IOP (mmHg), mean ± SD	15.8 ± 2.5	15.5 ± 3.2	.67*

*Independent *t* test. †χ^2 Test. ‡Mann-Whitney *U* test. CDVA = corrected distance visual acuity; DM = diabetes mellitus; NA = not applicable; UCDVA = uncorrected distance visual acuity.

Statistical Analysis

Data analysis was performed using SPSS 19.0 (IBM, Armonk, NY) for this pilot study. Continuous variables were expressed as means ± standard deviation and, depending on their distribution, were analyzed using the independent-sample *t* test (normal distribution) or Mann-Whitney *U* test (nonnormally distributed) to determine the between-group differences. Categorical variables were expressed as frequency and percentage, and the χ^2 test was used for statistical analysis. Repeated-measures analysis of variance was used for the analysis of a variable across multiple time points within the same group. The Bonferroni correction for repeated testing was applied as appropriate. Associations between optical parameters and age or duration of diabetes mellitus were tested using the Spearman rank test or Pearson correlation coefficient, as appropriate. $P < .05$ was considered statistically significant.

RESULTS

The participants' characteristics are shown in Table 1. A total of 54 participants were included in this study, including 27 patients with diabetes (27 eyes) and 27 healthy controls (27 eyes). The duration of diabetes mellitus was between 1 and 20 years, with a mean of 8.2 ± 5.7 years. There were no significant differences between the two groups (all, $P > .05$).

The optical quality parameters of the two groups are shown in Table 2. There were significant statistical differences in all of the optical quality parameters between the diabetic and control groups (all, $P < .01$). More specifically, the modulation transfer function cutoff frequency was lower in the diabetic group (29.80 ± 8.04 vs. 40.05 ± 5.38, $P < .001$), Strehl ratio was lower (0.17 ± 0.04 vs. 0.21 ± 0.04, $P < .001$), objective scatter index was higher (0.87 ± 0.52 vs. 0.51 ± 0.28, $P = .006$), Optical Quality Analysis System value at 100% contrast level was lower (0.99 ± 0.27 vs. 1.33 ± 0.18, $P < .001$), Optical Quality Analysis System value at 20% contrast level was lower (0.70 ± 0.20 vs. 0.93 ± 0.19, $P < .001$), and Optical Quality Analysis System value at 9% contrast level was lower (0.43 ± 0.13 vs. 0.55 ± 0.12, $P < .001$; Table 2). Within the same groups and in both groups, Optical Quality Analysis System value at 20% contrast level was consistently smaller than Optical Quality Analysis System value at 100% contrast level, and Optical Quality Analysis System value at 9% contrast level was consistently smaller than Optical Quality Analysis System value at 20 and 100% contrast levels (all, $P < .001$; Table 3).

The associations between optical quality parameters and age and duration of diabetes mellitus in the diabetic group are shown in Figs. 1 and 2. There were no associations between the optical quality parameters and age or the duration of diabetes mellitus in the diabetic participants (all, $P > .05$). The associations between optical quality parameters and age in the control group are shown in Fig. 3. Moderate associations were found between all parameters obtained from the Optical Quality Analysis System and age in the control group (modulation transfer function cutoff frequency: $r = -0.570$, $P = .002$; Strehl ratio: $r = -0.613$, $P < .001$; objective scatter index: $r = 0.608$, $P < .001$; Optical Quality Analysis System value at 100% contrast level: $r = -0.583$, $P = .001$; Optical Quality

TABLE 2. Optical quality parameters of the diabetic and control groups

Parameter	Diabetic group (n = 27)	Control group (n = 27)	*P*
MTF cutoff frequency	29.80 ± 8.04	40.05 ± 5.38	<.001*
SR	0.17 ± 0.04	0.21 ± 0.04	<.001*
OSI	0.87 ± 0.52	0.51 ± 0.28	.006†
OV 100%	0.99 ± 0.27	1.33 ± 0.18	<.001*
OV 20%	0.71 ± 0.20	0.93 ± 0.19	<.001*
OV 9%	0.43 ± 0.13	0.55 ± 0.12	<.001*

*Independent *t* test. †Mann-Whitney *U* test. MTF = modulation transfer function; OSI = objective scatter index; OV = Optical Quality Analysis System value; SR = Strehl ratio.

TABLE 3. Comparison of OV at different contrasts in the diabetic and control groups

Group	OV 100%	OV 20%	OV 9%	*P*
Diabetic group (n = 27)	0.99 ± 0.27	0.71 ± 0.20*	0.43 ± 0.13*†	<.001
Control group (n = 27)	1.33 ± 0.18	0.93 ± 0.19*	0.55 ± 0.12*†	<.001

*P < .001 versus OV 100%. †P < .001 versus OV 20%. OV = Optical Quality Analysis System value.

Analysis System value at 20% contrast level: $r = –0.600$, $P < .001$; and Optical Quality Analysis System value at 9% contrast level: $r = –0.651$, $P < .001$).

DISCUSSION

The aim of this pilot study was to assess objective optical quality parameters (including modulation transfer function cutoff, Strehl ratio, Optical Quality Analysis System values, and objective scatter index) in patients with diabetes mellitus but without diabetic retinopathy and healthy volunteers using the Optical Quality Analysis System. Compared with the control group, the diabetic group showed lower modulation transfer function cutoff, Strehl ratio, and Optical Quality Analysis System values and higher objective scatter index, indicating that the optical quality of the diabetic eye was decreased, although they had comparable best-corrected visual acuity and normal fundus with the control group and although overt retinopathy has not developed yet.

Recently, Hwang et al.[35] found that the intraocular stray light level, which is similar to the measurement of objective scatter index in this study, was gradually increased with increased severity of diabetic retinopathy. Moreover, the intraocular stray light level was higher in patients with diabetes mellitus but without diabetic retinopathy than in normal eyes. Although we used a different instrument to test the optical quality of patients with diabetes in this study, the results agreed with their research.[35] We detected higher intraocular objective scatter index in the diabetic group without diabetic retinopathy than in the control group. Lens opacity level plays an important role in intraocular scattering measurement. Therefore, we only enrolled subjects with nuclear opalescence (according to the Lens Opacities Classification System III standards, 0.1 to 2.9) to assess the optical quality difference, and we excluded subjects with posterior subcapsular cataract and cortical cataract to eliminate this potential bias. Moreover, no significant nuclear opalescence score difference was found between the two groups in our study, which made the optical quality comparison results more reliable. It could be possible that the results observed in the present study may actually be greater, as the diabetic subjects may have more advanced forms of cataracts on average, but this will have to be confirmed.

Even if they were not assessed in the present study, part of the differences between the two groups could be due to differences in higher-order aberrations. Indeed, Adnan et al.[36] demonstrated that intraocular stray light, total horizontal coma, and total vertical coma were greater in subjects with type 1 diabetes mellitus than in controls. Shahidi et al.[17] reported a greater amount of total high-order aberrations in subjects with diabetes than in controls. Calvo-Maroto et al.[37,38] studied the distribution of total, corneal, and internal high-order aberrations in 18 patients with well-controlled diabetes mellitus (7 subjects with type 1 diabetes mellitus, 11 subjects with type 2 diabetes mellitus) and found that people with diabetes mellitus showed high values of total and internal vertical coma. According to the study by Lee et al.,[39] total higher-order aberrations were positively associated with objective scatter index and negatively associated with the modulation transfer function cutoff frequency and Strehl ratio. These previous studies support our findings of lower modulation transfer function cutoff, Strehl ratio, and Optical Quality Analysis System values and higher objective scatter index in the diabetic group, globally suggesting the possibility of greater higher-order aberrations in diabetic eyes.

Considering the potential effect of age on the optical quality and visual function,[40] the present study chose age- and sex-matched healthy volunteers as a control group. In our study, the optical quality parameters (modulation transfer function cutoff, Strehl ratio, Optical Quality Analysis System values, and objective scatter index) were significantly associated with age in the control group, as supported by the study by Martinez-Roda et al.[40] On the other hand, there were no significant associations between age and the optical quality parameters in the diabetic group. These findings demonstrated that diabetes mellitus might have an impact on optical quality measurement and even weaken the associations of optical quality parameters with age. Furthermore, no significant associations were found between the duration of diabetes mellitus and modulation transfer function cutoff, Strehl ratio, Optical Quality Analysis System values, and objective scatter index, which is supported by the study by Hwang et al.[35] Indeed, they found that there was no significant correlation between duration of diabetes mellitus and stray light level. These findings may suggest that the duration of diabetes mellitus may not be the main risk factor affecting optical quality, at least when measured using the current imaging technology.

As a preliminary study to evaluate the optical quality in diabetes mellitus eyes without diabetic retinopathy, several possible limitations of this study should be noticed. First, the relatively small sample size and the inclusion of Chinese subjects only may have biased the results. Second, the blood glucose levels in patients with diabetes mellitus were not recorded when their optical parameters were assessed. Finally, the repeatability of the Optical Quality Analysis System test has been confirmed by some studies,[25,41,42] but it has never been tested in diabetic patients. Although evidence was not given, we reduced the possible errors by repeating the measurements three times and by taking the mean value for analysis. Therefore, further study with a larger sample size and more data is needed in the future.

CONCLUSIONS

This pilot study suggests that compared with normal eyes, optical quality declines and intraocular light scatter increases in diabetic eyes, even in the absence of overt retinopathy. Moreover, associations between optical quality parameters and age are

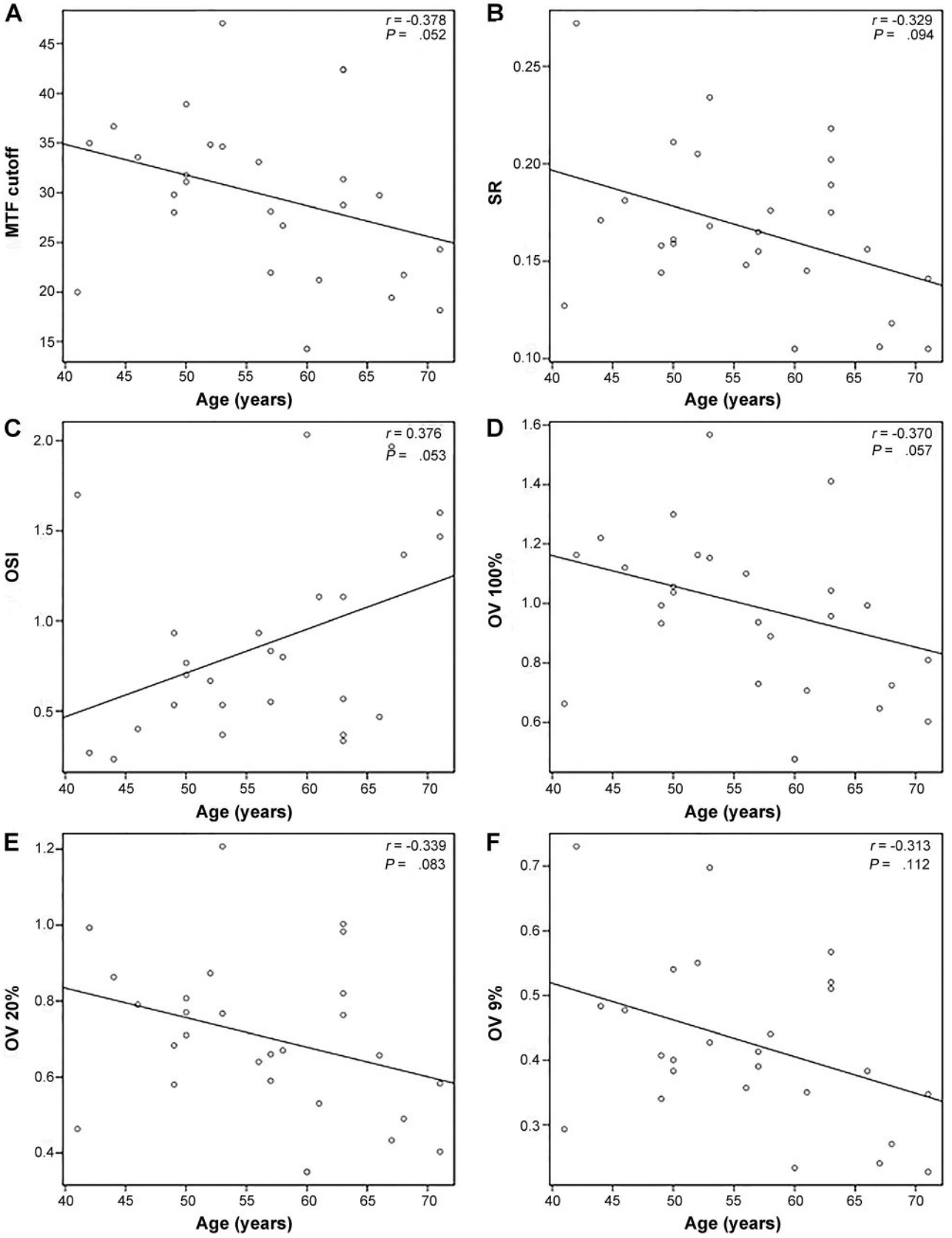

FIGURE 1. Correlations between the parameters obtained from the Optical Quality Analysis System and age in the diabetic group. MTF = modulation transfer function; OSI = objective scatter index; OV = Optical Quality Analysis System value; SR = Strehl ratio.

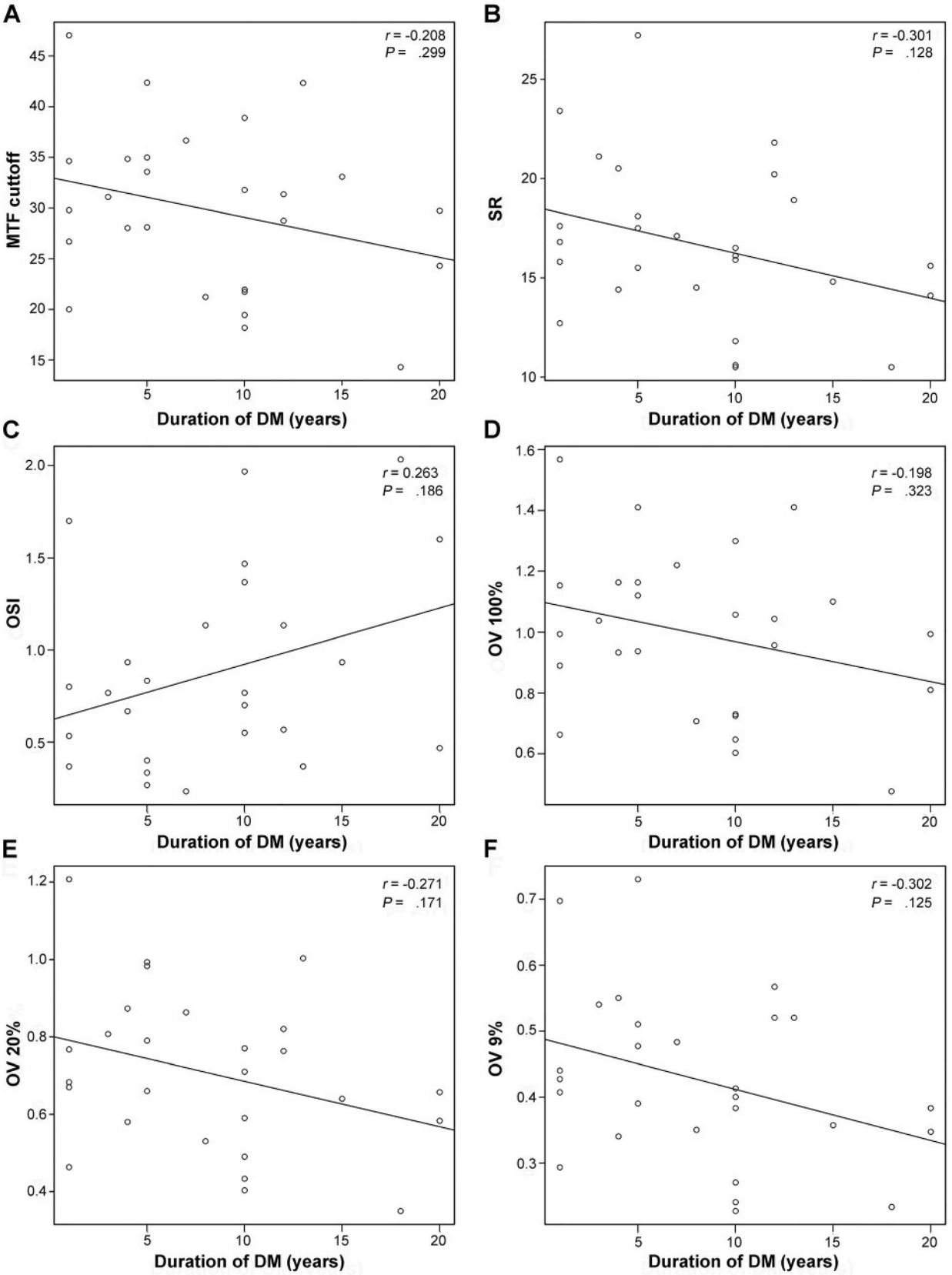

FIGURE 2. Correlations between the parameters obtained from the Optical Quality Analysis System and duration of diabetes mellitus in the diabetic group. DM = diabetes mellitus; MTF = modulation transfer function; OSI = objective scatter index; OV = Optical Quality Analysis System value; SR = Strehl ratio.

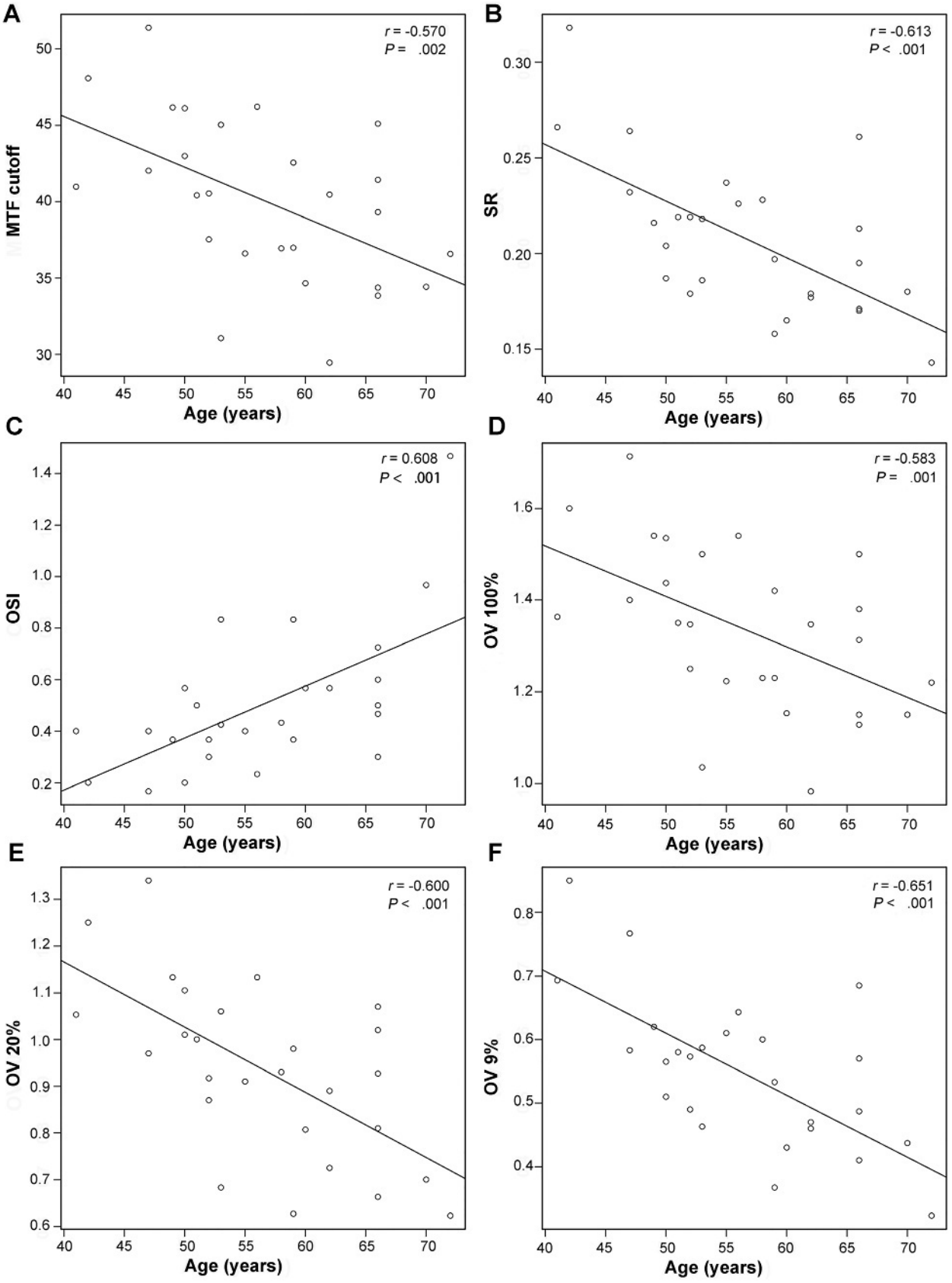

FIGURE 3. Correlations between the parameters obtained from the Optical Quality Analysis System and age in the control group. MTF = modulation transfer function; OSI = objective scatter index; OV = Optical Quality Analysis System value; SR = Strehl ratio.

absent in patients with diabetes mellitus, whereas those associations are observed in the controls. No associations were found between optical quality parameters and the duration of diabetes mellitus in patients with diabetes mellitus. The Optical Quality Analysis System is a fast, objective, and noninvasive method for assessing the optical quality and could be a useful complementary test for screening and monitoring the visual function of patients with diabetes mellitus.

ARTICLE INFORMATION

Submitted: June 21, 2018

Accepted: December 26, 2018

Funding/Support: None of the authors have reported funding/support.

Conflict of Interest Disclosure: The authors declare that they have no conflict of interests.

Author Contributions and Acknowledgments: Investigation: JL, XW, JW, HG; Methodology: JL, XW, JW, HG; Validation: JL; Visualization: JL; Writing – Original Draft: JL, XW, JW, HG; Writing – Review & Editing: JL, XW, JW, HG.

The authors appreciate the dedication of the Department of Ophthalmology, the First Affiliated Hospital of Shanxi Medical University, Taiyuan, China.

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