Title: Reading Deficits in Diabetic Patients Treated with Pan Retinal Photocoagulation and Good Visual Acuity.

Short title: Reading Deficits and PRP.

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Purpose:

Patients with proliferative diabetic retinopathy (PDR) treated with panretinal photocoagulation (PRP) can have abnormal visual functioning that may be missed by Snellen visual acuity alone. We investigated reading deficits in patients treated with PRP for PDR using the Minnesota Reading (MNREAD) test.

Methods:

30 patients treated with PRP and 15 controls underwent best-corrected visual acuity (BCVA), the MNREAD, Frequency Doubling Perimetry (FDP), and fundus photography. PRP-treated subjects were compared to controls on MNREAD results by 2-sample t-tests and Wilcoxon tests, and Pearson correlations were used to assess the association between performance on MNREAD and other central visual function tests within PRP subjects.

Results:

PRP-treated patients had reduced MNREAD acuity (p< 0.0001) and increased critical print size (p=0.01) compared to controls but not a significantly reduced maximum reading speed (p = 0.06). Logmar MNREAD acuity was strongly positive correlated with logMAR BCVA (r=0.58, p=0.0098) and strongly negatively correlated with FDP foveal threshold (r = -0.63, p= 0.0030). Maximum reading speed was positively correlated with FDP foveal threshold (r = 0.57, p =0.0143) and FDP mean deviation (r = 0.51, p = 0.0432). Visual acuity did not correlate with the sensitivities on the FDP.

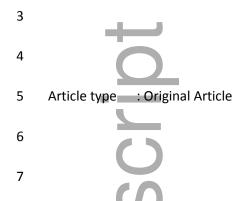
Conclusion:

The MNREAD test reveals that PRP reduces reading ability and other aspects of macular function, and thus provides new understanding of how vision-related quality of life is impaired. These findings may lead to improved means to evaluate and enhance vision following treatment for PDR.

Key words: Pan Retinal Photocoagulation, Diabetes, Diabetic Retinopathy, Minnesota Reading Test.

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8 Introduction:

9 Proliferative diabetic retinopathy (PDR) is characterized by retinal neovascularization (Duh et al. 2017), and its treatment commonly includes pan-retinal photocoagulation 10 (PRP) (El Rami et al. 2017, Martinez-Zapata et al. 2014, Bressler et al. 2017). 11 Treatment outcomes are typically evaluated based on central visual acuity (VA) 12 (Stewart 2016), but other measures of visual function (Spreng et al. 2018), including 13 tests of contrast sensitivity, reading ability, visual field sensitivities, and vision in dim 14 light conditions provide more comprehensive information about macular function 15 (Boynton et al. 2015). As such, patients often feel their reduced vision negatively 16 impacts their quality of life (QOL), which may be overlooked when vision assessment is 17 based on acuity alone. Recent gene therapy studies have demonstrated the ability to 18 restore central vision in persons with advanced retinal degeneration (Bainbridge et al. 19 2015, Russell et al. 2017). Eyes treated with PRP exhibit reduced peripheral and 20 macular function and fundus lesions similar to those in eyes with retinitis pigmentosa. 21 22 Similar future efforts to improve vision in persons who have undergone PRP will require comprehensive measures of visual function and impact on the QOL to determine 23 successful responses to therapy. 24

Reading charts have been used to quantify central visual function for retinitis
pigmentosa, macular degeneration, and glaucoma (Varadaraj et al. 2017, Radner 2017,
Ishii et al. 2013, Virgili et al. 2004). Unlike Snellen VA charts that use single letter

optotypes, reading charts provide more information on visual function by using 28 sentences in a logarithmic scale. In addition to the reading acuity, reading tests provide 29 the maximum reading speed and the critical print size that can assess the ease with 30 which patients can read. Previous studies have also correlated reductions in reading 31 speeds with reduced sensitivity on microperimetry (Edington et al. 2017), suggesting 32 33 that reading tests uncover other aspects of visual dysfunction. Moreover, reading is more representative of the impact of vision on the QOL than Snellen VA, because it 34 reflects real world function in patients with macular pathologies (Kanonidou 2011, 35 Jackson & Owsley 2003). It also tests vision at a different distance than standard 36 Snellen VA. To our knowledge, reading ability as measured by the Minnesota reading 37 (MNREAD) test has not been evaluated on persons who have undergone PRP. 38

Boynton et al (Boynton et al. 2015) initially described this cohort's performance on a 39 variety of visual function tests in comparison with nondiabetic controls. Over two thirds 40 of patients had a VA of 20/20 or better but severe deficits on photopic visual fields and 41 42 dark-adaptation testing. Furthermore, many patients at follow up have admitted that they gave up reading due to their retinopathy. Therefore, it is apparent that Snellen VA 43 does not adequately describe visual function related QOL in this cohort. In this analysis, 44 we investigated both the performance on the MNREAD in the PRP-treated subjects 45 compared to controls, and the relationship between results of the MNREAD test with 46 other deficits of macular visual functioning in PRP-treated subjects. Our central 47 hypothesis is that PRP-treated subjects will have a significantly reduced performance 48 on the MNREAD (as manifested by a reduced reading acuity, slower maximum reading 49 speed, and larger critical print size) compared to controls. We also predicted that the 50 reduction in MNREAD parameters would correlate with reductions on other macular 51 function tests such as Snellen VA and sensitivity on the frequency doubling perimetry 52 (FDP). 53

54 Materials and Methods:

This study was conducted at the University of Michigan W. K. Kellogg Eye Center. The
study adhered to the tenets of the Declaration of Helsinki, and was approved by the
University of Michigan Medical School Institutional Review Board (HUM 60596).

58 Diabetic patients with PDR treated by PRP and age-matched controls were enrolled into

the study after a screening visit in the retina clinic. Signed informed consent was

60 acquired from all participants before research testing.

61 **Patient enrollment and evaluation:**

Subject enrollment and the eligibility criteria were the same as the study by Boynton et 62 al (Boynton et al. 2015). Briefly, the PRP study group enrolled adults with type 1 or 2 63 diabetes mellitus who had PDR treated with PRP at least 6 months before enrollment 64 into the study. Inclusion criteria for the study group were: (1) age \geq 18 years old; (2) 65 diabetes mellitus as defined by the American Diabetes Association diagnostic criteria: 66 (3) treatment of PDR by PRP \geq 6 months prior to enrollment; (4) stable proliferative 67 diabetic retinopathy after the PRP treatment; and (5) best-corrected visual acuity 68 (BCVA) of 20/400 or better in the study eye. If both eyes were eligible, the one with the 69 worst BCVA was chosen as the study eye. 70

Exclusion criteria for the PRP study group were: (1) any retinal or ocular disease other 71 than PDR; (2) any significant cystoid macular edema; (3) any high risk ocular 72 73 neovascularization; (4) history of drug or alcohol abuse; (5) any neurologic or systemic disease that could impair vision, other than diabetes; (6) any systemic or ocular 74 75 medication that could affect vision; (7) hospitalization within 1 month of screening; (8) difference in two recent consecutive hemoglobin A1c measurements \geq 5%; (9) unable to 76 77 give informed consent or unable to complete testing; (10) spherical equivalent $> \pm 6.00$ diopters; (11) pregnant or nursing; (12) blood pressure \geq 180/100 mmHg. 78

The study also enrolled 15 age-matched controls enrolled as volunteers. Inclusion and exclusion criteria were the same for controls, except that they had no condition that could affect vision.

All subjects underwent a comprehensive ophthalmologic examination including a slit lamp exam and dilated fundus exam with a 90D lens (performed by T.W.G). Age and demographic data were taken to allow age matching for comparisons between groups. Medical and ocular histories were taken to ensure that subjects met enrollment criteria and that we knew the type and duration of diabetes in PRP subjects. Optimal refraction was assessed manually using the phoropter, and measurement of BCVA was done
using the electronic visual acuity tester (EVA) with Snellen chart line testing. LogMAR
VA was recorded and used for statistical analysis. A blood sample was obtained from
each participant to measure glycosylated hemoglobin (HbA_{1c}) levels if they had not
been measured within the last 6 months.

92 If patients were eligible and consent was given, screening was completed and patients 93 returned for a study visit. During this visit, functional vision tests were performed in the 94 same order, which included MNREAD testing and FDP. Phenotyping included fundus 95 photography.

96 Minnesota reading test:

The MNREAD test is performed with a single reading card that contains multiple 10-97 word text phrases, each in different font sizes, and with the characters and lines equally 98 spaced. The largest font size of a phrase corresponds to a Snellen line of 20/400 and 99 100 the smallest font size corresponds to a Snellen line of 20/06. Subjects underwent MNREAD testing in a designated room where light intensity was calibrated to standard 101 room light conditions at a luminescence of around 100 cd/m². The reading card was 102 placed 40 cm from the subject and vision was corrected to that distance. Subjects read 103 104 aloud progressively smaller MNREAD text phrases starting at 20/400, and decreasing in logMAR increments of -0.1, using only the study eye. While subjects read a phrase, the 105 106 other phrases were blocked out so that they could not read ahead. The amount of time 107 to read each phrase was recorded, as well as the number of words read correctly and 108 incorrectly. Different MNREAD cards were used based on whether the study eye was a right or left eye. All the characteristics of the cards were the same, but the letters had a 109 different orientation. 110

Three variables were calculated from testing results: the MNREAD testing acuity, maximum reading speed, and the critical print size. The MNREAD testing acuity was determined as the phrase with the smallest font size where a patient could read all the words, even if they read some of them incorrectly. If the subject did not read any of the words correctly, then we recorded the MNREAD acuity as the phrase above. The reading speed for a standard ten-word phrase (600) was calculated using the followingformula:

118 Reading speed = (60 x (10- number words read incorrectly)) / time (seconds).

119 The maximum reading speed was deduced as the fastest speed at which the patient 120 could read of all the lines that were successfully read.

The critical print size was the MNREAD phrase with the smallest font that the patient could read at the maximum reading speed. The font size was converted to a corresponding Snellen VA line that is automatically computed on the MNREAD reading cards. The critical print size served as a surrogate for the minimum size of the letters that the patient can read at the maximum reading speed, thereby indicating the ease with which subjects can read.

127 **FDP:**

Participants performed FDP with the 24-2 protocol using the Matrix perimeter (Carl 128 Zeiss Meditec, Dublin, California, USA). The reliability criteria used were < 33% fixation 129 errors, < 33% false positive errors, and < 33% false negative errors. The FDP 24-2 130 strategy was performed on the Humphrey Matrix 715 Visual Field Analyzer[®]. The 131 stimulus was 0.25 cycles per degree monochrome sinusoidal grating of vertical grey 132 stripes that was phase reversed at 18 Hz (Joltikov et al. 2017, Leeprechanon et al. 133 2007). The minimum contrast threshold of the 5° diameter stimulus was measured at 134 each of 55 test locations (Joltikov et al. 2017). The testing time was approximately 5 135 minutes per eye. Subjects wore their own distance prescription glasses if needed. 136 Foveal sensitivity (FS), mean deviation (MD), and pattern standard deviation (PSD) 137 were recorded. FS represents the minimum intensity of the stimulus at the fovea 138 required for a patient response. PSD measures localized deficits by factoring out 139 140 generalized reductions in sensitivity.

141 **Fundus photographs:**

- 142 A 200-degree color photograph centered on the macula was taken of each study eye
- using a non-simultaneous stereoscopic, on-axis, non-steered, 200° ultrawide field
- 144 (UWF) imaging on the Optos camera (Optos®, Dunfermline, United Kingdom).

145 Statistical Analysis:

Descriptive statistics were used to summarize patient demographics, clinical measures 146 147 of the study eye, tests of macular function, and MNREAD testing performance, for the PRP study subjects and controls. Differences between PRP study subjects and controls 148 149 were tested with 2-sample t-tests and Wilcoxon tests for continuous measures, and with Chi-square and Fisher's exact tests for categorical measures. Within the PRP study 150 151 group, scatterplots and Pearson's correlations (r) were used to assess the association between performance on MNREAD testing with other visual function parameters. All 152 measures of VA were converted to LogMAR (Holladay 1997) for analysis. P-values 153 were adjusted for multiple comparisons with the Holm method. Associations were 154 considered statistically significant when p-value < 0.05. All statistical analyses were 155 performed using SAS version 9.4 (SAS Institute, Cary, NC). 156

157 **Results:**

158 Thirty study patients who had PRP to treat their PDR and 15 age-matched, healthy controls were enrolled in this study. **Table 1** compares the demographics of the PRP 159 and control subjects. PRP patients and controls were age-matched (mean ± standard 160 deviation, SD; 58.6 \pm 13.4 and 59.8 \pm 17.8 years, respectively; p=0.79) and had a 161 similar gender distribution (both 60% male, p=1.00). Groups were similar with respect to 162 IOP (PRP_group: 15.7 ± 2.8 mmHg; control group: 15.0 ± 3.7 mmHg; p=0.46). The PRP-163 treated group had higher hemoglobin A_{1C} (7.4% ± 1.2 versus 5.5% ± 0.3, respectively) 164 and a worse visual acuity $(0.17 \pm 0.19 \text{ LogMAR} \text{ units versus } 0.08 \pm 0.10 \text{ LogMAR} \text{ units},$ 165 respectively, as measured by Snellen). The PRP-treated group had an average 166 diabetes duration of 36.3 years (SD=12.6) and their PRP was an average of 13.3 years 167 prior to testing (SD=8.6), consistent with their inactive retinopathy. 168

169 **MNREAD:**

PRP-treated subjects had worse performance on the MNREAD test than controls for 170 two of the three MNREAD testing measures (**Table 2**). The PRP group had significantly 171 172 worse MNREAD acuity (p<0.0001), corresponding to a Snellen acuity of 20/32 versus 20/20 for controls. There was also an increase in the critical print size for PRP-treated 173 subjects compared to controls (p=0.01), corresponding to a Snellen letter size of 20/200 174 for PRP subjects and 20/100 for controls. Although on average PRP-treated subjects 175 exhibited reduced reading speed relative to controls, the difference was not statistically 176 significant (157.1 \pm 30.0 versus 170.9 \pm 18.1 characters/second, respectively, p=0.06). 177 Collectively, these results reveal significant impairment of reading ability in the PRP-178 treated individuals. 179

180 **FDP**:

Table 2 also contains central visual field testing results on the FDP in PRP and controlgroups. PRP-treated subjects showed reduced foveal threshold ($22.1 \pm 7.4 \, dB$ versus $30.0 \pm 5.1 \, dB$; p<0.0001), and reduced mean deviation on the FDP 24-2 (-8.20 ± 5.76</td>dB versus 1.09 ± 2.52 dB; p<0.0001).</td>

185 **Correlations between MNREAD and other functional parameters:**

Table 3 and Figure 1 summarize the association between performance on MNREAD 186 testing and other central visual function tests in PRP-treated subjects. The logMAR 187 reading acuity was significantly correlated with performance on central vision tests. 188 Specifically, a strong positive correlation was noted with logMAR Snellen VA (r = 0.58, p 189 = 0.0007), and strong negative correlations were noted with FDP foveal threshold (r = -190 0.63, p = 0.0002). The maximum reading speed correlated positively with the 191 performance on FDP foveal threshold (r = 0.57, p = 0.0011), and FDP 24-2 MD (r =192 0.51, p =0.0036). The Snellen VA did not correlate with either the FDP foveal threshold 193 or FDP MD. The critical print size correlated only with Snellen logMAR visual acuity (r = 194 0.47, p = 0.0085), but this finding was not significant after adjustment for multiple 195 comparisons (adjusted p=0.093). 196

197 **Discussion:**

Our study shows for the first time that PRP-treated patients have reduced 198 reading performance on the MNREAD compared to controls. Although these deficits are 199 200 expected due to a slightly worse visual acuity in the PRP-treated group, the MNREAD test provides more information on central visual function than standard Snellen VA. 201 First, the MNREAD assesses performance on a task that many patients with macular 202 203 diseases, such as age-related macular degeneration, have difficulty with and believe is important for their QOL (Patel et al. 2011). The reading speed and critical print size yield 204 more information about how easy or difficult subjects find reading. There were many 205 examples of patients who read on the same acuity line but had very different reading 206 speeds and critical print sizes (figure 2), suggesting that they have different levels of 207 difficulty with reading. Furthermore, the deficits on MNREAD testing were associated 208 with multiple deficits in central visual functioning, including visual acuity, FDP mean 209 deviation, and FDP foveal threshold. The Snellen VA, however, did not have significant 210 correlations with FDP sensitivities, suggesting that the MNREAD provides more 211 information about global macular functioning. We advise clinicians to counsel patients 212 213 undergoing PRP that they may experience difficulties with reading over time.

Notable strengths of this study are that we were able to detect significant reading 214 deficits in PRP treated subjects as compared to controls, and show that this test 215 provides more information about visual functioning than standard Snellen VA alone. 216 Weaknesses of this study include the small number of subjects, which may explain why 217 maximum reading speed was not significantly reduced. Also, we did not have patients 218 with proliferative diabetic retinopathy but no pan retinal photocoagulation as a control to 219 220 compare the effects of PRP alone. However, all of the PRP patients had guiescent retinopathy, so this is unlikely to have had an effect on the results of our study. Another 221 222 limitation was the heterogeneity in both the length of time that patients had diabetes, and the number of years after they had PRP. We did not find any significant 223 associations between any MNREAD parameters and either age or duration of diabetes. 224 However, the number of years since PRP was negatively correlated with the maximum 225 reading speed (r= -0.605, p = 0.002) but not with logMAR MNREAD acuity. 226

- 227 Clinical trials for diabetic retinopathy (Cai & Bressler 2017) and retinal
- dystrophies (Schatz et al. 2017, Neto et al. 2017) employ endpoints for central vision
- function aimed at preserving and/or improving Snellen VA, but patients may have
- multiple visual function deficits that are missed when Snellen VA is used alone.
- 231 Therefore, in developing future clinical trials to improve or restore central visual function
- for those with PDR treated by PRP, more comprehensive measures to quantify
- 233 improvement and vision related QOL are needed. Reading tests like the MNREAD may
- provide another endpoint for measuring visual function in therapeutic trials.
- Furthermore, reading tests may easily be integrated into clinical practice as an objective
- 236 measure of central visual function.

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Table 1. Descriptive statistics summarizing the differences between the PRP and control subject samples.

ot	PRP group (n=30)	Control group (n=15)	P value*	
	# (%)	# (%)		
Male	18, (60%)	9, (60%)	1.0	
Female	12, (40%)	6, (40%)	1.0	
SI	Mean (SD)	Mean (SD)		
Age (years; SD)	58.6 (13.4)	59.8 (17.8)	0.80	
Duration diabetes mellitus (years)	36.3 (12.6)	NA	NA	
Years Since PRP	13.3 (8.6)	NA	NA	
Hemoglobin A _{1C} (%)	7.4 (1.2)	5.5 (0.3)	0.0001	
LogMAR Snellen visual acuity	0.17 (0.19)	-0.08 (0.10)	0.0001	*2-
IOP (mm Hg)	15.7 (2.8)	15.0 (3.7)	0.46	sample

for age, IOP, LogMAR visual acuity; 2-sample Wilcoxon test for hemoglobin A1C; Chisquare test for gender. SD, standard deviation; IOP, intraocular pressure; PRP, Pan retinal photocoagulation; ETDRS, Early Treatment Diabetic Retinopathy Study. **Table 2.** Comparison of performance on the MNREAD testing and FDP between PRP-treated and Control subjects.

	PRP group (n=30)	Control group (n=15)	P value*
	Mean (SD)	Mean (SD)	
logMAR reading	0.23 (0.27)	-0.05 (0.05)	0.0001
acuity			
Maximum reading	157.1 (30.0)	170.9 (18.1)	0.062
speed			
(characters/second)			
LogMAR Critical	0.98 (0.26)	0.75 (0.32)	0.013
Print Size			
FDP Foveal			
sensitivity (decibels)	22.1 (7.4)	30.0 (5.1)	0.0002
FDP 24-2MD	-8.20 (5.76)	1.09 (2.52)	0.0001
(decibels)	-0.20 (0.70)	1.09 (2.32)	0.0001
0			

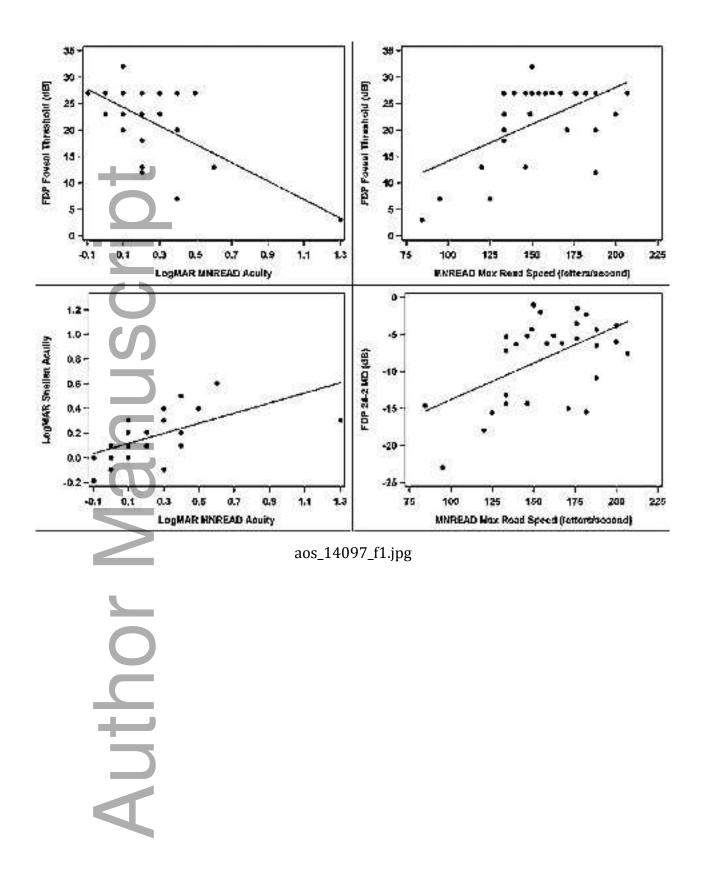
*2-sample t-test for maximum read speed and LogMAR critical print size; 2-sample Wilcoxon test for LogMAR reading acuity; SD, standard deviation; PRP, panretinal photocoagulation.

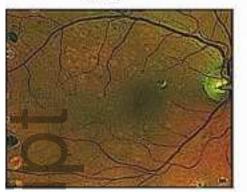
*2-sample Wilcoxon test for FDP foveal sensitivity and FDP MD; FDP, [Frequency Doubing Perimetry]; MD, [Mean Deviation].

Table 3. Correlation between performance on MNREAD and other visual function parameters, within PDR subjects treated with PRP (n=30). The correlation coefficient is listed with the p-value in parentheses. P-values adjusted for multiple comparisons by the Holm method are also provided. Statistically significant associations are highlighted in bold.

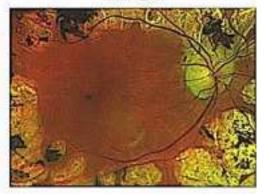
	ogMAR Snellen VA	FDP foveal threshold	FDP 24-2 MD (dB)		
	г	(dB)			
LogMAR	0.58	-0.63	-0.43		
MNREAD	(p=0.0007)	(p=0.0002)	(p=0.0166)		
acuity	(adj p=0.0098)	(adj p=0.003)	(adj p=0.1149)		
MNREAD	-0.35	0.57	0.51		
maximum reading speed	(p=0.0595)	(p=0.0011)	(p=0.0036)		
(characters/ second)	(adj p=0.4165)	(adj p=0.0143)	(adj p=0.0432)		
	1				
LogMAR	0.47	-0.02	0.09		
MNREAD critical print size	(p=0.0085)	(p=0.9283)	(p=0.6505)		
C	(adj p=0.0935)	(adj p=1.0000)	(adj p=1.0000)		
)				
	1				

*PDR, proliferative diabetic retinopathy; PRP, pan retinal photocoagulation; VA, visual acuity; FDP, frequency doubling perimetry; MD, mean deviation; PR, MNREAD, Minnesota Reading Test.





MNREAD acuity = 20/20 Reading speed = 148.9 Critical print size = 20/400 Years since PRP = 9 Age = 71 years PRP 23



MNREAD acuity = 20/20 Reading speed = 182.0 Critical print size = 20/80 Years since PRP = 7 Age = 61 years

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